Republic of Latvia

Cabinet
Regulation No. 482
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Regulations Regarding Protection Against Ionising Radiation in Medical Exposure

Issued pursuant to
Section 3, Paragraph three of the Law on Radiation Safety and Nuclear Safety

1. General Provisions

1. The Regulation prescribes the implementation of basic principles for radiation safety and nuclear safety in the protection of human beings against ionising radiation in medical exposure.

2. The following terms are used in the Regulation:

2.1. **exposure** – a process during which a human being is exposed to ionising radiation;

2.2. **prescriber** – a medical doctor, dentist or other health professional with appropriate qualification and right to refer individuals for medical exposure;

2.3. **voluntary assistant** – a person who comes into contact with a patient undergoing medical exposure when knowingly and willingly providing support to such patient if it is not a part of the professional duties of such person;

2.4. **diagnostic reference levels** – dose levels of ionising radiation in radiodiagnostic intervention or, in the case of radio-pharmaceuticals, levels of total radioactivity, when carrying out examinations for standard-sized patients (body weight is 70 kg) or when carrying out standard examinations using a radiological installation according to the description of the method to be used in medical exposure. These levels are expected not to be exceeded for standard interventions when good and normal practice regarding diagnostic and technical performance is applied;

2.5. **dose constraint** – a restriction on the prospective doses to individuals (which may result from a defined source of ionising radiation) for use in radiation protection planning and exposure optimisation;

2.6. **individual detriment** − clinically observable deleterious effects that are expressed in individuals or their descendants. Appearance of clinically observable deleterious effects is either immediate or delayed and, in the latter case, implies a probability rather than a certainty of appearance;

2.7. **medico-legal interventions** – exposure interventions performed for insurance or legal purposes without a medical indication;

2.8. **clinical audit** – a systematic examination or review of medical radiological interventions which seeks to improve the quality and the outcome of patient care. A structured review shall be carried out during a clinical audit whereby radiological practices, interventions and results are examined against agreed standards for good medical radiological interventions, with modification of practices where indicated and the application of new standards if necessary;

2.9. **quality control** – a part of quality assurance comprising the set of operations (programming, coordinating, implementing) intended to maintain or to improve quality, and also covering monitoring, evaluation and maintenance at required levels of all characteristics of performance of equipment that can be measured, and controlled;

2.10. **quality assurance** – all those planned and systematic actions necessary to provide adequate confidence that radiological interventions will be performed satisfactorily complying with agreed standards and approved medical technologies;

2.11. **medical exposure** – a process during which ionising radiation exerts influence on human tissues, organs and body in general for medical purposes;

2.12. **technical aspects of medical exposure** – preparation and conduct of radiological interventions, handling and use of a radiological installation related to the radiological intervention, the assessment of technical and physical parameters of the radiological installation including ionising radiation doses, patient dosimetry, maintenance of the radiological installation and assessment of conformity of the functions, the development of films and preparation and administration of radio-pharmaceuticals;

2.13. **medical physics expert** – a medical physics expert with at least master's degree in medical physics or an expert in ionising radiation physics or ionising radiation technology applied to medical exposure, and who has obtained a certificate of the radiation safety expert in medical physics in accordance with the laws and regulations regarding protection against ionising radiation;

2.14. **patient dose** – the dose of ionising radiation received by patients or other individuals undergoing medical exposure;

2.15. **patient dosimetry** – the dosimetry (determination of a dose) concerning patients or other individuals undergoing medical exposure;

2.16. **practitioner** – a certified health professional who is entitled to carry out radiological intervention and who is responsible for selection of radiological intervention and each medical exposure (for example, radiotherapist, radiodiagnostician or dentist);

2.17. **radioactive pharmaceutical preparations** – any medicinal products to be used in radiology which contain one or several radionuclides – radioactive isotopes in a ready for use form, except isotopes from closed radiation sources intended for medical purposes;

2.18. **radiodiagnostic intervention** – medical examination using a source of radionuclides or other ionising radiation only for diagnostic purposes (for example, diagnostic nuclear medicine intervention, general roentgenology, computed tomography, interventional radiology, and dental radiology);

2.19. **radiodiagnostic** – pertaining to *in vivo* diagnostic nuclear medicine, medical diagnostic radiology, and dental radiology;

2.20. **radiological intervention**– intervention concerning medical exposure. Radiological intervention is divided into radiodiagnostic and radiotherapeutic intervention;

2.21. **radiological installations** – medical installations used in radiology which generate ionising radiation or contain the source of ionising radiation;

2.22. **radiological** – pertaining to radiodiagnostic and radiotherapeutic interventions, and interventional radiology or other planning and guiding radiology;

2.23. **radiotherapeutic intervention** – medical treatment using a source of radionuclides or other ionising radiation (for example, therapeutic intervention of nuclear medicine, utilisation of accelerators and other sources of ionising radiation in radiotherapy and interventional radiology);

2.24. **radiotherapeutic** – pertaining to radiotherapy including nuclear medicine for therapeutic purposes;

2.25. **health screening** – a procedure using radiological installations for early diagnosis in population groups at risk.

3. The Regulation shall apply to the following types of medical exposure:

3.1. the exposure of persons that is related to the diagnosis or treatment of a disease, or health surveillance;

3.2. the exposure of employees in mandatory health surveillance and examination of employees;

3.3. the exposure of such individual who voluntarily participates in medical or biomedical, diagnostic or therapeutic, research programme;

3.4. the exposure of individuals as part of a medico-legal intervention;

3.5. exposure of the voluntary assistant.

4. Methods approved in accordance with the laws and regulations regarding approval of medical technologies to be used in medical treatment and procedures for introduction of new medical technologies, and also medical devices which have been placed on the market in accordance with the laws and regulations regarding registration of medical devices shall be used in medical exposure.

5. Clinical responsibility of a practitioner in relation to medical exposure shall be:

5.1. to evaluate the justification for medical exposure;

5.2. to ensure the optimisation of medical exposure:

5.2.1. to select a radiological installation conforming to the radiological intervention;

5.2.2. to obtain the radiodiagnostic information or to provide a radiotherapeutic result;

5.2.3. to involve in evaluation of the technical aspects of medical exposure in order to reduce radiation of the personnel and other persons;

5.2.4. to evaluate the dose of radiological interventions and the patient dose;

5.3. to evaluate the radiodiagnostic information or radiotherapeutic result obtained during medical exposure;

5.4. co-operate with other specialists related to medical exposure (for example, medical physics experts, assistants to radiologist or radiographers) with respect to the technical aspects of medical exposure, particularly with respect to radiological interventions for pregnant and breastfeeding women, volunteers in research and helping persons;

5.5. to seek, where possible, to obtain information regarding previous radiological interventions carried out for a person and consider these data to avoid unnecessary exposure;

5.6. to deliver the information to other medical treatment practitioners, including other practitioners and prescribers, regarding the radiological interventions carried out for a person, and also, where necessary, to obtain the previous medical records to reduce individual detriment which may be caused by unnecessary medical exposure;

5.7. to provide the patient and the voluntary assistant with information regarding the potentially harmful effects of ionising radiation.

6. If radiological interventions are performed in conformity with typical radiodiagnostic interventions, also a physician certified in other speciality and trained in performance of the relevant interventions and compliance with the radiation safety has the right to carry out the radiological intervention.

7. The operator shall ensure:

7.1. the development and implementation of a radiation safety quality assurance programme;

7.2. a clinical audit not less than once in five years, except dentistry. The operator shall involve practitioners, medical physics experts and performers of quality control in order

to introduce diagnostic reference levels and clinical protocols appropriate for the specifics of the institution, including:

7.2.1. using reference levels recommended in Annex 1 to this Regulation;

7.2.2. carrying out measurements of a patient dose or parameters related thereto in radiological interventions with a standard-sized patient (body weight is 70 kg);

7.2.3. determining a patient dose or parameters related thereto which may be acquired with a measuring equipment owned by the institution, as a control value;

7.3. involvement of a medical physics expert and medical physicist in radiological interventions (including patient dosimetry and quality assurance optimisation by including also quality control) in conformity with the minimum work loads of medical physics experts and medical physicists indicated in Annex 2 to this Regulation. The medical physics expert, where necessary, shall be involved also in other radiological interventions;

7.4. placement of patients and employees who are related to medical exposure and performance of radiological interventions in premises that conform to the radiation safety requirements;

7.5. access by voluntary assistants to radiation safety instructions;

7.6. provision of information to other medical treatment institutions upon their written request regarding medical exposure performed for a patient;

7.7. work organisation and distribution of responsibility in conformity with the activities with sources of ionising radiation specified in a permit (licence).

8. The following requirements shall be laid down in the radiation safety quality assurance programme:

8.1. conditions and regularity of inspections of technical parameters of the radiological installation, of the equipment for obtaining the image, of the facilities for the protection against ionising radiation and of the technical device related to the generating of ionising radiation, and also conditions of technical maintenance services;

8.2. medical exposure is to be performed by such radiological installation the technical parameters of which conform to the criteria for technical parameters of radiological installation referred to in Annex 3 to this Regulation;

8.3. ensuring the conformity between the purpose of radiodiagnostic or radiotherapeutic intervention and the technical possibilities of the radiological installation used in medical exposure;

8.4. development of written descriptions (protocols) of an intervention for each typical radiodiagnostic intervention of the radiological installation;

8.5. the requirements for control of a patient dosimetry, inspections of measuring devices and medical exposure control devices, including daily inspections of the measuring instrument performance;

8.6. additional requirements for regular quality control measures with respect to the medical exposure of children and the evaluation of patient dose or medical radiological interventions performed on children by involving experts of relating institutions;

8.7. ensuring access to information regarding filtration, focus area sizes, distance from a source of ionising radiation to the image detector, area size indication, and also other parameters which characterise the operation of the radiological installation;

8.8. the requirements for use and inspection of individual protection means (including collars and aprons);

8.9. the requirements for the quality assurance programme laid down in other laws and regulations regarding protection against ionising radiation.

9. Medical technologies related to ionising radiation which the National Health Service has approved in accordance with the laws and regulations regarding the procedures for approval of medical technologies to be used in medical treatment and introduction of new medical

technologies, shall be used in medical exposure. The abovementioned technologies shall be used in conformity with the basic principles of radiation safety and nuclear safety for human protection against ionising radiation laid down in this Regulation.

10. The Radiation Safety Centre of the State Environmental Service (hereinafter – the Centre) shall:

10.1. develop recommendations in cooperation with the relevant professional association regarding study subjects to be included in educational programmes related to radiation safety in medical exposure, including quality assurance issues in order to increase radiation safety level in the country;

10.2. compile information regarding patient doses by assessing the total doses of ionising radiation for certain groups of inhabitants;

10.3. analyse possibilities to reduce a patient dose in conformity with available technologies and methods;

10.4. once a year, provide information to the National Health Service and the Centre for Disease Prevention and Control regarding the special permits (licences) granted and cancelled for the operators and sources of ionising radiation in medicine.

11. In carrying out supervision and control of medical treatment institutions, the Health Inspectorate has the right to request certifications from the operator regarding testing of electric safety and function conformity of radiological installations.

