

DEC 14 1992

Docket No. 030-31765  
CAL No. 1-192-020

License No. 37-28540-01

Oncology Services Corporation  
ATTN: Dr. Douglas R. Colkitt  
President  
110 Regent Court, Suite 100  
State College, Pennsylvania 16801

Dear Dr. Colkitt:

SUBJECT: Confirmatory Action Letter No. 1-192-020

On December 1, 1992, the Indiana Cancer Treatment Center of Oncology Services Corporation reported an incident involving the Omnitron 2000 high dose rate (HDR) afterloader brachytherapy device. That incident, in which a source broke off and remained in the patient is under investigation by an NRC Incident Investigation Team (IIT) led by Dr. Carl Paperiello. Further, a similar incident was reported to the NRC on December 7, 1992, by the Greater Pittsburgh Cancer Center of Oncology Services Corporation. However, due to the prompt and appropriate actions taken by the therapy physicist during the December 7, 1992, incident, the radioactive source was safely recovered and secured with minimal exposures to the patient and involved personnel.

On December 8, 1992, inspectors from the Region I office conducted special inspections of your facilities at the Exton Cancer Center, Exton, Pennsylvania and the Mahoning Valley Cancer Center, Lehighton, Pennsylvania. Both centers operate under the NRC license issued to Oncology Services Corporation.

Based on the reported incidents and the inspections conducted by this office, the Region identified several radiation safety concerns and apparent violations of NRC requirements. The nature of these concerns and violations is such that immediate corrective action is necessary.

Pursuant to a meeting between you and Dr. Mohamed Elanbaky on December 9, 1992, and a telephone conversation between you and me on December 10, 1992, we understand that you have taken or will take the following actions:

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1. Have an independent audit performed to evaluate your radiation safety program and its implementation relative to the use of high dose rate remote afterloader (HDR) brachytherapy devices. The audit shall include, but not be limited to (1) the adequacy of RSO oversight of the radiation safety program, including the frequency, scope, and effectiveness of the corporate audit program (2) the currency, scope, frequency, and methods for verifying the effectiveness of training provided to staff in general radiation safety, HDR operating procedures (including familiarity of staff response to alarms and error messages, including those which are software driven), HDR emergency procedures and the Quality Management (QM) program, (3) control, use, review and evaluation of personnel dosimetry, and (4) HDR maintenance history/equipment failures and adequacy of staff response to such failures. These audits will be conducted at Oncology Services physics office in Harrisburg, Pennsylvania, and at all field offices that use HDR devices.
2. The name and credentials of the individual who will perform the independent audits will be submitted for review and approval by the NRC prior to performance of the audits. These audits shall be completed by January 22, 1993, and the results shall be submitted to the NRC Region I Office for review within 5 days after completion of documentation by the independent auditor.
3. Within two weeks of your receipt of the audit report, formulate corrective actions directed to the findings and submit your corrective action plan to the NRC Region I Office for review.
4. Pending completion of the independent audit, take interim measures to (1) assure that all appropriate staff are trained in general radiation safety, HDR operating and emergency procedures, and your QM program and (2) communicate to your field offices the specifics and significance of the two incidents at your Indiana and Pittsburgh facilities and actions taken to minimize radioactive exposure and your management expectation relative to continued use of the Omnitron 2000 HDR units. This shall be completed by December 23, 1992.
5. Develop, or revise existing written procedures, as necessary, to clarify the reporting and oversight responsibilities of the Corporate RSO named on the license. To ensure uniform implementation of all safety related aspects of the program at each site, these procedures will be complete with training on them provided to each site by January 30, 1993.

These actions are in addition to, and not in lieu of, existing commitments you have made as documented in our December 2, 1992 Confirmatory Action Letter to Dr. Bauer of your Indiana Regional Cancer Center; furthermore, these actions are in addition to those that you should have taken in response to NRC Bulletin NRCB 92-03, December 8, 1992.

Any responses directed by this letter are not subject to the clearance procedures of the Office of Management and Budget, as required by the Paperwork Reduction Action of 1980, Pub. L. 96-511.

In accordance with 10 CFR 2.790(a), a copy of this letter will be placed in the NRC Public Document Room.

Pursuant to Section 162 of the Atomic Energy Act, 42 U.S.C. 2232, and 10 CFR 2.204, you are required to:

1. Notify me immediately if your understanding differs from that set forth above,
2. Notify me if for any reason you cannot complete the actions within the specified schedule and advise me in writing of your modified schedule in advance of the change, and
3. Notify me in writing when you have completed the actions addressed in this Confirmatory Action Letter.

Issuance of the Confirmatory Action Letter does not preclude the issuance of an Order formalizing the above commitments or requiring other actions on the part of Oncology Services Corporation nor does it preclude the NRC from taking enforcement action for violations of NRC requirements that may have prompted the issuance of this letter.

Your cooperation with us is appreciated.

Sincerely,

Original Signed By:  
Richard W. Cooper, II

Richard W. Cooper, II, Director  
Division of Radiation Safety  
and Safeguards

cc:

Public Document Room (PDR)  
Nuclear Safety Information Center (NSIC)  
Commonwealth of Pennsylvania

Oncology Services Corporation  
ATTN: David Cunningham  
775 South Arlington Avenue  
Harrisburg, Pennsylvania 17109

bcc:

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