# Eurachem online workshop

## Revised ISO/IEC 17025: 2017 – Laboratory view
Dr. Pharm. Isabelle Vercruysse – May 17, 2021

**belab**

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# Who is Belab?

❖ Non profit organisation

❖ Groups Belgian laboratories

❖ Active in different fields:
  ❖ construction to food, textile to pharmaceuticals, environment to medical
  ❖ Public, private, governmental, university, ...

❖ Includes different sectors: test, inspection or calibration

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# Who is Belab?

❖ Is represented at Belac : Coordination Committee and National Council and represents the laboratories in the Belac Board of Appeal

❖ Has informal contacts with Belac and brings up pain points that laboratories struggle with towards Belac

❖ Closely follows Belgian and European legislation and standards

❖ Belab is member of Eurachem (GA, Exec, WG) and Eurolab

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# Joint survey Belac-Belab 2021

**Topics**

❖ Flexible scope

❖ Bottlenecks/issues with ISO 17025:2017

❖ Collaboration with Belac



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# Joint survey Belac-Belab 2021

**Timeline 2021**

❖ 21st March: survey sent via Google forms (270 labs: 38 CAL/232 TEST)

❖ 21st April: end date

❖ Results: 171 replies (63,3%)

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# ISO17025: 2017: what was new?



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## ISO 17025: 2017- What was new?

❖ Structure has changed :
*2005: two important chapters (4. management requirements and 5. technical requirements)*

    4. General requirements

    5. Structural requirements

    6. Resource requirements

    7. Process requirements

    8. Management system requirements

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## ISO 17025: 2017- What was new?

❖ A risk based approach § 8.5

    ❖ *e.g.* risk linked to independence, facilities (access, contamination), equipment (calibration program), conformity assessment, non-conformities, management of information, internal audits, improvement, ….

❖ More flexibility at the level of requirements for pre-processes, pre-procedures, documented information and responsibilities

❖ IT becomes more important § 7.11

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## ISO 17025: 2017- What was new?

❖ More process-driven approach in line with ISO9001

   ❖ Thinking more in terms of processes:

      ❖ Input :        request (§ 7.1)

      ❖ Process :    sampling (§7.3, § 7.4)

                    test or calibration (§7.2, §7.5; §7.6, § 7.7)

      ❖ Output :     report (7.8)

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## Survey: Google forms

### ISO 17025 Questionnaire

▶ Please rate (at least) 3 clauses that caused you most difficulties to implement the 2017 version of ISO 17025

▶ Please Use codes A to D as to the reason why:
  ▶ (A) we needed extra training for it
  ▶ (B) different interpretation by us than by the assessor/auditor
  ▶ (C) it required a lot of extra work
  ▶ (D) other reason

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## Survey: Google forms

❖ **ISO 17025 questionnaire on the different clauses**

(new points in 2017)

❖ Impartiality (§4.1)

❖ Confidentiality (§4.2)

❖ Personnel (§6.2)

❖ Equipment (§6.4)

❖ Metrological traceability (§6.5)

❖ Suppliers (§6.6)

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## Survey: Google forms

❖ **ISO 17025 questionnaire on the different clauses**
(new points in 2017)

❖ Review of requests, tenders and contracts (§7.1)

❖ Selection, validation of methods (§7.2)

❖ Requirements relating to sampling (§7.3)

❖ Measurement uncertainty (§7.6)

❖ Validity of results (§7.7)

❖ Reporting of results (§7.8)

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## Survey: Google forms

❖ **ISO 17025 questionnaire on the different clauses**
(new points in 2017)

❖ Complaints (§7.9)

❖ Control of data and information management (§7.11)

❖ Risks and opportunities (§8.5)

❖ Requirements related to improvement (§8.6)

❖ Management reviews (§8.9)

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# Overview of results

| Number of labs | Clause | Description |
|---|---|---|
| 141 | 8.5 | Risks and opportunity |
| 70 | 7.6 | MU |
| 69 | 4.1 | Impariality |
| 54 | 7.11 | Control of data and information managm |
| 53 | 6.5 | Metrological traceability |
| 47 | 6.6 | Suppliers |
| 46 | 7.2 | Selection, validation of methods |
| 46 | 7.8 | Reporting of results |
| 43 | 7.7 | Validity of results |
| 40 | 7.9 | Complaints |
| 39 | 8.9 | Management reviews |
| 38 | 4.2 | Confidentiality |
| 38 | 6.2 | Personnel |
| 37 | 7.3 | Sampling |
| 32 | 7.1 | Review of requests |
| 31 | 6.4 | Equipment |
| 27 | 8.6 | To improvement |

