Journal of Laws No. 180 - 9315 - Item 1325

1325

REGULATION OF THE MINISTER OF HEALTH[1)]

of 21 August 2006

on the detailed conditions of safe use of radiological equipment

Pursuant to Article 46 of the Act of 29 November 2000 - Atomic Law (Journal of Laws of 2004 No. 161 Item 1689, as amended[2)]) it is hereby ordered as follows:

Chapter 1 **General provisions**

Article 1. Terms used in the Regulation mean:

1) X-ray ambulance - a vehicle with X-ray equipment installed, used for medical purposes;

2) X-ray set - piece or set of equipment consisting of devices used for the generation and use of X-rays, in which an X-ray tube is the source of ionizing radiation;

3) X-ray lab - a room or group of rooms designed to perform medical radiological procedures using X-ray;

4) X-ray room - a room in the X-ray lab, where at least one X-ray tube is permanently installed.

Chapter 2

Requirements for X-ray labs, rooms and ambulances

Article 2. 1. The structure of walls, ceilings, windows, doors and protective devices installed in the X-ray lab, subject to Article 3, protect personnel working:

1) In the X-ray room against receiving a dose exceeding 6 millisieverts (mSv) during the year;

2) In the rooms of the X-ray lab outside of the X-ray room, against receiving a dose exceeding 3 mSv during the year;

3) in areas outside the X-ray lab, as well as the general public in the vicinity against receiving a dose exceeding 0.5 mSv during the year.

2. When planning and carrying out activities with the use of X-rays, which require the presence of the operator of the equipment or medical personnel near the X-ray tube, a classification of workplaces is introduced in accordance with the requirements of Article 18 of the Act of 29 November 2000 - Atomic Law, taking into account information about the distribution of dose rates around the X-ray set, provided by the manufacturer, and the results of dosimetric measurements taken around the device.

Article 3. 1. The structure of walls and ceilings, as well as windows and doors of the X-ray lab located in residential buildings prevents the receipt by the general public of an effective dose in the calendar year, associated with the use of ionizing radiation in an X-ray lab, in excess of 0.1 mSv.

2. X-ray dose rate on the external walls of an X-ray ambulance up to a height of 2.5 m from the ground surface does not exceed 0.1 milligrays per hour (mGy/h) at maximum parameters of the tube and the largest aperture opening and the most common direction of the radiation beam.

Article 4. The height of the X-ray lab may not be less than 2.5 m.

Article 5. 1. The area of the X-ray room, where an X-ray diagnostic set with a separate tube is installed, subject to Section 2 and 3 may not be less than 15 m^2. For each additional tube, subject to Section 3, at least 5 m^2 should be additionally allocated.

2. The area of the X-ray room, where an X-ray set for interventional radiology is installed, may not be less than 20 m^2.

3. The area of the X-ray room, with the following equipment installed:

1) Dental X-ray,

2) Mammograph,

3) Bone densitometry equipment

- must not be less than 8 m^2; for each subsequent of these devices, installed in the same room, 4 m^2 must be additionally allocated.

1) **Minister of Health manages the department of government administration - health, on the basis of Article 1 Section 2 of the Regulation of the President of the Council of Ministers of 18 July 2006 on the detailed scope of responsibilities of the Minister of Health (Journal of Laws No. 131, Item 924).**

2) **Amendments to the Act were published in the Journal of Laws of 2004, No. 173, Item 1808, of 2005, No. 163, Item 1362 and of 2006, No. 52, Item 378, No. 104, Item 708 and No. 133, Item 935.**

4. The area of the X-ray room, where an X-ray set for surface radiotherapy is installed, may not be less than 15 m².

5. The area of X-ray rooms does not include the area of the control room, if it is in a separate room.

6. It is permissible to reduce the area of the rooms referred to in Sections 1-3, by 5%.

Article 6. The area of the X-ray ambulance is adapted to scope of the diagnostics conducted and allows for at least the following:

1) Installing and servicing an X-ray machine and equipment necessary for their correct work in accordance with the requirements specified by the manufacturer;
2) Allocating space for the patients' clothes;
3) Allocating space for the clothes for staff;
4) Installation of a sink with running water intended for human consumption and an effluent receiver;
5) Installation of equipment to maintain the proper temperature and air exchange.

