

Course Unit	Hygiene, Safety and Quality Laboratory		Field of study	Biomedical Laboratory Sciences	
Bachelor in	Biomedical Laboratory Sciences		School	School of Health	
Academic Year	2021/2022	Year of study	1	Level	1-1
Type	Semestral	Semester	2	ECTS credits	5.0
Code	9995-550-1206-00-21				
Workload (hours)	135	Contact hours	T -	TP 40	PL -
			TC -	S -	E -
			OT 5	O -	

T - Lectures; TP - Lectures and problem-solving; PL - Problem-solving, project or laboratory; TC - Fieldwork; S - Seminar; E - Placement; OT - Tutorial; O - Other

Name(s) of lecturer(s) Andrea Luisa Fernandes Afonso

### Learning outcomes and competences

At the end of the course unit the learner is expected to be able to:

1. Know the international and national laws on hygiene and safety at work, biosafety, biosecurity and chemical safety.
2. Identify the main safety risks and procedures and practices for their prevention and control.
3. Acquire basic knowledge of microbiology.
4. Understand the concept of quality. Know the legislation and normative references for good laboratory practices.
5. Understand the objectives and methodologies of the certification and accreditation processes.
6. Use the main statistical tools for quality control.
7. Recognize the need to analyze and evaluate new diagnostic methodologies prior to routine use (validation).
8. Evaluate and interpret calibration reports of measuring laboratory equipment.

### Prerequisites

Not applicable

### Course contents

Hygiene and safety at work - national and european legislation. Safety in clinical, public health and pathological anatomy laboratories. Biossecurity and biosafety. Good laboratorial practice. Implementation of a quality management system. Accreditation of laboratories. Laboratory quality control. Methods validation. Calibration and evaluation of laboratory equipment. Basic concepts of microbiology and immunity.

### Course contents (extended version)

1. Safety and occupational health. National and european legislation
  - Occupational health and safety. Ergonomics.
  - Individual protection equipment.
  - Signage and ecoefficiency.
  - Manual of good laboratory practice: clinical analysis and pathological anatomy.
  - ACSP e APTC laboratories licensing.
2. Biosafety and biosecurity in ACSP and APCT laboratories
  - Biosafety program: classification of biological agents.
  - Good laboratory practice in level 2 areas.
  - Biological risks and their determination.
  - Biological risk management.
  - Containment levels: BSL1, 2, 3 and 4.
  - Sterilization and disinfection.
3. Chemical safety in ACSP and APCT laboratories
  - Classification, packaging and labeling.
  - Acquisition and storage of chemicals.
  - Chemical handling care (good practice).
  - Risk estimation of exposure to chemicals.
  - Specific legislation and exposure values.
4. Other types of laboratory risk
  - Risk of fire, electric hazards and radiation.
5. Accidents at work
  - Factors contributing to accidents, risk management, prevention and treatment.
  - Accidents involving infectious substances, chemicals and cuttings.
  - Fire and natural disasters.
  - First aid.
6. Laboratory waste
  - Hospital waste management - Legislation.
  - Laboratory waste as a public health problem, and its processing and control.
7. Concepts of microbiology and immunology
  - Global description (morphology and structure) of microorganisms.
  - Microorganisms classification: bacteria, virus, fungi, parasites, prions.
  - Immune response to infection.
  - Innate and acquired immunity.
8. Transport of dangerous substances
9. Certification and Accreditation process
  - Implementation of a quality management system (NP EN ISO 9001).
  - Accreditation of laboratories by standards NP EN ISO/IEC 17025 e NP EN ISO 15189.
10. Methods validation and laboratory quality control
  - Methods validation.
  - Internal quality control vs. external quality control.
  - Process quality control- quality control charts.
  - Determination of uncertainties.
  - Practical exercises.
11. Metrological control
  - Evaluation of calibration reports of measuring laboratory equipment.

### Recommended reading

1. CDC (2020). "Biosafety in Microbiological and Biomedical Laboratories", 6ª Edição, Centers for Disease Control and Prevention, National Institutes of Health
2. Miguel, S. R. , (2014). "Manual de Higiene e Segurança do Trabalho", 13ª. Edição, Porto: Porto Editora
3. WHO (2020). "Laboratory Biosafety Manual", 4ª Edição, World Health Organization
4. WHO (2011). "Laboratory quality management system: handbook", World Health Organization

**Recommended reading**

5. Guias para Certificação e Acreditação de laboratórios, determinação de incertezas e validação de métodos do Instituto Português de Acreditação (IPAC)

**Teaching and learning methods**

Lectures using powerpoint presentations, resolution of practical exercises in statistics applied to quality control, validation of methods and determination of uncertainties. Lectures notes deposited in the e-learning resources. In tutorial classes, working document will be provided to students, being guided to explore requirements and analyze internal and external quality control results.

**Assessment methods**

1. Alternative 1 - (Regular, Student Worker) (Final)
  - Final Written Exam - 60% (Written exam)
  - Presentations - 40% (Work presentation)
2. Alternative 2 - (Regular, Student Worker) (Supplementary, Special)
  - Final Written Exam - 100% (Written exam)

**Language of instruction**

Portuguese

**Electronic validation**

Andrea Luisa Fernandes Afonso	Josiana Adelaide Vaz	Juliana Almeida de Souza	Adília Maria Pires da Silva Fernandes
22-03-2022	23-03-2022	05-04-2022	06-04-2022