" ALEXANDRU IOAN CUZA" UNIVERSITY OF IASI (UAIC)
11 Carol I, 700506 Iasi, Romania
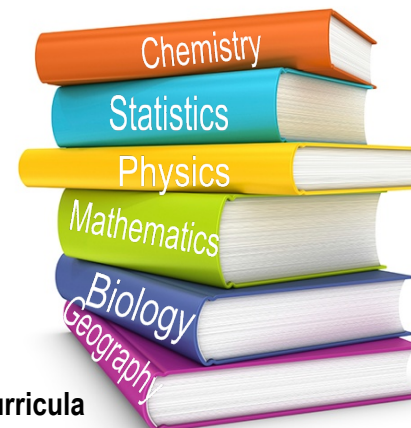
FACULTY OF CHEMISTRY

The importance of the laboratory quality management system in the academic curricula in developing appropriate student competences for our current societal needs

Cecilia ARSENE

Analytical Chemistry Laboratory

carsene@uaic.ro

Virtual Scientific Workshop

Eurachem 2020, Quality Assurance for Analytical Laboratories in the University Curricula

14 – 15 July 2020

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Innovative education, the education used to foster students' knowledge, innovation ability, creative spirits, and practice for…

Teaching - Learning - Thinking

Education – the tool helping young people assessing the media critically and strengthen their sense of belonging….

Education institutions, the core of the European higher education system.

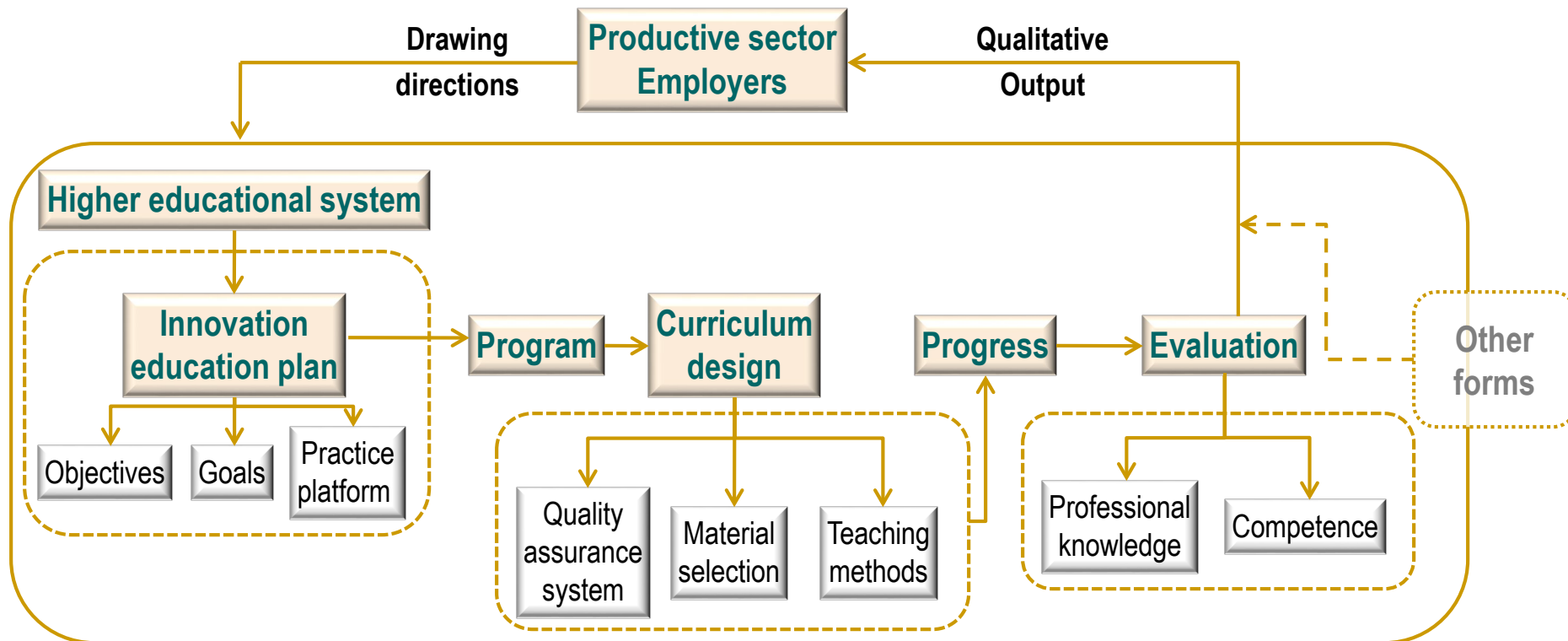**Education plays fundamental roles in**:

✓ **sharing and teaching fundamental values**;

✓ **instilling and fostering competences**:

    ✓ essential related knowledge;

    ✓ skills and attitudes;

    ✓ critical thinking skills and critical use of all forms of media support;

    ✓ open-minded social attitudes.

✓ **European students** (Bachelor's degrees and Master's degrees):

    ✓ more than 70% are enrolled in institutions offering a broad range of study programmes;

