

# Quality management: illuminating the path to ISO 15189 accreditation

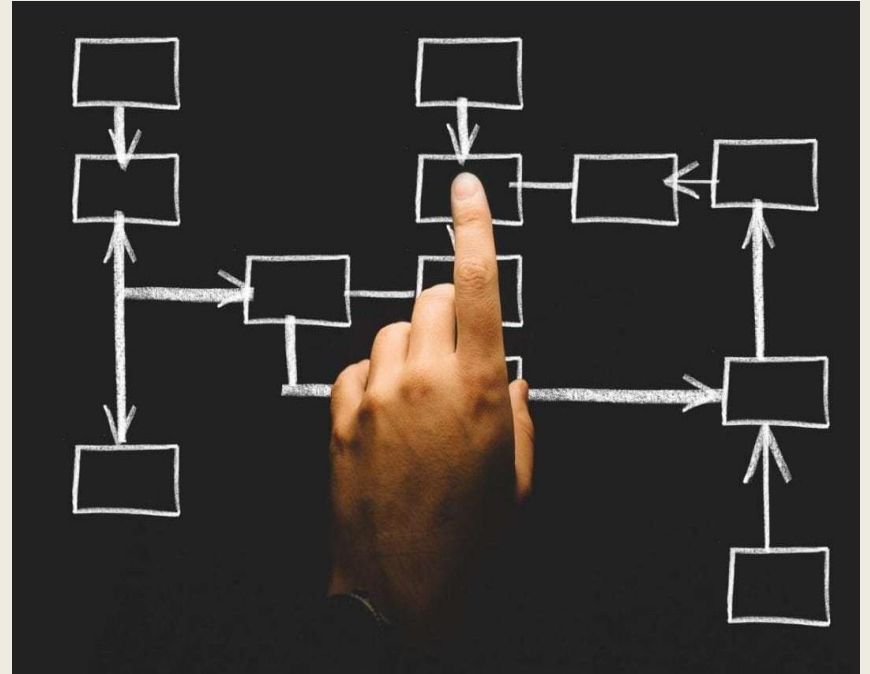
A view from the Republic  
of North Macedonia

KATERINA TOSHESKA-TRAJKOVSKA



# Overview

- Explain the systems approach to lab quality and its benefits;
- Identify the essential elements of a lab quality system;
- Describe the purpose and key benefits of accreditation.



# Quality

The ability of a product or service to satisfy stated or implied needs of a specific customer

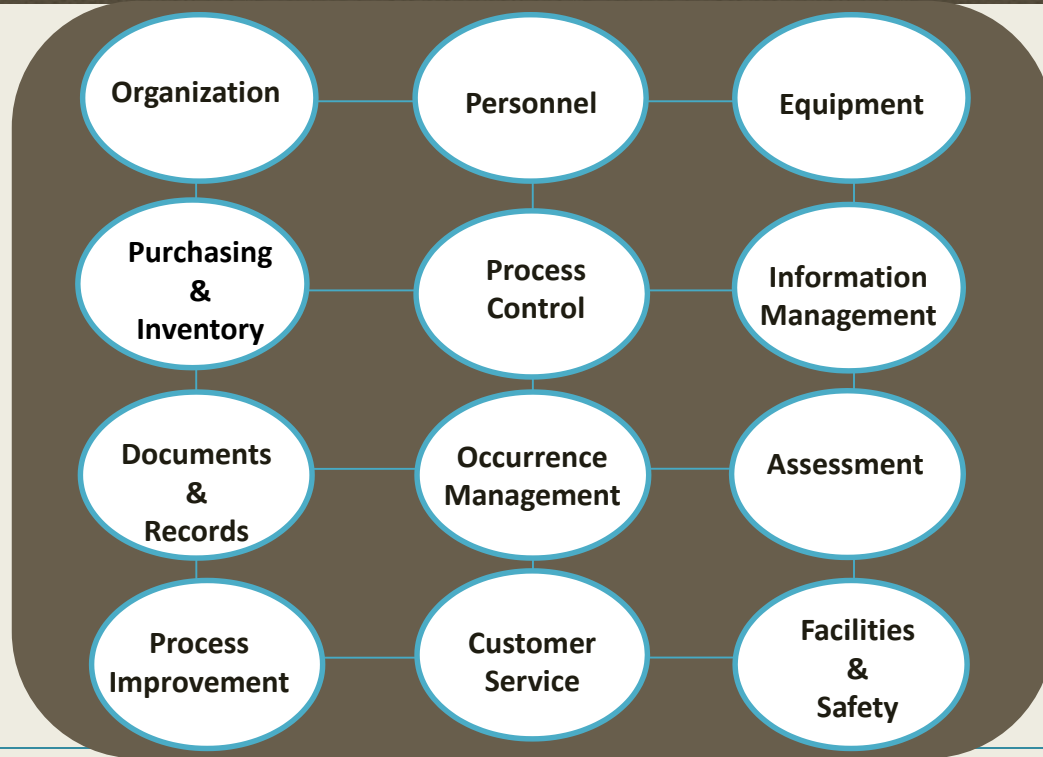
# What is Laboratory Quality?

