COURSE CONTENT

(1) GENERAL INFO

SCHOOL	ENGINEERING			
DEPARTMENT	BIOMEDICAL ENGINEERING			
MSc PROGRAM	BIOMEDICAL ENGINEERING AND TECHNOLOGY			
STUDY LEVEL	POSTGRADUATE, MSc			
COURSE CODE	**BMET108**	**SEMESTER**	**A**	
COURSE TITLE	**Quality Assurance and Medical Device Regulations**			
TEACHING			**HOURS**	**ECTS**
		LECTURES	26	5
COURSE TYPE	SPECIALIZATION			
COURSE REUIREMENTS:	-			
TEACHING AND EXAMINATION LANGUAGE:	ENGLISH			
IS THIS COURSE OFFER TO ERASMUS STUDENTS	YES (IN ENGLISH)			
COURSE WEBPAGE (URL)	https://eclass.uniwa.gr/courses/304/			

(2) LEARNING OUTCOMES

Learning outcomes

Course Objectives:
The primary aim of this course is to explore the concept of quality assurance in Medical Devices (MD), and the jurisprudential and regulatory framework that regulates the Delivery, Maintenance and disposal of Medical Devices within the European Community (EC) and internationally. The concepts of Quality Control and Quality Assurance will be analyzed, as well as how to compose, establish and perform quality control procedures. The course will cover Basic Quality Control Procedures for patient and user safety as well as specialized knowledge on the principles of Radiation Protection from Ionizing and non-ionizing radiation. Additionally, Radiation Protection Protocols used in X-ray and Nuclear Medicine Departments will be analyzed. The key-point parameters in Total Quality Management Systems in conjunction with the integration of quality control procedures in these systems will be analyzed. Students will learn and emphasize in the design of quality control protocols and they will study cases of implementation and integration of these protocols into a Quality Management System. They will become familiar with the application of medical image quality control software using digital models and evaluate methods for the improvement of medical image quality.

Learning Outcomes:
1. Acquire fundamental knowledge regarding the European Regulations and the European Directives for the Manufacture, Management and Disposal of Medical Devices,
2. Acquiring knowledge of Greek and International legislation regarding Radiation Protection and Quality Control of Medical Equipment that use radiation
3. Evaluation of the effects of radiation (ionizing and non-ionizing) on humans based on radiation characteristics (intensity, frequency, energy, etc.) and awareness of the factors that influence the reduction of radiation exposure of examinees, patients and staff in order to choose the appropriate prevention and protection, from radiation, methods Analysis of serious incidents and field safety corrective actions (FSCA) in Hospital environment for Medical Devices using ionizing and non-ionizing radiation and Radiation Protection (RP) methods
4. Distinguish and differentiate between standards and quality assurance systems applied to Medical Devices
5. Understanding of the importance of assessing the Conformity of existing and innovative medical devices (CE marking) and the obligations arising from it and the good administrative practice between Manufacturers, Users-Operators and Notified Bodies,
6. Theoretical and experimental application of medical image quality controls using digital phantoms

7. Understanding of the established principles regarding risk assessment and risk management, vigilance data and complaints Understanding the classification and categorization of medical devices and methods of reporting serious adverse events or incidents to notified bodies and parties engaged.

Achievement of Course Objectives and Learning Outcomes:
To fulfill the above objectives and learning outcomes, students will initially be taught basic concepts for quality standards, quality controls and quality assurance of Medical Devices. The difference between quality checks and safety checks will be analyzed as well as the recommended frequency of their application. In particular, the principle of operation of some of the basic instruments used for the detection of radiation and their measurement methodology will be analyzed. Reference will be made to the main sources of radioactive waste and their management methods as well as Greek and International legislation regarding Radiation Protection (Radiation Protection Law).Subsequently, quality checks will be carried out on images of medical imaging systems using the RAD_IQ software developed by partners and by members of the statutory laboratory of Radiophysics, Materials Technology and Biomedical Imaging, AKTYVA (Director Professor G. Fountos), (https://aktyva.uniwa.gr/software/). The next phase of the course is to familiarize with the existing quality management systems, their application and implementation procedures, as well as ways to systematically record and organize measurements and measuring devices. Finally, in the form of group work, there will be a study of the European Regulations and Directives that cover Medical Devices and the communication and reporting procedures between the Manufacturer, the User and the Notified Body.

