Ministry of Health and Family
No 285/19.04. 2002

Ministry of Water and Environmental Protection.
National Commission for Nuclear Activities Control
No. 79/4.03.2002

ORDER

approving the Norms on radiation protection of individuals in case of medical exposure to ionising radiation[*)]

The Minister of Health and Family and the President of National Commission of Nuclear Activities Control,

taking into account the provisions of:

- Art. 5 from the Law no. 111/1996 on safe development of nuclear activities, republished, with subsequent modifications;
- Art. 12 from the Law no. 100/1998 concerning the public health assistance,

on the basis of:

- Governmental Decision no. 22/2001 on organization and functioning of the Ministry of Health and Family, with subsequent modifications and completions;
- Governmental Decision no. 17/2001 on organization and functioning of the Ministry of Water and Environmental Protection, with subsequent modifications and completions;

taking into account the approval decisions no. DB 4.212/19.04.2002 of the General Division for Public Health within the Ministry of Health and Family and no. 41.555/4.03.2002 of the Division on ionizing radiation sources applications within the President of National Commission of Nuclear Activities Control.

issue the following order:

Art. 1. – There is approved *the Norms on radiation protection of individuals in case of medical exposure to ionising radiation*, , provided in the appendix which is integral part of this order.

Art. 2. - This order shall entry into force on January 1st, 2003 and shall be published in the Romanian Official Bulletin, Part I.

Art. 3. - Ministry of Health and Family, through the General Division for Public Health, General Division for Medical Assistance, Programs and Integrated Medical Services, Pharmaceutical Division, general Divion on Human Resources and General Division of Budget, and National Commission of Nuclear Activities Control through Division on Nuclear Safety, Division on Quality Assurance and Operators licensing, Division on ionizing radiation sources applications, Division on Cernavoda NPP surveillance, Division on Development and Resources and the independent departments, shall fulfill the provisions of this order.

Minister of Health and Family,
Daniela Bartos

President of the National Commission
for Nuclear Activities Control,
Lucian Biro,
State Secretary

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***)** The Order no. 285/79 /2002 was published in the Romanian Official Bulletin, part I, no 446/25.06.2002 and it is reproduced in this number.

APPENDIX)*

NORMS ON THE RADIATION PROTECTION OF INDIVIDUALS IN CASE OF MEDICAL EXPOSURE TO IONIZING RADIATION

Article 1

Scope and Purpose

1. These Norms supplement the Fundamental Norms on Radiological Safety and lay down the general principles of radiation protection of individuals subject to the exposure to ionizing radiation defined in paragraph 2 and paragraph 3.

2. These Norms shall apply to the following medical exposure to ionizing radiation:

(a) the exposure of patients as part of their own medical diagnosis or treatment;
(b) the exposure of individuals as part of 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 procedures.

3. These Norms shall also apply to ionizing radiation exposure of individuals knowingly and willingly helping (other than part of their occupation) in the support and comfort of individuals undergoing medical exposure

Article 2

Definitions

The terms and expressions utilized in these Norms are defined in the Fundamental Norms on Radiological Safety and in Appendix no. 1.

Article 3

Justification

1. Medical exposure to ionizing radiation referred to in Article 1 paragraph 2 shall show a sufficient net benefit weighing the total potential therapeutic benefits or diagnostics it produces, including direct health benefits to an individual and benefits to society, against the individual detriment that the exposure may 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.

In particular:

(a) - all new types of practices involving medical exposure to ionizing radiation shall be justified in advance before being generally adopted.

- existing types of practices involving medical exposure to ionizing radiation may be reviewed whenever new and important information about their efficacy or consequences is acquired.

(b) – all individual medical exposure to ionizing radiation shall be justified in advance taking into account the specific objectives of the exposure and the characteristics of the individual involved.

- if a type of practice involving a medical exposure is not justified in general , a specific individual exposure of this type could be justified in special circumstances, being evaluated on a case-by-case basis;

- the prescriber and the practitioner shall seek, where possible, to obtain the previous diagnostic or relevant medical information for the exposure provided to ionizing radiation and to consider these data in order to avoid an unnecessary exposure to ionizing radiation;

(c) – medical exposure to ionizing radiation for medical and biomedical research shall be examined by an ethics committee, set up in accordance with the specific regulations of the Ministry of Health and Family;

(d) – special attention shall be given to the justification of that medical exposure to ionizing radiation when there is no direct health benefit for the person undergoing the exposure and especially for that exposure required for medico-legal grounds.

2. Exposure to ionizing radiation referred to in Article 1 paragraph 3 shall show a sufficient net benefit, taking into consideration both the direct health benefits to a patient, the advantages of individuals referred to in Article 1 paragraph 3 as well as the detriment that the exposure might cause. The final decision rests upon the practitioner.

3. If an exposure to ionizing radiation cannot be justified, this one should be prohibited.

Article 4

Optimization

1. (a) All doses due to medical exposure for radiological purposes except for therapeutic procedures referred to in Article 1 paragraph 2 shall be kept as low as reasonably achievable in order to allow to obtaining the sought diagnostic information, taking into consideration social and economic factors.

(b) For all medical exposure to ionizing radiation of individuals for therapeutic purposes, as it is mentioned in Article 1 paragraph 2 (a), exposures of target volumes shall be individually planned, taking into account that doses of non-target volumes and tissues shall be as low as reasonably achievable and consistent with the intended radiotherapeutic purpose of the exposure.

2. (a) In the radiodiagnostic examinations referred to in Article 1 paragraph 1 (a), (b), (c), and (e) the diagnostic reference levels established in appendix 2 shall not be exceeded.

(b) The reference levels established at paragraph 2 (a) shall be revised whenever necessary, taking into account the evolution of the knowledge and information and reference levels for diagnostic established by the European Commission.

(c) For each medical or biomedical research project mentioned in Article 1 paragraph 2, (d), the following shall be ensured:

- the individuals concerned participate voluntarily;

- these individuals are informed about the risks of this exposure;
- a dose constraint is established for individuals for whom no direct medical benefit is expected from this exposure;
- in case of patients, who voluntarily accept to undergo a experimental therapeutic or diagnostic practice and who expect to receive a therapeutic or diagnostic benefit from this practice, the target levels of doses are established by the practitioner and/or prescriber.

(d) A special attention shall be granted, including to procedure types, in order to keep the dose arising from the medico-legal exposure referred to in Article 1 paragraph 2, (e) as low as reasonably achievable.

3. The optimization process shall include the selection of equipment, practical aspects, obtaining an adequate diagnostic information or an adequate therapeutic outcome, quality assurance including quality control and establishment and evaluation of patient doses or activities administered to the patient, taking into account economic and social factors.

4. (a) There are established dose constraints in Appendix 3, point I, for exposure mentioned in Article 1 paragraph 3 of individuals knowingly and willingly assuring the support and comfort for individuals undergoing medical diagnosis or treatment where appropriate.

(b) There are established specific recommendations in Appendix 3, point II, for the exposure mentioned in Article 1 paragraph 3.

