

THE MINISTRY OF HEALTH AND SOCIAL WELFARE

2770

Pursuant to Article 16 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 FOR APPLICATION OF IONISING RADIATION SOURCES IN MEDICINE AND DENTISTRY

I GENERAL PROVISIONS

Article 1

This Ordinance prescribes the conditions, manner and measures of protecting patients against ionising radiation during their exposure for diagnostic or therapy purposes in medicine and dentistry.

Article 2

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

1. *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.
2. *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.
3. *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.
4. *Quality control* is an integral part of quality assurance. It is a set of procedures (programming, coordination, 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.
5. *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.
6. *Systematic examination* is a procedure for early diagnosis of a disease in population groups at risk, by using radiological devices.

Article 3

- (1) A diagnostic procedure involving application of an ionising radiation source may be proposed (prescribed) by:
- a) a general practitioner,
 - b) a dentist,

- c) a medical doctor specialised in radiology,
 - d) a medical doctor specialised in nuclear medicine,
 - e) a medical doctor specialised in another appropriate clinical branch.
- (2) A proposed diagnostic procedure involving application of ionising radiation sources may be approved by:
- a) a medical doctor specialised in radiology for diagnostic procedures involving x-ray units,
 - b) a medical doctor specialised in nuclear medicine for diagnostic procedures involving radionuclides,
 - c) a dentist for diagnostic procedures in dentistry,
 - d) a medical doctor specialised in another branch of medicine, exclusively in the field of his/her specialisation.

Article 4

- (1) A therapy (treatment) with application of ionising radiation sources may be proposed (prescribed) by:
- a) a medical doctor specialised in radiotherapy and oncology,
 - b) a medical doctor specialised in radiology, who passed the postgraduate specialist exam by 1974,
 - c) a medical doctor specialised in nuclear medicine,
 - d) a medical doctor specialised in another clinical branch, in his/her field of specialisation.
- (2) A proposed therapeutic procedure with application of ionising radiation sources may be approved by:
- a) a medical doctor specialised in radiotherapy and oncology,
 - b) a medical doctor specialised in radiology, who completed the postgraduate specialist studies by 1974,
 - c) a medical doctor specialised in nuclear medicine,
 - d) a medical doctor specialised in another clinical branch, who performs practice in the area of nuclear medicine or radiotherapy.

Article 5

Procedures involving ionising radiation sources in interventional radiology may be performed by a medical doctor specialised in radiology.

Article 6

Irradiation for the purpose of diagnostics or treatment shall be directly performed exclusively by persons who have obtained appropriate professional qualifications of medical vocation and who have taken a special training course for the use of ionising radiation sources for medical purposes as well as for the implementation of measures for ionising radiation protection.

Article 7

- (1) A medical doctor or dentist who has proposed (prescribed) a diagnostic procedure or treatment with application of ionising radiation sources shall estimate medical justification of ionising radiation application for each patient, taking into consideration alternative procedures not involving the use of ionising radiation.
- (2) Medical justification of a diagnostic procedure or treatment involving ionising radiation sources shall be estimated according to the type and severity of the disease, the degree of immediate threat to the patient's life and health, the patient's age and sex, as well as potential detriment that the proposed procedure might cause to the patient.

Article 8

A medical doctor or dentist of appropriate specialisation, who approves a diagnostic or therapeutic procedure involving the use of ionising radiation sources, shall select the type of the ionising radiation source to be applied, as well as the type of the diagnostic or therapeutic procedure, in which process he/she shall determine:

- a) whether the patient's exposure is medically justified in terms of obtaining optimal diagnostic findings or achieving the intended effect of treatment, not achievable by an alternative diagnostic or therapeutic procedure involving no ionising radiation sources;
- b) conditions of procedure implementation, so as to ensure the lowest reasonably achievable irradiation of the patient which will provide diagnostic data of optimal quality, or the intended effects of the treatment.

Article 9

(1) A medical doctor or dentist of appropriate specialisation who approves a diagnostic or therapeutic procedure involving the use of ionising radiation sources may reject the implementation of a proposed diagnostic or therapeutic procedure if he/she estimates that they are not appropriate with regard to medical indicators stated in the referral slip and other enclosed medical documentation, and that they will not significantly contribute to the making of a correct diagnosis or that they will not have an intended therapeutic effect.

