**RULES ON RADIATION PROTECTION MEASURES IN CONTROLLED AND MONITORED AREAS**

**(SV8A)**

**UNOFFICIAL TRANSLATION**

*Prepared by the Slovenian Nuclear Safety Administration in January 2019.*

*The official text of these Rules is located on the pages of* [*the Legal Information System*](http://www.pisrs.si/Pis.web/pregledPredpisa?id=PRAV13512)*.*

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

Based on the fourth paragraph of Article 44 of the Ionising Radiation Protection and Nuclear Safety Act (Official Gazette of the Republic of Slovenia, No. 76/17) the Minister for Health and the Minister for the Environment and Spatial Planning hereby issue the

## RULES

**on the radiation protection measures in controlled and monitored areas**

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

These Rules, in accordance with Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for the protection against the dangers arising from ionizing radiation and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom (OJ L No 13 of 17. 1. 2014, p. 1), last amended by Corrigendum (OJ L 72, 17. 3. 2016, p. 69) provides:

1. criteria for categorisation of controlled and monitored areas;
2. obligations of the provider carrying out a radiation practice in controlled and monitored areas concerning the performance of radiation protection measures;
3. method of delineating and marking controlled and monitored areas;
4. drawing up written instructions for safe work and other procedures in controlled and monitored areas;
5. training of workers concerning specific properties of controlled and monitored areas;
6. rules regarding personal protective equipment used in controlled and monitored areas;
7. performing surveillance measurements;
8. time limits and other conditions in which provider carrying out a radiation practice must ensure the verification of working conditions and the radiation conditions of an independent authorized radiation protection expert.

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## Article 2 (Definitions)

The terms used in these Rules shall have the following meanings:

1. Administrative measures are measures that prevent entry to persons who do not have the authority to enter the controlled area. Administrative measures may be in form of access cards or a system of authorisation.
2. Active particles are free, charged and moving radioactive particles with an activity that causes high dose rates.
3. An etalon is a material measure, a measuring instrument, a reference material, or a measurement system, the purpose of which is to define, realise, maintain or reproduce a unit or one or more values of the measured so that it serves as a reference.
4. The dose rate is the time derivative of a given dose (absorbed, equivalent, effective, committed equivalent, committed effective) or its equivalents (ambient, directional, personal) and refers to the rate of change of the dose in unit time. The unit of dose rate is Gy/s or Sv/s.
5. The control point is a controlled and regulated transition between areas with different levels of radioactive contamination or with different levels of radiation.
6. Personal protective equipment is a device that the worker wears on himself, handles it, or otherwise uses it to reduce his exposure.
7. The competent authority means the administrative body responsible for issuing licences to carry out radiation work or the registration of radiation work in accordance with the Ionising Radiation Protection and Nuclear Safety Act (Official Gazette of the Republic of Slovenia, No. 76/17; hereinafter: ZVISJV-1).
8. Radiation conditions are all working conditions that affect exposure at workplaces, especially dose rate and type of radiation, where appropriate, also:
   * the concentration of radionuclides in the air and the type, the physical and chemical composition of the radioactive material,
   * surface contamination and type, the physical and chemical composition of the radioactive material.
9. Traceability is a characteristic of the measurement result or the value of the etalon, which allows affiliation to references, usually national or international standards, through a continuous chain of comparisons that have defined uncertainty.
10. Calibration is a set of operations for determining the connection between the values indicated by the measuring instrument or measuring system, or the values represented by the material measure of reference material, and the corresponding values realized by the etalons, under certain conditions.

## Article 3 (Categorisation of areas)

1. Areas, where workers or other persons are exposed to radiation, depending on the expected exposure and the probability and size of potential exposure, are divided into controlled and monitored areas, as specified in as defined in Articles 4 and 7 of these Rules.
2. In controlled and monitored areas, radiation protection measures must be implemented according to the type of radiation sources and the size of the risk associated with them. The scope of radiation protection measures, determining the exposure of workers, control measurements of radiation in controlled and monitored areas and their nature and quality must be proportionate to the risk of exposure to a particular work.
3. A provider carrying out a radiation practice must specify his responsibilities relating the implementation of radiation protection in controlled and monitored areas in writing to inform the workers.

