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RELATED CORRESPONDENCE

June 17, 1994

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OFFICE OF SECRETARY
DOCKETING & SERVICE

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

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

OSC'S REQUEST FOR ADMISSIONS DATED JUNE 17, 1994

OSC serves the following Requests for Admissions Dated June 17, 1994 and requests a timely response to each.

Definitions

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 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)."

Directions

For each and every one of the following Requests for Admissions, if your answer is other than an unqualified admission, provide a detailed explanation for your response and identify and produce any and all documents which support your response.

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1. Dr. Bauer, as well as all Omnitron trained authorized users, were trained pursuant to Omnitron's course, that the source wire could not break.

2. No HDR treatments were performed at any OSC facilities prior to the completion of proper training under the pertinent regulations and license conditions.

3. OSC provided training regarding licensed activities in Atlantic City, NJ in August 1992, including basically radiation safety, training requirements, HDR emergency responses, film badge use, time distance in shielding and handheld survey meter use.

4. Medical Director/Authorized Users received OSC refresher training consistent with applicable regulations and license conditions by Dr. Cunningham at semi-annual meetings which addressed HDR and regulatory compliance.

5. Rudy Balko was trained in how to use a handheld survey meter by Greg Hay.

6. Sharon Rickett had used a handheld survey meter at IRCC prior to December 16, 1992.

7. Greg Hay is a qualified physicist.

8. During the November 16, 1992 HDR treatment, the patient was surveyed before, during and after the HDR procedure using the PrimeAlert.

9. During the November 16, 1992 HDR treatment at IRCC, the physician/authorized user systematically reviewed the various Omnitron internal safety check alerts.

10. The NRC has determined that the Omnitron 2000 unit did not notify the IRCC personnel that an emergency condition existed.

11. At the Exton facility emergency procedures were available and located right at the console of the Omnitron 2000 HDR Afterloader because various attempts physically to attach the document to the console were unsuccessful.

12. All treating personnel at IRCC, including the Medical Director/Authorized User, the physicist and technologists Rickett and Balko received training from Omnitron using the Omnitron emergency procedures and Omnitron operating manual.

13. OSC complied with the survey requirement of 10 CFR Section 20.201(b) on November 16, 1992 through the use of the wall-mounted survey meter.

14. Dr. Cunningham did not delegate his RSO responsibilities via the December 12, 1992 letter.

15. A PrimeAlert is a radiation survey instrument.

16. As of November 16, 1992, there was no NRC regulation that required that a patient be surveyed with a radiation survey detection instrument following the removal of an iridium 192 wire source.

17. The use of and reliance on the PrimeAlert was reasonable under the circumstances on November 16, 1992 at IRCC to evaluate the extent of the radiation hazard that may have been present.

18. There was no 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.

19. The IRCC personnel did not recognize an emergency situation existed on November 16, 1992.

20. License Condition 17 does not require entry into the treatment room with a portable survey meter or an audible dosimeter where there was not a known PrimeAlert failure or malfunction.

21. The Licensee may properly rely, in part or in whole, on instructions an employee has received through his schooling.

22. Individuals who do not administer HDR treatments to patients at OSC facilities were not required to be trained in and know the specific terms of the NRC regulations and the license conditions.

23. It is not a violation of any regulation or license condition when staff, who do not administer HDR treatments, are not familiar with the specifics of the quality management program.

24. Under the OSC license a physicist cannot administer an HDR treatment without an authorized user providing an oral or written directive.

25. The NRC did not have a complete and full understanding of what had occurred at the IRCC on November 16, 1992 until at least December 15, 1992.

26. Dr. Rogers contacted or attempted to contact all of the Medical Directors shortly after the Indiana incident was determined to have happened.

27. 10 CFR Section 20 does not require OSC to establish and/or implement a periodic corporate audit program.

28. 10 CFR Part 30 does not require OSC to establish and/or implement a periodic corporate audit program.

29. 10 CFR Part 35 does not require OSC to establish and/or implement a periodic corporate audit program.

30. An RSO may delegate tasks but not responsibilities without being in violation of 10 CFR Part 35.

31. An attempted delegation of RSO responsibility is not a violation of 10 CFR Section 35.21 where it was not completed.

32. Unauthenticated or hearsay evidence is not admissible in support of the OSC license Suspension Order.

33. Statements by agents, employees or other representatives of the NRC constitute admissions against the NRC.

34. Where the NRC clarifies existing regulations said clarification provides evidence of ambiguities of said regulations.

35. Statements by former employees and/or agents of OSC constitute admissions against OSC.

36. The NRC determined that the wire breakage accident at the Greater Pittsburgh Cancer Center was handled appropriately and safely.

37. Prior to the November 16, 1992 incident, the NRC had no reason to believe that Dr. David Cunningham was not a qualified and competent RSO.

38. Prior to November 16, 1992, the NRC never determined that OSC had a breakdown of corporate management with respect to licensed activities.

39. On September 4, 1991, Region I performed a complete safety inspection and review of the entire OSC HDR Radiation Safety Program.

40. During the September 4, 1991 inspection, the NRC found no deficiencies with regard to OSC's corporate oversight, HDR operation or treatment procedures.

41. The Omnitron training provided to OSC personnel did include a dry run involving the failure of the source to retract into the Afterloader.

42. OSC's alleged lack of corporate control of licensed activities at IRCC did not contribute to the occurrence of the incident at IRCC on November 16, 1992.