Article 7. 1. X-ray labs equipped with X-ray machines with a sectioned-off switchgear or control station, subject to Sections 2 and 3, have a control room separated from a part of the lab or arranged in an adjacent room or in the corridor which is a passageway intended solely for persons employed in the X-ray lab.

2. In the case of labs equipped with X-ray radiotherapy simulator or an X-ray set for surface radiotherapy, the control room is arranged in a separate room adjacent to the X-ray room.

3. In the case of diagnostic X-ray equipment, the switchboard or control station can be placed inside the lab or behind a screen guard or permanent shield.

4. In diagnostic X-ray labs, instead of a door between the control room and the lab, there can be a corridor (labyrinth) formed using permanent shields arranged in such a way that the place of administration of the primary radiation beam is not visible from the entrance to the corridor (labyrinth).

Article 8. 1. X-ray machines are installed so that:

1) Free access is provided to the patient from at least two sides;
2) Distance of the source of radiation (tube focal spot) from the nearest wall should be at least 1.5 m at a vertical direction of the radiation beam;
3) The primary radiation beam is not directed toward the control room and the door.

2. The provision of Section 1.2 shall not apply to X-ray machines installed in ambulances.

3. The provisions of Section 1.2 and 1.3 shall not apply to mammographs, X-ray dental machines and bone densitometry equipment.

Article 9. In X-ray labs, voice and visual communication is ensured between medical staff present in the control room and the patient present in the X-ray room.

Article 10. 1. X-ray rooms, subject to Section 2, are equipped with a ventilation system, which provides at least 1.5 air changes per hour.

2. X-ray labs equipped with X-ray machines designed to perform interventional radiology treatments are equipped with ventilation in accordance with the requirements laid down in the provisions of the Regulation of the Minister of Health of 22 June 2005 on requirements to be met by health care facilities and equipment in technical and sanitary aspects (Journal of Laws No. 116, Item 985 and No. 250, Item 2115).

Article 11. 1. Rooms with diagnostic X-ray machines are equipped with warning traffic lights placed above the door to the room, turned on simultaneously with powering the generator.

2. The provision of Section 1 does not apply:

1) If the exposure is done from behind the only door leading to the X-ray room;
2) In medical dental offices equipped with X-ray machines;
3) In rooms, in which X-ray machines designed exclusively for bone densitometry are used.

3. Rooms with X-ray machines for surface radiotherapy, X-ray simulators and CT scanners are equipped with warning lights, placed above the door to the X-ray rooms, informing about switching high voltage to the X-ray tube.

Article 12. The possibility of dimming the lighting is provided in X-ray rooms where the X-ray station is equipped with a light indicator of the size of the irradiated field or with a video channel.

Article 13. Devices not connected with the operation of X-ray machines or radiological procedures performed cannot be placed in X-ray rooms.

Article 14. 1. Diagnostic, interventional and therapeutic X-ray labs are equipped with equipment protecting against X-ray radiation matched to the type of X-ray machines installed and the kind of tests or radiologic procedures performed.

2. Diagnostic X-ray labs, as appropriate, include:

1) A screen, a display screen and a set of shields that are a part of the set provided by the manufacturer, placed on a permanent basis or attached to the X-ray machine as needed;
2) Personal protection equipment for employees, in particular aprons, gloves and collars made of lead rubber, glasses, goggles or visors made of glass or lead plastic, hereinafter referred to as "PPE";
3) Shield for the patients, in particular shields for gonads, aprons and half-aprons and collars made of a lead sheet or lead rubber.

3. Those whose nature of work requires extended periods of wearing personal protective equipment, should be provided with lead rubber aprons with a cut taking into account a reduced burden on the spine and, where appropriate, goggles combined with corrective lenses.

4. Shields for gonads are made of a material with an equivalence of at least 1.0 mm of lead (Pb).

5. Persons performing interventional radiology procedures are subject to individual control of doses received by the skin of the hands.

