

Medical Device Risk Management

Strategies for Product Liability

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Overview

- Some Working Definitions
- Product Liability /Risk Management Alignment
- Overview of RM components

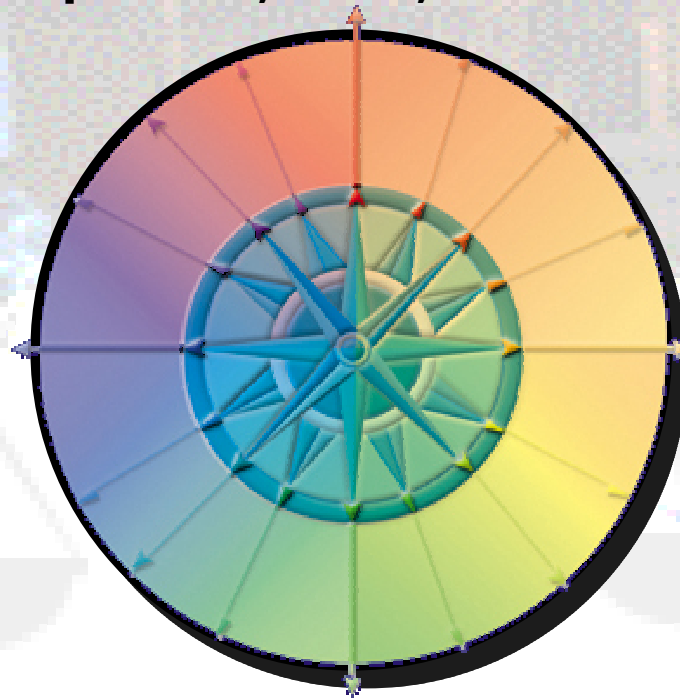
Areas of Risk

**Risk to safety of
patients, users, handlers**

Business

Regulatory

Product liability



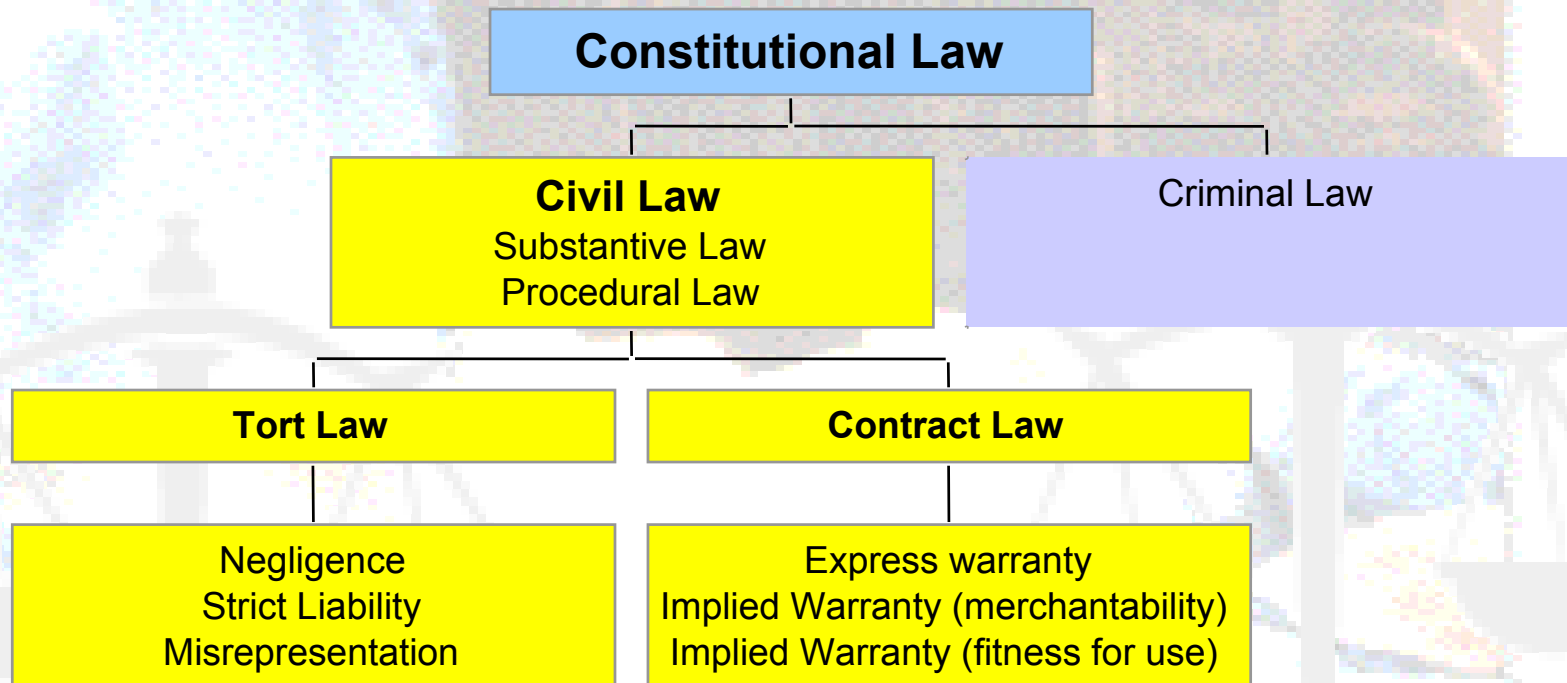
Definitions

- **Harm**: physical injury/damage to the health of people or to property and environment.
- **Hazard**: potential source of harm
- **Risk**: combination of the probability of occurrence of harm and the severity of that harm
- **Minimal Risk**: 21 CFR 50: the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during routine physical or psychological exam or test.
- **Risk management**: systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating and controlling risk.

Definitions

- Product liability: the liability of any or all parties along the chain of manufacture/distribution of any product for damage caused by the product:
 - Component manufacturers
 - Assembling manufacturer
 - Wholesaler
 - Distributor
 - Retail store owner (in OTC and non-medical products)

Law systems



Why Is Product Liability a Serious Issue?

- They generate more \$1-million plus verdicts than any other type of personal injury suits except malpractice.
- 29% of all verdicts are returned with judgments of \$1 million or more.
- Defendants lose 56% of all cases which go to trial.



Basis of Liability Cases

- Product Defects
 - Design defects
 - Manufacturing defects
 - Warning defects
- Other Theories of liability include:
