Structure of the program

I SEMESTER – first year

No.	Code	Courses	ECTS	Hours	Total
1.		Basic (Applied) Pharmacy	4	24+24+12+12+38	120
2.		Nuclear Physics, Radiation Safety and Regulations	5	30+30+15+15+60	150
3.		Radiopharmaceutical Chemistry	10	60+60+30+30+120	300
4.		Radioisotope production and Radiopharmaceutical preparation	5	30+30+15+15+60	150
5.		Quality control of radiopharmaceuticals	6	36+36+18+18+72	180
		Total ECTS	30		900

II SEMESTER – first year

No.	Code	Courses	ECTS	Hours	Total
6.		Radiopharmaceutical preparation-SPECT, PET and therapeutic radiopharmaceuticals	8	48+48+24+24+76	240
7.		Good Manufacturing Practice in Radiopharmaceutical production	4	24+24+12+12+38	120
8.		Optional course	4	24+24+12+12+38	120
9.		Optional course	4	24+24+12+12+38	120
10.		Thesis	10	300	300
		Total ECTS	30		900

Program of the Course

Annex No.3	Program of the Course - second cycle studies, Academic specialty				
1.	**Title of the Course**	**Basic (Applied) Pharmacy**			
2.	**Code**				
3.	**Study Program**	**Radiopharmacy**			
4.	**Organizer of the study program (unit or institute, Faculty, department)**	University Goce Delcev Faculty of Medical Sciences			
5.	**Cycle (first, second and third cycle)**	Second cycle – Academic specialty			
6.	**Academic year / semester**	First semester/ First year	**7.**	**Number of credits**	4
8.	**Professor (s)**	Prof. Bistra Angelovska Prof. Elena Drakalska			
9.	Requirements **for enrollment the Course**	/			
10.	Purposes **of the curriculum (**competencies): - Give to the student the scientific knowledge with practical and theoretical skills necessary the pharmacists and to operate with the medicinal products and health related products (radiopharmaceuticals, diagnostic products) in the relevant institutions				
11.	Content **of the course program**: 1. Basic Pharmaceutical Technology 2. Good Manufacturing Practice 3. Sterile Manufacture 4. Pharmaceutical microbiology 5. Parenteral Preparations 6. Formulation and Packaging 7. Pharmaceutical Analysis 8. Pharmacopoeia monographs 9. Quality Assurance and Product Performance 10. Quality Control Procedures 11. Stability and Shelf Life 12. Regulations and Legal Aspects 13. Marketing Authorizations 14. Responsibilities of Personnel				

12.	**Learning methods:** – lectures - contact teaching, – e-teaching, – theoretical and practical exercises, – assignments, – consultations, – preparation of independent seminar work, – home learning, – preparatory classes for exams, – consultations, – colloquia, – practical final exercise, – e-exams			
13.	Total **available time**		4 EKTC x 30 hours = 120 hours	
14.	**Distribution of available time**		30+30+15+15+30=120	
15.	Forms of **teaching / learning activities**	**15.1.**	**lectures / theoretical - contact teaching, e-teaching**	30 hours
		15.2.	**theoretical and practical exercises, e-exams, preparation of independent seminar work**	30 hours
16.	**Other forms of activities**	**16.1.**	Project tasks	15 hours
		16.2.	Individual **tasks**	15 hours
		16.3.	Home **learning**	30 hours
17.	Method of **assessment**			
	17.1.	Tests / oral exams		70 points
	17.2.	**Seminars (paper / project - presentation: written and/or oral)**		10 points
	17.3.	Activity **and participation**		20 points
18.	Assessment **Criteria (**points **/ score**)	up **50 points**	**5 (five) (F)**	
		51 to **60 points**	**6 (six) (E)**	
		61 to **70 points**	**7 (seven) (D)**	
		71 to **80 points**	**8 (eight) (C)**	
		81 to **90 points**	**9 (nine) (B)**	
		91 to **100 points**	**10 (ten) (A)**	
19.	Signature **requirement and passing the final exam**			
20.	Language **of teaching / study**	**English**		
21.	Method **of monitoring the quality of teaching**	**Self-evaluation**		

22.	Literature					
	22.1.	Required **literature**				
		No.	Author	**Title**	Publisher	**Year**
		1.	Tony Theobald (Editor)	Sampson's Textbook of Radiopharmacy	Pharmaceutical Press	2010
		2.	Loyd Allen	Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems	LWW; 11th edition	2017
		3.	Parick J. Sinko	Martin's Physical Pharmacy and Pharmaceutical Sciences	LWW; Seventh, North American edition	2016
	22.2.	Additional literature				
		No.	Author	Title	Publisher	Year
		1.	Deborah Lester Elder	A Practical Guide to Contemporary Pharmacy Practice and Compounding	LWW; 4th edition	2017
		2.	Loyd V. Allen	Ansels Pharmaceutical Dosage Forms and Drug Delivery Systems	Lippincott Williams & Wilkins; 8th edition	2004
		3.	K. Solanki (Editor)	Operational Guidance on Hospital Radiopharmacy A Safe and Effective Approach	IAEA	2008

Annex No.3	**Program of the Course - second cycle studies, Academic specialty**

1.	**Title of the Course**	**Nuclear Physics, Radiation Safety and Regulations**			
2.	**Code**				
3.	**Study Program**	Radiopharmacy			
4.	**Organizer of the study program (unit or institute, Faculty, department)**	University Goce Delcev Faculty of Medical Sciences			
5.	**Cycle (first, second and third cycle)**	Second cycle – Academic specialty			
6.	**Academic year / semester**	First semester/First year	**7.**	**Number of credits**	5
8.	**Professor (s)**	Prof. Zdenka Stojanovska			
9.	Requirements **for enrollment the Course**	/			
10.	Purposes **of the curriculum (**competencies): *To have high level of knowledge for the Protection and the Safe Use of Radiation Sources, handling the radioactive materials for human application including Radioactivity Measurement as well doses estimations.*				
11.	**Content of the course program:** 1. Structure and Properties of Atoms 2. Nuclear transformations 3. Interactions of Radiation with Matter 4. Radiation Detection and Measurement 5. Dosimetry 6. Principles of Radiation Protection, Radiation Safety, 7. Safety of radioactive materials, equipment and facilities 8. Occupational exposure. Personnel Monitoring, Area Monitoring and Precautions 9. Public exposure. 10. Prevention and mitigation of accidents. 11. Safety in the transport of radioactive material				

12.	**Learning methods:** – lectures - contact teaching, – e-teaching, – theoretical and practical exercises, – assignments, – consultations, – preparation of independent seminar work, – home learning, – colloquia, – e-exams			
13.	Total **available time**		5 EKTC x 30 hours = 150 hours	
14.	**Distribution of available time**		30+30+15+15+60=150	
15.	Forms of **teaching / learning activities**	**15.1.**	**lectures / theoretical - contact teaching, e-teaching**	30 hours
		15.2.	**theoretical and practical exercises, e-exams, preparation of independent seminar work**	30 hours
16.	**Other forms of activities**	**16.1.**	Project tasks	15 hours
		16.2.	Individual **tasks**	15 hours
		16.3.	Home **learning**	60 hours

17.	Method of **assessment**		
	17.1.	Tests / oral exams	70 points
	17.2.	**Seminars (paper / project - presentation: written and/or oral)**	10 points
	17.3.	Activity **and participation**	20 points

18.	Assessment **Criteria (**points **/ score**)	up **50 points**	**5**	**(five)**	**(F)**
		51 to **60 points**	**6**	**(six)**	**(E)**
		61 to **70 points**	**7**	**(seven)**	**(D)**
		71 to **80 points**	**8**	**(eight)**	**(C)**
		81 to **90 points**	**9**	**(nine)**	**(B)**
		91 to **100 points**	**10**	**(ten)**	**(A)**
19.	Signature **requirement and passing the final exam**				
20.	Language **of teaching / study**	**English**			
21.	Method **of monitoring the quality of teaching**	**Self-evaluation**			

22.	Literature					
	22.1.	Required **literature**				
		No.	Author	**Title**	Publisher	**Year**
		1.	Christoph Hoeschen, Sören Mattsson (Editors)	Radiation Protection in Nuclear Medicine	Springer	2013
		2.		Specific Safety Guide No. SSG-46: Radiation Protection and Safety in Medical Uses of Ionizing Radiation	IAEA	2010
		3.	James E. Martin	Physics for Radiation Protection, 3rd Edition	Wiley	2013
	22.2.	Additional **literature**				
		No.	Author	**Title**	Publisher	**Year**
		1.		IAEA, Safety Reports Series No. 40: Applying Radiation Safety Standards in Nuclear Medicine	IAEA	2005
		2.	Gopal B. Saha	Fundamentals of Nuclear Pharmacy	Springer	2010
		3.	K. Solanki (Editor)	Operational Guidance on Hospital Radiopharmacy A Safe and Effective Approach	IAEA	2008

Annex No.3	**Program of the Course - second cycle studies, Academic specialty**				
1.	**Title of the Course**	R**adiopharmaceutical Chemistry**			
2.	**Code**				
3.	**Study Program**	**Radiopharmacy**			
4.	**Organizer of the study program (unit or institute, Faculty, department)**	University Goce Delcev Faculty of Medical Sciences			
5.	**Cycle (first, second and third cycle)**	Second cycle – Academic specialty			
6.	**Academic year / semester**	First semester/ First year	**7.**	**Number of credits**	10
8.	**Professor (s)**	Prof. Emilija Janevik-Ivanovska			
9.	Requirements **for enrollment the Course**	/			

10. Purposes **of the curriculum (**competencies):

The course will provide a highly directed and focused training in radiopharmaceutical chemistry related to the convenient and PET radiopharmaceutical preparation. In addition the course will provide an overview of Production of Radionuclides and basic Radiopharmacolgy related to the Mechanisms of Localization of Radiopharmaceuticals depending of their own chemistry.

