

# THE MINISTRY OF HEALTH AND SOCIAL WELFARE

2768

Pursuant to Article 23 Paragraph 2 of the Act on Ionising Radiation Protection and Safety of Ionising Radiation Sources (Official Gazette 64/06), the Minister of Health and Social Welfare hereby issues the

## ORDINANCE

### ON THE CONDITIONS AND MEASURES FOR PROTECTION AGAINST IONISING RADIATION FOR CARRYING OUT ACTIVITIES WITH RADIOACTIVE SOURCES

#### I GENERAL PROVISIONS

##### 1. General conditions

###### Article 1

(1) This Ordinance prescribes conditions and measures for ionising radiation protection for carrying out activities with radioactive sources.

(2) This Ordinance regulates:

- conditions that premises and installations in which radioactive substances are stored or used must meet, in accordance with the purpose and place of usage,
- technical properties, basic requirements for radioactive sources and work conditions that radioactive sources must comply with considering their physical state, structure, composition, physical and chemical properties, purpose and other properties required for obtaining a licence for work,
- conditions of ionising radiation exposure of workers and other persons in the course of carrying out activities with radioactive sources,
- measures of ionising radiation protection as well as the type, properties, quantity and method of using protective equipment and personal protective equipment in the course of carrying out activities with radioactive sources, and
- other technical and organisational measures necessary for the improvement of safety and ionising radiation protection for carrying out activities with radioactive sources.

###### Article 2

For the purposes of this Ordinance, the following terms shall have the following meanings:

*Brachytherapy* is a therapy performed by inserting sealed radioactive sources in the body of a patient;

*Etalon* is a measurement standard, measuring instrument, reference material or measuring system intended to define, establish, keep or renew units of one or more values of a parameter so as to serve as a reference;

*Etaloning (calibrating)* is a set of procedures for establishing, under certain conditions, the relation between the value of parameters shown by a measuring instrument or a measuring

system or the value shown by a measurement standard or a reference material and the corresponding values received with etalons,

*Ionising smoke detector* is an integral part of an automatic fire alarm system that has a built in sealed radioactive source;

*Radionuclide activity concentration (specific activity)* is the activity of the sample containing that radionuclide divided by its volume (mass);

*Medical physicist* is a graduate engineer of physics who has been, in the course of his/her graduate or postgraduate studies or at a specialised course, trained to perform activities involving radiotherapy and ionising radiation protection;

*Quality assurance* comprises all planned and systematically conducted activities required to provide a high degree of reliability that the system, its components or the process meet the requirements prescribed by corresponding standards;

*Quality control* is an integral part of quality assurance. It is a set of procedures (programming, co-ordination, implementation) aiming at quality maintaining and improving. Quality control comprises testing, evaluation and maintenance of all verifiable and measurable properties of the system or devices at the prescribed level;

*Radiography quality control* is a procedure for testing items without destroying them or impairing their unity, applied in the economy by using sealed radioactive sources fitted in special instruments (defectosopes) for the purpose of researching and discovering imperfections, errors and damage of tested items;

*Half-life* of radionuclides is the interval of time needed for the initial activity of radionuclides in the surveyed sample to be decreased to the half of the initial value.

### Article 3

Provisions of this Ordinance shall apply to all types of radioactive substances and operations involving those substances whose activity or activity concentration (specific activity) of radionuclides, i.e. the total activity or activity concentration (specific activity) of radionuclides involved in the operations, exceeds the values set out in Table 1 of Annex I, which is an integral part of this Ordinance.

### Article 4

(1) A holder of licence for work with radioactive sources shall provide guarding as well as keeping of logs of transport and usage of radioactive sources so as to prevent their potential loss or non-controlled usage.

(2) A holder of a licence for work with radioactive sources shall keep the records referred to in paragraph 1 of this Article for at least 24 months.

(3) On 31 December each year, a holder of a licence for work with radioactive sources shall make a list of all radioactive sources whose half-life is longer than 100 days. The list shall be submitted to the State Institute for Radiation Protection by the end of January of the following year.

### Article 5

(1) A legal or natural person that produces, sells, delivers, imports, sets or installs, leases or conducts other kind of trade with radioactive sources shall present the legal or natural person that will use the radioactive source with a certificate for the radioactive source, a certificate for the container if the use of the container is related to the use of that radioactive source, a report and an opinion of an authorised, qualified technical service regarding the compliance with conditions prescribed by the Act on Ionising Radiation Protection (hereinafter referred to

as: the Act) and this Ordinance, as well as operating and maintenance instructions in Croatian and a warranty sheet.

(2) The legal or natural person referred to in paragraph 1 of this Article shall not deliver a radioactive source to an end user if the end user does not present a permit for procurement of the radioactive source issued by the State Institute for Radiation Protection.

(3) The provisions of paragraphs 1 and 2 of this Article shall not apply to the open radioactive sources referred to in Article 18 paragraph 6 of the Ordinance on the register of activities, requirements and the manner of issuing, and the validity of licences for work with sources of ionising radiation and the use of sources of ionising radiation.

## 2. Conditions for premises in which radioactive sources are used, produced or stored

### Article 6

(1) Type, composition, thickness, method of installation and other properties of construction materials intended for construction of premises in which a radioactive source will be used or stored shall be provided for and specified in the design, taking into consideration the highest possible radioactive source activity, energy and radiation strength, orientation of the radiation beam as well as workplaces in the neighbouring premises, i.e. presence of persons in the surroundings of the premises.

(2) The walls, doors, door-posts, windows, floor and ceiling of premises in which radioactive sources are used or stored shall be made of construction materials that provide appropriate protection of all persons in neighbouring workplaces in accordance with the categorization of the area referred to in a special regulation on the exposure limits, on the conditions of exposure for special purposes and on intervention levels.

### Article 7

Premises in which radioactive sources are used or stored shall be designed, constructed and equipped in a manner that the walls, doors, door-posts, windows, floor and ceiling do not, when those devices are used in any working conditions, leak a dose or a dose rate radiation above the prescribed limits.

(2) The dose or the dose rate radiation referred to in paragraph 1 of this Article shall be under the prescribed limits, as low as is reasonably achievable taking into consideration technical, economic, social and other factors while designing, constructing and equipping the premises.

### Article 8

(1) Premises intended for usage of a radioactive source shall be constructed in a manner that their walls, doors, windows, floor and ceiling present a border of the exposed area.

(2) A special room with an operating device shall be considered a supervised area.

### Article 9

(1) Regarding the design of premises in which radioactive sources will be used or stored, the designer shall, prior to the commencement of the construction, obtain an opinion of an authorised, qualified technical service stating whether appropriate measures for ionising radiation protection are provided for by the design, in accordance with the type and purpose of the radioactive source.

(2) Upon the construction and equipping and prior to the commencement of use, an opinion regarding the compliance with conditions of ionising radiation protection for premises in

which radioactive sources will be used, produced or stored shall be obtained, issued by an authorised, qualified technical service.

(3) The opinion of an authorised, qualified technical service referred to in paragraph 2 of this Article shall be issued at the request of the owner, investor, contractor or user of the premises. A building permit shall be enclosed to the request.

(4) The opinion of an authorised, qualified technical service referred to in paragraph 1 of this Article, preceded by an inspection of compliance with conditions of ionising radiation protection, shall be requested anew after each building intervention or a change of the purpose of the premises if they may change the quality of the ionising radiation protection inside and outside the premises.

#### Article 10

(1) Radioactive sources may occasionally also be used in premises that were not specially constructed for the purpose of their usage or at an outdoor worksite, provided that prescribed dose limits for exposed workers and other persons are not exceeded.

(2) If a radioactive source is only occasionally used in premises that were not specially constructed for the purpose of using radiation sources or at an outdoor worksite, the border of the exposed area shall be determined by measuring the corresponding dose rate and the effective dose estimate under the given circumstances, as well as by determination of the minimal distance to the radioactive source where access of workers and other persons may be allowed.

(3) While a radioactive source is being used outdoors, the border of the exposed area shall be clearly marked with a warning inscription, a sign of danger from radiation, a light or a sound signal; or persons who are able to enter the exposed area without authorisation shall be warned and stopped in some other way, on account of possible ionising radiation exposure.

#### Article 11

(1) When not in use, radioactive sources, except those installed in stationary devices, shall be kept in a specially equipped room – storage space.

(2) Storage spaces shall meet the requirements referred to in Articles 6, 7, and 9 of this Ordinance.

(3) Storage spaces shall be secured against fire, decreasing the danger from fire to the least possible extent.

(4) Storage spaces shall be equipped with a ventilation unit in case radioactive sources release radioactive gases, steam or aerosols during their storage.

#### Article 12

(1) Radioactive sources shall be stored and kept so that during their placement in and taking out from the storage space the radiation exposure originating from other radioactive sources stored in the storage space be minimized.

(2) Different sources with different activity shall be arranged and placed in special compartments or drawers.

(3) Individual vessels for keeping radioactive sources as well as doors of compartments or drawers shall be marked with a label and a legible inscription for a clear recognition of the radionuclide type and activity.

(4) Access to the storage space and stay therein shall be supervised in line with the conditions prescribed by Article 10 of the Act.

#### Article 13

(1) Radioactive sources may be moved and transported within premises and within a building only in prescribed containers which do not leak ionising radiation above prescribed limits and which prevent release of radioactive contents in the environment (dispersion, evaporation, and similar) or their loss.

(2) A sealed radioactive source shall not leak radioactive contents in the environment.

(3) Sealed radioactive sources, tools, containers and working surfaces shall be checked occasionally, within prescribed intervals, by taking swabs so as to determine potential leakage of their radioactive content or radioactive contamination.

