1. General information on the course

Full course name	Life Safety; Basics of Bioethics and Biosafety
Full official name of a higher education institution	Sumy State University
Full name of a structural unit	Faculty of Technical Systems and Energy Efficient Technologies. Department of Ecology and Environmental Protection Technologies
Author(s)	Bataltsev Yevhen Volodymyrovych, Ablieieva Iryna Yuriivna
Cycle/higher education level	The Second Level Of Higher Education, National Qualifications Framework Of Ukraine – The 7th Level, QF-LLL – The 7th Level, FQ-EHEA – The Second Cycle
Semester	16 weeks across 1 semester
Workload	3 ECTS, 90 hours, out of which 32 hours are working hours with the lecturer (16 hours of lectures,16 hours of seminars)
Language(s)	English

2. Place in the study programme

Relation to curriculumCompulsory course available for st programme "Medicine"	
Prerequisites	There are no specific pre-requisites
Additional requirements	There are no specific requirements
Restrictions	There are no specific restrictions

3. Aims of the course

The aim of the course is the formation of knowledge, skills and competencies to preserve human health and life in modern living conditions, to protect it from the dangers of man-made, anthropogenic, natural origin, as well as theoretical knowledge and practical skills about moral and ethical principles of human activity in medicine, introduction into practice of new medical and biological technologies, the achievements of biology and medicine in terms of determining the degree of their danger.

4. Contents

Module 1. Safety of human life in modern conditions

Topic 1 Theoretical foundations of life safety. Hazards and their classification. Risk as a quantitative assessment of hazards.

Urgency of life safety problems. Purpose, structure of life safety discipline. Axioms of life safety. Basic concepts and definitions in life safety. Areas of life safety. Taxonomy of dangers. Criteria for the transition from a dangerous event to an emergency. Classification of emergencies. The concept of "risk". Risk classification. The concept of acceptable risk. Risk management.

Topic 2 Healthy lifestyle.

Factors affecting human health. Social factors affecting human life and health. Bad habits, social diseases and their prevention. Alcoholism, smoking and drug addiction. Basic principles of a healthy lifestyle. The environment of human life. Human adaptation. Types of adaptation.

Topic 3 Man-made hazards and consequences of their action. Typology of accidents at potentially dangerous objects. Socio-political dangers, their types and features. Algorithm of protective behavioral reactions.

Technosphere. Anthropogenic impact on the environment. Typology of accidents at potentially dangerous objects and protection of the population from harmful and dangerous factors. Accidents with the release of highly toxic substances. Providing medical care in case of defeat by strong poisonous substances. Actions of the population after notifying about radioactive contamination of the environment. Socio-political dangers. Classification of socio-political dangers. The growth of crime as a danger factor. The concept and varieties of the crowd. Human behavior in the crowd. Socio-political conflicts. Types of terrorism, its striking factors. Algorithm of protective behavioral reactions.

Topic 4 Natural hazards, the nature of their manifestation and effects on people and objects of the economy. Protection of the population from harmful and dangerous factors.

Characteristics of dangerous geological processes and phenomena. Protection of the population from harmful and dangerous factors. The nature of fire. Hydrological dangerous phenomena. Meteorological natural phenomena. Protection of the population from harmful and dangerous factors. Biological hazards.

Module 2. Basics of bioethics and biosafety

Topic 5 Bioethics as a theory and practice of medical activity.

Bioethics: subject, purpose and tasks in the health care system. Directions and methods of bioethics. History of professional medical ethics, nooethics. Bioethical components of medical practice. Bioethics and the formation of the national health care system in Ukraine. International instruments governing human rights. Bioethical bases of professional activity of the doctor. Relationships between healthcare professionals, the patient and his family in the context of transcultural bioethics. The bioethical principle of equity in the allocation of health resources. Bioethical and legal assessment of medical error.

Topic 6 Bioethics of medical and biological experiments and clinical trials.

Methodology, types, design of clinical trials. The concept of evidence-based medicine. Moral and legal evaluation of medical research. The doctrine of informed consent. Ethics committees. History of experimental medicine. Moral evaluation of the use of animals for the experiment. Legal aspects of biomedical experiments. Modeling as an alternative to animal experiments.

Topic 7 Dignity and inviolability of human life from conception. Reproductive medicine. Medico-ethical and legal aspects of transplantation and donation. The problem of euthanasia: ethical, legal and theological aspects.