Competencies after competition of the course:

- understanding of radiopharmaceutical chemistry principles, radionuclide production processes
- understanding of metallic and organic radiopharmaceutical radiolabeling techniques.
- understanding of chemical mechanisms underlying radiolabeling methods of metallic and organic radiopharmaceuticals.
- understanding of the chemical structure of diagnostic, therapeutic and biological radiopharmaceuticals.
- understanding of radiolabeling techniques.

11. Content **of the course program**:

1. Introduction - Basics on radiochemistry, Radiopharmaceutical Definition, Essential Properties of Radiopharmaceuticals – physical, chemical, biological, pharmaceutical properties
2. Production of Radionuclides - Nuclear reactor, Cyclotron, Radionuclide generators
3. Radiometal pharmaceuticals I - Radiopharmaceutical chemistry of 99mTc-Radiopharmaceuticals,
4. Radiometal pharmaceuticals II - Radiopharmaceutical chemistry: Re, Cu, In, Ga, Y
5. Organic radiopharmaceuticals I - Introduction to PET, 11C-radiopharmaceuticals
6. Organic radiopharmaceuticals II Radiofluorinations - 18F-radiopharmaceuticals
7. Organic radiopharmaceuticals III - Radiohalogenations: Br, I, At
8. Methods of radiolabeling, Specific factors, Kits

	9. Basic Radiopharmacology – Mechanisms of Localization of Radiopharmaceuticals, Pharmacology Versus Mechanisms of Localization, Biological Basis of Distribution of Radiopharmaceuticals 10. Radiopharmaceuticals for Diagnostic Purpose 11. Radiopharmaceuticals for Therapeutical Purpose 12. Radiolabeled Blood Cells					
12.	**Learning methods:** – lectures - contact teaching, – e-teaching, – theoretical and practical exercises, – assignments, – consultations, – preparation of independent seminar work, – home learning, – preparatory classes for exams, – consultations, – colloquia, – practical final exercise, – e-exams					
13.	Total **available time**		10 EKTC x 30 hours = 300 hours			
14.	**Distribution of available time**		90+60+30+30+90=300			
15.	Forms of **teaching / learning activities**	**15.1.**	**lectures / theoretical - contact teaching, e-teaching**	90 hours		
		15.2.	**theoretical and practical exercises, e-exams, preparation of independent seminar work**	60 hours		
16.	**Other forms of activities**	**16.1.**	Project tasks	30 hours		
		16.2.	Individual **tasks**	30 hours		
		16.3.	Home **learning**	90 hours		
17.	Method of **assessment**					
	17.1.	Tests / oral exams		70 points		
	17.2.	**Seminars (paper / project - presentation: written and/or oral)**		10 points		
	17.3.	Activity **and participation**		20 points		
18.	Assessment **Criteria (**points **/ score**)		up **50 points**	**5**	**(five)**	**(F)**
			51 to **60 points**	**6**	**(six)**	**(E)**
			61 to **70 points**	**7**	**(seven)**	**(D)**
			71 to **80 points**	**8**	**(eight)**	**(C)**
			81 to **90 points**	**9**	**(nine)**	**(B)**
			91 to **100 points**	**10**	**(ten)**	**(A)**

19.	Signature **requirement and passing the final exam**	
20.	Language **of teaching / study**	**English**
21.	Method **of monitoring the quality of teaching**	**Self-evaluation**

22. Literature

22.1. Required **literature**

No.	Author	**Title**	Publisher	**Year**
1.	Tony Theobald (Editor)	Sampson's Textbook of Radiopharmacy	Pharmaceutical Press	2010
2.	Gopal B. Saha	Fundamentals of Nuclear Pharmacy	Springer	2010
3.	I. Buvat, E.C. Frey, A.J. Green and M. Ljungberg (Editors)	Quantitative Nuclear Medicine Imaging: Concepts, Requirements and Methods	IAEA	2014

22.2. Additional **literature**

No.	Author	**Title**	Publisher	**Year**
1.	Richard J. Kowalsky, Steven W. Falen	Radiopharmaceuticals in Nuclear Pharmacy and Nuclear Medicine	American Pharmacist Association	2011
2.	Azuwuike Owunwanne, Mohan Patel, Samy Sadek	The Handbook of Radiopharmaceuticals	Springer	1995
3.	K. Solanki (Editor)	Operational Guidance on Hospital Radiopharmacy A Safe and Effective Approach	IAEA	2008

Annex No.3	**Program of the Course - second cycle studies, Academic specialty**

1.	**Title of the Course**	**Radionuclide production and Radiopharmaceutical preparation**			
2.	**Code**				
3.	**Study Program**	**Radiopharmacy**			
4.	**Organizer of the study program (unit or institute, Faculty, department)**	University Goce Delcev Faculty of Medical Sciences			
5.	**Cycle (first, second and third cycle)**	Second cycle – Academic specialty			
6.	**Academic year / semester**	First semester/ First year	**7.**	**Number of credits**	5
8.	**Professor (s)**	Prof. Emilija Janevik-Ivanovska			
9.	Requirements **for enrollment the Course**	/			

10. Purposes **of the curriculum (**competencies):

The course will provide a highly directed and focused training in radionuclide production and radiopharmaceutical preparations including conventional and PET radiopharmaceuticals, methods of formulation, manufacturing, compounding, labelling and produce the final product as a dosage form for human application.

Competencies after competition of the course:

- understanding the production of radionuclide from nuclear reactors
- understanding the production of radionuclide from accelerators/cyclotrons
- understanding the production of radionuclide from generator systems
- understanding the production of radiopharmaceuticals for diagnostic and therapeutic purpose

11. Content **of the course program**:

1. Definition of radiopharmaceuticals
2. Compounding radiopharmaceuticals
3. Essential components and additives, Conservation, Stability, Conditioning
4. Formulation of radiopharmaceuticals- pharmaceuticals dosage forms: capsules, parenteral preparations, oral solutions, suspensions, gases and aerosols
5. Pharmacovigilance
6. Kits formulations
7. 99m-Tc labelled radiopharmaceuticals
8. Other diagnostic radiopharmaceuticals
9. Radiolabelled blood cells as radiopharmaceuticals
10. Positron emission radiopharmaceuticals
11. Magistral preparations
12. Industrial radiopharmacy , centralized radiopharmacy

12.	**Learning methods:** – lectures - contact teaching, – e-teaching, – theoretical and practical exercises, – assignments, – consultations, – preparation of independent seminar work, – home learning, – preparatory classes for exams, – consultations, – colloquia, – practical final exercise, – e-exams			
13.	Total **available time**		5 EKTC x 30 hours = 150 hours	
14.	**Distribution of available time**		30+30+15+15+60=150	
15.	Forms of **teaching / learning activities**	**15.1.**	**lectures / theoretical - contact teaching, e-teaching**	30 hours
		15.2.	**theoretical and practical exercises, e-exams, preparation of independent seminar work**	30 hours
16.	**Other forms of activities**	**16.1.**	Project tasks	15 hours
		16.2.	Individual **tasks**	15 hours
		16.3.	Home **learning**	60 hours

17.	Method of **assessment**		
	17.1.	Tests / oral exams	70 points
	17.2.	**Seminars (paper / project - presentation: written and/or oral)**	10 points
	17.3.	Activity **and participation**	20 points

18.	Assessment **Criteria (**points **/ score**)	up **50 points**	**5**	**(five)**	**(F)**
		51 to **60 points**	**6**	**(six)**	**(E)**
		61 to **70 points**	**7**	**(seven)**	**(D)**
		71 to **80 points**	**8**	**(eight)**	**(C)**
		81 to **90 points**	**9**	**(nine)**	**(B)**
		91 to **100 points**	**10**	**(ten)**	**(A)**
19.	Signature **requirement and passing the final exam**				
20.	Language **of teaching / study**	**English**			
21.	Method **of monitoring the quality of teaching**	**Self-evaluation**			