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## Clause 8.5 Risks and opportunities

Risks and opportunities (§8.5) - 141 labs

| 45 | 16 | 69 | 11 |
|---|---|---|---|
| A. we needed extra training for it | B. different interpretation by us than by the auditor | C. it required a lot of extra work | D. other |
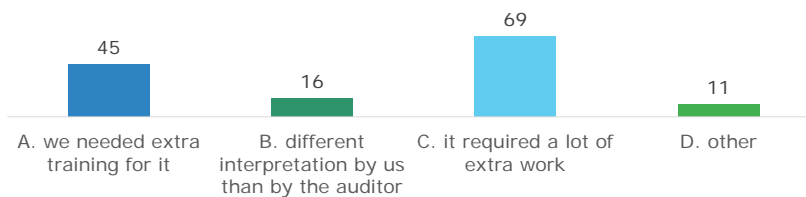
- ❖ It required a lot of work (49%)
- ❖ Need for extra training (32%)
- ❖ How far do we have to go? Do we need to include all subjects already managed in the procedures? When is it enough?
- ❖ What is really expected? Some assessors expect a lot
- ❖ Need for extra guidelines and practical explanations in human language

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# Clause 7.6 Measurement uncertainty

Measurement uncertainty (§7.6) – 70 labs



- A. we needed extra training for it — 19
- B. different interpretation by us than by the auditor — 6
- C. it required a lot of extra work — 32
- D. other — 13
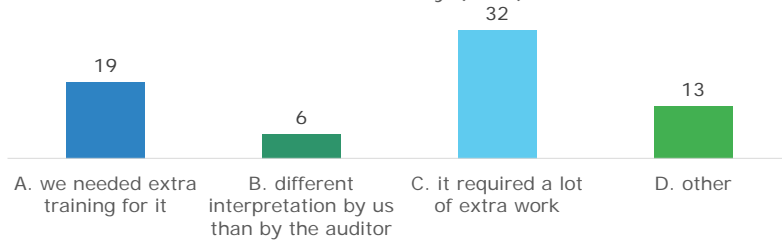
- ❖ It required a lot of work (46%)
- ❖ Need for extra training (27%)
- ❖ Information concerning trainings on measurement uncertainty and method validation
- ❖ Guidance documents on measurement uncertainty are needed

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# Clause 4.1 Impartiality

Impartiality (§4.1) – 69 labs



- A. we needed extra training for it — 15
- B. different interpretation by us than by the auditor — 20
- C. it required a lot of extra work — 19
- D. other — 15
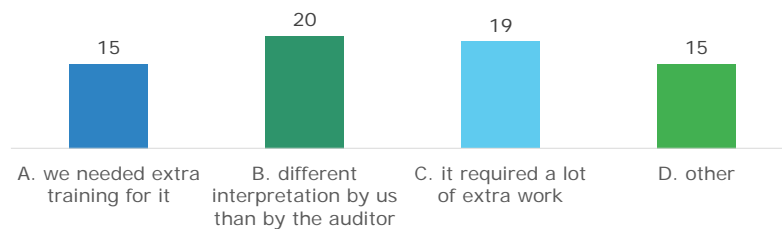
- ❖ Different interpretation by lab than by the assessor (29%)
- ❖ It required a lot of work (28%)
- ❖ Difficulties in understanding difference between impartiality and independence
- ❖ Assessor didn't agree : our impartiality wasn't deep enough

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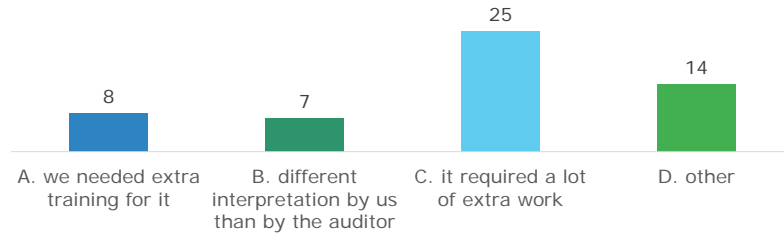## Clause 7.11 Control for data and information management