Article 15. 1. Chemical treatment process of X-ray film, subject to Article 16, is carried out in a separate X-ray darkroom.

2. The lab has:

1) A light-tight room allowing for exposing test film with a sensitometer;
2) A place for cleaning X-ray cassettes and amplifying foil.

3. X-ray darkroom is equipped with mechanical ventilation providing at least 3 air changes per hour, whereas the beginning of the exhaust system should be located near sources of air pollution.

Article 16. It is permitted, after fulfilling the requirements specified by manufacturers, in particular requirements regarding ventilation, to install:

1) All kinds of X-ray film processors - in dental offices;
2) Automatic X-ray film processors with a daylight cassette loader - in any room of the X-ray lab, with the exception of the X-ray room;
3) X-ray film processors coupled with the X-ray and X-ray film processors used in mammography labs - in X-ray rooms.

Article 17. 1. Mammography labs are equipped with at least:

1) An automatic X-ray film processor dedicated to mammography film and appropriately adjusted for this purpose;
2) Cassettes with amplifying foils and X-ray films adapted exclusively for mammograms;
3) A negatoscope for viewing mammograms;
4) Equipment for controlling the imaging process in the extent provided for basic tests as part of internal inspection of technical parameters.

2. The provisions of Section 1.1 - 1.3 do not apply to labs equipped with mammographs with digital recording of radiological images.

Article 18. 1. Evaluation and interpretation of the results of X-ray tests is carried out in a separate room, whereas the equipment installed in this room allows for:

1) Blacking out windows;
2) Such arrangement of negatoscopes that they are not in the vicinity of light sources;
3) Arrangement of negatoscopes in a way that prevents their interaction as light sources.

2. External light for the negatoscope measured at the surface does not exceed 50 lux.

3. The provisions of Sections 1 and 2 shall not apply in the case of evaluation and interpretation of intraoral dental images.

Article 19. In the X-ray lab, information is displayed in a prominent place about the need to notify the medical receptionist and the X-ray machine operator before the test about the fact that the patient is pregnant.

Article 20. 1. The door to the X-ray lab contains an information board with a symbol warning about ionizing radiation.

2. The model of the board referred to in Section 1 is specified in Appendix No. 1 to the Regulation.

Article 21. 1. The unit providing health services with the use of ionizing radiation, which includes an X-ray lab (X-ray room), shall develop and implement a programme of nuclear safety and radiation protection.

2. Guidelines to develop the programme referred to in Section 1, are specified in Appendix No. 2 to the Regulation.

Article 22. 1. The original or certified copies of the following documents are stored in the X-ray lab:

1) Permit to run and use X-ray machines located in the lab and to run the lab;
2) The plan of the lab or room (floor plans of the facilities) with the design and a description of permanent screens and ventilation, approved before the start-up of the X-ray machine by a competent Regional Public Sanitary Inspector during the approval of the design documentation;
3) Technical documentation concerning the construction, operation and maintenance of X-ray machines, including signalling and interlocking devices;
4) User manuals and dosimetric equipment calibration certificates, if included in the lab;
5) Dosimetric measurement certificates;
6) Inspection certificates;
7) Documents relating to nuclear safety and radiation protection, referred to in Article 21, as well as instructions for radiation protection, as specified in Appendix No. 3 to the Regulation, developed in accordance with the guidelines set out in Appendix No. 2 to the Regulation;
8) Records relating to internal tests as part of the inspection of technical parameters of X-ray machines and X-ray film processing in the darkroom as well as documents confirming the compliance with acceptance test of newly installed equipment;
9) Records relating to:
   a) People employed in the X-ray lab, divided into appropriate categories of exposure,
   b) Doses received by employees,
   c) Medical certificates confirming absence of contraindications for employees at a given position;
10) Training programme and documents confirming its implementation.

2. A set of laws concerning radiation protection and rules for the application of ionizing radiation sources in medicine shall also be available in the lab referred to in Section 1.