(4) Radioactive contamination of any surface that is in contact with a sealed radioactive source shall not exceed 1.85 kBq. Otherwise, the source or the equipment shall not be used until the contamination and its cause have been removed.

#### Article 14

The entrance into an exposed area shall be supervised by workers carrying out activities in that area and it shall be specially marked with a warning sign of danger from ionising radiation shown in Figure 1 in Annex II to this Ordinance, which is its integral part.

#### Article 15

Only persons whose presence is necessary due to the nature of work may be present in an exposed area at any hour.

#### Article 16

If a radioactive source is being installed in a working or transport device or a container, they shall meet the requirements for ionising radiation protection prescribed by this Ordinance.

(2) A container in which a radioactive source is installed or which is used for transport of radioactive sources shall contain:

- name of the manufacturer and the model,
- certificate number,
- serial number,
- transport index,
- sticker with a warning sign of danger from ionising radiation shown in Figure 1 in Annex II to this Ordinance, which is its integral part.

#### Article 17

(1) If a user does not intend to use a sealed radioactive source any more, the source shall first be offered to another user, so that it may be included in another practice, or it shall be returned to the manufacturer. If this is not possible, it shall be stored in accordance with a special regulation or its disposal shall be provided.

(2) If an end user of a radioactive source stops using it, alienates it or stores it, the end user shall, within 15 days, inform the State Institute for Radiation Protection thereof, indicating the name and address of the legal or natural person where the radioactive source is located, or he/she shall enclose a certificate of the storage space regarding the takeover of the radioactive source, or a statement of the end user on the takeover of the radioactive source, or a copy of a single customs declaration.

## II CONDITIONS OF USE AND TRANSPORT OF RADIOACTIVE SOURCES IN THE HEALTH CARE SECTOR

## A USE AND TRANSPORT OF OPEN RADIOACTIVE SOURCES IN MEDICAL DIAGNOSTICS

### 1. General conditions

#### Article 18

- (1) Ionising radiation protection during the transport and use of open radioactive sources refers to protection against external and internal irradiation as well as against radioactive contamination of premises, air and persons.
- (2) The basic principle of protection against contamination by radioactive substances is the prevention of spreading of radioactive substances from the place of use into the surroundings, as well as a high degree of cleanness at the workplace.
- (3) Work with open radioactive sources shall be carried out in line with written determined rules and prescribed procedures which shall be displayed at the workplace.

#### Article 19

While designing and constructing premises intended for work with open radioactive sources, appropriate protection measures shall be taken into consideration: sufficient number and proper arrangement of rooms, equipment in rooms, technological course of work with optimal organisation of working posts and measures for personal hygiene of the staff, appropriate ventilation system as well as organised and safe system of collecting and disposal of radioactive waste created in the course of work.

#### Article 20

- (1) Furnishing and equipping of storage spaces intended for keeping open radioactive sources shall meet requirements prescribed for premises where such sources are used.
- (2) Open radioactive sources may also be stored in premises where they are used, but if they release radioactive gases, steams or aerosols, the premises used for their storage shall be equipped with a special ventilation unit.

#### Article 21

All activities with open radioactive sources shall be classified in three levels of danger: low, medium and high, for the purpose of implementation of ionising radiation protection. The levels of danger, together with the field of activity they refer to, are set out in Table 1 of Annex III, which is printed along with this Ordinance and is its integral part. A certain radionuclide of a certain activity shall be classified into one of the levels on the basis of the weighting factors specified in Table 2 of Annex III and of the factors specified in Table 3 of Annex III to this Ordinance.

#### Article 22

- (1) Premises where open radioactive sources are used shall be built of constructing materials resistant to chemicals and heat and not absorbing moisture. The floors of premises shall be constructed coherently, without any cracks and breaks, for easier maintenance.
- (2) If release of radioactive aerosols is expected during the usage of open radioactive sources, such operations shall be carried out in digestors with ventilation. As required, special carbon filters shall be installed if activities are performed with radioactive iodine

### Article 23

- (1) In premises where open radioactive sources are used, an autonomous system for artificial ventilation shall be installed.
- (2) Ventilation units shall be designed so as to prevent the air in the premises where radionuclides are used from recirculation or passing into premises where those substances are not used.
- (3) If radionuclides with different activity are used in several rooms, ventilation shall be designed so as to ensure the direction of the airflow from the room with lower activity to the rooms with higher activity.

### Article 24

- (1) In all premises where activities with open radioactive sources are performed, wash basins and sinks for washing hands shall be fitted near the exit door. In laboratories or units of medium or high danger level, a tap shall be installed which may be turned on without using hands, for example by pressing a foot pedal under the wash basin, and for drying hands special hot air dryers or disposable absorbing towels shall be installed.
- (2) Water outlet pipes from wash basins and sinks to the main sink shall be as short as possible and have obstacles where samples may be taken for occasional control of radioactive contamination.
- (3) In laboratories of medium or high danger level, a special drainage system shall be provided, with chambers where liquid radioactive waste remains for some time prior to its discharge into the sewerage.
- (4) If open radioactive sources with long-term half-life are used, such water outlet pipes shall be marked with a sign of danger from ionising radiation, so as to warn persons engaged in repairs and maintenance.

### Article 25

In laboratories of low danger level where open radioactive sources are used, it is necessary to provide an instrument for measuring ionising radiation level; in laboratories of medium or high danger level, an instrument for measuring ionising radiation level and an instrument for measuring surface contamination shall be obligatory parts of the equipment.

### Article 26

- (1) Basic quality requirements for devices and measuring instruments used in nuclear medicine as well as intervals of inspecting their essential properties are set out in Table 1 of Annex IV to this Ordinance, which is its integral part.
- (2) A holder of a licence for work with open radioactive sources shall adopt a programme of quality maintenance and control, as well as conduct inspection of certain properties of devices or processes within the deadlines set out in Table 1 of Annex IV to this Ordinance.

## 2. Protection of workers carrying out activities with open radioactive sources and of other persons

### Article 27

Rooms in which open radioactive sources are prepared for use or stored prior to usage shall be considered a controlled area. Signs of danger from ionising radiation shall be displayed on the

doors of those rooms and the entrance shall be secured against non-authorised access both during the work and while the room is not in use. The number of persons in a room shall be limited to the number necessary for carrying out activities, but there shall always be at least two persons present in the room.

#### Article 28

(1) Working surfaces or tables shall have smooth, unbroken and undamaged surfaces which can be easily maintained. They shall have shields against radiation installed, for protection of workers operating open radioactive sources as well as of other workers in the room.

(2) Table tops shall provide appropriate protection of workers' parts of the body under the waist, depending on the type of radionuclide and the highest activity on the table surface. Table tops shall have a protective effect that will diminish the dose rate under the table at least a thousand times in relation to the dose rate on the surface of the table, taking into account the highest activity of the usually used radionuclide.

#### Article 29

(1) When open radioactive sources are not in use, they shall be stored at a safe place: a special container, a safe, a refrigerator, etc.

(2) The container or the safe referred to in paragraph 1 of this Article shall have compartments with clear labels indicating the radionuclide type and the activity.

### 3. Storage and transport of open radioactive sources

#### Article 30

(1) Open radioactive sources received from a supplier shall be regularly and accurately recorded.

(2) Usage and consumption as well as storage of open radioactive sources shall be accurately recorded in a log on spending and transport of radionuclides.

(3) Containers for storage of open radioactive sources shall, prior to their use, be marked with the sign of danger from ionising radiation shown in Figure 1 in Annex II to this Ordinance; furthermore, the type of radionuclide and its activity along with the date shall be clearly displayed.

#### Article 31

Special protective containers which prevent dispersion of radioactive content in the environment shall be used for transport of open radioactive sources.

#### Article 32

(1) Storage spaces, containers as well as glass and other vessels for storing radioactive sources shall be opened and closed easily.

(2) Glass vessels containing liquid radioactive solutions shall be kept within metal or plastic vessels having sufficient volume for storage of the total liquid quantity in case the glass vessel is broken.

### 4. Handling open radioactive sources

#### Article 33

- (1) Only persons whose presence is necessary due to the nature of work may be present in a controlled area.
- (2) In an exposed area, workers shall not consume food and drinks, smoke or use face and body cosmetic products which during their use come in direct contact with the skin and mucous membrane.
- (3) Workers shall not enter an exposed area with open skin injuries. Prior to entering that area, open injuries shall be treated with waterproof protection. If a worker hurts the skin in the course of work with open radioactive sources, the wound shall be cleaned immediately, radiation contamination shall be checked and decontamination shall be carried out if necessary.

#### Article 34

Upon receipt of a container with open radioactive sources from a carrier or a supplier, the accompanying documentation regarding its content shall be checked and compared with the order which shall be in accordance with the permit for procurement of the radioactive sources. When performing the clearing out, gloves shall be used and each individual part of the consignment shall be checked. Received radionuclides and their activity shall be immediately recorded and transported to a storage space.

#### Article 35

- (1) Patients shall be given radioactive preparations in a controlled area.
- (2) A syringe used for giving a radioactive preparation to a patient shall prior to its use, for the sake of the worker's protection, be put in a special lead or lead glass container.
- (3) When applying a radioactive preparation using a syringe, an absorbing pad shall be placed under the part of the body in which the preparation is inserted, so as to prevent radioactive contamination in case a minor quantity of the radioactive preparation is poured out during the application.
- (4) After the use, syringes and needles shall be put in a special vessel for radioactive waste.

#### Article 36

- (1) Due to the danger from radioactive contamination during application of a radioactive preparation on a patient, workers shall wear gloves and protective working clothing.
- (2) Upon the completion of work, workers shall put gloves in a special vessel for radioactive waste.
- (3) Prior to commencing any other work, workers shall carefully wash their hands and check radioactive contamination on the hands by measuring the ionising radiation on the hands using a measuring instrument.
- (4) Should a worker find or establish radioactive contamination traces on his/her hands, body or clothes, he/she shall, without leaving the workplace, inform the responsible person thereof and take further necessary measures.

