On a Popular Myth: "Scientific Research Cannot be Subject to Quality Management" Think Again! Who Says it Cannot be?

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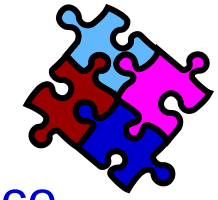
Overview

- Introduction
- Framework that ensures good practice & discipline
  - Why necessary?



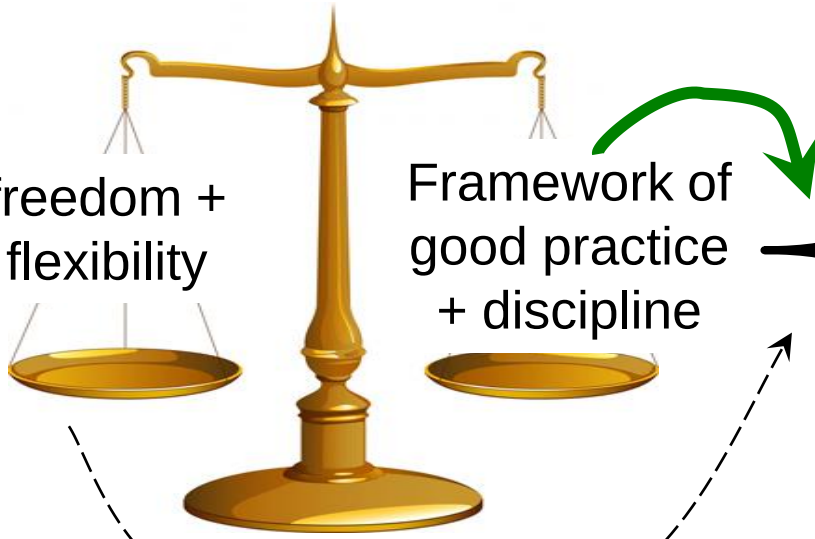
- ISO/IEC 17025, common sense & laboratory practice

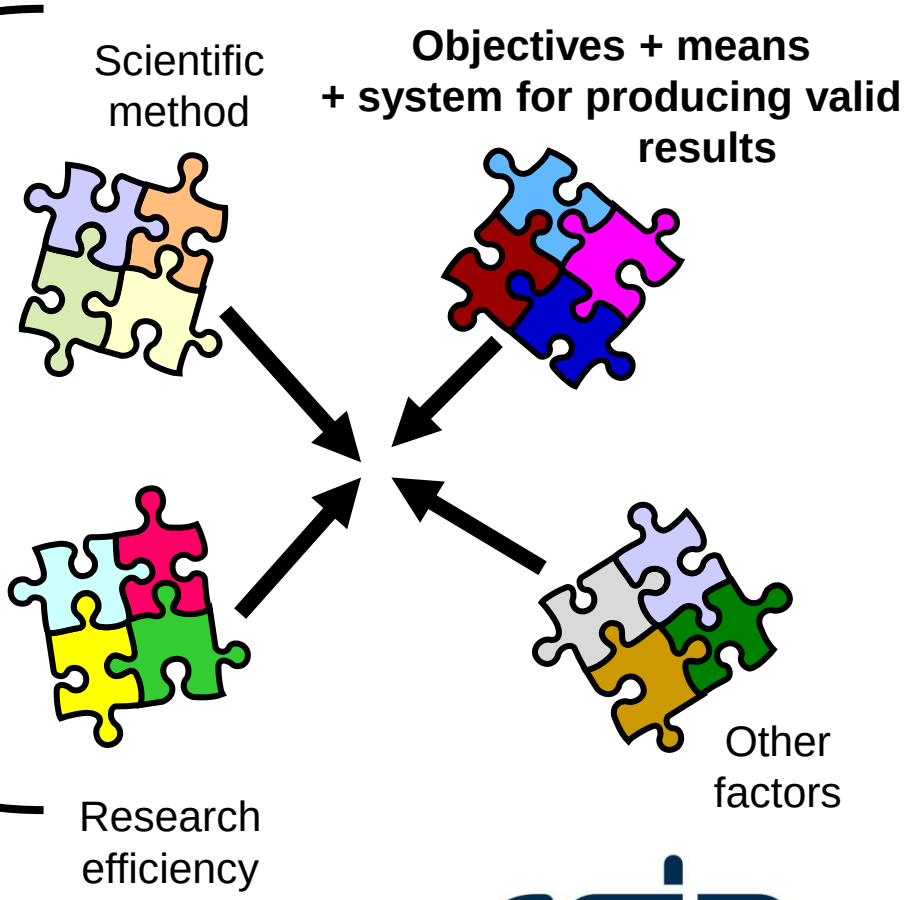
- Technical validity of measurements & reported results:
  - Relevant factors +
  - Guidance from technical requirements of ISO/IEC 17025
- Some **misconceptions** about quality management