(c) In case of a patient undergoing a treatment or diagnosis with radionuclides, the practitioner or user of the radiological installation shall provide to the patient or to user or to legal guardian of with written instructions, with a view to the restriction of doses to persons in contact with the patient at the lower achievable level and shall provide information on the risks of exposure to ionizing radiation.

These instructions shall be handed out before leaving the hospital, clinic or a similar institution.

Article 5

Responsibilities

1. The prescriber as well as the practitioner shall be involved in the justification process at an appropriate level, according to the competences established by the Ministry of Health and Family.

2. Any exposure mentioned in Article 1 paragraph 2 is effected under the medical responsibility of a practitioner, as specified in the regulations of the Ministry of Health and Family.

3. The practical aspects for a procedure or part of it may be delegated, as appropriate, by the user of the installation or by the practitioner, to one or more individuals entitled to act in this respect, in a recognized field of specialization.

4. The procedures laid down by the regulations issued by the Ministry of Health and Family shall be observed in case of medico-legal examinations.

Article 6

Procedures

1. Written protocols for each type of radiological practice and for each type of equipment shall be established.

2. The recommendations concerning referral criteria for medical exposure including the radiation doses established by specific regulations of the Ministry of Health and Family shall be available to the prescriber of medical exposure.

3. (a) A medical physics expert shall be compulsorily involved in radiotherapeutic practices.

(b) A medical physics expert shall be available in current therapeutical nuclear medicine practices and diagnostic nuclear medicine practices.

(c) For other radiological practices, a medical physics expert shall be involved, as appropriate, for consultation on optimization process including patient dosimetry, quality assurance and control and to give advice, as required, on matters relating to radiation protection concerning medical exposure.

4. Clinical audits shall be carried out in accordance with the specific regulations of the Ministry of Health and Family.

5. The County Public Health Departments and Bucharest Public Health Department shall evaluate yearly the cases of regular exceeding of diagnostic reference levels and the corrective actions undertaken in such situations, informing the competent authorities.

Article 7

Training

1. (a) It shall be ensured that the practitioners and those individuals mentioned in Article 5 paragraph 3 and Article 6 paragraph 3 have an adequate practical and theoretical training for the purpose of radiological practice and they are competent in radiation protection.

(b) The educational and training requirements for the radiation protection in Appendix no. 4 are established as compulsory for the personnel mentioned at paragraph (a).

(c) The Ministry of Health and Family shall also take into account the training requirements specified in Appendix 4 within procedures for recognition of diplomas, certificates or formal qualification of individuals.

2. Individuals undergoing relevant training programmes may participate in practical aspects for the procedures mentioned in Article 5 paragraph 3.

3. The continuing theoretical and practical training after granting a diploma and especially in case of the clinical use of new techniques, the organization of training related to these techniques and the relevant radiation protection requirements shall be ensured.

4. The introduction of a course on radiation protection in the basic curriculum of medical and dental education schools shall be ensured.

Article 8

Equipment

1. The competent authorities shall take all measures they consider necessary with a view to avoiding unnecessary proliferation of radiological equipment.

2. The competent authorities shall ensure that:
   a) all radiological equipment is kept under strict surveillance regarding radiation protection;
   b) an up-to-date inventory of radiological equipment for each type of radiological installation is available;
   c) appropriate quality assurance programmes including quality control measures and the patient dose or administered activity assessments are implemented by the user of the radiological installation;
   d) acceptance testing is carried out by the units authorized according to the law before the first use of the equipment for clinical purposes and thereafter performance testing on a regular basis and after each major maintenance procedure.

3. The user of the radiological installation has the obligation to take all necessary measures in order to remedy the lacks or defectives features of the radiological equipment.

4. (a) The specific criteria of acceptability for radiological installations are established in Appendix no. 5.

(b) Equipment that not fulfill the criteria established in Appendix no. 5 shall be take out of service in case the corrective measures necessary to bring their parameters up to values established in Appendix no. 5 cannot be taken.

5. In case of fluoroscopy, examinations without an image intensification or other equivalent techniques are not justified and therefore shall be prohibited.

6. Fluoroscopic examinations without devices to control the dose rate shall be accepted only for a limited period of time and for justified reasons.

7. If new radiodiagnostical equipment is used, it shall have, where practicable, a device informing the practitioner of the quantity of radiation produced by the equipment during the radiological procedure.

Article 9

Special Practices

1. The competent authorities shall supervise that the radiological equipment and ancillary equipment as well as the used practices are adequate for each case of medical exposure:
   - of children;
   - as part of a health screening programs;
   - involving high doses to the patient, such as interventional radiology, computed tomography or radiotherapy.

Special attention shall be given to the quality assurance programmes including also quality control measures and patient dose or administered activity assessment, as mentioned in Article 8 for these practices.

2. The competent authorities shall ensure that the practitioners and those individuals referred in Article 5 paragraph 3 performing the exposure mentioned in paragraph 1 of this Article obtain appropriate training on these radiological practices as it required by Article 7 paragraphs 1 and 2.

Article 10

Special Protection during Pregnancy and Breastfeeding

1. (a) In case of a female of childbearing age, the prescriber and the practitioner shall establish, according to the regulations of the Ministry of Health and Family, whether she is pregnant or breastfeeding, and

(b) if the probability of pregnancy cannot be excluded, depending on the type of medical exposure to ionizing radiation, in particular if pelvic or abdominal regions are involved, special attention shall be given to the justification, particularly the urgency, and to the optimization of the medical exposure, taking into account the exposure both for the expectant mother and the foetus.

2. In nuclear medicine, depending on the type of medical examination or treatment, in case of breast-feeding females, special attention shall be given to the justification, particularly the urgency, and to the optimization of the medical exposure, taking into account the exposure of the expectant mother and the foetus.

3. Without prejudice to the provisions of paragraph 1 and paragraph 2, any measure contributing to a better information of women subject to this Article could be useful, such as posting sanitary education materials in adequate places, specifically destined for the public.

Article 11

Potential Exposure

The competent authorities shall ensure that possible reasonable measures are taken in order to reduce the probability and the magnitude of accidental or unintended doses received by patients during radiological practices, economic and social factors being taken into account.

The main emphasis in accident prevention shall be put on the equipment and procedures used in radiotherapy, but some attention should be also paid to accidents susceptible to occur with diagnostic equipment.

The written working instructions and protocols as referred to in Article 6 paragraph 1 and quality assurance programmes as referred to in Article 8 paragraph 2 and the criteria referred to in Article 8 paragraph 3 are of particular relevance for this purpose, being an authorization condition for the respective nuclear activities according to the law.

Article 12

Estimates of Doses Received by the Population

The Public Health Departments shall ensure that the determination of distribution of individual doses from medical exposure mentioned in Article 1 paragraph 2, is accomplished yearly for population and for relevant reference groups of population and communicated to the competent authorities, according to the specific regulations of the Ministry of Health and Family.

