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UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

DOCKETED
USNRC

ATOMIC SAFETY AND LICENSING BOARD

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Before Administrative Judges:

G. Paul Bollwerk, III, Chairman
Dr. Charles N. Kelber
Dr. Peter S. Lam

OFFICE OF SECRETARY
DOCKETING & SERVICE
BRANCH

SERVE MAR 15 1994

In the Matter of
ONCOLOGY SERVICES CORPORATION

(Order Suspending
Byproduct Material
License No. 37-28540-01)

Docket No. 030-31765-EA
EA 93-006
ASLBP No. 93-674-03-EA
March 15, 1994

ORDEF

(Adopting Transcript Corrections for
January 26, 1994 Prehearing Conference;
Forwarding Documents for Docketing)

In response to the Board's February 1, 1994 prehearing conference order, on February 8, 1994, licensee Oncology Services Corporation (OSC) submitted proposed corrections to the transcript for the prehearing conference session held on January 26, 1994. After reviewing OSC's proposed corrections and the transcript itself, we adopt the revisions set forth in the appendix to this order, subject to the condition set forth below.

Those corrections in the appendix marked with an asterisk (*) were identified by OSC as a result of its transcript review. If either party has any objection to the unmarked, Board-designated corrections, it should advise us in writing by Monday, March 28, 1994. Absent any exceptions

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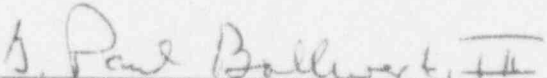
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filed by the parties, the Board-designated corrections will become effective on that date.

Also regarding the prehearing conference, the transcript makes reference to a group of documents relating to an agency subpoena enforcement action that OSC counsel gave to the Board and staff counsel. See Tr. 92. To ensure that the record of this proceeding is complete, the Board is providing a copy of those documents to the Office of the secretary for filing in the docket of this proceeding.

It is so ORDERED.

FOR THE ATOMIC SAFETY
AND LICENSING BOARD


G. Paul Bollwerk, III, Chairman
ADMINISTRATIVE JUDGE

Bethesda, Maryland

March 15, 1994

APPENDIX

Docket No. 030-31765-EA

ASLBP No. 93-674-03-EA

Prehearing Conference Transcript Corrections (January 26, 1994)

<u>Page</u>	<u>Line(s)</u>	<u>Correction</u>
4	6	Change "First" to "The first"
4	8	Change "radium" to "iridium-"
4	11	Change "Second" to "The second"
4	18	Change "done with" to "under"
4	25	Delete "of"
5*	1	Change "licenseship" to "relationship"
5	10	Change "both" to "name"
7	4	Change "fell" to "feel"
7	17	Change "How" to "Here's how" and change the question mark after "proceed" to a period
8	20	Delete "and"
9	5	Change "delayed, that" to "delayed, says that"
10*	8	Change "of protective" to "on protected"
10*	22	Change "aware. There" to "aware that there"
11	21	Change "while you said that" to "what you said is that"
13	3	Change "facility" to "facilities"
14*	6	Change "of" to "a"
15*	13	Change "the" to "being"
15	19	Change "request" to "requests"

<u>Page</u>	<u>Line(s)</u>	<u>Correction</u>
15	22	Change "issues" to "else"
17*	11	Change "do and" to "do with the referrals and"
20	11	Change "relatives hearing" to "the Lehighton inspection"
21	8	Change "feeding" to "proceeding"
22	5	Change "had" to "would"
23	23	Change "Protected" to "Protective"
24	12	Change "for Protected" to "for a Protective"
24	21	Delete "is"
24	22	Change "sends" to "sets"
25	6	Change "file or to" to "fully"
25	8	Change "their opportunity" to "our responsibility"
25	10	Add "way" after the word "proper" at the end of the line
25	15	Change "hasn't" to "haven't"
25	18	Change "objections?" to "objections to?"
26	7	Change "say" to "says"
26	20	Delete the comma after "point" and change the period at the end of the line to a comma
26	21	Change "You're" to "you're" and change "so, but" to "so. But"
28	10	Change "don't Ms." to "don't think Ms."
29	11	Change "connected" to "conducted"
29	18	Change "scenario." to "scenarios."

<u>Page</u>	<u>Line(s)</u>	<u>Correction</u>
30	22	Insert "If" before "Ms."
30	23	Change "MR. CARSON" to "MS. ZOBLER"
31	14	Change "break seems" to "break, it seems"
31*	17	Change "presenting them." to "presented to them."
32	9	Change "there" to "their"
33	21	Change "say" to "says"
35	18	Change "believes" to "beliefs"
36	12	Add "are" at the beginning of the line, change "respond" to "responding", and change "I" to "you"
38*	3	Insert "and" after "fact" at the end of the line
39	5	Change "facility" to "facilities"
41*	3	Change "term" to "term's" in both places on the line
43	19	Change "redress" to "revise" and change the question mark to a period after "here"
43	21	Change "redress" to "revise"
45	4	Delete "little"
45	10	Change "2201" to "20.201"
46*	10	Change "absent" to "absence"
48*	7	Change "and" to "hand"
48	18	Delete "a" between "survey" and "was"
48	19	Change "2201" to "20.201"
49*	1	Change "when" to "one of"

<u>Page</u>	<u>Line(s)</u>	<u>Correction</u>
49	3	Change "Mr." to "Dr."
50	11	Change "requested appended to Request One." to "request appended as Production Request II.B.1"
50	18	Change "you want us to have" to "do you have"
54	19	Change "some unpublished Memorandum Order" to "an unpublished Memorandum and Order"
57*	22-24	Place quotation marks around the sentence beginning with "To call" and ending with "itself."
58	4	Change "the Staff." to "the Staff's discretion."
58*	10	Change "abut" to "are but"
60	13	Change "Regulations]" to "Regulations]"
62*	11-12	Change "wasn't it Staff who identified the other opinion? Was the Court in its opinion?" to "it wasn't the Staff who identified the other opinion, it was the Court in its opinion."
62	22	Delete "of this"
62	23	Change "basis" to "basic"
63	2	Change "burdensome" to "burdensomeness"
64*	12	Insert "it" between "which" and "deems"
65	20	Change "understand" to "understanding" and add "it" on the end of the line
65	24	Insert a comma after "saying"
67*	3	Change "or" to "are"

<u>Page</u>	<u>Line(s)</u>	<u>Correction</u>
67*	5	Change "IRCC" to "OSC"
68	21	Change "do we need," to "do or do we need more,"
68	24	Change "minutes" to "minute"
75	8	Insert a comma after "us"
75	10	Delete first "so" on the line
75	17	Change "is" to "as"
75	19	Change "OSC's" to "OSC"
76	2	Delete first "what" on the line
76	19	Change "other" to "others"
78	10	Change "or" to "on"
78*	24	Change "though" to "so"
79	3	Change "believes" to "believed" and "10 (C) of Part" to "10 CFR"
79	5	Change "meant" to "met" and "treatment." to "treatment room."
82	6	Change "in Omnitron air" to "in the Omnitron error"
86*	6	Change "product's" to "products"
91	10	Change "instruct me with" to "it struck me this is"
92*	14	Change "missing so the" to "missing, the"
92*	19	Change "prior and no order" to "prior order and no subsequent order"
94	21	Change "that out" to "without"
94	22	Change "Made you think" to "Maybe you should think"

<u>Page</u>	<u>Line(s)</u>	<u>Correction</u>
94	23	Change "out" to "out loud"
95	19	Change "OI" to "OIA"
96	4	Change "IG" to "IG's"
96	16	Insert "that to be" between "understand" and "anything"
99	5	Change "saying" to "setting"
102	16	Change "Do" to "Does"
103	9	Change "properly, after" to "promptly after"
104	22	Change "actions where" to "actions, here"
104	24	Change "experience, and" to "experience that"
107	11	Change "using" to "holding"
108	7	Change "ZOBLE" to "COLKITT"
109	8	Change "ask" to "asked"
109	12	Change "9321" to "93-21"
116	9	Insert "what" between "with" and "the"
119	25	Change "as" to "and"
124	7	Change "ask" to "asked"
125	14	Insert "Cancer" between "Regional" and "Center"
126	25	Insert a comma after "involving"
127	10	Change second "that" to "the"
137	2	Change "Great." to "I agree."
138	1-2	Sentence beginning "But the word" should be attributed to Judge Bollwerk

<u>Page</u>	<u>Line(s)</u>	<u>Correction</u>
138	20	Change "versus" to "hearing"
139	8	Change "What I'm" to "One was" and delete the comma after "about"

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

In the Matter of

ONCOLOGY SERVICES CORPORATION,
HARRISBURG, PA
(Byproduct Material License
No. 37-28540-01 - EA 93-006)

Docket No.(s) 30-31765-EA

CERTIFICATE OF SERVICE

I hereby certify that copies of the foregoing LB ORDER (ADOPT'G TR...W/DOCS) have been served upon the following persons by U.S. mail, first class, except as otherwise noted and in accordance with the requirements of 10 CFR Sec. 2.712.

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

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

Administrative Judge
Charles N. Kelber
Atomic Safety and Licensing Board
U.S. Nuclear Regulatory Commission
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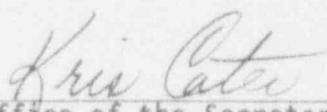
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State College, PA 16801

Dated at Rockville, Md. this
15 day of March 1994


Office of the Secretary of the Commission

OSC/NRC
ADMINISTRATIVE SUBPOENA
PLEADINGS

1. PETITION FOR SUMMARY ENFORCEMENT OF
ADMINISTRATIVE SUBPOENA (LOOSE IN FILE) 11/15/93
2. CONSENTED-TO MOTION FOR SCHEDULING THE
RESPONSE BY ONCOLOGY SERVICES CORPORATION
TO THE PETITION OF THE UNITED STATES OF
AMERICA FOR SUMMARY ENFORCEMENT OF
ADMINISTRATIVE SUBPOENA 11/22/93
3. ORDER 12/2/93
4. MOTION OF ONCOLOGY SERVICES CORPORATION
TO VACATE ORDER OF COURT DATED 11/22/93 12/6/93
5. MEMORANDUM IN SUPPORT OF MOTION OF
ONCOLOGY SERVICES CORPORATION TO VACATE
ORDER OF COURT DATED 11/22/93 12/6/93
6. RESPONSES OF RESPONDENT ONCOLOGY SERVICES
CORPORATION TO THE PETITION OF THE UNITED
STATES OF AMERICA FOR SUMMARY ENFORCEMENT
OF ADMINISTRATIVE SUBPOENA 12/6/93
7. MEMORANDUM IN SUPPORT OF RESPONSES OF
RESPONDENT ONCOLOGY SERVICES CORPORATION
TO THE PETITION OF THE UNITED STATES OF
AMERICA FOR SUMMARY ENFORCEMENT OF
ADMINISTRATIVE SUBPOENA 12/6/93
8. ORDER 12/7/93
9. UNOPPOSED MOTION FOR ENLARGEMENT OF TIME 12/13/93
10. ORDER 12/16/93
11. REPLY OF THE UNITED STATES OF AMERICA TO
RESPONSE OF ONCOLOGY SERVICES CORPORATION
TO PETITION FOR SUMMARY ENFORCEMENT OF
ADMINISTRATIVE SUBPOENA 12/21/93
12. RESPONSE OF RESPONDENT ONCOLOGY SERVICES
CORPORATION TO THE REPLY OF THE UNITED
STATES OF AMERICA TO THE RESPONSES OF
ONCOLOGY SERVICES CORPORATION TO THE
PETITION OF THE UNITED STATES FOR
ENFORCEMENT OF ADMINISTRATIVE SUBPOENA 1/10/94

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

_____)	
UNITED STATES OF AMERICA,)	
)	
Petitioner,)	
)	
v.)	MISC. NO. _____
)	
ONCOLOGY SERVICES CORPORATION,)	
)	
Respondent.)	
_____)	

PETITION FOR SUMMARY ENFORCEMENT
OF ADMINISTRATIVE SUBPOENA

Petitioner, the United States of America, by its undersigned attorneys, hereby petitions this Court for an order requiring respondent, Oncology Services Corporation, to comply with certain subpoenas issued by the Office of Investigations of the U.S. Nuclear Regulatory Commission. This request is made pursuant to 42 U.S.C. § 2281. In further support of this petition, the Court is respectfully referred to petitioner's Memorandum of Points and Authorities in Support of Petition for Summary Enforcement of Administrative Subpoena, which is filed herewith.

As the basis for the petition, the United States avers as follows:

PARTIES, JURISDICTION, AND VENUE

1. Petitioner is the United States of America, suing on behalf of the U.S. Nuclear Regulatory Commission ("NRC").

2. Respondent, Oncology Services Corporation ("OSC"), is a corporation, with headquarters and business office in State College, Pennsylvania.

Handwritten initials

3. This Court has jurisdiction over this action pursuant to 42 U.S.C. § 2281 and 28 U.S.C. §§ 1331 and 1345.

4. Venue in this district is proper pursuant to 28 U.S.C. § 1391(b).

STATUTORY AND REGULATORY BACKGROUND

5. The NRC is an independent regulatory agency created by Congress to regulate atomic energy and safety pursuant to the Atomic Energy Act of 1954, as amended. 42 U.S.C. §§ 2011 et seq. The NRC's responsibilities include licensing and regulating nuclear facilities in the interest of, inter alia, public health and safety, the environment, and national security. See 10 C.F.R. § 1.11(b).

6. The NRC may:

make such studies and investigations, obtain such information, and hold such meetings or hearings as the [NRC] may deem necessary or proper to assist it in exercising [its authority] For such purposes the [NRC] is authorized to administer oaths and affirmations, and by subpoena to require any person to appear and testify, or to appear and produce documents, or both, at any designated place.

42 U.S.C. § 2201(c).

7. The NRC has delegated authority to issue subpoenas to its Office of Investigations ("OI"). 10 C.F.R. § 1.36(e).

8. 42 U.S.C. § 2281 empowers district courts to issue orders enforcing subpoenas issued under 42 U.S.C. § 2201(c).

FACTS

9. On February 22, 1993, the NRC-OI issued seven identical document subpoenas, one to each of six OSC facilities in the

state of Pennsylvania, and one to OSC's headquarters in State College, Pennsylvania, in aid of an investigation into potential deliberate violations of NRC regulations by OSC. ("First Subpoenas"). True and correct copies of the first subpoenas are attached as Exhibit 2.

10. The first subpoenas relate to OSC's practices under NRC licenses which enable it to use or possess nuclear material in the treatment of human beings with radiation therapy, primarily in the treatment of cancer. The first subpoenas required OSC to produce documents relating to its licensed activities at several OSC cancer treatment facilities. The information requested pursuant to the first subpoenas is necessary for the satisfactory completion of the NRC investigation into possible deliberate violations of NRC regulations by OSC and for the protection of public health and safety.

11. The first subpoenas directed the Custodian of Records at the individual OSC facilities and at OSC headquarters in State College, Pennsylvania, to appear and provide documents at the offices of the NRC at 475 Allendale Road, King of Prussia, Pennsylvania 19406, on the 12th day of March, 1993, at 9:00 a.m..

12. NRC-OI investigators personally served the first subpoenas on the individual OSC facilities on February 25 and 26, 1993.

13. OSC provided some documents in response to the first subpoenas. However, based on the ongoing NRC investigation, the NRC has learned of the existence of specific documents and other

records which are, or should be, in the possession of OSC and are responsive to the first subpoenas, but which have not been produced by OSC.

14. In several oral and written communications with OSC legal counsel, NRC investigator Gerard F. Kenna requested that the respondent produce additional documents pursuant to the first subpoenas which he had reason to believe existed and to be within the possession of OSC.

15. During a July 9, 1993, telephone conversation with NRC investigator Kenna, OSC legal counsel stated that OSC would not release any remaining documents on the basis that they were not pertinent. In addition, by letter dated July 14, 1993, counsel for OSC claimed that the respondent had produced all documents in its possession which it considered to be relevant to the NRC investigation. However, in late July, OSC produced some additional documents responsive to the first subpoenas.

16. On August 24, 1993, the Director of NRC-OI issued a second subpoena to OSC headquarters. ("Second Subpoena"). A true and correct copy of the second subpoena is attached as Exhibit 7. In the second subpoena, the NRC made every effort to carefully describe the documents sought and to limit the subpoena to documents which it believed to be necessary for the satisfactory completion of the investigation.

17. The date for compliance specified in the second subpoena was September 13, 1993. The second subpoena was faxed

to OSC legal counsel who agreed to accept service by fax. In addition, service was accomplished by certified mail.

18. On September 16, 1993, OSC issued a letter objecting to the requests for information under various document categories identified in the second subpoena on the basis that they sought "irrelevant information," "information outside the scope of NRC's jurisdiction," were "unduly burdensome," or had previously been responded to by OSC.

19. Despite OSC's allegations, and based on information derived from its investigation of OSC to date, the NRC is aware of numerous additional records which are responsive to the first and second subpoenas, relevant to the investigation, not already within the possession of NRC, and which have not been produced by OSC.

20. OSC's failure to comply in full with the NRC subpoenas by refusing to produce additional documents within its possession, undermines the NRC's ability to complete its investigation into OSC's licensed practices and may seriously threaten public health and safety.

21. Both the first and second subpoenas advised OSC that it could request the Commission to quash or modify the subpoenas if such request is made "at or before the time specified in the subpoena for compliance." OSC did not file such a motion within the specified deadline and has not done so to the date of filing this petition.

RELIEF REQUESTED


WHEREFORE, petitioner United States of America respectfully requests this Court to:

1. Order respondent, Oncology Services Corporation, to appear and produce documents in accordance with the first subpoenas and second subpoena at the time and place specified in those subpoenas on a date specified by the Court; and
2. Grant petitioner the costs of this action.
3. Grant such other and further relief as this Court deems necessary and appropriate.

Respectfully submitted,

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OSC's radiation safety program contributed to the death of an individual who had received radiation treatment at an OSC facility on November 16, 1992, and that, in addition, residents, staff members and visitors at the OSC facility and the nursing home where the patient resided, as well as individuals at other locations, had been exposed to unnecessary radiation between November 16 and December 1, 1992. See Exhibit 1. In response to this determination, the NRC instituted a new investigation to ascertain whether OSC had intentionally violated NRC regulations. In order to satisfactorily complete this investigation, it is imperative that the NRC be allowed to gather the information necessary to conduct a comprehensive review of OSC's licensed activities.

Although the subpoenas were properly served and authorized by law, OSC has failed to produce many of the requested documents by the dates provided for compliance, arguing that the requests for information are either not within the scope of NRC's statutory authority, not relevant to the NRC investigation, unduly burdensome, seek nonexistent material or have previously been complied with by OSC. The respondent's failure to fully comply with the subpoenas continues to thwart the completion of the NRC investigation and may seriously undermine public health and safety. Accordingly, the United States seeks a court order, pursuant to 42 U.S.C. § 2281, requiring respondent to produce documents in accordance with the subpoenas at the time and place specified in the subpoenas on a date specified by the Court.

STATUTORY AND REGULATORY BACKGROUND

The Nuclear Regulatory Commission ("NRC") is an independent agency created by Congress to regulate atomic energy and safety pursuant to the Atomic Energy Act of 1954, as amended. 42 U.S.C. §§ 2011, et seq. The NRC's responsibility includes licensing and regulating nuclear facilities and materials in the interest of, inter alia, public health and safety, the environment, and national security. See 10 C.F.R. § 1.11(b). To aid in the fulfillment of these responsibilities, the NRC may:

make such studies and investigations, obtain such information, and hold such meetings or hearings as the [NRC] may deem necessary or proper to assist it in exercising [its authority] For such purposes the [NRC] is authorized to administer oaths and affirmations, and by subpoena to require any person to appear and testify, or to appear and produce documents, or both, at any designated place.

42 U.S.C. § 2201(c). The NRC has delegated authority to issue subpoenas to its Office of Investigations ("OI"). See 10 C.F.R. § 1.36(e). In the case of refusal to obey an administrative subpoena issued by NRC-OI, the federal district courts are empowered to enforce the subpoena. In this regard, 42 U.S.C. § 2281 states that:

In case of failure or refusal to obey a subpoena served upon any person pursuant to section 2201(c) of this title, the district court for any district in which such person is found or resides or transacts business, upon application by the Attorney General on behalf of the United States, shall have jurisdiction to issue an order requiring such person to appear and give testimony or to appear and produce documents, or both, in accordance with the subpoena; and any failure to obey such order of the court may be punished by such court as a contempt thereof.

FACTS

Oncology Services Corporation holds three NRC licenses which allow it to possess and use nuclear material for the treatment of human beings with radiation therapy, primarily in the treatment of cancer. Declaration of Gerard F. Kenna ("Kenna Declaration") ¶ 5. In early December, 1992, the NRC initiated an investigation into OSC's licensed activities after the death of an individual on November 21, 1992, who had received radiation therapy at one of the OSC cancer treatment facilities on November 16, 1992 ("November 16, 1992, incident"). Kenna Declaration ¶ 6. The NRC Incident Investigation Team ("IIT") concluded that serious weaknesses in the OSC radiation safety program were a primary cause of the death of the individual and subsequent radiation exposure of patients, employees and members of the public at the OSC cancer treatment center and other locations.²

The NRC Office of Investigation initiated a separate investigation ("investigation") into possible willful violations of NRC regulations at various cancer treatment centers operated by OSC under NRC licenses. Kenna Declaration ¶ 9. This investigation seeks to review, inter alia, OSC's compliance with NRC regulations governing training requirements and administration of radiation therapy programs, OSC's compliance with the conditions contained in its licenses, the actions of OSC

²See NUREG-1480, "Loss of an Iridium-192 Source and Therapy Misadministration at Indiana Regional Cancer Center Indiana, Pennsylvania, on November 16, 1992," published February 1993, Abstract and Executive Summary, attached hereto as Exhibit 1.

personnel at the Indiana Regional Cancer Center during and after the November 16, 1992, incident and the possibility that OSC employees provided incomplete and/or inaccurate information to the NRC. Id. ¶ 11.³

On February 22, 1993, in furtherance of the investigation and in accordance with 42 U.S.C. § 2201(c), the Director of OI issued seven identical document subpoenas, one to each of six OSC facilities listed under License No. 37-28540-01 and one to OSC headquarters in State College, Pennsylvania ("first subpoenas").⁴ Each subpoena was signed by Ben B. Hayes, Director of OI, on February 22, 1993. Kenna Declaration ¶¶ 12,13.

NRC-OI investigators personally served the six subpoenas on the individual facilities on February 25 and 26, 1993. Kenna Declaration ¶ 13. The OSC headquarters subpoena was served by registered mail after an OSC employee refused to accept the document. The subpoena was later returned by the post office stamped "unclaimed."⁵ It was eventually accepted by OSC legal counsel. Id.

The first subpoenas directed the respondent to produce records at the offices of the U.S. Nuclear Regulatory Commission

³The regulations which OSC may have deliberately violated, include, inter alia, 10 C.F.R. § 19.12 (failure to instruct workers); 10 C.F.R. § 20.201(b) (failure to conduct radiation survey); and 10 C.F.R. § 30.9 (failure to provide complete and accurate information). Kenna Declaration ¶ 10.

⁴Copies of the seven first subpoenas are attached hereto as Exhibit 2.

⁵See Exhibit 3.

in King of Prussia, Pennsylvania, on March 12, 1993, at 9:00 a.m. Kenna Declaration ¶ 14; see Exhibit 2. These subpoenas sought various categories of documents relevant to the NRC investigation into OSC's practices and necessary for the satisfactory completion of this investigation.⁶ Kenna Declaration ¶ 15. More specifically, the subpoenas sought information from OSC regarding, inter alia, its application to the NRC for a materials license; its radiation safety training, procedures and policies; purchase and repair records for radiation detection devices; training-related expense and travel vouchers; employment applications of various OSC personnel; and certain business records relating to OSC's licensed activities. See Exhibit 2.

Between March and September, 1993, OSC provided some documents in response to the first subpoenas. Kenna Declaration ¶ 16. On April 26, 1993, OSC legal counsel, Marcy Colkitt, submitted an affidavit to the NRC stating that all documents had been produced under the subpoenas.

On several occasions thereafter, NRC-OI conferred with Ms. Colkitt by telephone, letter, and in person, and informed her that, based on the NRC investigation to date, NRC investigators had learned of the existence of specific documents within the custody of OSC which were responsive to the subpoenas and which OSC had failed to produce. Id. ¶ 18. By letter dated June 4, 1993, the NRC provided Ms. Colkitt with a list of documents that

⁶Each subpoena requested documents in several distinct document categories. See Exhibit 2.

the NRC had reason to believe existed and were within the possession of OSC, but which had not been provided to the NRC pursuant to the subpoenas. Id. ¶ 19; see Exhibit 4.

On July 9, 1993, NRC-OI again contacted Ms. Colkitt and requested that OSC comply with the first subpoenas by close of business Monday, July 12, 1993. Kenna Declaration ¶ 20. NRC-OI informed Ms. Colkitt that the NRC would consider legal action to enforce the subpoenas if OSC did not fully comply with the subpoena by that date. Id. During that conversation, Ms. Colkitt stated that the NRC would not receive some of the documents requested in the June 4 letter because they were not pertinent. Id.

By letter dated July 14, 1993, Ms. Colkitt indicated that OSC had produced all documents in its possession that it believed were relevant to the NRC investigation. Kenna Declaration ¶ 21; see Exhibit 6. Nevertheless, in late July and September, OSC submitted some additional documents to NRC which were responsive to the first subpoenas. Kenna Declaration ¶ 22.

On August 24, 1993, NRC issued a second subpoena to OSC headquarters ("second subpoena") specifically requesting information which the NRC believed was relevant to the investigation and within the possession of OSC, but which had not been produced pursuant to the first subpoenas. Kenna Declaration ¶ 23; see Exhibit 7. The second subpoena sought specific materials relating to, inter alia, OSC's licensed activities, training procedures and policies and radiation equipment for NRC

License Nos. 37-28540-01 and 37-28179-01. See Exhibit 7. In the second subpoena, the NRC made every effort to carefully describe the materials sought and to limit the subpoena to documents which it believed necessary for the satisfactory completion of the investigation. The date for compliance specified in the second subpoena was September 13, 1993. Id. OSC failed to comply with the second subpoena by the specified deadline. Kenna Declaration ¶ 24.

Instead, on September 16, 1993, OSC issued a letter stating its objections to the request for documents under several of the document categories listed in the second subpoena.⁷ Kenna Declaration ¶ 25. First, OSC objected to the requests for information under seven document categories on the basis that they sought "irrelevant information" and "information outside the scope of the NRC's jurisdiction."⁸ See Exhibit 8. Second, OSC objected to document requests under two document categories on the basis that they were unduly burdensome.⁹ Id. Third, OSC alleged that it had produced all documents in existence with respect to eleven document categories.¹⁰ Id. Finally, OSC

⁷Each document category is identified by a specific paragraph number in the second subpoena ("Subpoena Paragraph No.")

⁸OSC made this objection with respect to Subpoena Paragraph I, Nos. 1, 3, 5, 6, 7, 10 and 14.

⁹OSC made this objection with respect to Subpoena Paragraph I, Nos. 10 and 14.

¹⁰Specifically, OSC claims to have produced all existing documents under Subpoena Paragraph I, Nos. 2, 3, 4, 7, 8, 9, 11, 12, 13, 15 and 17.

refused to produce any information relating to NRC License No. 37-28179-01, on the basis that the license in question was not issued to OSC. Id.

Based on interviews of OSC personnel and other information obtained during the course of the investigation, NRC has been informed that specific documents or other records exist with respect to several of the document categories under which OSC claims to have produced all existing materials.¹¹ Kenna Declaration ¶ 27; see Appendix to Declaration of Gerard F. Kenna ("Appendix"). Moreover, even though NRC License No. 37-28179-01 is not specifically issued to OSC, the license indicates that the nuclear material in question is to be used at an OSC-operated cancer treatment facility and that the authorized user under the license is an employee of an affiliated company which is owned or managed by OSC. Appendix, p. 12 ¶ a.

Both the first subpoenas and the second subpoena to OSC headquarters advised OSC that it could request the Commission to quash or modify the subpoenas if such request were made "at or before the time specified in the subpoena for compliance." See

¹¹Specifically, NRC is aware of the existence of documents which are responsive to Subpoena Paragraph I, Nos. 1, 2, 3, 4, 5, 6, 10, 13, 14, 15 and 17, but which have not been produced by OSC. NRC is willing to drop its requests for information pursuant to Subpoena Paragraph I, Nos. 8 and 9 because it is not aware of the existence of specific additional documents in these categories. Moreover, by letter dated October 14, 1993, OSC legal counsel indicated that OSC was unable to produce legible slides in response to Subpoena Paragraph I, No. 16, but that NRC investigators could view the original slides at OSC headquarters in State College, Pennsylvania. The NRC will make arrangements to travel to State College for this purpose.

Exhibits 2 & 7. At the time of filing this petition, OSC has not moved to quash or modify any of the subpoenas duces tecum issued to it. Id.

ARGUMENT

NRC'S ADMINISTRATIVE SUBPOENAS SATISFY THE MINIMAL REQUIREMENTS NECESSARY FOR SUMMARY ENFORCEMENT

It is well-settled that proceedings to enforce administrative subpoenas are summary in nature and that the scope of judicial review is "strictly limited." See, e.g., United States v. Stuart, 489 U.S. 353, 359-60 (1989); FTC v. Texaco, Inc., 555 F.2d 862, 871-72 (D.C. Cir. 1977), cert. denied sub nom. Standard Oil Co. v. FTC, 431 U.S. 974 (1977). To obtain summary enforcement of its subpoena, NRC need only make a showing that "the inquiry is within the authority of the agency, the demand is not too indefinite, and the information sought is relevant to the agency's inquiry." United States v. Morton Salt Co., 338 U.S. 632, 652 (1950) ("Morton Salt Co."); see also United States v. Powell, 379 U.S. 48, 57-58 (1964) ("Powell"); Dole v. Trinity Industries, Inc., 904 F.2d 867 (3rd Cir. 1990); United States v. Westinghouse Electric Corporation, 788 F.2d 164 (3rd Cir. 1986). Once petitioner satisfies this minimal standard, the burden then shifts to respondent to show that the Court's process would be abused by enforcement. Powell, 379 U.S. at 58. Unless respondent meets this burden, the district court must enforce the subpoena. See National Labor Relations Board v. Interstate Dress Carriers, 610 F.2d 99 (3rd Cir. 1979).

In the present case, the subpoenas issued to OSC are well within the authority granted to NRC under 42 U.S.C. § 2201; the request for information relating to OSC's licensed activities is relevant to determining, inter alia, whether OSC deliberately violated NRC regulations; and the requests are not unduly burdensome. Accordingly, the subpoenas should be enforced by this Court.

A. The Instant Subpoenas Are Well Within
NRC's Statutory Authority

OSC has objected to the requests for information under seven of the document categories enumerated in the second subpoena on the basis that they seek "information outside the scope of the NRC's jurisdiction - safety and training."¹² However, it is clear that the NRC's "jurisdiction" goes well beyond the narrow confines alleged by OSC. In this regard, 10 C.F.R. § 1.11 (b) sets forth the NRC's broad jurisdiction as follows:

The Commission is responsible for licensing and regulating nuclear facilities and materials and for conducting research in support of the licensing and regulatory process . . . [t]hese responsibilities include protecting public health and safety, protecting the environment, protecting and safeguarding nuclear materials and nuclear power plants in the interest of national security, and assuring conformity with antitrust laws.

