



JOURNAL OF LAWS OF THE REPUBLIC OF POLAND

Warsaw, 6th of May 2022

Item 967

NOTICE OF PRIME MINISTER

of 29 March 2022

on the announcement of the consolidated text of the Regulation of the Council of Ministers on detailed conditions for safe work with ionising radiation sources

1. Pursuant to Article 16 (3) of the Act of 20 July 2000 on the promulgation of normative acts and some other legal acts (Dz. U. 2019, item 1461), the consolidated text of the Regulation of the Council of Ministers of 12 July 2006 on the detailed conditions for safe work with ionising radiation sources (Dz. U., item 994), taking into account the amendments introduced by the Regulation of the Council of Ministers of 30 November 2020 amending the Regulation on detailed conditions for safe work with ionising radiation sources (Dz. U., item 2300).

2. The consolidated text of the Regulation given in the Annex to this notice does not include reference No. 1 and § 2 and § 3 of the Regulation of the Council of Ministers of 30 November 2020 amending the Regulation on detailed conditions for safe work with ionising radiation sources (Dz. U., item 2300), which state:

"¹⁾ This Regulation implements, within its scope, Council Directive 2003/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom (OJ EU L 13, 17.1.2014, p. 1, OJ EU L 72, 17.3.2016, p. 69, OJ EU L 152, 11.6.2016, p. 128 and OJ EU L 324, 13.12.2019, p. 80)."

"§ 2. "§ 2. Organisational entities which, on the date of entry into force of this Regulation, are conducting activities with high-activity sources shall adapt the record sheets for high-activity sources to the requirements of the Regulation referred to in § 1, as amended by this Regulation, within 6 months from the date of entry into force of this Regulation.

§ 3. This Regulation shall enter into force 30 days following its promulgation."

Prime Minister: *M. Morawiecki*

Annex to the Prime Minister's notice
of 29 March 2022 (item 967)

REGULATION OF THE COUNCIL OF MINISTERS

of 12 July 2006

on detailed conditions for safe work with ionising radiation sources¹

Pursuant to Article 45 of the Act of 29 November 2000 on the Atomic Law (Dz. U. of 2021, item 623 and 1941), it is ordered as follows:

Chapter 1

General provisions

§ 1. This Regulation establishes:

- 1) the technical and radiological protection requirements for laboratories using radioactive sources or devices containing such sources and the requirements for radiation generators and laboratories using such devices;
- 2) templates of information boards for marking the entrances to the laboratories, specimen of information board for marking the place of storage of radioactive sources;
- 3) the division of isotope laboratories with open radioactive sources into classes and the criteria for this division;
- 4) the requirements for working with radioactive sources, devices containing such sources and radiation generators used outside the laboratories referred to in point 1;
- 5) the manner of conducting control of ionising radiation sources and records of radioactive sources, the frequency of such control and the manner of documenting its results;
- 6) templates of record sheets for keeping records of radioactive sources, the storage period of these sheets and other record documents;
- 7) documents of record, copies of which shall form the basis for registration in the register of high-activity sources with which exposure activities are conducted and other sealed radioactive sources used and stored in organisational entities conducting licensed activities involving the use or storage of radioactive sources or devices containing such sources;
- 8) the frequency with which copies of the record documents shall be forwarded to the President of the National Atomic Energy Agency, as well as the period of retention of such copies by him/her.

§ 2. The terms used in this Regulation shall mean:

- 1) accelerator - a device that produces ionising radiation by accelerating charged particles, in particular: linear accelerator, betatron, cyclotron, neutron generator;
- 2) X-ray machine – a machine or set of machines consisting of a device designed to produce and use X-rays, in which the source of ionising radiation is an X-ray tube;
- 3) isotope groups - groups into which radioactive isotopes are divided depending on the value of the effective dose to workers at a single inhalation penetration of the isotope;
- 4) (repealed);²
- 5) irradiation room - a room in which, for irradiation purposes, a beam of radiation from an installed accelerator, an X-ray machine or a machine containing a sealed radioactive source is used, and a room in which, for irradiation purposes, a radioactive source from a machine containing a sealed radioactive source is used;

¹ The provisions of this Regulation implement the provisions of Directive 2003/122/Euratom of 22 December 2003 on the control of high-activity sealed radioactive sources and orphan sources (OJ EU L 346, 31.12.2003, p. 57 - OJ EU Polish Special Edition, Chapter 15, Volume 7, p. 694).

² By § 1(1) of the Regulation of the Council of Ministers of 30 November 2020 amending the Regulation on detailed conditions for safe work with ionising radiation sources (Dz. U., item 2300), which entered into force on 21 January 2021.

- 6) therapy room - an irradiation room in which a radiation beam or a radioactive source is used to provide ionising radiation treatment;
- 7) (repealed);²⁾
- 8) (repealed);²⁾
- 9) (repealed);²⁾
- 10) (repealed);²⁾
- 11) control room - a room from which the operation of an accelerator, an X-ray machine or a machine containing a sealed radioactive source is remotely controlled;
- 12) sanitary-dosimetric sluice - a separate area of the isotopic laboratory with open radioactive sources, equipped with a stationary dosimetric instrument and sanitary facilities (washbasin and, if the work being carried out so requires, also a shower), adapted for the removal of external radioactive contamination from the surface of the human body, from personal protective equipment and for changing work clothes and shoes;
- 13) source certificate - documentation of the radioactive source prepared by the manufacturer of that source;
- 14) certificate of starting radioactive material - documentation of the output radioactive material, prepared by the manufacturer of that material;
- 15) starting radioactive material - disc material after activation or other material used in the production of radioactive sources;

licence - licence to conduct activities involving exposure to ionising radiation as referred to in Article 4(1) of the Act of 29 November 2000 on the Atomic Law.

§ 3. The safety of work with sources of ionizing radiation requires observance of the principle of limiting exposure by reducing the time of exposure, increasing the distance from the source of ionizing radiation, limiting the field of ionizing radiation and eliminating radioactive contamination, in particular by:

- 1) using equipment and devices in accordance with their intended purpose and the manufacturer's recommendations;
- 2) using personal protective equipment;
- 3) allowing persons trained and certified to work in individual workstations;
- 4) continuous monitoring of the procedures used and ongoing inspection and maintenance of the equipment in operation.

Chapter 2

The technical and radiological protection requirements for laboratories using radioactive sources or devices containing such sources and the requirements for ionising radiation generators and laboratories using such devices

§ 4. The provisions of this Chapter shall not apply to X-ray machine for medical diagnosis, interventional radiology, surface radiotherapy and radiotherapy of non-oncological diseases or to laboratories using such machine.