3. In the unit, where the X-ray machine is used without running an X-ray lab, the documents referred to in Sections 1 and 2 are available from the radiation protection officer.

Chapter 3

Requirements for X-ray machines

Article 23. The individual elements of X-ray sets are used in accordance with their design and purpose and maintaining the parameters specified by the manufacturer.

Article 24. 1. The length of the trailing cable for remote triggering of exposure used in equipment that under normal use does not require the operator to stay close to the patient, must provide the operator with the ability to control the equipment from a distance of at least 2 m from the focal spot of the X-ray tube.

2. Length of the cable referred to in Section 1, or wireless control of the X-ray equipment should make it possible for the staff to be sheltered behind a permanent shield or a screen. In the absence of such a possibility, the equipment operators should use personal protective equipment.

Article 25. Diagnostic X-ray machines for images are equipped with signalling devices which indicate the exposure in an acoustic or optical way. Signalling should be heard or seen from place where the release is activated.

Article 26. The design of diagnostic X-ray machines prevents under normal operating conditions the reduction of the distance between the tube focal spot and the patient body surface, respectively for:

1) X-ray machines, with the exception of machines used in surgery - less than 30 cm;
2) X-ray machines used in surgery - less than 20 cm;
3) X-ray imaging equipment, subject to paragraphs 4-9 - less than 45 cm;
4) X-ray images made using a mobile and portable machine - less than 20 cm;
5) X-ray images taken during surgery - less than 20 cm;
6) Mammograms with geometric magnification - less than 20 cm;

7) Dental X-ray machines for intraoral images operating at voltages up to 60 kV - less than 10 cm;

8) Dental X-ray machines for intraoral images operating at voltages above 60 kV - less than 20 cm;

9) Dental X-ray machines for panoramic images - less than 15 cm.

Article 27. 1. The label on the tube head and the user manual contain information about the thickness of the X-ray tube window filter and the tube head filter.

2. X-ray machines provide the possibility of selecting the thickness of the additional filter to obtain the desired value of the first half-value layer, wherein:

1) The X-ray tube head is equipped with a set of additional filters of different equivalent thicknesses, expressed in mm of aluminium (Al) or copper (Cu);

2) Each filter is labelled so it can be identified;

3) Assembly and disassembly of an additional filter is done without the use of tools;

4) A description of how to replace and secure an additional filter is located in the machine's user manual.

Article 28. 1. In medical diagnosis, it is not permitted to use X-ray machines:

1) For X-rays without a video channel or digital recording of the radiological image;

2) Half-wave (single-pulse);

3) Full-wave (two-pulse);

4) Mammographs without a generator with frequency conversion and without a table with a moving anti-scatter grid;

5) Mammographs, which with the use of focus detector distance of at least:

a) 60 cm - are equipped with X-ray tubes with large focal spot greater than 0.3 mm x 0.3 mm,

b) 70 cm - are equipped with X-ray tubes with large focal spot greater than 0.4 mm x 0.4 mm.

2. The provisions of Section 1.2 and 1.3 shall not apply to dental X-ray machines.

3. The provision of Section 1.3 shall not apply to mobile and portable bedside X-ray machines.

Article 29. 1. X-ray sets used for X-rays are equipped with:

1) Indicators of current and voltage values in the X-ray tube;

2) Exposure timer, which turns off the high-voltage to the X-ray tube after a period not longer than 10 minutes earlier, if time greater than 10 minutes was not specified, and which emits a sound signal no later after every 5 minutes of exposure and at least 30 seconds before automatically switching off exposure.

2. X-ray sets used in interventional radiology, in addition to equipment referred to in Section 1, are equipped with:

1) Exposure value meter (dose recorder) enabling the assessment of patient exposure during the test;

2) Pulsed fluoroscopy;

3) System for remembering the last image.

Article 30. 1. X-ray machines for surface radiotherapy are equipped with sets of interchangeable tubes and additional filters.

2. Marking of the thickness of an additional filter, referred to in Section 1 is visible after its insertion in the head holder and displayed on the machine switchgear.