(2) A medical doctor or dentist referred in paragraph 1 of this Article shall give a written statement of reasons for rejecting implementation of the proposed diagnostic or therapeutic procedure.

Article 10

(1) The medical doctor of appropriate specialisation who approves a diagnostic procedure and the health professional who directly performs the diagnostic procedure shall warn a woman for whom there is a possibility of pregnancy in advance about the dangers arising from exposure to ionising radiation in a certain post-menstrual period due to possible pregnancy, and they shall determine whether requirements for further implementation of the diagnostic procedure have been unambiguously met.

(2) If pregnancy of a woman referred to in paragraph 1 of this Article cannot be excluded, only the medical doctor of appropriate specialisation who approves a diagnostic or therapeutic procedure may approve further implementation of the procedure involving the use of ionising radiation sources, if there are justified medical indicators for urgent application of that procedure.

(3) A written warning for women of childbearing age shall be displayed at a visible place in the waiting room, stating: «If you are or might be pregnant, be warned that ionising radiation may be harmful for the unborn child. Please contact our doctor for advice.»

(4) The health professional who performs a diagnostic procedure may, prior to the commencement of the procedure, request a woman's written statement that she is aware of risks of exposure in case of pregnancy or possible pregnancy.

Article 11

A diagnostic procedure involving the use of radioactive substances that are administered into the patient's body (hereinafter referred to as: radiopharmaceutical preparations) shall not be applied to pregnant and breastfeeding women, except when there are justified medical

indicators for urgent application of that procedure, according to the estimation of the medical doctor of appropriate specialisation who approves the procedure.

Article 12

(1) If a patient is referred to a repeated examination or treatment, available findings and data obtained during previous diagnostic examinations or therapeutic procedures, which had been performed by using ionising radiation sources, shall be used for estimation of justification of repeated exposure of the patient.

(2) The medical doctor of appropriate specialisation who approves a diagnostic or therapeutic procedure may reject the proposal to apply such a procedure if he/she estimates that repeated exposure of a patient to ionising radiation shall not result in new, more thorough or better diagnostic data or treatment effects, and he/she shall write an explanation of his/her rejection in the referral slip.

(3) With the purpose of urgent assistance to a patient and in any other clinically unambiguously justified case, when it is inappropriate to wait for findings and data obtained during previous diagnostic and therapeutic procedures, if they exist, because the patient's health and life may be endangered, a diagnostic procedure involving the use of ionising radiation sources may be implemented with an approval of a medical doctor of appropriate specialisation.

Article 13

(1) A health-service institution, a company conducting health-service activities or a private practitioner applying ionising radiation sources for diagnostic or therapeutic purposes shall establish and maintain a quality assurance programme adapted to the type, diversity and range of procedures carried out there. The purpose of the quality assurance programme is to prevent, discover and correct potential errors in diagnostic or therapeutic procedures.

(2) Persons entitled to approve, plan and implement a diagnostic or therapeutic procedure shall be familiar with the quality assurance programme referred to in paragraph 1 of this Article.

Article 14

(1) The quality assurance programme is an integral part of the act on the implementation of measures for ionising radiation protection accompanied by a programme of quality assurance and maintenance in relation to practices and ionising radiation sources, the plan of measures for preventing and eliminating possible consequences of an emergency situation, and the plan of disposal of radioactive waste, which shall be adopted by health-service institutions, companies conducting health-service activities or private practitioners in the process of obtaining a license for performing their practice involving ionising radiation sources.

(2) The quality assurance programme referred to in paragraph 1 of this Article shall contain the following components:

1. Appointed person responsible for the quality assurance programme implementation,
2. Content of the programme and outline of general quality assurance procedures,
3. Procedures and properties of the systems inspected in accordance with the quality programme,
4. Inspecting and measuring methods,
5. Inspecting and measuring frequency,
6. Measuring instruments and devices required to implement inspecting of individual properties of a system or procedure,

7. Competence and responsibility of persons assigned to implement individual inspections and measurements,
 8. Inspection forms for records that shall be kept,
 9. Tabular presentation of the prescribed inspecting and measurement programme,
 10. Tabular presentation of processed measurement results,
 11. Instructions for drawing up and keeping of reports on each inspection, which accurately, clearly and unambiguously show inspection results, remarks, observations, and all other necessary information.
- (3) Records and reports on inspection of certain properties which are used to control certain properties within the frameworks of the quality assurance programme shall be kept for at least twelve months, or until the independent audit referred to in Article 15 of this Ordinance has been performed.

