Random Fact 7.2

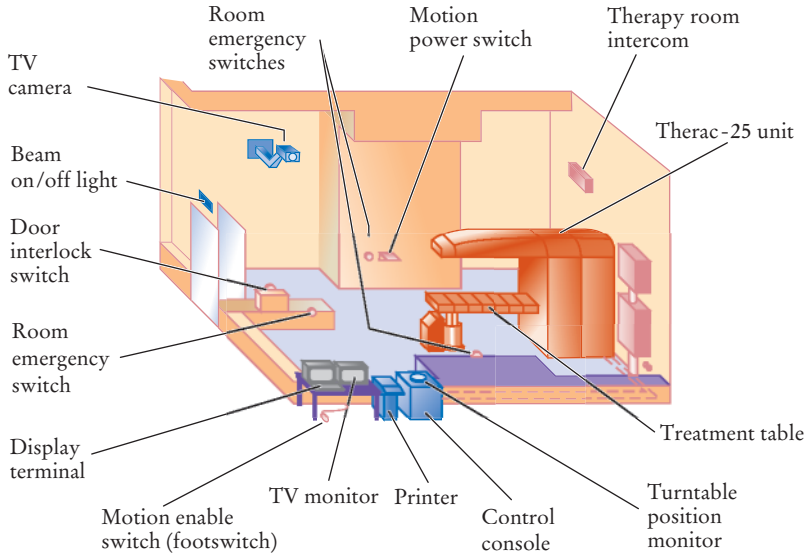
The Therac-25 Incidents

The Therac-25 is a computerized device to deliver radiation treatment to cancer patients (see the figure). Between June 1985 and January 1987, several of these machines delivered serious overdoses to at least six patients, killing some of them and seriously maiming the others.

The machines were controlled by a computer program. Bugs in the program were directly responsible for the overdoses. According to Leveson and Turner ("An Investigation of the Therac-25 Accidents," *IEEE Computer*, July 1993, pp. 18–41), the program was written by a single programmer, who had since left the manufacturing company producing the device and could not be located. None of the company employees interviewed could say anything about the educational level or qualifications of the programmer.

The investigation by the federal Food and Drug Administration (FDA) found that the program was poorly documented and that there was neither a specification document nor a formal test plan. (This should make you think. Do you have a formal test plan for your programs?)

The overdoses were caused by an amateurish design of the software that had to control different devices concurrently, namely the keyboard, the display, the printer, and of course the radiation device itself. Synchronization and data sharing between the tasks were done in an ad hoc way, even though safe multitasking techniques were known at the time. Had the programmer enjoyed a formal education that involved these techniques, or taken the effort to study the literature, a safer machine could have been built. Such a machine would have probably involved a commercial multitasking system, which might have required a more expensive computer.



Typical Therac-25 Facility

The same flaws were present in the software controlling the predecessor model, the Therac-20, but that machine had hardware interlocks that mechanically prevented overdoses. The hardware safety devices were removed in the Therac-25 and replaced by checks in the software, presumably to save cost.

Frank Houston of the FDA wrote in 1985: “A significant amount of software for life-critical systems comes from small firms, especially in the medical device industry; firms that fit the profile of those resistant to or uninformed of the principles of either system safety or software engineering”.

Who is to blame? The programmer? The manager who not only failed to ensure that the programmer was up to the task but also didn’t insist on comprehensive testing? The hospitals that installed the device, or the FDA, for not reviewing the design process? Unfortunately, even today there are no firm standards of what constitutes a safe software design process.