

Therac-25: Will history repeat itself?

Ash Tyndall

October 8, 2014

Table of Contents

Measuring Software-Related Failure

Bibliography

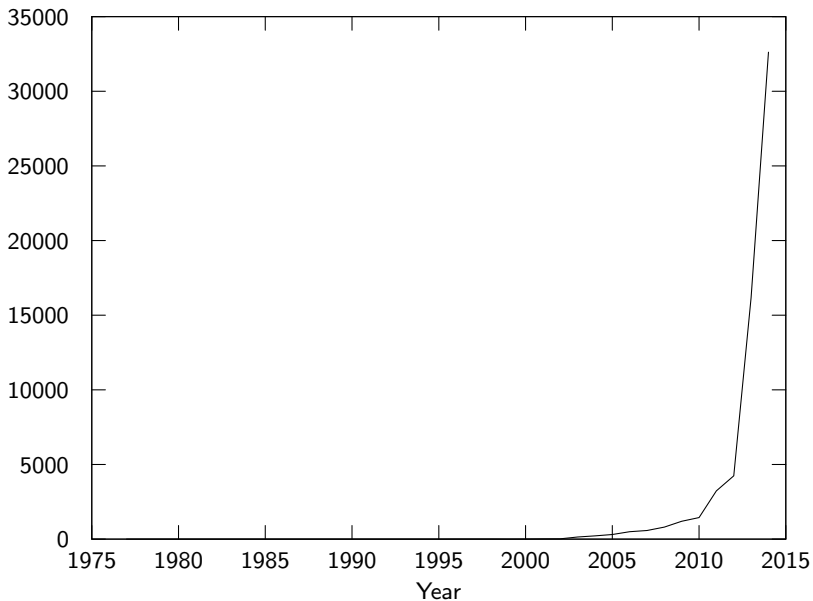
Example Adverse Event Categories

- ▶ Failure to run on AC/DC
- ▶ Abnormal
- ▶ Absorption
- ▶ Accessory incompatible
- ▶ Measurements, inaccurate
- ▶ Adaptor, failure of
- ▶ Agglutinate, failure to
- ▶ Automatic injection system overinfusion
- ▶ Failure to back-up
- ▶ Failure to convert to back-up
- ▶ Balloon rupture
- ▶ Balloon asymmetrical
- ▶ Balloon burst
- ▶ Contamination during use
- ▶ Intermittent continuity
- ▶ Continuous
- ▶ Cooling system, failure of
- ▶ Insufficient cooling
- ▶ Display misread
- ▶ Erratic display
- ▶ No display or display failure
- ▶ Incorrect display
- ▶ Disposable
- ▶ Dissection
- ▶ Distilled water, contaminated
- ▶ Dome collapse
- ▶ Rupture due to trauma
- ▶ Saline, use of homemade
- ▶ Salt tablet(s), use of
- ▶ Seal, incorrect
- ▶ Sediment filter problems
- ▶ Self-activation or keying
- ▶ Sensing intermittently
- ▶ Transducer failure
- ▶ Transmitter failure
- ▶ Trocar/instrument incompatibility
- ▶ Tube(s), exploding of
- ▶ Tubing, incorrect placement of
- ▶ Twisting
- ▶ Ultrafiltration
- ▶ Ultraviolet
- ▶ Ultraviolet absorbing
- ▶ Uncoiled
- ▶ Undercorrection
- ▶ Warning light, incorrect
- ▶ Water softener process, failure of
- ▶ Water treatment
- ▶ Wedge filter problem
- ▶ Wedge, difficult to
- ▶ Screw head(s), incorrect
- ▶ Metal shedding debris
- ▶ Electrical wires, defective
- ▶ Water softener regeneration cycle, mistiming of
- ▶ Temperature probe, loose
- ▶ Bubble detector, failure of
- ▶ Valve(s), defective
- ▶ Tube(s), defective
- ▶ Air eliminator, defective
- ▶ Seal, defective
- ▶ Cable, defective
- ▶ Underdelivery
- ▶ Electro-magnetic interference (EMI), compatibility/incompatibility
- ▶ Tube(s), buckling

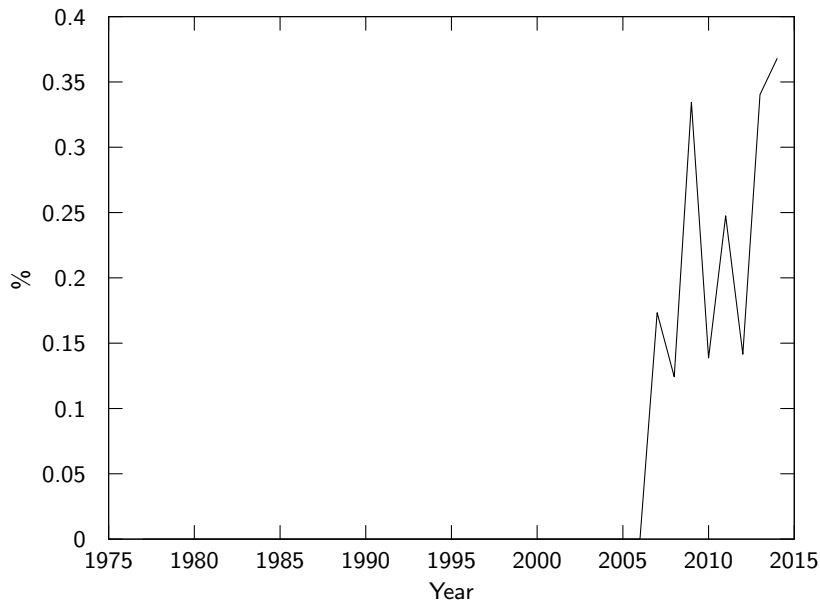
Adverse Events that are “Computer Related”