3. Machines referred to in Section 1, prevent switching on high voltage without the additional filter.

4. For a deliberate unfiltered irradiation, frames without an additional filter can be used.

Article 31. In X-ray sets, X-ray tubes can be used only in tube heads or other devices protecting against side radiation, so that at a distance of 1 m from the tube focal spot, with a completely covered radiation beam outlet, and a maximum voltage and maximum load of the tube for 1 hour, the radiation dose rate does not exceed:

1) 0.25 mGy/h - for dental X-ray machines for extraoral images;

2) 1.0 mGy/h - for all other types of diagnostic and treatment X-ray machines.

Article 32. In machines for surface radiotherapy, X-ray tubes can be used only in tube heads or other devices as protecting against side radiation, so that with a completely covered radiation beam outlet, and a maximum voltage

and continuous load of the tube, the radiation dose rate does not exceed:

1) 1 mGy/h at a distance of 1 m from the focal spot - for therapeutic devices with voltage up to 100 kV, with the exception of machines for contact therapy up to 50 kV;
2) 1 mGy/h at a distance of 5 cm from the surface of the X-ray tube housing and the beam limiting device - for machines for contact therapy up to 50 kV.

Chapter 4

Nuclear medicine

Article 33. 1. The health care unit providing health services in the field of diagnostic tests and treatment using radiopharmaceuticals establishes a nuclear medicine unit (lab), hereinafter referred to as the "nuclear medicine unit".

2. The following areas are designated in the nuclear medicine unit:

1) Storage and preparation area for radiopharmaceuticals;
2) Patient service area;
3) Clinical activity area - in the case of inpatient treatment.

3. Isotope laboratories are established in the areas referred to in Section 2, satisfying the requirements of the regulations issued under Article 45 of the Act of 29 November 2000 - Atomic Law.

Article 34. In the nuclear medicine unit, in addition to the requirements specified for the relevant isotope laboratory class, rooms are sectioned off, intended for:

1) Receipt and storage of radioactive sources;
2) Carrying out work related to the preparation and dispensing of radiopharmaceuticals;
3) Hospitalisation of patients undergoing treatment with iodine-131, at doses exceeding the maximum therapeutic dose for outpatient use;
4) Collection and storage of contaminated bedding, underwear and radioactive waste;
5) Clothing store with a separate lock, dosimetry station and cloakroom, as well as a cabin with shower and wash basins;
6) Diagnostic equipment;
7) Photochemical laboratory if chemical processing of photometric film is used;
8) Doctor's surgery;
9) A waiting room with the possibility of separating the space occupied by patients before and after administration of radiopharmaceuticals;
10) Bathroom equipped with liquid soap, disposable towels or hand dryer and disposable toilet seat covers.

Article 35. 1. The nuclear medicine unit is equipped with devices to measure the activity of radiopharmaceuticals, dose rates, radioactive contamination, appropriate to the type and scope of work carried out, and the right type of protection against ionizing radiation.

2. Exits from the ward where radioactive sources are used in cancer therapy are monitored, in particular using a radiation portal monitor with sound alarm.

Article 36. Staff and patients present on the premises are obligated to comply with the instructions aimed at limiting exposure to ionizing radiation, developed in accordance with the recommendations of the national consultant in the field of nuclear medicine.

Article 37. 1. Isotope laboratories, referred to in Article 33 Section 3, shall have rooms for scintillation cameras that meet the following requirements:

1) The room area must not be less than 20 m^2;
2) The ceiling height shall be not less than 2.5 m;
3) The rooms are equipped with air conditioning, if required by the scintillation camera manufacturer;
4) The distance of the scintillation camera operator from the patient during the test shall be at least 1.5 m, and if that is not possible, a protective screen is placed between the operator and the patient;
5) Only one scintillation camera can be installed in the same room.

2. The scintillation camera is installed so as to ensure that free access to the patient from at least two sides.

3. The scintillation camera room cannot have equipment devices not related to its operation or with the performance or tests.

Article 38. In the nuclear medicine units, information is displayed in a prominent place about the need to notify the medical receptionist and the physician before the test or treatment about the fact that the patient is pregnant or breastfeeding.

