Pursuant to Article 26-e, paragraph 1, item 14 of the Law on Ionising Radiation Protection and Radiation Safety (Official Gazette of the Republic of Macedonia No. 48/02 and 135/07), the Director of the Radiation Safety Directorate hereby adopts a

RULEBOOK

ON THE MANNER OF AND DEADLINES FOR EXAMINING IONISING RADIATION SOURCES, MEASURING PATIENTS' EXPOSURE DURING DIAGNOSTIC AND THERAPEUTIC PROCEDURES, KEEPING RECORDS AND SUBMITTING REPORTS(*)

Article 1

This Rulebook shall prescribe the manner of and deadlines for examining the ionising radiation sources, measuring patients' exposure during diagnostic and therapeutic procedures, keeping records and submitting reports.

Article 2

The examination of ionising radiation sources for the purpose of guaranteeing their quality and optimising the exposure to ionising radiation shall be performed by means of quality control tests to the ionising radiation sources.
The examination of ionising radiation sources after their installation and before they are put into use shall be performed by means of acceptability tests.

Article 3

The quality control of ionising radiation sources shall be performed by measuring the following parameters: radiation quality, field geometry, quality of the diagnostic image, conditions for image viewing, film processing system, as well as other mechanical, dosimetry and safety parameters, for the purpose of ensuring compliance with the criteria established in the regulations relating to protection against ionising radiation, radiation safety and the manufacturer's recommendations.
The acceptability test referred to in Article 2 paragraph 2 of this Rulebook shall be performed by means of:
- check of the technical specification and other documentation relating to the ionising radiation source in order to determine whether the source is compatible with its purpose,
- check of the source installation location in order to determine whether the source, taking into account the installation location, can be used safely,
- checks whether the safety devices of the source, such as the devices for turning the source on and off, the signal warning devices and the remote control devices are functional, and
- quality control tests.

Article 4

The ionising radiation sources shall be examined on the location where they are used under regular conditions.
Mobile ionising radiation sources may be examined elsewhere and under conditions for their regular use, provided this does not represent an obstacle in the examinations.

Article 5

Ionising radiation sources shall be examined in the following deadlines:

1. after their installation and before they are put into use (acceptability test);
2. at least once a year when using the sources unless otherwise provided by the provisions of

---

(*) This Rulebook shall comply with the Council Directive 97/43/EURATOM of 30 July 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure and repealing Directive 84/466/EURATOM (CELEX number 31997L0043)

this Rulebook;
3. after each maintenance procedure and any change relevant in terms of the radiation protection and safety of the sources, but before re-usage of the sources, and
4. in time intervals recommended by the manufacturer.

Article 6

The deadlines for examining accelerators intended for radiotherapy, X-ray machines for simulation in radiotherapy and therapeutic kilovoltage X-ray machines shall be given in Appendix 1 which is a constituent part of this Rulebook.
The deadlines for examining devices with a sealed radioactive source intended for teletherapy shall be given in Table 1 of Appendix 2 which is a constituent part of this Rulebook.
The deadlines for examining calibrators and gamma cameras in nuclear medicine shall be given in Table 1 and Table 2 of Appendix 3 which is a constituent part of this Rulebook.

Article 7

Measuring patients' exposure in diagnostic and therapeutic procedures shall be performed by measuring the dose with the appropriate instruments (dosimeters, ionising chambers, etc.) or evaluating the dose in accordance with the parameters that were used in the procedure (radiation type and energy, period of exposure of the patient, amperage, projection of the scan, number of the diagnostic or therapeutic procedures, etc.).
The dose of the patient referred to in paragraph 1 of this Article in the diagnostic procedure shall be compared to the diagnostic reference levels established in Appendix 4 which is a constituent part of this Rulebook.

Article 8

Records shall be kept of patients' exposure in the diagnostic and therapeutic procedure and they shall contain the following information:
1) General information on the patient: name and surname, date and place of birth, sex, profession, date of performing the diagnostic or therapeutic procedure, type of disease;
2) Additional information on the procedure as follows:
a) diagnostic radiology:
- type of diagnostic radiological procedure;
- information on the parameters used in the diagnostic radiological procedure on the basis of which the dose of the patient or the measured dose of the patient can be assessed, as well as other information important for the procedure;
- comparison of the assessed or measured dose with the diagnostic reference levels and the measures taken for the purpose of overcoming them;
b) nuclear medicine:
- the procedure in nuclear medicine;
- the radionuclide, the type and form of the radiopharmaceutical, and
- the confirmed activity or the dose of the patient, as well as other information important for the procedure;
- comparison of the assessed or measured dose in the diagnostic procedures with the diagnostic reference levels and the measures taken for the purpose of overcoming them;
c) radiotherapy:
1. external radiotherapy:
- the procedure in radiotherapy, and
- the dose of the patient, the parameters used, as well as other information important for the procedure;
2. brachytherapy (a radioactive source implant or applicator, an additional recharging

method, etc.):

- a procedure in brachytherapy;
- a radionuclide and its chemical and physical form;
- duration of the implant, where appropriate, and
- a confirmed activity or the dose of the patient, and
- other information important for the procedure.