Article 15

- (1) The health-service institution, company conducting health-service activities or private practitioner referred to in paragraph 1 of Article 14 of this Ordinance shall engage an authorised, qualified technical service to perform an independent audit of its quality assurance programme regarding the use of ionising radiation sources.
- (2) The independent audit referred to in paragraph 1 of this Article shall comprise:
- control of documentation relating to the use of ionising radiation sources,
 - control of reports on inspections and inspection results performed so as to maintain the quality level in accordance with the quality assurance programme referred to in Article 13 of this Ordinance,
 - inspecting of properties of ionising radiation sources, so as to verify whether they comply with basic requirements significant for the quality and reliability of diagnostic information and therapeutic effects.
- (3) After each audit referred to in paragraph 1 of this Article, a report shall be drawn up, describing the measuring conditions, measuring instruments used, and measurement results, as well as an opinion regarding the established situation and the necessity to take measures for maintaining the system efficiency and measures for its improvement.

Article 16

- (1) The quality programme audit referred to in Article 14 of this Ordinance may be:
- the first one,
 - periodical,
 - exceptional.
- (2) The first quality programme audit is the obligatory first control of particular properties or procedures, for determining reference values of parameters and factors significant for achieving optimal system efficiency.
- (3) A regular quality programme audit is periodical control of maintenance of reference values of parameters and factors determined by the first evaluation; it shall be carried out at least once over a period of twelve months.
- (4) An extraordinary quality programme audit means every quality system control carried out as necessary, which is neither the first nor a periodical one.

Article 17

An ionising radiation source used for implementation of a diagnostic or therapeutic procedure shall be etaloned (calibrated) so that for each selection of parameters a dose imparted to the patient in the course of the procedure may be estimated.

Article 18

(1) The management of a health-service institution or a company conducting health-service activities, or a responsible person in a private practitioner's office that applies ionising radiation sources for diagnostic or therapeutic purposes shall conduct a special investigation in case of an emergency in which a patient took part.

(2) The following cases are deemed the emergency referred to in paragraph 1 of this Article:

a) Wrong irradiation due to:

- use of a wrong ionising radiation source,
- radiation application to a wrong patient or wrong tissue,
- wrong dose has been delivered or the dose has been delivered in a wrong manner;

b) A pregnant woman has been exposed;

c) Exposure required for obtaining diagnostic information with recommended parameters for a diagnostic procedure systematically exceeds the usual or recommended doses for the same type of diagnostic procedure;

d) In the course of exposure, the device broke down, which caused excessive irradiation of a patient or possible excessive irradiation of a patient.

Article 19

In the emergency situations referred to in Article 18 of this Ordinance, it shall be necessary to take the following steps:

a) estimate the dose administered to the patient during the incident,

b) take measures so as to prevent similar incidents in the future,

c) draw up a register and a report and submit them to the ministry in charge of health care and to the State Institute for Radiation Protection,

d) inform the patient and his/her elected practitioner about the incident.

II X-RAY DIAGNOSTICS

Article 20

Diagnostic procedures involving an x-ray unit shall be implemented under supervision of a medical doctor specialised in radiology, a dentist for dental imaging, or a medical doctor specialised in another branch of medicine, who is responsible for the correctness of the implemented procedure and for the application of measures for protecting the patient against unnecessary exposure.

Article 21

(1) Systematic preventive imaging of children's hips is not medically justified unless there are clear medical indicators for each individual patient.

(2) Whenever possible, due to the nature of the diagnostic procedure, means of immobilisation shall be used when children are being examined.

Article 22

(1) Systematic examinations may be implemented only for certain population groups, for which there is an increased risk of disease.

(2) Systematic examinations may be performed exclusively by x-ray imaging, upon a previously obtained approval of a minister in charge of health care.

(3) For each systematic examination, the minister in charge of health care shall, at the proposal of the director of the State Institute for Radiation Protection, determine additional requirements for the equipment and staff.

Article 23

(1) Systematic preventive breast imaging for women up to the age of 40 without clear medical indicators for each individual patient shall not be deemed medically justified exposure.