2. Justification for Medical Exposure

12. A prescriber shall complete the referral form for performance of a radiological intervention by justifying the necessity for medical exposure.

13. A practitioner shall evaluate the justification for medical exposure provided by the prescriber and, if such justification is sufficient, shall permit the medical exposure to be performed.

14. Medical exposure without relevant justification is prohibited. The requirements laid down in the laws and regulations regarding organising and financing of health care shall be taken into account in cancer screening.

15. The requirements referred to in Paragraphs 12, 13 and 14 of this Regulation shall not apply to medical researches and medico-legal interventions.

16. In justifying and evaluating the necessity for medical exposure, the practitioner:

16.1. shall compare the possibilities for curing the patient, reducing the expected pain, increasing the medical treatment possibilities or lengthening the life span with the possible individual detriment caused by medical exposure. In comparing, the efficiency, benefit and risk presented by available alternative methods having the same purpose, however, not related to or less related to such medical exposure (for example, ultrasonic examination and chemotherapy) shall be taken into account;

16.2. shall take into account the purposes of medical exposure and physical peculiarities of a person;

16.3. shall take into account the diagnostic reference levels which are indicated in Annex 1 to this Regulation and the diagnostic standard levels for specifics of the institution, if any;

16.4. shall take into account the previously obtained radiodiagnostic information or the data of health history that is related to the planned medical exposure;

16.5. may determine restrictions or refuse performance of a radiological intervention if:

16.5.1. a new medical radiological intervention is started to be used in the medical treatment institution;

16.5.2. evidence of insufficient efficiency of the relevant radiological intervention or possible adverse side effects have been acquired;

16.5.3. if there is no direct diagnostic or therapeutic benefit to the health of the person from medical exposure (also if the person himself or herself requests such exposure). In such cases, medical exposure may be carried out taking into account the restrictions determined by the practitioner, except the case when such exposure causes significant threat to the health or life of the person.

17. When justifying medical exposure of a volunteer assistant, the practitioner shall take into account the direct benefit to the health of the patient and possible harm caused by exposure to the volunteer assistant and the patient.

18. If the use of any radiological intervention is not justified in general, in individual cases the doctors' council may take a decision to permit medical exposure by evaluating the possibility to gain benefit for the health of the patient and the possible individual detriment caused by exposure.

19. Health screening is only permitted if the anticipated benefit for the relevant group of population or for the whole population compensates for the economic and social expenditures that may be caused by the harmful effects of ionising radiation, and if the opportunities of such exposure in discovering of diseases, medical treatment possibilities of the discovered diseases and public benefit from the restriction of the spread of such diseases have been taken into account.

20. Persons may not undergo exposure in a medical or biomedical research (hereinafter – the research), except a case where a consent for the commencement of a research programme has been obtained from the Medical Ethics Commission and the person to be exposed is informed regarding the expected risk and has given a written consent for participation in such research. The Medical Ethics Commission shall monitor that the number of persons involved in the research and subjected to medical exposure is as small as possible, but sufficient in order to obtain precise and reliable information.

21. Before a person undergoes exposure in the research, it shall be necessary to evaluate the possible diagnostic and therapeutic benefit that the person could gain by participating in such research, and to obtain a written consent from his or her attending practitioner.

22. Prior to taking a decision on exposure of a person in the research, the Medical Ethics Commission shall check whether the person intended to be involved in the research and subjected to medical exposure:

22.1. is not dependent on the person performing the research;

22.2. has not given a consent to participate in the research for payment, except the direct compensation for participation in the research, or has been otherwise influenced.

23. The researcher shall be responsible that:

23.1. a person who is intended to be involved in the research and exposed to medical exposure at least one day before exposure is informed regarding the possible risk in writing in form understandable for him or her;

23.2. a person who is intended to be involved in the research and exposed to medical exposure receives information regarding the potential influence on health of the research, and also regarding the side effects which may arise during the research or after it;

23.3. confidentiality of information is ensured regarding the persons involved in the research;

23.4. a possibility to refuse at any time from participation in the research is ensured for persons involved in the research without providing any justification for such refusal.

3. Radiological Interventions

3.1. General Requirements

24. In carrying out a radiological intervention (depending on the purpose of exposure and the organ or tissues to be exposed), organs that are sensitive to ionising radiation which are in the vicinity of the body part to be exposed and which may be affected by ionising radiation (organs of lesser pelvis, mammary glands and thyroid glands) shall be protected during radiological interventions.

25. The practitioner shall:

25.1. be responsible for taking a decision to permit or prohibit the relevant radiological intervention;

25.2. carry out the necessary corrections in performance of medical exposure if the radiological intervention does not ensure radiodiagnostic information or radiotherapeutic result in general;

25.3. take measures in order:

25.3.1. to reduce further medical exposure of persons in general, if patient doses constantly exceed the diagnostic reference levels in a radiodiagnostic intervention;

25.3.2. to reduce medical exposure if a person undergoes a non-standard examination;

25.4. ensure that the dose of ionising radiation received by a voluntary assistant does not exceed 5 mSv per year.

26. If the dose of ionising radiation assessed for the voluntary assistant may exceed 5 mSv per year, such assistant shall be equated to an employee who performs activities with the sources of ionising radiation, and the operator shall ensure individual dosimetry for such assistant.

27. Students, residents and non-certified medical treatment practitioners who are acquiring corresponding education programmes may carry out radiologic intervention or a part thereof in accordance with the laws and regulation regarding medical treatment practitioners and students who are acquiring first or second level vocational higher medical education programmes, their competence in medical treatment and the amount of theoretical and practical knowledge of these persons.

28. A practitioner, an assistant to radiologist and a medical physicist shall control the performance of medical exposure of the patient and ensure documentation of the particular radiological intervention on the relevant medical document forms in accordance with the laws and regulations regarding the procedures for record-keeping of medical documents.

29. An operator shall ensure that inspection of personal protection means is carried out within the time period specified by the manufacturer of lead equivalent, but if it is not determined – not less than once in two years, it shall be carried out by a laboratory accredited in the

national accreditation authority in accordance with the laws and regulations regarding assessment, accreditation and supervision of conformity assessment authorities or in the accreditation authority of another European Union Member State.

3.2. Medical Exposure for Radiodiagnostic Purposes

30. In a radiodiagnostic intervention the practitioner shall be liable for:

30.1. exposure of patients to as small dose of medical exposure as possible taking into account the economic and social factors and choosing such parameters of medical exposure which ensure the obtaining of a qualitative image;

30.2. taking into account of the technical parameters of the relevant radiological installation;

30.3. the possibility to avoid additional medical exposure by using the radiodiagnostic information obtained in the previous medical exposure as much as possible.

31. In order to reduce the patient dose and concurrently provide the necessary radiodiagnostic information, the following parameters of medical exposure shall be taken into account in planning and performing a radiodiagnostic intervention:

31.1. the size of the field to be examined;

31.2. the number and size of digital images, and the number of pictures during the examination or the number sections in computed tomography;

31.3. the type of image detector, its sensitivity and resolution;

31.4. existence of the detection grid of dispersed ionising radiation;

31.5. collimation of the primary beam;

31.6. the technique for improvement of images in dynamic imaging, including the number of images per second;

31.7. the temperature of the developer, algorithm for the reconstruction of images and other factors related to the processing of images;

31.8. the high voltage supplied to the x-ray tube, electric power, duration of examination and other technical parameters of radiological installation;

31.9. physical peculiarities of a patient.

32. A mobile radiological installation shall be used in a radiological intervention only if it is not possible to transfer the patient to the radiodiagnostic room due to medical contra-indications.

3.3. Medical Exposure in Diagnostic Interventions of Nuclear Medicine and for Radiotherapeutic Purposes

33. A radiologist diagnostician in a diagnostic intervention of nuclear medicine shall:

33.1. select a radionuclide with as short half-life as possible;

33.2. select such total radioactivity of the dose to be administered and of the algorithm for obtaining of images that the combination thereof would ensure minimum patient dose and a qualitative image;

33.3. take into account the diagnostic reference levels of total radioactivity;

33.4. introduce the necessary additional requirements for patients with dysfunctions of organs or systems of organs;

33.5.use methods that accelerate the removal of radioactive pharmaceutical preparations;

33.6. if a diagnostic intervention of nuclear medicine is necessary for a child, make adjustments to the total radioactivity of the dose to be administered to the patient by taking into account the physical parameters of the child, and shall choose an appropriate amount

between the minimum dose of a radioactive pharmaceutical preparation for a child (Annex 1, Paragraphs 7 and 8) and the maximum dose for an adult (Annex 1, Paragraph 6);

33.7. ensure that the radioactive pharmaceutical preparation is prepared, the total radioactivity of the dose to be administered to the patient is measured and the amount of such dose is recorded directly before the radiological intervention is performed;

33.8. place the patients who have been administered a radioactive pharmaceutical preparation in a special ward.

34. A radiation therapist in cooperation with a medical physicist shall plan medical exposure of the relevant part of the body in a radiotherapeutic intervention individually, so that the doses of ionising radiation on the surrounding tissues which are not the objects of medical exposure, would be as low as reasonably achievable in conformity with the intended radiotherapeutic objective.

35. A medical physicist or technician in physics shall prepare a plan for medical exposure for each patient in a radiotherapeutic intervention, to be examined by another medical physicist or medical physics expert. The plan shall be approved by a radiation therapist. The plan for medical exposure shall include:

35.1. the total dose of ionising radiation in the object of medical exposure, surrounding tissues and against ionising radiation in sensitive organs;

35.2. the topographic scheme of medical exposure;

35.3. the source of ionising radiation, the type and energy of ionising radiation, the geometric parameters of the field to be exposed, field modifiers, monitor units and other parameters of the field to be exposed;

35.4. the number of medical exposure fractions, the dose rate time of ionising radiation in each exposure fraction.

36. A radiation therapist in a therapeutic intervention of nuclear medicine shall:

36.1. select an appropriate radionuclide;

36.2. comply with the special requirements for patients with dysfunctions of organs or systems of organs;

36.3. be liable for:

36.3.1. receiving the necessary dose of ionising radiation by the planned target (object) volume of medical exposure, protecting other organs and tissues as much as possible;

36.3.2. preparing the radioactive pharmaceutical preparation, measuring the total radioactivity of the dose to be administered to the patient and recording of the amount of such dose directly before the intervention;

36.3.3. placing the patient who has undergone an intervention in a special ward, in order to protect employees related to medical exposure, other patients and visitors against the ionising radiation, and determine the following dose restrictions:

36.3.3.1. the dose of ionising radiation received by a visitor from the patient who is or has been subjected to the radiological intervention of nuclear medicine, may not exceed 5 mSv per year for the whole body;

36.3.3.2. if the visitor has not reached 18 years of age, the dose of ionising radiation received by the visitor from the patient who is or has been subjected to the radiological intervention of nuclear medicine, may not exceed 1 mSv per year for the whole body.

