Pursuant to Article 16(1) of the Law on Radiation and Nuclear Safety in Bosnia and Herzegovina ("Official Gazette of BiH" 88/07) and Article 61(2) of the Law on Administration ("Official Gazette of BiH" 32/02 and 102/09), the director of the State Regulatory Agency for Radiation and Nuclear Safety issues:

# REGULATION
# on the ionizing radiation protection in medical exposure

## PART I – GENERAL PROVISIONS

## CHAPTER I – INTRODUCTORY PROVISIONS

### Article 1
### (Subject)

(1) This regulation lays down the main principles of radiation protection of individuals in relation to medical exposure; responsibilities and obligations of licensees, including quality assurance programs; rules, measures and organization of the radiation protection in diagnostic radiology, nuclear medicine, and radiotherapy.

(2) This regulation shall apply to the following medical exposures:

a) the exposure of patients as part of their diagnostic procedure or treatment,

b) the exposure of individuals as part of regular occupational health surveillance,

c) the exposure of individuals as part of health screening programs,

d) the exposure of healthy individuals or patients voluntarily participating in medical or biomedical diagnostic or therapeutic research programs

e) the exposure of individuals as part of medico-legal procedure.

(3) This regulation shall also apply to exposures of the individuals who, other than as part of their occupation, knowingly and willingly help in the support and comfort of individuals undergoing medical exposure.

### Article 2
### (Objective)

The objectives of this regulation are:

a) radiation protection at the radiodiagnostic departments through establishing the quality control criteria that ensure the quality of radiological images and keep doses for patients, staff, and general public at the lowest possible levels,

b) establishment and implementation of the justification and optimization principles in the application of radiopharmaceuticals,

c) establishment of quality control criteria in nuclear medicine,

d) establishment of radiation protection measures for patients and also for other individuals regarding the radiation emitted by patients,

e) establishment of quality criteria in radiotherapy to optimize radiotherapy treatment in all health-care institutions that have radiotherapy departments.

**Article 3**
**(Definitions)**

(1) The terms and expressions, as used in this regulation, mean:

a) **Diagnostic reference level**: A dose level in medical radiodiagnostic practices or in the case of applying radiopharmaceuticals; activity levels for typical examinations for groups of standard-sized patients or standard phantoms for broadly defined types of equipment. These levels are expected not to be exceeded during standard procedures when an appropriate practice regarding diagnostic and technical performance is applied.

b) **Patient dose**: The dose received by the patient or another individual undergoing medical exposure.

c) **Patient dosimetry**: The dosimetry concerning the patient or another individual undergoing medical exposure.

d) **Clinical audit**: A systematic examination or review of medical radiological procedures with the aim of improving the quality and the outcome of patient care through structured review whereby radiological practices, procedures and results are compared with established standards for good medical radiological procedures, with modification of practices where indicated and application of new standards if necessary.

e) **Clinical responsibility**: Responsibility of practitioners regarding individual medical exposures, with the following important matters: justification; optimization; clinical evaluation of outcomes; cooperation with other specialists and the staff, depending on practical aspects in a given situation; if appropriate, obtaining information of previous examinations; giving existing radiological information and/or records to other medical doctors, as required; giving information on the risk of ionizing radiation to patients and other involved individuals, as appropriate.

f) **Quality control**: Part of quality assurance. The set of actions (programming, coordination, implementation) carried out with the intention to maintain or improve quality. It covers monitoring, evaluation and maintenance at required levels of all equipment characteristics that can be defined, measured, and controlled.

g) **Quality criteria:** The set of actions and parameter values serving to consider a procedure, document or service as appropriate in relation to a set goal.

h) **Individual detriment**: Clinically observable immediate or delayed detrimental effects that are expressed in individuals or their descendants. If the effects are late or delayed, it implies a probability rather than a certainty of appearance.

i) **Medical radiological procedure**: Any procedure related to medical exposure.

j) **Medico-legal procedure**: A procedure without a medical indication, performed for the needs of an insurance company or for legal purposes.

k) **Practitioner**: A medical doctor or dentist entitled to assume clinical responsibility for an individual medical exposure.

l) **Dose constraint**: A restriction on potential doses for individuals that may result from a defined source. It is used in the planning stage for radiation protection whenever optimization is involved.

m) **Quality assurance**: All planned and systematic actions necessary to provide adequate confidence that a structure, system, its components or procedures will be implemented under the existing standards.

n) **Postal TLD audit**: Validation of calibration of radiotherapy machines in an accredited laboratory by means of special thermoluminiscent dosimeters, with the exchange of dosimeters between licensees and laboratories via mail.

o) **Practical aspects**: Physical conduct of any exposure referred to in Article 1(2) and any other associated aspect, including the management and use of radiological equipment, the assessment of technical or physical parameters including radiation doses, calibration and maintenance of equipment, preparation and administration of pharmaceuticals, and film processing.

p) **Radiodiagnostic**: Pertaining to *in vivo* diagnostic nuclear medicine, medical diagnostic radiology, and dental radiology.

r) **Radiological installation**: A facility containing radiological equipment.

s) **Radiological equipment (hereinafter: equipment)**: Devices with associated tools, instrumentation and instruments used in radiodiagnostics, nuclear medicine, and radiotherapy.

t) **Radiological department**: An organizational unit within a health-care institution, which carries out the practices of radiotherapy and/or nuclear medicine and/or radiodiagnostics.

u) **Radiological**: Pertaining to radiodiagnostic or radiotherapeutic procedures, as well as interventional radiology or any other radiology for the purpose of planning or providing treatment.

v) **Radiotherapeutic**: Pertaining to radiotherapy, including nuclear medicine used for therapeutic purposes.

z) **Medical physics service:** An internal organizational unit separated from radiological departments within a health-care institution. It has relevant staff and equipment, and is competent to carry out all medical physics tasks needed for the functioning of the radiological departments and for training.

aa) **Medical physics specialist**: An expert in medical radiation physics applied to exposures within the scope of this regulation, whose training and competence to act is recognized by the entity ministries of health under the applicable legislation and who, when necessary and required, acts or advises on patient dosimetry, on the development and use of complex techniques and equipment, on optimization, on quality assurance including quality control, and on other aspects regarding the radiation protection, in relation to the exposures within the scope of this regulation.

bb) **Referrer**: A medical doctor or a dentist entitled to refer individuals for medical exposure to a practitioner.

cc) **Licensee**: Any legal person carrying out a specific medical practice and obligated to act under the Law on Radiation and Nuclear Safety in BiH and regulations regarding a given radiological installation.

dd) **Health-care institution**: An institution that provides health-care services under the applicable health-care legislation.

ee) **Health surveillance:** Medical examination of workers under the applicable legislation.

ff) **Health screening**: A procedure using radiological installations for early diagnostics of population groups at risk.

(2) Definitions of other terms used in this regulation are laid down in the Law on Radiation and Nuclear Safety in BiH.

## CHAPTER II – BASIC PRINCIPLES IN THE MEDICAL EXPOSURE

### Section A - Justification

#### Article 4
#### (Justification of the medical exposure)

(1) The medical exposure referred to in Article 1(2) shall have sufficient benefit, weighing the total potential diagnostic or therapeutic benefits it produces, including direct health benefits to an individual and the benefits to society against the individual detriment that the exposure might cause, taking into account the efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionizing radiation.

(2) At an appropriate level of their responsibilities, the referrer and the practitioner shall be involved in the process of considering justification of the medical exposure referred to in paragraph (1), with the final decision on justification being made by the practitioner.

(3) The referrer and the practitioner shall pay special attention to the justification of medical exposures without direct health benefit for persons undergoing the exposure and especially for exposures on medico-legal basis.

(4) Justification criteria for the medical exposure shall be part of quality assurance programs in the departments of radiodiagnostics, nuclear medicine and radiotherapy.

(5) If an exposure cannot be proved to be justified, then the practitioner shall not approve it.

**Article 5**
**(Steps before evaluating justification of the medical exposure)**

(1) Unless exceptionally, the referrer and the practitioner shall request information on earlier diagnostic examinations relevant for planning the exposure and consider that data to avoid unnecessary exposure to radiation.

(2) The referrer and the practitioner shall consider the need for diagnostic examination, having in mind alternative examinations that do not involve ionizing radiation.

(3) When the use of ionizing radiation is necessary, the referrer and the practitioner shall request a minimum number of examinations or projections indicated for conducting the diagnostic procedure.

**Article 6**
**(Justification for the types of procedures)**

(1) New procedures involving medical exposure shall be justified before their adoption.

(2) Existing types of procedures involving medical exposure may be revised whenever any new important evidence on their efficiency or consequences has appeared.

(3) Justification criteria for some types of procedures shall be part of quality assurance programs in relevant radiological departments.

**Article 7**
**(Justification of individual medical exposures)**

(1) If a procedure involving the medical exposure is not generally justified, specific individual exposures of that type may be justified in special circumstances, which shall be evaluated separately for each case.

(2) Individual medical exposures shall be justified in advance, taking into account specific goals of exposure and characteristics of the individual undergoing exposure.

**Section B - Optimization**

**Article 8**
**(Optimization in the medical exposure)**

(1) All doses resulting from the medical exposures for radiological purposes laid down in Article 1(2), except for radiotherapeutic procedures, shall be kept as low as reasonably achievable and consistent with obtaining appropriate diagnostic information, taking into account economic and social factors.

(2) The exposure of target volume shall be individually planned for the medical exposures of individuals for radiotherapeutic purposes laid down in Article 1(2), taking into account that doses for other tissues are kept as low as possible and consistent with the purpose of radiotherapeutic exposure.

**Article 9**
**(Diagnostic reference levels)**

(1) The State Regulatory Agency for Radiation and Nuclear Safety (hereinafter: Agency) shall ensure the establishment and use of diagnostic reference levels for radiodiagnostic procedures, as laid down in Article 1(2)(a),(b),(c) and (e),

(2) The diagnostic reference levels referred to in paragraph (1) are given in Annex 1.1 that is an integral part of this regulation.

(3) If diagnostic referent levels are consistently exceeded, the licensee for radiodiagnostics shall ensure that relevant checks are conducted and relevant corrective actions are taken.

**Article 10**
**(Practical aspects of optimization)**

The optimization process shall include the selection of suitable equipment, consistent production of appropriate diagnostic information or therapy outcomes, as well as the practical aspects, quality assurance including quality control, dose estimates for patients or applied activities, taking account of economic and social factors.

**Section C – Research projects and medico-legal exposures**

**Article 11**
**(Biomedical and medical research projects)**

The following shall be ensured with regard to the biomedical and medical research projects referred to in Article 1(2)(d):

a) approval of the projects by a relevant ethics committee,

b) voluntary participation of the concerned individual who shall be previously informed about the exposure risk,

c) dose constraints for the individuals that are not expected to have direct medical benefit from the exposure,

d) the practitioner shall plan individual target dose levels for the patients who willingly accept exposures in experimental diagnostic and therapeutic procedures and who are expected to receive diagnostic or therapeutic benefit from such procedures.

**Article 12**
**(Medico-legal exposures)**

(1) As for medically non-indicated exposures that are administered for medico-legal or life insurance purposes, special attention shall be paid to keep such doses as low as reasonably achievable.

(2) Radiodiagnostic departments conducting the examinations referred to in paragraph (1) shall establish and implement a quality assurance program documenting justification and laying down relevant written procedures for this type of exposure.

**Section D – Radiation protection of individuals helping patients**

**Article 13**
**(Quality assurance)**

(1) Exposure of the individuals who willingly help persons undergoing medical exposures shall have sufficient benefit in relation to detrimental effects it might cause.

(2) Quality assurance programs of the radiodiagnostic and nuclear medicine departments shall contain dose constraints for the non-professionals who knowingly and willingly cooperate by helping in the support and comfort of individuals undergoing medical exposures.

(3) The dose constraint referred to in paragraph (2) shall not exceed effective dose of 5 mSv per radiological procedure.

(4) A written instruction with basic information about the effects of ionizing radiation shall make an integral part of the quality assurance program. It shall be given to the individuals referred to in paragraph (1) and be available for inspection purposes.

**Article 14**
**(Immobilization)**

(1) As a rule, individuals undergoing medical exposures shall be immobilized with the aid of mechanical devices or otherwise with the voluntary help of one or more individuals.

(2) The immobilization referred to in paragraph (1) shall not be carried out by minors, pregnant women, and students in practical training.

(3) Individuals helping in the patient immobilization at the radiodiagnostic department shall receive precise instructions on how to reduce own exposure to the lowest possible extent, thus ensuring that no such individuals will be exposed to direct radiation field at any moment, and that they will use protective equipment as needed.

(4) The number of persons referred to in paragraph (3) shall be the lowest practicable number.

(5) As a rule, the patient immobilization shall be carried out by volunteers from the patient escort.

(6) If there are no volunteers, the patient immobilization shall be carried out by occupationally exposed workers, in which case it shall not be permitted to expose some workers to radiation longer than other workers.

**Article 15**
**(Protection against radiation emitted by patients)**

(1) In the case of a patient undergoing a treatment or diagnostic procedure involving radiopharmaceuticals, the nuclear medicine specialist or a person delegated by the specialist shall give a written instruction to the patient, with the aim of restricting doses to persons in contact with the patient as far as reasonably achievable and establishing dose constraints for such individuals.

(1) The dose constraint referred to in paragraph (1) shall not exceed effective dose of 5 mSv per treatment or diagnostic procedure for adults and 1 mSv for pregnant women and children.

(2) Before leaving the health-care institution, the patient referred to in paragraph (1) shall receive written information on the radiation risk for other persons staying near the patient.

## CHAPTER III – RESPONSIBILITY FOR MEDICAL EXPOSURES, AND PROCEDURES

### Section A – Prescribing and approving medical exposures

**Article 16**
**(Prescribing)**

(1) Radiodiagnostic procedures shall be prescribed:

a) as for diagnostic procedures in diagnostic radiology or nuclear medicine, by the medical doctor specialist in a specific medical field,

b) as for radiodiagnostic procedures in dentistry, by the dentist or the dental medicine specialist.

(2) Radiotherapeutic procedures shall be prescribed:

a) as for radiotherapeutic procedures, by the radiation oncology specialist or the radiology specialist with three years of experience in radiation oncology,

b) as for therapeutic procedures in nuclear medicine, by the nuclear medicine specialist.

**Article 17**
**(Conduct)**

(1) Procedures involving medical exposure shall be conducted only under the clinical responsibility of the following practitioners:

a) for procedures in diagnostic and interventional radiology it shall be the radiology specialist or another medical specialist only within the field of specialization,

b) for diagnostic and therapeutic procedures in nuclear medicine it shall be the nuclear medicine specialist,

c) for radiotherapeutic procedures it shall be the radiation oncology specialist or the radiology specialist with three years of experience in radiation oncology,

d) for diagnostic procedures in dentistry it shall be the dentist or the specialist in dentistry.