#### Article 37

- (1) In rooms designated for work with open radioactive sources, radioactive contamination of the room surfaces, working surfaces, clothes and skin of workers shall not exceed the limits set out in Table 1 of Annex V to this Ordinance, which is its integral part.
- (2) Periodical radioactive contamination checks shall be carried out either by direct measurement using a special measuring device for surface radioactive contamination or by

taking swabs from appropriate surfaces and conducting subsequent measuring so as to determine the presence and content of radionuclides in the swab.

(3) Measuring of radioactive contamination on workers' clothes or skin shall be carried out on the most appropriate place on the body surface of 100 cm<sup>2</sup>. If it is necessary to determine radioactive contamination on the walls, floor or ceiling of the room, a surface of up to 1,000 cm<sup>2</sup> shall be chosen, and for other surfaces 300 cm<sup>2</sup> are sufficient.

#### Article 38

(1) Handling and work with radioactive iodine shall be carried out in a digestor.

(2) Workers working with radioactive iodine shall periodically, using an appropriate measuring instrument, measure radiation on their thyroid gland, with the purpose of checking potential internal radioactive contamination and intake of radionuclides in the body by inhalation or through the skin.

### 5. Removal of radioactive contamination from the body of a worker

#### Article 39

Removal of internal or surface radioactive contamination shall be carried out in accordance with written procedures determined for each single radionuclide, which shall be available to workers in the unit in which open radioactive sources are used.

#### Article 40

(1) Radioactive contamination on the skin shall be cleaned by washing it with soap and water. If the radioactive contamination level does not decrease, an appropriate solution for radioactive contamination removal shall be used.

(2) In case of a complete radioactive contamination of the worker's body, the surface contamination shall be removed as soon as possible, so as to facilitate the determination of internal contamination.

(3) Special attention shall be paid to open wounds on the skin which may be contaminated; they shall be cleaned and medically treated.

### 6. Disposal of radioactive waste created by using open radioactive sources

#### Article 41

(1) Liquid and solid radioactive waste shall be immediately removed from the workplace. Solid waste shall be separated in special containers, according to the type of radionuclides.

(2) Solid waste containers shall be strong enough so as to prevent their content from scattering around and causing contamination of the environment.

(3) Prior to the transport into a storage space, all vessels and bags containing solid radioactive waste shall be shut and their content labelled. If the transport is performed outside an exposed area, additional measures shall be taken to prevent radioactive contamination of the environment.

#### Article 42

Liquid radioactive waste shall be discharged through sinks into special basins for temporary holding or it shall be directly discharged into sewerage, in which case massive rinsing with

water for the purpose of dilution is necessary. The discharging method and quantity of radioactive waste shall be within the limits prescribed by a special regulation.

## 7. Proceeding in case of an emergency

### Article 43

- (1) In each room used for handling and working with open radioactive sources, written procedure instructions for the case of an accident or emergency shall be displayed.
- (2) An emergency case may occur due to incorrect handling of open radioactive sources, scattering of radionuclides, incorrect application to the patient, in case of fire or explosion.
- (3) Holders of a licence for work with open radioactive sources shall provide training and periodical exercises of their workers regarding the application of protective measures in case of an emergency.

### Article 44

- (1) Equipment for application of appropriate measures in an emergency case involving open radioactive sources shall be easily accessible and in working order.
- (2) The equipment referred to in paragraph 1 of this Article comprises:
  - a) protective clothing, caps and covers for shoes,
  - b) agents for cleaning radioactivity from surfaces and articles, hydroscopic materials, and similar,
  - c) agents for cleaning radioactivity from staff,
  - d) warning signs and tapes for delineating danger area,
  - e) tools, vessels and plastic bags for collecting and temporary disposal of contaminated articles,
  - f) portable instruments for ionising radiation measuring, including personal dosimeters with direct dose reading.

### Article 45

- (1) Measures for restricting the movement through and within a contaminated area shall be implemented until a thorough decontamination has been completed and until an authorised, qualified technical service has confirmed by measurement that the area is safe for work.
- (2) An authorised, qualified technical service shall be called for without delay to carry out a special inspection of the area from which radioactive contamination has been removed.

## B USE AND TRANSPORT OF OPEN RADIOACTIVE SOURCES FOR MEDICAL THERAPY

### 1. General conditions

#### Article 46

- (1) Premises for conducting therapy with open radiation sources shall be constructed and equipped in accordance with the type of radionuclide and the highest activity applied; there shall be a special waiting room for patients waiting for source application and a special waiting room for patients who have received radionuclides, a place where open radioactive sources are applied or stored, as well as wards and rooms where patients who have received radionuclides are accommodated.

(2) A place for receiving radionuclides or a laboratory shall be close to the hospital ward where patients lie during the therapy so as to avoid their moving through parts of the building which are not considered exposed areas, such as elevators, corridors and similar places.

#### Article 47

The effective dose for family members and other persons irradiated by a patient who has been applied a radionuclide for therapy purposes at the time of his/her discharge shall be as low as is reasonably achievable and shall not exceed the limits set out in Table 1 of Annex VI to this Ordinance.

#### Article 48

(1) A patient who has received radionuclide for therapy purposes shall be detained in a special hospital ward or a special room until the requirements laid down in Article 47 of this Ordinance have been satisfied.

(2) The special hospital wards and special rooms referred to in paragraph 1 of this Article shall have protective screens for staff protection.

(3) Due to radioactive contamination danger, patients who have received radionuclides shall use separate showers and toilets, detached from showers and toilets used by the staff and other patients.

#### Article 49

After receiving radionuclides for therapy, patients shall obtain instructions on measures which they shall follow in order to lower the risk of external irradiation or radioactive contamination of other persons.

#### Article 50

Immediately upon receiving radionuclides, the following shall be entered in the patient's medical records:

- a) type and activity of radionuclides,
- b) date and time of their receipt.

#### Article 51

(1) The room where a patient with a received radionuclide lies and the space around his/her bed shall be considered an exposed area until the activity value he/she bears has fallen under the values set out in Table 1 of Annex VI to this Ordinance.

(2) Only the staff conducting the care and treatment shall be allowed access to the patient, and the patient's movement shall be restricted.

(3) The staff having access to the patient who has received radionuclides shall wear gloves and protective work clothing, i.e. aprons, caps and covers for shoes, for the purpose of protection against radioactive contamination of the clothes.

(4) All things exposed to direct contact with the patient shall, after their use, be deposited in a special container for radioactive waste, if it is determined by the radiation measuring device that they have been radioactively contaminated.

#### Article 52

- (1) Immediately after a patient has received a radionuclide, he/she shall be given only the necessary care from the largest possible distance and with the shortest possible stay in his/her vicinity.
- (2) After leaving the exposed area where the patient is accommodated, gloves and protective clothing shall be taken off and hands shall be washed if the patient was touched with hands.
- (3) If an obvious radioactive contamination has occurred due to possible spilling of secretions of the patient who received a radionuclide, he/she shall be urgently moved to another room and the radioactive decontamination shall be carried out.
- (4) All items used by the patient who has received a radionuclide shall be checked for radioactive contamination before they are reused and, if required, decontaminated from residual radioactivity.

#### Article 53

Transport of a patient within the ward shall be performed so as to prevent or limit his/her contact with other persons, i.e. to reduce it to the least possible number of other persons. While transporting the patient, special care should be taken to avoid passage through crowded corridors and elevators.

#### Article 54

A patient who has received radionuclides shall be allowed to leave the hospital ward only with a written approval issued by a medical doctor specialised in nuclear medicine; the approval shall be granted depending on the residual radioactivity in the patient's body, on the type of transportation and the time required to reach home.

#### Article 55

Transportation of a patient to his/her home by means of public transport shall not be allowed if the activity of radionuclide  $^{131}\text{I}$  applied into the patient's body exceeds 800 MBq.

#### Article 56

Autopsy and cremation of deceased persons who, for therapy purposes, received radionuclides whose residual activity is above the limits referred to in Article 55 of this Ordinance, shall be performed by applying all protective measures against ionising radiation, aiming at avoiding external irradiation and radioactive contamination.

### III CONDITIONS FOR USE AND TRANSPORT OF SEALED RADIOACTIVE SOURCES IN THE HEALTH CARE SECTOR

#### A DIAGNOSTICS

#### Article 57

Sealed radioactive sources used for diagnostic purposes (measuring of bone structure, examination of thyroid gland by fluorescence of characteristic x-rays or analysis by neutron activation) shall be installed in instruments that have an opening for leaking the useful beam which may be regulated and that are made in such a manner that their protective power is efficient enough to weaken the radiation in other directions to a level below the prescribed limits.

## Article 58

Sealed radioactive sources installed in diagnostic devices shall have micro-switches which prevent accidental opening of the collimator. On the operating device there shall be designations indicating that the device contains a sealed source, and whether the collimator is open or not. A sign indicating the danger from radiation shall be displayed next to the designation.

## Article 59

A patient shall be placed in a position for diagnostic examination using a sealed radioactive source before the collimator of the device opens. Useful radiation beam shall be restricted only to the examined part of the patient's body.

## Article 60

(1) During examination, only the patient may be present in the room referred to in Article 59 of this Ordinance.

(3) When the device is not in use, its collimator shall be closed and the device locked so as to prevent unauthorised switching on.

## B THERAPY

### 1. General conditions

## Article 61

(1) Preparation and application of sealed radioactive sources used for brachytherapy and therapy with remote control of sources shall be performed exclusively in special premises constructed for that purpose.