37. In order to limit persons receiving radiation from patients who have undergone a therapeutic intervention of nuclear medicine, the operator shall ensure that the patient is not discharged and released from the medical treatment institution until the total radioactivity

present in his or her body is less than 400 MBq I-131, but if the patient lives together (in one room) with minor children until 14 years of age – 200 MBq I-131. If other radionuclides are used, the total level of radioactivity shall be determined by the radiation therapist, taking into account the protection against the ionising radiation of the persons with whom the patient lives or works together, and that the foreseeable dose of ionising radiation may not exceed 0.1 mSv per year for the whole body, if the patient complies with the instructions of the medical treatment institution.

38. If a patient has been subjected to a radiological intervention of nuclear medicine, the radiologist:

38.1. shall inform the patient regarding the provisions of stay until the end of the radiodiagnostic intervention;

38.2 shall provide visitors to the patient with information regarding the potentially harmful effects of ionising radiation;

38.3. when discharging the patient from the medical treatment institution, shall issue written instructions to the patient or to the member of his or her family, trustee or guardian regarding the measures to be taken for the protection against ionising radiation and information regarding the potential dose of ionising radiation that other persons may receive from the relevant patient.

39. In radiological interventions the operator shall be liable for:

39.1. the recording, collection, labelling, storing for radioactive degradation in accordance with the laws and regulations regarding the requirements for activities with radioactive waste and materials related thereto or release into the environment as are created from patients or in relation to patients on whom radiological interventions of nuclear medicine are or have been performed, of radioactive waste produced in the area controlled by the operator (for example, excretions of patients), radioactively contaminated materials and reusable objects;

39.2. regular dosimetry measurements in premises where radiological interventions of nuclear medicine are performed or in which patients on whom radiological interventions of nuclear medicine are or have been performed, are situated.

4. Radiological Installation

40. An operator shall ensure that the radiological installation used in a radiodiagnostic intervention and the devices thereof conform to the following requirements:

40.1. medical exposure is maintained in conformity with the diagnostic reference levels that would allow to obtain sufficient radiodiagnostic information;

40.2. high-voltage of the generating tube, electric power and exposition time or the electric power multiplied by the exposure time is clearly and accurately indicated on the radiological installation or the instructions for use appended by the manufacturer;

40.3. the radiological installation is equipped with a device which after a specific period of time, and also after reaching the given dose of ionising radiation automatically discontinues generating the ionising radiation;

40.4. the radiological installation and the installations thereof are appropriate and ensure the possibilities for reducing patient doses when performing medical exposure in health examinations, and also when performing such medical exposure in which large patient doses are received, including interventional radiology and computed tomography;

40.5. fluoroscopic device is supplied with a device for measuring the patient dose. If it is not possible to supply the fluoroscopic device with a device for measuring the patient dose, the patient dosimetry shall be carried out by using other methods.

41. In order to reduce medical exposure for children, the operator shall ensure that specialised health care institutions use the following devices for the following examinations:

41.1. a radiodiagnostic device which in addition to 2.5 mm aluminium filter used in devices, is equipped with 0.1 mm aluminium and 0.1 mm copper filter or 0.2 mm copper filter, and there is a possibility to disconnect the device for automatic regulation of dose rate;

41.2. a computed tomography unit which ensures that the patient dose does not differ from that laid down by the manufacturer for more than ±15 % of the diagnostic parameters laid down for children.

42. Fluoroscopic examinations:

42.1. are prohibited:

42.1.1. without an electronic optical image intensification device or equivalent technology;

42.1.2. in screening examination programmes without a device for digital image processing;

42.1.3. without a device for automatic regulation of dose rate in examinations;

42.2. with a switched-off device for automatic regulation of dose rate are permitted:

42.2.1. in examining small parts of the body, including extremities;

42.2.2. in examining a child not older than 5 years or whose weight does not exceed 12 kilograms;

42.2.3. in other cases, taking into account the technical possibilities of the radiological installation.

43. The operator shall ensure that the radiological installation to be used in a radiotherapeutic intervention and the installations thereof conform to the following requirements:

43.1. the device to be used and the installations thereof are supplied with devices that provide a choice of medical exposure and the maintenance of operating parameters in conformity with the purpose of use, with continuous and unambiguous indication regarding such technical parameters of the radiological installation as the type of ionising radiation, energy, primary beam modifiers, including filters, distance to the patient, zone dimensions, orientation of the beam, time of medical exposure and the patient dose;

43.2. the source of ionising radiation in radiological installation is switched off automatically (the generation of ionising radiation is switched off or the source of ionising radiation is transferred from the working position to a safe keeping position, or termination or essential reduction of the exposure is ensured in some other way) if the supply of electric power is discontinued, and the control mechanism of the beam may be restarted only from the control panel;

43.3. the radiological installation of a high dose rate is supplied with safety blocking devices or other devices that do not allow to use such radiological installation otherwise than indicated on the control panel, and such installations are ensured with at least two mutually independent systems for terminating the operation of the installation;

43.4. in the construction of safety blocking devices such physical protection systems as codes and keys are used which guarantee that the operation of the radiological installation with a switched-off blocking device when performing repair work or calibration, is possible only under direct control of the operation employees, using two mutually independent systems for blocking which are switched-off by two specialists concurrently;

43.5. control installations give a warning regarding any deflections in operation of the radiological installation without delay and terminate operation of such installation if deflections exceed the parameters for safe operation.

44. The operator shall ensure that:

44.1. any damage to a component of a radiological installation is detected as soon as possible, but such damage which may create large doses of ionising radiation, is detected without delay and, if technically possible, it is ensured that the source of ionising radiation is not in working condition;

44.2. the probability of a human error in operation of the source of ionising radiation is reduced to the minimum;

44.3. the electrical safety check and testing and assessment of the function conformity of a radiological installation is performed (assessment of technical parameters);

44.4. the dose restrictions in relation to the use of the radiological installation are determined so that the potential dose from one installation at maximum operation parameters does not exceed 1/3 of the dose limits per year (for employees − 6 mSv, for volunteer assistants – 1.5 mSv, but for visitors − 0.3 mSv). If several installations are concurrently used in the relevant room, the restrictions of these doses shall be determined together for all installations.

45. Electrical safety checks of a radiological installation and testing and assessment of its function conformity in relation to technical parameters which are referred to in Tables 1 and 2 of Annex 3 to this Regulation, shall be carried out by the inspecting authority which is accredited by the national accreditation authority in accordance with the laws and regulations regarding assessment, accreditation and supervision of conformity assessment authorities or by an accreditation authority of another European Union Member State:

45.1. when commencing the use of the radiological installation;

45.2. after each such use, maintenance and repair procedures which affect the technical parameters of the radiological installation;

45.3. during use for dental installations not less than once in three years, for other radiological installations – not less than once a year.

46. In addition to that laid down in Paragraph 45 of this Regulation the operator shall ensure that assessment of the technical parameters referred to in Table 3 of Annex 3 to this Regulation in accordance with the requirements and regularity provided for in the quality assurance programme are carried out for:

46.1. radiological installations to be used in a radiodiagnostic intervention – by the inspecting authority, the radiation safety unit, the medical physicist, the medical physics expert or the work manager;

46.2. radiological installations to be used in a radiotherapeutic intervention – by the inspecting authority or the medical physics expert.

47. Calibration of a dose and area multiplication meter referred to in Table 2, Section I, Paragraph 8 of Annex 3 to this Regulation shall be carried out not less than once in two years by a laboratory which is accredited in the national accreditation authority in accordance with the laws and regulations regarding assessment, accreditation and supervision of conformity assessment authorities or in the accreditation authority of another European Union Member State.

48. The inspecting authority has the following obligations:

48.1. not less than four times a year (until 15 April, 15 July, 15 October and 15 January of the current year) to inform the Centre in writing regarding the electrical safety checks and testing and assessment of the function conformity (assessment of technical parameters) carried out for radiological installations, indicating the following information:

48.1.1. the name and registration number of the operator;

48.1.2. the name and location (address) of the radiological installation;

48.1.3. the date and number of the report on testing and assessment (assessment of technical parameters) of the function conformity of the radiological installation;

48.2. after issuance of a report on testing and assessment of the function conformity of the radiological installation to the operator, to immediately inform the Centre in writing regarding non-conformities detected during the electrical safety check and testing and assessment (assessment of technical parameters) of the function conformity of the radiological installation.

49. In carrying out surveillance in radiation safety and nuclear safety, the Centre shall:

49.1. assess the possibility of use of the radiological installation according to the planned purposes;

49.2. control whether the regularity of assessment of the technical parameters referred to in Table 3 of Annex 3 to this Regulation is included in the quality assurance programme, and, where necessary, request that the operator adjusts the regularity of assessment;

49.3. where necessary, request that the operator improves the technical parameters of the radiological installation or rectifies defects;

49.4. request to suspend the use of the radiological installation until performance of corrective activities or termination of operation of the installation, if its operation fails to conform to the radiation safety requirements, the technical parameters of the radiological installation do not conform to the requirements laid down (Annex 3) or the radiological installation does not ensure the necessary radiodiagnostic information or radiotherapeutic result.

50. The Centre shall inform the State Agency of Medicines, the Health Inspectorate and the National Health Service regarding the decision to prohibit the use of a radiological installation.

5. Protection of Pregnant Women, Breastfeeding Mothers and Children against Ionising Radiation

51. If it is intended for a woman of childbearing age to undergo medical exposure, the prescriber or practitioner shall find out whether she is not pregnant or breastfeeding, and shall make a relevant entry in the medical document and referral thereof. The woman shall certify with a signature that the information provided by her is correct.

52. If medical exposure is necessary for a pregnant woman, especially, if abdominal and pelvic regions are subjected to exposure, the prescriber and practitioner in the justification for medical exposure shall perform additional evaluation of the urgency of medical exposure and the optimisation of medical exposure, taking into account also exposure of the foetus.

53. Any medical exposure of a pregnant woman shall be planned so that she would receive the minimum patient dose. The practitioner shall inform the pregnant woman regarding the potential risk for the foetus.

54. In the case of a breastfeeding mother, the prescriber and practitioner in the justification for the medical exposure of nuclear medicine shall, in addition, evaluate the urgency of medical exposure and the optimisation of medical exposure, taking into account also the expected exposure of the child. The practitioner shall plan medical exposure so that the mother and the child would receive the minimum patient dose.

55. If in a medical radiological intervention the practitioner uses radionuclides on a breastfeeding mother, the mother shall terminate breastfeeding and continue it only when the amount of radioactive pharmaceutical preparation in the human milk is smaller than the permissible total radioactivity. The permissible limits of the total radioactivity of radioactive pharmaceutical preparations in human milk are specified in Annex 4 to this Regulation.

56. Medical treatment institutions shall organise measures where women of childbearing age, pregnant women and breastfeeding mothers are warned regarding the potential threats of ionising radiation, and shall promote the awareness of such women by preparing and placing materials regarding such issues in appropriate places in the relevant medical treatment institutions.

57. The practitioner shall ensure that when children undergo medical exposure, only such radiological installation and additional installations are used which are adequate for children, and that the diagnostic reference levels laid down in Paragraph 2 of Annex 1 and Paragraphs 7 and 8 of Annex 1 to this Regulation are observed.

