RULEBOOK
ON APPLICATION OF IONIZING RADIATION SOURCES IN MEDICINE

I. GENERAL PROVISIONS

Article 1

This rulebook stipulates:
1. requirements for performing radiation practice or nuclear activity in medicine, as well as the way for protection of patients during medical exposure in the diagnostic or therapeutic procedure;
2. types and methods of measurements for assessment of medical exposure to ionizing radiation.

Article 2

Certain terms used in this rulebook shall have the following meanings:

1. A*gency* is a short name for the Serbian Radiation Protection and Nuclear Safety Agency;

2. e*xposure* is the process in which exposure to ionizing radiation occurs;

3. *medical radiology procedure* is every procedure relating to medical exposure;

4. c*linical audit* is a systematic examination or revision of medical radiological procedure that improves the quality of patient care through continuous surveillance of radiological practices, procedures and results, and as necessary modifications shall be made to the existing and implementation of new procedures in order to achieve the standards of good practice.
5. *clinical responsibility* is the responsibility of medical specialist for individual medical exposure, in particular: justification, optimization, clinical evaluation of the outcome, cooperation with other specialists and staff, as appropriate, regarding practical aspects, providing information, if necessary, on a previous examinations, providing existing radiological information and/or records to other medical specialists who prescribe application of radiation; giving information on the risks of ionizing radiation to patients and other individuals involved, if needed.
6. *diagnostic reference levels are* dose levels in medical radiological diagnostic or, in the case of radio-pharmaceuticals, levels of activity, for typical examinations for groups of patients of average body size or standard phantoms for equipment types described in detail. These levels shall not be exceeded when common good practice is applied when performing standard diagnostic and technical procedures;

7. *dose constraint* is a restricted expected dose of exposure from a defined source per individuals, for use at the planning stage in radiation protection when performing optimization;

8. *program of early diagnosis* in terms of this rulebook is a program of systematic examination of health of population using ionizing radiation, conducted by the ministry responsible for health;

9. *preventive health examinations* are preliminary and periodic medical examinations of workers in accordance with the regulations on safety and health at work;

10. *per caput effective dose is* the ratio between the effective dose and total of population, including both the population exposed and population not exposed to ionizing radiation;

11. *health screening* (or just screening) is a procedure with use of ionizing radiation sources for early diagnosis in population groups at risk;

12. *license holder* is a legal person that has the legal responsibility under the local law on carrying out radiation practices;

13. *individual detriments* are consequences of exposure that can be clinically observed and monitored in exposed individuals or their descendants, the appearance of which is either immediate or delayed, with a different probability of appearance;

14. *medico-legal procedure* is a procedure performed for insurance or legal purposes without a medical indication;

15. *patient dose* is the dose concerning patients or other individuals undergoing medical exposure;

16. *radio-diagnostic is in vivo* diagnostic nuclear medicine, medical diagnostic radiology and dental radiology;

17. r*adiotherapy* is the use of ionizing radiation sources, including nuclear medicine for therapeutic purposes, for the treatment of patients;

Article 3

Radioactive waste in the medical use of ionizing radiation may arise from the use of sealed or open sources of ionizing radiation as well as from the use of accelerators that produce particles of sufficiently high energies.

Holders of license to perform radiation practices in medicine referred to in paragraph 1 of this Article shall be obliged to comply with the regulations governing waste management.

Article 4

Before prescribing a program of early diagnosis, the ministry in charge of health matters shall obtain the approval from the Agency on the measures of protection against ionizing radiation required by the program.

Article 5

Holder of a license to use the ionizing radiation sources in veterinary medicine is required to:

1. implement the prescribed protection measures for occupationally exposed persons;

2. implement the prescribed protection measures for the population and environment;

3. apply the principle of justification and optimization in the process of planning application of ionizing radiation sources to animal;

4. apply the prescribed protective measures for individuals assisting in the process of application of ionizing radiation sources to the animal;

5. obtain a license from the Agency for the application of ionizing radiation sources on animals for scientific research purposes.

Article 6

Medical exposures to ionizing radiation are:

1. exposure of patients for diagnostic or therapeutic purposes;

2. exposure of workers during preventive health examinations;

3. exposure of individuals as part of the program of early diagnosis;

4. exposure of healthy individuals or patients voluntarily participating in medical, biomedical, diagnostic or therapeutic research programs;

5. exposure of individuals in the medico-legal procedures;

Medical exposures to ionizing radiation are also the exposure of individuals which knowingly and willingly (outside of their professions) assist and facilitate the exposure of patients.

Justification of exposure

Article 7

Medical exposure shall be implemented so that the total benefit to which leads, including direct medical benefit to the individual and to the society shall be greater than the possible harm to the health that such exposure can cause to the individual.

When evaluating justification the purpose and objective of the diagnostic or therapeutic procedure shall be compared; the total prospective benefit to the individual and society; harm to health that may occur and risk of available alternative techniques that can achieve the same objective without the use of ionizing radiation or by the use of small doses of ionizing radiation.

Article 8

It is particularly important that justification of any new practice that includes exposure shall be evaluated before approving its application.