- The right result?
- Lack of errors?
- Improved health outcome?
- Increased efficiencies

# Laboratory quality



# The Quality Management System



# Quality Improvement

“Everyone in healthcare really has two jobs when they come to work every day: to do their work and to improve it.”

Paul Batalden, MD, The Dartmouth Institute

# Continuous improvement

## Continuous improvement is essential to success

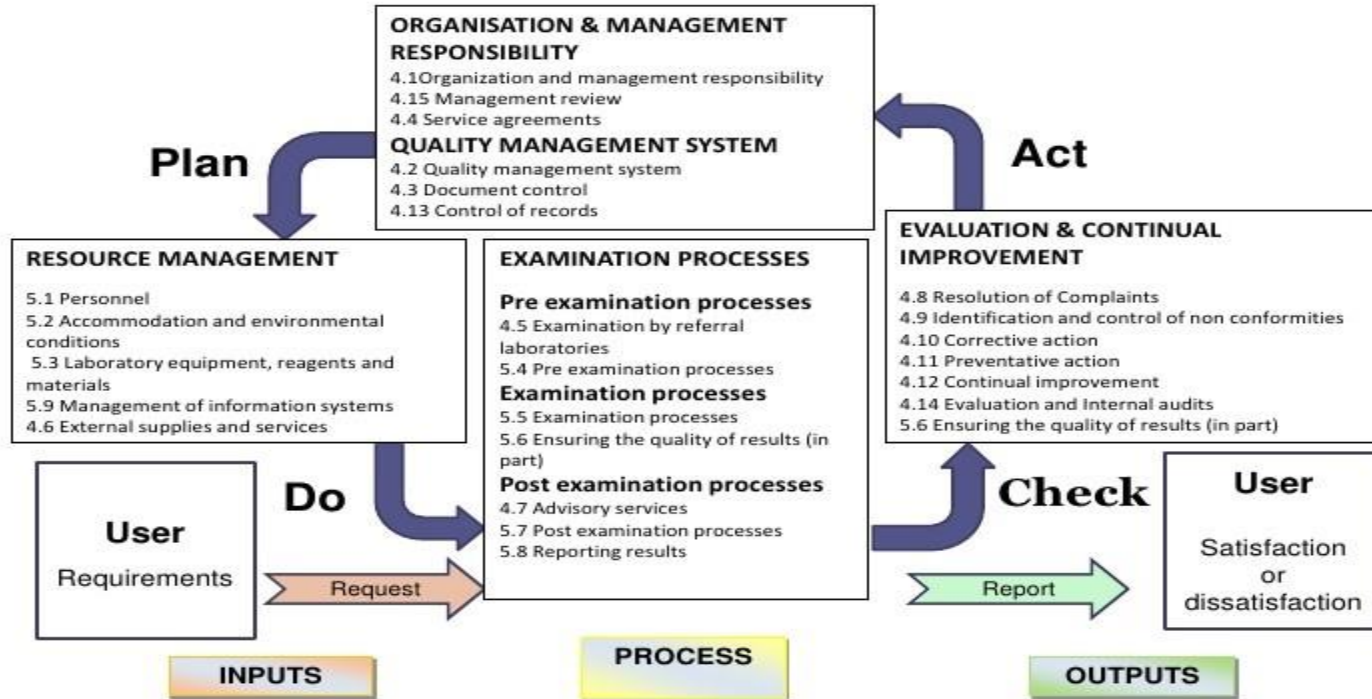
To minimize the costs and maximize benefits, use:

- standardized, structured approach;
- effective project management;
- effective engagement of staff, leaders, sponsors.





