**RULES ON THE CRITERIA OF USING IONISING RADIATION SOURCES FOR MEDICAL PURPOSES AND PRACTICES INVLOVING NON-MEDICAL IMAGING EXPOSURE**

**(SV3)**

**UNOFFICIAL TRANSLATION**

*Prepared by the Slovenian Nuclear Safety Administration in December 2018.*

*The official text of these Rules is located on the pages of* [*the Legal Information System*](http://www.pisrs.si/Pis.web/pregledPredpisa?id=PRAV13401)*.*

***WARNING****: The unofficial text of this Act is just an informative work tool, for which the Slovenian Nuclear Safety Administration does not guarantee.*

Based on the fourth paragraph of Article 34, tenth paragraph of Article 75, eighth paragraph of Article 76, fourth paragraph of Article 77, sixth paragraph of Article 81 and third paragraph of Article 83 of the Ionising Radiation Protection and Nuclear Safety Act (Official Gazette of the Republic of Slovenia, No. 76/17) the Minister of Health hereby issues the

# RULES

**on the criteria of using ionising radiation sources for medical purposes and practices involving non-medical imaging exposure**

1. **GENERAL PROVISIONS**

**Article 1** **(Content)**

These Rules in accordance with Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom (OJ L 13, 17. 1. 2014, p. 1), last amended with Corrigendum (OJ L 72, 17. 3. 2016, p. 69) govern:

* + the exposure of patients as part of their own medical diagnosis or treatment,
	+ the exposure of individuals as part of occupational health surveillance,
	+ the exposure of individuals as part of health screening programmes,
	+ the exposure of healthy individuals or patients voluntarily participating in medical or biomedical, diagnostic or therapeutic, research programmes,
	+ the exposure of carers and
	+ the exposure of individuals for non-medical imaging purposes.

# Article 2 (Definitions)

The definitions, used in these Rules, have the following meaning:

1. Dosimetrist is a radiological engineer with special knowledge about the quality of radiological procedures in a particular field (diagnostic and interventional radiology, radiotherapy or nuclear medicine).
2. Interventional radiological procedure means the use of X-ray imaging techniques to facilitate the introduction and guidance of devices in the body for diagnostic or treatment purposes.
3. The carrying out of the radiological procedure is the physical conduct of the radiological procedure and any supporting aspects including handling and use of radiological equipment, and the assessment of technical and physical parameters, including radiation doses, calibration and maintenance of equipment, preparation and administration of radio-pharmaceuticals, and image processing.
4. A useful beam of radiation is a bundle that is directed through the aperture system and is intended for x-ray imaging or fluoroscopy of objects or patients or the treatment of patients. A cross-section of a useful beam is the useful radiation field.
5. The referred person is a patient, or other individual sent for a radiological procedure.
6. Carers are individuals, knowingly and willingly incurring exposure to ionising radiation by helping, other than as part of their occupation, to care and comfort of patients and other individuals undergoing medical exposure.
7. The irradiation of the patient is the dose of ionising radiation received by a patient or other person exposed to ionising radiation for medical purposes.
8. Occupational health surveillance is a preventive medical examination of specific categories of workers exposed to the effects of dangerous environmental factors.
9. Health screening means a procedure using medical radiological installations for early diagnosis in population groups at risk.
10. Radiodiagnostic means pertaining to in-vivo diagnostic nuclear medicine, medical diagnostic radiology using ionising radiation, and dental radiology.
11. Radiotherapeutic means pertaining to radiotherapy, including nuclear medicine for therapeutic purposes.
12. X-ray radiation encompasses x-ray diagnostics and interventional procedures using x- ray light.
13. Imaging detector is the radiation detector for recording the information needed for producing the image.
14. The specific exposure dose is the ratio between the absorbed dose and the streamed current through the tube of the X-ray device at a certain distance from the tube.
15. Individual detriment is clinically observable deleterious effects that are expressed in individuals or their descendants, the appearance of which is either immediate or delayed. In the case of stochastic effects of radiation that can occur only after a certain time, the damage is expressed with the likelihood of occurrence of these effects.
16. Practitioner responsible for radiology procedure is a medical practitioner or a dental health professional, who is entitled to take clinical responsibility for an individual medical exposure.

# THE PRINCIPLES OF THE IONISING RADIATION PROTECTION OF PATIENTS AND OTHER INDIVIDUALS SUBJECT TO EXPOSURE FOR MEDICAL PURPOSES

**Article 3**

**(Justification of a radiological exposure)**

1. The radiological procedure is justified, when the total anticipated benefit due to a diagnostic or therapeutic procedure, including the direct health benefits to an individual and the benefits to society, is greater than the risks or the detriment that the exposure might cause to an individual.
2. In the justification assessment, the following must be considered:
	* the purpose and objectives of the radiology procedure;
	* the expected benefits to health and well-being of an individual and the benefits to society;
	* the individual detriment that the exposure might cause;
	* the efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionising radiation.

# Article 4(The justification assessment)

1. All new types of radiological procedures shall be justified in advance before being adopted in practice.
2. Whenever new, relevant evidence of the efficacy or consequences that can be caused by radiological interventions in practice, their justification must be reassessed.
3. The justification should be assessed with particular care in cases where there is no direct benefit to the health of exposed persons in interventions carried out for non-medical indications.
4. The justification of radiological interventions carried out in the framework of the screening programme must be examined and approved by the medical council, considering the opinion of the authority responsible for radiation protection.
5. Any medical radiological procedure on an asymptomatic individual, to be performed for the early detection of disease, shall be part of a health screening programme. Otherwise, the justification assessment of the procedure for that individual shall be prepared by the medical practitioner, in consultation with the referrer. In doing so, the guidelines of professional medical societies and the authority competent for radiation protection must be considered. It also must be ensured that the patient or legal guardian is provided with adequate information relating to the benefits and risks associated with the medical exposure.
6. Medical exposure for medical or biomedical research is examined by the Commission of the Republic of Slovenia for Medical Ethics, considering the opinion of the body responsible for radiation protection.
7. For each individual radiological procedure, the eligibility assessment shall be carried out before the intervention is carried out, considering the specific objectives of the exposure and the characteristics of the individual involved.
8. If a particular type of radiological procedure is generally not justified, it may be justified in specific circumstances for a given individual, but it must be assessed and documented on a case-by-case basis.

# Article 5 (Optimization)

1. All doses due to medical exposure for radiological purposes except radiotherapeutic procedures shall be kept as low as reasonably achievable consistent with obtaining the required diagnostic information, considering economic and social factors.
2. The irradiation of clinical volumes in radiotherapy must be planned for each patient separately, and the irradiation should be adequately verified. The irradiation of organs and tissues outside clinical volumes should be as low as can reasonably be achieved while considering the expected goals of the radiotherapeutic procedure. Radiation therapy planning is the responsibility of an authorised medical physics expert.
3. The practitioner responsible for radiology procedure, the authorised medical physics expert and the provider of a radiation procedure shall participate in the optimisation of the radiological procedure.
4. In the optimisation process, the practitioner responsible for radiology procedure must consider the economic and social factors of the procedure:
* select appropriate equipment to perform the procedure;
* select appropriate radiological practice, including quality assurance and quality control;
* ensure an equivalent level of quality and the adequacy of diagnostic results and the outcome of treatment;
* assess and evaluate patient’s exposure the activity of administered doses of radiopharmaceuticals, considering the diagnostic reference levels.
1. **CONDITIONS FOR CARRYING OUT RADIOLOGICAL PROCEDURES**

# Article 6

**(The approval for carrying out the radiological procedure)**

1. The practitioner, responsible for radiological procedure, authorises the procedure, if it is justified and if the anticipated purpose and goal of the procedures are not possible to achieve with other, less risky method.
2. The practitioner, responsible for radiological procedure, shall, by considering the objective and the goal of the procedure, prescribe the conditions of the procedure so that it is carried out with lowest possible radiation of the patient.
3. The practitioner, responsible for radiological procedure, must reject all unjustified procedures.

