CHBE 412 Senior Design Ethics Case Study #1

Handout - A History of the Introduction and Shut Down of Therac-25

Adapted from:
http://computingcases.org/case_materials/therac/supporting_docs/therac_case_narr/therac_case_intro.html

Normally, when a patient is scheduled to have radiation therapy for cancer, he or she is scheduled for several sessions over a few weeks and told to expect some minor skin discomfort from the treatment. The discomfort is described as being on the order of a mild sunburn over the treated area. In the case you are about to read, a very abnormal thing happened to several patients: they received severe radiation burns resulting in disability, and, in 3 cases, death.

The Therac-25 was a device that targeted electron or X-ray beams on cancerous tissue to destroy it. Electron beams were used to treat shallow tissue, while photon beams could penetrate with minimal damage to treat deep tissue. Even though operators were told that there were "so many safety mechanisms" that it was "virtually impossible" to overdose a patient, this is exactly what did occur in six documented cases.

Therac-25 was released on the market in 1983. In 1987, all treatment with the eleven machines in operation was suspended. Those machines were refitted with the safety devices required by the FDA and remained in service. No more accidents were reported from these machines. At about that time, the division of AECL that designed and manufactured Therac-25 became an independent company.

The major innovations of Therac-25 were the double pass accelerator (allowing a more powerful accelerator to be fitted into a small space, at less cost) and the move to more complete computer control. The move to computer control allowed operators to set up the machine more quickly, giving them more time to speak with patients and making it possible to treat more patients in a day. Along with the move to computer control, most of the safety checks for the operation of the machine were moved to software and the hardware safety interlocks removed.

AECL's FDA Testing and Safety Analysis

Before release of Therac-25 on the US market, AECL obtained approval to market it from the FDA. This approval was obtained by declaring what FDA called pre-market equivalence. Since the software was based on software already in use, and the linear accelerator was a minor modification of existing technology, designation of Therac-25 as equivalent to this earlier technology meant that Therac-25 bypassed the rigorous FDA testing procedures. In 1984, 94% of medical devices entered the market in this manner. This declaration of pre-market equivalence seems optimistic, since most of the safety mechanisms were moved into the software, a major change from previous version of the machine.

In 1983, just after AECL made the Therac-25 commercially available, AECL performed a safety analysis of the machine using Fault Tree Analysis. This involves calculating the probabilities of the occurrence of varying hazards (e.g. an overdose) by specifying which causes of the hazard must jointly occur in order to produce the hazard.

In order for this analysis to work as a Safety Analysis, one must first specify the hazards (not always easy), and then be able to specify the all possible causal sequences in the system that could produce them. It is certainly a useful exercise, since it allows easy identification of single-point-of-failure items and the identification of items whose failure can produce the hazard in multiple ways. Concentrating on items like these is a good way to begin reducing the probabilities of a hazard occurring.

In addition, if one knows the specific probabilities of all the contributing events, one can produce a reasonable estimate of the probability of the hazard occurring. This quantitative use of Fault Tree Analysis is fraught with difficulties and temptations, as AECL's approach shows.

In order to be useful, a Fault Tree Analysis needs to specify all the likely events that could contribute to producing a hazard. Unfortunately, AECL's analysis left out consideration of the software in the system almost entirely. Since much of the software had been taken from the Therac-6 and Therac-20 systems, and since these software systems had been running many years without detectable errors, the analysts assumed there were no design problems in the software. The analysts considered software failures like "computer selects wrong mode" but assigned them probabilities like 4 x 10**-9.

These sorts of probabilities are likely assigned based on the remote possibility of random errors produced by things like electromagnetic noise. They do not at all take into account the possibility of design flaws in the software. This shows a major difficulty with Fault Tree Analysis as it is often practiced. If the only items considered are "failure" items (e.g. wear, fatigue, etc.) a Fault Tree Analysis really only gives one a reliability for the system.

AECL's Response to the Accidents

In July of 1985, AECL was notified that a patient in Hamilton, Georgia had been overdosed. AECL sent a service engineer to the site to investigate. AECL also informed the United States Food and Drug Administration (FDA), and the Canadian Radiation Protection Board (CRPB) of the problem. In addition they notified all users of the problem and issued instructions that operators should visually confirm hardware settings before each treatment. AECL could not reproduce the malfunction, but its engineers suspected that a hardware failure in a microswitch was at fault. They redesigned the hardware and claimed that this redesign improved the safety of the machine by five orders of magnitude. After modifications were made in the installed machines, AECL notified sites that they did not need to manually check the hardware settings anymore.

In November of 1985, AECL heard of another incident in Georgia. The patient in that incident (Linda Knight) filed suit that month based on an overdose that occurred in June. There is no evidence that AECL followed up this case with the Georgia hospital. Though this information was clearly received by AECL, there is no evidence that this information, was communicated internally to engineers or others who responded to later accidents.

