RULES ON THE USE OF RADIOACTIVE SOURCES AND ON PRACTICES INVOLVING RADIATION
(JV/SV 2)

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Pursuant to the Ionising Radiation Protection and Nuclear Safety Act (Official Gazette of the Republic of Slovenia, No. 102/04 – official consolidated text) Article 9, paragraph 6, Article 10, paragraph , Article 12, paragraph 2, Article 14, Article 15, paragraph 4, Article 16 and Article 131, paragraph 6 the Minister of the Environment and Spatial Planning and the Minister of Health issue the following

RULES
on the use of radioactive sources and on practices involving radiation

I. GENERAL PROVISIONS

Article 1
(purpose and content of the Rules)

(1) These Rules lay down the technical requirements for the type approval of radioactive sources, the form of the notification of the intention, the content of the application for authorisation of practice involving radiation and the content of the application for authorisation of use of a radioactive source, the management of radioactive sources, and the form and method of keeping registers of practices involving radiation, radioactive sources and nuclear and radiation facilities.


Article 2
(definitions)

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

1. central storage of radioactive waste means a storage facility operated by the public service provider of the services of management of radioactive waste in accordance with the act governing ionising radiation protection and nuclear safety (hereinafter referred to as the Act);
2. supplier means a natural or legal person that supplies a radioactive source or makes it available in any other way;
3. authorisation means an official document issued on the applicant’s request by the competent ministry to permit a practice involving radiation or use of a radioactive source;
4. exposition means the procedure of radiography, fluoroscopy or exposure by means of a radioactive source;
5. holder means a natural or legal person responsible for a radioactive source, including manufacturers, suppliers and users of radioactive sources, but excluding the operator of the central storage of radioactive waste management;
6. industrial radiography means a non-destructive method of material testing applying radioactive sources to produce a radioagraphical image of an object interior;
7. control point means the boundary between two zones differing in their level of radioactive contamination or in their level of radiation;
8. useful radiation beam means a beam, directed through an assembly of shutters, used for the purposes of radiography or fluoroscopy of objects or patients or of the treatment of patients. The cross-section of the useful beam is the useful radiation field;

9. exposure dose means the dose received by the patient in the course of treatment involving radiation;

10. transfer of a radioactive source means the transfer of a source from one holder to another one;

11. manufacturer means a natural or legal person that manufactures a radioactive source;

12. radiotoxicity is the property of a radioactive substance characterising its threats in terms of radiation protection;

13. temporary storage means an area in which the user may keep radioactive sources or radioactive waste until their transfer to the service provider of the public service of management of radioactive waste in accordance with the Act;

14. imaging detector means a radiation detector that captures information for the generation of an image. Imaging detectors include radiographical cartridges containing films and amplifier foils, image amplifiers, digital planar detectors, detector systems of computer tomographs, etc.;

15. specific exposure dose is the ratio of the absorbed dose and the charge flowed through the tube of an x-ray device at a given distance from the tube;

16. disused radioactive source means a radioactive source that is no longer used or intended to be used for the practice for which authorization was granted;

17. orphan source means a sealed radioactive source, the activity level of which, at the time of its discovery, is above the exemption level provided by the regulation governing practices involving radiation and which is not under regulatory control by the competent ministry, because it has never been under regulatory control or because it has been abandoned, lost, misplaced, stolen or transferred to a new holder without proper notification of the competent ministry or without informing the recipient;

18. high-activity sealed radioactive source means a sealed radioactive source in the meaning given by the regulation governing practices involving radiation;

19. source container means the containment of a sealed radioactive source not being an integral part of the source, but meant for transport, handling, etc;

20. sealed radioactive source means a radioactive source the structure of which prevents, under foreseen conditions of use and wear and in foreseen incidents, any release of radioactive substances into the environment, including, where applicable, a capsule enclosing the radioactive substance as an integral part of the source;

21. shielding capacity of a shield means the thickness of the substance shielding a radioactive source and may be expressed as the equivalent thickness of lead (Pb), in mm;

22. a new x-ray apparatus means an x-ray apparatus put on the market following the entry of these Rules into force.

**Article 3**

(reporting the intention to carry out a practice involving radiation)

The application for the notification of the intention to carry out a practice involving radiation shall contain information showing the following:

- the purpose of the notification of intention;
- the name and address of the natural or legal person intending to carry out a practice involving radiation;
- the name and address of the authorised representative of the person carrying out radiation practice;
- information on the practice involving radiation;
- as a minimum, the following information on the used radioactive source: location where the source is used, location where the source is stored, and the characteristics of the source such as its type, activity, maximum voltage and current, etc.;
- information on the commencement and duration of the practice involving radiation, or information on the date of import, shipment from another Member State of the European Union (hereinafter referred to as: EU), procurement, reselling, disposal, export, shipment to another EU Member State, disposal or decommissioning or destruction of the radioactive source.

**Article 4**

(*contents of an application for authorisation of practice involving radiation*)

(1) The application for authorisation of practice involving radiation shall contain, as a minimum, the following information:

a) assessment of safety of exposed workers against radiation, approved by the ministry competent for health;

b) information on the radiation protection organisational unit or on the radiation protection officer;
   - the list of the workers of the radiation protection organisational unit;
   - the organisational chart of the organisation indicating the structural position of the radiation protection unit;
   - the decision on the appointment of the radiation protection officer;
   - documentary evidence of the education level and qualifications laid down by the regulation governing the obligations of the person carrying out a radiation practice and of the holder of a source of ionising radiation;

c) technical documentation of the type of the used radioactive source and on any source container showing, as a minimum, the following:
   - a sketch and description of the radioactive source, device or protective container, and the type of practice involving radiation supported by the radioactive source;
   - recommended service life of the radioactive source;
   - type of radioactive source (unsealed, sealed radioactive source, X-ray device, isotope type, other) and the type of radiation;
   - initial activity level and the date of the initial activity level of the radioactive source or, in the case of an X-ray device or an accelerator the maximum voltage and current or radiation energy;

d) information on the method of use of the radioactive source, showing, as a minimum:
   - source mobility (stationary, mobile, portable);
   - method of shielding against radiation during application and during storage;
   - duty cycle of the radioactive source (continuous 24 h, periodic etc.);
   - schedule of maintenance of the radioactive source or device containing a radioactive source, and the person authorised to carry out maintenance;

e) radiation protection measures related to the used type of radioactive source, showing, as a minimum:
   - the list of exposed workers including information on compliance with the requirements for education levels and qualifications and health fitness to work with radioactive sources or within areas of radiation;
- information on the participation of the exposed workers in the personal monitoring system in accordance with the assessment of safety of exposed workers;

f) approved physical protection plan for the radioactive source where laid down by regulations governing physical protection of nuclear materials, nuclear facilities and radiation facilities. In the case of high-activity sealed radioactive sealed sources and other radioactive sources requiring physical protection, also the description of physical protection measures, such as:
- appropriate protection during use and storage preventing misappropriation or other illegal handling;
- defence in depth or other deterrent measures to prevent unauthorised access to the radioactive source;
- controlled access to radioactive sources;
- timely detection of any unauthorised access to the radioactive source or its illegal misappropriation;
- regular verification of the radioactive source status in intervals specified by the radioactive source holder;
- information on workers that are granted access to the radioactive source and that must be informed of good protection practices;
- protection and surveillance during transport, stopovers, storage and use of portable and mobile radioactive sources.

(2) Information referred to in subparagraph e) of the previous paragraph may be provided as a part of the assessment of safety of exposed workers against radiation referred to in subparagraph a) of the previous paragraph.

(3) In the case of the applicant being unable to submit the technical documentation for an orphan source, the report on surveillance and measurement of the radioactive source referred to in Article 93 of these Rules shall be deemed to be the technical documentation.

(4) In the case of the applicant has not previously notified the intention to undertake a radiation practice, information referred to in Article 3 of these Rules shall be enclosed with the application for authorisation of radiation practice.

(5) In the case of a radiation practice in a radiation facility, documentary evidence of financial securities shall be enclosed with the application.

(6) In the case of a radiation practice in a nuclear facility, the application for authorisation of radiation practice shall include, in addition to information referred to in paragraph 1 of this article, information on radioactive sources and radiation practices not covered by the safety analysis report produced in accordance with the Act.

(7) In the case of use of a high-activity sealed radioactive source, the application shall also include documentary evidence of the holder’s financial security for safe handling of the radioactive source upon the termination of its use in the case of the holder’s insolvency or bankruptcy.

**Article 5**

*(content of an application for authorisation of use of a radioactive source)*

(1) The application for authorisation of use of a radioactive source shall contain, as a minimum, the following information:

a) the code and date of issue of the authorisation of practice involving radiation;
b) assessment of the safety of exposed workers against radiation, endorsed by the ministry competent for health;

c) technical documentation of the radioactive source and any source container, if this documentation differs from that enclosed with the application for authorisation of practice involving radiation, showing, as a minimum:
- a sketch of the radioactive source and device, including the presentation of the shielding during use and storage (e.g. source container, a sketch of the X-ray tube and its relevant equipment);
- type (unsealed, sealed radioactive source, isotope type, X-ray device etc.) and the description of the radioactive source and the type of practice involving radiation supported by the radioactive source;
- recommended service life of the radioactive source;
- foreseeable date of commencement and date of termination of the use of the radioactive source;
- initial activity level and the date of the initial activity level of the radioactive source or, in the case of an X-ray device or an accelerator, the maximum voltage and current or radiation energy;
- leakage test, if applicable, and the frequency of such tests if specifically indicated by the manufacturer of the sealed source;
- manufacturer of the radioactive source;
- number or designation of the radioactive source assigned by the manufacturer of the radioactive source;
- limitations and safety measures specified by the manufacturer;

d) information concerning the conditions of use and storage of the radioactive source;
- the location where the radioactive source is used and stored, including the town and street name and the designation of the facility or building. Where several radioactive sources are used within the same facility, the location of the particular source shall be indicated in detail;

e) the report on surveillance and measurement of the radioactive source referred to in Article 93 of these Rules;

f) radiation protection measures related to the use and maintenance of the radioactive source, showing, as a minimum:
- active and passive protection of the radioactive source during use;
- schedule of maintenance (services) of the radioactive source or device containing a radioactive source, the person authorised to carry out maintenance;
- written instruction for safe operation of the radioactive source, including the procedure for operation of the source (use, storage, records etc.) and instructions covering emergencies (analysis of potential emergencies, measures to be taken, list of agencies to be notified of the emergency). Written instructions shall be drawn up in the language understood by the workers;

g) foreseeable handling of the radioactive sources upon the termination of use, indicating whether the radioactive source is to:
- be dismantled by a qualified organisation (e.g. an X-ray tube);
- be exported or shipped out to any other EU member state;
- be handed over to the public service provider of the services of management of radioactive waste;
- following the termination of use, have an activity level below the clearance level;
be discharged into the environment (in such case, a description of discharges into the environment shall be provided);
- undergo some other procedure.

