RESOLUTION OF THE GOVERNMENT OF GEORGIA No: 317
On Approval of Technical Regulation - "Radiation Safety Requirements in the Sphere of Medical Irradiation."

7 July 2016 **Tbilisi**

Article 1

In accordance with Subsection "b", Section 7, Article 53 of Georgian Law on Nuclear and Radiation Safety the Technical Regulation – "Radiation Safety Requirements in the Sphere of Medical Irradiation" shall be approved.

Article 2

In accordance with Article 25 of the Law of Georgia on Normative Acts, the following shall be deemed invalid:

a) Resolution No: 83 of 16 January 2014 of the Government of Georgia on Approval of Technical Regulation – "Norms of Radiation Safety in Medical X-ray-Radiology Diagnostic Procedures and Treatment"
b) Resolution No: 438 of 31 December 2013 of the Government of Georgia on Approval of the Technical Regulation – Rules and Norms of Arrangement of the Radioisotope Laboratories and Use of the Unsealed Radio Pharmaceuticals in Medicine"

Article 3

1. Resolution shall be effective from 1 September 2016, with the exclusion of Subsection "a", Section 4, Article 8 of the Technical Regulation approved by this Resolution, Section 2, Chapter 5, and Sections 1 and 2, Chapter 6 of Annex 3 thereof.
2. Subsection "a", Section 4, Article 8 of the Technical Regulation shall be effective from 1 September 2018.
3. Section 2, Chapter 5, and Sections 1 and 2, Chapter 6 of Annex 3 of the Technical Regulation shall be effective from 1 September 2017.

Prime Minister George Kvirikashvili

Technical Regulation
Requirements of Medical Exposure Radiation Safety

Chapter I. General Provisions

Article 1. Scope of Regulation

1. This Technical Regulation was developed in accordance with the laws of Georgia: "On Nuclear and Radiation Safety", "On Environment Protection", "On Public Health", as well as international regulations on nuclear and radiation safety.
2. Technical Regulation states:
a) Key requirements for radiation protection of the personnel, patient and general population in the process of performing medical X-ray diagnostic, preventive and therapy procedures and allowable and reference levels of medical exposure;
b) Requirements of radiation safety for design, construction, reconstruction, equipment layout, operation, technical maintenance and withdrawal from operation of the medical X-ray imaging rooms;
c) Requirements and criteria for ensuring of radiation protection of the healthcare personnel, patient and population in the diagnostic and therapy procedures using radio-pharmaceuticals in nuclear medicine;
d) Radiation safety requirements in radiotherapy.
3. Norms and requirements stated by this Technical Regulation shall be binding for all natural persons and legal entities, irrespective of their organization-legal form, as well as all state and local government authorities engaged in the activities related to radiotherapy and whose activities are regulated by Georgian Law on Nuclear and Radiation Safety.

Article 2. Purpose of Technical Regulation

Goals of the technical regulation include:
a) Radiation protection of the patients, personnel and the population from the harmful impact of ionizing radiation and elimination of radioactive pollution of the environment as a result of medical procedures;
b) Reduction of the patient exposure doses maintaining the quality of diagnostic information and therapeutical effect of the medical procedures;
c) Providing radiation protection of the population in the area of performing x-ray procedures;
d) Introduction of the modern nuclear and radiation safety standards in the medicine for the purposeof radiation protection of the patient, personnel and population.

Article 3. Definition of the terms used in the Technical Regulation:

1. Angiography – x-ray study of the blood vessels combined with the surgical treatment manipulations.
2. Nuclear medicine – sphere of medicine where, for the purpose of diagnostics and therapy/treatment the radio pharmaceuticals with the active radionuclide element are used. Nuclear medicine includes also the medical and bio-medical researches with the use of radio-pharmaceuticals.
3. Sealed-source radiotherapy (brachytherapy) – contact radiotherapy where the sealed source of ionizing radiation is implanted into the human body (tissue or organ cavity).

4. Portable radiation protection equipment – shields and protection screens intended and used for x-ray studies for protection of human body or individual organs.
5. In vitro study – radionuclide study performed in the test tubes.
6. In vivo study – study involving introduction of the radio pharmaceuticals into the human body and observation of the radionuclide distribution by means of the radio diagnostic equipment.
7. Low dose brachytherapy – brachytherapy with the maximal dose at the target is (0.4-2)Gs/hr and the source of ionizing radiation is placed into the human body without use of any special devices.
8. Radiation – individual's exposure to ionizing radiation that can be both, external an internal. External radiation is provided from the open or sealed ionizing radiation sources located out of the human body and internal exposure – the one from the open or sealed ionizing radiation sources placed in the human body. External exposure from the sealed or open sources does not differ qualitatively.
9. Exposure target – geometrical body (organ (or part thereof) or tissue) for which the absorbed ionizing radiation doze is calculated in designing the radiotherapy.
10. Teletherapy – radiotherapy method where human body is radiated from the certain distance with collimated ionized radiation flow.
11. Dose rate – radiation dose per unit time (second, minute, hour).
12. Individual protective equipment – equipment for protection of external exposure to radiation, occurrence of the radioactive substances into the organism and protection of the skin from radioactive contamination.
13. Computed x-ray tomography scan – method of x-ray research using special equipment and computer to obtain the layered digital x-ray image.
14. High dose brachytherapy – brachytherapy where dose at the target is higher than 2 Gs/hr and the source of ionizing radiation is inserted into the human body using special device.
15. Acceptance test – check compliance of the physical & technological parameters of the equipments at a time of launching of the x-ray units with the values specified in the manufacturer's technical documentation.
16. Positron emission tomography (PET) center – specialized department of in vivo radionuclide diagnostics intended for production of positron emitting radio pharmaceuticals, their quality control and/or for performing positron emission tomography (PET) diagnostic procedure.
17. Person responsible for radiation safety – individual competent in radiation protection issues appointed by the licensee.
18. Radioactive contamination – presence of radioactive substance on any surfaces, in the solid, liquid or gas substances causing individual exposure over 10 μSv per year or collective exposure dose over 1 individual – Sv / per year.
19. Radionuclide half-life – radionuclide characteristic, time required for reduction of the given radionuclide activity to the half as a result of nuclear transformation.
20. Radio pharmaceutical – diagnostic or treatment pharmaceutical with radionuclide as an active element.
21. X-ray radiation – photon radiation generated by striking of the accelerated electrons the x-ray tube anode.
22. X-ray emitter – x-ray tube placed in the protective cover (mono-block) equipped with the filter and collimation arrangement (diaphragm).

23. X-ray tube – electric vacuum tube installed in the x-ray generator for generating radiation.
24. Computed tomography facility – part of the building of the medical institution where computerized tomography is used for diagnostics.
25. Radiography (roentgenography) – x-ray test method generating static image (x-ray pattern).
26. X-ray unit – equipment used for obtaining of x-rays in medical diagnostics and therapy. It contains x-ray generating device (generator, power supply device), radiation receiver-transformer (x-ray therapy unit has no such element) and the supports/racks.
27. X-ray diagnostic facility – set of specially equipped premises where the division of radiology department of the medical – prevention institution is located and where the x-ray radiation is used for diagnostics.
28. Treatment room of the x-ray diagnostic room – specially equipped room of the x-ray diagnostic facility where x-ray generator is located and x-ray diagnostic tests or x-ray therapy is provided.
29. Control room of the x-ray diagnostic facility – place where the x-ray unit remote control system is located and from where observation over the patient's condition takes place at a time of x-ray tests.
30. Radiology department – part of the medical institution composed of one or more x-ray diagnostic facilities where generators of ionizing radiation are used for diagnostics or treatment of the diseases.
31. X-ray procedure – use of the x-rays for imaging of the patient's certain organ or part of the body for diagnostics, prevention or for the purpose of the patient's medical exposure.
32. Radioscopy – x-ray research method providing multi-projection dynamic image on the fluorescent or monitor screen.
33. Reference level – recommended values of the dose, dose rate or activity in standard exposure procedures for the typical adult patient (representative individual) in nuclear medicine, exceeding of which shall be subject to inspection for the purpose of investigation of the specific causes of such non-compliance.
34. Medical exposure – patient's exposure at a time of medical diagnostics or treatment; person intentionally and voluntarily assisting the patient to provide comfortable conditions (with the exclusion of persons subject to professional exposure); students and volunteers, engaged in the medical-biological programs within the scopes of their education.
35. Medical physicist – medical worker with the special education, trained for application of the methods and concepts of physics in the medicine, competent to independently perform his/her professional activities in one or more specialized areas of medical physics.
36. Medical linear accelerator – equipment generating high energy x-rays and their delivery to the treatment area (target).
37. Target volume – geometrical concept used in radiotherapy in planning of the treatment procedure, taking into consideration movement of the patient and the tissue subject to exposure, changes of the tissue size and shape, as well as the beam geometry.
38. Work place – place where the sources of ionizing radiation are used and work with these sources takes place for more than half of the working hours or for 2 hours, continuously.

39. Operation stability test – periodical (daily, weekly etc.) test of the x-ray unit parameters for compliance with the manufacturer's technical documentation.
40. Work class – characteristic of the work with the unsealed ionizing radiation sources by degree of potential danger to the personnel determining requirements to radiation safety,
41. Scanner – device allowing registration of the spatial location of the radionuclide substances, i.e. radionuclide imaging of the organs and systems.
42. Stationary radiation protection equipment – building structures and appliances ensuring protection from x-ray radiation and comprising integral part of the x-ray diagnostic facility, also radiation protection equipment with limited portability range (protecting doors, shutters, louvers).
43. Scintigraphy – type of registration of scintillation resulting from decay of the radioactive substances in the gamma chamber.
44. Radiotherapy – therapy using the sources of ionizing radiation.
45. Radiotherapy facility – set of premises of the medical institution specially equipped for radiotherapy procedures.
46. Control room of the radiotherapy facility – room of the radiotherapy facility where the control panel, radiation control systems are located and where the audio-video communication with the patient is ensured at a time of radiotherapy procedures.
47. Radiotherapy facility treatment room – room where the radiotherapy equipment is located and radiotherapy procedures are performed.
48. Lead equivalent – thickness of lead layer in millimeters ensuring reduction of the x-ray radiation in given conditions of irradiation similar to the material under consideration.
49. Fluorography – x-ray test method where x-ray image photo is obtained from the fluorescent screen.
50. Photo laboratory – premises in the x-ray diagnostic facility equipped for chemical-photographical processing of the information on the film (images).
51. Long-term stability test (status test) – periodical test of physical and technical parameters of the x-ray unit and imaging equipment for compliance with the requirements provided by this Technical Regulation.
52. Quality assurance – set of the measures and their safe implementation intended for achievement of the planned outcomes of the radiotherapy and providing dose at the target area, to ensure minimal dose in the normal tissues, as well as minimal exposure of the personnel.
53. Other terms used in this Technical Regulation shall have the same meanings as in the Law of Georgia on Nuclear and Radiation Safety.

Article 4. Key Principles of Radiation Protection and Safety in the Sphere of Medical Irradiation

1. Radiation protection and safety system in the sphere of medical irradiation is based on nuclear and radiation rating, grounding and optimization principles stated by Georgian Law on Nuclear and Radiation Safety.

a) In performing medical x-ray tests, implementation of the rating principle for the personnel is provided by setting permissible exposure dose limits and in case of medical irradiation of the patients (at a time of x-ray procedures) the rating principle is not applicable. For medical

exposure of the patient the diagnostic reference levels are ser by Resolution No: 450 of 27 August 2015 of the Government of Georgia on Approval of Technical Regulation: "Radiation Safety Norms and Key Requirements for Handling of the Sources of Ionizing Radiation".
b) Justification of medical x-ray procedures shall be provided through evaluation of the diagnostic benefits for the patient's health and possible harm resulting from exposure and taking into consideration the possibility of use of the alternative methods;
g) Principles of justification and protection optimization shall be taken into consideration in conducting intervention studies as in addition to the risk of stochastic effect as a result of exposure, there is also the risk of skin deterministic effects;
d) Principle of optimization of the radiation protection of personnel, patient and population is implemented through reduction of the exposure doses to the lowest achievable level without affecting quality of diagnostic information and therapeutic effects, with due consideration of the economic and social factors. Optimization shall include selection of the most effective technologies and modern equipment, as well as dealing with the issues of ensuring quality, radiation protection and doses evaluation.
2. Methods/guidelines of medical diagnostics based on x-ray imaging compliant with the internationally recognized standards, tom include standard modes of x-ray procedures for the representative (standard) individual shall be approved by the head of medical institution.

Chapter II. Radiation Safety Requirements in Diagnostic and Intervention Radiology

Article 5. General Radiation Safety Requirements in Diagnostic and Intervention Radiology

1. Licensee shall develop, introduce and operate the quality assurance program for x-ray procedures. Quality control shall be a part of such program. Quality control ensures compliance of the technical and operation parameters of plants and equipment with the established criteria. Quality control procedures shall be performed with the frequency and within the scopes specified in sections 4, 5 and 6, Art. 8 of this Technical Regulation.
2. Technical maintenance, installation and design of the radiation protection equipment and installation of x-ray diagnostic facility shall be provided by the person licensed for such activities.
3. Natural person or legal entity that procures and/or disposes of, transfers, writes off the x-ray equipment, shall inform the regulatory authority within 10-day term for registration with the industry registry and/or amendment of the registration records.
4. Licensee shall be responsible for operation of the x-ray diagnostic facility equipment and radiation safety.
5. Licensee shall ensure:
a) Compliance with the requirements specified by Georgian legislation and this Technical Regulation;
b) Compliance with the terms and conditions specified by radiation protection program;
c) Arrangement and timely performance of the measurements specified by the monitoring program; equipping with the dosimeters, their calibration, in accordance with the rules established by the legislation;
d) Setting of the list of personnel engaged in the x-ray tests, appointing of the person responsible for the radiation safety by the relevant act; providing personnel training in the radiation safety

issues, improvement of their qualification and retraining, in accordance with the rules established by the legislation;
e) Compliance with the terms and conditions of acceptance, storage, operation and decommissioning of the x-ray equipment, to exclude the possibility of their uncontrolled use and transfer, assigning of a person responsible for registration and storage;
f) Decommissioning of the x-ray equipment;
g) Inspection of the personnel's knowledge in the radiation safety issues, providing briefing and periodical medical screenings;
h) Timely notification f the regulatory authority about radiation incidents / radiation accidents;
i) Ensuring radiation safety of the patients and personnel;
j) Informing of the patients about exposure doses, possible outcomes of exposure and measures taken for the radiation safety;
k) Improvement of the qualification and knowledge of the personnel (doctor specialists, x-ray laboratory workers etc.) in the sphere of radiation safety principles, radiation safety methods and equipment.
6. The key functions of a person responsible for radiation safety include inventory of ionizing radiation sources, control of the personnel and patient individual doses and data recording, delivery of the briefings, development and implementation of the emergency readiness plans, supervision over the implementation of the monitoring and quality control programs.
7. Administration of the medical institution, in case of designing of the x-ray department or expansion of its activities, shall ensure compliance of the design, dislocation and installation with the legal requirements.
8. Prevention screening shall not be performed by radioscopy (fluoroscopy) method.
9. X-ray diagnostic tests for children shall not be performed by fluorography method.
10. X-ray equipment (with the exclusion of the dental x-ray equipment) without diaphragm regulation functions shall not be used. Portable (dental) x-ray equipment shall be used for the purposes specified in the manufacturer's technical documentation and not for the routine tests.
11. Development of the x-ray films shall be provided by the automated development system. The exclusion may be few x-ray tests (no more than 70 per week) where manual development of the films may be permissible (this restriction shall not be applicable to the dental/intraoral x-ray films).
12. Portable x-ray equipment shall not be use for the routine x-ray tests at the x-ray diagnostic facility of the medical institution. Portable x-ray equipment shall be used for the purposes specified in the manufacturer's technical documentation, normally at the resuscitation, surgery or hospital ER, at the patients' wards and for the purposes of performing of the tests to the patients not subject to transportation at their homes. For each of such tests the radiation protection shall be provided.
13. Scientific researches on humans, using the sources of ionizing radiation shall be conducted in accordance with the rules established by Georgian legislation.
14. Results of x-ray tests shall be stored at the database (desirably electronic database) and shall be available to the doctor in charge at al stages of treatment.

Article 6. Requirements to Location of X-ray Diagnostic Facility
1. X-ray diagnostic facility shall not be located in the children's, education and teaching institutions. Operation of the x-ray diagnostic facility shall be permissible at the polyclinics and

medical institutions located in the residential buildings if the adjacent premises are not used for residential purposes and radiation protection is ensured.
2. Treatment rooms of the x-ray diagnostic facilities shall not be located adjacent to the wards of children and pregnant women.
3. It is not reasonable to locate the x-ray diagnostic facility under the premises from where water leakage is possible (swimming pools, shower rooms, sanitary facilities etc.).
4. In planning of the new medical institutions, it should be taken into consideration that the x-ray diagnostic facility shall not be walk-through.
5. Requirements to the dental x-ray diagnostic facilities in the residential buildings are stated in Article 12 of this Technical Regulation.
6. X-ray equipment may be used in the special vehicles if at the outer walls of the vehicle the exposure dose rate is no more than 2.8 μSv/hr in any mode of operation of the x-ray equipment.
7. Stationary barriers of radiation protection of the x-ray diagnostic facility (walls, ceiling, floor, protecting doors, observation window, shutter etc.) shall ensure reduction of x-ray radiation to the levels where the doses can be optimized so that the maximal permissible dose is not exceeded.
8. Methods of calculation of the radiation protection shall comply with the internationally recognized standards and methods (Annex 2).
9. Calculation of radiation protection in case where two or more x-ray units are installed in the same treatment room, shall be provided separately for each if the units, necessary reduction factor and thickness of the protecting structures shall be selected in accordance with the stricter conditions.

