

## List of Resources for Privacy laws, FDA Regulations, and Evaluation pertaining to software

Overview of the Privacy Act of 1974, (2015 Ed.) < <http://www.justice.gov/opcl/overview-privacy-act-1974-2015-edition> >

Therac-25 < <https://en.wikipedia.org/wiki/Therac-25> >

Proprietary software puts pacemaker users at risk < [http://www.theregister.co.uk/2010/07/27/buggy\\_pacemaker\\_code/](http://www.theregister.co.uk/2010/07/27/buggy_pacemaker_code/) >

MAUDE Adverse Event Report: MEDICAL INFORMATION TECHNOLOGY, INC. MEDITECH BLOOD BANK

SOFTWARE < [http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi\\_id=2379545](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=2379545) >

Inspections, Compliance, Enforcement, and Criminal

Investigations < <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm376296.htm> >

General Principles of Software

Validation < <http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm085281.htm> >

ISO 9000 < [http://www.iso.org/iso/home/standards/management-standards/iso\\_9000.htm](http://www.iso.org/iso/home/standards/management-standards/iso_9000.htm) >