Article 9

Records shall be kept of the examination of ionising radiation sources.

A report shall be prepared on the basis of the information in the records referred to in paragraph 1 of this Article.

Article 10

The report referred to in Article 9 paragraph 2 of this Rulebook, depending on the ionising radiation source which it refers to, shall contain the following information:

1) the title and headquarters of the authorised expert technical service that performs the examination, person/persons that has/have performed the examinations and prepared the report;
2) title and headquarters of the legal entity;
3) date on which the examinations were performed;
4) information on the ionising radiation source being examined;
5) measuring instruments and other equipment used in the examinations;
6) a parameter being examined, results obtained, comparison of the measured values with the prescribed criteria, and
7) notes.

Article 11

A report shall be prepared of the investigation performed and the measures undertaken for optimising the diagnostic procedure when diagnostic reference levels are exceeded and it shall be submitted to the Radiation Safety Directorate.

Article 12

On the day of entry into force of this Rulebook, Article 3 of the Rulebook on the manner of keeping records of ionising radiation sources and radiation of the population and individuals exposed to ionising radiation at work (Official Gazette of the SFRY No. 40/86) and Article 37 of the Rulebook on the limits over which the population and individuals working with ionising radiation sources must not be exposed to radiation, on measuring the degree of exposure to ionising radiation of individuals working with the sources of such radiation and on checking contamination in the environment (Official Gazette of the SFRY No. 31/89), shall cease to be valid.

Article 13

This Rulebook shall enter into force on the day following that of its publication in the Official Gazette of the Republic of Macedonia.

No. 01-1057/2
7 September 2010

Director,

APPENDIX 1

Table 1: *Deadlines for examining accelerators intended for radiotherapy*

Ordinal number	Parameter	Examination deadlines
1	**Mechanical**	
1.1	Distance indicator (telemeter)	daily
1.2	Laser placement	daily
1.3	Gantry angle indicator	monthly
1.4	Collimator angle indicator	monthly
1.5	Field size indicator	monthly
1.6	Positioning of multi-leaf collimators	monthly
1.7	Blend symmetry	monthly
1.8	Indicators for positioning the treatment table	
1.8.1	Longitudinal and lateral movements	monthly
1.8.2	Vertical movement	monthly
1.8.3	Isocentric rotation	monthly
1.9.1	Light and radiation field coincidence	monthly
1.9.2	Coincidence of radiation and light field centres	monthly
1.10	Light field illumination	monthly
1.11	Fixating the handle, tube and filter	monthly
1.12	Electronic imaging device	monthly
1.13	Variation of the mechanical isocentre with rotation	
1.13.1	Collimator rotation	yearly
1.13.2	Gantry rotation	yearly
1.13.3	Treatment table rotation	yearly
1.14	Coincidence of collimator, gantry and treatment table axes with the isocentre	yearly
1.15	Coincidence of radiation and mechanical isocentre	yearly
1.16	Treatment table sag with 80 kg mass evenly distributed	yearly
2	**Dosimetry**	
2.1	Constancy of the output of photon beams	daily
2.2	Constancy of the output of electron beams	twice per week