## Article 4 (Controlled areas)

1. Controlled areas are those where:
2. the annual effective dose may exceed 6 mSv,
3. the annual equivalent dose for eye lenses may exceed 15 mSv,
4. the annual equivalent dose for the hands, arms, forearms or skin can exceed 150 mSv,
5. the average dose rate within 8 hours is greater than or equal to 3 μSv/h,
6. the maximum dose rate of one exposure for a duration of up to 1 minute is greater than or equal to 60 μSv/h, or
7. there is a risk of the spread of radioactive substances that would cause contamination above the prescribed limits.
8. A provider carrying out a radiation practice, in cooperation with an authorised radiation protection expert, shall determine the boundaries of the controlled area and shall, where possible and sensibly, physically, or in another appropriate way, separate it from other areas. In the case of a mobile radiation source, the controlled areas are demarcated in the manner best suited to the given circumstances and the time in which the radiation source works. A provider carrying out a radiation practice shall keep records of such controlled areas. The demarcation of controlled areas must be included in the radiation protection assessment, which is laid down in the ZVISJV-1 (hereinafter: radiation protection assessment).
9. A provider carrying out a radiation practice shall, at the edge of the controlled area and in other appropriate visible places, affix signs indicating the controlled area and the risk of radiation, and where appropriate, also the characteristics of the radiation source in that area and the risk associated with this source. Warning signs of the danger of radiation are laid down in a regulation laying down the rules of conduct and conditions for the use of individual radiation sources and radiation safety measures to be undertaken by users of radiation sources.

## Article 5

**(Access to controlled areas)**

1. A provider carrying out a radiation practice must ensure by means of administrative measures and physical barriers, locks, automatic bolts and other appropriate means that access to the controlled area is limited and controlled.
2. Access is permitted only to persons who:
   1. are aware of work-related risks,
   2. have the appropriate knowledge of radiation protection measures to be implemented at work,
   3. are familiar with the written procedures and instructions,
   4. are, based on a medical examination, capable of carrying out the work and tasks in which they are exposed to radiation,
   5. who are included in personal dosimetry, and
   6. who use personal protective equipment, if necessary.
3. Notwithstanding the provisions of the preceding paragraph, in the controlled area, there may be persons who assist the patient during the performance of the radiological procedure provided they are aware of the risk.
4. Other persons may enter the controlled area in exceptional cases, provided they were informed of the risk and are accompanied by the persons referred to in the second paragraph of this Article.
5. If there is a risk of the spread of radioactive contamination from a controlled area, the employer shall prevent it by reasonable measures. If this is followed based on a radiation protection assessment, it is installed:
6. at entry points:
   * protective clothing and personal protective equipment,
   * measuring devices,
   * suitable storage for personal clothing,
7. at exit points:
   * equipment for measuring contamination of skin,
   * clothing and footwear,
   * equipment for measuring the contamination of objects and substances or activities of activated objects and substances that emerge from the controlled area,
   * washbasins (showers) for personal decontamination,
   * suitable storage rooms for the storage of contaminated protective clothing and equipment.
8. If there is a probability that active particles are present in the controlled area, the employer shall further restrict the area with active particles by reasonable measures and prevent their spread.

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## Article 6

**(Written procedures and instructions)**

1. A provider carrying out a radiation practice shall provide written procedures for monitoring the controlled area.
2. A provider carrying out a radiation practice shall provide written instructions for safe work in a controlled area. The scope and content of the instructions must be defined in the radiation protection assessment. The instructions must be made according to the nature and characteristics of the radiation source and work with this source in a language understood by the worker. Instructions must be made available at the workplace.
3. A provider carrying out a radiation practice shall ensure that the work is carried out according to the instructions from the previous paragraph and the workers and other persons who are exposed to radiation in the controlled areas are familiar with the instructions.
4. A provider carrying out a radiation practice shall regularly check the adequacy of the instructions and inform workers about changes in procedures and administrative measures related to the implementation of radiation protection.