(2) The radiology specialists and other practitioners referred to Article (1)(a) and (d) shall each be responsible within respective fields for: evaluation of known earlier exposures in order to avoid unnecessary repetition; approval of medical examinations; proper conduct and possible repetition of unsatisfactory examinations; writing radiological reports including pathological findings, differential diagnosis, and a conclusion indicating complementary examinations as needed.

(3) The nuclear medicine specialist shall be responsible for: evaluating whether the procedure was properly indicated; its approval; selection of radiopharmaceuticals needed for a diagnostic or therapeutic procedure; determining activity of radiopharmaceuticals to be applied according to the procedures; issuing reports containing pathological findings or treatment results.

(4) The radiation oncology specialist or the radiology specialist with three years of experience in radiation oncology shall be responsible for: evaluating indications and making decisions on radiotherapy treatment; choosing a volume to be irradiated; prescribing absorbed dose for each volume; writing reports containing treatment results, and monitoring the patient condition after the treatment ends.

**Article 18**
**(Delegation)**

(1) The licensee or the practitioner may delegate some or all practical aspects of a procedure involving medical exposure to one or more persons entitled to act in that matter within their respective fields of specialization.

(2) The delegation referred to in paragraph (1) shall be done in writing, but the practitioner shall not be relieved of clinical responsibility for the procedure.

**Section B – Medical physics**

**Article 19**
**(Medical physics specialist)**

(1) The medical physics specialist shall be involved in practical aspects of the medical exposure, such as: calibration of equipment, calculation of the patient dose, development of complex techniques, creation of quality assurance program, implementation of quality control, and radiation protection matters regarding the exposures referred to in this regulation, including the training of practitioners and other staff.

(2) Responsibility of the medical physics specialists in radiodiagnostics, nuclear medicine, and radiotherapy is elaborated in Parts II, III, and IV of this regulation.

**Article 20**
**(Medical physics service)**

(1) The licensee for the following three specific medical practices: radiotherapy, nuclear medicine, and radiodiagnostics shall establish a medical physics service as a separate organizational unit in relation to the above three departments for specific practices.

(2) The licensee referred to paragraph (1) shall ensure that at least three medical physics specialists are employed in the medical physics service referred to in paragraph (1) to perform the duties referred to in Article 19(1).

(3) The Agency shall evaluate each individual case to establish whether the licensee for two of the three specific medical practices referred to in paragraph (1) shall establish the medical physics service.

**Section C – Procedures during the medical exposure**

**Article 21**
**(Protocols)**

(1) Written protocols for each type of standard radiological procedure shall be established for all equipment.

(2) The protocols referred to in paragraph (1) shall be available to the individuals involved in the conduct of radiological procedures.

**Article 22**
**(Clinical audit)**

(1) The licensee for specific medical practices of radiotherapy, nuclear medicine, and radiodiagnostics shall conduct clinical audit at least once in five years.

(2) The Agency shall issue the instruction regarding the organization and conduct of the clinical audit referred to in paragraph (1).

**Article 23**
**(Estimate of population doses)**

(1) The Agency shall ensure that dose estimates for the medical exposures referred to in Article 1(2) are determined for the population as a whole.

(2) If it considers necessary, the Agency shall determine dose estimates for relevant reference groups of the population.

**Section D – Equipment**

**Article 24**
**(Duties of the licensee)**

The licensee shall ensure that:

a) the equipment is strictly supervised in view of radiation protection,

b) appropriate quality assurance program is established and implemented, including quality control measures and the assessment of patient dose or activity of administered radiopharmaceuticals,

c) acceptance testing is conducted before the first of use of any equipment for clinical purposes, later regular performance testing, and testing after any major maintenance procedure,

d) an equipment maintenance program is established and implemented, including taking the equipment out of service as needed.

**Article 25**
**(New equipment)**

The equipment for diagnostic and interventional radiology that is acquired after entering of this regulation into force shall have a device informing the practitioner of the radiation dose produced by the equipment during the procedure.

**Section E – Radiation protection during special procedures**

**Article 26**
**(Special procedures)**

(1) The licensee shall ensure that appropriate equipment, practical techniques and ancillary equipment are used for medical exposures:

a) of children,

b) as part of a health screening program,

c) involving high doses to patients, such as interventional radiology, computed tomography or radiotherapy.

(2) Special attention shall be paid to the quality assurance programs, including quality control measures and the assessment of patient dose or administered activity, as laid down in Article 24.

(3) The licensee shall ensure that practitioners and individuals performing the exposures referred to in paragraph (1) receive appropriate training in radiation protection for relevant radiological procedures.

**Article 27**
**(Special protection during pregnancy and breastfeeding)**

(1) The referrer and the practitioner shall inquire whether a woman is pregnant or in childbearing age or, for the nuclear medicine procedure, whether she is breastfeeding.

(2) If pregnancy cannot be excluded, special attention shall be paid to the justification of the procedure, taking into account the type of medical exposure, particularly if the organs in abdominal or pelvic region will be exposed to direct beam, and also to the urgency of examination and the risk for the expectant mother and her unborn child.

(3) If an examination is justified, necessary measures shall be taken to optimize it properly.

(4) Special attention shall be paid to the assessment of justification, particularly urgency and optimization of the medical exposure of breastfeeding women in the nuclear medicine procedure, depending on the type of medical examination or treatment and taking into account the exposure of both the mother and the child.

(5) The licensee shall post notices in conspicuous places and take all other necessary measures to raise the awareness of women about their need to inform medical staff about possible pregnancy or breastfeeding.

**Article 28**
**(Potential exposure)**

(1) In the conduct of radiological procedures, the licensee shall take necessary measures to reduce the probability of accidental and unintended doses to patients, and to reduce doses taking account of economic and social factors.

(2) In accident prevention, special attention shall be paid to the equipment and procedures in radiotherapy.

(3) Attention shall also be paid to accident prevention in diagnostic and interventional radiology.

(4) The working instructions and written protocols referred to in Article 21, the quality assurance programs, and the criteria related to proper equipment maintenance referred to in Article 24(b) and (d) shall be of particular relevance for implementing the measures referred to in paragraph (1).

# PART II – RADIODIAGNOSTICS

## CHAPTER I – QUALITY ASSURANCE AND PROCEDURES

### Section A - Quality assurance in radiodiagnostics

**Article 29**
**(Quality assurance program)**

(1) The licensee for radiodiagnostics shall implement a quality assurance program.

(2) The quality assurance program shall be prepared in writing and be available to the Agency inspectors both because of supervision and the clinical audit referred to in Article 22. It shall be subject to amendments in accordance with new scientific and technical knowledge.

**Article 30**
**(Elements of the quality assurance program)**

The program referred to in Article 29 shall include:

a) justification and optimization aspects for radiodiagnostic examinations,

b) quality control measures for equipment, image receptors, data processing systems, image display systems, and measuring instruments,

c) procedures for estimating patient dose indicators, referred to in Annex 1.1, in the most often radiodiagnostic examinations and for the quality assessment of diagnostic images. Mean values of the indicators shall be compared with the reference values given in Annex 1.1. If the latter are exceeded, corrective actions shall be taken.

d) procedures for the analysis of discarded images,

e) description of job positions and equipment needed to implement the procedures,

f) responsibilities and duties of the staff handling the equipment or working in radiodiagnostic departments,

g) staff training plan regarding the use of equipment, radiation protection for existing techniques, and the case of introducing new radiodiagnostic techniques,

h) procedures for keeping records on incidents and accidents in radiodiagnostic departments, results of investigating their causes, and corrective actions.

**Article 31**
**(Health screening)**

(1) If a radiodiagnostic department performs a health screening, the licensee shall establish quality control criteria as part of the quality assurance program.

(2) The Agency shall issue the instruction establishing the quality control criteria for the health screening referred to in paragraph (1).

**Article 32**
**(Quality assurance program – Clinical part)**

Clinical part of the quality assurance program shall concern:

a) the need to justify radiological examinations,

b) the practitioner's responsibility and supervision during radiological examinations,

c) selection of appropriate equipment for conducting examinations under the applicable protocols,

d) technical standards minimizing the patient dose without losing necessary radiological information,

e) writing medical reports by the practitioner.

**Article 33**
**(Duties of the licensee)**

(1) In addition to the duties referred to in Article 24, the licensee shall:

a) create, develop and implement a quality assurance program, the copy of which shall be submitted to the Agency during the authorization process,

b) keep archive records of the results of the procedures set out in the quality assurance program,

c) notify the Agency of the accidents and incidents that can cause exceeding of threshold doses for deterministic radiation effects in patients,

d) ensure repair and/or temporary or permanent suspension of the equipment that does not meet the criteria defined in the quality assurance program, and keep records thereof.

(2) The licensee may delegate some of the duties referred to in paragraph (1) to one or more persons, thus not reducing responsibility of the licensee.

(3) The licensee shall appoint the person(s) referred to in paragraph (2) and specify their tasks exactly.

**Section B. – Procedures in radiodiagnostics**

**Article 34**
**(Radiodiagnostic procedures)**

(1) By implementing the quality assurance program, the licensee shall ensure that radiodiagnostic departments have written protocols for standard procedures. The protocols shall contain possibilities to optimize the patient dose with preserving

diagnostic information, and they shall be updated and revised whenever standard examinations are changed or new techniques introduced.

(2) The protocols for radiodiagnostic procedures for children and pregnant women, high-dose procedures and health screening programs shall contain risk reduction measures, in which case the practitioner shall be responsible for the assessment of justification and the selection of an appropriate imaging technique.

(3) Medical staff conducting radiodiagnostic procedures shall be qualified for proper selection and use of the equipment, and be properly trained in radiation protection.

**Article 35**
**(Interventional procedures)**

Medical doctors-specialists shall conduct interventional procedures by using the equipment and premises specifically designed for this practice.

**Section C. – Patient dosimetry**

**Article 36**
**(Dose estimates for standard procedures)**

(1) The practitioner shall be responsible for the optimization of radiodiagnostic examinations so as to keep minimum doses to patients and in doing so avoid repeating images, significant loss of image quality or other diagnostic information.

(2) The medical physics specialist shall verify patient doses at least once in three years in accordance with the indications and methods described in Annex 1.1. The results shall be archived and be available to the Agency inspectors.

(3) The data on the examination conditions for each patient shall form the basis for the estimates of population doses referred to in Article 23.

**Article 37**
**(Dose estimates for individual patients)**

(1) In special cases, when required by an examination type or a patient's characteristic, the dose shall be estimated for each patient individually.

(2) Estimates of embryonic and fetal doses shall be mandatory for radiodiagnostic examinations of pregnant women.

**Article 38**
**(Providing information to the patient)**

Before conducting the high-dose procedure, the practitioner shall inform the patient about potential risks.

**Section D. – Medical physics specialist in radiodiagnostics**

**Article 39**
**(Employment of the medical physics specialist)**

(1) The licensee for radiodiagnostics shall employ a medical physics specialist, either as a full-time or external staff member in the health-care institution.

(2) If the licensee is unable to employ a medical physics specialist, the commission referred to in Article 98(1) shall, for the purpose of licensing, assess qualifications of the staff practicing medical physics.

**Article 40**
**(Duties of the medical physics specialist)**

The medical physics specialist referred to in Article 39(1) shall discharge the following duties:

a) preparation of the quality assurance program,

b) preparation of technical specifications regarding radiation protection for the purpose of the equipment acquisition,

c) optimization and quality control of the image and digital data processing,

d) quality control of the equipment,

e) check of relevant parameters of the equipment after its corrective servicing,

f) radiation protection in the medical exposure,

g) estimation of patient doses.

**CHAPTER II – RADIODIAGNOSTIC EQUIPMENT AND SPECIFIC REQUIREMENTS**

**Section A. – Commissioning and quality control of the radiodiagnostic equipment**

**Article 41**
**(Acceptability of the equipment)**

The equipment for interventional radiology and computed tomography that is acquired after entering of this regulation into force shall have a system for measuring and recording patient doses.

**Article 42**
**(Acceptance testing of the equipment)**

(1) Acceptance testing shall be conducted before takeover of the equipment.

(2) Acceptance testing shall be done by the vendor in the presence of a medical physics specialist as a representative of the health-care institution.

(3) The report with acceptance test results shall be prepared by a representative of the legal person referred to in paragraph (2) and shall be approved by the medical physics specialist.

(4) New equipment shall be accepted only if measured parameters are identical to the requested specifications and if the acceptability criteria referred to in Annex 1.2 are met.

(5) The medical physics specialist shall submit the report referred to in paragraph (3) to the licensee and the head of radiodiagnostics department.

**Article 43**
**(Establishing initial condition of the equipment)**

(1) In the period between the equipment takeover and its clinical use, a medical physics specialist shall define parameters of its initial condition.

(2) Later routine tests laid down in Annex 1.3 enable monitoring of the equipment stability over its entire useful life or until establishment of new reference condition.

(3) Parameters of initial condition shall also be defined for the equipment acquired before publication of this regulation, and they shall be used for the same purpose as the parameters referred to in paragraph (1).

(4) Parameters of initial condition shall be set out in a report available to the Agency inspectors.

**Article 44**
**(Quality control program for the equipment)**

(1) Quality control shall be exercised for the radiodiagnostic equipment to ensure that the patient dose is kept as low as possible and consistent with obtaining appropriate diagnostic information.

(2) The quality control program shall ensure that the equipment meets the requirements laid down in Annex 1.2.

(3) Minimum frequency of routine quality control tests and the positions of responsible staff are laid down in Annex 1.3.

**Article 45**
**(Responsibility for quality control)**

The responsible person designated in the quality assurance program shall manage quality control and make a report on the equipment condition, obtained results, and corrective actions, while the practitioner shall be responsible for the evaluation of diagnostic value of radiological images.

**Article 46**
**(Procedure in the case of malfunctions)**

(1) The quality control program shall include verification of the patient dose and the image quality, as laid down in Annex 1.1, and in the case of equipment malfunctions, tests shall be conducted to determine the cause.

(2) If observed malfunctions of the equipment referred to in paragraph (1) can endanger radiation safety, that is, the loss of diagnostic information or the dose increase above reference levels, the responsible person designated in the quality assurance program shall decide on further equipment testing or its possible suspension.

(3) If the equipment has not met the requirements laid down in Annex 1.2 even after repair, the licensee shall take out of service the equipment referred to in paragraph (2).

**Section B. – Equipment maintenance**

**Article 47**
**(Equipment maintenance program)**

(1) The licensee shall ensure appropriate preventive and corrective maintenance program for the equipment, which shall be prepared in cooperation with a licensed technical service for installation, servicing and maintenance.