6. Unplanned Exposure

58. In order to reduce the risk of unplanned exposure, the operator shall provide an analysis of potential radiation accidents, ascertain possible damages of a radiological installation and mistakes of the employees that could facilitate unplanned exposure of a person.

59. The practitioner shall, without delay, inform the operator regarding failure to comply with the requirements of this Regulation or of a radiation accident and shall ensure the necessary protection measures during medical exposure in order to reduce the risk and amount of unplanned exposure of patients.

60. The operator shall, without delay, investigate the following radiation accidents and cases of unjustified exposure:

60.1. medical exposure for radiotherapeutic purposes which has caused individual detriment to the patient if:

60.1.1. inadequate radiopharmaceutical preparation has been used;

60.1.2. the dose of ionising radiation for medical exposure of a person or the fractionation of the dose differs from that determined by the practitioner;

60.1.3. medical exposure of a patient may cause unexpected acute effects outside the target volume;

60.1.4. the total patient dose exceeds the dose determined by the radiation therapist by 5%;

60.2. radiodiagnostic exposure that differs from the diagnostic reference level (exceeds it) by 30% (Annex 1);

60.3. unjustified repeated medical exposure of a patient;

60.4. damage to a radiological installation or other unexpected cases due to which radiodiagnostic exposure of a patient differs from the planned exposure by more than 20 %;

60.5. medical exposure has been carried out for a person for whom the relevant medical intervention was not necessary.

61. If the accident referred to in Paragraph 60 of this Regulation or a case of unjustified exposure has occurred, the operator together with the practitioner and the medical physics expert shall:

61.1. calculate or evaluate the received patient dose and the distribution of such dose in the body of the patient, and also inform the prescriber and the patient of the abovementioned dose and the potential consequences of the accident;

61.2. determine and perform a set of correcting measures in order to prevent the recurrence of such accidents;

61.3. within 24 hours inform the Centre of any radiation accidents that may cause health disorders to a patient or the death of a patient;

61.4. within 30 days after a radiation accident which may cause health disorders to a patient or the death of a patient, submit to the Centre a written report in which the causes of the accident have been specified, information regarding the used patient doses, measures taken and any other substantial information is provided;

61.5. notify the State Agency of Medicines regarding accidents which are related to the use of radiological medical installations in accordance with the procedures laid down in the laws and regulations regarding the requirements for ensuring the medical device vigilance system.

7. Use of Radiodiagnostic Interventions in Medico-Legal Interventions

62. Exposure with a written consent of the person to be examined or his or her guardian may be carried out in the following medico-legal interventions without any medical indications:

62.1. in order to discover items hidden in the human body;

62.2. according to the person directing the proceedings or a court decision in order to ascertain regarding a hidden trauma or health damage which could not be otherwise discovered;

62.3. in forensic medicine.

63. Exposure without a written consent of the person to be examined may be carried out if there is a significant threat to the public safety.

64. A physician practising in medico-legal interventions or a work manager shall inform the person to be examined together with the prescriber prior to any exposure regarding the justification for the intervention and the potential adverse effect.

65. Exposure in medico-legal interventions for children in order to detect the consequences of physical violence, if there are not clinical indications, is permissible only as an exception if alternative methods may not be used.

8. Closing Provisions

66. Cabinet Regulation No. 97 of 5 March 2002, Regulations Regarding Protection Against Ionising Radiation in Medical Exposure (*Latvijas Vēstnesis*, 2002, No. 38; 2005, No. 176), is repealed.

67. The Regulation shall come into force on 1 October 2014.

68. The requirement laid down in Paragraph 29 of this Regulation regarding accreditation of laboratories shall come into force on 1 September 2015.

69. Paragraph 47 of and Annex 3 to this Regulation shall come into force on 1 September 2015. Until 31 August 2015 electric safety inspections and function conformity testing and assessment of radiological installations in accordance with Paragraphs 45 and 46

of this Regulation shall be carried out in conformity with accreditation of the inspecting authority which has been carried out until the day of coming into force of this Regulation.

Informative Reference to Directives of the European Union

The Regulation contains legal norms arising from:

1) Council Directive 97/43/EURATOM of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/Euratom;

2) Council Directive 96/29/EURATOM of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation.

Prime Minister — Laimdota Straujuma

Minister for Environmental Protection and Regional Development — Romāns Naudiņš

Annex 1
Cabinet Regulation No. 482
19 August 2014

Diagnostic Reference Levels

1. Diagnostic Reference Levels in Roentgenography

No.	Object to be examined	Projection	Entrance surface dose[1] for a patient in one roentgenography (mGy)
1.	Lumbar vertebrae	Antero-posterior (AP) projection	10
		Lateral (LL) projection	30
		Lumbosacral transition with an oblique cranially	40
2.	Abdominal cavity	Antero-posterior (AP) projection	10
3.	Pelvic cavity	Antero-posterior (AP) projection	10
4.	Hip joint	Antero-posterior (AP) projection	10
5.	Chest cavity	Postero-anterior (PA) projection	0.4
		Lateral (LL) projection	1.5
6.	Mammary glands	Craniocaudal (CC) projection (with a grid)	10
		Mediolateral oblique (MLO) projection (with a grid)	10
		Lateral (LL) projection (with a grid)	10
7.	Urinary system:		
7.1.	before contrasting substance is administered		10
7.2.	after contrasting substance is administered		10
8.	Thoracic vertebrae	Antero-posterior (AP) projection	7
		Lateral (LL) projection	20
9.	Teeth	Intraoral projection	7
		Antero-posterior (AP) projection	5
10.	Head	Postero-anterior (PA) projection	5
		Lateral (LL) projection	3

Note.
[1] Dose of ionising radiation into the air (mGy) together with the dispersed radiation at the entrance surface shall conform to the film-screen combination with the relative sensitivity of 200. The value of the film-screen combination of high sensitivity (400-600) shall be reduced two to three times.

2. Diagnostic Reference Levels in Roentgenography Paediatrics[1]

No.	Object to be examined	Projection	Entrance surface dose[2] for a patient in one roentgenography (mGy)
1.	Chest cavity	Postero-anterior (PA) projection	0.10
		Antero-posterior (AP) projection	0.10
		Lateral (LL) projection	0.20
		Antero-posterior (AP) projection for newborn infants	0.08
2.	Head	Postero-anterior/antero-posterior (PA/AP) projection	1.50
		Lateral (LL) projection	1.00
3.	Pelvic cavity	Antero-posterior (AP) projection	0.90
		Antero-posterior (AP) projection for infants	0.20
4.	Abdominal cavity	Antero-posterior/postero-anterior (AP/PA) projection with a vertical/horizontal beam	1.00

Notes.
[1] The dose of ionising radiation into the air (mGy) intended for a five-year old child, in other cases adjustments shall be made by taking into account the age and weight of the patient.
[2] The dose of ionising radiation into the air (mGy) together with the dispersed radiation at the entrance surface shall conform to the film-screen combination with the relative sensitivity of 200. The value of the film-screen combination of high sensitivity (400-600) shall be reduced two to three times.

3. Diagnostic Reference Levels in Computed Tomography

No.	Type of examination	For one manipulation (many sections) the average dose of ionising radiation[1] (mGy)
1.	Head	50
2.	Lumbar vertebrae	35
3.	Abdominal cavity	25

Note.
[1] To be determined in the measurements of a phantom of the head produced of a material that is equivalent to water and the length of which along the rotation axis is 15 cm, diameter –

16 cm, and of a phantom of abdominal cavity produced of a material equivalent to water, the length of which is 15 cm, diameter – 30 cm.

4. Diagnostic Reference Levels in Mammography

No.	Average dose of ionising radiation of mammary glands in each craniocaudal projection[1] (mGy)	
1.	With a grid	3
2.	Without a grid	1

Note.
[1] To be determined for a breast that is compressed to a thickness of 4.5 cm and that consists of 50 % gland tissues and 50 % fat tissues by using an x-ray tube of film and a screen system with molybdenum anode and molybdenum filter.

5. Diagnostic Reference Levels in Fluoroscopy

No.	Type of activities	Dose rate for entrance surface[1] (mGy/min)
1.	Fluoroscopy with a normal beam load	25
2.	Fluoroscopy with a large beam load[2]	100

Notes.
[1] Dose of ionising radiation into the air (mGy) together with the dispersed ionising radiation at the entrance surface.
[2] Fluoroscopy examinations the equipment of radiological installations of which provides the possibility to perform fluoroscopy with a large beam load which is frequently used in invasive radiology.

6. Diagnostic Reference Levels in Nuclear Medicine

No.	Organ to be examined or type of scintigraphy	Radionuclide	Chemical form	Maximum total radioactivity of the dosage to be administered per one examination (MBq)
1.	Skeleton	^{99m}Tc	Phosphates and other phosphorus compounds	600
2.	Skeleton (single photon emission computed tomography SPECT)	^{99m}Tc	Phosphates and other phosphorus compounds	800
3.	Red bone marrow	^{99m}Tc	Colloid	400
4.	Brain (static)	^{99m}Tc	Sodium pertechnetate	500
		^{99m}Tc	Diethylene-triamino-penta	500

			acetate (DTPA), gluconate and glucoheptonate	
5.	Brain (single photon emission computed tomography SPECT)	^{99m}Tc	Sodium pertechnetate	800
		^{99m}Tc	Diethylene-triamino-penta-acetate (DTPA), gluconate, glucoheptonate	800
		^{99m}Tc	Exametazime	500
6.	Radionuclide angiography of brain	^{133}Xe	Isotonic solution of sodium chloride	400
		^{99m}Tc	Hexa-methyl-propylene amine oxime (HMPAO)	500
7.	Cisternography	^{111}In	Diethylene-triamino-penta-acetate (DTPA)	40
8.	Lacrimal glands and the drainage thereof	^{99m}Tc	Sodium pertechnetate	4
		^{99m}Tc	Marked colloid	4
9.	Thyroid gland	^{99m}Tc	Sodium pertechnetate	200
		^{123}I	Iodide	20
10.	Metastases of thyroid gland	^{131}I	Iodide	400
11.	Epithelium cells	^{201}Tl	Thallium chloride	80
12.	Lung perfusion	^{81m}Kr	Water solution	6000
		^{99m}Tc	Human serum albumin (macro-aggregates or micro-spheres)	100
		^{133}Xe	Isotonic solution of sodium chloride	200
		^{127}Xe	Isotonic solution of sodium chloride	200
13.	Lungs (single photon emission computed tomography SPECT)	^{99m}Tc	Human serum albumin macro-aggregates (MAA)	200
14.	Lung ventilation	^{81m}Kr	Gas	6000
		^{99m}Tc	Diethylene-triamino-penta-acetate (DTPA) aerosol	80
		^{133}Xe	Gas	400
		^{127}Xe	Gas	200
15.	Liver	^{99m}Tc	Colloid	80
16.	Liver (single photon emission computed tomography SPECT)	^{99m}Tc	Colloid	200
17.	Liver and gall tract	^{99m}Tc	Iminodiacetate derivatives	150