    ✓ ~30% enrolled in focused or specialized institutions, producers of professionally-oriented higher education, sometimes developed to respond to specific market needs (Education and Training Monitor, 2018).
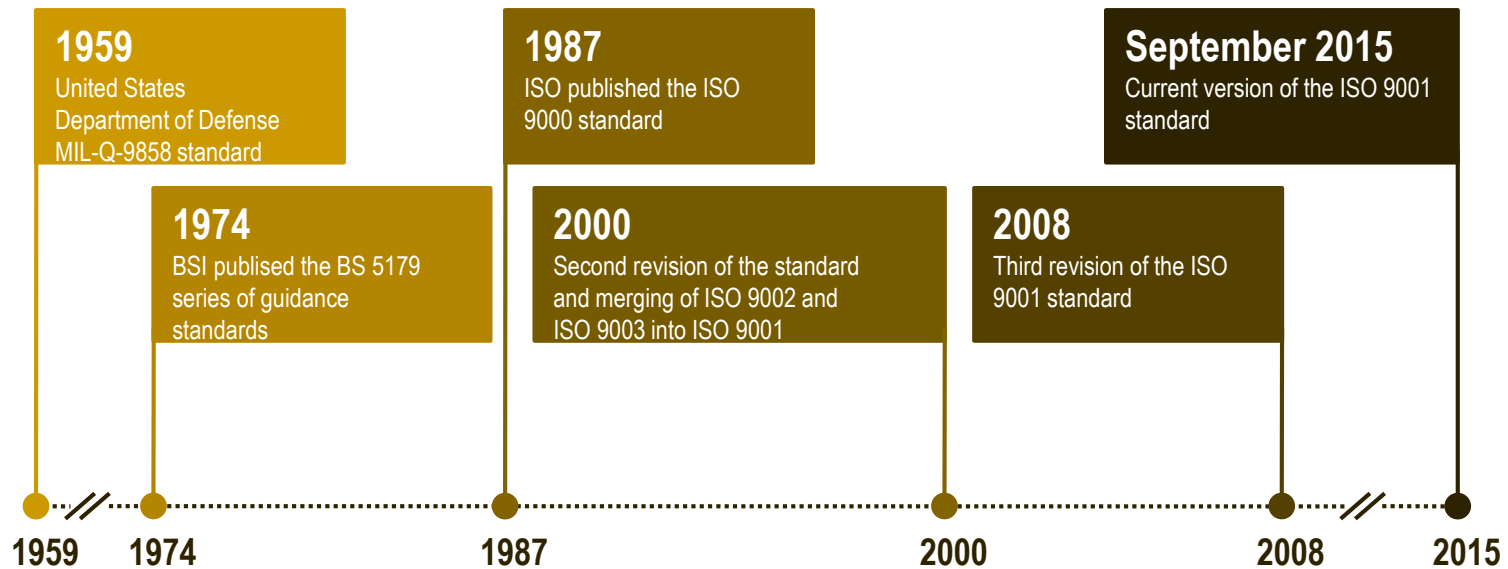
PhD
ISCED 8

Master
ISCED 7

….Bachelor
ISCED 6

European Commission

Education and Training
MONITOR 2018

Higher Educational Systems – Universities – Employers tandem

Universities

✓ basically **teaching and research institutions aimed at qualifying human resources** and producing knowledge;

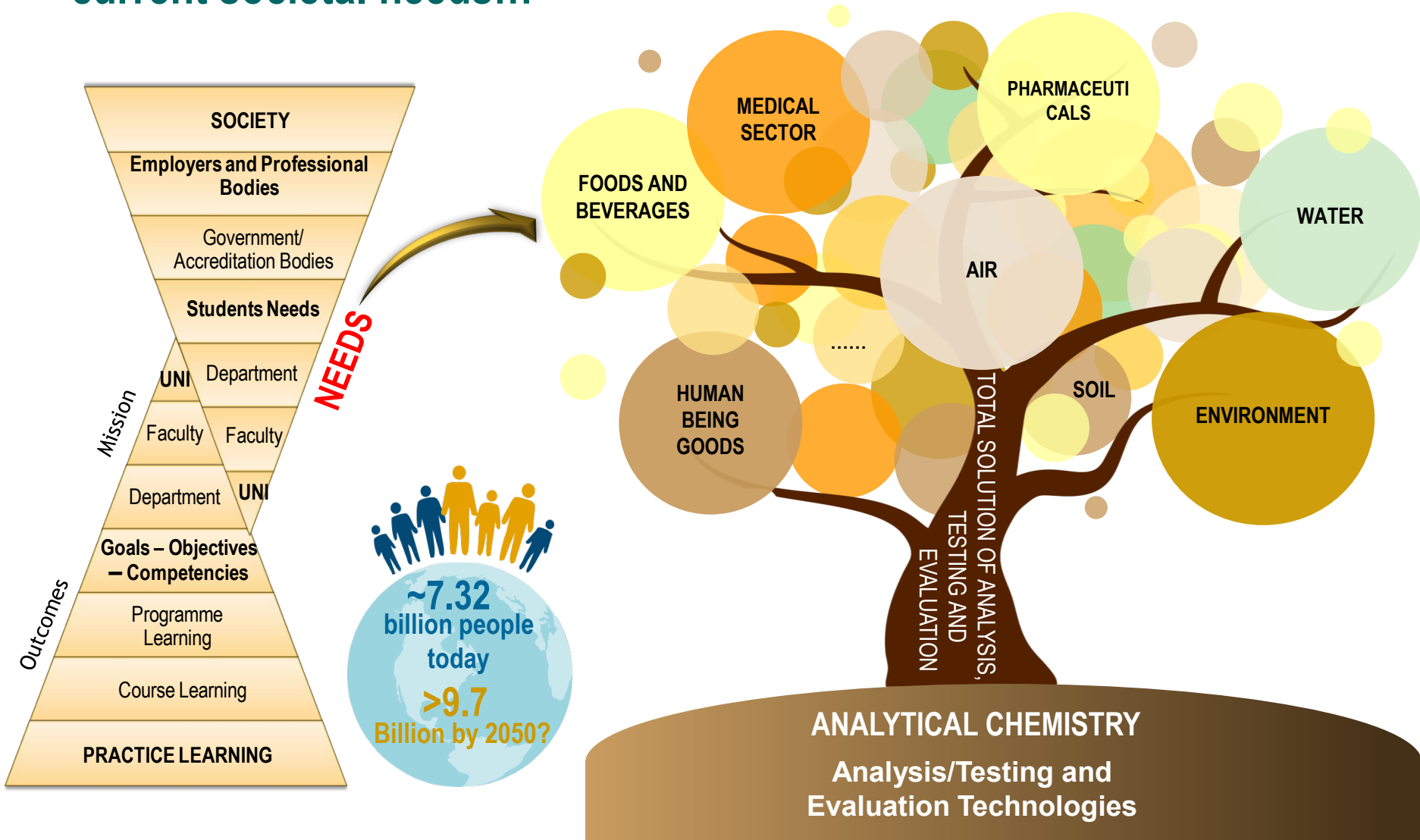✓ **educational units responding to the demands of society**, interacting with other institutions and companies.