(2) Preventive service shall be done under the manufacturer's instructions at least annually, followed by a written report thereof.

**Article 48**
**(Corrective equipment maintenance)**

(1) After the repairs that can cause the change of image quality or patient dose, it shall be necessary to check relevant equipment parameters whose initial values are listed in the acceptance test.

(2) A representative of the technical service referred to in Article 47(1) who performed corrective maintenance shall submit the report on the restoration of equipment performance to the licensee.

(3) Acceptance test results, serving as a reference for the condition before the malfunction both for the image quality and dose indicators, shall form the basis for checking relevant parameters of the equipment after its repair.

**Section C. – Specific requirements**

**Article 49**
**(Prohibited equipment)**

Clinical use of fluoroscopic equipment without electronic image intensifiers shall be prohibited.

**Article 50**
**(Limitation on the use of equipment)**

Clinical use of image-intensified fluoroscopic equipment without control devices and dosimeters shall be limited to low-dose procedures.

**Article 51**
**(Calibration)**

(1) Measuring instruments used in the quality control shall be calibrated in an accredited laboratory at least once in three years.

(2) The type and frequency of the quality control tests of the instruments referred to in paragraph (1) shall be part of the quality assurance program.

**Article 52**
**(Archiving of the documentation)**

(1) The licensee shall keep archive of the documentation.

(2) The reports referred to in Articles 36(2) and 37 shall be kept at least 30 years.

(3) The reports referred to in Articles 42(3), 43(4), 45 and 48(2) shall be kept as long as the equipment is in use.

(4) The reports referred to in paragraphs (2) and (3) shall be available to the Agency inspectors.

(5) After the closure of a health-care institution or termination of using a radiation source, the licensee shall submit a report to the Agency within five days.

PART III – NUCLEAR MEDICINE

## CHAPTER I – QUALITY ASSURANCE AND PROCEDURES

### Section A. – Quality assurance in nuclear medicine

**Article 53**
**(Quality assurance program)**

(1) The licensee for diagnostic and/or therapeutic nuclear medicine practice shall establish and implement a quality assurance program drawn up under the applicable legislation and international standards.

(2) The program shall be prepared in writing and in accordance with Annexes 2.1-2.6. It shall be always available to the Agency inspectors both because of supervision and the clinical audit referred to in Article 22. It shall be subject to amendments in accordance with new scientific and technical knowledge.

**Article 54**
**(Elements of the quality assurance program)**

The quality assurance program referred to in Article 53 shall cover all aspects regarding the work with open radiation sources, and as a minimum it shall contain the following elements:

a) definition of the program goals,

b) description of the procedures in use,

c) description of job positions and equipment necessary to conduct procedures,

d) responsibilities and obligations of the nuclear medicine staff,

e) staff training plan,

f) work procedures related to open radiation sources,

g) procedures and notes related to incidents and accidents in the nuclear medicine department.

**Article 55**
**(Duties of the licensee)**

(1) In addition to the duties referred to in Article 24, the licensee shall:

a) create, develop and implement a quality assurance program, the copy of which shall be submitted to the Agency before the nuclear medicine department becomes operational,

b) keep archive of the results from the procedures laid down in the quality assurance program,

c) notify the Agency of the accidents and incidents that can cause exceeding of threshold doses for deterministic radiation effects in patients,

d) ensure repair and/or temporary or permanent suspension of the equipment that does not meet the criteria defined in the quality assurance program, and keep records thereof.

(2) The licensee may delegate some of the duties to one or more persons, thus not reducing responsibility of the licensee. The person responsible for these duties shall be appointed by the licensee's written decision containing the list of duties.

**Section B. – Procedures in nuclear medicine**

**Article 56**
**(Responsibility for preparation and application of radiopharmaceuticals)**

(1) The preparation and application of radiopharmaceuticals for diagnostic or therapeutic purposes shall be supervised by a nuclear medicine specialist.

(2) Measurement of the prescribed activity shall be supervised by a medical physics specialist.

**Article 57**
**(Providing information to the patient)**

(1) Before the application of radiopharmaceutical preparations, a nuclear medicine specialist shall explain the procedure to the patient.

(2) After the application of radiopharmaceuticals, the patient shall receive a written instruction to be followed in order to reduce the risk of contamination and unnecessary irradiation of other persons. The instruction shall also set out the period of delaying planned conception, depending on an applied radiopharmaceutical, in accordance with Annexes 2.2 and 2.4.

**Article 58**
**(Application of radiopharmaceuticals for diagnostic procedures)**

(1) During the application of radiopharmaceuticals in diagnostic procedures, a nuclear medicine specialist shall be responsible to keep the patient dose minimal, depending on the procedure, and also to select an appropriate procedure in order to avoid repeating the procedure and additional irradiation of the patient.

(2) To reduce the patient dose to the lowest possible level, a nuclear medicine specialist shall determine the best radiopharmaceutical and optimal activity, with particular concern for children, pregnant, and breastfeeding women, and taking into account that the activity may not exceed the maximum levels laid down in Annex 2.1.

(3) The equipment used in diagnostic procedures shall have such characteristics that provide reliable diagnostic information for prescribed activities of radiopharmaceuticals.

**Article 59**
**(Application of radiopharmaceuticals for therapeutic purposes)**

(1) In the application of radiopharmaceuticals for therapeutic purposes, a nuclear medicine specialist and a medical physics specialist shall calculate absorbed dose for a relevant organ under the kinetic laws and the biodistribution laws for radiopharmaceuticals, and also the effective and equivalent doses.

(2) Therapeutic application of radiopharmaceuticals shall be carried out both in outpatient and inpatient units.

(3) After the completion of the therapeutic procedure, a nuclear medicine specialist shall explain possible risks and risk reduction measures to the patient.

(4) After hospital discharge of a patient who received a dose of radioactive iodine I-131, a nuclear medicine specialist shall provide the patient with a written instruction based on the measured dose rate at 1 m distance and estimated remaining activity in the body. The instruction shall indicate the time period of complying with it and the limitations regarding work duties, as laid down in Annex 2.2.

**Article 60**
**(Application of radiopharmaceuticals in children)**

(1) Application of radiopharmaceuticals in children shall be strictly medically indicated. The activity of radiopharmaceuticals shall be adjusted with regard to bodily mass of the child and other medically relevant characteristics.

(2) Weighting factors for applied doses of the radiopharmaceutical preparations referred to in paragraph (1) are given in Annex 2.3.

**Article 61**
**(Application of radiopharmaceuticals in pregnant women)**

(1) Application of radiopharmaceuticals in pregnant women may be approved only as an exception and with application of all available radiation protection measures for the embryo or fetus.

(2) In the application of radiopharmaceuticals for the purposes referred to in paragraph (1), the embryonic or fetal radiation dose shall be assessed and serve as a basis for the decision on continuing the pregnancy.

**Article 62**
**(Application of radiopharmaceuticals in breastfeeding women)**

(1) Application of radiopharmaceuticals in breastfeeding women may be approved only as an exception and with application of all available radiation protection measures for the woman and the child.

(2) A written instruction shall be given to the female patient after such interventions, and in addition to other information it shall indicate duration of temporary suspension of breastfeeding, as laid down in Annex 2.4.

**Article 63**
**(Protection against the radiation emitted by patients)**

After the application of radiopharmaceuticals, patients shall be put in a separate waiting room specially designed and constructed for that purpose in accordance with the radiation protection requirements.

**Article 64**
**(Patient's consent for diagnostic or therapeutic procedures)**

Before each diagnostic or therapeutic procedure involving radiopharmaceuticals, the patient shall consent in writing and confirm it with own signature.

**Article 65**
**(Patient's medical record)**

For each application of radiopharmaceuticals the following shall be entered into the patient's medical record:

a) Name and activity of radiopharmaceuticals and the time of their application,

b) Dosimetry data, as needed,

c) Adverse effects of radiopharmaceuticals, if any.

**Article 66**
**(Autopsy and cremation)**

(1) Autopsy and cremation of the deceased persons who received radiopharmaceuticals for therapeutic purposes during their life shall be performed only when the activity of applied radionuclides in the body decrease below the values given in Annex 2.5.

(2) As an exception and for justified reasons, autopsy of the persons referred to in paragraph (1) may be carried out when the radiopharmaceutical activity exceeds the values given in Annex 2.5, provided that protective equipment and other measures are applied as instructed by a radiation protection officer.

**Section C. – Medical physics specialist in nuclear medicine**

**Article 67**
**(Duties of the medical physics specialist)**

Except for the laboratories using radioimmunoassays (RIA and IRMA tests), the licensee for nuclear medicine shall employ a medical physics specialist with the following duties in addition to those referred in Articles 56(2) and 59(1):

a) involvement in the optimization and quality control of image processing,

b) exercise of quality control of the equipment,

c) involvement in technical and physical aspects of dosimetric control of the staff,

d) involvement regarding radiation protection during the development of specifications of the equipment to be acquired.

**Article 68**
**(Assessment of qualifications)**

If the licensee referred to in Article 67 is unable to employ a medical physics specialist, the commission referred to in Article 98(1) shall, for the purpose of licensing, assess qualifications of the staff practicing medical physics.

## CHAPTER II – NUCLEAR MEDICINE EQUIPMENT AND SPECIFIC REQUIREMENTS

### Section A. – Commissioning and quality control of nuclear medicine equipment

**Article 69**
**(Acceptance testing of new equipment)**

(1) The licensee referred to in Article 67 shall organize acceptance testing of new equipment before its clinical use.

(2) Acceptance testing shall be conducted by the vendor in the mandatory presence of a medical physics specialist as a representative of the licensee referred to in Article 67.

(3) The report on acceptance test results shall be prepared by the vendor and approved by the medical physics specialist.

(4) New equipment shall be accepted provided that the requirements laid down in Annex 2.6 are met.

(5) The medical physics specialist shall submit the report referred to in paragraph (3) to the licensee and the head of nuclear medicine department.

**Article 70**
**(Quality control of the equipment)**

(1) The equipment used in nuclear medicine shall be subject to quality control to ensure that the patient dose during the application of radiopharmaceuticals for diagnostic purposes is as low as possible while obtaining appropriate diagnostic information.

(2) Minimum quality control requirements for the equipment and radiopharmaceuticals in nuclear medicine are laid down in Annex 2.6.

(3) A medical radiology engineer or a medical technician shall be responsible for the daily quality control tests given in tables 21 to 23 in Annex 2.3.

(4) With the exception of the tests referred to in paragraph (3), a medical physics specialist shall be responsible for quality control tests.

(5) A holder of a university degree in pharmacy or chemistry (General Chemistry Department) shall be responsible for the controls laid down in table 24 in Annex 2.3.

(6) The test results referred in paragraphs (3), (4) and (5) shall be part of the written report made by the responsible person.

**Section B. – Equipment maintenance**

**Article 71**
**(Maintenance and servicing)**

The equipment used in nuclear medicine shall be maintained preventively and correctively under a maintenance program prepared in cooperation with a licensed technical service for installation, servicing and maintenance.

**Article 72**
**(Preventive maintenance)**

The preventive equipment maintenance referred to in Article 71 shall be conducted under the manufacturer's specifications at least annually and followed by a written report thereof.

**Article 73**
**(Corrective maintenance)**

A representative of the technical service referred to in Article 71 who performed corrective maintenance shall submit the report on the restoration of equipment performance to the licensee.

**Section C. – Specific requirements**

**Article 74**
**(Archiving the patient dose data)**

The patient data referred to in Article 59(1) shall be kept for at least 30 years and be available to the Agency inspectors.

**Article 75**
**(Archiving the equipment test reports)**

(1) The test reports referred to in Articles 69(3) and 70(6), and the equipment maintenance reports referred to in Articles 72 and 73 shall be kept until the use of equipment is terminated, and they shall be available to the Agency inspectors.

(2) After discontinuation of the health-care institution or using the radiation source, the licensee shall submit a report to the Agency within five days.

# PART IV – RADIOTHERAPY

## CHAPTER I – QUALITY ASSURANCE AND PROCEDURES

### Section A. – Quality assurance in radiotherapy

**Article 76**
**(Quality assurance program)**

(1) The licensee for radiotherapy shall establish and implement a quality assurance program developed under the applicable legislation and international standards that shall be set out in the program.

(2) The quality assurance program shall cover all stages of radiotherapeutic process and the following elements as a minimum:

a) definitions of the program goals,

b) description of the procedures to be used and foreseen in quality control program; minimum equipment and staff resources needed for the procedures given in ANNEX 3.1, including the names of responsible persons for any decision and procedure, and specified levels of their responsibility,

c) relation between successive stages of radiotherapeutic process and quality control tests foreseen for these stages and for the equipment related to each stage, including its initial reference condition,

d) description of the evaluation system and analysis of results of the radiotherapeutic process.

(3) The quality assurance program shall be made in writing and always available to the Agency inspectors both because of supervision and the clinical audit referred in Article 22. It shall be subject to amendments in accordance with new scientific and technical knowledge.

**Article 77**
**(Duties of the licensee)**

(1) In addition to the duties referred to in Article 24, the licensee shall:

a) establish the commission for quality assurance in radiotherapy, which shall be responsible for the program implementation and development,

b) submit a copy of the quality assurance program to the Agency before the radiotherapy department becomes operational, and submit all later program modifications.

(2) The licensee may delegate fulfillment of the responsibilities referred to in paragraph (1) to one or more persons with exactly specified tasks.

(3) The licensee shall appoint:

a) the practitioner responsible for the radiotherapy department (hereinafter: responsible radiotherapy specialist),

b) the medical physics specialist, responsible for the medical physics department (hereinafter: responsible medical physics specialist).

**Article 78**
**(Commission for quality control in radiotherapy)**

(1) The commission for quality control in radiotherapy shall consist of a health-care institution managers, a practitioner, a medical physics specialist, and a medical radiology engineer (or a health-care worker with a two-year university degree in radiology), and also representatives of other professions involved in the radiotherapeutic process.

(2) The quality control commission shall submit a report to the licensee in the following cases:

a) when the patient during radiotherapy treatment receives a dose different than prescribed, provided that this represents a considerable risk for the patient's health,

b) when it considers that the quality assurance program is not being implemented,

c) whenever it considers necessary.

(3) The licensee shall notify the Agency about the information referred in paragraph (2) within 72 hours.

**Article 79**
**(Quality control)**

Activities of the radiotherapy department and the medical physics service shall be subject to quality control to verify whether clinical decisions and equipment guarantee:

a) that the physical properties of the available radiation fields, prescribed absorbed dose, and absorbed dose to defined volumes received by the patient are appropriate for any clinical situation, and that they correspond to the information indicated during the treatment prescribing and planning,

b) that the exposure of normal tissue is as low as reasonably achievable.