Justification of existing types of practices involving medical exposure shall be revised each time when new important evidence about their effectiveness or consequences arises.

Article 9

Each individual exposure shall be justified in advance, taking into account the specific aims and specific characteristics of the exposed individual.

If a type of practice involving a medical exposure is not justified in general, a specific individual exposure of this type could be justified in special circumstances, to be evaluated on a case-by-case basis.

Article 10

The prescriber and the practitioner that approves exposure shall seek, where practicable, to obtain previous diagnostic information or medical records relevant to the planned exposure and consider these data to avoid unnecessary exposure.

Article 11

Exposure for biomedical and medical research shall be examined by an ethics committee established in accordance with the healthcare regulations.

Special attention shall be given to the justification of those medical exposures where there is no direct health benefit for the person undergoing the exposure and especially for those exposures on medico-legal grounds.

Article 12

Exposure referred to in Article 6 paragraph 1 item 3 shall show enough benefit compared to the potential detriment from a statistical point of view for an individual in the target group, but also it should be justified from the point of view of each exposed individual.

Article 13

If an exposure cannot be justified, shall be prohibited.

Optimization of exposure

Article 14

All doses occurring due to medical exposure referred to in Article 6 paragraph 1 item 1 except doses in radiotherapeutic procedures shall be kept as low as possible, at the level appropriate for obtaining diagnostic information, taking into account economic and social factors.

For all medical exposures of individuals in radiotherapeutic purposes, exposure of target tissue volume shall be individually planned, taking into account that doses of non-target volumes and tissues shall be as low as reasonably achievable and consistent with the intended radiotherapeutic purpose of the exposure.

In order to achieve optimization the national diagnostic reference levels for radio-diagnostic examinations under Article 6 paragraph 1 items 1, 2, 3 and 5, are established and used. The values of European reference levels shall be taken into account in the optimization process, where available, until the establishment of national diagnostic reference levels.

Article 15

Biomedical and medical research referred to in Article 6 paragraph 1 item 4 shall be realized in such a manner that the individuals concerned shall participate voluntarily, these individuals shall be informed about the risks of such exposure, and a dose constraint shall be established for individuals for whom no direct medical benefit is expected from such exposure.

In the case of a patient who voluntarily agrees to undergo an experimental diagnostic or therapeutic practice which is expected to bring a beneficial effect, the exposure doses shall be planned by a practitioner responsible for application of radiation sources under specific conditions applicable to the individual patient;

Article 16

Optimization of exposure shall be performed in the exposure in medico-legal procedures.

Article 17

Exposures of persons under Article 6 paragraph 1 item 4 shall be planned on the basis of the principles of justification and optimization. Authorized representatives of the body that represents the legal grounds for exposure of persons shall participate in the process of justification review.

Exposure of person under paragraph 1 this Article shall be carried out if a person signs consent for exposure.

Exposure of person under paragraph 1 of this Article shall be carried out only by the relevant license holders for corresponding radiation activity in medicine whereby they are obliged to submit to the Agency a report on conducted procedure with the relevant data upon which it is possible to estimate the exposure dose.

Article 18

The optimization process of exposure include the selection of equipment, the consistent recording and keeping of diagnostic data or therapeutic results as well as the practical aspects, quality assurance including quality control and the assessment and calculation of patient doses or activities of applied radio-pharmaceuticals, taking into account economic and social factors.

Article 19

Exposure of person under Article 6 paragraph 2 shall comply with the limits given in the rulebook on limits for exposure to ionizing radiation.

Holder of a license for the use of open radiation sources in medicine shall provide the patient or the patient's legal guardian with written instructions in order to reduce the doses to the persons in contact with the patient, as far as reasonably achievable, and to provide information on the risks of ionizing radiation.

The instructions under paragraph 1 of this Article shall be handed out before leaving the institution in which the application of open radiation sources is being performed.

Responsibility for implementation of exposure

Article 20

The medical doctor prescriber as well as practitioner who approves the medical exposure is responsible for the justification of medical exposure at their decision-making level.

Medical exposures referred to in Article 6 paragraph 1 shall be conducted under the clinical responsibility of a practitioner.

Article 21

Practitioners responsible for carrying out different types of medical exposure:

1. radiology specialist for exposure in the diagnosis and interventional radiology;
2. specialist in nuclear medicine for exposures in nuclear medicine;
3. radiology specialist or radiation therapy specialist for exposure in radiotherapy, and
4. doctor of dental medicine for exposures in dental medicine.

Practitioners responsible for carrying out medical exposure in the diagnostic radiology can be specialists in the branches of medicine not listed in paragraph 1 of this Article provided that they are trained to work with radiation sources in medical diagnostics and for implementation of radiation protection measures.

Doctor of veterinary medicine shall be responsible for the application of ionizing radiation sources in veterinary medicine.

Procedures

Article 22

Holder of a license for radiation practice in medicine shall have a written protocol for each device and for every type of standard radiological equipment.

Prescribers who prescribe medical exposure shall be familiar with a manner of prescribing and the basic criteria of medical exposure including radiation doses.