2.3 2.3.1 2.3.2 2.3.3 2.3.4	Uniformity of radiation fields Linearity of the photon beam Symmetry of the photon beam Linearity of the electron beam Symmetry of the electron beam	 daily daily twice per week twice per week
2.4	Energy constancy	daily
2.5	Constancy of the output of the photon beam	monthly
2.6	Constancy of the output of the electron beam	monthly
2.7 2.7.1 2.7.2 2.7.3 2.7.4	Uniformity of radiation fields Linearity of the photon beam Symmetry of the photon beam Linearity of the electron beam Symmetry of the electron beam	 yearly yearly yearly yearly
2.8 2.8.1 2.8.1.1 2.8.1.2 2.8.2 2.8.2.1 2.8.2.2 2.8.2.3	Characteristics of the depth dose Photon beams Constancy of the dosimetry parameters (PDD, TAR) of the central axis Penetration quality/Quality index Electron beams Constancy of the dosimetry parameters (PDD) of the central axis Relation of the practical level with the 80% isodose level Penetration quality/Quality index	 yearly yearly yearly yearly yearly
2.9 2.9.1 2.9.2 2.9.3 2.9.4	Monitoring system / Dose monitoring: Linearity Reproducibility Proportionality Gantry angle variations	 yearly yearly yearly before putting into use and after use
3	**Safety**	
3.1	Safety switch / door interlock	daily
3.2	Audiovisual monitor	daily
3.3	Safety switch / door interlock	monthly
3.4	Emergency switch	monthly
3.5 3.4	Safety switch / handle interlock, applicators Safety light warning devices	monthly monthly

Table 2: *Deadlines for examining X-ray machines for simulation in radiotherapy*

Ordinal number	Parameter	Examination deadlines
1	**Mechanical**	
1.1	Distance indicator (telemeter)	daily
1.2	Laser placement	daily
1.3	Field size indicator	monthly
1.4	Collimator angle indicator	monthly
1.5	Gantry angle indicator	monthly
1.6	Cross centring (collimator cross-hairs)	monthly
1.7	Coincidence of radiation and light fields	monthly
1.8	Distance focus – film indicator	monthly
1.9 1.9.1 1.9.2 1.9.3	Isocentre Collimator rotation Gantry rotation Treatment table rotation	 yearly yearly yearly
1.10	Coincidence of collimator, gantry and treatment table axes with the isocentre	yearly
1.11	Coincidence of contrary radiation fields	yearly
1.12	Vertical movement of the simulation table	yearly
1.13	Simulation table sag with 80 kg mass evenly distributed	yearly
2	**Safety**	
2.1	Safety switch / door interlock	daily
2.2	Audiovisual monitor	daily
2.3	Safety switch / door interlock	monthly
2.4	Emergency switch	monthly
2.5	Safety light warning devices	monthly
2.6	Safety switch / rotation interlock	monthly

Table 3: *Deadlines for examining a computerised tomograph for simulation in radiotherapy*

Ordinal number	Parameter	Examination deadlines
1	**Mechanical**	
1.1	Placement of lasers at the CT gantry	
1.1.1	With the intersection level (scan)	once in three months
1.1.2	Parallel and normal along the laser projection	once in three months
1.2	Placement of wall lasers	
1.2.1	Distance to the scanned surface	once in three months
1.2.2	With an intersection level along the length of the laser projection	once in three months

1.3	Placement of the ceiling laser	
1.3.1	Normal at the level of intersection	once in three months
1.4	Orientation of the scanner table	
1.4.1	Normal at the level of intersection	once in three months
1.5	Reading the longitudinal position of the table	once in three months
1.6	Verification of the electron density/CT number	once in three months
1.7	Simulation table sag	once in three months
2	**Safety**	
2.1	Emergency switch	daily
2.2	Safety light warning devices	daily

Table 4: *Deadlines for examining therapeutic kilovoltage X-ray machines*

	Parameter:	Examination deadlines
1.	**Mechanical**	
1.1	Light and X-ray beam congruence	yearly
1.2	Uniformity of the field	yearly
1.3	Timer precision	yearly
1.4	Measuring the thickness of semi-thinning	yearly
2.	**Dosimetry**	
2.1	Output constancy	yearly
2.2	Output callibration	yearly
3.	**Safety**	
3.1	Safety switch / door interlock	daily
3.2	Audiovisual monitor	daily
3.3	Emergency switch	daily
3.4	Safety switch / filter interlock, applicators	daily
3.5	Safety light warning devices	daily

APPENDIX 2

Table 1: *Deadlines for examining a ^{60}Co teletherapy device*

Ordinal number	Parameter		Examination deadlines		
			Daily	Monthly	Annually
1.	**Mechanical**	Collimator rotation			**X**
		Gantry rotation			**X**
		Treatment table rotation			**X**
		Coincidence of collimator, gantry and treatment table axes with the isocentre			**X**
		Coincidence of mechanical isocentre and the radiation field			**X**
		Treatment table sag with 80 kg mass evenly distributed			**X**
		Vertical movement of treatment table			**X**
		Laser placement	**X**		
		Optical distance indicator (ODI)	**X**		
		Light and radiation field coincidence		**X**	
		Field size indicator (collimator set-up)		**X**	
		Indicator of the gantry angle and the collimator		**X**	
		Cross centring (collimator cross-hairs)		**X**	
		Light field illumination			**X**
		Fixing (blocking) wedge-shaped filters and handles		**X**	
		Check of source positioning		**X**	
2.	**Dosimetry**	Output constancy		**X**	**X**
		Output constancy vs. gantry angle		**X**	**X**
		Output constancy vs. SSDL			**X**
		Field size dependence of output constancy			**X**
		Constancy of the dosimetry parameters (PDD, TAR) of the central axis			**X**

