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

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.

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
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<tbody>
<tr>
<td>1959</td>
<td>United States Department of Defense MIL-Q-9858 standard</td>
</tr>
<tr>
<td>1974</td>
<td>BS1 published the BS 5179 series of guidance standards</td>
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<tr>
<td>1987</td>
<td>ISO published the ISO 9000 standard</td>
</tr>
<tr>
<td>2000</td>
<td>Second revision of the standard and merging of ISO 9002 and ISO 9003 into ISO 9001</td>
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<tr>
<td>2008</td>
<td>Third revision of the ISO 9001 standard</td>
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<tr>
<td>September 2015</td>
<td>Current version of the ISO 9001 standard</td>
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The importance of Shewhart’s (PDCA) or Deming’s (PDSA) cycle

Deming’s “study” – S with many connotations

W. Edwards Deming (1900-1993)

Walter A. Shewhart (1891-1967)
Shewhart’s (PDCA) or Deming’s (PDSA) cycle applicability for our current societal needs…

Approximately 7.32 billion people today, 9.7 billion by 2050?

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
“Quality” and “ISO requirements” in the academic curricula at the Alexandru Ioan Cuza University of Iasi...

Members of the Analytical Chemistry Laboratory

<table>
<thead>
<tr>
<th>Year I</th>
<th>Semester: II</th>
<th>No.</th>
<th>Courses</th>
<th>Hours/sem</th>
<th>VF</th>
<th>Cr</th>
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<tr>
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UAIC Chemistry 2014-2016

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<th>Courses</th>
<th>Hours/sem</th>
<th>VF</th>
<th>Cr</th>
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UAIC Chemistry 2017-2019

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<th>Courses</th>
<th>Hours/sem</th>
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UAIC Chemistry 2018-2020

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<th>Courses</th>
<th>Hours/sem</th>
<th>VF</th>
<th>Cr</th>
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<td>8</td>
<td>Other disciplines</td>
<td>2</td>
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<td>EVP</td>
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</table>

UAIC Chemistry 2019-2021

Original papers

Standardization, quality control and education in analytical chemistry

Wolffhard Wegscheider

Institute for Analytical Chemistry, Micro- and Radiocchemistry, Graz University of Technology, Technikerstrasse 4, A-8010 Graz, Austria

Received: 23 September 1993; Revised: 27 January 1994
If ISO, than what’s the best for developing quality competences in a chemical analysis lab for testing?

- **1972**: Good Laboratory Practice – GLP (first introduced in New Zealand and Denmark)
- **1999**: Publication of First Edition of ISO/17025 and Revised
- **2005**: Standard under revision
- **2010**: Publication of ISO/17025 Last Edition
- **2017**: The ISO Journal May 1952
Apart from teaching students about “Quality management in chemical analysis. ISO requirements”, the strategy for practice includes:

### Principal Objectives
- **Implement**
  - Methods validation (GFAAS, IC, UV-vis)
  - Shewart’s diagram
- **Analysis of different analytes and matrices**
- **Research Adapted to Quality Assurance Principles and Practices**
  - Developing analysis methods;
  - Solving analytical problems;
  - Publications;
  - Dissemination of scientific data;

ISO/IEC 17025

- "General requirements for the competence of testing and calibration laboratories."
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

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ISO/IEC 17025:2005

- Scope
- Normative references
- Terms and definitions
- Management requirements
- Technical requirements
  - Annex B (informative) Guidelines for establishing applications for specific fields

ISO/IEC 17025:2018

- Scope
- Normative references
- Terms and definitions
- General requirements
- Structural requirements
- Resource requirements
- 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)

Micropipettes

<table>
<thead>
<tr>
<th>Volume (µL)</th>
<th>Increment (µL)</th>
<th>Accuracy (±%)</th>
<th>Repetability (±%)</th>
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</thead>
<tbody>
<tr>
<td>min</td>
<td>max</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1000</td>
<td>10000</td>
<td>10</td>
<td>0.6</td>
</tr>
<tr>
<td>200</td>
<td>1000</td>
<td>5</td>
<td>0.9</td>
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</table>

