Eurolabin toiminta, julkaisut ja oppaat

Mikä Eurolab on

- Euroopan kansallisten mittaus-, testaus- ja analyysilaboratorioiden yhdistysten liitto
- Voittoa tavoittelematon järjestö
  - koostuu 26 kansallisesta yhdistyksestä Eurooppassa ja sen ulkopuolella
  - jäseninä 5 000 vaatimustenmukaisuuden arviointilaitosta
  - yli 9 000 akkreditoitua laboratoriota

Mitä Eurolab tekee (1)

- Edustaa eurooppalaista vaatimustenmukaisuuden arviointialaa poliittisissa ja teknisissä kysymyksissä, joilla on suora vaikutus eurooppalaiseen laatuinfrastruktuuriin
  - edistää kuluttajien turvallisuutta, yritysten kilpailukykyä, sisämarkkinoiden kestävyyttä ja akkreditoinnin yhdenmukaistamista

- Verkostoituu ja jakaa tietoa keskeisten sidosryhmien kanssa, joilla on suora vaikutus laatuinfrastruktuuriin ja vaatimustenmukaisuuden arvioinnin alaan
  - vältetään päällekkäistä työtä ja vahvistetaan vaatimustenmukaisuuden arviointialan ääntä

Mitä Eurolab tekee (2)

- Toimii ja osallistuu tarvittaessa keskeisiin sääntelykehityksiin
  - tarjoamalla riittävät keinot tiedon, kokemusten ja teknisen asiantuntemuksen jakamiseen
  - organisoimalla teknisiä työryhmiä
  - järjestämällä seminaareja
  - julkaisemalla kannanottoja, teknisiä raportteja ja keittokirjoja

EUROLABin SIHTEERISTÖ Brysselissä

Aktiivinen strategisella ja operatiivisella tasolla

Laura MARTIN
Pääsihteeri

Gaia DETTORI
Politiikka- ja viestintävastaava

Yhteistyö ja -toiminta EU:n toimielinten ja keskeisten sidosryhmien kanssa

EU:n lainsäädännön ja kansainvälisen kehityksen seuraaminen ja niihin osallistuminen

Uutiskirjeen, teknisten ja poliittisten asiakirjojen sekä viestintämateriaalien julkaiseminen