(2) Paragraph 1 of this Article does not refer to women noted for increased risk of illness.

(3) Women who are 40 to 49 years old are recommended to undergo preventive breast imaging once in two years, with the purpose of early and timely diagnosis of the breast cancer.

(4) Women over the age of 50 are recommended to undergo preventive breast imaging with the purpose of early and timely diagnosis of the breast cancer once a year.

Article 24

Breast imaging (mammography) may be performed exclusively by special x-ray unit intended for that purpose.

Article 25

(1) X-ray units with six or more rectifiers may be used for diagnostic purposes.

(2) Exceptionally for dental imaging, for imaging by mobile x-ray units in patients' rooms and fluoroscopy in operating theatres, x-ray units with less than six rectifiers may be used for diagnostic purposes.

Article 26

X-ray fluoroscopes shall have an electronic image amplifier and a television chain.

Article 27

(1) Mobile x-ray fluoroscopes may be used only in operating theatres.

(2) Mobile x-ray units used only for imaging may be used exclusively in patients' rooms and operating theatres, if it is inappropriate to carry or transport a patient to a stationary x-ray unit.

(3) When using a mobile x-ray unit, appropriate protective measures for workers and other persons in the vicinity of the place of usage shall be applied.

Article 28

(1) While implementing a diagnostic procedure, protective means for reduction of exposure of the patient's body parts which are not being examined shall be used, regardless of the procedure that is being implemented, unless the application of such means hinders proper implementation of the diagnostic procedure.

(2) Protection of the thyroid gland, the lens of the eye, ovaries or testes and blood-forming organs of a patient shall be especially provided using protective measures with implementation of appropriate protective means.

(3) Protective means used for protection of a patient shall have protective power equivalent to at least 0.5 mm thick lead.

Article 29

Pregnant women, women for whom there is a possibility of pregnancy and persons under the age of 18 shall not support a patient during x-ray examination.

Article 30

(1) A health professional who directly carries out a diagnostic procedure using a device for restricting the radiation field, which is installed on the opening of the housing of an x-ray tube for transmitting the useful x-ray beam, shall reduce the cross section of the useful x-ray beam at the place of its entering the patient's body to the size which enables achieving of the expected quality of diagnostic image, not exceeding the size of the entrance surface of an electronic image amplifier or a cassette.

(2) The provision of paragraph 1 of this Article shall not apply to x-ray units for dental imaging.

Article 31

(1) Imaging of teeth and jaws may be performed only by a special x-ray unit intended for that purpose.

(2) Persons undergoing dental imaging shall be protected by an apron or a shield with protective power of at least 0.25 mm lead equivalence.

Article 32

(1) For imaging and target imaging by an x-ray unit, cassettes with amplifying rare earth screens and films of optimal sensitivity in accordance with the nature of diagnostic procedure shall be used.

(2) In the premises where an x-ray unit for imaging is used, a sufficient number of cassettes of all sizes with amplifying rare earth screens shall be at workers' disposal.

(3) Along with a certain type of screen in a cassette, only the appropriate type of compatible films, as recommended by the manufacturer, shall be used.

(4) The entrance surface of cassettes for imaging and target imaging shall be made of low absorbing x-ray radiation materials (plastics, carbon fibres).

Article 33

(1) Quality inspection of an x-ray unit used for diagnostics, with the aim of ensuring the minimum possible exposure of a patient, shall be performed by an authorised, qualified technical service at the request of a deliverer, prior to delivery of the x-ray unit to the end user, and after the replacement of the x-ray tube or any other modifications of the x-ray unit which may effect the diagnostic information quality.

(2) The deliverer of an x-ray unit shall submit the results of the inspection referred to in paragraph 1 of this Article to the end user. Those results serve as reference values for periodical inspections.

(3) Periodical quality inspection of an x-ray device and a film developing system shall be ensured by the end user within prescribed time intervals.

(4) Properties, deviation limits for certain parameters and properties that are inspected, manner and intervals of inspection are determined by the Ordinance on the conditions and measures for protection against ionising radiation for carrying out activities involving x-ray units, accelerators, and other devices generating ionising radiation.

Article 34

(1) Recommended (reference) values of parameters and imparted doses for the implementation of a certain diagnostic procedure are listed in Table 1 of the Annex to this Ordinance, which is its integral part.

