Risk

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Risk

- What?
- Why?
- When?
- Where?
- How?
- What do I do?

What is Risk?

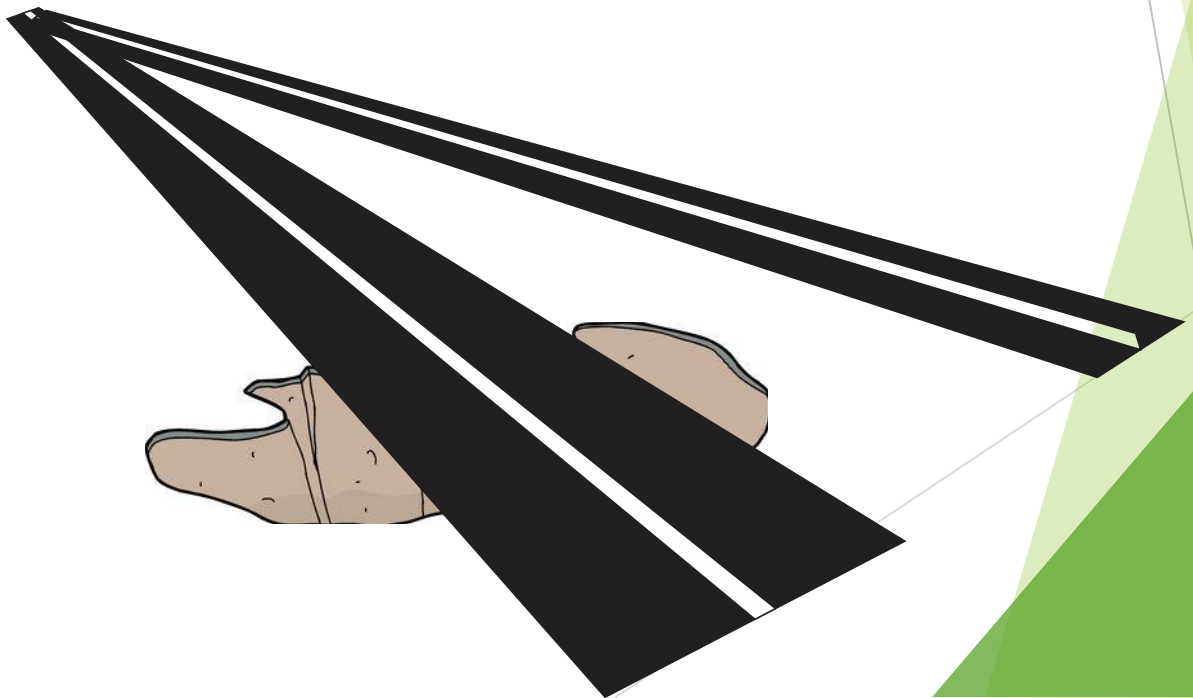
ISO 9000:2015

definition

risk
combination of the probability of occurrence of harm and the severity of that harm

Why identify risk?

- Admitting there is a potential problem
- To take a proactive approach
- It is "Preventive Action"



When do I assess risk?

- ASAP!
  - ISO 9001:2015 – September 2018
  - ISO 13485:2016 – February 2019
  - AS 9100 Rev D – September 2018
- QMS / Process Changes
- Feedback
- Nonconformance
- Periodic

Where do I assess risk?

- QMS Process/Operation
  - ISO 9001, ISO 13485, AS 9100

Management	Documented Information
Resources	Planning
Customer Related	Purchasing
Product Realization	Shipping
Data Collection / Analysis	Corrective Action

- Product design
  - ISO 13485, AS 9100
- Product realization
  - ISO 13485, AS 9100

How to identify risk?

- Brainstorm
- Bring in Experts
- Trend nonconforming data
- Online checklists
- ISO 14971 (Risk Management medical devices)
- ISO 31000 (Risk Management – Principles)

Need to Document Risk?

- There is no requirement in ISO or AS9100 for documented information.

Benefits of Documenting Risk

- Makes it easy to audit
- Training
- Prioritization
- Adjust tasks based on risk

Tools for Risk Assessment

- FMEA
- Checklist (i.e. new product)
- Action Item / Continual Improvement Log
- Approved Supplier List
- Risk Matrix

Risk Management

- Risk vs. Opportunity
- Corrective Action
- Monitor / Accept

Management System Support

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