Control of data and information management (§7.11) – 54 labs



| | | 25 | |
| 8 | 7 | | 14 |
| A. we needed extra training for it | B. different interpretation by us than by the auditor | C. it required a lot of extra work | D. other |

- ❖ It required a lot of work (46%)
- ❖ Need for extra training about data information management (IT, validate IT and software)
- ❖ Need for additional guidelines

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## Clause 6.5 Metrological traceability

Metrological traceability (§6.5) – 53 labs



| 11 | 11 | 19 | 12 |
| A. we needed extra training for it | B. different interpretation by us than by the auditor | C. it required a lot of extra work | D. other |
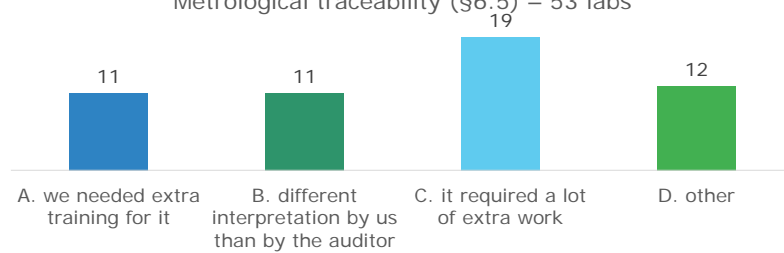
- ❖ It required a lot of work (36%)
- ❖ Need for extra training and additional guidelines
- ❖ Not all analytical standards have traceability to national/international metrological standards

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# Clause 6.6. Suppliers

Suppliers (§6.6) – 47 labs



| A. we needed extra training for it | B. different interpretation by us than by the auditor | C. it required a lot of extra work | D. other |
| --- | --- | --- | --- |
| 4 | 9 | 18 | 16 |

- ❖ It required a lot of work (38%)
- ❖ Need for extra training and additional guidelines
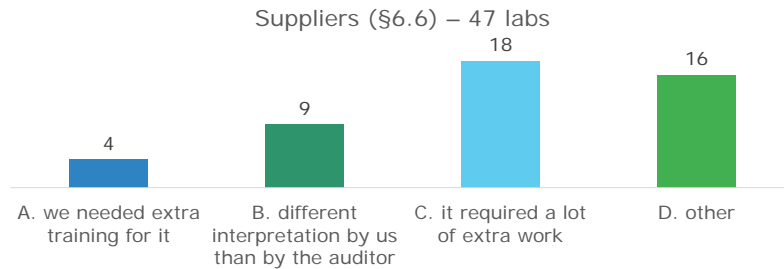- ❖ Difficult to implement some criteria *e.g.* 6.6.3c (*lab shall communicate its requirement to suppliers for competence, including qualification of personnel*)

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# Clause 7.6 Selection & validation of methods

Selection, validation of methods (§7.2) – 46 labs



| A. we needed extra training for it | B. different interpretation by us than by the auditor | C. it required a lot of extra work | D. other |
| --- | --- | --- | --- |
| 8 | 7 | 19 | 12 |
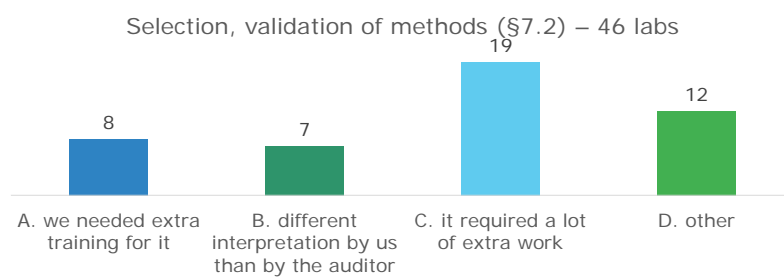
- ❖ It required a lot of work (46%)
- ❖ No need for extra training and additional guidelines anymore ?!