Article 7. Requirements to Planning and Equipment of X-ray Diagnostics Room

1. In designing x-ray diagnostics facility premises' composition and areas the x-ray equipment manufacturer's recommendations shall be applied so that not to contradict to the requirements of this Technical Regulation.
2. If the dimensions of the premises intended for the x-ray diagnostics equipment are not specified in the manufacturer's technical documentation the dimensions shall be set as follows:
a) For the x-ray unit for general profile – rectangular (ratio of the length and width no less than 2/3) or square room of no less than 20 m^2 area;
b) For two x-ray units of general profile – area of the treatment room shall be no less than 36 m^2;
c) For the CT x-ray unit - rectangular (ratio of the length and width no less than 2/3) or square room of no less than 24 m^2 area;
d) Dental x-ray unit, 60-70 kV voltage – no less than 6 m^2;
e) Dental digital x-ray unit – no less than 5.0 m^2;
f) Dental panoramic x-ray unit with 90 kV maximal voltage – no less than 10 m^2;
g) For dental CT x-ray unit – no less than 14 m^2.
3. Installation of two dental x-ray units within one and the same room is allowed if:
a) One of the units – dental panoramic unit with 90 kV maximal voltage – no less than 16 m^2;
b) One of the units – dental panoramic with digital transformation or CT units – no less than 10 m^2.
4. For the mammography unit the room area shall be no less than 11 m^2.
5. For the osteodensimeter unit the room area shall be no less than 10 m^2.
6. The treatment room shall be designed so that:
a) The direct x-ray beams were not directed to any barrier and/or door that is not screened;

b) The treatment room door shall be protected also from the scattered radiation;
c) The radioscopy and computed tomography rooms shall be equipped with the door blockage systems so that to avoid exposure of the patient and other persons if the door opens (in designing the new rooms).
7. In the radioscopy and intervention radiology treatment rooms, in the conditions where the operator is together with the patient, for operator's protection from the x-ray exposure, the fixed protective screens shall be installed, they shall be attached to the ceiling, in addition, on the table for the patient the curtains of lead containing material (screens).
8. X-ray (calculated and measured) dose values at the external surface of the x-ray treatment facilities and for various premises shall not exceed the following values of the allowable radiation doses:
a) Premises intended for permanent presence of the personnel (all rooms of the x-ray diagnostic facility, control room) – 13 mcGr/hr;
b) Premises adjacent to the x-ray diagnostic facility (vertical and horizontal) with permanent workplaces – 2.5 mcGr/hr;
c) Premises adjacent to the x-ray diagnostic facility (vertical and horizontal) with non-permanent workplaces (hall, dressing area, staircase, corridor, restroom for the personnel, water closet, storeroom etc.) – 10 mcGr/hr;;
d) Premises where the personnel is present episodically (technical floor, basement, attic floor etc.) – 40 cGr/hr;
e) Wards located adjacent to the treatment room vertically and horizontally – 1.3 mcGr/hr;
f) Territory adjacent to the treatment facility – 2.8 mcGr/hr.
9. X-ray equipment shall be located in the treatment room in accordance with the following requirements:
a) X-ray diagnostic apparatus (with the exclusion of the dental one) shall be located in the center of the room;
b) Distance from the x-ray tube focus of the radioscopic (fluoroscopic) unit to the building wall shall be determined based on calculation of radiation protection requirements but shall be no less than 1.5 m;
c) Distance from the x-ray tube of mammographic x-ray tube to the personnel's workplace shall be no less than 1.5 m.
10. X-ray-diagnostic mobile (portable) units are used where the diagnostic tests cannot be conducted on the stationary x-ray equipment (patients not subject to transportation, at the place of residence, in the departments of resuscitation, emergency care) and ensuring suitable radiation protection.
11. It is allowed to install and operate the x-ray units intended for various purposes (stationary general x-ray diagnostic, mammography, dental x-ray units) within the same premises provided that the requirements to the nominal aggregate operating load and blockage systems excluding simultaneous operation of two units are complied with. Two computerized tomographs in shall not be placed one and the same treatment room, any other cases not specified in this Section shall be acceptable.
12. In the treatment rooms the equipment shall be placed if not provided for in the license documents and no works shall be performed if not specified therein.
13. Photo laboratory may consist of single room. If the laboratory is equipped with the automated development and performs large volumes of work, additional room shall be provided for marking and sorting of the mages.

14. For manual development (with the exclusion of dental) – the minimal area of the darkroom shall be 6 m^2.
15. For the x-ray diagnostic facilities under construction the autonomous ventilation system shall be designed and for the existing/operating radiographic departments, with the exclusion of computed tomography and x-ray diagnostic departments of the infectious hospitals, non-autonomous positive-pressure ventilation systems are allowed.
16. Air exchange rate in the premises of x-ray diagnostic facilities is specified in Annex 6 to this Technical Regulation. Air supply shall be provided to the upper zone, ratio of the suction rates from the lower and upper zones shall be 50±10%. Digital dental, mammography, osteodensimtry x-ray units may be placed in the premises with natural ventilation, provided that the microclimate parameters are complied with.
17. Floors of the treatment room and control room, with the exclusion of x-ray operation and photo laboratory facilities shall be made of the natural or artificial electric insulating material. The treatment room intended for urological tests shall be equipped with the slop hopper.
18. In the x-ray operation room, pre-operation treatment room and photo laboratory the floor shall be antistatic, covered with the water impermeable material easy to clean, suitable for frequent washing and disinfection.
19. In the treatment room and control room the ceiling and wall surfaces shall be smooth, easily cleanable and suitable for wet cleaning.
20. Walls of the photo laboratory shall be faced with the tiles of light color, primarily, at the water sink and area for photo film processing. The wall shall be faced to 2 m height. The upper part of the wall shall be finished with the material suitable for multiple wet cleaning.
21. In the x-ray operation room the walls shall be faced with the material that is not light reflecting.
22. In the radioscopy treatment room the windows shall be equipped with the lightproof appliances (the louvre shutters) to protect it from the natural light (direct sunlight).
23. In the treatment rooms, with the exclusion of the fluorography and –ray operation rooms, the water supply system shall be provided.
24. At the entrance of the x-ray diagnostic facility treatment room and x-ray therapy control room, at 1.6-1.8 m above the floor level or above the door the white-red lighting panel shall be placed with the words: “access denied”, automatically switching simultaneously with the x-ray unit. It is allowed to place the sign of radiation danger on the lighting panel.
25. X-ray units shall be placed so that the direct radiation flow/beams were oriented towards the main wall adjacent to the premises with lower occupation rate. The direct radiation shall not be directed towards the observation window (of the control room, protection shield), If the x-ray diagnostic room is located on the first floor or it is located closer than in 30 m from the residence or public buildings, the treatment room windows shall be shielded with the protective shutters at 2 m from the floor level.
26. The control panel of x-ray units, with the exclusion of the portable, ward, surgical, fluorography, dental, mammography, osteodensimetry units, shall be located in the control room. I is allowed to place the second x-ray television monitor as well.
27. For the purpose of visual control of the patient’s condition the observation window and audio-communication system shall be provided. The glass in the observation window of the control room shall have the marking showing lead equivalent. Size of the window glass shall ensure proper observation of the patient both, at the procedure preparation stage and at a time of test.

28. Control of the portable, ward, surgical, fluorography, dental, mammography units shall be provided in the premises intended for x-ray study (treatment room, ward, surgery), using portable control panel to be located at no less than 2.5 m from the x-ray tube and no less than 1.5 m from the osteodensimetry unit. X-ray tests shall be conducted using portable and individual protection equipment (shields, aprons, collars etc.)
29. Height of the treatment room in the x-ray diagnostic facility shall ensure proper functioning of the technical equipment, in particular, ceiling fixtures of the x-ray emitter, support, television monitor and shadowless lamp.
30. X-ray units with the ceiling emitter, screen and recording equipment or x-ray image intensifier requires that the premises were no less than 3 m of height. Height of the treatment room with the rotational radiation function shall be no less than 3 m.

Article 8. Requirements to the X-ray Equipment

1. At a time of commissioning the sources generating ionizing radiation (x-ray units) shall comply with the International Electro-technical Commission (IEC) and International Standardization Organization (ISO) standards and shall be accompanied with the relevant technical documentation.
2. For the purpose of radiation safety of the personnel and population, at the work places and in the adjacent premises the allowable radiation doses shall not exceed values specified in Article 7 of this Technical Specification,
3. Maintenance and technical service of the x-ray units shall be provided with due regard to the manufacturer's recommendations. If the manufacturer has not provided the relevant recommendations, the technical maintenance frequency shall be specified by the licensee, together with the maintenance personnel.
4. Necessary conditions for use of the equipment intended for x-ray examinations:
a) Equipping of the units with the x-ray image intensifiers (unit operating in the radioscopy mode) and ensuring measurement of the patient exposure doses (by the dose area product (SAP) measuring or other equipment);
b) X-ray unit acceptance test protocol (check of compliance of the technical parameters with the established requirements);
c) All x-ray diagnostic parameters, time, optimal operation modes shall be selected for the specific x-ray unit.
5. Control/testing of the technical parameters of medical x-ray diagnostic and x-ray therapeutic equipment and imaging system shall be provided in the following cases:
a) Acceptance of the new equipment;
b) In the period of equipment operation, testing of the long-term stability (status test) once per yrat and for the dental (intra-oral) units – once per 2 years;
c) Operation stability test – current control of the status of x-ray units shall be provided by the licensee (daily, weekly, monthly tests);
d) For the purpose of extension of the operation term of the equipment or its writing off;
e) Extraordinary test to be conducted in case of change of the x-ray unit operation condition (tube, emergency situation, repair of the equipment) etc.
6. If 15 years have elapsed after manufacturing of the x-ray unit, control/testing of the technical parameters of such equipment shall be performed once per 6 months.

7. Control of the medical x-ray equipment shall be provided by the entities having relevant licenses for technical measurements and relevant staff with special qualification with the documents evidencing such qualification.
8. Testing of the technical parameters shall be provided using the approved methodologies, in accordance with the guidelines, with the measurement equipment suitable for such purpose, with the relevant calibration documents.
9. Technical parameters test results shall be recorded in the relevant protocols (results of current control – records with the log) executed in two copies. One of the copies shall be maintained with the organization performing measurements and the other shall be kept at the x-ray diagnostic facility.
10. In case of technical parameters' non-compliance the information about the test results shall be immediately provided to licensee and the person responsible for radiation safety, as well as to the regulating authority.
11. In case of non-compliance of the technical parameters of x-ray unit with the requirements of this Technical Regulation the unit operation shall be suspended. After conducting the relevant measures and re-testing the decision on continuation of operation shall be made.
12. Withdrawal of the x-ray unit from operation / de-commissioning includes removal of the x-ray unit and withdrawal of the x-ray tube for the purpose its further utilization. Written notification about this shall be submitted to the regulating authority.
13. List of technical parameters subject to control is provided in Annex 3 to this Technical Regulation.

Article 9. Providing Radiation Protection of the Personnel

1. X-ray procedures may be performed by the persons over 18, without medical counter-indications, having the documents evidencing relevant professional knowledge and qualification, duly trained and aware in legal requirements in the sphere of radiation safety.
2. Persons on internship, specialization and/or training (students of the education institutions of medical profile, residents/seekers of medical specialty) are allowed to work at the x-ray diagnostic facilities only after technical safety briefing.
3. Licensee shall:
a) Comply with the requirements of effective legislation and this Technical Regulation;
b) Ensure the system of constructive protection measures in manufacturing of the x-ray equipment;
c) Select optimal operation modes in x-ray tests;
d) Perform radiation control of the personnel work places and individual doss (within the scopes of monitoring program);
e) Maintain stationary, portable and individual protection equipment and ensure their use, regarding the test types, including complex x-ray studies (angiography, x-ray endoscopy, testing of children and severely ill patients);
f) Perform preliminary (at a time of employing) and periodical medical testing of the personnel;
g) Women working directly with the x-ray unit shall be transferred to the lower risk work for the entire period of pregnancy and lactation;
h) Exclude serving of two or more x-ray units simultaneously by one and the same operator;
i) Supply the personnel with individual dosimeters and ensure control of individual doses and data recording.
4. Personnel shall:

a) Prevent checking of x-ray equipment installation, repair and adjustment quality by means of x-ray tests on humans;
b) In case of damage of the x-ray units and protection equipment, immediately inform the person responsible for radiation safety;
c) In performing x-ray diagnostic procedures, observe the patient's condition from the control room, through observation window or other audio/video system;
d) Be able to provide first medical aid, know the addresses and phone numbers of the organizations and persons that shall be informed in case of radiation incident or radiation accident;
e) In performing x-ray tests, use the individual and portable protection equipment (Table 3);
f) Be knowledgeable of the plan of prevention of the radiation accidents/radiation incidents and liquidation of the outcomes thereof and in case of radiation incident and/or radiation accident, perform the measures provided for by the plan.
5. Doctor-specialist shall:
a) Make final decision on performing radiological tests, stating the scopes, type and necessity of the test;
b) If necessity of the test is not properly grounded, the doctor-radiologist shall be entitled to refuse to provide x-ray study, the information shall be provided to the doctor in charge and refusal shall be recorded in the patient's medical documentation;
c) In conducting radiological studies, ensure compliance with the intervals specified in the equipment technical documentation between the high voltage switches. Also ensure selection of the optimal modes of the physical-technical parameters (anode voltage, anode current, exposure, thickness of filters, diaphragm size, compression, distance skin-focus etc.);
d) After x-ray tests, provide registration of the patient's individual effective dose in the patient's treatment (ambulatory) card.

6. X-ray Laboratory Worker shall ensure:
a) Conducing of x-ray diagnostic study;
b) Before commencement of the work, check proper technical condition of the x-ray equipment and image systems, as well as adequacy of chemicals;
c) Selection of optimal test modes (voltage, current, filter thickness, diaphragm size, skin-focus distance etc.);
d) Maximally effective positioning of the patient;
e) Ensuring the patient's radiation safety;
f) Testing complying with the optimal test modes;
g) Minimization of the test / exposure area dimensions and test time maintaining the test quality;
h) Obtaining of the high quality x-ray image.

Article 10. Ensuring the Patient's Radiation Protection
1. In the x-ray procedures the basis for the patient's radiation safety is justification of the x-ray procedures and optimization of the patient's radiation protection. Peculiarities and restrictions related to protection of the pregnant women and children.
2. Doctor in charge, based on the justified clinical data, prescribes the x-ray study to the patient. At a time of the procedure prescription the doctor is aware in the expected exposure dose, patient's individual bodily response and risk of the stochastic effect. In prescribing the procedure the expected exposure dose, individual bodily response and risk of the stochastic effect,

3. Information about the other, alternative treatment, related risks and possible effectiveness, as well as expected and received dose and possible outcomes shall be provided to the patient in any form. Decision on x-ray procedures shall be made by the patient and if he/she is minor or inability of making conscious decisions – his/her authorized representative.
4. A person providing patient's care, comfortable conditions and/or participation in the biomedical studies shall be provided with the information about advantages and expected risks of the diagnostic and therapeutic procedures to the patient's health.
5. Optimization of the patient's protection shall be provided through selection of the modern technologies and diagnostic equipment, practical implementation of the quality assurance program, introduction of the diagnostic reference levels through medical x-ray visualization and patient's exposure doses assessment.
6. Licensee shall comply with the diagnostic reference levels in medical x-ray visualization, including visually controlled intervention procedures, with due regard to the proper quality of the images.
7. Diagnostic reference levels shall be established based on the periodical evaluation of typical doses. If the mentioned levels are excessively high or unusually low, it should be investigated, whether optimization is provided and whether intervention is required.
8. Licensee shall ensure registration of the patient's exposure doses after x-ray procedure.
9. Registration of the patient's doses shall be provided through completion of the relevant table/form in the patient's charts (Table 1)

Table 1

Patient's Doses Registration Form

Patient's doses registration form			
Surname, name	Date	Test type	E, μSv

10. Medical facility shall record the doses resulting from the radiological procedures in the patient's doses recording card, to be provided by the patient to any medical facility as required (Table 2).
11. For the purpose of excluding of unreasonable additional exposure, at all stages of medical services providing, the results of x-ray tests performed earlier shall be taken into consideration. With the patient's referral to the x-ray test, for consultation or hospital treatment, from one hospital to the other one, the results of x-ray tests (descriptions, images) shall be transferred together with the doses recording card.

Table 2

Patient's Doses Record Card

Patient's doses record card
Patient's name, surname, patronymic: ……..
Birth date: ……..
Sec: ……
Address: …….

Patient's exposure dose			
No:	Date	Test type	E μSv
No: 1			
No: 2			

Article 11. Requirements to the Individual and Portable Radiation Protection Equipment

1. For the purpose of ensuring protection of the personnel and patients at a time of x-ray tests all x-ray diagnostic facilities, according to the x-ray procedures conducted therein, shall be equipped with the portable and individual protection equipment (Table 3).

Table 3

Radiation Protection Equipment

Radiation protection equipment	Purpose of x-ray diagnostic facility					
	Fluorography	Radioscopy	Radiography	Urography	Mammography, densitometry	Angiography
Large protective shield (in case of absence of the other equipment)						
Small protection shield						
Movable protection shield attached to the x-ray operation table						
Protective one-sided apron		1	1	1	1	1
Protective two-sided apron				1		1
Protective collar	1	1	1	1	1	1
Protective jacket with protective skirt		1		1		1
Protective apron for the gonads or protective skirt	1	1	1	1	1	1
Protective gloves		1		1		1
Protective goggles		1		1		1
Protective hat		1		1		1
Set of patient's protection plates (various sizes and shapes)						
For children: Small protection equipment regarding sex and age, as well as special equipment of the enfant pad shape.			1	1		1

The list can be adjusted according to the medical technologies
In case of children testing wide range of small protective equipment shall be used.