 - Negligence (focus in on the conduct of the manufacturer)
 - Strict Liability (even if the best care has been exercised)
 - Breach of Warranty (express or implied) (based on UCC)
 - Misrepresentation (may be considered the product defect)

Design

- Design defects as a theory of liability-
“conscious” defects
- Defective in design:
 - Foreseeable risks
 - Could have been reduced or avoided
 - Omission of reasonable, alternative design
 - Risk analysis of alternate designs (clause 6.2)
 - *“The designer shall identify risk control measures that are appropriate for reducing risks to an acceptable level”.*

Design

- Design Control Issues: Likely to favor plaintiffs
 - Easy to pick it apart and find some flaw
 - For IVD - need to prove misdiagnoses was result of inherently imperfect sensitivity and specificity rather than a flaw in design controls

Risk vs. Benefit

- Risk/Benefit (Clause 6.5):
 - Risk Utility Test
 - Not reasonably safe if the foreseeable risks of harm are sufficiently great in relation to the foreseeable therapeutic benefits
 - Pharmaceutical implication: strict liability for design defects applies only if there is no therapeutic effect for **any** class of patient

Duty to Warn

- Duty to warn (labeling) (Clause 6.2):
 - Extends to all reasonably foreseeable risks of use *and* misuse
 - May also extend to storage and handling/clean up of spills and disposal of product.
 - Liability exists if you *fail* to warn or *inadequately* warn
 - Covers warning of the specific risk and providing instructions for use that describe how to avoid the risk or help otherwise mitigate the risk
 - *Guidance on information for safety covered in annex J of revised draft of standard.*