Koulutusten ja tapahtumien järjestäminen

Tietoisuuden lisääminen ja asemointi laboratorioyhteisöissä

Tutkimus, suunnittelu ja osallistuminen EU-hankkeisiin

Lähde: Laura Martin
Finntesting
Kevätseminaari 2024

Eurolabin painopistealueet 2026

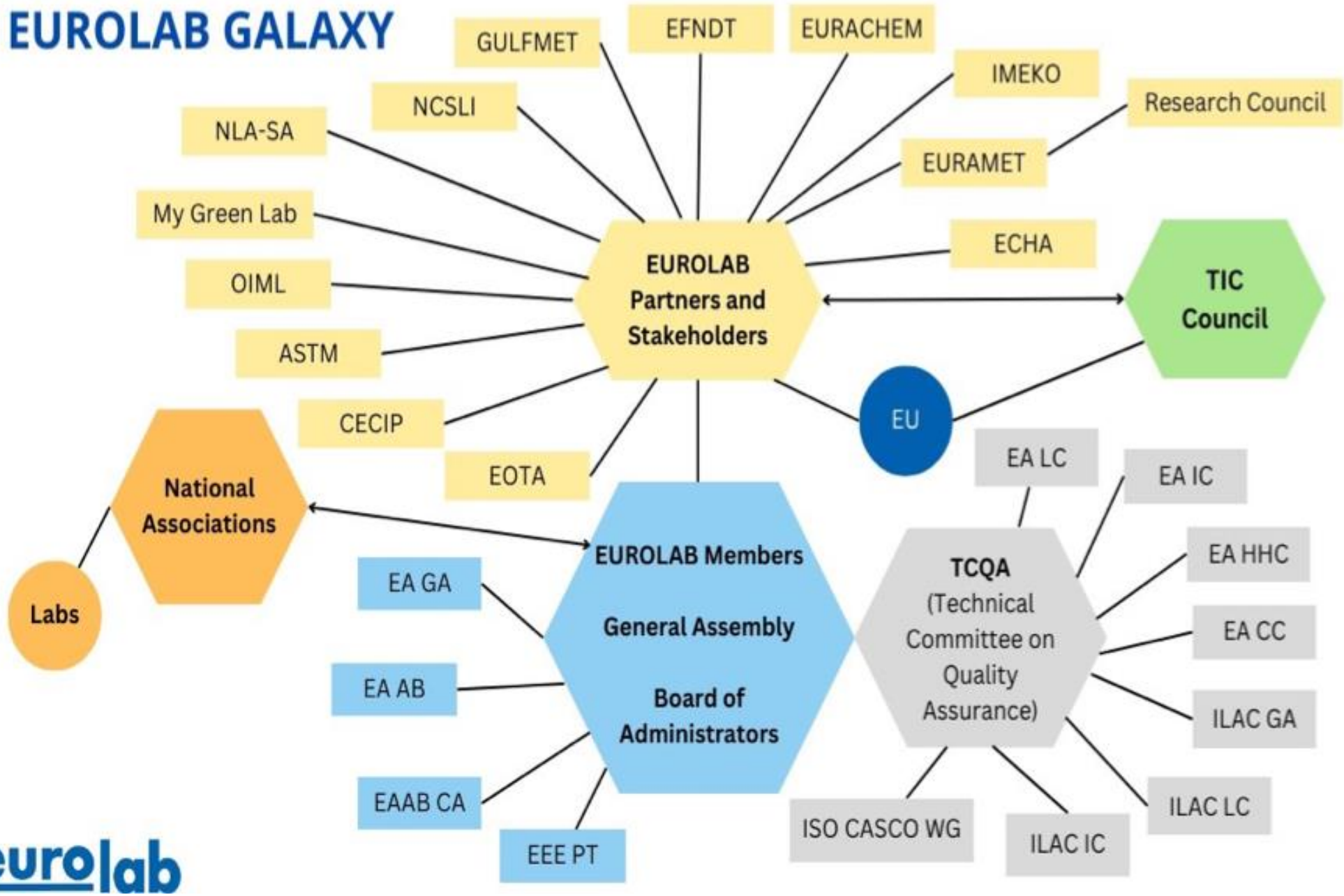
Sääntelyelimet
Eurooppalaisen testausta, vaatimustenmukaisuuden arviointia ja tuoteturvallisuutta koskevan lainsäädännön kehityksen seuranta seuraavilla aloilla:

ESG
- kestävyys
- vihreän kehityksen ohjelma
- yritysten yhteiskuntavastuu

Elintarvikkeet
Lääkinnälliset laitteet
Energia

Metrologia ja kalibrointi
Akkreditointi ja standardointi
Tulevaisuuden laboratorio
- koneoppiminen, digitalisaatio
- kyberturvallisuus, robotisaatio
- tekoäly, lohkoketju, jne.

Lähde: Laura Martin Finntesting Kevätseminaari 2024

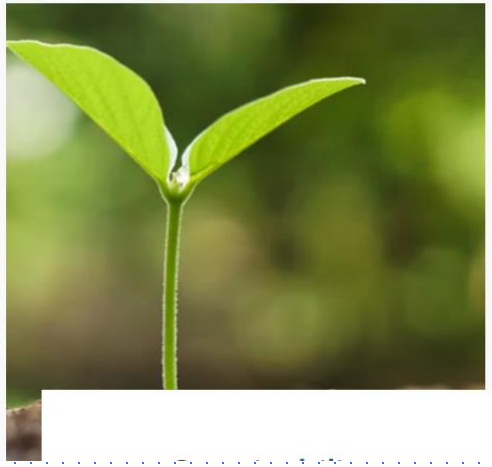


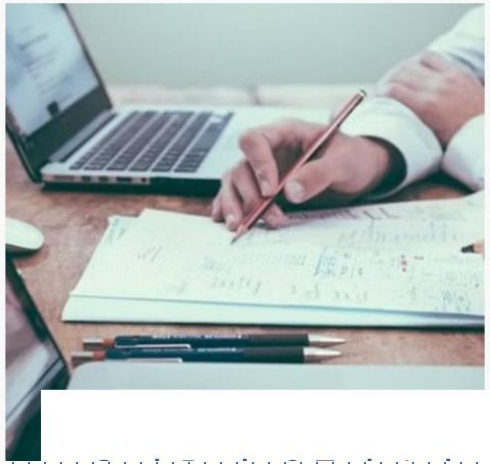
Lähde: Laura Martin Finntesting Kevätseminaari 2024