Article 23

In radiotherapeutic practices and diagnostic and therapeutic nuclear medicine, an expert in physics application in medicine shall be closely involved.

For other medical practices the license holder shall be obliged to involve experts in physics, as appropriate, for consultation on optimization, including patient dosimetry and quality assurance including quality control, and also to give advice on matters relating to radiation protection concerning medical exposure.

Clinical audit in the procedures involving medical exposure shall be carried out in accordance with national regulations.

Training

Article 24

Medical doctors responsible for the application of ionizing radiation sources in medicine, except with a specialization in radiology, nuclear medicine and radiotherapy are required to obtain a proof of additional training to work with the corresponding sources of ionizing radiation.

All persons occupationally exposed to ionizing radiation in the medical practice of ionizing radiation shall be trained to implement radiation protection measures and shall undergo periodic renewal of knowledge in accordance with the regulations.

Medical exposures of special importance

Article 25

Holder of a license for radiation practice of medical exposure shall be required to adjust the equipment and procedures to the requirements of special medical exposure: exposure of children, as part of a program of early diagnosis and exposure involving high doses to the patient such as interventional radiology, computed tomography or radiotherapy.

Protection of special groups

Article 26

The medical doctor prescriber and doctor who approves medical exposure shall ask, if relevant for the exposure, whether a person is pregnant or breast feeding.

If pregnancy cannot be excluded, depending on the type of medical exposure, in particular if abdominal and pelvic regions are involved, special attention shall be given to the justification, particularly the urgency, and to the optimization of the medical exposure taking into account the exposure both of the expectant mother and the unborn child.

In the case of breastfeeding females patients in nuclear medicine, depending on the type of medical examination or treatment, special attention shall be given to the justification, particularly the urgency, and to the optimization of the medical exposure, taking into account the exposure for both the mother and the child.

Without prejudice to paragraph 2 and paragraph 3 of this Article, any measure contributing to increasing the awareness of women subject to this Article, such as public notices in appropriate places, could be helpful.

Potential exposure

Article 27

Holder of a license for radiation practice in medicine shall ensure that all reasonable steps to reduce the probability and the magnitude of accidental or unintended doses to patient from radiological practices are taken, taking into account economic and social factors.

The main emphasis in accident prevention should be on the equipment and procedures in radiotherapy, but some attention should be paid to accidents with diagnostic equipment.

II.CONDITIONS FOR PERFORMANCE OF RADIATION PRACTICE IN MEDICINE AND WAYS OF PATIENTS PROTECTION

X-ray diagnostics and interventional radiology

Article 28

Devices for diagnostic and interventional radiology can be stationary and mobile X-ray devices for imaging or illumination, devices for diagnostics in dentistry, combined imaging and illumination devices, for computed tomography devices and other diagnostic devices that use X-ray radiation.

Devices for diagnostic and interventional radiology are usually used in special premises designed for that purpose (diagnostic area).The exception is a use of such equipment during operations or for immobile patients in hospital bed, when portable X-ray devices shall be used.

In one diagnostic area only one radiological procedure can be carried out at time.

If there are several devices installed in the room, simultaneous start up function of two or more devices shall be disabled by suitable voltage control.

Entrances into the diagnostic area shall be marked with a radioactivity warning sign. If direct control of the entrance to the diagnostic area, is not possible then it should be protected by blocking the entrance (locking during diagnostic procedure practice, signal light, etc).

Control panel of the device shall be positioned so that the operator is able to see the patient at any time. If not, the video surveillance and intercom connection shall be running.

Article 29

All persons who are in controlled zone shall use the protective equipment marked with data on the protective power (protective lead equivalent).

The type of protective equipment, protective power and ways of use shall be described in the instructions for every type of exposure.

Article 30

Protective equipment for patient shall contain information on its protective power.

The manner of application of protective equipment for patient shall be described in the instructions for every type of exposure where the application of protective equipment is obligatory for the patient.

Article 31

Persons that perform X-ray diagnostic procedure shall not be exposed to the X-ray beams, and shall not hold people undergoing the illumination procedure or imaging and shall not hold film cassettes during imaging.

Persons who assist the immobile patients and the elderly persons shall use protective equipment whose protective power is at least 0.25 mm thick lead.

Persons who hold children during the imaging and in such a way expose parts of their bodies to the primary X-ray beam, shall use special protective screens with the equipment for fixing child. The protective power of such screens shall be at least 1 mm thick lead.

Article 32

When using X-rays for tooth imaging patients shall be protected by the protective aprons or shields with protective power of at least 0.25 mm thick lead. Aprons and shields shall be of such a size and shape to protect during imaging of patient's thyroid, sternum and gonads.

Distance focus-patient's skin (or focus - carrier of a patient) under conditions of illumination and imaging shall be in accordance with the applicable standard.

The distance between the focus and patient's skin shall not be less than 150mm in the X-ray devices for panoramic jaw imaging and 100mm in intraoral X-ray imagining machine.

Article 33

When using films in the X-ray diagnostics the application of amplifying foils based on the rare soils and films of good quality shall be required.

Article 34

A prominent place on the X-ray tube housing shall be marked with a tube serial number and a focus size.