Duty To Warn

- Purpose of warning is to compel the user to behave so as to avoid injury
- What a plaintiff must prove
 - Duty
 - None or inadequate warning
 - Injury occurred
- Adequacy of warning (conspicuousness, position on label/insert, specificity of risk, intensity of language):
 - Noticeable
 - Comprehensible
 - Degree of intensity
 - Commensurate with risk
 - Undiluted/noticeable

Duty to Warn

- Product may be adequately designed and manufactured but will pose a risk in the absence of a warning or – risk communication.
- Duty may be defined as such: a reasonable person would want to be warned.
- MDR's can be admissible and plaintiff's attorney can argue for admissibility.
 - Can be used to show that manufacturer knew of certain risks and had a duty to warn.

Duty to Warn

- Manufacturer needs to be expert in the field (clause 3.3 *Qualification of Personnel*)
- Learned intermediary theory
 - Reasonably foreseeable uses of the product
 - Direct to consumer advertisement
 - Ultimately liable to the patient
 - If warning to the intermediary is inadequate or misleading- liability remains

Duty to Warn

- Duty to warn (Clause 6.2):
 - Consciously disregarding a danger.
 - Remedies:
 - Punitive damages:
 - If a manufacturer knew of defects or risks and failed to act or concealed them
 - Manufacturer must anticipate the environment in which a product will be used (thorough hazard analysis).
 - Remote risks (assessing frequency).

Post Sale Duty to Warn

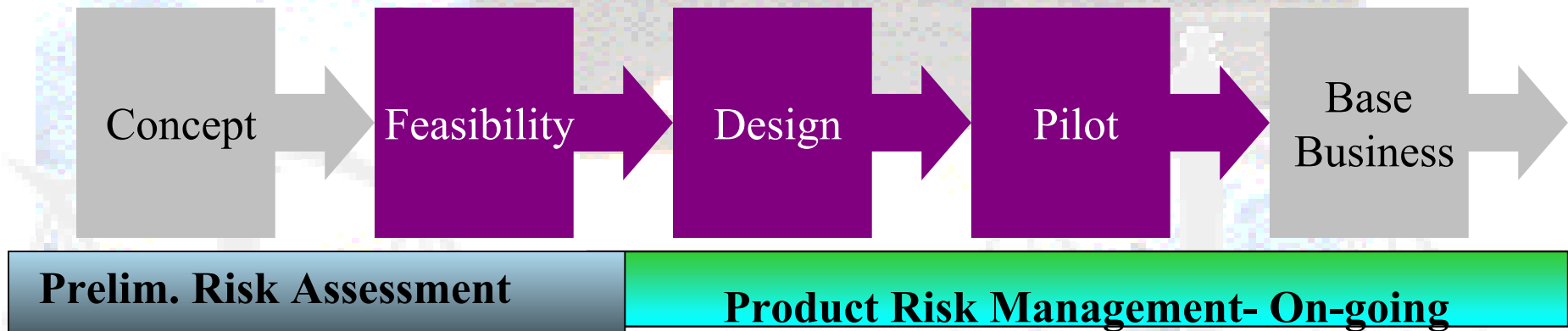
- Post sale duty to warn (Clause 9).
 - Those latent risks that become evident after distribution (closed loop risk management).
 - Includes a duty to monitor changes in technology
 - Product complaints and post production risk monitoring.
- May not need to warn if a danger is obvious or commonly known by the general public.
- Manufacturer knew or should have known about the risk.

Risk Communication(Annex J)