# Article 7

**(Carrying out the radiological procedure)**

1. The referrer, who refers an individual to the radiological procedure, must justify such procedure in advance, considering the specific objectives of the procedure and the characteristics of the individual involved; this includes type, form and the situation of the disease, age, gender, the level of threat to the life and health, the expected benefits and possible harmful consequences associated with the procedure.
2. Prior carrying out the radiological procedure, the referrer and the practitioner, responsible for the procedure, 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.
3. Prior carrying out the radiological procedure, the referrer and the practitioner, responsible for the procedure must provide the patient or legal guardian with adequate information relating to the benefits and risks associated with the medical exposure before the procedure. All information, the guidelines and recommendations, must be passed on to the carers.
4. In case of exposure of carers, the practitioner, responsible for the radiological procedure, must ensure that the expected total benefit, considering the direct health benefits for a patient, the possible benefits for the carer, is greater than the health damage that may be caused by the exposure.
5. Radiological procedures must be carried out in accordance with an approved radiological programme prepared to the extent specified in Annex 1, which is an integral part of these Rules.

**Article 8**

**(The referrer and the practitioner, responsible for radiological procedure)**

1. A radiological procedure may be performed only:
* when prescribed by the referrer and authorised by the practitioner, responsible for radiological procedure, or
* when prescribed by the practitioner, responsible for a radiological procedure.
1. The practitioner, responsible for radiological procedure, bears clinical responsibility for individual medical exposures to ionising radiation, with special attention to the justification and optimisation of the procedure.
2. For particular types of radiological procedures, the practitioner, responsible for radiological procedure may be a health professional of the following speciality:
* a specialist in radiology, in diagnostic procedures in radiology, except for nuclear medicine;
* a specialist in nuclear medicine, in the field of nuclear medicine interventions, including the use of computerised tomography for localisation and attenuation corrections, and
* specialist in radiotherapy in radiotherapy procedures, including radiotherapy planning.
1. Notwithstanding the previous paragraph, the practitioners, responsible for radiological procedure in the field of diagnostic and therapeutic intervention may only be individuals, who have demonstrated appropriate knowledge, skills and experience in the field of radiation protection in these procedures. The qualification criteria are prepared and updated by the ministry responsible for health. In doing so, the guidelines and recommendations of the European Commission and international professional associations in this field are considered.
2. Specialist practitioners, not listed in the third paragraph of this Article, may be responsible for radiological procedures in their speciality, if they demonstrate that they have acquired the necessary knowledge in the field of protection against ionising radiation during their education and training. List of specialities and procedures for which medical practitioner of this speciality may be held responsible for the radiological procedure is prepared and updated by the ministry responsible for health, in cooperation with the highest professional bodies in the areas referred to in the third paragraph of this article. The guidelines and recommendations of the European Commission and international professional associations in this field should be considered when preparing and amending the list.
3. The licence holder shall state in the programme of radiological procedures the specialisation of medical practitioners who are responsible for radiological procedures or should indicate by name the medical practitioners referred to in the fourth paragraph of this Article, who will bear responsibility for radiological procedures. Furthermore, the licence holder must ensure that the said doctors maintain the competence in the area for which they will be held responsible for the radiological procedure.

# Article 9

**(The practitioner of the radiological procedure)**

1. The practitioner must adequately prepare the patient before the radiological procedure, and the procedure must be performed with the principles of good radiological practice and appropriate means for patient protection. The practitioner of the radiological procedure may be:
* the practitioner, responsible for radiological procedure, and
* a radiological engineer.
1. In carrying out measurements of bone density, the performer of the radiological procedure may be, in addition to the persons referred to in the previous paragraph of this Article, also a person who has at least education acquired according to a study programme of the first degree or an education corresponding to the level of education, obtained by the first-level study programme, and in accordance with the law governing the Slovenian Qualifications Framework ranked at level VII. Or at least education acquired by study programmes for obtaining higher education, adopted before 1 January 1994 and in accordance with the law governing the Slovenian Qualifications Framework ranked at level VI., is qualified to work with radiation sources and for the implementation of radiation protection measures and has evidence of this.
2. The practitioner of radiological procedure in dental medicine may be a dentist, a maxillofacial surgeon or a radiological engineer.

# Article 10

# (Authorised medical physics expert)

1. Depending on the medical radiological practice, the authorised medical physics expert shall take responsibility for dosimetry, including physical measurements for evaluation of the dose delivered to the patient, give advice on medical radiological equipment, and contribute to the following:
2. optimisation of the radiation protection of patients and other individuals subject to medical exposure, including the application and use of diagnostic reference levels;
3. preparation and implementation of quality assurance programmes;
4. the acceptance testing of medical radiological equipment;
5. the preparation of technical specifications for medical radiological equipment and installation design;
6. the surveillance of the medical radiological installations;
7. the analysis of events involving, or potentially involving, accidental or unintended medical exposures;
8. the selection of equipment required to perform radiation protection measurements; and
9. the training of practitioners and other staff in relevant aspects of radiation protection.
10. The authorised medical physics expert shall, where appropriate, liaise with the radiation protection expert.
11. The method of participation of the authorised expert referred to in the first and second paragraphs depends on the type of radiological procedure and the radiological risk due to its performance:
* in the field of radiotherapy, except for standard therapeutic nuclear medical procedures, the licence holder must ensure that an authorised medical physics expert is involved in the process of any radiotherapeutic procedure;
* in the field of standard therapeutic and diagnostic nuclear medical procedures, computed tomography and interventional procedures that cause high patient exposure, an authorised medical physics expert should participate in the planning of the procedures;
* in other areas, an authorised medical physics expert should be included as a consultant in optimisation and in all other aspects of radiation protection referred to in the preceding paragraph.

# Article 11 (Education and training)

1. The licence holder must ensure that the practitioners responsible for radiology procedure, providers of radiation procedures and authorised medical physics experts have adequate theoretical and practical knowledge, skills and competence in the field of radiological practices and obtain appropriate additional knowledge, skills and competence in the field of radiation protection. To that end, the ministry responsible for health shall ensure that appropriate curriculum are established in accordance with the recommendations of the European Union and shall recognise the corresponding diplomas, certificates or formal qualifications.
2. An individual, undergoing training for radiological procedures, may perform a radiological procedure or part of the procedure under the supervision of a radiologist from Article 9 of these Rules, even if it is not adequately qualified for this.
3. The licence holder shall ensure the complementation and renewal of education and professional training of practitioners of radiological procedures and authorised medical physics expert even after obtaining a basic education. Before the start of the clinical use of new radiological techniques and radiological equipment, the licence holder must ensure that all practitioners are properly trained and have acquired the necessary knowledge and skills to perform these techniques and related radiation protection requirements.
4. The scope and content of theoretical and practical knowledge and the frequency of complementarity and renewal of education and professional training referred to in paragraphs 1 and 3 of this Article are given in the programme of radiological procedures.
5. The ministry responsible for health shall encourage the introduction of a course on radiation protection in the basic curriculum of medical and dental schools.

# Article 12

# (Special radiological procedures)

1. The licence holder must ensure that the procedures are carried out using the adapted radiological and other necessary equipment and adopted procedures, in case of special radiological procedures:
* of children,
* as part of a health screening programme, and
* procedures involving high doses to the patient (interventional procedures, nuclear medicine, computed tomography or radiotherapy).
1. In the case of procedures referred to in the preceding paragraph, particular attention shall be paid to quality assurance and verification, including the assessment of patients' exposure or the verification of the activity of the administered radioisotopes.
2. The licence holder must provide adequate additional training to the practitioners, responsible for radiological procedure referred to in the first paragraph of this Article and the practitioners of such procedures.

