National Technical University of Ukraine
“Igor Sikorsky Kyiv Polytechnic Institute”

Department
biomedical engineering

[BM12] Expertise and engineering support of medical equipment

Work program for primary discipline (Sylabus)

Details of the initial discipline

Level of higher education	First (bachelor's)
Discipline	16 - Chemical Engineering and Bioengineering
Specialty	163 - Biomedical Engineering
Educational program	163 BMI - Medical Engineering (ЄДЕБО id: 28920)163Б MI+ - Medical Engineering (ЄДЕБО id: 58753)G22Б MI - Medical Engineering (ЄДЕБО id: 85587)
Discipline status	Regulatory
Form of obtaining higher education	Full-time
Year of training, semester	4th year, fall semester
Scope of the discipline	120 hours 4 credits. (Lecture 30 hours, Practical 30 hours, Lab. hours, SRS. 60 hours)
Semester control/control measures	Final test
Class schedule	https://schedule.kpi.ua
Language of instruction	Ukrainian / English
Information about the course leader/teachers	Lecturer: A. G. Dubko, Practitioner: A. G. Dubko, SRS.: A. G. Dubko
Course placement	Sikorsky Platform - course "Fundamentals of Clinical Engineering and Radiology - 2. Expertise and Engineering Support of Medical Equipment"

Academic discipline program

1. Description of the academic discipline, its purpose, subject of study and learning outcomes

The main goal of the academic discipline "Expertise and Engineering Support of Medical Equipment" is to develop in students an understanding of the principles, skills, and practical abilities in conducting expertise and engineering support of medical equipment.

The purpose of teaching the discipline is to provide students with theoretical knowledge and develop practical skills and abilities in the ability to solve complex specialized tasks and practical problems of creating, operating and testing medical devices, apparatus and complexes for surgery, therapy and diagnostics, designing circuits, calculating and modeling the main components of medical equipment, and developing and modeling modern medical technologies.

The objectives of studying the academic discipline are:

- mastering the general principles of using regulatory legal acts that regulate the circulation of medical devices;
- mastering the procedure and order of conducting the main stages of registration of medical equipment or medical devices;
- mastering the procedure and order of conducting examinations and testing of medical devices;
- mastering knowledge about the reliability of medical equipment;
- mastering knowledge about the maintenance and repair of medical equipment.

Teaching methods

Interactive teaching methods, discussion method, “Case Studies” method (problem analysis), brainstorming, public speaking, group work.

Integral competence

IC - The ability to solve complex specialized tasks and practical problems in biomedical engineering or in the process of learning, which involves the application of certain theories and methods of chemical, biological and medical engineering, and is characterized by the complexity and uncertainty of the conditions.

General Competencies (GC)

GC 01 - Ability to apply knowledge in practical situations.

GC 02 - Knowledge and understanding of the subject area and understanding of professional activity.

GC 04 - Skills in using information and communication technologies.

GC 05 - Ability to conduct research at an appropriate level.

GC 06 - Ability to search, process and analyze information from various sources.

GC 07 - Ability to generate new ideas (creativity).

GC 08 - Ability to make informed decisions.

GC 11 - Ability to assess and ensure the quality of work performed.

Special (professional) competencies (OP put into effect by the Rector's Order NON/89/2021 dated April 19, 2021):

FC 1 - Ability to apply engineering software packages for research, analysis, processing, and presentation of results, as well as for automated design of medical devices and systems

FC 2 - Ability to provide engineering and technical expertise in the planning, development, evaluation and specification of medical equipment.

FC 3 – Ability to study and apply new methods and tools for analysis, modeling, design, and optimization of medical devices and systems

FC 4 - Ability to provide technical and functional characteristics of systems and devices used in medicine and biology (in prevention, diagnostics, treatment and rehabilitation).