Moreover, Section 2201(c) grants the NRC wide investigatory powers to fulfill its far-reaching regulatory responsibilities. Accordingly, the Commission is authorized by statute to:

¹²OSC has made this objection with respect to Subpoena Paragraph I, Nos. 1, 3, 5, 6, 7, 10 and 14. See Exhibit 8.

make such . . . investigations, obtain such information . . . [it] may deem necessary or proper to assist it in exercising any authority provided in this chapter, or in the administration or enforcement of this chapter, or any regulations or orders issued thereunder.

For such purposes, the Commission is specifically authorized to issue subpoenas and subpoenas duces tecum. Id.

The statute places no restrictions on NRC's ability to issue such subpoenas. Indeed, such broad subpoena powers are necessary to ensure that the NRC can fulfill its statutory duties to regulate facilities licensed to possess and use nuclear material; specifically, that it will be able to obtain the information it needs to investigate and halt licensed operations which pose a threat to public health and safety, the environment, and national security.

In the instant case, there can be no question that it is within the NRC's broad statutory and regulatory authority jurisdiction to issue subpoenas to companies, such as respondent herein, which are the subject of a formal NRC investigation. Indeed, pursuant to 42 U.S.C. § 2201(c), the NRC has the authority to issue subpoenas seeking any information from the respondent which is relevant to its investigation of OSC's licensed activities and which will enable it to determine whether the respondent has deliberately violated NRC regulations at various radiation treatment facilities.

Thus, for example, OSC's objection that the request for information under Subpoena Paragraph I, No. 3 (seeking manuals and incentive plans for the High Dose Rate Gamma Iii ("HDR"))

machine) is not within the NRC's jurisdiction, is obviously misplaced. See Exhibit 8. The HDR machine uses a radioactive source for the administration of radiation therapy to cancer patients. Regulation of such sources is within the exclusive jurisdiction of the NRC. Failure to follow correct procedures while using a similar machine was a major contributing cause of death in the November 16, 1992, incident. See Exhibit 1.

More specifically, the earlier NRC investigation determined that some of the weaknesses in OSC's radiation safety program were the result of a rapid expansion in the respondent's HDR brachytherapy program from one facility to ten facilities in less than a year. See Exhibit 1. Furthermore, that investigation determined that radiation technologists at the OSC facility did not survey patients, the HDR machine, or the treatment room following HDR treatments. Id. Accordingly, the NRC is authorized to seek information regarding training and use of the HDR machine at OSC facilities because it relates directly to potential violations of NRC regulations by the respondent.

Similarly, NRC's requests for information under Subpoena Paragraph 1, Nos. 5, 6 & 7 (seeking Weekly Activity Reports and records of Regional Administrators and Medical Directors meetings relating to licensed activities), are well within the agency's statutory authority. Again, the Commission has statutory authority to request such information, which will assist it in determining whether OSC intentionally failed to comply with NRC regulations. In particular, this information will shed light on

the propriety of actions taken by OSC personnel with respect to the November 16, 1992, incident and the accuracy of statements made by OSC employees.

Likewise, information requested pursuant to Subpoena Paragraph I, No. 1 (seeking records of internal OSC meetings relating to licensed activities) and Subpoena Paragraph I, No. 10 (requesting expense and travel vouchers of certain OSC employees relating to licensed activities) will assist the NRC in determining whether OSC intentionally violated NRC regulations and specific conditions of its licenses. In addition, Subpoena Paragraph I, No. 14 (seeking names and addresses of current and former OSC employees) will enable NRC investigators to interview OSC personnel in connection with the issues under investigation. Accordingly, these requests for information relate directly to the NRC's investigation of OSC and are, therefore, well within the scope of the agency's broad authority under 42 U.S.C. § 2201(c) and 10 C.F.R. § 1.11(b).

B. The Information Sought Is Reasonably Relevant to the Purposes of the Investigation

The test for relevance in subpoena enforcement actions is extremely broad. A court is required to order production of information sought unless such material is "plainly incompetent or irrelevant to any lawful purpose of the agency." Endicott Johnson Corp. v. Perkins, 317 U.S. 501 (1943), 63 S. Ct. 339; United States v. Westinghouse Electric Corporation, 788 F.2d 164 (3rd Cir. 1986).

It is well-settled that the standard for judging relevancy in an investigatory proceeding is more relaxed than in an adjudicatory one. FTC v. Invention Submission Corporation, 965 F.2d 1086, 1090 (D.C. Cir. 1992) ("Invention Submission Corp."); United States v. Westinghouse Electric Corporation, 615 F. Supp. 1163, 1182 (D.C. Pa. 1985) ("Westinghouse I"), aff'd, 788 F.2d 164 (3rd Cir. 1986) ("Westinghouse II"). Thus, "[e]ven if one were to regard the request for information . . . as caused by nothing more than official curiosity, nevertheless law-enforcing agencies have a legitimate right to satisfy themselves that corporate behavior is consistent with the law and the public interest." Westinghouse I, 615 F. Supp. at 1182, quoting Morton Salt Co., 333 U.S. at 652. Accordingly, it is not necessary for the agency to have "probable cause" in issuing the subpoena. Westinghouse I, 615 F. Supp. at 1182. Moreover, a reviewing court may look only to the general purpose of the investigation and determine if the information sought, however broad, is relevant to that purpose." United States v. Firestone Tire & Rubber Co., 455 F. Supp. 1072, 1083 (D.D.C. 1978) (emphasis in original). The agency's own appraisal of relevancy must be accepted so long as it is not 'obviously wrong.'" Invention Submission Corp., 965 F.2d at 1089.

Here, the general purpose of the investigation is to determine whether the respondent has deliberately violated NRC regulations at various OSC radiation treatment facilities. Kenna Declaration ¶ 9. More specifically, the NRC investigation seeks

to discover whether OSC has deliberately violated regulations relating to, inter alia, training of employees involved in the administration of radiation treatment, radiation safety policies and procedures, maintenance and repair of radiation equipment, and other conditions of its NRC licenses. Id. ¶ 11. In addition, the investigation seeks to examine the propriety of actions taken by OSC personnel at the Indiana Regional Cancer Center during and after the November 16, 1992, incident and to determine whether incomplete and/or inaccurate statements were made by OSC personnel. Id.

Measured against the "general purpose" of this investigation, all of the information requested in the subpoenas is relevant to accomplishing the NRC's investigatory objectives. The subpoenas seek information relating to OSC activities conducted under NRC License Nos. 37-28540-01 and 37-28179-01 ("licenses"), including: business records pertaining to OSC's licensed activities; qualifications and training of OSC personnel responsible for the administration of radiation therapy; training relating to, as well as transportation and operation of the High Dose Rate ("HDR") machine; purchase and repair records for protective equipment needed in radiation treatment; inter-office communications and other business records relating to the November 16, 1992, incident; the names and addresses of current and former employees who may be interviewed in connection with various aspects of OSC's licensed operations and with the November 16, 1992, incident. See Exhibits 2 & 7.

The NRC's determination that this information is relevant and necessary for the completion of its broad investigation into OSC's licensed activities is reasonable and, accordingly, should be upheld by this Court.

C. The Subpoenas Are Not Unduly Burdensome

The burden of showing that an agency subpoena is unduly burdensome rests with the subpoenaed party. Powell, 379 U.S. at 58; Morton Salt Co., 338 U.S. at 653-54. A subpoena will not ordinarily be modified unless compliance threatens unduly to disrupt or seriously hinder normal operations of a business. Id. In other words, the fact that the subpoenaed party will suffer some burden is not enough. Id. Rather, the issue is whether a "demand is unduly burdensome" in light of the purpose of the inquiry, and "that burden is not easily met where, as here, the agency inquiry is pursuant to a lawful purpose and the requested documents are relevant to that purpose." Id. (Emphasis in original).

In the instant case, OSC claims that document requests under Subpoena Paragraph I, Nos. 10 and 14 of the second subpoena are unduly burdensome. See Exhibit 8. Subpoena Paragraph I, No. 10 seeks information concerning OSC's activities under NRC License No. 37-28540-02, including expense and travel vouchers of OSC employees and records related to training, maintenance and use of the HDR machine at OSC facilities.¹³ Although the respondent may

¹³Specifically, Subpoena Paragraph I, No. 10 requests:
[e]xpense vouchers and sub-vouchers, including, but not limited
(continued...)

be required to produce a large number of documents in response to this request, the request is reasonably definite and was purposely tailored to NRC's investigation. See United States v. International Business Machines Corporation, 83 F.R.D. 97, 107 (S.D.N.Y. 1979) ("International Business Machines") ("where large numbers of documents are involved and the identity of each specific document may be unknown until disclosure is made, 'common sense dictates that questions framed in terms of categories or types of documents are sufficient'").

Subpoena Paragraph I, No. 14 seeks payroll documents containing the names and addresses of OSC employees.¹⁴ This information would enable NRC investigators to locate and interview current and former employees regarding the issues involved in the investigation. Appendix p. 9 ¶ 14.b. Contrary to OSC's allegations, NRC is not seeking to obtain confidential and personal salary information. Indeed, NRC-OI has discussed

¹³(...continued)
to, travel vouchers submitted by any officer or employee of OSC or any of its owned or managed facilities. The records should include, but not be limited to, HDR maintenance travel records, HDR training records, and the semiannual Medical Directors' meetings and regional administrators' meetings regarding any activities conducted either in whole or in part, under NRC License No. 37-28540-01.

¹⁴Specifically, Subpoena Paragraph I, No. 14 requests: [p]ayroll documents which contain the name and home address of all employees of OSC, including its corporate headquarters personnel, and the employees of any of its owned or managed facilities in which OSC conducted activities under NRC License No. 37-28540-01, from June 1, 1990, through August 8, 1993.

with OSC the option of deleting the salary figure from the relevant documents. Id. As discussed above, such inquiry is clearly within the NRC's statutory duty to determine whether OSC has deliberately violated NRC regulations and is reasonably relevant to such inquiry.

Furthermore, courts have long recognized that a substantial burden of compliance may be justified by the nature and importance of the inquiry involved. See, e.g., FTC v. Rockefeller, 441 F. Supp. 234, 242 (S.D.N.Y. 1977), aff'd, 591 F.2d 182 (2d Cir. 1979); International Business Machines, 83 F.R.D. 97 (S.D.N.Y. 1979); Westinghouse Electric Corporation v. City of Burlington, 351 F.2d 762, 767 (D.C. Cir. 1965). Accordingly, "considerations of cost and burdensomeness must give way to the search for truth" in cases "of undoubted importance to the public weal." International Business Machines, 83 F.R.D. at 109.¹⁵

This principle applies especially in the instant case, where the NRC's investigation into possible deliberate violations of federal regulations by OSC fulfills a vital function in minimizing danger to life and property and thereby protecting public health and safety. It has already been established that serious deficiencies in OSC's radiation safety program

¹⁵Thus, even if production of evidence imposes some burden, so long as the information requested is relevant and material, the cost is considered to be "'part of the social burden' of our present day society." E.E.O.C. v. University of Pittsburgh, 487 F. Supp. 1071, 1077 (W.D. Pa. 1980), citing Bradley Lumber Co. v. NLRB, 84 F.2d 97 (5th Cir. 1936).

contributed to an individual's death on November 21, 1992, and for the fact that over 90 individuals, including employees, patients, and visitors of the OSC facility, the nursing home where the patient resided and at other locations, were unknowingly exposed to radiation between November 16 and December 1, 1992. See Exhibit 1. Hence, it is imperative that NRC be allowed to gather the information necessary to complete its investigation and prevent the reoccurrence of such tragic incidents in the future.

D. OSC Has Failed to Produce Existing Documents in Several Document Categories Despite Its Allegations to the Contrary

In addition to OSC's objections to certain document categories requested under the second subpoena, the respondent has also refused to produce documents on the basis that it has previously produced this information or that the material in question does not exist. See Exhibit 8. However, based on its investigation of OSC to date, the NRC has learned of the existence of specific documents and other records which are, or should be, in the possession of OSC and are responsive to the subpoenas but which have not been produced by the respondent.

For example, with respect to Subpoena Paragraph I, No. 1,¹⁶

¹⁶Subpoena Paragraph I, No. 1 requests: [a]ll minutes, notes, or records of any meetings held by Oncology Services Corporation (OSC) or any of its owned or managed facilities, relating to any activities conducted under NRC License No. 37-28540-01, including minutes of staff meetings, training sessions, supervisory meetings, HDR Committee meetings, or corporate meetings, and any interoffice or center memoranda relating to those meetings.

NRC-OI was informed that OSC headquarters personnel held periodic meetings with their Regional Administrators ("RA") and Medical Directors at its various facilities. Appendix p. 1-2 ¶ b,c. In this regard, NRC investigators were advised that personnel at the RA meetings were directed to take notes for those who were not present, and that at least some staff meetings were tape recorded. Id. NRC also learned that a video tape of a RA meeting was made on at least one occasion. OSC has failed to produce any written notes, tapes or videotapes of such meetings. Id.

Similarly, with respect to Subpoena Paragraph I, No. 2,¹⁷ OSC alleges that resumes of physicians, physicists and technologists employed by OSC have previously been produced, to the extent that they exist. See Exhibit 8. OSC also claims that it does not maintain job applications and resumes of its employees on file. Id. Although OSC consists of over two hundred employees, it has submitted fewer than ten resumes and no job applications in response to the subpoenas. Appendix p. 2 ¶ 2a. Yet NRC investigators have verified, through interviews of current and former employees, that OSC maintains files of both employment applications and/or resumes of employees. Id. ¶ 2b.

¹⁷Subpoena Paragraph I, No. 2 requests: [e]mployment applications and resumes submitted by any persons employed by OSC as an officer, director, employee, vendor, contractor, subcontractor, at any of its owned or managed facilities, or who performed activities at the direction of or on behalf of OSC or any of its owned or managed facilities, under NRC License No. 37-28540-01, during the period between June 1, 1990 and February 15, 1993.

Although OSC legal counsel agreed to provide some additional resumes, these documents have not been received by NRC to date. Id. ¶ 2d.

With respect to Subpoena Paragraph I, No. 4,¹⁸ OSC claims that it has previously produced all existing documents responsive to this request. See Exhibit 8. Although the time period specified in the request is over two and a half years, OSC has only produced two cancer patient treatment documents to date. Appendix p. 4 ¶ 4b. These documents indicate that cancer patient treatment reports are issued on a weekly or bi-weekly basis. Id. Moreover, the NRC also obtained several other cancer patient treatment reports during the course of its investigation which confirm that these documents are generated on a regular basis. Id. The foregoing demonstrates, therefore, that OSC has failed to produce all existing documents in this category.

Similarly, NRC has been informed that specific documents exist which are responsive to several of the remaining document categories in the second subpoena, despite the fact that OSC claims to have produced all existing documents in those categories.¹⁹

¹⁸Subpoena Paragraph I, No. 4 requests: [m]onthly HDR Logs, HDR Monthly Log Utilization and the weekly/bi-weekly Cancer patient treatment documents for the period between June 1, 1990 and February 15, 1993, which recorded, either in whole or in part, any activities conducted under NRC License No. 37-28540-01.

¹⁹For a detailed discussion of the basis for the NRC's belief that OSC has failed to produce documents in several document categories, see Appendix, pp. 1-12.

Finally, OSC has failed to submit any documents in response to Subpoena Paragraph II (relating to activities under NRC License No. 37-28179-01), on the basis that the license in question is not issued to OSC. See Exhibit 8. Although OSC's response is correct in the literal sense, it is misleading. NRC License No. 37-28179-01 indicates that the nuclear material is to be used at an OSC-operated facility and identifies the authorized user as an employee of an affiliated company which is owned or managed by OSC.²⁰ Appendix p. 12 ¶ II. a,b.

Respondent's continued failure to fully comply with the subpoenas prevents the NRC from satisfactory completion of its investigation into OSC's licensed activities. An expeditious and comprehensive investigation of possible deliberate violations of NRC regulations at OSC facilities is clearly in the public interest of protecting public health and safety, by seeking to prevent the reoccurrence of fatal incidents such as that which occurred at the OSC-operated cancer treatment facility on November 16, 1992. To allow respondent to unjustifiably delay the investigation may seriously harm that public interest and undermine the NRC's ability to fulfill its statutory responsibilities.

CONCLUSION

For the foregoing reasons, the NRC is entitled to judicial enforcement of its subpoenas to respondent. Accordingly, the

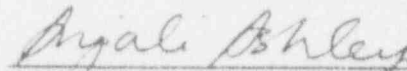
²⁰Specifically, the Indiana Regional Cancer Treatment Center where the incident occurred on November 16, 1992, which resulted in the death of a patient on November 21, 1992.

Court should require respondent to appear and produce documents in accordance with the subpoenas at the time and place specified in the subpoenas on a date specified by the Court.

Respectfully submitted,

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the death of the individual and subsequent radiation exposure of over 90 individuals (including residents, staff members and visitors at the OSC facility where the patient received the radiation treatment; the nursing home where the patient resided; as well as other locations) between November 16 and December 1, 1993.¹

8. The NRC suspended License No. 37-28540-01, with respect to operations at six OSC facilities located in the state of Pennsylvania. Subsequently, the NRC allowed OSC to resume treatments at two facilities. The NRC ordered OSC not to receive or use any NRC licensed material under License No. 29-28685-01 at its Radiation Oncology Center in Marlton, New Jersey. The third license, License No. 37-28179-01, remains in force for the present.

9. In December 1992, during the pendency of the IIT investigation, NRC-OI initiated a special investigation in order to determine whether OSC had deliberately violated NRC regulations.

10. The regulations which OSC may have intentionally violated, include, *inter alia*, 10 C.F.R. § 19.12 (failure to instruct workers); 10 C.F.R. § 20.201(b) (failure to conduct radiation survey); and 10 C.F.R. § 30.9 (failure to provide complete and accurate information). In addition, OSC may have deliberately violated certain license conditions regarding requirements for the transportation of the High Dose Rate ("HDR") source machine.

11. The NRC-OI investigation was designed to review OSC's compliance with the NRC's requirements for the conduct of operations and the training of personnel at OSC facilities and OSC's compliance with conditions specified in its NRC licenses. In addition, the investigation was designed to review the actions of the OSC personnel at the Indiana Regional Cancer Center during and after the November 16, 1992, incident and potentially incomplete and/or inaccurate statements made by OSC personnel.

12. In furtherance of this investigation, NRC-OI issued seven subpoenas to OSC for information, one to each of six OSC facilities listed under License No. 37-28540-01, and one to the Custodian of Records at OSC headquarters in State College, Pennsylvania ("First Subpoenas"). See Exhibit 2.

¹ The details of the IIT investigation are set forth in a public report, NUREG-1480, the Abstract and Executive Summary of which is attached hereto as Exhibit 1.

13. Each of the first subpoenas was signed by Ben B. Hayes, Director of OI, on February 22, 1993. NRC-OI investigators personally served the six subpoenas on the individual facilities on February 25 and 26, 1993. The OSC headquarters subpoena was served by registered mail after an OSC employee refused to accept the document. The subpoena was later returned by the post office stamped "unclaimed." See Exhibit 3. It was eventually accepted by OSC legal counsel.

14. The first subpoenas directed the respondent to produce records at the offices of the U.S. Nuclear Regulatory Commission in King of Prussia, Pennsylvania, on March 12, 1993, at 9:00 a.m. See Exhibit 2.

15. All information requested in the first subpoenas is relevant to the NRC investigation into OSC's practices and is necessary for the satisfactory completion of this investigation.

16. Between March and September, 1993, OSC submitted some documents in response to the first subpoenas.

17. By affidavit dated April 26, 1993, OSC legal counsel, Marcy Colkitt, stated that all documents had been produced pursuant to the first subpoenas. See Exhibit 4.

18. On several occasions thereafter, the undersigned, with a witness, notified Ms. Colkitt both by telephone and in person that the NRC had reason to believe, based on its investigation of OSC to date, that OSC had failed to forward various records requested under the first subpoenas.

19. In a letter dated June 4, 1993 ("June 4 letter"), NRC provided OSC legal counsel with a list of the documents which NRC had reason to believe were responsive to the first subpoenas and were within the custody, control, or possession of OSC, but had not been provided to the NRC. See Exhibit 5.

20. On July 9, 1993, the undersigned, with a witness, telephoned Ms. Colkitt and requested that OSC comply with the NRC subpoenas by close of business Monday, July 12, 1993. The undersigned informed Ms. Colkitt that the NRC would consider legal action to enforce the subpoenas if OSC did not fully comply with the subpoenas by that date. In that conversation, Ms. Colkitt stated that the NRC would not receive some of the documents requested in the June 4 letter because they were not pertinent.

21. By letter dated July 14, 1993, Ms. Colkitt set forth OSC's objections to the production of many records requested in the first subpoenas and listed in the June 4 letter. However, she agreed to forward some documents at a later date. See Exhibit 6.

22. In late July and September, 1993, OSC produced some additional documents responsive to the subpoenas and listed in the June 4 letter.

23. On August 24, 1993, the Director of the NRC-OI issued another subpoena to OSC in an effort to obtain the information it needs for the satisfactory completion of its investigation into OSC's licensed activities ("Second Subpoena"). See Exhibit 7. The second subpoena was faxed to Ms. Colkitt who agreed to accept service via fax. In addition, service was accomplished by certified mail.

24. The date for compliance identified in the second subpoena was September 13, 1993. See Exhibit 7. OSC failed to comply with the second subpoena by the specified deadline.

25. In a letter dated September 16, 1993, OSC objected to requests under several document categories listed in the second subpoena on the grounds that they either sought "irrelevant information;" "information outside the scope of the NRC's jurisdiction;" or were "unduly burdensome." In addition, OSC alleged that it had produced all documents in existence with respect to a number of document categories. OSC also refused to produce any information concerning NRC License No. 37-28179-01, on the basis that this license was not issued to OSC. See Exhibit 8.

26. On September 22, 1993, OSC produced some documents responsive to both the first and second subpoenas.

27. Based on interviews of OSC personnel and other information obtained during the course of the investigation, NRC has learned of the existence of specific documents and other records which are, or should be in the possession of OSC, are responsive to the subpoenas, but which have not been produced by the respondent. A detailed discussion of the foregoing is set forth in the attached Appendix and is hereby incorporated by reference.

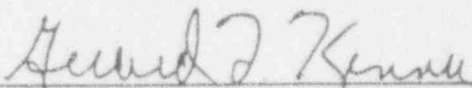
28. Both the first subpoenas issued on February 22, 1993, and the second subpoena issued to OSC headquarters on August 24, 1993, advised OSC that it could submit a request to the NRC to quash or modify the subpoenas if such request were made "at or before the time specified in the subpoena for compliance." To date, OSC has not moved to quash or modify the subpoenas issued to it.

29. All information requested in the first and second subpoenas is sought pursuant to the NRC's statutory and regulatory authority and is relevant to the issues under investigation. OSC's failure to fully comply with the subpoenas prevents the NRC from satisfactorily completing its investigation

into OSC's licensed activities and may seriously endanger public health and safety.

I declare under penalty of perjury that the following is true and correct to the best of my ability.

Executed this 8 day of November, 1993.


GERARD F. KENNA

APPENDIX

Subpoena Paragraph Number

1. All minutes, notes, or records of any meetings held by Oncology Services Corporation (OSC) or any of its owned or managed facilities, relating to any activities conducted under NRC License No. 37-28540-01, including minutes of staff meetings, training sessions, supervisory meetings, HDR Committee meetings, or corporate meetings, and any interoffice or center memoranda relating to those meetings.

OSC Response¹

Oncology Services has complied with this request on prior submissions of materials to the NRC to the extent said materials were relevant to the jurisdiction of the NRC - safety and training. OSC objects to the request in so far as it seeks irrelevant material and OSC will not provide irrelevant responses. Certain additional meeting minutes referencing the technical service department have been located and will be forwarded within the next four business days.

Office of Investigations Response

- a. The U.S. Nuclear Regulatory Commission Office of Investigation ("NRC-OI") has received approximately 88 pages of documents from OSC which could be classified as interoffice or internal memoranda. However, most of these documents are dated after the November 16, 1992, incident at the Indiana Regional Cancer Center. Of the total, only 34 pages, including attachments to the memoranda, are dated prior to the November 16, 1992, incident.
- b. Through interviews of current and/or former OSC employees, the NRC-OI has learned that OSC headquarters personnel held periodic meetings with OSC Regional Administrators ("RA") and Medical Directors ("MD") from the various OSC facilities. NRC-OI has also been informed that OSC personnel present at the RA meetings were directed to take notes for others who were absent. NRC-OI was also advised that staff meetings were tape recorded. OSC has not produced any written notes or tape recordings of meetings. OSC has produced the agenda for six MD meetings, but has not submitted the agendas for any RA meetings.

¹All entries entitled "OSC Response" in this Appendix, with the exception of that listed under Subpoena Paragraph No. 16 (to which OSC responded more recently), are taken from a September 16, 1993, letter from Marcy L. Colkitt, OSC General Counsel, to Barry R. Letts, Director, NRC Office of Investigations, which is attached hereto as Exhibit 8.

- c. Through interviews of current and/or former OSC employees, NRC-OI was informed that a video tape of an RA meeting was made. One interviewee stated that he/she had reviewed the tape. OSC has not produced this videotape.

Subpoena Paragraph Number

2. Employment applications and resumes submitted by any persons employed by OSC as an officer, director, employee, vendor, contractor, subcontractor, at any of its owned or managed facilities, or who performed activities at the direction of or on behalf of OSC or any of its owned or managed facilities, under NRC License No. 37-28540-01, during the period between June 1, 1990 and February 15, 1993.

OSC Response

Resumes of physicians, physicists and many technologists, to the extent they exist, have previously been produced. Because OSC has been denied access to the transcripts of the 45 plus individuals that OI has interrogated over the past eight months and because OI has complete access to those transcripts OI should provide OSC with a list of the relevant personnel and OSC will produce the relevant existing documents. As OI is well aware, it has not been the practice at any time for OSC to complete or maintain employment applications for any employee.

Office of Investigations Response

- a. OSC has in excess of two hundred employees. Yet it has produced less than ten resumes to NRC-OI under the subpoenas. OSC has not produced any employment applications.
- b. NRC-OI verified, through interviews of current and/or former employees, that OSC maintains employment applications and/or resumes of employees on file. An interview of an employee who had access to personnel files at the OSC headquarters office confirmed that personnel files contain either resumes or applications or both. The Regional Administrator for the Harrisburg Cancer Center, during a transcribed interview and in the presence of OSC legal counsel, stated that there is a file containing resumes at the Greater Harrisburg Cancer Center.
- c. The "Personnel Policies and Procedures Manual for Oncology Services Corporation Oncology Services, Inc., and its Subsidiaries and Affiliates" provides, in pertinent part, that:

- i. Section 100, Code No. 103, General Employment Practices, Selection of New Employees, #3 Screening procedures include: a. Written application (Resume)....."
- ii. Section 100, Code No. 113, General Employment Practices, Promotion and Transfer, #3 "Selection of the successful candidate for a position will be based upon the individual's qualifications....."
- iii. Section 100, Code No. 1_5, General Employment Practices, Employee Inspection of Personnel Files, #2 " Specifically the employee shall have access to the following in his/her file a. Application for employment...."
- d. During a transcribed interview on July 22, 1993, counsel for OSC agreed to provide additional resumes of some employees. These documents have not been received to date.

Subpoena Paragraph Number

3. HDR Introduction Manuals and Incentive Plans in effect during the period June 1, 1990 through February 15, 1993, which were applicable, either in whole or in part, to any activities conducted under NRC License No. 37-28540-01.

OSC Response

OSC has previously produced all relevant HDR manuals. However, OSC objects to this request because it seeks irrelevant information and information outside the scope of the NRC's jurisdiction - safety and training.

Office of Investigations Response

- a. During the course of the investigation, NRC obtained HDR Incentive Plan documents from a former employee which indicated that the Incentive Plan would be updated periodically.

Subpoena Paragraph Number

4. Monthly HDR Logs, HDR Monthly Log Utilization and the weekly/bi-weekly Cancer patient treatment documents for the period between June 1, 1990 and February 15, 1993, which recorded, either in whole or in part, any activities conducted under NRC License No. 37-28540-01.

OSC Response

Monthly HDR Logs, HDR Monthly Log Utilization and the weekly/bi-weekly Cancer patient treatment documents for the period between June 1, 1990 and February 15, 1993, which recorded, either in whole or in part, any activities conducted under NRC License No. 37-28540-01.

Office of Investigations Response

- a. OSC forwarded some HDR monthly logs.
- b. OSC has submitted only two cancer patient treatment documents (dated 3/1/93 and 1/4/93). These documents indicate that cancer patient treatment reports are issued on a weekly or bi-weekly basis. Moreover, during the course of its investigation to date, NRC obtained cancer patient treatment forms from a former employee dated 1/4/93, 1/11/93, 1/25/93, 2/1/93, and 2/15/93.

Subpoena Paragraph Number

5. Weekly Activity Reports prepared for OSC and submitted to OSC corporate headquarters by the various OSC centers regarding activities conducted under NRC License 37-28540-01 between June 1, 1990 and February 15, 1993.

OSC Response

OSC objects to this request because it seeks irrelevant information and information outside the scope of the NRC's jurisdiction - safety and training.

Office of Investigations Response

- a. Current and former employees of OSC have stated that each OSC facility was required to forward a Weekly Activity Report to OSC headquarters via fax for review by corporate officials. During the investigation, NRC-OI reviewed Weekly Activity Reports from an OSC facility. These documents refer to problems with the HDR equipment which had been encountered by OSC.
- b. OSC has failed to submit any Weekly Activity Reports regarding activities undertaken pursuant to License No. 37-28540-01.

Subpoena Paragraph Number

6. Notes or memoranda from monthly OSC Regional Administrator meetings conducted between June 1, 1990 and February 15, 1993, including audio tape recordings, video tapes, typed minutes, handwritten notes, and roster of participating personnel.

OSC Response

OSC objects to this request because it seeks irrelevant information and information outside the scope of the NRC's jurisdiction - safety and training.

Office of Investigations Response

- a. During interviews of current and/or former OSC employees, NRC-OI was advised that a video tape of a Regional Administrators meeting was made and one person advised that he/she had reviewed the tape.
- b. During interviews of current and/or former OSC employees, NRC-OI learned that corporate staff members were directed to take notes during at least one RA meeting so that notes of the meeting could be forwarded to staff members who did not attend the meeting. NRC-OI was also advised that staff meetings were tape recorded.
- c. Although normal business practice would reflect that notes or minutes of meetings would exist, OSC has failed to produce any records of RA meetings to date.

Subpoena Paragraph Number

7. Staff, training, corporate, and supervisory meeting records from any semi-annual Medical Directors meetings conducted between June 1, 1990 and February 15, 1993, to include the syllabi, roster of personnel, and notes.

OSC Response

OSC objects to this request because it seeks irrelevant information and information outside the scope of the NRC's jurisdiction - safety and training. However, to the extent the requested documents contain information related to safety and training, said documents have been previously provided.