## Article 7 (Monitored areas)

1. Monitored areas are those areas:
   * access restriction due to radiation protection is not necessary, but the control of radiation conditions is necessary,
   * where the annual effective dose may exceed 1 mSv,
   * the average dose rate within 8 hours is greater than 0.5 μSv/h and less than 3 μSv/h or
   * the maximum dose rate of one exposure for a duration of up to 1 minute is greater than 3 μSv/h or less than 60 μSv/h.
2. A provider carrying out a radiation practice shall, in cooperation with the authorised radiation protection expert, determine the boundaries of the monitored area. In the case of a mobile radiation source, the monitored areas are demarcated in the manner best suited to the given circumstances and the time in which the radiation source works. The demarcation of monitored areas must be included in the radiation protection assessment.
3. A provider carrying out a radiation practice shall, where appropriate, draw up written instructions for safe work in the monitored area, taking due account of the provisions of the preceding Article.
4. If this is followed from the radiation protection assessment, a provider carrying out a radiation practice shall mark the monitored area in visible places with signs indicating the monitored area, the type of radiation source in the area and the associated risk. Warning signs of the danger of radiation are laid down in a regulation laying down the rules of conduct and conditions for the use of individual radiation sources and radiation safety measures to be undertaken by users of radiation sources.

## Article 8

**(Control measurements in controlled and monitored areas carried out by** **a provider carrying out a radiation practice)**

1. A provider carrying out a radiation practice regularly controls radiation conditions in controlled and monitored areas with measurements (hereinafter: control measurements).
2. A provider carrying out a radiation practice, in cooperation with an authorised radiation protection expert, shall develop a programme for the implementation of control measurements, which is an integral part of the radiation protection assessment, in which it shall determine:
   * measured quantities,
   * location, time and frequency of measurements,
   * measurement methods and procedures,
   * measuring equipment and the frequency of equipment and calibration checks and
   * reference radiation levels and the measures to be taken, if they are exceeded.
3. A provider carrying out a radiation practice shall ensure that the personnel performing control measurements have written instructions for carrying out the measurements and are adequately trained to carry out the measurements.
4. A provider carrying out a radiation practice shall keep the results of the control measurements for at least three years and shall inform the workers thereof. Where necessary, the results may be used to assess the individual dose of the worker. In this case, the employer shall keep the results in accordance with the fifth paragraph of Article 49 of the ZVISJV-1.

## Article 9 (Measuring equipment)

1. A provider carrying out a radiation practice for the implementation of the control measurements referred to in the previous Article shall provide the measuring equipment of the appropriate quality regarding the intended use, consulted by an authorised radiation protection expert.
2. A provider carrying out a radiation practice shall ensure that the measuring equipment used to perform the control measurements is calibrated in a way that ensures traceability before the first use. A provider carrying out a radiation practice checks the measuring equipment in regular periods in such a way as to ensure that the measuring equipment gives reproducible results within the specified accuracy in known and predefined conditions. After each repair of the measuring equipment, otherwise, during the regular periods specified in the programme of implementation of control measures, the employer shall ensure calibration in a way that ensures traceability. A provider carrying a radiation practice shall keep a log of checks on the measuring equipment and shall keep documentation of the measuring equipment, repair of equipment and calibration.

## Article 10

**(Control measurements in controlled and monitored areas carried out by an authorised radiation protection expert)**

1. The radiation conditions in controlled and monitored areas in activities where people are exposed to sources of radiation are checked by an authorized radiation protection expert at regular intervals specified for carrying out checks and measurements of these sources of radiation in the Rules laying down the rules of conduct and conditions for the use of individual radiation sources and radiation safety measures to be undertaken by users of radiation sources.
2. Notwithstanding the provisions of the preceding paragraph, an authorised radiation protection expert shall check the radiation conditions in the controlled and observed areas:
   * every six months in nuclear facilities,
   * once a year for activities where workers handle materials or waste which, due to their characteristics, have an increased content of natural radionuclides or have, due to technological processing, an increased content of natural radionuclides.
3. An authorised radiation protection expert shall prepare a report on the performed control measurements, which a provider carrying out a radiation practice must keep for at least three years and inform the workers about its contents. Where necessary, the results may be used to assess the individual dose of the worker. In this case, the provider carrying a radiation practice shall keep reports in accordance with the fifth paragraph of Article 49 of the ZVISJV-1.
4. Notwithstanding the provisions of the previous paragraph, the provider carrying out a radiation practice shall keep at least the last two reports on the performed surveillance measurements.