(2) Information referred to in subparagraphs f) and g) of the previous paragraph may be provided as a part of the assessment of safety of exposed workers referred to in subparagraph b) of the previous paragraph.

(3) Without prejudice to the provisions of paragraph 1 of this article, the information already provided by the applicant with the application for authorisation of practice involving radiation need not be provided with the application for authorisation of use of the radioactive source.

### Article 6
(Contents of the application for a certificate of entry into the register of radioactive sources)

(1) The application for a certificate of entry into the register of radioactive sources shall contain, as a minimum, the following information:
- the code and date of issue of the authorisation of practice involving radiation;
- technical documentation of the radioactive source and any source container or device, if this documentation differs from the one enclosed with the application for authorisation of practice involving radiation, showing, as a minimum: manufacturer, number or designation of the radioactive source assigned by the manufacturer of the radioactive source, isotope type, initial activity and the date of initial activity of the radioactive source or the maximum voltage and current or radiation energy for the X-ray device or accelerator;
- information concerning the maintenance of the radioactive source or the device and container;
- the report on surveillance and measurement of the radioactive source referred to in Article 93 of these Rules;
- radiation protection measures at the source itself (active and passive protection of the source);
- information concerning the date of commencement and foreseen duration of the use of the radioactive source;
- information on the location and premise in which the radioactive source is to be used and stored;
- description of the handling of the radioactive source following the termination of its use.

(2) Without prejudice to the provisions of the previous paragraph, the information already provided by the applicant with the application for authorisation of practice involving radiation need not be provided with the application for a certificate of entry into the register of radioactive sources.

### Article 7
(Termination of use of a radioactive source)

(1) The person carrying out a radiation practice who terminates the use of a radioactive source shall report this, within 15 days, to the ministry that issued the authorisation of use of the radioactive source.

(2) Where a radioactive material is involved, the person carrying out a practice involving radiation shall hand it over, within three months, to the public service provider of the services of management of radioactive waste or to another holder of authorisation of practice involving radiation, or return it to the manufacturer or supplier. The person carrying out a radiation practice shall, within 8 days of a transfer of a radioactive source, furnish the ministry that issued the
authorisation of use of the radioactive source, with a document of the transfer of the radioactive source that records the transfer of the radioactive source to another person.

(3) In the case of an X-ray device, the person carrying out a radiation practice shall hand it over, within six months, to the public service provider of the services of the management of hazardous waste or to another holder of authorisation of practice involving radiation, or return it to the manufacturer or supplier, or notify its intention to keep the X-ray device as spare to the competent ministry. The person carrying out a radiation practice shall, within 8 days of a transfer of a radioactive source, furnish the ministry that issued the authorisation of use of the radioactive source, with a document of the transfer of the radioactive source or the documentary evidence of its destruction.

(4) The holder of a radioactive source may transfer the source to another holder only provided that the other holder is duly authorised to carry out a practice involving radiation.

Article 8
(termination of a practice involving radiation)

Upon termination of a practice involving radiation, the person carrying out a radiation practice shall hand over any generated radioactive waste to the public service provider of the services of management of radioactive waste. In cases where unsealed radioactive sources are involved or in cases where the equipment and premises involved in the practice may have been contaminated, an authorised radiation protection expert shall carry out surveillance measurements and determine the level of contamination. The premises and equipment shall be decontaminated so as to bring their radioactivity into conformance with the limit values set out for surfaces in the human living and working environment not being a part of a supervised area.

Article 9
(record keeping)

(1) The person carrying out a radiation practice shall retain the following documentation and records of the following information:
- code, date of the notifying of intention to carry out a practice involving radiation, date of issue and date of validity of the authorisation of a practice involving radiation and respective authorisations of use of radioactive sources;
- number and properties of radioactive sources, protective containers or devices used;
- software relevant for the operation of the radioactive source and radiation protection;
- dates of the commencement of use of radioactive sources;
- location (address) where the radioactive source is installed, used or stored;
- in the case of unsealed radioactive sources: type, quantity and activity of radioactive isotopes at the time of supply and their quantities and activities consumed in the practice involving radiation and contamination of working environment or persons;
- date and details of radioactive source inspections carried out by an authorised radiation protection expert;
- interventions in the radioactive source, including its maintenance;
- reports and opinions by the authorised expert on the state of radiation protection;
- name and surname of the person responsible for radiation protection and the documentary evidence of its radiation protection training;
- exposed workers and the documentary evidence of their radiation protection training;
- medical examinations of workers working with radioactive sources.
(2) For high-activity sealed radioactive sources, the holder shall, in addition to the records referred to in the previous paragraph, keep records on:
- the type of radionuclide used;
- the type of the radioactive source;
- the certificate for material of a specific form;
- the physical and chemical properties of the high-activity sealed radioactive source;
- the date of manufacture or the date of the first placing of the high-activity sealed radioactive source on the market;
- the activity on the date of manufacture or on the date of the first placing of the high-activity sealed radioactive source on the market;
- information on the manufacturer or supplier of the high-activity sealed radioactive source (name, address, country);
- information on the date of acceptance of the high-activity sealed radioactive source and on the name, address and country of the legal or natural person from whom the source was accepted (manufacturer, supplier or other person);
- information on the date of transfer of the high-activity sealed radioactive source to another holder and on the name, address and country of the legal or natural person to whom the source was transferred (manufacturer, supplier, central storage of radioactive waste or other person);
- identification number of the high-activity sealed radioactive source;
- identification number of the capsule;
- date of loss, theft or finding of the high-activity sealed radioactive source, if applicable.

Article 10
(radiation hazard warning signs)

(1) The basic sign to warn of radiation hazards or radioactive materials shall be a trefoil radiation warning sign with ratios of elements to the central circle as shown in Appendix 1, which is a constituent part of these Rules.

(2) The radiation hazard warning sign shall be black on yellow background and is presented in Appendix 1 to these Rules.

(3) All radioactive sources shall be marked with the radiation hazard warning sign and an inscription “RADIOACTIVE”. The size of the letters shall equal the diameter of the central circle of the basic sign. In cases where the radioactive source is too small or cannot be marked as above for other reasons, it shall be fitted with a tag or label with dimensions allowed by the circumstances.

(4) In cases where the sign is applied to warn of hazards of radiation emitted by a device or increased levels of radiation can be expected within a certain area, the device or premise shall be marked, in a visible place, with the radiation hazard warning sign and the inscription “CAUTION - RADIATION”. The size of the letters shall equal the diameter of the central circle of the basic sign.

(5) The radiation hazard warning signs may not be applied for any other purposes than for the marking of radioactive materials or areas of increased radiation levels.

(6) The person carrying out a radiation practice shall ensure that the radiation hazard warning signs are properly affixed, visible and readable at all times.
II. MANAGEMENT OF RADIOACTIVE SOURCES

Article 11
(prohibition of use)

Use of a radioactive source not complying with the conditions set out in the authorisation of the practice involving radiation or authorisation of use of the radioactive source or not conforming to the technical documentation of the radioactive source is prohibited.

Article 12
(requirements for premises where radioactive sources are used)

(1) The use of radioactive sources is only allowed in special facilities or premises constructed and fitted so as to ensure dose rates at the external surfaces of the building or premises lower than the levels that may, in given circumstances and according to expert assessment, cause a level of exposure of a member of the public to radiation that leads to exceeding statutory dose limits for the public.

(2) Radioactive sources may also be used in the living environment provided that their use does not cause the statutory dose limits for the public to be exceeded.

Article 13
(storage of radioactive sources)

(1) Portable radioactive sources, when not in use, shall be stored in premises constructed and fitted so as to ensure dose rates at the external surfaces of the building or premise lower than the levels that may, in given circumstances and according to expert assessment, cause a level of exposure of a member of the public to radiation that leads to exceeding the statutory dose limits for the public.

(2) Radioactive materials shall not be stored together with other hazardous materials.

(3) The location and construction of the storage shall minimise the risk of fire or flood.

(4) Where, during storage of radioactive materials, radioactive gases, vapours or aerosols are released, the storage shall be fitted with appropriate ventilation.

(5) Radioactive materials shall be stored, moved or transported within the premises of the holder of authorisation of practice involving radiation in protective containers or vessels that prevent any release of radioactive materials into the environment and ensure that the doses sustained by the persons involved in the movement or transport of radioactive materials do not exceed statutory dose limits.

(6) Protective containers and vessels used for the storage of radioactive materials shall be designed so as to allow easy opening and closing. The manufacturer of vessels shall provide special safety measures for the opening of vessels containing highly volatile or inflammable radioactive materials. Vessels containing radioactive liquids shall be kept in metal or plastic containers the volume of which shall be large enough to accommodate all the liquid in the event of the failure of the vessel.

(7) Each protective container or vessel used to store radioactive materials shall be fitted with a mark and readable inscription clearly indicating the type of radioactive sources, their activity, the date of initial activity or date of disposal into storage upon termination of use of the radioactive material.
Article 14
(instruction for safe operation of the radioactive source and instructions covering emergencies)

(1) The holder of authorisation of use of a radioactive source shall keep written instructions for safe operation of the radioactive source and instructions covering emergencies in accordance with the assessment of safety of exposed workers against radiation. The written instructions shall be drawn up in the language understood by the workers and shall contain the description of the work flow and protection measures for the workers involved in the work with the radioactive source. The instructions must be available at the working place. The workers must adhere to these instructions.

(2) Where a mobile or stationary high-activity sealed radioactive source is involved, the written instructions shall also cover the measures to prevent unauthorised access to the radioactive source and measures in the event of loss, theft or damage in a fire.

(3) The written instructions referred to in paragraphs 1 and 2 of this article shall list agencies or services to be notified or consulted in emergencies.

(4) The written instructions referred to in paragraphs 1 and 2 of this article shall be regularly reviewed and adjusted as necessary to the actual circumstances and good practice in safe use of radioactive sources.

Article 15
(dose rates close to devices containing sealed radioactive sources)

(1) Dose rates of non-useful radiation at the external surfaces of stationary devices containing sealed radioactive sources shall not exceed 1 mGy/h, and, at a distance of 1 m, 30 µGy/h.