Office of Investigations Response

- a. NRC has received no records of these meetings other than the daily schedule/itinerary for the meetings. HDR is listed on the agenda as a

topic for discussion in some of these schedules.

- b. Common business practice would indicate that any policies or procedures formulated during these meetings would be recorded for uniformity in future application. Normal business practice would also indicate that records of meeting would be maintained for future reference.

Subpoena Paragraph Number

8. Telephone records for any person or persons functioning as the Radiation Safety Officer under NRC License No. 37-28540-01 between June 1, 1990 and April 30, 1991.

OSC Response

The license believes all existing telephone records have been previously produced, however the Licensee will forward any additional documents to the extent they exist.

Office of Investigations Response

- a. OSC has submitted some telephone records from April 1991 until 1993. NRC-OI has no further response.

Subpoena Paragraph Number

9. Any records of any maintenance conducted between June 1, 1990 and February 15, 1993, on any HDR equipment belonging to OSC or any of its owned or managed facilities and used to conduct licensed activities under NRC License No. 37-28450-01.

OSC Response

All existing maintenance records have previously been produced.

Office of Investigations Response

- a. OSC has submitted some maintenance records. NRC-OI has no further response.

Subpoena Paragraph Number

10. Expense vouchers and sub-vouchers, including, but not limited to, travel vouchers submitted by any officer or employee of OSC or any of its owned or managed facilities. The records should include, but not be limited to, HDR maintenance travel records, HDR training records, and the semiannual Medical Directors' meetings and

regional administrators' meetings regarding any activities conducted either in whole or in part, under NRC License No. 37-28540-01.

OSC Response

OSC objects to this request because it seeks irrelevant information and information outside the scope of the NRC's jurisdiction - safety and training. Moreover, this request is so overly burdensome that it is incapable of being complied with even if it was relevant, which it is not. Furthermore, OI has interrogated in excess of 45 individuals over the past eight months and to the extent there were any questions relating to the issue of expense vouchers they have been asked or could have been asked by OI.

Office of Investigations Response

- a. OSC has submitted some travel vouchers for two physicians, Dr. Cunningham and Dr. Ying, but has not provided any other documents under this category.
- b. The "Personnel Policies and Procedures Manual for Oncology Services Corporation Oncology Services, Inc., and its Subsidiaries and Affiliates," Section 200, Code 220 (Business Travel and Entertainment) requires that OSC personnel submit vouchers for business-related travel.
- c. OSC does not dispute the existence of these documents. The documents are needed to verify statements made by individuals during interviews and to confirm statements made by officials.

Subpoena Paragraph Number

11. Roster of employees and participant handouts relating to any and all company business meetings conducted either by, or for, OSC or any of its owned or managed facilities, held in Atlantic City, New Jersey, between April 1 and November 1, 1992.

OSC Response

To the extent relevant documents were maintained they have previously been produced.

Office of Investigations Response

- a. OSC did not provide a roster of employees attending the training session and meeting in Atlantic City, NJ. Normal business practices would dictate that some type of list would be prepared so that hotel reservations could be made or bills paid as a result of the trip. Also, OSC has not submitted any travel vouchers for this meeting. In addition, because this was a training meeting, it may reasonably be expected that participant handouts would be distributed during the classes -- OSC has not produced any such handouts.

Subpoena Paragraph Number

12. All documents relating to the use of the HDR GammaMed Ili Machine from 1990 to 1992 at Greater Pittsburgh Cancer Center, Indiana Regional Cancer Center, and The Life Care Center. These documents should include, but not be limited to, the HDR Quality Assurance and Calibration forms for the GammaMed Ili.

OSC Response

To the extent relevant documents were maintained they have previously been produced.

Office of Investigations Response

- a. No documents were submitted by OSC regarding the use of the HDR equipment at the aforementioned centers, even though OSC was licensed to conduct activities at these facilities.

Subpoena Paragraph Number

13. Documents describing any initial or refresher training in the operation of the HDR loading devices for Dr. Cunningham or Dr. Ying between June 1, 1990 and February 15, 1993. In addition, any documents relating to any training that Dr. Cunningham or Dr. Ying received from the manufacturer regarding the installation, relocation or removal of high dose loader units containing sources.

OSC Response

OSC believes it has previously produced all existing responsive documents. However, to the extent any additional documents exist they will be produced.

Office of Investigations Response

- a. NRC-OI did not receive any documents under this category pursuant to subpoena. In a letter to NRC dated August 16, 1991, OSC stated that "Initial and refresher training in the operation of the HDR loading devices will be provided by the manufacturer or David Cunningham, Ph.D. or Dr. William Ying, Ph.D., who are both approved HDR source exchangers. Documents regarding their training are maintained at the Harrisburg Cancer Center." OSC has not submitted the latter documents in response to the subpoena.

Subpoena Paragraph Number

14. Payroll documents which contain the name and home address of all employees of OSC, including its corporate headquarters personnel, and the employees of any of its owned or managed facilities in which OSC conducted activities under NRC License No. 37-28540-01, from June 1, 1990 through August 8, 1993.

OSC Response

OSC objects to this request because it seeks completely irrelevant information and information outside the scope of the NRC's jurisdiction - safety and training. Further, OI is improperly seeking to obtain confidential and personal salary information. OI has had an opportunity to ask for said information during its interrogations. Certain OI personnel asked this information previously. Therefore, the request is also unduly burdensome and oppressive.

Office of Investigations Response

- a. OSC has not produced any documents under this category.
- b. During the investigation, the NRC has determined that OSC maintains payroll documents which contain the name and home address of OSC personnel. Access to this information would enable NRC-OI investigators to locate and interview former employees in connection with the issues under investigation. NRC has no interest in obtaining salary information of OSC employees and has previously discussed with OSC the option of deleting the salary figure from these documents.

Subpoena Paragraph Number

15. Any documents relating to any experiments conducted with any nuclear source used by OSC to conduct activities under NRC License No. 37-28540-01. The term "documents" includes, but is not limited to, documents produced regarding when the nuclear source was exposed outside the Harrisburg Cancer Center.

OSC Response

To the extent any responsive documents exist, they will be produced within the next four business days.

Office of Investigations Response

- a. To date, the only document produced under this category is a one page document which was forwarded to NRC-OI with a transmittal letter dated September 22, 1993.
- b. OI verified through several interviews of OSC employees that a nuclear source was exposed in an open space between the OSC Greater Harrisburg Cancer Center and a local hospital, thereby violating NRC regulations and conditions of OSC's license. The interviewees stated that calculations were taken during this incident to determine the shielding requirements for the nuclear source. (The person NRC-OI believes was the supervisor of this unauthorized exposure was issued a subpoena by OI. This individual is no longer an OSC employee).
- c. The only document received in this category (see a. above) is an internal meeting memorandum dated April 15, 1991, which indicates the intention of the OSC Physics Department to conduct an experiment involving the exposure of a nuclear source. The document does not contain shielding calculations.

Subpoena Paragraph Number

16. Legible photocopies of slides submitted in response to the previous subpoena served on OSC on March 1, 1993. OSC's original submission is illegible.

OSC Response

By letter dated October 14, 1993, OSC legal counsel indicated that the respondent was unable to produce legible photocopies of the requested material, but that the original slides would be made available for inspection by NRC investigators at OSC headquarters in State College, Pennsylvania.

Office of Investigations Response

- a. NRC investigators will make arrangements to travel to State College to inspect the original slides.

Subpoena Paragraph Number

17. Purchase and repair records for the prime alert and survey meters for the period June 1, 1990 through February 15, 1993. The records should include the calibration records for any prime alert, Ion chamber and/or survey meter belonging to OSC or any of its owned or managed facilities and used by OSC to conduct licensed activities under NRC License No. 37-28540-01 during that time.

OSC Response

To the extent any responsive documents exist, they have previously been produced to the NRC.

Office of Investigations Response

- a. Documents for the repair and/or calibration of the prime alert and survey meter have been received from the Mahoning Valley Cancer Center, the Greater Pittsburgh Cancer Center and the Exton Cancer Center. OSC has failed to submit any documents under this subpoena category for the Indiana Regional Cancer Center, Life Care Center or the Harrisburg Cancer Center. In addition, OSC has not produced documents reflecting the purchase of the survey meters and prime alerts.

IIA 1 through 11 and B

OSC Response

NRC License No. 37-28179-01 is not issued to Oncology Services Corporation.

Office of Investigations Response

- a. The OSC response in the literal sense is correct; however, it is misleading. NRC License No. 37-28540-01 indicates that the nuclear material will be used at the Indiana Regional Cancer Center, 877 Hospital Road, Indiana, PA. The Indiana Regional Cancer Center is listed as an OSC operating entity in documents submitted by OSC.
- b. In addition, NRC License No. 37-28179-01 identifies the authorized user of the nuclear material as Dr. Bauer, who is an employee of an affiliated company owned or managed by OSC.

Loss of an Iridium-192 Source and
Therapy Misadministration at
Indiana Regional Cancer Center
Indiana, Pennsylvania, on
November 16, 1992

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U.S. Nuclear Regulatory Commission
Washington, DC 20555



ABSTRACT

On December 1, 1992, the Indiana Regional Cancer Center reported to the U.S. Nuclear Regulatory Commission's (NRC) Region I that they believed a $1.37 \text{ E}+11$ becquerel (3.7-curie) iridium-192 source from their Omnitron 2000 high dose rate remote brachytherapy afterloader had been found at a biohazard waste transfer station in Carnegie, Pennsylvania. After notifying the NRC, this cancer center, one of several operated by the licensee, Oncology Services Corporation, retrieved the source, and Region I dispatched an inspector and a supervisor to investigate the event. The source was first detected when it triggered radiation alarms at a waste incinerator facility in Warren, Ohio. The licensee informed the NRC that the source wire had apparently broken during treatment of a patient on November 16, 1992, leaving the source in the patient. On the basis of the seriousness of the incident, the NRC elevated its response to an Incident Investigation. The Incident Investigation Team initiated its investigation on December 3, 1992. The investigation team concluded that the patient received a serious misadministration and died on November 21, 1992, and that over 90 individuals were exposed to radiation from November 16 to December 1, 1992. In a press release dated January 26, 1993, the Indiana County Coroner stated that the cause of death listed in the official autopsy report was "Acute Radiational Exposure and Consequences Thereof." An almost identical source wire failure occurred with an afterloader in Pittsburgh, Pennsylvania, on December 7, 1992, but with minimal radiological consequences. This incident was included in the investigation. This report discusses the Omnitron 2000 high dose rate afterloader source-wire failure, the reasons why the failure was not detected by Indiana Regional Cancer Center, the potential consequences to the patient, the estimated radiological doses to workers and the public, and regulatory aspects associated with this incident.

EXECUTIVE SUMMARY

On November 16, 1992, an elderly patient was treated for anal carcinoma at the Indiana Regional Cancer Center (IRCC) in Indiana, Pennsylvania, using high dose rate (HDR) brachytherapy. The IRCC is one of ten cancer treatment centers using HDR units operated by the Oncology Services Corporation (OSC), the license holder. The patient died on the evening of November 21, 1992, five days after the treatment. Before the treatment, five catheters were placed in the tumor. During the treatment, an approximate $1.6 \text{ E} + 11$ becquerel (4.3-curie) iridium-192 source was placed at various positions in each catheter to irradiate the tumor by use of a remotely controlled Omnitron 2000 afterloader. The treatment was conducted in the same shielded facility in which linear accelerator treatments were conducted. This treatment was the first of a series of three 600-centigray (rad) treatments planned by the physician, and the five catheters were to remain in the patient for subsequent treatments.

After a trial run through the five catheters with a dummy wire, the iridium source wire was placed in four catheters without difficulty. After several unsuccessful attempts to insert the source wire and the dummy wire into a fifth catheter, the treatment was terminated. An area radiation monitor in the treatment area was observed in an alarm condition at various times when the source should have been retracted during the unsuccessful attempts to insert the source wire through the catheter. Although three technologists and the physician attending the patient were aware of the alarm condition, no one conducted a survey for radiation levels with the available portable radiation survey instrument. The only action taken was to check the control console of the HDR remote afterloader. Because the console indicator showed "safe," they believed the source to be fully retracted into the lead shield and assumed the area radiation monitor was malfunctioning. They were unaware the source wire had broken, leaving the source in one of the catheters in the patient. The staff at the IRCC stated they had experienced difficulties with the area radiation monitor that had alarmed after patient linear accelerator treatments and that a survey after a previous false alarm had shown no radiation was present.

Before the incident, breakage of the wire encapsulating the iridium source was not considered credible by the vendor or the licensee. Omnitron International, Inc.'s (Omnitron's) emergency procedures were directed toward emergency retraction of a wire with a source that was stuck out and required manual retraction. The only individual interviewed who stated he believed that wire breakage was credible was the medical physicist at the Greater Pittsburgh Cancer Center (GPCC), another facility operated by OSC.

OSC appears to have provided no systematic radiation safety training to the staff at the IRCC. Dependence was placed on the staff's previous formal training; training by Omnitron on the HDR remote afterloader, which included Omnitron emergency procedures but did not include radiation safety; and an expectation that either the medical director or the medical physicist at each site would provide radiation safety training. This expectation was neither met nor were steps taken to confirm it.

Given the conflict between the data provided by the area radiation monitor and the Omnitron 2000 control panel, and the lack of radiation safety training that should have conditioned the staff to respond properly to radiation alarms, the licensee staff failed to respond to the alarm. Instead, a technologist unplugged and reset the radiation monitor. The technologist should have responded by using the portable survey meter available at the control console for the afterloader. This meter would have identified the fact that the source had not returned to the afterloader shield.

The patient spent 50 minutes in the treatment room. After the patient was removed from the treatment room, one catheter was observed to be loose and it was removed. The patient was returned to the nursing home where the patient resided with four catheters, one containing the iridium-192 source, in the patient's body. The source remained in the patient's body for almost four days. The catheter with the source came loose on the fourth day and, eventually, the catheter fell out (early on the morning of November 20, 1992). It was placed in a medical biohazards bag (red-bag) in a storage room by nursing home personnel who did not know it contained the radioactive source.

Later, on the same day, the catheter containing the source was moved to another storage location at the nursing home and placed in a box with other red bags. From November 16 through November 25, 1992, numerous residents, employees, and visitors to the nursing home were unknowingly irradiated. The ambulance staff who returned the patient to the nursing home were irradiated along with employees and patients at the IRCC who were present for the approximately 10 minutes while the patient was outside the treatment room after the treatment.

On November 25, 1992, a driver for Browning-Ferris Industries (BFI) picked up the nursing home red-bag waste as part of the driver's normal rounds. The driver had an operable portable radiation survey meter but, contrary to company procedures, did not survey the waste from the nursing home. The nursing home waste along with other medical waste was taken to a BFI facility in Carnegie, Pennsylvania, where it was loaded onto a trailer. This trailer remained in Carnegie throughout the following day, which was Thanksgiving, and early on November 27, 1992, was driven to a BFI medical waste incinerator in Warren, Ohio. At the Warren facility, fixed radiation monitors identified radiation emanating from the trailer, and, on facility personnel direction, the trailer was returned to Carnegie the same day. It was left over the weekend and on Monday, November 30, 1992, the BFI staff searched the truck for the radiation source. They identified the box with the radiation source and looked at individual red bags to identify the origin of the waste. On December 1, 1992, BFI successfully identified a name found with the red-bag waste in the box, and traced it to the nursing home.

After being notified by BFI, the nursing home called the IRCC on December 1, 1992. The cancer center had not used the HDR afterloader after the single treatment on November 16, 1992. Upon being informed of the source discovery, the medical physicist determined that

no source was present in the HDR afterloader and informed the NRC Region I office of this fact. The physician and the medical physicist drove to Carnegie to retrieve the source.

A second Omnitron 2000 source wire broke at the GPCC on December 7, 1992. This failure was included in the scope of this investigation. This wire broke in the same approximate location as the first wire. The GPCC medical physicist who was conducting the treatment was aware of the first incident and immediately recognized the problem and promptly and appropriately intervened, thereby preventing significant dose consequences to the patient or the cancer center staff. Apparently, the patient stressed the wire by an arm movement when the source was being retracted.

The NRC issued a Bulletin on December 8, 1992, to all licensees authorized to use the Omnitron 2000 afterloader requesting that they ensure patients are surveyed immediately after completing each therapy treatment; provide for prompt surgical intervention, if needed, in the event a source does not retract into the shielded container after treatment; and ensure that training on routine and emergency procedures is provided to licensee staffs initially and semiannually. In addition, an NRC Information Notice was issued December 17, 1992, informing all NRC medical licensees of this incident, reminding them of NRC requirements for positive assurance that all implanted sources have been removed before patients are released after treatment and informing them of the information provided in the Bulletin.

The cause of the source wire failures was investigated by the vendor, Omnitron, and their consultant and by the NRC team and its consultant laboratory, Southwest Research Institute. The Food and Drug Administration (FDA), which has responsibilities for the HDR afterloader as a medical device, conducted an independent inspection. The team shared its data with the FDA. The FDA issued its Form 483 with 37 findings to Omnitron on January 11, 1993. These findings were primarily in the quality assurance and quality control (QA/QC) area. The NRC team also interacted with the State of Louisiana because certain of Omnitron's activities are also overseen by this Agreement State.

Although the team identified a number of weaknesses in Omnitron's QA/QC program in addition to concerns with the design and prototype testing of the source wire, the cause of the wire failure is not known with certainty at this time. The wire broke at the bottom section of the source-wire cavity. The vendor had not calculated the maximum allowable stress in the design. The wire is made from Nitinol, a shape-memory alloy of nickel and titanium in approximately equal atomic percentages. The vendor believes it has evidence to show that storage of the source wire in teflon, if moisture is present, causes degradation of the teflon with release of fluorine or hydrogen fluoride that causes degradation of the Nitinol wire. The NRC and its consultant are still evaluating this hypothesis and conducting further studies.

An NRC medical consultant, who is a radiation oncologist, assisted the team in evaluating the effect of the source on the patient. The medical consultant concluded that an analysis of the medical records and physical dosimetry would indicate that the massive radiation dose

was a probable contributing cause of death in this patient. The consultant added that even if the exact cause of death could be attributed to other causes such as cancer or heart disease, the extent of the radiation received would have soon caused death. The consultant stated the radiation accident would probably have eventually resulted in a fatality in a younger, healthier patient within days or weeks of an equivalent accident.

The licensee reported the prescribed dose at one centimeter was $1.8 \text{ E}+03$ centigray (rad) to be delivered in three treatments and that the delivered dose was $1.6 \text{ E}+06$ centigray (rad) to the same point, an overdose of about three orders of magnitude. The licensee stated the effect on the patient would be significant local tissue damage and possible significant tissue damage to organs outside the treatment area, depending upon the progression of radiation damage with time before the patient expired. The licensee stated the dose was of sufficient magnitude that it believed it was highly probable that the radiation exposure was at least a contributing factor to the patient's subsequent death. In a press release dated January 26, 1993, the Indiana County Coroner stated that the cause of death listed in the official autopsy report was "Acute Radiation Exposure and Consequences Thereof."

In addition to the patient, the team evaluated the radiation doses to 94 persons associated with the IRCC event. Exposures of individuals wearing film badges were taken from the badge reading. Except for the physician, all other exposures were derived by calculations based on time-motion studies. These data were based on interviews and records. Individuals visiting the patient were identified through interviews with nursing home staff and known visitors. Becoming aware of a previously unidentified visitor from a newspaper article, the team interviewed that person and placed an advertisement in the local Indiana, Pennsylvania, newspaper. The advertisement requested any individual who was concerned about having come into contact with radiation from the source and who had not been interviewed to contact the NRC. A collect telephone number was provided. This led to two additional contacts. Table A presents a summary of the whole body doses received by the 94 individuals specifically evaluated. Table B presents a summary of collective doses for all locations. Extremity (i.e., hands and forearm) doses were calculated for those individuals who were judged to have the highest exposures because of the proximity of their hands to the source when caring for the patient or searching for the source. The highest extremity dose was calculated to be between 0.73 to 1.6 sieverts (73 to 160 rem) to the hands of one of the Certified Nursing Assistants.

Further studies were conducted by blood counts and cytogenetic studies on selected individuals. Blood counts are simple to perform but have sensitivity limited to 0.75 to 1.5 sieverts (75 to 150 rem). Cytogenetic studies are more sensitive [0.2 sieverts (20 rem)] but are much more difficult to perform. Cytogenetic studies were performed for the NRC by the Radiation Emergency Assistance Center/Training Site at Oak Ridge. Individuals selected for cytogenetic studies were almost always those with the greatest calculated dose. Because the highest calculated doses were at about the limit of detection [0.2 sieverts (20 rem)], the team expected that the cytogenetic data would show if there were significant nonconservative errors in the calculated doses (i.e., measured doses were higher than calculated doses).

Cytogenetic results were consistent with calculated doses within the limits of accuracy of both techniques.

No occupational worker received a radiation dose above the NRC occupational limit of 0.0125 sieverts (1.25 rem). While members of the public received radiation doses above applicable limits, no one received a dose at which acute radiation injury or clinical signs are expected to occur.

In addition to the radiological consequences and the cause of the wire failure the team made a number of findings:

1. OSC had weaknesses in their radiation safety program that were a major contributing cause of the seriousness of the event and radiation exposure consequences. Some of these were a result of a rapid expansion in their HDR brachytherapy program from one facility to ten facilities in less than a year. The Radiation Safety Officer (RSO) failed to ensure that the staffs at all facilities received adequate radiation safety training and that all management instructions relating to HDR were being followed. Informal and unwritten procedures that may have been adequate when the licensee possessed one HDR unit under the direct control of the RSO were ineffective for the expanded program.
2. A number of weaknesses were found in the design and testing of the Omnitron 2000. Weaknesses were identified in the testing and validation of source-wire design, and in the design of certain safety features of the HDR afterloader. These could allow the undetected retraction and further use of a broken wire with no warning to the user. Although not contributing to this event, weaknesses were found in Omnitron's QA/QC program.
3. The safety culture at IRCC contributed significantly to the event. Technologists routinely ignored the PrimAlert-10 alarm. Its problems were worked around and not fixed. Technologists did not survey patients, the afterloader, or the treatment room following HDR treatments. No one was sure who was responsible for radiation safety training or the radiation safety program. The authorized user failed to wear a film badge on both occasions when the source was encountered.
4. Overall regulatory oversight was weak. NRC regulations do not directly address HDR brachytherapy to the extent that teletherapy and low dose rate brachytherapy are addressed. Licensing guidance for HDR has been unchanged since 1986 in spite of significant changes in medical regulations and other medical licensing guidance. Inspection guidance for medical licensees does not specifically address HDR brachytherapy. Although inspected by the NRC Region I office within a year of initial licensing, the inspection program does not require early reinspection in cases where licensees significantly expand the scope of their program through license amendments. The regulatory interaction between the NRC, the FDA, and the

involved Agreement States in the regulation and authorization of the Omnitron 2000 HDR afterloader is poorly defined.

5. NRC guidance for scrap dealers needs to be given to waste brokers and collectors. Discovery of the lost iridium-192 source by BFI may have prevented additional significant radiation exposures; however, subsequent actions taken by BFI employees led to their receiving unnecessary exposures when they moved and searched for the source. Assistance from radiation protection experts should have been sought.

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION
OFFICE OF INVESTIGATIONS

IN THE MATTER OF: NRC INVESTIGATION

CASE NO. 1-92-060R

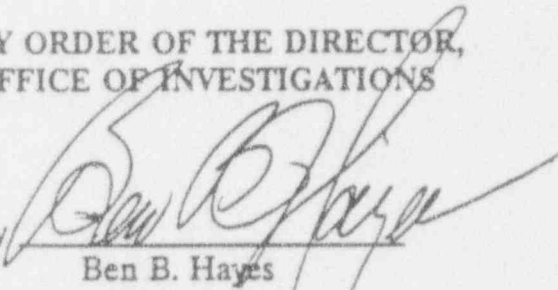
TO: Custodian of Records
Oncology Services Corporation
110 Regent Court, Suite 100
State College, PA 16801

YOU ARE HEREBY COMMANDED, pursuant to Section 161 (c) of the Atomic Energy Act of 1954, as amended, to appear at the offices of the U.S. Nuclear Regulatory Commission, 475 Allendale Road, King of Prussia, PA 19406, (215) 337-5305, on the 12th day of March, 1993, at 9:00 a.m., and to provide the NRC

SEE ATTACHED

BY ORDER OF THE DIRECTOR,
OFFICE OF INVESTIGATIONS

By


Ben B. Hayes

Date

2-22-93

Requested by: Gerard F. Kenna
Office of Investigations, Region I
U.S. Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, PA 19406
Phone: (215) 337-5305

On motion made promptly, and in any event at or before the time specified in the subpoena for compliance by the person to whom the subpoena is directed, and on notice to the party at whose instance the subpoena was issued, the Commission may (1) quash or modify the subpoena if it is unreasonable or requires evidence not relevant to any matter in issue, or (2) condition denial of the motion on just and reasonable terms. Such motion should be directed to the Secretary of the Commission, Washington, DC 20535. Failure to comply with the terms of this subpoena may result in the Commission's seeking judicial enforcement of the subpoena pursuant to Section 233 of the Atomic Energy Act of 1954, as amended, 42 U.S.C. 2281.

RETURN

CERTIFICATE OF PERSONAL SERVICE:

I certify that I delivered a copy of this subpoena in hand to:

on _____, 19 ____, at _____ o'clock _____ M., at _____

CERTIFICATE OF SERVICE BY MAIL:

I certify that I caused a copy of this subpoena to be mailed by REGISTERED, RESTRICTED

DELIVERED BY RETURN RECEIPT mail, postage prepaid, to the address specified and with delivery restricted

to the person named thereon on 2/26, 1993, Receipt No. R494181733

Gerard Kenna
(Signature)

GERARD KENNA
INVESTIGATOR
(Printed Name and Title)
Office of Investigations
U.S. Nuclear Regulatory Commission

- I. Any and all documents in your custody, control, or possession, covering the period from June 1, 1990 through February 15, 1993, either original or copy, including but not limited to any records maintained on a computer disk or in any computer file, relating to:
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 2. any radiation safety procedures, radiation safety policies, or any radiation safety training issued by or for OSC or any of its owned or managed facilities;
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 6. all minutes, notes, or records kept by OSC or any of its owned or managed facilities relating to the materials license or any licensed activities, of
 - a. training sessions,
 - b. staff meetings,
 - c. supervisory meetings, or
 - d. corporate meetings, including but not limited to the bi-annual authorized user meetings, and
 - e. the minutes and contemporaneous notes of the radiation safety committee of OSC or any of its owned or managed facilities;
 7. log books relating to quality control reports, radiation survey reports, and maintenance reports for any equipment belonging to OSC or any of its owned or managed facilities;
 8. training documents and procedure manuals relating to radiation safety training at OSC or any of its owned or managed facilities;

9. expense vouchers and sub-vouchers, including but not limited to travel vouchers, submitted by any officer or employee of OSC or any of its owned or managed facilities for training purposes;
 10. all documents relating to training issued by or for OSC or any of its owned or managed facilities, including but not limited to announcements, correspondence, memoranda (including but not limited to inter-office memoranda), and notes, both formal and informal; and
 11. records relating to any and all company business meetings conducted either by or for OSC or any of its owned or managed facilities, in Atlantic City, New Jersey, during the summer of 1992, including but not limited to the meeting agenda, syllabi, participant handouts, and rosters of personnel attending the meeting.
- II. The employment application of any officer, director, employee, contractor, or subcontractor, employed by OSC or any of its owned or managed facilities, or who performed activities at the direction of or on behalf of OSC or any of its owned or managed facilities, during the period between June 1, 1990, and February 15, 1993.

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION
OFFICE OF INVESTIGATIONS

IN THE MATTER OF: NRC INVESTIGATION

CASE NO. 1-92-060R

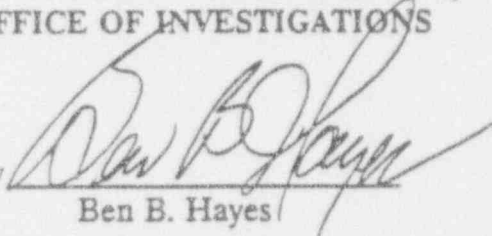
TO: Custodian of Records *in the person of Dr. ABDURRAHMAN UAL*
Harrisburg Cancer Center
775 South Arlington Avenue
Harrisburg, PA

YOU ARE HEREBY COMMANDED, pursuant to Section 161 (c) of the Atomic Energy Act of 1954, as amended, to appear at the offices of the U.S. Nuclear Regulatory Commission, 475 Allendale Road, King of Prussia, PA 19406, (215) 337-5305, on the 12th day of March, 1993, at 9:00 a.m., and to provide the NRC

SEE ATTACHED

BY ORDER OF THE DIRECTOR,
OFFICE OF INVESTIGATIONS

By


Ben B. Hayes

Date

2-22-93

Requested by: Gerard F. Kenna
Office of Investigations, Region I
U.S. Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, PA 19406
Phone: (215) 337-5305

On motion made promptly, and in any event at or before the time specified in the subpoena for compliance by the person to whom the subpoena is directed, and on notice to the party at whose instance the subpoena was issued, the Commission may (1) quash or modify the subpoena if it is unreasonable or requires evidence not relevant to any matter in issue, or (2) condition denial of the motion on just and reasonable terms. Such motion should be directed to the Secretary of the Commission, Washington, DC 20555. Failure to comply with the terms of this subpoena may result in the Commission's seeking judicial enforcement of the subpoena pursuant to Section 233 of the Atomic Energy Act of 1954, as amended, 42 U.S.C. 2281.

RETURN

CERTIFICATE OF PERSONAL SERVICE:

I certify that I delivered a copy of this subpoena in hand to:

DR. ABDURRAHMAN UNAL

on THURSDAY 2/25, 19 93, at 10:03 o'clock A. M., at 775

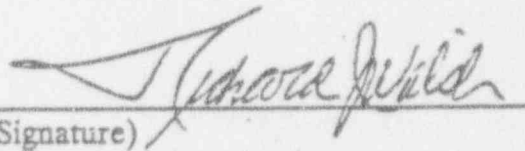
SOUTH ARLINGTON AVENUE, HARRISBURG, PA 17111

CERTIFICATE OF SERVICE BY MAIL:

I certify that I caused a copy of this subpoena to be mailed by _____

_____ mail, postage prepaid, to the address specified and with delivery restricted

to the person named thereon on _____, 19 ____, Receipt No. _____.