§ 5. 1. The degree of attenuation of ionising radiation through the external walls and ceilings of the laboratory shall prevent persons from the general public, during a consecutive period of 12 months, from receiving an effective dose of ionising radiation, associated with the conduct of activities with ionising radiation in the laboratory, exceeding:

- 1) 0.1 millisieverts (mSv) in the case of a laboratory located in a residential building or in a communal residence building,
- 2) 0.3 millisieverts (mSv) in the case of other laboratories - taking into account the duration of exposure of those persons, the type of work carried out in the laboratory and the type of shielding used.

2. The laboratory shall be equipped, depending on the type of work carried out, with:

- 1) dosimetry equipment adapted to the used ionising radiation sources;
- 2) fixed or movable shields against ionising radiation;
- 3) containers for storing sources and separate containers for storing radioactive waste;
- 4) gravitational ventilation, unless mechanical ventilation is required for the type or class of laboratory, and, if the

manufacturer of the equipment installed in the laboratory so requires, also air conditioning;

5) water and sewage installations.

3. The entrance to the laboratory shall be marked by information boards, the templates of which are set out in Annex No. 1 to this Regulation.

4. Radioactive sources and waste shall be stored in a way that prevents the spread of radioactive contamination.

5. The place of storage of radioactive sources shall be marked with an information board, the design of which is specified in Annex No. 2 to this Regulation, and the place of storage of radioactive waste with an information board for marking the radioactive waste storage facility, the design of which is specified in *Annex No. 4 to the Regulation of the Council of Ministers of 3 December 2002 on radioactive waste and spent nuclear fuel (Dz. U., item 1925)*³.

6. Flammable, explosive, corrosive and oxidising substances and compressed gases shall not be stored in a room where radioactive sources or radioactive waste are stored.

7. Laboratory documentation shall include:

- 1) the licence;
- 2) work regulations referred to in the Labour Code;
- 3) instructions for work with ionising radiation sources and radioactive waste, setting out detailed radiological protection procedures for each type of work performed;
- 4) a company emergency plan;
- 5) a register of the results of dosimetry measurements in the working environment;
- 6) a list of employees working in the laboratory, divided into categories A and B;

and, depending on the type of work carried out in the laboratory, also:

- 7) technical descriptions and operating instructions for accelerators, X-ray machines or devices containing radioactive sources;
- 8) handling instruction intended for patients who have been administered a radioactive substance for medical diagnosis or treatment;
- 9) operating instructions and calibration certificates for dosimetry equipment;
- 10) records of sources and radioactive waste and records of nuclear materials;
- 11) records of individual doses of ionising radiation received by workers.

8. Persons taking part in work carried out in the laboratory should be equipped with:

- 1) personal protective equipment appropriate to the work being carried out;
- 2) individual acoustic signalling devices for ionising radiation - in the exceptional case where the work carried out in the laboratory may result in the usable dose limit (dose constraint) established in the licence being exceeded.

9. Isotope laboratories shall be located in rooms protected against flooding, in buildings of at least class D fire resistance, with rooms in which radioactive sources and waste are stored located in buildings of at least class B fire resistance.

§ 6. In the case of an isotope laboratory with sealed radioactive sources and an isotope laboratory with devices containing radioactive sources (class Z laboratories):

- 1) the area of the room in which work with radioactive sources is carried out shall not be less than 10 m², with the area of the therapy room in a Class Z laboratory intended for medical purposes being not less than 20 m²;
- 2) the area of free space in rooms intended for work with radioactive sources shall not be less than 5 m² per employee working in the laboratory.

³ The Regulation was repealed as of 25 November 2015 pursuant to Article 9 of the Act of 4 April 2014 amending the Act - Atomic Law and certain other acts (Dz. U., item 587), which entered into force on 24 May 2014.

§ 7. 1. The area of an X-ray laboratory room in which a defectoscopic X-ray or other X-ray machine with a radiation energy above 300 keV is installed shall not be less than 20 m².

2. The area of an X-ray laboratory room in which an X-ray machine with a radiation energy of up to 300 keV is installed shall, subject to § 8, not be less than 10 m² unless otherwise specified in the licence.

3. The height of a veterinary x-ray laboratory room in which an x-ray machine is installed shall not be less than 2.5 m and, if the total time spent by an employee therein does not exceed four hours per day, shall not be less than 2.2 m.

4. The area of an irradiation room in an accelerator room shall not be less than 20 m² unless otherwise specified in the licence.

5. In accelerator rooms, X-ray rooms, with the exception of veterinary X-ray rooms, and in class Z rooms with a separate control room:

- 1) the entrance to the laboratory shall be equipped with a traffic light indicating that the high-voltage power supply to the machine or accelerator is switched on or that the radioactive source is in the operating position;
- 2) the geometry of the positioning of fixed shields shall exclude the possibility of the primary beam of ionising radiation hitting the door to the irradiation room;
- 3) mechanical supply and exhaust ventilation providing at least 6 air changes per hour shall be installed in therapy rooms, unless more frequent air changes are required by the manufacturer of the installed ionising radiation source;
- 4) the design of the door shall allow it to be opened from inside and outside the irradiation room.

6. In addition to the requirements of paragraph (5), in equipped with a dedicated control room:

- 1) accelerator laboratories, X-ray laboratories, except veterinary X-ray laboratories, and class Z laboratories, voice and visual communication between the control room and the therapy room shall be provided;
- 2) accelerator and X-ray laboratories, except veterinary X-ray laboratories, shall have a system to prevent the high voltage power supply to the X-ray or accelerator unit being switched on when the door to the irradiation room is open;
- 3) a system shall be used in class Z laboratories to cause the sources to be placed in a protected position when the door to the irradiation room is opened.

7. Paragraph (3) shall not apply to a veterinary X-ray laboratory room in which an X-ray machine is installed if a harmful working environment factor other than ionising radiation is also present in the room.

§ 8. 1. The area of the small animal veterinary x-ray laboratory room in which an x-ray machine is installed shall ensure that for a typical diagnostic examination - in the case of a portable machine or with the head hung and the beam directed downwards - the radiation source is at least 1 m from the nearest wall.

2. The surface area of a veterinary x-ray laboratory room for larger animals in which an x-ray machine is installed shall ensure that the radiation source is at least 1.5 m from the nearest wall.