Leaking radiation of X-ray tube at a distance of 1m shall not exceed 1mGy/h.

Article 35

The X-ray radiation in diagnostic and interventional radiology shall be filtered and all filters shall be marked in such a way to make possible to determine the overall filtration of the useful beam.

Article 36

The X-ray device for imaging shall be equipped with an indicator light. The difference between the irradiated and illuminated field shall not exceed 2%, except in the X-ray devices for imaging children where shall not exceed 1%.

Radiotherapy

Article 37

Therapeutic dose shall be determined with the measurement uncertainty better than 5% and homogeneously assigned to the tumour volume.

The therapeutic dose shall have prior dosimetric verification according to the relevant metrology regulations in the phantom under conditions simulating irradiation of the patient.

Article 38

Preparation and application of sealed sources of ionizing radiation (applicators) for interstitial, intracavital and surface radiotherapy shall be performed in separate rooms provided for such purposes, with the mandatory use of mobile protective screens, manipulators, protective containers and other.

Irradiation of patients using ionizing radiation sources referred to in paragraph 1 of this Article shall be carried out in the separate rooms and protective boxes.

After irradiation of a patient, the dosimetric control shall be performed to determine if the source of radiation remained in the patient.

Nuclear medicine

Article 39

Patients waiting for examination or therapy applying radiopharmaceutical products shall be placed in the separate waiting rooms, separated from patients who have already applied radiopharmaceuticals.

Application of radiopharmaceutical products in women during breastfeeding shall be approved only if there are vital indications. A woman shall be provided with instructions to stop breastfeeding for at least fifteen days before the application of radioactive iodine or other radiopharmaceutical with a similar metabolism. A patient shall be provided with written instructions after such intervention, in addition to other information on protective measures, shall be indicated the duration of temporary interruption of breastfeeding determined according to the type and activity of the applied radiopharmaceutical, and at least as defined in Table 1 set out in Appendix 1 to this rulebook constituting its integral part.

Application of the radiopharmaceutical products in children shall be strictly medically indicated. Activity of a radiopharmaceutical product shall be adjusted in relation to body weight and body surface of a child, as well as in relation to other medically relevant characteristics.

Article 40

Activity of radiopharmaceutical products for therapy shall be determined on the basis of calculation of the required therapeutic dose of radiation and measurement of activities.

Measuring uncertainty in measurements of radiopharmaceutical activity shall not exceed 20%.

Article 41

The patient shall not be released from the hospital in case that:

1. any member of the public will receive an effective dose of exceeding 0.3 mSv due to radiopharmaceuticals in the body of a released patient;

2. members of a patient's household who voluntarily take care of his/her health, receive an effective dose exceeding 5 mSv due to radiopharmaceuticals in the body and of a released patient.

3. other household members of a patient receive an effective dose exceeding 1 mSv due to radiopharmaceuticals in the body of the released patient.

Article 42

During release of a patient from the hospital upon therapeutic or diagnostic procedure, the patient shall be provided with instructions on behaviour to prevent the harmful effects to the persons with who the patient comes into contact, due to radiopharmaceuticals that entered in the patient's body.

A patient who has been administered less than 200 MBq of one of the following radiopharmaceuticals ^{32}P, ^{90}Y, ^{186}Re, ^{153}Sm or ^{89}Sr can be released without prescribing specific restrictive measures of behaviour.

Article 43

Therapeutic use of radiopharmaceutical products shall be carried out in ambulatory settings and in hospital.

If the activity of the applied radiopharmaceutical product is greater than 400 MBq ^{131}I, the therapy shall be performed in the hospital, in separate rooms designed as controlled radiation zone. The patient shall be released from the hospital when the ^{131}I activity drops below 400 MBq.

Instructions on the behaviour of a patient to whom the radioactive ^{131}I was applied when released from the hospital shall provide, among other things, the recommendations on time intervals spent in the close proximity of other persons listed in Table 2 in Appendix 1 to this rulebook constituting an integral part thereof.

Article 44

If the condition of a patient who is kept in the hospital after application of radiopharmaceutical gets worse, the staff taking care of him/her shall be provided with accurate and clear instructions on radiation protection.

If a patient needs surgery under paragraph 1 of this Article, the activity in the patient shall be evaluated, and together with the person responsible for radiation protection, the protective measures for people who come into contact with the patient, shall be proposed.

Article 45

When releasing a patient from hospital his clothing and personal items shall be tested for contamination and, as necessary, shall be conducted a decontamination of such items or shall be retained.

After release of a patient who has received the radiopharmaceutical it is necessary to perform measurements in the hospital room and perform decontamination, as appropriate.

Article 46

Autopsy and cremation of deceased persons who received, when they were still alive, radiopharmaceutical products for therapeutic purposes, shall be made only when the activities of administered radionuclides in the body drop below the value given in Table 3 set out in Appendix 1 to this rulebook constituting its integral part.

Exceptionally, where there are reasonable grounds, autopsy of the person pursuant to paragraph 1 of this Article shall also be performed when the activity of radiopharmaceuticals exceeds the prescribed values, with the use of protective equipment and other measures, according to the instructions of the person responsible for the implementation of radiation protection measures.