# Article 13

# (Procedures in radiotherapy, except in nuclear medicine)

1. A course of radiotherapy procedure, involving choice of the type of radiotherapy, dose determination and irradiation regimen may only be prescribed by a specialist in radiotherapy.
2. In therapeutic use, when radionuclides are input into the body of the patient, the licence holder or therapeutic procedure provider must ensure that, before leaving the health-care institution, the patient or his legal guardian receives written instructions on the treatment following dismissal from the health-care institution. Written instructions are part of a programme of radiological procedures.
3. The written instructions referred to in the preceding paragraph shall inform the patient or his legal guardian on the risks of radiation and appropriate instructions to minimise, as far as reasonably achievable, the irradiation of people, who come in contact with the patient.

# Article 14

# (Procedures in nuclear medicine)

1. The activity of dose of the radiopharmaceutical preparation used for diagnostic or therapeutic procedures is prescribed by the practitioner, responsible for procedures in nuclear medicine, and it is determined based on the calculation of the required radiation dose.
2. The activities and preparation of doses of radiopharmaceuticals referred to in the first paragraph may be measured and prepared by a person who is professionally qualified.
3. The scope and content of professional competence, including the qualifications in the field of radiation protection referred to in the second paragraph of this Article, shall be given by the licence holder in the programme for the quality assurance and quality control of radiological procedures.

# Article 15

# (Instructions for procedures in nuclear medicine)

1. The licence holder or the practitioner of a nuclear medicine procedure must ensure that the patient or his legal guardian receives written instructions on the conduct before the patient leaves the health facility. Written instructions are part of a programme of radiological procedures.
2. The written instructions referred to in the preceding paragraph shall inform the patient or his legal guardian on the risks of radiation and appropriate instructions to minimise, as far as reasonably achievable, the irradiation of people who come in contact with the patient. In the event of a therapeutic procedure, the instructions must be in writing.
3. The licence holder or a nuclear medicine therapist upon the dismissal of patients who received the therapeutic dose of the radioisotope, 131I, in addition to the instructions, also issues a nuclear medicine treatment card issued by the authority responsible for radiation protection.
4. The licence holder or a nuclear medicine therapist issues a nuclear medicine treatment card to patients who have had diagnostic interventions with the 99m Tc radioisotope and will leave the country in less than three days.
5. The Nuclear Medicine Treatment Card contains basic patient information (name, surname, date of birth and address), type and activity of the radioisotope, application date and contact details of the hospital and the person in charge of verifying this information (telephone number and e-mail address). The period for which the patient is recommended to have the card with him is three months for the use of therapeutic doses of a radioisotope, 131I and three days for the use of 99m Tc doses.

# Article 16

# (Procedures in x-ray radiology)

The licence holder or the practitioner of interventional procedure must inform the patient or his legal representative of the possibility of radiological damage prior carrying out radiological procedure. If the patient is exposed to a dose that may cause deterministic effects during the procedure, the patient and his chosen personal practitioner must be informed also about the methods of treatment after the procedure.

#

# Article 17

# (Protection during pregnancy and breastfeeding)

1. In the case of a female of childbearing age, the referrer and the practitioner, responsible for radiological procedure, shall inquire whether she is pregnant or breastfeeding. The pregnancy or breastfeeding information should be indicated on the referral by the referrer.
2. If pregnancy cannot be excluded, special attention shall be given to the justification, particularly the urgency, and the expected exposure of the mother and the unborn child. This is particularly important in the case of medical exposure, involving abdominal and pelvic regions.
3. In the case of breastfeeding females, in nuclear medicine depending on the type of medical examination or treatment, special attention shall be given to the justification and to the optimisation of the medical exposure, considering the urgency and the expected exposure of the mother and the child.
4. The licence holder must have established written procedures for the procedures referred to in the third and fourth paragraphs of this article.
5. Where appropriate and possible (e.g. waiting rooms outside the facilities in which radiological procedures are taking place), the licence holder must alert women with measures such as notices, warnings or leaflets, to inform the practitioner of the procedure of the possibility of being pregnant, or they are breastfeeding.

# Article 18

# (Voluntary care and comfort of patients)

1. The licence holder must ensure the establishment and implementation of dose constraints for the carers.
2. The practitioner, responsible for radiological procedure, must inform the carers about the risk associated with the radiological procedure and, if necessary, issue appropriate written instructions.

# Article 19

# (Biomedical or medical research)

1. The licence holder shall ensure for each biomedical and medical research project that:
* the individuals concerned participate voluntarily;
* these individuals are informed about the risks of exposure; and
* a dose constraint is established for individuals for whom no direct medical benefit is expected from exposure.
1. In the case of patients who voluntarily accept to undergo an experimental diagnostic or therapeutic practice and who are expected to receive a diagnostic or therapeutic benefit from this practice, the dose levels concerned shall be considered on an individual basis by the practitioner and referrer.

# Article 20

# (Unintended exposures while carrying out radiological procedures)

1. The licence holder shall ensure all reasonable steps are taken to minimise the probability and magnitude of accidental or unintended exposures of patients while carrying out an activity involving radiological procedures.
2. The measures referred to in the preceding paragraph are particularly:
* preparation of working instructions and written protocols of radiological procedures;
* the implementation of the quality assurance programmes as referred to in the second paragraph of Article 22 of these Rules and
* compliance with the criteria for the acceptability of radiological equipment referred to in the third indent of the third paragraph of Article 22 of these Rules.
1. It is particularly important that the licence holder prevents accidental and unintended medical exposures in the field of radiotherapy, but adequate attention should also be paid to interventional procedures and radiodiagnostics.
2. In radiotherapy procedures, the quality assurance programme should include a risk analysis for accidental or unintended exposures.
3. The contents of the training of radiologist practitioners include contents on unintentional and incidental irradiation and corrective action taken, including information on experiences gained in important events.

# THE RADIOLOGY EQUIPMENT AND QUALITY ASSURANCE

# Article 21 (Radiology equipment)

1. If new radiodiagnostic equipment is used, it shall have, where practicable, a device informing the practitioner of the quantity of radiation produced by the equipment during the radiological procedure.
2. The authority competent for radiation protection shall, with supervision, identify and implement measures to prevent the use of inappropriate radiological equipment or radiological equipment that does not meet the acceptability criteria. The licence holder shall be obliged to take the necessary measures to eliminate the inadequacy or defects of the radiological equipment, including taking the equipment out of service.

# Article 22

# (Quality assurance of radiological equipment)

1. The radiological procedure may only be carried out using equipment that meets the acceptance criteria for the chosen type of procedures referred to in the third indent of the third paragraph of this Article.
2. The licence holder shall ensure the implementation of the quality assurance programme for radiological equipment and radiation practice for which the permit is issued, including the quality assurance and assessment of patient exposure, or the verification of the activity of the administered radioisotopes for individual radiological procedures. The quality assurance programme is prepared by an authorised medical physics expert in cooperation with the responsible medical practitioner and the representative of the providers of radiation procedures.
3. The quality assurance programme, which is part of an approved programme of radiological procedures, prepared to the extent specified in Annex 2 of these Rules, must include:
* an indication and regular verification of the parameters that affect the quality of the procedure and exposure incurred by patients;
* the frequency of individual tests and
* acceptability criteria or tolerances of the optimum values of the parameters measured, considering the recommendations of the European Union and sectoral professional associations.
1. The licence holder must ensure that all radiological equipment is under the strict professional supervision of an authorised medical physics expert who demonstrates the acceptability of the radiological equipment for performing the radiological procedures for which it is used. Expert supervision comprises:
* acceptance testing of radiological equipment before the first use of the equipment for clinical purposes;
* regular acceptance tests within the deadlines set out in the quality assurance and quality assurance program under the program of radiological procedures; and
* acceptance tests after all radiological equipment interventions which may have a key effect on its operation.
1. If the results of quality assurance programme tests indicate that the patient’s safety is at risk or the appropriate performance of the radiological procedure, the licence holder must act upon the request of an authorized medical physics expert.
2. The licence holder, authorised to carry out radiation practice may appoint a dosimetrist to perform tasks in the areas related to internal quality control of radiological equipment, exposure incurred by patients, planning of radiological procedures and other fields of quality assurance of radiological procedures. The tasks of the dosimetrist are further defined in the approved programme of radiological procedures.
3. Dosimetrist referred to in the preceding paragraph of this Article may be a person with a master’s degree in radiological technology with at least two years of work experience in the workplace of a dosimetrist or consultant or radiological engineer with at least three years of work experience in the workplace of a dosimetrist or consultant.
4. The licence holder must keep an up-to-date record of the training and professional qualifications of practitioner responsible for radiology procedure, providers of a radiation procedure and authorised medical physics expert.
5. The licence holder must keep an up-to-date record of the radiological equipment in each radiological facility. The records must include:
* a list of radiological equipment;
* records on repair interventions and maintenance of equipment;
* records on the regular acceptance testing of radiological equipment and
* records on quality verification.