(Signature)

RICHARD J. WALSH
SENIOR INVESTIGATOR

(Printed Name and Title)
Office of Investigations
U.S. Nuclear Regulatory Commission

- I. Any and all documents in your custody, control, or possession, covering the period from June 1, 1990 through February 15, 1993, either original or copy, including but not limited to any records maintained on a computer disk or in any computer file, relating to:
1. the application to the NRC for a Materials License and any subsequent amendments by Oncology Services Corporation ("OSC") or any of its owned or managed facilities;
 2. any radiation safety procedures, radiation safety policies, or any radiation safety training issued by or for OSC or any of its owned or managed facilities;
 3. contracts with medical physicists, doctors, technologists, and other personnel providing personal services to OSC or any of its owned or managed facilities, including but not limited to job descriptions;
 4. billing statements for the purchase or repair of all radiation detection devices owned or leased by OSC or any of its owned or managed facilities, including but not limited to the prime alert and survey meters;
 5. all telephone logs, appointment calendars, desk calendars, diaries, expense reports, and travel vouchers for any person or persons functioning as a Radiation Safety Officer ("RSO") for OSC or any of its owned or managed facilities during that time period;
 6. all minutes, notes, or records kept by OSC or any of its owned or managed facilities relating to the materials license or any licensed activities, of
 - a. training sessions,
 - b. staff meetings,
 - c. supervisory meetings, or
 - d. corporate meetings, including but not limited to the bi-annual authorized user meetings, and
 - e. the minutes and contemporaneous notes of the radiation safety committee of OSC or any of its owned or managed facilities;
 7. log books relating to quality control reports, radiation survey reports, and maintenance reports for any equipment belonging to OSC or any of its owned or managed facilities;
 8. training documents and procedure manuals relating to radiation safety training at OSC or any of its owned or managed facilities;

9. expense vouchers and sub-vouchers, including but not limited to travel vouchers, submitted by any officer or employee of OSC or any of its owned or managed facilities for training purposes;
 10. all documents relating to training issued by or for OSC or any of its owned or managed facilities, including but not limited to announcements, correspondence, memoranda (including but not limited to inter-office memoranda), and notes, both formal and informal; and
 11. records relating to any and all company business meetings conducted either by or for OSC or any of its owned or managed facilities, in Atlantic City, New Jersey, during the summer of 1992, including but not limited to the meeting agenda, syllabi, participant handouts, and rosters of personnel attending the meeting.
- II. The employment application of any officer, director, employee, contractor, or subcontractor, employed by OSC or any of its owned or managed facilities, or who performed activities at the direction of or on behalf of OSC or any of its owned or managed facilities, during the period between June 1, 1990, and February 15, 1993.

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION
OFFICE OF INVESTIGATIONS

IN THE MATTER OF: NRC INVESTIGATION

CASE NO. 1-92-060R

TO: Custodian of Records
Greater Pittsburgh Cancer Center
1145 Bower Hill Road
Suite 105,
Pittsburgh, PA 19341

YOU ARE HEREBY COMMANDED, pursuant to Section 161 (c) of the Atomic Energy Act of 1954, as amended, to appear at the offices of the U.S. Nuclear Regulatory Commission, 475 Allendale Road, King of Prussia, PA 19406, (215) 337-5305, on the 12th day of March, 1993, at 9:00 a.m., and to provide the NRC

SEE ATTACHED

BY ORDER OF THE DIRECTOR,
OFFICE OF INVESTIGATIONS

By


Ben B. Hayes

Date

2-22-93

Requested by: Gerard F. Kenna
Office of Investigations, Region I
U.S. Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, PA 19406
Phone: (215) 337-5305

On motion made promptly, and in any event at or before the time specified in the subpoena for compliance by the person to whom the subpoena is directed, and on notice to the party at whose instance the subpoena was issued, the Commission may (1) quash or modify the subpoena if it is unreasonable or requires evidence not relevant to any matter in issue, or (2) condition denial of the motion on just and reasonable terms. Such motion should be directed to the Secretary of the Commission, Washington, DC 20555. Failure to comply with the terms of this subpoena may result in the Commission's seeking judicial enforcement of the subpoena pursuant to Section 233 of the Atomic Energy Act of 1954, as amended, 42 U.S.C. 2281.

RETURN

CERTIFICATE OF PERSONAL SERVICE:

I certify that I delivered a copy of this subpoena in hand to:

MITCHELL JACOSZ

on 2/25, 1993, at 935 o'clock A M., at

1145 BOWER HILL RD

PITTSBURGH, PA

CERTIFICATE OF SERVICE BY MAIL:

I certify that I caused a copy of this subpoena to be mailed by _____

_____ mail, postage prepaid, to the address specified and with delivery restricted

to the person named thereon on _____, 19 __, Receipt No. _____.

Gerard Kenna

(Signature)

GERARD KENNA
INVESTIGATOR

(Printed Name and Title)

Office of Investigations

U.S. Nuclear Regulatory Commission

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UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION
OFFICE OF INVESTIGATIONS

IN THE MATTER OF: NRC INVESTIGATION

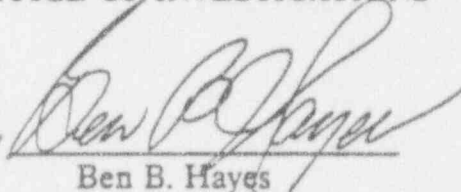
CASE NO. 1-92-060R

TO: Custodian of Records
Mahoning Valley Cancer Center
800 Mahoning Street, Suite E
Leighton, PA

YOU ARE HEREBY COMMANDED, pursuant to Section 161 (c) of the Atomic Energy Act of 1954, as amended, to appear at the offices of the U.S. Nuclear Regulatory Commission, 475 Allendale Road, King of Prussia, PA 19406, (215) 337-5305, on the 12th day of March, 1993, at 9:00 a.m., and to provide the NRC

SEE ATTACHED

BY ORDER OF THE DIRECTOR,
OFFICE OF INVESTIGATIONS

By 
Ben B. Hayes

Date 2-22-93

Requested by: Gerard F. Kenna
Office of Investigations, Region I
U.S. Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, PA 19406
Phone: (215) 337-5305

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RETURN

CERTIFICATE OF PERSONAL SERVICE:

I certify that I delivered a copy of this subpoena in hand to:

Dr. Abne Hasan

on 25 February, 19 93, at 10 o'clock A M., at OS

Mehoning Valley Cancer Center
800 Mahoning Street Suite E
Lehighton Pa

CERTIFICATE OF SERVICE BY MAIL:

I certify that I caused a copy of this subpoena to be mailed by _____
_____ mail, postage prepaid, to the address specified and with delivery restricted
to the person named thereon on _____, 19 ____, Receipt No. _____.

Kusti Mauer

(Signature)

Investigator, Office
(Printed Name and Title)
Office of Investigations
U.S. Nuclear Regulatory Commission

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UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION
OFFICE OF INVESTIGATIONS

IN THE MATTER OF: NRC INVESTIGATION

CASE NO. 1-92-060R

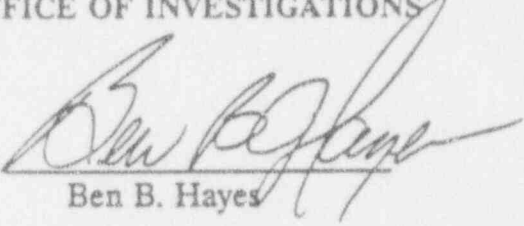
TO: Custodian of Records
Indiana Regional Cancer Center
877 Hospital Road
Indiana, PA

YOU ARE HEREBY COMMANDED, pursuant to Section 161 (c) of the Atomic Energy Act of 1954, as amended, to appear at the offices of the U.S. Nuclear Regulatory Commission, 475 Allendale Road, King of Prussia, PA 19406, (215) 337-5305, on the 12th day of March, 1993, at 9:00 a.m., and to provide the NRC

SEE ATTACHED

BY ORDER OF THE DIRECTOR,
OFFICE OF INVESTIGATIONS

By


Ben B. Hayes

Date

2-22-93

Requested by: Gerard F. Kenna
Office of Investigations, Region I
U.S. Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, PA 19406
Phone: (215) 337-5305

On motion made promptly, and in any event at or before the time specified in the subpoena for compliance by the person to whom the subpoena is directed, and on notice to the party at whose instance the subpoena was issued, the Commission may (1) quash or modify the subpoena if it is unreasonable or requires evidence not relevant to any matter in issue, or (2) condition denial of the motion on just and reasonable terms. Such motion should be directed to the Secretary of the Commission, Washington, DC 20555. Failure to comply with the terms of this subpoena may result in the Commission's seeking judicial enforcement of the subpoena pursuant to Section 233 of the Atomic Energy Act of 1954, as amended, 42 U.S.C. 2281.

RETURN

CERTIFICATE OF PERSONAL SERVICE:

I certify that I delivered a copy of this subpoena in hand to:

JAMES BAUER

on 2/25, 1973, at 1:10 o'clock P. M., at

877 HOSPITAL RD

INDIANA, PA

CERTIFICATE OF SERVICE BY MAIL:

I certify that I caused a copy of this subpoena to be mailed by _____

_____ mail, postage prepaid, to the address specified and with delivery restricted

to the person named thereon on _____, 19 __, Receipt No. _____.

Gerard Kenna

(Signature)

GERARD KENNA
INVESTIGATOR

(Printed Name and Title)

Office of Investigation ::

U.S. Nuclear Regulatory Commission

- I. Any and all documents in your custody, control, or possession, covering the period from June 1, 1990 through February 15, 1993, either original or copy, including but not limited to any records maintained on a computer disk or in any computer file, relating to:
 1. the application to the NRC for a Materials License and any subsequent amendments by Oncology Services Corporation ("OSC") or any of its owned or managed facilities;
 2. any radiation safety procedures, radiation safety policies, or any radiation safety training issued by or for OSC or any of its owned or managed facilities;
 3. contracts with medical physicists, doctors, technologists, and other personnel providing personal services to OSC or any of its owned or managed facilities, including but not limited to job descriptions;
 4. billing statements for the purchase or repair of all radiation detection devices owned or leased by OSC or any of its owned or managed facilities, including but not limited to the prime alert and survey meters;
 5. all telephone logs, appointment calendars, desk calendars, diaries, expense reports, and travel vouchers for any person or persons functioning as a Radiation Safety Officer ("RSO") for OSC or any of its owned or managed facilities during that time period;
 6. all minutes, notes, or records kept by OSC or any of its owned or managed facilities relating to the materials license or any licensed activities, of
 - a. training sessions,
 - b. staff meetings,
 - c. supervisory meetings, or
 - d. corporate meetings, including but not limited to the bi-annual authorized user meetings, and
 - e. the minutes and contemporaneous notes of the radiation safety committee of OSC or any of its owned or managed facilities;
 7. log books relating to quality control reports, radiation survey reports, and maintenance reports for any equipment belonging to OSC or any of its owned or managed facilities;
 8. training documents and procedure manuals relating to radiation safety training at OSC or any of its owned or managed facilities;

9. expense vouchers and sub-vouchers, including but not limited to travel vouchers, submitted by any officer or employee of OSC or any of its owned or managed facilities for training purposes;
 10. all documents relating to training issued by or for OSC or any of its owned or managed facilities, including but not limited to announcements, correspondence, memoranda (including but not limited to inter-office memoranda), and notes, both formal and informal; and
 11. records relating to any and all company business meetings conducted either by or for OSC or any of its owned or managed facilities, in Atlantic City, New Jersey, during the summer of 1992, including but not limited to the meeting agenda, syllabi, participant handouts, and rosters of personnel attending the meeting.
- II. The employment application of any officer, director, employee, contractor, or subcontractor, employed by OSC or any of its owned or managed facilities, or who performed activities at the direction of or on behalf of OSC or any of its owned or managed facilities, during the period between June 1, 1990, and February 15, 1993.

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION
OFFICE OF INVESTIGATIONS

IN THE MATTER OF: NRC INVESTIGATION

CASE NO. 1-92-060R

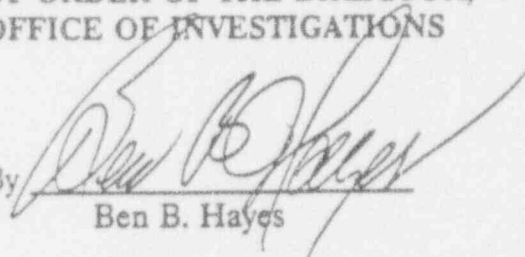
JAN MORTON
TO: Custodian of Records
Exton Cancer Center
460 Creamery Way, Suite B
Exton, PA 19341

YOU ARE HEREBY COMMANDED, pursuant to Section 161 (c) of the Atomic Energy Act of 1954, as amended, to appear at the offices of the U.S. Nuclear Regulatory Commission, 475 Allendale Road, King of Prussia, PA 19406, (215) 337-5305, on the 12th day of March, 1993, at 9:00 a.m., and to provide the NRC

SEE ATTACHED

BY ORDER OF THE DIRECTOR,
OFFICE OF INVESTIGATIONS

By


Ben B. Hayes

Date

2-22-93

Requested by: Gerard F. Kenna
Office of Investigations, Region I
U.S. Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, PA 19406
Phone: (215) 337-5305

On motion made promptly, and in any event at or before the time specified in the subpoena for compliance by the person to whom the subpoena is directed, and on notice to the party at whose instance the subpoena was issued, the Commission may (1) quash or modify the subpoena if it is unreasonable or requires evidence not relevant to any matter in issue, or (2) condition denial of the motion on just and reasonable terms. Such motion should be directed to the Secretary of the Commission, Washington, DC 20555. Failure to comply with the terms of this subpoena may result in the Commission's seeking judicial enforcement of the subpoena pursuant to Section 233 of the Atomic Energy Act of 1954, as amended, 42 U.S.C. 2281.

RETURN

CERTIFICATE OF PERSONAL SERVICE:

I certify that I delivered a copy of this subpoena in hand to:

JAN MORTON, OFFICE MANAGER

on FEB 25, 19 93, at 9:55 o'clock A M., at the
Exton Cancer Center, 460 Creamery Way,
Suite B, Exton, PA

CERTIFICATE OF SERVICE BY MAIL:

I certify that I caused a copy of this subpoena to be mailed by _____
_____ mail, postage prepaid, to the address specified and with delivery restricted
to the person named thereon on _____, 19 __, Receipt No. _____.

Richard A. Matukas
(Signature)

Richard A. MATUKAS
Sr. Investigator, OI
(Printed Name and Title)
Office of Investigations
U.S. Nuclear Regulatory Commission

- I. Any and all documents in your custody, control, or possession, covering the period from June 1, 1990 through February 15, 1993, either original or copy, including but not limited to any records maintained on a computer disk or in any computer file, relating to:
 1. the application to the NRC for a Materials License and any subsequent amendments by Oncology Services Corporation ("OSC") or any of its owned or managed facilities;
 2. any radiation safety procedures, radiation safety policies, or any radiation safety training issued by or for OSC or any of its owned or managed facilities;
 3. contracts with medical physicists, doctors, technologists, and other personnel providing personal services to OSC or any of its owned or managed facilities, including but not limited to job descriptions;
 4. billing statements for the purchase or repair of all radiation detection devices owned or leased by OSC or any of its owned or managed facilities, including but not limited to the prime alert and survey meters;
 5. all telephone logs, appointment calendars, desk calendars, diaries, expense reports, and travel vouchers for any person or persons functioning as a Radiation Safety Officer ("RSO") for OSC or any of its owned or managed facilities during that time period;
 6. all minutes, notes, or records kept by OSC or any of its owned or managed facilities relating to the materials license or any licensed activities, of
 - a. training sessions,
 - b. staff meetings,
 - c. supervisory meetings, or
 - d. corporate meetings, including but not limited to the bi-annual authorized user meetings, and
 - e. the minutes and contemporaneous notes of the radiation safety committee of OSC or any of its owned or managed facilities;
 7. log books relating to quality control reports, radiation survey reports, and maintenance reports for any equipment belonging to OSC or any of its owned or managed facilities;
 8. training documents and procedure manuals relating to radiation safety training at OSC or any of its owned or managed facilities;

9. expense vouchers and sub-vouchers, including but not limited to travel vouchers, submitted by any officer or employee of OSC or any of its owned or managed facilities for training purposes;
 10. all documents relating to training issued by or for OSC or any of its owned or managed facilities, including but not limited to announcements, correspondence, memoranda (including but not limited to inter-office memoranda), and notes, both formal and informal; and
 11. records relating to any and all company business meetings conducted either by or for OSC or any of its owned or managed facilities, in Atlantic City, New Jersey, during the summer of 1992, including but not limited to the meeting agenda, syllabi, participant handouts, and rosters of personnel attending the meeting.
- II. The employment application of any officer, director, employee, contractor, or subcontractor, employed by OSC or any of its owned or managed facilities, or who performed activities at the direction of or on behalf of OSC or any of its owned or managed facilities, during the period between June 1, 1990, and February 15, 1993.

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION
OFFICE OF INVESTIGATIONS

IN THE MATTER OF: NRC INVESTIGATION

CASE NO. 1-92-060R

TO: Custodian of Records
Life Care Center
RD#1
Sandy Lake Road
Stoneboro, PA

DR. GILBERT A. LAWRENCE
321 B EAST LAKE ROAD
TRANSFER, PA 16154

YOU ARE HEREBY COMMANDED, pursuant to Section 161 (c) of the Atomic Energy Act of 1954, as amended, to appear at the offices of the U.S. Nuclear Regulatory Commission, 475 Allendale Road, King of Prussia, PA 19406, (215) 337-5305, on the 12th day of March, 1993, at 9:00 a.m., and to provide the NRC

SEE ATTACHED

BY ORDER OF THE DIRECTOR,
OFFICE OF INVESTIGATIONS

By 

Ben B. Hayes

Date 2-22-93

Requested by: Gerard F. Kenna
Office of Investigations, Region I
U.S. Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, PA 19406
Phone: (215) 337-5305

On motion made promptly, and in any event at or before the time specified in the subpoena for compliance by the person to whom the subpoena is directed, and on notice to the party at whose instance the subpoena was issued, the Commission may (1) quash or modify the subpoena if it is unreasonable or requires evidence not relevant to any matter in issue, or (2) condition denial of the motion on just and reasonable terms. Such motion should be directed to the Secretary of the Commission, Washington, DC 20555. Failure to comply with the terms of this subpoena may result in the Commission's seeking judicial enforcement of the subpoena pursuant to Section 233 of the Atomic Energy Act of 1954, as amended, 42 U.S.C. 2281.

RETURN

CERTIFICATE OF PERSONAL SERVICE:

I certify that I delivered a copy of this subpoena in hand to:

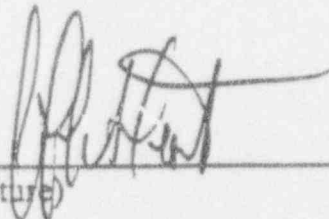
DR GILBERT A. LAWRENCE, 321 B EAST LAKE
ROAD, TRANSFER, PA 16154

on 2/25/93, 19 93, at 10:35 o'clock A M., at

LIFE CARE CENTER, RD #1, SANDY LAKE ROAD,
STONGBORN, PA

CERTIFICATE OF SERVICE BY MAIL:

I certify that I caused a copy of this subpoena to be mailed by _____
_____ mail, postage prepaid, to the address specified and with delivery restricted
to the person named thereon on _____, 19 ____, Receipt No. _____.



(Signature)

JERREY A. TEATOR
INVESTIGATOR

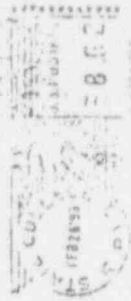
(Printed Name and Title)
Office of Investigations
U.S. Nuclear Regulatory Commission

NRC-OI-KENNA
475 ALLENDALE RD.
KING OF PRUSSIA, PA
19406

REGISTERED MAIL
R 494 181 733

RECEIVED BY MAIL

93 1985 to NU-04



RESTRICTED DELIVERY

RETURN RECEIPT REQUESTED

UNCLAIMED

DOUGLAS R. COLKITT
PRESIDENT
ONCOLOGY SERVICES CORP.
110 REGENT COURT, SUITE 100
STATE COLLEGE, PA 16801

8-31

1st Notice 3/1/93
2nd Notice 3/6/93
Return 3/16/93

Sender: Complete items 1 and 2 on additional services. Complete items 3 and 4 on the reverse of this form so that we can return the card to you. Attach this form to the front of the package or on the back if space does not permit. Write "Return Receipt Requested" on the envelope below the article number delivered for return.

3. Article Addressed to:
DOUGLAS R. COLKITT
PRESIDENT
ONCOLOGY SERVICES CORP
110 REGENT COURT SUITE 100
STATE COLLEGE PA 16801

4a. Article Number: P-255-63-3020

4b. Service Type:
 Registered Insured
 Certified COO
 Express Mail Return Receipt for Merchandise

5. Date of Delivery: 3/1/93

6. Addressee's Address (Only if requested and fee is paid):

6.1. Signature (Addressee):
6.2. Signature (Agent):

PS Form 3811, December 1991 © U.S.P.D. 1289-907-630 DOMESTIC RETURN RECEIPT

RESTRICTED DELIVERY

370



UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF INVESTIGATIONS FIELD OFFICE, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406

June 4, 1993

Marcy L. Colkitt
General Counsel
Oncology Services Corporation
110 Regent Court, Suite 100
State College, PA 16801

Re: Document Subpoenas to Oncology Services Corporation

Dear Ms. Colkitt:

Reference is made to your telephone conversation of Wednesday, May 19, 1993, with Investigators Gerard Kenna and Kristin Monroe concerning the U.S. Nuclear Regulatory Commission (NRC), Office of Investigations (OI), subpoenas for documents of Oncology Services Corporation, the Indiana Regional Cancer Center, the Greater Pittsburgh Cancer Center, the Greater Harrisburg Cancer Center, the Life Care Center, the Mahoning Valley Cancer Center, and the Exton Cancer Center, dated February 25 and 26, 1993.

OI has conducted a preliminary review of the documents forwarded pursuant to the subpoenas. We have determined there are documents that have not been provided that are within the parameters of the subpoenas. We are forwarding to you a list of those documents. In addition, some documents that have been received are not legible, list is provided. Also, please submit the actual slides for review because the photocopies of them are not legible.

Your cooperation in this matter is greatly appreciated. Should you desire additional information, please contact the aforementioned investigators at (215) 337-5305.

Sincerely,

A handwritten signature in black ink, appearing to read "Barry R. Letts", written over a large, stylized "X" mark.

Barry R. Letts, Director
Office of Investigations
Field Office, Region I

Attachment:
As stated

DOCUMENTS

1. All minutes, notes, or records of OSC or any of its owned or managed facilities relating to the materials license or any licensed activities, including staff meetings, training sessions, supervisory meetings, corporate meetings and interoffice or center memorandum.
2. Employment applications of any officers, directors, employees, contractors or subcontractors, employed by OSC or any of its owned or managed facilities, or who performed activities at the direction of or on behalf of OSC or any of its owned or managed facilities, during the period June 1, 1990 and February 15, 1993. Contracts/agreements with Sayed Mansort, Steve Kirsner, and David Moylan.
3. ADT Summary (Oncology Services Corporation Patient Treatment).
4. HDR Introduction Manual and HDR Marketing Manual.
5. Monthly HDR Logs and HDR Monthly Log Utilization Procedure.
6. HDR Marketing Plan, Objectives, Activities.
7. Weekly Activity Reports prepared for OSC and submitted to OSC corporate headquarters by the centers.
8. Any notes or memoranda from monthly Regional Administrator meetings, to include audio tape recordings, video tapes, typed minutes and handwritten notes.
9. Staff, training, corporate, and supervisory meeting records from the semi-annual Medical Directors meetings, to include the syllabi, roster of personnel, and notes.
10. Telephone records for any person or persons functioning as the Radiation Safety Officer for June to December 1990; January to October 1991; August, September and November 1992; and January to February 1993.
11. Appointment calendars, desk calendars, diaries of any person or persons acting as the Radiation Safety Officer.
12. Radiation safety procedures and policies from 1990 to 1992.
13. Maintenance reports for any equipment belonging to OSC or any of its owned or managed facilities.
14. Expense vouchers and sub-vouchers, including, but not limited to, travel vouchers submitted by any officer or employee of OSC or any of its owned or managed facilities for training, to include the conference in Atlantic City, New Jersey, and the semiannual Medical Director's meetings.

15. Rosters of employees and participant handouts relating to any and all company business meetings conducted either by, or for, OSC or any of its owned or managed facilities, in Atlantic City, New Jersey, during the summer of 1992.
16. Minutes and contemporaneous notes of the radiation safety committee of OSC or any of its owned or managed facilities.
17. Documents related to the HDR GammaMed Iii machine use from 1990 to 1992 at the Exton Cancer Center, Greater Pittsburgh Cancer Center, Indiana Regional Cancer Center and The Life Care Center. These documents should include, but not be limited to, the HDR Quality Assurance and Calibration forms for the GammaMed Iii.
18. Documents for the initial and refresher training in the operation of the HDR loading devices for Dr. Cunningham and Dr. Ying.

Documents that were submitted but require legible copies:

1. Photocopy of slides submitted are not legible. Please submit original slides for review.
2. The following photocopies are not legible.

E 000100	E 000128
E 000102	E 000130
E 000105	E 000131
E 000107	E 000132
E 000114	E 000134
E 000116	E 000138
E 000118	E 000140
E 000120	E 000142
E 000122	E 000144
E 000124	E 000146
E 000126	E 000148
E 000151	
I 000035	

ONCOLOGY SERVICES CORPORATION

110 Regent Court • Suite 100 • State College, PA • 16801

814-238-0375 • 800-628-9076 • Fax: 814-238-8069

(412) 463-3570

July 14, 1993

VIA TELECOPY: 215/337-5131
AND CERTIFIED MAIL/
RETURN RECEIPT REQUESTED

Barry R. Letts, Director
Office of Investigations
U.S. Nuclear Regulatory Commission - Region I
475 Allendale Road
King of Prussia, PA 19406-1415

Re: NRC Subpoena to OSC -- Letts' Letter 6/4/93

Dear Mr. Letts:

On June 4, 1993, you sent me a letter saying that OSC owed you additional documents under the subpoenas dated February 25 and 26, 1993 which were issued to OSC pursuant to an NRC investigation of licensed HDR operations at six HDR centers of OSC in Pennsylvania. Since that investigation began, OSC has cooperated in your interviews of approximately 40 witnesses and has produced over 12,000 documents. It is our belief that OSC has absolutely met the requirements of the subpoena by producing all relevant documents covered by the subpoena. These subpoenas have imposed an enormous and very costly burden on OSC. Despite the burden, I am willing to discuss with you any category of documents which you say was subpoenaed and which you say was not produced. By letter dated May 20, 1993 to Jerry Kenna, I asked him to set forth why certain categories of documents he thought the agency might want were relevant to an investigation of HDR operations at the licensed centers in Pennsylvania. To date, I have had no response from the agency setting forth the paragraph of the original subpoena or more importantly, the relevancy of the additional documents you have requested OSC to produce.

I am particularly troubled by the fact that at the same time that you sent the June 4 letter saying how much additional information OSC owed to the Agency, you prepared an affidavit in support of yet another staff motion for delay of OSC's request that it have a prompt hearing on its license suspension. In that affidavit in support of additional delay, you represented that the NRC had not yet reviewed the 12,000 documents produced by OSC. It seems odd to say that the 12,000 documents have not been reviewed on the very same day that the Agency is telling OSC the 12,000 documents do not meet the request of the original subpoena.

Barry R. Letts, Director
July 14, 1993
Page 2

In reviewing the attachment to the June 4 letter, OSC has already produced all the relevant and existing documents requested in paragraphs 1, 2, 9, 12, 13, 15, 16, 17 and 18. We have no other documents responsive to these paragraphs, with the sole exceptions of a letter to Sayed Monsour and an agreement with a corporation with which I believe Dr. Moylan is affiliated. HDR documents relative to paragraphs 3 and 5 will be forwarded along with those referred to above. I have requested additional responsive documentation, to the extent it exists, for paragraph 11. However, OSC has no control over said documents. I have, however, requested it. If we receive it, we will forward them. With respect to paragraph 10, there are no specific telephone records for the RSO, however, I have requested that you receive copies of all Harrisburg based phone records, to the extent they exist.

With regard to certain other paragraphs of the attachment to the June 4 letter, we do not understand the relevance and invite OI to explain where the requests were covered in the original subpoena and to set forth how the requested documents relate to the NRC's mandate to provide for safety and proper training in HDR operations. In particular the paragraphs which do not seem to have relevance to this investigation are: 4, 6, 7, 8 and 14. In no event will OSC be compelled to produce documents not relevant to this investigation.

Additional copies of the photocopies you indicated are illegible are being sent to you under separate cover. It is my understanding that these are as legible as they get. If you want to review the originals, I will make them available in State College. Likewise, because we only have one set of slides I am unable to provide you with the originals. I will, however, be glad to also make them available for review in State College. Alternatively, I can attempt to have copies made if you are willing to pick up the cost. Our Company cannot withstand any further

Barry R. Letts, Director
July 14, 1993
Page 3

expenses in connection with this extremely costly and burdensome investigation.

I look forward to speaking with you further.

Very truly yours,

Marcy L. Colkitt
sjg

Marcy L. Colkitt

General Counsel and
Executive Vice President

MLC/sjg

cc: Kerry A. Kearney, Esquire (via telecopy)

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION
OFFICE OF INVESTIGATIONS

IN THE MATTER OF: NRC Investigation

CASE NO. 1-92-060R

TO: Custodian of Records
Oncology Services Corporation
110 Regent Court, Suite 100
State College, PA 16801

YOU ARE HEREBY COMMANDED, pursuant to Section 161 (c) of the Atomic Energy Act of 1954, as amended, to appear at the offices of the U.S. Nuclear Regulatory Commission, 475 Allendale Road, King of Prussia, PA 19406, (215-337-5305), on the 13th day of September, 1993, at 9:00 a.m., and to provide the NRC--See Attachment.

BY ORDER OF THE DIRECTOR,
OFFICE OF INVESTIGATIONS

By


Ben B. Hayes

Date August 24, 1993

Requested by: Gerard Kenna, Investigator
Office of Investigations, Region I
U.S. Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, PA 19406
Phone: (215) 337-5305

On motion made promptly, and in any event at or before the time specified in the subpoena for compliance by the person to whom the subpoena is directed, and on notice to the party at whose instance the subpoena was issued, the Commission may (1) quash or modify the subpoena if it is unreasonable or requires evidence not relevant to any matter in issue, or (2) condition denial of the motion on just and reasonable terms. Such motion should be directed to the Secretary of the Commission, Washington, DC 20555. Failure to comply with the terms of this subpoena may result in the Commission's seeking judicial enforcement of the subpoena pursuant to Section 233 of the Atomic Energy Act of 1954, as amended, 42 U.S.C. 2281.

RETURN

CERTIFICATE OF PERSONAL SERVICE:

I certify that I delivered a copy of this subpoena in hand to:

on _____, 19 ____, at _____ o'clock _____ M., at _____

CERTIFICATE OF SERVICE BY MAIL:

I certify that I caused a copy of this subpoena to be mailed by airmail

_____ mail, postage prepaid, to the address specified and with delivery restricted

to the person named thereon on 8/26, 19 93, Receipt No. P48573572

AND VIA FAX 412-463-3569 PER INSTRUCTIONS
OF MARCY COLKITT, VICE PRESIDENT ONCOLOGY
SERVICES CORP.

Gerard Kenner
(Signature)

GERARD KENNER - INVESTIGATOR
(Printed Name and Title)
Office of Investigations
U.S. Nuclear Regulatory Commission

I. The following list of documents pertains to NRC License No. 37-28540-01 issued to Oncology Services Corporation. The term "documents" includes, but is not limited to, any records maintained on a computer disk or computer file and includes either original or copy of the applicable document. The time period covered by this subpoena is the period from June 1, 1990 through February 15, 1993.