22.	Literature					
	22.1.	Required **literature**				
		No.	Author	**Title**	Publisher	**Year**
		1.	Tony Theobald (Editor)	Sampson's Textbook of Radiopharmacy	Pharmaceutical Press	2010
		2.	Gopal B. Saha	Fundamentals of Nuclear Pharmacy	Springer	2010
		3.	I. Buvat, E.C. Frey, A.J. Green and M. Ljungberg (Editors)	Quantitative Nuclear Medicine Imaging: Concepts, Requirements and Methods	IAEA	2014
	22.2.	Additional **literature**				
		No.	Author	**Title**	Publisher	**Year**
		1.	Richard J. Kowalsky, Steven W. Falen	Radiopharmaceuticals in Nuclear Pharmacy and Nuclear Medicine	American Pharmacist Association	2011
		2.	Azuwuike Owunwanne, Mohan Patel, Samy Sadek	The Handbook of Radiopharmaceuticals	Springer	1995
		3.	K. Solanki (Editor)	Operational Guidance on Hospital Radiopharmacy A Safe and Effective Approach	IAEA	2008

Annex No.3	**Program of the Course - second cycle studies, Academic specialty**

1.	**Title of the Course**	**Quality control of radiopharmaceuticals**			
2.	**Code**				
3.	**Study Program**	**Radiopharmacy**			
4.	**Organizer of the study program (unit or institute, Faculty, department)**	University Goce Delcev Faculty of Medical Sciences			
5.	**Cycle (first, second and third cycle)**	Second cycle – Academic specialty			
6.	**Academic year / semester**	First semester/ First year	**7.**	**Number of credits**	6
8.	**Professor (s)**	Prof. Biljana Gjorgeska Prof. Zorica Arsova Prof. Marija Darkovska Serafimovska			
9.	Requirements **for enrollment the Course**	/			
10.	Purposes **of the curriculum (**competencies): Develop understanding in theoretical and practical aspects of Quality Control of radiopharmaceuticals together with methods and equipment necessary to analyze the purity of the samples. This course will also illustrate procedures and instrumentation that allow to asses purity specifications required to ensure injectability of a radiopharmaceutical. Moreover, this course will also cover topics such as principles of Good Laboratory Practice (GLP), validation plan and methods, quality assurance, record keeping and documentation.				
11.	Content **of the course program**: 1. Introduction to Quality Control of Radiopharmaceuticals Pharmacopoeia Quality Control of starting materials Specific yield and integrity of labelled compounds 2. Radionuclidic purity Determination of Radionuclidic purity Radiation detectors for radiopharmaceuticals - Dose calibrators Radiation detectors for radiopharmaceuticals - gamma spectrometry Gamma-spectrum analysis 3. Radiochemical purity Principles of Chromatography Planar and Gas Chromatography Electrophoresis Column Chromatography: HPLC HPLC equipment 4. Chemical purity Principles Determination of chemical impurities Pharmaceutical requirements				

	5. Biological purity Sterility Apirogenicity Cells viability 6. Practical aspects of QC for radiopharmaceuticals QC for SPECT radiopharmaceuticals QC for PET radiopharmaceuticals QC for PET radiopharmaceuticals QC for Therapeutic radiopharmaceuticals 7. Principles of GLP Standard Operating Procedures Performance of the study and reporting of study results Guideline on the non-clinical requirements for radiopharmaceuticals 8. Methods of validation Validation of analytical procedures Types of validated analytical procedures Methodology for validation Methodology for validation 9. Quality assurance in radiopharmacy Approval for marketing authorization of a radiopharmaceutical Calibration, validation and verification of equipment, instruments, and other devices Calibration, validation and verification of equipment, instruments, and other devices 10. Perform tests at appropriate intervals and record results Quality specifications Quality control of radiopharmaceuticals Stability testing of radiopharmaceuticals 11. Documentation and keeping records			
12.	**Learning methods:** – lectures - contact teaching, – e-teaching, – theoretical and practical exercises, – assignments, – consultations, – preparation of independent seminar work, – home learning, – preparatory classes for exams, – consultations, – colloquia, – practical final exercise, – e-exams			
13.	Total **available time**		6 EKTC x 30 hours = 180 hours	
14.	**Distribution of available time**		60+30+15+15+60=180	
15.	Forms of **teaching / learning activities**	**15.1.**	**lectures / theoretical - contact teaching, e-teaching**	60 hours
		15.2.	**theoretical and practical exercises, e-exams, preparation of independent seminar work**	30 hours

16.	**Other forms of activities**	**16.1.**	Project tasks	15 hours
		16.2.	Individual **tasks**	15 hours
		16.3.	Home **learning**	60 hours

17.	Method of **assessment**		
	17.1.	Tests / oral exams	70 points
	17.2.	**Seminars (paper / project - presentation: written and/or oral)**	10 points
	17.3.	Activity **and participation**	20 points

18.	Assessment **Criteria (**points **/ score**)	up **50 points**	**5**	**(five)**	**(F)**
		51 to **60 points**	**6**	**(six)**	**(E)**
		61 to **70 points**	**7**	**(seven)**	**(D)**
		71 to **80 points**	**8**	**(eight)**	**(C)**
		81 to **90 points**	**9**	**(nine)**	**(B)**
		91 to **100 points**	**10**	**(ten)**	**(A)**
19.	Signature **requirement and passing the final exam**				
20.	Language **of teaching / study**	**English**			
21.	Method **of monitoring the quality of teaching**	**Self-evaluation**			

22. Literature

22.1. Required **literature**

No.	Author	**Title**	Publisher	**Year**
1.	Tony Theobald (Editor)	Sampson's Textbook of Radiopharmacy	Pharmaceutical Press	2010
2.	Gopal B. Saha	Fundamentals of Nuclear Pharmacy	Springer	2010
3.	IAEA	IAEA-TECDOC-1856 Quality Control in the Production of Radiopharmaceuticals	IAEA	2018

22.2. Additional **literature**

No.	Author	**Title**	Publisher	**Year**
1.	Richard J. Kowalsky, Steven W. Falen	Radiopharmaceuticals in Nuclear Pharmacy and Nuclear Medicine	American Pharmacist Association	2011
2.	Azuwuike Owunwanne, Mohan Patel, Samy Sadek	The Handbook of Radiopharmaceuticals	Springer	1995
3.	K. Solanki (Editor)	Operational Guidance on Hospital Radiopharmacy A Safe and Effective Approach	IAEA	2008

Annex No.3	**Program of the Course - second cycle studies, Academic specialty**				
1.	**Title of the Course**	**Radiopharmaceutical preparation - SPECT, PET and therapeutic radiopharmaceuticals**			
2.	**Code**				
3.	**Study Program**	**Radiopharmacy**			
4.	**Organizer of the study program (unit or institute, Faculty, department)**	University Goce Delcev Faculty of Medical Sciences			
5.	**Cycle (first, second and third cycle)**	Second cycle – Academic specialty			
6.	**Academic year / semester**	Second semester/ First year	**7.**	**Number of credits**	8
8.	**Professor (s)**	Prof. Emilija Janevik-Ivanovska			
9.	Requirements **for enrollment the Course**	/			
10.	Purposes **of the curriculum (**competencies): Understanding practical aspects of manufacturing of SPECT, PET and therapeutic radiopharmaceuticals and capability to contribute in all steps of production process, methods of labelling including quality control of final products and clinical application				
11.	Content **of the course program**: 1. Basic principles of preparation of SPECT, PET and therapeutic radiopharmaceuticals 2. Orientation to Radiopharmacy Practice 3. Procurement of Radiopharmaceuticals 4. Compounding Procedure of Radiopharmaceuticals 5. Principles of Cyclotron Operation/ Generator- Radionuclide Production 6. 99Mo/99mTc generator production 7. 99mTc radiopharmaceuticals 8. Kit preparation for 99mTc radiopharmaceuticals 9. Synthesis and Applications of F18 based radiopharmaceuticals - Synthesis and Applications of 18F- fluorodeoxyglucose 10. Synthesis and Applications C11 based radiopharmaceuticals 11. Production of very short-lived PET radiopharmaceuticals - N13, O15 12. Generator produced Radionuclides 82Rb, Ga68, 62Cu - Production of Ga-68 based radiopharmaceuticals 13. Production of new PET radiopharmaceuticals Cu64, Zr 89 14. Preparing therapeutic radiopharmaceuticals 15. Preparation of the material for production 16. Release of produced SPECT, PET and therapeutic radiopharmaceuticals				