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# Clause 7.8 Reporting of results

The reporting of results (§7.8) — 46 labs

| | | 15 | |
|---|---|---|---|
| | 13 | | 13 |
| 5 | | | |

A. we needed extra training for it    B. different interpretation by us than by the auditor    C. it required a lot of extra work    D. other
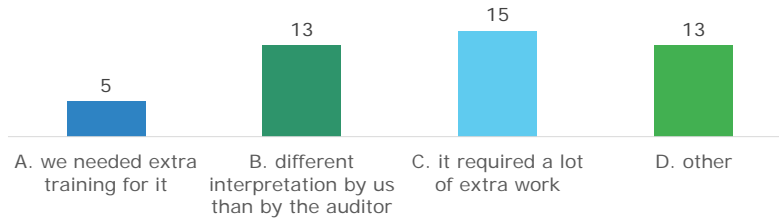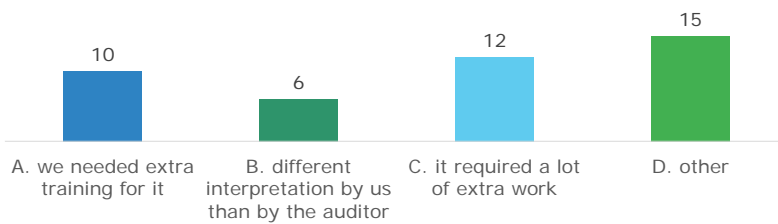
- ❖ It required a lot of work (33%)
- ❖ Different interpretation by us than by the assessor (28%)
- ❖ Additional guidelines about declarations of conformity in reports and opinions and interpretations (*e.g.*: 7.8.3.1 b) and d) + 7.8.6 + 7.8.7)

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# Clause 7.7 Ensuring the validity of results

Validity of results (§7.7) — 43 labs

| | | | 15 |
|---|---|---|---|
| 10 | | 12 | |
| | 6 | | |

A. we needed extra training for it    B. different interpretation by us than by the auditor    C. it required a lot of extra work    D. other
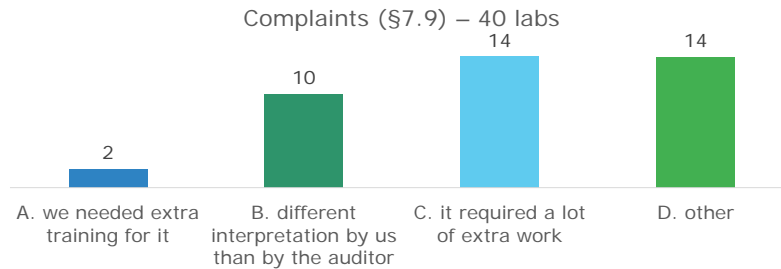
- ❖ It required a lot of work (27%)
- ❖ Not all testing can be covered by PT tests
- ❖ Microbiological area is a difficult area

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# Clause 7.9 Complaints

Complaints (§7.9) – 40 labs



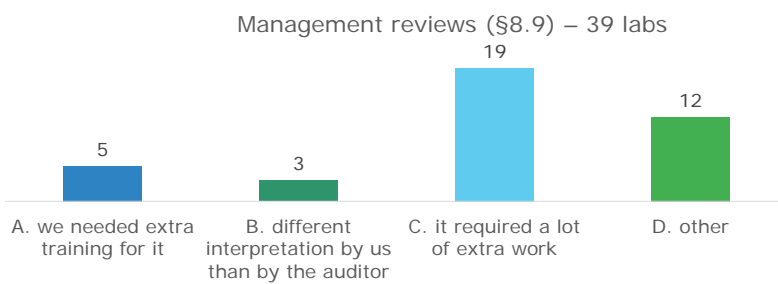| A. we needed extra training for it | B. different interpretation by us than by the auditor | C. it required a lot of extra work | D. other |
| 2 | 10 | 14 | 14 |

- ❖ It required a lot of work (35%)
- ❖ Different interpretation by us than by the assessor (25%)
- ❖ Review of complaints by independent person in small labs is difficult
- ❖ Handling by a person outside the laboratory is a pointless rule that only causes delay.