In January of 1986, AECL heard from a hospital in Yakima, Washington that a patient had been overdosed. The AECL technical support supervisor spoke with the Yakima hospital staff on the

91 phone, and contacted them by letter indicating that he did not think the damage they reported
92 was caused by the Therac-25 machine. He also notified them that there have "apparently been no
93 other instances of similar damage to this or other patients."
94
95 In March of 1986, AECL was notified that the Therac-25 unit in Tyler, Texas had overdosed a
96 patient. They sent both a local Texas engineer and an engineer from their Canada home office to
97 investigate the incident the day after it occurred. They spent a day running tests on the machine
98 but could not reproduce the specific error. The AECL engineer suggested that perhaps an
99 electrical problem had caused the accident. He also said that AECL knew of no accidents
100 involving radiation overexposure with the Therac-25. An independent engineering firm checked
101 out the electric shock theory and found that the machine did not seem capable of delivering an
102 electric shock to a patient.
103
104 On April 11th of 1986, AECL was alerted to another overdose that had occurred in Tyler. After
105 communication with the medical physicist at Tyler, AECL engineers were able to reproduce the
106 overdose and the sequences leading up to it.
107
108 AECL filed a medical device report with the FDA on April 15, 1986 to notify them of the
109 circumstances that produced the two Tyler accidents.
110
111 At this point, the FDA, having been notified of the first Tyler accident by the hospital, declared
112 Therac-25 defective and ordered the firm to contact all sites that used the machine, investigate
113 the problem, and submit a report called a corrective action plan. AECL contacted all sites and
114 recommended a temporary fix involving removing some keys from the keyboard at the computer
115 console.
116
117 The FDA was not satisfied with the notification that AECL gave sites, and in May 1986 required
118 AECL to re-notify all sites with more specific information about the defect in the product and the
119 hazards associated with it. AECL was also at this time involved in meetings with a "user's group"
120 of Therac-25 sites to help formulate its corrective action plan. After several exchanges of
121 information among AECL and the FDA (in July, September, October, November, and December
122 of 1986), AECL submitted a revised corrective action plan to FDA.
123
124 In January 1987, AECL was notified of another overdose occurring again at the Yakima,
125 Washington hospital. After sending an engineer to investigate this incident, AECL concluded
126 that there was a different software problem that allowed the electron beam to be turned on
127 without the device that spread it to a safe concentration being placed in the beam.
128
129 Therac-25 is Shut Down
130
131 In February, 1987, the FDA and its Canadian counterpart cooperated to require all units of
132 Therac-25 to be shut down until effective and permanent modifications were made. After another
133 6 months of negotiation with the FDA, AECL received approval for its final corrective action
134 plan. This plan included numerous software fixes, the installation of independent, mechanical
135 safety interlocks, and a variety of other safety related changes.
136

Several of the surviving victims or the deceased victim's families filed suit in US courts against AECL and the medical facilities using Therac-25. All of these suits were settled out of court.

AECL Medical Goes Independent

The division of AECL that designed and manufactured Therac-25 has become an independent private Canadian company. They still make radiation therapy machines.

Government and FDA response to the Accidents

The Therac-25 case pointed to significant weak links in communication between FDA, medical device manufacturers, and their customers or users. Users were not required to report injuries to any government office, or to the manufacturers of the devices that had caused injury.

A 1986 GAO study found 99% of injuries caused by medical devices were not reported to the FDA. At that time, hospitals reported only about 51% of problems to the manufacturer. The hospitals mostly reported dealing with problems themselves. Problems were mainly the result of wear and tear on machines and design flaws.

The breakdown in communication with hospitals and clinics using medical devices prevented FDA from knowing about the isolated and recurring problems with the Therac-25 until after two deaths occurred in Tyler, TX.

Even when the FDA became aware of the problem, they did not have the power to recall Therac-25, only to recommend a recall. After the Therac-25 deaths occurred, the FDA issued an article in the Radiological Health Bulletin (Dec. 1986) explaining the mechanical failures of Therac-25 and explaining that "FDA had now declared the Therac-25 defective, and must approve the company's corrective action program."

After another Therac-25 overdose occurred in Washington state, the FDA took stronger action by "recommending that routine use of the system on patients be discontinued until a corrective plan had been approved and implemented" (Radiological Health Bulletin, March 1987). AECL was expected to notify Therac-25 users of the problem, and of FDA's recommendations.

After the Therac-25 deaths, the FDA made a number of adjustments to its policies in an attempt to address the breakdowns in communication and product approval. In 1990, health- care facilities were required by law to report incidents to both the manufacturer and FDA.