WORKING **GROUPS**

Työryhmät

- EUROLABin laadunvarmistuksen tekninen komitea (TCQA) on äskettäin uudistettu perustamalla neljä työryhmää (WG)
- Kunkin teema-alueen työryhmä on avoin kaikille, jotka haluavat osallistua asiantuntemuksellaan
- Jos olet kiinnostunut liittymään tiettyyn työryhmään, ota rohkeasti yhteyttä osoitteessa info@eurolab.org





Akkreditointi ja standardointi

Kestävä kehitys

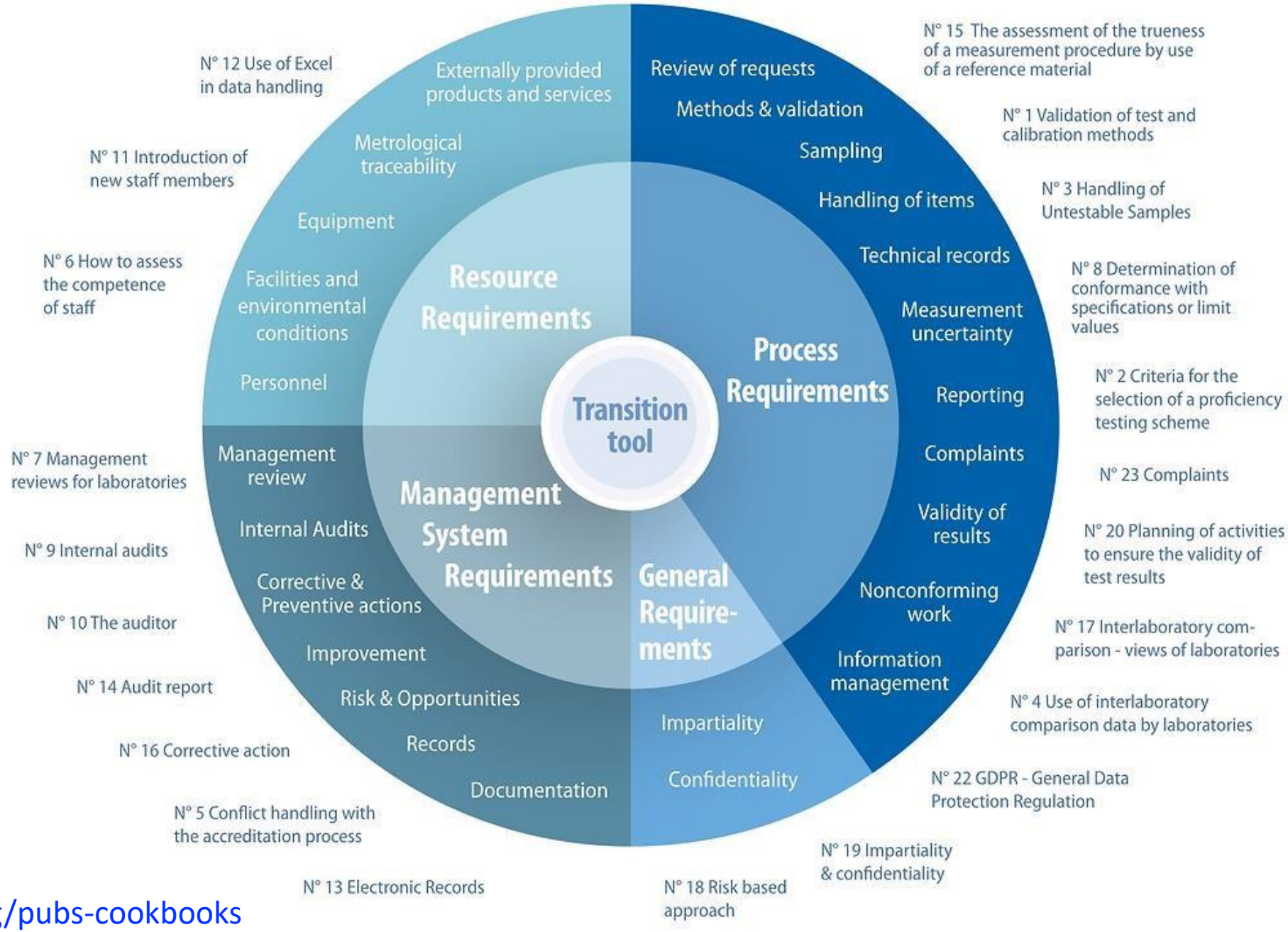
Digitalisaatio

Keittokirjat ja tekniset raportit

Katso: https://www.eurolab.org/services-4

Keittokirjat

Lyhyitä laatukysymyksiä käsitteleviä asiakirjoja, jotka auttavat noudattamaan standardia ISO/IEC 17025.