Volumetric flasks

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<tr>
<th>No</th>
<th>Volume (mL)</th>
<th>Uncertainty (±mL)</th>
<th>Class</th>
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<tr>
<td>1</td>
<td>100</td>
<td>0.20</td>
<td>B</td>
</tr>
<tr>
<td>4</td>
<td>50</td>
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<td>B</td>
</tr>
<tr>
<td>4</td>
<td>25</td>
<td>0.08</td>
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OLARU Anda
CRACIUN Bogdan
BUCUR Stefan
VARLAN Constantin
“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)

<table>
<thead>
<tr>
<th>Code</th>
<th>Unit</th>
<th>Value</th>
<th>A</th>
<th>1st reading</th>
<th>2nd reading</th>
<th>3rd reading</th>
<th>Average</th>
<th>SD(±)</th>
<th>PW</th>
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<tbody>
<tr>
<td>C1_cal_std</td>
<td>mg/L</td>
<td>1.55000</td>
<td>A1</td>
<td>0.243</td>
<td>0.254</td>
<td>0.255</td>
<td>0.251</td>
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<tr>
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<td>mg/L</td>
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<td>0.479</td>
<td>0.494</td>
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<td>0.752</td>
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<tr>
<td>C4_cal_std</td>
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<td>6.20000</td>
<td>A4</td>
<td>0.973</td>
<td>0.964</td>
<td>0.973</td>
<td>0.970</td>
<td>0.003000</td>
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<table>
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<th>SD(±)</th>
<th>PW</th>
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</table>

OLARU Anda
CRACIUN Bogdan
BUCUR Stefan
VARLAN Constantin

Calibration curve

\[ y = 0.15654x + 0.00767 \]
\[ R^2 = 0.99855 \]

Calibration curve

\[ y = 0.11897x + 0.00567 \]
\[ R^2 = 0.99940 \]
2013-2014: Nitrate ion analysis by UV spectrophotometry. Method validation (standards, calibration range, linearity, trueness, accuracy, recovery, uncertainty)

<table>
<thead>
<tr>
<th>No. of replicates</th>
<th>Method's rightness for the first point on the calibration curve (mM)</th>
<th>A averaged</th>
<th>C averaged</th>
<th>Unit</th>
<th>inc_calib. (±)</th>
<th>Unit</th>
<th>inc_calib. (%)</th>
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<td>0.2507</td>
<td>1.55</td>
<td>mg/L</td>
<td>0.0342 mg/L</td>
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<tr>
<td>(N-2)</td>
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<td>2</td>
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<tr>
<td>y=a + bx</td>
<td></td>
<td>b</td>
<td></td>
<td></td>
<td>0.1565</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>a</td>
<td></td>
<td></td>
<td>0.0077</td>
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<tr>
<td></td>
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<th>A averaged</th>
<th>C averaged</th>
<th>Unit</th>
<th>inc_calib. (±)</th>
<th>Unit</th>
<th>inc_calib. (%)</th>
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<tr>
<td>3</td>
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<td>mg/L</td>
<td>0.0342 mg/L</td>
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<tr>
<td>(N-2)</td>
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<td>2</td>
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<tr>
<td>y=a + bx</td>
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<td>b</td>
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<td>0.1190</td>
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<td></td>
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<td>a</td>
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<td>0.1198</td>
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</table>
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) 
$\lambda = 360$ nm

Curba de etalonare

<table>
<thead>
<tr>
<th>$T_R$ (min)</th>
<th>Area</th>
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<tbody>
<tr>
<td>5.953</td>
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<td>5.931</td>
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<td>930.6</td>
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<td>6.041</td>
<td>1369</td>
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SPE C18
40 ppm spiked sample

Activated cartridge (H$_2$O-MeOH)

$\% \ e_R = 2.31$

Inactivated cartridge

$\% \ e_R = 89.57$
“Quality Management in Chemical Analysis. ISO Requirements”, how it worked......

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

**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%
“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 Andrad-Mihaela

Shewhart
PIRGHIE Georgeta

Tehnicians
SAVU Marius
GRAZAVU Raluca
DANCIU Daniela
IRIMIA Cornelia

Student’s vision for a relationship diagram

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

- 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

At master program, part of CARLab analysis report laboratory unit
“Quality Management in Chemical Analysis. ISO Requirements”, through the eyes of

Dr. Giorgiana Alina NEGRU-GALON

ISO regulations (ISO 9001; ISO 17025)

Uncertainty estimation

...provided new topics including...

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

Operational plans and strategies for quality assurance in chemical analysis

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

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.
Concluding remarks

- Quality and qualitative concepts still represent 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.
Let's 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/