1. All minutes, notes, or records of any meetings held by Oncology Services Corporation (OSC) or any of its owned or managed facilities, relating to any activities conducted under NRC License No. 37-28540-01, including minutes of staff meetings, training sessions, supervisory meetings, HDR Committee meetings, or corporate meetings, and any interoffice or center memoranda relating to those meetings.
2. Employment applications and resumes submitted by any person employed by OSC as an officer, director, employee, vendor, contractor or subcontractor, at any of its owned or managed facilities, or who performed activities at the direction of or on behalf of OSC or any of its owned or managed facilities, under NRC License No. 37-28540-01, during the period between June 1, 1990 and February 15, 1993.
3. HDR Introduction Manuals and Incentive Plans in effect during the period June 1, 1990 through February 15, 1993, which were applicable, either in whole or in part, to any activities conducted under NRC License No. 37-28540-01.
4. Monthly HDR Logs, HDR Monthly Log Utilization and the weekly/bi-weekly Cancer patient treatment documents for the period between June 1, 1990 and February 15, 1993, which recorded, either in whole or in part, any activities conducted under NRC License No. 37-28540-01.
5. Weekly Activity Reports prepared for OSC and submitted to OSC corporate headquarters by the various OSC centers regarding activities conducted under NRC License 37-28540-01 between June 1, 1990 and February 15, 1993.
6. Notes or memoranda from monthly OSC Regional Administrator meetings conducted between June 1, 1990 and February 15, 1993, including audio tape recordings, video tapes, typed minutes, handwritten notes, and roster of participating personnel.

7. Staff, training, corporate, and supervisory meeting records from any semi-annual Medical Directors meetings conducted between June 1, 1990 and February 15, 1993; to include the syllabi, roster of personnel, and notes.
8. Telephone records for any person or persons functioning as the Radiation Safety Officer under NRC License No. 37-28540-01 between June 1, 1990 and April 30, 1991.
9. Any records of any maintenance conducted between June 1, 1990 and February 15, 1993, on any HDR equipment belonging to OSC or any of its owned or managed facilities and used to conduct licensed activities under NRC License No. 37-28540-01.
10. Expense vouchers and sub-vouchers, including, but not limited to, travel vouchers submitted by any officer or employee of OSC or any of its owned or managed facilities. The records should include, but not be limited to, HDR maintenance travel records, HDR training records, and the semiannual Medical Directors' meetings and regional administrators' meetings regarding any activities conducted, either in whole or in part, under NRC License No. 37-28540-01.
11. Roster of employees and participant handouts relating to any and all company business meetings conducted either by, or for, OSC or any of its owned or managed facilities, held in Atlantic City, New Jersey, between April 1 and November 1, 1992.
12. All documents relating to the use of the HDR GammaMed III machine from 1990 to 1992 at Greater Pittsburgh Cancer Center, Indiana Regional Cancer Center, and The Life Care Center. These documents should include, but not be limited to, the HDR Quality Assurance and Calibration forms for the GammaMed III.
13. Documents describing any initial or refresher training in the operation of the HDR loading devices for Dr. Cunningham or Dr. Ying between June 1, 1990 and February 15, 1993. In addition, any documents relating to any training that Dr. Cunningham or Dr. Ying received from the manufacturer regarding the installation, relocation or removal of high dose loader units containing sources.

14. Payroll documents which contain the name and home address of all employees of OSC, including its corporate headquarters personnel, and the employees of any of its owned or managed facilities in which OSC conducted activities under NRC License No. 37-28540-1, from June 1, 1990 through August 8, 1993.
15. Any documents relating to any experiments conducted with any nuclear source used by OSC to conduct activities under NRC License No. 37-28540-01. The term "documents" includes, but is not limited to, documents produced regarding when the nuclear source was exposed outside the Harrisburg Cancer Center.
16. Legible photocopies of slides submitted in response to the previous subpoena served on OSC on March 1, 1993. OSC's original submission is illegible.
17. Purchase and repair records for the prime alert and survey meters for the period June 1, 1990 through February 15, 1993. The records should include the calibration records for any prime alert, Ion Chamber and/or survey meter belonging to OSC or any of its owned or managed facilities and used by OSC to conduct licensed activities under NRC License No. 37-28540-01 during that time.

II. The following list of documents pertains to NRC License No. 37-28179-01, issued for the OSC facility at the Indiana Regional Cancer Center, Indiana, PA.

A. Any and all documents in your custody, control, or possession, covering the period from March 28, 1988 through August 20, 1993, either original or copy, including but not limited to any records maintained on a computer disk or in any computer file, relating to:

1. the application to the NRC for each Materials License by OSC and any subsequent amendments to NRC License No. 37-28179-01 by the NRC to OSC;
2. any radiation safety procedures, radiation safety policies, or any radiation safety training issued by or for OSC for any operations to be conducted under NRC License No. 37-28179-01;

3. any contracts with medical physicists, doctors, technologists, and other personnel providing personal services to OSC under NRC License No. 37-28179-01, including but not limited to job descriptions;
4. billing statements for the purchase or repair of all radiation detection devices owned or leased by OSC and used to conduct activities under NRC License No. 37-28179-01, including but not limited to the prime alert and survey meters;
5. all telephone logs, appointment calendars, desk calendars, diaries, expense reports and travel vouchers for any person or persons functioning as a Radiation Safety Officer (RSO) for OSC under NRC License No. 37-28179-01;
6. all minutes, notes, or records kept by OSC or any of its owned or managed facilities relating to NRC License No. 37-28179-01, or any licensed activities conducted under that license, of
 - a. training sessions,
 - b. staff meetings,
 - c. supervisory meetings,
 - d. corporate meetings, including but not limited to the bi-annual authorized user meetings, and,
 - e. radiation safety committee meetings;
7. log books relating to quality control reports, radiation survey reports, and maintenance reports for any equipment belonging to OSC or its owned or operated companies and used by OSC to conduct activities under NRC License No. 37-28179-01;
8. training documents and procedure manuals relating to radiation safety training at OSC in conducting activities under NRC License No. 37-28179-01;

9. expense vouchers and sub-vouchers, including but not limited to travel vouchers, submitted by any officer, employee, contractor, subcontractor, or vendor of OSC or any of its owned or managed facilities, related to training purposes for activities conducted under NRC License No. 37-28179-01;
 10. all documents relating to training for activities to be conducted under NRC License No. 37-28179-01, issued by or for OSC or any of its owned or managed facilities, including but not limited to announcements, correspondence, both inter-office and intra-office memoranda, and notes, both formal and informal; and
 11. records relating to any and all company business meetings conducted either by or for OSC or any of its owned or managed facilities, held in Atlantic City, N.J., between April 1, 1992 and November 1, 1992, including but not limited to the meeting agenda, syllabi, participant handouts, and rosters of personnel attending the meeting.
- B. Employment applications and resumes of any officers, directors, employees, contractors or subcontractors, employed by OSC or any of its owned or managed facilities in order to conduct licensed activities under NRC License No. 37-28179-01, or who performed activities at the direction of or on behalf of OSC or any of its owned or managed facilities under NRC License No. 37-28179-01, during the period between March 28, 1988 and August 8, 1993.

ONCOLOGY SERVICES CORPORATION

2171 Sandy Drive • State College, PA • 16803

814-238-0375 • Fax: 814-238-8069

(412) 463-3570

September 16, 1993

VIA TELECOPY: 215-337-5131 AND
CERTIFIED MAIL/RETURN
RECEIPT REQUESTED

Barry R. Letts, Director
Office of Investigations
U.S.-NRC-Region I
475 Allendale Road
King of Prussia, PA 19406

RE: NRC Subpoena - Case No. 1-92-060R

Dear Mr. Letts:

Please be advised that the licensee, Oncology Services Corporation (OSC), objects to the requested documents in so far as many seek irrelevant information and/or information that the production of which would be overly burdensome and oppressive. However, OSC continues to invite OI to explain to OSC the relevancy of any objected to requests. As always, OSC is willing to discuss relevancy with OI. However, despite repeated requests by OSC for an explanation of the relevancy of previous requests, OI has failed to even respond. Now, OI is once again asking the same questions. OSC does not understand OI's action. Be advised, however, that absent a federal court order, OSC will not be compelled to respond to irrelevant and/or overly burdensome requests. Set forth below are OSC's responses to your most recent subpoena pertaining to NRC License No. 37-28540-01 issued to OSC.

1. All minutes, notes, or records of any meetings held by Oncology Services Corporation (OSC) or any of its owned or managed facilities, relating to any activities conducted under NRC License No. 37-28540-01, including minutes of staff meetings, training sessions, supervisory meetings, HDR Committee meetings, or corporate meetings, and any interoffice or center memoranda relating to those meetings.

Response

Oncology services has complied with this request on prior submissions of materials to the NRC to the extent said materials were relevant to the jurisdiction of the NRC - safety and training. OSC objects to the request in so far as it seeks irrelevant material and OSC will not provide irrelevant responses. Certain additional meeting minutes referencing the technical service department have been located and will be forwarded within the next four business days.

SEP 21 AM 10 24

Barry R. Letts, Director
September 16, 1993
Page 2

2. Employment applications and resumes submitted by any person employed by OSC as an officer, director, employee, vendor, contractor or subcontractor, at any of its owned or managed facilities, or who performed activities at the direction of or on behalf of OSC or any of its owned or managed facilities, under NRC License No. 37-28540-01, during the period between June 1, 1990 and February 15, 1993.

Response

Resumes of physicians, physicists and many technologists, to the extent they exist, have previously been produced. Because OSC has been denied access to the transcripts of the 45 plus individuals that OI has interrogated over the past eight months and because OI has complete access to those transcripts OI should provide OSC with a list of the relevant personnel and OSC will produce the relevant existing documents. As OI is well aware, it has not been the practice at any time for OSC to complete or maintain employment applications for any employee.

3. HDR Introduction Manuals and Incentive Plans in effect during the period June 1, 1990 through February 15, 1993, which were applicable, either in whole or in part, to any activities conducted under NRC License No. 37-28540-01.

Response

OSC has previously produced all relevant HDR manuals. However, OSC objects to this request because it seeks irrelevant information and information outside the scope of the NRC's jurisdiction - safety and training.

4. Monthly HDR Logs, HDR Monthly Log Utilization and the weekly/bi-weekly Cancer patient treatment documents for the period between June 1, 1990 and February 15, 1993, which recorded, either in whole or in part, any activities conducted under NRC License No. 37- 28540-01

Response

OSC has previously produced all existing documents responsive to this request.

5. Weekly Activity Reports prepared for OSC and submitted to OSC corporate headquarters by the various OSC centers regarding activities conducted under NRC License 37-28540-01 between June 1, 1990 and February 15, 1993.

Barry R. Letts, Director
September 16, 1993
Page 3

Response

OSC objects to this request because it seeks irrelevant information and information outside the scope of the NRC's jurisdiction - safety and training.

6. Notes or memoranda from monthly OSC Regional Administrator meetings conducted between June 1, 1990 and February 15, 1993, including audio tape recordings, video tapes, typed minutes, handwritten notes, and roster of participating personnel.

Response

OSC objects to this request because it seeks irrelevant information and information outside the scope of the NRC's jurisdiction - safety and training.

7. Staff, training, corporate, and supervisory meeting records from any semi-annual Medical Directors meetings conducted between June 1, 1990 and February 15, 1993, to include the syllabi, roster of personnel, and notes.

Response

OSC objects to this request because it seeks irrelevant information and information outside the scope of the NRC's jurisdiction - safety and training. However, to the extent the requested documents contain information related to safety and training, said documents have been previously provided.

8. Telephone records for any person or persons functioning as the Radiation Safety Officer under NRC License No 37-28540-01 between June 1, 1990 and April 30, 1991.

Response

The License believes all existing telephone records have been previously produced, however the Licensee will forward any additional documents to the extent they exist.

9. Any records of any maintenance conducted between June 1, 1990 and February 15, 1993, on any HDR equipment belonging to OSC or any of its owned or managed facilities and used to conduct licensed activities under NRC License No. 37-28450-01.

Barry R. Letts, Director
September 16, 1993
Page 4

Response

All existing maintenance records have previously been produced.

10. Expense vouchers and sub-vouchers, including, but not limited to, travel vouchers submitted by any officer or employee of OSC or any of its owned or managed facilities. The records should include, but not be limited to, HDR maintenance travel records, HDR training records, and the semiannual Medical Directors' meetings and regional administrators' meetings regarding any activities conducted, either in whole or in part, under NRC License No. 37-28540-01.

Response

OSC objects to this request because it seeks irrelevant information and information outside the scope of the NRC's jurisdiction - safety and training. Moreover, this request is so overly burdensome that it is incapable of being complied with even if it was relevant, which it is not. Furthermore, OI has interrogated in excess of 45 individuals over the past eight months and to the extent there were any questions relating to the issue of expense vouchers they have been asked or could have been asked by OI.

11. Roster of employees and participant handouts relating to any and all company business meetings conducted either by, or for, OSC or any of its owned or managed facilities, held in Atlantic City, New Jersey, between April 1 and November 1, 1992.

Response

To the extent relevant documents were maintained they have previously been produced.

12. All documents relating to the use of the HDR GammaMed III Machine from 1990 to 1992 at Greater Pittsburgh Cancer Center, Indiana Regional Cancer Center, and The Life Care Center. These documents should include, but not be limited to, the HDR Quality Assurance and Calibration forms for the GammaMed III.

Response

To the extent relevant documents were maintained they have previously been produced.

Barry R. Letts, Director
September 16, 1993
Page 5

13. Documents describing any initial or refresher training in the operation of the HDR loading devices for Dr. Cunningham or Dr. Ying between June 1, 1990 and February 15, 1993. In addition, any documents relating to any training that Dr. Cunningham or Dr. Ying received from the manufacturer regarding the installation, relocation or removal of high dose loader units containing sources.

Response

OSC believes it has previously produced all existing responsive documents. However, to the extent any additional documents exist they will be produced.

14. Payroll documents which contain the name and home address of all employees of OSC, including its corporate headquarters personnel, and the employees of any of its owned or managed facilities in which OSC conducted activities under NRC License No. 37-28540-01, from June 1, 1990 through August 8, 1993.

Response

OSC objects to this request because it seeks completely irrelevant information and information outside the scope of the NRC's jurisdiction - safety and training. Further, OI is improperly seeking to obtain confidential and personal salary information. OI has had an opportunity to ask for said information during its interrogations. Certain OI personnel asked this information previously. Therefore, the request is also unduly burdensome and oppressive.

15. Any documents relating to any experiments conducted with any nuclear source used by OSC to conduct activities under NRC License No. 37-28540-01. The term "documents" includes, but is not limited to, documents produced regarding when the nuclear source was exposed outside the Harrisburg Cancer Center.

Response

To the extent any responsive documents exist, they will be produced within the next four business days.

16. Legible photocopies of slides submitted in response to the previous subpoena served on OSC on March 1, 1993. OSC's original submission is illegible.

Barry R. Letts, Director
September 16, 1993
Page 6

Response

Another set of photocopies will be provided within the next four business days. As always, the originals are available for inspection at State College, PA.

17. Purchase and repair records for the prime alert and survey meters for the period June 1, 1990 through February 15, 1993. The records should include the calibration records for any prime alert, Ion Chamber and/or survey meter belonging to OSC or any of its owned or managed facilities and used by OSC to conduct licensed activities under NRC License No. 37-28540-01 during that time.

Response

To the extent any responsive documents exist, they have previously been produced to the NRC.

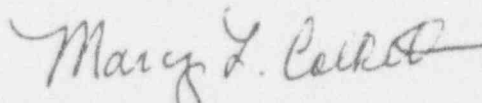
IIA. 1 through 11 and B

Response

NRC License No 37-28179-01 is not issued to Oncology Services Corporation.

As always, I am fully available to discuss the issues raised herein. Finally, can I please get proposed dates for the fifteen additional individuals that OI continually maintains it still needs to interrogate so that schedules can be worked out for all involved and we can get this process completed. I have requested this information for a number of occasions and your office has not even responded.

Very truly yours,



Marcy L. Colkitt

General Counsel

MLC/sjg

cc: Kerry Kearney, Esquire (via telecopy)

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA,
Petitioner,

v.

ONCOLOGY SERVICES CORPORATION,
Respondent.

MISC. NO. _____

CERTIFICATE OF NONCONCURRENCE

I, Anjali A. Ashley, counsel for petitioner, United States of America, do hereby state that on November 9, 1993, I contacted Marcy L. Colkitt, General Counsel, Oncology Services Corporation, in order to seek her concurrence in the foregoing Petition for Summary Enforcement of Administrative Subpoena ("Petition"). Ms. Colkitt stated that she did not concur with the Petition.

Date: 11/10/93

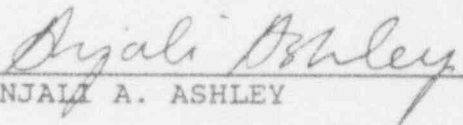
Anjali Ashley
ANJALI A. ASHLEY

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing Petition for Summary Enforcement of Administrative Subpoena, Memorandum of Points and Authorities in support thereof, Exhibits, proposed Order, and Certificate of Nonconcurrency were sent by overnight mail, this 15th day of November, 1993:

Marcy L. Colkitt, Esq.
General Counsel
Oncology Services Corporation
176 Timbersprings Lane
Indiana, PA 15701

Kerry A. Kearney, Esq.
Reed, Smith, Shaw & McClay
435 Sixth Avenue
Pittsburgh, PA 15219-1886


ANJALI A. ASHLEY

FILED
10/23
4

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA,)	
)	
Petitioner,)	
)	
v.)	MISC. DOCKET NO. 3:93MC207
)	
ONCOLOGY SERVICES CORPORATION,)	(Conaboy, J.)
)	
Respondent.)	
)	
_____)	

CONSENTED-TO MOTION FOR SCHEDULING THE RESPONSE
BY ONCOLOGY SERVICES CORPORATION
TO THE PETITION OF THE UNITED STATES OF AMERICA
FOR SUMMARY ENFORCEMENT OF ADMINISTRATIVE SUBPOENA

AND NOW, by its counsel Reed Smith Shaw & McClay, comes Respondent Oncology Services Corporation ("OSC"), to move this Court for an order setting December 6, 1993 as the date by which OSC must respond to the Petition of the United States of America for Summary Enforcement of Administrative Subpoena, and in support of this Consented-to Motion, OSC states as follows:

1. On or about November 15, 1993, Petitioner United States filed its Petition for Summary Enforcement of Administrative Subpoena (the "Petition") and served a copy of same on OSC and its counsel.

2. On behalf of the Office of Investigation of the Nuclear Regulatory Commission, the Petition seeks the enforcement of outstanding subpoenas so as to compel production of records which the Petitioner alleges are "responsive to the [outstanding] subpoenas, relevant to the [pertinent] investigation, not already within the possession of NRC, and which have not been produced by OSC."

3. OSC intends to respond to the Petition.

4. Because of, inter alia, the factual issues underlying this dispute, the development of a full response to the Petition will significantly draw upon the time of OSC's personnel and other resources of OSC. For approximately the past year, a substantial measure of those resources has been directed to responding to various legal proceedings arising from the November 16, 1992 incident at Indiana Regional Cancer Center.

5. After research and other investigation, OSC is not aware of any rule of procedure expressly setting forth the time by which it is required to respond to the Petition.

6. OSC, however, wishes to avoid any collateral controversy regarding the timeliness of its Response to the Petition.

7. Because of OSC's concerns regarding both the effort response to the Petition will require and the time by which such response would be required, on Friday, November 19, 1993, Joseph W. Klein, counsel for OSC spoke with Anjali A. Ashley of the U.S. Department of Justice, counsel for the Petitioner.

8. Mr. Klein proposed that to end uncertainty and to provide OSC with time to respond to the Petition, OSC would seek an Order from this Court requiring OSC's response to the Petition by December 6, 1993.

9. Should the Court find any rule of procedure existed that would require earlier response from OSC, Mr. Klein indicated that he was willing to seek the December 6th date as an extension of the time provided under that rule of procedure.

10. On behalf of her client, Ms. Anjali concurred in Mr. Klein's proposal setting December 6, 1993 as the time for OSC's response to the Petition.

11. Accordingly, in light of the concerns of OSC and the agreement of counsel, described above, OSC now respectfully seeks an order from this Court setting December 6, 1993 as the date on which it is required to respond to the Petition filed in this action.

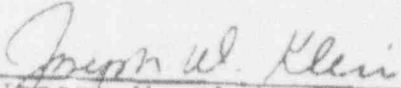
12. An appropriate form of order is attached hereto.

Respectfully submitted,

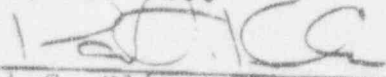
Marcy L. Colkitt, Esquire
(PA I.D. No. 53447)
General Counsel and
Executive Vice President

Oncology Services Corp.
P.O. Box 607
Indiana, PA 15701-0607
(412) 463-3570

OF COUNSEL



Joseph W. Klein, Esquire
(PA I.D. No. 36887)
REED SMITH SHAW & McCLAY
Mellon Square
435 Sixth Avenue
Pittsburgh PA 15219-1886
(412) 288-3046
(412) 288-7206



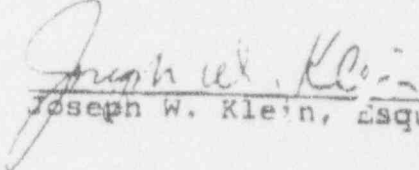
Paul S. Kline, Esquire
(PA I.D. No. 63008)
REED SMITH SHAW & McCLAY
213 Market Street
P.O. Box 11844
Harrisburg, PA 17108
(717) 234-5988

COUNSEL FOR ONCOLOGY SERVICES
CORPORATION
Douglas Colkitt, M.D.,
President
Oncology Services Corporation
110 Regent Court, Suite 100
State College, PA 16801
814/238-0375

DATED: November 22, 1993

CERTIFICATE OF CONCURRENCE

I hereby certify that on Friday, November 19, 1993, I spoke with Anjali A. Ashley, Esquire, of the U.S. Department of Justice, counsel for the Petitioner United States of America in this proceeding, regarding the within motion and obtained her concurrence in setting December 6, 1993 as the date upon which OSC will be required to respond to the Petition in this proceeding.



Joseph W. Klein, Esquire

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA,)	
)	
Petitioner,)	
)	
v.)	MISC. DOCKET NO. 3:93MC207
)	
ONCOLOGY SERVICES CORPORATION,)	(Conaboy, J.)
)	
Respondent.)	
)	
)	
)	

ORDER

AND NOW, upon the consideration of the Consented-to Motion for Scheduling the Response by Oncology Services Corporation to the Petition of the United States of America for Summary Enforcement of Administrative Subpoena, it is hereby,

ORDERED, ADJUDGED and DECREED, that Respondent Oncology Services Corporation shall have until December 6, 1993 to respond to said Petition.

Richard P. Conaboy
United States District Judge

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing Consented-To Motion for Scheduling the Response by Oncology Services Corporation to the Petition of the United States of America was served upon the following this day, by first class mail, postage pre-paid:

Arthur R. Goldberg, Esquire
Anjali A. Ashley, Esquire
U.S. Department of Justice
Federal Programs Branch
Civil Division, Room 905
901 E Street, N.W.
Washington, D.C. 20530



Paul S. Kline, Esquire

November 22, 1993

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA,)

Petitioner,)

v.)

ONCOLOGY SERVICES CORPORATION,)

Respondent.)

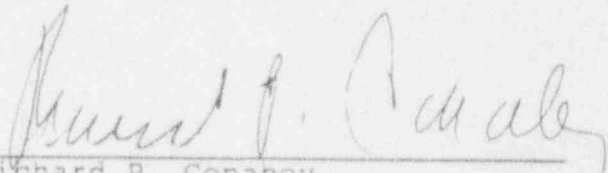
MISC. DOCKET NO. 3:93MC207

(Conaboy, J.)

ORDER

AND NOW, upon the consideration of the Consented-to Motion for Scheduling the Response by Oncology Services Corporation to the Petition of the United States of America for Summary Enforcement of Administrative Subpoena, it is hereby,

ORDERED, ADJUDGED and DECREED, that Respondent Oncology Services Corporation shall have until December 6, 1993 to respond to said Petition.


Richard P. Conaboy
United States District Judge

CR

FILED
NOV 22 1993
U.S. DISTRICT COURT
MIDDLE DISTRICT OF PENNSYLVANIA

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA,)	
)	
Petitioner,)	
)	
v.)	MISC. NO. 3:93MC207
)	
ONCOLOGY SERVICES CORPORATION,)	(Conaboy, J.)
)	
Respondent.)	
)	
_____)	

MOTION OF ONCOLOGY SERVICES CORPORATION
TO VACATE ORDER OF COURT DATED
NOVEMBER 22, 1993

AND NOW, by its counsel Reed Smith Shaw & McClay, comes Respondent Oncology Services Corporation ("OSC"), to move this Court for a Order vacating the Court's Order of November 22, 1993 in this proceeding and in support of this Motion, OSC states as follows:

1. On or about November 15, 1993, Petitioner United States filed its Petition for Summary Enforcement of Administrative Subpoena (the "Petition") and served a copy of same on OSC and its counsel.

2. On behalf of the Office of Investigation of the Nuclear Regulatory Commission, the Petition seeks the enforcement of outstanding subpoenas so as to compel production of records

which the Petitioner alleges are "responsive to the [outstanding] subpoenas, relevant to the [pertinent] investigation, not already within the possession of NRC, and which have not been produced by OSC."

3. OSC has intended (and does intend) to respond to the Petition. OSC, however, felt that the development of an adequate response would take a substantial measure of time, and was uncertain of the due date for its response.

4. Accordingly, on Friday, November 19, 1993, Joseph W. Klein, counsel for OSC spoke with Anjali A. Ashley of the U.S. Department of Justice, counsel for the Petitioner.

5. Mr. Klein proposed that, to end uncertainty and to provide OSC with time to respond to the Petition, OSC would seek an Order from this Court requiring OSC's response to the Petition by December 6, 1993.

6. Should the Court find any rule of procedure existed that would require earlier response from OSC, Mr. Klein indicated that he was willing to seek the December 6th date as an extension of the time provided under that rule of procedure.

7. On behalf of her client, Ms. Anjali concurred in Mr. Klein's proposal setting December 6, 1993 as the time for OSC's response to the Petition.

8. On November 22, 1993, OSC filed a motion with the Court embodying the understanding reached between Mr. Klein and Ms. Anjali.

9. On that same date, the Court executed and entered the Order submitted by the United States with its Petition to summarily enforce the administrative subpoenas that are the subject of this proceeding.

10. The November 22, 1993 entry of that Order submitted by the United States results in the denial to OSC of any opportunity to respond to the Petition of the United States and to be heard thereon.

11. It is OSC's present understanding that the Court has executed the Order OSC sought granting OSC until December 6, 1993 to respond to the Petition of the United States. In OSC's further understanding, the Court's execution of the Order OSC submitted would, as a matter of law, vacate the Court's Order of November 22, 1993.

12. Nonetheless, because of the time limitations imposed by governing rules of procedure and the necessity of protecting the record as to its right and desire to respond to the Petition of the United States, OSC now moves this Court under Rules 59 and 60 of the Federal Rules of Civil Procedure, as well as the Constitution of the United States and general principles of law and equity, to vacate its Order of November 22, 1993, and to consider any response that OSC might make to the Petition.

13. Under governing law, OSC is entitled to both respond and to review of that response by this Court, and would be improperly denied opportunity for such response and review were this Court's Order of November 22, 1993 to be given continuing effect.

14. Counsel for Petitioner has indicated it will not oppose this motion of OSC.

Wherefore, OSC now moves this Court to vacate its Order of November 22, 1993 and to declare same to be null, void and of no further effect.

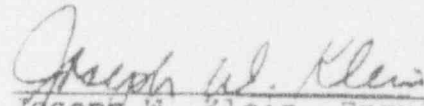
An appropriate Order is attached.

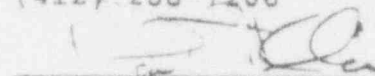
Respectfully submitted,

Marcy L. Colkitt, Esquire
(PA I.D. No. 53447)
General Counsel and
Executive Vice President

Oncology Services Corp.
P.O. Box 607
Indiana, PA 15701-0607
(412) 463-3570

OF COUNSEL


Joseph W. Klein, Esquire
(PA I.D. No. 36887)
REED SMITH SHAW & McCLAY
Mellon Square
435 Sixth Avenue
Pittsburgh PA 15219-1886
(412) 288-3046
(412) 288-7206


Paul S. Kline, Esquire
(PA I.D. No. 63008)
REED SMITH SHAW & McCLAY
213 Market Street
P.O. Box 11844
Harrisburg, PA 17108
(717) 234-5988

COUNSEL FOR ONCOLOGY SERVICES
CORPORATION
Douglas Colkitt, M.D.,
President
Oncology Services Corporation
110 Regent Court, Suite 100
State College, PA 16801
814/238-0375

DATED: December 6, 1993

CERTIFICATE OF CONCURRENCE

I hereby certify that on Friday, December 3, 1993, I spoke with Anjali A. Ashley, Esquire, of the U.S. Department of Justice, counsel for the Petitioner United States of America in this proceeding, regarding the within Motion. At that time Ms. Ashley indicated that the Petitioner would not oppose the Motion.

Joseph W. Klein

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA,)	
)	
Petitioner,)	
)	
v.)	MISC. NO. 3:93MC207
)	
ONCOLOGY SERVICES CORPORATION,)	(Conaboy, J.)
)	
Respondent.)	
)	
)	
)	

ORDER

AND NOW, upon the consideration of the Motion of Oncology Services Corporation To Vacate the Order of Court Dated November 22, 1993, it is hereby,

ORDERED, ADJUDGED and DECREED, that the Order of November 22, 1993 issued in this proceeding, shall be null, void and of no further effect.

DATED:

CONABOY, J.

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing Motion of Oncology Services Corporation To Vacate Order of Court Dated November 22, 1993 was served upon the following this day, by first class mail, postage pre-paid:

Arthur R. Goldberg, Esquire
Anjali A. Ashley, Esquire
U.S. Department of Justice
Federal Programs Branch
Civil Division, Room 905
901 E Street, N.W.
Washington, D.C. 20530



Paul S. Kline, Esquire

December 6, 1993

FILED
1993
JULY 6
MILFORD

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA,)	
)	
Petitioner,)	
)	
v.)	MISC. NO. 3:93MC207
)	
ONCOLOGY SERVICES CORPORATION,)	(Conaboy, J.)
)	
Respondent.)	
)	
_____)	

MEMORANDUM IN SUPPORT OF
MOTION OF ONCOLOGY SERVICES CORPORATION
TO VACATE ORDER OF COURT DATED
NOVEMBER 22, 1993

AND NOW, by its counsel Reed Smith Shaw & McClay, comes Respondent Oncology Services Corporation ("OSC"), to submit this Memorandum in support of its motion to this Court for an Order vacating the Court's Order of November 22, 1993.

MEMORANDUM

The facts underlying this Memorandum are stated in the Motion to which this Memorandum relates and are, to the extent necessary, incorporated by reference herein.

Rules 59 and 60 of the Federal Rules of Civil Procedure empower this Court to grant relief from its Orders. The constitutional grant of due process, as well as general principles of law and equity, require such relief in this case, so as to

provide Oncology Services Corporation with the opportunity to respond to the Petition of the United States and to be heard thereon.