	17. Quality Control of produced radiopharmaceuticals - GC and HPLC as tools for purification and quality assurance; 18. Dispensing and Distribution of Radiopharmaceuticals 19. Waste disposal and radiation safety procedures 20. cGMP Standards for Clinical application of Radiopharmaceuticals 21. Accepted Clinical Applications of SPECT, PET and therapeutic radiopharmaceuticals - Neurology, Oncology, Cardiology 22. Kinetic Modelling of SPECT, PET and therapeutic radiopharmaceuticals 23. Radiation measurement					
12.	**Learning methods:** – lectures - contact teaching, – e-teaching, – theoretical and practical exercises, – assignments, – consultations, – preparation of independent seminar work, – home learning, – preparatory classes for exams, – consultations, – colloquia, – practical final exercise, – e-exams					
13.	Total **available time**			8 EKTC x 30 hours = 240 hours		
14.	**Distribution of available time**			90+60+15+15+60=180		
15.	Forms of **teaching / learning activities**	**15.1.**	**lectures / theoretical - contact teaching, e-teaching**	90 hours		
		15.2.	**theoretical and practical exercises, e-exams, preparation of independent seminar work**	60 hours		
16.	**Other forms of activities**	**16.1.**	Project tasks	15 hours		
		16.2.	Individual **tasks**	15 hours		
		16.3.	Home **learning**	60 hours		
17.	Method of **assessment**					
	17.1.	Tests / oral exams		70 points		
	17.2.	**Seminars (paper / project - presentation: written and/or oral)**		10 points		
	17.3.	Activity **and participation**		20 points		
18.	Assessment **Criteria (**points **/ score**)	up **50 points**	**5**	**(five)**	**(F)**	
		51 to **60 points**	**6**	**(six)**	**(E)**	
		61 to **70 points**	**7**	**(seven)**	**(D)**	
		71 to **80 points**	**8**	**(eight)**	**(C)**	

		81 to **90 points**	**9**	**(nine)**	**(B)**
		91 to **100 points**	**10**	**(ten)**	**(A)**
19.	Signature **requirement and passing the final exam**				
20.	Language **of teaching / study**	**English**			
21.	Method **of monitoring the quality of teaching**	**Self-evaluation**			

22.	Literature					
	22.1.	Required **literature**				
		No.	Author	**Title**	Publisher	**Year**
		1.	Tony Theobald (Editor)	Sampson's Textbook of Radiopharmacy	Pharmaceutical Press	2010
		2.	Gopal B. Saha	Fundamentals of Nuclear Pharmacy	Springer	2010
		3.	**Sharma S.K.**	Progress in PET Radiopharmaceuticals (Quality Control and Theranostics)	Nova Biomedical USA	2016
	22.2.	Additional **literature**				
		No.	Author	**Title**	Publisher	**Year**
		1.	Richard J. Kowalsky, Steven W. Falen	Radiopharmaceuticals in Nuclear Pharmacy and Nuclear Medicine	American Pharmacist Association	2011
		2.	**Scott P.J.H., Hockley B.G.**	Radiochemical Synthesis Radiopharmaceuticals for Positron Emission Tomography Volume 1	Wiley	2011
		3.	K. Solanki (Editor)	Operational Guidance on Hospital Radiopharmacy A Safe and Effective Approach	IAEA	2008

Annex No.3	Program of the Course - second cycle studies, Academic specialty				
1.	**Title of the Course**	**Good Manufacturing Practice in Radiopharmaceutical production**			
2.	**Code**				
3.	**Study Program**	**Radiopharmacy**			
4.	**Organizer of the study program (unit or institute, Faculty, department)**	University Goce Delcev Faculty of Medical Sciences			
5.	**Cycle (first, second and third cycle)**	Second cycle – Academic specialty			
6.	**Academic year / semester**	Second semester/ First year	**7.**	**Number of credits**	4
8.	**Professor (s)**	Prof. Emilija Janevik-Ivanovska			
9.	Requirements **for enrollment the Course**	/			
10.	Purposes **of the curriculum (**competencies): Understanding GMP principles and practice and be able to plan and implement Good manufacturing practice in Radiopharmacy. Be able to develop comprehensive list of Standard Operating procedures for implementation of Good Manufacturing Practice for clinical and research applications. Be able to plan and implement Pharmaceutical Quality system and complete cycle of internal quality audits.				
11.	Content **of the course program**: 1. Good Manufacturing Practice: definitions, requirements and historical background 2. GMP Categories 3. GMP for Manufacture of Radiopharmaceuticals 4. Quality Management and Standard Operating Procedures SOPs 5. Quality Assurance 6. Quality Control 7. Qualification and validation (DQ, IQ, OQ, PQ) 8. Principles for documentation in GMP 9. Complaints 10. Risk analysis and risk assessment 11. Sterile and aseptic production 12. Audit and Inspection 13. Process of manufacturing of PET of Radiopharmaceuticals – example 14. Requirements for radiolabeling of cell lines and proteins.				

12.	**Learning methods:** – lectures - contact teaching, – e-teaching, – theoretical and practical exercises, – assignments, – consultations, – preparation of independent seminar work, – home learning, – preparatory classes for exams, – consultations, – colloquia, – practical final exercise, – e-exams					
13.	Total **available time**		4 EKTC x 30 hours = 120 hours			
14.	**Distribution of available time**		30+30+15+15+30=120			
15.	Forms of **teaching / learning activities**	**15.1.**	**lectures / theoretical - contact teaching, e-teaching**	30 hours		
		15.2.	**theoretical and practical exercises, e-exams, preparation of independent seminar work**	30 hours		
16.	**Other forms of activities**	**16.1.**	Project tasks	15 hours		
		16.2.	Individual **tasks**	15 hours		
		16.3.	Home **learning**	30 hours		
17.	Method of **assessment**					
	17.1.	Tests / oral exams		70 points		
	17.2.	**Seminars (paper / project - presentation: written and/or oral)**		10 points		
	17.3.	Activity **and participation**		20 points		
18.	Assessment **Criteria (**points **/ score**)	up **50 points**	**5**	**(five)**	**(F)**	
		51 to **60 points**	**6**	**(six)**	**(E)**	
		61 to **70 points**	**7**	**(seven)**	**(D)**	
		71 to **80 points**	**8**	**(eight)**	**(C)**	
		81 to **90 points**	**9**	**(nine)**	**(B)**	
		91 to **100 points**	**10**	**(ten)**	**(A)**	
19.	Signature **requirement and passing the final exam**					
20.	Language **of teaching / study**	**English**				
21.	Method **of monitoring the quality of teaching**	**Self-evaluation**				

9.	**Literature**					
	9.1.	**Required literature**				
		No.	**Author**	**Title**	**Publisher**	**Year**
		1.	WHO	ANNEX 3 Guidelines on Good Manufacturing Practices for radiopharmaceutical products	WHO WHO Technical Report Series, No. 908	2003
		2.	EU	Annex 3 Manufacture of Radiopharmaceuticals	EudraLex	2009
		3.	The Radiopharmacy Committee of the EANM	Guidance on current good radiopharmacy practice (cGRPP) for the small-scale preparation of radiopharmaceuticals	Eur J Nucl Med Mol Imaging 37:1049–1062	2010
	9.2.	**Additional literature**				
		No.	**Author**	**Title**	**Publisher**	**Year**
		1.	EMA	Compilation of Community Procedures on Inspections and Exchange of Information	EMA	2014
		2.	IAEA	Quality Control in the Production of Radiopharmaceuticals	IAEA IAEA-TECDOC-1856 Vienna	2018
		3.	K. Solanki (Editor)	Operational Guidance on Hospital Radiopharmacy A Safe and Effective Approach	IAEA	2008

Annex No.3	Program of the Course - second cycle studies, Academic specialty

1.	**Title of the Course**	**Regulatory Requirements for Radiopharmaceuticals – preclinical and clinical studies**			
2.	**Code**				
3.	**Study Program**	**Radiopharmacy**			
4.	**Organizer of the study program (unit or institute, Faculty, department)**	University Goce Delcev Faculty of Medical Sciences			
5.	**Cycle (first, second and third cycle)**	Second cycle – Academic specialty			
6.	**Academic year / semester**	First / Second semester/ First year - optional	**7.**	**Number of credits**	4
8.	**Professor (s)**	Prof. Emilija Janevik-Ivanovska			
9.	Requirements **for enrollment the Course**	/			

10. Purposes **of the curriculum (**competencies):

To understand regulatory requirements related to usage of radiopharmaceuticals in preclinical and clinical trials.
To have a closer look at each stage to better understand what goes into early clinical development and preparation for approval of a radiopharmaceuticals
To understand whether a radiopharmaceuticals are ready for clinical trials (the so-called move from bench to bedside) involves extensive preclinical studies that yield preliminary efficacy, toxicity, pharmacokinetic and safety information.

