F-08-92-169 107 #44

December 21, 1992

PRELIMINARY NOTIFICATION OF EVENT OR UNUSUAL OCCURRENCE--PNO-IIT-92-01B

This preliminary notification constitutes EARLY notice of events of POSSIBLE safety or public interest significance. The information is as initially received without verification or evaluation, and is basically all that is known by the IIT on this date.

FACILITY:
Oncology Services Corporation
Indiana Regional Cancer Center
877 Hospital Road
Indiana, PA 15701

Licensee Emergency Classification
Notification of Unusual Event
Alert
Site Area Emergency
General Emergency
X Not Applicable

SUBJECT: UPDATE ON INCIDENT INVESTIGATION TEAM (IIT) INVESTIGATION OF HIGH DOSE RATE THERAPY MISADMINISTRATION AND LOST SOURCE

The Incident Investigation Team convened in Bethesda on Monday, December 14. During the week, two team members went to Omnitron facilities in Louisiana where the source is fabricated and to Texas where most of the High Dose Rate remote after loader is assembled. Interviews with NRC staff were begun to obtain an understanding of the current regulatory requirements, policies and guidance provided to license reviewers and inspectors on HDR licensing and inspection.

Testing of the nickel-titanium broken wires is ongoing by both an NRC contractor, Southwest Research Institute, and a contractor for Omnitron. The fracture of both wires occurred near the bottom of the cavity containing the iridium source. Scanning electron microscope examinations, microstructure examinations, and microhardness tests have been performed.

A "dummy" wire built to the same specifications as the active wire, except that it contained non-radioactive iridium, was broken under test conditions and is also being examined.

The observations made to date on the three wire samples (including the dummy wire) have shown the three fractures to be generally similar and no material flaws or defects have been identified as associated with the two in-service failures. All of the fractographic features observed to date are consistent with bending overload failures.

The team continues to seek the root cause for the failure of the individuals involved in the treatment of the patient to respond to the Prime Alert area radiation monitor. The Oncology Services Radiation Safety Officer has been interviewed and a further interview is planned. Some individuals have been telephonically reinterviewed. It currently appears that systematic radiation safety training was not provided and reliance was placed on the fact that the individuals involved were certified in their medical or technical field. Omnitron stated they only provide training on routine and emergency operating procedures for their device.

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Dr. Carl J. Paperiello and Dr. Mohamed Shanbaky conducted an interim exit interview with Oncology Services management representatives on Thursday, December 17 in Harrisburg, Pennsylvania. An FDA representative was present. At the conclusion of the meeting, which was transcribed, Dr. Paperiello reminded the licensee of its reporting obligations under 10 CFR Part 20, Part 30 and Part 35.

The medical physicist at the Greater Pittsburgh Cancer Center who was involved in the second break of the Omnitron wire reported his dosimeter results and his calculation of patient dose. His badge exposure was 20 millirems and his calculated patient exposure was 93 millirems. The patient result is being reviewed but these results are consistent with the team's view that the response to the second event was appropriate.

Blood count results for Brown Ferris Industries employees, the waste removal company, have been received and show no acute effects. Therefore, all 39 blood counts are negative for acute effects. The Oak Ridge chromosome studies for six individuals show exposures less than the statistical detectable limit for any one individual. However, Dr. Littlefield stated the set of data for the six persons as a whole shows 13 dicentric chromosomes in 3,000 metaphases as compared to an expected background of 6 dicentrics in 3,000 metaphases. Dr. Littlefield stated the data provide evidence that the group as a whole did receive an exposure in excess of background with an average dose of about 6 rad for the group. A seventh blood sample was sent to Oak Ridge on December 14 but results have not yet been received. These results are consistent with previously reported NRC calculations for the highest exposed individuals. Systematic calculations for all identified individuals who may have potentially received radiation exposure are being performed by team members using the computer code MICROSHIELD.

There has been continual cooperation with the FDA. NRC attendance has been requested at the FDA's exit with Omnitron which is expected to be held in the next two weeks. On Thursday, December 17, NMSS issued Information Notice 92-84 to inform all medical licensees of this event and the need to survey patients with temporary implants before release.

A significant number of documents requested from Omnitron and Oncology Services are still outstanding. These include licensee written reports required by the regulations cited above. A few interviews remain to be conducted. Dose calculations will take about a week to complete. More results are expected from Southwest Research Institute on test results on the wire. The projected date for completion of the Incident Investigation Report is February 2, 1993.

This information is current as of 2:00 p.m. (EST), December 21, 1992.

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Survey of Ambulance Used to Transport Patient After Incident

Instrumentation:

Ludlum Model 19 Micro R Meter, SN:NRC033512
Background: 8 micro R/hour (uR/hr)

Results:

Location #	Exposure Rate (uR/hr)	Remarks
47	8	Ambulance Stretcher
48	8	Back Entrance to Ambulance

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Survey of Scenery Hill Manor

Instrumentation:

Ludlum Model 19 Micro R Meter, SN:NRC033512
Background: 8 micro R/hour (uR/hr)

Results:

Location #	Exposure Rate (uR/hr)	Remarks
41	8	Patient Room
42	8	Entrance-Patient Room
43	8	Entrance-Soiled Utility
44	8	Soiled Utility Room
45	8	Entrance-Outside Storage
46	8	Outside Storage

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Survey of Indiana Regional Cancer Center

Instrumentation:

1. Ludlum Model 16 Analyzer, SN:NRC019621, with Ludlum Model 44-3 NaI probe, SN:NRC019626, Background: 220 cpm

2. Ludlum Model 19 Micro R Meter, SN:NRC033512
   Background: 8 micro R/hour (uR/hr)

Results:

Location #	Exposure Rate (uR/hr)	Dose Rate (cpm)	Remarks
1	15	300	Treatment Room Entrance
2	10	300	Treatment Room Doorway
3	8	250	End of Labyrinth
4	8	200	Accelerator Bedside
5	8	250	HDR Location
6	14	300	Side of Gantry
7	8	250	Treatment Room Area
8	11	400	Stretcher Room
9	11	700	Phlebotomist Station
10	12	300	Entrance Stretcher Room
11	9	320	Gowned Waiting Area
12	9	300	Gowned Waiting Area
13	30	1000	Exam Room 1
14	50	1400	Exam Room 1
15	1000	60,000	Bench - Exam Room 2
16	25	4000	Exam Room 2
17	20	800	Entrance-Exam Room 1
18	15	2600	Entrance-Exam Room 2
19	2000	140,000	Sr-90 Storage-Exam Room 3
20	50	2000	Exam Room 3
21	20	6000	Entrance-Exam Room 3
22	30	800	Lounge
23	20	800	Entrance to Conference Room
24	10	200	Conference Room
25	10	220	Conference Room
26	8	280	Simulator Entrance
27	8	240	Simulator Room
28	30	2000	Toilet
29	10	220	Office
30	12	340	Drs. Office
31	10	360	Entrance to Office
32	18	400	Entrance to Drs. Office
33	10	300	Secretary's Office
34	12	300	Entrance-Secretary's Office
35	10	260	Reception Area
36	10	280	Entrance Hallway
37	10	280	Mold Room
38	10	260	Mold Room
39	10	220	Entrance - Mold Room
40	10	260	Ambulance Entrance

Note: High readings at location #'s 13-21 due to Sr-90 Source

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