		Constancy of the transmission factor for all standard accessories			**X**
		Constancy of the transmission factor of wedge-shaped filters			**X**
		Bean uniformity vs. gantry angle			**X**
		Timer linearity and error			**X**
		Off axis points measurements with or without wedge-shaped filters			**X**
3.	**Safety**	Safety switch / door interlock	**X**		
		Audiovisual monitor	**X**		
		Dose speed monitor in the premises	**X**		
		Emergency switch		**X**	
		Safety switch / wedge-shaped filter interlock		**X**	

APPENDIX 3

Table 1: *Deadline for examining calibrators in nuclear medicine*

Ordinal number	Parameter		Examination deadlines		
			Daily	Monthly	Annually
1.	Calibrator	Linearity		**X**	**X**
		Reproducibility		**X**	**X**
		Accuracy	**X**	**X**	**X**

Table 2: *Deadline for examining gamma cameras in nuclear medicine*

Ordinal number	Parameter		Examination deadlines		
			Daily	Monthly	Annually
1.	Gamma camera (high resolution collimator) ^{99m}Tc)	Uniformity		**X**	**X**
		Sensitivity			**X**
		Rotation centre deviation			**X**
	Multi-headed camera	Difference in the sensitivity of any two heads			**X**
		Geometry			**X**

APPENDIX 4

Diagnostic reference levels

Table 1: *Diagnostic reference levels for diagnostic radiography procedures concerning a typical adult patient*

Examination		**Entrance surface doses per image [a] (mGy)**
Lumbar spine	AP	**10**
	LAT	**30**
	LSJ	**40**
Stomach, intravenous urography and cholecystography	AP	**10**
Pelvis	AP	**10**
Coxa	AP	**10**
Thorax	PA	**0.4**
	LAT	**1.5**
Thoracic spine	AP	**7**
	LAT	**20**
Stomatological	Periapical	**7**
	AP	**5**
Head and face bones	PA	**5**
	LAT	**3**

Notes: PA: posterior-anterior projection; LAT: lateral projection; LSJ: lumbar-sacral joint projection; AP: anterior-posterior projection.

[a] In the air including dispersion. Conventional film values – screen/foil combination with relative sensitivity of 200. For film – screen/foil combination with great sensitivity (400-600), values should be reduced by a factor of 2 to 3.

Table 2: *Diagnostic reference levels for computerised tomography concerning a typical adult patient*

Examination	**Medium multi-scanning dose[†] (mGy)**
Head	**50**
Lumbar spine	**35**
Stomach	**25**

[†] Obtained from measurements of the rotation axis in water phantoms or their equivalents, 15 cm in length and 16 cm (head) and 30 cm (lumbar spine and stomach) in diameter.

Table 3: *Diagnostic reference levels for mammography procedures concerning a typical adult patient*

Medium dose of a gland after a craniocaudal projection[‡]
1 mGy (without a grid) 3 mGy (with a grid)

Table 4: *Diagnostic reference levels for a dose speed in a fluoroscopy procedures concerning a typical adult patient*

Work mode	**Entrance surface dose speeds**[a] **(mGy/min)**
Normal mode	25
High dose speed mode [b]	100

[a] In the air including dispersion.
[b] For fluoroscopy, where there is an optional high dose speed mode, such as those frequently used in intervention radiology.

[‡] Determined in a 4.5 cm compressed breast consisting of 50% glandular and 50% adipose tissue, for film-screen/foil systems and the appropriate Mo-meta Mo-filter mammographic unit.