# Radiotherapy

# Article 23

# (Quality assurance in radiotherapy)

1. The implementation of the quality assurance programme in radiotherapy must ensure the proper functioning of radiotherapy equipment and the preparation and execution of irradiation.
2. The quality assurance programme and procedures and test results must be verified at least annually by an independent medical physics expert. The verification shall include at least the tests specified in Table 1 of Annex 4, which forms an integral part of these Rules.
3. Within the framework of the quality assurance programme in radiotherapy, it is also necessary to verify the hardware and software relevant for the calculation of the dose and irradiation of the patient.
4. If the results of the quality tests indicate that the patient's safety or the accuracy of the irradiation are at risk, the licence holder must take appropriate action, upon the request of an authorised medical physics expert.

# Article 24 (Facilities)

1. The area, where patient irradiation is performed, is a controlled area.
2. Whenever possible, only one irradiation device should be in the irradiation room. If two irradiation devices are installed in the room, it is necessary to prevent simultaneous operation with the implementation of technical measures.
3. The control panel must be outside the area where the therapy is taking place. In the case of surface therapy with energies below 50 keV, the control panel can be in the area where the therapy is taking place, but the adequate protection of the practitioner must be provided with protective partitions.
4. The installations must cross the walls in such a way that in places where radiation penetrates the adjacent spaces, the prescribed limits are not exceeded.
5. Doors with an electrical mechanism in the irradiation room must have the possibility of mechanical opening in the event of an emergency. The mechanism must be checked regularly, and staff must be able to manage it.
6. In rooms where irradiation is performed, switches must be installed on the door, which prevents operation if the door is open or interrupts operation if the doors are opened during irradiation. In case of use of the gamma teleradiotherapy device, the return of the source to the protective position is triggered.
7. The practitioner of the procedure must have the possibility to control the space and the entrance to the irradiation room directly or through the video surveillance system.
8. The control room and the room for irradiation must be connected to the intercom connection.
9. At the entrance to the irradiation room, lights must be installed that unequivocally indicate that the irradiation takes place or the system is in standby mode.
10. In the irradiation room, sound or light indicators must be installed to indicate that irradiation takes place.
11. Indicators, which unambiguously indicate that irradiation takes place, must be installed on the control panel.
12. The operation of the warning devices must be tested every day before the start of the irradiation. If the devices do not work properly, the work must not begin until the error has been corrected.

# Article 25 (Emergency shutdown)

1. In the control panel, in front of the entrance to the irradiation room and the radiation room, the emergency stop switches must be installed.
2. The switches must be installed in the irradiation space in such way that can be reached by a person who is unintentionally in the room at the beginning of the irradiation. The switch must be positioned in such a way that the person does not cross the useful beam when triggering the switch.

# Article 26 (Safe operation)

1. Radiotherapy equipment must be designed in such a way that radiation can only be triggered from the control panel. The control panel must clearly show which radiation mode is selected.
2. The control panel for the implementation of teleradiotherapy must be an irradiation dose indicator.
3. In irradiation control equipment, there must be at least two independent irradiation control systems. In the event of a power failure, at least one of them must ensure that the dosage already received can be determined.
4. Teleradiotherapy equipment for irradiation with photons with nominal beam energy exceeding 1 MeV or with particles whose energy exceeds 1 MeV shall have a device or system for checking the key irradiation parameters.

# Article 27

# (Installation and maintenance of radiotherapy equipment)

1. Before the use of radiotherapy equipment, it is necessary to perform acceptance tests of all parameters that are important for the safe and reliable operation of the equipment.
2. An authorised medical physics expert is responsible for taking over the equipment and carrying out acceptance tests.
3. All irradiation practitioners must be informed of any changes in equipment or new methods of irradiation.

#

# Article 28

# (Dosimetric calibration of radiotherapy equipment)

1. Before the clinical use of radiotherapy equipment, an authorised medical physics expert must carry out a dosimetric calibration for all types of radiation and energy radiations produced or clinically used by the device and must be additionally verified by another independent medical physics expert.
2. The dosimetric calibration must be carried out in accordance with written procedures following international protocols or protocols approved by the competent authority.
3. The dosimetric calibration must be verified by an authorised medical physics expert at regular intervals specified in the quality assurance program. The dosimetric calibration for particulate accelerators must be performed at least once a week and monthly for gamma teleradiotherapy devices.
4. After all major radiotherapeutic equipment interventions that can alter the conditions of irradiation, the equipment must be re-calibrated or verified before clinical use.
5. Measuring equipment for conducting dosimetric calibrations of irradiation devices must be traceable to primary standards. It must be checked at least once a year in the measuring range used in the normal operation.
6. A record of measuring equipment must be kept with the following information:
7. the type and nature of the equipment,
8. the manufacturer of the equipment,
9. model of equipment,
10. serial number or other identification of equipment,
11. the year of production,
12. the date of calibration.

# Article 29

# (Maintenance of radiotherapy equipment)

1. In the case of servicing radiotherapy equipment, the control panel must be equipped with labels or other relevant indicators to demonstrate that the service is in progress.
2. The personnel responsible for the technical operation of the equipment must be informed of any service interventions that may affect the conditions of radiation or the source protection. After the interventions, the equipment must not be returned to the clinical use until tests have been performed to determine the suitability of its operation. Written procedures must be in place to inform and test the equipment after servicing.

# Article 30 (Radiation detectors)

1. In the irradiation room with radioactive sources, a detector or radiation indicator (that is independent of an irradiation device) must be installed, that continually measures the dose rate in the place. The radiation detector must be connected to the warning device, which must be positioned in such a way that, before entering the room, the workers are warned that the source is not in the protective position. The operation of the detectors must be verified at least once a week.
2. If irradiation is performed with radioactive sources, a portable radiation detector must be available outside the radiation room, which, if the source does not return to the protective position after irradiation, is used to detect the position of the source.

# Article 31

# (Placing or replacing a radioactive source)

1. To place or replace a radioactive source, permission must be obtained for carrying out the radiation practice if these works are not already included in a valid licence for carrying out the radiation practice.
2. Written procedures must be available for placing or replacing a radioactive source in the irradiation device. When replacing the source, a person responsible for radiation protection must be present.
3. At least two people with appropriate knowledge and experience must be replacing the source. Only workers who are replacing the source and the person responsible for radiation protection can enter the room where the replacement is being performed.
4. The protective container in which the spent radiation source is set must be positioned as close as possible to the irradiation head so that the spent source is in the protective position during the transfer.
5. In addition to personal dosimeters, personnel carrying out the replacement of the radiation the source must also be equipped with electronic alarm dosimeters which warn of an increased dose rate with an acoustic signal.

# Article 32

# (Entering the area, where irradiation takes place)

1. During the irradiation, only the patient should be in the radiation room. If there is a need for another person due to medical reasons, consultation with an authorised radiation protection expert or an authorised medical physics expert is needed to set out appropriate radiation protection measures.
2. In the case, wherein the room with an irradiation device with a radioactive source is not equipped with the detector, which, with an acoustic signal, warns of an increased level of radiation in the room, the personnel entering this space must, in addition to personal dosimeters, carry an electronic alarm dosimeter which warns of an increased dose rate with an acoustic signal.

