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Therac-25

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1. It was concluded that the root of the problems arose from bad software design and development practice. The therac-25 was different from the therac-6 because it was a dual machine that worked in both x-ray and electron modes as to the 6 that only did x-ray. It was also different from the therac-20 because it relied a lot more on software for error analysis where the 20 relies on mechanical interlocks for monitoring. One specific problem with the software was that it used software from the other models which was bad because those had hardware interlocks for safety and this one didn’t. Also there was an error in the flagging process sometimes causing an arithmetic overflow which caused the software to avoid safety checks.
2. At first there was no reporting system and the AECL did not even know about the first incident until they were greeted with a lawsuit from the patient and then they filed an incident report to the FDA. After the first incident it was not clarified what the reporting system was. The general procedure was that after an incident at the hospital; the hospital would contact the AECL and let them know and then they would officially report the incident to the FDA. The only way users found out about these problems was talking to other users. The company did not let users know of the harms to other patients even though they did sometimes let them know about the errors within the machine.
3. The article states that the device was used tens of thousands of times before the first incident even occurred and the previous model the Therac-20 had no incidents at all. There were six accidents within a three year span using the Therac-25. There were countless amounts of successes because even the day after an accident the machine would be used again for other patients without problem. Even though the ratio of failures to successes is extremely low, that is still six people being hurt from radiation within a short three year span. With that being said, it was very necessary to take action on this issue because the machine would have kept malfunctioning the way it was and potentially cause the death of two people every year. This should be avoided at all costs especially if the problem could be fixed.
4. From the article, I observed that the company reacted to issues promptly. Whenever they were contacted by a hospital; a technician or engineer was sent to check the machine right away. They were also in constant contact with the FDA and let them know of any issues and filed all the necessary incident reports when they found out about them. Yes, they did communicate in a timely fashion and were professional about their faulty product.
5. The AECL saw no fault in their product. They did not think that it was their fault at all and believed their machine and software was created correctly. The assumed that the software was 100% OK and then after their testing came to the conclusion that the software could not have been the cause for the over treatment of patients even though it became obvious that the software was the issue. It seemed from the article that the company was trying to avoid a major overhaul to the software as much as they could. They were obviously a bit lazy when coming to the software due to the fact that they just reused older software from the previous versions.
6. Something that needs to be changed is that every single aspect of a machine should be tested thoroughly and not just the machine as a whole. The addition of a mandatory software review/revision is something that is also very necessary. Above all the most important thing would be to make sure that the practices of making a new device are organized and professional. And as people we need to realize that there can be a fault in a machine’s software or the machine itself. We have an idea in our heads that this stuff always works flawlessly.
7. Ethically the consumers (the users) need to be more informed and find the information necessary to make sure what they are using is safe and not just believe everything they hear sometimes. Also companies need to abandon the “good enough” mentality and make the best quality product they can. This “good enough” mentality appeared when they just used previous software on the Therac-25 instead of being innovative and making the best they could from scratch. Agencies like the FDA just need to make sure that they are not taking it easy at all on these companies. Make the companies go through near impossible tests just to make sure their product is completely safe and monitor them even after it has been approved. With these changes issues like this shouldn’t resurface.