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NRC STAFF PROPOSES \$280,000 FINE OF ONCOLOGY SERVICES CORPORATION
FOR ALLEGED VIOLATIONS SURROUNDING THE DEATH OF A PATIENT IN
INDIANA, PA; ALSO PROPOSES \$80,000 FINE FOR RADIATION ONCOLOGY

The Nuclear Regulatory Commission staff proposes to fine Oncology Services Corporation (OSC) of Harrisburg, PA, \$280,000, and Radiation Oncology Center at Marlton, NJ, (ROCM) \$80,000 for alleged violations of NRC safety rules. OSC operates six radiation treatment facilities in Pennsylvania. The alleged violations involving the OSC facilities were found through a series of inspections, following the November 1992 death of a patient treated at the Indiana, PA, Regional Cancer Center.

Both enforcement actions were sent to Douglas R. Colkitt, M.D., who was president of both OSC and ROCM, at the time of the alleged violations.

The inspections were prompted by an event at the Indiana, PA, facility, where on November 16, 1992, a highly radioactive 4.2 curie iridium-192 source from a High Dose Rate (HDR) afterloader machine, used to treat internal cancers, broke off from the wire that had been reeled out of the machine and into the patient, through a catheter secured inside the patient, for a radiation treatment. The disconnected source was not detected by the center's staff, and the patient was transported back to a nursing home with the source inside her. The patient was exposed to more than one million rads of radiation near the wall of her bowel, plus extremely high levels of radiation to other organs, including the bone marrow, during the time the source remained in her body. She died on November 21. The official autopsy report listed the cause of death as acute radiation exposure and its consequences.

The catheter, with the undetected radiation source still inside of it, was removed from the patient the day before her death, and was discarded with other biohazardous (non-radioactive) trash at the nursing home. The presence of the undetected source--in the nursing home for five days, and during the transporting of the trash that contained it, first to a transfer station in Western Pennsylvania, and then to a biohazardous waste incinerator in Warren, Ohio, where the radioactive source was detected, and ultimately returned to the

Indiana, PA, facility on December 1, 1992--resulted in high radiation exposures of 49 persons significantly above the implicit NRC regulatory limit (500 millirems per year).

Those exposed included nursing home workers and visitors, sanitation workers, and ambulance staff. An NRC Incident Investigation Team, tracking persons who may have come within range of the radiation from this source, reported that other members of the public may have received smaller exposures that fell within the 500 millirems per year implicit NRC limit in force at the time. A recent change of regulations has explicitly changed this limit to 100 millirems per year.

Two groups of alleged violations were each categorized as Severity Level I, the most serious on a scale of I to V. Each group was assessed a cumulative civil penalty of \$100,000. The violations included: (1) failure to perform a radiation survey before taking the patient out of the treatment room (which would have disclosed that the source was lodged in her body), and failure to respond appropriately to an alarm signal from the wall-mounted radiation monitor (which sensed that a source was in the treatment room and not within a shielded compartment of the treatment machine); (2) loss of control of licensed material that caused radiation dose rates in unrestricted areas (the public domain) in excess of regulatory limits and that resulted in significant radiation exposure.

Additional violations at OSC facilities were categorized as Severity Level II, indicative of a very significant corporate management breakdown in the control of licensed activities. These additional violations were collectively assessed an \$80,000 penalty. In a letter informing Dr. Colkitt of the proposed fine, Thomas T. Martin, Regional Administrator of NRC Region I, said, "These violations demonstrate a lack of attention to, and understanding of, regulatory requirements on the part of licensee management and the corporate RSO that contributed to the November 1992 event." Mr. Martin also said that the NRC staff was particularly concerned that a failure to devote sufficient time and attention to radiation safety program activities contributed to these violations. NRC inspectors found that the Radiation Safety Officer (RSO) had not visited the Lehighton, PA, facility in the 6 to 9 months prior to the inspection. Also, the Medical Director of the Lehighton facility indicated that he had not read the terms and conditions of the license and was not aware that a particular individual was named as the RSO on the license. The NRC license issued to OSC entrusts responsibility for radiation safety to the RSO, and requires effective oversight of the licensed programs by the management of the facility. Mr. Martin said it was incumbent upon OSC management in general, and the RSO in particular, to carry out the responsibility to protect the public health and safety by ensuring that all requirements of the

NRC license are met and that any potential violations of NRC requirements are identified and expeditiously corrected. This did not occur, he said.

The NRC staff issued an Order Suspending OSC's License for Pennsylvania facilities on January 20, 1993. Oncology Services Corporation has appealed the NRC order that suspended its license, and there is an ongoing Atomic Safety and Licensing Board (ASLB) proceeding considering whether the Order to OSC should be sustained.

The alleged violation at ROCM, which was classified as Severity Level II, involved failure of the Radiation Safety Officer (RSO) to ensure that radiation safety activities were performed in accordance with approved procedures and regulatory requirements. Some examples of this failure on the part of the RSO are: replacement of radiation sources were performed on the High Dose Rate (HDR) afterloader device by personnel from the manufacturing company without being observed by the RSO, as required; radiation surveys were not performed in building locations adjacent to where several source exchanges were occurring (to prevent inadvertent exposure of passers-by); the required daily checks of interlocks, safety systems, and alarms were not always performed; operators of the HDR device did not individually demonstrate competence in the emergency procedures for the HDR afterloader device; a backup battery did not exist to operate the room radiation monitor; and appropriate training was not provided to an individual on the use of certain radiation survey instruments and on how to interpret and respond to the computerized HDR's error messages. An \$80,000 fine was proposed for this alleged violation.

In his letter regarding ROCM, Mr. Martin said, "The NRC is particularly concerned that an atmosphere of complacency existed at the corporate level regarding the role of the RSO in assuring that regulatory requirements were met." Mr. Martin said that during an enforcement conference with Dr. Colkitt and ROCM officials on April 16, 1993, the RSO named on the license stated that, although she had signed the license submittal, she believed that her responsibilities and authorities were primarily a medical function and not a regulatory function. She said that she was aware that she was named as the RSO on the license and added, 'I was told that being -- I was the fixed fixture there, that was the easiest thing to do, and that is all I was told. I had no concept of what that entailed.' The RSO also stated that she had not read the license application before she signed it.

"The fact that the RSO failed to devote sufficient time and attention to the radiation safety program represents a very significant lack of management attention to, and oversight of, licensed activities at the facility," Mr. Martin said, and added

that this created a potential for the same kind of "significant misadministration" as occurred at the Indiana, PA facility. The NRC issued a Confirmatory Order to suspend the use of all NRC-licensed radioactive material at ROCM, on March 9, 1993.

The two licensees, OSC and ROCM have been given 30 days either to pay the proposed fine or to request in writing that part or all of the fine be withdrawn, giving their reasons for any such request. The companies also have been given 30 days to admit or deny the alleged violations, to give reasons for them if admitted, to describe the actions that have been taken or are to be taken to prevent similar violations from happening in the future, and to give the date by which they expect to be in full compliance with NRC requirements.

The Commonwealth of Pennsylvania and the States of New Jersey and Ohio have been informed of this enforcement action.

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