**Therac-25 Questions**

Answer the following questions. You may use the Therac-25 paper that is posted on WebCampus, or other references. However, make sure you provide reference information for any that you use. Briefly and concisely answer the following questions with at least 3-5 sentences for each answer, but no more than a half page paragraph; place the question above your answer and upload your document to this BBLearn assignment. Remember that your papers must be printed using 12 point Times New Roman or other easy-to-read black font.

**1. What was the root cause of the problems? What made the Therac-25 different from the previous models?**

The root cause of the problems with the Therac-25 was that it removed reliance upon hardware safety protections that the previous Therac-6 and Therac-20 had. Instead it placed these responsibilities on its software. More specifically the independent protective circuits that monitored the electron-beam scanning, and some mechanical interlocks were removed in favor of software functionality. [PAGE 3]

1. **What was the specific HCI (Human Computer Interface) problem?**

The Operator interface was a specific HCI problem. The machine was designed to provide operators with Error messages to report on the conditions of the Therac, however these messages were often cryptic with messages like “MALFUNCTION” with an error code associated. However, as one operator noted these messages were common and seldom involved patient safety, so they had become desensitized to seeing them. [PAGE 7]

1. **What was the specific OS problem (race condition?)?**

The specific OS problem was that the software was developed in a dual-mode machine system, to facilitate separate energy levels between modes. However in X-ray mode it utilizes a beam flattener to shift the high output electron beam across a larger area. This is an issue if a photon beam is to be produced when the flattener has not properly been positioned, resulting in the full dose directed sent to the patient. [PAGE 5]

1. **What other technical issues might have been involved?**

In addition to the above, as the system was designed to replace many of its original hardware safety features, this opened the Therac-25’s key safety features up to software failures. Further in a March 1983 safety report, only the hardware was considered in the fault tree. Claiming that Programming errors have been reduced by extensive testing on a hardware simulator, instead of some other method such as Unit tests. Leaving the software open to edge cases and unexpected operations. [PAGE 8]

**2. How did the reporting system work? How did the company, the FDA, and the other Therac-25 users find out about the problems?**

In short, it didn’t. The initial reports of the 61-year old patient were not reported to the FDA until after further incidents occurred in 1986. At the time, the requirements of reporting an incident were only applicable to equipment manufacturers/importers, not users. This resulted in the FDA and even other Therac-25 users to be unaware of any problems with the Therac-25 until after multiple accidents. Later the law would be amended in 1990 to require health-care facilities to report incidents to the FDA. [PAGE 11]

**3. What was the overall impact on patients as a group? In other words, how many patients were negatively affected by this machine compared to others who did not experience any difficulties? Given this information, how necessary was it to take action on the issue? Explain why it should have been, or should not have been, necessary to take action on this issue.**

A 61-year old woman who was overdosed by the machine, later had to have her breast removed due to radiation burns, and experienced paralyzation of her arm and shoulder.[Page 10] A 40-year old patient was treated by the Threac-25 as multiple doses were administered (unbeknownst to the operator) suffered radiation exposed to her hip that would have deemed a replacement necessary, if she hadn’t died of a virulent cancer beforehand.[PAGE 12]

I believe that it was necessary for the company to have taken action due to these events. As Computer Scientists, were live in a world of edge cases, but that does not diminish our responsibility to erect safeguards and conditions to counter them. Especially when the safety of the end users is in concern. This case is more severe as it can involve bodily harm to the end users, making it a moral and ethical responsibility to ensure that it either doesn’t happen, or the machine is taken out of operation.

**4. How did the companies react to the issues presented? Were they responsive and helpful? Did they communicate all the known information to all the parties that needed information in a timely fashion?**

While the AECL did respond and usually in a timely fashion to formal requests from the FDA, they kept their cards close to their chest. Only revealing important information when directly asked, further they withheld the knowledge of incidents involving the Therac-25 until it became no longer possible to do so. In my opinion, the AECL was running the fine tightrope of what was legal such they did not have to recall their faulty device. [PAGE 29]

**5. What was the company’s opinion about the software? Did they assume that the failures were due to the software, or not due to the software? Describe their attitude about the software.**

I think it is apparent that the AECL was hesitant to even consider the possibility of a software design failure, given that in the face of many operational errors (even on software controlled actions) they defaulted to a stance on hardware issues. [PAGE 44] Even when confronted with the reality a response was to hire an outside consultant to review the code and search for errors. With no detailed plan or testing regiment to be conducted, in an almost sort of arrogance they believed they could just look at the code and see that no RTE could be possible. [PAGE 40]

**6. Describe the safety and quality implications of this issue. What might be changed to improve the safety and quality of this or other comparable products?**

Due to the safety features being placed on the software, the responsibility of reliable design of the system is critical. While I believe it’s important to combine software/hardware protections (Defense in Depth). If the goal is to replace the hardware, then the software must have another system to error-check itself to act in the place of the removal of hardware locks. Another safety implication was that the engineers confused the general reliance of the machine with its safety, not considering the worst case scenarios but rather the general-case, opening the product to rare but dangerous fringe sets. [PAGE 45]

**7. Describe the ethical implications of this issue. What might be changed about the attitudes of the company, the users, and the agencies (e.g., the FDA) to keep this issue from resurfacing?**

From the stance of the AECL, I think it is clear that they violated most rational opinions of ethics, from negligence to arrogance, to even outright cover-up of the issues with the Therac-25. The members of the AECL seemed to have very little regard for the wellbeing of the patients of the system. From the user’s perspective I believe the operators had an ethical responsibility to evaluate their own perspectives about the device, becoming desensitized to a set of error codes can place their patient’s life at risk, and if the machine was consistently “buggy” they should have taken more steps to ensure it was reported to their superiors. From the FDA’s perspective I believe their response was rational and ethical, even in the face of unknown systems, their appending of laws to ensure that more accurate reporting is required shows their understanding of the problem and a willingness to improve.

**8. At what point did the issue change from an ethics situation to a legal situation (i.e., at what point would it have become fraud)?**

I believe the key turning point for when the AECL was no longer just being ethically incorrect to performing a legal wrong, was when they had sufficient evidence of faulty operations but continued to ignore them. Instead they chose to believe it could not be a problem, and even furthered their position by not placing any adequate software QA programs. This negligence lead to continued malfunctions across the other Therac-25’s in operation.[PAGE 32]

**REFERENCES:**

[1] LEVESON, N. 1995. Medical Devices: The Therac-25. In *Safeware: System Safety and Computers.* Addison-Wesley. [Therac-25 Report Hyperlink](https://learn-us-east-1-prod-fleet01-xythos.s3.us-east-1.amazonaws.com/5b6cbef360ea4/8207191?response-content-disposition=inline%3B%20filename%2A%3DUTF-8%27%27Therac_25_Report.pdf&response-content-type=application%2Fpdf&X-Amz-Algorithm=AWS4-HMAC-SHA256&X-Amz-Date=20190429T143715Z&X-Amz-SignedHeaders=host&X-Amz-Expires=21600&X-Amz-Credential=AKIAIBGJ7RCS23L3LEJQ%2F20190429%2Fus-east-1%2Fs3%2Faws4_request&X-Amz-Signature=5290068df1161fcb5637a3f45c87eb9252ad915b3ca9d317627572338a966de6)