2. Portable radiation protection equipment includes:

a) Large protection shield with the observation window for the personnel, intended for protection of the entire height of standing human body from radiation;

b) Small protection shield with for the personnel, intended for protection of lower part of the body in sitting position;
c) Small protection shield for protection of the lower part of the patient's body and/or used in the wards to protect the other patients lying next to the tested one;
d) Rotating protection screen intended for protection of certain human organs in standing, sitting or lying positions.
3. In case of use of the movable or portable x-ray units (ward, surgery room) out of the x-ray diagnostic facilities the following requirements shall be applicable:
a) Allocation of the temporary or permanent premises for storage of the x-ray unit;
b) Turn of the x-ray radiation flow to the place where there are less people;
c) Placing of the x-ray unit as far from the operator as possible (no less than 2.5 m);
d) Use of the individual protection equipment by the personnel and patient;
e) Restriction of the access to the x-ray unit to the individuals not engaged in the procedure.
4. Effectiveness of the individual and portable protection equipment for the personnel and patients as expressed by the value of lead equivalent shall be no less than the values specified in Table 4.

5. Radiation protection equipment shall have the factory marking, specifying lead equivalent. In case of absence of the marking the protection equipment shall be tested and their lead equivalent shall be found out.
6. Control of the parameters of the radiation protection equipment and protection effectiveness shall be provided by the relevant licensed/accredited organizations, no less than once per 2 years.

Article 12. Radiation Safety of X-ray Dental Tests
1. The layout of the premises intended for x-ray dental tests and stationary protection shall be determined based on the x-ray unit type, workload and physical-technical parameters. Standardized physical-technical parameters of the x-ray units and their operation are specified in Table 5.
2. Dental units, including panoramic orthopantomographs, may be placed in the x-ray diagnostic facilities of the institutions of medical-preventive, general medical or dentistry profile. If the dental clinic is located within the residential building, placement of only dental x-ray unit with image digitizer (visiograph) shall be allowed.
3. If there are several patients in the dental office, at the location of the patient not engaged in x-ray test the radiation dose shall not exceed 1 μSv /hr.
4. If in the facility there are several dental x-ray units than the control system shall ensure that operation of only one unit was possible at one and the same time.
5. If more than one x-ray unit is located in the treatment room, the area of the room, in relation with the minimal area, shall be increased, regarding the type of the x-ray unit but no less than by additional 4 m^2.

Table 5

Physical-Technical Parmateres of Dental X-ray Unit

#	X-ray unit	Work load (mA min/kWt)	Anode voltage kV
1	Dental x-ray unit working with the ordinary films without intensifying screen	200	70
2	Dental x-ray unit with image digitizer (without	40	70

	photo laboratory)		
3	Panoramic x-ray unit, pantomograph	200	90

6. Dental x-ray diagnostic facility shall be provided with the portable and individual radiation protection equipment for the personnel and patients (Table 6).

Table 6

List of the portable and individual radiation protection equipment for the personnel and patients of dental x-ray diagnostic facility

#	Equipment	Quantity (pc)
1	Large protection shield with observation window for the units working on ordinary films, without intensifying screen, as well as panoramic x-ray units, pantomographs (where the control panel and the treatment facility are located in the same room)	1
2	Protective one-sided apron: - Light, for the personnel	1
3	Protective dental apron (for the patient)	2
4	Protective cape (wrap) and protective collar (for the patient)	1

7. Radiation protection of the population in the residential building adjacent to the dental x-ray diagnostic facility (where radio visiographs are used) shall be provided in compliance with the following requirements:
a) Work load of the dental x-ray unit shall not exceed 40 (ma min)/week;
b) On the surfaces of the walls or stationary protective structures in the facility the radiation dose rate shall not exceed 0.3 μSv /hr.

Article 13. Radiation Safety of X-ray Procedures
1. Purpose of x-ray tests is obtaining of the high quality diagnostic information with as low exposure dose as possible.
2. For the purpose of skin protection at a time of x-ray tests the minimal allowable distance from the x-ray tube focus to the surface of patient's body is established (Table 7).

Table 7

Minimal Allowable Distance between the Skin and Focus (DSF)

Test type	DSF (cm)
Mammography (with magnification)	20
Radiography: ward, portable and surgical units	20
Radioscopy with surgical x-ray unit (with intensifier)	20
Radioscopy on stationary x-ray unit	30
Radiography on stationary x-ray unit	45

3. Only one patient may be present in the treatment room at a time of x-ray test.
4. Patient's age, sex, complexity and characteristics of the test, in particular, tests of women and children, prevention and intervention x-ray procedures comprise significant aspect of the x-ray study.
5. In x-ray diagnostic procedures the automated control of the exposure time shall be used.
6. Radiographic tests shall not be substituted by the radioscopy procedures.

Distance from the focus to skin surface shall not exceed 45 cm. Image intensifier shall be placed on the patient's side, as close to the plane of x-rays delivery as possible as this reduces exposure dose and improves image quality.

7. In diagnostic radiology (with the exclusion of mammography) the voltage over 50 kV shall be used, this reduces exposure times.

Article 14. Radiation Safety of X-ray Tests for the Women of Reproductive Age

1. Where women of reproductive age are referred for x-ray tests the time of last menstruation time shall be taken into consideration. It is recommended that the radiography of the gastrointestinal tract, femoral joint, urography and other tests related to gonads exposure were performed in the first decade of the menstrual cycle to exclude fetus exposure.

2. X-ray examination of the pregnant women shall be provided only in case of clinical indications. Such examination should be conducted in the second trimester, as far as possible, with the exclusion of cases there the option of abortion should be considered or urgent or emergency medical assistance is needed.

3. Participation of the pregnant women in medical-biological studies and/or x-ray tests for assistance (holding of a child at a time of test or assistance to the severely ill patient) shall not be allowed.

4. X-ray tests of pregnant women shall be performed with the use of all radiation protection means so that the fetus exposure dose was not more than 1 mSv for the first two months of pregnancy. Doctor shall inform the patent about possible outcomes and offer abortion.

Article 15. Radiation Safety of X-ray Tests of Children

1. Regarding that exposure is related to increased danger for the developing organism of a child, in case of testing, to reduce harmful effect of radiation, all methods of limitation shall be used:

a) Modern x-ray units, including high-speed films and additional equipment;

b) For the pediatric tests, it is reasonable to use the equipment specially intended for this purpose. Where the tests are conducted on the equipment intended for adults, the scattering grids shall be removed and the unit shall be equipped with the automated exposure control device, to take into consideration the child's age, height and specific size;

c) Optimal testing modes (Annex 3);

d) All means for attraction of a child's attention and preventing his/her movement (toys and various decorations);

e) Individual protection equipment for the patient;

f) Most recent standards and recommendations (guidelines) of pediatric tests;

g) Alternative, non-ionizing methods of imaging.

2. Pediatric procedures shall be performed by the highly qualified personnel knowledgeable of radiation safety of children's testing.

3. The key method of x-ray examination of children (younger than 15 years) shall be radiography. Advantages of this method include: high resolution, low exposure doses to the patient and recording of the obtained information (on the film of disc).

4. Regarding that the radioscopy method has number of weaknesses, limiting its use for children's x-ray examination: low brightness of image and contrast, high exposure doses to the patients, subjectivity of image interpretation (information is not recorded), radioscopy is used in pediatrics only in exceptional cases, as the examination additional to radiography.

5. Radioscopy provided in the exceptional cases shall be performed only on the x-ray units equipped with the image intensifier and device for limitation of the exposure time.

6. X-ray tests of children aged under 12 shall be performed in the presence of the accompanying person (paramedical staff, parent or relative), who should bring the patient to the place of examination and observe the procedure.
7. In x-ray tests of the infants special immobilization equipment excluding the assistance from the side of personnel shall be used. In case of urgent necessity, if no such equipment is available at the treatment room, children shall be immobilized by the individuals over 18. They shall be briefed In advance and provided with the individual protection equipment.
8. No preventive x-ray tests are applicable to children under age of 14. In special cases (unfavorable epidemiological situation) the preventive x-ray tests shall be provided by the decision of the Minister of Labor, Health and Social Affairs.
9. Lung radioscopy in children, due to high exposure doses, shall be provided only in exceptional cases and for no more than 1 minute.
10. In x-ray examination of child's femoral joint, particular attention shall be paid to protection of the child's gonads. In such cases, for the purpose of the dose reduction, test shall be performed strictly based on clinical indications, with optimal modes and mandatory use of the individual protection equipment.
11. Examination of the child's gastrointestinal tract shall be provided only on the specialized stationary x-ray units, equipped with the intensifier, as well as with all measures for the patient protection.
12. In x-ray examination of children with scoliosis the highly radiosensitive organs are exposed (red marrow, lungs, mammal glands, thyroid) and for their protection the following shall be complied with:
a) Tests shall be performed based on clinical indications only;
b) Test shall be performed in posteroanterior projection, instead of the anteroposterior one;
c) In the tests the increase of skin-focus distance (over 1 m) shall be used instead of the scattering grid;
d) Highly sensitive imaging system – "intensifier screen – x-ray film" shall be used.
13. Dental x-ray examination shall be provided on the basis of clinical indications, by the qualified specialists, with the individual protection equipment (including protective aprons ad collars), based on the detailed study of the information obtained through prior examinations.
14.At the treatment facility, where a child is tested, for the purpose of attraction of a child's attention, toys and various decorations can be used.

Article 16. Radiation Safety of Preventive Tests
1. In case of preventive medical x-rat test or scientific research annual effective dose for the actually healthy individual shall not exceed 1mSv.
2. In case of unfavorable epidemiological situation requiring additional tests or forced use of the high dose methods, preventive exposure dose can exceed the established dose limit – 1 mSv. Such tests shall be agreed upon with the Ministry of Labor, Health and Social Affairs.
3. Preventive x-ray tests shall not be applicable to children aged under 14 and pregnant women.
4. Preventive tests shall not performed by radioscopy method.
5. Preventive chest fluorography is permitted only using digital receiver of x-ray radiation.
6. The following requirements shall be complied with for mammography tests:
a) High speed film/screen in combination with high resolution or equivalent imaging systems shall be used;
b) Use of aluminum filters shall not be permitted;

c) Film processors intended for mammography shall be used;
d) Special view boxes of high luminance and collimation located in the low illumination premises shall be used;
e) Automated exposure control shall be used with the exception of cases where the chest thickness is small and where anti-diffusion grid is used. Chest shrinkage is used for increasing of the image quality and dose reduction.

Article 17. Radiation Safety of Interventional X-ray Tests

1. Interventional x-ray tests imply introduction of the additional devices and substances into the human body and normally comprise invasive intervention with x-ray imaging and use of the special instruments.
2. Interventional x-ray tests, unlike routine x-ray examinations, are characterized with high complexity, long duration and high exposure doses. These shall be performed with control of effective (measure of stochastic outcomes risk) and maximal absorbed doses in the skin (revealing of the deterministic effect). Effective optimization methods include practical use of the relevant technologies and equipment quality assurance and reference diagnostic levels.
3. Justification of the interventional x-ray examinations and their optimization shall be provided for each patient, individually. Tests shall be performed in accordance with the relevant guidelines developed for the standard conditions for each test type. The mentioned guidelines shall include the following information: typical time of radioscopy, exposure doses for different modes of x-ray equipment operation, possible dose accumulated in the patient's skin. This information is basic for the surgeon for comparison with the actual conditions of the procedure.
4. Angiography x-ray units shall be equipped with the ionization chamber to measure product of the absorbed dose and area ($Gr*cm^2$). Such chamber shall be attached to the x-ray generator. Normally, the equipment shall work with the relevant software to provide exposure control, imaging and digital processing.
5. To avoid deterministic effects the reference levels of the product of the absorbed dose and area ($Gr*cm^2$) are adopted as provided in Table 8.

Table 8

Test type	Absorbed dose*area ($Gr*cm^2$)
Heart vessels angiography	600
Heart vessels angioplasty	300
Brain and carotid angiography	300
Brain vessels embolization	300
Diagnostics of abdominal and pelvic organs	500
Treatment of abdominal and pelvic organs	500

6. In case of exceeding of the values specified in Table 8 the probability of skin erythema formation is significant. In such case, after completion of the tests, the patient and his/her doctor shall be informed about possible outcomes and patient's condition shall be observed for 2 weeks. If necessary, the treatment shall be provided.
7. Clinically apparent skin damage shall be considered as accident and the case shall be investigated, to eliminate the causes.

Article 18. Radiation Safety Quality Assurance System

1. Licensee shall develop, introduce and operate the quality assurance program. Quality control shall be a part of such program.
2. Quality assurance program shall include:
a) Person responsible for program implementation (surname, name, position, order number and date);
b) Evaluation of the x-ray diagnostic image quality;
c) Optimal modes of x-ray diagnostic procedures (standard modes for standard individuals, in a form of the table);
d) Written instructions on recording of the x-ray procedures and clinical dosimetry data;
e) Control of compliance of the performed x-ray procedures with the doctor's prescriptions;
f) Inspection of the x-ray procedure parameters (modes) and evaluation of the patient exposure doses;
g) Training and improvement of qualification of the personnel in radiation safety issues;
h) Control of the operation technical parameters of x-ray equipment (sections 4, 5 and 6, Art. 8);
i) Inspection of the conditions of operation of the control-measurement and dosimetric equipment and their calibration;
j) Regular review and improvement of the quality assurance program.
3. Goal of quality control is to ensure the following at a time of medical x-ray diagnostic tests (procedures): proper operation of the x-ray diagnostic equipment, timely identification and elimination of the defects. As well as obtaining optimal diagnostic information with minimization of the patient's exposure and costs.
4. Requirements and criteria to the technical parameters of x-ray equipment are specified in Annex 3 to this Technical Regulation.

Article 19. Radiation Monitoring

1. The radiation protection program procuded by the licenses shall include the monitoring program. The licensee shall, independently or with the assistance of the other licensed organization, monitor the workers' individual doses and their work places.
2. Monitoring includes:
a) Individual monitoring, i.e. determining and recording of the annual effective doses of all individuals working in the control zone, taking into consideration the potential risks of exposure;
b) Periodical monitoring of the work places in the control and observation zones, as well as in the adjacent premises.
3. Personnel shall be equipped with the individual dosimeters. The exposure doses shall be controlled, recorded and registered in accordance with the rules established by the legislation.
4. Licensee shall provide evaluation of the professional exposure and forecasting of the outcomes on the basis of the obtained results.
5. The monitoring results shall be registered in the log (printed or electronic). The results of work places monitoring shall be specified on the layout-drawing of the work premises, specifying the generating sources.
6. Monitoring shall use the measurement equipment compliant with the standards and have a calibration documents. The results of dosimetric measurement shall be recorded in the protocol.
7. Measured dose rate values shall not exceed the permissible exposure dose rates specified in Section 8, Art. 7 of this Technical Regulation and individual exposure dose limit set by the Resolution No: 450 of 27 August 2015 of the Government of Georgia on Approval of Technical

Regulation: “Radiation Safety Norms and Key Requirements for Handling of the Sources of Ionizing Radiation”.
8. Methods of radiation control of the work places of the personnel and adjacent premises and form of the dosimetry control protocol are specified in Annex 1 to this Technical Regulation.

Article 20. Prevention of the Radiation Incidents and Radiation Accidents and Recovery of the Potential Outcomes

1. In case of x-ray diagnostic procedures the radiation incidents include the following:
a) The procedure was conducted to the wrong patient;
b) The procedure was conducted to correct patient but on the wrong organ;
c) The procedure other than specified in the doctor’s prescription was conducted thus no required diagnostic information was obtained;
d) Personnel’s exposure dose exceeds annual permissible dose limit.
2. Radiation accident may be caused by the natural disaster (earthquake, flood, storm, etc.), as well as man-caused disasters (water supply, heating or sewage system damage, power cut, damage of the electric equipment).
3. Licensee shall prepare the emergency plan specifying the ways of accident identification, duties of the personnel in emergency situation and measures to be taken for recovery of the emergency outcomes.
4. Licensee shall investigate all cases of radiation accidents, find the causes, eliminate the defects, make relevant conclusions and assessments, set and implement the measures for prevention of similar cases.

Article 21. Requirements to Decommissioning of the Medical Equipment

1. Decommissioning of the medical equipment includes administrative and technical actions intended for environment protection, ensuring safety of the personnel and population at all stages of work. Before completion of the writing off and utilization procedures the control over the equipments, their storage and protection shall be provided by the organization that uses the mentioned equipments.
2. After withdrawal of the sources generating ionizing radiation (generators) from operation the equipment shall be brought to the condition excluding any possibility of their use as the sources of ionizing radiation. X-ray tube shall be removed and tube components shall be utilized as the industrial wastes.

Article 22. Documentation Related to Nuclear and Radiation Activities

1. Medical institutions engaged in x-ray diagnostic tests shall have the following documentation:
a) License (order on issuance of the license), license certificate;
b) Design of the x-ray diagnostic facility with relevant calculations of the radiation protection;
c) List of the x-ray equipment, their data and operation manuals/instructions in the state language;
d) Relevant recommendations (guidelines), description of the standard procedures (optimal modes);
e) Data about technical maintenance of the equipment, technical control log (Annex 4);
f) Radiation protection program (monitoring and quality assurance programs);
g) Data of the personnel individual doses and work places monitoring;
h) X-ray equipment quality control protocols;

i) Documents evidencing personnel's qualification, re=training in radiation safety sphere and health monitoring;
j) Control and measurement, dosimetry equipment calibration documents;
k) Log for recording performed radiological procedures (or documentation containing records on the patients' exposure doses (log, record cad, database etc.);
l) Radiation safety and radiation accidents prevention and recovery instructions/plan;
m) X-ray equipment maintenance log (installation, repair, testing and maintenance records).
2. Documentation specified in Section 1 of this Article shall be available to the personnel and regulatory authority.