Article 39. 1. To ensure safety, the nuclear medicine unit personnel is obligated to use shields against ionizing radiation, appropriate to the type of sources and scope of work carried out, including the use of disposable syringes fitted with covers absorbing gamma and beta rays.

2. It is not permitted to manipulate sources with activity expressed in megabecquerels more than 100 MBq without a cover with a thickness of at least equivalent

to 3 mm Pb in a manner allowing for their contact with the skin of hands and fingers, also sheltered with a glove to prevent surface contamination.

Article 40. 1. Staff in a nuclear medicine unit using open sources of iodine-131 for thyroid cancer treatment is subjected to internal inspections of the content of radioactive iodine in the thyroid gland.

2. The frequency of inspections referred to in Section 1 is dependent on the degree of risk of internal contamination with iodine-131.

3. In nuclear medicine units which use labelling of radiopharmaceuticals using isotope ^{99m}Tc obtained from a generator, individual radiation doses to the skin of the hands must be measured in case of persons carrying out the labelling procedure with the daily use of isotope above 1 GBq.

Article 41. 1. Patients hospitalised as a result of the treatment of thyroid tumours using sources of iodine-131 shall stay in at the most two-person rooms, in which the distance between the patients' beds of not less than 1.5 m is ensured. In the absence of such a possibility, a protective screen is placed between the patients.

2. Contact medical personnel with the patients within the first day after administration of radioactive iodine-131 for the treatment of thyroid tumours is limited to the necessary minimum.

3. Visits of the patients referred to in Section 1, within 24 hours after administration of the iodine-131 isotope, are prohibited.

4. Admission of children under the age of 10, unless they are patients, on the premises of the nuclear medicine unit is prohibited.

Article 42. 1. In the absence of possibility to set up sanitary facilities in the patient rooms, referred to in Article 41 Section 1, a special room is sectioned off and marked exclusively for use by these patients.

2. Sanitary facilities are subject to daily dosimetric measurements as well as cleaning and removal of any radioactive contamination.

3. The sanitary facilities are equipped with liquid soap, paper towels or hand dryer and disposable toilet seat covers, as well as instructions for patients on how to use the facilities.

Article 43. 1. Spaces in the nuclear medicine unit are subject to daily documented dosimetric measurements and cleaning, including cleaning the floors, work surfaces and sanitation appliances.

2. It is forbidden to remove cleaning equipment outside the premises of the given isotope laboratory.

3. Radioactive waste collected during the work with radiopharmaceuticals is removed at least twice during a shift into the waste storeroom.

Chapter 5 **Radiotherapy**

Article 44. In the newly opened accelerator laboratories, the protection class of walls and ceilings allows the use of irradiation techniques:

1) With a modelled intensity beam or
2) Total body irradiation.

Article 45. If radiological equipment is operated using special keys or codes, only professionally qualified personnel to operate the equipment has access to the equipment.

Article 46. Therapeutic equipment used in brachytherapy units used directly for irradiation of the patient by remote application of radioactive sources, fulfils the following requirements:

1) Switching on and off again the device cannot eliminate the error signal;
2) The equipment has a safety system to ensure the withdrawal of radioactive sources into a protective container in case of failure of the equipment, power failure, accidental disruption of treatment or intrusion into the room by unauthorised persons.

Article 47. Therapeutic equipment for irradiation with a high dose rate used in brachytherapy units, in addition to the requirements specified in Article 46, should also:

1) Have two independent systems for timing and informing about the completion of irradiation;
2) Only implement treatment in accordance with the treatment selected in the control unit;
3) Verify the conditions set and indicate random errors of the personnel;
4) Print all information regarding obstacles and errors in the implementation of treatment in the treatment report;
5) Have sets of instruments for the controllable verification of the safe operation of the equipment.

Chapter 6

Supervision of the patient's radiation protection

Article 48. 1. Supervision of the patient's radiation protection is exercised by the relevant regional public sanitary inspector.