# Process map



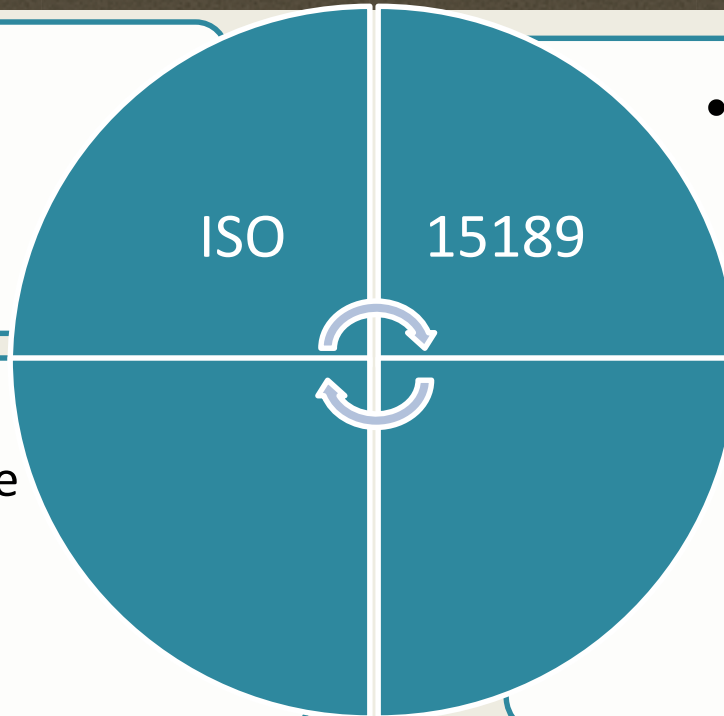
# ISO process for continual improvement

- identify potential sources of any system weakness or error;

- develop and implement the plan;

- review the effectiveness of the action through the process of focused review and audit;

- adjust the action plan and modify the system in accordance with the review and audit results



# Laboratory Accreditation

❓ Procedure used to provide formal notice that a body or person is competent to carry out specific tasks

❓ Key Words:

❓ “competent”

❓ specific tasks

❓ Accreditation is having a Management System and demonstrating competency

❓ Laboratories are accredited for specific tests

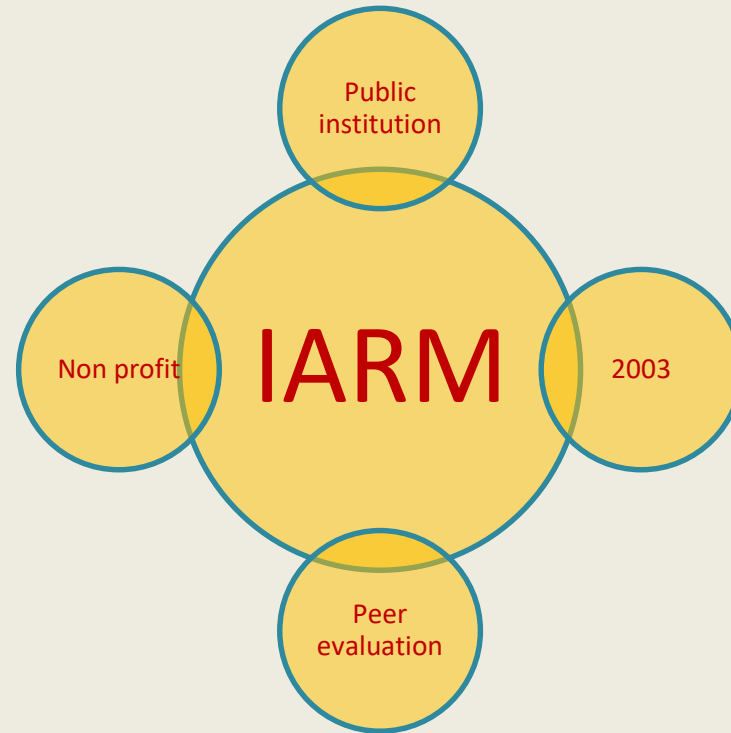
# Laboratory accreditation

Meeting the International Standard means the laboratory meets the technical competence requirements & the managerial system requirements....