Article 13

Inspection

1. Competent authorities shall ensure a system of inspection, as defined in Appendix no. 1 (definition of inspection), concerning the application of provisions of these norms.

2. The inspection entities of the competent authorities with inspection responsibilities according to paragraph 1 are as follows:

a) Radiation Hygiene Laboratories within the County Public Health Departments and Bucharest Public Health Department, according to the competencies established by legal regulations in force;
b) National Commission for Nuclear Activities Control (CNCAN), by its specialized personnel empowered by CNCAN President, according to the competencies established by the Law.

Article 14

Transitory and Final Dispositions

1. The interdiction of using the installations provided in Article 8 paragraph 4, is applied starting with December 31st, 2005.

2. Until the above-mentioned date, the necessary corrective measures shall be taken for the compliance of non-conforming installations mentioned in Article 8 paragraph 3.

3. When these norms come into force, any other disposition of the competent authorities contrary to its provisions is repealed.

4. Appendixes no. 1 – 5 represent an integral part of these norms.

APPENDIX No. 1
of the norms

DEFINITIONS

a) *Quality Assurance*

- the set of planned and systematic operations necessary to guarantee a satisfactory level of confidence concerning the fact that an installation, a system, a component or a procedure functions adequately according to the applicable norms.

b) *Practical Aspects*

- the physical conduct of any exposure referred to in Article 1, paragraph 2 and supporting aspects, including handling and use of radiological equipment, assessment of technical and physical parameters as well as the radiation doses, calibration and maintenance of equipment, preparation and administration of radio-pharmaceuticals and the development of films.

c) *Clinical Audit*

- a systematic examination or review of medical radiological procedures with the purpose of improving the quality and the outcome of patient care through structured review whereby radiological practices, procedures and results are compared to the agreed standards for the correct medical radiological procedures, with modification of practices where this is also required with the application of new references, if necessary.

d) *Competent Authority*, through *the competence provided by the Law:*

1. Ministry of Health and Family hereinafter referred to as MSF, concerning medical aspects;

2. National Commission for Nuclear Activities Control hereinafter referred to as CNCAN, regarding regulation, authorization and nuclear activities control.

e) *Quality Control*

- is a part of quality assurance system; the set of operations (programming, coordinating, implementing) intended to maintain or to improve quality. It covers monitoring, evaluation and maintenance at required levels of all characteristics of performance of equipment that can be defined, measured and controlled.

f*) Health* S*creening*

- an early diagnosis procedure, practised with a radiological installation on a population group subjected to the risk of being taken ill.

g) *Individual Detriment*

- clinically observable deleterious effects that are expressed in individuals or their descendants, the appearance of which is either immediate or delayed, situation where the appearance is rather probable than certain.

h) *Patient Dose*

- the dose received by a patient or other individual undergoing medical exposure.

i) *Patient Dosimetry*

- the dosimetry concerning the patient or other individuals undergoing medical exposure.

j) *Medical Physics Expert*

- an expert in radiation physics or radiation technology applied to the relevant exposure for the application field of these norms, whose training and competence to act is recognized by the competent authorities and who, as appropriate, acts or gives advice on patient dosimetry, on the development and use of complex techniques and equipment, on optimization, on quality assurance, including quality control and on other matters relating to radiation protection concerning relevant exposure from the application field of these norms.

k) *Inspection*

- an investigation carried out by the competent authority in order to verify the compliance with radiological protection provisions from the norms applicable to medical radiological procedures, equipment in use or radiological installations.

l) *Radiological Installation*

- a facility containing the installed radiological equipment.

m) *Prescriber*

- a medical doctor or another health professional who, according to the specific regulations of MSF, is entitled to refer a patient for medical exposure to a practitioner.

n) *Diagnostic Reference Levels*

- dose levels in medical radiodiagnostic practices or, in the case of radio-pharmaceutical products, levels of activity for typical examinations for groups of standard-sized patients or standard phantoms, for broadly categories of types of equipment. These levels must not be exceeded for standard procedures if normal and correct practices regarding technical performance and diagnostic are applied.

o) *Practitioner*

- a medical doctor, a dentist or other health professional who is entitled to take clinical responsibility for an individual medical exposure, in accordance with the MSF regulations.

p) *Medical Radiological Procedure*

- any procedure concerning medical exposure.

q) *Medico-Legal Procedures*

- procedures performed for legal judiciary or insurance purposes.

r) *Radiological*

- pertaining to radiotherapeutic or radiodiagnostic procedures, interventional radiology or other radiological methods of detection and guidance.

s) *Radiodiagnostic*

- any *in vivo* medical radiological procedure for diagnostic purposes.

t) *Radiotherapeutic*

- pertaining to radiotherapy, including nuclear medicine for therapeutic purposes.

u) *Clinical Responsibility*

- responsibility attributed to a practitioner regarding individual medical exposure, mainly with regard to: justification, optimization, clinical evaluation of the outcome; cooperation with other specialists and other personnel, as appropriate, with regard to the practical aspects; obtaining information, if necessary, of previous examination; providing existing radiological information and/or records to other practitioners and/or prescribers, as required; giving information on the risk of ionizing radiation to patients and other individuals involved, as appropriate.

v) *Occupational Health Surveillance*

- the medical surveillance of health status for the exposed occupational workers, in accordance with regulations issued by MSF.

w) *User*

- any legal person who has the legal responsibility for a given radiological installation.

APPENDIX No. 2
of the norms

DIAGNOSTIC REFERENCE LEVELS

According to the EC Radiation Protection series no. 109/1999

I. Legal implementation and practical application of diagnostic reference levels (DRLs)

1. DRL represents a set of levels for a standard procedure, for groups of standard-sized patients or for a standard phantom and not for individual exposures and individual patients.

Taking this into account, if this level is generally exceeded, the procedures and/or equipment shall be reviewed and corrective measures shall be taken, as appropriate.

If this level is exceeded, that does not mean that the examination is inadequately performed and meeting this level does not automatically mean that a god practice is being carried out, because the image may have an inadequate quality.

As the procedures for examinations are not identical, each procedure needs its own diagnostic reference level (DRL).

2. In principle, DRL are applicable for standard procedures in all areas of radiology, both in radiodiagnostics and nuclear medicine. However, they are particularly useful in those areas where a considerable reduction in collective or individual doses may be achieved, or where a reduction in absorbed dose means a relatively high reduction in risk:

- frequent examinations, including health screening;
- high dose examinations such as the computerized tomography and procedures which require long fluoroscopy times, such as for interventional radiology, and
- examinations with more radiosensitive patients, such as children.

3. After the DRLs have been established, the patient dose must be assessed either in standard phantoms or groups of standard-sized patients, on radiological equipment in every room of every laboratory periodically, with the long-term aim of annual assessment and after every major change or service.

4. There are two different methods for applying the DRLs: using a phantom or using patients.

The use of a phantom presents some advantages. Normally, one or two exposures for each view, for each examination type and for each item of radiological equipment are sufficient. However, using a phantom is only possible if:

- the DRLs are set for a phantom and the specific type of phantom is available for all radiological facilities, or
- conversion factors from the phantom to patient are available.