2. As part of the supervision, the regional public sanitary inspector conducts inspections of health care units

providing health services of diagnosis and treatment using ionizing radiation, hereinafter referred to as "controlled entities" not less than once every 4 years.

2. The scope of the inspections referred to in Section 2 includes:

1) Assessment of the condition of radiological equipment used for diagnosis or therapy;

2) Comparing the current state with the requirements necessary to obtain a permit to carry out activities involving exposure to ionizing radiation for medical purposes.

3. As part of the inspections carried out, the regional public sanitary inspector also has the right to carry out, depending on the needs, independent measurements as part of internal control tests of physical parameters of radiological equipment.

4. The measurements referred to in Section 4 can be performed by the regional public sanitary inspector directly or on its behalf by the competent accredited bodies which are not in professional or organisational subordination to the controlled entity.

5. Evaluation of the condition of radiological equipment is documented in a way allowing for updating the database kept pursuant to Article 33k of the Act of 29 November 2000 - Atomic Law.

Chapter 7

Transitional and final provisions

Article 49. 1. The regional public sanitary inspector in justified cases may agree to an exemption from the requirements laid down in the Regulation for X-ray labs and X-ray machines operating on the date of entry into force of the Regulation, provided that the effects of the exemption will not result in exceeding the dose limits for ionizing radiation to employees and the general public.

2. The exemption referred to in Section 1 may be granted for a period not longer than until 31 December 2006.

Article 50. If the regulation refers to the regional public sanitary inspector, in the case of health care units subordinate to the Minister of National Defence and Minister of Interior and Administration, or supervised by them or for which they are the founding bodies, this applies correspondingly to the military commander of the preventive medicine centre or state sanitary inspector of the Ministry of Internal Affairs and Administration.

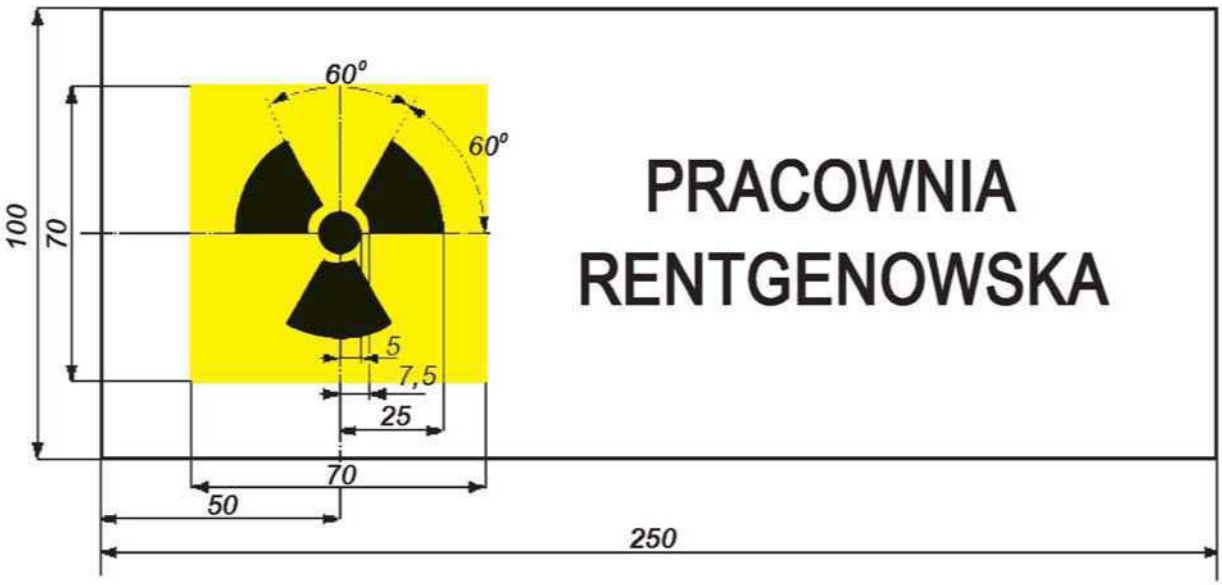
Article 51. This Regulation shall enter into force after 14 days from the date of publication.