			(IDA)	
18.	Spleen	^{99m}Tc	Denatured erythrocytes	100
19.	First passage of blood through the heart	^{99m}Tc	Sodium pertechnetate	800
		^{99m}Tc	Diethylene-triamino-penta-acetate (DTPA), gluconate, glucoheptonate	800
		^{99m}Tc	Globulin-3 macro-aggregates (MAG3)	400
20.	Heart cavities and blood vessels	^{99m}Tc	Human serum albumin	800
		^{99m}Tc	Marked erythrocytes	800
21.	Myocardium	^{99m}Tc	Phosphonates and phosphate compounds	
		^{99m}Tc	Isonitrils	300
22.	Myocardium (single photon emission computed tomography SPECT)	^{201}Tl	Chloride	100
		^{99m}Tc	Phosphonates and phosphate compounds	800
		^{99m}Tc	Isonitrils	600
23.	Salivary gland and stomach	^{99m}Tc	Sodium pertechnetate	40
24.	Meckel's diverticulum	^{99m}Tc	Sodium pertechnetate	400
25.	Bleeding of stomach and intestinal canal	^{99m}Tc	Colloid	400
		^{99m}Tc	Erythrocytes	400
26.	Emptying of stomach	^{99m}Tc	Non-absorbing compounds	12
		^{111}In	Non-absorbing compounds	12
		^{113m}In	Non-absorbing compounds	12
27.	Passage of oesophagus and regurgitation	^{99m}Tc	Non-absorbing compounds	40
		^{99m}Tc	Colloid	40
28.	Static scintigraphy of kidneys	^{99m}Tc	Dimercapto-succinic acid (DMSA)	160
29.	Radionuclide angiography and dynamic scintigraphy of kidneys	^{99m}Tc	Diethylene-triamino-penta acetate (DTPA), gluconate and glucoheptonate	350
		^{99m}Tc	Globulin-3 macro-aggregates (MAG3)	100
		^{123}I	O-iodine hippuran	20
30.	Adrenal gland	^{75}Se	Seleno-cholesterol	8
31.	Tumour or abscess	^{67}Ga	Citrate	300
		^{201}Tl	Chloride	100
		^{99m}Tc	Dimercapto-succinic acid (DMSA)	400

32.	Abscess	^{99m}Tc	Exametazime-marked leucocytes	400
		^{111}In	Marked leukocytes	20
33.	Tumour	^{99m}Tc	Dimercapto-succinic acid (DMSA)	400
34.	Neuroectodermal tumours	^{123}I	Metha-iodine-benzyl-guanidine (MIBG)	400
		^{131}I	Metha-iodine-benzyl-guanidine (MIBG)	20
35.	Lymph nodes	^{99m}Tc	Marked colloid	80
36.	Thrombi in blood vessels	^{111}In	Marked thrombocytes	20

7. Diagnostic Reference Levels in Nuclear Medicine Paediatrics

No.	Radionuclide	Minimum total radioactivity of dosage to be administered[1] to a child (MBq)
1.	^{67}Ga – citrate (tumours)	10
2.	^{123}I – amphetamine (brain)	18
3.	^{123}I – hippuran (kidneys)	10
4.	^{123}I – iodide (thyroid gland)	3
5.	^{123}I – metha-iodine-benzyl-guanidine (MIBG) (tumour)	35
6.	^{131}I – metha-iodine-benzyl-guanidine (MIBG) (tumour)	35
7.	^{99m}Tc – albumin (heart)	80
8.	^{99m}Tc – colloid (liver, spleen and red bone marrow)	15
9.	^{99m}Tc – colloid (stomach regurgitation)	10
10.	^{99m}Tc – diethylene-triamino-penta-acetate (DTPA) (kidneys)	20
11.	^{99m}Tc – dimercapto-succinic acid (DMSA) (kidneys)	15
12.	^{99m}Tc – phosphorus compounds (skeleton)	40
13.	^{99m}Tc – denatured erythrocytes (spleen)	20
14.	^{99m}Tc – IDA derivatives (gall duct)	20
15.	^{99m}Tc – hexamethylpropylene amine oxime (HMPAO) (brain)	100
16.	^{99m}Tc – hexamethylpropylene amine oxime (HMPAO) (inflammation)	40
17.	^{99m}Tc – human serum albumin macro-aggregates (MAA) or micro-spheres (lungs)	10
18.	^{99m}Tc – globulin-3 micro-aggregates (MAG_3) (kidneys)	15

19.	^{99m}Tc − pertechnetate (miction cystourethrography)	20
20.	^{99m}Tc − pertechnetate (first passage)	80
21.	^{99m}Tc − pertechnetate (Meckel's diverticulum and ectopic mucous membrane of stomach)	20
22.	^{99m}Tc − pertechnetate (thyroid gland)	10
23.	^{99m}Tc − marked erythrocytes (for the visualising of lumen)	80

Note.
[1] 1/10 from the total radioactivity intended for an adult.

8. Conversion Factors for Children of the Total Radioactivity of Dosage to be Administered to Patients

No.	Child's weight (kg)	Conversion factor
1.	3	0.10
2.	4	0.14
3.	6	0.19
4.	8	0.23
5.	10	0.27
6.	12	0.32
7.	14	0.36
8.	16	0.40
9.	18	0.44
10.	20	0.46
11.	22	0.50
12.	24	0.53
13.	26	0.56
14.	28	0.58
15.	30	0.62
16.	32	0.65
17.	34	0.68
18.	36	0.71
19.	38	0.73
20.	40	0.76
21.	42	0.78
22.	44	0.80
23.	46	0.82
24.	48	0.85

25.	50	0.88
26.	52−54	0.90
27.	56-58	0.95
28.	60-62	1.00

Minister for Environmental Protection and
Regional Development Romāns Naudiņš

Annex 2
Cabinet Regulation No. 482
19 August 2014

Minimum Workload of Medical Physicists and Medical Physics Experts Working with a Radiological Installation

No.	Radiological installation	Minimum workload of a medical physicist[1]	Minimum workload of a medical physics expert[1]
1.	Accelerator	0.88	0.37
2.	Radiological installation (with closed sources of radiation)	0.34	0.14
3.	Roentgen equipment in medicine	0.07	0.03
4.	Radiological installation used for medical exposure in body cavities	0.42	0.18
5.	Simulator	0.30	0.13
6.	Radiation planning system:		
6.1.	for external radiotherapy	0.38	0.16
6.2.	for brachitherapy	0.08	0.04
7.	For 100 patient years[2]:		
7.1.	for external radiotherapy	0.27	0.11
7.2.	for brachitherapy	0.22	0.09
8.	Activities with radioactive substances (for each TBq)	0.40	0.20
9.	Portable or mobile radiological installation	0.30	0.15
10.	Radiotherapy device the source of ionising radiation of which in operating condition is located outside the device	0.50	0.30

Notes.
[1] Full workload shall be presumed as 1.
[2] 100 patient years – apply to patients who undergo the relevant medical radiological intervention for the first time or a repeat intervention, or an intervention of a new type (including an intervention of medical exposure if the purpose of exposure is changed).

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Annex 3
Cabinet Regulation No. 482
19 August 2014

Technical Parameters of Radiological Installations and Measurement Conditions Thereof

Table 1

Parameters to be Assessed During Electric Safety Inspections of Radiological Installations, Minimum Conformity Criteria and Measurement Conditions Thereof[1]

No.	Parameter to be assessed	Conformity criterion	Measurement conditions
1.	Resistance of protective conductors	< 0.3 Ω	Measurements are carried out in the operating mode of radiological installations in conformity with the connection scheme specified by the manufacturer
2.	Body leakage current	< 0.1 mA	Measurements are carried out in the operating mode of radiological installations in conformity with the connection scheme specified by the manufacturer

Note.
[1] The conditions for electrical safety checks shall apply to the radiological installations which are referred to in Table 2 of Annex 3 to this Regulation.

Table 2

Technical Parameters of Radiological Installations, Minimum Conformity Criteria and Measurement Conditions Thereof in Function Testing and Assessment

No.	Technical parameters	Conformity criterion[1]	Measurement conditions
I. Parameters of Diagnostic Radiography Equipment[2]			
1.	Accuracy of high-voltage of the tube:		
1.1.	conformity of the voltage measured with the parameters indicated on the scale and high-voltage deflection in repeated measurements	≤ ± 10 %	Measurements: 1) with the following high-voltage values: 60, 80, 100 and 120 kV. If it is not possible to set the abovementioned values, the nearest possible value shall be used.

			At ~80 kV measurements shall be carried out also at the minimum current value and at 80 % of the maximum current value; 2) anode current ~50 % of the maximum value of anode current. Generators which have the possibility of setting only mAs values, current and time multiplication of a large focus ~32 mAs, but for a small focus ~20 mAs; 3) exposure time – 100 ms; 4) for all usable focuses of the tube
1.2.	replicability of high-voltage, when modifying electric power of the tube	< ± 5 %	Measurements if high-voltage is ~80 kV with minimum and 80 % of the maximum anode current
2.	Half-value layer:		Measurements with high voltage ~80 kV for tube with wolfram anode. If it is not possible to set 80 kV value, the nearest possible shall be used and a linear interpolation method shall be used for determination of the value of half-value layer
2.1.	half-value layer	≥ 2.9 mm Al	
2.2.	half-value layer for the installations which are manufactured before 2008	≥ 2.3 mm Al	
3.	Air kerma[2] linearity	< ± 20 %	Measurements at high-voltage ~80 kV with five different values of anode current and exposition time multiplication
4.	Air kerma[3] replicability[4]	< ± 5 %	Measurements: 1) at high-voltage ~80 kV with five different anode currents, including minimum and 80 % of the maximum value of anode current; 2) for all usable focuses of roentgen equipment
5.	Dose return of ionising radiation at the distance of 1 m from the focus of tube	> 25 µGy/mAs	Measurements at high voltage ~80 kV and full filtration of tube – 2.5 mm Al
6.	Replicability of exposition dose in automatic control regime by using one of the following methods:		
6.1.	if dosimetry method is used	< ± 5 %	Measurements at high-voltage ~80 kV