Legal status of the embryo. Medical, social and theological problems of abortion. Moral and ethical problems of stem cell use. Assisted reproductive technologies. Legal status of the embryo as a component of reproductive technologies. Surrogacy. Prenatal genetic diagnosis. History and achievements of transplantology. Problems of transplantation and donation. Legal and theological aspects of transplantology. Blood donation: historical, legal and ethical aspects. Definitions, terms and history of euthanasia. Bioethical and theological problems of euthanasia.

Topic 8 Fundamentals of biosafety.

Biological danger, biological risk, biological terrorism. Biological weapons. The main characteristics of biological weapons. Biological safety of work in laboratories. Modern biotechnology, genetic engineering: historical background, methodological techniques. Genetically modified organisms: scientific and practical significance. Biological and medical risks of using genetically modified plants and food derived from them. Human genetic engineering. Genodiagnostics. Genetically engineered drugs and vaccines. Gene therapy. Ethical aspects and legal regulation of creation, examination and use of genetically modified organisms.

5. Intended learning outcomes of the course

After successful study of the course, the student will be able to:		
LO1	To determine the basic principles of the safety of human life.	
LO2	To predict the consequences of violations of the valeological basis for the formation of a healthy lifestyle and their impact on the safety of human life.	
LO3	To analyze and evaluate situations dangerous to life, health and professional activity and independently decide on taking urgent measures.	
LO4	To apply moral, ethical and professional norms in professional activities and demonstrate an understanding of the legal regulation of the relationship «doctor – patient».	
LO5	To be able to identify and analyze conflict situations that arise at the intersection of medicine, biology, philosophy and law, identify ways to resolve them.	

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6. Role of the course in the achievement of programme learning outcomes

Programme learning outcomes achieved by the course. For 222 Medicine:

PO19	To assess environmental impact on public health.
PO21	To organize an appropriate level of individual safety (own and of those cared for) in case of typical dangerous situations in the individual field of activity.
PO25	To make effective healthcare decisions assessing resources and considering social, economic, and ethical implications.

7. Teaching and learning activities

7.1 Types of training

Topic 1. Theoretical foundations of life safety. Hazards and their classification. Risk as a quantitative assessment of hazards.

lect.1 "Theoretical foundations of life safety. Hazard risk assessment and the concept of acceptable risk" (full-time course)

The urgency of life safety problems. Purpose, structure of life safety discipline. Axioms of life safety. Basic concepts and definitions in life safety. Areas of life safety. Taxonomy of dangers. Criteria for the transition of a dangerous event to an emergency. Classification of emergencies. The concept of "risk". Risk classification. The concept of acceptable risk. Risk management.

pr.tr.1 "Assessment and forecasting of the level of danger" (full-time course)

Assessment and forecasting of the level of danger

Topic 2. Healthy lifestyle.

lect.2 "Healthy lifestyle" (full-time course)

Factors affecting human health. Social factors affecting human life and health. Bad habits, social diseases and their prevention. Alcoholism and drug addiction. Basic principles of a healthy lifestyle. The environment of human life. Human adaptation. Types of adaptation.

pr.tr.2 "Evaluation of food quality and nitrate content in plant products" (full-time course) Evaluation of food quality and nitrate content in plant products

pr.tr.3 "Study of the effects of alcohol on the human body" (full-time course) Study of the effects of alcohol on the human body

pr.tr.4 "Human adaptation to environmental conditions" (full-time course) Human adaptation to environmental conditions

pr.tr.5 "The effect of toxins on the human body" (full-time course)

The effect of toxins on the human body

Topic 3. Man-made hazards and consequences of their action. Typology of accidents at potentially dangerous objects. Socio-political dangers, their types and features. Algorithm of protective behavioral reactions.

lect.3 "Man-caused hazards and consequences of their action. Typology of accidents at potentially dangerous objects. Socio-political hazards, their types and features. Algorithm of protective behavioral reactions" (full-time course)

Technosphere. Anthropogenic impact on the environment. Typology of accidents at potentially dangerous objects and protection of the population from harmful and dangerous factors. Accidents with the release of highly toxic substances. Providing medical care in case of defeat by strong poisonous substances. Actions of the population when notifying about radioactive contamination of the environment. Socio-political dangers. Classification of socio-political dangers. The growth of crime as a danger factor. The concept and varieties of the crowd. Human behavior in the crowd. Socio-political conflicts. Types of terrorism, its striking factors. Algorithm of protective behavioral reactions.

Topic 4. Natural hazards, the nature of their manifestation and effects on people and objects of the economy. Protection of the population from harmful and dangerous factors.

lect.4 "Natural hazards, the nature of their manifestation and effects on people and objects of the economy. Protection of the population from harmful and dangerous factors" (full-time course)

Characteristics of dangerous geological processes and phenomena. Protection of the population from harmful and dangerous factors. The nature of fire. Hydrological dangerous phenomena. Meteorological natural phenomena. Protection of the population from harmful and dangerous factors. Biological hazards.

