Online Ethics Center
FOR ENGINEERING AND SCIENCE

Therac-25 Timeline

Author(s)

Charles Huff

Description

A timeline of events of the Therac-25 case.

Body

Early 1970’s	AECL and a French Company (CGR) collaborate to build Medical Linear Accelerators (linacs). They develop Therac-6, and Therac-20. (AECL and CGR end their working relationship in 1981.)
1976	AECL developes the revolutionary "double pass" accelerator which leads to the development of Therac-25.
March, 1983	AECL performs a safety analysis of Therac-25 which apparently excludes an analysis of software.
July 29,1983	In a PR Newswire the Canadian Consulate General announces the introduction of the new "Therac 25" Machine manufactured by AECL Medical, a division of Atomic Energy of Canada Limited.
ca. Dec. 1984	Marietta Georgia, Kennestone Regional Oncology Center implements the new Therac-25 machine.

June 3, 1985	Marietta Georgia, Kennestone Regional Oncology Center Katherine (Katy) Yarbrough, a 61-year-old woman is overdosed during a follow-up radiation treatment after removal of a malignant breast tumor. Tim Still, Kennestone Physicist calls AECL asking if overdose is possible; three days later he is informed it is not.
July 26, 1985	Hamilton, Ontario, Canada. Frances Hill, a 40-year-old patient is overdosed during treatment for cervical carcinoma. AECL is informed of the injury and sends a service engineer to investigate.
November 3, 1985	Hamilton Ontario patient dies of cancer, but it is noted on her autopsy that had she not died, a full hip replacement would have been necessary as a result of the radiation overdose.
November 8, 1985	Letter from CRPB to AECL requesting additional hardware interlocks and changes in software. Letter also requested treatment terminated in the event of a malfunction with no option to proceed with single key-stroke. (under Canada’s Radiation Emitting Devices Act.)
November 18, 1985	Katy Yarbrough files suit against AECL and Kennestone Regional Oncology Center. AECL informed officially of Lawsuit.
December 1985	Yakima Valley Memorial Hospital, Yakima Washington. A woman being treated with Therac-25 develops erythema on her hip after one of the treatments.

January 31, 1986	Staff at Yakima sends letter to AECL and speak on the phone with AECL technical support supervisor.
February 24, 1986	AECL technical support supervisor sends a written response to Yakima claiming that Therac-25 could not have been responsible for the injuries to the female patient.
March 21, 1986	East Texas Cancer Center, Tyler Texas. Voyne Ray Cox is overdosed during treatment on his back. Fritz Hager notifies AECL. Company suggests some tests and suggests hospital might have an electrical problem. AECL claims again that overdoes is impossible and that no other accidents have occurred previously.
March 22, 1986	Ray Cox checks into an emergency room with severe radiation sickness. Fritz Hager calls AECL again and arranges for Randy Rhodes and Dave Nott to test Therac. They travel to Texas and test Therac but find nothing wrong.
April 7, 1986	ETCC has investigated electrical problem possibility, finding none, put Therac-25 back in service.
April 11, 1986	East Texas Cancer Center. Another Verdon Kidd is overdosed during treatments to his face. Operator is able to explain how Malfuction 54 was achieved. Fritz Hager tests computer’s readout of no dose, and discovers the extent of the overdoses. Hager spends weekend on phone with AECL explaining findings.
April 14, 1986	AECL files report with FDA. AECL sends letter to Therac-25 users with suggestions for avoiding future accidents, including the removal of the up-arrow editing key and the covering of the contact with electrical tape.

May 1, 1986	Verdon Kidd, who was to have received treatments to left ear dies as a result of acute radiation injury to the right temporal lobe of the brain and brain stem. He is the first person to die from therapeutic radiation accident.
May 2, 1986	FDA declares Therac-25 defective, and their "fix" letter to users inadequate. FDA demands a CAP from AECL.
June 13, 1986	AECL produces first CAP for FDA.
July 23, 1986	FDA has received CAP, asks for more information.
August, 1986	Therac-25 users create a user group and meet at the annual conference of the American Association of Physicists in Medicine
August, 1986	Ray Cox, overdosed during back treatment, dies as a result of radiation burns.
September 23, 1996	Debbie Cox and Cox family file lawsuit
September 26, 1986	AECL provides FDA with more information.
October 30, 1986	FDA requests more information.
November 1986	Physicists and engineers from FDA’s CDRH conducted a technical assessment of the Therac-25 at AECL manufacturing plant in Canada (R.C. Thompson).
November 12, 1986	AECL submits revision of CAP.
December	Therac-20 users notified of a software bug.

December 11, 1986	FDA requests more changes to CAP.
December 22, 1986	AECL submits second revision of CAP.
January 17, 1987	Second patient, Glen A. Dodd, a 65-year-old man, is overdosed at Yakima.
January 19, 1987	AECL issues hazard notification to all Therac-25 users and told them to visually confirm the position of the turntable before turning on beam.
January 26, 1987	Conference call between AECL quality assurance manager and Ed Miller of FDA. AECL sends FDA revised test plan. AECL calls Therac users with instructions on how to avoid beam on when turntable is in field light position.
February 3, 1987	AECL announces additional changes to Therac-25
February 6, 1987	Ed Miller calls Pavel Dvorak of Canada's Health and Welfare department with news that FDA will recommend that all Therac 25 units be taken out of service until CAP is completed.
February 10, 1987	FDA sends notice to AECL advising that Therac is defective under US law and requesting AECL to notify customers that it should not be used for routine therapy. Canadian Health Protection Branch does the same.
March 1987	Second User Group Meeting
March 5, 1987	AECL sends third revision of CAP to FDA.

April 1987	Glen A. Dodd, overdosed at Yakima, dies of complications from radiation burns to his chest.
April 9, 1987	FDA asks for additional information regarding third CAP revision.
April 13, 1987	AECL sends update of CAP and list of nine items requested by users at March meeting.
May 1, 1987	AECL sends fourth revision of CAP to FDA as a result of FDA commentary at user meeting.
May 26, 1987	FDA approves fourth CAP subject to final testing and analysis.
June 5, 1987	AECL sends final test plans to FDA along with safety analysis.
July, 1987	Third Therac-25 User Group Meeting
July 21, 1987	AECL sends final (fifth) CAP revision to FDA.
January 28, 1988	Interim safety analysis report issued from AECL.
November 3, 1988	Final safety analysis report issued.

Rights