FC 5 – Ability to apply physical, chemical, biological, and mathematical methods in the analysis and modeling of the functioning of living organisms and biotechnical systems

FC 6 - Ability to effectively use tools and methods for analysis, design, calculation, and testing in the development of biomedical products and services

FC 7 - Ability to plan, design, develop, install, operate, maintain, service, control and coordinate the repair of devices, equipment and systems for prevention, diagnosis, treatment and rehabilitation used in hospitals and research institutes.

FC 10 - Ability to apply the principles of modern automated control systems in the production of medical devices, their technical, algorithmic, informational, and software support

FC 11 - Ability to develop, plan, and conduct experiments using specified technical and biomedical techniques, applying mathematical methods in the analysis and modeling of the functioning of living organisms, systems, and processes in biology and medicine, computer processing, analysis, and synthesis of the obtained results.

The program learning outcomes after studying the discipline "Expertise and engineering support of medical equipment" are (OP put into effect by the Order of the Rector NON/89/2021 dated April 19, 2021):

PRN 1 - The ability to apply knowledge of the fundamentals of mathematics, physics and biophysics, bioengineering, chemistry, engineering graphics, mechanics, materials resistance and strength, properties of gases and liquids, electronics, computer science, signal and image acquisition and analysis, automatic control, system analysis, and decision-making methods at a level necessary for solving biomedical engineering tasks

PRN 2 - Formulate logical conclusions and reasoned recommendations regarding the assessment, operation, and implementation of biotechnical, medical-technical, and bioengineering tools and methods.

PRN 5 - Be able to use databases, mathematical and software tools for data processing and computer modeling of biotechnical systems

PRN 7 - Provide engineering support, service, and technical maintenance during the operation of laboratory analytical equipment, medical diagnostic and therapeutic complexes and systems in accordance with the rules established by technical documentation and regulatory documents governing the procedures for commissioning, application, and repair of medical equipment, as well as to form the standard documentation by types of work according to the technical regulation on medical devices

PRN 8 - Understand theoretical and practical approaches to the creation and management of medical equipment and medical technology

PRN 16 - Ability to utilize computer-aided design and drafting systems for developing the technological and hardware schematics of medical devices and systems, taking into account the specifics of their components

PRN 17 - Application of knowledge in chemistry and bioengineering to create, synthesize, and apply artificial biotechnical and biological objects

PRN 20 - Knowledge and application of research methods in biomedical engineering, methods and tools for organizing and processing experimental data, statistical methods for modeling and simulating processes and systems of physical and biological nature, modern programming technologies and supporting tools, methods for designing digital and microprocessor-based medical systems

2. Prerequisites and postrequisites of the discipline (place in the structural and logical scheme of study according to the relevant educational program)

The educational discipline "Expertise and engineering support of medical equipment" belongs to the cycle of professional training and is interdisciplinary in nature. It integrates, in accordance with its subject, knowledge from other educational disciplines: Electrical engineering and electronics; Analog and digital circuit engineering; Biomedical devices, apparatus and complexes. According to the structural and logical scheme of the specialist training program, the discipline "Expertise and engineering support of medical equipment" is closely related to other disciplines in modern scientific research in the specialty, in particular with the disciplines: Devices for monitoring human physiological parameters; Pre-graduate practice.

3. Content of the academic discipline

The main sections and topics that will be covered during the course:

Section 1. Main regulatory legal acts regulating the circulation of medical devices.

Topic 1. Technical regulations and conformity assessment.

Topic 2. Standardization. Metrology and metrological activities. Principles of state supervision (control).

Topic 3. Procedure for conducting clinical trials of medicinal products and examination of clinical trial materials and Model Regulations on Ethics Commissions.

Chapter 2. Design of biomedical equipment.

Тема 4. Конструктивні складові біомедичної апаратури. Інженерні методи конструювання.

Topic 5. System approach to designing BMA. Main stages in designing biomedical equipment BMA.

Topic 6. Protection of intellectual property.

Topic 7. Mathematical models: definition, characteristics, stages of construction.