(2) The premises referred to in paragraph 1 of this Article shall be entered either through a protective door or a maze or through a door and a maze.

## Article 62

Premises for usage of sealed radioactive sources whose activity exceeds 370 GBq shall also be equipped with a ventilation system ensuring the rate of two to ten air exchanges per hour, depending on the activity of the sources.

## Article 63

(1) An instrument with an installed sealed radioactive source shall be resistant to mechanical, thermal, chemical, and other influences and it shall be used in line with prescribed technical conditions determined by the manufacturer.

(2) Use of instruments with a sealed radioactive source in conditions that are not foreseen by their technical documentation is prohibited.

(3) Use of sealed radioactive sources which are mechanically damaged or leak radioactive substances is prohibited.

## Article 64

(1) A room for irradiation by a brachytherapy device with high dose rates with subsequent introduction of a radioactive source and with a device for external irradiation shall be equipped with a television system ensuring the control of a patient and the room where the irradiation takes place.

(2) The provisions from paragraph 1 of this Article shall not refer to the application of sealed radioactive sources in a therapy where the source is directly applied to a patient without a remote control device for operating the source.

#### Article 65

(1) Devices for therapy with sealed radioactive sources and a remote control shall have a switch installed that will enable their operating if any of the entrances to the room where the radiation takes place is open.

(2) Safety switches enabling instantaneous termination of radiation at any time shall be located both on the operating device from paragraph 1 of this Article and in the irradiation room.

(3) A new irradiation procedure may only be initiated from the operating device.

#### Article 66

(1) Clear indicators of irradiation commencement, course and termination shall be fitted on the operating device as well as in the irradiation room.

(2) On the entrance door to the room a light indicator shall be placed, which will, by changing the colour of the light, warn that irradiation of a patient is underway.

(3) The entrance door to the irradiation room shall be constructed in such a manner that it may always be opened from the inside, regardless whether irradiation is underway or not.

#### Article 67

The operating device of a sealed radioactive source with a remote control shall have a time switch installed, which will automatically terminate the irradiation upon the expiry of the selected period of time.

#### Article 68

Workers using sealed radioactive sources shall have at their disposal a portable device for measuring ionising radiation level and checking the radioactive source position.

### 2. Use of sealed radioactive sources for brachytherapy

#### Article 69

While using sealed radioactive sources for brachytherapy, protection shall be organised in the following premises:

- a) storage spaces in which sealed radioactive sources are stored when not in use,
- b) areas, wards or rooms for irradiation of patients,
- c) operating theatres,
- d) x-ray devices for diascopy and imaging used for positioning of a sealed radioactive source in a patient,
- e) passageways for transport of sealed radioactive sources and patients with sealed radioactive sources inserted into the body.

(2) The areas referred to in paragraph 1 of this Article shall be considered exposed areas.

#### Article 70

- (1) Working surfaces where preparation of sealed radioactive sources for brachytherapy is performed shall be smooth, undamaged and without cracks. Protection power of shields that are placed on the table surrounding the handling place, as well as working surfaces themselves, shall be in accordance with the activity and type of the sealed radioactive source.
- (2) A lead glass shield with 5 cm lead equivalence shall be used for observation of activities with sealed radioactive sources. The workplace shall be well illuminated, and a magnifier shall be used as required.

#### Article 71

- (1) Whilst sealed radioactive sources are not in use, they shall be stored in a special container or a safe. The distance between the safe or the container and the working table shall be small, so as to ensure the shortest possible way of transportation when they are removed from the container or the safe. This shall also apply in cases when in an operating theatre a source is inserted into a patient's body directly, instead of using the technique of subsequent insertion.
- (2) Access to premises where sealed radioactive sources are stored when not in use shall be in line with the conditions prescribed by Article 10 of this Ordinance.

#### Article 72

If a sealed radioactive source is being prepared on a working table by cutting (e. g. iridium wire) into smaller pieces, it shall be necessary to provide a container for radioactive waste where unnecessary and waste parts shall be stored. In the process of cutting, radioactive contamination of cutting tools is possible; therefore, the tools shall be checked and put aside until the decontamination is carried out or until after a sufficient period of time the activity falls below the prescribed limits. Radioactive contamination shall be checked with an appropriate device for measuring ionising radiation.

#### Article 73

Use of sealed radioactive sources which in the course of radioactive decay produce gaseous radioactive progeny is prohibited in brachytherapy.

#### Article 74

- (1) Patients with sealed radioactive sources inserted for therapy purposes shall be irradiated in specially constructed rooms or secured areas.
- (2) During irradiation, patients shall have no visits.
- (3) During irradiation, the entrance into the patient's room shall be marked by a sign of danger from ionising radiation shown in Figure 1 of Annex II to this Ordinance.

#### Article 75

In the course of care of a patient irradiated with a sealed radioactive source inserted in his/her body, all the usual measures of ionising radiation protection shall be taken, and it shall especially be necessary to spend as little time as possible in the vicinity of the patient, to keep as great a distance as possible from the patient, and to use movable shields.

#### Article 76

After exposure, a patient shall be examined so as to find out whether a sealed radioactive source or a part of that source has remained in the patient's body, or if it has caused radioactive contamination.

#### Article 77

Sealed radioactive sources used for therapy with subsequent insertion shall be carried or transported inside the therapy ward exclusively in containers intended for that purpose.

#### Article 78

Special x-ray units (simulators), to which corresponding regulations for diagnostic x-rays units apply, shall be used to check the position of a sealed radioactive source in a patient.

#### Article 79

(1) The position of a sealed radioactive source in the room where therapy takes place shall be known at every moment. Removal of the source from a container or a safe, as well as its returning and application, shall be recorded.

(2) In all rooms where a sealed radioactive source is placed permanently or temporarily, a sign of danger from ionising radiation shall be displayed.

#### Article 80

(1) In premises where sealed radioactive sources for therapy with subsequent application are used, instructions for proceeding in case of an accident shall be displayed in a visible place.

(2) All workers participating in conducting the therapy shall be familiar with the instructions for proceeding in case of an accident with sealed radioactive sources used in brachytherapy and they shall be trained for their application.

### 3. Therapy with remotely operated sealed radioactive sources with external irradiation of patients

#### Article 81

A maze leading to the place where irradiation is carried out shall protect the entrance to the room in which a remotely operated sealed high activity radioactive source is used for external irradiation therapy.

#### Article 82

A sealed radioactive source intended for external irradiation therapy shall be set in the irradiation position exclusively by using a remote control device.

#### Article 83

A room used for irradiation shall have a special ventilation unit installed.

#### Article 84

- (1) A sealed radioactive source for therapy operated by remote control shall have an additional time switch that will turn the irradiation off if the main time switch fails to do so upon the expiry of the selected time.
- (2) The additional time switch shall have a longer irradiation interval than the one set on the main time switch.

#### Article 85

The container of a device with a sealed radioactive source shall provide such protection that the absorbed dose rate in the air at any point at the distance of 1 m from the container surface does not exceed 0.02 mGy/h. Leakage of ionising radiation shall be measured at the closed opening for useful beam passage.

#### Article 86

- (1) In the course of irradiation, only the patient is allowed to be present in the room.
- (2) A radiation measuring device connected with a light or sound indicator which will warn if the collimator is open shall be installed in the room.
- (3) A room containing a sealed radioactive source for external irradiation therapy operated by remote control shall be considered a monitored area regardless whether the collimator is open or closed.

#### Article 87

Basic quality requirements for a device for therapy with a sealed radioactive source operated by remote control and intervals of inspecting its essential properties are set out in Table 1 of Annex VII, which is an integral part of this Ordinance.

#### Article 88

- (1) The first inspection of parameters setting reference values of parameters of a device with a sealed radioactive source, which influence the quality of the therapy, shall be provided for by the supplier. The first inspection shall be attended by an appointed representative of the end user who shall countersign the testing report. The supplier of the sealed radioactive source shall, along with other documentation, present the end user with results of the first inspection of essential properties of the device for therapy with a sealed radioactive source.
- (2) A legal or natural person that performs therapy using a device with a sealed radioactive source operated by remote control shall adopt a programme for quality maintenance and control in the course of usage of the device on the basis of reference values obtained during the first inspection and the inspection of certain properties of the therapy procedure in the periods of time set out in Table 1 of Annex VII to this Ordinance.

#### Article 89

- (1) A sealed radioactive source for therapy in a device with a sealed radioactive source operated by remote control shall be etaloned (calibrated) so that the dose a patient has received during the therapy may be determined.
- (2) It is necessary to provide an appropriate phantom and a dosimeter for calibration, which shall comply with conditions determined by measurement regulations.
- (3) Calibration shall be carried out once a week by a medical physicist or another qualified person, and measuring records shall be kept for at least twelve months.

## IV CONDITIONS OF TRANSPORT AND USE OF RADIOACTIVE SOURCES IN THE ECONOMY

### 1. Open radioactive sources

#### Article 90

(1) In the course of handling radioactive luminous paints, safety measures shall be implemented in the manner specified for the handling of open radioactive sources in the health care sector.

(2) Only  $^3\text{H}$  and  $^{147}\text{Pm}$  may be used as components in radioactive luminous paints, in which radionuclides shall be bound chemically or in some other manner so as to form an insoluble or poorly soluble matter.

#### Article 91

(1) Total activity of a luminous paint with a radionuclide applied to the dial and the hands of a timepiece (wrist watch, pocket watch, clock, alarm clock, etc.) and to the dials of gauges (for measuring pressure, temperature, direction of movement, etc.) shall not exceed the values set out in Table 1 of Annex VIII, which is an integral part of this Ordinance.