11. Content **of the course program**:

1. **Preclinical studies**
2. **Phase 0 clinical trial**
3. **Phase I–IV versus early and late phase clinical trials**
4. **Phase I**
5. **Phase II**
6. **Phase III**
7. **Phase IV**
8. Toxicological studies
9. Design and perform observational and experimental clinical research
10. Bioequivalence
11. ***Bioequivalence trials at Profil***
12. Biosimilars

12.	**Learning methods:** – lectures - contact teaching, – e-teaching, – theoretical and practical exercises, – assignments, – consultations, – preparation of independent seminar work, – home learning, – preparatory classes for exams, – consultations, – colloquia, – practical final exercise, – e-exam					
13.	Total **available time**			4 EKTC x 30 hours = 120 hours		
14.	**Distribution of available time**			30+30+15+15+30=120		
15.	Forms of **teaching / learning activities**	**15.1.**	**lectures / theoretical - contact teaching, e-teaching**	30 hours		
		15.2.	**theoretical and practical exercises, e-exams, preparation of independent seminar work**	30 hours		
16.	**Other forms of activities**	**16.1.**	Project tasks	15 hours		
		16.2.	Individual **tasks**	15 hours		
		16.3.	Home **learning**	30 hours		
17.	Method of **assessment**					
	17.1.	Tests / oral exams		70 points		
	17.2.	**Seminars (paper / project - presentation: written and/or oral)**		10 points		
	17.3.	Activity **and participation**		20 points		
18.	Assessment **Criteria (**points **/ score**)	up **50 points**	**5**	**(five)**	**(F)**	
		51 to **60 points**	**6**	**(six)**	**(E)**	
		61 to **70 points**	**7**	**(seven)**	**(D)**	
		71 to **80 points**	**8**	**(eight)**	**(C)**	
		81 to **90 points**	**9**	**(nine)**	**(B)**	
		91 to **100 points**	**10**	**(ten)**	**(A)**	
19.	Signature **requirement and passing the final exam**					
20.	Language **of teaching / study**	**English**				
21.	Method **of monitoring the quality of teaching**	**Self-evaluation**				

22.	Literature					
	22.1.	Required **literature**				
		No.	Author	**Title**	Publisher	**Year**
		1.	Tony Theobald (Editor)	Sampson's Textbook of Radiopharmacy	Pharmaceutical Press	2010
		2.	Gopal B. Saha	Fundamentals of Nuclear Pharmacy	Springer	2010
		3.	Mark Rogge David R.Taft	Preclinical Drug Development (Drugs and the Pharmaceutical Sciences)	CRC Press; 2nd edition	2009
	22.2.	Additional literature				
		No.	Author	Title	Publisher	Year
		1.	Richard J. Kowalsky, Steven W. Falen	Radiopharmaceuticals in Nuclear Pharmacy and Nuclear Medicine	American Pharmacist Association	2011
		2.	Stephen B. Hulley	Designing Clinical Research	Lippincott Williams & Wilkins; 4th edition	2013
		3.	Lawrence M. Friedman	Fundamentals of Clinical Trials	Springer; 5th edition	2015

Annex No.3	**Program of the Course - second cycle studies, Academic specialty**				
1.	**Title of the Course**	**Quality Assurance, Quality Risk Management, Marketing Authorisations**			
2.	**Code**				
3.	**Study Program**	**Radiopharmacy**			
4.	**Organizer of the study program (unit or institute, Faculty, department)**	University Goce Delcev Faculty of Medical Sciences			
5.	**Cycle (first, second and third cycle)**	Second cycle – Academic specialty			
6.	**Academic year / semester**	First / Second semester/ First year - optional	**7.**	**Number of credits**	4
8.	**Professor (s)**	Prof. Biljana Gjorgeska			
9.	Requirements **for enrollment the Course**	/			
10.	Purposes **of the curriculum (**competencies): Develop through understanding of regulatory requirements of radiopharmaceutical product registration process, compounding and manufacturing of radiopharmaceuticals. Develop through understanding of practical aspects of external audits and regulatory inspections				
11.	Content **of the course program**: 1. EU and FDA Radiopharmacy regulations 2. Quality assurance process 3. Quality management 4. Compounding and manufacturing of radiopharmaceuticals 5. Marketing authorisation process 6. Regulatory audits 7. Regulatory inspections 8. Risk assessment 9. Audit – internal and external auditing				
12.	**Learning methods:** – lectures - contact teaching, – e-teaching, – theoretical and practical exercises, – assignments, – consultations,				

	– preparation of independent seminar work, – home learning, – preparatory classes for exams, – consultations, – colloquia, – practical final exercise, – e-exam					
13.	Total **available time**		4 EKTC x 30 hours = 120 hours			
14.	**Distribution of available time**		30+30+15+15+30=120			
15.	Forms of **teaching / learning activities**	**15.1.**	**lectures / theoretical - contact teaching, e-teaching**	30 hours		
		15.2.	**theoretical and practical exercises, e-exams, preparation of independent seminar work**	30 hours		
16.	**Other forms of activities**	**16.1.**	Project tasks	15 hours		
		16.2.	Individual **tasks**	15 hours		
		16.3.	Home **learning**	30 hours		
17.	Method of **assessment**					
	17.1.	Tests / oral exams		70 points		
	17.2.	**Seminars (paper / project - presentation: written and/or oral)**		10 points		
	17.3.	Activity **and participation**		20 points		
18.	Assessment **Criteria (**points **/ score**)	up **50 points**	**5**	**(five)**	**(F)**	
		51 to **60 points**	**6**	**(six)**	**(E)**	
		61 to **70 points**	**7**	**(seven)**	**(D)**	
		71 to **80 points**	**8**	**(eight)**	**(C)**	
		81 to **90 points**	**9**	**(nine)**	**(B)**	
		91 to **100 points**	**10**	**(ten)**	**(A)**	
19.	Signature **requirement and passing the final exam**					
20.	Language **of teaching / study**	**English**				
21.	Method **of monitoring the quality of teaching**	**Self-evaluation**				

22.	Literature					
	22.1.	Required literature				
		No.	Author	Title	Publisher	Year
		1.	Tony Theobald (Editor)	Sampson's Textbook of Radiopharmacy	Pharmaceutical Press	2010
		2.	IAEA	Good Manufacturing Practices for Pharmaceutical Products. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-second report.	Geneva, World Health Organization, (WHO Technical Report Series, No. 986). Annex 2	2014
		3.	Gopal B. Saha	Fundamentals of Nuclear Pharmacy	Springer	2010
	22.2.	Additional literature				
		No.	Author	Title	Publisher	Year
		1.	Richard J. Kowalsky, Steven W. Falen	Radiopharmaceuticals in Nuclear Pharmacy and Nuclear Medicine	American Pharmacist Association	2011
		2.	IAEA	HD-Guidance document Authorization radiopharmaceutical	Swissmedic	IAEA
		3.	IAEA	Good Practice for Introducing Radiopharmaceuticals for Clinical Use	Vienna, International Atomic Energy Agency,	IAEA

Annex No.3	**Program of the Course - second cycle studies, Academic specialty**				
1.	**Title of the Course**	**Radiopharmacology**			
2.	**Code**				
3.	**Study Program**	**Radiopharmacy**			
4.	**Organizer of the study program (unit or institute, Faculty, department)**	University Goce Delcev Faculty of Medical Sciences			
5.	**Cycle (first, second and third cycle)**	Second cycle – Academic specialty			
6.	**Academic year / semester**	First / Second semester/ First year - optional	**7.**	**Number of credits**	4
8.	**Professor (s)**	Prof. Marija Darkovska Serafimovska			
9.	Requirements **for enrollment the Course**	/			
10.	Purposes **of the curriculum (**competencies): To provide the knowledge of basic principles of effects of radiopharmaceuticals after their application for diagnostic and therapetical purpose including dosimetry.				
11.	Content **of the course program**: 15. Medical terminology used in radiopharmacy 16. Basic principles of pharmacology 17. LADME process 18. Ideal qualities of radiopharmaceuticals, methods of radiolabeling 19. Principles of mechanism of localization of radiopharmaceuticals 20. The principles of imaging procedures using radiopharmaceuticals 21. The principles of therapeutic procedures using radiopharmaceuticals 22. Dosimetric aspects of radiopharmaceutical applications				
12.	**Learning methods:** – lectures - contact teaching, – e-teaching, – theoretical and practical exercises, – assignments, – consultations, – preparation of independent seminar work, – home learning, – preparatory classes for exams, – consultations, – colloquia, – practical final exercise, – e-exam				

13.	Total **available time**		4 EKTC x 30 hours = 120 hours	
14.	**Distribution of available time**		30+30+15+15+30=120	
15.	Forms of **teaching / learning activities**	**15.1.**	**lectures / theoretical - contact teaching, e-teaching**	30 hours
		15.2.	**theoretical and practical exercises, e-exams, preparation of independent seminar work**	30 hours
16.	**Other forms of activities**	**16.1.**	Project tasks	15 hours
		16.2.	Individual **tasks**	15 hours
		16.3.	Home **learning**	30 hours

17.	Method of **assessment**		
	17.1.	Tests / oral exams	70 points
	17.2.	**Seminars (paper / project - presentation: written and/or oral)**	10 points
	17.3.	Activity **and participation**	20 points

18.	Assessment **Criteria (**points **/ score**)	up **50 points**	**5**	**(five)**	**(F)**
		51 to **60 points**	**6**	**(six)**	**(E)**
		61 to **70 points**	**7**	**(seven)**	**(D)**
		71 to **80 points**	**8**	**(eight)**	**(C)**
		81 to **90 points**	**9**	**(nine)**	**(B)**
		91 to **100 points**	**10**	**(ten)**	**(A)**
19.	Signature **requirement and passing the final exam**				
20.	Language **of teaching / study**	**English**			
21.	Method **of monitoring the quality of teaching**	**Self-evaluation**			