(2) The recommended values listed in Table 1 are not mandatory values for a diagnostic procedure which shall be achieved by etaloning (calibrating), but they shall be deemed guidelines ensuring optimal performance for a typical adult patient. For each individual patient, especially for children, the age, constitution and weight of the person shall be taken into account while planning and preparing a diagnostic procedure.

Article 35

(1) For each diagnostic procedure performed by a certain x-ray unit, the appropriate set of relevant data, on the basis of which the dose received by the patient during the examination may be estimated, shall be recorded into the patient's examination report.

(2) The relevant set of data referred to in paragraph 1 of this Article for each individual irradiation shall be as follows:

1. X-ray tube voltage;
2. Current and exposure time or current-time product;
3. Total filtration of x-ray radiation;
4. Focus-skin distance at the point of entrance of x-rays;
5. Projection: AP – from the front, PA – from the back, L – lateral;
6. Focus size: small or large;
7. Slice thickness and scan number for computed tomography.

(3) If an x-ray unit is etaloned (calibrated) so that for each set of data referred to in paragraph 2 of this Article the dose received by the patient during the examination may be estimated, or if an instrument for measuring the absorbed dose which enters the patient's body is installed into an x-ray unit, the measured dose shall, along with other data, be entered into the x-ray examination report.

III APPLICATION OF OPEN IONISING RADIATION SOURCES IN MEDICINE

Article 36

(1) Radionuclides shall be administered to the patient's body in the form of radiopharmaceutic preparations.

(2) A radiopharmaceutic preparation shall meet the requirements prescribed by the Act on Medicinal Products and Medical Devices and regulations adopted on the basis of that Act.

Article 37

(1) The type and activity of a radiopharmaceutic preparation which is to be administered to the patient's body for the purpose of a certain diagnostic procedure or therapy shall be determined by a medical doctor specialised in nuclear medicine or a medical doctor specialised in another branch of medicine, who is trained to apply radionuclides according to the requirements prescribed by this Ordinance.

(2) Activity of the radiopharmaceutic preparation shall be determined on the basis of calculations of the required radiation dose and of the dose measurement, in which process the following shall be done:

1. Ensure the least possible level of patient's exposure to ionising radiation from administered radionuclides, which is sufficient to achieve the diagnostic or therapeutic purpose;

2. Take into account the patient's weight and age, as well as special requirements if the patient is a child or person with organ malfunction;
3. In medical records, check findings of previous procedures involving the use of radionuclides, if there are any;
4. Follow instructions on good radiopharmaceutical practice during the application of radionuclides for diagnostic or therapeutic purposes.

Article 38

Proposed activities and corresponding doses of radiopharmaceutical preparations which correspond to those activities of radionuclides applied in most frequently used diagnostic and therapeutic procedures are listed in Table 2 of the Annex to this Ordinance, which is its integral part.

Article 39

- (1) The activity of a radiopharmaceutical preparation required for implementation of a diagnostic or therapeutic procedure may be determined and measured only by a person who is professionally trained to perform that task.
- (2) Devices for measuring activity or radiation doses, which are used for purposes of diagnostic or therapeutic procedures in nuclear medicine, shall comply with metrology regulations.

Article 40

- (1) Radiopharmaceutical preparations shall be administered to the body under supervision of a medical doctor specialised in nuclear medicine or a medical doctor specialised in another branch of medicine, who is trained to apply radionuclides according to the requirements prescribed by this Ordinance.
- (2) A medical doctor responsible for the implementation of administration of radionuclides shall especially take care:
 1. that the appropriate radiopharmaceutical preparation and its activity has been applied,
 2. that the manner has been applied in which entry of radionuclides in organs which are not examined is disabled in the highest reasonably achievable degree and that accelerated secretion of radionuclides has been stimulated, provided that the course of the diagnostic or therapeutic procedure is not endangered thereby.

Article 41

- (1) Control of essential properties of devices used for measuring activity, radiation doses and other parameters essential for obtaining diagnostic information or therapeutic effect, as well as appropriate procedures in the course of performing practices involving open radioactive sources in line with the established quality assurance programme, with the aim of achieving the least possible exposure of a patient, shall be provided by a health-service institution, a company conducting health-service activities or a private practitioner with an approval to perform practices involving open radioactive sources.
- (2) Characteristics, deviation limits for certain inspected parameters and inspection conditions are determined by the Ordinance on the conditions and measures for protection against ionising radiation protection for carrying out activities with radioactive sources.