(2) When a device containing a sealed radioactive source is moved, the dose rate at its surface shall not exceed 0.5 mGy/h, and, at a distance of 1 m, 15 µGy/h. Appropriate measures shall be taken to prevent the dose rates at accessible locations close to a radioactive source from exceeding the statutory dose limit.

Article 16
(warning and marking)

(1) Devices containing radioactive sources shall be fitted with signs referred to in Article 10 of these Rules to warn of radiation hazards.

(2) When a device containing a sealed radioactive source or an X-ray device is in operation, acoustic or visual alarming devices shall be applied to warn against radiation hazards, where required.

(3) Close to a radioactive source, relevant information on the radioactive source shall be displayed at visible locations, and as a minimum, information on the type and activity of the isotope or the maximum voltage and current, the name, surname and telephone number of the person responsible for radiation protection and the code, date of issue and date of validity of the authorisation of use of the radioactive source.

(4) The manufacturer shall mark each high-activity sealed radioactive source with a unique marking. For unmarked imported high-activity sealed radioactive sources, such marking shall be provided by the supplier. Such marking may be engraved or stamped on the radioactive source, as well as on the container of a high-activity sealed radioactive source. Where such marking is not
practicable, and in the case of reusable transport containers, the radioactive source container shall at least be provided with information on the characteristics of the radioactive source.

(5) The manufacturer shall provide a photograph of each high-activity sealed radioactive source design type and of typical containers for high-activity sealed radioactive sources.

(6) The holder of authorisation of use of a high-activity sealed radioactive source shall ensure that each high-activity sealed radioactive source is accompanied by written documentation showing that the radioactive source is marked in accordance with paragraphs 4 and 5 of this article and that the markings and labels remain readable. The documentation shall include photographs of the radioactive source, radioactive source container, transport packaging or device or equipment.

Article 17
(exposure reduction measures)

(1) Where devices containing sealed radioactive sources or X-ray devices are used outside dedicated premises, their useful radiation beam shall be directed towards the object examined by exposure, and access to the beam prevented.

(2) If the device containing a sealed radioactive source is fitted with protective shutters, these shall be shut and the device locked when not in use.

(3) The sealed radioactive source may only be set into operating position by means of a remote control device. The useful radiation beam shall be directed as accurately as possible.

(4) A device containing a sealed radioactive source or an X-ray device shall be fitted with a switch allowing immediate interruption of the useful beam at any time. Where such arrangement is impracticable, the devices may, except in the case of field industrial radiography, be used in a premise that can only be entered through a protection door or a labyrinth. The premise door shall be fitted with a mechanism that interrupts the useful radiation beam on any attempt of entry.

(5) The holder of authorisation of use of a high-activity sealed radioactive source shall, in the scope of informing and regular training of exposed workers, specifically emphasise the requirements of radioactive source safety and security and inform the workers of possible threats arising from a loss of control over such radioactive sources. The workers shall be alerted of such events and prepared appropriately.

Article 18
(leakage testing of sealed radioactive sources)

(1) With sealed radioactive sources, leakage tests shall be carried out if damage of the radioactive source is suspected, and otherwise, in time intervals laid down in Article 93 of these Rules in conjunction with paragraph 1 of Article 35 of these Rules, or in intervals specified in the technical documentation of the radioactive source. The test shall be carried out on accessible surfaces of the protective container in accordance with applicable international standards.

(2) If the activity on the smear is lower than 200 Bq, the radioactive source shall be considered adequately sealed. If the activity exceeds 200 Bq, any further use of the radioactive source shall be suspended, measures shall be taken to mitigate potential contamination and procedures to replace the radioactive source undertaken.
**Article 19**  
*prohibition of use of damaged or faulty radioactive sources*

Use of sealed radioactive sources or their containers is prohibited, if they are mechanically damaged or suspected to leak or be faulty in any way. Sealed radioactive sources and their containers may only be repaired by organisations qualified for such repairs.

**Article 20**  
*loss of a radioactive source and emergency involving a radioactive source*

1. The holder of a radioactive source shall immediately notify the competent ministry that issued the authorisation of any loss, theft or unauthorised use of the radioactive source or of any emergency such as fire.

2. Following an event referred to in the previous paragraph, the holder of a radioactive source shall verify the integrity of the radioactive source and undertake corrective measures as necessary and report such measures to the competent ministry that issued the authorisation.

3. The holder of a radioactive source shall immediately notify the competent ministry that issued the authorisation, of any event or accident involving the radioactive source and resulting in an inadvertent exposure of a worker or a member of the public to radiation.

**Article 21**  
*orphan sources*

1. The management and workers of facilities where the presence or emergence of orphan sources is high (e.g. large depots for scrap metals or scrap metal reprocessing plants) and the management and workers of major transit hubs (e.g. customs warehouses), shall receive assistance from the competent ministries in the form of information on the possible ways of coming into contact with the radioactive sources, advice and assistance in training personnel to detect radioactive sources and their containers, information on the fundamentals of ionising radiation and its effects, and information and assistance in training for measures to be taken upon detection or suspected detection of a radioactive source.

2. The ministry responsible for the environment shall provide immediate technical advice and assistance to persons not normally involved in practices requiring radiation protection in cases of suspected encountering of an orphan source.

**Article 22**  
*international cooperation*

The competent ministry shall immediately exchange information and cooperate with EU Member States or third countries or relevant international organisations in any event of loss, misappropriation, theft or discovery of a high-activity sealed radioactive source and in the follow-up activities or investigations, in compliance with the regulations governing data confidentiality.

**Article 23**  
*ionising smoke detectors*

1. The dose rate at a distance 10 cm from any external surface of an ionising smoke detector may not exceed 1 µGy/h.
(2) An ionising smoke detector shall be designed so that its radioactive source is not easily accessible, i.e., its housing shall not be designed for opening by simple means and reaching into the area of the radioactive source by hand.

(3) Ionising smoke detectors may not use a radioactive source generating gaseous daughter products.

(4) Any cleaning or maintenance of ionising smoke detectors which requires intervention into the radioactive source may only be carried out by qualified persons authorised for practices involving radiation by the competent ministry.

**Article 24**
(radioactive luminescent paints)

(1) The only isotopes allowed in radioactive luminescent paints are $^3\text{H}$ and $^{147}\text{Pm}$, provided that they are bonded chemically or otherwise so as to be insoluble or poorly soluble.

(2) The total activity of a radioactive luminescent paint applied on a clock face or instrument dial may not exceed exemption limits.

(3) Radioactive luminescent paints shall be provided with a protective coating to prevent their removal owing to vibrations or temperature variations in normal use.

(4) A clock or other instrument with radioactive luminescent paints applied shall be kept in a box with a transparent cover. The box and the cover shall be resistant to vibrations and shocks under conditions of normal use or minor accidents.

(5) Special clocks and other instruments shall be provided with radioactivity signs on their faces, to warn the user or the person repairing it of the presence of radionuclides.

**Article 25**
(radioactive lightning rods)

Use of radioactive lightning rods is prohibited.

**Article 26**
(luggage, mail and other object inspection X-ray devices)

Luggage, mail and other object inspection X-ray devices shall be provided with protective covers ensuring that the dose rate at their surface does not exceed the levels that may cause exposure of a member of the public to radiation exceeding the statutory dose limits for the public.
III. UNSEALED RADIOACTIVE SOURCES

III.1. CLASS III PREMISES

Article 27
(premises)

(1) floors and working surfaces in premises in which unsealed radioactive sources are used shall be made of materials impermeable to moisture and resistant to common chemicals (e.g. diluted acids or alkali, organic solvents).

(2) Walls, ceilings and floors shall have smooth surfaces and shall be made of materials that are easy to clean.

(3) Working surfaces shall be made of materials that do not adsorb dust and are easy to clean.

(4) Water taps shall allow elbow operation (elbow operated sets).

(5) Ventilation shall be arranged so as to prevent air from premises where unsealed radioactive sources are used circulating or entering other premises. In cases where unsealed radioactive sources of different activities are used in different premises, ventilation shall be arranged so as to provide air circulation from premises with lower activity levels to premises with higher activity levels.

(6) Where, owing to the nature of the work and characteristics of the radioactive substances, radioactive substances may be released into the atmosphere, the preparation of radioactive substances shall take place in fume cupboards or special ventilated chambers.

Article 28
(contamination)

(1) In the event of radioactive contamination, the workers present shall assess the level of contamination with radioactive substances.

(2) Prior to the commencement of work, working surfaces shall be covered with an absorbent lining to prevent spreading of contamination.

III.2. CLASS II PREMISES

Article 29
(premises)

In addition to the requirements applying to class III premises of the previous subsection, a class II premises shall fulfill the following requirements:

- class II premises shall be located in a separate section of the building so as to be separated from other premises;
- they shall be equipped with a control point with a sanitary node;
- the control point shall provide adequate room for changing into protective clothing and personal contamination measurement;
- the floor shall be lined or painted free of cracks and the lining shall reach to a height of at least 10 cm up the wall;
- the installations shall penetrate the walls so as to allow no spreading of radiation into adjacent premises;
- ventilation shall maintain negative pressure in the premises where radioactive substances are handled. Nuclear medicine premises, where patients are treated, are exempt from this requirement. Ventilation shall be provided with a separate exhaust, normally through filters;
- fume cupboards or special chambers for radioactive substance preparation shall be equipped with light indication of ventilation in operation.

**Article 30**

(_radiation monitors_)  

(1) Each premise shall be equipped with a contamination monitor and a radiation dose rate monitor and the personnel shall be qualified to operate these monitors.

(2) Contamination and radiation dose rate measurements shall be carried out in regular intervals and whenever contamination is suspected.

(3) To select the monitors and determine the intervals of measurements, the holder of authorisation shall consult with an authorised expert, who shall issue a written recommendation.

**III.3. CLASS I PREMISES**

**Article 31**

(_premises_)  

In addition to the requirements applying to class III and class II premises of subsections III.1. and III.2., class I premises shall fulfill the following requirements:
- class I premises shall be located in a separate building or in a building section with a separate entrance and a control point;
- class I premise shall be divided into zones, according to the radioactive substance activities and types of work;
- to prevent the risk of spreading of radioactive contamination from higher to lower activity level zones, control point shall be fitted between zones.

**IV. SPECIAL REQUIREMENTS FOR SPECIFIC PRACTICES**

**IV.1. INDUSTRIAL RADIOGRAPHY**

**Article 32**

(_radiation monitors and measurements_)  

(1) Persons carrying out industrial radiography shall have an appropriate dose rate monitor and personnel qualified to operate it. Prior to any material testing, the monitor shall be checked for proper performance.
(2) Following the testing, the person carrying out industrial radiography shall switch off the device and check, by means of the radiation monitor, for the absence of the useful radiation beam.