Topic 8. Psychological compatibility of a person and BMA. Ergonomics and its influence on the design of BMA. Basics of the composition of the appearance of the device.

Section 3. Development and attitude towards the production of medical devices.

Topic 9. Basic requirements for biomedical equipment. Development and attitude to the production of medical devices.

Topic 10. Medical and technical requirements. Technical conditions.

Topic 11. Sterilization of medical instruments.

Topic 12. Maintenance and repair of medical equipment.

Chapter 4. Electrical safety of medical equipment.

Topic 13. Elements of electrical safety of medical equipment. The effect of electric current on the human body.

Topic 14. Methods of ensuring the protection of patients from electric shock. Methods of performing grounding in medical equipment.

4. Educational materials and resources

Basic literature:

1. Sundararajan V. Madihally. Principles of Biomedical Engineering. Artech House, 2010. - 481 p.
2. Shreefal Menta. Commercializing Successful Biomedical Technologies. Basic Principles for the Development of Drugs, Diagnostics, and Devices. Cambridge University Press, 2008. – 336 p.
3. Medical Devices and Human Engineering. Edited by: Joseph D. Bronzino, Donald R. Peterson. © Taylor & Francis Group, 2015. - 858 p.
4. Medical Device Design. Innovation from Concept to Market . First edition. Peter J. Ogrodnik. Academic Press is an imprint of Elsevier. Kidlington, Oxford, 2013. - 275 p.

Additional literature:

1. IEC 60601-1 subclause 2.2.1, 3rd. ed., 2005.
2. Medical device regulations : global overview and guiding principles. World Health Organization 2003. – 54 p.
3. International Medical Device Regulators Forum, http://www.imdrf.org/index.asp
4. Office of Human Research Protections, http://www.hhs.gov/ohrp/.
5. World Medical Association, http://www.wma.net/e/policy/.
6. FDA, http://www.fda.gov/cdrh/devadvice/.
7. Basic Principles of Risk Management for Medical Device Design, https://www.wipro.com/medical-devices/basic-principles-of-risk-management-for-medical-device-design/
8. Strategic Plan 2021 2025 // International Medical Device Regulators Forum. -2020. – 16p.

Educational content

5. Methodology for mastering the academic discipline (educational component)

To study the discipline, 30 lectures and 30 computer workshops (CP) are planned, during which modular control work is planned.

The following teaching methods are used when studying the **educational material:**

Lectures are held using the explanatory-illustrative method, the problem-based presentation method, and the interactive method during lectures, which is used to establish a dialogue with the audience.

Computer workshops are held using:

1) Reproductive method, thanks to which students consolidate the studied theoretical material and learn to use it in specific tasks.

2) Partial search, or heuristic method, which teaches the search for the right ways and methods for solving problems.

3) Interactive method, which is used during practical classes to involve students in the process of solving problems and the theoretical facts that are used for this.

4) Presentation and discussion of the results obtained involves the use of problem-based and interactive learning methods.

5) Mathematical modeling, which is used during practical classes.

Below is the distribution of classroom hours by course topics and the calendar of their implementation.

Chapter and topic names	**Lectures**		**KP**		**Evaluation**
	Weeks of training	**Hours**	**Weeks of training**	**Hours**	
Topic 1. Technical regulations and conformity assessment.	1	2	-	-	--
Topic 2. Standardization. Metrology and metrological activities. Principles of state supervision (control).	2	2	3	2	KPN№1 Express control (EC)№1
Topic 3. Procedure for conducting clinical trials of medicinal products and examination of clinical trial materials and Model Regulations on Ethics Committees.	3	2	4	2	EC №2
Topic 4. Structural components of biomedical equipment. Engineering design methods.	4	2	5	2	KP №2 EC №3
Topic 5. Systemic approach to designing BMA. Main stages in designing BMA biomedical equipment.	5	2	6	2	KP №3 EC №4
Topic 6. Intellectual property protection.	6	2	7	2	EC №5
Topic 7. Mathematical models: definition, characteristics, stages of construction.	7	2	8	2	KP №4 EC №6
Topic 8. Psychological compatibility of a person and a BMA. Ergonomics and its influence on the design of a BMA. Basics of the composition of the appearance of the device.	8	2	9	2	EC №7