(2) Radioactive luminous paint on coated surfaces under normal conditions of usage shall adhere in such a way that it does not come off when shaking off or when the temperature changes.

#### Article 92

(1) Timepieces and other devices, parts of which are coated with radioactive luminous paint, shall be placed in boxes with a transparent lid. The box and the lid shall be resistant to stress and impact under conditions of normal usage and in minor accidents.

(2) Special timepieces and devices shall have a radioactivity label on the dial, warning users or servicepersons that they contain radionuclides

#### Article 93

(1) Workplaces where radioactive luminous paints are used shall be well lit and ventilated.

(2) Workers shall have special protective clothing to change into before they start working, and a special changing room and sanitation area shall be provided for them.

(3) When leaving the workplace, workers shall always wash their hands thoroughly to remove possible radioactive contaminants from their hands and then undergo a testing for radioactive contamination of their clothing and body with an appropriate device.

#### Article 94

(1) Radioactive luminous paint shall be kept in a closed container before usage. The container shall be clearly labelled regarding its content and activity.

(2) Waste created in the course of usage of radioactive luminous paint shall be collected in a special container or in plastic bags which shall later be treated in accordance with a special regulation on radioactive waste.

### 2. Sealed radioactive sources

#### 2.1 Radiography quality control with the use of sealed radioactive sources

#### Article 95

(1) Sealed radioactive sources used for radiography quality control shall be kept, transported to the place of usage and used in a container that is at the same time a working device. The working device shall be equipped with a safety lock which shall always be locked when the source of radiation is not being used.

(2) The container in which a sealed source for radiography quality control is locked, and which serves as a working and transport container, shall be in compliance with requirements of Croatian standards, European standards or international harmonised standards, and especially with ISO 3999.

(3) The absorbed dose rate in the air at any accessible point on the surface of the container referred to in paragraph 1 of this Article shall not exceed 2 000  $\mu\text{Gy/h}$ , or be higher than 20  $\mu\text{Gy/h}$  at the distance of 1 m from any point on the surface of the container.

#### Article 96

A device with a sealed radioactive source for radiography quality control may be taken out of the storage space in which it is kept when not in use only by a worker with a work order for carrying out a certain activity, who shall sign a transport log for the sealed radioactive source when taking the device over. From the moment of taking over of the device with a sealed radioactive source until its return to its storage space, the worker shall assume responsibility for the source and for the implementation of safety measures during the transfer, transport and usage of the source.

#### Article 97

Only persons authorised for surveillance and keeping logs on sealed radioactive sources may be in possession of keys to working devices with a sealed radioactive source for radiography quality control, as well as keys for the storage space in which they are kept.

#### Article 98

When a sealed radioactive source for radiography quality control is used, at least two persons shall take part in the procedure; during the usage, these two persons shall not leave the place in which the procedure is being carried out.

#### Article 99

(1) A sealed radioactive source for radiography quality control shall be set in the working position exclusively with a special remote control device.

(2) Use of devices with a sealed radioactive source for radiography quality control is prohibited if the sealed radioactive source is being set in the working position without a remote control option.

#### Article 100

(1) Prior to the commencement of an operation involving a device with a sealed radioactive source for radiography quality control outside specially equipped premises or on work-sites, the irradiation point shall be selected in such a manner as to include already existing obstacles which may reduce exposure of workers; and in the course of operation, movable protective

screens shall be used, or a remote control device shall be placed in such a position that their exposure is as low as possible, making sure that it is below the prescribed limits.

(2) In the course of use of a sealed radioactive source for radiography quality control, the operating device shall have connectors that are long enough to ensure the necessary distance from the irradiation point.

(3) During operations outside specially equipped premises, the operation point shall be secured in such a manner that only exposed workers necessary for the operation performance have access to the exposed area.

#### Article 101

(1) A monitored area around the device with a sealed radioactive source for radiography quality control shall be surrounded by physical obstacles to block unauthorised access. On borders of the monitored area the dose rate shall not exceed 20  $\mu\text{Gy/h}$  during irradiation.

(2) No person shall be present in the controlled area during irradiation and only authorised workers who carry out radiography quality control procedure shall be allowed to stay and move in the supervised area.

(3) If a good overview of the work-site is ensured, light, sound, written or other clear signs of danger from radiation may be used instead of physical obstacles.

#### Article 102

(1) Borders of an exposed area as well as an adequate point from which irradiation will be operated shall be determined using a portable device for measuring radiation dose rate.

(2) Workers who perform imaging with a sealed radioactive source in a device for radiography quality control shall have, along with prescribed personal dosimeters, a portable device for measuring radiation dose rate.

#### Article 103

Upon the completed use of a sealed radioactive source in a device for radiography quality control, it shall be verified by a device for measuring the dose rate that the source is in the container, and the device shall then be locked.

#### Article 104

If a sealed radioactive source cannot be returned to the container using remote control, it shall be necessary to:

- a) delineate the work-site and deny access to all persons in the vicinity of the operation point;
- b) set a physical barrier at the point where the dose rate is 7.5  $\mu\text{Gy/h}$  at the most;
- c) inform the person responsible for ionising radiation protection about the incident;
- d) take all measures of ionising radiation protection according to the post-accident damage control plan which was adopted by a legal or natural person before obtaining an approval for use of a sealed radioactive source, and without delay inform thereof the State Institute for Radiation Protection as well as the sanitary inspector of the ministry in charge of health care.

#### Article 105

A sealed radioactive source shall be placed in a special carrier-needle with which it is set through connectors to the irradiation position using remote control. The carrier shall be inspected for radiation contamination before replacing the new sealed radioactive source.

#### Article 106

At the end of the connector by which a sealed radioactive source is set to the irradiation position there shall be a screen for limiting the useful beam of ionising radiation, which directs radiation to the inspection point.

#### Article 107

(1) On the surface of a device with a sealed radioactive source used for radiography quality control there shall be the permanently printed sign of danger from ionising radiation shown in Figure 1 of Annex II to this Ordinance, the chemical symbol of the radionuclide for which it is intended and the maximum permissible activity which may be set in the container.

(2) A device with a sealed radioactive source used for radiography quality control shall be accompanied by accurate data regarding activity of the sealed radioactive source at the moment of its usage. The data shall be determined for the purpose of planning irradiation either by means of an enclosed curve of the decay of radionuclides starting from a certain day or based on the calculation of the decay from the day when the activity was established.

#### Article 108

(1) Transfer of a sealed radioactive source from one container to another shall be performed exclusively with the use of special tools designed for such a transfer, and exclusively by authorised persons who are trained for the task.

(2) The transfer of a sealed radioactive source referred to in paragraph 1 of this Article shall be recorded so that it is known at all times which container contains a sealed radioactive source.

(3) For sealed radioactive sources in the situation stated in paragraph 1 of this Article it shall be necessary to apply for a permit for use issued by the State Institute for Radiation Protection, accompanied by a report and an opinion of an authorised, qualified technical service regarding the compliance with conditions laid out in the Act and this Ordinance.

#### 2.2 Sealed radioactive sources for level indicators, thickness meters, humidity meters and similar uses

#### Article 109

Devices with a sealed radioactive source which are used during a production process or during an automated production operation – thickness meters, altimeters, level indicators, density meters, humidity meters or similar devices – shall be resistant to environmental influences and shall preserve their integrity in all technological conditions for which they are designed.

#### Article 110

(1) The construction of devices and other technical solutions, the position of a sealed radioactive source in the device and the position of the device itself in a certain place in the technological process shall ensure that the absorbed radiation dose rate on the surface of those devices does not exceed 100  $\mu\text{Gy/h}$  and, at the distance of 1 m from any accessible point on the surface, does not exceed 20  $\mu\text{Gy/h}$ .

(2) The area around a device with a sealed radioactive source in premises where it is used in the process technology and in automated operation shall be marked with the sign of danger

from ionising radiation shown in Figure 1 of Annex II to this Ordinance, which is its integral part.

#### Article 111

The devices with sealed radioactive sources referred to in Article 109 of this Ordinance shall be repaired, cleaned and maintained only by persons trained for carrying out these tasks. Those devices shall, as a rule, be repaired in the same place where they were installed or in a special room in a maintenance facility.

##### 2.2.1 Thickness meters with a sealed radioactive source

#### Article 112

(1) The device shall be positioned so that no person may be directly exposed to the useful beam of radiation.

(2) The device shall have a screen that may be closed, if necessary. On the operating device there shall be an indicator as to whether the screen is closed.

##### 2.2.2 Level indicators with a sealed radioactive source

#### Article 113

(1) A container with a sealed radioactive source shall have a lock and a screen which can be closed, thus interrupting the useful beam of radiation. There shall be a clear indication on the container, as well as on the operating device, as to whether the screen is closed.

(2) The device shall have a built-in lock which can be locked in the closed position, but not in the open position.

#### Article 114

A sealed radioactive source shall be safely placed inside the container. The protective strength of the container shall ensure a dose rate lower than 7.5  $\mu\text{Gy/h}$  at the distance of 1 m.

#### Article 115

Repair or maintenance of level indicators shall be performed only by specially trained persons implementing all radiation protection measures.

##### 2.3 Installation containing a sealed radioactive source for sterilisation and preservation of foodstuffs and consumer goods using ionising radiation

#### Article 116

(1) An installation for sterilisation and preservation of foodstuffs and consumer goods using a sealed radioactive source of high activity (irradiation installation) shall be located in a separate building which complies with safety conditions for workers, other persons and the environment, and its construction shall have ensured that during the use of a sealed radioactive source there will be no radioactive contamination of the work premises and the environment.

(2) Potential accidents shall be reduced to a minimum with the use of automated and binary operating systems.