Chapter III Radiation Safety Requirements in Nuclear Medicine

Article 23. Requirements to Location of the Nuclear Medicine Department

1. Department of nuclear medicine is intended for the radionuclide diagnostic tests and treatment using unsealed sources of ionizing radiation.
2. Radio pharmaceuticals used for diagnostics and treatment shall be registered by the Ministry of Labor, Health and Social Affairs in accordance with the rules established by the legislation.
3. It shall be regarded that the radiation safety of the personnel and population is ensured if the key principles of radiation safety and radiation safety requirements are complied with as per Georgian Law on Nuclear and Radiation Safety and other normative acts.
4. In performing radionuclide diagnostic in vivo tests and treatment, to ensure nuclear and radiation safety, as one of the types of medical irradiation, the principles of grounding and optimization shall be applied. No rating principles shall be applicable to the patients.
5. Personnel engaged in the nuclear medicine department shall have adequate knowledge and skills with the relevant qualification documents and be aware in the requirements of radiation safety.
6. At the departments of nuclear medicine where unsealed source of ionizing radiation are used for the purposes of diagnostic tests and treatment the staff shall include the medical physicist.
7. For the purpose of ensuring radiation safety of the patient, the radionuclide diagnostic tests and treatment shall be provided only on the basis of clinical indications, application of the doctor in charge and prescription of the doctor-specialist in nuclear medicine.
8. Testing of the pregnant and lactating women shall be provided only strictly according to clinical indications and all procedures shall be grounded in written by the physician in charge.
9. For the purpose of minimization of the patient's exposure levels the reference exposure levels are specified in Resolution No: 450 of 27 August 2015 of the Government of Georgia on Approval of Technical Regulation: "Radiation Safety Norms and Key Requirements for Handling of the Sources of Ionizing Radiation".
10. Department of nuclear medicine shall have available individual protection equipment sufficient and suitable for the personnel, patients and support personnel.
11. Radio pharmaceuticals for medical purposes shall be used only at the specially equipped inpatient nuclear medicine department of the medical institution.
12. In selecting of the radio pharmaceuticals their physical, chemical and biological properties shall be taken into consideration. Particular attention shall be paid to the radio pharmaceuticals intended for children as risk of absorbed dose is much higher in children than in adults.
13. For the purpose of reduction and optimization of professional exposure at work place the control and observation zones shall be specified. The requirements to the control and observation zones are set by Resolution No: 450 of 27 August 2015 of the Government of Georgia on

Approval of Technical Regulation: “Radiation Safety Norms and Key Requirements for Handling of the Sources of Ionizing Radiation”.
14. When entering the control zone the individual dosimeters and individual protection equipment shall be used. After leaving of the control zone, monitoring of radioactive contamination of the cloths and skin surface shall be provided.
15. After leaving of the control zone, the level of radioactive contamination shall be checked by dosimeter equipment. Special containers shall be used for the contaminated cloths. Individual decontamination shall be provided as required.
16. The license documentation submitted by the license seeker shall provide descriptions of the following: premises of the control zone, their demarcation, dimensions, calculation and grounding, with due regard to the maximal permissible levels (plan sketch), number of individuals working in the control zone, radiation accidents’ prevention plan, work safety instructions, monitoring and quality assurance programs, maintenance of the documentation related to the activities.
17. All works with the unsealed sources of ionizing radiation are categorized into three classes. Class of work shall be as per Resolution No: 450 of 27 August 2015 of the Government of Georgia on Approval of Technical Regulation: “Radiation Safety Norms and Key Requirements for Handling of the Sources of Ionizing Radiation”, according to the radiation danger group of the radionuclide and minimal activity used at the work place.
18. Requirements to the layout of the premises and equipment intended for work with the unsealed sources of ionizing radiation shall be determined according to the work class.
19. In work with the unsealed sources of ionizing radiation individual protection equipment (lead containing aprons, overalls, gloves, masks, goggles) shall be used, as well as special equipment (remote handled instruments – pincers, tongs, containers etc.).

Article 24. Radiation Protection of the Personnel
1. Before practical implementation of the activities by the license applicant the potential number of the patients requiring nuclear medicine procedures (diagnostics, therapy) shall be forecasted. Based on this forecast the necessary personnel for the nuclear medicine department shall be identified. In case of new equipment and radio pharmaceuticals, new methods of diagnostics and therapy, and/or reduction or increase of the quantity of procedures the number of personnel shall be revised.
2. Personnel shall have adequate knowledge and skills in the sphere of radiation safety with the relevant qualification documents. Personnel shall be properly trained, briefed and examined for knowledge of the work safety rules and instructions; in case of change of the equipment or the technological cycle the casual training shall be delivered to the personnel (Annex 5). Radiation protection of the personnel work places shall correspond to the work-specific requirements.
3. Personnel performing procedures with the children shall be additionally trained/prepared.
4. In case of lack of the medical physicists, some tasks can be vested in the other relevant specialist. Information about his/her education, qualification and work experience shall be submitted to the regulatory body. The specialist may perform the mentioned work only after approval of the regulatory authority.
5. Licensee shall:
a) By issuing of the relevant act, appoint the person responsible for radiation safety and assign to him/her the functions provided for by the legislation;
b) Develop and launch radiation safety program;

c) Provide monitoring of the professional exposure of the personnel and their work places, record and maintain the monitoring data in accordance with the rules established by the legislation.
d) Identify the personnel requiring internal exposure monitoring and provide monitoring in accordance with the rules established by the legislation; where exposure of the extremities is expected, use suitable finger dosimeters;
e) Ensure compliance with the key dose limits provided for by Resolution No: 450 of 27 August 2015 of the Government of Georgia on Approval of Technical Regulation: "Radiation Safety Norms and Key Requirements for Handling of the Sources of Ionizing Radiation". It is recommended that personnel body exposure dose was no more than 0.5 mSv and finger exposure – 12 mSv;
f) Provide sufficient quantities of collective and individual protection equipment: stationary protection, protecting shields, screens, protecting technological equipment, appliances intended for storage and transportation of the radioactive sources, containers, manipulation instruments, overalls, gloves, boot covers etc, as well as emergency kits;
g) Ensure personnel health monitoring;
h) Develop procedures and safety instructions to ensure radiation safety of the personnel and adequate protection level;
i) Develop radiation accidents prevention and recovery plan. Personnel shall be familiar with the radiation accident prevention and emergency recovery plan and be ready to implement the relevant measures.
j) Provide personnel with the individual dosimeters, control and recording of the exposure doses, as well as their evaluation.
6. Protection of the personnel from external exposure shall be provided in case of close location to the radioactive source (elution of technetium generator, eluate washing, "active" patients), where particularly high exposure dose rates are recorded, with maximal limitation of the personnel presence, using the manipulation instruments with long handles, lead containers for the radioactive substances and wastes, plastic bags.
7. Personnel protection from the internal radioactive contamination shall be provided through isolation of the manipulations with the radio pharmaceuticals, use of the ventilation hoods, hot cells and semi-hot cells. In addition, individual protection equipment shall be used (rubber gloves, protective overalls, respirators, pincers, automatic pipettes etc.).
8. In the control and observation zones consumption of the food and beverages, smoking, use of the cosmetics is prohibited.
9. Work inventory intended for cleaning and decontamination of the personnel work places shall be properly marked.
10. In the ventilation hood work with only one radionuclide at one time shall be allowed.
11. At a time of patient discharge radioactive contamination of the wards, equipment, furniture and other items shall be checked. All articles, patient's personal items and food remains shall be removed from the ward and checked for presence of radioactive contamination. Food remains are the radioactive wastes.

Article 25. Radiation Protection of the Population
1. Population's radiation safety at a time of nuclear medicine procedures shall be ensured through:
a) Physical protection of the ionizing radiation sources,
b) Imposing control over the technological processes safety;

c) Compliance with the principles of nuclear and radiation safety in designing, construction, operation and decommissioning processes.
2. Licensee shall ensure that:
a) The exposure dose of the patient's visitor or family member was no more than 5 mSv and for children – 1 mSv;
b) No access to the control zone was permitted to the unauthorized persons;
c) In case of visitor's access to the control zone, preliminary briefing on radiation safety rules was delivered to him/her and he/she was accompanied by the personnel.
3. After treatment, at a time of discharge from the medical facility, to protect the family members and the population, as well as to prevent radioactive contaminations, the patient shall be provided with the written safety reminder card.

Article 26. Patient's Radiation Protection
1. Medical exposure of the patient for the purpose of obtaining of the diagnostic information or therapeutic effect shall be provided based on the doctor's prescription and with the patient's consent. Final decision on performing of the relevant procedure shall be made by the doctor specialist.
2. Diagnostic tests and therapy in the nuclear medicine shall be provided only based on the medical indications and where there are no any other alternative tests or such tests cannot be performed.
3. Diagnostic tests and therapy in the nuclear medicine shall be provided only based on the relevant recommendations (guidelines) specifying the optimal modes of the procedures and patient's exposure levels at a time of the procedures.
4. Nuclear medicine diagnostic and therapy departments shall be provided with the portable and individual protection equipment for the personnel and patients and they shall use such equipment.
5. Specialist with the education of medical physicist shall participate in therapeutic procedures. All procedures shall be grounded in written, by the doctor in charge.
6. Doctor specialist of nuclear medicine shall select the suitable treatment method for each individual patient, regarding the patient's condition, radio pharmaceutical and activity. Activity of the radio pharmaceutical shall be suitable for the patient's clinical condition, regarding that minimal effective exposure dose should yield maximal therapeutic effect.
7. Before each procedure the activity of the radio pharmaceutical work solution shall be checked by doze-calibrator.
8. In nuclear medicine diagnostics the activity levels shall be applied as specified in the Resolution No: 450 of 27 August 2015 of the Government of Georgia on Approval of Technical Regulation: "Radiation Safety Norms and Key Requirements for Handling of the Sources of Ionizing Radiation".
9. Patients expecting radiometric and scintigraphic tests who have received the radio pharmaceuticals, shall be placed in the special waiting rooms/premises with maximal possible distances between them.
10. The following shall be recorded in the patient's ambulatory card or personal card for registration of medical exposure doses: name of the administered radio pharmaceutical, activity, method of administration, patient's effective exposure dose.
11. Radiotherapy procedures are not recommended for the pregnant or supposedly pregnant women, with the exclusion of the emergencies. In such cases the acceptable doses for the woman

and fetus shall be evaluated in advance. The patient shall be informed about the exposure dose and expected outcomes. If the patient's exposure dose exceeds 100 mSv, the option of abortion should be considered.
12. Woman patient shall be informed about the period after therapy when pregnancy is not recommended.

Article 27. Discharge of the Patient from Medical Institution after Nuclear Procedures
1. Residual activity of the patient discharged from the hospital after nuclear procedures shall be no more than 400 mgBq (this activity, in 1 m from the patient, provides 22 μSv /hr dose rate).
2. At a time of the patient's discharge from the medical institution the dose rate shall be controlled in 1 m from the patient's body and the results shall be recorded.
3. If for the purposes of diagnostics and therapy, the radionuclide other than I^{131} is used, the equivalent activity of such radionuclide is calculated by the formula:

$$A=\frac{D\times T_{ef}}{0.3}; \qquad T_{ef}=\frac{T_{1/2}\times T_B}{T_{1/2}+T_B}$$

Where:
D is the dose rate (μSv/hr) in 1 m from the patient;
T_{ef} – effective half-life of the radionuclide;
A – activity MGBQ;
T_B – biological half-life;
0.3 – correction coefficient.
a) Other radionuclide activity calculated by the above formula shall not exceed 400 MGBQ as well. If T_{ef} data of the radionuclide are not used, its $T_{1/2}$ shall be used.
b) In case of thyrotoxicosis, T_{ef} of ^{131}I is 6 days.
4. If activity of the patient discharged after nuclear procedures exceeds 30 MGBq, the patient and his/her family members shall be briefed about radiation safety issues and radiation safety reminder card shall be provided, acceptance confirmed by signature (Annex 7).
5. Patients subjected to ^{99M}Tc radionuclide test shall be informed about 24-hour restrictions.
6. For the purpose of reduction of the patient's radiation absorbed dose resulting from administration of the radio pharmaceuticals the following measures shall be taken:
a) Oral and intravenous administration of large quantities of water as the effective way for removing radionuclide from the body;
b) After obtaining diagnostic information, administration of the thyroid blockers;
c) For the purpose of reduction of radionuclide accumulation in certain organs, administration of diuretic, choleretic, purgative medicines.
7. At discharge the patient shall leave at the facility contaminated cloths and footwear, take shower, put on clean cloths. After this the patient shall be subjected to dosimeter measurements procedure at the radiation control point.
8. In case of treatment procedures with I^{131}, according to the activity of the preparation, the effective dose rate dependence in 1 m from the patient and its correlation with time shall be as per Table 9.

Table 9

I^{131} activity MGBq	Effective dose rate in 1 m from the patient (μSv /hr)	Time of activity maintenance (days)

<800	<40	21
<400	<20	14
<200	<10	7
<100	<5	4
<60	<3	1

Article 28. Requirements to Treatment with Radio Pharmaceuticals

1. Responsibility for treatment with radio pharmaceuticals shall be vested in duly authorized doctor specialist with knowledge, work experience and qualification in the sphere of treatment procedures of nuclear medicine, also aware in the potential of alternative methods (surgery, chemotherapy, hormone therapy).
2. Medical physicist shall be responsible for identification of the radio pharmaceuticals, calculation of the doses, dosimetry of internal exposure and radiation protection of the personnel, patient's family members and population.
3. At a time of treatment of the malignant diseases, doses close to maximal permissible limit or even doses greater than those able to cause deterministic effects can be achieved in the normal tissues. In such cases possible lethal outcome is compared to the harm caused by treatment to the patient. Particular attention shall be paid to forecasting of such harm in case of treatment of children.
4. In treatment of benign diseases the decisive factor is the patient's age.
5. In case of treatment with I^{131} the radiation protection shall ensure prevention of radiation exposure and radioactive contamination danger.
6. Radiation protection is based on three factors (time, distance, shielding).
7. Sources of radioactive contamination include:
a) Iodine vapor in the air;
b) Patient's bodily fluids;
c) Direct contact with the source;
d) Spillage of the radioactive solutions.
8. Regarding that radio pharmaceuticals containing I^{131} move rapidly to the placenta, before treatment possible pregnancy of a woman shall be tested.
9. Treatment with the radio pharmaceuticals at a time of pregnancy shall be prohibited. In the special cases (vital indications) the exposure dose of the fetus shall be evaluated and if required, the issue of abortion shall be considered.
10. Contraception is necessary until the patient's residual activity reduces below 1 milligray.
11. In the treatment period the lactating mothers are prohibited to breastfeed the infants.
12. Patient's discharge from the hospital shall be permitted only if exposure of the individuals under 18 close to the patient, for the entire treatment period is no more than 1 μSv and no more than 6 μSv for the other individuals.
13. Before commencement of treatment, based on the patient's history, the fact of previous administration of the radio pharmaceutical and the date thereof shall be established.
14. The annual dose received by the family members shall be taken into consideration where the patient is subject to several courses of treatment during one year.
15. Release of the radioactively contaminated discharges is permitted in such quantities that in no calendar year the average effective dose for the representative individual of the population (critical group) were no more than 10 μSv and collective dose – no more than 1 Sv. This

requirement is complied with where the sum of the products of volume activities and dose factors of the radionuclides intended for the patients do not exceed $10^{-2}Sv/m^3$.

16. Outpatient treatment with the radio pharmaceuticals at the nuclear medicine department shall be acceptable provided that the following requirements are complied with:

a) Before commencement of treatment the patient shall be briefed, especially emphasizing necessity of compliance with the hygiene requirements and provided with the radiation safety reminder card (Annex 7);

b) Outpatient treatment shall be prohibited if the patient suffers from urinary incontinence and is not able to comply with the key hygiene rules, as well as in case of unsuitable living conditions.

17. At a time of the patient's discharge from the hospital the doctor in charge shall take into consideration the way of his/her transportation home and the time required for this.

18. If, at discharge, the patient's residual activity is no more than 10 MGBq, no restrictions shall apply. If the residua activity is higher than 10 MGBq, the patient shall be briefed about restrictions.

19. Patient at hospital subjected to therapeutic procedure using I^{131} shall receive the following recommendations from the doctor in charge:

a) Time of stay at the radiology ward;

b) Consumption of large quantities of water (no less than 2 litres);

c) Consumption of lemons;

d) After use of the toilet, flush with water at least 3 times;

e) Males shall use the toilet in the sitting position;

f) After using of the toilet the patient must wash hands with soap and running water, using plenty of water;

g) Individual clothes and linen shall be washed separately;

h) Immediately call the medical personnel in case of vomiting or urinary incontinence.

20. To the ambulatory patient subjected to I^{131} therapy procedure the doctor in charge shall provide the following written recommendations:

a) After administration of the treatment dose, avoid consumption of food and beverages for one hour;

b) Consume large quantities of the liquids for the following 2 days;

c) Use only personal toilet, flush 2-3 times. Males shall use the toilet in the sitting position;

d) Take shower every day and wash hands frequently;

e) Avoid close contacts with the family members, especially with the children and pregnant women;

f) Do not accumulate domestic wastes;

g) If the problems arise, apply to the licensed medical facility.

21. Permissible exposure doses for the individuals close to the patient in 1 m from the patient's body after treatment are specified in Table 10.

Table 10

I^{131} activity	Exposure dose in 1 m from the patient	Permissible contact time with the patient (hr) so that the effective exposure dose was no more than:					
MGBq	MSv/hr	> 50 m		> 100 m		> 150 m	
		Child /hr/	Adult /hr/	Child /hr/	Adult /hr/	Child /hr/	Adult /hr/
200	10	0,77	0,71	1,65	1,5	2,53	2,3

400	20	1,65	1,5	3,3	3,0	4,95	4,5
800	40	3,3	3,0	6,71	6,1	9,9	9,0

Note: Effective external exposure dose for children is calculated by multiplying the adult doses by coefficient 1.1

22. Patient who was administered treatment dose of I^{131} shall comply with the limitations specified in Table 11.

Table 11.