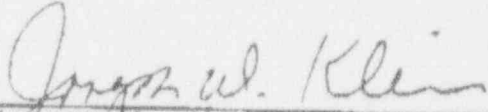
United States v. Powell, 379 U.S. 48 (1964), states the governing authority upon which OSC's motion is based. Under that authority, the subject of an administrative subpoena is entitled to challenge a subpoena on any appropriate ground and to be heard thereon. As the Powell court states, "It is the court's process which is invoked to enforce the administrative summons and a court may not permit its process to be abused." Id. at 58.

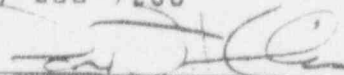
Accordingly, based on those reasons and authority, Oncology Services Corporation submits this Court's Order of November 22, 1993 should be vacated and held to be null, void and of no further effect.

Marcy L. Colkitt, Esquire
(PA I.D. No. 53447)
General Counsel and
Executive Vice President

Oncology Services Corp.
P.O. Box 607
Indiana, PA 15701-0607
(412) 463-3570

OF COUNSEL


Joseph W. Klein, Esquire
(PA I.D. No. 36887)
REED SMITH SHAW & McCLAY
Mellon Square
435 Sixth Avenue
Pittsburgh PA 15219-1886
(412) 288-3046
(412) 288-7206


Paul S. Kline, Esquire
(PA I.D. No. 63008)
REED SMITH SHAW & McCLAY
213 Market Street
P.O. Box 11844
Harrisburg, PA 17108
(717) 234-5988

COUNSEL FOR ONCOLOGY SERVICES
CORPORATION

Douglas Colkitt, M.D.,
President

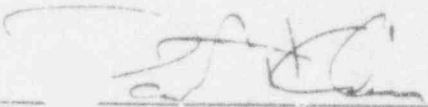
Oncology Services Corporation
110 Regent Court, Suite 100
State College, PA 16801
814/238-0375

DATED: December 6, 1993

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing Memorandum in Support of Motion of Oncology Services Corporation To Vacate Order of Court dated November 22, 1993 was served upon the following this day, by first class mail, postage pre-paid:

Arthur R. Goldberger, Esquire
Anjali A. Ash, Esquire
U.S. Department of Justice
Federal Programs Branch
Civil Division, Room 905
901 E Street, N.W.
Washington, D.C. 20530


Paul S. Kline, Esquire

December 6, 1993

Paragraphs 5-8: The cited statutory and regulatory provisions speak for themselves and their legal effect; accordingly, no further response is required from OSC.

Paragraph 9: OSC is without knowledge or information sufficient to form a belief as to the truth of the averment of NRC's purpose behind the subpoenas; OSC otherwise admits the allegations of this paragraph.

Paragraph 10: The subpoenas speak for themselves, and their legal effect has yet to be determined; accordingly, no further response is in this regard required from OSC. OSC denies the necessity, averred in this paragraph, of the information requested either to satisfactory completion of the NRC investigation or to protection of public health and safety.

Paragraph 11: The subpoenas speak for themselves, and their legal effect has yet to be determined; accordingly, no further response is required from OSC.

Paragraph 12: The allegations of this paragraph are admitted.

Paragraph 13: OSC is without knowledge or information sufficient to form a belief as to what the NRC has learned regarding "the existence of specific documents and other records." To the extent further response may be required, OSC has always understood itself to be in full compliance with the subject subpoenas.

Paragraph 14: OSC is without knowledge or information sufficient to form a belief as to the reasonable belief of Gerard F. Kenna. To the extent further response may be required, OSC has always understood itself to be in full compliance with the subject subpoenas. In all other respects, the allegations of this paragraph are admitted.

Paragraph 15: OSC denies that its legal counsel made the statement averred in this paragraph and denies the allegations fairly summarize OSC's letter of July 14, 1993. In further response, OSC's letter of July 14, 1993, a copy of which is attached as Exhibit 6 to the Declaration of Gerard F. Kenna, speaks for itself; accordingly, no further response is required from OSC.

Paragraph 16: OSC is without knowledge or information sufficient to form a belief both as to NRC belief regarding the documents "it believed to be necessary for the satisfactory

completion of the investigation" and as to NRC's efforts at careful description. In further response, OSC denies such necessity.

Paragraph 17: The subpoenas speak for themselves; accordingly, no further response is required in this regard from OSC. OSC admits all other allegations of this paragraph.

Paragraph 18: OSC's letter of September 16, 1993, a copy of which is attached as Exhibit 8 to the Declaration of Gerard F. Kenna, speaks for itself; accordingly, no further response is required from OSC.

Paragraph 19: OSC is without knowledge or information sufficient to form a belief as to the NRC's awareness. To the extent further denial may be required, OSC has always understood itself to be in full compliance with the subject subpoenas.

Paragraph 20: The allegations of this paragraph are denied.

Paragraph 21: It is admitted that OSC has not filed a motion with the NRC to quash or modify the subject subpoenas. In further response to this paragraph, OSC states that the subpoenas speak for themselves; accordingly, no further response is required from OSC.

SECOND RESPONSE

To the extent the NRC now seeks documents beyond those documents that OSC has produced or has agreed to produce or otherwise proffer, the subject subpoenas are unenforceable for lack of relevance. By letter of December 3, 1993, OSC agreed to further production and proffering of materials to the NRC. See Exhibit "A" to the affidavit of Marcy L. Colkitt, submitted as Exhibit 3 hereto. OSC's past production, together with the production and proffer under that letter, encompass all relevant documents of which OSC is aware.

THIRD RESPONSE

To the extent the NRC now seeks documents beyond those documents that OSC has produced or has agreed to produce or otherwise proffer, the subject subpoenas are unenforceable because of their burdensomeness. See Verified Statement of Jude Spak, submitted as Exhibit 5, hereto.

FOURTH RESPONSE

To the extent the subpoenas seek information which is already or which will be in the possession of the NRC as the

result of the documents OSC has produced or agreed to produce or otherwise proffer, the subpoenas are unenforceable.

FIFTH RESPONSE

Certain of the documents the NRC now seeks do not exist, are not known to OSC, and/or are not in its control. See Verified Statement of Robert Beauvais, submitted as Exhibit 1 hereto, of Raymond J. Caravan, Jr., submitted as Exhibit 2 hereto, of Marcy Lynn Colkitt, submitted as Exhibit 3 hereto, of Edward T. Russell, Jr., submitted as Exhibit 4 hereto, and of William Ying, submitted as Exhibit 6 hereto.

SIXTH RESPONSE

To the extent the NRC now seeks documents beyond those documents that OSC has produced or has agreed to produce or otherwise proffer, the subject subpoenas are unenforceable because outside the scope of agency authority.

SEVENTH RESPONSE

To the extent the subpoenas seek information from licensees other than OSC, they are unenforceable against OSC.

WHEREFORE OSC respectfully requests

1. dismissal of this proceeding against it since the documents that it has produced or has agreed to produce or otherwise proffer constitute full compliance with the subject subpoenas;

2. to the extent the NRC still contends that OSC will not be in full compliance following its full performance with respect to the documents it has agreed to produce or otherwise proffer, a hearing on any deficiencies the NRC contends remain in OSC's compliance with the subpoena; and

3. depending upon the deficiencies, if any, the NRC contends remain in OSC's compliance with the subpoena, the right of discovery against the NRC; and

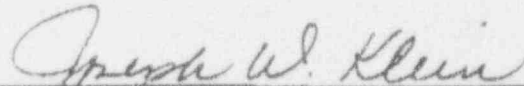
4. such other relief as the Court deems just and proper.

Respectfully submitted,

Marcy L. Colkitt, Esquire
(PA I.D. No. 53447)
General Counsel and
Executive Vice President

Oncology Services Corp.
P.O. Box 607
Indiana, PA 15701-0607
(412) 463-3570

OF COUNSEL


Joseph W. Klein, Esquire
(PA I.D. No. 36887)
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(PA I.D. No. 63008)
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P.O. Box 11844
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COUNSEL FOR ONCOLOGY SERVICES
CORPORATION
Douglas Colkitt, M.D.,
President
Oncology Services Corporation
110 Regent Court, Suite 100
State College, PA 16801
814/238-0375

DATED: December 6, 1993

EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

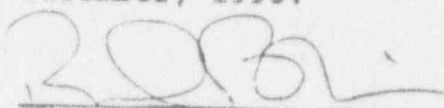
UNITED STATES OF AMERICA, : MISC. NO. 3:93MC207
Petitioner :
 :
v. :
 :
ONCOLOGY SERVICES CORPORATION, :
Respondent :

VERIFIED STATEMENT OF ROBERT BEAUVAIS

1. My name is Robert Beauvais.
2. I am employed as Regional Administrator in Central Pennsylvania, for Oncology Services Corporation, 2171 Sandy Drive, State College, Pennsylvania 16803.
3. In the performance of my duties with OSC, I am familiar with the telephone records for persons functioning as Radiation Safety Officers under NRC License No. 37-28540-01 between June 1, 1990, and April 30, 1991.
4. All telephone records for persons functioning as Radiation Safety Officers under NRC License No. 37-28540-01 between June 1, 1990, and April 30, 1991, previously have previously been provided to Marcy L. Colkitt for production to the NRC.

I declare under penalty of perjury set forth in the Pennsylvania Crimes Code, 18 Pa. C.S. §4904, that the foregoing is true and correct according to my best knowledge, information and belief.

Executed this 2nd day December, 1993.



ROBERT BEAUVAIS

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA,

Petitioner,

v.

ONCOLOGY SERVICES CORPORATION,

Respondent.

MISC. NO. 3:93MC207

VERIFIED STATEMENT OF MARCY LYNN COLKITT, ESQ.

1. My name is Marcy Lynn Colkitt, Esquire.
2. I am employed as the General Counsel of Oncology Services Corporation. In that role, I have been responsible for responses to the subpoenas served on OSC by the NRC in February and August 1993.
3. Thus far in responding to those subpoenas OSC has produced approximately 14,000 pages of documents.
4. Thus far in responding to those subpoenas OSC has produced approximately 40 witnesses.
5. The only employees who would have conducted licensed activities under NRC License No. 37-28450-01 were located at the six facilities identified in that License.
6. The only employees who would have been involved in licensed activities under NRC License No. 37-28179-01 were located at the Indiana Regional Cancer Center in Indiana, Pennsylvania.
7. With regard to subpoena paragraph no. 1, 6 and 7: To the extent not already supplied, I am not aware of any "notes" of meetings held by Oncology Services Corporation relating to any activities conducted under NRC License No. 37-28540-01. To the extent any such notes were discovered after the date of this statement they will be supplied.
8. With regard to subpoena paragraph no. 2: OSC does not as a corporate practice require employment applications. To the extent any documents are discovered after the date of this statement which were used, despite corporate practice to the

contrary, as employment applications for any of the personnel for whom OSC is supplying resumes, those documents will be supplied.

9. With regard to subpoena paragraph no. 4: OSC believes it has produced these documents. To the extent the production by OSC remains in dispute, if the NRC will provide an example of type of document which it believes have not fully been produced, and such is the case, OSC will complete production of those documents with patients' names redacted.

10. With regard to subpoena paragraphs nos. 3, 7, 8, 9, 11, 12, 15 and 17, I believe all responsive documents have been produced. To the extent any responsive documents should nonetheless be discovered after the date of this certified statement, they would be produced.

11. Any documents that Dr. William Ying identifies in his verified statement as having been provided me by him were provided by me to the NRC.

12. Any documents that Robert Decuvaie identifies in his verified statement as having been provided me by him were provided by me to the NRC.

13. Any documents relating to the Atlantic City Conference that relate to the provision of HDR services were provided by me to the NRC.

14. To resolve any outstanding issues, I have authorized issuance of the letter to counsel for Petitioner United States in this action, a copy of which is attached as Exhibit A to this verified statement.

I declare under penalty of perjury set forth in the Pennsylvania Crimes Code, 18 Pa. C.S. §4804, that the foregoing is true and correct according to my best knowledge, information, and belief.

Executed this 3rd day of December 1933

Marcy L. Colkitt

MARCY LYNN COLKITT

REED SMITH SHAW & McCLAY

435 SIXTH AVENUE
PITTSBURGH, PA 15219-1886

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PHILADELPHIA, PA
HARRISBURG, PA
MCLEAN, VA
PRINCETON, NJ

December 3, 1993

Anjali A. Ashley, Esquire
U.S. Department of Justice
Federal Programs Branch
Civil Division, Room 905
901 E Street, N.W.
Washington, D.C.

re: United States of America v. Oncology Services
Corporation (M.D. Pa.)

Dear Ms. Ashley:

In accordance with our prior conversations, the following letter further responds to the subpoena at issue in the above-named action and lists materials that Oncology Services Corporation ("OSC") will supply or otherwise proffer the Nuclear Regulatory Commission ("NRC"). The further response OSC makes hereunder constitutes what OSC understands to constitute complete compliance with the subpoenas issued against it.

OSC's response on a subpoena-item-by-subpoena-item basis is as follows:

1. All minutes, notes, or records of any meetings held by Oncology Services (OSC) or any of its owned or managed facilities, relating to activities conducted under NRC License No. 37-28540-01, including minutes of staff meetings, training sessions, supervisory meetings, HDR Committee meetings, or corporate meetings, and any interoffice or center memoranda relating to those meetings.

My understanding is that the provision to you of Regional Administrator minutes completes OSC's provision of any documents responsive to this request. These documents will be redacted to remove materials not "relating to activities conducted under NRC License No. 37-28540-01." My further understanding is that the one videotape OSC made of a Regional Administrator meeting was not retained; additionally, no agenda for such meetings were located. To the extent they are subsequently located, they will be produced. Pertinent records of Medical Directors' meetings have previously been provided.

EXHIBIT A

2. Employment applications and resumes submitted by any persons employed by OSC as an officer, director, employee, vendor, contractor, subcontractor, at any of its owned or managed facilities, or who performed activities at the direction of or on behalf of OSC or any of its owned or managed facilities, under NRC License No. 37-28540-01, during the period between June 1, 1990 and February 15, 1993.

According to my understanding, there are no application forms that OSC uses as a matter of corporate practice. Individual cancer centers may, on occasion, have used commercially generated application forms; no such forms have yet been located. OSC will provide the NRC with the resumes that are in its possession, of all employees, including those who had nothing to do with the provision of HDR services, at each facility during the period in which that facility conducted any operations under License No. 37-28540-01. To extent that documents are found which were used, despite corporate practice to the contrary, as employment applications for any of the personnel for whom OSC is supplying resumes, those documents would also be provided.

3. HDR Introduction Manuals and Incentive Plans in effect during the period June 1, 1990 through February 15, 1993, which were applicable, either in whole or in part, to any activities conducted under NRC License No. 37-28540-01.

As your papers note, OSC has previously produced all relevant HDR manuals. My understanding is that there has been no update of the HDR Incentive Plan and therefore your materials are complete in that regard also.

4. Monthly HDR Logs, HDR Monthly Log Utilization and the weekly/bi-weekly Cancer patient treatment documents for the period between June 1, 1990 and February 15, 1993, which recorded, either in whole or in part, any activities conducted under NRC License No. 37-28540-01.

My understanding is that these materials have been provided. Some confusion may arise from the fact that no HDR Logs were generated before November 1992. Confusion also exists as to the identity of the "weekly/bi-weekly Cancer patient treatment documents" referred to; to those extent such documents are further identified by the NRC's provision of an example to OSC and indicate treatment with HDR, OSC will produce them with patients' names redacted.

5. Weekly Activity Reports prepared by OSC and submitted to OSC corporate headquarters by the various OSC centers regarding activities conducted under NRC License 37-28540-01 between June 1, 1990 and February 15, 1993.

OSC will supply you with all Weekly Activity Reports. These documents will be redacted to remove materials not "regarding activities conducted under NRC License No. 37-28540-01."

6. Notes or memoranda from monthly OSC Regional Administrator meetings conducted between June 1, 1990 and February 15, 1993, including audio tape recordings, video tapes, typed minutes, handwritten notes, and roster of participating personnel.

See response to No. 1.

7. Staff training, corporate, and supervisory meeting records from any semi-annual Medical meetings conducted between June 1, 1990 and February 15, 1993, to include the syllabi, roster of personnel and notes.

My understanding is that all documents relating to any activities conducted under NRC License No. 37-28540-01 have previously been supplied. Additionally, OSC does not believe it has any rosters; to the extent it subsequently discovers any such rosters, they will be supplied.

8. Telephone records for any person or persons functioning as Radiation Safety Officer under NRC License No. 37-28540-01 between June 1, 1990 and April 30, 1991.

My understanding is that all such documents have been supplied.

9. Any records of any maintenance conducted between June 1, 1990 and February 15, 1993, on any HDR equipment belonging to OSC or any of its owned or managed facilities and used to conduct licensed activities under NRC License No. 37-28540-01.

My understanding is that the Omnitron HDR equipment was serviced by Omnitron, and that any maintenance records regarding that equipment are in Omnitron's possession. In other regards, my understanding is that all such documents have been supplied.

REED SMITH SHAW & McCLAY

Anjali A. Ashley, Esq.

-4-

December 3, 1993

10. Expense vouchers and sub-vouchers, including, but not limited to, travel vouchers submitted by any officer or employee of OSC or any of its owned or managed facilities. The records should include, but not be limited to, HDR maintenance travel records, HDR training records, and the semiannual Medical Directors' meetings and regional administrators' meetings regarding any activities conducted either in whole or in part, under NRC License No. 37-28540-01.

OSC proffers at its corporate headquarters for NRC review all expense voucher files since June 1, 1990 for all personnel at any of the facilities under NRC License No. 37-28540-01.

11. Roster of employees and participant handouts relating to any and all company business meetings conducted either by, or for, OSC or any of its owned or managed facilities, held in Atlantic City, New Jersey, between April 1 and November 1, 1992.

My understanding is that all such documents relating to the provision of HDR have been produced. No rosters exist other than that which was previously supplied.

12. All documents relating to the use of the HDR GammaMed Iii Machine from 1990 at Greater Pittsburgh Cancer Center, Indiana Regional Cancer Center, and The Life Care Center. These documents should include, but not be limited to, the HDR Quality Assurance and Calibration forms for the GammaMed Iii.

My understanding is that the GammaMed Iii was used only at the Harrisburg, Exton and Mahoning Valley Centers and that all documents have been produced.

13. Documents describing any initial or refresher training in the operation of the HDR loading devices for Dr. Cunningham or Dr. Ying between June 1, 1990 and February 15, 1993. In addition, any documents relating to any training that Dr. Cunningham or Dr. Ying received from the manufacturer regarding the installation, relocation or removal of high dose loader units containing sources.

REED SMITH SHAW & McCLAY

Anjali A. Ashley, Esq.

-5-

December 3, 1993

My understanding is that all documents pertinent to this request have been produced.

14. Payroll documents which contain the name and home address of all employees of OSC, including its corporate headquarters personnel, and the employees of any of its owned or managed facilities in which OSC conducted activities under NRC License No. 37-28540-01, from June 1, 1990 through August 8, 1993.

OSC will provide the NRC with the names and addresses of all employees, including those who had nothing to do with the provision of HDR services, at each facility during the period which that facility conducted any operations under License No. 37-28540-01 and at corporate headquarters during entire period any operations were conducted under that License.

15. Any documents relating to any experiments conducted with any nuclear source used by OSC to conduct activities under NRC License No. 37-28540-01. The term "documents" includes, but is not limited to, documents produced regarding when the nuclear source was exposed outside the Harrisburg Cancer Center.

My understanding is that all such documents have been produced.

16. Legible photocopies of slides submitted in response to the previous subpoena served on OSC on March 1, 1993. OSC's original submission is illegible.

My understanding is that this request has been resolved.

17. Purchase and repair records for the prime alert and survey meters for the period June 1, 1990 through February 15, 1993. The records should include the calibration records for any prime alert, Ion chamber and/or survey meter belonging to OSC or an of its owned or managed facilities and used by OSC to conduct licensed activities under NRC license No. 37-28450-01 during that time.

My understanding is that all responsive documents have been produced.

REED SMITH SHAW & McCLAY

Anjali A. Ashley, Esq.

-6-

December 3, 1993

IIA 1 through 11 and B

All documents responsive to these items will be produced upon service of a subpoena addressed to the Indiana Regional Cancer Center, the holder of NRC License 37-28179-01.

To address concerns you raised in our conversations, OSC will use its best efforts to supply any of the materials it indicated it will supply above by December 15, 1993.

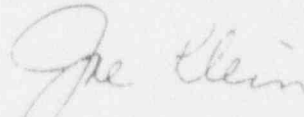
OSC further will make the vouchers available at any reasonable time the NRC wishes them for review; possibly, review of the vouchers could occur at the same time the NRC investigators are in State College, Pennsylvania to review copies of the slides identified as subpoena item 16. And finally, OSC will provide the documents relating to NRC License 37-28179-01 promptly upon service of a subpoena addressed to the holder of that license.

Please do not hesitate to call me if you have any questions regarding the foregoing.

Very truly yours,

REED SMITH SHAW & McCLAY

By


Joseph W. Klein

cc: Marcy Lynn Colkitt, Esq.

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, : MISC. NO. 3:93MC207
Petitioner :
 :
v. :
 :
ONCOLOGY SERVICES CORPORATION, :
Respondent :

VERIFIED STATEMENT OF EDWARD T. RUSSELL, JR.

1. My name is Edward T. Russell, Jr.
2. I am employed as Director of Human Resources at the corporate offices of Oncology Services Corporation, 2171 Sandy Drive, State College, Pennsylvania 16803.
3. In performance of my duties with CSC, I am generally familiar with the employment practices followed by OSC and related entities, the number of employees, and the positions which they fill.
4. OSC and related entities currently employ in excess of 275 employees in approximately ten (10) states.
5. Of those employees, approximately twenty (20) employees in Pennsylvania are involved with the delivery of HDR services under NRC License No. 37-28540-01.
6. Although the Personnel Policies and Procedures Manual for Oncology Services Corporation, Oncology Services, Inc., and Its Subsidiaries and Affiliates provides for the use of either a written application or resume, OSC did not regularly require prospective employees to fill out written applications.
7. Accordingly, OSC has employees who have never filled out a written application for employment.
8. In my position, I am also aware of the HDR Introduction Manuals and Incentive Plans.
9. The HDR Incentive Plan Documents has never been updated.
10. In the further performance of my duties, I am also generally familiar with meetings held for OSC Medical Directors and its Regional Administrators. Such meetings address all

aspects of operation of each cancer center and, in substantial part, involve topics that are unrelated to the administration of HDR.

11. OSC has formal agendas for meetings of the Medical Directors. I understand those agenda have been provided to the NRC.

12. We have been unable to locate any formal agendas prepared by OSC for meetings of Regional Administrators.

13. There has been only one occasion on which an attempt was made to videotape a portion of a meeting of Regional Administrators; that attempt failed because of the lack of quality in the videotape.

14. Because of its poor quality, no effort was made to retain that videotaping.

15. In addition, certain staff meetings have been audiotaped so that minutes of those meetings may be more easily prepared.

16. Following transcription of the minutes, those tapes are reused.

17. I am not aware of any such audiotape which currently exists.

18. Weekly Activity Reports are prepared by the OSC treatment centers and submitted to the OSC corporate headquarters in State College, Pennsylvania.

19. The Weekly Activity Reports contain, in substantial part, confidential business and personnel issues concerning the operation of each OSC treatment center.

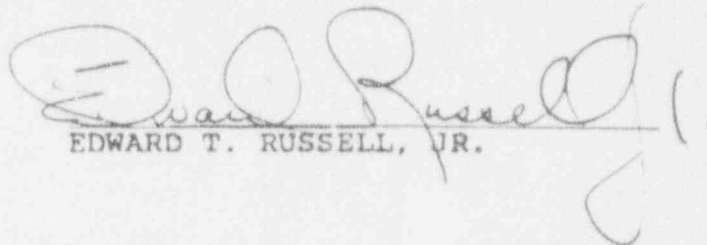
20. Little, if any, information is contained in those reports regarding activities conducted by OSC under NRC License 37-28540-01; moreover, to the extent any reference to such activity does occur, it occurs in cursory, nondetailed fashion.

21. Finally, in the performance of my duties with OSC, I am familiar with the company meetings conducted either by or for OSC or any of its owned or managed facilities and held in Atlantic City, New Jersey, between April 1, 1992 and November 1, 1992, and any documents relating to HDR in connection therewith.

22. To the extent they still existed, any documents identified above have previously been provided to Marcy L. Colkitt for production to the NRC.

I declare under penalty of perjury set forth in the Pennsylvania Crimes Code, 18 Pa. C.S. §4904, that the foregoing is true and correct according to my best knowledge, information and belief.

Executed this 3 day December, 1993.


EDWARD T. RUSSELL, JR.

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

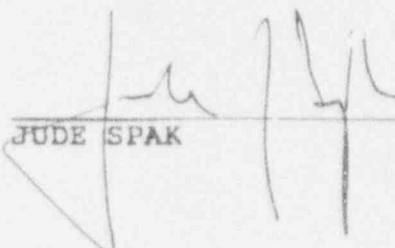
UNITED STATES OF AMERICA, : MISC. NO. 3:93MC207
Petitioner :
 :
v. :
 :
ONCOLOGY SERVICES CORPORATION, :
Respondent :

VERIFIED STATEMENT OF JUDE SPAK

1. My name is Jude Spak.
2. I am employed as the chief financial officer of Oncology Services Corporation, 2171 Sandy Drive, State College, Pennsylvania 16803.
3. In performance of my duties as chief financial officer. I am familiar with the keeping and maintenance of expense vouchers and sub-vouchers, including but not limited to, travel vouchers submitted by any officer or employee of OSC at any of its own or managed facilities.
4. I have reviewed the request contained at Paragraph 10 of the NRC Subpoena dated August 24, 1993.
5. OSC currently maintains off-site storage for vouchers and sub-vouchers for various expenses.
6. As a general matter, because of their lack of detail, the vouchers and sub-vouchers may not contain a meaningful reference to HDR maintenance travel, the semi-annual Medical Directors' Meetings or Regional Administrators' meeting.
7. In any event, OSC does not have a system in place that would identify and permit the relatively easy withdrawal of vouchers and sub-vouchers for certain types of expenses from storage; rather vouchers are organized according to the member of personnel incurring the expense and the company billed.
8. Accordingly, inspection and review of the expense vouchers and sub-vouchers for possible reference to HDR maintenance travel, HDR training, the semi-annual Medical Directors' meetings and Regional Administrators' meetings, will constitute an extraordinary burden in terms of man hours producing very little benefit.

I declare under penalty of perjury set forth in the Pennsylvania Crimes Code, 18 Pa. C.S. §4904, that the foregoing is true and correct according to my best knowledge, information and belief.

Executed this 3rd day December, 1993.



JUDE SPAK

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

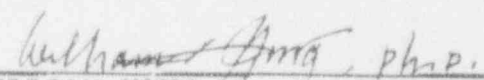
UNITED STATES OF AMERICA, : MISC. NO. 3:93MC207
 Petitioner : :
 : :
 v. : :
 : :
ONCOLOGY SERVICES CORPORATION, : :
 Respondent : :

VERIFIED STATEMENT OF WILLIAM YING

1. My name is Dr. William Ying.
2. I am employed as Physicist at the Greater Harrisburg Cancer Center, 775 South Arlington Avenue, Harrisburg, Pennsylvania 17109.
3. In performance of my duties with OSC, I am familiar with records regarding any maintenance conducted between September 4, 1990, and February 15, 1993, on any HDR equipment belonging to OSC or any of its owned or managed facilities which conduct licensed activities under NRC License No. 37-28540-01.
4. The HDR GammaMed III Machine was used by OSC at its Harrisburg, Exton and Mahoning Valley facilities only.
5. I am familiar with documents, including HDR Quality Assurance and Calibration forms, relating to the use of the HDR GammaMed III Machine from 1990 to 1992 at cancer treatment centers owned or managed by OSC.
6. I am also familiar with documents relating to experiments conducted with nuclear sources used by OSC for activities under NRC License No. 37-28540-01. This includes documents produced regarding authorized exposure of a nuclear source outside the Harrisburg Cancer Center.
7. All of the documents identified above have previously been provided to Marcy L. Colkitt for production to the NRC.

I declare under penalty of perjury set forth in the Pennsylvania Crimes Code, 18 Pa. C.S. §4904, that the foregoing is true and correct according to my best knowledge, information, and belief.

Executed this 3 day December, 1993.



DR. WILLIAM YING

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing Responses of Respondent Oncology Services Corporation to the Petition of the United States of America For Summary Enforcement of Administrative Subpoena was served upon the following this day, by first class mail, postage pre-paid:

Arthur R. Goldberg, Esquire
Anjali A. Ashley, Esquire
U.S. Department of Justice
Federal Programs Branch
Civil Division, Room 905
901 E Street, N.W.
Washington, D.C. 20530



Paul S. Kline, Esquire

December 6, 1993

FILED
1993
CLERK

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA,)	
)	
Petitioner,)	
)	
v.)	MISC. DOCKET NO. 3:93MC207
)	
ONCOLOGY SERVICES CORPORATION,)	(Conaboy, J.)
)	
Respondent.)	
)	
)	

MEMORANDUM IN SUPPORT OF
RESPONSES OF RESPONDENT ONCOLOGY SERVICES CORPORATION
TO THE PETITION OF THE UNITED STATES OF AMERICA
FOR SUMMARY ENFORCEMENT OF ADMINISTRATIVE SUBPOENA

Respondent Oncology Services Corporation submits the following in support of its Responses to the Petition of the United States of America for Summary Enforcement of Administrative Subpoena.

I. INTRODUCTION

As a threshold matter, OSC notes

- 1. the substantial production of documents and witnesses it has produced as part of this investigation; see Verified Statement of Marcy L. Colkitt, attached to the Responses as Exhibit 3 (approximately 40 witnesses and 14,000 documents);

2. the fact that its production has at times overwhelmed the Office of Investigation's ability for timely review; see Exhibit 6 to the Declaration of Gerard F. Kenna; and

3. that OSC has very recently committed itself to further production and proffer of documents in order to resolve any disputes regarding its obligations under the pertinent subpoenas; see Exhibit A to the Verified Statement of Marcy L. Colkitt, attached to the Responses as Exhibit 3.

Given those and other details of the history of this investigation, OSC now looks to this Court for review, guidance and determination of the limitations of enforceability to the subpoenas now at issue. OSC seeks that review under decisions such as that issued in United States v. McGovern, 87 F.R.D. 584 (M.D. Pa. 1980), in which United States District Court for the Middle District of Pennsylvania (per Rambo, J.) stated:

Although the court is of the opinion that substantial deference should be afforded to the NRC's opinion that it lacks sufficient information to effectively execute its many responsibilities, the court cannot ignore the requirements expressly set forth in [United States v. Powell, 379 U.S. 48 (1964)]. The role of the court in subpoena enforcement proceedings is "not that of a mere rubber stamp, but of an independent reviewing authority called upon to insure the integrity of the proceeding." [W.L. Wearly v. F.T.C., 616 F.2d 662, 665 (3d Cir. 1980)].

Id. at 588.