(3) Potential accidents shall be further prevented through the automation of technological procedures prescribed in detail, which may not be altered arbitrarily and which are adapted and inspected in the course of workers' training. There shall be written instructions for workers regarding all procedures.

#### Article 117

(1) In the course of operation no person shall be present in the room in which irradiation is taking place.

(2) Workers' entrance shall be protected with a door or a door and a maze in case of an installation with panoramic irradiation. The door shall be marked with a sign indicating danger from ionising radiation or with a warning regarding the presence of a radioactive source.

(3) A sealed radioactive source shall be in a safe position if the door is open, that is, opening of the door shall not be possible if the source is in the operating position.

(4) It shall be possible to open the door to the room with a sealed radioactive source from the inside at any point in time.

#### Article 118

(1) In a room with a sealed radioactive source for panoramic irradiation, but not in the direct beam, there shall be a built-in device for measuring ionising radiation, which is connected with the workers' entrance, and which by measuring the radiation level in the irradiation room shows whether the source is inside or outside the safe position. The device shall be connected to sound and light signals.

(2) At the distance of 1 m from any point on the surface of a container with a sealed radioactive source in a safe position the dose shall not exceed 20  $\mu\text{Gy/h}$  and at the distance of 5 cm from any point on the surface of the container it shall not exceed 200  $\mu\text{Gy/h}$ .

#### Article 119

(1) A sealed radioactive source shall be operated by remote control. Prior to the commencement of irradiation and before moving the sealed radioactive source from its safe position, light and sound signals shall be turned on and last long enough during the preparation stage, for all persons who happen to be in the irradiation room to exit.

(2) There shall be light indicators on the control desk which, by changing lights, indicate the position of the sealed radioactive source in the irradiation room.

(3) There shall be safety switches installed in the irradiation room, which are turned on in a simple manner so that a person who happens to be in the room may turn the source back to its safe position independently of the control desk.

#### Article 120

A sealed radioactive source shall be automatically returned to its safe position in case of a power failure in the installation that lasts longer than 10 seconds. In such a case entry into the irradiation room shall be allowed only with the use of a device for measuring the ionising radiation level.

#### Article 121

(1) A preparatory switch shall be installed in an irradiation room; this switch shall have to be turned on in order to be able to activate irradiation from the operating device. An authorised

worker shall enter and inspect the room before each turning of the main switch. Only then shall the worker turn the preparatory switch on, exit the room, close the entrance door, and then he/she may start the irradiation procedure with the main key.

(2) The switch referred to in paragraph 1 of this Article shall be connected to the main operating device so that it is not possible to move the sealed source from its safe position from the main control desk, unless the complete procedure referred to in paragraph 1 of this Article has been previously conducted.

(3) The main key on the operating device shall be the only key that is in use. A spare key shall be kept separately in the manager's office or in the safe and may be used only in accordance with specific instructions.

(4) It shall be made impossible for the main key to be taken out of the operating device until the sealed radioactive source has come in the safe position. The same key opens the entrance door to the irradiation room. This key shall be permanently attached to a portable radiation measuring device, so that the worker who opens the entrance door to the irradiation room must also carry the ionising radiation measuring device along with the key from which it shall never be separated.

#### Article 122

(1) If a sealed radioactive source is protected in a pool of water when not in use, access to that pool shall be made impossible by physical obstacles and it shall be locked with a key that only authorised workers have. That key shall be used only when there is a special need and with the authorisation from the management for the purpose of monitoring, repair or maintenance.

(2) Water level in the pool shall be monitored and maintained and any loss of water shall automatically be replenished.

(3) The conductivity shall not exceed 10 msimens/cm. A conductivity measuring device shall be in continuous operation and it shall maintain conductivity below the stated level.

#### Article 123

(1) A device for measuring ionising radiation level shall be installed at the drain of the pool used for demineralisation or decontamination, so as to monitor radioactive contamination of the pool water. If radioactive contamination of the water exceeds a certain prescribed limit, that opening shall automatically be closed.

(2) In case the device referred to in paragraph 2 of this Article is activated, the reason for its activation shall be checked by analysing the water for radioactive contamination.

(3) Prior to the commencement of the use of the pool, it shall be necessary to check whether it is watertight as well as to check the quality of its construction, which is to be maintained; this shall be confirmed by a special certificate in accordance with the Building Act.

#### Article 124

Absorbed dose rate shall not exceed 20  $\mu\text{Gy/h}$  at the distance of 30 cm from any point on the surface of the pool water when a source is in the safe position.

#### Article 125

(1) If transfer of an irradiation package to an irradiation room is carried out by an automatic system with a continuous conveyer belt, exit for packages shall have an installed device for measuring radiation to ensure that a sealed radioactive source is not displaced from the support and transported by the belt outside the room.

(2) Physical obstacles (wire fence) shall be put up between the sealed radioactive source and the conveyer belt for transportation of objects that are to be irradiated, to prevent contact with the source even if there is an accident.

#### Article 126

An irradiation installation must not operate if there are not at least two authorised workers in the control area.

### V RADIOACTIVE SOURCES IN COMMON OR PUBLIC USE

#### 1. General conditions

##### Article 127

(1) It is prohibited to perform activities through which radioactive substances are added to foodstuffs and consumer goods in accordance with special regulations.

(2) Installation of radioactive lightning-conductors is prohibited in the Republic of Croatia.

##### Article 128

Manufacturers, importers and suppliers shall print a label on consumer goods containing radionuclides above the levels set in this Ordinance, stating that:

- a) the consumer goods contain a radioactive substance;
- b) the minister in charge of health care has approved trade and use of the consumer goods in common use.

If appropriate, identical labels and notes shall also be printed on the packaging of products thus delivered.

##### Article 129

Manufacturers, importers and suppliers of consumer goods containing radionuclides above the levels set in this Ordinance shall, during delivery, enclose:

- a) instructions on use, servicing, repair and maintenance of the consumer goods;
- b) the type of radionuclide contained therein and its activity;
- c) the radiation dose from the radionuclide in the consumer goods and an assessment of the danger arising from their use;
- d) instructions on disposal after the cessation of the use of consumer goods.

#### 3. Smoke detectors with sealed radioactive sources

##### Article 130

(1) Sealed radioactive sources whose activity does not exceed 100 kBq per detector may be installed and used in smoke detectors with sealed radioactive sources.

(2) Sealed radioactive sources which have gaseous progeny shall not be used in smoke detectors.

##### Article 131

The absorbed dose rate at the distance of 10 cm from any point on the outer surface of a smoke detector with a sealed radioactive source shall not exceed 1 mGy/h

#### Article 132

- (1) Cleaning (dusting and degreasing) of sealed radioactive sources used in smoke detectors may be performed only by persons qualified for that activity.
- (2) Cleaning shall be performed exclusively using the products prescribed by the manufacturer.
- (3) Following taking a single swab, a swab from the base of the support shall not contain more than 0.5 % of the total activity of the sealed radioactive source.

#### Article 133

- (1) Malfunctioning, spare and other smoke detectors with a sealed radioactive source shall be kept in specific places monitored by persons responsible for monitoring ionising radiation sources.
- (2) Responsible persons, in the case of fire, theft or disappearance of a smoke detector with a sealed radioactive source, shall notify thereof the State Institute for Radiation Protection and a sanitary inspector of the ministry in charge of health care.

### VII TRANSITIONAL AND FINAL PROVISIONS

#### Article 134

Within thirty days from the entry into force of this Ordinance, a permit for use of a radioactive source must be obtained for all radioactive sources for which no such permit has been obtained; otherwise, the radioactive source must be stored in a storage place in accordance with a special regulation.

#### Article 135

On the date of the entry into force of this Ordinance, the Ordinance on the conditions and measures for protection against ionising radiation for carrying out activities with radioactive sources (OG 84/03 and 106/03) shall cease to have effect.

#### Article 136

This Ordinance shall enter into force on the eighth day after the day of its publication in the Official Gazette.

Class: 011-02/06-01/19  
Reg. No: 534-07-06-1  
Zagreb, 20 October 2006

Minister  
**Neven LJUBIČIĆ, Assistant Professor, MD, PhD, m.p.**

## ANNEX I

*Table 1*  
BORDER VALUES OF ACTIVITY CONCENTRATION AND RADIONUCLIDE  
ACTIVITY BELOW WHICH A PARTICULAR RADIONUCLIDE SHALL BE  
EXEMPTED FROM SUPERVISION

Radionuclide	Activity concentration (Bq/g)	Activity (Bq)
H-3	1 E+06	1 E+09
Be-7	1 E+03	1 E+07
C-14	1 E+04	1 E+07
O-15	1 E+02	1 E+09
F-18	1 E+01	1 E+06
Na-22	1 E+01	1 E+06
Na-24	1 E+01	1 E+05
Si-31	1 E+03	1 E+06
P-32	1 E+03	1 E+05
P-33	1 E+05	1 E+08
S-35	1 E+05	1 E+08
Cl-36	1 E+04	1 E+06
Cl-38	1 E+01	1 E+05
Ar-37	1 E+06	1 E+08
Ar-41	1 E+02	1 E+09
K-40	1 E+02	1 E+06
K-42	1 E+02	1 E+06
K-43	1 E+01	1 E+06
Ca-45	1 E+04	1 E+07
Ca-47	1 E+01	1 E+06
Sc-46	1 E+01	1 E+06
Sc-47	1 E+02	1 E+06
Sc-48	1 E+01	1 E+05
V-48	1 E+01	1 E+05
Cr-51	1 E+03	1 E+07
Mn-51	1 E+01	1 E+05
Mn-52	1 E+01	1 E+05
Mn-52m	1 E+01	1 E+05