For a qualitative output, the Quality Management System might be the solution we are looking for…

1959
United States Department of Defense MIL-Q-9858 standard

1974
BSI publised the BS 5179 series of guidance standards

1987
ISO published the ISO 9000 standard

2000
Second revision of the standard and merging of ISO 9002 and ISO 9003 into ISO 9001

2008
Third revision of the ISO 9001 standard

September 2015
Current version of the ISO 9001 standard

| 1959 | 1974 | 1987 | 2000 | 2008 | 2015 |

The **Quality Management System (QMS)**

✓ **collection of processes and functions aimed at continuous improvement of quality** such as to ensure customer expectations and requirements to be met or exceeded;

✓ framework of **organized structures, methods, techniques, policies, procedures, processes, and resources;**

✓ methods by which **each entity can ensure responsibilities, schedules, relationships, contracts, and agreements in full agreement with environmental, food, and product safety standards;**

✓ **highly complex and difficult successfully to implement.**

The importance of Shewhart's (PDCA) or Deming's (PDSA) cycle

Walter A. Shewhart
(1891-1967)

Deming's "study" – S
with many connotations

Improvement → Stakeholders' Needs

Competences

Learning Outcomes

Standardisation

Curriculum

Feedback/ Evaluation

Results Analysis

Assessment ← Learning Teaching

Act | **Plan**
Check | **Do**

W. Edwards Deming
(1900-1993)

Shewhart's (PDCA) or Deming's (PDSA) cycle applicability for our current societal needs…

SOCIETY

Employers and Professional Bodies

Government/ Accreditation Bodies

Students Needs

UNI — Department

Mission

Faculty — Faculty

Department — UNI

Goals – Objectives – Competencies

Programme Learning

Outcomes

Course Learning

PRACTICE LEARNING

NEEDS

~7.32 billion people today
>9.7 Billion by 2050?

FOODS AND BEVERAGES

MEDICAL SECTOR

PHARMACEUTICALS

WATER

AIR

……

HUMAN BEING GOODS

SOIL

ENVIRONMENT

TOTAL SOLUTION OF ANALYSIS, TESTING AND EVALUATION

ANALYTICAL CHEMISTRY

Analysis/Testing and Evaluation Technologies

In a chemical analysis lab…skills training…the quintessence for teaching analytical quality assurance adhered to international standards

Skills training

quality assurance

performance

„Alexandru Ioan Cuza" University of Iasi

reliable
work class

standards

warranty
requirements
ISO 17025
guidance
teacher
tools

implementation
analytical method
audit
accredited
safety

company
quality
learn
Faculty of Chemistry

requirements

product
student
standard
company
management
efficiency

certified
laboratories
sustainable

calibration
validation
learning
control

measuring

standardization
assurance

maintainable
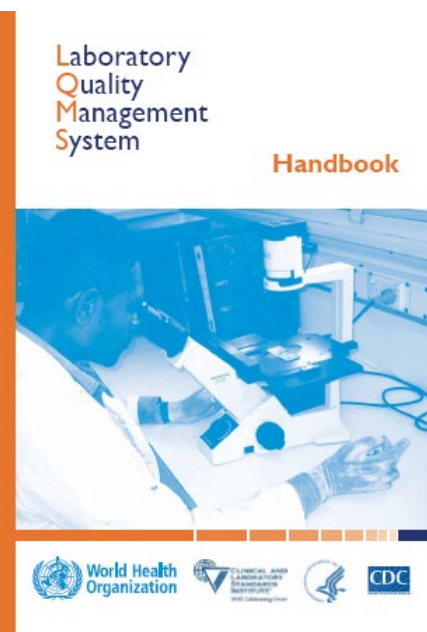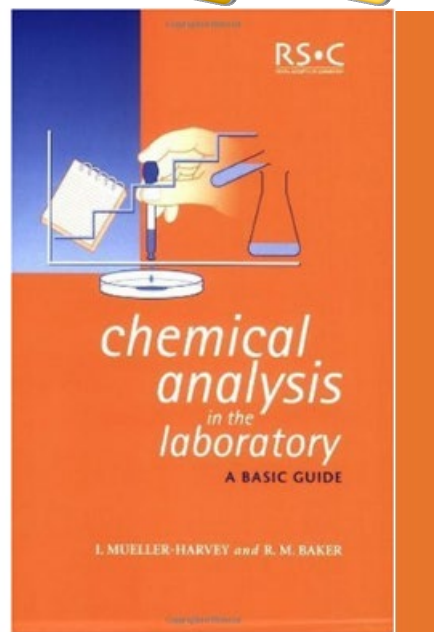
"Quality" and "ISO requirements" in the academic curricula at the Alexandru Ioan Cuza University of Iasi…

2010-2013 Prof. OLARIU

2013-2015 Prof. ARSENE

2015-2016 Assoc. prof. CUCU-MAN

2016-2019 Prof. ARSENE

Members of the Analytical Chemistry Laboratory

UAIC Chemistry 2014-2016

MASTER CURRICULA — Year I

No.	Courses		Semester: II			VF	Cr
			C	S	L		
	Mandatory						
8	Managementul calităţii în analiza chimică. Reglementări ISO / *Quality management in chemical analysis. ISO regulations.*		2		3	E	6

UAIC Chemistry 2017-2019

MASTER CURRICULA — Year I

No.	Courses		Semester: II			VF	Cr
			C	S	L		
	Mandatory						
8	Managementul calităţii în cercetarea stiintifică. Reglementări ISO / *Quality management in chemical analysis. ISO regulations.*		2		1	E	6