§ 9. In ionising radiation generators not used for diagnostic, therapeutic or scientific and technical applications, emitted by vacuum tubes excited by a voltage exceeding 5 kV, the dose rate of this radiation at a distance of 0.05 m from any accessible surface of the device shall not exceed 5 microgreys per hour (µGy/h).

§ 10. 1. X-ray machines and accelerators:

- 1) shall be operated in accordance with the environmental requirements and electrical supply conditions specified in the technical description and in accordance with the operating instructions;
- 2) shall be serviced in accordance with the recommendations laid down in the operating manual;
- 3) shall be inspected in accordance with the nuclear safety and radiological protection programme and calibration checks.

2. The design of the X-ray machine and accelerators shall ensure electrical and mechanical safety by:

- 1) protection against the danger of injury which may result from touching the X-ray machine or accelerator;
- 2) protection against the development of a temperature or electric arc capable of causing a hazard.

§ 11. 1. The design of X-ray machines shall ensure:

- 1) the possibility of fitting radiation limiters corresponding to the purpose of the X-ray machine;
- 2) limitation of the radiation dose rate with the radiation beam window sealed and at the highest operating parameters specified by the manufacturer to a value that does not exceed:
 - a) 25 µGy/h at a distance of 0.5 m from the focus of the tube - for X-ray machines used for X-ray diffraction, microradiography and X-ray spectral analysis,
 - b) 2.5 mGy/h, for voltages up to and including 200 kV, or 10 mGy/h, for voltages above 200 kV, at a distance of 1 m from the focus of the tube - for other types of the X-ray machine;
- 3) for the X-ray machine in which the protective housing protects the X-ray tube and the irradiated object, a limitation of the dose rate at a distance of 0.1 m from the accessible surface of the housing to a value that does not exceed:
 - a) 7.5 µGy/h (fully protected X-ray machines),
 - b) 25 µGy/h (high-protection X-ray machines).

2. The fully protected X-ray machine and high-protection X-ray machine shall be equipped with two independent safeguards to prevent their operation when the casing is opened.

3. Fully protected X-ray machines shall not be equipped with the protections referred to in paragraph 2 if the use of the X-ray machine does not allow the housing to be closed and the dose rate at an accessible point of the open housing does not exceed 7.5 µGy/h.

4. High-protection X-ray machines shall not be equipped with the protections referred to in paragraph 2 if the dose rate in the internal space of the X-ray machine, at maximum performance, does not exceed 0.25 mGy/h at any point, or the use of the X-ray machine does not allow the housing to be closed, and the dose rate in an accessible area of the open housing does not exceed 25 µGy/h.

5. Diagnostic X-ray generator for veterinary purposes shall be equipped with:

- 1) filters allowing a filtration of not less than the equivalent value of 1.5 mm aluminium (Al);
- 2) a remote exposure trigger button to ensure that the operator maintains a distance of at least 2 m from the focus of the tube;
- 3) a device to give an acoustic or optical signal that the exposure has taken place; the signal is to be audible and visible from the trigger point;
- 4) current and voltage indicators on the X-ray tube;
- 5) an illuminated indicator of the irradiated field, providing an average field illumination of not less than 100 lux (lx) in a plane perpendicular to the beam axis at a distance of 1 m from the focus, if this distance is less than 1 m under normal operating conditions.

§ 12. 1. The therapeutic accelerator shall ensure:

- 1) patient safety during treatment;
- 2) signalling in the therapy room and in the control room of the presence of the radiation beam in the therapy room;
- 3) control of radiation dose and radiation dose rate using two independent dosimetry tracks;
- 4) keeping a record of radiation dose indications after completion of irradiation.

2. The design of the accelerator shall ensure that irradiation is terminated or interrupted when:

- 1) in the situation of a normal course of ionising radiation therapy, the radiation dose measurement system has indicated the attainment of the radiation dose value established prior to the commencement of irradiation;
- 2) there is a difference between the readings of the independent dosimetry tracks of more than 5% of these readings;
- 3) the measurement of the irradiation time has reached the value set prior to the commencement of irradiation.

§ 13. 1. Depending on the activity of the radioactive isotopes used at the same time and their affiliation to a group of radioactive isotopes, isotope laboratories with open radioactive sources shall be classified as Class III, II and I, in

accordance with Annex No. 3 to this Regulation.

2. The isotope groups referred to in paragraph 1 are defined in Annex No. 4 to this Regulation.

3. Sealed radioactive sources may be used in isotope laboratories with open radioactive sources.

§ 14. 1. In the case of a Class III isotope laboratory:

- 1) it shall be ensured that the requirements referred to in § 6 are met;
- 2) it shall be ensured that such laboratory is located in:
 - a) a building which is neither a residential building nor a collective residence building, or
 - b) a separate, non-residential part of the residential building or collective residence building, with a separate entrance and separate internal communication routes;
- 3) working surfaces shall be constructed in such a way as to prevent the spread of radioactive contamination and to allow for its removal;
- 4) if necessary due to the nature of the work to be carried out, workstations shall be equipped with radiochemical extractors, as well as with gloveboxes or other devices to prevent the spread of radioactive contamination;
- 5) floors, walls and installations shall be prepared in such a way as to enable the removal of radioactive contamination formed on their surfaces;
- 6) mechanical ventilation of the rooms shall be provided by a separate ventilation system allowing at least 3 air changes per hour;
- 7) depending on the type of work carried out with open radioactive sources, there shall be provided:
 - a) measurement of the content of radioactive substances in the air and effluents discharged from this laboratory,
 - b) collection and storage of solid and liquid radioactive waste in special containers or receptacles,
 - c) the purification of the air discharged from that laboratory,
 - d) technical equipment for the cleaning of working clothes used in the laboratory,
 - e) negative pressure in sealed working chambers of at least 200 Pa (pascals) in relation to the surroundings.

2. Activities that could facilitate the intrusion of radioactive substances into the body, in particular eating and smoking, are not permitted in a Class III isotope laboratory.

3. The organisation of work in the Class III isotope laboratory shall ensure communication between rooms without the need to go outside the laboratory.

4. If a Class III laboratory is equipped with a store of radioactive sources or radioactive waste located outside the laboratory, the provision of paragraph (3) shall not apply to that store.