III.TYPES AND METHODS FOR MEASUREMENT TO EVALUATE LEVEL OF MEDICAL EXPOSURE TO IONIZING RADIATION

Article 47

Assessment of the level of medical exposure shall set out as follows:

1. analysis of trends in relation to the annual collective dose and average annual per caput dose from medical exposure;

2. determining the average annual dose from medical exposure per person;

3. determining the contribution of specific procedures to the total collective dose for the population;

4. determining the relation between the frequency of specific procedures, typical dose for a patient and the corresponding contribution to the collective dose;

5. identification of regional variations in terms of frequency of examinations and typical doses for patients;

6. comparison of frequency and annual *per caput* dose from medical exposures in different countries, and

7. comparison of the contribution from medical exposures with other sources of radiation for the population.

Article 48

Assessment of the level of medical exposure to ionizing radiation shall be performed in the following stages: planning studies, pilot projects, dose measurements campaigns, collecting data on the frequency of certain procedures, data processing, data analysis, formulation of conclusions and recommendations, publication and dissemination of the results.

The team that determines the levels of medical exposure to ionizing radiation shall be composed of experts from the following areas: radiology and nuclear medicine, dosimetry of ionizing radiation, public health, statistics and management.

Article 49

Dose measurements for patients shall be conducted to assess typical effective dose for each type of procedure in the country, based on the results of measurements and calculations in the selected sample of health facilities.

The effective dose shall not be used for evaluation of radiation risk for an individual patient.

Article 50

Assessment of the level of medical exposure to ionizing radiation for the population shall be carried out at regular intervals, based on: analysis of the frequency of certain radiological examinations in five-year intervals and typical dose measurements for patients in five-year intervals.

Both analyses shall be performed simultaneously or in close time interval.

Article 51

Assessment of the level of medical exposure to ionizing radiation shall be based on the analysis of diagnostic and interventional procedures that significantly contribute to the collective dose for the population.

List of procedures is given in Tables 1-4 in Appendix 2 to this rulebook and form its integral part.

Article 52

Dose assessment for patients and population from nuclear medicine practice shall be based on collecting data on the number of procedures in a calendar year, the frequency of certain procedures in nuclear medicine, type of radiopharmaceuticals used for each type of procedure for the average adult patient and the activity of the radionuclide used for each type of procedure for the average adult patient.

Article 53

Patient's exposure in the radiation therapy in terms of this rulebook shall not contribute to the collective dose of the population and shall not be included in the study for the assessment of population dose from medical exposure.

Article 54

Acceptance test and periodic examination of X-ray devices, accelerators and other devices that produce ionizing radiation in medicine and dental medicine shall include the procedures set out in Appendix 3 to this rulebook forming its integral part.

Article 55

This rulebook shall enter into force on the eighth day following its publication in the Official Gazette of the Republic of Serbia.

APPENDIX 1

Table 1 The shortest period of temporary interruption of breastfeeding in the case of application of radiopharmaceuticals in female during breastfeeding

Radionuclide	period
^{131}I	3 weeks
^{201}Tl	3 weeks
^{67}Ga	3 weeks
In^{111}	3 weeks
^{123}I	2 days

^{99m}Tc	12 hours

Table 2 Instructions on behaviour of the patient after release from hospital

Distance maintenance	Applied ^{131}I activity (MBq)		
	30	200	400
	Duration of ban (number of days)		
At a distance less than 1m from children under 3 years	1	15	21
At a distance less than 1m from children 3-5 years old	-	11	16
At a distance less than 1m from children older than 5 years	-	5	11
Avoid contact with adults	-	-	-

Table 3 Threshold activities of radionuclides in the body of a deceased, below which the autopsy and cremation can be performed without the use of special radiation protective measures

Radionuclide	Limit value of activities		
	for burial [MBq]	for autopsy [MBq]	for cremation [MBq]
^{131}I	400	10	400
^{125}I	4000	40	-
^{90}Y	2000	200	70
^{198}Au	400	400	100
^{32}P	2000	100	30
^{89}Sr	2000	50	20

APPENDIX 2

List of diagnostic and interventional procedures that significantly contributes to the collective dose for the population

Table 1 Procedures in radiography without the use of contrast

Type of procedure	Specific examinations	Typical techniques

	included within the procedure type	(Radiographic projections)
Lungs	Lungs and ribs	PA LAT
Cervical spine	Cervical spine	AP and LAT / oblique projection
Thoracic spine	Thoracic spine	AP and LAT
Lumbar spine	Lumbar spine Lumbo-sacral joint Sacroiliac joint Sacrum and coccyx	AP and LAT
Mammography	Symptomatic examinations Screening	MLO and/or CC projections of one or both breasts
Abdomen	Abdomen	AP
Pelvis and hips	Pelvis (One or both hips)	AP or AP and LAT

AP: Anterior-posterior, PA: Posterior-anterior; LAT: Lateral; MLO: mediolateral
CC: craniocaudal