UAIC Chemistry 2018-2020

MASTER CURRICULA — Year I

No.	Courses		Semester: II			VF	Cr
			C	S	L		
	Compulsory						
8	Managementul calităţii în cercetarea stiintifică. Reglementări ISO / *Quality management in chemical analysis. ISO regulations.*		2		2	EVP	6

UAIC Chemistry 2019-2021

MASTER CURRICULA — Year I

No.	Courses		Semester: II			VF	Cr
			C	S	L		
	Compulsory						
8	Other disciplines						

If ISO, than what's the best for developing quality competences in a chemical analysis lab for testing?
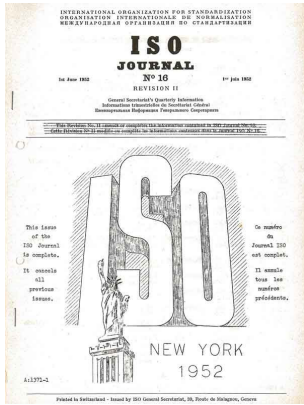
The ISO Journal May 1952

2017
Publication of ISO/ 17025 Last Edition

2010
Standard under revision

2005
Publication of ISO/ 17025 Second Edition

1999
Publication of First Edition of ISO/ 17025 and Revised

1992
OECD Principles of GLP & ISO/IEC Guide 25

1987
87/017/EEC European Council Directive on application of GLP principles

1972
Good Laboratory Practice – GLP (first introduced in New Zeeland and Denmark)
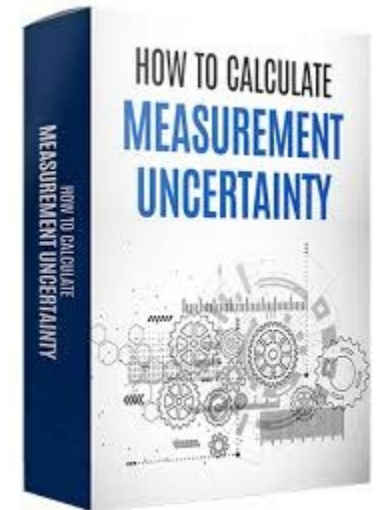
Apart teaching students about "Quality management in chemical analysis. ISO requirements", the strategy for practice

ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories."

Simulation of a QMS implementation in student's developed units

"Quality Management in Chemical Analysis. ISO Requirements" – Methods validation and implementing Analytical Research

Basic Analytical Research

Applied Research

Principal Objectives

Implement

Methods validation (GFAAS, IC, UV-vis)

Shewart's diagram

Analysis of different analytes and matrices

-Developing analysis methods;
-Solving analytical problems;
-Publications;
-Dissemination of scientific data;

Quality Systems

ISO/IEC 17025

Research Adapted to Quality Assurance Principles and Practices

ISO 17025 curriculum design in "Quality Management in Chemical Analysis. ISO Requirements"……

1. Plan

- 1.1. Initiate activity
- 1.2. Understand laboratory organization
- 1.3. Analysis of the objectives
- 1.4. Organization structure/management commitment
- 1.5. Simulation aim
- 1.6. Identification and selection of methods
- 1.7. Risk management

2. Do

- 2.1. Resource management
- 2.2. Requests
- 2.3. Handling of testing and calibration items
- 2.4. Sampling
- 2.5. Documentation record management
- 2.6. Reporting results and measurement uncertainty

3. Check

- 3.1. Monitoring
- 3.2. Evaluation
- 3.3. Assessment

4. Act

- 4.1. Remedial
- 4.2. Improvement for the future

Understanding the difference

ISO/IEC 17025:2005	ISO/IEC 17025:2018
Scope	Scope
Normative references	Normative references
Terms and definitions	Terms and definitions
Management requirements	**General requirements**
Technical requirements	**Structural requirements**
Annex A (informative) Nominal cross-reference to ISO 9001:2000	**Resource requirements**
Annex B (informative) Guidelines for establishing applications for specific fields	**Process requirements**
	Management system requirements
	Annex A (informative) Metrological traceability
	Annex B (informative) Management system options