**Article 80**
**(Quality control program for clinical stage**s**)**

(1) Quality control program for radiotherapeutic process shall apply to all clinical stages and be adjusted to the established protocols that are accepted and confirmed by the national or international scientific associations, agencies or institutions whose competence is widely accepted.

(2) Quality control results shall be evaluated by a practitioner who shall submit report with the results and their possible deviations to the head of radiotherapy department.

(3) Clinical stages of radiotherapy process, including actions, evaluations and decisions in the stages, the frequency of controls required in radiotherapeutic procedures, and human resources criteria are given in Annex 3.1.

(4) The quality assurance program shall contain tolerances for: the volume delineation, patent anatomic data, prescribing of absorbed dose, and patient positioning during the radiotherapy treatment.

(5) Actions, evaluations and decisions in clinical stages, the frequency of controls and the tolerances may be changed in accordance with justified criteria that take account of the treatment purpose and available technology.

**Section B. – Procedures in radiotherapy**

**Article 81**
**(Radiotherapy procedures)**

(1) The commission referred to in Article 78(1) shall periodically update and revise the procedures used in the radiotherapy department whenever a therapy is modified or new therapeutic techniques are introduced.

(2) The procedures referred to in paragraph (1) shall be implemented under the applicable regulations by the staff qualified for individual radiotherapy techniques, the use of equipment, and radiation protection.

**Article 82**
**(Radiotherapy treatment)**

(1) Radiotherapy treatment of the patient shall take place under the guidance and responsibility of a practitioner.

(2) As for the radiotherapy treatment, a practitioner shall determine the volumes to be treated, prescribe absorbed dose for each volume, and indicate critical organs and maximum absorbed dose for each of them.

(3) The practitioner shall provide the medical physics specialist with the hard-copy documentation containing all information needed to make the radiotherapy plan.

(4) Radiotherapy treatment plan for the patient shall be developed under the guidance and responsibility of a medical physics specialist and in accordance with the documentation referred to in paragraph (3).

(5) Radiotherapy treatment of pregnant women shall be done so as to keep the embryonic and fetal absorbed doses as low as possible.

**Article 83**
**(Adverse reactions of the patient)**

(1) If the patient shows any adverse reaction during a radiotherapy treatment, the practitioner shall investigate the reasons that may have lead to such reaction, and make a report stating all conducted actions and investigations, including possible deviations from prescribed treatment.

(2) If required by the case severity, the report referred to in paragraph (1) shall be urgently submitted to the quality assurance commission that shall act in accordance with the quality assurance program.

(3) The documentation regarding all adverse reactions of the patient and all commission decisions shall be properly archived and available to the Agency inspectors.

**Article 84**
**(Treatment chart)**

(1) The treatment chart with the following information shall be filled in for the radiotherapy treatment:

a) identification of the patient,

b) description of the treated disease,

c) decision on therapy with the description of treatment-related volumes, absorbed dose to be delivered, clinical parameters of radiation and elements to be checked, and maximum absorbed dose to critical organs,

d) planned treatment scheme, and radiotherapy plan created on the basis of the decision on therapy referred in point c),

e) information from the radiotherapy plan needed for initial positioning of the patient,

f) all complementary data needed to ensure reproducibility of the treatment.

(2) Before the radiotherapy treatment begins and whenever it changes, the treatment chart shall be verified and signed by a practitioner, a medical physics specialist, and medical staff conducting the treatment.

(3) The information contained in the treatment chart shall be archived as part of the patient's medical history.

**Article 85**
**(Providing information to the patient)**

(1) Before the treatment begins, the practitioner shall provide the patient with a written instruction informing the patient about the treatment and related risks, and which shall be signed by the patient.

(2) If the patient has not signed the written instruction referred to in paragraph (1), the radiotherapy treatment shall not be conducted.

(3) Pregnant women shall be additionally informed about the treatment-related risk for embryo or fetus.

**Section C. – Medical physics in radiotherapy**

**Article 86**
**(Medical physics section)**

(1) The licensee for radiotherapy practice only shall establish a separate medical physics section with necessary equipment and human resources.

(2) At least one medical physics specialist shall be employed in the medical physics section.

(3) The licensee referred to in Article 20(1) shall establish a medical physics section referred to in paragraph (1), as an integral part of the medical physics service.

(4) If the licensee is unable to employ a medical physics specialist, the commission referred to in Article 98(1) shall assess qualifications of the staff practicing medical physics for the purpose of licensing.

**Article 87**
**(Medical physics specialist)**

(1) The medical physics specialist shall be responsible for:

a) acceptance testing,

b) establishment of initial reference condition of the equipment producing radiation for radiotherapy purposes and of the system for dose planning and calculation,

c) establishment and implementation of the quality control program for the above-mentioned equipment and system, and for physical and technical aspects of the radiation dosimetry without reducing responsibility of the equipment maintenance service and other professionals listed in the quality assurance program,

d) preparation of the specifications during the acquisition of radiotherapy equipment, which refers to technical characteristics of the equipment in terms of radiation protection; specification of dosimetry and quality control equipment needed for proper functioning of the radiotherapy equipment subject to acquisition,

e) preparation and creation of the report on the treatment plan referred to in Article 82(4).

**CHAPTER II – RADIOTHERAPY EQUIPMENT AND SPECIFIC REQUIREMENTS**

**Section A. – Commissioning and quality control of radiotherapy equipment**

**Article 88**
**(Acceptability testing of the equipment)**

(1) Radiotherapy devices, equipment for localization and simulation, treatment planning systems, and measuring instruments acquired and installed after entering of this regulation into force shall be subject to acceptance testing before its clinical use.

(2) The procedure for equipment acquisition shall contain the provisions regarding the vendor's obligation to conduct acceptance tests, the provisions specifying the protocol for conducting the test, and an indication that the equipment meets the requirements under applicable legislation.

(3) Before handover of the equipment, the vendor shall conduct necessary tests in the presence of the medical physics specialist from the health-care institution in order to verify requirements regarding technical specifications and equipment performance.

(4) The report on acceptance test results shall be prepared by a representative of the vendor and approved by the medical physics specialist.

(5) The responsible medical physics specialist shall submit the report referred to in paragraph (4) to the licensee and the responsible radiotherapy specialist.

**Article 89**
**(Initial reference condition of the equipment)**

(1) In the period between the equipment takeover and its clinical use, initial reference condition shall be established in accordance with full tests and tolerances given in Annex 3.2.

(2) Initial reference condition of the equipment shall serve for periodic checks of the equipment stability during its lifetime or until establishment of a new reference condition used for comparison against periodic controls.

**Article 90**
**(Quality control program for the equipment)**

(1) Quality control program for the systems for dose planning and calculation, and equipment producing radiation for radiotherapeutic purposes shall be harmonized with established protocols that are accepted and confirmed by the domestic or international scientific associations, agencies or institutions whose competence is widely accepted.

(2) Tests, tolerances and frequency of implementing quality control of the equipment are given in Annex 3.2.

(3) Except for the DLA12 and DLA14 tests given in table 28 in Annex 3.2, the medical radiology engineer shall be responsible for the daily quality control tests given in tables 28 to 33 and table 35 in Annex 3.2.

(4) The quality control tests referred to in Annex 3.2 but not referred to in paragraph (3) shall be the responsibility of the medical physics specialist.

(5) Tests, tolerances and frequency of their implementation may be changed in accordance with justified criteria that take account of the treatment purpose and available technology.

**Article 91**
**(Procedures for anomalies)**

(1) An anomaly or suspected anomaly in the operation of radiotherapy devices or an unusual reaction of a patient treated with such devices shall be urgently reported to the responsible radiotherapy specialist and the responsible medical physics specialist.

(2) For any situation referred to in paragraph (1) or any anomaly found during periodic controls, the responsible medical physics specialist shall decide on possible temporary suspension of the radiotherapy device or propose conditions of its use to the responsible radiotherapy specialist.

(3) Having considered the report of the responsible medical physics specialist, the responsible radiotherapy specialist shall decide on the equipment to be used and possibly limited, the equipment to be taken out of use, and the types of treatment to be conducted.

(4) The decisions referred to in paragraph (3) shall be delivered to the licensee in writing within 24 hours.

**Section B. – Equipment maintenance**

**Article 92**
**(Equipment maintenance program)**

(1) In cooperation with a licensed technical service for installation, servicing and maintenance, the licensee for radiotherapy shall establish an equipment maintenance program stipulating that the radiotherapy devices shall not be out of use more than 5% of the working days annually.

(2) In cooperation with a licensed technical service for installation, servicing and maintenance, the licensee shall make an annual equipment maintenance plan by 31 January of the current year, attaching the documentation confirming the stipulation referred to in paragraph (1).

**Article 93**
**(Corrective equipment maintenance)**

(1) Repairs or interventions regarding radiotherapy devices shall be announced to the responsible medical physics specialist.

(2) A licensed technical service for installation, servicing and maintenance that repairs or intervenes regarding the equipment shall be responsible for the equipment operation within the specifications guaranteed by the vendor, and shall make a report containing: the cause for repair, names of repairmen, conducted procedures, and possible changes in the equipment operation resulting from the repair.

(3) After the repair, the medical physics specialist shall verify whether the repaired equipment meets requirements for its clinical use, and shall perform needed measurements and tests to verify that the reference level tolerances set out in Annex 3.2 are not exceeded for the parameters that may have changed according to the repairman's report.

(4) If it is not possible to re-establish initial reference condition either because of a repair or modification intended to change equipment functioning, a new reference level shall

be established to meet the tolerance levels set out in Annex 3.2. All needed changes in the treatment planning system and in each stage of the radiotherapy process shall be made.

**Article 94**
**(Equipment maintenance reports)**

(1) Reports on repairs or modifications, and results of later controls shall be delivered to the responsible medical physics specialist who shall prepare and provide information to the responsible radiotherapy specialist.

(2) The responsible radiotherapy specialist shall decide on the continuation of radiotherapy treatment and provide written information on possible limitations.

**Section C. – Specific requirements**

**Article 95**
**(Postal TLD audit)**

(1) In addition to the requirements referred to in Article 22, the licensee for radiotherapy shall participate in an external postal audit carried out by using thermoluminiscent dosimetry.

(2) The licensee shall participate in the audit referred to in paragraph (1) before clinical use of the equipment and every second year thereafter.

**Article 96**
**(Calibration)**

(1) Reference instruments for measuring physical quantities shall be calibrated periodically, at least once in three years.

(2) Calibration shall be traceable to the primary laboratory, that is, the primary standard for measuring a given physical quantity.

(3) The type and frequency of quality control tests of the equipment referred to in paragraph (1) shall be part of the quality assurance program.

**Article 97**
**(Archiving)**

(1) The licensee shall archive and keep all reports set out in Articles 76 to 96 for at least 30 years.

(2) The reports referred to in paragraph (1) shall be available to the Agency inspectors.

(3) After discontinuation of the health-care institution or using the radiation source, the licensee shall submit a report to the Agency within five days.

## PART V – TRANSITIONAL AND FINAL PROVISIONS

### Article 98
### (Establishment of the commission)

(1) In cooperation with the entity ministries of health, the Agency shall establish the commission to define the criteria for evaluating job qualifications for the medical physics specialist referred to in Article 19(1) for those practicing medical physics in health-care institutions during the licensing period without qualifications for that job under the entity laws on health care.

(2) The commission referred to in paragraph (1) shall adopt the rules of procedure specifying the criteria referred to in paragraph (1), the way of the committee's work and decision making, and other matters from its competence.

### Article 99
### (Composition of the commission)

(1) The commission referred to in Article 98 shall consist of: an Agency representative, one representative from each of the two entity ministries of health, two holders of a university degree in physics or electrical engineering and with at least seven years of experience in medical physics job, a specialist in radiology or radiation oncology or nuclear medicine, and a university professor of medical physics.

(2) If the Agency considers appropriate, representatives of other institutions may join the commission referred to in paragraph (1).

### Article 100
### (Deadlines)

(1) The health-care institutions covered by the provisions of this regulation shall harmonize their operations with the provisions of this regulation within one year from the day of entering of this regulation into the force.

(2) The health-care institutions referred to in paragraph (1) shall adopt a quality assurance program and submit it to the Agency within six months from the day of entering this regulation into force.

(3) Within six months from entering of this regulation into force, the health-care institutions referred to in paragraph (1) shall establish reference condition of the radiotherapy equipment already in use.

### Article 101
### (Accountability for non-compliance with the regulation provisions)

Any non-compliance with the provisions of this regulation shall be punished under the penalty provisions of the Law on Radiation and Nuclear Safety in Bosnia and Herzegovina ("Official Gazette of BiH" 88/07).

**Article 102**
**(Entering into force)**

This regulation shall enter into force on the eighth day following that of its publication in the "Official Gazette of BiH."

**D I R E C T O R**

**Enes Cengic, M.S.**

## Annex 1.1: Verification of patient dose

1) Dose verification is performed in order to detect irregularities in workers performance or equipment usage, as well as to make necessary corrections. It is required to:

   a) make measurements of quantities related to patient doses,

   b) make evaluation of parameters that objectively describe image quality.

2) Standard examinations in diagnostic radiology are listed in Table s 1–6, and they are used for dose and image quality evaluation. Values from Table s 1–6 represent diagnostic reference levels that are valid for Bosnia and Herzegovina.

3) Doses to paediatric patients need to be as low as possible.

4) Not in any case patients are allowed to be exposed to radiation just to perform quality control of equipment.

5) Procedures of patient dose verifications should follow following guidelines::

   a) Quantities that are related to patient doses are determined in accordance to one of the following options:

      i) Percentage of rejected images and entrance skin dose (ESD) for all standard examinations from Table 1 is evaluated in all radiodiagnostic rooms (except those for fluoroscopy and those with low number of projections per patient). Dose evaluation is performed for usual projections that are performed in the room for ten patients minimum. It is required to note all technical parameter of imaging (selected voltage, product of current and time of exposure, focus-image receptor distance, patient thickness and type of image receptor).

      ii) Entrance skin dose for usual projections in Table 4 is evaluated in all diagnostic rooms dedicated for conventional complex procedures (fluoroscopy with several images). Number of images and fluoroscopy time is recorded (if used) for all common examinations in the room.
      Entrance dose rate for fluoroscopy is measured at patient or phantom that simulates patient. As an alternative, it is recommended to measure kerma area product ($P_{KA}$) for the controlled type of examination.
      Dose evaluation is performed on 5 patients minimum.

      iii) Patient entrance skin dose (ESD) is measured in one of the standard projections in rooms where special types of examinations in performed (vascular, hemodynamic interventions etc.), as well as skin dose at the point most likely to be exposed to direct beam, kerma area product, number of

images, and (if possible) fluoroscopy time.
Dose evaluation is performed on 5 patients minimum.

iv) Normalized weighted computed tomography dose index ($CTDI_{n,w}$) in phantom, or CTDI in air is measured for common procedures in computed tomography in Table 5, where work methodology is recorded. Later, according to imaging parameters (voltage, anode current-exposure time product, slice thickness, pitch and length of scanned area) dose evaluation is performed ($CTDI_w$, DLP) for 5 patients minimum.

b) Evaluation of parameters used for objective image quality assessment can be performed according to following methodology:

i) Sample of five or ten patients is chosen according to the type of examination described in Table 1, using criteria recommended from international scientific associations or expert groups, or those justified by practitioner for a diagnostic room or service. In the last case, alternative criteria must be recorded, together with analysis result.

ii) Basic physical parameters of image are evaluated using test objects, where obtained values and tolerances are recorded.

c) Corrective actions are to be applied if:

i) average patient doses are greater than reference levels by 30%,

ii) parameters of image quality are significantly lower than standards noted in the QA programme; criteria for corrective actions must be part of the programme.

