HOSPITAL

EVENT NUMBER: 24707

LICENSEE: ONCOLOGY SERVICES, INC.
CITY: PITTSBURGH REGION: 1
COUNTY: ALLEGHENY STATE: PA
LICENSE#: 37-28540-01 AGREEMENT: N
DOCKET: 03031765

NOTIFICATION DATE: 12/07/92
NOTIFICATION TIME: 16:54 [ET]
EVENT DATE: 12/07/92
EVENT TIME: 15:30 [EST]
LAST UPDATE DATE: 12/08/92

NOTIFICATIONS

HAROLD GRAY	RDO
JOHN HICKEY	EO
SHANKMAN	RI
CUNNINGHAM	NMSS

NRC NOTIFIED BY: MITCHELL JAROSZ
HQ OPS OFFICER: WILLIAM HUFFMAN

EMERGENCY CLASS: NOT APPLICABLE
10 CFR SECTION:
NINF INFORMATION ONLY

EVENT TEXT

HIGH DOSE RATE AFTERLOADING BRACHYTHERAPY (HDR) DEVICE SUSTAINED AN APPARENT SOURCE BREAK-OFF FROM THE UNIT DRIVE CABLE SIMILAR TO OVEREXPOSURE EVENT AT INDIANA, PA (SEE EVENT #24679).

A SENIOR PHYSICIST FROM THE GREATER PITTSBURGH CANCER CENTER (1145 BOWER HILL ROAD, PITTSBURGH PA 15243) REPORTED THAT A 3.447 CURIE IRIDIUM-192 SEALED SOURCE APPARENTLY BROKE-OFF FROM THE END OF THE DRIVE CABLE WHILE BEING REMOVED FROM A PATIENT FOLLOWING A COMPLETED BRONCHOSCOPY TREATMENT. THE PITTSBURGH FACILITY IS OPERATED BY ONCOLOGY SERVICES INCORPORATED WHICH IS THE SAME LICENSEE INVOLVED IN THE RECENT OVEREXPOSURE EVENT.

THE SOURCE HAD BEEN INSERTED INTO THE PATIENT'S LUNG THROUGH A NASAL CATHETER. FOLLOWING COMPLETION OF THE TREATMENT, THE SOURCE WAS BEING EXTRACTED AND WAS BETWEEN THE NOSE OF THE PATIENT AND THE HDR DEVICE WHEN A MALFUNCTION ALARM WAS RECEIVED BY THE DEVICE'S MONITORING INSTRUMENTATION. RADIATION MONITORS IN THE TREATMENT ROOM INDICATED THAT THE SOURCE WAS STILL EXPOSED AND NOT FULLY RETRACTED. THE PHYSICIST IMPLEMENTED HIS CONTINGENCY PROCEDURES AND ENTERED THE TREATMENT AREA TO REMOVE THE SOURCE FROM THE PATIENT, IF NECESSARY. THE SOURCE WAS OBSERVED TO BE IN A SECTION OF THE CATHETER EXTERNAL TO THE PATIENT AND THE PHYSICIST CUT THE CATHETER BEHIND THE SOURCE AND IMMEDIATELY TOOK THE PATIENT OUT OF THE TREATMENT ROOM. THE CATHETER WAS REMOVED FROM THE PATIENT TO CONFIRM THAT NO PART OF THE SOURCE HAD REMAINED WITHIN IT. THE PATIENT WAS ALSO SCANNED WITH A SURVEY INSTRUMENT TO VERIFY THAT SOURCE HAD NOT SOMEHOW BECOME DISLODGED WITHIN THE PATIENT.

THE PHYSICIST THEN RE-ENTERED THE TREATMENT ROOM AND DECOUPLED THE REMAINING PIECE OF THE CATHETER WHICH CONTAINED THE SOURCE FROM ITS

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INTERFACE WITH THE HDR DRIVE AND PLACED IT IN A SHIELDED PIG. THIS REDUCED THE AREA BACKGROUND RADIATION LEVELS TO NORMAL. THE PHYSICIST STATES THAT HE SPENT APPROXIMATELY ONE MINUTE TOTAL TIME WITHIN THE VICINITY OF THE IRIDIUM SOURCE WHILE IN THE PROCESS OF SECURING IT. HE ESTIMATES THAT THE PATIENT WAS ALSO EXPOSED TO THE SOURCE EXTERNALLY FOR NO MORE THAN ONE MINUTE. HE STATES THAT THE TOTAL INCIDENT-RELATED RADIATION EXPOSURE TO HIMSELF OR THE PATIENT WAS NEGLIGIBLE. THE PHYSICIST WAS WEARING A FILM BADGE AND USED FORCEPS FOR HANDLING THE SOURCE DURING THE INCIDENT.

