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Eurachem
A focus for analytical chemistry in Europe

Risk assessment in analytical laboratories

Presentation at

A two-day training course

ACCREDITATION OF ANALYTICAL, MICROBIOLOGICAL AND MEDICAL LABORATORIES - ISO/IEC 17025:2017 AND ISO 15189:2012

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Quality management in a laboratory

How often does your laboratory calibrate your analytical balances? (with metrological traceability)

Is your laboratory participating in Proficiency Testing Schemes?

How often do you check the volumetric glasware?

Would you recall previously sent out reports when a non-conformity is discovered in the routine work in your laboratory?

How many replicates do your run on your control samples?

Is your laboratory performing regular preventive maintenance of equipment?

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…risk assessment is nothing new!

- The 2005 version of ISO/IEC 17025 only mentions only the concept of risk specifically in 4 cases:
  - **4.11.3** Selection and implementation of corrective actions
    "…to a degree appropriate to the magnitude and the risk of the problem"
  - **4.11.5** Additional audit
    "…should be necessary only when a serious issue or risk to the business is identified" (Note)
  - **4.12** Preventive actins (OBS: Not included in 2017-edition!)
    "Apart from….preventive action might involve analysis of data, including trend and risk analyses…" (Note)
  - **5.4.5** Validation of methods
    "Validation is always a balance between costs, risks and technical possibilities" (Note)
- BUT in the 2017 version it is mentioned specifically in 28 cases (incl. 11 in notes)

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The main changes from 2005 to 2017 version

- New approach with regard to necessary documentation.
- Re. "Foreword":
  - *the **risk-based thinking** applied in this edition has enabled **some reduction in prescriptive requirements** and their **replacement by performance-based requirements**;*
  - *there is **greater flexibility** than in the previous edition in the **requirements for processes, procedures, documented information and organizational responsibilities**;*
- Reflected in the wording throughout the standard
  - E.g. 5.5 c): *The laboratory shall…document its procedures **to the extent necessary** to ensure the consistent application of its laboratory activities and the validity of the results.*
- Not "just" ticking off a checklist anymore !

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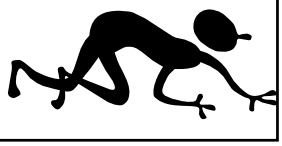
The "risk based approach"

NEW!

- From the introduction to the standard:
  - *This document requires the laboratory to **plan and implement actions to address risks and opportunities**.*
  - *Addressing both risks and opportunities establishes **a basis for increasing the effectiveness of the management system**, **achieving improved results** and **preventing negative effects**.*
  - *The laboratory is **responsible for deciding which risks and opportunities need to be addressed**.*
- "Forces" the single laboratory to **deliberately consider, what is relevant in their situation**



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Quality-Conscious Quality Management

- Considerations and consciousness related to…
  - **Which requirements are important** to comply with in relation to OUR processes – and OUR clients
  - **What can go wrong** – and what have we done to **prevent it from happening**
  - Which **options** do we have for **improving** our processes and services
  - Where will it be **acceptable**, **NOT to elaborate a lot of documentation** (as it is not important anyway – neither for ourselves, nor for our clients)
  - How can we **justify** (and document) our **decisions**?
- Look out for the necessary changes (to avoid/reduce risk) and/or opportunities for improvements (of processes and services)
- **More brain work - Less paper work!**

Take "ownership" of your Quality Management System ☺

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EA Laboratory Committee "Train the Trainer" Sessions Paris, January 2018

RISK BASED APPROACH - THE GENERAL CASE

A risk based approach to management system implementation is one in which the breadth and depth of the implementation of particular clauses is varied to best suit the perceived risk involved for the particular laboratory

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Example: Handling of non-conforming work

- According to clause 7.10.1, the following issues must be considered
  - *The responsibilities and authorities for the management of nonconforming work*
  - ***Actions** (including halting or repeating of work and withholding of reports, as necessary) are **based upon the risk levels established by the laboratory**;* **The "tricky" one!**
  - *Evaluation of the **significance** of the nonconforming work, including an **impact analysis on previous results**;*
  - *Decision is taken on the **acceptability** of the nonconforming work;*
  - *Where necessary, the **customer is notified** and **work is recalled***