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# Clause 8.9 Management review

Management reviews (§8.9) – 39 labs
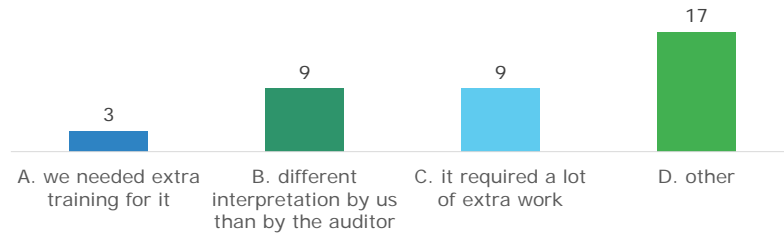


| A. we needed extra training for it | B. different interpretation by us than by the auditor | C. it required a lot of extra work | D. other |
| 5 | 3 | 19 | 12 |

- ❖ It required a lot of work (49%)

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# Clause 4.2 Confidentiality

Confidentiality (§4.2) – 38 labs

| | | | |
|---|---|---|---|
| 3 | 9 | 9 | 17 |
| A. we needed extra training for it | B. different interpretation by us than by the auditor | C. it required a lot of extra work | D. other |

- ❖ It required a lot of work (24%)
- ❖ Different interpretation by us than by the assessor (24%)
- ❖ Additional guidelines are needed

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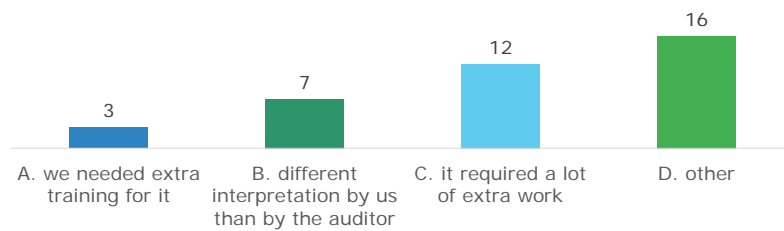
33

# Clause 6.2 Personnel

Personnel (§6.2) - 38 labs

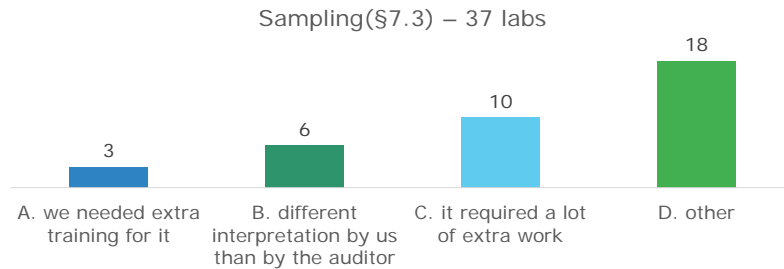| | | | |
|---|---|---|---|
| 3 | 7 | 12 | 16 |
| A. we needed extra training for it | B. different interpretation by us than by the auditor | C. it required a lot of extra work | D. other |

- ❖ It required a lot of work (32%)
- ❖ Specification of competence requirements is difficult (*e.g.*: 6.2.5b)
- ❖ The whole concept of the declaration of competence in relation to a task and a function very complex and unclear.

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# Clause 7.3 Requirements relating to sampling

Sampling(§7.3) – 37 labs



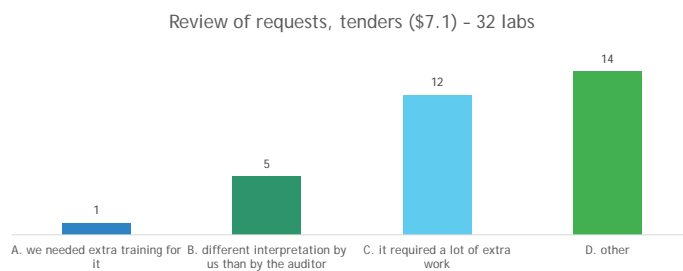| | |
|---|---|
| A. we needed extra training for it | 3 |
| B. different interpretation by us than by the auditor | 6 |
| C. it required a lot of extra work | 10 |
| D. other | 18 |

- ❖ It required a lot of work (27%)
- ❖ Other problems related to this clause (49%)
- ❖ MU on sampling is difficult to implement
- ❖ No external training of personnel on sampling
- ❖ No PT available

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# Clause 7.1 Review of requests, tenders and contracts