22. Literature

22.1. Required **literature**

No.	Author	**Title**	Publisher	**Year**
1.	Tony Theobald (Editor)	Sampson's Textbook of Radiopharmacy	Pharmaceutical Press	2010
2.	Gopal B. Saha	Fundamentals of Nuclear Pharmacy	Springer	2010
3.	I. Buvat, E.C. Frey, A.J. Green and M. Ljungberg (Editors)	Quantitative Nuclear Medicine Imaging: Concepts, Requirements and Methods	IAEA	2014

	22.2.	Additional **literature**				
		No.	Author	**Title**	Publisher	**Year**
		1.	Richard J. Kowalsky, Steven W. Falen	Radiopharmaceuticals in Nuclear Pharmacy and Nuclear Medicine	American Pharmacist Association	2011
		2.	Azuwuike Owunwanne, Mohan Patel, Samy Sadek	The handbook of Radiopharmaceutical	Springer	1995
		3.	K. Solanki (Editor)	Operational Guidance on Hospital Radiopharmacy A Safe and Effective Approach	IAEA	2008

Annex No.3	Program of the Course - second cycle studies, Academic specialty				
1.	**Title of the Course**	**Radiation Biology**			
2.	**Code**				
3.	**Study Program**	**Radiopharmacy**			
4.	**Organizer of the study program (unit or institute, Faculty, department)**	University Goce Delcev Faculty of Medical Sciences			
5.	**Cycle (first, second and third cycle)**	Second cycle – Academic specialty			
6.	**Academic year / semester**	First / Second semester/ First year - optional	**7.**	**Number of credits**	4
8.	**Professor (s)**	Prof. Nevenka Velickovska			
9.	Requirements **for enrollment the Course**	/			
10.	Purposes **of the curriculum (**competencies): The objectives of the training programme are to educate and train pharmacist in radiation biology up to the level of being recognized as a specialist that should have: - Enough theoretical knowledge and practical skills for the competent, safe, ethical and compassionate practice of radiation biology at the level for which they have been trained. - Technical expertise in radiation biology at the required level based on the available resources and knowledge of the whole scope of radiation biology and the adverse effects of radiation including radiation related complications. - Sufficient interest, knowledge and skills to contribute to future developments in radiation biology. -				
11.	Content **of the course program**: 12. Interaction of Ionizing Radiation with Matter - Types of radiation, Interactions of Radiation with Emphasis on Biological Systems, Units of Energy Transfer 13. Initial Physical and Chemical Actions of Imparted Energy (including application to RBE and Quality Factors) 14. Radiation Chemistry - General Concepts, Aqueous Systems, Ionization, excitation and formation of free radicals 15. Initial reactions (including influence of LET, oxygen and various compounds on free radical forming reactions) and Factors Affecting Reactions				

	16. Cellular Response - Effect on Cells, Sensitive Organelles, Concept of Target(s) and Radiosensitivity, Response to Increasing Radiation Dose, Factors Influencing Response and effects on Nucleic Acids and Radiation Genetics (Hereditary Effects) 17. Whole-Body Effects of Ionizing Radiation 18. Acute and Delayed Effects of Ionizing Radiation 19. Low Level (Low Dose Exposure to Ionizing Radiation) 20. Basic Principles of Radiotherapy and Application to Dosimetry (including MIRD techniques) 21. Effects of Ionizing Radiation on the Embryo and Foetus					
12.	**Learning methods:** – lectures - contact teaching, – e-teaching, – theoretical and practical exercises, – assignments, – consultations, – preparation of independent seminar work, – home learning, – preparatory classes for exams, – consultations, – colloquia, – practical final exercise, – e-exam					
13.	Total **available time**		4 EKTC x 30 hours = 120 hours			
14.	**Distribution of available time**		30+30+15+15+30=120			
15.	Forms of **teaching / learning activities**	**15.1.**	**lectures / theoretical - contact teaching, e-teaching**	30 hours		
		15.2.	**theoretical and practical exercises, e-exams, preparation of independent seminar work**	30 hours		
16.	**Other forms of activities**	**16.1.**	Project tasks	15 hours		
		16.2.	Individual **tasks**	15 hours		
		16.3.	Home **learning**	30 hours		
17.	Method of **assessment**					
	17.1.	Tests / oral exams		70 points		
	17.2.	**Seminars (paper / project - presentation: written and/or oral)**		10 points		
	17.3.	Activity **and participation**		20 points		
18.	Assessment **Criteria (**points **/ score**)	up **50 points**	**5**	**(five)**	**(F)**	
		51 to **60 points**	**6**	**(six)**	**(E)**	
		61 to **70 points**	**7**	**(seven)**	**(D)**	
		71 to **80 points**	**8**	**(eight)**	**(C)**	
		81 to **90 points**	**9**	**(nine)**	**(B)**	
		91 to **100 points**	**10**	**(ten)**	**(A)**	

19.	Signature **requirement and passing the final exam**	
20.	Language **of teaching / study**	**English**
21.	Method **of monitoring the quality of teaching**	**Self-evaluation**

22.	Literature					
	22.1.	Required **literature**				
		No.	Author	**Title**	Publisher	**Year**
		1.	Tony Theobald (Editor)	Sampson's Textbook of Radiopharmacy	Pharmaceutical Press	2010
		2.	Steve Forshier	Essentials of Radiation, Biology and Protection	Cengage Learning; 2nd edition	2008
		3.	IAEA	Radiation Biology: A Handbook for Teachers and Students	IAEA	2011
	22.2.	Additional **literature**				
		No.	Author	**Title**	Publisher	**Year**
			K. H. Chadwick	Understanding Radiation Biology From DNA Damage to Cancer and Radiation Risk	CRC Press	2020
		2.	Gopal B. Saha	Fundamentals of Nuclear Pharmacy	Springer	2010
		3.	Gopal B. Saha	Physics and Radiobiology of Nuclear Medicine	Springer	2006

Annex No.3	**Program of the Course - second cycle studies, Academic specialty**

1.	**Title of the Course**	**Animal models in radiopharmaceutical investigations**			
2.	**Code**				
3.	**Study Program**	**Radiopharmacy**			
4.	**Organizer of the study program (unit or institute, Faculty, department)**	University Goce Delcev Faculty of Medical Sciences			
5.	**Cycle (first, second and third cycle)**	Second cycle – Academic specialty			
6.	**Academic year / semester**	First / Second semester/ First year - optional	**7.**	**Number of credits**	4
8.	**Professor (s)**	Prof. Darko Bosnakovski			
9.	Requirements **for enrollment the Course**	/			

10. Purposes **of the curriculum (**competencies):

To develop through an understanding of the use of animals for clinical research in all aspects such as regulatory, ethical and practical.

11. Content **of the course program**:

1. Introduction of animal models in biomedical research
2. Creation of appropriate cell-based and animal models of pathology and the clinical translation of the optimized concepts to help detect disease and therapeutic response in people
3. Legislation for the protection of animals used for scientific purposes; Ethics in animal research.
4. Animal husbandry, environmental enrichment and safe transportation of laboratory animals; Animal handling and techniques
5. Animal welfare; Biology of laboratory animals (Mouse; Rat; Dog)
6. Introduction to surgery and surgical techniques; Anesthesia and analgesia; Humane methods of killing
7. Invasive and/or semi-automated chronic blood sampling techniques in rodents.
8. Imaging techniques used in animal studies
9. Alternatives to animal procedures. Cost-Benefit analysis
10. Statistics and methodology

12.	**Learning methods:** – lectures - contact teaching, – e-teaching, – theoretical and practical exercises, – assignments, – consultations, – preparation of independent seminar work, – home learning, – preparatory classes for exams, – consultations, – colloquia, – practical final exercise, – e-exam						
13.	Total **available time**			4 EKTC x 30 hours = 120 hours			
14.	**Distribution of available time**			30+30+15+15+30=120			
15.	Forms of **teaching / learning activities**	**15.1.**	**lectures / theoretical - contact teaching, e-teaching**	30 hours			
		15.2.	**theoretical and practical exercises, e-exams, preparation of independent seminar work**	30 hours			
16.	**Other forms of activities**	**16.1.**	Project tasks	15 hours			
		16.2.	Individual **tasks**	15 hours			
		16.3.	Home **learning**	30 hours			
17.	Method of **assessment**						
	17.1.	Tests / oral exams		70 points			
	17.2.	**Seminars (paper / project - presentation: written and/or oral)**		10 points			
	17.3.	Activity **and participation**		20 points			
18.	Assessment **Criteria (**points **/ score**)		up **50 points**	**5**	**(five)**	**(F)**	
			51 to **60 points**	**6**	**(six)**	**(E)**	
			61 to **70 points**	**7**	**(seven)**	**(D)**	
			71 to **80 points**	**8**	**(eight)**	**(C)**	
			81 to **90 points**	**9**	**(nine)**	**(B)**	
			91 to **100 points**	**10**	**(ten)**	**(A)**	
19.	Signature **requirement and passing the final exam**						
20.	Language **of teaching / study**		**English**				
21.	Method **of monitoring the quality of teaching**		**Self-evaluation**				

