

14814

March 21, 1994
DOCKETED
USARC

'94 MAR 22 P2:21

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))	

NRC STAFF RESPONSES AND OBJECTIONS TO
LICENSEE'S SECOND REQUEST FOR ADMISSIONS
AND NRC STAFF MOTION FOR PROTECTIVE ORDER

INTRODUCTION

Pursuant to 10 C.F.R. §§ 2.740 and 2.742, the staff of the Nuclear Regulatory Commission (Staff) hereby files its responses and objections to the Licensee's second request for admissions. "OSC's Second Set of Interrogatories, Request For Production of Documents and Requests For Admissions," dated March 1, 1994.¹

I. STAFF RESPONSES AND OBJECTION TO LICENSEE'S REQUEST FOR ADMISSIONS

Please either admit or deny the following requests for admissions. If your response is anything other than an unqualified admission, provide a detailed explanation for your response.

¹ On March 4, 1994, the parties agreed that the Staff's responses to the Licensee's requests for admissions would be filed on March 21, 1994.

9403300159 940321
PDR ADOCK 03031765
C PDR

DS07

REQUEST FOR ADMISSION 1

The only specific regulation for HDR in Title 10 of the Code of Federal Regulations is at section 35.2.

RESPONSE

The Staff can neither admit nor deny this request. Although there are many regulations which apply to the use of High Dose Rate brachytherapy, section 35.2 is the only regulation which only applies to HDR brachytherapy.

REQUEST FOR ADMISSION 2

Failure of the wall mounted survey meter did not occur on November 16, 1992 at IRCC.

RESPONSE

The Staff can neither admit nor deny this request. The IRCC technologists interviewed by the Incident Investigation Team (IIT) stated that the wall mounted PrimeAlert alarmed during the November 16, 1992 incident. The IIT determined that the source was exposed at the time the PrimeAlert alarmed. Subsequently, during the IIT investigation, Dr. Bauer, in the presence of Dr. Paperiello, was able to cause the PrimeAlert to alarm using Dr. Bauer's Sr-90 eye applicator. The alarm ceased when the source was removed. However, Rudy Balko stated that he manipulated the power supply during, and perhaps subsequent to, the event on November 16, 1992. Therefore, Mr. Balko may have made the alarm inoperable for a certain period of time during the event.²

² Dr. Paperiello, who assisted in the preparation of the Staff's response to this request for admission, as well as others, was unable to sign his affidavit. An unsigned
(continued...)

REQUEST FOR ADMISSION 3

Rudy Balko had used a hand held survey meter at IRCC prior to November 16, 1992.

RESPONSE

Admit in part. Mr. Balko had held and turned on a hand held survey meter at IRCC prior to November 16, 1992. However, Mr. Balko was not trained in its use at the IRCC prior to November 16, 1992. He told the IIT that he had a little bit of survey meter experience in therapy school and that he was uncomfortable in its use. He was not clear on the sensitivity of the various scales.

REQUEST FOR ADMISSION 4

Sharon Rickett had used a hand held survey meter at IRCC prior to November 16, 1992.

RESPONSE

The Staff can neither admit nor deny this request. The IIT does not know if Sharon Rickett had ever used a hand held survey meter at the IRCC prior to November 16, 1992. She told the IIT that no one showed her how to use the survey meter or what the readings meant.

REQUEST FOR ADMISSION 5

Greg Hay instructed Rudy Balko in the use of a hand held survey meter prior to November 16, 1992.

²(...continued)

copy has been attached and a signed and notarized copy of the affidavit will be forwarded as soon as possible.

RESPONSE

Deny. Mr. Hay told the IIT that he had shown Mr. Balko how to use a survey meter, but that he did not train Rudy Balko in the use of the survey meter since he (Greg Hay) was not responsible for training.

REQUEST FOR ADMISSION 6

The OSC license did not require any level of frequency that the RSO conduct visits to each facility listed as a place of use.

RESPONSE

Admit. The OSC license does not specifically require any level of frequency with which the RSO is required to conduct visits to each facility listed as a place of use on the OSC license.

REQUEST FOR ADMISSION 7

No regulation or license condition was violated by Dr. Cunningham's failure to be physically present at the Lehigh facility for a period of 6 to 9 months.

