No. 92-184 FOR IMMEDIATE RELEASE
Tel. 301-504-2240 (Friday, December 11, 1992)

NRC'S INCIDENT INVESTIGATION TEAM LOOKING INTO FAILURE OF A CANCER TREATMENT MACHINE, IN INDIANA, PA, ISSUES REPORT ON PRELIMINARY FINDINGS

Dr. Carl J. Paperiello, Team Leader of the Nuclear Regulatory Commission's Incident Investigation Team (IIT) that has spent the last week in Indiana, Pennsylvania, investigating two cases of failure of two machines used in cancer radiation treatments, today (12/11/92) issued a statement giving the team's preliminary findings.

The IIT has been in the Indiana and Pittsburgh areas to investigate two instances of the failure of the machine that employed a radioactive source, iridium-192, to treat cancer patients. In the Indiana case, the patient died shortly after the treatment and it is the preliminary conclusion of the NRC's consultant physician that radiation appears to have been a potential contributing cause of her death.

The second machine failure, in Pittsburgh, appears to have caused no injuries to the patient or the physician performing the treatment. In both instances the machines, duplicate models by the same manufacturer, used a thin metal cable inside a plastic tube (catheter) to insert a radioactive source in the tip of the cable into the patients' bodies. The machine is called a High Dose Rate Afterloader brachytherapy machine. In both cases, the radioactive tip broke off the end of the cable. In the Indiana, PA case, the tip remained in the patient's body. In the Pittsburgh case, the tip had been withdrawn after treatment and was located in the catheter, just outside the patient's body.

Dr. Paperiello said the Incident Investigation Team (IIT) was nearing completion of its investigation in the Indiana, PA, area. A team member and a contractor have been dispatched to the facilities of Omnitron International, in Texas, the vendor of the brachytherapy device involved in the event. The team has also investigated a second failure of an Omnitron 2000 on December 7 at the Greater Pittsburgh Cancer Center of Oncology Services Corporation. On December 9, the President of Omnitron informed me (Dr. Paperiello), that the break on the second device was at the same location as on the first device. This is approximately

at the interface between the source cavity of the wire and the cold portion of the wire.

In the second incident, said Dr. Paperiello, the patient was being treated with a single catheter in the lung. The break occurred as the source was being withdrawn from the lung into the remote afterloader. The source was out of the patient and near the connection of the catheter to the afterloader. The medical physicist operating the device received an alarm from the device indicating that the source had not fully retracted. The medical physicist entered the treatment area with a Geiger counter. Both the Geiger counter and area radiation monitor showed radiation. The medical physicist saw the source in the catheter. He immediately cut the catheter between the source and the patient and removed the patient from the room.

The patient was surveyed after removal from the room and only background levels of radiation were detected. The medical physicist entered the room, took a pair of forceps, cut the catheter to free the patient from the machine, wheeled the patient out of the shielded treatment room, and then went back and placed the source into a lead container next to the afterloader. Room radiation levels dropped to usual levels. The medical physicist surveyed the room and identified no contamination or unexpected radiation levels.

The source used in the Pittsburgh treatment center was about 3 curies at the time of the event. The patient dose from the source outside the body is estimated to be in the order of 0.5 - 1.0 rem., a level on the same order of magnitude of many routine diagnostic medical procedures. Dosimeters for the medical physicist and two others involved with aiding the patient and recovering the source were sent for processing. None is expected to show overexposures.

Film badge readings for the Indiana Regional Cancer Center staff involved in the first event on November 16 ranged from .11 to .82 rem. The NRC occupational limit is 1.25 rem per calendar quarter-year. All facilities involved have been surveyed for radiation and contamination. The nursing home where that patient had lived, and ambulance that transported her to and from the treatment, showed radiation levels to be at normal background levels. The Indiana Regional Cancer Center had radiation levels that were emitted by known medical treatment sources only.

"Although the cause of the source break is still not known, the IIT has made the following preliminary findings for the failure of the Indiana Regional Cancer Center staff to detect the source remaining in the patient's body: (1) Wire breakage was not considered a credible accident by the Center staff. (2) Although a radiation monitor in the treatment room was alarming, it was

disregarded. Some staffers considered it unreliable because it had alarmed in the past when no radiation was present. (3) the staff gave more credence to the Omnitron control computer which they stated showed the source fully retracted and which they considered reliable. The only problem they believed they had was an inability to insert the source into the 5th and last catheter. Had the available Geiger counter been used to check the validity of the radiation monitor alarm in the treatment room the source would have been discovered and removed," said Dr. Paperiello.

Dr. Paperiello said that blood tests were conducted on 39 individuals who came into the greatest contact with the source and who were not wearing radiation detection badges. Results have not yet been received for six Browning Ferris Industries (BFI) workers (the waste removal company, but results for the other 33 show no effect. Preliminary calculations show maximum potential exposures of 11 - 20 rem to several individuals at the nursing home and 5 - 8 rem to two individuals at BFI. Results for four of six individuals whose blood was undergoing chromosomes studies at Oak Ridge show no exposures above 20 rems, the lower limit of detection. Oak Ridge is still working on the other two. (The Oak Ridge laboratory will be looking for patterns of chromosome breaks that would be attributable to radiation exposure of these blood cells. Chromosome breaks may be present to some degree because of environmental factors such as smoking, use of various drugs, including cancer chemotherapy, or other factors, the extent of which is widely known.)

"Due to severe weather, the IIT had to defer its preliminary exit meeting with licensee corporate officials. The planned media briefing was also cancelled, and this statement provides the information I would have presented to the media," Dr. Paperiello said.

#