Chapter and topic names	Lectures		KP		Evaluation
	Weeks of training	Hours	Weeks of training	Hours	
Topic 9. Basic requirements for biomedical equipment. Development and attitude to the production of medical devices.	9	2	10	2	KP №5 EC №8
Topic 10. Medical and technical requirements. Technical conditions.	10	2	11	2	EC №9
Topic 11. Sterilization of medical instruments.	11	2	12	2	KP №6 EC №10
Topic 12. Maintenance and repair of medical equipment.	12	2	13	4	EC №-11
Topic 13. Elements of electrical safety of medical equipment. The effect of electric current on the human body.	13	4	14-15	4	KP №7 EC №12
Topic 14. Methods of ensuring protection of patients from electric shock. Methods of performing grounding in the BMA.	14	2			
Modular test work			16	2	MTW
Abstract			16-18		abs
Final test			***18***	***(2)***	
Total hours		**30**		**30**	

The adequacy of teaching and assessment methods is reflected in the rating system of assessment, which includes: defense of practice reports, modular test work, HT, and exam.

5.1. Lecture classes

№	Title of the lecture topic and list of main questions
1	**Topic 1. Technical regulations and conformity assessment.** Law of Ukraine “On Technical Regulations and Conformity Assessment”. Technical Regulations on Medical Devices. Technical Regulations on Medical Devices for In Vitro Diagnostics. Technical Regulations on Active Implantable Medical Devices. Accreditation of Conformity Assessment Bodies.
2	**Topic 2. Standardization. Metrology and metrological activities. Principles of state supervision (control).** Law of Ukraine "On Standardization". Law of Ukraine "On Metrology and Metrological Activities". Law of Ukraine "On the Basic Principles of State Supervision (Control) in the Sphere of Economic Activity".
3	**Topic 3. Procedure for conducting clinical trials of medicinal products and examination of clinical**

№	Title of the lecture topic and list of main questions
	trial materials and Model Regulations on Ethics Committees. Law of Ukraine “On Approval of the Procedure for Conducting Clinical Trials of Medicinal Products and Expertise of Clinical Trial Materials and the Model Regulation on Ethics Commissions.” General Principles of Conducting Clinical Trials.
4	**Topic 4. Structural components of biomedical equipment. Engineering design methods.** Parts of complex equipment design. Medical device. Medical device. Features of the design of BMA. Basis of BMA design. Components of the designer's work.
5	**Topic 5. Systemic approach to designing BMA. Main stages in designing BMA biomedical equipment.** Search for the optimal variant of the BMA design. Design design (design). Research and design work (RDW). Main stages of conducting scientific and research work (R&D).
6	**Topic 6. Intellectual property protection.** Intellectual property sphere. Objects of copyright. Inventions. Utility models. Industrial designs. Protection of intellectual property objects.
7	**Topic 7. Mathematical models: definition, characteristics, stages of construction.** Definition of a mathematical model. Stages of mathematical modeling. Main characteristics of mathematical models. Adequacy of modeling. Algorithm for building a mathematical model.
8	**Topic 8. Psychological compatibility of a person and a BMA. Ergonomics and its influence on the design of a BMA. Basics of the composition of the appearance of the device.** Interaction between a doctor and an electronic computer (ECM). The influence of human factors on the information processing process. Ensuring maximum psychological compatibility between a doctor and a computer on the one hand, and a computer and a patient on the other. Definition of ergonomics and its history. Problems solved by ergonomics. Methods of ergonomic analysis, prospects for the development of ergonomics. Basics of the composition of the device's appearance. Principles of placing controls on the front panel.
9	**Topic 9. Basic requirements for biomedical equipment. Development and attitude to the production of medical devices.** General requirements for BMA. Basic provisions of the state standard DSTU 3627:2005 "Medical products. Development and attitude to production. Basic provisions." Procedure for acceptance testing and product acceptance. Clinical testing. Adjustment and development of production.
10	**Topic 10. Medical and technical requirements. Technical conditions.** Development of medical and technical requirements (MTR). Requirements for customers and MTR performers. Contents of Technical Conditions.
11	**Topic 11. Sterilization of medical instruments.** Basic terms and concepts of sterilization. Stages of sterilization of medical devices. Disinfection, pre-sterilization cleaning of devices, sterilization.
12	**Topic 12. Maintenance and repair of medical equipment.** Basics of medical equipment care. Maintaining the functionality of medical equipment.