RESPONSE

Admit. However, Dr. Cunningham's failure to be physically present at the Lehigh facility for a period of 6 to 9 months was an indication that Dr. Cunningham was not performing his responsibilities as a Radiation Safety Officer as defined in 10 C.F.R. § 35.21.

REQUEST FOR ADMISSION 8

10 CFR 35.31(b) does not require a level of frequency with respect to the RSO being physically present at a facility listed as a place of use.

RESPONSE

Admit.

REQUEST FOR ADMISSION 9

10 CFR 35.59(d) does not require a level of frequency with respect to the RSO being physically present at a facility listed as a place of use.

RESPONSE

Admit.

REQUEST FOR ADMISSION 10

10 CFR 35.59(g) does not require a level of frequency with respect to the RSO being physically present at a facility listed as a place of use.

RESPONSE

Admit.

REQUEST FOR ADMISSION 11

10 CFR 35.59(i) does not require a level of frequency with respect to the RSO being physically present at a facility listed as a place of use.

RESPONSE

Admit.

REQUEST FOR ADMISSION 12

10 CFR 35.415(b) does not require a level of frequency with respect to the RSO being physically present at a facility listed as a place of use.

RESPONSE

Admit.

REQUEST FOR ADMISSION 13

10 CFR 35.21(a) does not require a level of frequency with respect to the RSO being physically present at a facility listed as a place of use.

RESPONSE

Deny, in part. Although no frequency is specifically prescribed in the regulation with respect to physical presence of the RSO, the regulation requires the RSO to ensure "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) lists the various responsibilities of the radiation safety officer. Read together, section 35.21 requires 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 the regulations are met.

REQUEST FOR ADMISSION 14

10 CFR 35.21(b) does not require a level of frequency with respect to the RSO being physically present at a facility listed as a place of use.

RESPONSE

See the Staff's response to request for admission 13.

REQUEST FOR ADMISSION 15

Regulatory Guide 10.8, Revision 2, appendix G does not specify either the manner or frequency of contact between the RSO and the users and workers.

RESPONSE

Deny in part. Although the manner of contact between the RSO and the users and workers is not specified in Regulatory Guide 10.8, Revision 2, Appendix G, section 3.c.(1) states that "[t]he RSO will be in close contact with all users and workers. . . ." In order to comply with the Licensee's commitment, in its license, to follow Regulatory Guide 10.8, Revision 2, Appendix G, it would be necessary for the radiation safety officer to have frequent contact with the locations of use listed on the license.

REQUEST FOR ADMISSION 16

OSC was under no regulatory obligation or regulatory requirement to notify the physicists at Exton and Lehighton of the November 16, 1992 IRCC event.

RESPONSE

Deny. Under 10 C.F.R. § 35.21(b)(1), the RSO has the responsibility to investigate overexposures, accidents, and misadministrations, and to implement corrective actions as necessary. Under 10 C.F.R. § 19.12, the licensee has a responsibility to instruct all affected workers in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material. Failure to even communicate the circumstances of the accident at the IRCC to all other locations under the RSO's supervision that were performing similar treatments is a complete abdication of these responsibilities.

REQUEST FOR ADMISSION 17

Failure by OSC to notify the physicists at Exton and Lehighton of the November 16, 1992 IRCC event does not constitute a violation of the license.

RESPONSE

Admit.

REQUEST FOR ADMISSION 18

Failure by OSC to notify the physicists at Exton and Lehighton of the November 16, 1992 IRCC event does not constitute a severity level I, II, III, IV or V violation.

RESPONSE

Objection. The Staff objects to this request because it seeks irrelevant information. The Order Suspending License, issued on January 20, 1993, did not assess a civil penalty, and no severity level was assigned. Therefore, the information sought cannot reasonably lead to the discovery of admissible evidence. *See* 10 C.F.R. §§ 2.740, 2.742.

REQUEST FOR ADMISSION 19

10 CFR 35.21(a) does not require or define if and/or when appropriate corporate radiation safety communications should be made.

RESPONSE

Admit.

REQUEST FOR ADMISSION 20

10 CFR 35.21(b) does not require or define if and/or when appropriate corporate radiation safety communications should be made.

