Technological Momentum Analysis of the Failure Behind the Therac-25

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By

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On my honor as a University student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments.

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Introduction

From 1985 to 1987, the Therac-25, a radiation therapy machine, caused 6 cases of radiation overdose by giving patients up to one hundred times the intended dose of radiation. Many professionals and scholars have analyzed the incident and have pointed out software bugs as a root cause of the incidents, exacerbated by the involved organizations failing to make effective responses to the incident. Specifically, these scholars have analyzed the programmer, failure of Atomic Energy of Canada Limited (AECL), the company that produced the Therac-25, to protect users from the errors of its staff, lackluster response by the Food and Drug Administration (FDA), and a software bug called a race condition where a system's behavior is dependent on the sequence of uncontrollable events as the root causes of the Therac-25 incident (Leveson & Turner, 1993).

However, this view is lacking in that the reason for these causes to exist in the first place is not considered or analyzed. By failing to understand why such problems exist in the first place and continuing to adopt this current view, readers lose a new understanding of how society can be influenced by technologies that they first influenced. These understandings can be analyzed through the framework of technological momentum. Technological momentum is a framework used to analyze how, over time, society loses its influence over technology and begins to be influenced by technology instead (Bijker et al., 2012).

I argue that the Therac-25 gained momentum, causing the technological system around the Therac-25 to influence the practices and values of the society that designed and shaped it, leading to the existence of the problems that caused 6 incidents of radiation overdose through the development of three key characteristics within the technological system: increased complexity, skills and knowledge to maintain, and bureaucracy. To support my argument, I will analyze the classic report *An Investigation of the Therac-25 Accidents* (Leveson & Turner, 1993), where author Nancy Leveson was an expert witness involved with the Therac-25 accidents.

Background

X-rays were first discovered by Wilhelm Conrad Roentgen, and radiation machines were first designed by the medical community for physicians to diagnose and primarily cure skin cancers with single large exposures because of the low penetration of tissues from the low-energy x-rays (Gianfaldoni et al, 2017). The Therac series used external beam radiation therapy, which according to Radiology.info (n.d.) aims high-energy beams into one's body using a machine called a linear accelerator. The Therac-25 was a double-pass linear accelerator released in 1983 by AECL, with its double-pass design allowing for a more powerful accelerator taking up less space at a lower cost (Huff, 2003). Its operation and safety management were computer-controlled via a Programmed Data Processor (PDP-11) minicomputer, with the software's sole programmer sourcing code from the preceding Therac-20 and Therac-6 (Leveson & Turner, 1993). The Therac-25's role in the healthcare industry was to deliver precise, high-energy fractionated doses over several treatment sessions utilizing software instead of manually operated hardware (Connell & Hellman, 2009).

However, due to a software bug called a race condition, where a system's behavior is dependent on the sequence of uncontrollable events, the radiation therapy machine gave patients doses more than a hundred times greater than what they should have received (Leveson & Turner, 1993). This led to 6 incidents of radiation overdose, with 4 of those incidents leading to death (Fabio, 2015).

Literature Review

Many scholars have approached analyzing the Therac-25 cases by focusing on the technical causes of the radiation overdose. Some examples include the race condition bug in the software, the sole programmer, or different aspects of the development cycle of the software, like testing. Others focus on the FDA and AECL, and how these organizations failed to act or act properly throughout the life of the Therac-25. While these causes are important to consider and have been thoroughly researched, scholars have not yet adequately considered how the Therac-25 gained momentum in its technological system, influencing society to cause the very issues that led to 6 cases of radiation overdose.

In Jonathan Jacky's report titled *Safety-critical Computing: Hazards, Practices, Standards, and Regulation,* Jacky states that "Much of the blame lies with the product and the vendor" (Kling et al., 1991). Jacky blames the product by pointing out the problems with the X-ray target and a poor user interface. The vendor, AECL, is blamed for the fact that as an organization, it failed to protect customers from staff errors. The development process of AECL is used to point out AECL's lack of measures to ensure the safety of the Therac series as a whole. An example is provided where AECL fails to fix a hardware failure on all machines in use. AECL's failure as an organization, poor user interface, and problems with the X-ray target were all problems that led to 6 incidents of radiation overdose. However, how these problems came to be due to the technology, the Therac-25, gaining momentum to influence society is never considered and analyzed.