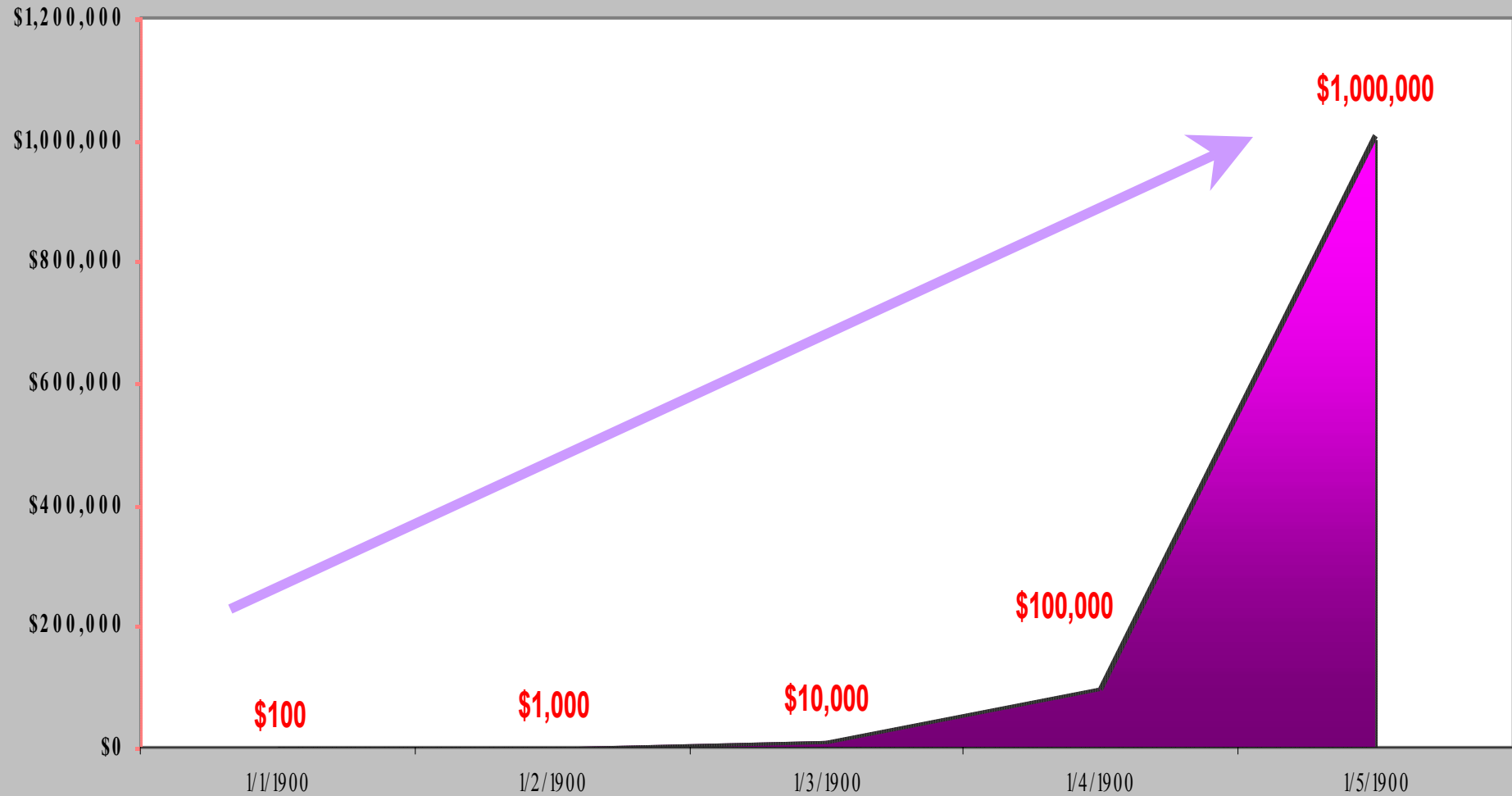
- Is the least preferred method of risk control.
- Allows users to proactively take measures to minimize exposure to residual or overall residual risk.
- Both content and format of communication needs to be taken into consideration.

Product Development Phases

(MEDICAL DEVICES)



Cost of Change



	Concept	Feasability	Dasign	Pilot	Base Buisness
Cost of Change	\$100	\$1,000	\$10,000	\$100,000	\$1,000,000

ISO 14971 Process Overview

➤ Risk Analysis

- o determining user needs / intended uses
- o hazard identification
- o risk estimation

➤ Risk Evaluation

- o risk acceptability decisions

➤ Risk Control

- o option analysis
- o implementation
- o residual risk evaluation
- o overall risk acceptance