In what follows OSC sets forth what it believes to be some of the limits of enforceability to the subpoenas at issue in this proceeding, which limits OSC believes it has or will meet due to the documents that OSC has produced or has agreed to produce or

otherwise proffer. OSC sets forth its discussion below more in terms of governing principles rather than documents, since, as noted above, it has recently made a proffer of materials to the NRC, the NRC has had virtually no time between OSC's proffer and the filing of this memorandum to formulate its response to OSC's proffer, and as a result, OSC is presently uncertain what, if any, subpoena requests remain in contention between the parties.

II. GOVERNING LAW

The United States Court of Appeals for the Third Circuit has summarized the general principles underlying the enforceability of administrative subpoenas as follows:

The general standards that determine the enforceability of an administrative subpoena are well established. Courts will enforce a subpoena if (1) the subpoena is within the statutory authority of the agency; (2) the information sought is reasonably relevant to the inquiry; and (3) the demand is not unreasonably broad or burdensome. See, e.g., United States v. Powell, 379 U.S. 48, 57-58, 85 S.Ct. 248, 254-55, 13 L.Ed.2d 112 (1964); United States v. Morton Salt Co., 338 U.S. 632, 652, 70 S.Ct. 357, 368, 94 L.Ed. 401 (1950). In addition, if a subpoena is issued for an improper purpose, such as harassment, its enforcement constitutes an abuse of the court's process. See Pickel v. United States, 746 F.2d 176, 185 (3d Cir. 1984). SEC b. Wheeling Pittsburgh Steel Corp., 648 F.2d 118, 125 (3d Cir. 1981) (in banc).

United States v. Westinghouse Electric Corporation, 788 F.2d 164, 166-67 (1986). Those principles guide the following discussion.

III. ARGUMENT

1. OSC Has Produced All Reasonably Relevant Materials.

As Petitioner's Memorandum of Points and Authorities In Support of Petition for Summary Enforcement of Administrative Subpoena ("Memorandum of Points") indicates, the instant investigation stemmed from an earlier NRC inquiry and included the service of subpoenas on six facilities operating under License 37-28540-01, a license naming OSC as licensee, and on OSC's corporate headquarters. See Memorandum of Points at 1-2. License 37-268540-01 permitted OSC's use of Iridium-192 as a radioactive source for High Dose Rate ("HDR") therapy. As stated by Petitioner, the purpose of the investigation was "to ascertain whether OSC had intentionally violated NRC regulations." Memorandum of Points at 2.

Given the materials OSC has provided and will provide or otherwise proffer, OSC is aware of no other materials reasonably relevant to inquiry regarding the licensed activity of OSC or the six cancer centers regulated under OSC's License No. 37-268540-01.

Accordingly this proceeding should be dismissed on that basis alone.

2. Production by OSC of Any Vouchers or Sub-Vouchers That Can Be Identified As Reasonably Relevant Is So Burdensome As to Be Unenforceable.

As the affidavit of Jude Spak, submitted as Exhibit 5 to OSC's Responses herein, indicates, production by OSC of any voucher or sub-voucher that can be identified as reasonably relevant to the activities under License 37-268540-01 would be burdensome: the number of vouchers and sub-vouchers is so great as to require their off-site storage, the vouchers and sub-vouchers are not organized so as to permit retrieval on the basis of the type of expense they involve, and, even if retrieved, the vouchers and sub-vouchers contain such cursory description as to be inconclusive to any reasonable relevance they may or may not possess.

Accordingly, in the absence of any likelihood of benefit, OSC objects to its compelled review of such vouchers and submits the expense and time involved in performing fruitless conduct is so unduly burdensome as to be unenforceable under an administrative subpoena.

Nonetheless, in order to resolve any questions regarding the vouchers, OSC is willing to provide the NRC with the opportunity to review vouchers for any personnel involved in any

way under License 37-268540-01, the facilities licensed thereunder, or OSC's headquarters. See Exhibit A to Verified Statement of Marcy L. Colkitt, attached as Exhibit 3 to OSC's Responses. Under the circumstances, OSC submits that this proffer fulfills any obligation it has under the subject subpoenas.

3. The NRC Cannot Compel Production of Information That Is Already In Its Possession.

United States v. Powell, 379 U.S. 48 (1964), establishes the principle that bars an agency from enforcing a subpoena to the extent that subpoena seeks information already in the possession of the agency. That principle applies against the NRC, see United States v. McGovern, 87 F.R.D. 590, 592 (M.D. Pa. 1980), and operates to limit the enforceability of the instant subpoenas.

Certain of the documents the NRC seeks are obviously repetitive of information already in NRC's possession. Thus the Appendix to the Declaration of Gerard F. Kenna (the "Appendix") states that the vouchers and sub-vouchers are "needed to verify statements made by individuals during interviews and to confirm statements made by officials." Id. at 7. Such repetitive requests for information, even when characterized as "verification" and "confirmation," in addition to being burdensome, do not constitute an enforceable obligation under the subpoena sufficient to compel response from OSC.

Other items listed in the Appendix similarly suggest they seek information already in the possession of the NRC. See, e.g., Subpoena Paragraph Numbers 3 (NRC already in possession of HDR Incentive Plan), and 14 (names and addresses requested includes those of employees from whom NRC has taken statements that include their names and addresses).

OSC suspects that if the transcripts of statements the Office of Investigation has taken in this investigation were available to it, OSC could demonstrate that a substantial amount of the information sought through the subpoenas subject to this proceeding is duplicative of information already in the NRC's possession. Accordingly, OSC submits that, before any enforcement of the subpoenas now at issue, it would be proper to require "petitioner to address, in a hearing specifically what information it is that petitioner hopes to gain from [enforcement of the subpoenas beyond what OSC has already committed to provide] that it does not already possess or what inconsistencies exist in the present information that warrant further investigation." United States v. McGovern, 87 F.R.D. 584 (M.D. Pa. 1980). For this reason alone the pertinent subpoenas are not further enforceable.

4. OSC Cannot Produce Documents Which Are Outside Its Knowledge and Control.

Despite NRC inference or assumption to the contrary, certain of the documents the NRC now seeks do not exist, are not, despite OSC's efforts, known to OSC, and/or are not in its control. See Verified Statement of Robert Beauvais, submitted as Exhibit 1 to OSC's Responses, of Raymond J. Caravan, Jr., submitted as Exhibit 2 thereto, of Marcy Lynn Colkitt, submitted as Exhibit 3 thereto, of Edward T. Russell, Jr., submitted as Exhibit 4 thereto, and of William Ying, submitted as Exhibit 6 thereto. It is axiomatic that OSC cannot produce these documents and therefore, that the subject subpoenas are not enforceable in these regards.

5. OSC Has Produced All Documents Within The Subpoena Authority of the NRC.

The NRC in its Memorandum of Points correctly identifies 42 U.S.C. §2201(c) as authorizing the NRC's subpoena power; that section states, in pertinent part, that the Commission is authorized to:

make such studies and investigations, obtain such information. . . as the Commission may deem necessary or proper to assist it in exercising any authority provided in this chapter, or in the administration or enforcement of this chapter, or in any regulations or orders issued thereunder.

In its Memorandum of Points the NRC appears to argue that 42 U.S.C. §2201(c) therefore empowers investigation into any matter included in the broad jurisdictional statement of 10 C.F.R. §1.11

OSC submits that 42 U.S.C. §2201(c) expressly ties the issuance of subpoenas not to 10 C.F.R. but to Chapter 23 of Title 42, entitled "Development and Control of Atomic Energy." Thus Section 2201(c) limits the subpoena power to situations involving "exercis[e] of any authority provided in this chapter, . . . the administration of this chapter, or any regulations or orders issued thereunder."

OSC submits that the only authority provided the NRC under Chapter 23 that is relevant in the instant situation is that authority addressing the licensing of source materials. Thus, for reasons analogous to those involving relevance, OSC submits that to the extent the NRC now seeks documents beyond those documents that OSC has produced or has agreed to produce or otherwise proffer, the subject subpoenas are unenforceable because outside the scope of agency authority.

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6. The Subpoena Is Not Enforceable Against OSC
For Documents of A Licensee Other Than OSC.

The NRC's attempt to seek enforcement of items II A (1 through 11) and B of the Second Subpoena against OSC plainly is improper and should be rejected by this Court.

As the NRC concedes, the documents sought under those items relate to NRC License No. 37-28179-01. As the NRC further concedes, OSC is not the licensee under NRC License No. 37-28179-01; rather the licensee of NRC License No. 37-28179-01 is the Indiana Regional Cancer Center. As Exhibit 2 to the Declaration of Gerard F. Kenna demonstrates, the Office of Investigation acknowledged the separateness of OSC from the Indiana Regional Cancer Center by issuing separate subpoenas to each entity in February 1993. Since that time, the NRC has made no showing sufficient to disregard the separateness of those entities; moreover, by objecting to the subpoena in this regard, OSC has demonstrated the importance of its status as a entity separate from the Indiana Regional Cancer Center.

Finally, there is no real barrier to NRC acquisition of the documents relating to License No. 37-28179-01. The NRC has been informed that production of those documents will be made upon service of a subpoena properly directed to the licensee under that license.

Under these circumstances, the subpoena items relating to NRC License No. 37-28179-01 cannot and should not be enforced against OSC.

IV. CONCLUSION

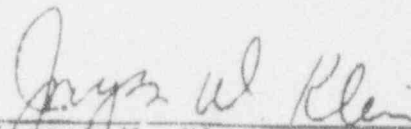
On the basis of all the reasons and authorities stated above, Petitioner's request for an order should be denied and this proceeding should be dismissed.

Respectfully submitted,

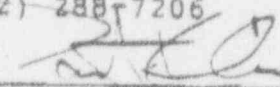
Marcy L. Colkitt, Esquire
(PA I.D. No. 53447)
General Counsel and
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P.O. Box 607
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OF COUNSEL



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Paul S. Kline, Esquire
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213 Market Street
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Harrisburg, PA 17108
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COUNSEL FOR ONCOLOGY SERVICES
CORPORATION
Douglas Colkitt, M.D.,
President
Oncology Services Corporation
110 Regent Court, Suite 100
State College, PA 16801
814/238-0375

DATED: December 6, 1993

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing Memorandum in Support of Responses of Respondent Oncology Services Corporation to the Petition of the United States of America for Summary Enforcement of Administrative Subpoena was served upon the following this day, by first class mail, postage pre-paid:

Arthur R. Goldberg, Esquire
Anjali A. Ashley, Esquire
U.S. Department of Justice
Federal Programs Branch
Civil Division, Room 905
901 E Street, N.W.
Washington, D.C. 20530



Paul S. Kline, Esquire

December 6, 1993

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA,)	
)	
Petitioner,)	
)	
v.)	MISC. NO. 3:93MC207
)	
ONCOLOGY SERVICES CORPORATION,)	(Conaboy, J.)
)	
Respondent.)	
_____)	

ORDER

AND NOW, upon the consideration of the Motion of Oncology Services Corporation To Vacate the Order of Court Dated November 22, 1993, it is hereby,

ORDERED, ADJUDGED and DECREED, that the Order of November 22, 1993 issued in this proceeding, shall be null, void and of no further effect.

DATED:

12/7/93

Paul P. Conaboy
CONABOY, J.

FILED
SCRANTON
DEC 7 1993

PER

ER
DEPUTY CLERK

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

_____)	
UNITED STATES OF AMERICA,)	
)	
Petitioner,)	
)	
v.)	MISC. DOCKET NO. 3-93MC207
)	
ONCOLOGY SERVICES CORPORATION,)	(CONABOY, J)
)	
Respondent.)	
_____)	

UNOPPOSED MOTION FOR ENLARGEMENT OF TIME

Petitioner, United States of America, through undersigned counsel, pursuant to Rule 6(b) of the Federal Rules of Civil Procedure, hereby moves for an extension of time until December 21, 1993 to file its reply to "Responses of Respondent Oncology Services Corporation to the Petition of the United States of America for Summary Enforcement of Administrative Subpoena" ("response"). In support of this motion, the Petitioner, United States of America, states as follows:

1. Petitioner's reply brief is otherwise due on December 16, 1993.
2. The petitioner seeks an extension of time to file its reply because the unavailability of key personnel at the U.S. Nuclear Regulatory Commission, the agency involved in this case, during the time period provided under Local Rule 401.7 for filing of petitioner's reply brief, has limited the time available for consultation regarding significant factual issues pertaining to that reply brief. In addition, due to illness,

petitioner's counsel has been absent from the office during the same time period thereby further restricting the time available for preparation of petitioner's reply brief.

3. Petitioner, United States of America, therefore requests an extension of time of five (5) days, or until December 21, 1993, to file its reply brief.

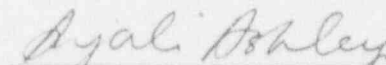
4. Respondent, who will not be prejudiced by the extension of time, does not object to the granting of this motion.

WHEREFORE, petitioner, United States of America, respectfully requests the Court to allow it until December 21, 1993, to file its reply to petitioner's response.

Respectfully submitted,

FRANK W. HUNGER
Assistant Attorney General

DAVID BARASCH
United States Attorney



ARTHUR R. GOLDBERG
ANJALI A. ASHLEY

U.S. Department of Justice
Federal Programs Branch
Civil Division, Room 905
901 E Street, N.W.
Washington, D.C. 20530

Attorneys for Petitioner

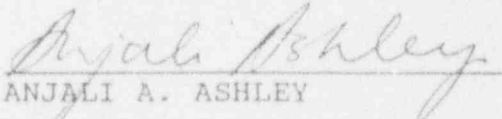
OF COUNSEL:

CHARLES E. MULLINS

Senior Attorney
Office of the General Counsel
Nuclear Regulatory Commission
Washington, D.C.

CERTIFICATE OF CONCURRENCE

I hereby certify that on Monday, December 13, 1993, I spoke to Joseph W. Klein of Reed, Smith, Shaw & McClay, counsel for respondent, regarding the foregoing Motion for Enlargement of Time. Mr. Klein indicated that the Respondent did not oppose the Motion.


ANJALI A. ASHLEY

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

_____)	
UNITED STATES OF AMERICA,)	
)	
Petitioner,)	
)	
v.)	MISC. DOCKET NO. 3-93MC207
)	
ONCOLOGY SERVICES CORPORATION,)	(CONABOY, J)
)	
Respondent.)	
_____)	

ORDER

Upon consideration of Petitioner's Unopposed Motion for Enlargement of Time to reply to Responses of Respondent Oncology Services Corporation to the Petition of the United States of America for Summary Enforcement of Administrative Subpoena, it is hereby ORDERED that:

Petitioner's Unopposed Motion for Enlargement of Time is GRANTED; it is further ORDERED that:

Petitioner's reply brief must be served and filed no later than December 21, 1993.

Date: _____

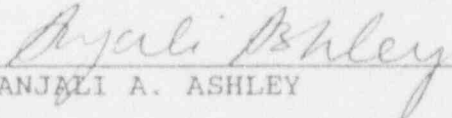
UNITED STATES DISTRICT JUDGE

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing
"Unopposed Motion for Enlargement of Time" was sent by first
class mail, postage prepaid, this 13th day of December, 1993, to:

Joseph W. Klein, Esq.
Paul S. Kline, Esq.
Reed, Smith, Shaw & McClay
Mellon Square
435 Sixth Avenue
Pittsburgh, PA 15219-1886

Marcy L. Colkitt, Esq.
General Counsel
Oncology Services Corporation
176 Timbersprings Lane
Indiana, PA 15701


ANJALI A. ASHLEY

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA,
Petitioner,

v.

ONCOLOGY SERVICES CORPORATION,
Respondent.

MISC. DOCKET NO. 3-93MC207

(CONABOY, J)

ORDER

Upon consideration of Petitioner's Unopposed Motion for Enlargement of Time to reply to Responses of Respondent Oncology Services Corporation to the Petition of the United States of America for Summary Enforcement of Administrative Subpoena, it is hereby ORDERED that:

Petitioner's Unopposed Motion for Enlargement of Time is GRANTED; it is further ORDERED that:

Petitioner's reply brief must be served and filed no later than December 21, 1993.

Date:

12/16/93

Richard P. Conaboy
UNITED STATES DISTRICT JUDGE

FILED
DEC 21 1993
CR

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

_____)	
UNITED STATES OF AMERICA,)	
)	
Petitioner,)	
)	
v.)	MISC. DOCKET NO. 3-93MC207
)	
ONCOLOGY SERVICES CORPORATION,)	(CONABOY, J)
)	
Respondent.)	
_____)	

REPLY OF THE UNITED STATES OF AMERICA
TO RESPONSE OF ONCOLOGY SERVICES CORPORATION TO
PETITION FOR SUMMARY ENFORCEMENT OF ADMINISTRATIVE SUBPOENAS

In this proceeding, petitioner, United States of America, seeks judicial enforcement of administrative subpoenas issued by the U.S. Nuclear Regulatory Commission ("NRC"), which require the respondent, Oncology Services Corporation ("OSC"), to produce information relating to an NRC investigation into possible intentional violations of agency regulations by OSC. Although OSC has recently indicated that it will provide additional information in connection with several of the NRC subpoena document categories, it continues to withhold information which is vital to the completion of the NRC investigation into the respondent's licensed practices, thereby undermining the agency's ability to fulfill its statutory duty to protect public health and safety.¹

¹A detailed description of the facts in this case are set forth in the "Memorandum of Points and Authorities in Support of Petition for Summary Enforcement of Administrative Subpoena" ("Petition") and, consequently, will not be repeated here.

ARGUMENT

A. This Court Should Defer to the NRC's Determination of What Information is Relevant to Its Own Investigation

The respondent has recently agreed to produce additional material in response to certain subpoena document categories² despite its previous claims, including sworn affidavits, that it had provided all existing documents responsive to the NRC subpoenas in question.³ While the OSC proposal eliminates a number of disputes regarding information to be provided under the subpoenas, significant issues remain unresolved which continue to hinder completion of the NRC investigation.⁴

OSC once again contends that, given the information that it has produced or has offered to produce, it would have provided the NRC with "all reasonably relevant materials" under the subpoenas and that the instant proceeding should subsequently be dismissed.⁵ In this regard, OSC continues to operate under the

²See Letter to Anjali A. Ashley from Joseph W. Klein, dated December 3, 1993, attached to Memorandum in Support of Motion of Oncology Services Corporation to Vacate Order of Court Dated November 22, 1993, as Exhibit A ("OSC Proposal").

³See "Verified Statement of Marcy L. Colkitt" dated April 26, 1993 (attached to Petition as Exhibit 4); Letter to Barry R. Letts from Marcy L. Colkitt (attached to Petition as Exhibit 6).

⁴Thus, assuming that the respondent produces the documents which it has agreed to provide under the OSC proposal, the NRC is satisfied that it has or will comply with requests for information contained in Subpoena Paragraph I, Nos. 3, 7, 8, 9, 11, 12, 15, 16 & 17. However, NRC requests for information pursuant to the remaining subpoena paragraphs remain in contention.

⁵See "Memorandum in Support of Responses of Respondent Oncology Services Corporation to the Petition of the United
(continued...)

misguided notion that it may unilaterally determine what information is relevant to the NRC investigation. For example, although OSC has finally agreed to provide the NRC with minutes of its Regional Administrators' meetings (in response to Subpoena Paragraph I, Nos. 1 & 6) and Weekly Activity Reports (in response to Subpoena Paragraph I, No. 5), the respondent indicates that it intends to redact these documents to remove material which it deems not to be relevant to the NRC investigation. See OSC Proposal at 1 & 3. Indeed, in a recent submission of documents to the NRC, OSC has included redacted versions of Weekly Activity Reports and minutes of Regional Administrators' meetings.⁵

However, the case law makes clear that it is for the agency, and not the respondent, to determine what information may or may

⁵(...continued)
States of America for Summary Enforcement of Administrative Subpoena" ("OSC Mem."), at 4.

⁶During the late afternoon of Friday, December 17, 1993, NRC-OI received a package containing documents from OSC ("December 17 submission"). See Second Declaration of Gerard F. Kenna ("Second Kenna Declaration"), attached hereto, at note 1. Mr. Kenna did not have adequate time to review these documents prior to sending his signed declaration on December 17 by overnight mail to the undersigned attorneys at the Department of Justice in Washington, D.C., so that this reply memorandum and the original declaration could, in turn, be sent by overnight mail to Pennsylvania, for filing by the December 21 deadline. However, Mr. Kenna has since had the opportunity to review the December 17 submission which contains, inter alia, incomplete versions of Weekly Activity Reports and Regional Administrators' meetings. Although these documents do not specifically indicate that they have been redacted, they include numerous numbered blank pages and pages containing only a few lines with the rest of the page left blank. Under these circumstances, it is impossible for the NRC to ascertain whether it has received all relevant information pursuant to this subpoena request.

not be relevant to a particular agency investigation. See, e.g., Dole v. Trinity Industries, Inc., 904 F.2d 867 (3rd Cir. 1990); SEC v. Arthur Young & Company, 584 F.2d 1018 (D.C. Cir. 1978) ("Arthur Young & Co.").

The breadth of an investigation is for the investigators to determine . . . the test is relevance to the specific purpose and the purpose is determined by the investigators.

Arthur Young & Co. citing K. Davis, Administrative Law Treatise, § 3.06, at 188-189 (1956).

It is equally well-settled that a court should defer to the agency's determination of relevance. See FTC v. Invention Submission Corporation, 965 F.2d 1086, 1090 (D.C. Cir. 1992); United States v. Westinghouse Electric Corporation, 788 F.2d 164 (3rd Cir. 1986); Petition at 14-17. Accordingly, in the instant case, the Court should defer to the NRC's discretion, as embodied in its specific subpoena requests, and order the respondent to produce the complete, unredacted versions of the minutes of the Regional Administrators meetings and Weekly Activity Reports, thereby allowing agency investigators, and not OSC, to decide what information contained therein is relevant to the NRC investigation.⁷

⁷OSC also makes the unclear assertion that "for reasons analogous to relevance," the NRC subpoenas are unenforceable because they go beyond the scope of agency authority (OSC Mem. at 9). However, as the Petition sets forth in full, the instant subpoena requests relate directly to the NRC investigation of OSC and are therefore well within the scope of the NRC's broad statutory authority. See Petition at 3, 11-14. Indeed, despite OSC's vague allegations to the contrary, 42 U.S.C. § 2201(c) is directly linked to 10 C.F.R. § 1.11(b) by its express language ("the [NRC may] obtain such information . . . as [it] may deem necessary or proper to assist it in exercising any authority (continued...)

However, in order to allay OSC's concerns regarding confidential business or personnel information which may be contained in these materials, the NRC is willing to enter into a nondisclosure agreement with OSC with respect to these documents. Alternatively, NRC investigators are willing to travel to OSC headquarters to review these documents for relevant information prior to any redaction of the materials by the respondent.

B. The NRC's Request for Expense Vouchers and Sub-Vouchers Is Not Overly Burdensome

OSC persists in arguing that the NRC's request for expense vouchers and sub-vouchers under Subpoena Paragraph I, No. 10 is unduly burdensome and therefore unenforceable. See OSC Mem. at 5. However, as the Petition demonstrates, and as set forth further herein, respondent's arguments in this regard are simply without merit.

It is well-settled as a legal matter that the burden rests with the subpoenaed party to show that a subpoena is overly burdensome. United States v. Powell, 379 U.S. 48, 57-58 (1964). See Petition at 17-20. This burden is particularly heavy where, as here, there is a significant public interest involved in the inquiry in question. International Business Machines, 83 F.R.D. 97 (S.D.N.Y. 1979). Petition at 19-20. OSC's argument that the number of documents and the fact that the material is stored off-

⁷(...continued)
under this chapter . . . or any regulation issued thereunder").
10 C.F.R. §1.11(b), in turn, sets forth the NRC's broad responsibilities which include the protection of public health and safety through licensing and regulation of facilities such as OSC which employ nuclear materials.

site in a disorganized fashion renders retrieval and review of these documents unduly burdensome simply does not meet this heavy burden. The mere inconvenience to the respondent involved in the responding to this request clearly does not outweigh the important public interest underlying the need for this information -- to complete the NRC investigation in order prevent the reoccurrence of fatal incidents such as that which occurred at the OSC-operated cancer treatment facility on November 16, 1992. In any event, NRC investigators are willing to travel to OSC headquarters to review the vouchers in question and complete the task which OSC appears to find so "burdensome." See Second Kenna Declaration, ¶ 7.

C. OSC Continues to Withhold Documents Which Are Responsive to the Subpoenas

Despite OSC's proposal to produce additional material responsive to the subpoenas and its December 17 submission, the NRC is aware of specific additional documents which the respondent continues to illegally withhold.* For example, OSC persists in its claim that it has produced all existing documents with respect to Subpoena Paragraph I, No. 13 (documents relating to HDR training for Drs. Cunningham and Ying). See OSC Proposal at 5. However, as indicated in the Petition, NRC has not received any documents under this category pursuant to the

*The existence of such documents was disclosed through interviews of OSC employees and other information obtained during the course of the NRC investigation to date.

subpoena.⁹ Moreover, in a letter to the NRC dated August 16, 1991, OSC specifically indicated that documents regarding initial and refresher training for Dr. Cunningham and Dr. Ying are maintained at the Harrisburg Cancer Center. See Exhibit 1. OSC has failed to submit the latter material in response to the subpoenas.

Similarly, with respect to Subpoena Paragraph No. I, No. 2 (seeking employment applications and resumes of OSC employees who have performed activities under NRC License No. 37-28540-01 between June 1, 1990 and February 15, 1993), several OSC employees who were interviewed during the course of the NRC investigation stated that they had submitted job applications to the respondent. Moreover, an interview of an OSC employee who had access to personnel files at the OSC headquarters confirmed that personnel files contain job applications. See Second Kenna Declaration ¶ 6. Although OSC continues to state that it does not use application forms (see OSC Proposal at 2), it has produced one job application in its December 17 submission. The NRC continues to seek all remaining job application and resumes in accordance with Subpoena Paragraph I, No. 2.

Furthermore, with respect to Subpoena Paragraph I, No. 14, OSC indicates that it will provide the NRC with its own list of names and addresses of OSC employees employed at OSC headquarters or any of the facilities in which OSC conducted activities under

⁹See Appendix to Declaration of Gerard F. Kenna ("Kenna Declaration"), which is attached to the Petition, p. 9 ¶ 13a.

NRC License No. 37-28540-01. See OSC Proposal at 5. However, the NRC subpoena request specifically asks for payroll information relating to these employees, rather than an OSC-compiled list, because without an official record of this kind it would be impossible for NRC investigators to ensure that a list provided by OSC is accurate and complete. (As previously indicated, NRC will accept the documents with the salary figure deleted).

Finally, in order to clear up OSC's "confusion" with respect to the identity of weekly/bi-weekly cancer patient treatment documents requested under Subpoena Paragraph I, No.4 (OSC Proposal, p. 4), the NRC will provide the OSC with an example of this document under separate cover. The NRC continues to seek cancer patient treatment reports between June 1, 1990 and February 15, 1993, other than those which are already in its possession.¹⁰

D. The NRC Does Not Possess the Information Which it Seeks Through Enforcement of the Subpoenas

Contrary to OSC's allegations, NRC investigators have repeatedly reviewed every page of the material submitted to date by OSC and are not in possession of any information which the NRC continues to seek through enforcement of the subpoenas. See

¹⁰For a complete listing of cancer patient treatment reports which the NRC already possesses, see Appendix to Kenna Declaration (attached to the Petition), at 4b.

Second Kenna Declaration ¶ 4.¹¹ Respondent's argument that requests for information for the purpose of verifying statements made by OSC officials are "repetitive" (OSC Mem. at 6), is obviously without merit. For example, with respect to Subpoena Paragraph I, No. 10, the NRC should not be required to rely on potentially self-serving statements made by OSC officials regarding training courses which they claim to have attended without seeking confirmation of such statements through training-related travel or expense vouchers. Similarly, the mere fact that the NRC possesses the names and addresses of certain OSC employees whom it has interviewed to date obviously does not render the request for the remaining names and addresses unenforceable.¹²

CONCLUSION

Respondent's continued failure to fully comply with the outstanding subpoena requests which remain at issue undermines the satisfactory completion of the NRC investigation into OSC's

¹¹As of December 20, 1993, this includes all documents received in the OSC submission of December 17, 1993.

¹²Finally, with respect to Subpoena Paragraph II (relating to activities under NRC License No. 37-28179-01), the NRC will issue a separate subpoena to the Indiana Regional Cancer Center. However, because Dr. Douglas Colkitt, President of Oncology Services Corporation, has indicated that the Indiana Regional Cancer Center is, in fact, owned or managed by OSC (See Exhibit 2), the NRC retains the right to seek judicial enforcement of this subpoena request from OSC if it does not receive the documents which it seeks in response to a subpoena specifically addressed to the Indiana Regional Cancer Center.

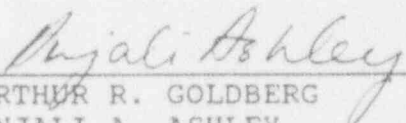
licensed activities and gravely threatens public health and safety.

Accordingly, the NRC is entitled to judicial enforcement of the remaining subpoena requests. The Court should, therefore, reinstate its Order of November 22, 1993, directing the respondent to appear and produce documents in accordance with the subpoenas on a date specified by the Court.

Respectfully submitted,

FRANK W. HUNGER
Assistant Attorney General

DAVID BARASCH
United States Attorney


ARTHUR R. GOLDBERG
ANJALI A. ASHLEY

U.S. Department of Justice
Federal Programs Branch
Civil Division, Rm 905
901 E. Street, N.W.
Washington, D.C. 20530

Attorneys for Petitioner

OF COUNSEL:

CHARLES E. MULLINS
Senior Attorney
Office of the General Counsel
Nuclear Regulatory Commission
Washington, D.C.

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA,)	
)	
Petitioner,)	
)	
v.)	MISC. DOCKET NO. 3-93MC207
)	
ONCOLOGY SERVICES CORPORATION,)	(CONABOY, J)
)	
Respondent)	
)	

SECOND DECLARATION OF GERARD F. KENNA

1. My name is Gerard F. Kenna. I make the following statements based upon my personal knowledge or upon information obtained by me in the course of my employment and relied upon by me in the performance of my duties. I have previously submitted a declaration dated November 8, 1993, in support of the Petition for Summary Enforcement of Administrative Subpoenas in the above-captioned matter ("First Kenna Declaration").
2. I am the lead investigator for the U.S. Nuclear Regulatory Commission Office of Investigations ("NRC-OI") which has been assigned to investigate whether the Oncology Service Corporation ("OSC") deliberately violated NRC regulations during the period from June 1990 to February 15, 1993.
3. In furtherance of this investigation, in February 1993, NRC-OI issued subpoenas to each of six OSC facilities listed under License No. 37-28540-01 and to OSC headquarters ("First Subpoenas"). In August 1993, the NRC-OI issued a second subpoena to OSC in a further attempt to obtain the information it needs for the satisfactory completion of its investigation into OSC's licensed activities ("Second Subpoena"). (The First and Second Subpoenas are hereinafter referred to collectively as "the subpoenas").
4. To date, OSC has submitted approximately 12,000 pages of documents pursuant to the subpoenas. I have reviewed every page of these documents during the course of the investigation. To my knowledge, the NRC-OI does not possess any of the documents which it continues to seek through enforcement of the subpoenas, as identified in the "Reply of the United States of America to Response of Oncology Services Corporation to Petition for Summary Enforcement of Administrative Subpoenas."¹

¹Immediately prior to executing this declaration I received a package from OSC containing approximately 137 pages of documents. I have not been able to review these document; however, I will review the documents within the next day and supplement this declaration if necessary.