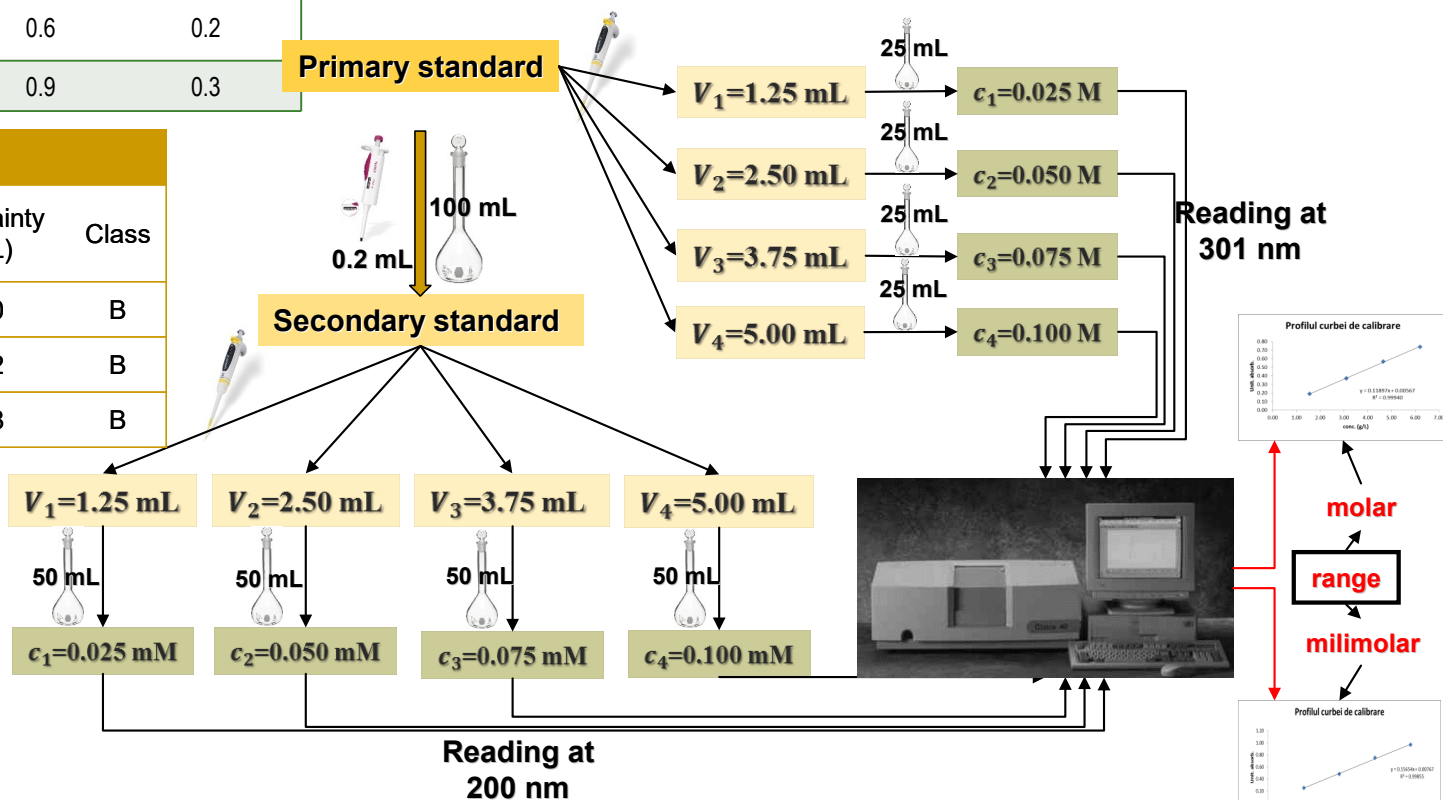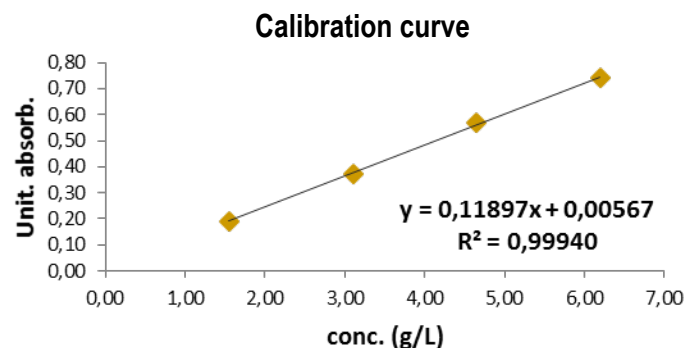# "Quality Management in Chemical Analysis. ISO Requirements", how it worked……

2013-2014: **Nitrate ion analysis by UV spectrophotometry. Method validation (standards, calibration range, linearity, trueness, accuracy, recovery, uncertainty)**

OLARU Anda
CRACIUN Bogdan
BUCUR Stefan
VARLAN Constantin

Micropipettes

Volume (μL)		Increment (μL)	Accuracy (±%)	Repetability (±%)
min	max			
1000	10000	10	0.6	0.2
200	1000	5	0.9	0.3

Volumetric flasks

No	Volume (mL)	Uncertainty (±mL)	Class
1	100	0.20	B
4	50	0.12	B
4	25	0.08	B

Primary standard

100 mL

0.2 mL

Secondary standard

V_1=1.25 mL → 25 mL → c_1=0.025 M
V_2=2.50 mL → 25 mL → c_2=0.050 M
V_3=3.75 mL → 25 mL → c_3=0.075 M
V_4=5.00 mL → 25 mL → c_4=0.100 M

Reading at 301 nm

V_1=1.25 mL → 50 mL → c_1=0.025 mM
V_2=2.50 mL → 50 mL → c_2=0.050 mM
V_3=3.75 mL → 50 mL → c_3=0.075 mM
V_4=5.00 mL → 50 mL → c_4=0.100 mM

Reading at 200 nm
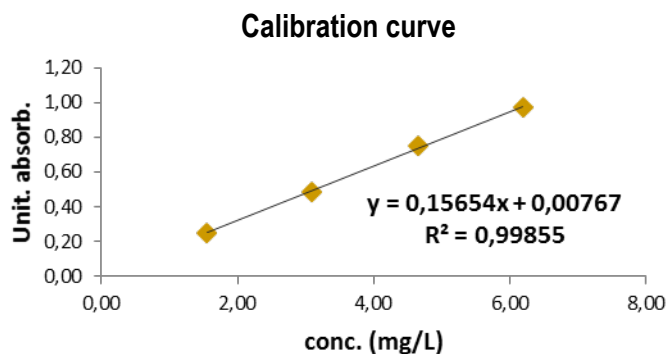
molar

range

milimolar

"Quality Management in Chemical Analysis. ISO Requirements", how it worked…… working range

2013-2014: **Nitrate ion analysis by UV spectrophotometry. Method validation (standards, calibration range, linearity, trueness, accuracy, recovery, uncertainty)**

OLARU Anda
CRACIUN Bogdan
BUCUR Stefan
VARLAN Constantin

Code	Unit	Value	A	Unit	1st reading	2nd reading	3rd reading	Average	SD(±)	PW
$C_{1\_cal\_std}$	mg/L	1.550000	A_1	unit. de abs.	0.243	0.254	0.255	0.251	0.003844	
$C_{2\_cal\_std}$	mg/L	3.100000	A_2	unit. de abs.	0.479	0.494	0.479	0.484	0.005000	0.61
$C_{3\_cal\_std}$	mg/L	4.650000	A_3	unit. de abs.	0.754	0.741	0.762	0.752	0.006119	
$C_{4\_cal\_std}$	mg/L	6.200000	A_4	unit. de abs.	0.973	0.964	0.973	0.970	0.003000	

Code	Unit	Value	A	Unit	1st reading	2nd reading	3rd reading	Average	SD(±)	PW
$C_{1\_cal\_std}$	g/L	1.55	A_1	unit. de abs.	0.187	0.195	0.189	0.190	0.002404	
$C_{2\_cal\_std}$	g/L	3.10	A_2	unit. de abs.	0.367	0.354	0.389	0.370	0.010214	7.87
$C_{3\_cal\_std}$	g/L	4.65	A_3	unit. de abs.	0.554	0.572	0.575	0.567	0.006557	
$C_{4\_cal\_std}$	g/L	6.20	A_4	unit. de abs.	0.729	0.752	0.737	0.739	0.006741	

Calibration curve

$y = 0.15654x + 0.00767$
$R^2 = 0.99855$

x-axis: conc. (mg/L); y-axis: Unit. absorb.

