

Extraction of critical success factors (CSFs) that effect the implementation of ISO/IEC 17025 Standard in UNILAB

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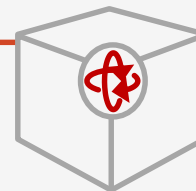
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УНИЛАБ

V International Conference "Quality and Competence"
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UNILAB



UNILAB as a part of the Faculty of Agriculture- Goce Delchev University from Shtip, function as a separate organization unit that operates under the legislative regulation, acts and standards, as follow:

- The Law of higher education;
- The Law of accreditation;
- The Standard MKC EN ISO/IEC 17025:2018



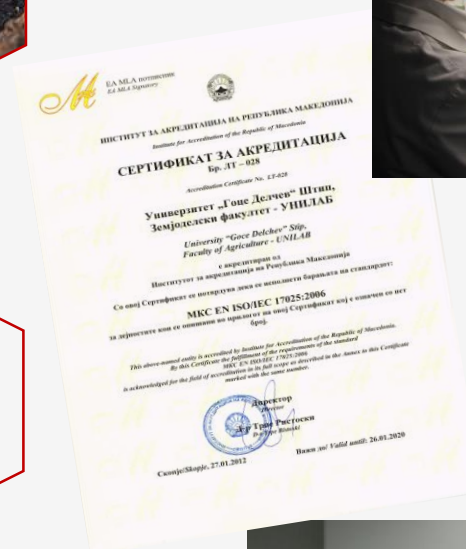
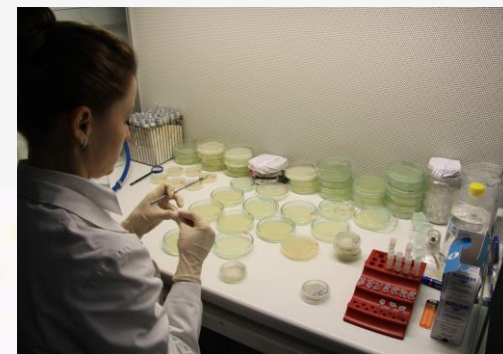
UNILAB is accredited with Accreditation Certificate no. LT - 028, for the implementation of Standard MKS EN ISO/IEC 17025:2018 in its operation and has accredited 51 methods

Accreditation is a formal recognition of the ability to perform certain activities.





Departments



In January, 2012 UNILAB has received the ISO certification



WHY Implementing a quality system such as ISO/IEC 17025

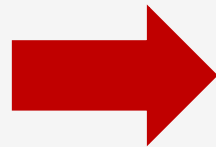


You can not manage what you cannot measure

The quality of decision making is only as good as the quality of data utilized

Tested once accepted everywhere!

Analytical testing laboratories seeking ISO/IEC 17025 will be impacted in multiple areas



Laboratories play an important role in company quality systems

MKC EN ISO/IEC 17025:2018



- 1 Laboratory performs agrochemical analyzes of the soil and giving appropriate recommendations for fertilization and plant nutrition; examination of the presence of macro and micro elements, heavy metals and trace elements in environmental samples: waters, soils, sediments, geological samples and waste.
- 2 The laboratory controls the safety and quality of available products by determining the multi-element analysis of food and nutritional supplements, beverages, plant material and extracts, as well as suspensions and concentrates of active substances and excipients in pharmaceutical products.



3

The laboratory determines the representation of nutrients in fertilizers; analysis of the quality of seed and planting material, determination and identification of the presence of diseases and pests in plants and stored agricultural products.



ISO/IEC 17025 Requirements key steps in accreditation for Testing Laboratories

! Specific requirements include:

- Sampling should be performed according to a sampling plan, and all sample details should be documented.
- Samples should be uniquely identified and the sample integrity should be protected during transport and storage.
- The quality of test results should be monitored.
- Test reports should include test results as well as an estimation of the overall measurement uncertainty. The report should also include detailed information about the sample and test conditions, or a link to a reference document.
- Records should be properly maintained to ensure data integrity and availability. Some requirements impact more than one value.
- All analytical methods and procedures should be validated. Validation includes methods and procedures for sampling, testing, and result evaluation.
- Equipment used for sampling and testing should be calibrated and well maintained. Material such as calibration standards should be qualified and traceable to System International (SI) units or to certified reference materials.
- Nonconforming test results should be documented and controlled.
- People should be qualified for their assigned tasks through education, experience, or training.
- Environmental conditions such as temperature, humidity, and electromagnetic interference should be monitored and controlled.
- All routine tasks should be performed according to written procedures.....