Review of requests, tenders ($7.1) - 32 labs



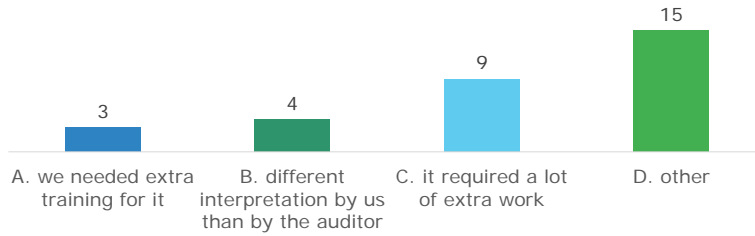| | |
|---|---|
| A. we needed extra training for it | 1 |
| B. different interpretation by us than by the auditor | 5 |
| C. it required a lot of extra work | 12 |
| D. other | 14 |

- ❖ It required a lot of extra work (38%)
- ❖ Other problems related to this clause (44%)

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## Clause 6.4 Equipment

Equipment ($6.4) – 31 labs



- ❖ It required a lot of work (29%)
- ❖ Other problems related to this clause (48 %)
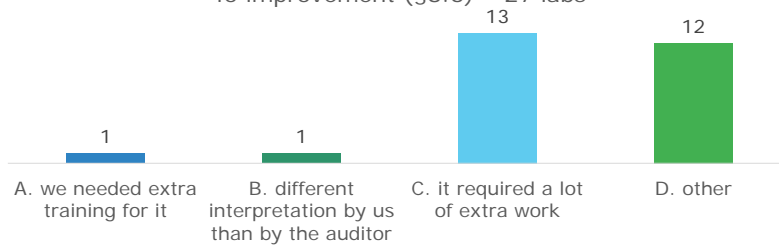- ❖ Additional guidelines are required

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## Clause 8.6 Requirements related to improvement

To improvement (§8.6) – 27 labs



- ❖ It required a lot of work (48%)

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## Conclusion related to new standard

| Number | Normpoint | Description |
|---|---|---|
| 141 | 8.5 | Risks and opportunity |
| 70 | 7.6 | MU |
| 69 | 4.1 | Impariality |
| 54 | 7.11 | Control of data and information management |
| 53 | 6.5 | Metrological traceability |
| 47 | 6.6 | Suppliers |
| 46 | 7.2 | Selection, validation of methods |
| 46 | 7.8 | Reporting of results |
| 43 | 7.7 | Validity of results |
| 40 | 7.9 | Complaints |
| 39 | 8.9 | Management reviews |
| 38 | 4.2 | Confidentiality |
| 38 | 6.2 | Personnel |
| 37 | 7.3 | Sampling |
| 32 | 7.1 | Review of requests |
| 31 | 6.4 | Equipment |
| 27 | 8.6 | To improvement |

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## Other remarks from the labs

- ❖ Improve the requirements of different assessors on new version of the standard

- ❖ Focus more on the key changes of 17025:2017 in order to arrive or make the correct interpretation of the clause(s)

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## General conclusions

- Clause 8.5 : Risks and opportunity
  - new and difficult to implement for 82% of labs

- Different interpretations between the assessor and the labs for :
  - clause 4.1: impartiality
  - clause 4.2: confidentiality
  - clause 6.5: metrological traceability
  - clause 7.8: reports of results
  - clause 7.9: complaints

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## General conclusions

❖ Labs needed extra training for :
- ❖ clauses 4.1: impartiality
- ❖ clause 6.5: metrological traceability
- ❖ clause 7.6: MU
- ❖ clause 7.7: validity of results
- ❖ clause 8.5: risks and opportunities

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## General conclusions

❖ Labs ask for additional (practical) guidelines for:
- ❖ clause 4.2: confidentiality
- ❖ clause 6.4: equipment
- ❖ clause 6.5: metrological traceability
- ❖ clause 6.6: suppliers
- ❖ clause 7.6: MU
- ❖ clause 7.8: reporting of results
- ❖ clause 7.11: control of data and information management
- ❖ clause 8.5: risks and opportunities

*Need for extra promotion on existing guidelines?*

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## General conclusions

❖ Each interrogated norm point required a great deal of extra work (balance costs-benefits?)

❖ Also "old" clauses of the standard were bottlenecks:
  - ❖ clause 6.5: metrological traceability
  - ❖ clause 7.2: selection, validation of methods
  - ❖ clause 7.6: MU
  - ❖ clause 7.7: validity of results

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## Thank you for your attention.

Questions?

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