Article 42

(1) For each diagnostic or therapeutic procedure carried out by administration of a certain radionuclide to the patient's body, the relevant set of relevant data, on the basis of which the dose received by the patient during the procedure may be estimated, shall be entered into the patient's medical record.

(2) The relevant set of data referred to in paragraph 1 of this Article for each procedure shall comprise:

1. Type of the radionuclide and the chemical compound in which it is used;
2. Activity or concentration of preparation administered to the patient's body;
3. Site and manner of administration;
4. Target organ;
5. Other relevant data.

IV APPLICATION OF IONISING RADIATION SOURCES FOR THERAPY

Article 43

(1) A therapy involving ionising radiation may be carried out only in accordance with the Radiation Protocol which establishes the manner and frequency of dose administration to the patient, the dose amount, the method of calculating the required dose for a certain test, the ionising radiation type and energy, entries and record keeping, as well as appropriate dose measuring.

(2) The Radiation Protocol, drawn up in accordance with the best clinical practice in line with international standards and recommendations for therapy involving ionising radiation sources, in the written form, shall be available to all workers in a health-service institution or a private practitioner's office who are authorised to plan or implement a therapy involving ionising radiation sources.

Article 44

(1) A therapy carried out by using an x-ray unit, accelerator or a sealed radioactive source may be carried out only if the radiation field topography for the planned procedure has been previously determined for each patient.

(2) For planning and preparation of a therapy involving an accelerator or remotely controlled devices with sealed radioactive high activity sources, special x-ray units (simulators), other devices, other tools and means shall be used.

(3) By using the devices and tools referred to in paragraph 2 of this Article, the irradiation procedure shall be simulated and the site and manner of irradiation, as well as preconditions for proper implementation of the therapeutic procedure, shall be determined.

Article 45

The manner and procedure of treatment using an x-ray unit, accelerator or a sealed radioactive source shall ensure the highest possible benefit of the treatment, with as low as reasonably achievable exposure of a patient, especially taking care to avoid unduly exposure of the patient's healthy tissues.

Article 46

The radiation plan in a therapeutic procedure for an individual patient shall be determined by a medical doctor specialised in radiotherapy, in co-operation with a medical physicist.

Article 47

For a therapeutic procedure carried out by using an x-ray unit, accelerator or a sealed radioactive source, the dose received by the patient during irradiation shall be entered into the medical record; if required, the appropriate set of relevant data, on the basis of which the dose received by the patient during the examination may be estimated, depending on the type of applied ionising radiation source, shall also be entered into the medical record.

Article 48

- (1) An x-ray unit, accelerator or a sealed radioactive source shall be etaloned (calibrated) so that the dose received by the patient during the therapy may be determined for each selection of parameters determined by the radiation plan.
- (2) Calibration of ionising radiation sources used in therapy shall be carried out by using appropriate dosimeters and appropriate phantoms.
- (3) Calibration shall be carried out by a medical physicist at least once a month, and records on calibration shall be kept for at least twelve months.
- (4) Ionising radiation measuring instruments used during radiotherapy for calibration or for determining exposure levels in the surroundings of an ionising radiation source shall comply with requirements of metrology regulations.

Article 49

- (1) So as to ensure the lowest possible exposure of patients, the quality control of an x-ray unit, accelerator or a sealed radioactive source used for therapy shall be ensured by the importer, supplier, legal or natural person that installs those devices, prior to the commissioning of the x-ray unit, accelerator or sealed radioactive source for therapy to the end user.
- (2) The importer, supplier, legal or natural person that installs an x-ray unit, accelerator or a radioactive source shall submit results of the inspection referred to in paragraph 1 of this Article to the end user, along with other documents. Those results serve as reference values for periodical inspections.
- (3) Periodical quality inspections of an x-ray unit, accelerator or a sealed radioactive source for therapy shall be ensured by a health-service institution, a company conducting health-service activities or a private practitioner with a licence for therapy involving ionising radiation sources.
- (4) In line with the quality assurance programme referred to in Article 13 of this Ordinance, as well as the first inspection referred to in paragraph 1 of this Article, a medical physicist carries out periodical – daily, weekly, and monthly – inspections of relevant parameters and keeps records on results of those inspections.
- (5) Properties, deviation limits for certain inspected parameters and inspection conditions are determined by the Ordinance on the conditions and measures for protection against ionising radiation for carrying out activities involving x-ray units, accelerators, and other devices generating ionising radiation and the Ordinance on the conditions and measures for protection against ionising radiation protection for carrying out activities with radioactive sources.