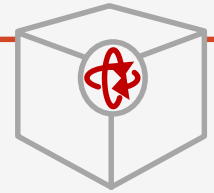
! Key Steps towards Accreditation:

1. Management defines a project owner.
2. The project owner studies details of the standard, supporting literature, and other relevant information.
3. The project owner defines the preliminary scope of accreditation and works with laboratory professionals to prepare a list with requirements.
4. The project owner and laboratory professionals perform a gap analysis to determine the difference between the requirements and what is currently implemented in the laboratory.
5. Based on the outcome of the gap analysis, the project owner, laboratory professionals, financing and documentation professionals, and external consultants estimate the costs for accreditation.
6. Estimated costs are presented to management, along with incremental opportunities.
7. Management decides to proceed with accreditation.
8. The project owner leads implementation steps.....

CONTINUOUS IMPROVEMENT



CRTICAL ISSUES in implementation



“A good system **recognises** the strategic benefit of **minimising risk and maximising opportunity**”



! Extraction of critical success factors (CSFs)



Is CSFs useful aspect of evaluation?

Rockart (1982)¹ stated " *CSFs as the limited number of areas in which results, if they are satisfactory, will ensure successful competitiveness performance for organisation*"

The advantage of identifying CSFs is to help the organization focus attention on major concerns, easy to monitor and can be used in accordance with strategic planning methodologies



CSFs are widely used in any business

¹Rockart, J.F. (1982). The changing role of the information systems executive: A critical success factors perspective. Sloan Management Review, Fall, 3–13



Literature review – available data

CSFs extracted for some laboratories from European, Asian and American countries

- *Management commitment,*
- *Employees commitment ,*
- *Understanding ISO 17025,*
- *Training and support,*
- *Financial support,*
- *Organisation culture,*
- *External consultant,*
- *Teamwork,*
- *Government support,*
- *Continuous improvement and availability*



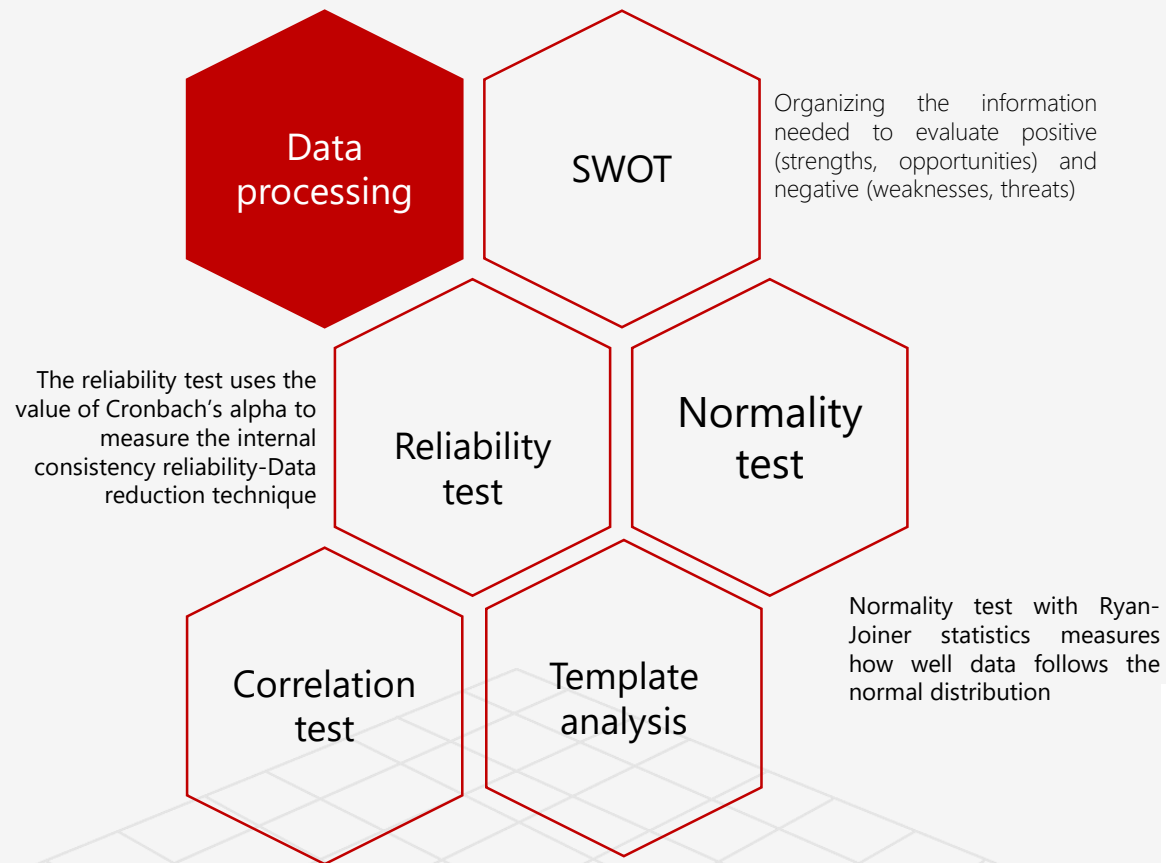
Need of self-evaluation vs. risk management