Calibration curve

$y = 0.11897x + 0.00567$
$R^2 = 0.99940$

x-axis: conc. (g/L); y-axis: Unit. absorb.

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"Quality Management in Chemical Analysis. ISO Requirements", how it worked…… method's rightness

2013-2014: **Nitrate ion analysis by UV spectrophotometry. Method validation (standards, calibration range, linearity, trueness, accuracy, recovery, uncertainty)**

OLARU Anda
CRACIUN Bogdan
BUCUR Stefan
VARLAN Constantin

Method's rightness for the first point on the calibration curve (mM)						
No. of replicates	A averaged	C averaged	Unit	inc $_{calib.}$ ($\pm$)	Unit	inc $_{calib.}$ (%)
3	0.2507	1.55	mg/L	0.0342	mg/L	2

	(N-2)	2	
		b	0.1565
	$\underline{y=a +bx}$	a	0.0077
		sy	0.0146
		s_{x0} methods standard deviation	0.0935
		V_{x0} methods coefficient variation	15.2193
		$2s_{x0}$	0.1870

Method's rightness for the first point on the calibration curve (mM)						
No. of replicates	A averaged	C averaged	Unit	inc $_{calib.}$ ($\pm$)	Unit	inc $_{calib.}$ (%)
3	0.2507	1.55	mg/L	0.0342	mg/L	1

	(N-2)	2	
		b	0.1190
	$\underline{y=a +bx}$	a	0.0057
		sy	0.0071
		s_{x0} methods standard deviation	0.0599
		V_{x0} methods coefficient variation	12.8408
		$2s_{x0}$	0.1198

"Quality Management in Chemical Analysis. ISO Requirements", how it worked……

2014-2015: **Development of an HPLC method for *p*-nitrophenol analysis**

CIOCARLAN Radu-George

CRACIUN Elena

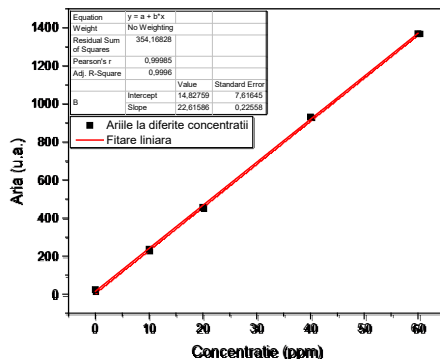**OLTEANU Oana-Elena**

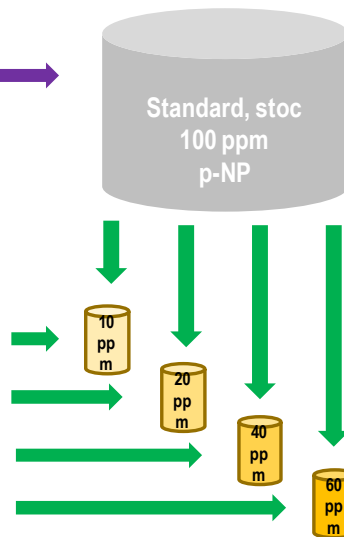**TANASA Georgiana**

ZORBAX 5 mm,
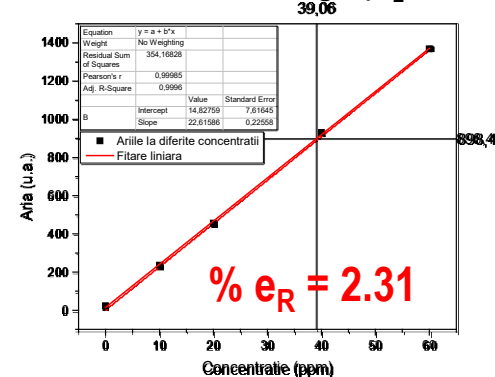Eclipse XDB-C8 (4,6.150 mm)
λ= 360 nm

Curba de etalonare

Standard, stoc 100 ppm p-NP

10 ppm

20 ppm

40 ppm

60 ppm
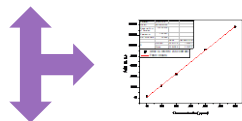
T_R (min)	Area
5.953	235.8
5.931	455.8
5.948	930.6
6.041	1369

SPE
C18
40 ppm
spiked sample

Activated cartridge (H$_2$O-MeOH)

% e$_R$ = 2.31

Inactivated cartridge

% e$_R$ = 89.57

16
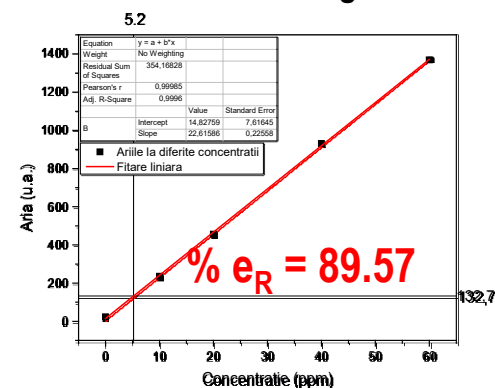
"Quality Management in Chemical Analysis. ISO Requirements", how it worked……

2016-2017: **Shewhart's diagram in dispensing volumes with automatic pipettes**

DONISA Andreea-Madalina
PUSCASU Roxana-Mihaela
USCATU Ana-Maria (Leonte)