6.2.	if roentgen film method is used	< 0.2 optical density units (at average gradient around 3.0)	Measurements at high voltage 80 kV with a patient phantom of different thickness that is equivalent to water (or PMMA[5]): 10, 15 and 20 cm
7.	Accuracy of exposition time[6]	≤ ± 10 %	Measurements in the following exposition time ranges: 20–50 ms, 100–200 ms and 500–800 ms
8.	Accuracy of dose and area multiplication meter	≤ ± 25 %	Measurements with the following high-voltage values: 50, 70, 90 and 110 kV. If it is not possible to set the abovementioned values, the nearest possible value shall be used
II. Additional Parameters for Fluoroscopy Installations[7]			
1.	Rate of air kerma[3] in the entrance field of the intensifier of roentgen image:		Examinations in automatic regime
1.1.	for general use roentgen installations	< 1.0 µGy/s	
1.2.	for indirect radiography installations	< 2.0 µGy/s	
1.3.	cineradiography installations	< 0.2 µGy/ per frame	
2.	Resolution:		
2.1.	with 15−18 cm intensifier of roentgen image	≥ 1.4 pairs of lines/mm	1) Visible image is at least 2/3 of rated field of the intensifier of roentgen image; 2) Test object of resolution is placed as close to the entrance field of the intensifier of roentgen image as possible
2.2.	with 23-25 cm intensifier of roentgen image	≥ 1.0 pairs of lines/mm	
2.3.	with 30-35 cm intensifier of roentgen image	≥ 0.8 pairs of lines/mm	
2.4.	for indirect radiography installations with 25 cm intensifier of roentgen image	≥ 2.0 pairs of lines/mm	
2.5.	for cineradiography installations with 25 cm intensifier of roentgen image	≥ 1.6 pairs of lines/mm	
III. Additional Parameters for Digital Radiography Devices and Digital Scanners			
1.	Contrast resolution:		
1.1.	test by using an object of different optical density (dynamic step ladder)	Steps of variable thickness (optical density) are visible	Copper test object of the following thickness: 0 mm, 0.3 mm, 0.65 mm, 1.0 mm, 1.4 mm, 1.85 mm and 2.3 mm

1.2.	test object of a low contrast	At least three low contract objects are visible	Aluminium test object of the following thickness: 0.1 mm, 0.15 mm, 0.25 mm, 0.35 mm, 0.5 mm and 0.7 mm
2.	Spatial resolution:		
2.1.	if air kerma[3] is between 5 to 10 µGy in the distance of focus–image detector	≥ 2.8 pairs of lines/mm	Test object of spatial resolution shall be used
2.2.	if air kerma[3] is less than 5 µGy in the distance of focus–image detector	≥ 2.4 pairs of lines/mm	
3.	Geometrical parameters of the image	≤ 3 % of the distance of focus–image detector	If there are coincidence deflections, the deflection in each axis (horizontally and vertically)
IV. Dental Roentgen Installations[8]			
1.	High-voltage precision of the tube	≤ ± 10 %	If it is possible to change high-voltage and anode current, the measurements shall be carried out at most often used high-voltage and anode current installations by using exposition time around 500 ms.
2.	Total filtration of primary beam:		
2.1.	complete filtration	≥ 1.5 mm Al	If high-voltage of roentgen installation is ≤ 70 kV
2.2.	complete filtration	≥ 2.5 mm Al	If high-voltage of roentgen installation is > 70 kV
2.3.	half-value layer thickness	≥ 1.95 mm Al	If high-voltage of roentgen installation is 65 kV
2.4.	half-value layer thickness	≥ 2.1 mm Al	If high-voltage of roentgen installation is 70 kV
3.	Dose of ionising radiation at the distance of 1 m from the focus with the range of voltage	> 30 µGy/mAs	Measurements with high-voltage 50-70 kV
4.	Replicability of air kerma[3]	< ± 5 %	Measurements by using exposition time ~ 500 ms
5.	Accuracy of exposition time	≤ ± 20 %	Measurements in the following exposition time ranges: 20–50 ms; 100–200 ms and 500–800 ms

V. Computed Tomography (CT) Installations			
1.	Image parameters:		
1.1.	image noise	≤ ± 10 % or ≤ 0.2 HU[9]	CT standard deflection of absorption figure in the centre of examination zone of the phantom that is equivalent to water or tissues in the examination area of at least 40 % of the test object (16 cm and/or 32 cm PMMA[5] phantom) image against the base value
1.2.	average deflection of CT−figure	≤ ± 4 HU[9]	Deflection of CT absorption figure (in the centre of examination zone in the examination area of at least 10 % of the test object) against the base value
1.3.	balance	≤ ± 2 HU[9]	Average deflection of CT absorption figure in periphery from CT absorption figure in the centre of examination zone of the phantom that is equivalent to water or tissues in the examination area of at least 10 % of the test object against the base value
2.	Spatial (high contrast) resolution	≥ 0.5 pairs of lines/cm or ≤ ± 15 % of the base value	
3.	CT dose index (or multiplication of the dose and length of the active part of measurement sensor)	≤ ± 20 %	Dose measurements of ionising radiation in the rotation centre of 16 cm and/or 32 cm PMMA[5]phantom and in the periphery (in the distance of 1 cm of the surface) against the base value
4.	Thickness of the section layer:		
4.1.	if the nominal thickness of the section layer is ≥ 2 mm	≤ ± 1.0 mm	At least with the minimum, average and maximum set value of the thickness of the section layer
4.2.	if the nominal thickness of the section layer is between 1 and 2 mm	≤ ± 50 %	
4.3.	if the nominal thickness of the section layer is ≤ 1 mm	≤ ± 0.5 mm	

5.	Positioning of the medical treatment table:		
5.1.	longitudinal positioning of the medical treatment table:	≤ ± 1.0 mm	Measurements with equivalent phantom the weight of which conforms to 70 kg (a standard-sized patient weight)
5.2.	backward positioning of the medical treatment table	≤ ± 1.0 mm	
VI. Mammography Installations			
1.	High-voltage precision of the tube	≤ 2 kV	Deviation from the installed high-voltage (25, 28 and 30 kV)
2.	Replicability of air kerma[2]	≤ 5 %	Measurements at 28 kV and ~20 mAs
3.	Automatic control of the exposition dose by using one of the following methods:		
3.1.	optical density constancy |D| by changing the tube voltage and phantom thickness of a patient equivalent (roentgen film method)	|D| ≤ 0.15 optical density units (applicable to average gradient 1.4–2.0 optical density units in a reference image, acquired with high-voltage 28 kV and 40 mm PMMA[5])	Measurements: 1) at high voltage of 28 kV with different phantom thickness of a patient equivalent – 20, 40 and 60 mm PMMA[5]; 2) at high voltage of 25 kV and 30 kV with equivalent phantom thickness – 40 mm PMMA[5]
3.2.	replicability (dosimetry method)	≤ 5 %	Measurements at high-voltage of 28 kV with phantom thickness of a patient equivalent – 40 mm PMMA[5]
4.	Average gland dose:		
4.1.	with a phantom of 40 mm PMMA[5]	< 2.0 mGy	Measurements in the automatic exposition regime with high-voltage of 28 kV
4.2.	with a phantom of 45 mm PMMA[5]	< 2.5 mGy	
4.3.	with a phantom of 50 mm PMMA[5]	< 3.0 mGy	
5.	Half-value thickness:		
5.1.	if molybdenum anode and 30 µm molybdenum filter is used	≥ 0.2 mm Al	Measurements: 1) with high-voltage 28 kV; 2) without compression plate
5.2.	if molybdenum anode and 25 µm rhodium filter is used	≥ 0.40 mm Al	
5.3.	if wolfram anode and 60 µm molybdenum filter is used	≥ 0.37 mm Al	

5.4.	if wolfram anode and 50 µm rhodium filter is used	≥ 0.51 mm Al	
5.5.	if rhodium anode and 25 µm rhodium filter is used	≥ 0.39 mm Al	
5.6.	if wolfram anode and 500 µm aluminium filter is used	≥ 0.46 mm Al	
6.	Air kerma[2] rate	≥ 7.5 mGy/s	Measurements: 1) in a distance which is applied to focus–image detector distance from the dispersed radiation under free circumstances; 2) at high-voltage of 28 kV and ~20 mAs
VII. Radiotherapy[10]			
1.	Mechanical inspections:		
1.1.	accuracy of setting of gantry rotation angle	± 1°	Measurements at gantry angles 0°, 90°, 180°, 270°
1.2.	accuracy of setting of collimation system rotation angle	± 1°	Measurements at collimation system angles 0°, 90°, 180°, 270°
1.3.	accuracy of setting of isocentric rotation angle of the medical treatment table	± 1°	Measurements at table angles 0°, 90°, 270°
1.4.	accuracy of setting of medical treatment table surface rotation angle	± 1°	Measurements at table angle 0°
1.5.	deflection of isocentre by rotating the gantry	2 mm (diameter)	Measurements at gantry angles 0°, 90°, 180°, 270°
1.6.	deflection of isocentre by rotating the collimation system	2 mm (diameter)	Measurements at collimation system angles 0°, 90°, 180°, 270°
1.7.	deflection of isocentre by isocentric rotating of the table	2 mm (diameter)	Measurements at table angles 0°, 90°, 270°
1.8.	accuracy of the indicator which indicates the distance from the source until surface	± 2 mm	Measurements at isocentre, and also at the maximum and minimum distance used in a clinical practice
1.9.	coincidence of beam alignment wire point of intersection with isocentre by rotating the collimation system	2 mm (diameter)	Measurements at isocentre plane at the collimation system angles 0°, 90°, 180°, 270°
1.10.	accuracy of indication of size numbers of the light field	± (2 mm or 1 %)	Measurements at isocentre plane for each axis of the light field

1.11.	accuracy of lateral movement indication of the medical treatment table	± 2 mm	Measurements at isocentre plane at least at three table positions used in clinical practice
1.12.	accuracy of longitudinal movement indication of the medical treatment table	± 2 mm	Measurements at isocentre plane at least at three table positions used in clinical practice
1.13.	accuracy of vertical movement indication of the medical treatment table (without load)	± 2 mm	Measurements at isocentre, and also in the range of heights used in the entire clinical practice
1.14.	coincidence of the light field with the field of ionising radiation	± 1 mm (the edge < 10 cm) ± 1 % (the edge ≥ 10 cm)	Measurements at the light fields 5 x 5 cm^2, 10 x 10 cm^2, 20 x 20 cm^2, 30 x 30 cm^2, 20 x 10 cm^2 (asymmetrical field with one edge of the field through the isocentre by setting it for each edge)
2.	Control system of the dose of ionising radiation:		
2.1.	replicability	± 0.5 %	Measurements at all radiation energies and dose rate regimes used in clinical practice
2.2.	linearity[11]	± 2 %, if ≥ 5 MU, ± 5 %, if 2−4 MU	Measurements at 2 MU, 5 MU, 20 MU, 100 MU, 500 MU all radiation energies and dose rate regimes used in clinical practice
2.3.	stability of the dose of ionising radiation at isocentre by rotating the gantry	± 2 %	Measurements at gantry angles 0°, 90°, 180°, 270° for all radiation energies and dose rate regimes used in clinical practice
3.	Assessment of the dose of ionising radiation of the central axis at the point of interest in a phantom		
3.1.	photon regime of a linear accelerator	± 2 %	Measurements for all radiation energies and dose rate regimes used in clinical practice
3.2.	electron regime of a linear accelerator	± 2 %	Measurements for all radiation energies and dose rate regimes used in clinical practice
3.3.	^{60}Co and ^{137}Cs therapy equipment	± 2 %	
3.4.	roentgen therapy equipment of a close focus	± 6 %	Measurements for all radiation energies used in

			clinical practice
4.	Homogeneity of beams[12] and symmetry[13]:		
4.1.	homogeneity of photon beam of a linear accelerator	± 3 %	Measurements for all radiation energies and dose rate regimes used in clinical practice in a water phantom in the depth of 10 cm, for fields − 10 x 10 cm² and 20 x 20 cm²
4.2.	symmetry of photon beam of a linear accelerator	± 2 %	Measurements for all radiation energies and dose rate regimes used in clinical practice in a water phantom in the depth of 10 cm, for fields − 10 x 10 cm^2 and 20 x 20 cm^2
4.3.	^{60}Beam symmetry of Co and ^{137}Cs equipment	± 3 %	
4.4.	beam symmetry of roentgen equipment of a close focus	± 6 %	
4.5.	homogeneity of electron beam of a linear accelerator	± 7 % (4 MeV), ± 5 % (> 4 MeV)	Measurements for all radiation energies and dose rate regimes used in clinical practice in a water phantom in maximum depth, for fields 10 x 10 cm^2 and 20 x 20 cm^2
4.6.	symmetry of electron beam of a linear accelerator	± 2 %	Measurements for all radiation energies and dose rate regimes used in clinical practice in a water phantom in maximum depth, for fields 10 x 10 cm^2 and 20 x 20 cm^2
5.	Compensators and wedges:		
5.1.	constancy of transmission factors of compensators and wedges	± 2%	Measurements for all ionising energies used in clinical practice Measurements for all ionising energies and dose rate regimes used in clinical practice for programmable wedges
5.2.	accuracy of dynamic wedge angle	± 2°	Measurements for all radiation energies and dose rate regimes used in clinical practice
6.	Portal imaging system:		
6.1.	Positioning accuracy of portal imaging system	± 2 mm	Measurements in isocentre plane