Article 33
(personal dosimeters)

Workers involved in industrial radiography shall, in addition to personal dosimeters, also carry electronic dosimeters with an acoustic alarm to warn of exceeded dose rate operating limits.

Article 34
(X-ray device)

(1) The housing of an X-ray device applied in industrial radiography shall prevent the housing leaking (dose rate) at any point at a distance of 1 m from the tube from exceeding the levels set out in Table 1 of Annex 2, which is a constituent part of these Rules.

(2) The total filtration of the useful radiation beam shall correspond to equivalent thicknesses set out in Table 2 of Annex 2 of these Rules.

(3) During the warming up of the X-ray device, the shutters shall be shut and their protective capacity shall prevent any exceeding of levels referred to in the previous paragraph of this article.

(4) The X-ray device control panel shall clearly indicate when the device is on and ready for exposition. In addition, an independent indication shall be provided to warn of the device operation.

(5) The X-ray device control panel shall be equipped with an emergency stop button.

(6) If the X-ray device is fitted with protective shutters, these shall be shut and the device locked when not in use.

(7) X-ray devices shall be inspected, in regular intervals and in accordance with Article 93 of these Rules, by an authorised radiation protection expert. In the scope of inspection, dose rates shall be measured and data obtained to allow the assessment of the doses sustained by workers and the active and passive protection performance verified.

Article 35
(devices containing radioactive sources)

Devices containing radioactive sources shall be inspected, in regular intervals and in accordance with Article 93 of these Rules, by an authorised radiation protection expert. In addition to parameters allowing the assessment of sustained doses, the following shall be checked, as a minimum:

- the cable is not corroded or damaged;
- the cable shows no signs of looping or knots;
- the contact between the cable and the radioactive source base is not damaged;
- the markings of the protective container;
- the protective container is not damaged;
- the connection to the cable is clean and not damaged;
- the shutters are in perfect operating order;
- the leakage of the sealed radioactive source;
- warning lamps;
- radiation monitors.

**Article 36**

*(premise)*

(1) Stationary X-ray devices for industrial radiography application shall be arranged so as to have the X-ray tube and the material testing table in one premise and the control panel and other parts of the device in a separate room.

(2) The doors of the premises where industrial radiography applying a stationary X-ray device is carried out shall be fitted with interlock switches to block the device operation with the doors open or to interrupt the device operation in the event of the opening of the door during testing.

(3) In front of the entrances to such premises, light indicators shall be installed to warn of radiation risks during material testing.

**Article 37**

*(number of personnel required to carry out activities)*

Any exposure outside specially designated premises shall be carried out by at least two properly trained and experienced persons.

**Article 38**

*(enclosure and supervision of the area)*

(1) Prior to an industrial radiography operation outside special designated premises, the area where the testing is to take place shall be enclosed and marked in such a way that the dose rate at the enclosure boundary does not exceed an average level of 3 µSv/h over eight hours or a maximum level of 60 µSv/h.

(2) Workers involved in the industrial radiography shall supervise the enclosed area and prevent entry by other persons during the entire material testing operation.

(3) Any persons present in the vicinity of the area where the industrial radiography operations take place shall be informed of appropriate radiation protection measures prior to the commencement of operations.

**Article 39**

*(industrial radiography with devices containing radioactive source)*

In cases where industrial radiography is carried out applying a device containing a radioactive source, the retirement of the source into its shielded position shall be checked by means of a radiation monitor upon the completion of the testing.

**Article 40**

*(protective container)*

(1) A protective container used to transport an industrial radiography radioactive source shall fulfill the requirements for a transport container pursuant to the European Agreement concerning the

(2) The protective container shall be fitted with a radiation hazard warning sign referred to in Article 10 of these Rules. In addition, the type of radionuclide, initial activity and the date of initial activity shall be indicated appropriately.

(3) The dose rate at the surface of the protective container shall not exceed 2 mGy/h, and at a distance of 1 m from the protective container, 0.02 mGy/h.

Article 41
(industrial radiography applying an X-ray device or other electrical device generating ionising radiation)

Where industrial radiography applying an X-ray device or other electrical device generating ionising radiation is carried out in the field, the following requirements shall be fulfilled:
- the X-ray device shall be fitted with warning lamps to warn of radiation during operation of the device;
- the radiation beam emitted by the radioactive source shall be narrow and directed and, wherever practicable, a shield shall be installed behind the image receiver;
- the length of the cable connecting the control panel and the X-ray device shall limit the dose rates at the control panel to levels below the limits referred to in Article 38 of these Rules.

IV.2. RADIOTHERAPY

IV. 2.1 General Requirements

Article 42
(radiotherapy devices)

Radiotherapy devices include particle accelerators, X-ray devices for therapy, gamma tele-radiotherapy devices, simulators, other devices for exposure applications with radioactive sources outside the patient’s body, and devices for exposure applications with radioactive sources inside the patient’s body.

Article 43
(premise)

(1) The premise in which exposure is carried out shall be a controlled area.

(2) Wherever practicable, only one exposure device shall be located in an exposure premise. Where two exposure devices are located in a common premise, their simultaneous operation shall be prevented by appropriate technical measures.

(3) The control panel shall be located outside the therapy premise. In the case of surface therapy applying energies of less than 50 keV, the control panel may be located in the therapy premise, provided that the operator is appropriately protected by means of shielding partitions.
The installations shall penetrate the walls so as to allow no propagation of radiation, exceeding the statutory limits, into adjacent premises.

The electrically powered entrance door of an exposure premise shall also allow mechanical opening in the event of an emergency. The mechanism shall be regularly checked and the personnel shall be qualified to operate it.

The doors of the premises where exposure is carried out shall be fitted with interlock switches to block operation with the doors open or to interrupt operation in the event of the opening of the door during exposure. In the case of a gamma tele-radiotherapy device, such opening shall also trigger the withdrawal of the source into its shielded position.

The operator shall be provided with means to observe the exposure premise and its entrance either directly or with a video surveillance system.

The control room and the exposure premise shall be interconnected through an interphone link.

At the entrance of the exposure premise, lights shall be installed to unambiguously indicate exposure in progress or system ready state.

In the exposure premise, acoustic or light indicators shall be installed to warn of exposure in progress.

At the control panel, indicators shall be installed to unambiguously warn of exposure in progress.

The function tests of warning devices shall be carried out every day, prior to commencement of exposure. If any indicator fails to function correctly, the work may not start until the fault is remedied.

**Article 44**

(emergency stop)

(1) Emergency stop buttons shall be installed on the control panel, next to the entrance to the exposure premise and inside the exposure premise.

(2) In the exposure premise, the switches shall be installed within reach of a person that may be present in the premise inadvertently at the start of exposure. The switch shall be installed so that such a person does not need to cross the useful beam to operate the switch.

**Article 45**

(radiation monitors)

(1) The premise in which exposure with radioactive sources takes place shall be equipped with a radiation monitor or indicator, independent of the exposure device, to continuously measure the dose rate in the premise. The radiation monitor shall be connected to a warning device, which shall be installed so as to warn the worker, before his/her entry into the premise, of the source displacement from the shielded position. Monitor functional tests shall be carried out at least once a week.

(2) Where radioactive sources are applied for exposure, a portable radiation monitor shall be available outside the exposure premise, to allow determination of the source position in case the source fails to withdraw into its shielded position upon the completion of exposure.
Article 46
(safe operation)

(1) A radiotherapy device shall be designed so as to allow exposure to be started only from the
control panel. The control panel shall clearly indicate the selected exposure mode.

(2) A tele-radiotherapy control panel shall be fitted with an exposure dose indicator. The measurement
range of the indicator shall be from 0 up.

(3) The exposure monitoring equipment shall include at least two independent exposure dose
monitoring systems. In the event of power loss, at least one of them shall allow a determination of
the dose already sustained.

Article 47
(installation of radiotherapy equipment)

(1) Prior to putting radiotherapy equipment into service, acceptance tests shall be carried out for all
the parameters important for the device’s safe and reliable operation.

(2) An authorised medical physics expert shall be responsible for the equipment acceptance and
execution of acceptance tests.

(3) Prior to routine operation, all the possible combinations and modes of exposure shall be verified.
In cases where any of the exposure modes are not verified, its application is not allowed.

(4) All the exposure operators shall be informed of any modifications of the device or new exposure
modes.

Article 48
(dosimetric calibration of radiotherapy devices)

(1) Prior to clinical application of radiotherapy devices, an authorised medical physics expert shall
carry out their dosimetric calibration for all the radiation types and energies generated by the
device or to be clinically applied, and the calibration shall be verified by another independent
medical physics expert.

(2) The dosimetric calibration shall be carried out pursuant to written procedures in accordance with
international protocols or protocols approved by the competent ministry.

(3) The dosimetric calibration shall be verified by the authorised medical physics expert in regular
intervals laid down in the quality assurance programme, at least once a week in the case of particle
accelerators and once a month in the case of gamma tele-radiotherapy devices.

(4) Following any major intervention in radiotherapy devices that may change the exposure
conditions, the device shall be recalibrated prior to resuming its clinical application.

(5) The measurement equipment applied in dosimetric calibration of exposure devices shall be
traceable to the primary standards. It shall be verified at least once a year within the measurement
range used in normal application.

(6) Records shall be kept of the measurement equipment, providing the following information:
   - type and sort of equipment;
- equipment manufacturer;
- equipment model;
- equipment serial number or other identification;
- year of manufacture;
- date of calibration.

Article 49
(maintenance and servicing of radiotherapy equipment)

(1) When under servicing, the radiotherapy equipment control panel shall be marked with stickers or other suitable indications that servicing is in progress.

(2) Any service intervention that may affect exposure conditions or source protection shall be notified to the personnel responsible for the technical performance of the equipment. Upon an intervention, clinical application may not resume until appropriate tests have been carried out. Notification and testing of equipment following servicing shall be regulated by written procedures.

Article 50
(insertion or replacement of the radioactive source)

(1) Insertion or replacement of the radioactive source in an exposure device shall be regulated by written procedures. The responsible radiation protection officer shall be present in the replacement of the source.

(2) Where the source replacement is not covered by the approved assessment of safety of exposed workers against radiation, an approved assessment of safety of exposed workers covering the source replacement shall be obtained.

(3) The source replacement shall be carried out by at least two properly trained and experienced persons. The premise in which the replacement is taking place may only be entered by the workers involved in the replacement and by the responsible radiation protection officer.