# Brachytherapy

# Article 33

# (Checking the source activity)

1. Before each brachytherapy radiation of the patient, the activity of the source should be measured and verified whether it corresponds to the activity indicated by the source manufacturer, considering the radioactive decay. In the case of long-lived radionuclides, the frequency of verification may be lower than indicated in the programme of radiological procedures.
2. A portable radiation detector must be available outside the radiation room, which, if the source does not return to the protective position after irradiation, is used to detect the position of the source.
3. After irradiation, it is necessary to check with radiation detectors that the radiation source has not remained in the patient.

# Article 34 (Mobile radiation shields)

If mobile radiation shields are used for protection, their proper position must be clearly marked on the ground and described in the procedures. The integrity of shields should be checked regularly.

# Article 35 (Sterilization, disinfection, cleaning)

1. In the case of sterilisation or disinfection of brachytherapy radiation sources, it is necessary to ensure that:
* the temperature does not exceed 180 °C;
* does not sterilise or disinfect resources that are damaged;
* for disinfection, liquids are used that do not damage the identification marks on the sources.
1. After sterilisation, disinfection or cleaning, the practitioner must check the identification marks at the source.

#

# Article 36

# (Protection of personnel and visitors)

1. For each irradiation with radiation sources in or on the body, the maximum dose rate should be measured and recorded at a distance of 1 m from the patient and consult an authorised medical physics expert who then proposes the appropriate radiation protection measures.
2. When entering the facilities where irradiation takes place, personnel and visitors must comply with written procedures approved by an authorised medical physics expert.
3. Patients with radiation sources in or on the body should not leave the room for irradiation, unless authorised by the medical personnel responsible for the therapy, in agreement with an authorised medical physics expert. A written record must be kept of the possible exit and return of the patient to the irradiation room.

# Article 37

# (Area for brachytherapy irradiation)

1. If possible, brachytherapy radiation should be carried out in the area only with one or up to two hospital beds, which, however, should be separated by a suitable shield.
2. The area and beds in which patients are irradiated must be marked with signs and inscriptions that warn of the danger of radiation. The nursing staff must be informed in writing about the time of irradiation, the duration of irradiation, the radionuclide, the activity of the radionuclide with which the irradiation takes place, and the dose rate at a distance of 1 m from the patient. The accuracy of the data shall be the responsibility of the authorised medical physics expert.

# Nuclear medicine

# Article 38

# (Quality assurance in nuclear medicine)

1. The implementation of the quality assurance programme in nuclear medicine must ensure the proper functioning of the radiological equipment and the implementation of the procedure.
2. The quality assurance programme and procedures and test results must be verified at least annually by an independent medical physics expert. The verification shall include at least the tests specified in Table 2 of Annex 4, which forms an integral part of these Rules.
3. If the results of the quality tests indicate that the patient's safety or the accuracy of the radiation procedure are at risk, the licence holder must take appropriate action, upon the request of an authorised medical physics expert.

# Article 39

# (Waiting for a nuclear medical procedure)

1. Patients who are waiting for examinations or radionuclide therapy are treated as individuals from the population regarding the irradiation.
2. Nuclear medicine departments must have separate waiting rooms for patients with applied radionuclides and patients waiting for the application, as well as separate sanitary facilities for patients with applied radionuclides.

# Article 40

# (General conditions for dismissal from a hospital)

1. The patient may be dismissed from the hospital, if for this reason:
* any individual from the population will unknowingly not receive an effective dose greater than 0.3 mSv;
* members of the household who voluntarily take care of the patient after dismissal, excluding pregnant or breastfeeding women, receive an effective dose of less than 5 mSv;
* other members of the household receive an effective dose of less than 1 mSv.
1. The method of determining the dose of exposed persons referred to in the preceding paragraph shall be assessed by an authorised radiation protection expert.
2. The patient with the applied radionuclide must receive written instructions and warnings about radiation hazards and procedures for radiation protection before dismissal from the hospital, which the patient must consider reducing the risk of unnecessary external irradiation or contamination of other persons.

# Article 41

# (Special conditions for dismissal from a hospital)

1. A patient who has received a therapeutic dose of a radionuclide 131I may leave the hospital when the activity of the radionuclide in the patient falls below 800 MBq.
2. Upon dismissal, the patient must receive further instructions on behaviour that he is obliged to follow in accordance with Table 1 of Annex 3, which is an integral part of these Rules.
3. In the treatment with radionuclides, which are sources of beta-radiation, for applications of less than 200 MBq, the patient may be discharged from the hospital without restrictive measures.
4. Autopsy and cremation of deceased persons who have received radionuclides for therapeutic purposes should be carried out in accordance with the instructions for radiation protection that the operator must have in written form.
5. Special radiation protection measures are not necessary if the activities are below the values in Table 2 of Annex 3 to these Rules.

# Article 42

# (Measures for the treatment that involves the use of open sources of radiation)

1. Patients who received radionuclide 131I, activity greater than 1100 MBq should be in a single patient hospital room with sanitary facilities during the therapy.
2. Hospitalized patients who have received radionuclide therapy 131I, with activity equal to or less than 1100 MBq can share the room if each patient is provided that the dose received by the presence of other patients in the room is below the prescribed threshold value for individuals from the population.
3. Patients referred to in the first and second paragraphs of this Article shall not leave the hospital room unless approved by the medical personnel responsible for the therapy. A written record must be kept of the possible exit and return of the patient to the irradiation room.
4. Before the entrance to the room, there must be a checkpoint where the nursing staff can change.

#

# Article 43

# (Protection of healthcare personnel)

1. If the patient's health condition deteriorates and intensive care is needed, it is necessary to follow the pre-written written instructions prepared in cooperation with an authorised radiation protection expert regarding the time of restraint near the patient.
2. Before the operation of a patient who received a therapeutic dose of a radionuclide, the activity still in the patient should be determined. Together with the person responsible for radiation protection, radiation protection measures should be established.

# Article 44

# (Measures at discharge from the hospital)

1. Before dismissing the patient from the hospital, it is necessary to check the contamination of the patient's clothes and personal belongings and, if necessary, decontaminate or retain them.
2. After dismissal, the patient from the hospital, measurements of contamination in the hospital room where it was lying should be performed and decontaminated if necessary.

# X-ray radiology, except procedures in dental medicine

# Article 45(Quality assurance in X-ray radiology)

1. The implementation of the quality assurance programme in X-ray radiology must ensure the proper functioning of radiology equipment and the preparation and implementation of the procedure.
2. The quality assurance programme and procedures and test results must be verified at least annually by an independent medical physics expert. Verification in dental X-ray radiology shall include at least the tests set out in Table 3 of Annex 2 of these Rules.

# Article 46 (The facilities)

1. X-ray diagnostic procedures are usually performed in specialised facilities (diagnostic facilities) designed and adapted for the implementation of such procedures. Exceptions are procedures between operations and procedures in immobile patients on hospital beds where mobile X-ray devices are used.
2. No more than one radiological procedure may be performed in one room at a time unless the room is specifically adapted to the implementation of several procedures. In doing so, it must be ensured that the rates of absorbed dose due to the implementation of another procedure in the room are less than the values that can cause exposure to radiation, which results in exceeding the prescribed dose limits for an individual from the population.
3. Entrances not under the direct supervision of the practitioner of the radiological procedure must be designed in a way to prevent entry into the diagnostic area during the procedure.
4. The control panel of the X-ray device must be installed in such way, that the practitioner of the radiological procedure sees the patient always. If a direct patient view is disabled, it is necessary to provide a video link between the control and the diagnostic area. If the control panel is in a separate room, there must be an interconnection between the command and diagnostic area.

# Article 47

# (Personal protective equipment)

1. Personal protective equipment must be used by all persons who are in controlled areas during the operation of the radiological procedure. The type of necessary protective equipment, its protective capability and the manner of its use for a particular type of procedure shall be determined in agreement with an authorised radiation protection expert.
2. All personal protective equipment must be marked with a safety data sheet (equivalent to lead thickness).