6) Patient doses and image quality evaluation are part of the documentation that needs to be available to the Agency's inspection.

*Table 1. Reference level for diagnostic radiography for a typical adult patient*

| **Projection** | **Entrance surface dose per projection, $D_{skin,e}$ (mGy)** | **Product of air kerma and area, $P_{KA}$ (mGycm²)** |
|---|---|---|
| Skull AP ili PA | 5 | – |
| Skull LAT | 3 | – |
| Cervical spine AP | 1.25 | – |
| Lung PA | 0.3 | – |
| Lung LAT | 1.5 | – |
| Thoracic spine AP | 7 | – |
| Thoracic spine LAT | 20 | – |
| Abdomen AP | 10 | – |
| Lumbar spine AP ili PA | 10 | – |
| Lumbar spine LAT | 30 | – |
| Lumbar spine LSJ | 40 | – |
| Pelvis AP | 10 | – |
| Hip AP | 10 | – |
| Urinary tract AP | 10 | – |

*Table 2. Reference level for diagnostic radiography for children*

| **Projection** | **Entrance surface dose per projection, $D_{skin,e}$ (μGy)** | **Product of air kerma and area, $P_{KA}$ (mGycm²)** |
|---|---|---|
| Skull AP ili PA (5 years) | 1500 | – |
| Skull LAT (5 years) | 1000 | – |
| Lung PA ili AP (5 years) | 100 | – |
| Lung LAT (5 years) | 200 | – |
| Lung AP (newborn) | 80 | – |
| Pelvis AP (younger child) | 200 | – |
| Pelvis AP (5 years) | 900 | – |
| Abdomen AP ili PA (5 years) | 1000 | – |
| MCU (0; 1; 5 i 10 years) | – | 600; 900; 1200 i 2400 |

*Table 3. Reference level for dental radiography*

| **Projection** | **Entrance surface dose per projection, $D_{skin,e}$ (mGy)** | **Product of air kerma and beam width, $P_{KW}$ (mGymm)** |
|---|---|---|
| Panoramic | – | 65 |
| Periapical | 7 | – |
| Dental AP | 5 | – |
| Cephalometric | 0.25 [$K_{a,e}$] | – |
| Intraoral | 4 [PED] | – |

*Table 4. Reference level for fluoroscopy*

| **Projection** | **Entrance surface dose rate, $\dot{D}_{\mathrm{skin,e}}$ (mGymin$^{-1}$)** | **Product of air kerma and area, $P_{KA}$ (mGycm$^2$)** |
|---|---|---|
| Normal mode | 25 | – |
| High image quality | 100 | – |
| Lumbar spine | – | 15 |
| Irrigography | – | 60 |
| Barium porridge | – | 25 |
| Intravenous urography | – | 40 |
| Abdomen | – | 8 |
| Pelvis | – | 5 |
| Coronary angiography | – | 50 |
| PTCA | – | 100 |

*Table 5. Reference level for computed tomography*

| **Projection** | **$CTDI_w$ (mGy)** | **DLP (mGycm)** |
|---|---|---|
| Head routine | 60 | 1050 |
| Lung routine | 30 | 650 |
| Abdomen routine | 35 | 780 |
| Pelvis routine | 35 | 570 |
| Face and sinuses | 35 | 360 |
| Vertebral trauma | 70 | 460 |
| High resolution CT lung | 35 | 280 |
| Liver and spleen | 35 | 900 |
| Pelvic bone | 25 | 520 |

*Table 6. Reference level for mammography*

| **Projection** | **Entrance surface dose per projection, $D_{\mathrm{skin,e}}$ (mGy)** | **Average glandular dose, $D_g$ (mGy)** |
|---|---|---|
| Breast LAT | 10 | |
| Breast MLO | 10 | 2 |
| Breast CC | 10 | 2 |

## Annex 1.2: Criteria for acceptability and control tests

*Table 7. Radiographic X-ray equipment*

| ID | Test | Criterion |
|---|---|---|
| | *Voltage* | |
| OR01 | Kilovoltage accuracy | The maximum deviation of the indicated value from the actual value should be less than ±10% . |
| OR02 | Variation with changes in tube current | The maximum variation should be less than 10%. |
| OR03 | Precision of tube voltage | For repeated meaurements the deviation in the tube voltage should be less than ±5% from the mean value. |
| | *Radiation output* | |
| OR04 | Magnitude | With a total filtration of 2.5 mm Al, the output should be greater than 25 μGy/mAs at 1 m for true 80 kV operation. |
| OR05 | Consistency of output | The output should be constant within ± 20% of the mean for repeated exposures. |
| OR06 | Variation with change in indicated current - exposure time product | The variation should be less than 10%. |
| | *Filtration in the useful beam* | |
| OR07 | Total filtration | The total filtration in the useful beam should be equivalent to not less than 2.5 mm Al. |
| | *Exposure time* | |
| OR08 | The accuracy of the exposure time | For indicated exposure times greater than 100 ms, the actual exposure time should be within ± 20% of the indicated exposure time. |
| | *The geometrical parameters* | |
| OR09 | X-ray/light beam alignment | The sum of the misalignment of the visually defined field with the respective edge of the X-ray field in each of the principal directions should not exceed 3% of the distance from the focus to the centre of the visually defined field. |
| OR10 | Orthogonality of X-ray beam and image receptor | The angle between the central axis of the X-ray beam and the plane of the image receptor should not differ by more than 1.5 degrees from 90 degrees. |
| OR11 | Automatic collimation | The X-ray beam shall not differ by more than 2% of the focus to image receptor distance at any side of the image receptor. One should be able to use smaller fields than the whole image receptor area. |
| | *Grid* | |
| OR12 | Artefacts | An X-ray image of the grid should be made at 50 kV. No disturbing artefacts should be visible. |

| | | |
|---|---|---|
| OR13 | Moving grid | The lamellae of a moving grid should not be visible on the image at the shortest exposure time used in practice. |
| | *Automatic exposure control (AEC)* | |
| OR14 | Limitation of overexposure | The maximal focal spot charge should be less than 600 mAs (not in the case of fluoroscopy and tomography). |
| OR15 | Limitation of exposure time (single exposure) | The exposure time for a single exposure should be limited to a maximum of 6 s. |
| OR16 | Difference in test image optical density as a function of the tube voltage | For a fixed attenuator thickness<br>– the maximum difference in test image optical density as a function of the tube voltage range used in practice should not exceed ± 0.3 OD.<br>– the maximum difference in measured $K_a$ value at the photoreceptor has to be less than 50% compared to the mean value, for the thickness of phantom greater than 5 cm PMMA. |
| OR17 | Difference in test image optical density as a function of attenuator thickness | For a fixed tube voltage<br>– the maximum difference in test image optical density as a function of attenuator thickness should not exceed ± 0.3 OD.<br>– the maximum difference in measured $K_a$ value at the photoreceptor has to be less than 50% compared to the mean value, for the thickness of phantom greater than 5 cm PMMA. |
| | *Leakage radiation* | |
| OR18 | Leakage radiation | Leakage radiation from the housing measured at a distance of 1 m from the focus should not exceed 1 mGy in one hour at the maximum rating specified by the manufacturer for the tube in that housing. |

*Table 8. Film processing and characteristics*

| ID | Test | Criterion |
|---|---|---|
| | *Automatic film processing* | |
| RF01 | Base and fog | The optical density of the base of the film and the fog should be less than 0.30 OD. |
| RF02 | Speed index | The speed index should be 1.2 ± 0.3. |
| RF03 | Contrast index | The contrast index should be 1.0 ± 0.3. |
| RF04 | Condition and cleanliness of intensifying screen(s) and cassette | Artefacts that could affect the information quality, and fields with visible difference in optical density and sharpness should not be visible on exposed films. |
| | *Darkroom* | |
| RF05 | Light leakage | No appreciable light leaks should be visible after adaptation of the eyes for at least five minutes to the darkroom with safelights and other lights off. |

| | | |
|---|---|---|
| RF06 | Red light | A pre-exposed film of unit optical density exposed at normal working distance for 4 min to darkroom conditions with safelights on and lights on in surrounding rooms should not show an increase of the density by more than 0.10 OD from a part of the same film not exposed to the darkroom conditions. |

*Table 9. Characteristics of CR plates and readers*

| ID | Test | Criterion |
|---|---|---|
| | *CR plate* | |
| DR01 | Condition and cleanliness of screen(s) and cassette | Demage on the plate should not be present. |
| DR02 | Uniformity | With the anode voltage of 70 kV, a filter thickness of 1.0 mmCu on the tube housing, a dose on the image receptor of 10 μGy and the linear algorithm reading, the inhomogeneity should be less then ± 20% from the mean value. |
| | *CR readers* | |
| DR03 | Dark noise | Detektor dose index (DDI) must meet (satisfy) the following criteria: Agfa SAL > 130; Fuji pixel value > 280; Kodak EIGP > 80; Kodak EIHR > 380; Konica pixel value < 3975 |
| DR04 | Linearity and the characteristics of the system transfer | Determine the function of air kerma depending on the pixel values. Use the manufacturer's recommendations as the eligibility criteria. |
| DR05 | Efficiency of the reader | An object should not be visible on the deleted images. |
| DR06 | The accuracy of the exposure indicator | Measured value of the exposition should not differ for more than ±20% from the initial value. |
| DR07 | Detector dose index (DDI) | The initial value ± 20% |
| DR08 | Scaling errors | Difference in software measured distance on a record and the real distance should not be greater than 2%. |
| DR09 | Blurring of the image | Blurriness should not be present. |
| DR10 | Spatial resolution | Spatial resolution should be greater than 2.8 lp/mm for less than 10 μGy, and greater than 2.4 lp/mm for less than 5 μGy. |
| DR11 | Contrast | All 7 fields of the phantom of the standard DIN 6868-58 (2001) should be visible, or the number of fields or contrast curve should be compared to baseline or to standard reference curve from MHRA reports. |
| | *DDR systems* | |
| DR12 | Uniformity | With the anode voltage of 70 kV, a filter thickness of 1.0 mmCu on the tube housing, a dose on the image receptor of 10 μGy and the linear algorithm reading, the inhomogeneity should be less then ± 5% from the mean value. |
| DR13 | Dark noise | Noise should not be overemphasized. |

| | | |
|---|---|---|
| DR14 | Linearity and the characteristics of the system transfer | Determine the function of air kerma depending on the pixel values. Use the manufacturer's recommendations as the eligibility criteria. |
| DR15 | Visualisation of the ghost image | An object should not be visible on the deleted images. |
| DR16 | The accuracy of the exposure indicator | Measured value of the exposition should not differ for more than ±20% from the initial value. |
| DR17 | Scaling errors | Difference in software measured distance on a record and the real distance should not be greater than 2%. |
| DR18 | Blurring of the image | Blurriness should not be present. |
| DR19 | Spatial resolution | Spatial resolution should be greater than 2.8 lp/mm for less than 10 μGy, and greater than 2.4 lp/mm for less than 5 μGy. |
| DR20 | Contrast | All 7 fields of the phantom of the standard DIN 6868-58 (2001) should be visible, or the number of fields or contrast curve should be compared to baseline or to standard reference curve from MHRA reports. |

*Table 10. Viewing conditions*

| ID | Test | Criterion |
|---|---|---|
| | *Image viewing conditionas* | |
| UO01 | Luminance of the viewboxes | Luminance of the viewboxes has to be more than 1000 cd/m², for the interpretation of the mammography film more than 3000 cd/m². It can not be more than 6000 cd/m². |
| UO02 | Uniformity of the viewboxes | Inhomogeneity should be less than 30%. |
| UO03 | Difference between adjacent viewboxes | The difference in luminance between adjacent viewboxes can not be more than 30% for a standard radiography, and 50% for mammography. |
| UO04 | Ambient illumination of the room with the viewboxes | Ambient illumination of the workplace at 1 m distance from the viewboxes has to be less than 150 lx for the interpretation in standard radiography, and 50 lx in mammography. |
| | *Monitor characteristics* | |
| UO05 | Luminance ratio of black and white | Ratio of $L_W/L_B$ must be greater then 200. |
| UO06 | Luminance of black and white fields | Measured value of luminance of black and white field in test image should not deviate for more than ±35% and ±30% in comparison to the baseline value, respectively. |
| UO07 | Distance and angle calibration – distortion (for CRT) | Difference in comparison to normal value should not be greater than 10%. This test is not applicable where distances and angles are measured directly on the screen. |
| UO08 | Resolution | Check the resolution of high and low contrast, in the centre and at the periphery of the monitor, and compare it to the baseline value. |
| UO09 | DICOM greyscale calibration | DICOM Grayscale Standard Display Function (GSDF) should not deviate more than ±10%. |
| UO10 | Uniformity | Inhomogeneity should be less than 40%. |

| | | |
|---|---|---|
| UO11 | Variation between adjacent monitors | Luminance differences of black and white fields should not be greater than 40%. |
| UO12 | Room illumination | Room illumination should not be greater than 25 lx. |

