

# Medical Devices

- **Risk Management**
- **Standards**
- **Design Controls**

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# Risk Management

- **Mandated by regulatory agencies (FDA, CE)**
- **Standards based**
  - ISO 14971 (previously IEC 513, EN 1441, IEC 601 series, including -2; -1-4)
  - Rigorous - specific risk analysis methods are needed to achieve the end goals (i.e.; design controls)
- **Focused on the safety risk to operator, patient, bystander, but particularly patient**
  - *Not* reliability, project or operational risk

# Risk Process

- **Risk analysis**
  - Use, hazard identification, risk estimation
  - Errors – Systemic, Random, User-initiated
    - User Interface Studies
- **Risk evaluation**
  - Risk acceptability assessment.
- **Risk control / monitoring**
  - Implement risk controls
  - Residual risk evaluation
  - Monitor and control changes

# Risk Definitions

**Risk = Probability \* Severity**

- the probability of occurrence of harm
- the consequences of that harm
- **Quantitative / Qualitative metrics**
- **Not acceptable** – risk must be reduced
- **ALARP** – As Low As Reasonably Practicable - risk has been reduced to the lowest level practicable, considering cost / benefit ratio of further mitigation
- **Broadly acceptable** – no further risk reduction is necessary

# Risk Management

	Likelihood of Hazard Occurrence after Risk Control Measures				
Severity/ Probability	Frequent (1)	Probable (2)	Occasional (3)	Remote (4)	Improbable (5)
Major	Not Acceptable	Not Acceptable	Not Acceptable	ALARP	ALARP
Moderate	Not Acceptable	Not Acceptable	ALARP	ALARP	Broadly Acceptable
Minor	Not Acceptable	ALARP	ALARP	Broadly Acceptable	Broadly Acceptable

# Risk Assessment Techniques

**Fault- tree analysis** – safety oriented / top down

Hazard → Possible causes

Graphical, logical, failure paths - events and consequences

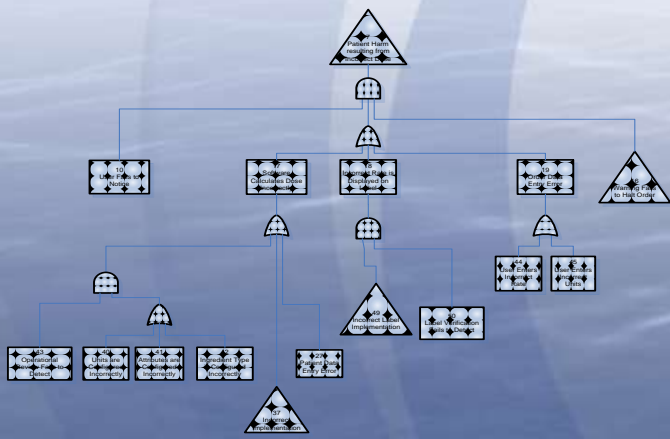
**Failure Mode and Effects Analysis (FMEA)**

Reliability based / bottom up

All causes → Possible hazards?

**Failure Mode, Effects, and Criticality Analysis (FMECA)**

If safety criticality is added, Safety FMECA



Failure Modes and Effect Criticality Analysis						
Subsystem: _____		Prepared by: _____		Date: _____		
Item	Failure Modes	Cause of Failure	Possible Effects	Probability	Criticality	Mitigation (prevention or detection)
Disk	Lack of data Integrity	1. Static electricity 2. Defective materials 3. Poor workmanship 4. Damage during handling and/or shipping	Incorrect result	0.0013	Critical	To be determined...