to **consistently** deliver technically **valid** results

# Laboratory Accreditation

- ❑ Need to identify which agency is this for your lab;
- ❑ Users of ISO 15189 Accreditation: Laboratory customers, regulatory authorities and associated bodies

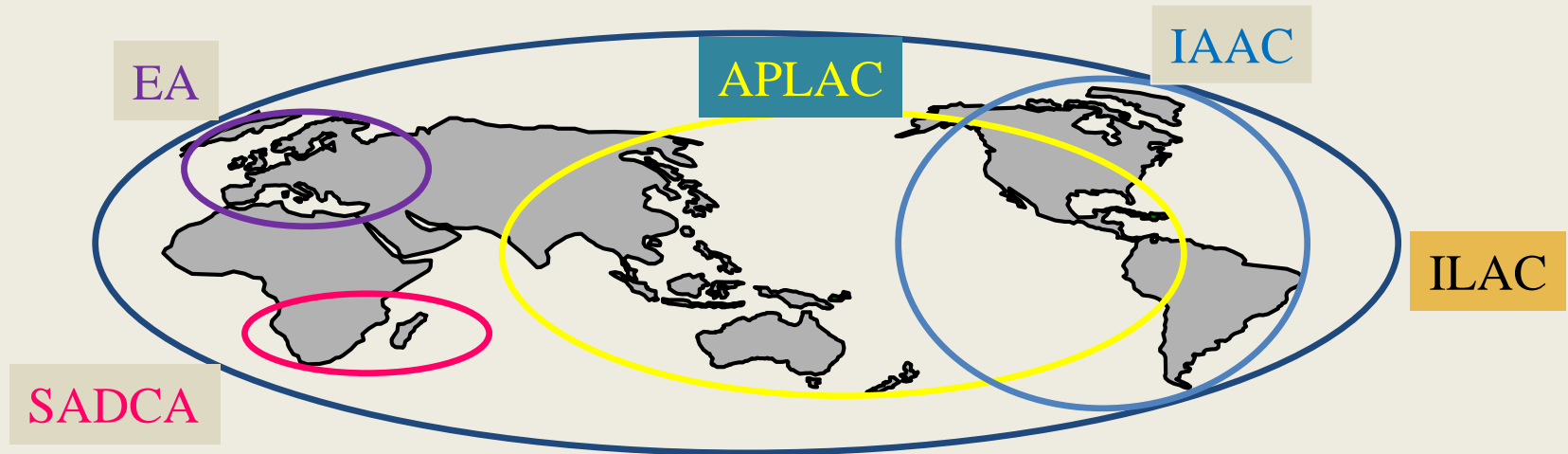


# One Test, Accepted Everywhere

- The acceptance of accredited laboratory data is facilitated through **mutual recognition** arrangements among accreditation bodies.
- **Mutual recognition** of accreditation requires harmonized requirements and an assessment procedure with comparable focus, attention and scope.



# Regional Accreditation Co-Operations



**EA**

**European cooperation for Accreditation**

**SADCA**

**Southern African Accreditation Cooperation**

**IAAC**

**Inter-American Accreditation Cooperation**

**APLAC**

**Asia Pacific Laboratory Accreditation Cooperation**

**ILAC**

**International Laboratory Accreditation Cooperation ([www.ilac.org](http://www.ilac.org))**



**Being accredited by an accreditation body that is part of the mutual recognition arrangement ensures that your data will be accepted globally**

# ISO 15189

## INTERNATIONAL STANDARD

## ISO 15189

Third edition  
2012-11-01

---

### Medical laboratories — Requirements for quality and competence

Laboratoires de biologie médicale — Exigences concernant la qualité et  
la compétence

### Management Requirement

- Organization
- Quality management system
- Document control
- Contract review
- Referral laboratories
- Supplier review
- Advisory services
- Complaint resolution
- Identification and control of nonconformities
- Corrective actions
- Preventive actions
- Continual Improvement
- Quality and technical records
- Internal audits
- Management review

### Technical Requirements

- Personnel authorities and responsibilities
- Accommodation and environmental conditions
- Laboratory equipment
- Pre-examination procedures
- Examination procedures
- Assuring quality of examination procedures
- Post-Examination procedures
- Reporting of results

### Annexes

# What is Audited?

## Management System:

- Management /administrative activities, such as -
  - purchasing of consumable materials;
  - management of calibration system;
  - contracts / client interactions;
  - document control and revision;
  - training records.
- Strict adherence to documented procedures.
- Audit can be conducted by non-technical personnel.