VI TRANSITIONAL AND FINAL PROVISIONS

Article 52

Health-service institutions, companies conducting health-service activities, and private health professionals that use ionising radiation sources for diagnostic purposes or treatment, and that do not comply with requirements prescribed by this Ordinance on the day of its entry into

force, shall be obliged to harmonise their work with the provisions of this Ordinance within one year from the entry into force of this Ordinance.

Article 53

On the date of the entry into force of this Ordinance, the Ordinance on conditions for ionising radiation sources use in medicine and dentistry (Official Gazette 113/99) shall cease to have effect.

Article 54

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

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Zagreb, 20 October 2006

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

Table 1
RECOMMENDED (REFERENCE) VALUES OF ABSORBED DOSES FOR MOST FREQUENTLY USED DIAGNOSTIC PROCEDURES INVOLVING X-RAY UNITS IN MEDICINE FOR A TYPICAL ADULT PATIENT "P"

I Radiography

Examination		Entrance surface absorbed dose per image (mGy) ^a
Lumbar spine	AP	10
	L	30
	LSJ	40
Stomach, intravenous urography and cholecystography	AP	10
Pelvis	AP	10
Hip joints	AP	10
Lungs	PA	4
	L	15
Thoracic spine	AP	7
	L	20
Dental	Periapical	7
Skull	AP	5
	PA	5
	L	3

"P" Patient with average weight of 70 kg

PA Posterior-anterior projection (entry of radiation from the patient's back)

LAT Lateral projection (radiation entrance from the patient's side)
 LSJ Lumbar-sacral joint projection
 AP Anterior-posterior projection (radiation entrance from the patient's front)

^a In the air, with backscatter. Values of the absorbed dose for a conventional film-screen combination and relative rate of 200. For high rate film-screen combinations (400-600), dose values should be 2 to 3 times lower.

II Computed tomography

Examination	Multiple scan average dose (mGy) ^b
Head	50
Lumbar spine	35
Abdomen (stomach)	25

^b Derived from the measurement on the rotation axis in a water equivalent phantom, length: 15 cm, diameter: 16 cm (for head) and 30 cm (for lumbar spine).

III Mammography

Average glandular dose per cranio-caudal projection ^c
1 mGy (without grid)
3 mGy (with grid)

^c Determined for a 4.5 mm thick compressed breast consisting of 50% of glandular and 50% of adipose tissue, with the use of an amplifying screen with molybdenum focus and molybdenum filter of the x-ray tube.

IV Fluoroscopy

Mode of operation	Absorbed dose rate on the surface of a patient (mGy/s) ^d
Normal	25
High level of entrance dose ^e	100

^d In the air with backscatter.

^e For x-ray fluoroscopes that have an optional high dose rate level operational mode, e.g. for intervention radiology.

Table 2

RECOMMENDED (REFERENCE) VALUES OF ACTIVITY OF INDIVIDUAL TYPES OF RADIONUCLIDES USED FOR DIAGNOSTICS INVOLVING OPEN SOURCES IN NUCLEAR MEDICINE FOR A TYPICAL ADULT PATIENT

Procedure	Radio-nuclide	Chemical compound ^a	Highest usual activity per procedure (MBq) ^b
Bones			
Bone examination	^{99m} Tc	Phosphonate and Phosphate compounds	600
Bone examination using single photon emission computed tomography (SPECT)	^{99m} Tc	Phosphonate and Phosphate compounds	800
	^{99m} Tc	Labelled colloids	400