➤ Post Production

- o post production experience
- o review of risk management experience

Risk Assessment

Risk Management

Critical Components ISO 14971

- Management responsibility
 - Risk acceptance policies/periodic reviews
- Qualification of personnel
 - Record of qualifications
- Risk management plan
 - Roadmap of RM (criteria for risk acceptance- before the analysis occurs)
- Risk management file
 - Where is the documentation
- Risk Evaluation
 - Risk acceptability decisions
- Risk Control
 - Risk reduction (eliminate, protect against, warn about)

Critical Components ISO 14971

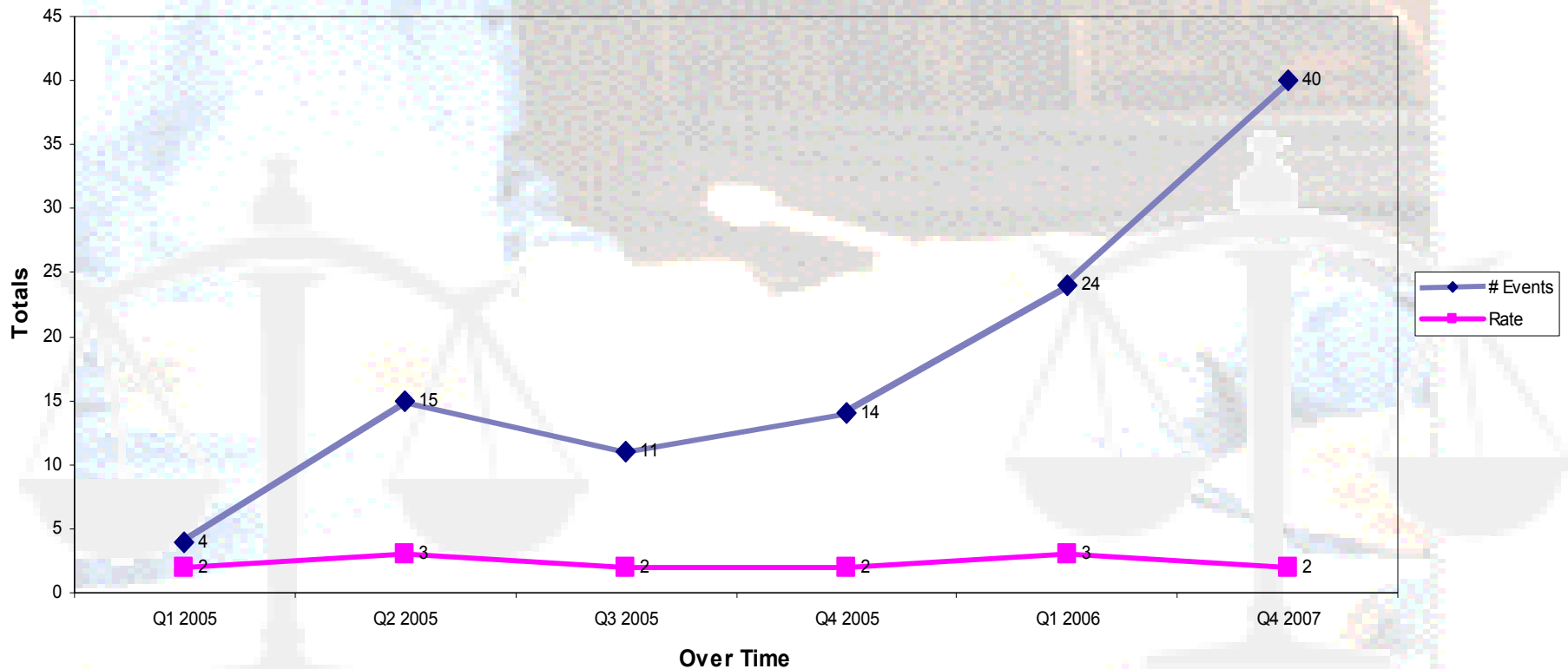
- Options analysis
 - Inherent safety by design
 - Protective measures in the product or in the process
 - Safety information (warning)
- Risk/benefit analysis
 - If the risk is greater than would be generally acceptable, the benefit must outweigh this risk-
- Overall residual risk
 - Combined impact of all risk for the product
- Risk Management Report
 - A summary of what was done- pointers to portions of the file
 - High level document/overview
- Post Production Information
 - Unanticipated risks
 - Under-anticipated risks