№	Title of the lecture topic and list of main questions
13	**Topic 13. Elements of electrical safety of medical equipment. The effect of electric current on the human body.** DSTU 3798-98 "Medical electrical products. General safety requirements". Requirements for medical electrical products. Effect of electric current on the human body.
14	**Topic 14. Methods of ensuring protection of patients from electric shock. Methods of performing grounding in the BMA.** Classes and types of protection of medical electrical products. Generalized structure of medical products of class I. Generalized structure of medical products of class II. Testing of electrical insulation strength. Division into types of medical electrical products according to the magnitude of leakage currents (B, BF, CF). Three groups of grounding: protective grounding, working (functional) grounding and lightning protection grounding.

5.2. Computer workshops

They repeat the topics of the lecture classes.

Distance learning platform:

For better assimilation of the subject material during the period of distance learning, e-mail, the Sikorsky distance learning platform based on the Google Classroom system, and the Google Meet and ZOOM online meeting platform are used, with the help of which:

• the placement of methodological recommendations, educational materials, literature, etc. is simplified;

• feedback is provided to students regarding educational tasks and the content of the subject;

• completed tasks are checked and evaluated;

• students' implementation of the discipline plan, adherence to the schedule for submitting educational/individual tasks and their evaluation are recorded.

6. Student's independent work

One of the main types of semester control during the mastering of the academic discipline "Expertise and engineering support of medical equipment" is the execution of an essay. The essay is performed in accordance with the requirements, within the time specified by the teacher.

The main goal of the essay is to solve a theoretical problem using theoretical material learned in lectures and independently. The student can write an essay only on a topic agreed with the teacher.

Approximate topics of the abstract:

№1 Organization of quality control and safety of medical devices.

№2 Import and territory of Ukraine of medical devices.

№3 Biomedical clinical research of a medical device.

№4 Bioethical expertise of medical devices.

№5 Inter-sectoral systems of standards.

№6 Medical and technical requirements for medical devices.

The title page of the abstract should have the following content: name of the university; name of the faculty; name of the department; name of the specialty, name of the educational and professional program, name of the academic discipline; topic of the abstract; surname and name of the student, course, academic group number, year.

The title page is followed by a detailed plan (table of contents) of the abstract, in which the introduction, sections of the main content (main topics studied), their subdivisions (if necessary), conclusion, list of sources used should be highlighted. The table of contents indicates the page numbers of the beginning of each question on the right. Each section begins with a new page.

The total volume of the abstract, depending on the chosen topic, can vary from 15 to 25 pages of the main text (in agreement with the teacher). The volume of the abstract is determined by the student's ability to concisely and at the same time comprehensively explain the results obtained.

Mandatory requirement: clear reference to sources of information. All figures, facts, opinions of scientists, quotes, formulas must have references in the form of [2, p. 54] (the first digit means the number of the source in the list of references given at the end of the creative work, and the second digit is the page number in this source). It is advisable to use tables, diagrams, graphs, charts, etc. The list of sources used (at least 10 sources) is drawn up in accordance with current rules. If the information is taken from the Internet, it is necessary, as for ordinary literature, to indicate the author, the title of the article, and then give the address of the site on the Internet.