43. The NRC has admitted that Dr. Bauer had at most 30 seconds to act on November 16, 1992.

44. Dr. Paperiello admitted that Dr. Bauer had at most 30 seconds to act on November 16, 1992.

45. Instruction in the use of a handheld survey meter takes no more than 2 minutes to complete.

46. The use of a handheld survey meter is extremely simple.

47. The PrimeAlert did not fail or malfunction during the November 16, 1992 incident at IRCC.

48. No personnel at IRCC, including Dr. Bauer, knew of any failure or malfunction of the PrimeAlert during the November 16, 1992 incident.

49. Reliance by IRCC personnel on safety features of the Omnitron was reasonable in November 1992.

50. The Omnitron machine on November 16, 1992 did not give off an audible alarm signal to indicate a problem with the wire retraction.

51. The Omnitron machine on November 16, 1992 did not indicate that an emergency condition existed.

52. The Omnitron unit on November 16, 1992 indicated that the source was back in the safe position.

53. On November 16, 1992, it was impossible for OSC to know that the source wire could break due to a chemical reaction resulting from the packaging container where Omnitron had failed to notify OSC of said matter and OSC was not otherwise informed of the possibility of such deterioration.

54. Dr. William Ying visited the Mahoning Center in Lehighton on approximately 10 occasions between November 1991 and March 1992 to, in part, train personnel in radiation safety.

55. Between November 1992 and March 1993 no HDR procedures were performed at Lehighton without supervision by Dr. Ying.

56. The technologists at Lehighton was 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.

57. The Lehighton radiation training program covered a review of HDR emergency procedures.

58. Dr. Cunningham was in continuous contact by fax and telephone with the Lehighton facility during the six to nine months prior to the December 1992 inspection.

59. There was no 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.

60. Dr. Ying provided radiation safety training and emergency training to the Exton employees during HDR sessions that occurred between November 1991 and February 1992.

61. The physicist at Exton received additional calibration training on the HDR unit by traveling to the Harrisburg facility.

62. The technologists at Exton were never in charge of an HDR administration.

63. The technologists at Lehighton were never in charge of an HDR administration.

64. The technologists at Exton never performed unsupervised HDR administrations.

65. The technologists at Lehighton never performed unsupervised HDR administrations.

66. The technologists at Exton were trained in and familiar with the required procedures and actions necessary to comply with the relevant license conditions and regulations.

67. The technologists at Lehighton were trained in and familiar with the required procedures and actions necessary to comply with the relevant license conditions and regulations.

68. A copy of the license with all documents incorporated by reference was physically present at the Exton center.

69. A copy of the license with all documents incorporated by reference was physically present at the Lehighton facility.

70. A copy of the license with all documents incorporated by reference was physically present at IRCC on November 16, 1992.

71. The emergency scenario that the Omnitron source wire would break was neither expected nor reasonably anticipated by OSC in general and the IRCC treating personnel in particular on November 16, 1992.

72. OSC had submitted a quality management plan to the NRC prior to January 1992.

73. OSC had a quality management plan in place prior to the required deadline in January 1992.

74. HDR is not brachytherapy.

75. It was impossible on the day of the Exton inspection for both the linear accelerator and the HDR unit to be activated simultaneously.

76. It was impossible on the day of the Mahoning Valley inspection for the linear accelerator and the HDR unit to be activated simultaneously.

77. The linear accelerator and the HDR unit were never simultaneously activated at Exton.

78. The HDR unit and the linear accelerator were never simultaneously activated at Mahoning Valley.

79. The HDR unit and the linear accelerator were never simultaneously activated at IRCC.

80. The HDR unit and the linear accelerator were never simultaneously activated at Greater Pittsburgh Cancer Center.

81. OSC's alleged lack of corporate control of licensed activities at IRCC did not cause the occurrence of the incident at IRCC on November 16, 1992.

82. OSC's alleged lack of corporate control of licensed activities at IRCC did not cause the iridium wire to break.

83. No regulations and/or license conditions required OSC to implement a periodic corporate audit program.

84. 10 CFR Section 20.201(b) does not define the type of "survey" required to be performed.

85. A primary goal of the NRC is to provide clear and understandable regulations.

86. The emergency procedures were available within 2 feet of the console at Exton.

87. Both the Exton facility and the Mahoning Valley facility had lead containers and forceps/thongs in the treatment room in case of an emergency.

88. Dosimetry is assigned and worn by all personnel at Exton and Mahoning Valley.

89. Badges for Exton, Mahoning Valley and IRCC are exchanged monthly.

90. Dosimetry reports at Exton indicated minimal exposures to staff.

91. Dosimetry reports at Mahoning Valley indicated minimal exposures to staff.

92. Dosimetry reports at IRCC indicated minimal exposures to staff.

93. Karen Wagner is a qualified physicist.

94. Paula Salanitro is a qualified physicist.

95. The stored data regarding error messages on the IRCC Omnitron unit did not indicate an emergency condition on November 16, 1992.

Respectfully submitted,

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Dated: June 17, 1994

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UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

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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 License No. 37-28540-01)	)	EA No. 93-006

CERTIFICATE OF SERVICE

I hereby certify that copies of OSC'S Request For Admissions Dated June 17, 1994 in the above-captioned proceeding have been served on the following via U.S. Mail, postage prepaid, this 17th day of June, 1994:

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U.S. Nuclear Regulatory Commission
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