§ 15. In the case of a Class II isotope laboratory, there shall be ensured:

- 1) compliance with the requirements laid down for a Class III isotope laboratory;
- 2) an area, excluding the sanitary-dosimetric sluice and the room for storing radioactive sources and waste, of not less than 15 m²;
- 3) entry and exit through the sanitary-dosimetry sluice;
- 4) mechanical supply and exhaust ventilation guaranteeing:
 - a) air flow towards rooms where radioactive contamination is more likely to occur,
 - b) an air movement or pressure system that prevents the spread of radioactive contamination arising from workstations,
 - c) air discharge at a height of at least 1 m above the ridge of the building that houses the Class II isotopic laboratory as well as the adjacent building;
- 5) marking personal protective equipment and working clothes and footwear in such a way as to prevent their use by persons to whom they have not been assigned as well as their use outside the laboratory;

- 6) storing sources and radioactive waste in a separate store room with mechanical supply and exhaust ventilation ensuring at least 6 air changes per hour while workers are inside, with the ventilation being turned on at least 10 minutes before workers will enter the store room.

§ 16. In the case of a Class I isotope laboratory:

- 1) it shall be ensured that the requirements laid down for a Class II isotope laboratory are met, except that a Class I laboratory may only be located in a building which is not a residential building or a collective residence building;
- 6) storing sources and radioactive waste in a separate store room with mechanical supply and exhaust ventilation ensuring at least 6 air changes per hour while workers are inside, with the ventilation being turned on at least 10 minutes before workers will enter the store room.

§ 17. In the case of laboratories in which sources of ionising radiation are used for medical purposes, it is additionally required to meet the relevant general requirements set out in the regulations for the premises and equipment of health care establishments.

Chapter 3

Requirements for work with radioactive sources, devices containing such sources and ionising radiation generators, used outside laboratories using radioactive sources, devices containing such sources or ionising radiation generators

§ 18. 1. Radioactive sources, devices containing such sources and ionising radiation generators may be used outside the laboratory if:

- 1) they are installed on the premises of an organisational unit in a manner that prevents uncontrolled exposure of persons and the environment, or
- 2) it is necessary to work in the field and radiological protection does not require the use of permanent shielding against ionising radiation and isolation of the places of use of ionising radiation sources from the surroundings.

2. In the conditions referred to in paragraph 1(2):

- 1) in the case of works requiring the use of open radioactive sources, the consent of the owner or administrator of the area where the works are to be carried out shall be obtained prior to the commencement of the works and the competent state sanitary inspector shall be notified;
- 2) in the event of the possibility of exceeding the usable dose limit (dose constraint) established in the licence, persons involved in the work shall be equipped with acoustic individual ionising radiation signalling devices;
- 3) all operations related to the use of open radioactive sources shall be carried out in the presence of the radiation protection officer;
- 4) in case it is necessary to store radioactive sources and waste outside the laboratory - they shall be stored in a supervised area secured according to the principles set out in fire regulations and protected against flooding by water and access of unauthorised persons, applying the requirements referred to in § 5 (4) to (6).

Chapter 4

Control of ionising radiation sources and records of radioactive sources

§ 19. 1. Control of radioactive sources shall include checking, at least once per calendar year:

- 1) compliance of the status of the sources with the radioactive sources record documents;
- 2) tightness of sealed radioactive sources;
- 3) conditions of use and storage of radioactive sources;
- 4)⁴ the manner in which radioactive sources are protected from loss, damage, theft or falling into the hands of unauthorised persons.

⁴ Added by § 1(2)(a) of the Regulation referred to in reference 2.

1a.⁵ In organisational entities carrying out the manufacture or processing of radioactive sources, the control shall also cover the course of the manufacture or processing of radioactive sources.

1b.⁵ The results of the inspections referred to in paragraph 1(1), (3) and (4) and paragraph 1a shall be recorded in an inspection report which contains, in particular:

- 1) date of inspection;
- 2) in the case of a sealed radioactive source:
 - a) the source number or the source certificate number,
 - b) the type of device containing the radioactive source to be controlled if the source is enclosed in the device;
- 3) in the case of an open radioactive source, the number of the certificate of the open radioactive source;
- 4) the findings of the control;
- 5) the name and address of the organisational entity and the name of the person who carried out the inspection;
- 6) name and signature of the head of the organisational entity.

2. The results of the leakage inspection of sealed radioactive sources shall be recorded in the source leakage inspection protocol, which shall include in particular:⁶

- 1) date of inspection;
- 2)⁷ the source number or source certificate number and the type of device containing the radioactive source to be checked, if the source is contained in the device;
- 3) the type of radioactive isotope, its activity and the date on which the activity was determined;
- 4) the type and number of the instrument used for the measurement;
- 5) the result of the measurement;
- 6) the results of the inspection;
- 7)⁸ name and address of the organisational entity carrying out the check;
- 8)⁹ name of the person who carried out the inspection and his/her signature.

3.¹⁰ In organisational entities carrying out the manufacture, processing, installation and marketing of radioactive sources or device containing such sources, the control referred to in paragraphs (1) and (1a) shall be carried out on an ongoing basis.

4. The inspection referred to in paragraph (1)(2) shall also be carried out following a radiological emergency and any other incident which may have an impact on the tightness of the source, in particular after a fire, the use of the source by an unauthorised person, temporary loss of possession of the source and its recovery after theft.

§ 20. 1. Inspection of device containing radioactive sources or ionising radiation generator before it is put into service shall include verification of compliance of the parameters of the device with the technical documentation, in particular determination of the ionising radiation dose rate at a distance of 0.1 m and 1 m from the housing of the device in a direction other than the direction of the radiation beam coming out from the device.

2. The results of the inspection referred to in paragraph 1 shall be recorded in the device handover report.

⁵ Added by § 1(2)(b) of the Regulation referred to in reference 2.

⁶ Introduction to the enumeration as amended by § 1(2)(c), first indent, of the Regulation referred to in reference 2.

⁷ As defined by § 1(2)(c), second indent, of the Regulation referred to in reference 2.

⁸ As defined by § 1(2)(c), third indent, of the Regulation referred to in reference 2.

⁹ Added by § 1(2)(c), fourth indent, of the Regulation referred to in reference 2.

¹⁰ As defined by § 1(2)(d) of the Regulation referred to in reference 2.

3.¹¹ A copy of the handover report referred to in paragraph (2) shall be forwarded by the head of the organisational entity conducting the inspection to the licensing authority without delay.

§ 21. 1. In organisational entities carrying out the activity of manufacturing and processing of radioactive sources, the records shall cover the output radioactive materials and the manufactured radioactive sources and shall be kept on a record sheet, the template of which is specified in Annex No. 5 to this Regulation, subject to paragraph 5.