The abstract is evaluated according to the following criteria: logical plan; completeness and depth of disclosure of the topic; reliability of the data obtained; reflection of practical materials and calculation results; correct formulation of the conclusions of the obtained results and conclusions; design; substantiation of the student's own opinion on this issue in the form of a conclusion.

Deadline for submitting an abstract for verification: 16th week of study.

The abstract is not checked for plagiarism, but must meet the requirements of academic integrity. If academic dishonesty is detected, the work is canceled and not checked.

Policy and control

7. Academic discipline policy (educational component)

Attendance at classes

Attendance at lectures is not mandatory. Attendance at practical classes is desirable, as they include writing quick tests/tests, and explaining the execution of subsequent practical assignments and their submission.

The assessment system is focused on obtaining points for student activity, as well as completing tasks that can develop practical skills.

Missed tests

Missed tests (practical work defense) must be completed in the following classes, provided that the task scheduled for the current class or consultations is completed.

Missed writing of modular tests and express tests are not completed.

An essay submitted for review after the deadline is evaluated with a decrease in the number of weight points.

Violation of task deadlines and incentive points

Incentive points		*Penalty points **	
Criterion	*Weighted score*	*Criterion*	*Weighted score*
Improving practical work	*1 point (for each practical work)*	*Untimely completion and defense of practical work*	*From -0.5 points to -3 points (depends on the deadline)*
Taking distance courses on topics agreed upon with the teacher	*5 points*	*Untimely execution and submission of the Abstract*	*From -2 points to -10 points (depends on the submission deadline)*
Preparation of a scientific paper for participation in a student scientific paper competition	*10 points*		
Writing theses, articles, participation in international, all-Ukrainian and/or other events or competitions on the topic of the academic discipline	*5 points*		

** If the control measure was missed for a good reason (illness confirmed by a certificate of the established form) - no penalty points are accrued.*

Academic Integrity

The policy and principles of academic integrity are defined in Section 3 of the Code of Honor of the National Technical University of Ukraine "Igor Sikorsky Kyiv Polytechnic Institute". More information: https://kpi.ua/code.

Standards of Ethical Conduct

The standards of ethical conduct of students and employees are defined in Section 2 of the Code of Honor of the National Technical University of Ukraine "Igor Sikorsky Kyiv Polytechnic Institute". More information: https://kpi.ua/code.

Procedure for appealing the results of control measures

Students have the opportunity to raise any issue related to the control measures procedure and expect that it will be considered in accordance with the pre-defined procedures.

A student has the right to appeal the results of the control measure in accordance with the approved Regulation On Appeals at Igor Sikorsky Kyiv Polytechnic Institute (approved by order No. HOH/128/2021 dated 05/20/2021) - https://osvita.kpi.ua/index.php/node/182

Inclusive Education

The course "Fundamentals of Clinical Engineering and Radiology - 2. Examination and Engineering Support of Medical Equipment" can be taught to most students with special educational needs, except for students with severe visual impairments that do not allow them to perform tasks using personal computers, laptops and/or other technical means.

Distance learning

Distance learning takes place through the Sikorsky Distance Learning Platform.

Distance learning through additional online courses on a specific topic is allowed subject to agreement with students. If a small number of students wish to take an online course on a specific topic, studying the material through such courses is allowed, but students must complete all the tasks provided for in the academic discipline.

The list of courses is offered by the teacher after students express their desire (since the bank of available courses is updated almost every month).

The student provides a document confirming the completion of the distance course (in the case of completing the full course) or provides completed practical tasks from the distance course and, subject to passing an oral interview with the teacher on the topics covered, can receive grades for the control measures provided for the topics studied (express control / test tasks, practical work).

The performance of practical work, as well as the performance of homework, is carried out during the independent work of students in remote mode (with the possibility of consulting with the teacher via email, social networks).

Studying in a foreign language

Study in English is carried out only for foreign students.