# What is Audited?

## Technical:

- Scientific judgment
  - performance of test;
  - sampling activities;
  - preparation of reagents and/or samples;
  - results.
- Strict adherence as well as technical correctness.
- Audit must be conducted by those familiar with test/technology.



# Three Critical Thoughts

Does the laboratory “say” what they do?

- Are there written documents (policies, procedures, arrangements) that meet the requirements of ISO 15189?

Does the laboratory “do” what they say?

- Are they in compliance with their own quality system, test methods and ISO 15189?

Can they “prove” it with their records?

- Including everything from training records to standards preparation records to work books to client reports to audit reports and everything in between?

# Accreditation

***Do what you **say** you are doing  
and be able to **prove** it!***

# For accreditation to be credible

The organisation should have prior knowledge of the document

The accreditation team should be trained, competent and objective

Performing a full examination consistent with document's requirements

Regular and continuous improvement process



# Accreditation Steps

## STEP 1



## STEP 2



## STEP 3



## STEP 4





# Implementation

Task	QSE	Delivery Timeline		
Development of a quality manual	<i>Organisation</i>	Date		
Development of Process Control	<i>Process Control</i>		Date	
Development of a management system for documents & records	<i>Document Control</i>			Date

# Implementation

Task	QSE	Delivery Timeline				
Staff training & competence testing	Personnel	Date				
Equipment management	Equipment		Date			
Purchase and inventory	Purchase and inventory			Date		
Control of non-conforming product	Occurrence Management				Date	
Internal quality indicators and audit	Internal Assessment					Date
Process improvement	Continual improvement	Date				
Monitoring of service & customer satisfaction	Service and Satisfaction			Date		



# Our experience...



LET'S



# Planned

Task 1

[Yellow sticky note]

# in Progress

Task 4

Task 5

Task 6

Task 7

# Done

Task 8

Task 9



# EQAS/PT and Accreditation

A laboratory must develop a plan to demonstrate how they will cover the test methods on their scope of accreditation over a 4-year period.



ПЛАН ЗА УЧЕСТВО ВО ШЕМИ НА ОЦЕНА НА ОСЛОБОБЕНОСТА (ТО), МЕЃУЛАБОРАТОРИСКИ СПОРЕДБИ (МЛС) И ПРОГРАМИ ЗА ЕКСТЕРНА  
ОЦЕНА НА КВАЛИТЕТОТ (ЕОК) И ПРИМЕНА НА ИНТЕРНИ МЕРКИ ЗА КОНТРОЛ НА КВАЛИТЕТОТ НА РЕЗУЛТАТИТЕ  
PLAN FOR PARTICIPATION IN PROFICIENCY TESTING SCHEMES (PT), INTERLABORATORY COMPARISONS (ILC) AND PROGRAMMES FOR EXTERNAL  
QUALITY ASSESSMENT (EQA) AND USE OF INTERNAL MEASURES FOR QUALITY CONTROL OF RESULTS

Ознака на извештајот<sup>1</sup>: \_\_\_\_\_ / **План**  
(Report code):

Име на лабораторијата/ите: \_\_\_\_\_  
(Name of laboratory/ies:)  
Датум на подготовка/ревизија \_\_\_\_\_  
(Date of preparation/revision)

Пополнил: \_\_\_\_\_  
(Filled by:)

Метод за тестирање/калибрација или поддисциплина	1 година	2 година	3 година	4 година	Забелешка на лабораторијата	Забелешка на тех. оценувач
	ТО/МЛС/ЕОК (организатор) Интерна Мерка за КК	ТО/МЛС/ЕОК (организатор) Интерна Мерка за КК	ТО/МЛС/ЕОК (организатор) Интерна Мерка за КК	ТО/МЛС/ЕОК (организатор) Интерна Мерка за КК		
1.						
2.						
3.						
-						

Издание/Issue 1  
Верзија-Version 1

ОБ 05-18-2

Страна/Pages 1 од/ of 2

# EQAS/PT and Accreditation

- Corrective action must be taken for any outlying results.
- Unacceptable EQAS/PT results may result in an adverse accreditation action such as suspension of that test from the scope until the lab can demonstrate acceptable performance.