https://www.eurolab.org/pubs-cookbooks

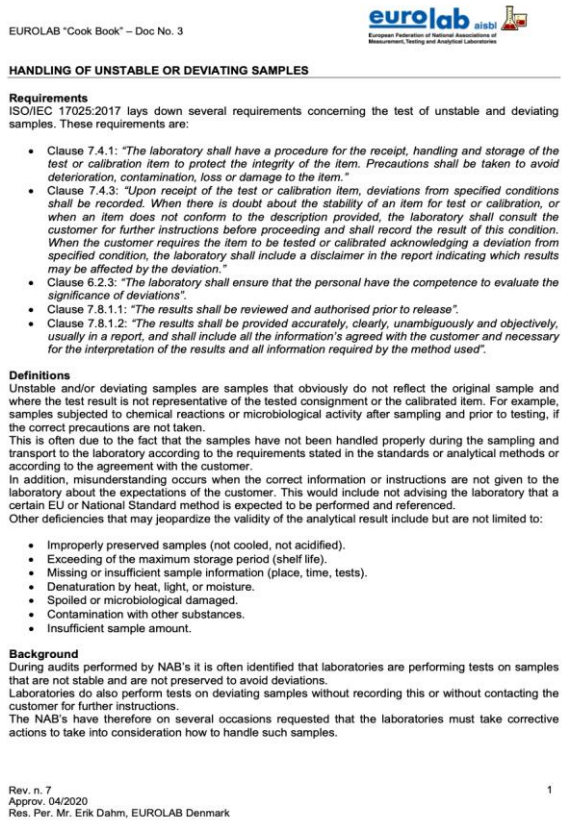
3 Handling of Unstable / Deviating Samples 4/2020

Unstable/deviating samples are items which have been received by a laboratory but do not adequately reflect the original sample. This document provides recommendations on how to deal with such samples in respect of the requirements of ISO/IEC 17025.

Sisältö

Vaatimukset
Määritelmät
Tausta
Suositukset
Johtopäätökset

Rev. n. 7
Approv. 04/2020
Res. Per. Mr. Erik Dahm, EUROLAB Denmark
EUROLAB “Cook Book” – Doc No. 3



HANDLING OF UNSTABLE OR DEVIATING SAMPLES

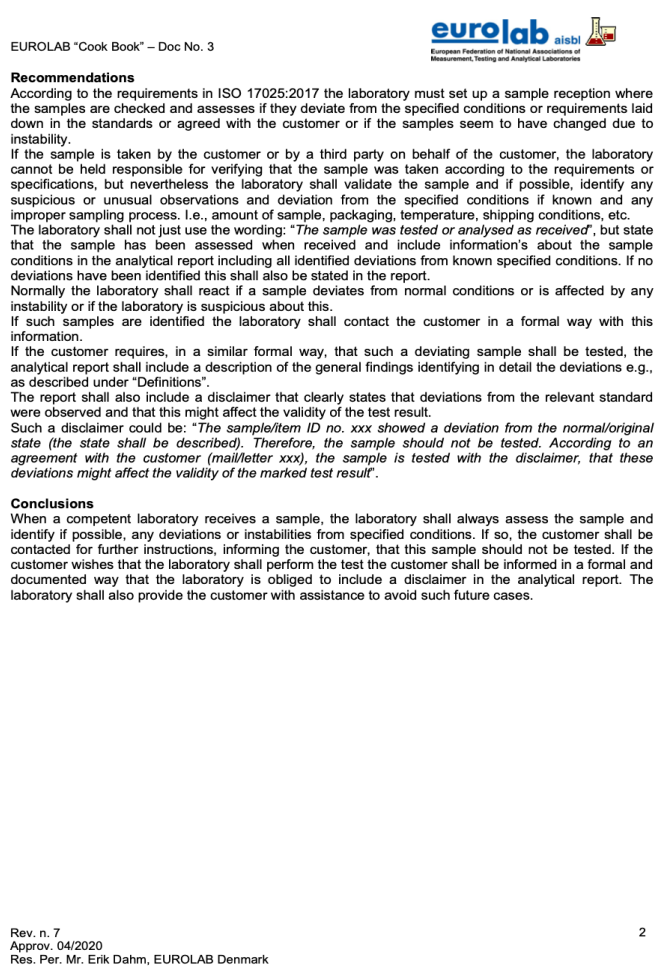
Requirements
ISO/IEC 17025:2017 lays down several requirements concerning the test of unstable and deviating samples. These requirements are:

