



**BME 590: FUNDAMENTALS OF
ENGINEERING DESIGN**

SAFETY AND HAZARDS

Salinas

SAFETY & HAZARD CONCERNS

Devices should work without failure. Two types of failure:

1. Device doesn't meet the needs of client
2. Device or component fails



DEVICE FAILURE:

Sorin Mitroflow
bioprosthetic valves
have shown rapid
deterioration in the
body.

Earlier than normal
blockage in the valve
causes severe
problems and even
death.



SAFETY ASSESSMENT AND EVALUATION OF:



**PHYSICAL
HAZARDS**

FAULT HAZARDS

**OPERATIONAL
HAZARDS**

**EXPECTED USE
AND
FORESEEABLE
MISUSE**

FAILURE MODES EFFECT ANALYSIS

PHYSICAL HAZARDS

LIST OF TYPICAL PHYSICAL HAZARDS

PHYSICAL HAZARDS INCLUDE (BUT ARE NOT LIMITED TO):

- ELECTRICITY (SHOCK)
- SHARPNESS (CUTS)
- PIECES (CHOKING)
- TEMPERATURE (HOT AND COLD)
- STABILITY (TIPPING)
- SOUNDS (INTENSITY)
- LIGHT (INTENSITY)

FAULT HAZARDS

LIST OF TYPICAL FAULT HAZARDS

FAULT HAZARDS INCLUDE (BUT ARE NOT LIMITED TO):

- BUTTONS, SWITCHES, CONNECTERS
- BAD SOLDER JOINT
- FASTENER FAILURE
- COMPONENT FAILURE
- MATERIAL DETERIORATION (LEACHING)
- FATIGUE
- LOGIC ERROR
- PROGRAMMING BUG

OPERATIONAL ERROR

MAKE DESIGN EASIER FOR USER
INTERFACE



**MAKE USE
OBVIOUS**



**MAKE DEVICE WORK
AS EXPECTED**



**ELIMINATE
"UNNECESSARY"
FEATURES**



**MINIMIZE
CONSEQUENCES OF
USER ERROR**

EXPECTED USE AND FORESEEABLE MISUSE

EVALUATE DESIGN FOR USE



**EVALUATE
DESIGNS/PROTOTYPES
WITH USERS
UNFAMILIAR TO THE
PRODUCT**



**BRAINSTORM WAYS
THE DEVICE COULD BE
MISUSED:**

- UNINTENDED ENVIRONMENT
- UNINTENDED APPLICATION
- USED BY CHILDREN/COGNITIVELY IMPAIRED ADULT
- USED BY UNTRAINED PROFESSIONAL
- USED BY NON-ENGLISH SPEAKER

GOALS

ULTIMATE NEEDS FOR DEVICE



**EFFECTIVE,
INTUITIVE DEVICE
THAT MEETS
CLIENT'S NEEDS
OVER THE LIFETIME
INTENDED**



**EVALUATED
COMPONENTS AND
IDENTIFIED 'WEAK
LINKS'**



**PROVIDE GOOD
DOCUMENTATION
AND USER MANUALS**

RISK ASSESSMENT



1

Hazards
Identification

2

Risk
Evaluation

3

Risk
Control

4

Residual Risk
Definition

5

Report and
Statistics



- Hazard category
- Foreseeable sequence of events
- Hazardous situation
- Harm

- Severity
- Likelihood
- Risk level

- CAPA
- Control Measures
- Re-evaluation

- Benefits
- Immediate recipients
- Means to be used

- Review
- Summary
- Chart

FREQUENCY OF OCCURRENCE

Occurrence	Details
Likely	Likely to occur often
Probable	Will occur several times in the lifetime of the device
Occasional	Likely to occur sometime in the lifetime of the device
Remote	Unlikely to occur, but possible
Improbable	Probability of occurrence highly unlikely
Incredible	Probability of occurrence is zero

CONSEQUENCE QUANTIFICATION

Severity	Details
Catastrophic	Failure would result in death or serious injuries
Critical	Failure would result in serious injury
Marginal	Failure would result in Non-serious injury
Negligible	Failure would cause no injury

RISK PREDICTION

Occurrence	Severity of Consequence			
	Negligible	Marginal	Critical	Catastrophic
Likely	II	I	I	I
Probable	III	II	I	I
Occasional	III	III	II	I
Remote	IV	III	III	II
Improbable	IV	IV	III	III
Incredible	IV	IV	IV	IV

I	Intolerable risk	III	Tolerable risk
II	Undesirable risk	IV	Negligible risk

REDESIGN

ITERATE THROUGH UNTIL DESIGN IS
FREE OF HAZARDS



REDESIGN



GUARD (PROTECTION FROM MISUSE)

- PHYSICAL
- SOFTWARE
- LOCKOUTS
- BACKUPS



WARN

YOUR GOAL:

- 1. Revisit Client Needs and SPG and Design specs docs**
- 2. Create Hazard doc**

Overview of the ISO14971 » Risk Assessment Tools » **FMEA**

HAZARD IDENTIFICATION

No	Identified Hazard	Hazardous situation	Hazard Type	Circumstance	Harm
1	Allergic reaction	Prolonged contact	Known	Abnormal	Clinical complications
2	Bleeding	Poor design/placement	Foreseeable	Abnormal	Blood loss
3	Artery blockage	Poor design/placement	Foreseeable	Abnormal	Heart attack
4	Infection	Inadequate product & procedural sterility	Foreseeable	Abnormal	Death
5	Restenosis	Injury/poor design or placement	Known	Normal	High blood pressure/heart attack
6	Material toxicity	Inappropriate material	Foreseeable	Abnormal	Clinical complications
7	Foreign body reaction	Inappropriate material/immune system	Known	Normal	Clinical complications
8	Degradation residue	Inappropriate material	Foreseeable	Normal	Clinical complications