Materials

Analytical balance

Pipettes: 1 mL, 5 mL, respectively, 200 µL

Berzelius and Erlenmeyer flasks

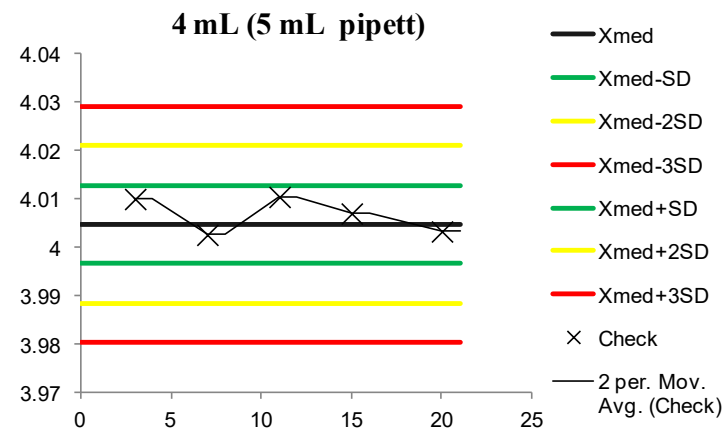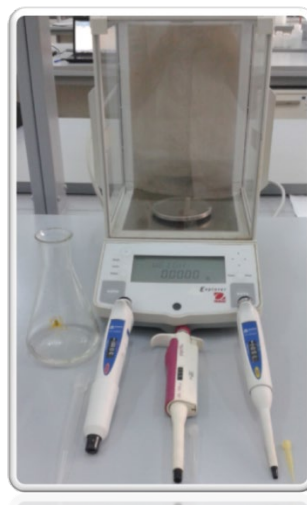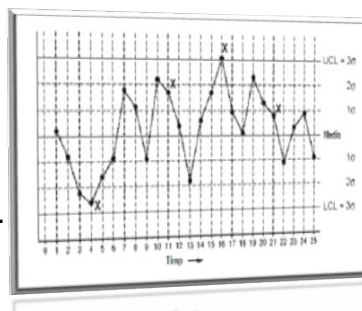

Sample

Distilled water

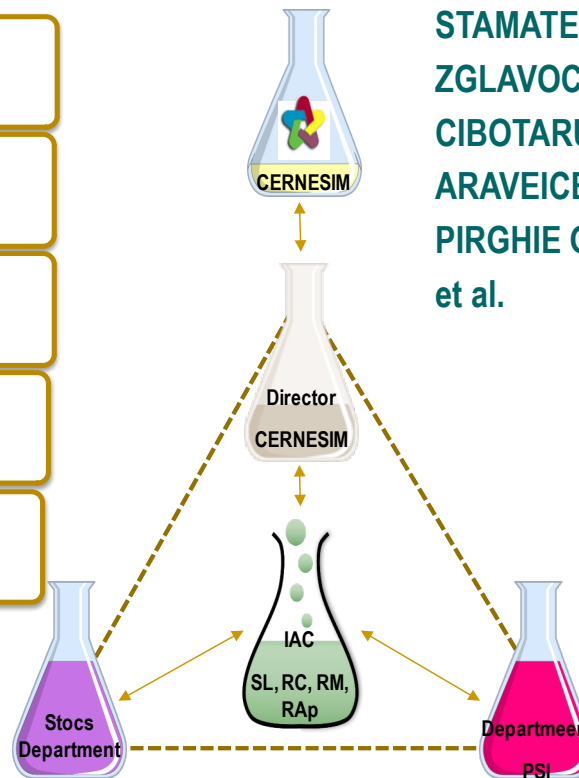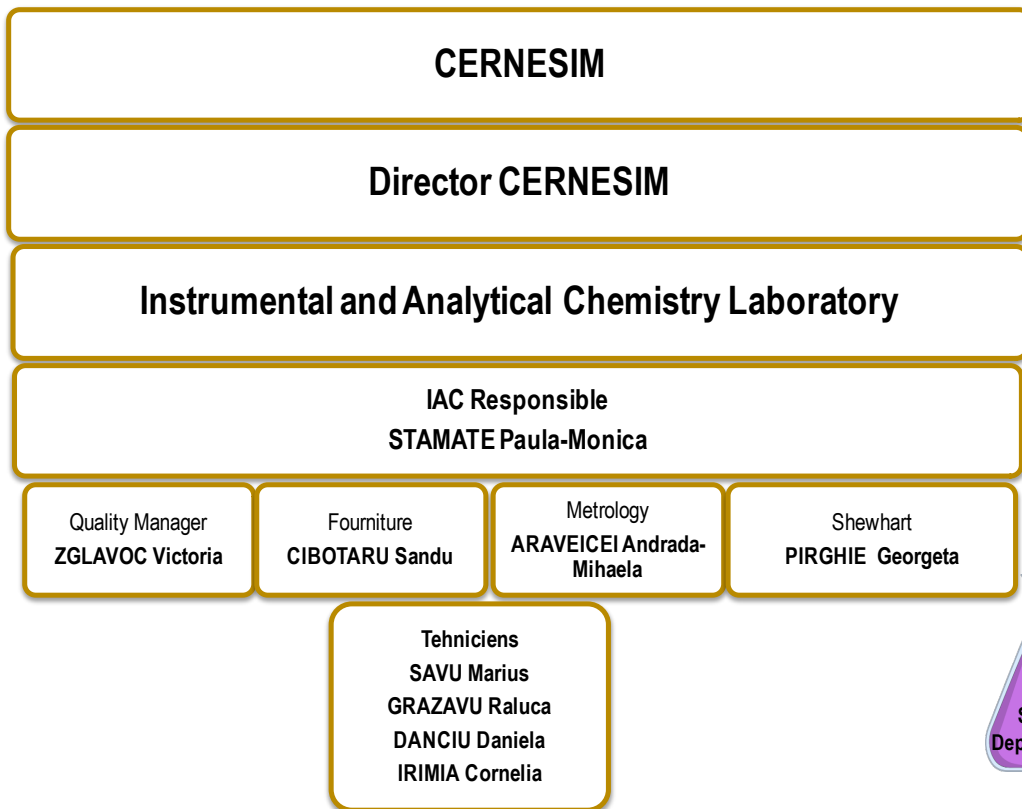## Environmental conditions