- Clause 7.4.1: *“The laboratory shall have a procedure for the receipt, handling and storage of the test or calibration item to protect the integrity of the item. Precautions shall be taken to avoid deterioration, contamination, loss or damage to the item.”*
- Clause 7.4.3: *“Upon receipt of the test or calibration item, deviations from specified conditions shall be recorded. When there is doubt about the stability of an item for test or calibration, or when an item does not conform to the description provided, the laboratory shall consult the customer for further instructions before proceeding and shall record the result of this condition. When the customer requires the item to be tested or calibrated acknowledging a deviation from specified condition, the laboratory shall include a disclaimer in the report indicating which results may be affected by the deviation.”*
- Clause 6.2.3: *“The laboratory shall ensure that the personal have the competence to evaluate the significance of deviations”.*
- Clause 7.8.1.1: *“The results shall be reviewed and authorised prior to release”.*
- Clause 7.8.1.2: *“The results shall be provided accurately, clearly, unambiguously and objectively, usually in a report, and shall include all the information’s agreed with the customer and necessary for the interpretation of the results and all information required by the method used”.*

Definitions
Unstable and/or deviating samples are samples that obviously do not reflect the original sample and where the test result is not representative of the tested consignment or the calibrated item. For example, samples subjected to chemical reactions or microbiological activity after sampling and prior to testing, if the correct precautions are not taken.
This is often due to the fact that the samples have not been handled properly during the sampling and transport to the laboratory according to the requirements stated in the standards or analytical methods or according to the agreement with the customer.
In addition, misunderstanding occurs when the correct information or instructions are not given to the laboratory about the expectations of the customer. This would include not advising the laboratory that a certain EU or National Standard method is expected to be performed and referenced.
Other deficiencies that may jeopardize the validity of the analytical result include but are not limited to:

- Improperly preserved samples (not cooled, not acidified).
- Exceeding of the maximum storage period (shelf life).
- Missing or insufficient sample information (place, time, tests).
- Denaturation by heat, light, or moisture.
- Spoiled or microbiological damaged.
- Contamination with other substances.
- Insufficient sample amount.

Background
During audits performed by NAB’s it is often identified that laboratories are performing tests on samples that are not stable and are not preserved to avoid deviations.
Laboratories do also perform tests on deviating samples without recording this or without contacting the customer for further instructions.
The NAB’s have therefore on several occasions requested that the laboratories must take corrective actions to take into consideration how to handle such samples.



Recommendations
According to the requirements in ISO 17025:2017 the laboratory must set up a sample reception where the samples are checked and assesses if they deviate from the specified conditions or requirements laid down in the standards or agreed with the customer or if the samples seem to have changed due to instability.
If the sample is taken by the customer or by a third party on behalf of the customer, the laboratory cannot be held responsible for verifying that the sample was taken according to the requirements or specifications, but nevertheless the laboratory shall validate the sample and if possible, identify any suspicious or unusual observations and deviation from the specified conditions if known and any improper sampling process. I.e., amount of sample, packaging, temperature, shipping conditions, etc.
The laboratory shall not just use the wording: “*The sample was tested or analysed as received*”, but state that the sample has been assessed when received and include information’s about the sample conditions in the analytical report including all identified deviations from known specified conditions. If no deviations have been identified this shall also be stated in the report.
Normally the laboratory shall react if a sample deviates from normal conditions or is affected by any instability or if the laboratory is suspicious about this.
If such samples are identified the laboratory shall contact the customer in a formal way with this information.
If the customer requires, in a similar formal way, that such a deviating sample shall be tested, the analytical report shall include a description of the general findings identifying in detail the deviations e.g., as described under “Definitions”.
The report shall also include a disclaimer that clearly states that deviations from the relevant standard were observed and that this might affect the validity of the test result.
Such a disclaimer could be: “*The sample/item ID no. xxx showed a deviation from the normal/original state (the state shall be described). Therefore, the sample should not be tested. According to an agreement with the customer (mail/letter xxx), the sample is tested with the disclaimer, that these deviations might affect the validity of the marked test result*”.