5. For some examinations, the number of patients available in a relatively short period is insufficient. Moreover, patients can differ widely in size and shape, so in fact there are only a few “standard-sized patients”. It is mentioned that as an example DRLs are used for standard-sized patients with 20 cm AP trunk thickness and 70 kg weight.

It is recommended that measurements be performed on standard-sized patients or patients close to standard size, preferably with an average weight that is 70 ± 3 kg. For a mammography, a standard phantom should be used.

6. Because of a small number of standard-sized patients, it may take all patients available in the measurement period and take the average of the dose as the outcome for a standard-sized patient. This will give reasonable information of the dose, provided that the number of patients is not too small: for example, a minimum of 10 patients. As people's shape and size differ from one population to another, a typical range of patients per country can be assessed. For the use of harmonized DRL, correction factors must be assessed and applied.

7. If the measured doses on a sample of standard-sized patients or on a standard phantom for a standard procedure generally exceed the relevant DRL, a local review of the procedures and equipment must be performed.

8. These reviews related to DRLs will cause, in the most cases, a reduction of the doses in the upper end of the tail of the curve giving the number of examinations and their doses. If for example competent authorities or professional bodies set the DRL at 75% or some other percentage of the dose curve in X-ray-diagnostic for a particular examination, this value must decrease over time.

Moreover, both in X-ray-diagnostic and nuclear medicine new techniques and improved procedures can influence dose distribution or administered activity in either direction.

9. As mentioned before, meeting the DRL does not always mean that good practice is performed. Quality assurance including quality control must be continued even if the DRL is not exceeded and particularly if the doses are far bellow the DRL.

10. Moreover, dose is not the only aspect: constantly checking image quality and clinical audit process will optimize the system.

11. DRL is also an important tool for clinical audit, which can provide a basis for a retrospective evaluation and for recommendations to improve procedures.

II. Procedures for establishing diagnostic reference levels

12. DRL must be established both for X-ray-diagnostic and for nuclear medicine, and if those are generally exceeded, an investigation must be carried out and appropriate corrective measures must be taken.

Therefore, in X-ray-diagnostic this level must be higher than the mean value of the measured patient doses on the patient or doses in a phantom. Given that the curve giving the number of examinations and their doses presents a long tail, the level of 75% seems appropriate. The use of this percentage is a first practical approximation to identifying those situations when an investigation is urgently necessary.

II.1 X-ray-diagnostic

13. DRL for X-ray-diagnostic must be based on doses measured in various types of hospitals, clinics and practices and not only in well-equipped hospitals. Table II.1 indicates the examples of DRL which have already been used for several years in various Member States. These values represent 75% of the entrance surface dose measured during the monitoring and testing operations

carried out in 1991/1992 in different Member States. Table II.2 gives DRL expressed in dose area product (SDP).

14. As mentioned before, because patients and the information required differ widely, DRLs are only applicable to standard procedures, standard phantoms or groups of standard-sized patients, and for specific groups of children distinguished by age, size and weight.

15. DRLs can be assessed using entrance surface doses, measured with a thermo-luminescent detector (TLD) fixed on the patient's body or using the surface dose product, SDP ($Gycm^2$).
SDP is a more efficient because:

- the whole examination is recorded;
- the position of the patient in the beam is less important than it would be with a TLD, so the measurement does not interfere with the examination of the patient, and
- the patient is not disturbed with the measurements.

For computerized tomography, the adequate sizes to be used as DRL are the weighted CT dose index and dose length product.

16. There are also some disadvantages in using the SDP. Due to the fact that it is necessary to know the absorbed organ dose, there must be a fixed relationship between the SDP and the absorbed dose. However, in some circumstances this is not the case, especially in pediatrics and the fluoroscopy used in cardiology and interventional radiology. In pediatrics, where the small surfaces are exposed, the SDP can be low while the absorbed dose can be high. On the other hand, when a large surface is exposed, SDP can be high also, but the absorbed dose can be low. Furthermore, in fluoroscopy the field size is often changed during the procedure.

However, the necessary devices to overcome these problems are not available on a large scale, but the measurement instruments for SDP are available on a large scale, and it is recommended to use SDP as DRL.

17. DRLs are particularly useful for the most of the common examinations, or examinations which may involve high doses or are frequently performed, such as:

- chest posterior anterior (PA) and lateral (LAT), dental radiography, lumbar spinal anterior the posterior (AP), lateral (LAT) and the lumbo-sacral joint, which determine relatively high doses and which are frequently performed;
- mammography: the breast is, relatively speaking, a highly radiosensitive organ and in screening programmes the mammography is carried out on healthy persons;
- bariun enema, which is a complex examination requiring several views and fluoroscopy;
- coronary angiography and some interventional radiological procedures (i.e. Percutaneus Transluminal Coronary Angioplasty, which require long fluoroscopy times and therefore give high doses);
- types of CT-examinations giving high doses (i.e. general Brain, Chest, Abdomen, Lumbar Spine and Pelvis).

18. When setting DRLs for procedures performed with digital systems it is important to remember that the level image of quality level can be selected by the user or automatically set by the X-ray system. In either case:

- the selected level of image quality must be justified by clinical requirements, otherwise the patient dose will be increased without clinical justification;

- the X-ray system and the image processing software must be optimized, if not, the patient dose will be increased without a better outcome;
- as digital images are very easy to obtain, the practitioner must be aware of the patient dose per image and must limit the number of images to what is strictly necessary for the diagnosis of a particular patient.

19. When performing fluoroscopy, one has to be aware that the automatic brightness control system may have been adjusted to an increased level due to deterioration of the image chain, which means that patient doses from fluoroscopy may be abnormally high.

If examinations are performed for which DRLs are not available, it is recommended to use as temporary DRLs the mean number of images and the mean total fluoroscopic time.

20. The human factor is also involved. Doses can be unnecessarily high due to inattention, indifference or too much work pressure, although sometimes such doses may be due to the individual opposition to accept generally-accepted standard procedures. DRLs can encourage changes in working procedures by showing what it is possible in other departments.

21. Table II.1a indicates the reference doses in X-ray-diagnostic in pediatrics, for a 5-year-old patient, expressed in entrance surface dose per patient, for a single exposure.

II.2 Nuclear medicine

22. In diagnostic nuclear medicine, DRLs are expressed in administered activities and not as absorbed doses.

23. This reference administrated activity is not based on the 75% percentage, but on the administered activity necessary for a good image during a standard procedure. In standard procedures for diagnostic nuclear medicine, a poorly-functioning gamma camera or other equipment are factors that can necessitate a higher activity.

Another important factor influencing the administered activity is the quality of the dose calibration.

24. Identically for X-ray-diagnostic, the human factor plays a certain role, intervening some mistakes due to inattention, indifference or individual opposition to accept generally- accepted standard procedures.

