A.3: EVENTS OF THERAC-25 MALFUNCTIONS

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Introduction

- Therac-25 was a radiation therapy machine produced by Atomic Energy of Canada Limited (AECL)
- 11 Therac-25's
  - 5 in the U.S
  - 6 in Canada
- 6 errors occurred
  - From 1985 - 1987

First Accident

- In Marietta, Georgia
- June 3, 1985
- Kennestone Regional Oncology Center

Details

- Radiation treatment to lymph nodes after a lumpectomy to remove a breast tumor.
- During first treatment patient claims she felt a high level of heat in her chest.
- Levels of the machine were all correct but patient still felt as if she was burned.
- When she went home she slowly began to develop a red mark that began to swell.
- Pain reached a level that her shoulder froze up due to spasms.
- From the complications her doctor sent her back to use the Therac-25 for treatment.
- Later they found a matching red swollen mark on the patients back.

What happened?

- Patient received a dose of radiation in the 15,000 to 20,000 rad(radiation absorbed dose) range.
- Standard doses are normally in the 200rad range.
- 1,000rad doses delivered to the entire body can be fatal.
- The patient had to have her breast removed from the radiation burns.
- Shoulder and arm became completely paralyzed.

Second Accident

- Ontario, Canada
- July 26, 1985
- Ontario Cancer Foundation

Details

- Patient came in for their 24th Therac-25 treatment.
- Carcinoma of the cervix treatment.
- Whenever treatment initiated the machine shut down.
- Screen read ‘No Dose Delivered’
- After 5 times the machine shutdown.
- Patient claimed she had a burning sensation in her hip after the “failed” attempts.

What Happened?

- Patient died on November 3, 1985
- Received between 13,000 and 17,000 rads
- Machine was taken out of service.

Third Accident

- Yakima, Washington
- December 1985
- Yakima Valley Memorial Hospital

Details

- Early signs of reddening skin on hip.
- Never stopped treatment.
- Reaction said to be normal and that there was no issue.
- Unsure why or how this happened.
- Nothing they thought to be the reason ended up being the cause of the redness.
- Still said it wasn't possible for the Therac-25 to be the blame.
- *Claimed that the cause for her issues were unknown and didn’t relate them to the machine*

Fourth and Fifth Accidents

- Tyler Texas
- March 21, 1986 & April 11, 1986
- East Texas Cancer Center

Details

March

- Treatment to upper back left of the spine.
- Ninth treatment felt as if someone poured burning coffee on his back.
- Knew that something was wrong and immediately left the treatment center.

April

- Treatment to the face for skin cancer.
- Machine shut down and said ‘Malfunction’
- Patient yelled immediately and said it felt like his face was on fire.

What happened?

March

- After examination they said it was just an electric shock.
- Later discovered there were doses of 16,500 to 25,000rads in less than a second.
- Patient eventually lost feeling in the left side of his body and both of his legs.
- Died within three weeks of his ninth treatment.

April

- Face experienced a severe burn.
- Severe burns to the head caused major disorientation.
- Patient went into a coma with a fever of 104 degrees.
- Soon died from high radiation dosages to the brain stem.

Sixth Accident

- Yakima, Washington
- January 17, 1987
- Yakima Valley Memorial Hospital

Details

- Similar to the third accident that was also in Yakima.
- 2 years later a problem they thought didn’t exist occurred again.
- Man developed the same markings and experienced the same pain.
- Leading to his death 4 months later.

Software Issues

- When looking to fix problems the focus was only on the “bugs” in the software.
- This didn’t make the Therac-25 safe for applications.
- The software alerts when something is wrong, but there isn’t a fail safe to actually stop the radiation.

AECL Changes

- “Atomic Energy of Canada Limited”
- February 3, 1987

1. A new software release to correct the problems
2. Hardware Single Pulse shutdown circuit
3. A turntable potentiometer to independently monitor turntable positions
4. A hardware turntable interlock circuit

Conclusion

- FDA has performed extensive review of the Therac-25 software and hardware safety systems. We cannot say with absolute certainty that all software problems might result in improper dose have been found and eliminated. However, we are confident that the hardware and software safety features recently added will prevent future catastrophic consequences of failure.
- Since the improvements of the Therac-25 there have been no accidents reported.