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Non-specific risk assessment "requirements"

- The standard has a number of clauses which indirectly requires some kind of risk assessment – e.g.:
  - **5.5 c)** The laboratory shall…
    "…document its procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of the results.
  - **6.3.1** Facilities and environmental conditions
    "…shall be suitable for the laboratory activities…"
  - **7.2.1** Verification of methods
    "…verification shall be repeated to the extent necessary."
  - **7.5.1** Technical records
    "…sufficient information to facilitate, if possible, identification of factors affecting the measurement result…"
- In all cases a deliberate evaluation of what and how much should be done is required
  - and with that some kind of consideration of any risk related to doing nothing (or less)

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Handling of risks and oportunities

- Part of Management system requirements
  - According to Cl. 8.5…
- *The laboratory shall consider the risks and opportunities associated with the laboratory activities in order to:*
  - *a) Give assurance that the management system **achieves its intended results**;*
  - *b) Enhance opportunities to achieve the **purpose and objectives** of the laboratory;*
  - ***c) Prevent, or reduce, undesired impacts** and potential failures in the laboratory activities;*
  - ***d) Achieve improvement**.*

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Risk based approach

✓ **Actions:**

- shall be planned and evaluated
- shall be proportionate to the potential impact
- shall be updated when a nonconformity occurs
- shall be proportional to the potential impact on the validity of laboratory results

✓ **Options to Address:**

- identifying and avoiding threats,
- taking risk in order to pursue an opportunity,
- eliminating the risk source,
- changing the likelihood or consequences,
- sharing the risk or retaining risk by informed decision

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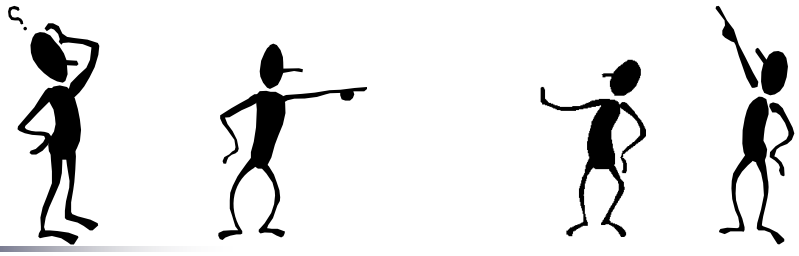
Risk based approach

✓ **Consequences:**

- „Preventive measures" no longer explicitly stated, because prevention is a core task of quality management and risk based approach
- No formalized risk management required
- Expression of measurement uncertainty gives conceptual basis for dealing with the risk of a measurement result

✓ Accreditation: Difficult to assess !!!



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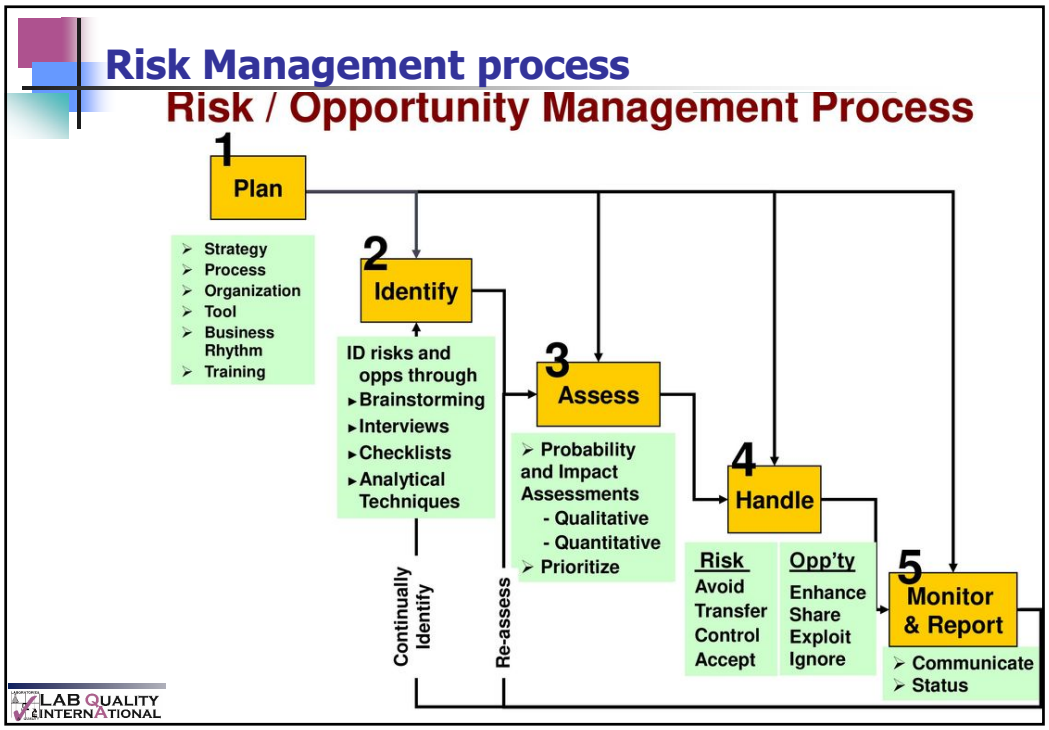

