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UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

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NRC

ATOMIC SAFETY AND LICENSING BOARD '94 FEB 15 P2:35

Before Administrative Judges:

OFFICE OF THE SECRETARY
FOR PUBLIC INFORMATION

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

SERVED FEB 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

February 15, 1994

NOTICE
(Forwarding Documents for
Docketing and Service)

Recently, the members of the Board have received by facsimile transmission a series of letters that were authored by counsel for licensee Oncology Services Corporation (OSC) and directed to the NRC staff. Although these letters were sent to or served on counsel for the NRC staff, as far as we can determine, they were not provided to the Office of the Secretary for docketing in the record of this proceeding.

Under 10 C.F.R. § 2.780 governing ex parte communications, documents sent to the Board by OSC (and other interested persons outside the agency) regarding any matter relevant to the merits of this proceeding must be provided to the Office of the Secretary for docketing in the record of the proceeding. In conformance with

DS02

section 2.780(c), we request that the Office of the Secretary docket the OSC communications in question, copies of which are included with this notice as Attachments 1-3, and serve those documents along with this notice.

If OSC sends any future communications of this type to the Board, it also should provide copies to the Office of the Secretary for docketing in accordance with 10 C.F.R. § 2.708(d).*

FOR THE ATOMIC SAFETY
AND LICENSING BOARD

G. Paul Bollwerk, III

G. Paul Bollwerk, III, Chairman
ADMINISTRATIVE JUDGE

Bethesda, Maryland

February 15, 1994

* In addition, we remind the parties of the directive in our recent memorandum and order that if a document is sent to the Board by facsimile transmission, a conforming copy must be served on each Board member by regular mail. See Memorandum and Order (Establishing Administrative Directives and Scheduling Prehearing Conference) (Dec. 17, 1993) at 2-3.

ATTACHMENT 1

ONCOLOGY SERVICES CORPORATION

2171 Sandy Drive • State College, PA • 16803

814-238-0375 • Fax: 814-238-8069



(412) 463-3570

February 2, 1994

Charles W. Hehl, Director
Division of Radiation Safety
& Safeguards
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406-1415

Re: Permanent Relaxation and Lifting of the Suspension Order

Dear Dr. Hehl:

This letter responds to your correspondence of December 23, 1993 requesting additional information:

1. Management does not feel comfortable assigning RSO oversight to all six locations as you have requested. Management does not feel such responsibilities would be fair for either the patients being treated or to the Radiation Safety Officer, Dr. Bernard Rogers. As you are aware, individual license applications were submitted approximately six months ago and have not been acted on by Region I. It has been Region I's position that: (1) until the suspension is lifted those applications will not be processed; and (2) the Licensee cannot remove various locations from the OSC license as I have previously suggested as a solution to this catch 22. However, in order to facilitate the lifting of the Suspension Order, the Licensee requests that the NRC complete inspections at each of the four locations where treatments are not currently being performed and if those inspections result in satisfactory findings, the NRC lift the suspension. OSC will agree, however, not to perform treatments at the 4 facilities (all others than Pittsburgh and Harrisburg) until such time as the new individual licenses are issued. I assume that the new licenses would be issued basically simultaneously with the suspension being lifted.

Charles W. Hehl, Director

February 2, 1994

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Additionally, under the new licenses Management believes an annual RSO audit should be performed.

The elements of the audit will include verifying that the elements of the quality management brachytherapy procedures which identity of patient, radiographs obtained to verify dummy position of source, dose calculation checks, emergency containers and all of the 18 items of the quality management brachytherapy procedure high dose rate as submitted to your previously on May 5, 1993 attachment 8 are followed. Additionally, identifying the items in the statement of responsibility for the physicist and the authorized user. Further, all items outlined in the treatment quality assurance check list form will be reviewed on twenty randomly selected cases. These charts will be evaluated for completeness as well as for reportable events and/or misadministrations. These reviews are based on the principles of statistical acceptance as outlined in Part 32.110, subpart C.