22.	Literature					
	22.1.	Required **literature**				
		No.	Author	**Title**	Publisher	**Year**
		1.	P. Michael Conn	Animal Models for the Study of Human Disease 2nd Edition	Academic Press; 2 edition	2017
		2.	Jann Hau and Steven J. Schapiro	Handbook of Laboratory Animal Science, Volume III, Third Edition: Animal Models	CRC Press	2013
		3.	Robert H. Weichbrod, Gail A. Thompson, John N. Norton	Management of Animal Care and Use Programs in Research, Education, and Testing	CRC Press; 2 edition	2017
	22.2.	Additional **literature**				
		No.	Author	**Title**	Publisher	**Year**
			Sarah Wolfensohn and Maggie Lloyd	Handbook of Laboratory Animal Management and Welfare	Wiley-Blackwell	2013
		2.	Gopal B. Saha	Fundamentals of Nuclear Pharmacy	Springer	2010
		3.	http://www.google.mk/search?tbo=p&tbm=bks&q=inauthor:"Gopal+B.+Saha"			

Annex No.3	**Program of the Course - second cycle studies, Academic specialty**

1.	**Title of the Course**	**Qualification and Validation in Radiopharmacy**			
2.	**Code**				
3.	**Study Program**	**Radiopharmacy**			
4.	**Organizer of the study program (unit or institute, Faculty, department)**	University Goce Delcev Faculty of Medical Sciences			
5.	**Cycle (first, second and third cycle)**	Second cycle – Academic specialty			
6.	**Academic year / semester**	First / Second semester/ First year - optional	**7.**	**Number of credits**	4
8.	**Professor (s)**	Prof. Emilija Janevik-Ivanovska			
9.	Requirements **for enrollment the Course**	/			

10. Purposes **of the curriculum (**competencies):

Develop understanding of different operational management structures of Radiopharmacy service and responsibilities of key personnel.
The course offers professional preparation for a quality assurance career, including indepth coverage of material that appears on the examinations for the professional designations of Qualified Person (QP), Quality Control of the process (QC), or Certified Quality Auditor (CQA).

11. Content **of the course program**:

1. Introduction
2. Validation of facility and equipment and protocols
3. Staff training, update and validation
4. Quality Assurance
5. Validation
6. Factory Acceptance Test (FAT) and Site Acceptance Test (SAT)
7. Process Validation (IQ, OQ, PQ)
8. Validation Master Plan
9. Building Management System
10. Qualified Person (QP)
11. Process Validation
12. Quality Control of the process
13. Documentation
14. Product safety
15. Radiopharmacy Management structure, responsibilities and governance

12.	**Learning methods:** – lectures - contact teaching, – e-teaching, – theoretical and practical exercises, – assignments, – consultations, – preparation of independent seminar work, – home learning, – preparatory classes for exams, – consultations, – colloquia, – practical final exercise, – e-exam					
13.	Total **available time**		4 EKTC x 30 hours = 120 hours			
14.	**Distribution of available time**		30+30+15+15+30=120			
15.	Forms of **teaching / learning activities**	**15.1.**	**lectures / theoretical - contact teaching, e-teaching**	30 hours		
		15.2.	**theoretical and practical exercises, e-exams, preparation of independent seminar work**	30 hours		
16.	**Other forms of activities**	**16.1.**	Project tasks	15 hours		
		16.2.	Individual **tasks**	15 hours		
		16.3.	Home **learning**	30 hours		
17.	Method of **assessment**					
	17.1.	Tests / oral exams		70 points		
	17.2.	**Seminars (paper / project - presentation: written and/or oral)**		10 points		
	17.3.	Activity **and participation**		20 points		
18.	Assessment **Criteria (**points **/ score**)	up **50 points**	**5**	**(five)**	**(F)**	
		51 to **60 points**	**6**	**(six)**	**(E)**	
		61 to **70 points**	**7**	**(seven)**	**(D)**	
		71 to **80 points**	**8**	**(eight)**	**(C)**	
		81 to **90 points**	**9**	**(nine)**	**(B)**	
		91 to **100 points**	**10**	**(ten)**	**(A)**	
19.	Signature **requirement and passing the final exam**					
20.	Language **of teaching / study**	**English**				
21.	Method **of monitoring the quality of teaching**	**Self-evaluation**				

22.	Literature					
	22.1.	Required **literature**				
		No.	Author	**Title**	Publisher	**Year**
		1.	Tony Theobald (Editor)	Sampson's Textbook of Radiopharmacy	Pharmaceutical Press	2010
		2.	FDA	Guidance for Industry Process Validation: General Principles and Practices	FDA	2011
		3.	K. Solanki (Editor)	Operational Guidance on Hospital Radiopharmacy A Safe and Effective Approach	IAEA	2008
	22.2.	Additional **literature**				
		No.	Author	**Title**	Publisher	**Year**
			IAEA	Competency based hospital radiopharmacy training	IAEA	2010
		2.	Gopal B. Saha	Fundamentals of Nuclear Pharmacy	Springer	2010
		3.	Orlando López	EU Annex 11 Guide to Computer Validation Compliance for the Worldwide Health Agency GMP	CRC Press Taylor & Francis Group, an Informa business	2015

Annex No.3	**Program of the Course - second cycle studies, Academic specialty**				
1.	**Title of the Course**	**Validation of Analytical Methods**			
2.	**Code**				
3.	**Study Program**	**Radiopharmacy**			
4.	**Organizer of the study program (unit or institute, Faculty, department)**	University Goce Delcev Faculty of Medical Sciences			
5.	**Cycle (first, second and third cycle)**	Second cycle – Academic specialty			
6.	**Academic year / semester**	First /second semester/ First year- optional	**7.**	**Number of credits**	4
8.	**Professor (s)**	Prof. Zorica Arsova-Sarafinovska			
9.	Requirements **for enrollment the Course**	/			
10.	Purposes **of the curriculum (**competencies): - to offer theoretical and practical solutions for determining the Validation characteristics - to learn how to deal with measurement uncertainty and to understand its impact on analytical methods Validation - to understand the qualification of laboratory Equipment as a precondition of reliable analytical testing - to discuss the scope of qualification & validation necessary to obtain approval by the Registration Authorities (EMA, FDA, MHRA, etc.) - to become familiar with the statistical parameters to be applied - to outline the documentation (SOPs, Validation Protocols and Reports, etc.) which you should have in your lab. - to provide an outline of the new USP & ICH developments of procedure validation				
11.	Content **of the course program**: 12. **Validation in Context -** Practical components of data quality, Assessment of data Quality **13. Basics of Measurement Uncertainty** 14. **Analytical Instrument Qualification** 15. **Measurement Uncertainty in Calibration and Qualification of Analytical Instruments** 16. **Analytical Procedure Lifecycle Management** 17. **Statistical Aspects of Analytical Methods Validation** 18. **Robustness and Ruggedness -** Method development cycle, Analytical process capability, Selecting factors and levels, HPLC experimental design example, Impact on system suitability tests 19. **Method Validation During the Development Lifecycle** 20. **Validation: Planning and Execution** 21. **Validation: Documentation** 22. **Error Budgets and Reportable Values** 23. **Transfer of Analytical Test Procedures**				

	During the course following 4 topics will be conducted in order to deepen the content of the lectures and to discuss practical aspects in detail: - **Analytical Instrument Qualification** - **Validation Plan** - **Validation Documents Critique** - **Method Transfer**					
12.	**Learning methods:** – lectures - contact teaching, – e-teaching, – theoretical and practical exercises, – assignments, – consultations, – preparation of independent seminar work, – home learning, – preparatory classes for exams, – consultations, – colloquia, – practical final exercise, – e-exams					
13.	Total **available time**		4 EKTC x 30 hours = 120 hours			
14.	**Distribution of available time**		30+30+10+10+40=120			
15.	Forms of **teaching / learning activities**	**15.1.**	**lectures / theoretical - contact teaching, e-teaching**	30 hours		
		15.2.	**theoretical and practical exercises, e-exams, preparation of independent seminar work**	30 hours		
16.	**Други форми на активности**	**16.1.**	Project tasks	10 hours		
		16.2.	Individual **tasks**	10 hours		
		16.3.	Home **learning**	40 hours		
17.	Method of **assessment**					
	17.1.	Tests / oral exams		70 points		
	17.2.	**Seminars (paper / project - presentation: written and/or oral)**		10 points		
	17.3.	Activity **and participation**		20 points		
18.	Assessment **Criteria (**points **/ score**)	up **50 points**	**5**	**(five)**	**(F)**	
		51 to **60 points**	**6**	**(six)**	**(E)**	
		61 to **70 points**	**7**	**(seven)**	**(D)**	
		71 to **80 points**	**8**	**(eight)**	**(C)**	
		81 to **90 points**	**9**	**(nine)**	**(B)**	
		91 to **100 points**	**10**	**(ten)**	**(A)**	
19.	Signature **requirement and passing the final exam**					
20.	Language **of teaching / study**	**English**				
21.	Method **of monitoring the quality of teaching**	**Self-evaluation**				