Handling risks and opportunities in the lab.

✓ Individual from lab. to lab.

1. **Planning**
   - The laboratory must have a general **plan/strategy** for how they will deal with risks and opportunities
     - in relation to THEIR types of activities
     - in relation to THEIR clients and types of analytical tasks
   - If relevant, **procedure(s)** and **tools** must be in place in accordance with plan
   - The staff must have the necessary knowledge (and responsibility) about who does what, when and how
2. **Identification** af potential risks – AND opportunities - in the laboratory process(es)
   - Brainstorming (based on various experiences within staff)
   - Building up experience over time
   - Various tools (Fishbone-diagrams, SWOT-analysis etc.)

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(cont.)

Handling risks and opportunities ... (cont'd)

3. Assessment

- Consequenses (positive/negative)
- Likelihood of occurence
  - frequence
- Qualitative / Quantitative
- Prioritization (e.g. matrix tool for classification)

4. Handling

- Risks (avoid, reduce, eliminate cause, accept etc.)
- Opportunities (promote, develop, ignore ..)

5. Monitori / Reporting

- Keep under surveillance, register
- Document (important part of building up experiences)

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Identification of (potential) risks and opportunities

✓ Two concerns with regard to the consequences

- **Clients** (and maybe even the clients' clients)
  Risks (e.g.): Unreliable results leading to wrong decisions
  Opportunities (e.g.): Results may be delivered quicker thatn expected
- **The Laboratory**
  Risks (e.g.): Unreliable results leading to loss of client(s)
  Opportunities (e.g.): A method can be performed with less costs

✓ Use available records in the lab. (relevant to activities) for current registration of ideas, observations etc.

- Structured in relation to various aspects of the standard (relevant for clients and lab.)
- Regular discussions and evaluations
- Current development of experiences

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Risk assessment

- ✓ The laboratory must select a strategy for the procedure to use in different situations
- ✓ Qualitative
  - Consequence: Good/Bad
  - Likelihood: Will happen / will not happen
- ✓ Quantitative
  - The risk (R) can be calculated as $R = L \cdot p$, where
    - L: Size of potential loss
    - p: The likelihood of the loss happening
  - May be related to measurement uncertainty of results
- ✓ Various tools for classification of consequences and likelihood
- ✓ How thorough?
  - Depends / build up experiences
  - **Prioritize!**

There will always be a risk for overlooking a risk

Classification

- ✓ Many (more or less complex) matrices exists for classification of a potential risk – e.g.:

Maybe as a tool for making your priorities?

Assessment by Accreditation Bodies (ABs)

- **The laboratory is responsible** for the decisions on which risks and opportunities to address
- But – **the AB evaluate**, whether the accredited laboratory has established **appropriate actions** to address risks and opportunities **!!**
- How will the assessors evaluate this?
- Compliance with the standard will be different from lab. to lab.
- They must look for "objective evidence" of compliance with the requirements in the standard - e.g.
  - What has been done to identify risks and opportunities
  - Have the decisions on what to do – and what not to do – been properly justified

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Thank you for your attention

…maybe, we should choose another strategy with regard to our risk management !

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