2. In organisational entities carrying out the activities of marketing radioactive sources, manufacturing, marketing or installing devices containing radioactive sources, the records shall cover the incoming and outgoing of radioactive sources and shall be kept on a record sheet, the template of which is specified in Annex No. 6 to this Regulation, subject to paragraph (5).

3. In organisational entities carrying out activities involving the transport of radioactive sources, excluding transport within the unit, the records shall include the transport documents specified in the regulations on the transport of dangerous goods, subject to paragraph 5.

4. In organisational entities carrying out operations with high-activity sources, the records of these sources shall be kept on a record sheet, the template of which is set out in Annex 11 to this Regulation.

5. The record sheets referred to in § 21(1) to (3) and (5) shall be kept by the head of the organisational entity for a period of 5 years after termination of the activity using this radioactive source.

§ 22. 1. The record sheets referred to in § 21(1) to (3) and (5) shall be kept by the head of the organisational entity for a period of 5 years after termination of the activity using this radioactive source.

2. The transport documents referred to in § 21(4) shall be kept by the head of the organisational entity for a period of 3 years from the date of completion of the transport of these radioactive sources.

3. The head of an organisational entity carrying out the activity referred to in § 21(3), for which authorisation is required, shall make a record of the sealed radioactive sources held as at 31 December of the year in question on a record sheet, the template of which is set out in Annex No. 12 to this Regulation, and shall send a copy of this sheet to the President of the National Atomic Energy Agency by 31 January of the following year.

4. The head of an organisational entity carrying out the activities referred to in § 21(5) shall send the President of the National Atomic Energy Agency copies of the record sheets of the high-activity sources with which he/she is carrying out activities:

- 1) immediately upon taking possession of such source;
- 2) immediately after the change of the entry in the record sheet of the source;
- 3) immediately after transfer of the source to another organisational entity;
- 4) immediately upon request by the President of the National Atomic Energy Agency;
- 5) annually by 31 January.

5. Copies of the record sheets referred to in paragraphs (3) and (4) shall form the basis for entry in the register referred to in Article 43c(1) of the Act of 29 November 2000 on the Atomic Law.

6. In the event of termination of the activities of an organisational entity, the head of that unit shall immediately forward to the President of the National Atomic Energy Agency the record sheets referred to in § 21(1) to (3) and (5).

7. The President of the National Atomic Energy Agency shall keep copies of the record sheets referred to in paragraphs (3) and (4) and the record sheets referred to in paragraph (6) for a period of 30 years from the date of their receipt.

§ 23. The Regulation of the Council of Ministers of 17 December 2002 on the detailed conditions for safe work with ionising radiation sources (Journal of Laws, item 2029) shall be repealed.

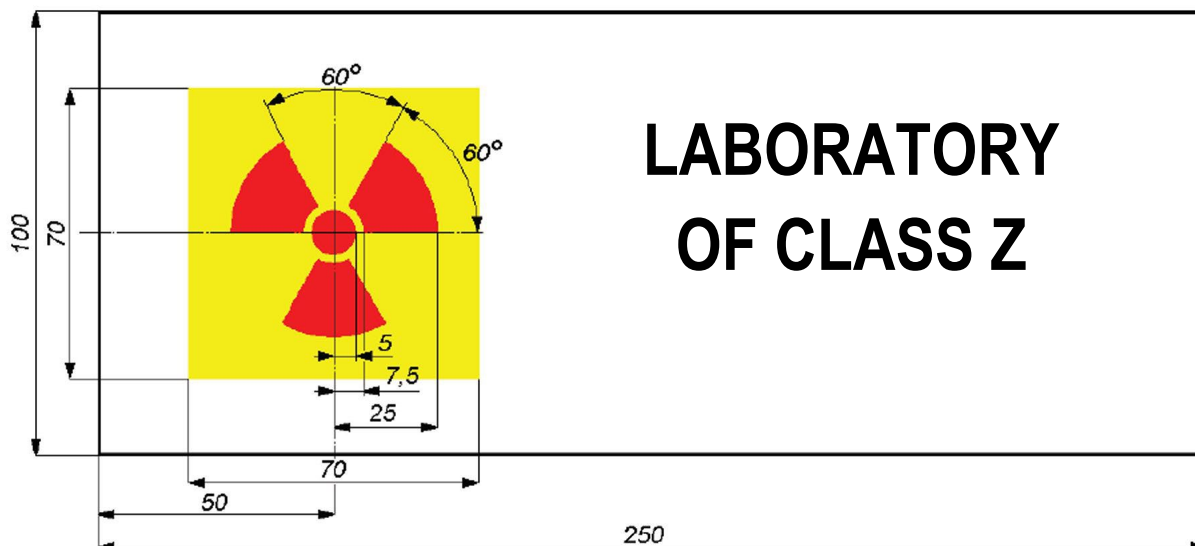
§ 24. This Regulation shall enter into force 14 days following its promulgation.¹²

¹¹ As defined by § 1(3) of the Regulation referred to in reference 2.

¹² This Regulation was promulgated on 7 August 2006.

TEMPLATES OF INFORMATION BOARDS FOR MARKING THE ENTRANCES TO THE LABORATORIES

1. Template for marking the entrance to a Class Z* isotope laboratory



* Dimensions are given in millimetres.

2. Template for marking the entrance to the accelerator laboratory*



* Dimensions same as for information board 1.

3. Template for marking the entrance to the X-ray laboratory*



* Dimensions same as for information board 1.

4. Templates of information boards for marking entrances to isotope laboratories with open radioactive sources*

a.



* Dimensions same as for information board 1.

b.