Brain			
Brain examination (static)	^{99m} Tc	TcO ₄	500
	^{99m} Tc	Diethyltriaminopentacetic acid (DTPA), gluconate and glucoheptonate	500
Brain examination (SPECT)	^{99m} Tc	TcO ₄	800
	^{99m} Tc	Diethyltriaminopentacetic acid (DTPA), gluconate and glucoheptonate	800
	^{99m} Tc	Exsametazine	800 (500)
Cerebral blood flow	¹¹³ Xe	Isotonic sodium chloride solution	400
	^{99m} Tc	Hexamethylpropylene amine oxime HM-PAO	500
Cisternography	¹¹¹ In	DTPA	40
Lacrimal	^{99m} Tc	TcO ₄	4
Lacrimal drainage	^{99m} Tc	Labelled colloid	4
Thyroid gland			
Thyroid gland examination	^{99m} Tc	TcO ₄	200
	¹²³ I	I -	20
Thyroid gland metastases (after ablation)	¹³¹ I	I -	400
Parathyroid gland examination	²⁰¹ Tl	Tl ⁺ , chloride	80
Lungs			
Lung ventilation imaging	^{81m} Kr	Gas	6000
	^{99m} Tc	DTPA-aerosols	80
Lung ventilation examination	¹³³ Xe	Gas	400
	¹²⁷ Xe	Gas	200
Lung perfusion imaging	^{81m} Kr	Aquaeous solution	6000
	^{99m} Tc	Human albumin (macroaggregates or microspheres)	100
Lung perfusion imaging (venography)	^{99m} Tc	Human albumin (macroaggregates or microspheres)	160
Lung perfusion examination	¹³³ Xe	Isotonic solution	200
	¹²⁷ Xe	Isotonic chloride solution	200
Lung imaging (SPECT)	^{99m} Tc	Macroaggregated albumin (MAA)	200
Liver and spleen			
Liver and spleen imaging	^{99m} Tc	Labelled colloid	80
Functional biliary system imaging	^{99m} Tc	Iminodiacetates and equivalent agents	150
Spleen imaging	^{99m} Tc	Labelled denaturated erythrocytes	100
Liver imaging (SPECT)	^{99m} Tc	Labelled colloid	200
Cardiovascular examinations			

Examination of first pass blood flow	^{99m} Tc	TcO ₄	800
	^{99m} Tc	DTPA	800
	^{99m} Tc	Microaggregated globulin 3	400
Blood pool examination	^{99m} Tc	Human albumin complex	40
Cardiac and vascular imaging/ probe examinations	^{99m} Tc	Human albumin complex	800
	^{99m} Tc	Labelled normal red blood cells	800
Myocardial examination	^{99m} Tc	Phosphonate and phosphate compounds	600
Cardiac imaging	^{99m} Tc	Isonitriles	300
		201mTl Tl + chloride	100
Myocardial examination (SPECT)	^{99m} Tc	Phosphonate and phosphate compounds	800
	^{99m} Tc	Isonitriles	600
Stomach, gastrointestinal tract			
Imaging of stomach / salivary glands	^{99m} Tc	TcO ₄	40
Imaging of Meckel's diverticulum	^{99m} Tc	TcO ₄	400
Gastrointestinal bleeding	^{99m} Tc	Labelled colloid	400
	^{99m} Tc	Labelled red blood cells	400
Oesophagus transit and reflux	^{99m} Tc	Labelled colloid	40
	^{99m} Tc	Non-absorbable compounds	40
Gastric emptying	^{99m} Tc	Non-absorbable compounds	12
	¹¹¹ In	Non-absorbable compounds	12
	^{113m} In	Non-absorbable compounds	12
Kidneys, urinary system and adrenal glands			
Renal imaging	^{99m} Tc	Dimercaptosuccinic acid	160
Renography	^{99m} Tc	DTPA, gluconate and glucoheptonate	350
	^{99m} Tc	MAG 3	100
	¹²³ I, ¹³¹ I	O-iodohippurate	20, 10
Adrenal examination	⁷⁵ Se	Selenorcholesterol	8
	¹³¹ I	Norcholesterol	40
Other examinations			
Imaging of tumour or ulcer (abscess)	⁶⁷ Ga	Citrate	300
	²⁰¹ Tl	Chloride	100
Tumour imaging	^{99m} Tc	Dimercaptosuccinic acid	400
Neuroectodermal tumour imaging	¹²³ I	Meta-iodo-benzyl guanidine	400
	¹³¹ I	Meta-iodo-benzyl guanidine	20
Lymph node imaging	^{99m} Tc	Labelled colloid	80
Ulcer (abscess) imaging	^{99m} Tc	Labelled leukocytes	400
	¹¹¹ In	Labelled leukocytes	20