In *Computing and accountability* (Nissenbaum, 1994), Nissenbaum analyzes the Therac-25 incidents from the point of view of accountability. Nissenbaum names 4 barriers to accountability: the problem of many hands, bugs, computer scapegoats, and ownership without liability. Nissenbaum analyzes the organizational setting in which the software is created, the inevitability of software bugs, blaming computers for harm or injuries, and the neglect of responsibilities of ownership. However, like Jacky, Nissenbaum fails to consider the accountability to be attributed to the technology due to it gaining momentum to influence society. If the Therac-25's influence over society is considered, another barrier to accountability would have to include the influence of technology over society.

Organizational responses, responsibilities, and software failures are all problems that led to 6 incidents of radiation overdose and should be analyzed. However, equally important is analyzing why these problems exist in the first place. Both Jacky and Nissenbaum provide an excellent analysis of the organizations and software at play to blame and hold accountable. Yet both authors fail to consider how the Therac-25 gaining enough momentum to influence society is to blame for creating these problems to begin with. Using technological momentum to analyze the Therac-25 and the technological system that surrounds it, the existence of the numerous technical problems - interface issues, software errors, and organizational response - will be explored and analyzed.

Conceptual Framework

My analysis of the Therac-25 incidents draws on technological momentum, which allows me to understand how the technological system around the Therac-25 influenced society to cause the existence of the technical problems that led to 6 incidents of radiation overdose. Therefore, the Therac-25 incidents can be analyzed and understood under a new interpretation with the technological momentum framework.

Technological momentum, developed by Thomas P. Hughes, says that as technology gains momentum, the influence of society over technology decreases, while technology's influence over society increases (Bijker et al., 2012). Hughes defines society as the world "that is not hardware or technical software," which includes "institutions, values, interest groups, social classes, and political and economic force." The technological system includes, as Hughes puts it, both the technical (technology) and the social. Early in the life of a technology, society has more power to shape the technology's design, purpose, meaning, and role, setting society as cause and technology as effect. After technology has gained momentum, technology has more power to influence society's practices, values, power relations, etc, setting technology as the cause and society as the effect.

Technological momentum has some key characteristics present in systems that can be spotted. These characteristics include the system gaining increased bureaucracy, complexity, scale, skills and knowledge to maintain, social integration, special-purpose machines and processes, and large physical structures and infrastructures. The system also gains increasing influence on aspects of the society that developed it, giving the system durability, inertia, rigidity, and resistance to change.

In the case of the Therac-25 incidents, the technology can be defined to be the linear accelerators, namely the Therac-25, Therac-20, and Therac-6. Society is everything outside of technology including the FDA, medical community, AECL, values held by these groups, and many other factors. When technological momentum is used to analyze the Therac-25 incidents, a new understanding of how technology gained momentum to influence the very society that once influenced it comes to light. The proceeding section draws on technological momentum to analyze the Therac-25 incidents, focusing on three key characteristics of technological momentum that best explain how the Therac-25 gained momentum, leading to 6 incidents of radiation overdose: increased complexity, skills and knowledge to maintain, and bureaucracy.

Analysis

Problems that are commonly analyzed in the Therac-25 incidents include interface issues, software errors, and organizational response. However, I argue that these problems existed due to the Therac-25 gaining momentum, causing the system to have three key characteristics that influenced society leading to the existence of the problems that caused 6 cases of radiation overdose: increased skills and knowledge to maintain, bureaucracy, and complexity of the technological system. Without the technology gaining momentum for the system to develop these characteristics, the problems would not have existed to begin with. In the subsections that follow, I will demonstrate that three key characteristics led to the development of the previously mentioned problems by analyzing evidence of each key characteristic and how they led to the development of such problems.