At the request of students, it is allowed to study the material using English-language online courses on topics that correspond to the topics of specific classes.

8. Types of control and rating system for assessing learning outcomes (RSO)

Evaluation system (current control):

№	*Control measure*	*%*	*Weighted point*	*Number*	*Total*

1.	*Express control work / test tasks*	*21*	*1,5*	*14*	*21*
2.	*Completion and defense of practical work*	*21*	*3*	*7*	*21*
3.	*Modular test work*	*8*	*8*	*1*	*8*
4.	*Abstract*	*10*	*10*	*1*	*10*
5.	Final test	*40*	*40*	*1*	*40*
	Total				*100*

Calendar control (CC) - is carried out twice a semester as a monitoring of the current status of implementation of the syllabus requirements.

The purpose of calendar control is to improve the quality of student learning and monitor the implementation of the educational process schedule by students.

Criterion			*First C C*	*Second C C*
Calendar control period			*8th week*	*Week 14*
Conditions for obtaining a positive result from calendar control	*Current rating*		*≥ 12 points*	*≥ 24 points*
	Performing practical work	*PW №№1-4*	*+*	*+*
		PW №№5-7	*-*	*+*
	Express control work / test tasks	*Minimum of 4 of any lectures*	*+*	*-*
		Minimum of 10 any lectures	*-*	*+*
	Modular test work	*Rated*	*-*	*+*
	Abstract	*Rated*	*-*	*-*

If academic dishonesty is detected during studies, the test will not be counted.

Semester certification of students

Mandatory condition for admission to the test		*Criterion*
1	*Current rating*	*RD ≥ 30*
2	*Receiving a positive grade for the completed essay*	*More than 6 points*
3	*All practical work is protected*	*More than 6 points*
4	*Writing at least 6 express control papers / test tasks*	*More than 6 points*

The results are announced to each student individually in person at the test event or remotely (by e-mail). They are also recorded in the "Electronic Campus" system.

Mandatory conditions for admission to the test:

1. Activity in practical classes.

2. Positive result of the first certification and the second certification.

3. Attendance at lectures.

The test is conducted orally.

Table of correspondence of rating points to university scale grades

Number of points	**Rating**
100-95	Perfectly
94-85	Very good
84-75	Good
74-65	Satisfactorily
64-60	Enough
Less than 60	Unsatisfactorily
Admission conditions not met	Not allowed

9. Additional information on the discipline (educational component)

The list of questions for preparing for the modular test, as well as for preparing for the final test, is given in Appendix 1.

Distance learning through taking additional online courses on a certain topic is allowed subject to agreement with students. If a small number of students wish to take an online course on a certain topic,

studying the material using such courses is allowed, but students must complete all the tasks provided for in the academic discipline.

The list of courses is offered by the teacher after the students express their desire (since the bank of available courses is updated almost every month).

The student provides a document confirming the completion of the distance course (in the case of completing the full course) or provides completed practical tasks from the distance course and, subject to passing an oral interview with the teacher on the topics covered, can receive grades for the control measures provided for the topics studied (express control / test tasks, practical work).

Description of the material, technical and information support of the discipline

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The working program of the academic discipline (syllabus):
Compiled by Dubko A. G.;
Approved by the BMI Department
Approved by the methodological committee of the faculty/NII

Appendix 1 to the syllabus of the discipline

"Expertise and engineering support of medical equipment"

List of questions for preparation for the module test,

as well as for preparation for the exam

1. List the main regulatory legal acts regulating the circulation of medical devices.

2. Define the terms: commissioning; placing on the market; specified requirements.

3. Define the terms: technical regulations; mark of conformity to technical regulations.

4. Define the terms: conformity assessment body; testing laboratory.

5. Define the terms: document of conformity; object of conformity assessment; European Union legislation on harmonization; harmonized European standard.