Table 2 Procedures in interventional radiology

Type of procedure	Specific examinations included in procedure type	Typical techniques
Coronary Angioplasty (RTS)	PTCA	Access to catheters, dilation, stenting

Table 3 Procedures in radiography/fluoroscopy with the use of contrast

Type of procedure	Specific examinations included in procedure type	Typical techniques
The upper part of gastrointestinal tract	Stomach and duodenum	2-3 min fluoroscopy 5-20 radiography
Irrigography	Colon	~ 5 min fluoroscopy 5-10 radiography
Intestinal passage	Small intestine	~ 5 min fluoroscopy 5-20 radiography
Intravenous urography	Kidneys, ureter and bladder	Several AP radiography after application of iodine-based contrast
Cardiac angiography	Coronary angiography Left and right ventriculography	~ 5 min fluoroscopy Several hundred images

Table 4 Procedures in computed tomography (CT)

Type of procedure	Specific examinations included in procedure type	Typical techniques
CT of head	Head, brain, facial bones	With or without contrast
CT of neck	Soft tissue in the neck, cervical spine	Without contrast
CT lungs	Lung /thorax	With or without contrast Standard or high resolution
CT spine	CT lumbosacral spine	With or without contrast
CT abdomen	Abdominal organs	With or without contrast
CT pelvis	Pelvic bone and/or organs	With or without contrast
CT trunk	CT of lungs, abdomen and pelvis CT of thoracic/abdominal aorta	With or without contrast With contrast

APPENDIX 3

Acceptance and periodic examinations of ionizing radiation sources in medical applications

Acceptance and periodic examination of X-ray devices, accelerators and other devices that produce ionizing radiation in medicine and dental medicine include the following:

1. checking of data about the X-ray device or accelerator;
2. visual inspection of premises where the X-ray device or accelerator is placed in terms of safety of use;
3. examinations of functional accuracy of safety devices of the X-ray devices or accelerators and turn on/off function, signalling devices and remote control, use in accordance with the manufacturer's specifications and
4. examination of certain parameters of an X-ray device or accelerator in order to determine whether the satisfying quality of diagnostic information is provided or therapeutic effect with minimal exposure to the patient. These parameters are given in Table 1 (X-ray device for imaging), Table 2 (X-ray mammography device), Table 3 (systems for film development), Table 4 (systems for film view), Table 5 (X-ray devices for illumination), Table 6 (computed tomography devices), Table 7 (dental X-ray devices) and Table 8 (accelerators in radiotherapy) in this Appendix.

Acceptance and periodic examination of sealed radioactive sources in medicine include the following:

1. verification of information on the sealed radioactive source and on the unit in which it is embedded;

2. visual inspection to check if the sealed radioactive sources and a device containing a sealed radioactive source are located so that can be safely used;

3. functional examination of safety devices for turn on/off functions of a machine with sealed radioactive source, accuracy of signalling devices and remote control, possibility of use in accordance with the manufacturer's specifications;

4. examination of certain parameters of sealed radioactive sources and devices containing a sealed radioactive source in order to determine whether a proper quality is provided as prescribed for a particular type and purpose of sealed radioactive source. These parameters are given in Table 9 to this Appendix.

Acceptance and periodic examination of open radioactive sources in medicine include the following:

1. visual review of the area in which the open radioactive source is being prepared, used or stored as appropriate for given purpose;
2. contamination check of persons, objects, work surfaces, air, floors and walls;
3. examination of certain parameters and criteria of devices and gauges to be used for work with the open radioactive sources in order to determine whether the required quality is met. The parameters to be tested for calibration and gamma cameras, and time intervals for testing are given in Table 10 to this Appendix.

Table 1 Examination parameters, allowed tolerance limits and examination intervals for X-ray imaging machine

Ordinal number	Quantity tested	Parameter tested	Allowed tolerance limits/reference value	Testing periods
1.	X-ray tube voltage	Repeatability	± 10°	Annually
		Accuracy	± 10% ili ±10 kV	Annually
2.	Exposure time	Accuracy	t≥0.1 s: ± 10% t<0.1 s: ± 30%	Annually
3.	Radiation output at a distance of 1 m from X-ray tube focus	Value	≥ 25 Gy/mAs for a voltage of 80 kV and a total filtration of 2.5 mm Al	Annually
		Repeatability	± 10%	Annually
		Accuracy	± 10%	Annually
4.	Attenuation half-thickness		≥ 2,3 mmAl for voltage of 80 kV	Annually
5.	Coordination of light and radiation field		≤ 2% of distance focus-test object	Monthly
6.	Position of central ray		≤ 1% of distance focus-test object	Monthly
7.	Limiting resolution	Without foil	≥ 2,0 lp/mm	Annually
		With film-foil	≥ 2,8 lp/mm	

		S=200		
8.	Focus size	Little focus	+50% of the nominal size	Acceptance testing
		Large focus	+50% of the nominal size	

Table 2 Examination parameters, allowed tolerance limits and examination intervals of X-ray equipment for mammography