*Table 11. Film Screen Mammography*

| ID | Test | Criterion |
|---|---|---|
| | *Automatic exposure control* | |
| KM01 | Target optical density | Optical density of the phantom images recorded using clinical settings should not be less than 1.3 or greater than 2.1. |
| KM02 | Repeatability of the exposure | The deviation of the exposition (dose or charge) from the mean value should be less than 5%. |
| KM03 | Test of AEC thickness compensation | The deviation of the optical density of the images for different phantom thicknesses should be less than ± 0.15 in terms of the target optical density. |
| | *Film and screen* | |
| KM04 | Film - screen contact | On the film should not be visible areas with bad contact greater then 1 $cm^2$. |
| KM05 | Spatial resolution | In both directions spatial resolution must be above 12 lp/mm for measurements with the phantom positioned 4 cm above the Table (PMMA phantom) and in the middle, at a distance of 6 cm from the thoracic photoreceptor. |
| KM06 | Prag contrast | The contrast in the PMMA phantom thickness of 45 mm should not be greater than 1.3% for the element size of 6 mm. |
| KM07 | Alignment of the X-ray field size and the photoreceptor | The thoracic side of the X-ray field should not exceed the limits of the photoreceptor by more than 5 mm. Lateral sides of the X-ray field should cover the image receptor to its limits. |
| | *Compression* | |
| KM08 | Compression force | The maximum compression force for powered compression should be no more than 200 N. Maximum manual compression force: <300 N. |
| KM09 | Repeatability of the compression force | The difference compared to the mean value should not exceed 20 N. |
| | *Anode voltage* | |
| KM10 | Accuracy of the kVp | The error by measuring anode voltage relative to the set voltage, in the range of 25–31 kV, should be not greater than ±1 kV. |

*Table 12. Digital mammography*

| ID | Test | Criterion |
|---|---|---|
| | *Automatic exposure control* | |

| | | |
|---|---|---|
| DM01 | Repeatability of the exposure | The deviation of the exposition (dose or charge) from the mean value should be less than 5%. |
| DM02 | Test of AEC thickness compensation | Contrast to noise ratio (CNR) for different phantom PMMA ($T_{PMMA}$) thicknesses, wherein the reference CNR for $T_{PMMA}$ = 5 cm, can not exceed the following values:<br>– 115% for $T_{PMMA}$ = 2,0 cm;<br>– 110% for $T_{PMMA}$ = 3,0 cm;<br>– 105% for $T_{PMMA}$ = 4,0 cm;<br>– 103% for $T_{PMMA}$ = 4,5 cm;<br>– 100% for $T_{PMMA}$ = 5,0 cm;<br>– 95% for $T_{PMMA}$ = 6,0 cm;<br>– 90% for $T_{PMMA}$ = 7,0 cm; |
| | *Image receptor* | |
| DM03 | Prag contrast | The contrast in the PMMA phantom thickness of 45 mm should not be greater than:<br>– 0.85% for the element size of 5-6 mm.<br>– 2.35% for the element size of 0.5 mm.<br>– 5.45% for the element size of 0.25 mm. |
| DM04 | Alignment of the X-ray field size and the photoreceptor | The thoracic side of the X-ray field should not exceed the limits of the photoreceptor by more than 5 mm. Lateral sides of the X-ray field should cover the image receptor to its limits. |
| | Compression | |
| DM05 | Compression force | The maximum compression force for powered compression should be no more than 200 N. Maximum manual compression force: <300 N. |
| DM06 | Repeatability of the compression force | The difference compared to the mean value should not exceed 20 N. |
| | *Anode voltage* | |
| DM07 | Accuracy of the kVp | The error by measuring anode voltage relative to the set voltage, in the range of 25-31 kV, should be not greater than ± 1 kV. |

*Table 13. Dental radiography*

| ID | Test | Criterion |
|---|---|---|
| | *Film processing* | |
| DN01 | Temperature developers | The temperature of the developer should not be less than 18 ºC and above 40 ºC. |
| DN02 | Dark room (or desktop day light processor) light proof | The total optical density of the base and the blur should not be greater than 0.3. |
| DN03 | Reproducibility of base + fog, speed and contrast | Optical density of base + fog should not be greater than 0.3, and index values of speed and contrast should not be greater than 0.3 from the baseline value. |
| | *Radiation quality* | |
| DN04 | Kilovoltage accuracy | The difference in the indicated value in relation to the actual value should be less than ±10%. |

| | | |
|---|---|---|
| | *Timer* | |
| DN05 | Accuracy of exposure time | The maximum deviation of the actual exposure time in relation to the indicated must be less than ± 50%. |
| DN06 | Precision of exposure time | For repeated measurements, the deviation from the mean exposure time value must be less than ± 20%. |

*Table 14. Panoramic radiography*[1]

| ID | Test | Criterion |
|---|---|---|
| | *Orthopantomograph* | |
| PR01 | Characteristics of panoramic image | Must satisfy the specifications of the manufacturer. |

[1] All criteria from the Table 13. are valid

*Table 15. Fluoroscopy*[1]

| ID | Test | Criterion |
|---|---|---|
| | *Alignment* | |
| PR01 | Radiation/image field size | The ratio of the areas of the radiation field and the image intensifier entrance surface should not exceed 1.15. |
| | *Filtration in the useful beam* | |
| PR02 | Total filtration | The total filtration in the useful beam should be equivalent to not less than 2.5 mm Al. |
| | *Dosimetry* | |
| PR03 | Patient (phantom) entrance surface air kerma rate in fluoro mode | Entrance surface air kerma rate with the smallest field of radiation and the phantom of 20 cm PMMA or equivalent should not be greater than 50 mGy/min.<br>The maximum entrance surface air kerma rate (with lead in the beam) by any size of radiation field should not be greater than 100 mGy/min. |
| PR04 | Patient (phantom) entrance surface air kerma in data acquisition mode | Entrane surface air kerma with the largest field of radiation should not be greater than 2 mGy, and for devices in interventional cardiology 0.2 mGy per exposition (puls). Use the phantom of 20 cm PMMA or equivalent. |
| PR05 | Detector entrance air kerma in fluoro mode | Detector entrance air kerma with the largest field of radiation should not be greater than 1 μGy/s in continuous fluoroscopy mode. |
| PR06 | Detector entrance air kerma in data acquisition mode | Detector entrance air kerma with the largest field of radiation should not be greater than 5 μGy, and for cardiac systems not more than od 0.5 μGy per exposure. |
| PR07 | Calibration of the integrated dosimeter | The difference between the read out dose value and the measured dose value must be greater than 35%. |
| | *Image quality* | |
| PR08 | Resolution | For the largest radiation field the resolution should be greater than 1.0 line pair per mm, and for devices in interventional cardiology 1.2 line pair per mm. |

| | | |
|---|---|---|
| PR09 | Threshold contrast | The contrast threshold under automatic operation and the greatest radiation field estimated from the TV monitor image should be 4% or less. |
| | *Timer (alarm)* | |
| PR10 | Timer | A means of termination should operate automatically when a predetermined integrated fluoroscopy time not exceeding 10 min has elapsed. An acoustic signal should warn of the impending termination at least 30 s in advance to enable the device to be reset if exposure needs to be prolonged. |

[1] If not specified, criteria from Table 7 should be used.

*Table 16. Computed tomography (CT)*

| ID | Test | Criterion |
|---|---|---|
| | *Dosimetry* | |
| CT01 | Accuracy of dosimetric data | Measured dosimetry data ($C_{VOL}$, $C_W$, $P_{KL,CT}$) should not differ by more than 20% compared to the value provided by the manufacturer. |
| | *Image quality* | |
| CT02 | Image noise | The standard deviation of the CT numbers in the central 500 $mm^2$ region of interest for a water or tissue equivalent phantom should not deviate more than 25% from the baseline value. |
| CT03 | CT number uniformity | Inhomogeneity between the CT number value in the center and the periphery of the water or tissue-equivalent phantom should not be greater than ± 8 HU. |
| CT04 | CT number values | The deviation in the CT number values for a water phantom should be less than ± 20 HU, and for other materials of different densities ± 30 HU. |
| CT05 | Artefacts | Artefacts that affect the quality of the diagnosis should not be visible on the image. |
| | *Slice thickness* | |
| CT06 | Slice thickness | The full width at half maximum of the dose profile should not differ more than<br>+0.5 mm for a nominal width less than 1 mm;<br>± 50% width of 1-2 mm;<br>±1 mm width of more than 2 mm. |

*Table 17. Dual-energy X-ray absorptiometry (DXA)*

| ID | Test | Criterion |
|---|---|---|
| DA01 | Accuracy of the bone and mineral densitometry | Error in relation to the specifications of the manufacturer should not be greater than ± 3%. |

## Annex 1.3: Quality control tests frequency

| Type of device | Frequency | Responsible person |
|---|---|---|
| Film processing (RF01–03), Target optical and repeatability of the exposure in film screen and digital mammography (KM01–02 i DM01), HU number values, uniformity and noise in CT (CT02, CT03 i CT04), accuracy of the bone and mineral densitometry (DA01), Film processing in panoramic radiography (DN01–03) | Daily | Engineer of medical radiology[1]<br>Photolaboratory technician for RF01–03 |
| Test of AEC thickness compensation (KM03) | Weekly | Engineer of medical radiology |
| X-ray/light beam alignment (OR09) and automatic collimation (OR11) | Monthly | Engineer of medical radiology |
| Film screen and digital mammography (all tests) in case the unit is used for screening purposes (non-symptomatic patients) | Semi-annualy | Medical physics specialist |
| CT, film screen and digital mammography, fluoroscopy in interventional radiology, digital receptors and readers (all tests) and viewing conditions (UO05–012) | Yearly | Medical physics specialist |
| Film screen radiography, fluoroscopy, panoramic radiography, veterinary radiography (all tests) and viewing conditions (UO01–04) | Once in 2 years | Medical physics specialist |
| Dental intraoral radiography (all tests) | Once in 3 years | Medical physics specialist |

[1]The term describes engineer of medical radiology, radiological technician or medical worker with a degree in radiolography.

## Annex 2.1: Maximal activities of radiopharmaceuticals

| Diagnostic procedure | Radiopharmaceuticals | Chemical form | Activity (MBq) |
|---|---|---|---|
| Scintigraphy of thyroid gland | $^{99m}$Tc | $TcO_4^-$ | 120 |
| The functionality of thyroid gland | $^{131}$I | $I^-$ | 2 |
| Scintigraphy of the sceleton(WB) | $^{99m}$Tc | Phosphonate and phosphate | 600 |
| Scintigraphy of the sceleton(WB) | $^{99m}$Tc | ciprofloxacin | 600 |
| Scintigraphy of the sceleton(WB) | $^{131}$I | $I^-$ | 200 |
| Scintigraphy of the sceleton(WB)) | $^{99m}$Tc | alkalescent DMS | 600 |
| Scintigraphy of the joints | $^{99m}$Tc | Phosphonate and phosphate | 600 |
| SPECT of the bones | $^{99m}$Tc | Phosphonate and phosphate | 800 |
| Scintigraphy of the bone marrow | $^{99m}$Tc | colloid | 400 |
| Scintigraphy of the bone marrow | $^{111}$In | transferrin | 74 |
| Dynamic scintigraphy of the brain | $^{99m}$Tc | | 900 |
| Static scintigraphy of the brain | $^{99m}$Tc | $TcO_4^-$ | 500 |
| Static scintigraphy of the brain | $^{99m}$Tc | DTPA, gluconate | 500 |

| | | | |
|---|---|---|---|
| SPECT of the brain | $^{99m}$Tc | $TcO_4^-$ | 800 |
| SPECT of the brain | $^{99m}$Tc | DTPA, gluconate | 800 |
| Blood flow of the brain | $^{99m}$Tc | HMPAO | 800 |
| Cisternography | $^{111}$In | DTPA | 40 |
| Scintigraphy of the lacrimal gland | $^{99m}$Tc | $TcO_4^-$ | 4 |
| Scintigraphy of the lacrimal gland | $^{99m}$Tc | colloid | 4 |
| Scintigraphy of the parathyroid gland | $^{99m}$Tc | $TcO_4^-$ | 120 |
| | | SESTAMIBI | 600 |
| Scintigraphy of lung ventilation | $^{99m}$Tc | DTPA, aerosol inhalation | 80 |
| Scintigraphy of lung perfusion | $^{99m}$Tc | Albumin (macroaggregates) | 100 |
| Perfusion scintigraphy of the lungs with venography | $^{99m}$Tc | Albumin (macroaggregates) | 160 |
| SPECT of the lungs | $^{99m}$Tc | Depreotide | 800 |
| Static scintigraphy of the kidneys | $^{99m}$Tc | DMSA | 160 |
| Dynamic scintigraphy of the kidneys and the determination of the GRF | $^{99m}$Tc | DTPA | 370 |
| Dynamic scintigraphy of the kidneys and tubular extraction | $^{99m}$Tc | MAG3 | 350 |
| Radiorenography | $^{131}$I | Hippuran | 15 |
| Scintigraphy of the marrow of the adrenal gland | $^{131}$I | Benzyl gvandin | 40 |
| Liver and spleen scintigraphy | $^{99m}$Tc | colloid | 100 |
| SPECT jetre | $^{99m}$Tc | colloid | 200 |
| Examination of the liver blood flow | $^{99m}$Tc | EHIDA | 200 |
| Examination of the liver blood flow | $^{99m}$Tc | Sn colloid | 200 |
| Functional biliary system | $^{99m}$Tc | Iminodiacetates | 150 |
| Examination of the first pass blood flow through the heart | $^{99m}$Tc | $TcO_4^-$ | 800 |
| Examination of the first pass blood flow through the heart | $^{99m}$Tc | DTPA | 800 |
| Scintigraphy of the blood stream | $^{99m}$Tc | Albumin complex | 40 |
| Scintigraphy of the acute myocardial infarction | $^{99m}$Tc | Phosphonate and phosphate | 600 |
| Myocardial SPECT | $^{99m}$Tc | Isonitriles | 800 |
| Myocardial SPECT | $^{99m}$Tc | Phosphonate and phosphate | 800 |
| Myocardial SPECT | $^{201}$Tl | $Tl^+$ chloride | 120 |
| Dynamic scintigraphy of the salivary glands | $^{99m}$Tc | $TcO_4^-$ | 200 |
| Scint. of the sentinel lymph node | $^{99m}$Tc | Rhenium sulfide colloid | 100 |

| | | | |
|---|---|---|---|
| Scintigraphy of the stomach | $^{99m}$Tc | $TcO_4^-$ | 40 |
| Examination of the oesophageal transit | $^{99m}$Tc | Sn colloid | 40 |
| Gastrointestinal bleeding | $^{99m}$Tc | colloid | 400 |
| Gastric emptying | $^{99m}$Tc | Non-absorbable compounds | 40 |
| Scintigraphy of the breasts | $^{99m}$Tc | Sestamibi | 800 |
| Scintigraphy of the tumor | $^{99m}$Tc | DMSA | 600 |
| Scintigraphy of the abscess | $^{99m}$Tc | Labeled leukocytes | 400 |
| Scintigraphy of the thrombus | $^{111}$In | Labeled platelets | 20 |
| Immunoscintigraphy | $^{99m}$Tc | Antibodies | 1000 |
| Detekcija inflamatornih promjena | $^{99m}$Tc | Leukociti | 1200 |
| Detection inflammatory changes | $^{111}$In | Antibodies | 200 |
| PET 2D | $^{18}$F | FDG | 600 |
| PET 3D | $^{18}$F | Fluorine | 600 |

