TMQA
Excellence in Research Quality Assurance

Audit Findings and Serious Breaches

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The Audit Process

INTERNATIONAL STANDARD

ISO 19011

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Guidelines for auditing management systems

Lignes directrices pour l'audit des systèmes de management

Definitions

- Audit (Section 3.1)
  - Systematic, independent and documented process for obtaining **audit evidence** and evaluating it objectively to determine the extent to which **audit criteria** are fulfilled.
- Audit Criteria (Section 3.2)
  - set of policies, procedures or requirements used as a reference against which audit evidence is compared
- Audit Evidence (Section 3.3)
  - records, statements of fact or other information which are relevant to the audit criteria and verifiable
    - Audit evidence can be qualitative or quantitative

Findings

- Findings are generated by a comparison of evidence against criteria.

- Evidence = criteria
  - Finding is conformity
  - ("Compliance" if it is a regulatory standard)

- Evidence ≠ criteria
  - Finding is non-conformity or variance
  - ("Non-compliance" if it is a regulatory standard)

Criteria

- What can be used as “Criteria”?

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Risk

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Risk

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Risk

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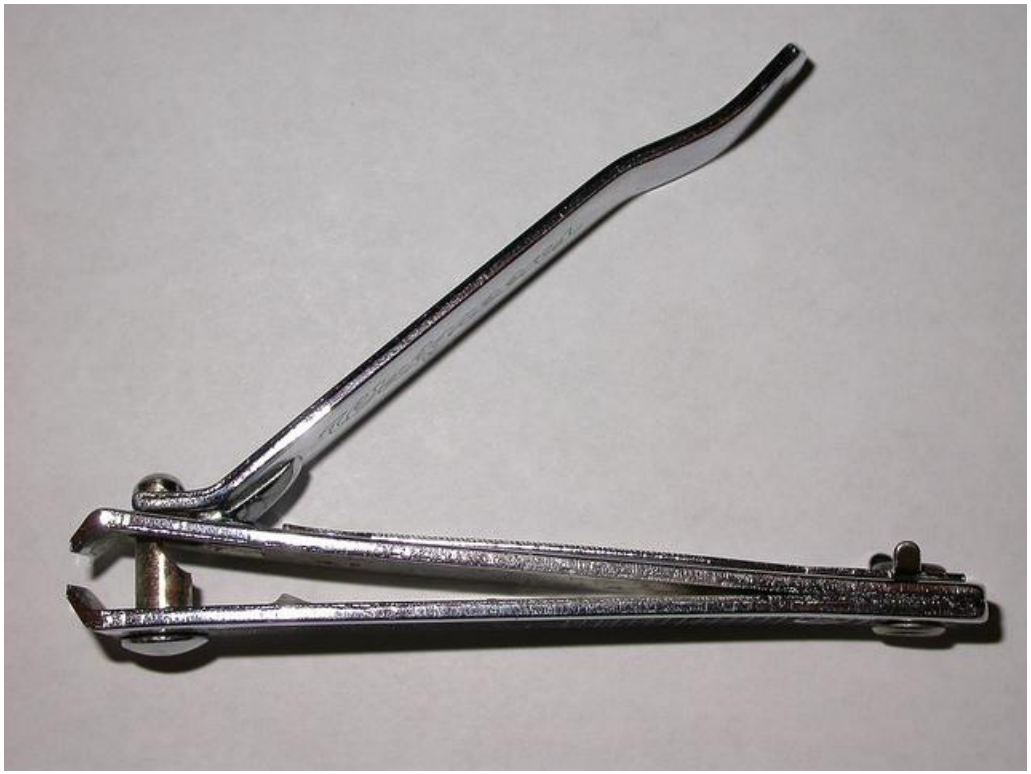
- Perception and reality are not the same



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Risk

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Analysing Risk

- What can go wrong?
- What would happen if it went wrong?
- What impact would this have?
- How likely is it to happen?
- Would we know if it happened?