Ordinal number	Quantity tested	Parameter tested	Allowed tolerance limits/reference value	Probation periods
1.	X-ray tube voltage	Repeatability	± 5%	SA/A[1]
		Accuracy	± 5% or ± 1 kV	SA/A
2.	Exposure time	Accuracy	± 5%	SA/A
3.	Radiation output at a distance of 1 m from X-ray tube focus	Value	> 30 µGy/mAs at 1 m, 28 kV, Mo/Mo	SA/A
		Repeatability	± 5%	SA/A
		Accuracy	± 5%	SA/A
4.	Attenuation half-thickness		≥0.31 mm Al	SA/A
5.	Force of compression		130-200 N	SA/A
6.	Distance focus-image receiver		600 mm	SA/A
7.	Coincidence of light and radiation field		< 5 mm on the side of chest wall	SA/A
8.	Mean glandular dose for standard breast		≤2.5 mGy	SA/A
9.	Optical density		1.5-1.9	Daily
10.	Automatic exposure control		±0.20 compared to baseline values or 1.3-2,1 (compensation for different thickness)	SA/A
			± 10% compared to baseline values mAs (constant)	Weekly
11.	Limiting resolution		≥12 lp/mm	SA/A
12.	Limiting contrast		≤ 1.2% for details 5-6 mm	SA/A
			≤ 5% for detaisl 0.5mm	SA/A
			≤ 8% for details 0.25mm	
13.	Focus size	0.3 mm	Width ≤0.45 mm, length ≤0.65 mm	Acceptance testing
		0.4 mm	width of ≤0.60 mm,	

			length ≤0.85 mm	

[1] SA/A - Semi-annually for mammograms used for systematic imaging or annually for other.

Table 3 Examination parameters, allowed tolerance limits and periods for testing of systems for film development

Ordinal number	Quantity tested	Parameter tested	Allowed tolerance limits	Probation periods
1.	Darkroom testing	Optical density of non-exposed developed film after 60s	≤ 0.05	Annually
2.	Optical density	Reference value 24h after preparation of new chemicals	± 0.30	Daily
3.	Primary unexposed film blackening	Optical density	≤ 0.25	Weekly
4.	Sensitometry	MGrad	3.0-4.0	Weekly
		Grad1/2	3.5-5.0	Weekly
		Repeatability	±10%	Weekly
5.	Temperature of developer		± 1 ° C in relation to value recommended by manufacturer	Weekly

Quantities given in Table 3 can be checked in case of different values of the given parameters if it is in accordance with the manufacturer's recommendations.
Mean gradient (MGrad) - a measure of contrast, corresponds to the gradient of the sensisometric curve between points D = $_{2\ min}$ OD and +2.00 D OD $_{1}$ = +0.25 $_{min.}$
Central gradient (Grad1 / 2) - a measure of contrast, corresponds to the gradient of sensitometric curve between points D = $_{2\ min}$ OD and +2.00 D OD $_{1}$ = +1.00 $_{min.}$

Table 4 Examination parameters, allowed tolerance limits and examination intervals for system of film reviewing

Ordinal number	Quantity tested	Parameter tested	Allowed tolerance limits	Probation periods
1	Brightness	value	1500-3000 cd/m^2 3000-6000 cd/m^2 (mammography)	Semi-annually or annually
2	Brightness	homogeneity	±30%	Semi-annually or annually

3	Brightness (ambient light)	value	≤ 50 lux at a distance of 1m	Semi-annually or annually

Table 5 Examination parameters, allowed tolerance limits and examination intervals for X-ray devices for illumination

Ordinal number	quantity tested	Parameter tested	Allowed tolerance limits	Probation period
1.	X-ray tube voltage	Repeatability	± 10%	Annually
		Accuracy	± 10%	Annually
2.	Exposure time	Accuracy	± 10%	Annually
3.	Maximum volume of dose output [1]	Normal volume of dose output	≤25 mGy/min	Annually
		Large volume of dose output	≤100 mGy/min	Annually
4.	Attenuation half-thickness		≥ 2.3 mmAl voltage of 80 kV	Annually
5.	Coincidence of light and exposure field		≤ 2% of distance focus-input image intensifiers	Annually
6.	Position of central ray		≤ 1% of distance focus-input image intensifiers	Annually
7.	Limiting resolution		36-40 cm: ≥0.7 lp/mm 30-35 cm: ≥0.8 lp/mm 20-24 cm: ≥0.9 lp/mm 15-19 cm: ≥1.25 lp/mm	Annually
8.	Threshold contrast		≤4%	Annually
9.	Air kerma at the input surface of the image amplifier		≤ 1 μGy/s (without grid, for phantom thickness of 20cm diameter of field 25 cm)	Annually

Table 6 examination parameters, allowed tolerance limits and examination intervals for X-ray equipment for computed tomography

Ordinal number	quantity tested	Parameter tested	Allowed tolerance limits	Probation periods
1.	X-ray tube voltage	Repeatability	± 10%	Annually
		Accuracy	± 10%	Annually
2.	Linearity CT no.	Water: $_{Water}$ CT = 0	± 4 CT	Monthly
		Air $_{air}$ CT = 1000	± 10 CT	Monthly