5. I have determined through interviews of current and former OSC employees during this investigation that certain documents exist which are responsive to the subpoenas but have not been provided to the NRC by OSC. A detailed description of the aforementioned documents are contained in the First Kenna Declaration and the Appendix attached hereto.

6. I have been informed by OSC personnel working at OSC headquarters, whom I have interviewed during the course of the investigation, that applications for employment and resumes are maintained by the OSC Personnel Department in State College, Pennsylvania. Specifically, eight interviewees stated that they had submitted employment applications and/or resumes to the respondent to facilities owned or managed by OSC. In addition, two OSC Regional Administrators stated that they forwarded employment applications and resumes to the Personnel Department at headquarters.

7. With respect to Subpoena Paragraph I, No. 10 of the Second Subpoena, NRC-OI is willing to drop the request for expense vouchers and sub-vouchers identified in that paragraph, if NRC-OI investigators are allowed to review all documents responsive to this request at OSC headquarters at a time and date which is mutually convenient to both parties.

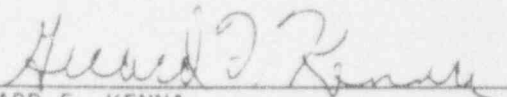
8. With respect to Weekly Activity Reports and minutes of Regional Administrators meetings which OSC has agreed to produce in response to Subpoena Paragraph I, Nos. 1, 5, & 6, it is imperative that NRC-OI investigators be allowed to review unedited and unredacted versions of these documents so that they may determine what information therein is relevant to the issues underlying this investigation. The NRC is willing to try to reach an agreement with OSC in order to preserve the integrity of confidential business or personnel information which may be included within this material.

9. With respect to Subpoena Paragraph I, No. 14, the NRC has specifically requested payroll documents so that NRC-OI investigators will have access to a complete and accurate list of the names and addresses of OSC employees during the time period in question, in order to be able locate and interview former employees in connection with the issues under investigation. It would be impossible for NRC-OI investigators to ensure the accuracy and completeness of an unofficial list which is now compiled by OSC.

10. All information requested in the subpoenas is sought pursuant to the NRC's statutory and regulatory authority and is relevant to the issues under investigation. OSC's continued failure to fully comply with the subpoenas prevents the NRC from satisfactorily completing its investigation into OSC's licensed activities and may seriously endanger public health and safety.

I declare under penalty of perjury that the following foregoing is true and correct to the best of my ability.

Executed this 17 day of December, 1993.


GERARD F. KENNA

August 16, 1991

License No. 37-28540-01
Docket No. 030-31765
Control No. 113502

Mail Control No. 121118

Nuclear Regulatory Commission
Ms. Jenny Johansen
Region I
476 Allendale Road
King of Prussia, PA 19406-1415

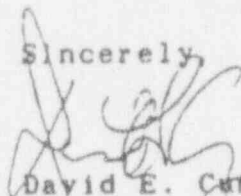
Dear Ms. Johansen:

This letter is in response to the NRC request for additional information regarding our Amendment License No. 20-27991-01. With respect to your questions please note the following:

1. The key for the Linear Accelerator and the key for the HDR unit will be on the same ring to prohibit the simultaneous activation of these units.
2. Calculation of treatment times for the HDR unit are performed with a treatment planning computer. An independent verification of the calculation times is performed on each patient. The procedure for performing in-depth verification is maintained at each treatment center for review by the NRC.
3. The source calibration performed at each source exchange will be capable of measuring the source output to within 5 percent. The qualification of the individual performing this calibration will meet the criteria of 10 CFR 35.961.
4. The initial and refresher training in the operation of HDR loading devices will be provided by the manufacturer or David E. Cunningham, Ph.D. or William Ying, Ph.D., who are both approved HDR source exchangers. Documents regarding their training are maintained at the Harrisburg Cancer Center.

If any additional information is required or I can be of any further assistance, please do not hesitate to contact me.

Sincerely,



David E. Cunningham, Ph.D., D.A.B.R.
Radiation Safety Officer
Director, Department of Technical Services

DEC\Jay

cc: Bernard Rogers, M.D.

cc: William Ying, Ph.D.

cc: Mr. Ed Russell, Director of Human Resources,
Oncology Services Corporation

DEC\NRC\NRCITEM2

ONCOLOGY SERVICES CORPORATION

110 Regent Court • Suite 100 • State College, PA • 16801

814-238-0375 • 800-628-9076 • Fax: 814-238-8069

April 30, 1993

Richard W. Cooper, II, Director
U.S. Nuclear Regulatory Commission
Region I
Division of Radiation Safety and Safeguards
475 Allendale Road
King of Prussia, PA 19406-1415
215-337-5281

via: UPS

Dear Mr. Cooper:

Please find enclosed the information as per your request.

There was no written separate contract for the extension of CNC Nuclear Systems to Marlton. This was done under oral agreement for the same terms and conditions as the Yonkers, New York, contract.

If you have any questions, please contact me.

Sincerely,



Douglas R. Colkitt, M.D.

DRC/amh
Enclosures

ONCOLOGY SERVICES CORPORATION MANAGED FACILITIES:

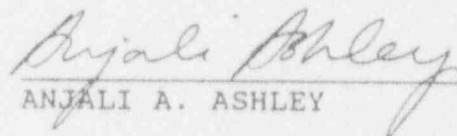
<u>Pennsylvania Location</u>	<u>Operating Entity</u>
Littlestown (Heritage Hills)	Heritage Hills Medical Limited Partnership
Pittsburgh (Jefferson)	Jefferson Oncology Center Limited Partnership
Phoenixville	Oncology Services Corporation
Indiana	Indiana Regional Cancer Center, Inc.
Harrisburg	Greater Harrisburg Cancer Center, Inc.
Lebanon	Lebanon Valley Cancer Center, Inc.
Exton	Exton Cancer Center, Inc.
Pittsburgh (Greater Pitt)	Greater Pittsburgh Cancer Center, Inc.
Lehighton (Mahoning Valley)	Mahoning Valley Cancer Center, Inc.
Warren	Onco Tech, Inc.
Stoneboro (Life Care)	Northwest Radiation Treatment Services, Inc. (Onco Tech, Inc. owns 25%)
<u>New Jersey Location</u>	
Marlton	Marlton Oncology, P.C.
<u>New York Location</u>	
Yonkers	Westchester Oncology, P.C.
<u>Ohio Location</u>	
Columbus (Park)	Onco Tech, Inc.
Bryan (Williams County)	Williams Co. Oncology Associates, Inc.
East Liverpool (Tri-State)	Tri-State Oncology Associates, Inc.
<u>Illinois Location</u>	
Kankakee	Onco Tech, Inc.
<u>North Carolina Location</u>	
Elizabeth City (Albemarle)	Albemarle Regional Cancer Ctr, LP
Laurinburg (Sandhills)	Sandhills Radiation Cancer Treatment Ctr, Inc.
<u>Florida Location</u>	
Pt. St. Lucie (Treasure Coast)	St Lucie County Radiation Oncology, LP
Ft. Lauderdale (Broward County)	Broward Radiation Therapy Corporation
<u>Arizona Location</u>	
Flagstaff (Cancer Ctr of No AZ)	Cancer Center of Northern Arizona Partnership
<u>Maryland Location</u>	
Baltimore (Union Memorial)	Union Memorial Oncology Center, Inc.
Randallstown (BCGH)	Randallstown Oncology Center, Inc.
Bellcamp (Riverside)	Riverside Medical Limited Partnership
Mechanicsville (Chesapeake)	Chesapeake Regional Cancer Center, Inc.
Baltimore (Maryland General)	Onco Tech, Inc.
Olney (MGH)	Onco Tech, Inc.

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing "Reply of the United States of America to Response of Oncology Services Corporation to Petition for Summary Enforcement of Administrative Subpoenas" and attached exhibits was sent by first class mail, postage prepaid, this 21st day of December, 1993, to:

Joseph W. Klein, Esq.
Paul S. Kline, Esq.
Reed, Smith, Shaw & McClay
Mellon Square
435 Sixth Avenue
Pittsburgh, PA 15219-1886

Marcy L. Colkitt, Esq.
General Counsel
Oncology Services Corporation
176 Timbersprings Lane
Indiana, PA 15701


ANJALI A. ASHLEY

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA,)
)
 Petitioner,)
)
 v.)
)
 ONCOLOGY SERVICES CORPORATION,)
)
 Respondent.)

PA
JAN 10 1994
DE S. WILSON CLERK

MISC. NO. 3:93MC207
(Conaboy, J.)

RESPONSE OF RESPONDENT ONCOLOGY SERVICES CORPORATION
TO THE REPLY OF THE UNITED STATES OF AMERICA TO THE
RESPONSES OF ONCOLOGY SERVICES CORPORATION TO THE PETITION
OF THE UNITED STATES FOR ENFORCEMENT OF ADMINISTRATIVE SUBPOENA

By its counsel Reed Smith Shaw & McClay, comes Respondent Oncology Services Corporation ("OSC"), to set forth its Response (the "Reply Response") to the Reply of the United States of America To Response of Oncology Services Corporation to Petition for Summary Enforcement of Administrative Subpoena (hereinafter the "Reply").

INTRODUCTION

As a threshold matter, OSC notes that, by virtue of informal communication and the more formal exchange of correspondence and pleadings, the Petitioner United States and Respondent OSC have been able to resolve and/or clarify many of

the issues initially in this proceeding. OSC now takes the opportunity provided by this Reply Response to make further effort at pre-hearing clarification and resolution of issues.

1. The Vouchers and the IRCC License Materials

By virtue of the willingness of NRC investigators to travel to OSC Headquarters to review the vouchers, see Reply at 5-6, and by virtue of their willingness to serve the Indiana Regional Cancer Center ("IRCC") with a subpoena for the documents relating to the strontium 90 license held by IRCC, see Reply at 9 n. 12, it appears to OSC that those issues have been resolved. In particular, it is OSC's understanding that review of vouchers will take place within the week of the filing of this Reply Response.

2. Payroll/Personnel Identification Materials

The issue of payroll records remains outstanding in the Reply; as stated by the United States therein:

[T]he NRC subpoena request specifically asks for payroll information relating to these employees, rather, than an OSC-compiled list, because without an official record of this kind it would be impossible for NRC investigators to ensure that a list provided by OSC is accurate and complete. (As previously indicated, NRC will accept the documents with the salary figure deleted.)

Reply at 8.

OSC is, however, aware of no payroll list that will supply the NRC with identification of the personnel at each of the centers during the period in which that center offered HDR. To address the United States' desire for verification, however, OSC supplies with this Response Reply, the affidavits of the Medical Directors of the cancer centers that offered HDR therapy during the pertinent period, copies of which are attached hereto as "Joint Exhibit A." In each of the affidavits, the Medical Director identifies all the personnel employed at that Medical Director's cancer center during the pertinent period; in addition OSC submits, as part of Joint Exhibit A, an affidavit identifying the personnel located at OSC's corporate headquarters who were involved with provision of HDR services.

OSC submits that these verified statements cumulatively provide all assurance the NRC could reasonably require.

3. Unredacted Regional Administrator and Weekly Activity Reports

To the extent the NRC continues to contend that the redacted minutes of Regional Administrators' meetings and Weekly Activity Reports do not satisfy the subpoenas, OSC replies as follows.

The United States relies, in quoted part, on the decision of the United States Court of Appeals for the District of Columbia Circuit in SEC v. Arthur Young & Co., 584 F.2d 1018 (D.C. Cir. 1978). OSC submits extended quotation of material preceding that quoted by the United States provides further instruction with respect to any compelled production of minutes of the Regional Administrator meetings or of Weekly Activity Reports:

Today, then "[t]he gist of the protection is in the requirement . . . that the disclosure sought shall not be unreasonable." Correspondingly, the need for moderation in the subpoena's call is a matter of reasonableness:

[T]he requirement of reasonableness. . . comes down to specification of the documents to be produced adequate, but not excessive, for the purposes of the relevant inquiry. Necessarily, . . . this cannot be reduced to [a] formula; for relevancy and adequacy or excess in the breadth of the subpoena are matters variable in relation to the nature, purposes and scope of the inquiry.

We are mindful, too, that investigative breadth and relevance of sought-after documents---each a vital consideration in subpoena enforcement---are closely related:

The breadth of an investigation is for the investigators to determine. The breadth of a subpoena or of a search made in records may be excessive, but the test is relevance to the specific purpose, and the purpose is determined by the investigators.

Id. at 1030-31.

Mr. Kenna, the lead investigator of the investigation of OSC, has stated that the object of his investigation is "whether Oncology Services Corporation ("OSC") deliberately violated NRC

regulations during the period from June 1990 to February 15, 1993." Declaration of Gerard Kenna at ¶ 3; Second Declaration of Gerard F. Kenna at ¶ 2." Certainly, there is no argument as to the propriety of this object of investigation, since it is within the limits of subpoena power stated in 42 U.S.C. § 2201(c), i.e., to situations "involving "exercis(e) of any authority provided in this chapter, . . . the administration of this chapter, or any regulations or orders hereunder."

Under the above authority, however, OSC submits that any redactions it has made to minutes of Regional Administrators' meetings and Weekly Activity Reports eliminate only materials unrelated to either NRC regulatory requirements or their violation and that therefore those eliminated materials are properly not within the subpoena power. Thus, even granting, for the sake of argument, the NRC's quoted proposition that "the test is relevance

¹ In his first Declaration, Mr. Kenna identified certain of the NRC regulations that might have been violated:

10. The regulations which OSC may have intentionally violated, include, inter alia, 10 C.F.R. § 19.12 (failure to instruct workers); 10 C.F.R. § 20.201(b) (failure to conduct radiation survey); and 10 C.F.R. § 30.9 (failure to provide complete and accurate information). In addition, OSC may have deliberately violated certain license conditions regarding requirements for the transportation of the High Dose Rate ("HDR") source machine.

Declaration of Gerard F. Kenna at ¶ 12.

to the specific purpose, and the purpose is determined by the investigators," the materials redacted by OSC nonetheless should not have to be produced, because those materials are not relevant to the investigator's purpose, quoted above. To require OSC nonetheless to produce those materials would be excessive and unreasonable under the authority the NRC cites. Accordingly, OSC should be held to have satisfied the subpoenas by its redacted production of the minutes of Regional Administrators' meetings and Weekly Activity Reports.

To the extent any questions remain about the propriety of its redactions of these documents, OSC herewith respectfully requests the Court to conduct an in camera review of those documents prior to any hearing in this proceeding.

4. Other Documents Purportedly Withheld by OSC

OSC responds to the NRC's continuing contentions regarding withheld documents concerning, inter alia, HDR training for Drs. Cunningham and Ying and employment applications, by reference to its prior responses to these requests and by that reference repeats that no documents are being held in this regards. To ensure that there is no confusion regarding what constitute Dr. Ying's papers in this regard, however, OSC is

sending what it believes to be a second set of those papers to the NRC.

CONCLUSION

Wherefore OSC respectfully repeats the prayer for relief it made in its prior responses and requests once more

1. dismissal of this proceeding against it since the documents that it has produced or has agreed to produce or otherwise proffer constitute full compliance with the subject subpoenas;

2. to the extent the NRC still contends that OSC will not be in full compliance following its full performance with respect to the documents it has agreed to produce or otherwise proffer, a hearing on any deficiencies the NRC contends remain in OSC's compliance with the subpoena; and


3. depending upon the deficiencies, if any, the NRC contends remain in OSC's compliance with the subpoena, the right of discovery against the NRC; and

4. such other relief as the Court deems just and proper.

Respectfully submitted,

Marcy L. Colkitt, Esquire
(PA I.D. No. 53447)
General Counsel and
Executive Vice President
Oncology Services Corp.
P.O. Box 607
Indiana, PA 15701-0607
412/463-3570

OF COUNSEL



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435 Sixth Avenue
Pittsburgh, PA 15219-1886
412/288-3044

Paul S. Kline, Esquire
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213 Market Street
P.O. Box 11844
Harrisburg, PA 17108
(717) 234-5988

COUNSEL FOR ONCOLOGY SERVICES
CORPORATION
Douglas Colkitt, M.D.,
President
Oncology Services Corporation
110 Regent Court, Suite 100
State College, PA 16801
814/238-0375

DATED: January 10, 1994

JOINT EXHIBIT A

VERIFIED STATEMENT OF JAMES E. BAUER, M.D.

1. My name is Dr. James E. Bauer.
2. I am the Associate Medical Director of Indiana Regional Cancer Center, and was Medical Director for that period of time during which Indiana Regional Cancer Center performed H.D.R. services.
3. I understand the United States Nuclear Regulatory Commission ("NRC") has requested the names and addresses of those individuals employed at Indiana Regional Cancer Center during that period of time in which that cancer center provided H.D.R. services, up through and including August, 1993.
4. I am familiar with the employees at Indiana Regional Cancer Center. Set forth below is, to the best of my knowledge, the complete list of said information requested by the NRC, as enunciated in Paragraph Three (3) above:

Roberta Ackerson R.D. #1, Box 316-A Creekside, PA 15732	X-ray technician
James Bauer 577 Chestnut Street Indiana, PA 15701	Associate medical director
Rudy Balke R.D. #1, Box 246-A South Fork, PA 15956	Radiation therapy technologist
Sharon Rickett 1618 Oliver Avenue Johnstown, PA 15909	Radiation therapy technologist
Edward Nealer Box 119 Rochester Mills, PA 15771	Van driver

VERIFIED STATEMENT OF GILBERT LAWRENCE, M.D.

1. My name is Dr. Gilbert Lawrence.
2. I am the Medical Director of Life Care Cancer Center, and was for that period of time during which Life Care Cancer Center performed H.D.R. services.
3. I understand the United States Nuclear Regulatory Commission ("NRC") has requested the names and addresses of those individuals employed at Life Care Cancer Center during that period of time in which that cancer center provided H.D.R. services, up through and including August, 1993.
4. I am familiar with the employees at Life Care Cancer Center. Set forth below is, to the best of my knowledge, the complete list of said information requested by the NRC, as enunciated in Paragraph Three (3) above:

Howard Barber 22 North Wood Street Greenville, PA 16125	Van driver
John Householder R.D. #1, Box 47B Hadley, PA 16130	Van driver
Rhonda Chriswell 5 West Homer Street Greenville, PA 16125	Office manager
Trisha Yeager 303 Main Street Fredonia, PA 16125	Radiation therapy technologist
Wade Dehaas 262 Smith Road Hadley, PA 16130	Radiation therapy technologist

VERIFIED STATEMENT OF GILBERT LAWRENCE, M.D. - CONTINUED

Bonnie Heckman
109 Forbes Road
Sandy Lake, PA 16145

Cleaning

Elizabeth Carr
270 Mabrick Avenue
Pittsburgh, PA 15228

Radiation therapy technologist

Earl Butterfield
8 Lancaster Avenue
Greenville, PA 16125

Medical assistant

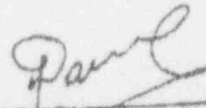
Gilbert Lawrence, M.D.
321-B
East Lake Road
Transfer, PA 16154

Medical director

5. If the NRC has any questions regarding the compilation of the listing provided in Paragraph Four (4) above, I will make myself available to answer such questions.

I declare under penalty of perjury set forth in the Pennsylvania Crimes Code, 18 Pa.C.S. Section 4904, that the foregoing is true and correct to my best knowledge, information, and belief.

Executed this 7 day of January, 1954.



GILBERT LAWRENCE, M.D.

VERIFIED STATEMENT OF DAVID J. MOYLAN, III, M.D.

1. My name is Dr. David J. Moylan, III.
2. I am the Medical Director of Mahoning Valley Cancer Center, and was for that period of time during which Mahoning Valley Cancer Center performed H.D.R. services.
3. I understand the United States Nuclear Regulatory Commission ("NRC") has requested the names and addresses of those individuals employed at Mahoning Valley Cancer Center during that period of time in which that cancer center provided H.D.R. services, up through and including August, 1993.
4. I am familiar with the employees at Mahoning Valley Cancer Center. Set forth below is, to the best of my knowledge, the complete list of said information requested by the NRC, as enunciated in Paragraph Three (3) above:

Melanie Prete 2213 Liberty Street Allentown, PA 18104	Radiation therapy technologist
Mary Ballin R.R. #1, Box 1244 Kunkletown, PA 18058	Registered nurse
Sonia Eckley 224 Ochre Street Lehighton, PA 18235	Van driver
Edythe Inhoffer 3678 West Lizard Creek Road Lehighton, PA 18235	Office manager
Barbara Perkins Address unknown	Radiation therapy technologist

VERIFIED STATEMENT OF DAVID J. MOYLAN, III, M.D. - CONTINUED

Richard Croley
R.D. #2, Box 79B-4
New Ringgold, PA 17960

Radiation therapy technologist

Abne Hasan
403 Village Road
Orwigsburg, PA 17961

Associate medical director

David J. Moylan, III, M.D.
713 Stallion Drive
Auburn, PA 17922

Medical director

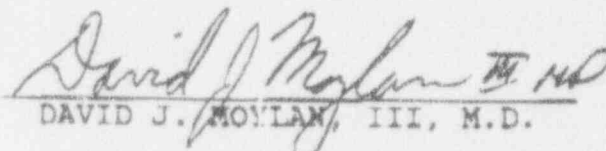
Ruth Utrata
154 South Fifth Street
Lehighton, PA 18235

Cleaning

5. If the NRC has any questions regarding the compilation of the listing provided in Paragraph Four (4) above, I will make myself available to answer such questions.

I declare under penalty of perjury set forth in the Pennsylvania Crimes Code, 18 Pa.C.S. Section 4904, that the foregoing is true and correct to my best knowledge, information, and belief.

Executed this 3rd day of January, 1994.


DAVID J. MOYLAN, III, M.D.

VERIFIED STATEMENT OF EDWARD T. RUSSELL, JR.

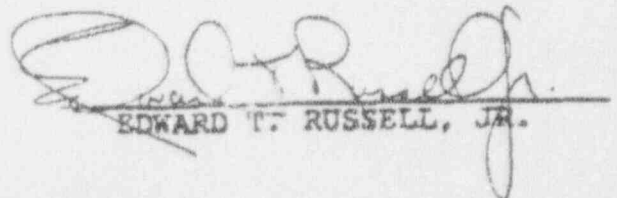
1. My name is Edward T. Russell, Jr.
2. I am employed as Director of Human Resources at the corporate offices of Oncology Services Corporation, 2171 Sandy Drive, State College, Pennsylvania, 16803.
3. I understand that the United States Nuclear Regulatory Commission ("NRC") has requested the names and addresses of those individuals employed at the corporate offices of Oncology Services Corporation who were involved with the provision of H.D.R. Services, up through and including August, 1993.
4. I am familiar with the employes at the corporate offices of Oncology Services Corporation. Set forth below is, to the best of my knowledge, the complete list of said information requested by the NRC, as enunciated in Paragraph Three (3) above:

Bernard Rogers, M.D.
550 Toftrees Avenue
State College, PA 16803

5. If the NRC has any questions regarding the compilation of the listing provided in Paragraph Four (4) above, I will make myself available to answer such questions.

I declare under penalty of perjury set forth in the Pennsylvania Crimes Code, 18 Pa. C.S. Section 4904, that the foregoing is true and correct to my best knowledge, information, and belief.

Executed this 5th day of January 1994.


EDWARD T. RUSSELL, JR.

VERIFIED STATEMENT OF ROGER TOKARS, M.D.

1. My name is Dr. Roger Tokars.
2. I am the Medical Director of Greater Pittsburgh Cancer Center, and was for that period of time during which Greater Pittsburgh Cancer center performed H.D.R. services.
3. I understand the United States Nuclear Regulatory Commission ("NRC") has requested the names and addresses of those individuals employed at Greater Pittsburgh Cancer Center during that period of time in which that cancer center provided H.D.R. services, up through and including August, 1993.
4. I am familiar with the employees at Greater Pittsburgh Cancer Center. Set forth below is, to the best of my knowledge, the complete list of said information requested by the NRC, as enunciated in Paragraph Three (3) above:

Tracy Dugan
R.D. #3, Box 132
Eighty Four, PA 15330

X-ray technologist

Joseph Dugan
R.D. #3, Box 132
Eighty Four, PA 15330

Radiation therapy technologist

Roger Tokars
128 Sidar Lane
McMurray, PA 15317

Medical director

Mitchell Jarosz
2326 School Road
Murrysville, PA 15668

Physicist

Michelle Markowitz
549 Pat Haven Drive
Pittsburgh, PA 15243

Registered nurse

VERIFIED STATEMENT OF ROGER TOKARS, M.D. - CONTINUED

John Ondos 713 Riders Way Coraopolis, PA 15108	Dosimetrist
Mary Lou Burns 1081 Connor Road Pittsburgh, PA 15234	Secretary
Raymon Jadrzejewski 411 Jillson Avenue Pittsburgh, PA 15228	Van driver
William Collins 219 West Main Street West Newton, PA 15089	Physicist
Amiril Hoque, Ph.D. 5434 Youngridge Drive Apt. #2 Pittsburgh, PA 15236	Physicist
Joan Grim 1243 Lakemont Drive Pittsburgh, PA 15243	Secretary
Kathy Lovkulich 312 West Grant Street Houston, PA 15342	Nurse
Anthony Milliron 94-A Locust Ridge Drive Pittsburgh, PA 15209	Radiation therapy technologist
Chris Ondos 713 Riders Way Coraopolis, PA 15108	Secretary
Patricia Schmuck 2303 James Street/Halar Heights McKeesport, PA 15134	Radiation therapy technologist
Anthony Gargotta 2203 Los Angeles Avenue Pittsburgh, PA 15216	Radiation therapy technologist

VERIFIED STATEMENT OF ROGER TOKARS, M.D. - CONTINUED

Gregory L. Bevilacqua Radiation therapy technologist
434 East Church Street
Wintersville, OH 43952

Kelly L. Chirpas Radiation therapy technologist
4808 Monroe Avenue
Shadyside, OH 43947

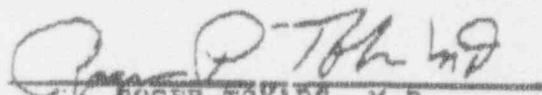
James W. Hess Radiation therapy technologist
60840 Armstrong Centerville Road
Jacobsburg, OH 43933

Beverly Herval Transcriptionist
3375 Walther Lane
Pittsburgh, PA 15241

5. If the NRC has any questions regarding the compilation of the listing provided in Paragraph Four (4) above, I will make myself available to answer such questions.

I declare under penalty of perjury set forth in the Pennsylvania Crimes Code, 18 Pa.C.S. Section 4904, that the foregoing is true and correct to my best knowledge, information, and belief.

Executed this 5th day of January, 1994.



ROGER TOKARS, M.D.

VERIFIED STATEMENT OF ABDURRAHMAN UNAL, M.D.

1. My name is Dr. Abdurrahman Unal.
2. I am the Medical Director of Greater Harrisburg Cancer Center, and was for that period of time during which Greater Harrisburg Cancer Center performed H.D.R. services.
3. I understand the United States Nuclear Regulatory Commission ("NRC") has requested the names and addresses of those individuals employed at Greater Harrisburg Cancer Center during that period of time in which that cancer center provided H.D.R. services, up through and including August, 1983.
4. I am familiar with the employees at Greater Harrisburg Cancer Center. Set forth below is, to the best of my knowledge, the complete list of said information requested by the NRC, as enunciated in Paragraph Three (3) above:

Lisa Abrams
 226 North 30th Street
 Harrisburg, PA 17111

Office manager

Rita Aoun
 1099A Michigan Drive
 Harrisburg, PA 17111

Radiation therapy technologist

Dale Caldwell
 122 Joya Circle
 Harrisburg, PA 17112

Dosimetrist

Nancy Cartwright
 34 West 3rd Street
 Hershey, PA 17033

Office assistant

VERIFIED STATEMENT OF ABDURRAHMAN UNAL, M.D. - CONTINUED

David Cunningham, Ph.D. 211 Cocoa Avenue Hershey, PA 17033	Physicist
John Daitch 4005 Eastbrook Road Harrisburg, PA 17109	Van driver
Sharon Drawbraugh 7249 Sleepy Hollow Road Harrisburg, PA 17112	Office manager
Kathie Harris Pittsburgh, PA	Radiation therapy technologist
Connie Hawkins 548 Main Street Bressler, PA 17113	Radiation therapy technologist
Amiril Hoque, Ph.D. 5434 Youngridge Drive Pittsburgh, PA 15236	Physicist
Susan Huhn 1410 Ford Avenue Harrisburg, PA 17109	Radiation therapy technologist
Harriet Jenakovich 4065 Swatara Drive Harrisburg, PA 17113	Van driver
Dot Lenahan 2362 Forest Hills Drive Harrisburg, PA 17112	Clinical coordinator
Melissa Maxwell 4323 New Jersey Avenue Harrisburg, PA 17112	Receptionist
Nitin Naik 630 Humphrey Court, #203 Harrisburg, PA 17109	Desimetrist
Frank Saluta 347 South 4th Street Steelton, PA 17113	Van driver

VERIFIED STATEMENT OF ABDURRAHMAN UNAL, M.D. - CONTINUED

I declare under penalty of perjury set forth in the Pennsylvania Crimes Code, 18 Pa.C.S. Section 4104, that the foregoing is true and correct to my best knowledge, information, and belief.

Executed this 6 day of January, 1984.

Abdurrahman Unal M.D.
ABDURRAHMAN UNAL, M.D.

VERIFIED STATEMENT OF RICHARD M. YELOVICH, M.D.

1. My name is Dr. Richard M. Yelovich.
2. I am the Medical Director of Exton Cancer Center, and was for that period of time during which Exton Cancer Center performed H.D.R. services.
3. I understand the United States Nuclear Regulatory Commission ("NRC") has requested the names and addresses of those individuals employed at Exton Cancer Center during that period of time in which that cancer center provided H.D.R. services, up through and including August, 1993.
4. I am familiar with the employees at Exton Cancer Center. Set forth below is, to the best of my knowledge, the complete list of said information requested by the NRC, as enunciated in Paragraph Three (3) above:

Barbara Gerber
446 Spruce Drive
Exton, PA 19341

Registered nurse

Donna Whitlock
R.D. #2, Box 11-A
Cambridge Road
Honey Brook, PA 19344

Office manager

Lillian Crampton
111 South Scott Street
Wilmington, DE 19702

Van driver

Lorraine Copenhagen
R.D. #3, Box 165 Z 3
Honey Brook, PA 19344

Radiation therapy technologist

Susan Gosney
555 South Coventry Lane
West Chester, PA 19382

Radiation therapy technologist

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing
was served upon the following this day, by first class mail,
postage pre-paid:

Arthur R. Goldberg, Esquire
Anjali A. Ashley, Esquire
U.S. Department of Justice
Federal Programs Branch
Civil Division, Room 905
901 E Street, N.W.
Washington, D.C. 20530

Paul S. Kline

January 10, 1994