Received activity MGBq	Public transport		Liberating from job	Sleeping separately from the partner		Limitation of close contact with children (days)		
	Next to the driver (hr)	Behind the driver (hr)	Days	Pregnant	Non-pregnant	< 2 years	2-5 years	5-11 years
200	3.5	24	0	15	1	15	11	5
400	1.5	14	3	20	8	21	16	11
600	1.0	9	6	24	11	25	20	14
800	0.5	7	8	26	13	27	22	16

Article 29. Requirements to Design, Equipping and Dislocation of the Nuclear Medicine Department

1. Premises of the nuclear medicine department shall be placed in the isolated part of the medical institution or in the special radiology building, in accordance with the technological process.
2. Nuclear medicine department shall not be placed in the residential buildings and children's institutions; premises intended for the work classes I and II shall not be located adjacent to the wards of children and pregnant women.
3. In designing the principle of optimization of radiation safety shall be followed:
a) Project terms of reference shall be issued for both, designing of the new premises and reconstruction of the existing ones;
b) Regarding the work nature, radionuclides and their activities, the premises shall be adequately distributed by zones;
c) Providing special safety measures (radiation shielding, ventilation, water supply, sewage system, interior facing of the premises).
4. Design and equipment of the premises shall ensure, using stationary (plants, walls, roofing) and dynamic (ventilation, sewage) protecting barrier systems, protection of the personnel and patients from the external exposure and exclude occurrence of the radionuclides in the premises and environment.
5. Control zone includes:
a) Storage room for the radio pharmaceuticals;
b) Premises for preparation and performing of the diagnostic procedures;
c) Premises where the patients who have received radio pharmaceuticals, are waiting for the procedures;
d) Radiology wards;
e) Toilets, shower rooms, bathrooms intended for the patients'

f) Storage room for the radioactive wastes;
g) Other premises that can be categorized as control zone.
6. All premises shall be used for intended purposes only. The premises shall be provided with all relevant equipment and inventory required for response to the radiation accident / radiation incident. The emergency kit shall include, at least: the gloves, boot covers, long forceps, adsorbent, alcohol, wet towels, set of the protective overalls, decontamination solution, powder, etc.
7. Design shall comply with the following requirements:
a) Gamma chamber and computed tomography facilities shall be located adjacent to the control rooms;
b) For the purpose of reduction of the laboratory radiation background in detectors the gamma chamber and computed tomography facilities shall not be located adjacent to the premises of the radionuclide provisioning block and patients' waiting premises.
8. Ventilation system shall ensure air flow from the less radioactively contaminated areas to those more contaminated. Air recirculation from the radionuclide provisioning block to the premises of general purposes, clean zone shall be impermissible.
9. System of the ventilation hoods and boxes intended for work with the radionuclides shall be isolated from the common ventilation network of the department. Ventilation hoods, in the work opening, shall ensure 1.5 m/sec air flow velocity, if the openings are open, reduction of the air flow velocity to 0.5 m/sec shall be acceptable for short time.
10. In the departments automated mechanically forced supply and exhaust ventilation. Air shall be supplied directly to the upper zone of the premises. Air removal shall be provided from two zones: 2/3 of air volume shall be from the upper zone and 1/3 – from the lower zone (in the premises for general purposes from the upper zone only). Air exchange rate shall be 3 for supply and 4 - for exhaust. In the radionuclide provisioning block shall be provided with permanently operating ventilation.
11. If work with the radionuclide gases takes place, the air removal is provided through exhaust ventilation. Air exhaust filters shall be located in the places easily accessible for their replacement.
12. If work with the volatile or emanating substances takes place, permanently operating exhaust ventilation shall be provided in the storage premises and radionuclide wastes collection premises.
13. Therapy department of nuclear medicine shall be categorize as work class I and radionuclide and in vivo diagnostic works and positron emission tomography (PET) center, are normally categorized as class II.
14. Nuclear medicine department shall include the following premises:
a) Radionuclide provisioning block;
b) Radio-diagnostic test block, in case of performing of the therapeutic procedures of nuclear medicine;
c) Therapeutic block;
d) General premises.
15. In construction or reconstruction, the radionuclide provisioning block shall be designed for class II works. It shall include the following premises:
a) Radio pharmaceuticals acceptance room;
b) Radio pharmaceuticals storage room;
c) Radio pharmaceuticals dispensing room;
d) Room for preparation of the work solutions;

e) Manipulation and treatment room;
f) Laundry and decontamination premises;
g) Premises for collection and storage of the radioactive wastes (storage facility for the wastes);
h) Sanitary passage facility and shower room.
16. Radionuclide test block shall be designed for class II works and contain premises for laboratory equipment of radio-diagnostic units and computer processing. Such block shall include photo laboratory, waiting room and special toilet for the patients.
17. Premises for general purposes include the storage room, doctor's room (staffroom), waiting room, personal hygiene room, toilet for the personnel etc.
18. If the department is intended for treatment with the radio pharmaceuticals, shared radionuclides acceptance and radioactive wastes storage facilities with the radio-diagnostic department shall be permissible.
19. In case of performing in vitro tests in the department the following additional premises shall be provided:
a) Radiochemical room;
b) Radiometry room;
c) Centrifuge room;
d) Cryogen room.
Where the institution has the independent department/laboratory of in vitro tests, in addition to the list provide in Section 19 of this Article, doctor's room, treatment room, waiting room and the room for the lab workers shall be provided.
21. For the premises intended for in vitro tests no special radiation protection requirements shall be applicable if the summary activity of the existing radioactive sources is no more than 10 times higher than minimal activity.
22. At the design stage of the nuclear medicine department the following requirements shall be complied with:
a) Premises intended for the works related to radionuclides shall be placed in the separated zone;
b) Premises if different classes shall be separated;
c) The premises' layout shall correspond to the technological processes;
d) At all stages of technological process protection from the ionizing radiation shall be provided for the personnel.
23. Radionuclides acceptance and radioactive wastes storage facilities shall have separate entrances and suitable access area for the special vehicles.
24. Premises for acceptance of the radionuclide sources and storage shall be located adjacent to one another and communication between them shall be provided by means of the carrier (trolley, elevator, transporter etc.).
25. Class II premises shall not contain the niches and protruded walls that are not required for the technological process or conditions of installation of the equipment and plants. Design of the premises, stationary protection structures and roofing shall ensure reduction of the dose rates at work place and external walls of the building to the acceptable values.
26. In the premises where the floor is located immediately above the ground, or the ceiling is immediately under the attic, no protection from radiation is required in these directions.
27. Communication system in the building structures shall exclude reduction of protection.
28. Exposure levels in arranging of the stationary protection structures shall be determined regarding the categories of the exposed individuals.

29. Permissible activity at the work place shall be as per Resolution No: 450 of 27 August 2015 of the Government of Georgia on Approval of Technical Regulation: “Radiation Safety Norms and Key Requirements for Handling of the Sources of Ionizing Radiation”.
30. In the newly constructed departments intended for the works of classes I and II the special sewage system shall be provided with no less than two setting wells. In case of reconstruction of premises, the issue of arrangement of the special sewage system for class II works shall be solved on the basis of the conclusion of regulatory authority.
31. Issues related to providing sanitary-technical systems for work with the unsealed sources of ionizing radiation shall be regulated by Resolution No: 450 of 27 August 2015 of the Government of Georgia on Approval of Technical Regulation: “Radiation Safety Norms and Key Requirements for Handling of the Sources of Ionizing Radiation”.
32. In the premises for works of classes I and II, the water taps shall be equipped with the hand free control devices and electric dryer.
33. Height of the premises in the diagnostics division of nuclear medicine department shall be no less than 3 m, width of the door in the radioisotope section shall be 1.2 m.
34. Premises in the diagnostics division of nuclear medicine department and their respective areas are specified in Annex 8 to this technical Regulation.
35. Premises where radio pharmaceuticals; administration, dispensing, radiometry and intravascular administration takes place, shall be lighted with the bactericide lamps.
36. Relative air humidity in the nuclear medicine department shall be within 30-80%.
37. In the premises of the gamma chamber constant temperature shall be maintained, using air condition system (temperature variation shall be within 2%).
38. License shall be responsible for safe handling of the radioactive wastes generated by his activities within the licensed scopes, that is regulated by Resolution No: 450 of 27 August 2015 of the Government of Georgia on Approval of Technical Regulation: “Radiation Safety Norms and Key Requirements for Handling of the Sources of Ionizing Radiation”.

Article 30. Requirements to Design, Equipping and Location of the Positron Emission Tomography (PET) Center

1. Design, construction, equipment of the positron emission tomography (PET) center, in accordance with the design and recommendations of the manufacturer of the PET equipment shall be provided by the specialized organizations having the permit or authority for such activities provided for by Georgian legislation. Radio safety part of the design shall be agreed upon with the regulatory authority.
2. Design and equipment of the premises shall ensure, using stationary (plants, walls, roofing) and dynamic (ventilation, sewage) protecting barrier systems, protection of the personnel and patients from the external exposure and exclude occurrence of the radionuclides in the premises and environment.
3. PET center shall have separate entrance for the personnel and ambulatory and hospital patients. All premises shall be accessible for the authorized persons only.
4. Cyclotron complex shall be a separate control zone with separate entrance (equipped with the airlock gates), additional exit and remises intended for production of radio pharmaceuticals. Access to the mentioned zone shall be denied to the unauthorized persons and patients.
5. Cyclotron shall be located in the special bunker with the concrete walls and roof. Thickness of the concrete walls shall be calculated at the design stage, based on the legal requirements and manufacturer’s recommendations.

6. Premises of the cyclotron complex shall be located n the first floor of PET center or in the separate building. Cyclotron may be placed on the ground floor, provided that the relevant construction and radiation safety regulations are complied with.
7. According to the technologies of installation of the cyclotron and radiochemical equipment, in the walls or roofing of the cyclotron bunker and radiochemical laboratory 2.8*2.8 m installation openings shall be provided. For the cyclotrons with their own radiation protection, the dimensions of openings shall be increased and compliance with the requirements of cyclotron and radiochemical equipment manufacturers.
8. Access road to the PET center building shall be asphalted and suitable for the trucks and cranes.
9. Entrance of the cyclotron bunker shall be closed with the protecting doors with no less than 4 types of blockage, according to the manufacturer's recommendations.
10. Cyclotron bunker, radiochemical laboratory and PET diagnostic facility shall be located adjacent or as close as possible to one another. Distance from the cyclotron bunker to the radiochemical laboratory shall not exceed 20 m.
11. Cyclotron bunker, radiochemical laboratory and PET diagnostic facility shall be connected with the closed channels where the pipelines of the gases and liquid supply and other required communications shall be placed, according to the manufacturer's recommendations.
12. Separate premises shall be provided for storage of the gas cylinders connected to the radiochemical laboratory and cyclotron bunker with the suitable gas pipeline.
13. Regarding the range and quantities of the synthesized radio pharmaceuticals, at the radiochemical laboratory one or more "active" storage space and/or mini spaces shall be installed for PET radiochemistry, according to the manufacturer's recommendations.
14. Space for temporary storage of the radio pharmaceuticals and treatment room shall be equipped with the ventilation hoods. The ventilation hoods shall be equipped with the protective walls from the inside.
15. Space for storage of radioactive wastes shall be equipped with:
a) Protective wall (barrier). The plastic bags and protecting containers of the solid radioactive wastes shall be placed behind such wall.
b) Impermeable metal case equipped with the local ventilation hood intended for the wastes of non-radioactive technologies.
16. At the entrance of the cyclotron entrance (regarding development of production of I^{123} in the future) and between the radionuclide provisioning and sections for general purposes separate facility shall be arranged and equipped with the shower room, hand wash sink, locker room and spaces for decontamination of the individual protection equipment. Surfaces of the walls, ceiling and floor of this facility shall be covered with moisture resistant cover weakly absorbing radioactivity that can be easily cleaned and decontaminated.
17. Toilet intended for the patients shall be located in immediate vicinity of the treatment room and PET facility.
18. Requirements to the cyclotron bunker, radiochemical laboratory and PET treatment room and control room (control panel), their areas/dimensions, configurations and engineering shall be set at the design stage, based on the technical specification data of the specific equipment and manufacturers' requirements (Annex 8, recommended composition and areas of the premises).
19. In the cyclotron bunker, radiochemical laboratory and PET facility special ventilation and air conditioning systems shall be provided separate from the other premises of the PET center. Autonomous mechanically forced supply and exhaust ventilation shall be installed. Air shall be

supplied directly to the upper zone of the premises. Air removal shall be provided from two zones: 2/3 of air volume shall be from the upper zone and 1/3 – from the lower zone.
20. In the cyclotron bunker, radiochemical laboratory and PET facility airways shall be equipped with the special air filters and devices containing radioactive gas adsorbents.
21. Ventilation system shall operate permanently (24-hour mode).
22. Backup of the ventilation system shall be determined by the design. Air exchange rate shall be as per manufacturer's recommendation.
23. Air from the "hot" chambers, premises and ventilation hoods shall be pre-treated by means of the filters and air traps contained in the equipment. If the openings are closed, in the impermeable chambers and premises no less than 20 mm water column negative pressure shall be provided. The chambers and premises shall be equipped with the measurement equipment for air rarefaction control. Adsorbents and filters of radioactive gases shall be located as close to the chambers, premises and exhaust hoods as possible to minimize radioactive contamination of the main airways.
24. In the premises for general purposes of the PET center the mechanically forced supply and exhaust ventilation shall be provided. Air shall be supplied directly to the upper zone of the premises. Air removal shall be provided from two zones: 2/3 of air volume shall be from the upper zone and 1/3 – from the lower zone (in the premises for general purposes from the upper zone only). Air exchange rate shall be 3 for supply and 4 - for exhaust.
25. Discharge of the sewage water from the radionuclide provisioning section (with the exclusion of the premises for synthesis of radio pharmaceuticals) and general premises to the common sewage system.

Article 31. Requirements to Acceptance, Recording, Storage and Use of the Radio Pharmaceuticals

1. The licensee shall appoint, by the relevant act, a person responsible for acceptance, recording and storage of the radio pharmaceuticals, whose functions include acceptance, recording and storage of the radio pharmaceuticals, as well as regulation of their transfer for further use and writing off.
2. The conditions of acceptance, recording, storage, use and writing off of the radio pharmaceuticals shall exclude possibility of their loss or uncontrolled use.
3. All accepted radio pharmaceuticals shall be recorded in the radio pharmaceuticals record log (Annex 10) and the accompanied documentation shall be registered by the finance department.
4. Work solutions of the radio pharmaceuticals produced from the eluate solutions of the radionuclide generators shall be registered in the relevant log (Annex 12). Data of the radionuclide administered to the patient shall be registered as well (Annex 13).
5. Radio pharmaceuticals that are not used shall be placed in the storage room where their physical protection is ensured.
6. Transportation of the unsealed sources of ionizing radiation, including the syringes, vials etc. between the department premises shall be provided so that to exclude radioactive contamination of the work premises.
7. In all premises where work with the unsealed sources of ionizing radiation takes place, wet cleaning of the premises shall be provided on a daily basis. Work inventory shall be marked.

Article 32. Radiation Safety Quality Assurance System

1. Licensee shall develop quality assurance program with particular attention to the image quality and patients' doses optimization, as well as the quality of radio pharmaceuticals.
2. Quality assurance program shall include:
a) Equipment acceptance test (before first clinical procedure, using the phantoms), for the purpose of assuring correspondence of their parameters with the manufacturer's technical requirements. Work shall be performed by a person licensed for these activities, in presence of the organization's medical physicist. Decision on launching of the equipment shall be made jointly, based on the signatures of the mentioned persons.
b) Long term stability test of the equipment (specifying the periodicity) using phantoms.
c) Quality test of the radio pharmaceuticals. In case of damage of the radio pharmaceutical's package and/or doubt, the supplier shall be contacted;
d) Testing of the patient's activity at his/her discharge after treatment;
e) Data storage/registration (including activity of radio pharmaceutical administered to each patient) and their cross-check system (data shall be stored at least for 3 years). In addition, in case of technical failure of the equipment, storage of information about the causes;
f) Check of compliance with the high standards of radionuclide, radiochemical and chemical purity of radio pharmaceuticals;
g) Setting duties of the person responsible for quality control and other personnel and reporting structure;
h) Periodical trainings and qualification improvement of the personnel;
i) Development of the relevant recommendations (guidelines) on diagnostic and treatment procedures.
3. For the purposes of quality assurance compliance of the equipment of the nuclear medicine department with the following criteria shall be inspected:
a) Gamma chamber:
a.a) Uniformity – change in the field area shall be no more than 10%. Tests shall be performed both, with and without collimator, within the stated energy range;
a.b) Sensitivity – difference of sensitivity (possibility of detection of gamma radiation from the source of ionizing radiation, units: MBq/sec) from the stated value shall be no more than 20%;
a.c) Gentry rotation (SPECT) – deviation of the rotation center shall not exceed maximum half pixel, this actually ensures its suability.
b) Round head chamber:
b.a) Sensitivity – difference between the heads shall be less than 10%;
b.b) Geometry – coincidence between the pixels from the opposite site shall be within half pixel.
c) Dose calibrator:
c.a) Linearity – for the given activity linearity shall be no more than within 5%;
c.b) Reproduction – reproduction shall be less than 5%;
c.c) Accuracy – error of evaluation of gamma radiation over 100 keV shall not exceed 5% and for beta and low energy gamma radiation – 10%.
4. Nuclear medicine department shall regularly inspect compliance with the criteria specified in Section 3 above. If non-compliance with any of the criteria was identified, more detailed inspection of the equipment shall be provided.

Article 32. Handling of the Radioactive Wastes
1. Rules of handling of the radioactive substances are established in accordance with Georgian laws "On Nuclear and Radiation Safety" and "On Radioactive Wastes" and requirements of the

Resolution No: 450 of 27 August 2015 of the Government of Georgia on Approval of Technical Regulation: "Radiation Safety Norms and Key Requirements for Handling of the Sources of Ionizing Radiation".