! Key matters

- ! Policy deployment and organization
- ! Organization of laboratories: the quality management system set out
- ! Human resources
- ! Budget
- ! Control of documents and records
- ! Customer relationship service
- ! Calibration, traceability to the SI and quality assurance of test results
- ! Maintenance planning and scheduling
- ! Maintenance performance
- ! Evaluation of uncertainty of measurements
- ! Strategies for implementation and its progress monitoring
- ! Implementation time scale
- ! Sustainable improvement
- ! Environment



Evaluation-Extraction-Evidence



SWOT analysis vs. Template analysis

SWOT analysis, developed in the 1960s, is an assessment tool for gathering and organizing the information needed to evaluate positive (strengths, opportunities) and negative (weaknesses, threats) elements of strategy or process

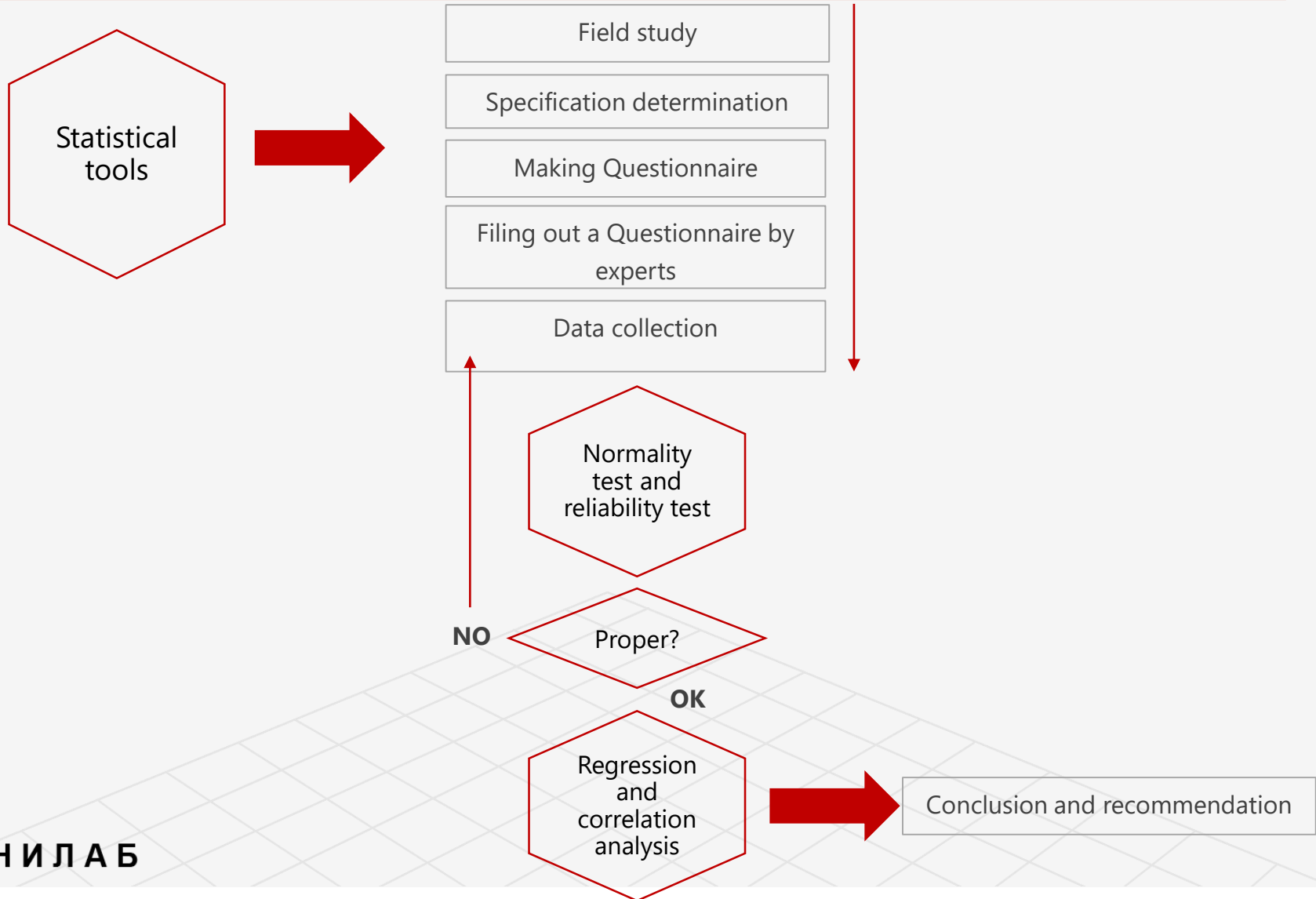
Aspect	Laboratories (internal) factors Strengths (factors)	Laboratories (external) factors Opportunities (factors)
Positive	<ul style="list-style-type: none"> Improving quality of Laboratories Improving performance Increasing lab productivity Improving data collection Build trust between you and your customer 	<ul style="list-style-type: none"> Public recognition Results accepted nationality & abroad Advantage in market competition Laboratory development Improve reputation of the laboratories
	Weaknesses (sub-factors)	Threats (sub-factors)