# Article 48

# (Personal protective equipment for the patient)

1. The type of protective equipment used, its protective capability and the mode of use for each type of procedure is determined by an authorised medical physics expert and must be an integral part of the written instructions for each type of procedure.
2. Patient safety equipment must be marked with protective capabilities (equivalent to lead thickness).

# Article 49

# (X-ray tube housing)

1. The housing in which the X-ray tube is located (including the apertures for limiting the useful beam) must be such that at a distance of 1 m from the focal spot under the maximum tube load conditions of the tube, the dose in the air due to the leakage of the housing does not exceed 1 mGy in one hour.
2. The type and number of an X-ray tube must be clearly marked on the X-ray tube housing or another suitable place.
3. Except for the device for computed tomography and X-ray devices for determining bone density, the location of the focal spot should be marked on the housing in which the X- ray tube is located.

#

# Article 50

# (The filtration of a useful beam)

1. A useful beam of Cray light used in X-ray radiological procedures must be filtered. The total filtration consists of an inherent filtration, which cannot be removed without tools, additional filters, and other installed equipment in the useful beam.
2. All filters must be marked on an X-ray device in such a way that it is possible to determine the total filtration of the useful beam.
3. The thickness of the inherent filtration must be legibly marked on the body of the X-ray tube and in the case where the tube body is inaccessible, even on the external accessible surfaces of an X-ray device.
4. Additional filters shall be marked with the chemical symbol of the substance from which the filter is made, and the thickness in mm or aluminium equivalent thickness measured in mm. If the filter is not made of aluminium and the thickness of the filter is expressed in aluminium equivalent thickness, it must be indicated for what energy of radiation the equivalent thickness was determined.
5. If the device allows modification of the filtration, and the radiographic technique does not use it, it is necessary to avoid accidental changes to the filter.
6. The total equivalent X-ray beam filtration for diagnostic purposes (except for mammography) must be at least 2.5 mm Al, of which the equivalent thickness of the permanent fitted filter must be at least 1.5 mm Al.

# Article 51

# (Determining the field of useful radiation)

1. X-ray devices must have an aperture system to limit the field of the useful X-ray beam. The apertures must be designed to minimise the field beyond the useful beam.
2. The maximum field permitted by the aperture system must match the dimensions of the largest imaging detector in use at the smallest distance that is clinically used.
3. The aperture system of X-ray devices should be equipped with a light beam indicator of the useful radiation beam. The difference between the radiation field and the light indication must not exceed 2 % of the distance between the focal spot and the image detector at any margin of the field. For X-ray devices used for the imaging of children, this difference should not exceed 1 %.
4. The X-ray device for fluoroscopy must ensure that the useful beam of radiation is always directed towards the image detector. The aperture system must automatically adjust the size of the useful field to the distance between the device's focal spot and the image detector, and the selected size of the image detector. In X-ray radiographic devices, the slice thickness on the imaging detector must match the set slice thickness.

# Article 52 (Active protection)

1. The indication on the control panel of the X-ray device that shows that the device is switched on and ready for exposure must be clearly visible.
2. If it is possible to trigger multiple X-ray tubes from one place, the control panel must clearly indicate which tube is selected and ready for exposure.
3. All trigger switches must be clearly marked.
4. For permanently installed X-ray devices, the switches must be located at the control point intended for the practitioner of the radiological procedure. For movable devices, the design of the switch must be such that it allows the performer of the radiological procedure to withdraw from the proximity of the useful beam to a distance of at least 2 m from the patient and the housing of the X-ray tube.
5. The switches must be designed and installed in such a way as to prevent the device from being accidentally triggered. Footswitch switches must be such that, in the case of an upside-down pedal, it is not possible to trigger the exposure.
6. The exposure trigger switches must be such that the exposure is only carried out until the practitioner is pressuring the switch and is stopped as soon as the pressure is released. The exposure trigger switch must be designed in a way that the next exposure can only be performed when the practitioner of the procedure completely lowers the switch. Exceptions are devices in which exposure is carried out by examination along the patient´s body. With these devices, the intervention practitioner must have the possibility to interrupt the operation before it is completed.
7. X-ray devices must have a clear light or acoustic indication of exposure that lasts for the entire duration of the exposure, or at least the time that it is clear that the exposure has been performed.
8. Mobile X-ray devices that do not need to be connected directly to the electrical network for exposure should have a locking system to prevent unauthorised persons from triggering the exposure. Such X-ray devices must be locked when not in use.

# Article 53 (Exposure parameters)

1. The X-ray device control panel must be equipped with a display that must show exposure information before, during and after the exposure. After exposure, the data must remain visible on the display until the practitioner of the radiological procedure selects new exposure parameters on the control panel or deliberately interrupts the display.
2. For X-ray image devices, the selected exposure parameters must be displayed before exposure, and after exposure, the parameters from which the radiation parameters can be determined.
3. In fluoroscopic devices, the selected fluoroscopy mode and the selected field size must be displayed before and during the exposure, while during the exposure also exposure parameters and the total duration of the fluoroscopy are shown.
4. All newly installed X-ray devices for computed tomography should have a system of automatic current modification, and before performing the procedure, display the parameters for the assessment of the dose in the procedure.

# Article 54 (Exposure Control)

1. X-ray imaging devices must have a maximum exposure limitation system. In addition, the device must have an independent system to allow early termination of the exposure if the practitioner of the radiological procedure estimates that it is incorrect. As such, it is also considered a switch that must be kept for the entire duration of the exposure involved.
2. X-ray imaging devices must have an automatic exposure control system. The exception is mobile devices, designed for x-ray imaging in hospital beds, in operating rooms or individual cases where the use of such devices is specifically justified.
3. X-ray fluoroscopy devices must have a meter for measuring the total duration of illumination, equipped with an audible alarm that is triggered after five minutes of illumination. The audible alarm must be such that it can be interrupted only manually.
4. X-ray machines for computed tomography should be able to interrupt the execution of the procedure before all scheduled slices are completed, during the heating or calibration of the detectors.

# Article 55

# (Requirements and restrictions for the devices)

1. For radiological procedures using fluoroscopy, only X-ray devices equipped with an automatic dose rate control system and image amplifiers or similar technology may be used to monitor images on a remote screen.
2. To reduce patient irradiation, X-ray fluoroscopy devices must have a system for maintaining the last image, possibly also other technical solutions, such as pulsed operation, the choice of different exposure levels and the frequency of image series.
3. Radiological equipment used for interventional procedures must include a device or system that informs the procedure operator of the amount of radiation that the equipment emits during the procedure.
4. Radiological equipment used for interventional procedures or computed tomography and any new radiological equipment used for the design, management or monitoring of treatment must include a device or system that, at the end of the procedure, provides information that enables the assessment of the patient's irradiation.
5. Radiological equipment used for interventional procedures or computed tomography must allow the information, which enables the assessment of patient's irradiation, to be transmitted in an inspection report on the device.
6. Notwithstanding the requirements of paragraphs 3 to 5, the new X-ray diagnostic equipment must include a device or system that provides information enabling the assessment of patient's irradiation. Where appropriate, the equipment must allow this information to be transmitted in an inspection report on the device.
7. The device for computed tomography with only one type of receiver cannot be used.
8. Mammographic devices may not be used for breast imaging:
	* with a distance between the focal spot and the imaging receiver of less than 60 cm;
	* with an image field of less than 18x24 cm2, except for performing stereotactic breast puncture;
	* without motorised breast compression device;
	* without showing the thickness of the painted breast and the compression force and
	* with an analogue receiver, without a radiographic grid.

# Dental X-ray diagnostics

# Article 56

# (Quality assurance in the dental X-ray radiology)

* 1. The implementation of a quality assurance program in dental X-ray radiology must ensure the proper functioning of the radiological equipment and the implementation of the intervention.
	2. The quality assurance program and the procedures and tests results must be verified at least annually by an independent medical physics expert. Verification in dental radiology should include at least the tests in Table 4 of Annex 2 to these Rules.