# Benefits of EQAS/PT

## Laboratory Improvement:

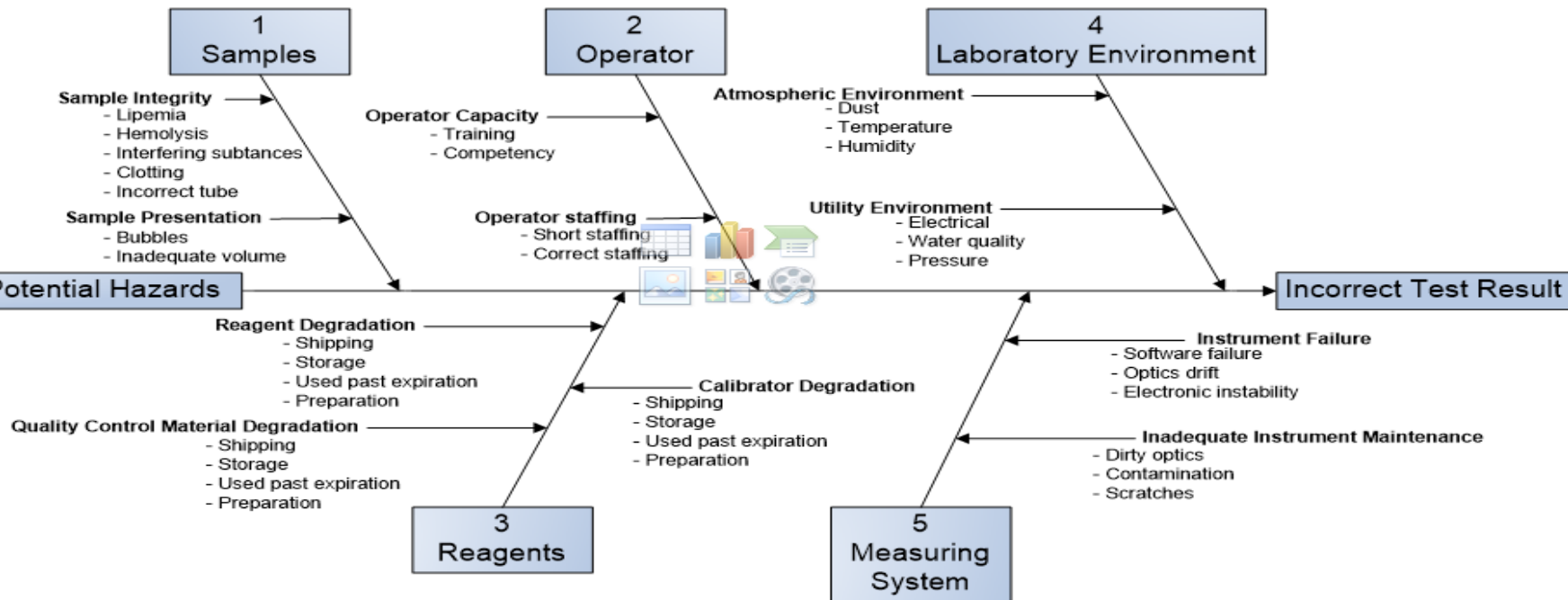
- Discover sources of error;
- Systematic errors;
- Demonstration of effectiveness of changes;
- Common understanding of method differences;
- Discovery of method sensitivities...

## Education:

- Interpretive information;
- New or rare analytes;
- Peer communication.



# Cause and effect diagram



# Root Cause Analysis

- A system of **problem solving** methods aimed at identifying the **root cause** of problems or incidents.
- By directing **corrective measures** at root causes, it is hoped that the likelihood of problem recurrence will be minimized.

# Corrective and Preventive Actions

## Corrective actions (CA) are issued for:

- Processes not followed as written;
- IQ or EQAS problems;
- Customer complaints;
- Audit non-conformances...