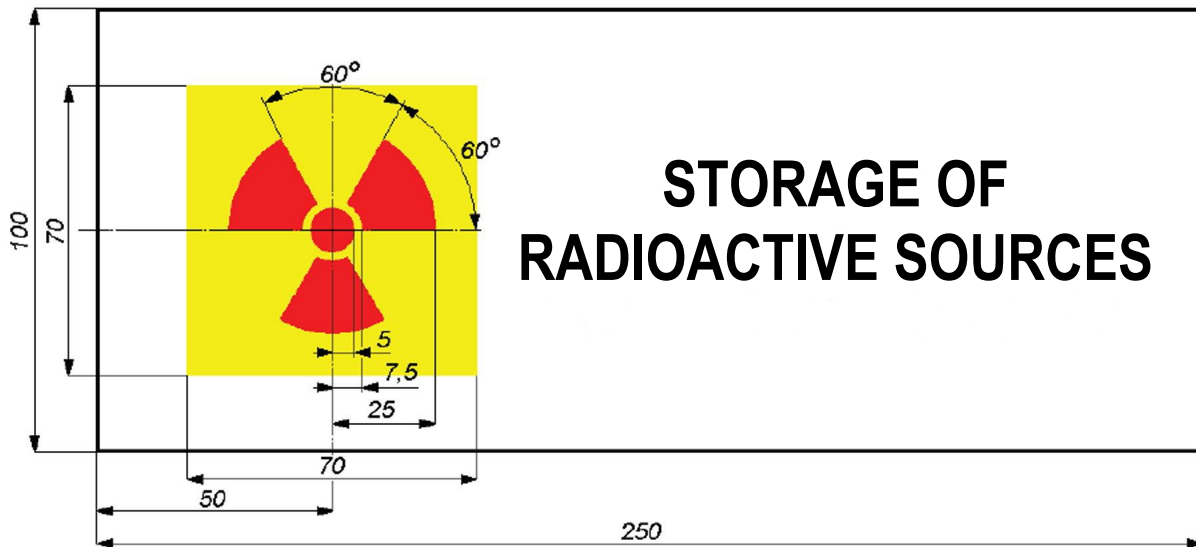
* Dimensions same as for information board 1.

c.



* Dimensions same as for information board 1.

TEMPLATE OF AN INFORMATION BOARD TO MARK A PLACE FOR THE STORAGE OF RADIOACTIVE SOURCES*



* Dimensions are given in millimetres.

CLASSES OF ISOTOPE LABORATORIES WITH OPEN RADIOACTIVE SOURCES, DEPENDING ON THE ACTIVITY OF THE RADIOACTIVE ISOTOPES USED SIMULTANEOUSLY IN THE LABORATORY AND THEIR ISOTOPE GROUP MEMBERSHIP

Isotope group	Class of the laboratory		
	I	II	III
	Activity of radioactive isotopes used simultaneously in the laboratory		
	MBq	MBq	MBq
1	above 1000	above 1 to 1000	up to 1
2	above 10000	above 10 to 10000	up to 10
3	above 100000	above 100 to 100000	up to 100
4	above 1000000	above 1000 to 1000000	up to 1000

Explanations:

1. In the case of a laboratory intended for work with radioactive isotopes of different isotope groups, the class of the laboratory shall be determined by comparing the activity calculated according to the formula: $A = A_1 + 0.1 A_2 + 0.01 A_3 + 0.001 A_4$

where A_1 , A_2 , A_3 , A_4 - simultaneously applied maximum activity of isotopes of respectively 1, 2, 3 or 4 isotope groups

with the activity of isotope group 1 provided for each class of the laboratory.

2. Depending on the type of activities performed with radioactive substances, the activity of the radioactive isotopes used simultaneously in the laboratory may be increased or decreased without changing the class of the laboratory, through multiplying by a factor:

Determination of activity	Factor
Storage	100
Medical diagnostics	100
Very simple wet operations	10
Normal chemical operations	1
Complicated wet operations with likelihood of spillage and simple dry operations with possibility of dusting	0.1
Complicated dry operations with possibility of dusting	0.01

GROUPS OF RADIOACTIVE ISOTOPES

Isotope group	Radioactive isotope									
1	2									
1	Sm-146	Sm-147	Gd-148	Gd-152	Pb-210	Bi-210m	Po-210	Ra-223	Ra-224	Ra-225
	Ra-226	Ra-228	Ac-225	Ac-226	Ac-227	Th-227	Th-228	Th-229	Th-230	Th-232
	Pa-231	U-230	U-232	U-233	U-234	U-235	U-236	U-238	Np-236	Np-237
	Pu-236	Pu-238	Pu-239	Pu-240	Pu-242	Pu-244	Am-241	Am-242m	Am-243	Cm-240
	Cm-242	Cm-243	Cm-244	Cm-245	Cm-246	Cm-247	Cm-248	Cm-250	Bk-247	Cf-248
	Cf-249	Cf-250	Cf-251	Cf-252	Cf-253	Cf-254	Es-253	Es-254	Fm-257	Md-258
2	Be-10	Al-26	Si-32	Ti-44	Fe-60	Co-60	Ge-68	Sr-82	Sr-90	Zr-93
	Nb-94	Ru-106	Rh-102	Ag-108m	Ag-110m	Cd-113	Cd-113m	In-114m	In-115	Sn-126
	I-126	I-129	I-131	La-137	La-138	Ce-144	Pm-146	Eu-150	Eu-152	Eu-154
	Tb-158	Ho-166m	Lu-176	Lu-177m	Hf-172	Hf-178m	Hf-182	Ta-180	Os-194	Ir-192m
	Hg-194	Pb-202	Pb-212	Bi-210	Bi-212	Bi-213	Bi-214	At-211	Fr-222	Ac-224
	Ac-228	Th-226	Pa-227	Pa-228	Pa-230	Pu-234	Pu-241	Am-242	Cm-241	Bk-249
	Cf-244	Cf-246	Es-254m	Fm-252	Fm-253	Fm-254	Fm-255	Md-257		
3	C-14	Na-22	Na-24	Mg-28	Si-31	P-32	P-33	S-35	Cl-36	K-40
	K-42	K-43	Ca-41	Ca-45	Ca-47	Sc-43	Sc-44	Sc-44m	Sc-46	Sc-47
	Sc-48	Ti-45	V-48	Cr-48	Mn-52	Mn-54	Mn-56	Fe-52	Fe-55	Fe-59
	Co-55	Co-56	Co-57	Co-58	Ni-56	Ni-57	Ni-59	Ni-63	Ni-65	Ni-66
	Cu-61	Cu-64	Cu-67	Zn-62	Zn-65	Zn-69m	Zn-71m	Zn-72	Ga-66	Ga-67
	Ga-72	Ga-73	Ge-66	Ge-69	Ge-77	Ge-78	As-70	As-71	As-72	As-73
	As-74	As-76	As-77	As-78	Se-70	Se-73	Se-75	Se-79	Br-74m	Br-76
	Br-77	Br-80m	Br-82	Rb-82m	Rb-83	Rb-84	Rb-86	Rb-87	Sr-80	Sr-83
	Sr-85	Sr-89	Sr-91	Sr-92	Y-86	Y-87	Y-88	Y-90	Y-90m	Y-91
	Y-92	Y-93	Zr-86	Zr-88	Zr-89	Zr-95	Zr-97	Nb-89	Nb-90	Nb-93m
	Nb-95	Nb-95m	Nb-96	Mo-90	Mo-93	Mo-93m	Mo-99	Tc-94	Tc-99	Tc-95m
	Tc-96	Tc-97	Tc-97m	Tc-98	Tc-99	Ru-97	Ru-103	Ru-105	Rh-99	Rh-100
	Rh-101	Rh-101m	Rh-102m	Rh-105	Rh-106m	Pd-100	Pd-101	Pd-103	Pd-107	Pd-109
	Ag-105	Ag-106m	Ag-111	Ag-112	Cd-107	Cd-109	Cd-115	Cd-115m	Cd-117	Cd-117m
	In-110	In-111	In-117m	Sn-110	Sn-113	Sn-117m	Sn-119m	Sn-121	Sn-121m	Sn-123
	Sn-125	Sn-127	Sn-128	Sb-118m	Sb-120	Sb-122	Sb-124	Sb-125	Sb-126	Sb-127
	Sb-128	Sb-129	Te-116	Te-121	Te-121m	Te-123	Te-123m	Te-125m	Te-127	Te-127m
	Te-129m	Te-131m	Te-132	Te-133m	Te-134	I-120	I-120m	I-123	I-124	I-125
	I-130	I-132	I-132m	I-133	I-135	Cs-132	Cs-134	Cs-135	Cs-136	Cs-137
	Ba-126	Ba-128	Ba-131	Ba-133	Ba-133m	Ba-135m	Ba-140	La-132	La-140	La-141
	La-142	Ce-134	Ce-135	Ce-137m	Ce-139	Ce-141	Ce-143	Pr-138m	Pr-142	Pr-143
	Pr-145	Nd-138	Nd-139m	Nd-147	Nd-149	Pm-143	Pm-144	Pm-145	Pm-147	Pm-148
	Pm-148m	Pm-149	Pm-150	Pm-151	Sm-142	Sm-145	Sm-151	Sm-153	Sm-156	Eu-145
	Eu-146	Eu-147	Eu-148	Eu-149	Eu-152m	Eu-155	Eu-156	Eu-157	Gd-146	Gd-147
	Gd-149	Gd-151	Gd-153	Gd-159	Tb-147	Tb-149	Tb-150	Tb-151	Tb-153	Tb-154
	Tb-155	Tb-156	Tb-156m	Tb-157	Tb-160	Tb-161	Dy-155	Dy-159	Dy-166	Ho-166
	Ho-167	Er-169	Er-171	Er-172	Tm-166	Tm-167	Tm-170	Tm-171	Tm-172	Tm-173
	Yb-166	Yb-169	Yb-175	Yb-178	Lu-169	Lu-170	Lu-171	Lu-172	Lu-173	Lu-174
	Lu-174m	Lu-176m	Lu-177	Lu-179	Hf-170	Hf-173	Hf-175	Hf-177m	Hf-179m	Hf-180m
	Hf-181	Hf-184	Ta-173	Ta-175	Ta-176	Ta-177	Ta-178	Ta-179	Ta-182	Ta-183
	Ta-184	W-178	W-185	W-187	W-188	Re-181	Re-182	Re-184	Re-184m	Re-186
	Re-186m	Re-188	Re-189	Os-181	Os-182	Os-185	Os-191	Os-191m	Os-193	Ir-184
	Ir-185	Ir-186	Ir-187	Ir-188	Ir-189	Ir-190	Ir-190m	Ir-192	Ir-193m	Ir-194