2. At the nuclear medicine department solid and liquid radioactive wastes are generated, as well as used radionuclide generators, glassware, syringes and needles, remains of the work solutions, radioactively contaminated linen, gloves etc. Solid radioactive wastes include the unused materials containing radioactive substances in concentrations higher than extraction levels. Liquid radioactive wastes include radioactive solutions not intended for use, with effective activity 10 times higher than potable water intervention level value. Radioactive wastes shall be collected separately from the common wastes, immediately at the point of their generation.

3. The department shall take measures for the purpose of the wastes minimization. In work, preference shall be given to use of radionuclides with shorter half lives in minimal quantities necessary for achievement of the patient's testing or treatment goals.

4. Radioactive wastes shall be recorded in the special registration log in a form provided in Annex 14 to this Technical Regulation.

5. Solid radioactive wastes shall be collected in the special containers lined with the polyethylene bags; these shall be delivered to the radioactive wastes storage facility in the end of each working day. In case of work with different radionuclides simultaneously it is recommended that each radionuclide was collected in separate containers, at the same time, remains of the radionuclides with 15 day half-life shall be collected in the same container. Used radionuclide generators shall be stored in the radioactive wastes storage facility, after expiry of the delay time and dosimeter control they shall be returned to the manufacturer of disposed as scrap in case of elimination of all signs of radiation danger.

6. For safety, technical and economic considerations, the method of neutralization of the wastes of radionuclides with short half-life is their delay for the respective time for their decay. After this the wastes comprise common domestic waste. Calculation of the period of activity reduction 10^N times (Annex 15) shall be provided by the following formula:

$T=LNR/K$

Where:

T is time (years);

K – decay rate;

R – recalculation factor expressed in 10^N.

7. Vials of technetium (99m T) shall be collected in the protection container specially intended for the wastes and located in the radio pharmaceuticals' work premises. After filling the polyethylene bag inside the container shall be sealed, specifying date and delay time (4 weeks after commencement of storage). Polyethylene bag shall be disposed to the storage facility where it shall be placed behind the protective lead barrier. After expiry of the storage time dosimeter measurements shall be performed on its surface. If dose rate does not exceed the background values, the wastes shall be disposed to the landfill, as common domestic wastes. Before disposal all marks of radiation danger shall be removed. If the dose rate exceeds the background values, the wastes storage time shall be extended by additional 4 weeks, specifying on the polyethylene bag the new storage term and date and it shall be returned to the place of storage.

8. Wastes including the used gloves and other materials shall be collected in the polymer bags intended specially for this purpose. After filling the bag shall be packaged. On the package the time of delay shall be specified (14 days from commencement of storage time) and it shall be placed in the storage facility. If dose rate on the surface does not exceed the background values,

the wastes shall be disposed to the landfill, as common domestic wastes. Before disposal all marks of radiation danger shall be removed. If the dose rate exceeds the background values, the wastes storage time shall be extended by additional 14 days, specifying on the package the new storage term and date and it shall be returned to the place of storage.

9. In case of wastes including solutions containing T^{201}, I^{111}, Ga^{67} the residual activity shall be measured. The vials containing the wastes shall be placed in the lead containers and stored in the storage facility. If activity of the solutions is less than 100 MGBq, they may be disposed in the special sink (storage) and the vial and sink shall be flushed with plenty of water. Vial washed in such manner shall be added to the common glassware wastes. Works shall be performed using the gloves and apron. Measurements shall be made to check of the sink surface radioactive contamination and if the contamination is present, decontamination shall be provided. If the residual activity of the solution is more than 100 MGBq, the storage time shall be determined based on the table. Further the delay time shall be specified on the vial (container) and it shall be placed in the storage facility.

10. Discharge of the radioactive substances into the environment (domestic and sewage collectors) from the nuclear medicine department shall be permitted in accordance with Resolution No: 450 of 27 August 2015 of the Government of Georgia on Approval of Technical Regulation: “Radiation Safety Norms and Key Requirements for Handling of the Sources of Ionizing Radiation”.

11. Technological solutions used for the purposes of cleaning and decontamination of the “active” premises in PET center shall be stored in the glass containers for delay as the low activity liquid wastes. The containers shall be placed in impermeable metallic cases equipped with the local exhaust ventilation system.

Article 34.Prevention and Containment of the Radiation Incidents/Radiation Accidents

1. Personnel, patient and population radiation safety system includes the measures for prevention of the radiation incidents/radiation accidents, ensuring the personnel’s adequate actions in the emergency situations and measures for minimization of the radiation exposure of individuals at a time of radiation accident response activities.

2. At the nuclear medicine department, in working with the unsealed radiation sources, the radiation incidents / radiation emergencies include the following:

a) Dose of the radio pharmaceutical administered to the patient is higher than calculated (due to the equipment failure, inadequate actions of the personnel, poor quality radio pharmaceutical);

b) Patient was administered wrong radio pharmaceutical (due to incorrect marking of the radio pharmaceutical, absence of accompanying documentation, negligence);

c) Personnel exposure or radioactive contamination is higher than maximal permissible values;

d) Radiation contamination of the premises, equipment is higher than maximal permissible values;

e) Loss of the radio pharmaceuticals or inconsistence of their quantities with the data specified in the acceptance and spending log;

f) Use and storage of the radio pharmaceuticals in the quantities exceeding the quantities and activity specified in the license documentation;

g) Seal failure of the radionuclide generator or spillage of the eluted solution;

h) Technical failure of the radio diagnostic equipment, cyclotron or other equipment;

i) Fire, damage of heating, sewage and water supply systems/

3. The nuclear medicine department shall have developed the plan for prevention of the radiation accidents and personnel's actions, readiness and response in emergency situations. The plan shall include the following information: description of the forecasted emergency situations; emergency response rules and list of the measures for personnel protection at a time of performing of the emergency works; rules of radioactive decontamination; rules of notification of the regulating authorities.
4. In the control zone of the department, in the easily accessible places the instructions for the personnel in case of radiation accident shall be posted.
5. In the easily accessible places of the department control zone the emergency kit shall be maintained, including: set of the protective overalls (including gloves, boot covers, hat), special decontamination means (including disposable towels for the floor, detergents, paper filters), containers intended for storage of the radioactively contaminated cloths and articles, polyethylene bags, instruments, labels with the radiation danger marks and marking kit, instructions for neutralization/decontamination of the contaminated work surfaces, as well as emergency medical aid kit.
6. Radiation emergency response measures are determined by the nature of the accident, its localization and other specific conditions. Response measures shall be determined by the instructions for prevention of the radiation accidents, readiness and actions in the emergency situation. If the accident is caused by the sources with no more than 6 hr half-life, entry into the premises shall be prohibited for one day (24 hr) and further repeated radiation control actions shall be performed. Based on the obtained results the methods and necessity of neutralization/decontamination of the premises and work surfaces shall be determined.

Article 35 Radiation monitoring
1. Radiation protection program provided by the license shall include the monitoring program demonstrating that the conditions of radiation protection optimization are complied with and the exposure limits are properly stated. Monitoring results shall be recorded in the log (or electronically) where the layout drawings of the work premises are provided, specifying locations of the radioactive sources and measurement points.
2. Regarding the nature and scopes of work with the radionuclide sources the monitoring program shall contain:
a) Individual dosimetry control of the personnel external exposure;
b) Individual control of the radionuclide incorporation (internal exposure) by the personnel in case of radiation accidents;
c) Control of radioactive contamination of the work surfaces, personnel's cloths and skin;
d) Radiation control at the work places of the personnel;
e) Control of the volumetric activity of the radioactive aerosols in the air of work premises;
f) Control over handling of radioactive wastes;
g) Water discharge radiation control;
h) Radiation control of the filters of ventilation system;
i) Dosimetry control of the external exposure at a time of the patient's discharge.
3. Licensee shall provide to the personnel the individual dosimeters, record the data, evaluate and store the results in accordance with the rules established by the legislation.
4. Radio pharmaceuticals of ^{125}I and ^{131}I are the potential sources of internal radioactive contamination, at a time of manipulations they can occur in lungs and accumulate in the thyroid. Internal exposure can be determined by direct measurement of the activity in human body or

measurement of the activity in the bodily discharges or exhaled air. Radiometric control of the incorporated radio pharmaceuticals can be provided by means of the specialized radiometers, gamma-chamber (scanning device) or gamma tomographs or special spectrometers intended for radiation measurements.

5. Purpose of the work place monitoring is to identify radiation protection defects at the work places of the personnel. Work place monitoring shall include control of the equivalent dose rate, surface radioactive contamination and air volume radioactive contamination control.

6. Monitoring of the surface radioactive contamination allows identification the deviations from the proper work methods, failure of the protective barriers, or their insufficiency, lack of cleanness and tidiness etc, Permissible values of the surface radioactive contamination are specified in Annex 9 to this Technical Regulation.

7. Surface radioactive contamination can be measured by means of the following methods:

a) Direct method – measurement in Bq/cm^2 units, by means of the calibrated device. In case of presence of radioactive contamination the radionuclide shall be identified and targeted use of the neutralization solutions shall be provided.

b) Alternative method – if the instrument is not calibrated to Bq/cm^2, the instrument for measurement of the absorbed pulse dose rate or other measurement instrument can be used, with pre-determining of the coefficient of the value to be measured and planar activity. The instrument with Geiger-Muller counter is not sufficient for surface monitoring. At the limit of the reference levels the hands monitoring shall be provided with the scintillation equipment with the sodium-iodine crystal;

c) Indirect method is based on measurement of the removable swap of radioactive contamination. The swap shall be taken with the cotton or paper filter wetted in water, alcohol, benzene, citric acid solution etc. The swap is taken from the 300 cm^2 area and measured with scintillation detector.

Planar activity As ($Bq\ cm^2$) can be calculated by formula:

$As= N/(KxE_FxP)$

Where:

N is the measured pulse frequency of the swap (min^{-1});

K – calibration coefficient ($min^{-1}\ Bq^{-1}$);

E_F – swap effectiveness, E_F =0.1

P – area from where the swap was taken.

Where contamination is radionuclide mixture, spectrum analysis would be reasonable.

8. In case of use of the ^{81}Kr, ^{133}Xe, ^{99m}Tc aerosols it is recommended to conduct measurements. For this, the air is sucked into the large polyethylene balloon (V=100-170 cm^3) and measured with the instrument equipped with NaI and calibrated with given radionuclide.

9. In case of use of ^{99m}Tc; ^{67}Ga; ^{201}Te; ^{111}In; ^{123}I and some other radionuclides the patient monitoring is not provided (in such cases the key dose limits are not exceeded). The same is applicable to the patient's family members and care takers.

10. IN case of use of the ^{89}Sr; ^{153}Sm; ^{186}Re radio pharmaceuticals the risk of exposure of the patient's family members is high. These radionuclides are beta radiation sources and ^{89}Sr has quite long half-life.

11. Patient's monitoring shall be provided in case of use of the radio pharmaceuticals containing I^{131}.

12. Decision on the patient's discharge shall be made on the basis of dosimeter control results (Measurement of the dose rate in 1 m from the individual's body). At discharge, content of the radionuclides in the patient's body shall not exceed 400 mgBq (this activity in 1 m from the patient provides 20-22 μSv /hr dose rate).
13. Dosimetric control of the radioactive wastes shall be provided:
a) For the purpose of their storage for delay;
b) For their disposal to the landfill after delay time;
c) Transfer of the radioactive wastes to the storage facility;
d) Delivery of the contaminated overalls and linen to the special laundry, for their sorting and selection of items subject to delay at the storage facility;
e) Measurement results shall be recorded.

Article 36. Documentation Related to Nuclear and Radiation Activities

Departments of nuclear medicine of the medical institutions shall have the following documentation related to the nuclear and radiation activities:
a) License (order on issuance of the license);
b) Layout drawing of the department premises (with all changes);
c) Radiation protection program (monitoring and quality assurance programs shall be parts thereof);
d) Information about the personnel (list of the personnel, documents on their health monitoring and qualification);
e) Data of the personnel individual and work places monitoring;
f) List of the ionizing radiation sources and relevant data, protocols of dosimetry; calibration and approval documents; clinical test protocol;
g) Data about technical maintenance and repair of the equipment;
h) Radio pharmaceuticals, radionuclide-generators registration logs (Annex 11);
i) Radio pharmaceuticals' solution preparation logs;
j) Log of registration of the radio pharmaceuticals administered to the patients;
k) Log for registration of the wastes placed in storage facility for delay;
l) Clinical dosimetry protocols (information providing basis for calculation of the patient's exposure dose);
m) Log for registration of the data of dosimetric measurements at the patient's discharge;
n) Documentation on the causes of radiation incidents / radiation accidents;

Chapter IV. Radiation Safety Requirements in Radiotherapy

Article 37 General Radiation Safety Requirements in Radiotherapy

1. Requirements provided in this chapter are not applicable to use of the unsealed radiation sources for medical purposes.
2. At a time of commissioning the equipment containing generators and sources of ionizing radiation shall comply with the International Electro-technical Commission (IEC) and International Standardization Organization (ISO) and national standards.
3. In the equipment, in visible places, the radiation danger mark shall be placed in accordance with ISO standards.

4. All documentation related to equipment operation, maintenance, protection and safety shall be in the state language.
5. Sealed sources of categories I and II, as well as high energy generators (accelerators) shall be equipped with the blockage systems and signalization showing the source location. They shall be equipped also with the equipment for remote forced return of the source to the storage state.
6. Medical equipment control system, in case of failure, shall exclude or minimize unplanned exposure of the patient or the personnel's errors.
7. Structure of the medical irradiation equipment shall ensure possible minimal level of exposure and at the same time, ensure possibility of obtaining high quality diagnostic information.
8. All sources (generators) generating the radiation for medical purposes shall have the radiation beam control mechanisms, including blockage and identification equipment demonstrating in the permanent mode the process of radiation beam switching on and off
9. Irradiation equipment shall be equipped with the appliances for limitation of the exposure field to reduce dose rate of the undesired (parasitic) radiation or scattering beyond the area of diagnostics and treatment.
10. Quality control of the ionizing radiation sources (acceptance test, operation and status tests) shall be provided"
a) Before commissioning the acceptance test shall be performed, in particular, compliance of the source technical parameters with the technical documentation and established normative shall be checked; equipment acceptance test – in case of the accelerator, shall be performed jointly, in the presence of the manufacturer and organization's medical physicist;
b) In the period of operation of the ionizing radiation sources, within the scopes of quality assurance program, once per year the status test shall be performed and operation tests in the operation mode shall be conducted regularly.
11. At procurement of the source, the contract shall provide for the guarantee of the returning of the waste sealed sources to the manufacturer.
12. Equipment installation, repair and maintenance works shall be performed in accordance with the manufacturer's technical documentation. Work shall be performed by the manufacturer or a person trained by the manufacturer, with relevant certificate issued.
13. Technical maintenance of the equipment shall be provided no less than once per year, data shall be officially registered and confirmed with the signatures of the service provider, authorized representatives of the receiving party and medical physicist.
14. If there is necessity of extension of the operation term of the sealed radioactive source for the period over the term specified in the manufacturer's technical documentation, radiation safety assessment shall be performed, the measurements mode related to the radiation protection shall be revised and the regulatory authority shall be informed.
15. Control of hermetic tightness of the equipment containing sealed radioactive sources shall be provided in accordance with the relevant standards and manufacturer's technical documentation (no less than once per year). Use of the damaged sealed sources shall be prohibited.
16. Procedure of withdrawal of the sealed radioactive sources from the container shall be provided using the special remote instruments. For this work the protecting screens and special manipulators shall be used. If, in 1 m the dose rate is 2 mSv/hr of higher, special protecting remote control appliances (boxes, cases etc) shall be used, These requirements shall not be applicable to emergency situations and emergency response works.

17. Transportation of the radioactive sources within the organization shall be provided in the containers and/or packages and high activity sources shall be moved using special transportation means (carts, cranes etc.) in compliance with the safety requirements.
18. High dose rate brachytherapy department shall be equipped with the dosimeter devices (work place and electronic dosimeters), remotely controlled instruments and protective container suitable for the emergency situations.