It is anticipated that the time expected to complete an annual audit will be between 1 day and 1 1/2 days. Further, the records of the audit as indicated above will be kept for a period of 3 years.

2. The training by device specific manufacturer will be required before patients are treated. If the device specific unit is changed, i.e., from Omnitron to Nucletron, then retraining by Nucletron will be required. The training by the device specific manufacturer will be required only on the unit employed at the facility.
3. The RSO will be informed whenever the source position accuracy exceeds +/- 1mm for a source positions checked on a channel. HDR checks will be performed prior to use but no earlier than 30 days before use.
4. The Authorized Physicist and/or RSO will review the results of the calibration before treating any patients.

Charles W. Hehl, Director
February 2, 1994
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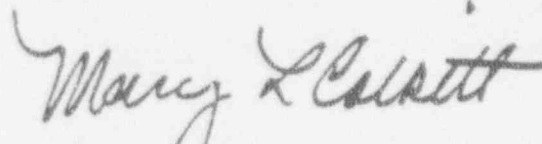
5. The electrometer and well chamber used to calibrate the HDR source will be calibrated at a Regional Calibration Laboratory traceable to the NIST.
6. The NRC is in possession of resumes on Dr. Saylor and Dr. Hoque. Further, with respect to Dr. Hoque please be advised that he has had in excess of one year of full time training in therapeutical physics and an additional year of full time work experience under the supervision of a medical physicist at a medical facility performing HDR procedures. Dr. Hoque has worked under both David Cunningham, Ph.D. and Mitch Jarosz, M.S. With respect to Dr. Saylor, between April 1989 and January 1993 he was employed at Allegheny General Hospital in Pittsburgh, Pennsylvania. During that period of time approximately 50 percent of the time he performed the services of a medical physicist in the Radiation Therapy Department under the Chief Clinical Physicist, Eric Lee, M.Sc. Additionally, Dr. Saylor has extensive LDR experience at Allegheny General, was trained by Omnitron as spent approximately five days observing the performance of HDR procedures with Mitch Jarosz.
7. Since a film is taken following each patient treatment and the chamber gives a reading during calibration, the source is accountable at all times.

At a hearing before the Board held January 26, 1994, counsel for the NRC staff indicated that Region I would need to do on-site inspections prior to full relaxation. Therefore, the Licensee requests that inspections of the four facilities be

Charles W. Hehl, Director
February 2, 1994
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scheduled immediately because of the pending suspension litigation
before the Atomic Safety and Licensing Board. Thank you very much.

Very truly yours,



Marcy L. Colkitt

General Counsel

MLC/sjg

cc: G. Paul Bollwerk, III, Esquire
Dr. Peter S. Lam
Dr. Charles N. Kelber
Mariar Zobler, Esquire
Douglas R. Colkitt, M.D.
Bernard Rogers, M.D.

ATTACHMENT 2

ONCOLOGY SERVICES CORPORATION

2171 Sandy Drive • State College, PA • 16803

814-238-0375 • Fax: 814-238-8069

(412) 463-3570

February 9, 1994

VIA TELECOPY: 301-504-3725
AND U.S. MAIL

Marian L. Zobler, Esquire
U.S. Nuclear Regulatory Commission
One White Flint North Building
11555 Rockville Pike
Rockville, MD 20852

Re: February 7, 1994 NRC Staff Status Report On
Criminal Referrals To The Department of Justice

Dear Marian:

I have reviewed the above and have a number of critical questions:

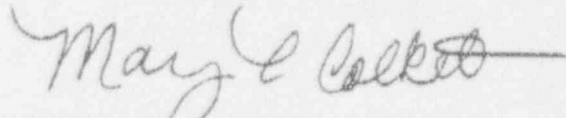
1. What was the referral to the Middle District that was denied.
2. At the hearing before the Board on January 26, 1994, you stated that there was a written referral. There is no mention of that matter in your status report. Was a written referral actually made. If so, to whom and what was it.
3. The report qualifies the denial of the Middle District as "at this time," and similarly states that "at this time, according to OI, there are no other outstanding matters which could impact on the proceeding related to the Order." What does "at this time" mean. This leaves me with additional questions. Are there any other possible criminal referrals and/or actions by any governmental entity related in any way to OSC By-product Material License No. 37-28540.01?