VIII. Nuclear Medicine			
1.	Gamma camera		
1.1.	image homogeneity within the limits of the used field	< ± 5 %	Measurements without a collimator, low energy point source (for example, ^{99m}Tc), energy window 15−20 %, counting speed 10000−30000 imp./s, image matrix at least 256 x 256 pixels
			With a low energy collimator of high resolution, leaf-shaped source around 10 cm above the collimator, energy window 15–20 %, counting speed 10000–30000 imp./s, image matrix at least 256 x 256 pixels
1.2.	stability of sensitivity	< 20 %	Deflection of sensitivity from the base value is examined, but not more than the ability to receive gamma radiation emitted by radioactive source, impulses/MBq. Measurements: without a collimator, low energy point source (for example, ^{99m}Tc), energy window 15−20 %
1.3.	deflection of rotation centre	< 2 mm (diameter)	SPECT gamma camera With a low energy collimator of high resolution, energy window 15−20 %
2.	Multi-head gamma cameras:		
2.1.	difference (deflection) in the sensitivity of any head	< 10 %	Without a collimator, low energy point source (for example, ^{99m}Tc), energy window 15−20 %
2.2.	offset of pixels of opposing images	< half pixel	With a low energy collimator of high resolution, low energy point source (for example, ^{99m}Tc), energy window 15–20 %
3.	Calibrator of isotope doses:		
3.1.	linearity of doses	< ± 5 %	In the entire range of used activities by measuring the activity in each ten-day period

3.2.	replicability of doses	< ± 5 %	In the entire range of used activities
3.3.	accuracy of dose measurement for gamma radiators with energy over100 keV	< ± 5 %	Sources with the nearest energy spectrum for radionuclides used in clinical practice shall be used for calibration
3.4.	accuracy of dose measurement for beta radiators and gamma radiators of low energy	< ± 10 %	Sources with the nearest energy spectrum for radionuclides used in clinical practice shall be used for calibration

Notes.
[1] Conformity criterion – when assessing conformity with the criterion, the uncertainty of the obtained value shall be taken into account which must comply with ~95 % empirical coverage.
[2] The parameters and criteria referred to in this Chapter apply to the diagnostic radiology installations for general use. The criteria for the installations of special diagnostic radiology are examined in Chapters II and III of this Annex. If these Chapters do not contain the necessary criteria, the criteria laid down in Chapter I shall be used.
[3] Air kerma (K) – the value related to ionising radiation dose which is the initial kinetic energy of charged particles released by radiation in the substance (dE_{tr}) per their mass unit (dm):

$$K = dE_{tr}/dm$$

Kerma has an absorbed dose unit (J/kg) or a special unit grey (Gy).
Linearity of air kerma (L) – it is determined for different set parameters (current−time) and the set parameters do not differ from each other for more than two times:

$$L = 2\frac{\left|\frac{\bar{K}_1}{Q_1} - \frac{\bar{K}_2}{Q_2}\right|}{\frac{\bar{K}_1}{Q_1} + \frac{\bar{K}_2}{Q_2}} * 100\%$$, where

$\bar{K}_1$ and $\bar{K}_2$ − the average values for measured air kerma;
Q_1 and Q_2 − multiplications of the presented parameters (current−time, Q = I x t, where I_1 and I_2 − presented anode current of the tube and t_1 and t_2 − presented exposition times);

[4] Air kerma replicability – standard deflection of measured values which is detected in several measurements with equal conditions for measuring:

$$\frac{[\delta = k * \left(\sqrt{\frac{1}{N-1}\sum_{i=1}^{N}(\square)X_i - X_{vid}}\right]^2}{X_{vid}}$$, where

N – the number of measurements;
X_i – i-consecutive measurement,
X_{vid} − average measurement value,
k – coefficient which is used in order for replicability to conform with approximately 95 % empirical coverage.

[5] PMMA – polymethilmethacrylate.
[6] Accuracy – nearness of the measured values to the true value:

$$p = \frac{m - t}{t} * 100\% \text{ , where}$$

m – measured value;
t − theoretical value.

[7] Additional requirements for fluoroscopic examinations are formulated in this Chapter. If this Chapter does not contain the necessary criteria, the criteria specified in Chapter I of this Annex shall be used.
[8] For the panoramic dental radiological installations and cephalometric radiological installations in the case referred to in Paragraphs 1, 4 and 5 of Chapter IV the measurements shall be carried out at the relevant exposition time which the installation allows to install.
[9] HU (Hounsfield unit) – relative indicator of the density of roentgen radiation. In the Hounsfield scale it is deemed that the linear radiation attenuation coefficient of distilled water at standard conditions is 0 HU, while that of air – 1000 HU. Relative density in HU units of the material X the linear attenuation coefficient of which is $\mu_x$shall be calculated by using the following formula:

$$\frac{\mu_x - \mu_{H_2O}}{\mu_{H_2O}} X\ 1000$$

[10]The criteria are intended for clinical use of radiotherapeutic devices, but are not intended for brachitherapy, intra-operative, dynamic, palliative radiological installations, for radiological installations for the whole body, and for simulators in radiotherapy. If this Chapter does not cover the required criterion, the criteria laid down in Chapter I shall be used.
[11] Linearity − determines dependency between control system monitor units and doses of ionising radiation by using the following formula:

$$L = 2\frac{\left|\frac{\bar{D}_1}{M_1} - \frac{\bar{D}_2}{M_2}\right|}{\frac{\bar{D}_1}{M_1} + \frac{\bar{D}_2}{M_2}} * 100\% \text{ , where}$$

$\bar{D}_1$and$\bar{D}_2$ – average values for the measured dose;
M_1 and M_2 − presented values of monitor units.

[12] Homogeneity:
1. Photons

$100 \times D_{max}/D_{min}$, where

D_{max} − shall be determined at any maximum point within the beam field;
D_{min} − shall be determined at any minimum point within flattened area of the beam field. A beam field shall be determined as follows:

a) with the field:: 5 ≤ size of the beam field ≤ 10 within the beam field. Width of the beam field – 2 x 1 cm;

b) with the field : 10 ≤ size of the beam field ≤ 30 within the beam field. Width of the beam field – 2 x (0.1 x width of the beam field);

c) with the field: size of the beam field > 30 within the beam field. Width of the beam field – 2 x 3 cm.

2. Electrons

Homogeneity shall be determined in the same way as with the photon beam fields where Dmax and Dmin are determined within the flattened area of the beam field which is determined as follows:

a) 2 cm ≤ width of the beam field ≤ 10 cm. Width of the beam field – 2 x 1 cm;

b)10 cm ≤ width of the beam field < 30 cm. 80 % of the width of the beam field;

c) width of the beam field ≥ 30 cm. Width of the beam field – 2 x 3 cm.

[13] Beam symmetry:

1. Photons

Maximum dose coefficient between the points in equal distance from the central axis within flattened area of the beam field (flattened area of the beam field shall be determined in the same way as with homogeneity).

100 x Max (point to the left/point to the right, point to the left/point to the right)

2. Electrons

They shall be determined in the same way as with photon beam fields, but the method for determination of the flattened area of the beam field is different, and it is: 1 cm in the direction of the centre of the beam field by subtracting from 90 % isodose.

Table 3

Technical Parameters of Radiological Installations, Their Minimum Conformity Criteria and Conditions for Measurements in Additional Assessment of Function Testing and Conformity

No.	Technical parameters	Conformity criterion	Measurement conditions
I. Diagnostical Radiography Installations[1]			
1.	Coincidence of beam and beam of light:		
1.1.	summary deflection in each main axis	≤ 3 %	Geometrical measurements by using a special test plate from the distance between the focus (radiator) and the centre of the visible field (image detector)
1.2.	summary deflection in both main axes	≤ 4 %	
1.3.	coincidence of the centre of x-ray field and the centre of image detector	≤ 2 %	
1.4.	coincidence of the centre of the beam of x-rays and the	≤ 1 %	

	centre of the beam of light		
1.5.	coincidence of the centre of beam of light and the film placed in the grid	≤ 1 %	
2.	Angle between the axis of the beam of x-rays and the plane of image detector	< 1.5°	Geometric measurements by using a special test plate, assess deflection from the angle of 90°
3.	Automatic collimation:		
3.1.	collimation precision	regardless of the distance between the focus and the image detector radiated area is located within the image detector	
3.2.	in automatic collimation regime the distance between the edges of the beam of light and the edges of image detector in any direction	< 2 %	Measurements from the distance between the focus and the image detector. Geometric measurements by using a special test plate
4.	Grid:		
4.1.	defects of image	none	Image is obtained with high-voltage 50 kV
4.2.	plates of the movable grid in the image	none	Image is obtained even during the shortest exposition time used in practice
5.	Accuracy of manual exposition data setting (accuracy of air kerma[2])	≤ ± 20 % of the reference value	Measurements in direct ionising radiation beam
6.	Automatic exposition dose control (any of the following methods may be used):		
6.1.	if dosimetry method is used	≤ ± 20 % of the reference value	Measurements at image detector plane with 25 mm A1 attenuator
6.2.	if roentgen film method is used	≤ ± 30 % of the reference value	
7.	Accuracy of a patient dose meter (dose and area multiplication meter)	≤ ± 25 %	Measurements at least with the following high-voltage values – 50, 70, 90 and 110 kV. If it is not possible to set the abovementioned values, the nearest possible value shall be used
II. Fluoroscopy Installations[3]			
1.	Rate of air kerma[2] in the entrance field of the intensifier of roentgen image		
1.1.	for general use roentgen	< 1.0 µGy/s	Examinations in automatic