Article 38. Requirements to the Design and Location of the Radiotherapy Facilities
1. Designing and construction of the radiotherapy facility shall be provided by the organizations licensed for such activities in accordance with Georgian legislation.
2. Design of the radiotherapy facility, with respect of radiation safety, shall be agreed upon with the regulatory authority. Distance between the radiotherapy facility and residential buildings shall be no less than 100 meters,
3. Radiotherapy facilities shall not be located in the residential or public buildings.
4. The areas and composition of the premises may be submitted as project proposal by the contractor company, to be considered at a time of project development. Final design shall be developed on the site, regarding the specific cases.
5. At the radiotherapy facility design stage, for the purpose of nuclear and radiation safety and compliance with the requirements the necessary measures for exposure doses limitation and optimization shall be taken.
6. Radiotherapy facility shall include specification and marking of the zones, types of the activities and types/characteristics of the equipment intended for radiotherapy.
7. Key requirements to planning and functional layout of the premises include:
a) Placing of the premises where work with the sources of ionizing radiation takes place in single block and their isolation'
b) Placing of the control panel of the radiotherapy equipment in the separate room;
c) Possibility of mechanized transportation of the radioactive sources to the work place and automation of the process of preparation of the radioactive sources for operation.
8. Radiotherapy equipment (with the exclusion of IORT and mobile equipment) shall be placed in separate premises, in the isolated part of medical institution. Automatic blockage of the treatment facility door at a time of moving of the radioactive source or switching high voltage shall be provided.
9. Radiotherapy facility shall be equipped with the adequate ventilation and air conditioning system, fire and protection signalization. Design shall provide for the safety systems connecting radiotherapy unit with the control room and including alarm systems.
10. Design shall provide for limitation of the exposure dose:
a) External – remote radiotherapy facility biological protection shall ensure that in any position of the source and radiation to any direction at the personnel work place annual effective dose was no more than 10 mSv and for the population the annual effective dose was 0.3 mSv. In case of any irradiation and in any place where an individual can be (with the exclusion of treatment room where control is provided) equivalent dose rate shall not exceed 20 μSv /hr;
b) Biological protection of the brachytherapy facility shall ensure that in any position of the source and radiation to any direction at the personnel work place annual effective dose was no more than 6 mSv and for the population the annual effective dose was 0.3 mSv. In case of any irradiation and in any place where an individual can be (with the exclusion of treatment room where control is provided) equivalent dose rate shall not exceed 20 μSv /hr;

c) In calculation of the thickness of 10 MeV and higher energy accelerator bunker walls the fact of generation of the neurons and activation products shall be taken into consideration;
d) Evaluation of the wall thickness (biological protection) shall be provided at the stage of preparation of the terms of reference. The design shall allow increasing of the wall thickness in the premises in any case.
11. If the premises intended for radiotherapy are located at zero mark from the ground surface the radiation protection in this direction is not provided.
Possibility of location of the medical facility for the other purposes above the radiotherapy premises (with the exclusion of stationary linear accelerator, without taking into consideration the intraoperative linear accelerator) shall be determined by the radiation protection that shall take into account the time required for the procedures and time of presence of the engaged personnel.
12. Calculation of the radiation protection shall be provided for the direct beams in the material of roofing structure and taking into consideration the scattered radiation. Calculation of the radiation protection shall be provided I accordance with the internationally recognized standards.
13. Entry to the treatment room shall be provided from the control room only, under the operator's control.
14. Radiation switching on shall be possible only if the treatment facility door is closed, from the control room.
15. For the purpose of control of the patient's condition at a time of the procedure the video surveillance system shall be provided allowing the operator to control, in any position of the patient's (treatment) table and radiation head, the procedure of the patient's exposure from the control room.
16. For the purpose of audio communication with the patient at a time of the procedure, the communication equipment shall be installed between the control room and treatment room.
17. If the door of the treatment room is the part of stationary radiation protection system and requires electrically forced closing and opening, in case of power cut, manual opening of the door from the inside and outside at any time shall be provided.
18. In the radiotherapy premises the autonomous supply and exhaust ventilation system shall be installed. Air recirculation in the mentioned premises shall be prohibited.
19. Air humidity and temperature shall be stable, within 20-25 C^0, and relative humidity (elution of technetium generator, elute washing, "active" patients) shall be within 30-75%.
20. To exclude two-directional movement of air related to the ventilation system, limitation of air characteristics change shall be provided: for the temperature – to 1 degree/min and for the pressure – 10 gPa/min.
21. Equipment for air withdrawal from the atmosphere shall be located horizontally, in no less than 15 m from the equipment of the air discharge to the atmosphere; ventilation system control equipment shall be placed out of the treatment facility (bunker).
22. Heating of the premises shall be provided by air or water heating systems.
23. At the radiotherapy facility the systems of power supply to the plants, equipment and appliances and earth connection shall comply with the safety requirements.

Article 39 Requirements to the Control and Observation Zones

1. Licensee shall ensure:
a) Setting of the limits of the control and observation zones;

b) Development of the requirements to the control and observation zones;
c) Restriction of access to control zone to the unauthorized persons;
d) Marking of the zones with special caution and radiation danger signs.
2. In the treatment facility, on all entrance doors to the simulator and radioactive storage facility the mark of radiation danger shall be posted. In the treatment room (bunker), at the entrance, the light panel shall be installed that will turn on when the radiotherapy equipment is on, as well as at a time of the patient's positioning, procedure and the prohibited period.
3. At the control zone entrance there shall be a sign with the words "control zone" and visual information about the sources and risks. In case of radioactive contamination danger, adequate control of the individuals' displacement, taking out of the articles and equipment items shall be provided.
4. For the purpose of marking of the observation zones, if required, the relevant signs shall be posted on the information board.

Article 10. Requirements to the Medical Linear Accelerator and its Operation
1. At a time of accelerator operation human health is affected negatively by the following radiation factors:
a) Flow of the accelerated electrons;
b) Radiation generated by interaction of the accelerated electrons with the environment;
c) Photo neutrons generated by interaction of the high energy radiation with the nuclei of the surrounding substances;
d) Other types of ionizing radiation resulting from the interaction of the accelerated electrons with the nuclei of the surrounding substances;
e) Undetected surface contamination in the treatment room, caused by the effect of the flow of electrons on the dust particles, activation of metallic articles and/or evaporation of the target substance of the accelerator;
f) Useless x-ray radiation from the high voltage electric equipment;
g) Radioactive gasses generated through air activation by the exposed objects, as well as resulting from activation of the accelerator cooling water.
2. Negative impact of accelerator operation on human health is caused also by the following non-radiation factors:
a) Heat released by the equipment and communication systems;
b) Ozone and various nitrogen oxides resulting from the air radiolysis due to radiation;
c) High and super-high frequency electromagnetic fields generated by the accelerator power supply systems;
d) Noise pollution resulting from accelerator operation;
e) Toxic substances resulting from exposure of various substances;
f) High voltage;
g) Permanent electric and magnetic fields;
h) Laser radiation;
3. Based on the parameters of the flow of electrons the accelerators are classified in two groups:
a) First group - accelerators with maximal energy of accelerated electrons of < 10 MeV (megaelectronvolt); in the case of such energy photo-nuclear reactions can take place only with certain isotopes and induced activity of the environment, due to its low value, is actually of no danger for human health;

b) Second group - accelerators with maximal energy of accelerated electrons of > 10 MeV (megaelectronvolt); in the case of such energy photo-nuclear reactions can take place with the most of isotopes resulting induced activity of the environment (including the air). (There is high probability of neutron flow generation as well).
4. For the accelerator the following premises shall be provided:
a) Treatment room (bunker) – no less than 40 m^2 or as per manufacturer's recommendations;
b) Control room – no less than 15 m^2;
c) Auxiliary premises required for normal operation of the accelerator and technological process, composition, configuration and areas, as well as equipment of which depend on the nature of performed activities;
5. Materials used for radiation protection of the accelerator shall ensure effective and maximal reduction of the accelerated electrons and secondary radiation and radiation outcomes.
6. Protection from the high and super high voltage electric fields, as well as constant electric and magnetic fields shall be provided for the accelerator.
7. Commissioning of the accelerator and its technical maintenance (repair and maintenance works) shall be provided by the organization with the relevant license (manufacturer or other), these works may be performed by the personnel specially trained by the manufacturer with the documents evidencing relevant training.
8. Technical documentation of the accelerator shall contain information about used construction materials (including their chemical composition) than could be activated as a result of irradiation.
9. Scope of radiation control, its frequency, method of the recording and registration of the findings shall be defined at the stage of accelerator design and agreed upon with the regulatory authority. Radiation control shall be provided by the licensee.
10. Radiation control system, for accelerator operation, includes:
a) Stationary dosimeter control of the ionizing radiation levels (electrons, stoppage, etc.);
b) Control of the personnel's individual doses;
c) Periodical control of the work places, adjacent premises and protection screens (barriers). Particular attention should be paid to the places of wall intersection with technical channels;
d) Dosimeter control in all cases of change of the protecting screens/barriers, construction elements and operation modes;
e) Control of the dose rates from the construction materials activated by accelerator operation and from the exposed objects;
f) Control over proper operation of the blockage and alarm systems.
11. Results of radiation control shall be registered.

Article 41. Gamma Teletherapy and High Dose Rate Brachytherapy
1. Premises of the department of gamma teletherapy and high dose rate brachitherapy shall be as follows:
a) Treatment room for radiotherapy equipment;
b) Control room for control panel;
c) Computerized tomography – simulator room;
d) Room for treatment planning;
e) Storage room for the radioactive sources (as required);
f) Medical consultation room;
g) Premises for the medical personnel;
h) Dressing room, sanitary facilities for the personnel and for the patients;

i) Regarding complexity of the equipment – other necessary technical premises.
2. In the premises where the ionizing radiation sources are placed no other works shall be performed and no equipment not intended for radiotherapy shall be placed.
3. The dose rate in 1 m from the surface of the protection unit of the gamma therapy machine containing sealed source of radiation (in the source storage condition) shall not exceed 20 μSv /hr.
4. Stationary protection items (walls, ceiling, floor, protecting doors) shall ensure reduction of irradiation to the acceptable level out of the facility to prevent exposure of the personnel and population in excess of the permissible dose limits.
5. High dose rate brachytherapy facility shall be equipped with the appliances ensuring safe and prompt removal of the remained source from the patient's body and its placement in the special protecting container if, in case of ordinary returning of the radioactive source the source was stuck.
6. High dose rate brachytherapy facility shall be equipped with the emergency container and emergency set of instruments for performing emergency works in case of delay of the source returning or sticking in the source transportation channels. The emergency container shall be placed close to the patient and its size shall be adequate to the sources used in the radiotherapy procedures.
7. Before commencement of the procedure the personnel shall make sure that no other persons are present in the treatment room and adjacent premises. At a time of radiotherapy procedures only the patient shall be present in the treatment room and he/she shall be subjected to permanent control.
8. In cases if the radioactive source is not returned to its storage container, the licensee shall have in place the relevant instructions containing specific measures that will ensure adequate level of nuclear and radiation safety. No less than two times per year inventory of the sources placed in the storage containers shall be provided, as well as control of radiation protection and safety.

Article 42 Low Dose Rate Brachytherapy
1. Work with the radioactive sources shall be permissible only in the premises specified in the license documentation.
2. Low dose rate Brachytherapy facility premises shall include the storage room for the radioactive sources, operation facility (operation and pre-operation rooms), equipped with the ultrasonic and/or x-ray diagnostic computed tomography equipment and properly equipped wards.
3. Area of the premises shall be sufficient for safe performing of the therapeutic procedures, including acceptance and storage of the radioactive sources, preparation of the sources for the procedures, their calibration and their returning to the safe after completion of the procedures.
4. For the purpose of minimization of the distance of transportation of the radioactive sources and the patient, all premises shall be close to one another.
5. Necessity of transportation of the patient with the implanted sealed radionuclide sources shall be excluded.
6.Storage room for the radioactive sources shall be equipped with the suitable safe with the blockage system (reliable lock). The sources shall be placed in the safe in accordance with the officially approved scheme.
7. In the operation room the centering catheters and applicators are placed into the patient's body takes place and control of its placement as per planned is provided by means of ultrasonography

equipment and/or x-ray diagnostic unit, also placed in the operation facility. The equipment shall ensure multi-projection visualization for exposure planning. The equipment required for anesthesia, sterilization and storage of the catheters, centering catheters etc. The sink shall be equipped with the protective net to prevent loss of the failed sources at a time of washing of the applicators and centering catheters.

8. The wards intended for the patients shall be equipped with all necessary appliances ensuring safe and reliable operation of the sources used in Brachytherapy, including the emergency container, radiation monitoring equipment etc.

9. In case of designing of the two-person wards, for the purpose of exposure optimization, the radiation protection screens/shields shall be placed close to the beds.

10. For working with the sealed radionuclide sources no special requirements to the facing of the premises are applicable. All surfaces where the radioactive source can be placed at a time of the procedure shall be well illuminated, regular, firm, easily subject to decontamination.

11. Radiation danger symbol shall be placed on the surfaces of the equipment, containers, packages, doors of the premises containing the radionuclide sources, as well as in all places where the work with the radioactive sources takes place.

12. Containers of the sealed radioactive sources shall comply, at least, the requirements to packaging type “A” for transportation. The manufacturer guarantees their sterility and ensures that the surfaces of the capsules containing the sources were not contaminated with the radioactive substances.

13. At packages acceptance the licensee shall inspect their mechanical integrity. If the packages are damaged, they shall not be opened. In case of failure of the seal of radionuclide sources the licensee shall act in accordance with the radiation accident response plan. If the package is not damaged, correspondence of the documentation and marking to the order/application data shall be checked. In case of discrepancy the package shall be placed in the safe and relevant notification shall be given to the manufacturer and supplier.

14. Container with the sealed radionuclide sources shall be recorded in the acceptance and consumption log, specifying its name, activity and acceptance date. Radioactive sources (implants) shall be recorded with their quantity and serial number of each lot. The serial number shall be specified on the lot package and in the certificate.

15. Containers with the sealed radionuclide sources shall be stored in the safe for storage of the radioactive sources.

16. Within the organization, the radioactive sources – implants shall be moved using the containers made of the material of no less than 0.5 mm lead equivalent.

17. Loading of the sealed source capsules into needles for implanting procedures and their positioning in the matrix of the special template shall be provided in the pre-operation room, on the special table (with the edges of no less than 0.5 cm height), behind the protective screen, using forceps so that the capsule integrity was not damaged. This procedure may be performed by means of the special equipment as well.

18. After completion of each procedure monitoring shall be provided to find out whether the sources have been remained in the patient’s body or in the room.

19. No any articles shall be taken out of the ward or radiotherapy facility without approval of the person responsible for radiation safety.

20. After completion of implanting and at a time of patient’s discharge from the hospital the dosimeter measurements shall be made in 1 m from the patient’s body. After therapeutic procedure with the sealed radionuclide sources (implants) the patient may be discharged if the

remained activity in the patient's body does not exceed 4 GBq, or, in 1 m from the patient's body the equivalent dose rate in the air is no more than 10 μSv /hr.
21. If the patient (with implanted radionuclide sources) deceased at the hospital where Brachytherapy was provided the sources shall be withdrawn from his/her body in the process of pathanatomical study and placed to the storage for the radioactive wastes, in accordance with the rules established by the legislation. Pathanatomical study and withdrawal of the sources shall be provided with radiation control.

Article 43. Ensuring Radiation Safety of the Workers (Personnel)
1. Before practical activities commence, the potential number of the patients requiring radiotherapy procedures shall be forecasted. Based on this forecast the necessary personnel for the radiotherapy facility shall be identified.
2. The medical facility where 400 patients are treated per year requires no less than one medical physicist. In case of increase of the patients' number per year, service of one additional medical physicist shall be provided for every additional 400 patients. Every 250 patients per year shall be served by at least one radiation oncology specialist. In case of introduction of the new equipment, number of procedures, their types, as well as significant change of the patients' number, the number of personnel shall be re-assessed.
3. Personnel shall have adequate knowledge and skills in the sphere of radiation safety with the relevant qualification documents. Personnel shall be properly trained, briefed and examined for knowledge of the work safety rules and instructions; in case of change of the equipment or the technological cycle the casual training shall be delivered to the personnel. Radiation protection of the personnel work places shall correspond to the work-specific requirements.

4. Medical physicist shall ensure:
a) Process of the patients' radiation protection optimization'
b) Correspondence of the exposure dose at the target to the value specified by the relevant recommendations (guidelines) and quality assurance program;
c) Accuracy of all physical parameters related to the irradiation procedures.
5. To ensure adequate level of the personnel radiation safety and protection the procedures and safety instructions shall be developed, functions and duties of each worker shall be defined, among them, in the issues of radiation safety and protection.
6. Licensee shall ensure monitoring of the personnel's health. Monitoring includes the personnel medical screening before commencement of work with the sources of ionizing radiation and further, periodically, one per year.
7. Licensee shall ensure periodical medical screening for the personnel in accordance with the rules established by the Minister of Labor, Health and Social Affairs of Georgia.
8. Personnel shall comply with the radiation safety rules, instructions and take all required measures to ensure their own safety, as well as the safety of the other personnel and population.
9. Personnel shall be provided with the individual dosimeters, control and recording of the exposure doses, as well as their evaluation shall be provided.
10. Personnel shall be familiar with the radiation accident prevention and emergency recovery plan and be ready to implement the relevant measures.

Article 44. Ensuring Patients' Radiation Safety

1. No exposure dose limits are applicable in case of the patient's therapeutic irradiation (as one of the medical irradiation types but the principles of grounding of the prescribed radiological procedures and optimization of the patient's protection shall be applied. The licensee shall ensure that:
a) The therapeutic procedures were grounded, performed only by the prescription of the radiation oncology specialist and with the patient's consent.
b) The patient shall be informed about the expected outcomes and risks;
c) Patient's exposure dose shall be registered;
d) Radiotherapy equipment shall comply with the requirements, provided with the adequate resources, with the instruments for their maintenance and calibration, as well as the patient's radiation protection equipment.
e) Develop and introduce the procedures for measurement of the radiotherapy equipment exposure dose rates and source activity;
f) Any exposure of the women of reproductive age for the therapeutic purposes shall be planned to minimize exposure of the fetus in case of pregnancy.
2. Sealed sources used for gamma teletherapy and brachytherapy shall be accompanied with the relevant calibration certificate issued by the manufacturer or relevant authorized body.
3. If the discrepancy between the results of measurement of the new brachytherapy sources and source activity and kerma rate specified in the manufacturer's certificate exceeds 5%, such sources shall not be used for the patients' treatment until the cause is identified and eliminated.
4. At a time of the patient's discharge from the hospital after low dose rate brachytherapy the dose rate control in 1 m from the patient's body shall be provided. The results shall be recorded.

Article 45. Ensuring Radiation Safety of the Population

1. Population's radiation safety at a time of radiotherapy procedures shall be ensured through physical protection of the ionizing radiation sources, imposing control over the technological processes safety, compliance with the principles of nuclear and radiation safety in designing, construction, operation and decommissioning processes.
2. Licensee shall provide control over the population's exposure conditioned by radiotherapy activities, prevent unauthorized use of the radiotherapy equipments and access to them.
3. In brachytherapy procedures the possible exposure doses for the family members or other persons living with the patient shall not exceed 5 mSv per year and for the other persons, as well as for the children the doses shall not exceed 1 mSv per year.
4. After treatment, at a time of discharge from the medical facility, to protect the family members and the population, as well as to prevent radioactive contaminations, the patient shall be provided with the written safety reminder card; it is recommended that the patient used separate bed, avoided contacts with the pregnant women and children for 6 months after the procedure. In case of maintaining of the sexual function the patient shall use the condoms.
5. After therapy with the sealed radionuclide sources (implants), to prevent loss of the source, at home, the patient shall not use the common sewage system for 5 days. For this period the patient shall use the personal urine collection reservoir with the mesh filter. If the radionuclide source was found on the mesh the patient shall immediately inform the healthcare personnel. The health care personnel, with the dosimetry control, shall place the capsule into the container for transportation, issues the act on withdrawal of the radionuclide source and returns the radioactive source to the clinic in accordance with the established procedure, for the purpose of temporary

placement in the storage facility, until the issue of its disposal to the radioactive wastes storage facility is not dealt with.