Risk Acceptance Policy

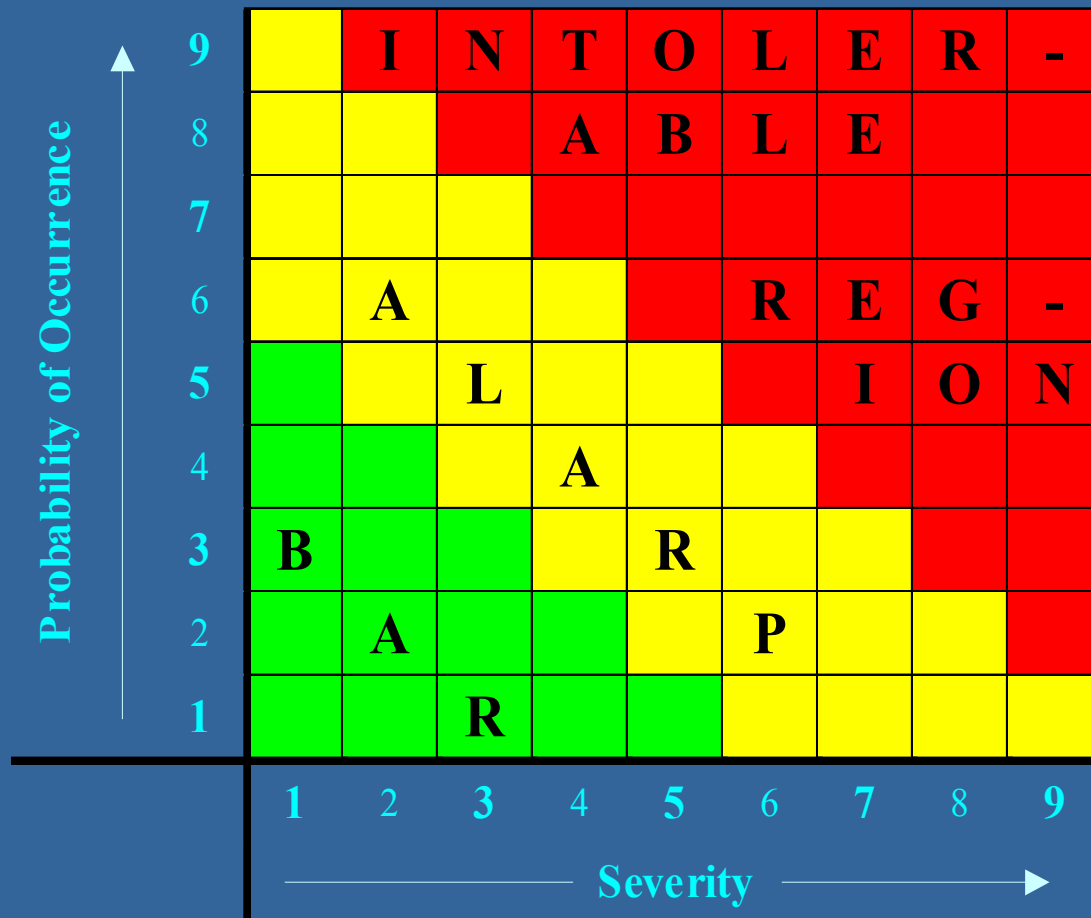
- Top Management shall document the policy for determining criteria for risk acceptability (Clause 3.2).
 - Stakeholder perception of acceptable risk
 - Comparison to similar devices
 - Acceptability may change over time
- Risk Management should be a part of the management review process.
- Go beyond the risk level approach.

Rate vs. Volume

Rate vs Volume of Events



Risk Concept According to ISO 14971



- **Intolerable Region**
- **As Low As Reasonably Practicable Region (ALARP)**
- **Broadly Acceptable Region (BAR)**

Thank You!

Questions

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