	Ir-194m	Ir-195	Ir-195m	Pt-188	Pt-191	Pt-193m	Pt-195m	Pt-197	Pt-200	Au-193
	Au-194	Au-195	Au-198	Au-198m	Au-199	Au-200m	Hg-193	Hg-193m	Hg-195m	Hg-197
	Hg-197m	Hg-203	Tl-198	Tl-200	Tl-202	Tl-204	Pb-200	Pb-201	Pb-202m	Pb-203
	Pb-205	Pb-211	Pb-214	Bi-201	Bi-202	Bi-203	Bi-205	Bi-206	Bi-207	Po-207
	At-207	Fr-223	Ra-227	Th-231	Th-234	Pa-232	Pa-233	Pa-234	U-231	U-237
	U-240	Np-234	Np-235	Np-238	Np-239	Np-240	Pu-237	Pu-243	Pu-245	Pu-246
	Am-239	Am-240	Am-244	Am-246	Cm-238	Bk-245	Bk-246	Bk-250	Es-250	Es-251
4	H-3	Be-7	C-11	F-18	Cl-38	Cl-39	K-44	K-45	Sc-49	V-47
	V-49	Cr-49	Cr-51	Mn-51	Mn-52m	Mn-53	Co-58m	Co-60m	Co-61	Co-62m
	Cu-60	Zn-63	Zn-69	Ga-65	Ga-68	Ga-70	Ge-67	Ge-71	Ge-75	As-69
	Se-73m	Se-81	Se-81m	Se-83	Br-74	Br-75	Br-80	Br-83	Br-84	Rb-79
	Rb-81	Rb-81m	Rb-88	Rb-89	Sr-81	Sr-85m	Sr-87m	Y-86m	Y-91m	Y-94
	Y-95	Nb-88	Nb-97	Nb-98	Mo-101	Tc-93	Tc-93m	Tc-94m	Tc-96m	Tc-99m
	Tc-101	Tc-104	Ru-94	Rh-99m	Rh-103m	Rh-107	Ag-102	Ag-103	Ag-104	Ag-104m
	Ag-106	Ag-115	Cd-104	In-109	In-112	In-113m	In-115m	In-116m	In-117	In-119m
	Sn-111	Sn-123m	Sb-115	Sb-116	Sb-116m	Sb-117	Sb-119	Sb-124m	Sb-126m	Sb-130
	Sb-131	Te-129	Te-131	Te-133	I-121	I-128	I-134	Cs-125	Cs-127	Cs-129
	Cs-130	Cs-131	Cs-134m	Cs-135m	Cs-138	Ba-131m	Ba-139	Ba-141	Ba-142	La-131
	La-135	La-143	Ce-137	Pr-136	Pr-137	Pr-139	Pr-142m	Pr-144	Pr-147	Nd-136
	Nd-139	Nd-141	Nd-151	Pm-141	Sm-141	Sm-141m	Sm-155	Eu-158	Gd-145	Dy-157
	Dy-165	Ho-155	Ho-157	Ho-159	Ho-161	Ho-162	Ho-162m	Ho-164	Ho-164m	Er-161
	Er-165	Tm-162	Tm-175	Yb-162	Yb-167	Yb-177	Lu-178	Lu-178m	Hf-182m	Hf-183
	Ta-172	Ta-174	Ta-180m	Ta-182m	Ta-185	Ta-186	W-176	W-177	W-179	W-181
	Re-177	Re-178	Re-187	Re-188m	Os-180	Os-189m	Ir-182	Pt-186	Pt-189	Pt-193
	Pt-197m	Pt-199	Au-200	Au-201	Hg-195	Hg-199m	Tl-194	Tl-194m	Tl-195	Tl-197
	Tl-198m	Tl-199	Tl-201	Pb-195m	Pb-198	Pb-199	Pb-209	Bi-200	Po-203	Po-205
	U-239	Np-232	Np-233	Pu-235	Am-237	Am-238	Am-244m	Am-245	Am-246m	Cm-249