Article 46. Radioactive Accidents in Radiotherapy, their Prevention and Recovery

1. At the radiotherapy facility the accident can be caused by various factors, such as:

a) Human error, like participation of various specialists in radiotherapy planning and includes incorrect execution of the medical and technical documents. As a result the following violations can take place:

a.a) The procedure was conducted to the wrong patient;

a.b) The procedure was conducted to correct patient but on the wrong organ;

a.c) Radiotherapy was conducted at different dose, ±10% higher or lower than prescribed by the doctor;

a.d) Radioactive source remained in the patient's body;

b) Technical error caused by failure of the equipment or any part thereof that can be caused by the following:

b.a) New equipment or new technology;

b.b) Inadequate calibration of the radiation cone / beam or source;

c) Wrong assessment of the topometry, dosimetric planning, dosimetric equipment;

d) Inconsistent and superficial implementation of the plants and equipment, technologies quality control program;

e) Natural disaster (earthquake, flood, storm, etc.), as well as man-caused disasters (water supply, heating or sewage system damage, power cut, damage of the electric equipment).

2. At the radiotherapy facility the radiation accidents include:

a) Loss of the radioactive source;

b) Sticking of the radioactive source in operation mode in the channel of the radiotherapy equipment channel;

c) Radioactive contamination of the work surfaces, patient's body in case of radioactive source seal failure;

d) Personnel exposure over the maximal permissible dose caused by non-compliance with the work technology, personal negligence or improper evaluation of the readings of the control equipment, indicators and dosimeters;

e) Exceeding the permissible exposure dose in the healthy organs (critical organs) as a result of topometry, dosimetric planning, irradiation errors.

3. At the radiotherapy facility non-radiation accidents include:

a) Fire;

b) Non-compliance with the sanitary requirements caused by damage of water supply, heating or sewage systems;

c) Power supply cut, damage of electric equipment causing violation of the patients' and workers' electric safety rules but without affecting population's radiation safety;

d) Unauthorized actions or unauthorized access to the radioactive sources or premises where they are stored or used.

4. Measures for prevention of the radiation and non-radiation accidents include:

a) Implementation of the significant technological procedures like beam calibration (two medical physicists) and results' comparison; by number of specialists independently from one another, double-check of the dosimetric planning results;

b) Workers' readiness for identification of violations and technological errors;
c) Development of the training programs for the workers on response to the near-miss situations in case of professional exposure;
d) Detailed description of all stages of radiotherapy procedures, implying also communication between the specialists of different profiles;
e) Written analysis of the measures for minimization of all radiation accidents and their outcomes;
f) Access to all available fire protection systems;
g) Regular inspection of the radiotherapy equipment operation;
h)Regular monitoring of the workers' knowledge followed by the official attesting of the employees in readiness for radiation accidents.
5. Radiotherapy facility shall be provided with the primary firefighting equipment and elimination of the radiation accidents, as well as the instruments and kits required for their prevention, such as:
a) Radiation accident response kit;
b) First aid kit;
c) Fire extinguisher with the sand box and shovel;
d)Equipment for decontamination of the surface areas at work place.
6. In case of possible radiation accidents the activities to be performed by the personnel include:
a) In case of loss of the radioactive source or control over it – based on the inventory and displacement rout investigation systems the type and activity of the lost source shall be identified; its last known location shall be found out; seeking of the source shall be provided through joint efforts of the radiation protection and medical division security services and highly sensitive equipment and relevant methods of radiological control shall be used.
b) In case of blockage of the radioactive source in the transportation channels of the equipment the effort for the source returning to the storage condition shall be made; if, as a result of repeated effort, the source cannot be returned to the storage mode, it is recommended either patient's removal from the canyon or removal of the centered catheter with the source from his/her body and after this the measures shall be taken for containment of the radiation accident outcomes;
In case of failure of the seal of the sealed source – after making the source inoperative (among them its removal from the patient's body), the measures shall be taken for decontamination of the contaminated surfaces (including the patient's skin) to prevent further radioactive contamination in the other places.
7. After each radiation incident or radiation accident, for the purpose of evaluation of the situation with respect of radiation, radiation control of the personnel's work places shall be performed.

Article 47 Quality Assurance System
1. Licensee shall develop quality assurance program. Quality control is the part thereof.
2. Program shall include:
a) Procedures of measurement of the physical parameters of the radiotherapy units and visualization equipment at a time of their commissioning and further, in the established intervals;
b) Impermeability check of the high doze rate brachytherapy sources;
c) Planning, software, dosimeter systems and physical protection elements' control;

d) Periodicity of measurement of contamination of the Low dose rate brachytherapy instruments (forceps, holders etc.) and transportation container surfaces;
e) Examination of the relevant clinical and physical factors used in the patient's treatment;
f) Written registration of the relevant procedures and outcomes;
g) Inspection of operation conditions and proper calibration of the dosimeters and monitoring tools.

3. License holder shall, by issuing of the relevant act, assign the person responsible for quality control.
4. After commissioning of the new radiation equipment, before performing procedures on the patients the measurements shall be made and data collected for further use in the process of irradiation planning process for clinical dosimetry. These data shall be recorded in the work log of the medical physicist.
5. All tests and inspections shall be performed using the phantoms. Alternative inspection method of treatment is in vivo dosimetry.
6. Quality assurance program shall include internal and external clinical audit. Based on the audit results the written report shall be issued providing assessment of the effectiveness of quality control systems and recommendations for optimization. The report shall be submitted to the licensee. The licensee shall consider the report and take adequate improvement measures.
7. Licensee shall develop the recommendations/guidelines according to the internationally recognized standards for all treatment procedures.
8. Registration of the radiation therapy procedures shall be provided (either electronically or in written) to include the following information: procedure name, patient data, the equipment used, treated organ, dies at the target and critical organs, patient's immobilization methods, treatment outcomes. Upon completion of the therapy course the final information shall be recorded in the patient's medical documentation.
9. Quality control of radiotherapy equipment shall be provided by establishing suitable requirements and criteria for the technical parameters, as provided in Annex 16 of this Technical Regulation.

Article 48. Requirements to Physical Protection and Transportation
1. Licensee shall be responsible for physical protection of the radioactive sources in accordance with the requirements established by the legislation.
2. Radioactive sources shall be stored in the specially equipped premises – storage rooms, safes and containers.
3. Storage room of the radioactive sources shall be equipped with the safety alarm device. In the storage room the scheme of dislocation of the radioactive sources shall be posted. Total activity of the radioactive sources shall not exceed the values specified in the license documentation.
4.The radioactive source shall be released from the storage room by the responsible person on the basis of the relevant request and shell be recorded in the special record log. Unused radioactive sources, in a form of solid radioactive wastes, shall be de-registered and transferred to the radioactive storage facility, in accordance with the rules established by the legislation.
5. Charging and withdrawal of the radioactive sources from the radiation therapy unit and transportation of the sources intended for brachytherapy out of the medical facility shall be provided by the organization licensed for such activities in accordance with the rules established by the legislation.

6. Supplier and licensee shall provide:
a) Special equipment required for manipulations with the sources for gamma teletherapy (hoisting crane, vehicle with the hoisting equipment etc.);
b) Measurements of the dose rates on the container and package surface;
c) Measurement of the superficial loose radioactive contamination on the external surfaces of the containers intended for transportation;
d) Checking of the load packages and transport indices;
e) Inspection of the transportation labels on the packages, containers and their replacement in case of damages;
f) Safe placement of the containers or packages within the vehicles, with proper marking of the vehicles.
g) Cargo protection at a time of transportation;
h) Complying with the requirements of customs control.
7. Transportation of the sources is allowed only with the transport containers, along the pre-designed shortest route.
8. After acceptance of the radioactive sources the licensee shall return to the supplier the used radioactive sources placed in the received packages and containers.

Article 49. Monitoring
1. Radiation safety program submitted by the licensee shall include the monitoring program. He, independently, or with the assistance of the other licensed organization, shall perform monitoring of the individual doses of the personnel and work places.
2. Radiation monitoring includes:
a) Individual monitoring – calculation of the annual effective doses for all individuals working in the control zone and their recording with due regard of the potential risk;
b) Periodical monitoring of the work place in the control and observation zone;
c) Control of impermeability of the sources for gamma teletherapy and high dose brachyterapy.
3. Monitoring of the non-radiation factors includes control of concentration of the toxic and harmful substances in the air of premises at a time of accelerator operation, effectiveness of the ventilation systems and performing tests of the functional status.
4. Impermeability of the sources for gamma teletherapy and high dose brachyterapy shall be measured by the method of wipe samples. Wipe samples shall be taken from the equipment, transportation containers and other places where radioactive contamination from the damaged sources can be expected. Taking of the wipe samples directly from the source surface is unacceptable.
5. Based on the obtained results the licensee shall provide assessment of professional exposure of the workers and forecasting of the outcomes.
6. Monitoring results shall be recorded in the log (or electronically) where the scheme-drawings of the work premises are provided, specifying locations of the radioactive sources and measurement points.
7. Licensee shall ensure introduction and application of the clinical dosimetry procedures recommended by International Atomic Energy Agency (IAEA) provided in the following publications: TECDOC-1079, TRS-398, TRS-381.
One of the internationally accepted methods for independent inspection of the gamma teletherapy beam and calibration of the physical dosimeters is also participation in the comparative measurements organized by IAEA and WHO through sending of the

thermoluminescence dosimeters (TLD) to the relevant organizations using modern communication systems.

8. Measured and calculated dose rate data shall not exceed the following values of the permissible dose rates:

a) Premises intended for permanent presence of the personnel (all rooms of the radotherapy facility, control room and other premises) – 13 mcGr/hr;

b) Premises adjacent to the rdiotherapy facility (vertical and horizontal) with permanent workplaces – 2.5 mcGr/hr;

c) Premises adjacent to the rdiotherapy facility (vertical and horizontal) with non-permanent workplaces (hall, dressing area, staircase, corridor, restroom for the personnel, water closet, storeroom etc.) – 10 mcGr/hr;;

d) Premises where the personnel is present episodically (technical floor, basement, attic floor etc.) – 40 cGr/hr;

e) Wards located adjacent to the treatment room vertically and horizontally – 1.3 mcGr/hr;

f) Territory adjacent to the external walls of treatment facility – 2.8 mcGr/hr.

9. No less than 3 measurements shall be performed in each point with further averaging of the results. Measurements shall commence with measuring of the background radiation, the source of radiation shall be in the “storage” mode. If the measurement equipment do not allow background compensation the background radiation shall be deducted from the values of the measured dose rates.

10. All dosimetric measurements shall be provided with tissue-equivalent (water) phantoms of 300x300x300 mm dimensions. The phantom shall be placed in the isocenter of the radiation flux. For the measurements for the intra-tissue and intra-cavity therapeutic equipment the phantoms included into the equipment set shall be used. In case of absence of the phantoms the measurements shall be provided in the process of therapeutic procedures where the source is placed within the patient’s body. Maximal dimensions of the radiation field are set, the radiation flux is completely covered by the phantom dimensions.

11. Where for the treatment of patient the rotation irradiation methods are applied the dosimetric measurements shall be performed for the entire rotation range (0-90-180-270 degrees).

12. In the premises adjacent to the treatment room the dose rate measurements shall be provided:

a) At 500 mm height from the floor level in the premises located above the treatment room, in the 1 m grid points;

b) At 2000 mm height from the floor level in the premises located below the treatment room, in the 1 m grid points;

c) In the horizontally adjacent premises – in 100 mm from the wall, at 2000, 1200 and 500 mm along the entire height of the wall of the treatment room, with 1 m increments (also along the entire the external wall of the treatment room).

13. Dosimetric measurements shall be made at the points of joining of the protection equipment, at the doors and technological openings.

14. Dosimetric measurements shall be performed in the adjacent territory - in 100 mm from the wall, at 2000, 1200 and 500 mm from zero level along the entire wall of the treatment room, with 1 m increments (also along the entire the external wall of the treatment room).

15. If the radiotherapy department (facility) is located in the extension of the main building, the dosimetric measurements shall be performed in the premises directly adjacent to the radiotherapy facility.

16. Dose rate values shall be adjusted to the established work load or temporary work mode of the unit by means of the formula:
a) For the contact radiotherapy (brachytherapy) units, as well as radioactive source storage, manipulation, surgical, treatment facilities, radiological wards etc. For the adjacent premises:

$$\dot{E}_n = \dot{E} \cdot \frac{t}{T}$$

b) For the gamma teletherapy equipment:

$$\dot{E}_n = \dot{E} \cdot \frac{W \cdot R^2}{T \cdot N \cdot H_1 \cdot 60}$$

Where:
En – is effective dose rate at measurement point adjusted to the unit work mode, μSv /hr;
E – average effective dose rate at various heights from the zero level, μSv /hr;
T – time of unit operation in the irradiation mode per shift, hour (time of actual work with the radiation source or time of source location in the mentioned premises shall be considered);
T – work shift time per day, hour;
H_1 – dose rate in 1 m from the source in the irradiation process, Gr m^2/sec;
W – operation load of the unit (patient's aggregate exposure dose per week), Gr/week;
R – distance from the source to isocenter, m;
N – number of working days per week;
60 – minutes per hour.

17. Results of dosimetric measurements shall be recorded in the measurement protocol.

Article 50. Requirements to Medical Equipment Decommissioning and Utilization
1. Decommissioning of the medical equipment includes administrative and technical actions intended for environment protection, ensuring safety of the personnel and population at all stages of work. Unused equipment containing the source of ionizing radiation (radionuclide or generator) is a potential danger and it is subject to utilization. Before completion of the writing off and utilization procedures the control over the equipments, their storage and protection shall be provided by the organization that will use the mentioned equipments. Unused medical equipment for x-ray and radiological tests and therapies shall not be disposed to the common landfills. Withdrawal of the medical equipment from operation shall be provided in accordance with the project / plan intended for ensuring work safety.
2. Only specially trained personnel shall be engaged in the works of withdrawal of the medical equipment containing the ionizing radiation sources and their utilization. Works for removal and dismantling of the ionizing radiation sources shall be performed by the organization with the relevant license. Radiation exposure levels for the personnel engaged in the utilization works shall not exceed the dose limit established for the personnel.
3. After withdrawal of the sources generating ionizing radiation (generators) from operation the equipment shall be brought to the condition excluding any possibility of their use as the sources of ionizing radiation. X-ray tube shall be removed and tube components shall be utilized as the industrial wastes.
4. In case of withdrawal from operation (decommissioning) of the medical equipment containing radionuclide sources, at all stages of work, the measures for ensuring radiation safety of the personnel and population shall be provided, including:
a) Preparation of the equipment, plants required for dismantling works;

b) Means and methods of decontamination of the dismantled equipment/plants;
c) Methods of collection, storage and utilization of radioactive wastes;
d) List and descriptions of the radiation protection measures to be taken at a time of work;
e) Decontamination of the medical equipment freed from the radionuclide source and premises;
f) Description of the radiation control (monitoring) procedures;
g) Evaluation of the expected collective exposure doses and individual doses for the personnel and population.
5. Radionuclide sources from the decommissioned medical equipment shall be returned to the manufacturer/supplier, as far as possible or transferred to the radioactive wastes storage facility for storage.
6. For the purpose of radiation protection, in the utilization process, the following is necessary:
a) Equipment protecting from the exposure and radioactive contamination;
b) Equipment for minimization of spreading of the radioactive substances;
c) Equipment for monitoring of the external exposure and superficial radioactive contamination;
d) Equipment required for monitoring of the radioactive contamination of air at work places;

7. Uncontrolled radioactive contamination shall not be spread to the clean territory and personnel.
8. To ensure radiation safety, a set of protection equipment shall be in place in case of a radiation accident.
9. Works for the equipment decommissioning and utilization of the equipment shall be completed with final inspection of radiation situation. Inspection results shall be recorded in a form or final report and the protocol of dosimetric control, exposure doses of the equipment utilization participants, documents evidencing transfer of the mentioned sources and wastes to the radioactive wastes storage facility or other organization shall be attached thereto.

Article 51. Documents Related to Nuclear and Radiation Activities
Radiotherapy facility of the medical institution shall have the following documents related to the nuclear and radiation activities:
a) License (order on issuance of the license), license certificate;
b) Layout drawing of the department premises (with all changes), design, with calculations of radiation protection (references specified);
c) Radiation protection program (monitoring and quality assurance programs shall be parts thereof);
d) Information about the personnel (list of the personnel, documents on their health monitoring, qualification);
e) Data of the personnel individual and work places monitoring;
f) List of the ionizing radiation sources and relevant data, protocols of dosimetry; calibration and approval documents; clinical test protocol;
g) Data about technical maintenance and repair of the equipment;
h) Clinical dosimetry protocols (information providing basis for calculation of the patient’s exposure dose);
i) Documentation on the causes of radiation incidents / radiation accidents;
j) Relevant recommendations / guidelines for all treatment procedures approved by the management;
k) Irradiation procedures registration log (written or electronic);

l) Patient’s safety instructions reminder card (written);
m) Log for registration of the data of dosimetric measurements (in 1 m from the patient’s body) after the patient’s discharge from the hospital after low dose rate brachytherapy procedures (treatment with the implants);
n) Log for registration of acceptance and use of the radioactive sources.