(4) The protective container designated for the spent source shall be placed as close to the exposure head as possible, to keep the spent source in its shielded position during transfer.

(5) The personnel involved in the source replacement shall, in addition to personal dosimeters, also carry electronic alarm dosimeters with acoustic warning of increased dose rate.

Article 51
(entry into the premise in which exposure is in progress)

(1) In the exposure premise, as a rule only the patient may be present while exposure is in progress. Where medical reasons justify the presence of another person, this shall be subject to consultation with the authorised medical physics expert, who shall determine appropriate radiation protection measures.

(2) The personnel entering the exposure premise shall, in the case the premise is not equipped with a monitor with acoustic warning of increased radiation level in the premise, in addition to personal dosimeters, also carry electronic alarm dosimeters with acoustic warning of increased dose rate.
Article 52
(reporting of faults)

The operators shall report to the responsible officers any fault that may compromise the safety of the patient or personnel or affect the accuracy of exposure. Prior to resuming clinical application, the reasons of the fault shall be investigated and remedied.

Article 53
(emergency procedures)

In relation to the emergency procedures referred to in Article 14 of these Rules, regular practical drills shall be carried out in accordance with the assessment of safety of exposed workers. Equipment necessary for such procedures shall be kept accessible near the entrance to the exposure premise. The personnel shall be trained to handle such equipment.

IV. 2.2 Brachyradiotherapy

Article 54
(verification of the source activity)

(1) Prior to each exposure of a patient, the source activity shall be measured and its conformance with the value declared by the source manufacturer verified, taking into account radioactive decay. In cases of long-lived isotopes, the frequency of verification may be reduced.

(2) Following exposure, radiation monitors shall be applied to verify that the radioactive source has not remained in the patient’s body.

Article 55
(movable shields)

Where movable shields are applied for radiation protection, their proper position shall be clearly marked on the floor and described in the relevant procedures. Shield integrity shall be checked regularly.

Article 56
(sterilisation, disinfection, cleaning)

(1) In sterilising or disinfecting radioactive sources, the following shall be ensured:
   - the temperature shall not exceed 180° C;
   - damaged sources may not be sterilised or disinfected;
   - only such disinfection agents may be applied that do not damage identification marks on the sources.

(2) Upon completion of sterilisation, disinfection or cleaning, the operator shall verify the source identification marks.
Article 57
(protection of personnel and visitors)

(1) At each exposure, the maximum dose rate at a distance of 1 m from the patient shall be measured and recorded and the findings shall be subject to consultation with the authorised medical physics expert, who shall determine appropriate radiation protection measures.

(2) When entering premises where exposure is in progress, the personnel and visitors shall observe written procedures approved by the authorised medical physics expert.

(3) As a rule, patients with radioactive sources in or on the body may not leave the exposure premise, unless allowed by the medical personnel responsible for the therapy in agreement with the authorised medical physics expert. Any exit and reentry of a patient from/into the exposure premise shall be recorded in writing.

Article 58
(exposure premise)

(1) Wherever practicable, exposure shall take place in premises with one or a maximum of two patient beds separated by an appropriate shield.

(2) Premises and beds in which patients are exposed shall be marked with radiation hazard signs and inscriptions. Patient tending personnel shall be informed, in writing, of the time of the commencement of exposure, duration of exposure, applied isotope and its activity, and the dose rate at a distance of 1 m from the patient. Accuracy of data is the responsibility of the authorised medical physics expert.

IV. 2.3 Nuclear medicine

Article 59
(scope of application of this subsection)

The provisions of this subsection shall apply to:
- unsealed sources applied to patients or used in research in the field of diagnostic techniques;
- unsealed sources used in “in vitro” medical examinations, and
- unsealed or sealed sources used to verify or calibrate equipment referred to in subparagraphs one and two of this article.

Article 60
(waiting for a radiological procedure)

(1) Patients waiting for examinations or therapy involving radionuclides shall be considered members of the public as regards exposure.

(2) Nuclear medicine wards shall be provided with waiting areas for patients with isotopes applied separate from waiting areas for patients waiting for application, and with separate sanitary facilities for patients with isotopes applied.
Article 61  
*(general conditions for discharge from a hospital)*

(1) A patient may only be discharged from a hospital provided that the following conditions are met:
   - any member of the public does not unknowingly sustain an effective dose exceeding 0.3 mSv;
   - members of the household that willingly participate in the care of the patient following discharge, except pregnant or breast-feeding women, sustain an effective dose less than 5 mSv;
   - other members of the household sustain an effective dose less than 1 mSv.

(2) The method of determination of doses sustained by exposed individuals referred to in the previous paragraph shall be assessed by an authorised radiation protection expert.

(3) Prior to discharge from a hospital, a patient with a radionuclide applied shall receive written instructions, radiation hazard warnings and instructions on radiation protection procedures to be followed to minimise the risks of undue external exposure or contamination of other individuals.

Article 62  
*(discharge from hospital following therapy)*

(1) A patient having received a therapeutic dose of $^{131}$I may leave a hospital only when the isotope activity decreases to a level below 800 MBq.

(2) Prior to discharge, the patient shall receive additional mandatory instructions in accordance with Table 1 in Annex 3, which forms a constituent part of these Rules.

(3) In cases of therapy with beta radioactive sources $^{32}$P, $^{90}$Y, $^{186}$Re, $^{153}$Sm or $^{89}$Sr and applied activities not exceeding 200 MBq, the patient discharge from the hospital is not subject to any restrictive measures.

(4) Autopsy or cremation of deceased persons having received radionuclides for therapy purposes shall be carried out in accordance with radiation protection instructions kept by the person carrying out a radiation practice in writing.

(5) No special radiation protection measures are required in cases where activities are below the levels set out in Table 2 in Annex 3 to these Rules.

IV. 2.4 Precautionary measures applying to therapy with unsealed sources

Article 63  
*(patient rooms)*

(1) A patient having received an $^{131}$I activity exceeding 1100 MBq shall be stationed in a single-bed room with sanitation facilities inside the room.

(2) Hospitalised patients having received $^{131}$I therapy with an activity of 1100 MBq or less may share a room provided that each such patient is protected against receiving a dose exceeding the statutory limit level for the members of the public due to the presence of other patients in the room.
(3) Patients referred to in paragraphs 1 and 2 of this article may not leave their patient rooms unless approved by the medical personnel responsible for the therapy. Any exit and reentry of a patient from/into the exposure room shall be recorded in writing.

(4) In front of the entrance in the room, a control point shall be provided where the nursing personnel changes clothes.

Article 64
(protection of personnel and public)

(1) In the event of the deterioration of the patient’s health condition and the need for intensive care, the personnel shall, as regards the duration of stay in the patient’s proximity, observe written instructions produced in advance in collaboration with an authorised radiation protection expert.

(2) Prior to a surgical operation on a patient having received a therapeutic dose of a radionuclide, the activity still present in the patient’s body shall be determined. Appropriate radiation protection measures shall be determined in collaboration with the person responsible for radiation protection.

Article 65
(discharge from hospital)

(1) Prior to discharging a patient from hospital, the patient’s clothing and personal belongings shall be checked for contamination and either decontaminated or withheld if necessary.

(2) Following the discharge of a patient from hospital, the contamination of the room in which he/she was staying shall be measured and the room decontaminated if necessary.

IV.3. X-RAY DIAGNOSTICS IN MEDICINE

IV. 3.1 X-ray diagnostics and intervention radiology

Article 66
(X-ray diagnostics and intervention radiology devices)

X-ray diagnostics and intervention radiology devices include stationary and mobile X-ray devices for radiography or fluoroscopy, except X-ray devices for dental diagnostics, combined X-ray devices (X-ray devices allowing both radiography and fluoroscopy), computer tomography devices and other devices for diagnostics and procedures in health care involving the use of X-ray radiation.

Article 67
(premises)

(1) As a rule, diagnostic radiology procedures shall be carried out in special premises designated and adapted for such procedures (diagnostic premises). Procedures during surgical operations, and procedures on immobile patients on hospital beds where mobile X-ray devices are applied, are exempt from this rule.

(2) Only one radiology procedure may take place at any time in a premise, except if the premise is specially adapted for performing more than one procedure simultaneously. In such case, the absorbed dose rates owing to another procedure in the premise shall be below the levels that may
cause a level of radiation exposure that causes an exceeding of the statutory dose limits for the members of the public.

(3) Entrances to diagnostic premises shall be fitted with signs warning of the procedure in progress or radiation during a procedure. Those entrances (doors) not under direct surveillance by the device operator, shall be designed to prevent entry into the diagnostic premise during a procedure.

(4) The X-ray device control panel shall be located so as to enable the operator to see the patient throughout the procedure. Where direct visual surveillance of the patient is impracticable, video link shall be provided between the control room and the diagnostic premise. Where the control panel is located in a separate room, an interphone link shall be provided between the control room and the diagnostic premise.

**Article 68**
**(personal protective equipment)**

(1) Personal protective equipment shall be used by all the individuals present in controlled areas during a radiology procedure. The type of necessary protective equipment, its protective capabilities and use shall be determined, for each type of procedure, in agreement with the authorised radiation protection expert and shall be covered by written procedures for each type of radiological procedure.

(2) All personal protective equipment shall be marked with data on its protective capability (equivalent lead thickness).

**Article 69**
**(protective equipment for patients)**

(1) The type of protective equipment used, its protective capabilities and use shall be determined, for each type of procedure, by an authorised medical physics expert and shall be covered by written procedures for each type of procedure.

(2) Protective equipment for patients shall be marked with the data on its protective capability (equivalent lead thickness).

**Article 70**
**(X-ray tube housing)**

(1) The housing containing an X-ray tube (including the shutters confining the useful beam of the device) shall be designed to limit the air absorbed dose in air owing to housing leakage, at a distance of 1 m from the focus and under the maximum tube load, to 1 mGy per 1 hour. The X-ray device or X-ray tube housing manufacturer shall provide data on the exposition conditions at which the dose rate was measured.

(2) On the X-ray tube housing or in some other suitable location on the device, a readable indication of the type and number of the X-ray tube and of the size of focuses shall be provided.

(3) With the exception of computer tomography devices and bone density measuring X-ray devices, the indication of the focus location shall be provided on the housing containing the X-ray tube.
Article 71
(useful beam filtration)

(1) X-ray radiation applied in diagnostic and intervention radiological procedures shall be filtered. The total filtration comprises a permanent integral filter that cannot be removed without tools, additional filters and other equipment installed into the useful beam.

(2) All the filters shall be marked on the X-ray device in the manner allowing the determination of the total filtration of the useful beam.