Negative	Part-time employees Lack of specific expertise's Difficulties in accepting new approaches Shifting time frames Accidents	Resource & funding cuts High costs for sustaining the programmes Training Programmes are costly. Calibrations are costly Weather disasters: floods, fires, earthquakes



Valuable extracting tools for risk assessment



Data processing and evaluation



CONCLUSIONS

The success in implementing a functional and flexible quality management system in science and testing laboratories depends not only on the effective and efficient handling of these key factors, but also on the use of a suitable approach for implementing the system

! The extraction methodology suggest that Human resources is the main factor in the success of the laboratory implementation of ISO 17025:2018 standard

- Training on understanding the quality system or ISO for all testing laboratory personnel.
- Training on the use of testing laboratory equipment for all testing laboratory personnel.
- Training in the maintenance of testing laboratory equipment for all testing laboratory personnel.
- **Personnel capacity building training and competency maintenance are conducted regularly to all testing laboratory personnel**



УНИВЕРЗИТЕТ „ГОЦЕ ДЕЛЧЕВ“ - ШТИП
ЗЕМЈОДЕЛСКИ ФАКУЛТЕТ
КАТЕДРА ЗА ЗАШТИТА НА РАСТЕНИЈАТА И ЖИВОТНАТА СРЕДИНА

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2021



THANK YOU FOR YOUR KIND ATENTION

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