



## Course Unit: 15729 – Metrology and Analytical Validation

Year 3 Semester 5 ISCED Code: 711 ECTS: 4,0

Type of Course Unit: Compulsory Delivery Mode: Face-to-face Language of Instruction: Portuguese

COURSE COORDINATOR: Maria Adelaide Araújo Almeida

### HOURS OF WORK

TOTAL HOURS	Contact Hours								Hours in autonomous work
	Theory	Theory and practice	Practical and laboratory work	Field work	Seminar	Internship	Tutorial guidance	Other	
100		45							55

Prerequisites (if applicable): Not applicable

### LEARNING OUTCOMES (knowledge, skills and competence)

It is intended that the student has bases and concepts of metrology necessary for routine work in a laboratory analysis. That the student use metrology and quality management tool.

Another objective is the development of concepts related to the strategy and implementation of analytical validation, application of "Good Laboratory Practice", phases of the study, analytical methods, evaluation of critical points, development of protocols and validation reports, and revalidation, in accordance with recent guidelines from the US.

### CONTENTS

Definition of metrology and metrological control. History of metrology. International system of units (SI). Role of the Portuguese Quality Institute in metrological control. Role of the "Bureau International des Poids et Mesures (BIPM)" in the global metrological control: Metro Convention, functions and role of the advisory committees of the BIPM. Rules for writing the names and symbols of the units and expression of values and quantities of the SI.

Consultation of the International Metrology Vocabulary (VIM) for correct implementation of the terms in the analytical reports in the laboratory. Measurement uncertainty. Traceability. Verification importance, calibration and measurement instruments. Analytical validation of analytical methods: fundamental concepts and terminology. Validation of parameters: selectivity, specificity, sensitivity, detection and quantification limits, accuracy, precision and robustness. Stability. Acceptance criteria. Certified materials. Reference methods.

### DEMONSTRATION OF THE CONTENTS COHERENCE WITH THE COURSE UNIT'S LEARNING OUTCOMES

The course is about topics related to metrology, and validation of analytical method and testing, so it is important that students understand the need to make the metrological control of measuring instruments in order to ensure the accuracy of the result of measurement within limits legally established, as well as the need for method validation and uncertainty calculations to ensure the quality of the results presented by testing laboratories.

### TEACHING METHODOLOGIES

Classes with a strong dialog component using essentially the visual media. Practical case studies listed in the bibliography recommended by the professor.

### DEMONSTRATION OF THE COHERENCE BETWEEN THE TEACHING METHODOLOGIES AND THE LEARNING OUTCOMES

The teaching methodology used, expository method supported by slides, and performing partial tests, presentation of studies case allow students to acquire consistently the theoretical bases and consolidate the knowledge necessary for the implementation of practical cases. The study of real cases including calibration, determination of uncertainty methods etc., held

in the classroom, promoting debate, allows students to acquire skills in accordance with the objectives of the course.

## EVALUATION METHODS

The continuous evaluation includes, team projects, problem solving, studies case, participation in discussions and resolution of case studies, with presentation and discussion of reports, with 40% of the final grade.

Final exam

## MAIN BIBLIOGRAPHY

Analytical method validation and instrument performance verification. Ed Wiley Interscience 2004.

Guideline Bioanalytical method validation.EMA. London, 2011.

Note for guidance validation of analytical procedures methodology (CPMP/ICH/281/95), London.

Guidance for industry. Bioanalytical method validation, U.S Department Health and Human Services, FDA,USA, 2013.

Guia RELACRE 3 (1996); Validação de resultados em laboratórios químicos

Guia RELACRE 13 (2000); Validação de métodos internos de ensaio em análise química.Guia RELACRE 24 (2012); Cálculo da incerteza na calibração de material volumétrico

ISO 5725-3 (1994); Accuracy (trueness and precision) of measurements methods and results – Part 3: Intermediate measures of the precision of a standard measurements methods.

ISO 5725-6 (1994); Accuracy (trueness and precision) of measurements methods and results – Part 6: Use in practice of accuracy values.

APHA (2013) Standard Methods for the Examination of Water and Wastewater, 22st Editi

Year of implementation: 2017/2018 | Date of approval by the Technical-Scientific Board: 2016-07-27