(3) The thickness of the permanent integral filter shall be marked in a readable manner on the X-ray tube housing, and, where the tube housing is not accessible, also on the external accessible surfaces of the device.

(4) Additional filters shall be indicated with the chemical symbol of their constituent material and their thickness in mm or equivalent Al thickness in mm. Where the filter is not made of aluminum and its thickness is expressed as equivalent Al thickness, the indication of the radiation energy at which the equivalent thickness was determined shall be provided.

(5) For a device allowing change of filtration in an application where the radiographic technique does not exploit such an option, any change of filtration shall be blocked.

(6) The total equivalent filtration of an X-ray beam applied in diagnostics (except in mammography) shall be 2.5 mm Al as a minimum, of which the equivalent thickness of the permanent integral filter shall be 1.5 mm Al as a minimum.

(7) The total equivalent thickness of the permanent integral filter of an X-ray device applied in mammography shall be 0.5 mm Al as a minimum.

Article 72
(determination of the useful radiation field)

(1) X-ray devices shall be equipped with a system of shutters to confine the useful radiation field. The shutters shall be designed to minimise the radiation field outside the useful beam.

(2) The maximum field allowed by the system of shutters shall coincide with the dimensions of the largest imaging detector positioned at the smallest distance applied in the clinical practice.

(3) The system of shutters of a radiography X-ray device shall be equipped with a light indicator of the useful radiation field. At any edge, the deviation of the light indication from the radiation field may not exceed 2% of the distance between the focus and the imaging detector. With X-ray devices applied for radiography of children, this deviation may not exceed 1%.

(4) X-ray devices applied for fluoroscopy shall be designed so that the useful radiation beam is directed towards the imaging detector at all times. The system of shutters shall automatically adjust the size of the useful field to the distance between the focus and the imaging detector and to the size of the selected imaging detector. The system of shutters shall allow a reduction of the radiation field to a size equivalent to 5 cm x 5 cm at a distance of 1 m from the focus.

(5) With X-ray devices for computer tomography, the width of the slice at the imaging detector shall coincide with the set slice width.
Article 73
(active protection)

(1) The X-ray device control panel shall clearly indicate when the device is on and ready for exposition.

(2) Where several X-ray tubes can be activated from a single control post, clear indication of which tube is selected and ready for exposition shall be provided on the control panel.

(3) All the exposition activation switches shall be clearly marked.

(4) With stationary X-ray devices, the switches shall be installed at the device operator control post. With mobile devices, the switch shall be installed so as to allow the operator to move away from the immediate vicinity of the useful beam, to a distance of at least 2 m from the patient and the X-ray tube housing.

(5) Switches shall be designed and installed so as to prevent inadvertent activation of the device. Switches designed as pedals shall prevent activation of exposition with the pedal turned in the inverse position.

(6) Exposition activation switches shall be designed so as to ensure that exposition only continues as long as the switch is pressed by the operator and is discontinued as soon as the pressure is released. The exposition activation switch shall be designed so as to allow the next exposition only following the operator’s full release of the switch. This does not apply to devices applied for exposition in examination along the patient’s body.

(7) X-ray devices shall be provided with clear light and acoustic indication of exposition, active throughout the duration of exposition or at least until it is unambiguously clear that exposition has taken place.

(8) Mobile X-ray devices not requiring direct connection to mains power for exposition shall be equipped with a locking system to prevent unauthorised persons from activating exposition. Such X-ray devices shall be locked when not in use.

Article 74
(exposition parameters)

(1) X-ray device control panels shall be equipped with a display showing exposition parameters before, during and after exposition. Following exposition, information shall remain displayed until the device operator selects new exposition parameters or positively cancels their display on the control panel.

(2) With radiography X-ray devices, prior to exposition, the selected exposition parameters shall be displayed, and following exposition, parameters allowing the determination of the radiation parameters shall be displayed as well.

(3) With fluoroscopy X-ray devices, prior to exposition, the selected fluoroscopy mode and the selected field size shall be displayed, while during exposition, exposition parameters and the total duration of fluoroscopy shall be displayed.

(4) All new installed X-ray devices for intervention radiological procedures shall also display the parameters necessary to assess the total dose at the patient’s skin.
(5) All new installed X-ray devices for computer tomography shall, prior to activation of the procedure, display parameters necessary to assess the dose received during the procedure.

Article 75
(monitors of expositions)

(1) A radiography X-ray device shall be equipped with a system to automatically discontinue exposition as soon as it reaches the predetermined level. Furthermore, the device shall be equipped with an independent system to allow early discontinuation of exposition where the operator establishes that exposition is not correctly determined. Such a system may consist of a switch that needs to remain depressed throughout the total duration of exposition.

(2) Radiography X-ray devices shall be equipped with a system to automatically monitor expositions. This does not apply to mobile devices designed for radiography on patient beds or in operating halls or to special cases, provided that use of such devices is specifically justified.

(3) Fluoroscopy X-ray devices shall be equipped with a total fluoroscopy duration meter, which shall automatically discontinue exposition after 10 minutes of fluoroscopy, however, at least 30 seconds prior to such discontinuation, the system shall audibly warn the operator of imminent discontinuation and thereby allow the operator to reset the system to the initial setting. New X-ray devices for fluoroscopy shall be equipped with total fluoroscopy duration with a resolution of at least 0.1 minute and with an acoustic alarm triggered following 5 minutes of fluoroscopy. The acoustic alarm may only be switched off manually.

(4) X-ray devices for computer tomography shall be provided with a function to discontinue the procedure prior to the completion of all the preset slices, during the warming up period or during the calibration of detectors.

(5) When applying a computer tomography X-ray device for fluoroscopy, the time limit of fluoroscopy shall be set so as to prevent the dose at the patient’s skin from exceeding 500 mGy.

Article 76
(imaging detectors)

(1) Fluoroscopy may only be carried out with X-ray devices equipped with image amplifiers or other dynamic imaging detectors allowing the observation of the image on a remote screen.

(2) To minimise patient exposure, fluoroscopy X-ray devices shall be equipped, as a minimum, with a system to retain the last image taken, and preferably also with other technical solutions such as pulsed operation, selection of different exposition levels and frequencies of image series.

(3) Fluoroscopy or bone density measuring X-ray devices and computer tomography devices shall be provided with the imaging detector holder having a protective capability equivalent to 2 mm lead as a minimum, if the device operates at anode voltages of up to 100 kV, plus an additional 0.01 mm of lead per each kV of anode voltage above 100 kV. Protective capability shall be clearly indicated on the device.

(4) An X-ray image generated by a digital imaging detector shall contain an indication of a quantity allowing the assessment of the received radiation dose.
IV. 3.2 Dental X-ray diagnostics

Article 77
(premises)

(1) As a rule, dental X-ray diagnostics shall be carried out in special premises designated and adapted for such procedures.

(2) Intraoral X-ray devices may also be used in premises not designated exclusively for X-ray diagnostics, provided that the adjacent premises are appropriately protected against the radiation emitted from the device and the premise dimensions allow the operator to move away to a safe distance and out of the useful beam direction.

Article 78
(housing)

(1) The housing of an intraoral X-ray device shall be designed to limit the air absorbed dose in air owing to leakage from the housing at a distance of 1 m from the focus to less than 0.25 mGy per 1 hour.

(2) The housings of other dental X-ray devices shall be designed to limit the absorbed dose in air owing to leakage from housing, at a distance of 1 m from the focus and at the maximum tube load, to less than 1 mGy per 1 hour.

(3) On the X-ray tube housing or in some other suitable location on the device, a readable indication of the type and number of the X-ray tube and of the size of focuses shall be provided.

(4) The position of the focus shall be indicated on the X-ray tube housing.

Article 79
(filtration)

(1) X-ray radiation applied in dental X-ray diagnostics shall be filtered.

(2) The X-ray device shall be provided with an indication of filters in the manner allowing the determination of the total filtration of the useful beam.

(3) The minimum total equivalent filtration of the X-ray beam shall be 1.5 mm Al with dental X-ray devices operating at anode voltages up to 70 kV, and 2.5 mm Al with dental X-ray devices operating at anode voltages exceeding 70 kV.

(4) Where, with an intraoral X-ray device, the total filtration of the useful beam significantly exceeds the levels referred to in the previous paragraph, means shall be provided to limit the exposition duration to a maximum of 1 second.

Article 80
(selection of the imaging technique)

(1) Intraoral X-ray devices shall operate at an anode voltage exceeding 50 kV, and all new X-ray devices in the range of 60 kV to 70 kV. It shall be possible to adapt the exposition parameters to the object to be imaged and to the imaging detectors.
(2) Panoramic dental X-ray devices shall operate at an anode voltage in the range of 60 kV to 90 kV.

**Article 81**
*(determination of the useful radiation field)*

(1) Intraoral dental X-ray devices shall be equipped with spacers to maintain an appropriate distance between the focus of the X-ray tube and the patient’s skin and confine the useful radiation beam. The spacer of an X-ray device for intraoral radiography shall maintain the distance between the focus of the X-ray tube and the patient’s skin of at least 200 mm, and confine the useful beam at the outlet of the spacer to:

- a field not exceeding the size of the applied imaging detector, at any edge, by more than 2.5 mm, and, in any case, to a field not exceeding 40 mm x 50 mm for devices with a rectangular shutter, or
- a field of a maximum diameter of 60 mm for devices with circular beam shutters.

(2) Panoramic dental X-ray devices shall be appropriately equipped to allow patient positioning and equipped with light indicators of the field. Radiation beam collimators shall direct the beam to the collimator slot in front of the imaging detector. The width of the radiation beam on the collimator in front of the imaging detector shall not exceed 5 mm, and its height shall not exceed the dimensions of the imaging detector.

(3) Cephalometry may only be carried out applying dental X-ray devices adapted to the procedure. The device shall be appropriately equipped with the system for positioning the patient (with a cephalostat). The minimum allowable distance between the focus and the film is 1 m, while the preferable distance is 1.5 m to 1.8 m.

**Article 82**
*(active protection)*

(1) The dental X-ray device control panel shall have a clear visual indication when the X-ray device is on or ready for exposition.

(2) Dental X-ray devices shall be provided with clear light and acoustic indication of the exposition, active throughout the duration of exposition or at least until it is unambiguously clear that exposition has taken place.

(3) Any new installed panoramic dental X-ray device shall be equipped with a system to automatically discontinue exposition in the event of discontinuation of rotation. In the event of discontinuation of exposition, resuming exposition from the position of discontinuation shall be disabled.