	installations		regime
1.2.	for indirect radiography installations	< 2.0 µGy/s	
1.3.	for cineradiography installations	< 0.2 µGy/frame	
2.	Spatial resolution:		
2.1.	with 15–18 cm intensifier of roentgen image	≥ 1.4 pairs of lines/mm	1) Visible image is at least 2/3 of rated field of intensifier of roentgen image 2) Test object of the spatial resolution is placed as close to the entrance field of the intensifier of roentgen image as possible
2.2.	with 23–25 cm intensifier of roentgen image	≥ 1.0 pairs of lines/mm	
2.3.	with 30-35 cm intensifier of roentgen image	≥ 0.8 pairs of lines/mm	
2.4.	for indirect radiography installations with 25 cm intensifier of roentgen image	≥ 2.0 pairs of lines/mm	
2.5.	for cineradiography installations with 25 cm intensifier of roentgen image	≥ 1.6 pairs of lines/mm	
III. Digital Radiography Installations (also Phosphorus Plate Systems and Digital Scanners)			
1.	Contrast resolution:		
1.1.	test by using a copper object of different optical density (dynamic step ladder)	Steps of variable thickness (optical density) are visible	A test object with the following thickness shall be used: 0 mm, 0.3 mm, 0.65 mm, 1.0 mm, 1.4 mm, 1.85 mm and 2.3 mm
1.2.	a test object with a low contrast of aluminium	At least 3 low contrast objects are visible	A test object with the following thickness shall be used: 0.1 mm, 0.15 mm, 0.25 mm, 0.35 mm, 0.5 mm and 0.7 mm
2.	Spatial resolution:		
2.1.	if air kerma[2] is between 5 and 10 µGy	≥ 2.8 pair of lines/mm	Resolution test object
2.2.	if air kerma[2] is less than 5 µGy	≥ 2.4 pair of lines/mm	
3.	Geometrical parameters of the image		
3.1.	complete visibility of the image	yes	Visual assessment
3.2.	double-contours (pseudo-contours)	none	
3.3.	image mistakes	none	
3.4.	deflection on each axis	< ± 3 % of focus–image	Geometric measurements

	(horizontally and vertically)	detector distance	by using a special test plate
4.	Image artefacts:	none	Assess visually
4.1.	scratches, blurred images	none	
4.2.	phantom images	none	
4.3.	geometrical distortions of the image	none	
IV. Development of Films [4, 5]			
1.	Base and emulsion	< 0.3 optic density units	Measuring optic density with sensi-densitometer
2.	Deflection from the basic value of sensitivity	< 0.2 optic density units	Measuring optic density with sensi-densitometer
3.	Deflection from the basic value of contrast index	< 0.2 optic density units	Measuring optic density with sensi-densitometer
V. Computed Tomography (CT) Installations			
1.	Image parameters:		
1.1.	image noise	≤ ± 10 % or ≤ 0.2 HU[7]	Standard deflection of CT absorption number in the centre of examination zone of the phantom that is equivalent to water or tissues in the area of at least 40 % of the test object image in size against base value
1.2.	average deflection of CT−number	≤ ± 4 HU[7]	CT absorption number (in the centre of examination zone in the area of at least 10 % of the test object image in size) against base value
1.3.	balance	≤ ± 2 HU[7]	Average deflection of CT absorption figure in periphery from CT absorption figure in the centre of examination zone of the phantom that is equivalent to water or tissues in the examination area of at least 10 % of the test object image in size against the base value
2.	Spatial (high contrast) resolution	≥ 0.5 pairs of lines/cm or ≤ ± 15 % of the base value	Measurements with resolution phantom

3.	CT dose index (or dose and length multiplication)	≤ ± 20 %	Dose measurements of ionising radiation in the rotation centre of 16 cm and/or 32 cm PMMA[6] and in the periphery (in the distance of 1 cm from the surface) against the base value.
4.	Thickness of the section layer:		
4.1.	if the nominal thickness of the section layer is ≥ 2 mm	≤ ± 1.0 mm	At least with the minimum, average and maximum set value of the thickness of the section layer
4.2.	if the nominal thickness of the section layer is between 1 and 2 mm	≤ ± 50 %	
4.3.	if the nominal thickness of the section layer is ≤ 1 mm	≤ ± 0.5 mm	
5.	Positioning of the medical treatment table:		
5.1.	longitudinal positioning of the medical treatment table	≤ ± 1.0 mm	Measurements with patient equivalent 70 kg
5.2.	backward positioning of the medical treatment table	≤ ± 1.0 mm	
VI. Mammography Installations			
1.	Exposition dose control (one of the following two methods shall be used):		
1.1.	setting exposition data manually	≤ ± 0.2 optical density units of the reference value	With 40 mm PMMA[6] at high-voltage of 28 kV high-voltage
1.2.	setting exposition data manually, dose replicability (dosimetry method)	≤ 5 %	Dose measurements with 40 mm PMMA[6] at high-voltage of 28 kV
1.3.	setting exposition data in automatic mode of exposition dose	≤ ± 0.2 optical density units of the reference value	Measurements at high-voltage of 28 kV with different thickness of a patient equivalent phantom – 20, 40 and 60 mm PMMA[6]
1.4.	setting exposition data manually, dose replicability (dosimetry method)	≤ 5 %	Dose measurements with 20, 40 and 60 mm PMMA[6] at high-voltage of 28 kV
2.	Spatial (high contract) resolution	≤ 1 groups of pairs of lines from the reference value	Spatial resolution phantom and 45 PMMA[6]
3.	Coincidence of radiation field:		
3.1.	radiation field on the frontal	≤ 5 mm outside the	Geometrical measurements

	side of the patient support	patient support	by using cassettes of two different sizes and materials absorbing ionising radiation. (exposure is carried out in the regime of AEK (automatic exposure control system))
3.2.	radiation field on the edges of the patient support	≤ 2 % of FFA (distance from the focus of the tube until the plane of film (image detector) outside patient support	
4.	Compression force	130−200 N	Pressure measurement equipment
5.	Coincidence of compression plate:		
5.1.	asymmetrical load permissible	< 15 mm	Geometrical measurements by using foam rubber between the surface of grid device and compression device
5.2.	symmetrical load permissible	< 5 mm	
6.	Air kerma^2 rate	≥ 7.5 mGy/s	Measurements: 1) in a distance which is applied to focus−image detector distance from the dispersed radiation under free circumstances 2) at high-voltage 28 kV
VII. Intensifying Screens and Cassettes[4,5]			
1.	Condition and cleanness of the screen and cassettes	no artefacts	On exposed films no artefacts should be present
2.	Darkening of cassettes	on non-exposed films black edges are not visible	The cassette with this film shall be examined by illuminating it at a negatoscope (each side for 10 minutes) with a luminous intensity of at least 1000 cd/m^2
3.	Contact of film and screen	cassette may not be a cause for a visible lack of sharpness or for a difference in the optic density of an x-ray picture	The cassette shall be examined by placing a metal net on the cassette
4.	Relative sensitivity of the film and screen combination of the same class of sensitivity with identical exposure conditions	difference of film blackening <0.3 optic density units	The same dose of ionising radiation, high-voltage and filtration for different cassettes shall be used for examination
VIII. Medical Image Display Monitors			
1.	Unchangeability of image	≤ 1 cd/m² and ≤ ± 25 %	Measurements with

	examination conditions	of base value	photometer. Measurement of monitor brightness and homogeneity thereof by fixing changes in lighting in the premises
2.	Grey gradation	≤ ± 25 % of the base value	Measurements with photometer
3.	Maximum contrast	maximum brightness against minimum brightness ≥ 100	Measurements with photometer
4.	Visual test:		
4.1.	visibility of restrictive lines	yes	Video test image with appropriate test objects
4.2.	similarity of the length of restrictive lines	yes	
4.3.	image visibility	yes	
4.4.	visibility of image edges	yes	
4.5.	image displacement or rotation	none	
4.6.	circle distortion	none	
4.7.	line conformity	yes	
4.8.	line distortion	none	
4.9.	colour convergence	none	
4.10.	shading change zones	none	
4.11.	damaged pixels	none	
4.12.	reflected image	none	
4.13.	light and dark spots	none	
4.14.	visible white diagonal lines	none	
4.15.	twinkling	none	
4.16.	horizontal/vertical image movement	none	
4.17.	accidental distortions	none	
4.18.	movement on image	none	
5.	Visual examination of resolution	line pairs/mm visibility	Video test image with appropriate resolution objects
6.	Brightness changes in the monitor		
6.1.	LCD monitor	≤ ± 15 %	Brightness homogeneity between the display edges and centre. Measurements with photometer

6.2.	CRT monitor	≤ ± 30 %	
IX. Examination of Radiological Image			
1.	Luminous intensity of negatoscope	≥ 1700 cd/m^2	Measurements with photometer
3.	Luminous intensity of negatoscopes used for examination of mammography images	≥ 3000 cd/m^2	Measurements with photometer
4.	Heterogeneity of light	< 30 %	Measurements with photometer. Heterogeneity of light between edges and centre
5.	Lighting of premises	< 50 l x 1 m distance from negatoscope	Measurements with photometer

Notes.
[1] The parameters and criteria referred to in this Chapter apply to the diagnostic radiology installation for general use. The criteria for the installations of special diagnostic radiology are examined in Chapters II and III of this Annex. If these Chapters do not contain the necessary criteria, the criteria laid down in Chapter I shall be used.
[2] Air kerma (K) – the value related to a ionising radiation dose which is initial kinetic energy of charged particles released by radiation in the substance (dE_{tr}) per their mass unit (dm):

$$K = dE_{tr}/dm$$

Kerma has an absorbed dose unit (J/kg) or a special unit grey (Gy).
[3] Additional requirements for fluoroscopic examinations are formulated in this Chapter. If this Chapter does not contain the necessary criteria, the criteria specified in Chapter I of this Annex shall be used.
[4] The requirements referred to in the Chapter shall not apply to dental roentgen installations.
[5] The criteria referred to in the Chapter are intended for obtaining qualitative roentgen images on photo materials of appropriate quality.
[6] PMMA – polymethilmethacrylate.
[7] HU (Hounsfield unit) – relative indicator of the density of roentgen radiation. In the Hounsfield scale it is deemed that the linear radiation attenuation coefficient of distilled water at standard conditions is 0 HU, while that of air – 1000 HU. Relative density in HU units of the material X the linear attenuation coefficient of which is μ, shall be calculated by using the following formula:

$$\frac{\mu_X - \mu_{H_2O}}{\mu_{H_2O}} X\ 1000$$

Minister for Environmental Protection and
Regional Development Romāns Naudiņš

Annex 4
Cabinet Regulation No. 482
19 August 2014

Permissible Total Radioactivity in Human Milk that during a One-year Period is Received by a Child

No.	Radionuclide	Permissible total radioactivity in a one-year period (MBq)
1.	^{67}Ga	56
2.	^{99m}Tc	5
3.	^{111}In	10.4
4.	^{123}I	0.5
5.	^{131}I	0.01
6.	^{201}Tl	1.2

Minister for Environmental Protection and
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