25. Excepting the size used, DRLs in nuclear medicine differ in two ways from those in the X-ray-diagnostic:

- The DRL in nuclear medicine is a guidance level for administered activity. It is recommended that this level of activity be administered for a certain type of examination in standard situations. (In X-ray-diagnostic, if the DRL is generally exceeded, there must be carried out a review or investigation).
- In nuclear medicine, for a recommended amount of administered activity, the outcome may be poor. This indicates that the efficacy of gamma cameras, the dose calibration or the procedures used by the staff need to be checked and inspected. (In X-ray-diagnostic, the criterion is normally a satisfactory image. However, the dose necessary for this image quality can be too high and, in this case, the radiological equipment shall be checked).

26. Those results in a major difference between the reference level systems for X-ray-diagnostic and diagnostic nuclear medicine: for X-ray-diagnostic the DRL is a level that is not expected to be exceeded and the dose in standard procedures shall be below that level, while in nuclear medicine, where the DRL is also expected not to be exceeded in standard procedures, the DRL shall be approached as closely as possible.

The Table II.5 establishes the DRL for nuclear medicine: administered activities (general observation: the values are presented for adults in normal biologic situations excepting the residual thyroid and cancer/metastasis).

27. In nuclear medicine, an "optimal" value for a DRL shall be used instead of a percentile; a reference level can be set for administrations of activities of radionuclide sufficient to obtain information for standard groups of patients (adults and children), based on the experience of the professional organizations.

28. The recommended methods in paragraph 27 are starting points. Even if meeting the DRLs, the practitioners shall be encouraged to reach the same good outcome using lower administered activities, for example changing procedures or equipment.

29. For children the administered activity shall be a fraction of that for adults. In practice this can be achieved by weighing the child or by age. If only weight is considered, the activity comparable to that for adults administered to children aged under 10 will lead to a low count density impulses per image, due to relatively larger organ mass or a shorter retention time.

The European Association of Nuclear Medicine's Task Group drew up a list of fractions of adult activity, (Table II.3), leading to the same count density as that an adult patient, although the effective dose is higher. These fractions are suitable for most nuclear medicine examinations.

Both methods require a minimum activity of $1/10^{th}$ of the adult activity, otherwise imaging times may be very long for children and it can be difficult to keep them still (see Table II.4).

30. Finally, administered activity may be based on age and this leads to approximately the same values as those in Table II.3.

Table II.1 Reference doses in X-ray-diagnostic, expressed in entrance surface dose per patient, for a single exposure

Radiograph	Entrance Surface Dose, for a single exposure mGy*)
Chest Posterior Anterior (PA)	0.3
Chest Lateral (LAT)	1.5
Lumbar spine Anterior Posterior (AP)	10
Lumbar spine Lateral (LAT)	30
Lumbar spine Lumbo-Sacral Joint (LSJ)	40
Breast Cranio-Caudal (CC)	10
Breast Medio-Lateral Oblique Side (MLO)	10
Breast Lateral (LAT)	10
Pelvis Anterior Posterior (AP)	10
Skull Posterior Anterior	5
Skull Lateral (LAT)	3
Urinary tract a simple radiography or before administration of contrast substance	10
Urinary tract after administration of contrast substance	10

*) Criteria for radiation dose of the patient: the entrance surface dose for standard-sized patients is expressed as the absorbed dose in air (mGy) at the point of intersection of the beam axis with the surface of a standard-sized patient (70 kg body weight or 5 cm compressed breast thickness), backscatter radiation included.

Table II.1a Reference Doses in X-Ray-Diagnostic in Pediatrics, for a 5-year-old patient, expressed in entrance patient surface dose, for a single exposure

Radiography	Entrance Surface Dose, for a single exposure µGy*)
Chest Posterior Anterior (PA)	100
Chest Anterior Posterior (AP, for non-co-operative patients)	100
Chest Lateral (LAT)	200
Chest Anterior Posterior (AP newborn)	80
Skull Posterior Anterior/ Anterior Posterior (PA/AP)	1500
Skull Lateral (LAT)	1000
Pelvis Anterior Posterior (AP)	900
Pelvis Anterior Posterior (AP infants)	200
Abdomen (AP/PA with vertical/horizontal beam)	1000

*) Criteria for radiation dose of the patient: The entrance surface dose standard-sized patients is expressed as the absorbed dose in air (µGy) at the point of intersection of the beam axis with the surface of a pediatric patient, backscatter radiation included .

Table II.2 Dose area product for total examinations

Examination	Reference dose Dose Area Product TOTAL EXAMINATION (Gy sq. cm.)	
Chest	-	1
Pelvis	-	4
Lumbar spine	-	10
Urography	40	20
Barium meal	25	25
Barium enema	60	50

Table II.3 Fraction of adult administered activity for different age groups of children recommended by the Pediatrics Task Group of the European Association of Nuclear Medicine

Kg	Fraction of adult administered activity	Kg	Fraction of adult administered activity	Kg	Fraction of adult administered activity
3	0.1	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	0.95
16	0.40	36	0.71	60-62	0.100
18	0.44	38	0.73	64-66	
20	0.46	40	0.76	68	

Table II.4 Minimum amounts of administered activities FOR CHILDREN in MBq

Radiopharmaceutical	Minimum administered activity for children (MBq)
Gallium-67 citrate	10
I-123 Amphetamine (brain)	18
I-123 Hippuran	10
I-123 Iodide (thyroid)	3
I-123 MIBG	35
I-131 MIBG	35
Tc-99m albumin (cardiac)	80
Tc-99m colloid (liver and spleen)	15
Tc-99m colloid (marrow)	20
Tc-99m colloid (gastric reflux)	10
Tc-99m DTPA (kidneys)	20
Tc-99m DMSA	15
Tc-99m MDP (phosphonate)	40
Tc-99m Spleen (denatured RBC marked red blood corpuscles)	20

Radiopharmaceutical	Minimum administered activity for children (MBq)
Tc-99m HIDA (biliary tracks)	20
Tc-99m HMPAO (brain)	100
Tc-99m HMPAO (WBC marked leucocytes)	40
Tc-99m MAA or microspheres	10
Tc-99m MAG3	15
Tc-99m pertechnetate (micturating-cystography)	20
Tc-99m pertechnetate (First Pass)	80
Tc-99m pertechnetate (Meckel's diverticulum)	20
Tc-99m pertechnetate (thyroid)	10
Tc-99m RBC marked red blood corpuscles (blood pool)	80

Table II.5 DRL in nuclear medicine: administered activities*)