Conclusions
When a competent laboratory receives a sample, the laboratory shall always assess the sample and identify if possible, any deviations or instabilities from specified conditions. If so, the customer shall be contacted for further instructions, informing the customer, that this sample should not be tested. If the customer wishes that the laboratory shall perform the test the customer shall be informed in a formal and documented way that the laboratory is obliged to include a disclaimer in the analytical report. The laboratory shall also provide the customer with assistance to avoid such future cases.

https://www.eurolab.org/pubs-cookbooks

EUROLABin Tekniset raportit (1)

Raporttien tavoitteena on tunnistaa ja havainnollistaa *laboratorioteknikkoja* kiinnostavia kysymyksiä sekä antaa ohjeita ja suosituksia

Accreditation of small laboratories
2/2000

An analysis of the competence, qualifications, responsibilities and authorisations of personnel involved in testing, investigations and expert judgement
2/1999

Cost of accreditation
1/2000

Decision rules applied to conformity assessment
01/ 2017

EUROLAB Leaflet on Decision Rules for Laboratories Customers
07/2021

Eurolab inquiry. Use of the accreditation symbol and accreditation with flexible scope. Results
2/2008

Guidance for the management of computers and software in laboratories with reference to ISO/IEC 17025:2005
2/2006

EUROLABin Tekniset raportit (2)

Guide to NMR Method Development and Validation – Part I: Identification and Quantification (update 2023)
No 01/2023

Guide to NMR Method Development and Validation – Part II: Multivariate data analysis
Guidelines for the proper use of chemometrics in NMR analysis
1/2015

Guide to the Evaluation of Measurement Uncertainty for Quantitative Tests Results
Alternative approaches to the “bottom-up” approach, based on a comprehensive mathematical model.
1/2006

Guidelines for managing sustainability in CABs
1/2025

Guidelines for the management of digitalised systems in laboratories accredited to ISO/IEC 17025
1/2024

Improving cost effectiveness in the assessment of laboratories. Copenhagen, September 10, 1997. Joint EAL/EUROLAB workshop in cooperation with Eurachem
2/1997

Independence and impartiality in testing laboratory operations
1/1997

Measurement uncertainty in testing. A short introduction on how to characterise accuracy and reliability of results including a list of useful references
1/2002

EUROLABin Tekniset raportit (3)

Measurement uncertainty revisited: Alternative approaches to uncertainty evaluation. Alternative approaches to uncertainty evaluation
1/2007

One-stop for the customer
2/1998

Quality assurance according to EN 45001 and OECD GLP. A guide to simultaneous implementation (in cooperation with EURACHEM Netherlands)
3/1996

Satisfaction of customers with European accreditation bodies
2/2002

The scope of accreditation and consideration of methods and criteria for the assessment of the scope
5/1996

The volume of accreditation activities in Europe
1/2001

Validation of test methods. General principles and concepts (in cooperation with EAL, European cooperation for accreditation of laboratories
4/1996

EUROLAB Leaflet on Decision Rules for Laboratories Customers 07/2021

TCQA_21_39
Rev. n. 1
Res. Per. Mr. Álvaro Silva Ribeiro, RELACRE,
and Mr. Christian Müller-Schöll, EUROLAB-CH

Sisältö

Johdanto
Mikä on päätössääntö?
Onko minulla asiakkaana valinnanvaraa päätössäännön suhteen?
Lisätietoja

TCQA_21_39
Rev. n. 1
Res. Per. Mr. Álvaro Silva Ribeiro, RELACRE,
and Mr. Christian Müller-Schöll, EUROLAB-CH

eurolab aisbl
European Federation of National Associations of Measurement, Testing and Analytical Laboratories

WHAT IS A CONFORMITY STATEMENT INVOLVING A DECISION?

Introduction

In a first step, a testing or calibration laboratory would produce some kind of **result** according to your order. This result comes by its very nature with an **uncertainty** which the laboratory calculates and usually states in the report document.