## Annex 2.2: Dose rate at 1 m from the patient who received the dose of radioactive $^{131}$I

*Table 18. Periodic compliance of instructions depending on the evaluation of the remaining activity in the patietnts body*

| Effective dose rate (μSv/h) | Evaluation of the remaining activity (MBq) | Minimum period in which the instructions need to be followed |
|---|---|---|
| < 20 | < 400 | 2 weeks |
| < 10 | < 200 | 1 week |
| < 5 | < 100 | 4 days |
| < 3 | < 60 | 24 hours |

*Table 19. Restrictions regarding the work duties*

| | The number of days a patient is forbidden to go to work, depending on the distance from other workers and working hours | |
|---|---|---|
| **Working hours and distance** | **Eval. of the remaining activity 200 MBq** | **Eval. of the remaining activity 400 MBq** |
| 8 hours at 1m | 4 | 10 |
| 4 hours at 1m | - | 4 |

## Annex 2.3: Weighting factors of applied doses of radiopharmaceuticals which are given to children

| Mass (kg) | Weighting factors | Mass (kg) | Weighting factors | Mass (kg) | Weighting factors |
|---|---|---|---|---|---|
| 3 | 0,10 | 22 | 0,50 | 42 | 0,78 |
| 4 | 0,14 | 24 | 0,53 | 44 | 0,80 |
| 6 | 0,19 | 26 | 0,56 | 46 | 0,82 |
| 8 | 0,23 | 28 | 0,58 | 48 | 0,85 |
| 10 | 0,27 | 30 | 0,62 | 50 | 0,88 |
| 12 | 0,32 | 32 | 0,65 | 52–54 | 0,90 |
| 14 | 0,36 | 34 | 0,68 | 56–58 | 0,92 |
| 16 | 0,40 | 36 | 0,71 | 60–62 | 0,96 |
| 18 | 0,44 | 38 | 0,73 | 64–66 | 0,98 |
| 20 | 0,46 | 40 | 0,76 | 68 | 0,99 |

## Annex 2.4: The period of temporary interruption of breastfeeding in the case of application of radiopharmaceuticals in women during lactation, depending on radiopharmaceuticals

| Radionuclide | Activity (MBq) | The period of temporary interruption of breastfeeding |
|---|---|---|
| $^{99m}$Tc pertechnetate | 185 | 4 hours |
| $^{99m}$Tc MAA | 148 | 12 hours |
| $^{99m}$Tc labeled erythrocytes | 740 | 12 hours |
| $^{99m}$Tc labeled erythrocytes | 185 | 2 days |
| $^{123}$I MIBG | 370 | 2 days |
| $^{123}$I NaI | 15 | 6 months |
| $^{201}$Tl | 111 | 10 days |
| $^{111}$In | - | 20 days |
| $^{67}$Ga | 185 | 6 months |
| $^{131}$I OIH | 11.1 | 10 days |
| $^{131}$I NaI | 370 | 3 months |
| $^{131}$I NaI | 3700 | 6 months |

## Annex 2.5: Maximum permissible radionuclide activity, applied during life time, in the body of deceased persons for autopsy and cremation without the use of special protection measures, estimated at the time of autopsy or cremation

| Radionuclide | Limit activity for autopsy (MBq) | Limit activity for cremation (MBq) |
|---|---|---|
| $^{131}$I | 10 | 400 |
| $^{125}$I | 40 | 4000 |
| $^{90}$Y | 200 | 70 |
| $^{32}$P | 100 | 30 |
| $^{89}$Sr | 50 | 200 |

## Annex 2.6: Quality control of equipment in nuclear medicine

*Table 20. Radionuclide activity calibrator*

| Lable | Quality control test | Tolerance |
|---|---|---|
| DK1 | The measuring range | The equipment needs to have the measuring range from 10 MBq to 10 GBq. |
| DK2 | Accuracy and precision | Checked every 3 months for all energy (low, medium and high) and should be 10% ; ±5%. |
| DK3 | Linearity | Checked every 3 months, measured by the short-lived isotope (eg. 99mTc), response to lin-log scale should have a linear trend. |
| DK4 | Reproducibility | Checked every day, measured by the longt-lived isotopes (133Ba, 137Cs ili 226Ra) should ensure the stability of the device, Tolerance within ±5%. |

*Table 21. Device for measuring binding radiopharmaceuticals in the thyroid gland*

| Lable | Quality control test | Tolerance |
|---|---|---|
| U1 | Energy resolution | Checked every 6 months, measured with $^{137}$Cs at 50% maximum energy (FWHM), should bel ess than ±10% of the$^{137}$Cs energy. |
| U2 | Linearity | Checked every 3 months, measured with isotopes of different energies (eg: $^{99m}$Tc, $^{131}$I, $^{113m}$In), response at all energies must be linear. |
| U3 | Maximum energy efficiency | Checked every 3 months, measured with $^{137}$Cs and should be grater than ±60% for $^{137}$Cs. |

*Table 22. Planar gamma camera[1]*

| Lable | Quality control test | Tolerance |
|---|---|---|
| GK1 | Energy resolution | Checked every day, with $^{99m}$Tc and deviation should not be greater than 10%, at 50% of maximum energy |

| | | |
|---|---|---|
| GK2 | Uniformity with the collimator (extrinsic) | Checked every week and must be less than 10%. |
| GK3 | Uniformity without the collimator (intrinsic) | Checked every 3 months and must be less than 5%. |
| GK4 | Sensitivity | Checked every 6 months, depending on the collimator to be used and should be greater than 80% of the manufacturer's specifications. |
| GK5 | The spatial resolution with the collimator (extrinsic) | Provjerava se svaki mjesec sa linijskim izvorima smještenim 10 cm od kolimatora, measured value at 50% of the maximum value (FWHM) must be within 5% the manufacturer's specifications. |
| GK6 | The pixel size | Checked every 6 months and the difference along the X and Y axis must be less than 5%. |

[1] When checking the quality of gamma-camera it is recommended to use the isotope $^{99m}$Tc or $^{57}$Co source plate; the energy window should be 20%; the maximum number of pulses per unit time should be 20 000 pulses per second, using a collimator with parallel hole collimators.

*Table 23. Gamma camera[1]– SPECT[1]*

| **Lable** | **Quality control test** | **Tolerance** |
|---|---|---|
| SPECT1 | Center of rotation | Checked every month and according to the manufacturer's specifications, the deviation of the center of rotation must be less than the size of the smallest pixels. |
| SPECT2 | Uniformity - tomographic | Checked every month with cylindrical phantom of a minimum diameter of 20 cm, and the ring must not be evident. |

[1] SPECT gamma camera must meet all requirements as planar gamma camera.

*Table 24. Quality control of radiopharmaceuticals in nuclear medicine*

| **Lable** | **Quality control test** | **Tolerance** |
|---|---|---|
| RF1 | The chemical purity of radiopharmaceuticals | Checked every time after preparing radiopharmaceuticals. |
| RF2 | Radiochemical purity of radiopharmaceuticals | Checked every time after preparing radiopharmaceuticals. |
| RF3 | Sterility of radiopharmaceuticals | Checked every time after preparing radiopharmaceuticals. |
| RF4 | Apyrogenecity of radiopharmaceuticals | Checked every time after preparing radiopharmaceuticals. |

## Annex 3.1. Staffing Criteria and QC for clinical stages of radiotherapy process

*Table 25. Key staff functions in radiation therapy ; MPE – Medical Physics Expert, RTT – radiotherapy technologist or engineer of medical radiology, Sim – Simulator, MR Mould room*

| | | |
|---|---|---|
| 1. Clinical evaluation | Radiation oncologist | |
| 2. Therapeutic decision | Radiation oncologist | |
| 3. Patient immobilization | RTT | Radiation oncologist |
| 4. Target volume localization: | Radiation oncologist | |
| a) Target volume determination | Radiation oncologist | RTT-Sim |
| b) Sensitive critical organs | Radiation oncologist | RTT-Sim |
| c) Patient contour | MPE | RTT-Sim |
| 5. Treatment planning: | | |
| a) Beam data computerization | MPE | |
| b) Computation of beams | MPE | |
| c) Shielding blocks, treatment | MPE | Radiation oncologist |
| aids, etc. | RTT-MR | |
| d) Analysis of alternative plans | Radiation oncologist | |
| | MPE | |
| e)Selection of treatment plan | Radiation oncologist | |
| | MPE | |
| f) Dose calculation | MPE | |
| g) Beam-on time (monitor unit calculation) | MPE | |
| 6. Simulation/verification of treatment plan | Radiation oncologist<br>RTT-Sim | MPE |
| 7. Treatment: | | |
| a) First day set-up | Radiation oncologist | MPE |
| | RTT | |
| b) Localization films | Radiation oncologist | MPE |
| | RTT | |
| c) Daily treatment | RTT | |
| 8. Evaluation during treatment | Radiation oncologist<br>RTT | Social worker<br>Dietician |
| 9. Follow-up examinations | Radiation oncologist | Social worker<br>Dietician |

*Table 26. Minimal personnel requirements for radiotherapy* [1]

| **Category** | **Staffing** |
|---|---|
| Radiation oncologist-in chief | 1 |

| | |
|---|---|
| Staff radiation oncologist | 1 for each 150-200 patients treated annually[2]. |
| MPE | 1 per 300 patients annually[3]. |
| RTT-MR | One per 600 patients treated annually |
| Supervisor of RTT-s | 1 |
| RTT | Two per mega voltage unit up to 25 patients treated daily; four per rnegavoltage unit up to 50 patients treated daily[3]. |
| RTT-Sim | 2 for every 500 patients simulated annually |
| RTT-MR | One per 600 patients treated annually |
| RTT-Br | 1 per brachytherapy unit |
| Maintenance engineer or electronics technician | One per centre |

[1]If advanced or special techniques are to be undertaken, staff additional to the above will be required.
[2]For patients treated by external radiotherapy, for brachytherapy it is needed 1 MPE for 200 patients treated annually
[3]Minimal duration of the treatment session for patients in external radiotherapy is 15 minutes

*Table 27. Quality Control of clinical stages of radiotherapy proces*

| **Clinical stage** | **Related QA procedures** |
|---|---|
| Positioning and immobilization | Port films. Laser alignment. |
| Simulation | Simulator QA including image quality and mechanical integrity |
| Patient data acquisition | CT, MRI QA includiog image quality and mechanical integrity Accuracy of mechanical contouring |
| Data transfer to treatment planning system | QA of the entire data transfer process, including digitizers, digital data transfer |
| Definitions of target volumes Aperture design Computation of dose distributions | Peer review, e.g., new patient planning conference, chart rounds. Independent check of delivery (e.g., port films), and peer review |
| Plan evaluation | Machine data from commissioning and QA of treatment machines and QA of treatment planning system |
| Prescription | Peer review of plan, e.g., during chart rounds (Sec. VI). Independent check by MPE |
| Computation of monitor units | Written, signed, and dated |
| Production at blocks, beam modifiers | Treatment planning system QA Independent check within 48 h. QA or block cutting and compensator systems |
| Plan implementation | Review of set-up by treatment planning team. Chart review |
| Patient QA | Treatment plan review Chart review after new or modified field, weekly chart review, port film review In vivo dosim:try for unusual fields, critical organ doses (e.g., gonadal dose) . Status |

| | |
|---|---|
| | check, follow up |

*Table 28: Quality Control Tests for Linear Accelerator*

| **Designator** | **Test** | **Performance** | |
|---|---|---|---|
| | | Tolerance | Action |
| Daily | | | |
| DL1 | Door interlock/last person out | Functional | |
| DL2 | Motion interlock | Functional | |
| DL3 | Couch brakes | Functional | |
| DL4 | Beam status indicators | Functional | |
| DL5 | Patient audio-visual monitors | Functional | |
| DL6 | Room radiation monitors | Functional | |
| DL7 | Beam interrupt/ counters | Functional | |
| DL8 | Lasers/crosswires | 1 | 2 |
| DL9 | Optical distance indicator | 1 | 2 |
| DL10 | Optical back pointer | 2 | 3 |
| DL11 | Field size indicator | 1 | 2 |
| DL12 | Output constancy - photons | 2% | 3% |
| DL13 | Dynamic wedge factors | 1% | 2% |
| DL14 | Output constancy - electrons | 2% | 3% |
| Monthly | | | |
| ML1 | Emergency off | Functional | |
| ML2 | Wedge, tray cone interlocks | Functional | |
| ML3 | Accessories integrity and centering | Functional | |
| ML4 | Gantry angle readouts | 0.5° | 1° |
| ML5 | Collimator angle readouts | 0.5° | 1° |
| ML6 | Couch position readouts | 1 | 2 |
| ML7 | Couch isocentre | 1 | 2 |
| ML8 | Couch angle | 0.5° | 1° |
| ML9 | Optical distance indicator | 1 | 2 |
| ML10 | Crosswire centering | 1 | 2 |
| ML11 | Light/radiation coincidence | 1 | 2 |
| ML12 | Field size indicator | 1 | 2 |
| ML13 | Relative dosimetry | 1% | 2% |
| ML14 | Central axis depth dose reproducibility | 1%/2mm | 2%/3mm |
| ML15 | Beam flatness | 2% | 3% |
| ML16 | Beam symmetry | 2% | 3% |
| ML17 | Records | Complete | |
| Annually | | | |

| | | | |
|---|---|---|---|
| AL1 | Reference dosimetry – TRS398 | 1% | 2% |
| AL2 | Relative output factor reproducibility | 1% | 2% |
| AL3 | Wedge transmission factor reproducibility | 1% | 2% |
| AL4 | Accessory transmission factor reproducibility | 1% | 2% |
| AL5 | Output reproducibility vs. gantry angle | 1% | 2% |
| AL6 | Beam symmetry reproducibility vs. gantry angle | 2% | 3% |
| AL7 | Monitor chamber linearity | 1% | 2% |
| AL8 | End monitor effect | 0.1 MU | 0.2 MU |
| AL9 | Collimator rotation isocentre | 1 | 2 |
| AL10 | Gantry rotation isocentre | 1 | 2 |
| AL11 | Couch rotation isocentre | 1 | 2 |
| AL12 | Coincidence of collimator, gantry, couch axes | 1 | 2 |
| AL13 | Coincidence of isocentres | 1 | 2 |
| AL14 | Couch deflection | 3 | 5 |
| AL15 | Records | Complete | |

Tolerances and action levels are specified in millimetres unless otherwise stated
DL12 and DL12: Dose measurement in phantom ( water phantom or water equivalent phantom ) with fixed parameters ( field size, beam energy , distance source-detector, depth in phantom of detector position, MU) which is compared with referent value obtained during the commissioning of linear accelerator.
AL 1: Complete procedure of the absolute dosimetry for all energies of photons and electrons according the IAEA protocol based on measurements of absorbed dose in water (IAEA TRS 398) l