## Article 11

**(The scope of control measurements in the controlled and monitored areas)**

1. The control measurements of the controlled and monitored areas referred to in the preceding Article include dose rate measurements. When exposed due to unsealed sources of radiation, surface contamination is also determined, or the concentration of individual radionuclides in the air is measured.
2. Dose rate measurements are performed:
   * at locations that allow the assessment of equivalent doses and the effective dose of exposed individuals;
   * at typical points in the room and adjacent rooms in conditions of operation and storage of the radiation source;
   * in a useful beam of X-ray devices and devices with sealed sources of radiation, if this is accessible by measuring instruments and
   * at a distance of 1 m and at other appropriate distances from a patient with a brachyradiotherapeutic source or a patient who received a dose of the radiopharmaceutical preparation.
3. The measurements of dose rates are made at settings and parameter values that are typical of the standard type of procedure, measurement, or task. In radiotherapy and X-ray diagnostics, measurements are made in the presence of a patient or using appropriate water phantoms, phantoms made from plexiglass or other appropriate material.
4. Surface contamination is determined by measurements of the surface specific activity of individual radionuclides on working surfaces, equipment, personal protective equipment, clothing and footwear, walls, floors and ceilings.
5. The concentration of individual radionuclides in the air is measured in the room and at the exhaust vents of the ventilation system.

## Article 12 (Personal exposure assessment)

The results of the control measurements referred to in the preceding Article together with the exposure duration details should be used to estimate the exposure of groups of workers and other persons. Exposure assessments are compared with the results of personal exposure control measurements and must be included in the radiation protection assessment.

## Article 13

**(Personal protective equipment)**

1. A provider carrying out a radiation practice shall ensure:
   1. that workers use appropriate personal protective equipment, including, where appropriate, protective clothing, protective aprons, gloves, shields for individual organs and respiratory protective equipment;
   2. that personal protective equipment is marked in such a way that its protective capacity, indicated in equivalent Pb thickness or other suitable quantity, is evident and that users are aware of its protective capabilities and the intended use;
   3. that workers have adequate instructions for the proper use of personal protective equipment, including the test of proper fit for respiratory protection equipment;
   4. regular checking of the effectiveness of personal protective equipment, including emergency equipment;
   5. that tasks assigned to the use of specific personal protective equipment are mandatory only to workers who are able to bear the necessary additional effort on the basis of health assessments, and
   6. that whenever personal protective equipment is to be used for a given task, any additional exposure that may arise due to additional time or difficulties and any additional risks not resulting from radiation and which may be related to carrying out the task with the use of personal protective equipment.
2. A provider carrying out a radiation practice shall ensure that the protective equipment is adequately maintained, that the workers are adequately trained to use it and that they have the appropriate instructions for this.
3. The type of protective equipment and its method of use must be defined in the radiation protection assessment.

## Article 14

**(Radiation protection measures)**

1. A provider carrying out a radiation practice shall provide appropriate radiation protection measures, including technical supervision and appropriate working conditions, which reduce the need for administrative measures and personal protective equipment.
2. The provider carrying out a radiation practice shall continuously monitor all situations in the controlled and monitored areas that may affect exposure.

## Article 15 (End of validity)

On the day, these Rules enter into force, Article 3 to 14 of the Rules on the obligations of the person carrying out an activity involving radiation and person possessing an ionising radiation source (Official Gazette of the Republic of Slovenia, No. 3/17, 8/17 and 76/17 – ZVISJV-1) shall cease to apply.

## Article 16 (Entry into force)

These Rules shall enter into force on the 15th day after the publication in the Official Gazette of the Republic of Slovenia.

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**I agree!**

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