Minister of Health: *Z. Religa*

Appendices to the Regulation of the Minister of Health of 21 August 2006 (Item 1325)

Appendix No. 1

MODEL INFORMATION BOARD WITH A SYMBOL WARNING ABOUT IONIZING RADIATION



Dimensions are in millimetres.
Background colour of the ionizing radiation symbol - yellow.
Colour of the ionizing radiation symbol - black.

Appendix No. 2

GUIDELINES FOR THE DEVELOPMENT OF THE PROGRAMME OF NUCLEAR SAFETY AND RADIATION PROTECTION IN THE X-RAY LAB (X-RAY ROOM)

I. Responsibility of the management of the health care unit

1. Ensuring that quality policy implemented in the field of radiation protection:

1) Is suitable for the type and scope of activities involving exposure to ionizing radiation;

2) Meets the requirements of existing legislation on radiation protection (specify which);

3) Is known and understood to the organisational units directly carrying out activities involving exposure to ionizing radiation and is reviewed for its effectiveness.

2. Ensuring that:

1) The radiation protection programme developed will be implemented, maintained, and its effectiveness improved; any changes in a system specified in the programme will not disrupt its integrity;

2) The frequency of reviewing the radiation protection programme will be determined to ensure its continuing suitability, adequacy and effectiveness;

3) The head of the health care unit will designate a person responsible for overseeing the implementation and maintenance of the radiation protection programme and determine that person's subordination and rights arising from the assigned responsibility.

II. Quality manual

1. Scope of activities of the health care unit covered by the radiation protection programme.

2. Regulations, instructions and other documents in effect at the health care unit, establishing procedures required by the regulations in the field of radiation protection.

3. Description of the scope of documents and their interactions.

III. Control of documents

1. Approval procedure for the documents created and review of documents, their update and re-approval.

2. Ensuring that the documents created are:

1) Updated on a regular basis;

2) Available at the point of use in the appropriate version;

3) Legible and easy to identify.

3. Ensuring that documents of external origin will be available in the specified location.

IV. Competence and training

1. Internal supervision of compliance with the requirements of radiation protection and competences of persons exercising supervision.

2. Positions which are essential for ensuring radiological safety and competence of persons on those positions.

3. Frequency and scope of internal training.

V. Healthcare

1. Personal protective equipment.

2. Medical care and supervision.

3. Medical records.

VI. Infrastructure

1. Facilities and equipment relevant to radiation protection and their recognition by the competent authorities.

2. Technical equipment of the working environment.

3. Dosimetric equipment and its calibration.

VII. Dosimetry

1. Method for controlling exposure to ionizing radiation.

2. Frequency and scope of dosimetric measurements.

VIII. Records

1. Records kept.

2. Model of registration cards.

Appendix No. 3

INSTRUCTIONS FOR RADIATION PROTECTION IN X-RAY LABS

1. Instructions for radiation protection in X-ray labs contain:

1) Information for the following persons (last names, location, phone number):
   a) Head of the lab,
   b) Radiation protection officer,
   c) Fire and safety inspector;
2) Information regarding who should be notified in case of:
   a) Radiation accident,
   b) Damage to an X-ray machine;
3) Information on:
   a) Which X-ray machines are located in the lab,
   b) Who and when issued a permit for the use of these machines,
   c) What types of tests (treatments) are performed;
4) Information about mobile shields and personal protection equipment for employees and patients in the lab;
5) Description of the procedure in the lab resulting from the placement of an information board with an ionizing radiation warning sign on the front door and the operation of warning signals;
6) Method of controlling employees' exposure to X-ray radiation;
7) Principles of supporting patients during tests;
8) Requirements for radiation protection of patients, particularly pregnant women;
9) List of legislation defining the principles of radiation protection, on the basis of which these instructions were developed;
10) Signature of the radiation protection officer and signature of the head of the lab authorising the instructions and the date of signature.

2. Instructions should be placed in the X-ray lab or X-ray room in a prominent place. The copy of the instructions stored with the lab's documentation should contain employees' signatures and the date of signature.