6. Explain the scope of the Law "On Technical Regulations and Conformity Assessment".

7. List the powers of the Cabinet of Ministers of Ukraine in the field of technical regulation.

8. List the goals of adopting technical regulations.

9. On what basis are technical regulations developed.

10. Define the terms: custom-made medical device; manufacturer.

11. Define the terms: clinical data; medical device.

12. Define the terms: medical device intended for clinical trials; single-use medical device.

13. In what cases is the placing on the market and operation of medical devices permitted.

14. List the main designated bodies for assessing product conformity according to the Technical Regulation on medical devices.

15. Which medical devices are subject to the Technical Regulation on medical devices for in vitro diagnostics.

16. Define the terms: product for self-monitoring; product intended for evaluating characteristics.

17. Define the terms: medical device for in vitro diagnostics.

18. List the main designated bodies for assessing product conformity according to the Technical Regulation on medical devices for in vitro diagnostics.

19. Which medical devices are subject to the Technical Regulation on active implantable medical devices.

20. Define the terms: active medical device; active implantable medical device.

21. Define the terms: instructions for use; clinical studies; clinical research plan.

22. What does the Technical Regulation on active implantable medical devices not apply to?

23. List the main designated bodies for product conformity assessment according to the Technical Regulation on active implantable medical devices.

24. Explain the scope of the Law of Ukraine “On Accreditation of Conformity Assessment Bodies”.

25. Define the terms: accreditation of conformity assessment bodies; mutual evaluation.

26. Define the terms: consulting; assessment; accreditation personnel.

27. Explain the purpose of accreditation.

28. Explain the basic principles of accreditation activities.

29. Explain the scope of the Law of Ukraine “On Standardization”.

30. Define the terms: code of good practice; international standardization organization.

31. Define the terms: international standard; national standardization body.

32. Define the terms: regulatory document; standard.

33. Define the terms: standardization, technical conditions.

34. Explain the purpose of standardization.

35. What are the objects of standardization.

36. Explain the scope of legally regulated metrology.

37. Define the terms: expert verification of measuring instruments; measuring instruments.

38. Define the terms: calibration laboratory; calibration.

39. Define the terms: metrological activity; periodic verification of measuring instruments; verification of measuring instruments.

40. Explain the main tasks of the metrological system of Ukraine.

41. Define the terms: state supervision; state supervision measures.

42. Define the terms: integrated automated state supervision system; risk.

43. Define the term - creating obstacles to state supervision bodies or their officials in the implementation of state supervision measures.

44. Explain the basic principles of state supervision.

45. List the general requirements for the implementation of state supervision.

46. What is the procedure for conducting clinical trials of medicinal products and examining clinical trial materials.

47. Define the terms: investigator's brochure; research subject.

48. Define the terms: investigator/co-investigator; examination of clinical trial materials.

49. Define the terms: healthcare institution; clinical trial applicant.

50. Define the terms: clinical trial report; informed consent.

51. Define the terms: clinical trial of a medicinal product or medical device; ethics committee at a medical institution.

52. Define the terms: trial site; clinical trial protocol.

53. Explain the general principles of conducting clinical trials.

54. In what case is a clinical trial conducted.

55. What structural parts does biomedical equipment consist of.

56. Define the terms: medical device; medical apparatus.

57. What are the characteristics of the design of biomedical equipment.

58. What are the components of the designer's work.

59. Explain the essence of a systems approach in the design of modern biomedical devices.

60. List the stages of research and development work.

61. Explain the features of intellectual property protection.

62. What applies to copyright objects.

63. What relates to inventions.

64. What relates to utility models.

65. What relates to industrial designs.

66. What stages does mathematical modeling go through.

67. Give an algorithm for building a mathematical model.

68. What factors influence human activity and the entire information processing process.

69. What problems does ergonomics solve.

70. What are the basic requirements for biomedical equipment.

71. What information should medical and technical requirements contain.

72. Give the basic terms and concepts of sterilization.

73. How to prevent serious malfunctions of medical equipment.