- Conclusion

This paper: Focuses on laboratory / facility level, or even just specific capability level

Introduction: Research + Researchers need Lab operational framework





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Introduction: When measurements are part of research

ISO/IEC 17025:2005
General requirements for the competence of
testing and calibration laboratories

formulated for

It is about objectives + means + system for producing valid results

BUT

Useful to consult even if just as guidance

→ **to consider key factors applicable** to broader range of laboratories / facilities, including research

- **Key technical factors** are also **relevant** to **measurements in research**
- Caution:
  Needs interpretation and tailoring
  + Non-technical factors also important
  + Etc (see paper)

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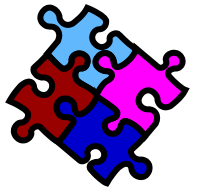
ISO/IEC 17025, Common sense & Laboratory practice

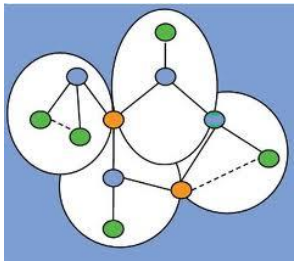
Requires nothing unusual or surprising

Just logical, common sense,
practical, good laboratory practice

So why consider it?



- Common sense + logic ≠ automatic practice
  - Needs managed, structured, pro-active, designed approach
- Promotes critical consideration of various factors
- Promotes a systems view of lab operation
  - Promotes structure in:
    - Budgeting + Capital expenditure + Records system + Document system + Schedules + etc



- Promotes balance between lab's objectives + resourcing + management commitment + readiness for sub-tasks of key importance

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Good Practice and Discipline: Realities demanding framework in the Lab

Researchers +
+ Research groups
+ Employers
+ Customers
+ Funders

invest

Time
+ Money
+ Equipment
+ other resources

into each research project.

Their expectation:

Scientifically valid results OR project deliverables.

Credibility of

Research groups
+ Managers / Leaders
+ Individual researchers
+ their track records

depends on it **+ continued**

contracts or funding

Constraints on

Availability of
Time + Funds + Equipment
+ Researchers / Assistants
+ Sufficient skills base
+ Other resources

make compromises necessary

Sometimes with risk to validity of results

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Good Practice and Discipline: **More** realities demanding framework in the Lab

Experienced scientists, under mentioned constraints, are heavily burdened.

Young scientists enter	working environment OR research scene	with	some theoretical knowledge + some skill to apply it.

BUT not knowing how those fit within a lab's framework of good practice & discipline.

Some research institutions:

- have management systems conforming to ISO 9001
- Often for only **administrative** + **higher-level** management processes
- Often NOT down to the research operational level

! **Good lab practice + discipline does NOT happen spontaneously** !

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Validity of results from Measurements: Technical factors affecting it

Inputs & input processes

- **Personnel** π
- **Accommodation + environment** α
- **Equipment / instrumentation** ε
- **Calibration** γ
- **Methods / procedures** μ
- **Collection of samples** on which measurements are to be taken σ
- **Handling** of items on which measurements are to be taken η

Quality assurance controls

Verifying validity of results

Processes to ensure that the combination produces valid results

(prior to, during and after measurement)

τ

Outputs

- **Reporting**

χ

$$\chi = \chi(\pi,\alpha,\varepsilon,\gamma,\mu,\sigma,\eta,\tau, \ldots)$$

Some Technical Factors: Discussion

- **Persons who perform measurements**
  - competence of each person for specific tasks / subtasks + to function within lab's management framework.
  - Not only qualifications + training matter, but also demonstrated skill.
  - Supervision to be provided (where necessary)

- **Methods + procedures**
  - For measurements + data analysis + calculation of results + etc
  - Documented (as briefly or elaborately as necessary)

- **Accommodation / Facilities @ which research is done**
  - Environmental conditions: Controlled / Monitored
  - Facilitate correct performance of measurements + limit adverse influences.

