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NRC STAFF SUSPENDS LICENSE
OF PENNSYLVANIA CANCER CENTERS

The Nuclear Regulatory Commission staff has suspended the license of Oncology Services Corporation, Indiana Regional Cancer Center. The license authorizes the possession of more than 500 curies of iridium-192 as sealed sources for use in a brachytherapy remote afterloader for the treatment of patients suffering with cancer at specified locations within the State of Pennsylvania.

The suspension follows an incident on November 16 last year when a source broke off in a patient and was not removed before the patient was returned to a nursing home where the source became loose and dislodged itself from the patient on November 20. It later was placed in a radiological waste bag and was picked up by a waste carrier on November 27 and transported to a disposal facility where it was detected by a radiation alarm.

The amount of radiation received by the patient was significant, notwithstanding the cause of death, and approximately 90 other individuals--health care workers, sanitation workers and other members of the general public--were unnecessarily exposed to radiation as a result.

The license has been suspended because facts revealed by the NRC staff's investigation of the event demonstrate a significant breakdown in the control of licensed activities where key personnel at several satellite facilities do not know the requirements of the NRC license, do not have access to the pertinent license documents and have not been adequately trained in either the pertinent regulatory requirements or the procedures and instrumentation to be employed to protect themselves and others from radiation exposure.

The NRC staff determined that, during the November 16 procedure, an area radiation monitor alarmed with a flashing red light and the attending physician, who is an authorized user named on the NRC license, went into the treatment room to examine the patient but without the required alarm rate dosimeter or

operational survey meter. The doctor, together with the technologists, believed that the area radiation monitor had

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malfunctioned--although the afterloader had provided error messages and signaled a false alarm--and did not survey the patient, following the discontinuation of treatment, to assure that all radioactive sources had been removed. Further, it was determined that the radiation therapy technologists had not been trained in the use of a survey meter and did not know when to use a survey meter or how to interpret the readings of a survey instrument to determine the presence of a radioactive source in the patient or in the area.

On December 8, the NRC staff conducted unannounced inspections at Oncology Service's Exton (Pennsylvania) Cancer Center and Mahoning Valley Cancer Center in Lehigh, Pennsylvania. They reviewed the organization and scope of licensed activities, training of personnel, posting, instrumentation, personnel monitoring, afterloader operations and the licensee's quality management (QM) program and concluded that:

-- The Radiation Safety Officer (RSO) named on the license had not visited the Lehigh facility in the past six to nine months.

-- The Medical Director of the Lehigh facility and authorized user on the license indicated that he had not read the terms and conditions of the license and was not aware of the name of the RSO named on the license.

-- At the Exton and Lehigh facilities, the licensee failed to provide training to the radiation therapy technologists in the requirements of the license conditions and the NRC regulations and copies of the documents incorporated into the license by reference were not available to the individuals at those facilities.

-- Emergency training given the radiation therapy technologists did not include a "simulation emergency" (dry run) of the source not retracting at the end of a treatment.

-- At the Exton facility, emergency procedures were not posted at the console of the afterloader.

-- At both the Exton and Lehigh facilities, the key to activate the linear accelerator and the key to activate the afterloader unit were not on the same key ring so as to prohibit the simultaneous activation of both units within the same room and, instead, the key to each unit was left in the respective console of that unit.

-- The staff of the Exton facility was not aware of the specifics of the licensee's QM program.

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Additionally, it was learned that the physicists at the Exton and Lehighton facilities, who are key personnel and bear responsibility for preventing the recurrence of an event such as the one on November 16, learned of the event through news media coverage and not an appropriate corporate radiation safety communication.

These findings demonstrate a breakdown in the control of licensed activities at the corporate level and is of the utmost regulatory concern because it contributed to a patient being unknowingly exposed to a significant amount of radiation and other members of the general public being exposed to unnecessary radiation.

In addition to the breakdown in the control of licensed activities, it appears that the RSO contributed in large part to this problem by not maintaining an adequate physical presence at the satellite facilities, failing to implement NRC-required training programs for licensee employees, failing to establish and implement a periodic corporate audit program to identify and correct violations of NRC requirements and the staff has concluded that the licensee, through its RSO, is not willing to supervise the radiation safety program on a routine basis at the various locations of use listed on the NRC license.

While, the NRC staff is continuing to investigate the activities of the licensee, it has concluded that it lacks the requisite reasonable assurance the current operations can be conducted under the NRC license in compliance with the agency's requirements for protecting the public health and safety and has suspended the license pending the completion of its ongoing investigations and licensee corrective actions. The Order allows the licensee to seek the approval of the NRC Regional Administrator to relax the Order for good cause.

The licensee, and any other person adversely affected by the Order, may submit an answer and request a hearing within 20 days. Unless the answer consents to the Order, it is to be made in writing and under oath or affirmation and must specifically admit or deny each allegation or charge in the Order and set forth the matters of fact and law on which the licensee or other persons relies and the reasons as to why the Order should not have been issued.

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