Crt. No.	Organ	Exploration type	Radiopharmaceutical	mSv (E) / 100 MBq	Activity MBq
1	Brain	Cerebral blood flow	TC-99m-HMPAO I-123-iofetamine (IMP) Tc-99m-ECD	1 32 1	750 185 500
2		Benzodiazepine receptors	I-123-IBZM		185
3		Dopamine receptors dopamine	I-123-iomazenil		185
4	Thyroid	Uptake and scan	Tc-99m-pertechnetate I-123-NaI	1.3 15	80 20
5		Kinetics and scan before I-131therapy	I-131-NaI I-123	1500 15	0.2 2
6		Residual thyroid cancer and metas (5% uptake presumed)	I-131-NaI	230 3.8	185 540
7	Cord and blood vessels	Perfusion (myocardial scan or SPECT)	Tc-99m-sestamibi Tc-99m-tetrofosmin Tc-99m-colloid (HAS)	1.25 ± 1 ± 1	300 400 (SPECT) 800
8		Myocardial scan	Tc-99m-pyrophosphate	0.5	600
9		Function / CAD	Tc-99m-pentetate	1.15	800
10		Ventricular function/equil.	Tc-99m-RBC	1	600
11		Myocardial viability scan	TI-201-chloride	22.5	200
12		Phleboscint.	Tc-99m-MAA		80
13		Deep vein thrombosis	I-125-fibrinogen (uptake test)	10	4
14	Blood and immune system system	Bone marrow	Tc-99m-colloid	1	400
15		Spleen	Tc-99m RBC (denatured red blood corpuscle)	2	100
16		Blood pool (blood volume)	Tc-99m RBC (labelled red blood corpuscle)	±1	800
17		Erythrocyte volume	Cr-51labelled erythrocytes	37.5	0.8
18		Plasma volume	I-125/131 HAS	30	0.2
19		Iron distribution	Fe-59-chloride	1000	0.4

20	Skeleton	Bone scan	Tc-99m-MDP/HDP	0.5	600 SPECT: 800
21	Detection of abscesses, tumours, etc	Scan with leucocytes	In-11- labelled WBC Tc-99m- labelled WBC	45 ±1	20 200
22		Gallium Scint.	Ga-67 citrate WB lungs	11.3	150
23		Neuroendocrine tumour detection	I-131-MIGB I-123-MIBG	20 1.8	20 400
24	Lungs	Perfusion	Tc-99m-MAA plane or SPEC	1.25	100 200
25		Ventilation	Kr-81m gas usually < 5 minutes Tc-99m-aerosols Xe-133-gas	0.003 ±1 0.1	6000 1000 400
26	Gastrointes-tinal tract	Gastric reflux	Tc-99m-Sn-colloid	2.25	40
27		Schilling test	Co-57-cyanocob. Co-58-cyanocob.	250 500	0.1
28		Meckel's diverticulum	Tc-99m-pertechn.	1.25	400
29		Liver/ spleen scan (Kupffer cells)	Tc-99m-Sn/S/white-colloid or phytate	1	80 SPECT 200
30		Bile duct scan	Tc-99m-HIDA/DISIDA/IODIDA	1.3	150
31	Kidneys	Renal function/GFR	I-125-IOT/IOH I-125-DPTA Cr-5-EDTA	1 0.67 0.2	2 300 3
32		Static Imaging	Tc-succimer	0.88	88
33		Renography/ERPF (effective renal plasma flow)	Tc-DTPA Tc-MAG3 I-123-hypurate (IOH) I-131-IOH I-125-IOH	0.67 0.7 1 1	300 100 20 2
34		Micturating cystogram	Tc-Na-pertechn.	1.2	25

*General remark: the values for adults are presented in normal biological situations except for residual thyroid and cancer/metastasis.

APPENDIX No. 3
of the norms

DOSE CONSTRAINTS AND SPECIFIC RECOMMENDATIONS

I. Dose constraints for persons who, aware of the situation and voluntarily provide support and comfort to persons subjected, as applicable, to diagnosis or medical treatment.

I.1 General

1. The dose constraint is a restriction imposed to doses that might be received by a person from a given source and represent an useful instrument in the radiation protection optimization process.

The dose constraint is based on a prospective evaluation of doses, using well-managed practices or the rationing of an expert and it does not represent a dose limit.

2. If a dose constraint is exceeded, this may lead to a review or investigation, but it does not represent an infringement.

3. The dose constraints are based on the risk factors: mean risk is not an appropriate measure because the risk does not continue throughout the whole life duration, given that this kind of exposure only happens once or twice in a person's life. Therefore 5 mSv can be considered as a useful reference value, according to the Fundamental Norms for Radiological Safety; persons are permitted under special conditions to receive more than 1 mSv during one year only if the mean of 5 years does not exceed 1 mSv).

4. The real risk depends on the age of the person at the date of exposure to ionizing radiations; consequently the age-related risk factors and not a mean throughout the life duration shall be applied. These age-related risk factors are: for adults the mean and for unborn children and children under 10 years old the risk three times higher than the mean, and for older persons the risk is of 3 or 5 up to 10 times lower than the mean.

5. The dose limits are not considered as values to be adopted, but as a reference value for the acceptability of certain exposures.

I.2 Groups of persons

6. Two groups of persons that can provide support and comfort to persons subjected to medical exposure are as follows:

a) Family or close friends (legal guardian or legal companion). The exposure of this group can be justified because for these persons the patient's medical exposure can be considered a benefit.
b) Where there is no family person or friend (legal guardian or legal companion), another person can provide on an awareness or voluntary basis the comfort and support to the person subjected to medical exposure. This person does not observe the provisions of this norm but is covered by the system for limitation of doses for the population.

I.3 Recommended dose constraints

7. The dose constraints for different groups of persons are as follows:

- For adults with an age of 18 to 60, if no other source of exposure did not exist, 5 mSv can represent an acceptable reference value for the dose constraint.
- For adults aged 60 and over: 15 mSv.
- For the person mentioned at the point I.2, paragraph 6, letter b) the dose constraint is not applied, but the dose limit is applied.

II. Specific recommendations

II. 1 X-ray-diagnostic and interventional radiology

8. Authorization holders shall have written protocols regarding the optimization of protection measures for persons supporting the patients during the radiological examination for very old, in a severe health condition or under age patients.

9. The protocol shall include the following:

- methods to avoid the exposure of the person supporting the patient, for example the administration of sedatives to the patient (especially for procedures that require long period of time, such as CT examinations) and the use of immobilizing means for children patients;
- authorization criteria of persons supporting such patients, such as friends and relatives, on condition that such persons are not pregnant;
- a description of the person's position towards the X-ray tube, namely far from the direct beam, for example in the situation of a child sitting on his/her mother's knees;
- type and thickness of lead equivalent for personal protection clothing that must be used, namely lead gloves or auxiliary screens that must be used.

10. The authorization holder, by the application of this protocol, shall be able to demonstrate that it is less probable that the effective dose received by the person supporting the patient exceeds the dose constraint established according to this Appendix.

II.2 Nuclear medicine

11. The most important exposure ways in case of therapy are the external irradiation of persons situated in the immediate vicinity of the patient, including those present at autopsies, tracing, at wakes or funerals. Moreover, for the iodine therapy, the internal contamination by inhaling the aerosols with I^{131} exhaled by the patient may cause a significant dose.

12. Consequently, there is one simple rule to be observed: **keep the distance!**

13. In case the patient dies shortly after the administration of I-131 for therapeutic purposes, in order to avoid the external exposure of persons situated in the vicinity, it is best to ask an expert's advice and consult the family about their intentions. If the family wants to take the deceased patient home, this will only be allowed after a certain period of time established by the expert is expired.