Discussion here only brief, on examples of requirements to demonstrate. practical factors considered. Some interpretation is applied. For full detail see ISO/IEC 17025 itself

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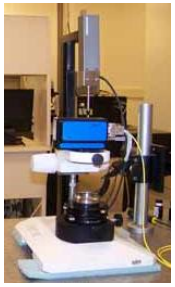
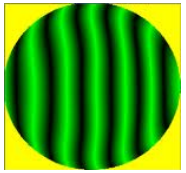
Some Technical Factors: Discussion



- **Equipment and instrumentation used**
  - Requires control over use
    - such that performance remains correct
    - such that inadvertent use of faulty instruments is prevented
    - such that inadvertent use of uncalibrated instruments is prevented
  - Requires planned maintenance & calibration programmes
  - Record keeping w.r.t. equipment / instrumentation



- **Handling of items on which measurements are to be done**
  - requirements regarding:
    - Transport + receipt + handling + protection + storage + identification of items + identification of data + + checking of item's functionality
    - Retention or disposal of items

Discussion here only brief, on examples of requirements to demonstrate. practical factors considered. Some interpretation is applied. For full detail see ISO/IEC 17025 itself

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Quality Management @ Lab's Level: Unpopularity

- **Acknowledgement:**
  - Quality management systems are often unpopular, unfortunately with reason
  - Bad experiences with misguided implementations to blame

- **Misguided implementation – Example 1**
  - excessive focus on processes + procedures + records + etc.
  - focus mostly on "paper"

Correct approach

  - balance such effort with laboratory's objectives + resourcing + management commitment + impact + readiness for sub-tasks of key importance + associated risk

- **Misguided implementation – Example 2**
  - Introduced as an artificial second management system
    But serving no real purpose

Correct approach

  - Build on existing management system
  - Don't start a new one

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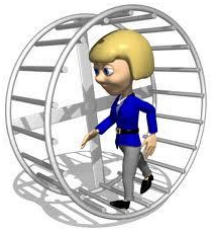
Quality Management @ Lab's Level. Some Misconceptions

- **Misconception 1**. It is about generating 'paper',
  OR it involves a lot of effort, OR it wastes time,
  OR it costs money, all without adding value
- **Rebuttal of misconception**
  - Acknowledgement:
    - misguided implementations cause these
  - Purposeful + well-implemented quality management system
    - paper work, effort and costs should be value-adding
  - If good practice was neglected previously
    - then expect:
      Value-adding extra effort + extra time spent + extra cost

Quality Management @ Lab's Level. Some Misconceptions (cont)

- **Misconception 2**. Procedures can cover only routine work
- **Rebuttal of misconception**
  - Acknowledgement:
    - It is definite mistake to treat non-routine work as if routine
  - Excessively detailed procedures is over-kill
  - BUT having no procedure also bad
  - Few research projects consist of purely non-routine
  - Procedures can be tailored to non-routine work



- **Misconception 3**. Conformance to ISO/IEC 17025 automatically implies laboratory accreditation
- **Rebuttal of misconception**
  - To seek accreditation is a separate business decision
  - Accreditation NOT suitable for non-routine work or research
  - Rather consider ISO/IEC 17025 for good practice

ISO/IEC 17025 ≠ Accreditation

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Conclusion

- Research lab does need good practice and discipline
- ISO/IEC 17025
  - Requires application of common sense
  - Nine key technical factors $\chi = \chi(\pi,\alpha,\varepsilon,\gamma,\mu,\sigma,\eta,\tau, \ldots)$

    Also relevant to measurements for scientific research
  - Any practical management system

    over operations where measurements are done,

    should address these factors.

    Applies down to lab level / Down to Research operational level

- Other factors exist
  - ISO/IEC 17025 non-technical factors **NB!!!**
  - Also factors not covered by ISO/IEC 17025 **NB!!!**

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