## Preventive Actions (PA) are issued when a potential problem is noted.

They are usually more complex and a longer term fix is needed.

**Both CA and PA are tracked. A timeline is assigned requiring completion and verification of effectiveness.**

# Internal audit



# Management Review

Management Review is a periodic meeting of members of management and supervisory staff. It allows for a broad review of the quality system including:

- status of CA taken and required PA;
- the outcome of recent internal audit;
- customer complaints;
- the outcome of EQAS;
- quality indicators...



# Overall Benefits of Accreditation

## Using an accredited laboratory:

- Increases confidence in data;
- Reduces uncertainties associated with decisions;
- Increases public confidence because accreditation is a recognizable mark of approval;
- Improves efficiency of the assessment process;

# Overall Benefits of Accreditation

- Issues with methods, personnel, and equipment are identified and resolved more quickly;
- Customer satisfaction is improved;
- Business opportunities may increase.

# Accredited medical laboratories



## Accredited medical laboratories

ML - 009 University "Ss. Cyril and Methodius" in Skopje Faculty of Medicine in Skopje Institute of Medical and Experimental Biochemistry Biochemical Analyses Laboratory (BAL)

[Read more](#)

ML - 008 Private Health Institution –Diagnostic/Biochemical Laboratory HEMOLAB Skopje

[Read more](#)

ML - 006 University Clinic for infectious diseases and Febrile conditions  
Department for laboratory and etiological diagnostics of infectious diseases Section for Molecular diagnostic laboratory

[Read more](#)

ML - 005 Institute of Microbiology and Parasitology

Medical Laboratory

[Read more](#)

ML - 004 Clinical Hospital Acibadem Sistina

Diagnostic Laboratories

[Read more](#)

ML - 003 PHI Avicena Laboratory-Skopje

[Read more](#)

ML - 001 The Private health institution – diagnostic laboratory with biochemical and microbiological laboratory SYNLAB Skopje

[Read more](#)

ML - 002 PHI General hospital RE-Medika Skopje

Diagnostic biochemical laboratory

IVF laboratory

Diagnostic microbiology laboratory



EA MLA потпишник  
EA MLA Signatory



ИНСТИТУТ ЗА АКРЕДИТАЦИЈА НА РЕПУБЛИКА МАКЕДОНИЈА

*Institute for Accreditation of the Republic of Macedonia*

## СЕРТИФИКАТ ЗА АКРЕДИТАЦИЈА

Бр. ML-009

*Accreditation Certificate No. ML-009*

Универзитет „Св. Кирил и Методиј“ во Скопје  
Медицински факултет во Скопје  
Институт за медицинска и експериментална биохемија  
Лабораторија за биохемиски испитувања (ЛБИ)

*University "Ss. Cyril and Methodius" in Skopje  
Faculty of Medicine in Skopje  
Institute of Medical and Experimental Biochemistry  
Biochemical Analyses Laboratory (BAL)*

е акредитиран од  
Институтот за акредитација на Република Македонија

Со овој Сертификат се потврдува дека се исполнети барањата на стандардот:

**MKS EN ISO 15189:2013**

за дејностаите кои се опишани во прилогот на овој Сертификат кој е означен со нег бр.ој.

*This above-named entity is accredited by Institute for Accreditation of the Republic of Macedonia.  
By this Certificate the fulfillment of the requirements of the standard  
MKS EN ISO 15189:2013  
is acknowledged for the field of accreditation in its full scope as described in the Annex to this Certificate  
marked with the same number.*



Скопје, 26.05.2017  
Skopje, 26.05.2017

Важи до: 25.05.2021  
Valid until: 25.05.2021



# What is Quality?

Crosby “Quality has much in common with sex”



Everyone is for it (Under certain conditions, of course)

Everyone feels they understand it (Even though they wouldn't want to explain it)

Everyone thinks execution is only a matter of following natural inclination

(After all, we do get along somehow)

Most people feel that all problems in these areas are caused by other people

(If only they would take time to do things right)

IT IS NOT  
ENOUGH  
THAT WE DO  
OUR BEST.  
SOMETIMES  
WE MUST DO  
WHAT IS  
REQUIRED.

— Winston Churchill