- ▶ Computer failure
- ▶ Computer hardware error
- ▶ Computer software issue
- ▶ Incorrect display
- ▶ Error or warning message, failure to produce
- ▶ Power calculation error due to software problem
- ▶ Incorrect software programming calculations
- ▶ Algorithms, inconsistent
- ▶ Semiautomatic code, failure to override
- ▶ Year 2000 (Y2K) related problem
- ▶ Date-related software issue
- ▶ Application network issue
- ▶ Application program issue
- ▶ Application program version or upgrade problem
- ▶ Application security issue
- ▶ Computer operating system issue
- ▶ Computer system security issue
- ▶ Data back-up problem
- ▶ Loss of Data
- ▶ Operating system becomes non-functional
- ▶ Operating system version or upgrade problem
- ▶ Problem with software installation
- ▶ Programming issue

Number of “Adverse Events”



Percentage of "Computer Related" Adverse Events



Bibliography I



BESNARD, D., BAXTER, G., ET AL.

Human compensations for undependable systems.



BROWN, S.

Overview of iec 61508. design of electrical/electronic/programmable electronic safety-related systems.
Computing & Control Engineering Journal 11, 1 (2000), 6–12.



BURTON, J., MCCAFFERY, F., AND RICHARDSON, I.

A risk management capability model for use in medical device companies.
In *Proceedings of the 2006 international workshop on Software quality* (2006), ACM, pp. 3–8.



CATAL, C.

Software fault prediction: A literature review and current trends.
Expert systems with applications 38, 4 (2011), 4626–4636.



DERREUMAUX, S., ETARD, C., HUET, C., TROMPIER, F., CLAIRAND, I., BOTTOLIER-DEPOIS, J.-F.,
AUBERT, B., AND GOURMELON, P.
Lessons from recent accidents in radiation therapy in france.
Radiation protection dosimetry (2008).



DUNN, W. R.

Designing safety-critical computer systems.
Computer 36, 11 (2003), 40–46.



ISRAELSKI, E. W., AND MUTO, W. H.

Human factors risk management as a way to improve medical device safety: a case study of the therac 25 radiation therapy system.
Joint Commission Journal on Quality and Patient Safety 30, 12 (2004), 689–695.

Bibliography II



JACKY, J.

Safety-critical computing: hazards, practices, standards, and regulation.

In *Computerization and controversy* (1991), Academic Press Professional, Inc., pp. 612–631.



JOHNSON, C.

Forensic software engineering: are software failures symptomatic of systemic problems?

Safety science 40, 9 (2002), 835–847.



JOHNSON, C.

Failure in Safety-Critical Systems: A Handbook of Accident and Incident Reporting.

University of Glasgow Press, 2003.



JORDAN, P.

Standard IEC 62304—medical device software—software lifecycle processes.

In *Software for Medical Devices, 2006. The Institution of Engineering and Technology Seminar on* (2006), IET, pp. 41–47.



KOPEC, D., AND TAMANG, S.

Failures in complex systems: case studies, causes, and possible remedies.

ACM SIGCSE Bulletin 39, 2 (2007), 180–184.



KRAMER, A.

Automotive and medical: can we learn from each other?

Journal of Software: Evolution and Process 25, 4 (2013), 373–379.



LEVESON, N.

SafeWare: System Safety and Computers.

Computer Science and Electrical Engineering Series. Addison-Wesley, 1995.

Bibliography III



LEVESON, N. G., AND TURNER, C. S.

An investigation of the Therac-25 accidents.

Computer 26, 7 (1993), 18–41.



LIN, L., VICENTE, K. J., AND DOYLE, D. J.

Patient safety, potential adverse drug events, and medical device design: a human factors engineering approach.

Journal of biomedical informatics 34, 4 (2001), 274–284.



MC CAFFERY, F., CASEY, V., SIVAKUMAR, M., COLEMAN, G., DONNELLY, P., AND BURTON, J.

Medical device software traceability.

In *Software and Systems Traceability*. Springer, 2012, pp. 321–339.



McHUGH, M., McCAFFERY, F., AND CASEY, V.

Barriers to adopting agile practices when developing medical device software.

In *Software Process Improvement and Capability Determination*. Springer, 2012, pp. 141–147.



NOLAN, T. W.

System changes to improve patient safety.

BMJ: British Medical Journal 320, 7237 (2000), 771.



OBRADOVICH, J. H., AND WOODS, D. D.

Users as designers: How people cope with poor hci design in computer-based medical devices.

Human Factors: The Journal of the Human Factors and Ergonomics Society 38, 4 (1996), 574–592.



RAKITIN, R.

Coping with defective software in medical devices.

Computer 39, 4 (2006), 40–45.

Bibliography IV



UNITED STATES OF AMERICA FOOD AND DRUG ADMINISTRATION.

Transcript of public meeting - device improvements to reduce the number of under-doses, over-doses, and misaligned exposures from therapeutic radiation, June 2010.

Accessed: 2014-09-21, URL:

<http://www.fda.gov/downloads/medicaldevices/newsevents/workshopsconferences/ucm224586.pdf>.



WALLACE, D. R., AND KUHN, D. R.

Lessons from 342 medical device failures.

In *High-Assurance Systems Engineering, 1999. Proceedings. 4th IEEE International Symposium on* (1999), IEEE, pp. 123–131.



WALLACE, D. R., AND KUHN, D. R.

Failure modes in medical device software: an analysis of 15 years of recall data.

International Journal of Reliability, Quality and Safety Engineering 8, 04 (2001), 351–371.



ZHIVICH, M., AND CUNNINGHAM, R. K.

The real cost of software errors.