# Article 57

# (The facilities of dental X-ray diagnostics)

1. Dental X-ray diagnostic is carried out in facilities designed and adapted to the implementation of these procedures.
2. Intraoral X-rays may also be used in facilities not intended exclusively for X-ray diagnostics provided that adequate protection of the adjacent rooms is provided against the radiation of the device, and if there is enough room for the provider of a radiation procedure to move to a safe distance and away from the direction of the useful beam.
3. The use of hand-held dental X-ray devices is permitted only in exceptional circumstances where the use of stationary or mobile dental X-ray devices is not possible, and the need for the radiological procedure is required.
4. Evidence of justification of the use of hand-held dental X-ray devices must be provided by the holder of the authorization and attached to the application for authorization.

# Article 58 (The housing)

1. The housing of intraoral X-ray devices must be such that, at a distance of 1 m from the focal spot under the maximum tube load conditions, the total dose in the air due to the leakage of the housing does not exceed 0.25 mGy in one hour.
2. The housing of other dental X-ray devices must be such that, at a distance of 1 m from the focal spot under the maximum tube load conditions, the dose in the air due to the leakage of the housing does not exceed 1 mGy within one hour.
3. The type and number of the X-ray tube and the size of the focal spots must be clearly marked on the X-ray tube housing or another suitable place on the device.
4. The location of the focal spot should be marked on the X-ray tube housing.

# Article 59(Filtration)

1. The X-ray beam used in dental X-ray diagnostics must be filtered.
2. On the X-ray device, the filter markings must be displayed in such a way that it is possible to determine the total filtration of the useful beam.
3. Total equivalent filtration of the X-ray beam must be at least 1.5 mm Al for dental X-ray devices operating at anode voltage up to 70 kV and at least 2.5 mm Al for dental X-ray devices operating at anode voltage greater than 70 kV.
4. If the total filtration of the useful beam of intraoral X-ray devices significantly exceeds the values in the previous paragraph, it should be ensured that the times of imaging do not exceed 1 second.

# Article 60

# (The selection of imaging technology)

1. Intraoral X-ray devices must operate at anode voltage above 50 kV, and all new X-ray devices in the voltage range from 60 kV to 90 kV. The exposure parameters must be such that they can be adapted to the picture object and image detectors.
2. Panoramic dental X-ray devices and devices for cephalometry must operate at an anodic voltage in the range between 60 kV and 125 kV.

# Article 61

# (Determining the field of useful radiation)

1. Intraoral dental X-ray devices must have spacers that provide the appropriate distance between the X-ray tube's focal spot and the patient's skin and limit the useful beam of radiation. The spacer of the X-ray device for the intraoral imaging of the teeth shall ensure that the distance between the focal spot of the X-ray tube and the patient's skin is at least 200 mm, and the useful beam at the spacer output shall be limited to:
* a field not exceeding the size of the image detector by more than 2.5 mm at any edge or, in any case, not exceeding 40 mm x 50 mm for devices with rectangular beam shielding, or
* a field with a diameter of not more than 60 mm for devices with circular beam shielding.
1. New intraoral dental X-ray devices may only have a rectangular shielding of a useful beam.
2. Panoramic dental X-ray devices must have the appropriate equipment for the patient's position and light field indicators. The beam collimators must focus the beam on the slot collimator in front of the imaging detector. The useful beam size must not exceed the size of the image receiver.
3. Cephalometry can only be carried out with adapted dental X-ray devices. The device must have a patient's positioning system (cephalostat). The size of the radiation beam must not exceed the size of the image receiver.

# Article 62(Active protection)

1. The indication on the control panel of the dental X-ray device that shows that the device is switched on and ready for exposure must be clearly visible.
2. Dental X-ray devices must have a clear light or acoustic indication of exposure that lasts for the entire duration of the exposure, or at least the time that it is clear that the exposure has been performed.
3. All newly installed panoramic dental X-ray devices must be equipped with a system that automatically stops the exposure in the event of a rotation interruption. In the event of exposure interruption, the exposure from the position in which the exposure was interrupted should be prevented from continuing.

# Article 63

# (Trigger and exposure control)

1. All trigger switches must be clearly marked. Inadvertent exposure triggering must be disabled.
2. The exposure trigger switches must be such that the exposure is only carried out until the practitioner is pressuring the switch and is stopped as soon as the pressure is released. The exposure trigger switch must be designed in a way that the next exposure can only be performed when the practitioner of the procedure completely lowers the switch.
3. The exposure trigger switches must be such that it allows the performer of the radiological procedure to withdraw from the proximity of the useful beam to a distance of at least 2 m from the patient and the housing of the X-ray tube.
4. Dental X-ray devices must have a system that automatically exits the exposure after it reaches a certain level. In addition, the dental X-ray device must have an independent system to allow early termination of the exposure, if the practitioner of the radiological procedure estimates that it is incorrect. As such, it is also considered a switch that must be kept for the entire duration of the exposure involved.

# Veterinary medicine

# Article 64

# (The use of X-ray devices in veterinary medicine)

When using X-ray devices in veterinary medicine, the provisions of these Rules for X-ray radiology for medical purposes shall apply mutatis mutandis.

# CLINICAL AUDIT AND EXPOSURE ASSESSMENT

# Article 65(Clinical audit)

1. A clinical audit of the implementation of radiological procedures shall be carried out by an independent commission appointed by a provider of a radiation practice. At least a representative of practitioners responsible for radiology procedure, a representative of providers of dosimetric service, and a representative of authorised medical physics experts must participate at the commission, all from the field in which the assessment is carried out.
2. The Commission referred to in the previous paragraph shall draw up a report of the audit with proposals for the elimination of any deficiencies which the licence holder must transmit to the authority competent for radiation protection, no later than three days after receipt. The authority competent for radiation protection may use the findings of a clinical audit of the performance of radiological procedures in determining measures to eliminate the deficiencies.
3. The frequency of clinical audits of the performance of radiological procedures referred to in the first paragraph of this Article and their extent and content shall be determined in the programme of radiological procedures.
4. The clinical audit of the performance of radiological procedures referred to in the first paragraph of this Article shall be carried out by the licence holder at least once every five years, and at least once a year for special radiological procedures defined in the first paragraph of Article 12.
5. The authority competent for radiation protection shall determine the clinical audit of the performance of radiological procedures if:
* the diagnostic reference levels have been continuously exceeded,
* there is a reasonable suspicion that radiological procedures are conducted contrary to written procedures or
* there is a reasonable suspicion that radiological procedures are performed by persons who are not adequately trained.

# Article 66(Exposure assessment)

The authority responsible for radiation protection shall provide an assessment of the exposure of the population due to radiodiagnostic and intervention procedures. Where possible, exposure should be displayed as a distribution by age and sex of the subject.

# NON-MEDICAL IMAGING

# Article 66

# (Non-medical imaging)

1. The operator carrying out an activity involving radiation must ensure the justification assessment for exposure due to imaging for non-medical purposes, while
* it is necessary to assess the eligibility of each individual exposure type due to the imaging for non-medical purposes;
* it is necessary to assess the eligibility of each individual exposure due to non-medical imaging purposes separately;
* in the case of non-medical imaging for which medical radiological equipment is used, the objectives and purpose of the examination and the characteristics of the subject must be considered with an advance assessment of each individual exposure.
1. The assessment of the eligibility of each individual type of exposure and each individual exposure due to non-medical imaging purposes should be repeated if there are new data or circumstances that would influence the assessment.
2. Notwithstanding the first and second paragraphs of this Article, exposure due to non-medical imaging purposes without the assessment of the eligibility for each individual examination may be granted in special circumstances by the authority responsible for radiation protection.
3. Circumstances which justify exposure for non-medical imaging purposes without the assessment of the eligibility to carry out each examination shall be subject to regular review by the competent administrative authority.
4. The provider of the procedure, which leads to exposure due to the non- medical imaging for which the medical radiological equipment is used, must
* meet the requirements defined for performing radiological procedures, including the requirements for medical equipment, optimisation, responsibility, competence, protection during pregnancy and appropriate involvement of an authorised medical physics expert
* have an approved programme of radiological procedures that is consistent with the purpose of the examination and the required image quality
* where appropriate, determine specific diagnostic reference levels.
1. For non-medical imaging exposure procedures not using medical radiological equipment, dose constraints must be set significantly lower than the dose limit for members of the public.
2. The license holder must provide the exposed individual with appropriate information about the imaging and obtain his consent to perform the imaging. Exceptionally, on suspicion of a criminal offence, the imaging may be carried out without the consent of the person being investigated.
3. The authority competent for radiation protection shall ensure the identification of activities involving the exposure to non-medical imaging, considering particularly the activities listed in Annex 1 to these Rules.
4. The authority competent for radiation protection cooperates with other competent authorities and professional medical associations in determining the required conditions for carrying out a radiation practice in which the exposure of individuals is due to non-medical imaging and the criteria for carrying out individual imaging within this radiation practice.