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Risk Assessment

- Impact
  - 1 = small
  - 2 = medium
  - 3 = large
- Probability
  - 1 = unlikely
  - 2 = possible
  - 3 = probable

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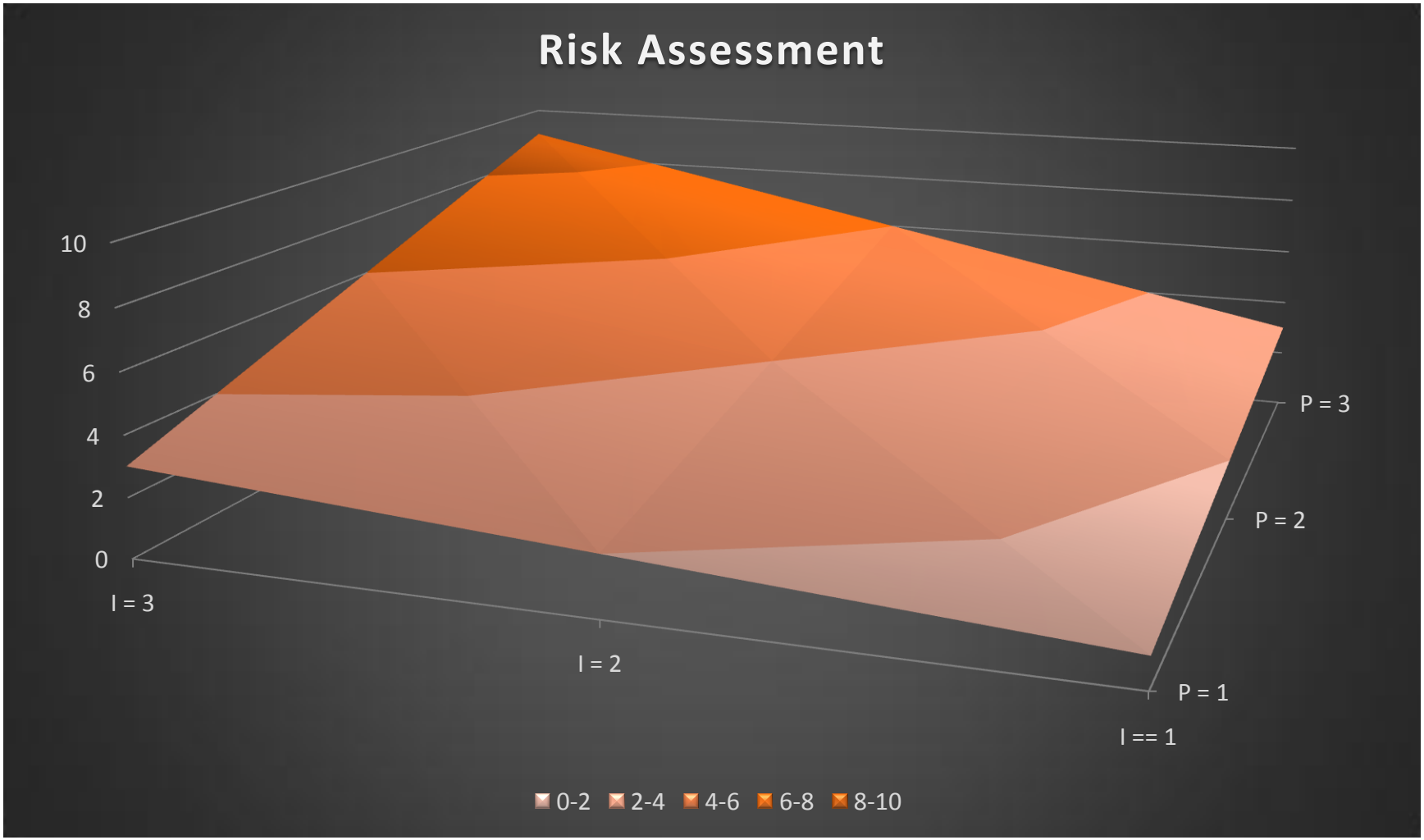
Risk Assessment



Input Risks

- Kit preparation
- Sample identification
- Sample handling
- Reagents and materials
- Facilities
- Equipment
- Protocol
- Contracts and agreements
- Laboratory manuals

Process Risks

- Method validation
- Calibration / qualification
- Stability
- Data recording
- Deviations
- Capacity
- Contamination

Post-Process Risks

- Computer system validation
- Data handling
  - Corrections and clarifications
  - Release of non-conforming results
- Data transfer
- Backup and recovery

Infrastructure Risks

- Quality management system
  - SOPs / documents
  - Quality Control / EQAS
- Training and competence
- Security
  - Physical
  - Logical
- Confidentiality
- Self-inspection / internal audit

Grading Audit Findings

- Critical
- Major
- Other
- Improvement?

Serious Breaches

- 2) A “serious breach” is a breach which is likely to effect to a significant degree:
  - (a) the safety or physical or mental integrity of the subjects of the trial; or
  - (b) the scientific value of the trial.

Serious Breaches

- Are all critical / major findings “serious breaches”?
- Who is responsible for deciding?