Table 5: *Diagnostic reference levels for activities in nuclear medicine procedures concerning a typical adult patient*

Tests	Radionuclide	Chemical form	Typical maximum activity per test (MBq)
Bones			
Skeleton scan	^{99m}Tc	Phosphonate and Phosphate compounds	600
Skeleton scan with the technique of Single Photon Emission Computed Tomography (SPECT)	^{99m}Tc	Phosphonate and Phosphate compounds	800
Bone marrow scan	^{99m}Tc	Labeled colloid	400
Brain			
Brain scan (statics)	^{99m}Tc	TcO_4	500
	^{99m}Tc	Diethylenetriaminepenta-acetic acid (DTPA), Gluconate and Glucoheptonate	500
Brain scan (SPECT)	^{99m}Tc	TcO_4	800
	^{99m}Tc	DTPA, Gluconate and Glucoheptonate	800
	^{99m}Tc	Exametazime	500
Cerebral blood flow	^{133}Xe	isotonic sodium chloride solution	400
	^{99m}Tc	Hexamethyl propylene amine oxime (HM-PAO)	500
Cysternography	^{111}In	DTPA	40
Lachrymal			
Lachrymal drainage	^{99m}Tc	TcO_4 [1]	4
	^{99m}Tc	Labeled coloid	4
Thyroid			
Thyroid scan	^{99m}Tc	TcO_4	200
	^{123}I	I^-	20
Thyroid metastases (post-ablation)	^{123}I	I	400
Parathyroid gland scan	^{201}Tl	$^{201}Tl^+$,chloride	80
Lungs			
Lung ventilation scan	$^{81}Kr^m$	Gas	6000
	$^{99m}Tc^m$	DTPA-aerosol	80

Lung ventilation examination	^{133}Xe ^{127}Xe	Gas Gas	400 200
Lung perfusion scan	^{81m}Kr ^{99m}Tc	Water solution Human albumins (microaggregates and microspheres)	6000 100
Lung perfusion scan (with venography)	^{99m}Tc	Human albumins (microaggregates and microspheres)	160
Lung perfusion examination	^{133}Xe ^{127}Xe	Isotonic solution Isotonic chloride solution	200 200
Lung scan (SPECT)	^{99m}Tc	Macroaggregate albumin (MAA)	200
Liver and spleen			
Liver and spleen scan	^{99m}Tc	Labeled coloid	80
Functional biliary system scan	^{99m}Tc	Iminodiacetates and equivalent agents	150
Spleen scan	^{99m}Tc	Labelled denaturated red blood cells	100
Liver scan (SPECT)	^{99m}Tc	Labeled colloid	200
Cardiovascular system			
Radioangiocardiography	^{99m}Tc ^{99m}Tc ^{99m}Tc	TcO_4 DTPA Macroaggregated globulin 3	800 800 400
Ventriculography	^{99m}Tc	Human albumin complex	40
Heart and blood vessel scan/ Test examination	^{99m}Tc ^{99m}Tc	Human albumin complex Labeled normal red blood cells	800 800
Myocardial scan/Test examination	^{99m}Tc	Phosphonate and Phosphate compounds	600
Myocardial scan	^{99m}Tc ^{201}Tl	Isonitriles Tl^+ choloride	300 100
Myocardial scan (SPECT)	^{99m}Tc ^{99m}Tc	Phoshonate and phosphate compounds Isonitriles	800 600
Stomach, gastrointestinal tract			
Stomach/salivary glands scan	^{99m}Tc	TcO_4^-	40

Meckel's diverticulum scan	^{99m}Tc	TcO_4^-	400
Gastrointestinal bleeding	^{99m}Tc ^{99m}Tc	Labeled colloid Labeled normal red blood cells	400 400
Alimentary canal and reflux	^{99m}Tc ^{99m}Tc	Labeled colloid Non-absorbable compounds	40 40
Stomach emptying	^{99m}Tc ^{111}In ^{113m}In	Non-absorbable compounds Non-absorbable compounds Non-absorbable compounds	12 12 12
Kidneys, urinary system and adrenal glands			
Kidney scan	^{99m}Tc	Dimercaptosuccinic acid	160
Kidney scan/renography	^{99m}Tc ^{99m}Tc ^{123}I	DTPA, gluconate и glucoheptonate Macroaggregated globulin O-iodohippurate	350 100 20
Adrenal gland scan	^{75}Se	Selenorcholesterol	8
Other			
Tumour and abscess scan	^{67}Ga ^{201}Tl	Citrate Cholide	300 100
Tumour scan	^{99m}Tc	Dimercaptosuccinic acid	400
Neuroectodermal tumour scan	^{123}I ^{131}I	Meta-idio-benzyl guanidine Meta-idio-benzyl guanidine	400 20
Lymph node scan	^{99m}Tc	Labelled colloid	80
Abscess scan	^{99m}Tc ^{111}In	Exametazime labeled white cells Labelled white cells	400 20
Thrombus scan	^{111}In	Labeled platelets	20