14. In case of children, the requirements are a lot more restrictive. It is important to keep the children away or, in case it is not possible, such as in the case of small children, they should be left in the care and attendance of friends or grandparents.

15. It is considered that there is no risk when a child visits his/her parent who is treated with radio-pharmaceuticals, if the visit is made by keeping an adequate distance, is as short possible and is not frequent. The patients shall be informed and explained that these requirements are for the children' best interest.

16. An important recommendation is that in case of therapy, the period for observing the requirements shall be extended to a week when small children are involved because the risk associated to this group is higher.

17. Breastfeeding shall be stopped entirely, in case of the mother therapy.

18. After a treatment with radiopharmaceuticals, it is recommended that a female patient of childbearing potential shall avoid pregnancy in the following 4 months.

19. With regard to the use of hygiene facilities, covers, plates and dishes, the purpose is to avoiding direct contamination, otherwise special instructions are not necessary, in case of therapy.

20. Even if the dose limits are not applied, these instructions are necessary because ALARA principle is applied. The doses in some situations can be as high as 20 mSv (sleeping in the same bed with the patient); such a dose cannot be dangerous but it is unacceptably high.

21. A mean dose of 2 mSv is already high compared to other sources, especially if the maximum dose from all sources is only of 1 mSv. Consequently, the instructions based on ALARA principle are not useless, they shall be observed carefully.

22. The authorization holder shall assure that the persons supporting the patients, visitors, family members and all persons living in the same house with the patient during the radionuclide treatment (for example ^{131}I for thyroidism and thyroid carcinoma, ^{89}Sr, ^{186}Re for easing the pain) receive enough written instructions (regarding the time spent in the vicinity of the patient and the distance from this patient) so that they do not exceed the dose constraint established in accordance with this Appendix.

II.3 Brachytherapy

23. The authorization holder shall ensure that the persons supporting the patients, visitors, family members, during the radionuclide treatment receive enough written instructions (regarding the time spent in the vicinity of the patient and the distance from such patient) so that they do not exceed the dose constraint established in accordance with this Appendix.

APPENDIX No. 4
of the norms

EDUCATIONAL AND TRAINING REQUIREMENTS FOR RADIATION PROTECTION WITHIN MEDICAL EXPOSURES

I. Introduction

1. The present educational and training requirements in radiation protection for medical exposures are established according to the Recommendations of European Commission, Radiation protection series no. 116/2000.

2. All persons with responsibility for medical exposures need training in radiation protection. The following categories of professionals have been identified:

2.1 Diagnostic Radiology and Medical Imaging specialist physicians;
2.2 Nuclear medicine specialist physicians;
2.3 Radiotherapy specialist physicians;
2.4 Cardiologists;
2.5 Other medical physicians using X-ray systems (especially fluoroscopy systems), for example urologists, vascular surgeons, orthopedists, traumatologists, etc.
2.6 Stomatologists and dentists;
2.7 Pediatrics specialized;
2.8 Radiological technologists;
2.9 Radiological assistants;
2.10 Technicians performing quality control in radiology installations;
2.11 Maintenance engineers and maintenance technicians of the radiology installations;
2.13 Chiropractors.

II. Radiation protection training programs

3. It is established a list of topics which shall be included in the training programs in radiation protection for every category of professionals. The training program in radiation protection in *radiological-diagnostic* shall include the following training areas:

3.1 The atomic structure and interaction of radiation;
3.2 Radiological quantities and units;
3.3 Physical characteristics of X-ray machines;
3.4 Fundamentals of radiation detection;
3.5 Detectors used in diagnostic installations;
3.6 Fundamentals of radiobiology: cell, systemic and whole body responses;
3.7 Radiation protection. General criteria;
3.8 Operational radiological protection;
3.9 General radiation protection aspects in diagnostic radiology;
3.10 Particular aspects of patient and staff in radiation protection;
3.11 Quality control and quality assurance;
3.12 National and European regulations and standards;
3.13 Practical training.

Also, the diagnostic radiology training program in radiation protection shall contain other topics, such as:

- Radiation effects;
- Definition of different terms used for dose;
- Relationship of equipment characteristics to dose and image quality;
- Relationship of exposure factors to dose and image quality;
- Concept of risk, comparative risk through for different ages and period of pregnancy;
- Protocols for over exposures and accidents;
- Clear communication at the appropriate level with patient, staff, comforters and careers the public;
- Diagnostic reference levels.

4. Training program in radiation protection for *interventional radiology (RI)* requires a second specific level of training for radiation protection in the following areas:

4.1 X ray systems for IR;
4.2 Dosimetric quantities specific IR;
4.3 Radiobiology: risks in IR;
4.4 Radiological protection of patient and staff in IR;
4.5 Quality assurance in IR;
4.6 Local and international rules concerned with IR;
4.7 Procedures optimization in IR.

5. Training program in radiation protection for *radiotherapy* shall include the following topics:

5.1 Radiotherapy equipment – safety and accuracy;
5.2 Dosimetric and geometric quantities for accuracy in radiotherapy;
5.3 Radiobiology and radiation risks;
5.4 Radiation treatment planning for optimizing delivery of radiation dose;
5.5 Optimal and safe use of radionuclides in radiotherapy;
5.6 Radiation hazards in radiotherapy facilities.

6. Training program in radiation protection for *nuclear medicine* shall contain:

6.1 Nature of ionizing radiations and its interactions with tissue;
6.2 Genetic and somatic effects and how to assess their risks;
6.3 Patient doses;
6.4 Quality assurance and quality control;
6.5 Dose limitation;
6.6 Pregnancy and breast feeding;
6.7 Unsealed sources;
6.8 Organization of radiation protection;
6.9 Statutory responsibilities.

7. Among other topics, nuclear medicine physicians have to be familiar and have knowledge of radiological protection. Among other topics, nuclear medicine physicians must have practical experience in patient dosimetry (both in diagnosis and in therapy) and in radiation protection (decontamination, waste disposal, staff dosimetry, etc.). 120 hours are recommended for assessing the basic science training. Practical training must also be added to the courses and formally controlled.

8. In addition, it is obvious that the topics to be included in training activities and the level of knowledge of those must be adapted to the various specialties (diagnostic radiology, radiotherapy,

cardiology, dentistry, etc.) and for the different kinds of work and responsibility (medical doctors, medical physicists, maintenance engineers, radiographers, nurses, etc.).

9. The guidelines issued during recent years under the radiation protection actions of the European Commission concerning image quality criteria (EUR, 1996 a, b, c, d, e) are good examples of training materials for diagnostic radiology specialists, medical physicists and radiographers. Also, the American Association of Physicists in Medicine has published relevant guidelines concerning the teaching of clinical radiological physics to residents in diagnostic and therapeutic radiology (AAPM report no. 64, January 1999).