This is a very serious matter and without clear and precise answers to these questions, it is not possible for the licensee to meaningfully respond to outstanding discovery. My goal is to avoid burdening the Board with motions.

Marian Zabler, Esquire
February 9, 1994
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I look forward to your prompt reply. Thank you.

Very truly yours,



Marcy L. Colkitt

General Counsel

MLC/sjg

cc: ALL VIA TELECOPY AND U.S. MAIL
G. Paul Bollwerk, III, Esquire
Dr. Charles N. Kelber
Dr. Peter S. Lam
Joseph W. Klein, Esquire

ATTACHMENT 3

ONCOLOGY SERVICES CORPORATION

2171 Sandy Drive • State College, PA • 16803

814-238-0375 • Fax: 814-238-8069

(412) 463-3570

February 14, 1994

VIA TELECOPY: 301-504-3725

Marian L. Zabler, Esquire
U.S. Nuclear Regulatory Commission
One White Flint North Building
11555 Rockville Pike
Rockville, MD 20852

Re: OSC Litigation

Dear Marian:

I have reviewed the original set of discovery you served on OSC in late December 1993 and the "revised" set dated February 7, 1994. My understanding is that the revised set has been modified so that they do not, in any capacity, relate to the alleged criminal investigation that may be done by the Assistant U.S. Attorney for the Western District of Pennsylvania. Set forth below is what I believe to be the changes or more accurately the deletions from the original set. Please advise me immediately if my list is incomplete or inaccurate in any capacity.

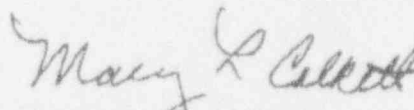
1. Interrogatory A5 - "Provide copies of the documents you have listed in response to interrogatory A4 above."
2. Interrogatory C1(e)
3. Interrogatory C2
4. Interrogatory C4
5. Interrogatory C5
6. Interrogatory C9
7. Interrogatory C10
8. Interrogatory C11
9. Interrogatory C12
10. Interrogatory C13
11. Interrogatory C17

Marian Zabler, Esquire
February 14, 1994
Page 2

12. Interrogatory C18
13. Interrogatory E25
14. Interrogatory E26
15. Interrogatory E27
16. Request for Admissions 2 and 3.

My understanding is that the only outstanding criminal referral relates to statements by Dr. James E. Bauer. If this is the case, then why have you excluded interrogatories E25-27 which relate to what David J. Moylan, III, M.D. told NRC inspectors. I am really confused. Thank you for your time to review this matter. I look forward to your reply.

Very truly yours,



Marcy L. Colkitt

General Counsel

MLC/sjg

cc: G. Paul Bollwerk, III, Esquire
Dr. Charles N. Kelber
Dr. Peter S. Lam

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 NOTICE (FORWARDING 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
Washington, DC 20555

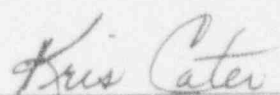
Administrative Judge
Peter S. Lam
Atomic Safety and Licensing Board
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Marian L. Zabler, Esq.
Michael H. Finkelstein, Esq.
Office of the General Counsel
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Kerry A. Kearney, Esq.
Counsel for Oncology Services Corp.
Reed, Smith, Shaw & McClay
Mellon Square, 435 Sixth Avenue
Pittsburgh, PA 15219

Marcy L. Colkitt, Esq.
General Counsel & E. V. President
Oncology Services Corporation
110 Regent Court, Suite 100
State College, PA 16801

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


Office of the Secretary of the Commission