**Article 83**
*(activation and monitoring of expositions)*

(1) Exposition activation switches shall be clearly marked. Inadvertent activation of expositions shall be prevented.

(2) Exposition activation switches shall be designed so as to ensure that exposition only continues as long as the switch is pressed by the operator and is discontinued as soon as the pressure is released. The exposition activation switch shall be designed so as to allow the next exposition only following the operator’s full release of the switch.
(3) Exposition activation switches shall be installed so as to allow the operator to move away from the immediate vicinity of the useful beam, to a distance of at least 2 m from the patient and the X-ray tube housing.

(4) Dental X-ray devices shall be equipped with a system to automatically discontinue exposition as soon as it reaches a predetermined level. Furthermore, dental X-ray devices shall be equipped with an additional independent system to allow early discontinue of exposition if the operator establishes that exposition is not correct. Such a system may consist of a switch that needs to remain depressed throughout the duration of exposition.

IV.4. X-RAY DIAGNOSTICS IN VETERINARY MEDICINE

Article 84
(application of X-ray devices in veterinary medicine)

Application of X-ray devices in veterinary medicine is governed, by analogy, by the provisions of these Rules applying to X-ray diagnostics in medicine.

V. REGISTERS

V. 1 Register of practices involving radiation

Article 85
(information on the persons carrying out radiation practice)

In the register of practices involving radiation, the following documentary information shall be kept as a minimum:
- the official title and business address or the name and address of the person carrying out a radiation practice;
- the date of notification of the intention to carry out a practice involving radiation;
- the description of the practice involving radiation;
- the conditions for the practice involving radiation;
- the name and surname of the person responsible for radiation protection;
- the date and audit number of the assessment of the safety of exposed workers;
- the date and code of the approval of the assessment of the safety of exposed workers;
- the date of commencement and the date of termination of the practice involving radiation and the reason for termination of the practice involving radiation;
- the date and code of issue of the authorisation of practice involving radiation;
- the validity of the authorisation of the practice involving radiation.
V. 2 Register of radioactive sources

Article 86
(information on the radioactive source)

In the register of radioactive sources, the following documentary information shall be kept as a minimum:
- the official title and business address or the name and address of the holder of authorisation of use of the radioactive source;
- the code and date of issue of the authorisation of use of the radioactive source;
- the validity of the authorisation of use of the radioactive source;
- the location where the radioactive source is used, and the location where the radioactive source is stored;
- the conditions of the use of the radioactive source;
- information on the radioactive source, such as: the type of isotope and its activity on a given date for radioactive substances; the maximum anode voltage and current for X-ray devices, and an indication whether the radioactive source is stationary or mobile;
- the serial number of the radioactive source and the serial number of the protective container or device for sealed radioactive sources; serial number of the X-ray tube and the serial number of the housing for X-ray devices;
- the registry designation of the radioactive source assigned by the register administrator;
- the assessment of discharges into the environment for unsealed radioactive sources;
- where radioactive waste is generated in the use of a radioactive source: assessment of the volume and activity of radioactive waste;
- the type of practice involving radiation applying the radioactive source, the purpose and method of application;
- the date of commencement and the date of termination of use of the radioactive source;
- for radioactive substances: the date of handing the radioactive source over to the public service provider of the services of radioactive waste management or of its return to the manufacturer or of its transfer to another person carrying out a radiation practice;
- for X-ray devices: the date of its dismantling by a qualified organisation;
- the required frequency of inspections, the date of the latest inspection, the validity of inspection and the findings of the inspection.

V. 3 Register of nuclear and radiation facilities

Article 87
(information on the radiation or nuclear facility)

In the register of nuclear and radiation facilities, the following documentary information shall be kept as a minimum:
- the official title and business address or the name and address of the person carrying out a radiation practice managing the facility;
- the name and surname of the authorised representative;
- the description of the nuclear or radiation practices carried out in the facility;
- the operating conditions for the practice involving radiation;
- the code and date of issue of the decision on the facility status;
- the code and date of issue of the consent concerning nuclear and radiation safety;
- the code and date of issue of the operating licence for the facility and the validity of the licence;
- the name and surname of the person responsible for radiation protection or information on the radiation protection service personnel;
- the designation and date of issue of the authorisation of practice involving radiation in the facility and the validity of authorisation.

V. 4 Method of keeping registers

Article 88
(method of keeping registers)

(1) The ministry keeping the register shall ensure prompt updating of the register records, including information on the transfers of radioactive sources, and regularly produce backup copies.

(2) Information to be entered in the register shall be collected from the notifications of intentions to carry out practices involving radiation, applications for authorisation of practices involving radiation, applications for authorisation of use of radioactive sources and regular inspections of radioactive sources carried out by authorised radiation protection experts, decisions issued by the competent ministry, inspections or based on specific requests by the competent ministry.

(3) Information may only be entered into the register by the authorised personnel of the ministry keeping the register.

Article 89
(method of fixing the costs of providing information)

The applicant shall be charged costs for an extract of information from the register referred to in Articles 85, 86 and 87 of these Rules from the register in accordance with the schedule of costs published by the ministry responsible for the keeping of the register in accordance with the act governing access to information of a public nature.

VI. SURVEILLANCE OF THE IMPLEMENTATION OF RADIATION PROTECTION

Article 90
(surveillance of the implementation of radiation protection in a nuclear or radiation facility)

(1) The holder of authorisation shall at least once a year consult with the authorised radiation protection expert on the operation of the radiation protection unit in the nuclear or radiation facility and the said expert shall produce a report on the radiation protection.

(2) In any outage or work within the controlled area of the nuclear or radiation facility during which the planned collective dose exceeds 0.1 man-Sv or the planned individual dose sustained by a worker exceeds 10 mSv, radiation protection implementation shall be controlled by an authorised radiation protection expert or an expert in radiation and nuclear safety.

(3) The number of authorised experts to participate in surveillance shall be determined by the competent ministry depending on the scope and complexity of works to be undertaken.
Article 91  
(obligations of the holder of a radioactive source)

The holder of a radioactive source shall provide for the following:
- regular inspection and maintenance of radioactive sources and safety and security systems;
- regular inspection and testing of properties and protection of radioactive sources;
- in works with unsealed radioactive sources, regular measurement of specific activities of radionuclides in the air and of surface contamination of working surfaces;
- the assessment of the duration of exposure to ionising radiation.

Article 92  
(quality assurance programmes in medicine)

(1) The holder of authorisation shall have in place and implement a quality assurance programme as part of the approved radiological procedures programme. The programme shall include:
- the indication of parameters that affect the quality of a procedure and patient exposure and need to be checked;
- the frequency of individual tests, and
- the permissible deviations of measured parameters from optimal values.

(2) An authorised medical physics expert shall be responsible for the preparation of a quality assurance programme.

(3) The quality control programme or the test procedures and findings shall be reviewed, at least once a month, by an independent medical physics expert.

Article 93  
(control of radioactive sources)

(1) The control and measurement of radioactive sources shall be carried out by an authorised radiation protection expert prior to putting a radioactive source into service and then in regular intervals:
- at least once every 6 months for radiation sources owing to which a facility is or may be considered a radiation facility or a less important radiation facility;
- at least once every three years for radioactive sources requiring only a certificate of entry of the radioactive source into the radioactive source register;
- at least once every five years for ionising smoke detectors;
- at least once a year for other radioactive sources.

(2) The inspection prior to putting into service referred to in the previous paragraph may be substituted by a certificate of an equivalent inspection by the manufacturer, provided that the assessment of the safety of exposed workers indicates that the conditions of use of the radioactive source do not depend on its installation and that there is no risk of damage to the radioactive source during transport.

(3) In addition to the radiation source, the condition of the container or equipment that contains a high-activity sealed radioactive source shall be verified at the location of its use or in the storage.
(4) In the case of control and measurement of radioactive sources applied in radiological procedures in medicine, the control shall also cover examination of the quality control programme implemented by the holder of authorisation as a part of the programme of radiological procedures.

(5) The quality control programme examination referred to in the previous paragraph shall be carried out by an independent medical physics expert and shall include the following checks:
- that the quality control programme is adapted to the type and purpose of the radiological equipment and does it comply with the current recommendations from the European Union;
- that the radiological equipment complies with the acceptance criteria specified in the programme;
- that the measured parameters are within the range of permissible deviations from the optimal values specified in the programme, and
- that individual tests are carried out with the frequencies specified in the programme.

(6) The holder of authorisation of use of a radioactive source shall keep control and measurement result records for a period of three years following the control and measurements and shall, as required, evaluate personal doses sustained by workers and other individuals and the exposure of patients based on information of the records.

(7) The authorised radiation protection expert shall produce a report on the control and measurement of radioactive sources.

**Article 94**
**(reporting on a high-activity sealed radioactive source)**

(1) The holder of a high-activity sealed radioactive source shall transmit to the competent ministry an electronic or a paper copy of the entire records referred to in paragraph 2 of Article 9 of these Rules:
- immediately upon the acquisition of the radioactive source;
- every 12 months;
- immediately upon any change of any information referred to in paragraph 2 of Article 9 of these Rules;
- immediately upon any change of ownership of the radioactive source, providing also the name of the new holder;
- immediately upon the cessation of holding any source, and
- on a request by the competent ministry.

(2) The competent ministry may, at any time, undertake an inspection of the records referred to in Article 9 of these Rules.

**Article 95**
**(quality assurance in radiotherapy)**

(1) The programme of quality assurance in radiotherapy shall ensure proper operation of the radiotherapy equipment and proper preparation and administering of therapies. The programme shall cover the verification procedures laid down in Table 1 of Annex 4, which forms a constituent part of these Rules.

(2) The quality assurance programme in radiotherapy shall also cover the verification of hardware and software important for the calculation of the received radiation dose and exposure of the patient.
(3) Where results of tests on quality indicate that the patient safety may be threatened or accuracy of exposure compromised, the holder of authorisation shall, on the request of the authorised medical physics expert, take appropriate measures.

Article 96
(quality assurance in nuclear medicine)

The programme of quality assurance in nuclear medicine shall ensure proper operation of radiological equipment and proper administering of procedures. The programme shall cover, as a minimum, the verification procedures laid down in Table 2 of Annex 4 to these Rules.

Article 97
(quality assurance in X-ray diagnostics)

(1) The programme of quality assurance in X-ray diagnostics shall ensure proper operation of radiological equipment and proper administering of procedures. The programme shall cover, as a minimum, the verification procedures laid down in Table 3 and Table 4 of Annex 4 to these Rules.