General abilities

- Search, analysis and synthesis of data and information, using the necessary technologies
- Adaptation to new situations
- Risk assessment
- Decision-making
- Autonomous work
- Teamwork
- Working in an interdisciplinary environment
- Project planning and management
- Promotion of free, creative and inductive thinking

(3) COURSE CONTENT

"Quality Assurance and Radiation Protection"
Introduction to the physics of radiation, sources of radiation. The electromagnetic spectrum, Ionizing and non-ionizing radiation, Natural and Artificial sources of radiation, Ways of exposure to Radiation. Radiation-matter interaction Shielding, Excitation, Ionization or Ionization Law of exponential decay. Detection of ionizing radiation, Detection of non-ionizing radiation, International-National radiation protection system, Legislation. Applied protection measures in Radiology, Nuclear Medicine, Radiotherapy. Quality control protocols in Radiology, Nuclear Medicine, Radiotherapy.

"Quality Assurance in Medical Imaging Equipment"
Digital imaging, Digital radiography, Mammography, X-ray detectors (a-Si, CCD, CMOS), Image quality, Modulation transfer function, system linearity, Noise power spectrum, Detective quantum efficiency, Beam quality, Dosimetry, Filters

"European Regulations and Directives for Medical Devices"
European Medical Device Regulations and Directives (MDR). European Regulations and Guidelines for In Vitro Medical Devices (IVD-MDR). Classification of devices and their components.
Methods of certification and assessment of reliability. ISO Quality Management Systems. Management and Diffusion of Biomedical Technology in Hospitals.

(4) TEACHING AND LEARNING METHODS - EXAMINATIONS

<table>
<tr><td>COURSE DELIVERY</td><td>Physical presence, face to face at the auditorium or laboratory</td></tr>
<tr><td>USE OF INFORMATION AND COMMUNICATION TECHNOLOGIES</td><td>The theoretical part of the course involves the use of a projector for presenting fundamental concepts and is supplemented by the use of the blackboard at the auditorium.</td></tr>
<tr><td>TEACHING ORGANIZATION</td><td>
<table>
<tr><th>Activity</th><th>Semester workload</th></tr>
<tr><td>Teaching / lectures</td><td>26</td></tr>
<tr><td>Lecture material study</td><td>30</td></tr>
<tr><td>Unsupervised literature review and preparation of the final project</td><td>69</td></tr>
<tr><td>Total</td><td>125</td></tr>
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<tr><td>STUNDET EVALUATION</td><td>50% Final exam paper with multiple-choice questions, short-answer questions, and problem-solving questions.
50% written Team assignment and oral presentation</td></tr>
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(5) SUGGESTED LITERATURE

Books, scientific articles and related scientific resources:

[1] J. Webster, Medical Instrumentation: Application and Design, Wiley; 4th edition, 2009.
[2] Productivity and Reliability-Based Maintenance Management, M.P.Stephens, Prentice Hall, 2003.
[3] Electrical Equipment Handbook: Troubleshooting and Maintenance, P.Kiameh, McGraw-Hill, 2003.
[4] Reliability Theory: With Applications to Preventive Maintenance, I.B.Gertsbakh, Springer Verlag, 2000
[5] Handbook of Medical Imaging, Volume1, Physics and Psychophysics, Jacob Beutel, Harold L. Kundel, Richard L. Van Meter editors. A publication of SPIE the International Society for optical Engineering Bellingham Washington, USA, copyright 2000.
[6] Principles of Radiological Health and Safety, J.E.Martin, John Wiley & Sons, 2003.
[7] A Konstantinidis, N Martini, V Koukou, G Fountos, N Kalyvas, I Valais and C Michail, 2021, J. Phys.: Conf. Ser. 2090 012107, https://iopscience.iop.org/article/10.1088/1742-6596/2090/1/012107/meta
[8] I. Betlloch-Mas, R. Ramón-Sapena, C. Abellán-García, J.C. Pascual-Ramírez, Implementation and Operation of an Integrated Quality Management System in Accordance With ISO 9001:2015 in a Dermatology Department, Actas Dermo-Sifiliográficas (English Edition), Volume 110, Issue 2, 2019, pp. 92-101, https://doi.org/10.1016/j.adengl.2019.01.003.
[9] PET/CT Atlas on Quality Control and Image Artefacts, STI/PUB/1642 978-92-0-101014-8 https://www.iaea.org/publications/10424/pet/ct-atlas-on-quality-control-and-image-artefacts IAEA Human Health Series No 27, 2014
[10] ISO 9001:2015(en) Quality management systems — Requirements, https://www.iso.org/obp/ui/#iso:std:iso:9001:ed-5:v1:en.
[11] Quality Management Systems ISO 9001:2015 https://www.researchgate.net/publication/342182999_Quality_Management_Systems_ISO_90012015
[12] ISO 13485:2016(en) Medical devices — Quality management systems — Requirements for regulatory purposes. https://www.iso.org/obp/ui/en/#iso:std:iso:13485:ed-3:v1:en
[13] Computers in Biology and Medicine, https://www.sciencedirect.com/journal/computers-in-biology-and-medicine.