Mn-53	1 E+04	1 E+09
Mn-54	1 E+01	1 E+06
Mn-56	1 E+01	1 E+05
Fe-52	1 E+01	1 E+06
Fe-55	1 E+04	1 E+06
Fe-59	1 E+01	1 E+06
Co-55	1 E+01	1 E+06
Co-56	1 E+01	1 E+05
Co-57	1 E+02	1 E+06
Co-58	1 E+01	1 E+06
Co-58m	1 E+04	1 E+07
Co-60	1 E+01	1 E+05
Co-60m	1 E+03	1 E+06
Co-61	1 E+02	1 E+06
Co-62m	1 E+01	1 E+05
Ni-59	1 E+04	1 E+08
Ni-63	1 E+05	1 E+08
Ni-65	1 E+01	1 E+06
Cu-64	1 E+02	1 E+06
Zn-65	1 E+01	1 E+06
Zn-69	1 E+04	1 E+06
Zn-69m	1 E+02	1 E+06
Ga-72	1 E+01	1 E+05
Ge-71	1 E+04	1 E+08
As-73	1 E+03	1 E+07
As-74	1 E+01	1 E+06
As-76	1 E+02	1 E+05
As-77	1 E+03	1 E+06
Se-75	1 E+02	1 E+06
Br-82	1 E+01	1 E+06
Kr-74	1 E+02	1 E+09
Kr-76	1 E+02	1 E+09
Kr-77	1 E+02	1 E+09
Kr-79	1 E+03	1 E+05
Kr-81	1 E+04	1 E+07
Kr-83m	1 E+05	1 E+12
Kr-85	1 E+05	1 E+04

Kr-85m	1 E+03	1 E+10
Kr-87	1 E+02	1 E+09
Kr-88	1 E+02	1 E+09
Rb-86	1 E+02	1 E+05
Sr-85	1 E+02	1 E+06
Sr-85m	1 E+02	1 E+07
Sr-87m	1 E+02	1 E+06
Sr-89	1 E+03	1 E+06
Sr-90*	1 E+02	1 E+04
Sr-91	1 E+01	1 E+05
Sr-92	1 E+01	1 E+06
Y-90	1 E+03	1 E+05
Y-91	1 E+03	1 E+06
Y-91m	1 E+02	1 E+06
Y-92	1 E+02	1 E+05
Y-93	1 E+02	1 E+05
Zr-93*	1 E+03	1 E+07
Zr-95	1 E+01	1 E+06
Zr-97*	1 E+01	1 E+05
Nb-93m	1 E+04	1 E+07
Nb-94	1 E+01	1 E+06
Nb-95	1 E+01	1 E+06
Nb-97	1 E+01	1 E+06
Nb-98	1 E+01	1 E+05
Mo-90	1 E+01	1 E+06
Mo-93	1 E+03	1 E+08
Mo-99	1 E+02	1 E+06
Mo-101	1 E+01	1 E+06
Tc-96	1 E+01	1 E+06
Tc-96m	1 E+03	1 E+07
Tc-97	1 E+03	1 E+08
Tc-97m	1 E+03	1 E+07
Tc-99	1 E+04	1 E+07
Tc-99m	1 E+02	1 E+07
Ru-97	1 E+02	1 E+07
Ru-103	1 E+02	1 E+06
Ru-105	1 E+01	1 E+06

Ru-106*	1 E+02	1 E+05
Rh-103m	1 E+04	1 E+08
Rh-105	1 E+02	1 E+07
Pd-103	1 E+03	1 E+08
Pd-109	1 E+03	1 E+06
Ag-105	1 E+02	1 E+06
Ag-110m	1 E+01	1 E+06
Ag-111	1 E+03	1 E+06
Cd-109	1 E+04	1 E+06
Cd-115	1 E+02	1 E+06
Cd-115m	1 E+03	1 E+06
In-111	1 E+02	1 E+06
In-113m	1 E+02	1 E+06
In-114m	1 E+02	1 E+06
In-115m	1 E+02	1 E+06
Sn-113	1 E+03	1 E+07
Sn-125	1 E+02	1 E+05
Sb-122	1 E+02	1 E+04
Sb-124	1 E+01	1 E+06
Sb-125	1 E+02	1 E+06
Te-123m	1 E+02	1 E+07
Te-125m	1 E+03	1 E+07
Te-127	1 E+03	1 E+06
Te-127m	1 E+03	1 E+07
Te-129	1 E+02	1 E+06
Te-129m	1 E+03	1 E+06
Te-131	1 E+02	1 E+05
Te-131m	1 E+01	1 E+06
Te-132	1 E+02	1 E+07
Te-133	1 E+01	1 E+05
Te-133m	1 E+01	1 E+05
Te-134	1 E+01	1 E+06
I-123	1 E+02	1 E+07
I-125	1 E+03	1 E+06
I-126	1 E+02	1 E+06
I-129	1 E+02	1 E+05
I-130	1 E+01	1 E+06

I-131	1 E+02	1 E+06
I-132	1 E+01	1 E+05
I-133	1 E+01	1 E+06
I-134	1 E+01	1 E+05
I-135	1 E+01	1 E+06
Xe131m	1 E+04	1 E+04
Xe-133	1 E+03	1 E+04
Xe-135	1 E+03	1 E+10
Cs-129	1 E+02	1 E+05
Cs-131	1 E+03	1 E+06
Cs-132	1 E+01	1 E+05
Cs-134m	1 E+03	1 E+05
Cs-134	1 E+01	1 E+04
Cs-135	1 E+04	1 E+07
Cs-136	1 E+01	1 E+05
Cs-137*	1 E+01	1 E+04
Cs-138	1 E+01	1 E+04
Ba-131	1 E+02	1 E+06
Ba-140*	1 E+01	1 E+05
La-140	1 E+01	1 E+05
Ce-139	1 E+02	1 E+06
Ce-141	1 E+02	1 E+07
Ce-143	1 E+02	1 E+06
Ce-144*	1 E+02	1 E+05
Pr-142	1 E+02	1 E+05
Pr-143	1 E+04	1 E+06
Nd-147	1 E+02	1 E+06
Nd-149	1 E+02	1 E+06
Pm-147	1 E+04	1 E+07
Pm-149	1 E+03	1 E+06
Sm-151	1 E+04	1 E+08
Sm-153	1 E+02	1 E+06
Eu-152	1 E+01	1 E+06
Eu-152m	1 E+02	1 E+06
Eu-154	1 E+01	1 E+06
Eu-155	1 E+02	1 E+07
Gd-153	1 E+02	1 E+07

Gd-159	1 E+03	1 E+06
Tb-160	1 E+01	1 E+06
Dy-165	1 E+03	1 E+06
Dy-166	1 E+03	1 E+06
Ho-166	1 E+03	1 E+05
Er-169	1 E+04	1 E+07
Er-171	1 E+02	1 E+06
Tm-170	1 E+03	1 E+06
Tm-171	1 E+04	1 E+08
Yb-175	1 E+03	1 E+07
Lu-177	1 E+03	1 E+07
Hf-181	1 E+01	1 E+06
Ta-182	1 E+01	1 E+04
W-181	1 E+03	1 E+07
W-185	1 E+04	1 E+07
W-187	1 E+02	1 E+06
Re-186	1 E+03	1 E+06
Re-188	1 E+02	1 E+05
Os-185	1 E+01	1 E+06
Os-191	1 E+02	1 E+07
Os-191m	1 E+03	1 E+07
Os-193	1 E+02	1 E+06
Ir-190	1 E+01	1 E+06
Ir-192	1 E+01	1 E+04
Ir-194	1 E+02	1 E+05
Pt-191	1 E+02	1 E+06
Pt-193m	1 E+03	1 E+07
Pt-197	1 E+03	1 E+06
Pt-197m	1 E+02	1 E+06
Au-198	1 E+02	1 E+06
Au-199	1 E+02	1 E+06
Hg-197	1 E+02	1 E+07
Hg197m	1 E+02	1 E+06
Hg-203	1 E+02	1 E+05
Tl-200	1 E+01	1 E+06
Tl-201	1 E+02	1 E+06
Tl-202	1 E+02	1 E+06

Tl-204	1 E+04	1 E+04
Pb-203	1 E+02	1 E+06
Pb-210*	1 E+01	1 E+04
Pb-212*	1 E+01	1 E+05
Bi-206	1 E+01	1 E+05
Bi-207	1 E+01	1 E+06
Bi-210	1 E+03	1 E+06
Bi-212*	1 E+01	1 E+05
Po-203	1 E+01	1 E+06
Po-205	1 E+01	1 E+06
Po-207	1 E+01	1 E+06
Po-210	1 E+01	1 E+04
At-211	1 E+03	1 E+07
Rn-220*	1 E+04	1 E+07
Rn-222*	1 E+01	1 E+08
Ra-223*	1 E+02	1 E+05
Ra-224*	1 E+01	1 E+05
Ra-225	1 E+02	1 E+05
Ra-226*	1 E+01	1 E+04
Ra-227	1 E+02	1 E+06
Ra-228*	1 E+01	1 E+05
Ac-228	1 E+01	1 E+06
Th-226*	1 E+03	1 E+07
Th-227	1 E+01	1 E+04
Th-228*	1 E+00	1 E+04
Th-229*	1 E+00	1 E+03
Th-230	1 E+00	1 E+04
Th-231	1 E+03	1 E+07
Th-nat		
(incl.Th-232)	1 E+00	1 E+03
Th-234*	1 E+03	1 E+05
Pa-230	1 E+01	1 E+06
Pa-231	1 E+00	1 E+03
Pa-233	1 E+02	1 E+07
U-230*	1 E+01	1 E+05
U-231	1 E+02	1 E+07
U-232*	1 E+00	1 E+03

