

Integrating distinct roles into the same entity led to the Therac-25 accidents. Making the AECL responsible for both production and safety auditing resulted in unacceptable risks. Similarly, the combination of both electron beam and X-ray treatment units into one system led to dramatic reductions in safety. This accumulation of different roles is the antithesis of hierarchical design.

Users and regulators depended on the AECL to ensure that the Therac-25 was reasonably safe, but the AECL failed to do so. The AECL's profit motive created a direct conflict of interest that compelled them to push safety concerns onto the back burner. In addition, developers were unlikely to detect errors in design, implementation or methodology when reviewing their own work. One solution for future products is to have an independent agent that certifies products as being reasonably safe. These auditors act much like insurance companies (such as Underwriter Laboratories) in assuming liability for major product defects that would have been prevented had reasonable safety and quality controls been in place. The FDA could encourage these contracts by offering fast track approval for certified products.

Certification impedes feature creep and untestable designs by placing a financial cost on system complexity and testability. Manufacturers lie about or ignore safety issues because it is in their financial interest to do so. Insurers have no such conflict and have significant experience in assessing and managing complex risks. Customers can rely on the certification in making decisions, thereby transferring risk. This system can fail when auditors and manufacturers collude together or are not sufficiently independent.

Integrating the X-ray and electron beam devices into one unit created many new failure modes. Either unit by itself was complex enough to build safely given the skills and experience the AECL had at the time. Combining them required new hardware (the turntable) and software systems to arbitrate between the different modes of operation. These new components proved to be fertile ground for subtle logic and consistency bugs.

Separating the different treatment mechanisms into two completely isolated machines would dramatically reduce system complexity, and, consequently, risk. The turntable along with its attendant failure modes disappear and the software becomes simpler. Two isolated systems are still vulnerable to software errors that can affect dosing, but it is no longer possible to expose a patient to more radiation than can pass through the beam flattener.

The AECL's ability to endanger the lives of patients stemmed directly from its ability to keep secrets. Had their clients and regulators known about the AECL's development process or the concurrent accidents with the Therac-25, they would not have continued using it. In fact, the situation only improved when all the parties met together and shared their information. In a similar fashion, a combined electron beam and X-ray treatment machine was too complex for the AECL to implement safely. Though the cause of the failures differ, the solution remains the same.