(2) The verifications referred to in the previous paragraph shall be carried out by an authorised radiation protection expert competent for the surveillance of diagnostic medical equipment, at least once a year.

VII. TRANSITIONAL AND FINAL PROVISIONS

Article 98
(revocation of application of rules)

On the date of entry into force of these Rules, the following shall cease to be valid:
- Rules regulating the marketing and use of radioactive substances with the activity exceeding permissible limits, of X-ray and other apparatuses generating ionising radiations, and on safety measures protecting from radiation emitted by those sources (Official Gazette of the SFRY, No. 40/86, 45/89, 67/02 – ZVISJV and 48/04, and
- the provisions of Article 2 of the Rules on maintaining the inventory of sources of ionising radiation and records of doses received by the population and persons exposed to ionising radiation at work place (Official Gazette of the SFRY, No. 40/86, 67/02 – ZVISJV and 33/04).

Article 99
(reporting of gained experience to the Commission)

By 31 December 2010, the ministry competent for the environment shall furnish the European Commission with a report on experience gained in the implementation of obligations related to high-activity sealed radioactive sources in accordance with Directive 2003/122/EURATOM. The report shall include information on the number of radioactive sources cleared as high-activity sealed radioactive sources owing to the decrease of their activity below the clearance levels.
Article 100
(disposal of radioactive lightning rods)

Owners or holders of radioactive lightning rods shall provide for their dismantling and handing over the radioactive sources to the public service provider of the services of radioactive waste management by 1 January 2007 at the latest.

Article 101
(transitional provisions for high-activity sealed radioactive sources)

(1) The provisions of paragraphs 4, 5 and 6 of Article 16 of these Rules do not apply to high-activity sealed radioactive sources put on the market before 31 December 2005.

(2) The provisions of Article 9, paragraph 2, Article 14, paragraph 2, Article 93, paragraph 3 and Article 94 of these Rules shall begin to apply to high-activity sealed radioactive sources referred to in the previous paragraph from 1 January 2008.

(3) Without prejudice to the provisions of paragraphs 1 and 2 of this article, the holder of a high-activity sealed radioactive source shall provide, by 31 December 2007 at the latest:
   - written documentation necessary to identify the source and its characteristics;
   - marking to alert people of the ionising radiation hazards.

Article 102
(entry into force)

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

Number: 0071-135/2005
Ljubljana, on 6 February 2006
EVA 2002-2511-0177

Janez Podobnik (signed) Mag. Andrej Bručan (signed)
Minister Minister
of the Environment and Spatial Planning of Health
ANNEX 1
Radiation hazard warning signs

1. Basic sign

1- radius of the central circle
2- 1.5-times the radius of the central circle
3- 5-times the radius of the central circle
2. Sign
ANNEX 2
Requirements for X-ray devices

Table 1

<table>
<thead>
<tr>
<th>Tube voltage (kV)</th>
<th>Leakage (mSv/h)</th>
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<tbody>
<tr>
<td>up to 150</td>
<td>1</td>
</tr>
<tr>
<td>150-200</td>
<td>2.5</td>
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<tr>
<td>higher than 200</td>
<td>5</td>
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</tbody>
</table>

Table 2

<table>
<thead>
<tr>
<th>Tube voltage (kV)</th>
<th>Total filtration</th>
</tr>
</thead>
<tbody>
<tr>
<td>up to 50</td>
<td>No requirements</td>
</tr>
<tr>
<td>50-100</td>
<td>2 mm Al</td>
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<tr>
<td>100-200</td>
<td>3 mm Al</td>
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<tr>
<td>200-300</td>
<td>4 mm Al</td>
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<tr>
<td>higher than 300</td>
<td>0.5 mm Cu</td>
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ANNEX 3
Instructions for discharge from hospital following therapy

Table 1

<table>
<thead>
<tr>
<th>Applied activity $^{131}$I (MBq)</th>
<th>30</th>
<th>200</th>
<th>400</th>
<th>600</th>
<th>800</th>
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</thead>
<tbody>
<tr>
<td>Limitation</td>
<td></td>
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<tr>
<td>Keep a distance of at least 1 m from a child less than 3 years old</td>
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<td>15</td>
<td>21</td>
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<td>27</td>
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<tr>
<td>Keep a distance of at least 1 m from a child 3-5 years old</td>
<td>-</td>
<td>11</td>
<td>16</td>
<td>20</td>
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<tr>
<td>Keep a distance of at least 1 m from a child more than 5 years old</td>
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<td>5</td>
<td>11</td>
<td>14</td>
<td>16</td>
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<tr>
<td>Sleep separate from other persons</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>4</td>
<td>8</td>
</tr>
<tr>
<td>Avoid prolonged contacts with adult persons (duration more than 3 hours, distance less than 1 m)</td>
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<td>-</td>
<td>-</td>
<td>-</td>
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Table 2

<table>
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<tr>
<th>Radionuclide</th>
<th>Burial</th>
<th>Cremation</th>
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<tbody>
<tr>
<td>$^{131}$I</td>
<td>400 MBq</td>
<td>400 MBq</td>
</tr>
<tr>
<td>$^{125}$I, granules</td>
<td>4000 MBq</td>
<td>-</td>
</tr>
<tr>
<td>$^{103}$Pd, granules</td>
<td>15000 MBq</td>
<td>-</td>
</tr>
<tr>
<td>$^{90}$Y, colloid solution</td>
<td>2000 MBq</td>
<td>70</td>
</tr>
<tr>
<td>$^{198}$Au, granules</td>
<td>4000 MBq</td>
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<td>$^{198}$Au, colloid solution</td>
<td>400 MBq</td>
<td>100</td>
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<td>$^{32}$P</td>
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<td>30</td>
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<tr>
<td>$^{89}$Sr</td>
<td>2000 MBq</td>
<td>200</td>
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ANNEX 4
Verification procedures in radiotherapy, in nuclear and X-ray medicine

Table 1

<table>
<thead>
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<th>Assembly</th>
<th>Tests</th>
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<tr>
<td>Mechanical and geometrical parameters</td>
<td>· accuracy of the isocentre</td>
</tr>
<tr>
<td>· distance indicators</td>
<td></td>
</tr>
<tr>
<td>· laser settings</td>
<td></td>
</tr>
<tr>
<td>· position and size of exposure fields</td>
<td></td>
</tr>
<tr>
<td>· coincidence of the field light indication and the exposure field</td>
<td></td>
</tr>
<tr>
<td>· mechanical stability</td>
<td></td>
</tr>
<tr>
<td>· patient positioning and immobilisation accessories</td>
<td></td>
</tr>
<tr>
<td>Dosimetric parameters</td>
<td>· dosimetric calibration of all beams in clinical application</td>
</tr>
<tr>
<td>· constancy of the exposure beam</td>
<td></td>
</tr>
<tr>
<td>Protection systems</td>
<td>· safety switches</td>
</tr>
<tr>
<td>· audio and video surveillance systems</td>
<td></td>
</tr>
</tbody>
</table>

Table 2

<table>
<thead>
<tr>
<th>Type of equipment</th>
<th>Tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>Activity meters</td>
<td>· Accuracy of the determination of the diagnostic dose;</td>
</tr>
<tr>
<td>· Repeatability;</td>
<td></td>
</tr>
<tr>
<td>· Linearity;</td>
<td></td>
</tr>
<tr>
<td>Gamma cameras</td>
<td>· Homogeneity;</td>
</tr>
<tr>
<td>· Sensitivity;</td>
<td></td>
</tr>
<tr>
<td>SPECT</td>
<td>All the parameters specified for a gamma camera, and in addition:</td>
</tr>
<tr>
<td>· Rotation centre</td>
<td></td>
</tr>
</tbody>
</table>

Table 3

<table>
<thead>
<tr>
<th>Diagnostic and intervention radiology</th>
</tr>
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<tbody>
<tr>
<td>Parameter</td>
</tr>
<tr>
<td>--------------------------------------</td>
</tr>
<tr>
<td>X-ray tube housing</td>
</tr>
<tr>
<td>· Measurement of the housing leakage</td>
</tr>
<tr>
<td>· Verification of the focus sizes</td>
</tr>
<tr>
<td>Filtration</td>
</tr>
<tr>
<td>· Measurement of the half value layer thickness (HVL)</td>
</tr>
<tr>
<td>Useful radiation field</td>
</tr>
<tr>
<td>· Coincidence of the field light indication and the exposure field</td>
</tr>
</tbody>
</table>
### Diagnostic and intervention radiology

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Method of verification</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(congruence)</td>
</tr>
<tr>
<td></td>
<td>Centering of the useful beam</td>
</tr>
<tr>
<td>Active protection</td>
<td>Indications on the control panel</td>
</tr>
<tr>
<td></td>
<td>Warnings</td>
</tr>
<tr>
<td></td>
<td>Operation of the activation switches</td>
</tr>
<tr>
<td></td>
<td>Operation of the emergency stop switches</td>
</tr>
<tr>
<td>Exposition parameters</td>
<td>Operation of the display</td>
</tr>
<tr>
<td></td>
<td>Deviations from true values</td>
</tr>
<tr>
<td></td>
<td>Repeatability</td>
</tr>
<tr>
<td></td>
<td>Linearity</td>
</tr>
<tr>
<td></td>
<td>Specific exposition dose</td>
</tr>
<tr>
<td>Monitoring of expositions</td>
<td>Operation of the automatic control of exposition</td>
</tr>
</tbody>
</table>

Table 4

### Dental X-ray diagnostics

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Method of verification</th>
</tr>
</thead>
<tbody>
<tr>
<td>X-ray tube housing</td>
<td>Verification of markings</td>
</tr>
<tr>
<td></td>
<td>Measurement of the housing leakage</td>
</tr>
<tr>
<td></td>
<td>Verification of the focus sizes</td>
</tr>
<tr>
<td>Filtration</td>
<td>Verification of filter markings</td>
</tr>
<tr>
<td></td>
<td>Measurement of the half value layer thickness (HVL)</td>
</tr>
<tr>
<td>Useful radiation field</td>
<td>Operation of the shutters or verification of the size of the useful beam</td>
</tr>
<tr>
<td>Active protection</td>
<td>Indications on the control panel</td>
</tr>
<tr>
<td></td>
<td>Warnings</td>
</tr>
<tr>
<td></td>
<td>Operation of the activation switches</td>
</tr>
<tr>
<td>Exposition parameters</td>
<td>Operation of the display</td>
</tr>
<tr>
<td></td>
<td>Deviations from true values Repeatability</td>
</tr>
<tr>
<td></td>
<td>Specific exposition dose</td>
</tr>
</tbody>
</table>