22.	Literature					
	22.1.	Required literature				
		No.	Author	Title	Publisher	Year
		1.	Tony Theobald (Editor)	Sampson's Textbook of Radiopharmacy	Pharmaceutical Press	2010
		2.	***Michael E. Swartz Ira S. Krull***	Handbook of Analytical Validation	CRC Press Taylor &Francis Group	2012
		3.	Eudralex Annex 1	Method Validation	EU	2020
	22.2.	Additional literature				
		No.	Author	Title	Publisher	Year
		1.	Tentu Nageswara Rao	Validation of Analytical Methods	IntechOpen	2018
		2.	Joachim Ermer John H.McB. Miller	Method Validation in Pharmaceutical Analysis: A Guide to Best Practice	Wiley	2006
		3.	K. Solanki (Editor)	Operational Guidance on Hospital Radiopharmacy A Safe and Effective Approach	IAEA	2008

РЕПУБЛИКА СЕВЕРНА МАКЕДОНИЈА
АГЕНЦИЈА ЗА КВАЛИТЕТ ВО ВИСОКОТО ОБРАЗОВАНИЕ
ОДБОР ЗА АКРЕДИТАЦИЈА НА ВИСОКОТО ОБРАЗОВАНИЕ

REPUBLIKA E MAQEDONISË SË VERIUT
AGJENCIA PËR CILËSI NË ARSIMIN E LARTË
BORDI PËR AKREDITIM I ARSIMIT TË LARTË

Врз основа на член 48 став (2) точка 6, член 165 став (2) и член 227 од Законот за високото образование* („Службен весник на Република Македонија" бр. 82/18), Одборот за акредитација на високото образование на Република Северна Македонија, на својата 16 седница одржана на 28.04.2021година, донесе

Р Е Ш Е Н И Е

за акредитација на студиската програма „Радиофармација", втор циклус на академски студии - постдипломски студии (60 ЕКТС) на англиски јазик на Факултет за медицински науки при Универзитет „Гоце Делчев" Штип

1. Се акредитира студиската програма „Радиофармација",", втор циклус на академски студии - постдипломски студии (60 ЕКТС) на англиски јазик на Факултет за медицински науки при Универзитет „Гоце Делчев" Штип, согласно Законот за високо образование* („Службен весник на Република Македонија" бр.82/18), Уредбата за нормативите и стандардите за основање на високообразовни установи и за вршење високообразовна дејност („Службен весник на Република Македонија" бр.103/10, 168/10 и 10/11) и Класификацијата на научно-истражувачки подрачја, полиња и области според Меѓународната фраскатиева класификација (дадена како Прилог 1 на наведената Уредба).

2. Акредитација за студиската програма од точка 1 на ова решение е за период од пет студиски години, почнувајќи од студиската 2021/2022 година.

3. По завршување на студиите на студиската програма од точка 1 од ова решение, студентот се стекнува со 60 ЕКТС кредити и се стекнува со академски назив: Специјализиран за Радиофармација /во меѓународен промет академски назив: Specialized in Radiopharmacy.

4. Научно - истражувачко подрачје: 3 Медицински науки и здравство
Научно – истражувачко поле: 306 Фармација;
Научно – истражувачка област: 30707 Радиофармација.

5. Вкупниот број на студенти кои можат да бидат запишани на наведената студиска програма од точка 1 на ова решение изнесува 20 студенти.

6. Ова решение е конечно и влегува во сила со денот на донесувањето.

РЕПУБЛИКА СЕВЕРНА МАКЕДОНИЈА
АГЕНЦИЈА ЗА КВАЛИТЕТ ВО ВИСОКОТО ОБРАЗОВАНИЕ
ОДБОР ЗА АКРЕДИТАЦИЈА НА ВИСОКОТО ОБРАЗОВАНИЕ

REPUBLIKA E MAQEDONISË SË VERIUT
AGJENCIA PËR CILËSI NË ARSIMIN E LARTË
BORDI PËR AKREDITIM I ARSIMIT TË LARTË

О б р а з л о ж е н и е

По предходно донесената одлука бр. 0201 - 777/32 од 25.03.2021 година од страна Сенатот на универзитетот, за усвојување на студиската програма „Радиофармација“, втор циклус на академски студии - постдипломски студии (60 ЕКТС) на англиски јазик на Факултет за медицински науки при Универзитет „Гоце Делчев“ Штип, до Одборот за акредитација на високото образование, достави барање бр.08 - 386/1 од 31.03.2021 година за прифаќање на елаборат, односно за акредитација на предметната студиска програма.

Одборот за акредитација на високото образование, на 15-та седницата одржана на 07.04.2020 година, формира стручна комисија за разгледување на барањето за акредитација со придружната документација и подготвување на извештај по однос на барањето и документацијата.

Врз основа на позитивната оценка содржана во извештајот на стручната комисија, бр.08 - 386/3 од 14.05.2021 година, согласно Законот за високо образование* („Службен весник на Република Македонија“ бр.82/18), Уредбата за нормативите и стандардите за основање на високообразовни установи и за вршење високообразовна дејност („Службен весник на Република Македонија“ бр.103/10, 168/10 и 10/11) и Класификацијата на научно-истражувачки подрачја, полиња и области според Меѓународната фраскатиева класификација и Правилникот за организацијата, работата, начинот на одлучување, методологијата за акредитација и евалуација, стандардите за акредитација и евалуација, како и други прашања во врска со работата на Одборот за акредитација и евалуација на високото образование („Службен весник на Република Македонија“ бр.151/12), Одборот за акредитација на високото образование, на својата 16-та седница одржана на 28.04.2021година, одлучи како во диспозитивот на ова решение.

Правна поука: Решението за акредитација на студиска програма е конечно и против него може да се поднесе тужба до Управниот суд.

Претседател
на Одборот за акредитација на високото образование

Академик Владо Камбовски

РЕПУБЛИКА СЕВЕРНА МАКЕДОНИЈА
АГЕНЦИЈА ЗА КВАЛИТЕТ ВО ВИСОКОТО ОБРАЗОВАНИЕ

Кеј Димитар Влахов 4, II кат
Центар, Скопје
Тел. 02/3220509

REPUBLIKA E MAQEDONISË SË VERIUT
AGJENCIA PËR CILËSI NË ARSIMIN E LARTË

Dimitar Vlahov 4, kati II
Qender, Shkup
Tel. 02/3220509

Врз основа на член 145 став (6) и член 227 од Законот за високото образование („Службен весник на Република Македонија" бр. 82/18 и „Службен весник на Република Северна Македонија" бр.154/19), директорот на Агенцијата за квалитет во високото образование, донесе

Р Е Ш Е Н И Е

за почеток со работа на студиската програма од втор циклус на академски студии - постдипломски студии (60 ЕКТС) на англиски јазик по „Радиофармација" на Факултет за медицински науки при Универзитет „Гоце Делчев" во Штип

1. Со ова решение се утврдува дека се исполнети условите за почеток со работа на студиската програма од втор циклус на академски студии - постдипломски студии (60 ЕКТС) на англиски јазик по „Радиофармација" на Факултет за медицински науки при Универзитет „Гоце Делчев" во Штип.

2. Ова решение влегува во сила со денот на донесување.

О б р а з л о ж е н и е

По добивање на Решение за акредитација бр.08-386/4 од 28.05.2021 година од страна на Одборот за акредитација на високото образование, Универзитет „Гоце Делчев" во Штип се обрати со барање бр.0809-410/2 од 14.06.2021 година, до Агенцијата за квалитет во високото образование, под наш бр. 08-576/1 од 15.06.2021 година, за утврдување на испонетоста на условите за почеток со работа на студиската програма од втор циклус на академски студии - постдипломски студии (60 ЕКТС) на англиски јазик по „Радиофармација" на Факултет за медицински науки при Универзитет „Гоце Делчев" во Штип.

Директорот на Агенцијата за квалитет во високото образование, со Решение бр.08-576/2 од 21.06.2021 година, формира Комисија за утврдување на исполнетоста на условите за почеток со работа на студиската програма наведена во точка 1 на ова решение.

Комисијата, на ден 29.06.2021 година, изврши увид и изготви Извештај бр.08-576/3 од 07.07.2021 година, каде е наведено дека, за студиската програма од втор циклус на академски студии - постдипломски студии (60 ЕКТС) на англиски јазик по „Радиофармација" на Факултет за медицински науки при Универзитет „Гоце Делчев" во Штип, се исполнети условите согласно одредбите утврдени со Законот за високото образование и Уредбата за нормативи и стандарди за основање на високообразовни установи и за вршење на високообразовна дејност („Службен весник на Република Македонија" бр. 103/10, 168/10 и 10/11).

Имајќи го во предвид изнесеното, се одлучи како во диспозитивот на ова решение.

ПРАВНА ПОУКА: Против ова решение, може да се заведе управен спор, со поднесување на тужба до Управниот суд на Република Северна Македонија, во рок од 30 дена од денот на приемот на ова решение.

ДИРЕКТОР/ DREJTOR
Dr. Agim Rushiti

Доставено до:
- Високообразовната установа
- Архива

изработил: Милена Ефремовска
одобрил: Севгил Муртези