176 **How to Produce a Malfunction 54 on a [AECL] Therac-25 Linear Accelerator**

177 This statement was written by the East Texas Cancer Center physicist after he discovered how to
178 reproduce the "Malfunction 54 error"

179 Enter the room and set up the machine for an electron beam treatment by selecting a field size
180 and installing the trimmers. Press the set button. Leave the room and close the door. At the
181 control console proceed to the patient set-up display. For Mode enter "X". The machine will
182 default to 25 MeV and go to dose rate of 250 rads/min. Use return key to go to dose. Enter 200.
183 Use return key to go to time. Enter 0.8 min. Use the return key to rapidly advance to the bottom
184 of the display. Immediately use the up arrow to move from the bottom of the display. You are
185 now in the edit mode. Use the up arrow to go to the top of the display and change the mode "X"
186 to "E" for electrons. Change the energy from 25 to 10. Use the return key to go back down to the
187 bottom of the display. Wait for the "beam ready" message then type "B" return. The unit will
188 have no indications on dose rate or dose 1 or dose 2 for about 3 to 4 seconds. Then the dose rate
189 will flash 550 to 575 for one cycle and return to zero. Dose 1 and Dose 2 will count to -6. A
190 malfunction 54 message will appear at the bottom of the display. You have just delivered a dose
191 of approximately 25,000 rads of 25 MeV electrons in less than two seconds.

192 **Impacts of Malfunction 54** - Malfunction 54, produced in this way would deliver a dose 25,000
193 rads of 25 MeV electrons in less than two seconds. The standard therapeutic dose is about 200
194 rads at any one time. A dose of 500 rads over the entire body is considered lethal to 50% of
195 individuals who receive it. Two persons were killed from the malfunction 54 overdose. One died
196 in 5 months, the other within one month.

197 **Operator Interview** - Susan operated a Therac-4 linear accelerator machine in the mid 1980's.
198 She enjoyed operating AECL's new Therac machine because it was the first computerized linear
199 accelerator. She remembered that while operating the machines, she did not think about whether
200 there could be computer software "bugs" in the system. The technology was new, and she trusted
201 the machine's components and designers. Susan reported being able to move more patients
202 through during the day. She also remembered feeling good about the extra time she had to talk
203 with patients when she was working with a computerized machine.

204 Susan learned about the Therac-25 incidents at a national radiation conference. A radiation
205 therapist spoke about how many times therapists involved in the accidents attempted to resume
206 treatment *in spite of* the computer error messages. How many attempts to resume treatment is too
207 many? What is the possibility of establishing institutional policies and limits on the number of
208 times an operator could resume treatment after having received an error message, such as the
209 cryptic "malfunction 54" messages that the operator received during the two fatal accidents in
210 Texas. Even today, there are no industry-wide standards for these situations. Susan felt that she
211 was lucky to have worked where there was a physicist available to help with error messages
212 operators received. She also felt that in other clinics, where this assistance is not available, there
213 was, and still is, a great deal more pressure on therapists to just keep going despite the error
214 messages. An operator might attempt, for example, to deliver the prescribed dose in 12
215 increments instead of 1 by continually clearing the faults generated by the computer. Susan
216 stated that this type of activity happens all the time in medical radiation therapy, particularly in
217 clinics where there is more pressure from the administration to keep patients moving through
218 quickly.
219

CHBE 412 Ethics Case Study – Introduction and Shut-down of the Therac 25

Name________________________________

1. List 3 to 5 relevant stakeholders in this case.

2. Pick three stakeholders, and describe the duties and rights these stakeholders have toward each other. This is best done with a drawing of each stakeholder with arrows indicating duties one owes to other and rights one has.

3. Using the three stakeholders identified in question 2,

a) Determine to what degree each stakeholder's duties were fulfilled or neglected.

b) Determine to what degree each stakeholder's rights were violated or protected, and by whom.

4. Construct a promising alternative scenario that could have potentially avoided the human disabilities and deaths. An alternative does not have to be perfect or even optimal, to be better than what happened.

5. The AIChE code of professional ethics is a guide for chemical engineers. What professional and ethical issues highlighted by this case are addressed in the AIChE code of Ethics?

AIChE Code of Ethics (Revised January 17, 2003) [http://www.aiche.org/About/Code.aspx]

Members of the American Institute of Chemical Engineers shall uphold and advance the integrity, honor and dignity of the engineering profession by: being honest and impartial and serving with fidelity their employers, their clients, and the public; striving to increase the competence and prestige of the engineering profession; and using their knowledge and skill for the enhancement of human welfare. To achieve these goals, members shall:

- Hold paramount the safety, health and welfare of the public and protect the environment in performance of their professional duties.
- Formally advise their employers or clients (and consider further disclosure, if warranted) if they perceive that a consequence of their duties will adversely affect the present or future health or safety of their colleagues or the public.
- Accept responsibility for their actions, seek and heed critical review of their work and offer objective criticism of the work of others.
- Issue statements or present information only in an objective and truthful manner.
- Act in professional matters for each employer or client as faithful agents or trustees, avoiding conflicts of interest and never breaching confidentiality.
- Treat fairly and respectfully all colleagues and co-workers, recognizing their unique contributions and capabilities.
- Perform professional services only in areas of their competence.
- Build their professional reputations on the merits of their services.
- Continue their professional development throughout their careers, and provide opportunities for the professional development of those under their supervision.
- Never tolerate harassment.
- Conduct themselves in a fair, honorable and respectful manner.