U-233	1 E+01	1 E+04
U-234	1 E+01	1 E+04
U-235*	1 E+01	1 E+04
U-236	1 E+01	1 E+04
U-237	1 E+02	1 E+06
U-238*	1 E+01	1 E+04
U-natural	1 E+00	1 E+03
U-239	1 E+02	1 E+06
U-240	1 E+03	1 E+07
U-240*	1 E+01	1 E+06
Np-237*	1 E+00	1 E+03
Np-239	1 E+02	1 E+07
Np-240	1 E+01	1 E+06
Pu-234	1 E+02	1 E+07
Pu-235	1 E+02	1 E+07
Pu-236	1 E+01	1 E+04
Pu-237	1 E+03	1 E+07
Pu-238	1 E+00	1 E+04
Pu-239	1 E+00	1 E+04
Pu-240	1 E+00	1 E+03
Pu-241	1 E+02	1 E+05
Pu-242	1 E+00	1 E+04
Pu-243	1 E+03	1 E+07
Pu-244	1 E+00	1 E+04
Am-241	1 E+00	1 E+04
Am-242	1 E+03	1 E+06
Am-242m*	1 E+00	1 E+04
Am243*	1 E+00	1 E+03
Cm-242	1 E+02	1 E+05
Cm-243	1 E+00	1 E+04
Cm-244	1 E+01	1 E+04
Cm-245	1 E+00	1 E+03
Cm-246	1 E+00	1 E+03
Cm-247	1 E+00	1 E+04
Cm-248	1 E+00	1 E+03
Bk-249	1 E+03	1 E+06
Cf-246	1 E+03	1 E+06

Cf-248	1 E+01	1 E+04
Cf-249	1 E+00	1 E+03
Cf-250	1 E+01	1 E+04
Cf-251	1 E+00	1 E+03
Cf-252	1 E+01	1 E+04
Cf-253	1 E+02	1 E+05
Cf-254	1 E+00	1 E+03
Es-253	1 E+02	1 E+05
Es-254	1 E+01	1 E+04
Es-254m	1 E+02	1 E+06
Fm-254	1 E+04	1 E+07
Fm-255	1 E+03	1 E+06

\* Parent radionuclides and their progeny included in long-term balance are listed below:

Sr-90	Y-90
Zr-93	Nb-93m
Zr-97	Nb-97
Ru-106	Rh-106
Cs-137	Ba-137m
Ba-140	La-140
Ce-134	La-134
Ce-144	Pr-144
Pb-210	Bi-210, Po-210
Pb-212	Bi-212, Tl-208 (0.36), Po-212 (0.64)
Bi-212	Tl-208 (0.36), Po-212 (0.64)
Rn-220	Po-216
Rn-222	Po-218, Pb-214, Bi-214, Po-214
Ra-223	Rn-219, Po-215, Pb-211, Bi-211, Tl-207
Ra-224	Rn-220, Po-216, Pb-212, Bi-212, Tl-208(0.36), Po-212(0.64)
Ra-226	Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
Ra-228	Ac-228
Th-226	Ra-222, Rn-218, Po-214
Th-228	Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Th-229	Ra-225, Ac-225, Fr-221, At-217, Bi-213, Po-213, Pb-209
Th-nat	Ra-228, Ac-228, Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Th-234	Pa-234m
U-230	Th-226, Ra-222, Rn-218, Po-214
U-232	Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36),Po-212 (0.64)
U-235	Th-231
U-238	Th-234, Pa-234m
U-natural	Th-234, Pa-234m, U-234, Th-230, Ra-226, Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
U-240	Np-240m
Np-237	Pa-233
Am-242m	Am-242

Am-243      Np-239

## ANNEX II

*Figure 1*

INTERNATIONAL SYMBOL FOR RADIATION ISO 361

**Error! Unknown switch argument.**

**Figure 1**

REMARK: The symbol is red or black on a yellow background.

### ANNEX III

*Table 1*  
LEVELS OF DANGER

Equivalent activity	Level
Less than 50 Mbq	Low danger
50 to 50 000 MBq	Medium danger
More than 50 000 MBq	High danger

*Table 2*  
WEIGHTING FACTORS FOR PARTICULAR RADIONUCLIDES

Class	Radionuclide	Weighting factor
A	<sup>75</sup> Se, <sup>89</sup> Sr, <sup>125</sup> I, <sup>131</sup> I	100
B	<sup>11</sup> C, <sup>13</sup> N, <sup>15</sup> O, <sup>18</sup> F, <sup>51</sup> Cr, <sup>67</sup> Ga, <sup>99m</sup> Tc, <sup>111</sup> In, <sup>113m</sup> In, <sup>123</sup> I, <sup>201</sup> Tl	1.0
C	<sup>3</sup> H, <sup>14</sup> C, <sup>81m</sup> Kr, <sup>127</sup> Xe, <sup>133</sup> Xe	0.01

*Table 3*  
WEIGHTING FACTORS FOR TYPES OF OPERATIONS OR  
AREAS FOR CARRYING OUT OPERATIONS WITH RADIONUCLIDES

Type or area of operation	Weighting factor
Storing	0.01
Waste disposal	0.1
Scintigraphy with application of radiopharmacs at another place	
Waiting room	
Patient's bed (diagnostics)	
Diluting	1
Radionuclide application	
Scintigraphy with application of radiopharmacs in the same room	
Preparation of radiopharmacs, simple	

Patient's bed (therapy)	
Preparation of radiopharmacs, complex	10

#### ANNEX IV

### BASIC QUALITY REQUIREMENTS FOR DEVICES USED IN A NUCLEAR MEDICINE UNIT

*Table 1*  
LIMITS OF ALLOWED DEVIATIONS OF PARTICULAR PROPERTIES OF DEVICES USED IN NUCLEAR MEDICINE

No.	Inspected device	Inspected device property	Deviation limits	Inspection frequency		
				Daily	Monthly	Annually
1	ACTIVITY CALLIBRATOR	Accuracy	$\pm 5\%$	x	x	x
		Relative response in relation to the source of reference	$\pm 2-5\%$		x	x
		Linearity of response	$\pm 5\%$		x	x
		Repeatability	$\pm 5\%$		x	x
		Geometry	$\pm 2\%$			x
2	GAMMA CAMERA	Uniformity	$\pm 6 - 7\%$		x	x
		Linearity	Visual	x	x	x
		Relative sensitivity	$\pm 10\%$			x
		Energy separation	Min. 50 channels at FWHM			x
		Spatial separation	According to referent values		x	x

## ANNEX V

*Table 1*  
DERIVED LIMITS OF SURFACE RADIOACTIVE CONTAMINATION

Surface	Class the radionuclide belongs to <sup>1</sup>		
	A	B	C
	Bq cm-2		
Surfaces and equipment in a controlled area	30	300	3000
Surface of a person's body	3 (0,3)	30	300
Supervised areas and public areas, staff's clothing, hospital bedclothes	3	30	300

<sup>1</sup> For classification of radionuclides, see Annex III, Table 2

## ANNEX VI

*Table 1*  
RESTRICTIONS AND LIMITS OF THE EFFECTIVE DOSE FOR VARIOUS CATEGORIES OF PERSONS IRRADIATED BY PATIENTS WHO HAVE BEEN APPLIED RADIONUCLIDES FOR THERAPY PURPOSES AFTER DISCHARGE FROM HOSPITAL

	Restriction per procedure	Effective dose limits
Persons (except pregnant women) who take care of the patient and assist him/her (voluntarily)	5 mSv	-
Other persons in the household	1 mSv	5 mSv in 5 years
Certain members of the population	0.3 mSv	5 mSv in 5 years

## ANNEX VII

### BASIC QUALITY REQUIREMENTS FOR REMOTELY OPERATED DEVICES WITH 60Co RADIOACTIVE SOURCE USED FOR EXTERNAL RADIATION THERAPY (TELE THERAPY)

*Table 1*  
LIMITS OF PERMISSIBLE DEVIATIONS OF PARTICULAR PROPERTIES OF  
DEVICES WITH 60Co FOR EXTERNAL RADIATION THERAPY

No.	Inspected parameter	Inspected property	Deviation limits	Inspection frequency		
				Daily	Monthly	Annually
1	MECHANICAL ACCURACY	Isocentre of collimator rotation	2 mm diameter		x	x
		Isocentre of gantry rotation	3 mm diameter		x	x
		Isocentre of patient's bed rotation	2 mm diameter		x	x
		Matching of isocentres of: collimator, gantry and patient's bed	2 mm diameter		x	x
		Matching of mechanical isocentre and radiation field isocentre	2 mm diameter	x	x	x
		Congruity of laser with isocentre	$\pm 2$ mm from isocentre for each laser		x	x
2		RADIATION	Stability of output beam in isocentre	2% of referent value		x
	Stability of output beam considering gantry angle		2% of referent value		x	x
	Time switch accuracy		1%		x	x
	Congruity of light field and radiation		$\pm 2$ mm from edge		x	x

		field (10 x 10 cm)	of light field			
		Centring of light field and radiation field (10 x 10 cm)	± 2 mm from centre of light field		x	x

## ANNEX VIII

*Table 1*

HIGHEST RADIONUCLIDE ACTIVITY WHICH MAY BE APPLIED TO DIAL AND HANDS OF TIMEPIECES AND MEASURING INSTRUMENTS

Type of timepiece	Radionuclide	Total activity
Wrist and pocket watch	$^3\text{H}$	0.30 GBq
	$^{147}\text{Pm}$	0.60 MBq
Clock	$^3\text{H}$	0.40 GBq
	$^{147}\text{Pm}$	7.40 MBq
Special	$^3\text{H}$	0.90 GBq
	$^{147}\text{Pm}$	18.50 MBq