This uncertainty is determined using statistical techniques. If you additionally require the laboratory to make a pass-fail statement with respect to some kind of limit or specification value, this is called a **decision** (also called acceptance or rejection). These decisions generally offer a high probability of being correct. But due to their statistical nature, these decisions themselves have an uncertainty which can result in wrong decisions. There are two cases of wrong decisions: false acceptance and false rejection and there are probabilities assigned with them: the **probability of false acceptance (PFA)** and the **probability of false rejection (PFR)**. These probabilities impose certain **risks** to you as customer of the lab.

The risk connected with PFA is sometimes called **consumer's risk** while the risk with PFR is sometimes called **producer's risk**.

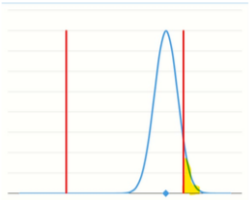


Figure 1

Measured value with its uncertainty distribution (blue) and tolerance lines (red): the result is "pass" (accept). However, there is a small area (yellow) which is outside of the limit, This area depicts the probability of false accept (PFA).

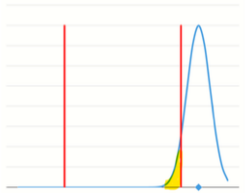


Figure 2

Measured value with its uncertainty distribution (blue) and tolerance limits (red); the result is "not pass" (reject). However, there is a small area (yellow) which is inside of the tolerance limits. This area depicts the probability of false reject (PFR).

eurolab *Laboratory and conformity assessment services supporting European technology and trade*

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What is a decision rule?

The way how the laboratory finds the decision based on the result, the uncertainty and the limit is called a **decision rule**. There are various decision rules and these differ in the PFA and PFR values.

As a customer, do I have a choice regarding the decision rule?

There are two general cases:

In many procedure standards (norms), the decision rule is **part of the standard**. In this case, the laboratory will apply this rule, but it will be able to explain the probabilities of this rule.

If the standard does not define a decision rule, you as a customer must reach an **agreement** with the lab on which decision rule(s) the laboratory should apply. The levels of PFA and PFR should be guiding you to the choice considering the intended use of the product to be tested. You should be aware that small risks require small uncertainties and might be more costly since they require more accurate procedures.

Further reading

More detailed information on this topic can be found in the following sources:

- ILAC Guidelines on Decision Rules and Statements of Conformity ILAC-G8:09/2019
- JCGM 106:2012: Evaluation of measurement data – The role of measurement uncertainty in conformity assessment. Download from BIPM website
- Eurolab Technical Report: Decision rules applied to conformity assessment. Download from the EUROLAB website
- Eurolab Cook Book 8: Determination of Conformance with Specifications or Limit Values. Download from the EUROLAB website

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- **EUROLABin Kannanotot**
- **Uutiskirjeet**
- **Vuosiraportit**
- **MoUs Yhteisymmärryspöytäkirjat (Memorandum of Understanding)**
- **Eurolab-kirjasto**

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EUROLAB Newsletter No. 1/2026

- Kannanotoissa (Position papers) ilmaistaan Eurolabin mielipide useisiin laboratorioihin ja eurooppalaiseen lainsäädäntöön liittyviin asioihin

- Yhteistyön vahvistamiseksi ja voimien yhdistämiseksi yhteisen edun mukaisissa kysymyksissä EUROLAB on allekirjoittanut useita yhteisymmärryspöytäkirjoja eri organisaatioiden kanssa

MoUs

- EUROLAB-kirjasto On kirjasto asiakirjoista, jotka liittyvät vaatimustenmukaisuuden arviointiyhteisölle tärkeisiin aiheisiin. Nämä asiakirjat liittyvät EUROLABin vuosittaisiin prioriteetteihin, työryhmiin (akkreditointi ja standardointi, digitalisointi ja kestävyys) sekä muihin alan keskeisiin kehityskulkuihin ja uutisiin

Seminaarit ja koulutukset

- ***Machine-Readable Documents: Challenges and Opportunities for Labs and other CABs***
- EUROLAB webinaari koneella luettavista asiakirjoista 27.5 2026
- Seminaarin tavoitteena on tuoda yhteen metrologian instituuttien, standardointielinten, vaatimustenmukaisuuden arvioinnin ja digitaalisten innovaatioiden asiantuntijoita jakamaan näkemyksiä, käytännön kokemuksia ja tulevaisuudennäkymiä

Viite

Laura Martin Finntesting Kevätseminaari 2024:
https://kemianseurat.fi/finntesting/wp-content/uploads/2024/10/EUROLAB-presentation_Finntesting-Seminar_29-May-2024.pdf

Kiitos !