Topic 5. Bioethics as a theory and practice of medical activity.

lect.5 "Bioethics as a theory and practice of medical activity" (full-time course)

Bioethics: subject, purpose and tasks in the health care system. Directions and methods of bioethics. History of professional medical ethics, nooethics. Bioethical components of medical practice. Bioethics and the formation of the national health care system in Ukraine. International instruments governing human rights. Bioethical bases of professional activity of the doctor. Relationships between health professionals, the patient and his family in the context of transcultural bioethics. The bioethical principle of equity in the allocation of health resources. Bioethical and legal assessment of medical error.

Topic 6. Bioethics of medical and biological experiments and clinical trials.

lect.6 "Bioethics of medical and biological experiments and clinical trials" (full-time course)

Methodology, types, design of clinical trials. The concept of evidence-based medicine. Moral and legal evaluation of medical research. The doctrine of informed consent. Ethics committees. History of experimental medicine. Moral evaluation of the use of animals for the experiment. Legal aspects of biomedical experiments. Modeling as an alternative to animal experiments.

Topic 7. Dignity and inviolability of human life from conception. Reproductive medicine. Medico-ethical and legal aspects of transplantation and donation. The problem of euthanasia: ethical, legal and theological aspects.

lect.7 "Reproductive medicine. Medical-ethical and legal aspects of transplantation and donation. The problem of euthanasia: ethical, legal and theological aspects" (full-time course)

Legal status of the embryo. Medical, social and theological problems of abortion. Moral and ethical problems of stem cell use. Assisted reproductive technologies. Legal status of the embryo as a component of reproductive technologies. Surrogacy. Prenatal genetic diagnosis. History and achievements of transplantology. Problems of transplantation and donation. Legal and theological aspects of transplantology. Blood donation: historical, legal and ethical aspects. Definitions, terms and history of euthanasia. Bioethical and theological problems of euthanasia.

pr.tr.6 "Bioethics and problems of human reproduction" (full-time course)

Bioethics, genetics, pre- and postnatal diagnosis and ethical and legal issues of human reproduction. Bioethical and legal problems of human reproduction and genetic technologies. The Universal Declaration on the Human Genome and Human Rights. The essence of gene therapy and genetic engineering. Regulations on genetic counseling and genetic engineering. Problems of postnatal and prenatal genetic diagnosis. Bioethical aspects of human cloning.

pr.tr.7 "Bioethics and abortion" (full-time course)

Bioethical positions on abortion. Fetal status. Embryo in terms of genetics, medicine, philosophy and religion. Conflict between the life of the mother and the life of the fetus. Therapeutic and "eugenic abortion". Statement on women's rights to use contraception. Application for artificial insemination and embryo transplantation.

pr.tr.8 "Bioethical problems of pain, suffering and euthanasia" (full-time course)

Bioethical problems of pain, suffering, death. The essence of euthanasia. Statement of persistent vegetative state. Policy statement on the treatment of terminally ill patients with chronic pain. Bioethical problems of palliative and rehabilitation medicine. Venetian declaration of terminal status. Bioethics of the final phase of life. Declaration of Sydney: A Statement of Death.

Topic 8. Fundamentals of biosafety.

lect.8 "Biological safety" (full-time course)

Biological danger, biological risk, biological terrorism. Biological weapons. The main characteristics of biological weapons. Biological safety of work in laboratories. Modern biotechnology, genetic engineering: historical background, methodological techniques. Genetically modified organisms: scientific and practical significance. Biological and medical risks of using genetically modified plants and food derived from them. Human genetic engineering. Gene diagnostics. Genetically engineered drugs and vaccines. Gene therapy. Ethical aspects and legal regulation of creation, examination and use of genetically modified organisms.

7.2 Learning activities

LA1	Performing practical tasks.
LA2	Writing an abstract on the topic of an individual research task.
LA3	Creation of multimedia presentations on the topic of individual research task.
LA4	E-learning in systems (Meet).
LA5	Self-study.

8. Teaching methods

Course involves learning through:

TM1	Interactive lectures.
TM2	Practical works.