TEMPLATE

.....
(name and address of organisational entity)

RECORD SHEET OF THE STARTING RADIOACTIVE MATERIAL AND THE RADIOACTIVE SOURCES MANUFACTURED FROM IT

Starting radioactive material:

- radioactive isotope
- description of the starting radioactive material
- activity
- date of activity determination
- number of the certificate of the starting radioactive material
- name and address of the manufacturer
- chemical form
- physical form
- mass, volume or quantity
- parameters
- kind, type and number of container in which the starting radioactive material is placed
-

Sources produced from the starting radioactive material:

Radioactive isotope

No.	Production date	Activity used	Date of determination of activity used	Other activity	Date of determination of other activity	Source code	Source number	Source activity	Date of determination of source activity	Number of sources	Source certificate number	Container kind, type and number	Remarks
1	2	3	4	6	7	8	9	10	11	12	13	14	15

.....
(name, signature of the person who drew up the sheet)

TEMPLATE

.....
(name and address of organisational entity)

RECORD SHEET FOR INCOMING AND OUTGOING RADIOACTIVE SOURCES

No.	Radioactive isotope	Activity by source certificate	Date of activity determination	Date of receipt of the source	Name and address of supplier	Name and specification of delivery document	Type of source*	Type of sealed radioactive source or physical and chemical form of an open radioactive source	Code of source and manufacturer's mark	Source number and source certificate number	Kind, type and number of container or device	Name and address of recipient	Date of source handover	Type and characteristics of the handover document	Kind, type and number of container or device	Name and signature of the person who made an entry on the sheet and date of entry
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17

*
s - sealed radioactive source
o - open radioactive source

TEMPLATE

.....
(name and address of organisational entity)

RECORD SHEET
OF THE OPEN RADIOACTIVE SOURCE

Radioactive isotope	Chemical and physical form	Activity	Date of activity determination	Quantity, mass, volume	Certificate no., number of portions	Date of receipt	Type and no. of storage container	Place of storage

.....
(name, signature of the person who drew up the sheet)

TEMPLATE

.....
(name and address of organisational entity)

RECORD SHEET
OF A MOVEMENT OF THE OPEN RADIOACTIVE SOURCE

.....
(name of radioactive isotope)

No.	Date	Released			Received by		Remains		Remarks
		activity and date of its determination	quantity, mass, volume	place of use	Full name	Full name	signature	quantity, mass, volume	
1	2	3	4	5	6	7	8	9	10

TEMPLATE

.....
(name and address of organisational entity)

RECORD SHEET
OF THE SEALED RADIOACTIVE SOURCE

Date of receipt		
Radioactive isotope		
Activity and date of its determination		
Type of source		
Source certificate number and source number		
Licence number		
Name and address of the manufacturer		
Name and address of supplier		
Place of storage or installation		
Type and number of storage or work container		
Leak-tightness measurement	date	
	result	
	protocol number	
Removed from the records	name and address of the receiving institution	
	No. and date of the handover document	
Full name and signature of the person who made an entry on the sheet and date of entry		

TEMPLATE

.....

(name and address of organisational entity)

RECORD SHEET
OF A MOVEMENT OF THE SEALED RADIOACTIVE SOURCE

.....

(radioactive isotope, activity and source number)

No.	Date	Received by					Returned		Remarks
		type of device, container	device serial number	place of use	Full name	Full name	date	Full name of receiving person	
1	2	3	4	5	6	7	8	9	10

RECORDING SHEET OF HIGH-ACTIVITY SOURCE (*in italics: supplementary items*)

Annex No. 11¹³

(1) Identification number <i>Device serial number:</i> <i>Area of use:</i>	(2) Details of organisational entity Name: Address: Country: Manufacturer: ☐ Supplier: ☐ User: ☐	(3) Location of source (use or storage), if different from (2) Name: Address: Country: Use Storage: ☐ Use stationary: ☐ portable: ☐
(4) Registration Date of first registration: Date of transfer of a sheet to the archive:	(5) Licence Number: Date of issue: Date of expiration:	(6) Control of the source Date Date Date Date
(7) Source characteristics Year manufactured: Radioactive isotope Activity on the day of manufacture: Date manufactured: Manufacturer/supplier: ¹⁾ Name: Address: Country: Physical and chemical characteristics: <i>Source type designation:</i> <i>Capsule designation:</i> <i>ISO classification:</i> <i>ANSI classification:</i> <i>IAEA Source Category:</i> Neutron source: <i>yes</i> ☐ <i>no</i> ☐ <i>Source disc material:</i> <i>Neutron flux:</i>	(8) Receipt of source Date received: Received from: Name: Address: Country: Manufacturer: ☐ Supplier: ☐ Other user: ☐	Date Date Date Date Date Date Date Date

¹³ As defined by § 1(4) of the Regulation referred to in reference 2.

	(9) Handover of source Date of handover Handover to: Name: Address: Country: Licence number: Licence date: Licence expiry date: Manufacturer: ☐ Supplier: ☐ Other organisational entity: ☐ Radioactive Waste Management Plant (ZUOP): ☐	(10) Additional information Loss: ☐ Date of loss: Theft: ☐ Date stolen: Found: yes ☐ no ☐ Date Place: Other information:
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¹⁾ In the case of a manufacturer of sources from outside the Community, the name and address of the importer/supplier may be given.

TEMPLATE

.....
(name and address of organisational entity)

RECORDING SHEET OF POSSESSED SEALED RADIOACTIVE SOURCES AS OF 31 December 2023.

No.	Radioactive isotope	Activity by source certificate	Date of activity determination	Certificate number, number and type of source	Container type or device name	Place of use or storage
1	2	3	4	5	6	7

Head of organisational entity:
.....
(Full name, signature)

Radiation Protection Officer:
.....
(Full name, authorisation number, signature)