3.	Homogeneity		± 2 CT	Daily
4.	Noise		± 0.2% CT or 10%	Annually
5.	Slice thickness	s ≤ 2 mm	± 50%	Annually
		2 mm < s < 8 mm	± 25%	Annually
		s ≥ 8 mm	± 10%	Annually
6.	Decomposition lp/cm- MTF		50%	Annually
			10%	Annually
			2%	Annually
7.	CT dose index-CTDI	In the middle of phantom	Acceptance testing	Annually
		up		
		down		
		left		
		right		
8.	Positioning of patient's bed under load of 70 kg	Deviation in the longitudinal direction when moving bed for 30 mm	± 2 mm	Annually
		Deviation to move forward by 30 mm and back to the beginning	± 2 mm	Annually

Table 7.examination parameters, allowed tolerance limits and examination intervals for dental X-ray devices

Ordinal number	quantity tested	Parameter tested	Allowed tolerance limits	Probation periods
1.	X-ray tube voltage	Repeatability	± 10%	Annually
		Accuracy	± 10%	Annually
2.	Exposure time	Repeatability	± 10%	Annually
		Accuracy	± 10%	Annually
		Linearity	± 10%	Annually
3.	Output dose at the tube top	Repeatability	± 10%	Annually
		Accuracy	± 10%	Annually
4.	Attenuation half-thickness	For voltage <70 kV	≥ 1.5 mmAl	Annually
		For voltage> 70 kV	≥ 2.5 mmAl	Annually
5.	Field quantity at the tube top [1]		N ≤ 6 cm	Annually

In dental X-ray devices for panoramic imaging the quantity under number 5 shall not be measured.

Table 8.Examination parameters, allowed tolerance limits and examination intervals for accelerators in radiotherapy

Ordinal number	quantity tested	Parameter tested		Allowed tolerance limits	Frequency of testing		
					Daily	Monthly	Annually
1.	MECHANICAL ACCURACY	Angle		± 1º	X	X	X
		Collimator angle		± 1 º		X	X
		Optical distance indicator		± 2 mm		X	X
		Field size indicators	10 x 10 cm	± 2 mm		X	X
			20 x 20 cm	± 2 mm		X	X
			30 x 15 cm	± 2 mm		X	X
			30 x 15 cm	± 2 mm		X	X
		Stability of indicator section with rotating collimator		1 mm half-meas.		X	X
		Coincidence with laser isocentre		± 2 mm form isocentre for each laser		X	X
		Position of patient brackets	Angle	± 1º		X	X
			Height of patient brackets	± 2 mm		X	
2.	RADIATION	Permanence of output beam of high-energy photons		3% of the reference value		X	X
		The permanence of output beam of low energy photons		3% of the reference value		X	X
		Permanence of one output beam of electrons (every day other)		3% of the reference value		X	X
		Correct operation of angular therapy functions		According to the reference values of manufacturer			X
		Symmetry /flatness	0º	± 2.5% of the reference value			X
			90º				
			180º				

			270º				
		Coincidence of light and radiation field (10x10 cm)		± 2 mm from the edge of light field		X	X
		Centering of the light field and radiation field (10x10cm)		± 2 mm from the center of light field		X	X

Table 9. Examination parameters, allowed tolerance limits and examination intervals of a devices with ^{60} Co for external radiation

Ordinal number	quantity tested	Parameter tested	Allowed tolerance limits	The frequency of testing		
				Daily	Monthly	Per year
1.	MECHANICAL ACCURACY	Isocentre collimator rotation	2 mm diameter		X	X
		Isocenter rotation gentry	3 mm diameter		X	X
		Izocenter rotation of patient table	2 mm diameter		X	X
		Matching of mechanical isocenter: screen, gentry and patient table	2 mm diameter		X	X
		Matching of mechanical isocenter and isocenter of radiation field	2 mm diameter	X	X	X
		Coincidence of laser with isocentre	± 2 mm from isocentre Xor each laser		X	X
2.	RADIATION	Permanence of output beam in izocentre	2% of the reference value		X	X
		Permanence of	2% of the		X	X

		output beam compared to the angle gentry	reference value					
		Accuracy Timer	1		X	X		
		Coincidence of light field and radiation field (10x10 cm)	± 2 mm from the edge of light field				X	X
		Centering of light field and radiation field (10 x 10 cm)	± 2 mm from the center point of light field				X	X

Table 10. Examination parameters, allowed tolerance limits and examination intervals for devices used in nuclear medicine

Ordinal number	Device under test	Parameter tested	Allowed tolerance limits	Frequency of testing		
				Daily	Monthly	Annually
1.	Calibrator of activities	Accuracy	± 5%	X	X	X
		Relative response to the reference source	± 2 – 5 %		X	X
		Linearity of response	± 5%		X	X
		Repeatability	± 5%		X	X
		Geometry	± 2%			X
2.	Gamma camera	Uniformity	± 6 – 7%		X	X
		Linearity	Visually	X	X	X
		Relative sensitivity	± 10%			X
		Energy resolution	A minimum of 50 channels per XWHM			X
		Spatial resolution	According to the reference values		X	X