Increased Complexity

One characteristic the system gained that led to the development of interface and software problems, causing 6 incidents of radiation overdose, is increased complexity. The second chronological incident, which took place at the Ontario Cancer Foundation on July 26, 1985, demonstrates how increased complexity led to interface and software problems. In order to understand how the system gained increased complexity, it is necessary to compare the Therac-25's predecessors to the Therac-25 itself. The Therac-6 and Therac-20 were designed around similar machines with established histories of clinical use without computer control

(Leveson & Turner, 1993). However, the Therac-25 relied more on software for maintaining safety instead of the previously used hardware safety mechanism and interlocks, with the minicomputer controlling and monitoring the hardware

With how the system gained increased complexity, it is now possible to look at the Ontario case to see how issues with the interface and software existed due to increased complexity. On July 26, 1985, an operator activated the Therac-25 but received an error message displayed as “H-tilt,” with the system displaying a reading that no dose was given and treatment was paused (Leveson & Turner, 1993). Since the machine did not suspend, the operator repeatedly tried to give a radiation dose four more times. The patient received an estimated 13,000 to 17,000 dose of rads, where 1000 rads can be lethal.

In this case, it is important to notice just how many times the operator ran the procedure due to the “no dose” system display and the failure of the machine to be suspended. This suggests that due to the increased complexity of technology, the system display and interface were not able to properly and correctly display the information needed for the operator to understand what the machine had done. This is because an interface abstracts from the software, allowing users to interact with the software at a high level without having to know anything about the software. This abstraction from the complexity of all the software being run by the computer made the interface for the Therac-25 insufficient in communicating with the operator about the status and result of all the complex software control being run by the computer. This increased complexity allowed for the interface issues to exist. The failure of the machine being suspended also suggests that, because the technology had become so complex with so much software and moving parts, the software was not able to correctly handle all the different outcomes due to the complexity of the technology. This increased complexity of the technology allowed for the existence of problems, both in the software and with the interface, in the socio-technical system of the Therac-25, leading to radiation overdose.

Increased Skills and Knowledge to Maintain

The second characteristic of the system gained by the Therac-25 gaining momentum, increased skills and knowledge to maintain, allowed for software errors' continued existence, leading to more incidents of radiation overdose. There are 5 phases in the software development life cycle: planning, analysis, design, implementation, and maintenance, with the cycle continuing to flow in this order. Although it is commonly said that there is no such thing as perfect code, through performing maintenance on software, bugs and errors are fixed and the updated software is released. As the East Texas cancer center incident on March 21, 1986 shows, the increased skills and knowledge to maintain the Therac-25 led to a failure in the maintenance phase of the software development lifecycle, leading to the continued existence of software errors that caused radiation overdose.

On March 21, 1986, a patient underwent treatment from the Therac-25 at the East Texas cancer center (Leveson & Turner, 1993). There, after the experienced operator fixed a typo from entering the session data, the Therac-25 verified the parameters and displayed a message indicating that the rays were ready. After turning the beams on, the machine stopped and displayed a "Malfunction 54" error, indicating the dose delivered was too high or low, pausing the treatment. The operator continued treatment, but the patient got up from the machine after noticing something was wrong and was sent home by a physician. A physicist checked the calibration of the machine, and after confirmation that the specifications were all correct, the hospital continued to use the machine. The next day, AECL technicians were sent out but could not replicate the error message previously observed. After ruling out electric shock as the cause of the error since the grounding was fine, the Therac-25 at the hospital resumed operation a little over two weeks later.

In this case, there are two important details to take into account. One is that a hospital physicist checked only the calibration specifications before the hospital put the machine back into use. The second detail to take note of is that the AECL technicians were not able to reproduce the error the operator originally observed, and the machine was back in operation after the technicians ruled out electric shock and nothing else. Note that the machine was first checked by a physician, and not a professional whose job revolves around programming and software. Also note that, after the AECL technicians were not able to reproduce the error, they resorted to checking the grounding for electric shock and did not check any software. As previously stated, the Therac-25 relied more on software and less on hardware than its predecessors. This means that software is responsible for a large part of the operation of the machine. If more software is used, then the amount and complexity of the software will naturally increase to replace the function the hardware originally served. As a result, the amount of skills and knowledge to maintain the Therac-25 increases. Taking this design change into account, along with the fact that a hospital physician and two AECL technicians were not skilled enough to replicate the error or knowledgeable enough to check the software for the source of the error, all this suggests that, as a result of the increased skills and knowledge to maintain the technology, the software errors that caused incidents of radiation overdose continued to exist and be a problem.