Lectures provide students with materials on general issues of life safety, which is the basis for self-study of higher education (LO1, LO2 and LO5). Lectures are complemented by practical classes that give students the opportunity to apply theoretical knowledge on practical examples (LO3). Practical-oriented training involves mastering the basic methods of preserving the life, health and ability to work of employees during future professional activities within their competence in the primary position and performing professional functions, duties and powers in the workplace (LO4). Independent learning will be facilitated by preparation for lectures and practicals, mandatory homework, as well as work in small groups to prepare reports on the implementation of practical tasks, which will be analyzed and discussed during the defense of reports. During the

preparation of reports, students will develop skills of independent learning.

During classes, students gain communication skills, the ability to work in a team, the ability to think logically and systematically, creativity; skills of written communication, reasoned expression of opinions. Preparing for presentations will help students develop and implement logical and systematic thinking skills. Preparation for practical work develops students' skills in the synthesis and analysis of information, expression of opinions in written and oral form.

9. Methods and criteria for assessment

9.1. Assessment criteria

ECTS	Definition	National scale	Rating scale
	Outstanding performance without errors5 (Excellent)		$170 \le RD \le 200$
	Above the average standard but with minor errors	4 (Good)	$140 \le RD < 169$
	Fair but with significant shortcomings	3 (Satisfactory)	$120 \le RD < 139$
	Fail – some more work required before the credit can be awarded	2 (Fail)	$0 \le RD < 119$

9.2 Formative assessment

FA1	Interviews and oral comments of the teacher on stedent's results
FA2	Defense of presentations and essays

9.3 Summative assessment

SA1	Report on the results of practical work.
SA2	Final control: test.
SA3	Summary (preparation, presentation, defense).
SA4	Multimedia presentation on the topic of individual research task (preparation of the presentation, defense).

Form of assessment:

1 semester		200 scores
SA1. Report	on the results of practical work.	80
	10x8	80
SA2. Final control: test.		80
		80
SA3. Summ	ary (preparation, presentation, defense).	20
		20
SA4. Multimedia presentation on the topic of individual research task (preparation of the presentation, defense).		20

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Form of assessment (special cases):

1 semester		200 scores
SA1. Report	on the results of practical work.	80
	10x8	80
SA2. Final c	SA2. Final control: test.	
		80
SA3. Summary (preparation, presentation, defense).		20
		20
SA4. Multimedia presentation on the topic of individual research task (preparation of the presentation, defense).		20
		20

A student who during the academic period performed all the planned types of educational work and as a result of modular certifications scored the required number of rating points, which corresponds to a positive grade (at least 120 points), receives a semester grade in accordance with the rating scores. Compilation of the final semester control in order to increase the positive assessment is not carried out. A student who during the current work has not scored the number of rating points, which corresponds to a positive assessment, but not less than 90 points, is required to pass the final semester control. Compilation of the final semester control is carried out after the completion of the module-attestation cycle in the semester or examination session, if it is provided. Upon successful completion of the final semester control, a grade of "satisfactory" ("E") is used – 120 points, which certifies the student's compliance with the minimum requirements without taking into account the accumulated points. The student has the right to pass two final semester controls: with the teacher and with the commission. A student who has scored less than 90 points as a result of modular attestations is not admitted to the final semester control, receives a grade of "unsatisfactory" ("F") and is expelled from the university.

10. Learning resources

10.1 Material and technical support

MTS1	Library funds.
MTS2	Multimedia, video and sound reproduction, projection equipment (projectors, screens).
MTS3	Measuring instruments.
MTS4	Computers, computer systems and networks, own mobile devices.

10.2 Information and methodical support

Essential Reading

1	Ablieieva, I. Yu. Basics of Bioethics and Biosafety : lecture notes for English-speaking students of specialty 222 "Medicine" all forms of training. Sumy : Sumy State University, 2018. – 90 p.
2	Methodological instructions to seminar classes on Safety of life, the basics of bioethics and safety (Module "Basics of Bioethics and Biosafety") : for English-speaking students of Medical Institute all forms of training / I. Yu. Ablieieva. — Sumy : Sumy State University, 2020. — 46 p.
3	Bioethics and Biopolitics : Theories, Applications and Connections / edited by Peter Kakuk. — 1st ed. 2017. — Cham : Springer International Publishing, 2017. — XVI, 135 p. 1 illus.
4	Communication and Bioethics at the End of Life : Real Cases, Real Dilemmas / by Lori A. Roscoe, David P. Schenck. — 1st ed. 2017. — Cham : Springer International Publishing, 2017.
5	Safety Assessment of Genetically Modified Foods / by Kunlun Huang. — 1st ed. 2017. — Springer, Singapore, 2017.
Supplemental Reading	
6	Life safety : lectures on Life safety for students of all specialities, who study in English of the full-time course of study / E. Y. Chernish. — Sumy : Sumy State University, 2015. — 53 p.