# TRANSITIONAL AND FINAL PROVISIONS

# Article 67 (Transitional provision)

The licence holder shall align his activity with point b of the third paragraph of Article 10 of these Rules within one year from the day of its entry into force.

# Article 68 (End of validity)

As of the date of entry into force of this Regulation, the following shall cease to apply:

* Rules on the criteria of using ionising radiation sources for medical purposes (Official Gazette of the Republic of Slovenia, No. 111/03 and 75/15);
	+ chapters IV.2 Radiotherapy, IV.3 X-ray diagnostics in medicine and IV.4 X-ray diagnostics in veterinary medicine of the Rules on the use of radiation sources and activities involving radiation (Official Gazette of the Republic of Slovenia, No. 27/06, 76/17 – ZVISJV-1 and 27/18).

# Article 69 (Entry into force)

This Act shall enter into force on the 15th day after its publication in the Official Gazette of the Republic of Slovenia.

No. 0070-35/2018
Ljubljana, 10th April 2018

EVA 2018-2711-0010

# Milojka Kolar Celarc

Minister of Health

# ANNEX 1

**The content, scope and format of the programme of radiological procedures**

1. Description of procedures.
2. Personnel responsibility (responsible medical practitioner, providers of procedures, authorised medical physics experts).
3. Patient referral (the referrer, method of referral and handling in case of pregnant patients).
4. Implementation of the procedure (preparation of the procedure and the patient, use of protective devices and personal protective equipment, implementation of the procedure, radiological equipment, parameters that influence the course and the quality of the intervention).
5. Patient irradiation (methodology for estimation of irradiation or exposure, measurement, potential exposure of patients).
6. Management and storage of data on performed procedures.
7. Quality assurance programme (training of personnel, provision of technical quality, servicing and maintenance of radiological equipment).
8. Past experience in cases of unintentional exposure or exposure of patients due to emergencies (description of past events, cause analysis, assessment of doses received, description of other events important in terms of patient care, description of measures taken after an emergency or unintentional exposure, and assessment of their effectiveness).

# ANNEX 2

**Verification procedures in radiotherapy, nuclear and X-ray medicine**

Table 1

|  |
| --- |
| **Radiotherapy** |
| Series | Tests |
| Mechanical and geometric parameters | * the accuracy of the isocentre
* distance indicators
* laser settings
* position and size of the irradiation fields
* overlapping of the light field indication and the irradiated field
* mechanical stability
* tools for positioning and immobilisation of the patient
 |
| Dosimetric parameters | * dosimetric calibration of all beams in clinical use
* stability of the irradiation beam
 |
| Security systems | * safety switches
* audio and video surveillance systems
 |

Table 2

|  |
| --- |
| **Nuclear medicine** |
| Type of equipment | Tests |
| Activity detectors | * The accuracy of diagnostic dose determination
* Repeatability
* Linearity
 |
| Gamma cameras | * Mechanical properties
* Background
* Homogeneity (internal, systemic)
* Sensitivity
* Uniformity of the response
* Energy resolution
* Spatial resolution
 |
| SPECT | All parameters as for gamma cameras, and also:* Rotation centre
* Reconstructed tomographic resolution
* Tests with Jaszczak phantom
 |
| PET | * Mechanical properties
* Sensitivity
* Energy resolution
* Spatial resolution
 |

Table 3

|  |
| --- |
| **X-ray radiology without dental X-ray diagnostics** |
| **Parameter** | **Method of verification** |
| X-ray tube housing | * Verification of markings
* Measuring the leakage of the housing
* Verifying the size of the focal spots
 |
| Filtration | * Verification of filter markings
* Half-value layer measurement (HVL)
 |
| Useful radiation field | * Aperture operation
* Matching light field indication with a radiation field (congruence)
* Centring a useful beam
 |  |  |  |  |
| Active protection | * Control panel indications
* Warnings
* Operation of trigger switches
* Operation of emergency switches
 |
| Exposure Parameters | * Operation of the display
* Deviation from the true values
* Repeatability
* Linearity
* Specific Exposure Dosage
 |
| Exposure control | * Automatic exposure control operation
 |

Table 4

|  |
| --- |
| **Dental X-ray diagnostics** |
| **Parameter** | **Method of verification** |
| X-ray tube housing | * Verification of markings
* Measuring the leakage of the housing
* Verifying the size of the focal spots
 |
| Filtration | * Verification of filter markings
* Half-value layer measurement (HVL)
 |
| Useful radiation field | * Aperture

beam | operation | or | size | verification | of | the | useful |
| Active protection | * Control panel indications
* Warnings
* Operation of trigger switches
 |
| Exposure Parameters | * Operation of the display
* Deviation from the true values
* Repeatability
* Specific Exposure Dosage
 |

# ANNEX 3

**Instructions for discharge from the hospital after treatment**

Table 1

|  |  |
| --- | --- |
|  | **Applied activity 131I (MBq)** |
|  | **30** | **200** | **400** | **600** | **800** |
| **Restriction** | **The time limit in days** |
| Keep at a distance of at least 1 m from a child under 3 years of age | **1** | **15** | **21** | **25** | **27** |
| Keep at a distance of atleast 1 m from a child aged 3-5 years | **-** | **11** | **16** | **20** | **22** |
| Keep at a distance of at least 1 m from a child over 5 years of age | **-** | **5** | **11** | **14** | **16** |
| Sleep separately fromother people | **-** | **-** | **-** | **4** | **8** |
| Avoid prolonged contact with adults (more than 3 hours at a distance of lessthan 1 m | **-** | **-** | **-** | **-** | **1** |

Table 2

|  |  |  |
| --- | --- | --- |
| **Radionuclide** | **The burial** | **Cremation** |
|  | **Activity (MBq)** | **Activity (MBq)** |
| 131 I | 400 | 400 |
| 125 I, grains | 400 | - |
| 103 Pd, grains | 15000 | - |
| 90Y, colloidal solution | 2000 | 70 |
| 198Au, grains | 4000 | - |
| 198Au, colloidal solution | 400 | 100 |
| 32P | 2000 | 3,0 |
| 89Sr | 2000 | 200 |

# ANNEX 4

# An indicative list of activities involving exposure due to non-medical imaging

Activities that involve intentional exposure of people for purposes other than medical are, among others:

1. Activities using medical radiological equipment:
	* a radiological health assessment for employment purposes;
	* a radiological health assessment for immigration purposes;
	* a radiological health assessment for the purposes of insurance;
	* a radiological assessment of the physical development of children and adolescents for the purposes of their careers in sport, dancing, etc.;
	* a radiological assessment of age;
	* the use of ionising radiation to identify hidden objects in the human body.
2. Activities in which medical radiological equipment is not used:
	* use of ionising radiation for the identification of objects hidden in or attached to the human body;
	* the use of ionising radiation for the identification of hidden people as part of the cargo examination;
	* activities involving the use of ionising radiation for legal or security purposes.