THE HDR DEVICE WAS AN OMNITRON MODEL 2000 WHICH IS THE SAME TYPE WHICH WAS INVOLVED IN THE INDIANA, PA OVEREXPOSURE EVENT.

BASED ON CONVERSATIONS WITH HEADQUARTERS NMSS(HICKEY AND CUNNINGHAM) AND REGION I(SHANKMAN), THE LICENSEE AGREED TO QUARANTINE THE DEVICE UNTIL NRC INSPECTORS COULD EXAMINE IT. THE SOURCE WILL ALSO REMAIN WITHIN ITS SHIELDED CONTAINER IN A LOCKED AND SECURED AREA.

UPDATE BY HUFFMAN AT 1930 EST ON 12/7/92
DUE TO THE SIMILARITY OF THIS EVENT WITH THE INDIANA, PA., OVEREXPOSURE EVENT UNDER IIT INVESTIGATION, A CONFERENCE CALL WAS ARRANGED WITH COGNIZANT NRC PERSONNEL INVOLVED WITH THE IIT. THE CONFEREES INCLUDED: BERNERO/CUNNINGHAM/HICKEY/SCHWARTZ/GLEN(NMSS); HEHL/COOPER/SHANKMAN/ JOHANSEN (REGION I); PAPERIELLO ET AL.(ITT INVESTIGATORS); ROSS/ SPESSARD(AEOD); THOMPSON (NMSS EDO); FOUCHARD(PAO); KAMMERER(STATE PROGRAMS). IT WAS DECIDED TO DISPATCH AN INSPECTOR AS PART OF THE IIT INVESTIGATION TO THE PITTSBURGH SITE FIRST THING TOMORROW. IN ADDITION, AN INFORMATION BULLETIN ON THESE RELATED EVENTS WILL BE ISSUED ASAP.

THE FOOD AND DRUG ADMINISTRATION CONTACT ON THIS ISSUE (SHARON DILLARD) WAS BRIEFED ON THE NRC POSITION AND INTENDED ACTIONS.

***UPDATE BY HUFFMAN**
COMMISSIONER'S ASSISTANTS BRIEFING CONDUCTED BY CUNNINGHAM(NMSS) AT 1230EST ON 12/8/92. PARTICIPANTS INCLUDED:ROSS/SPESSARD(AEOD); BERNERO(NMSS); FOUCHARD(PAO); UPSHAW(OIP); MYERS(OSP); McCREE(EDO-NMSS); MARTIN/SHANKMAN/ABRAHAM (RG I). THE COMMISSIONER ASSISTANTS AND OTHER INVOLVED PERSONNEL WERE PHYSICALLY PRESENT AT THE BRIEFING AND DID NOT TIE ONTO THE OPERATIONS CENTER BRIDGE.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
Office of Public Affairs
Washington, D.C. 20555

No. 92-178
Tel. 301-504-2240

FOR IMMEDIATE RELEASE
(Tuesday, December 8, 1992)

NRC INCIDENT INVESTIGATION TEAM GOES TO PITTSBURGH TO PROBE SECOND FAILURE OF CANCER TREATMENT DEVICE; PATIENT NOT INJURED

The Nuclear Regulatory Commission's Incident Investigation Team (IIT), here since last Thursday to investigate the root causes of the death of an 82-year-old woman, associated with the failure of the device that employed a radioactive source to treat her for cancer, last night began looking into a second such equipment failure in another treatment center run by the same company and using the same model treatment machine.

Fast action by medical personnel attending this latest patient appears to have averted a radiation injury to her.

Dr. Carl Paperiello, IIT Leader, and other team members, went to the Pittsburgh facility this morning (12/8/92).

Medical authorities have said that the patient treated in the Indiana Regional Cancer Center on November 16, 1992, and who died on November 21st, had the radioactive source used in her treatment remain in her afterwards, and the high exposure from the source contributed to her death.

About 3:35 p.m. yesterday (12/7/92), officials of the Greater Pittsburgh Cancer Center in Pittsburgh had just completed a treatment for lung cancer with the device when the attending radiation physicist noticed a malfunction alarm on the machine, the Center reported to the NRC about 5 p.m. Monday. The physicist, seeing that the source was suspended in a catheter between the patient and the machine that controls the movement of the source, cut the catheter and removed the patient from the treatment room. Then he reentered the room and, using forceps to reduce any potential exposure to himself, placed the source in a heavily shielded container. The physicist said he believed that his own exposure, and the exposure of the patient beyond what had been prescribed for her treatment, were negligible.

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