Increased Bureaucracy

The final key characteristic the system gained due to the technology, the Therac-25, gaining momentum is increased bureaucracy. This characteristic is the root cause of the poor organizational procedures and responses by the FDA and AECL that are often analyzed. The organizations involved were able to make poor decisions that abided by the regulations and procedures that were established, being lulled into a false sense of security that their actions were correct in some capacity. The increase in bureaucracy was misplaced and misguided within the technological system, leading organizations to make the wrong decisions.

The first case of radiation overdose occurred on June 3, 1985, at the Kennestone Regional Oncology Center (Leveson & Turner, 1993). There, after a patient experienced a red-hot sensation during treatment and was sent home, she experienced symptoms of radiation burns. The staff, not believing it to be possible that the Therac-25 could burn patients, treated it as a symptom of the patient's cancer. It was estimated that she received up to seventy-five to one hundred times the intended dose of two hundred rads. The patient sued the hospital in October of the same year, with AECL being notified in the following month of November. AECL only filed an accident report with the FDA in April of the next year. The FDA declared the Therac-25 defective and asked for a Conformity Assessment Program (CAP) and proper renotification of Therac-25 users on May 2nd, 1986. Then, in February of 1987, the FDA informed the AECL to notify users that the Therac-25 should not be used for routine therapy.

It is important to note several details here. The first is that the FDA was not notified by AECL or the judicial system of the lawsuit filed due to the Therac-25. It then took several more months and incidents of radiation overdose before AECL finally filed an accident report with the FDA. Even then, the Therac-25 was not immediately shut down by the FDA or AECL. This suggests that the increased bureaucracy within the socio-technological system of the Therac-25 allowed the organizations involved - the hospitals, FDA, and AECL - to believe they were responding as they should due to the increased bureaucracy that led to the establishment of such flawed procedures. This belief is misplaced because the regulations and procedures established as a result of the increased bureaucracy of the system were erroneous to begin with, allowing for organizations to make such lacking responses throughout the life of the Therac-25.

As I have shown, the characteristic of increased bureaucracy of the system surrounding the Therac-25 allowed organizations to incorrectly believe that they were making the right responses and decisions throughout the Therac-25 incidents. Some might blame a lack of bureaucracy for AECL's poor response. For example, McQuaid concludes that the company was unwilling and unable to investigate patient injuries and deaths (McQuaid, 2010). While some could then conclude that the company was unwilling and unable to investigate the incidents due to a lack of bureaucracy, it should be noted that there were established regulations in place that were used by both the FDA and AECL. These organizations acted by such established regulations, not by an absence of regulations and bureaucracy. Reporting regulations for medical equipment required manufacturers and importers to report deaths, serious injuries, or malfunctions that could result in those consequences (Leveson & Turner, 1993). Not only that but in the nearly 9-month span between the AECL filing an accident report and the Therac-25 being shut down, the Therac-25 was still in use as the AECL and FDA went back and forth with requests to change the CAP submitted by the AECL and the revisions submitted as a result. This shows the AECL and FDA making poor organizational responses despite abiding by established regulations put in place as a result of the increased bureaucracy within the system.

Conclusion

As the Therac-25 gained momentum, it started to influence the practices and values of the society that once designed and shaped it. This happened through the system surrounding the Therac-25 gaining three key characteristics that led to the existence of the problems that caused 6 incidents of radiation overdose: increased complexity, skills and knowledge to maintain, and bureaucracy. The characteristics in action can be observed and analyzed through the individual cases of radiation overdose that occurred.

By understanding how the problems that caused 6 incidents of radiation overdose developed and came to exist, we can prevent such problems from existing in other domains and prevent such incidents from happening. It is important for engineers to know not just how these problems caused such a devastating incident, but why these problems came to be. With this understanding, engineers can work to prevent other socio-technical systems from developing the same problems from existing again, avoiding incidents like the Therac-25 radiation overdose cases from happening again.

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