T1 = 23,61 °C, RH1 = 27.18%

T2 = 21.76 °C, RH2 = 44.36%

T3 = 21.56 °C, RH3 = 47.65%

4 mL (5 mL pipett)

- Xmed
- Xmed-SD
- Xmed-2SD
- Xmed-3SD
- Xmed+SD
- Xmed+2SD
- Xmed+3SD
- × Check
- 2 per. Mov. Avg. (Check)

"Quality Management in Chemical Analysis. ISO Requirements", how it worked……successful or not successful….at master level…

IAC Laboratory: complexity

CERNESIM

Director CERNESIM

Instrumental and Analytical Chemistry Laboratory

IAC Responsible STAMATE Paula-Monica

Quality Manager ZGLAVOC Victoria	Fourniture CIBOTARU Sandu	Metrology ARAVEICEI Andrada-Mihaela	Shewhart PIRGHIE Georgeta

Tehniciens SAVU Marius GRAZAVU Raluca DANCIU Daniela IRIMIA Cornelia

STAMATE Plopan
ZGLAVOC Victoria
CIBOTARU Sandu
ARAVEICEI Andrada
PIRGHIE Georgeta
et al.

CERNESIM

Director CERNESIM

IAC
SL, RC, RM, RAp

Stocs Department

Departmeent PSI

Student's vision for a relationship diagram

Vortex
We take the challenge!

Other students have taken the challenge but not successfully!!!

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"Quality Management in Chemical Analysis (QMCA). ISO Requirements", through the eyes of

PhD student Cornelia AMARANDEI

Discipline topics

- aspects in the field of ISO regulations
- quality assurance and quality control in a chemical analysis
- steps in validation of a chemical analysis method
- performance parameters used in evaluation
- process

Developed skills

- ✓ assimilation of indispensable information for analytical laboratory work
- ✓ understanding the importance of transdisciplinary approach in quality control assurance
- ✓ increasing motivation for a continuous professional training

- laboratory activity
- validation of an analytical method
- results presentation

At master program, part of

chemical
CARLab
analysis report laboratory
unit

- ✓ improving of team work abilities
  - ✓ highlighted skills of each team member
  - ✓ distribution of activities
  - ✓ support colleagues with lower theoretical and practical background
  - ✓ take and fulfil a task
  - ✓ ask for additional information in order to avoid misunderstanding of a task or work procedure
- ✓ improve organizational public speaking skills
- ✓ learning new analytical techniques

"Quality Management in Chemical Analysis. ISO Requirements", through the eyes of

Dr.
Giorgiana Alina NEGRU-GALON

ISO regulations
(ISO 9001; ISO 17025)

Operational plans and strategies for quality assurance in chemical analysis
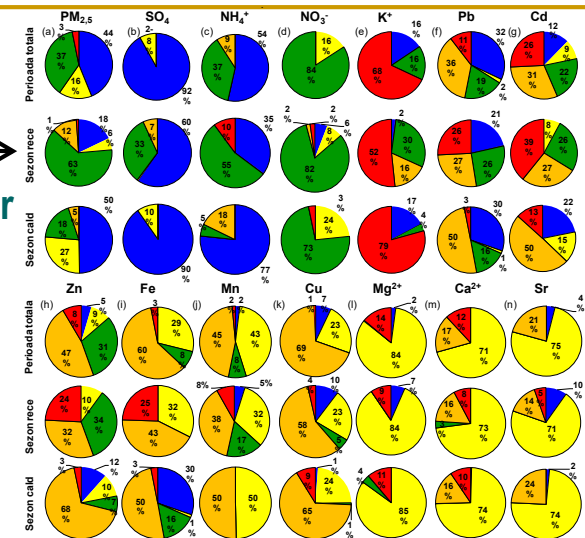
Uncertainty estimation

…provided new topics including…

✓ **uncertainty estimation for IC and ICP-MS data used in PMF analysis**

Performance parameters
➢ precision
➢ accuracy
➢ interval of linearity
➢ limit of detection
➢ limit of quantification
➢ robustness

Good skills for future needs

(Galon-Negru, A.G., Olariu, R.I., Arsene, C., Science of the Total Environment, 695, 133839, 2019.)

# Students suggestions for the "quality" concept future in the academic curricula….and what for….

✓ an optional discipline during bachelor's degree, with basics about quality, for students that intend to get a job in the field without a master's degree;

✓ inviting an expert in laboratory accreditation or quality assurance and quality control fields;

✓ an independent accredited course that can be accessed from outside the university by people that need to gain these type of knowledge, not just by students.

CREATE COMMUNITY TOGETHER

Concluding remarks

✓ **Quality and qualitative concepts still represents an important part of education in analytical chemistry;**

✓ **Training in quality matters should be required at all levels in education**;

✓ **Good analytical practice will help in keeping sample and data traceability, and will maintain the quality of a specific system everywhere;**

✓ **Clearly stated topics in a course, related to standard methods, accuracy, precision, trueness, uncertainty, error, traceability, certified reference materials, statistics of calibration and of data, validation, will make the issues of analytical quality assurance some of the most modern tools for our society.**

Lets have hopes that knowledge and competencies by training will create for us a better life in the future….
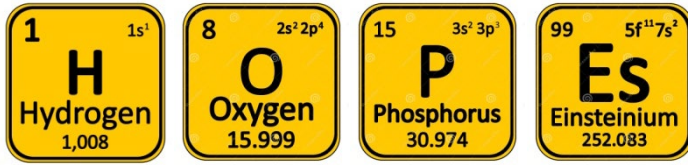
From the "Alexandru Ioan Cuza" University of Iasi "Thank you very much for your attention"….

http://www.uaic.ro/zpd/