RESPONSE

Deny. Section 35.21(b) requires a licensee through the radiation safety officer to make radiation safety communications to implement corrective actions after overexposures and misadministrations. In this case, the corporation is the Licensee.

REQUEST FOR ADMISSION 21

10 CFR 19.12 does not require or define if and/or when appropriate corporate radiation safety communications should be made.

RESPONSE

Deny. If the licensee is aware of health protection problems associated with exposure to radiation sources in its restricted areas, section 19.12 requires that the licensee keep individuals working in or frequenting its restricted areas informed of (communicate) the precautions and procedures necessary to minimize exposure. Once a new hazard is identified, the communication should be made immediately or before the next entry into the restricted area. In this case, the corporation is the Licensee.

REQUEST FOR ADMISSION 22

The term "significant corporate management breakdown in the control of licensed activities" is undefined in Title 10 of the Code of Federal Regulations.

RESPONSE

Admit. The term "significant corporate management breakdown in the control of licensed activities" is not specifically defined in Title 10 of the Code of Federal Regulations. However, on October 13, 1988, the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), 10 C.F.R. Part 2, Appendix C, was modified to add to Supplements I, III, IV, V, and VI examples that describe a "[b]reakdown in the control of licensed activities involving a number of violations that are related or, if isolated, that are recurring violations that collectively represent a potentially significant lack of attention or carelessness toward licensed responsibilities." The Statements of Consideration for this change to the Enforcement

Policy (53 FR 40019) indicate that the change was made to provide examples for "multiple or recurring violations that collectively reflect a potentially significant lack of attention or carelessness toward licensed responsibilities."

REQUEST FOR ADMISSION 23

It is possible that Dr. Moylan did not state that he was unaware that Dr. Cunningham was the RSO listed on the license and that he had not read the license.

RESPONSE

Deny. It is not possible that Dr. Moylan did not state that he was unaware that Dr. Cunningham was the RSO listed on the license and that he had not read the license. When interviewed by James Dwyer and Pamela Henderson at the Schuylkill Cancer Center in Pottsville, Pennsylvania on December 8, 1992, Dr. Moylan stated that he was not aware that Dr. Cunningham was the RSO for the OSC license nor had he read the OSC license.

REQUEST FOR ADMISSION 24

Paula Salanitro was aware that Dr. Cunningham was the RSO listed on the license.

RESPONSE

Deny. Paula Salanitro when questioned by the inspectors stated that she was the RSO and was not aware that Dr. Cunningham was listed as the RSO on the license. This is stated in the Inspection Report No. 030-31765/92-001.

REQUEST FOR ADMISSION 25

The NRC Staff is aware that IRCC personnel have stated that during the December 9 and 10, 1991 training session, Omnitron personnel did not state the possibility of or provide any training regarding emergency procedures to be followed in the event of a source wire break.

RESPONSE

Admit.

REQUEST FOR ADMISSION 26

The NRC approved Dr. Cunningham as the RSO for the OSC license.

RESPONSE

Admit.

REQUEST FOR ADMISSION 27

The NRC understood that HDR treatment would be provided at six locations under the OSC license.

RESPONSE

Admit.

REQUEST FOR ADMISSION 28

Prior to November 16, 1992 the NRC never questioned whether Dr. Cunningham could act as an RSO for all six locations listed on the OSC license.

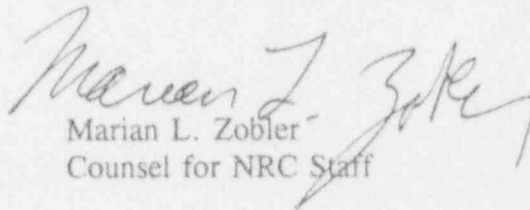
RESPONSE

Admit.

II. NRC STAFF MOTION FOR A PROTECTIVE ORDER

Pursuant to section 2.740(c) of the Commission's regulations, the Staff hereby requests that the Board enter a protective order directing that the Staff need not respond to the Licensee's request for admission 18. The information sought by the Licensee in request for admission 18 is not relevant and cannot reasonably lead to the discovery of admissible evidence. The Board should, therefore, grant the Staff's Motion.

Respectfully submitted,


Marian L. Zobler
Counsel for NRC Staff



Catherine L. Marco
Counsel for NRC Staff

Dated at Rockville, Maryland
this 21st day of March, 1994