*Table 29: Quality Control Tests for Electronic Portal Imaging*

| **Designator** | **Test** | **Performance** | |
|---|---|---|---|
| | | Tolerance | Action |
| Daily | | | |
| DE1 | Mechanical integrity | Functional | |
| DE2 | Electrical integrity | Functional | |
| DE3 | Collision interlocks | Functional | |
| DE4 | Image quality | Reproducibility | |
| Monthly | | | |
| ME1 | Positioning in the imaging plane | 1 | 2 |
| ME2 | Positioning perpendicular to the imaging plane | 10 | 20 |
| ME3 | Image quality | Reproducibility | |
| ME4 | Artifacts | Reproducibility | |
| ME5 | Spatial distortion | 1 | 2 |
| ME6 | Monitor controls | Reproducibility | |
| ME7 | Records | Complete | |
| Annually | | | |

| | | | |
|---|---|---|---|
| AE1 | Spatial resolution | Reproducibility | |
| AE2 | Noise | Reproducibility | |
| AE3 | On screen measurement tools | 0.5 | 1 |
| AE4 | Set-up verification tools | 0.5, 0.5° | 1, 1° |

Tolerances and Action Levels are specified in millimetres unless otherwise stated

*Table 30: Quality Control Tests for Multileaf Collimators*

| **Designator** | **Test** | **Performance** | |
|---|---|---|---|
| | | Tolerance | Action |
| Patient-specific | | | |
| PM1 | Verification of transferred data vs printed template | 1 | 2 |
| PM2 | Daily verification of correct data | Reproducibility | |
| PM3 | Verification of record & verify programming | Reproducibility | |
| Monthly | | | |
| MM1 | Digitizer check (if used) | Functional | |
| MM2 | Light and radiation field coincidence | 1 | 2 |
| MM3 | Leaf positions for standard field template | 1 | 2 |
| MM4 | Electron field interlocks | Functional | |
| MM5* | Leaf alignment | | 1 |
| MM6 | Records | Complete | |
| Yearly | | | |
| AM1 | Leaf transmission (all energies) | Reproducibility | |
| AM2 | Leakage between leaves (all energies) | Reproducibility | |
| AM3* | Transmission through abutting leaves | Reproducibility | |
| AM4 | Stability with gantry rotation | Reproducibility | |
| AM5 | Alignment with jaws | | 1 |

* May not apply to all MLC designs.
Tolerances and action levels are specified in millimetres unless otherwise stated
PM1 Comparison of the optical projection of the MLC field with a template, usually an appropriately-scaled printout of a DRR or a BEV.
PM2 Daily comparison of a template with corresponding field on MLC monitor.

*Table 31: Quality Control Tests for Telecobalt Unit*

| **Designator** | **Test** | **Performance** | |
|---|---|---|---|
| | | Tolerance | Action |
| Daily | | | |
| DCO1 | Door interlock/last person out | Functional | |
| DCO2 | Motion interlock | Functional | |

| | | | |
|---|---|---|---|
| DCO3 | Couch brakes | Functional | |
| DCO4 | Beam status indicators | Functional | |
| DCO5 | Patient audio-visual monitors | Functional | |
| DCO6 | Room radiation monitors | Functional | |
| DCO7 | Emergency off | Functional | |
| DCO8 | Beam interrupt/ counters | Functional | |
| DCO9 | Head swivel lock | Functional | |
| DCO10 | Lasers/crosswires | 1 | 2 |
| DCO11 | Optical distance indicator | 1 | 2 |
| DCO12 | Optical back pointer | 2 | 3 |
| DCO13 | Field size indicator | 1 | 2 |
| Monthly | | | |
| MCO1 | Wedge, tray interlocks | Functional | |
| MCO2 | Accessories integrity and centering | Functional | |
| MCO3 | Gantry angle readouts | 0.5° | 1° |
| MCO4 | Collimator angle readouts | 0.5° | 1° |
| MCO5 | Couch position readouts | 1 | 2 |
| MCO6 | Couch rotation isocentre | 1 | 2 |
| MCO7 | Optical distance indicator | 1 | 2 |
| MCO8 | Crosswire centering | 1 | 2 |
| MCO9 | Light/Radiation coincidence | 1 | 2 |
| MCO10 | Field size indicator | 1 | 2 |
| MCO11 | Relative Dosimetry | 1% | 2% |
| MCO12 | Shutter error | Reproducible | |
| MCO13 | Beam symmetry (source position) | 2% | 3% |
| MCO14 | Records | Complete | |
| Annually | | | |
| ACO1 | Reference dosimetry | 1% | 2% |
| ACO2 | Relative output factor reproducibility | 1% | 2% |
| ACO3 | Central axis depth dose reproducibility | 1% | 2% |
| ACO4 | Wedge transmission factor reproducibility | 1% | 2% |
| ACO5 | Accessory transmission factor reproducibility | 1% | 2% |
| ACO6 | Output reproducibility vs. gantry angle | 1% | 2% |
| ACO7 | Beam symmetry reproducibility vs gantry angle | 2% | 3% |
| ACO8 | Timer linearity | 1% | 2% |
| ACO9 | Shutter error | 0.03 min | 0.05 min |
| ACO10 | Collimator rotation isocentre | 1 | 2 |
| ACO11 | Gantry rotation isocentre | 1 | 2 |
| ACO12 | Couch rotation isocentre | 1 | 2 |

| | | | |
|---|---|---|---|
| ACO13 | Coincidence of collimator, gantry, couch axes | 1 | 2 |
| ACO14 | Coincidence of isocentres | 1 | 2 |
| ACO15 | Couch deflection | 3 | 5 |
| ACO16 | Records | Complete | |

*Table 32: Quality Control Tests for Simulator*

| **Designator** | **Test** | **Performance** | |
|---|---|---|---|
| | | Tolerance | Action |
| Daily | | | |
| DS1 | Door interlock | Functional | |
| DS2 | Motion interlock | Functional | |
| DS3 | Beam status indicators | Functional | |
| DS4 | Emergency off buttons | Functional | |
| DS5 | Collision avoidance | Functional | |
| DS6 | Lasers/crosswires | 1 | 2 |
| DS7 | Optical distance indicator | 1 | 2 |
| DS8 | Crosswires/Reticle/Block tray | 1 | 2 |
| DS9 | Light/radiation coincidence | 1 | 2 |
| DS10 | Field size indicators | 1 | 2 |
| Monthly | | | |
| MS1 | Gantry angle readouts | 0.5° | 1° |
| MS2 | Collimator angle readouts | 0.5° | 1° |
| MS3 | Couch position readouts | 1 | 2 |
| MS4 | Alignment of FAD movement | 1 | 2 |
| MS5 | Couch isocentre | 2 | 3 |
| MS6 | Couch parallelism | 1 | 2 |
| MS7 | Couch angle | 0.5° | 1° |
| MS8 | Laser/crosswire isocentricity | 1 | 2 |
| MS9 | Optical distance indicator | 1 | 2 |
| MS10 | Crosswire centring | 1 | 2 |
| MS11 | Light/radiation coincidence | 1 | 2 |
| MS12 | Field size indicators | 1 | 2 |
| MS13 | Records | Complete | |
| Annually | | | |
| AS1 | Lead apron | Functional | |
| AS2 | kVp | 5% | 10% |
| AS3 | Reference dosimetry | 5% | 10% |
| AS4 | Beam quality (HVL) | 5% | 10% |

| | | | |
|---|---|---|---|
| AS5 | Automatic exposure control | 5% | 10% |
| AS6 | Focal spot | Reproducible | |
| AS7 | Contrast | Reproducible | |
| AS8 | Resolution | Reproducible | |
| AS9 | Fluoroscopic timer | 5% | 10% |
| AS10 | Redefine isocentre | 1 | 2 |
| AS12 | Couch deflection | 3 | 5 |
| AS13 | Alignment of focal spots | 0.5 | 1 |
| AS14 | Independent quality control review | Complete | |

Tolerances and action levels are specified in millimetres unless otherwise stated

*Table 33: Quality Control Tests for CT-Simulators*

| **Designator** | **Test** | **Performance** | |
|---|---|---|---|
| | | Tolerance | Action |
| Daily | | | |
| DS1 | Door interlock | Functional | |
| DS2 | Beam status indicators | Functional | |
| DS3 | Emergency off buttons (Alternate daily) | Functional | |
| DS4 | Lasers: parallel to scan plane | 1° | 2° |
| DS5 | Lasers: orthogonality | 1° | 2° |
| DS6 | Lasers: position from scan plane | 1 | 2 |
| DS7 | Couch Level: lateral & longitudinal | 0.5° | 1° |
| DS8 | Couch motions: vertical & longitudinal | 1 | 2 |
| DS9 | CT number accuracy of water - mean | 0 ± 3 HU | 0±5 HU |
| DS10 | Image noise | 5 HU | 10 HU |
| DS11 | Field uniformity of water | 5 HU | 10 HU |
| DS12 | Simulated planning | 1 | 2 |
| Monthly | | | |
| MS1 | Lasers: parallel to scan plane | 1 | 2 |
| MS2 | Lasers: orthogonality | 1° | 2° |
| MS3 | Lasers: position from scan plane | 1 | 2 |
| MS4 | Lasers: linearity of translaTable lasers | 1 | 2 |
| MS5 | Couch Level: lateral & longitudinal | 0.5° | 1° |
| MS6 | Couch motions: vertical & longitudinal | 1 | 2 |
| MS7 | Gantry tilt | 1° | 2° |
| MS8 | Records | Complete | |
| Annually | | | |
| AS1 | Slice localization from pilot | 0.5 | 1 |

| | | | |
|---|---|---|---|
| AS2 | CT number accuracy of water - mean | 0 ± 3 HU | 0±5 HU |
| AS3 | CT number accuracy of other material - mean | * | |
| AS4 | Field uniformity of water – std deviation | 5 HU | 10 HU |
| AS5 | Low contrast resolution | 10 @ 0.3% | # |
| AS6 | High contrast resolution (5% MTF) | 5 lp/cm | ** |
| AS7 | Slice thickness (sensitivity profile) | 0.5 | 1 |
| AS8 | X-ray Generation : kV and HVL | 5% | 10% |
| AS9 | X-ray Generation: mAs linearity | 5% | 10% |
| AS10 | Radiation Dose (CTDI) | 5% | 10% |

Tolerance and Action Levels are specified in millimetres unless otherwise stated
* CT number accuracy of other materials will depend on the material and its uniformity. (Set tolerance at the time of acceptance).
** High contrast resolution will depend on scanning technique used (Set tolerance at the time of acceptance)
# Low contrast resolution will depend on scanning technique

*Table 34: Quality Control Tests Treatment Planning Systems*

| **Designator** | **Test** | **Performance** | |
|---|---|---|---|
| | | Tolerance | Action |
| Commissioning and following software updates | | | |
| CTPS1 | Understand algorithm | Functional | |
| CTPS2 | Single field or source isodose distribution | 1% or 1 | 2% [a]or 2[b] |
| CTPS3 | Treatment time calculation | 1% | 2% |
| CTPS4 | Treatment time calculation incl. inhomogenities | 3% | 5% |
| CTPS5 | Test cases | 1% or 1 | 2% or 2 |
| CTPS6 | I/O system | 0.5 | 1 |
| Patient specific/ Daily | | | |
| DTPS1 | Patient data | Data check | |
| DTPS2 | Beam geometry | Data check | |
| DTPS3 | Dose distribution | Data check | |
| DTPS4 | MU/ treatment time for every treatment field | 2MU/2% | 3MU/3% |
| DTPS5 | Treatment plan data transfer | Data check | |
| DTPS6 | i/O devices | 0.5 | 1 |
| Quarterly | | | |
| QTPS1 | Check sum | No change | |
| QTPS2 | Subset of reference QA test set ; if check sum NA | 1% or 1 | 2% or 2[c] |
| QTPS3 | Electronic data transfer | Data check | |
| QTPS4 | Plan detailes | Data check | |
| QTPS5 | I/O system | 0.5 | 1 |
| QTPS6 | System back up | Functional | |

| | | | |
|---|---|---|---|
| QTPS7 | CT/geometry / density | 2/0.02 | 3/0.03 |
| Annually | | | |
| ATPS1 | Reference QA test set | 1% or 1 | 2% or 2[d] |
| ATPS2 | Treatment time calculation | 1% | 2% |
| ATPS3 | I/O system | 0.5 | 1 |

Tolerances and Action Levels are specified in millimetres unless otherwise stated
[a]Difference between calculation of the computer TPS and measurement ( or independent calculation)
[b]In the region with high dose gradient , the distance between isodose lines is more appropriate than the percentage difference
[c]This limits refer to a comparison of dose calculation at commissioning with the same calculation subsequently
[d]This limits refer to a comparison of calculations with measurements in a water tan

*Table 35: Quality Control Tests - HDR Remote Afterloaders*

| **Designator** | **Test** | **Performance** | |
|---|---|---|---|
| | | Tolerance | Action |
| Daily | | | |
| DHRA1 | Door interlock/last person out | Functional | |
| DHRA2 | Treatment interrupt | Functional | |
| DHRA3 | Emergency off (console) | Functional | |
| DHRA4 | Room radiation monitor | Functional | |
| DHRA5 | Console displays (treatment status indicator, date, time, source strength) | Functional | |
| DHRA6 | Printer operation, Paper supply | Functional | |
| DHRA7 | Data transfer from Planning Computer | Functional | |
| DHRA8 | Audio/Visual communication system | Functional | |
| Weekly | | | |
| WHRA1 | Source positional accuracy | 1 | 2 |
| WHRA2 | Dwell time accuracy | 1% | 2% |
| Quarterly (or at source replacement) | | | |
| QHRA1 | Mechanical integrity of applicators, guide tubes, connectors | Functional | |
| QHRA2 | Emergency off (in room) | Functional | |
| QHRA3 | Power failure recovery | Functional | |
| QHRA4 | Source strength calibration | 3% | 5% |
| QHRA5 | Source positional accuracy | 1 | 2 |
| QHRA6 | Dwell time accuracy | 1% | 2% |
| QHRA7 | Timer linearity | 1% | 2% |
| QHRA8 | Records | Complete | |
| Annually | | | |

| | | | |
|---|---|---|---|
| AHRA1 | Transit dose reproducibility | 1% | 2% |
| AHRA2 | X-ray marker positional accuracy | 1 | 2 |
| AHRA3 | Review emergency response procedures | Complete | |

Tolerances and Action Levels are specified in millimetres unless otherwise stated