10. Table IV.1 presents training areas and levels of knowledge necessary for persons involved in medical exposures. The areas and levels presented in table IV.1 shall be considered as basic training. For certain groups, more detailed additional training could be required. The practical application of radiological protection specific to modality must be included in "operational radiological protection". Medical physics experts shall be know, in addition to physics, all the training areas at the highest level and all relevant aspects of quality assurance programs.

11. The number of hours indicated in table IV.1 should be considered as being in addition to the basic training for prescribers and shall be included in different training periods such as basic residency programmes and special training courses.

12. Training programmes shall include in any case details of the procedures to be followed occurring accidental or unintended doses to patients from radiological practices.

13. Practical exercises and practical sessions shall be included in the programmes for training in radiation protection. A minimum of 1 or 2 hours practical session in a clinical installation shall be included in the simplest training programmes, while 20 – 40% of the total time scheduled in more extensive courses shall be devoted to practical exercises.

14. Trainees shall have a previous experience in radiation protection in medical installations and in practical work in a clinical environment. Installations where practical training is provided shall be medical installations and not only laboratories or simulation exercises.

15. Also, for pediatric radiology, screening mammography and computed tomography, it is required a specific training in radiation protection for radiologists and nurses involved in these examinations.

III. Radiation protection of the patient for the individuals undergoing practical training programmes

16. Radiation protection of patient requires special consideration during the training of residents and nurses. The criteria of justification and optimization shall be applied carefully and all the procedures shall be performed under the responsibility of a senior specialist.

Also, some specific recommendations can be made for planning practical training in radiation protection for medical installations (i.e. X-radiation systems must remain in operative condition after the training programme). If patients are involved, simple procedures with low doses must be selected; it is not permitted to give some additional irradiation to the patient just for personnel training purposes.

17. In case of high patient dose procedures (interventional and some vascular diagnostic procedures) a strict patient dose control must be performed to guarantee that the patient does not receive significant additional doses due to personnel training. In pediatrics radiology, screening

mammography and computed tomography, also significant additional doses due to personnel training does not be administered to the patient.

IV. Continuous training and education after qualification and on implementation of new techniques.

18. For physicians and medical physicists it is required a minimum of 150 hours of approved education in category 1 and 2 every three years (to be renewed in a 3-year cycle), according to the Continuous Medical Education (CME) Standard, established by the American College of Radiology (ACR).

> 18.1 Category 1. The minimum number of hours is 60. Residencies and fellowships up up to 50 hours per year can be included.
>
> 18.2 Category 2. The maximum number of hours required is 90. Activities accepted: accepted meetings, lectures, course syllabuses, study of specialized medical literature, training of medical students in respect of issues related to radiology, preparation and publishing scientific papers, presentation of papers, courses or scientific exhibits, use of computer-assisted educational materials, designed to optimize patient care, review of manuscripts for magazines and review of abstracts for scientific meetings.

19. The programs shall include a certain training directed towards continuous education in radiation protection (together with practical education, particularly on the installation of new equipment), the extent depending on the kind of work. For example, a nurse, a radiotherapist or a medical physicist would need more time dedicated to continuous education in radiation protection than a dentist.

20. Whenever new radiation equipment is introduced in a hospital or clinic, specific training shall be provided before clinical use of the system and the participation of engineers of the firm supplying the system shall be required.

This training shall be a part of the commissioning process (putting into operation). It is important to consider the responsibility of the supplier for the availability of understandable and full instructions in the local language.

21. For new people hired for the use of installations practicing medical exposures, a specific training shall be provided before the clinical work begins. Additionally, whenever a new technique is implemented in a center, prior staff training shall be provided. In this case, the training shall be provided at another center with previous experience in this technique, taking into account the considerations mentioned in the in point "III. Recommendations for radiation protection of the patient for individuals undergoing practical training programmes". In some cases, a particular number of examinations and/or procedures which must be performed under the control of an experienced physician can be considered.

V. Course on radiation protection in the basic curriculum of medical and dental schools

22. This training shall include all the basic radiation protection knowledge needed by the prescriber. Prescriber shall be educated in the basic aspects of radiation protection, especially justification and optimization. This basic training shall be independent of the complementary training received where a doctor becomes practitioner.

23. These courses shall have a different orientation and content for medical and dental students. In medical schools, the main topics shall be the general aspects of patient protection, such as

biological effects, justification of medical exposures, risk-benefit analysis, typical doses per examination, etc., together with some basic knowledge of the advantages and disadvantages of the use of ionizing radiations in medicine (including the objective information about radioactive waste and its safe management). Medical students do not need specific training in the design and operation of the medical installations required for radiodiagnosis, nuclear medicine and radiotherapy. This specific training in radiation protection will form part of their programme as residents to become specialists.

24. The case of dental education is different. In addition to the basic aspects mentioned for medical schools, the course on radiation protection shall also include all the specific training for the safe operation of X-ray systems for diagnostic purposes, such as the principles of the X-ray tube operation, radiographic imaging, film processing, quality assurance programmes, occupational and patient dose control, etc.

25. Assuming that the basic training in radiation physics forms part of preclinical training (basic Medical Physics or equivalent), the general part of the recommended radiation protection course shall concentrate on topics addressing patient protection. A possible outline can be the content of the ICRP 73, Radiological Protection and Safety in Medicine (ICRP, 1996).
25.1 Introduction;
25.2 The Quantification of Radiation Dose and Risks (including radiation effects);
25.3 The Framework of Radiological Protection;
25.4 The Justification of practice;
25.5 The Optimization of Protection;
25.6 Individual Dose Limits;
25.7 Practical Methods of Protection;
25.8 Operational Guides and Reference Levels;
25.9 Accidents and Emergencies;
25.10 Institutional Arrangements.

26. Some practical sessions and seminars shall be focused on the following topics:

26.1 Justification of medical exposures for some specific diagnosis (advisability of simple radiography or CT); consideration of alternatives such as ultrasounds or magnetic resonance, etc.);
26.2 Responsibility of physician regarding medical exposure;
26.3 Different levels of risk as a function of the age of the patient;
26.4 Different levels of doses for different kinds of procedures (chest, abdomen and spine examinations, CT, nuclear medicine examinations, etc.);
26.5 Recommendations addressed to pregnant or breast feeding patients who need medical examinations (with X ray an with radionuclides);
26.6 Importance of diagnostic reference levels in optimization programmes and in standard risk estimation;
26.7 Why and how a hospital produces radioactive waste and the safe management of this kind of waste;
26.8 Practical examples of how to inform patients (and their helpers) about the risk of medical exposure. Comparison with other kinds of risk.

27. A part of this training can be merged with the basic training in radiology during the clinical period. This shall be have as part of its aims “to explain basic radiation protection in the light of these norms”. The problem of educating radiologists in radiation protection is a separate postgraduate issue.

28. A basic radiation protection course shall also be introduced in nursing schools.

29. The duration of this training in radiation protection shall be between 20 and 40 hours, assuming a prior knowledge of radiation physics. A percentage of 20 – 30% from this duration shall consist of practical sessions or seminars analyzing typical cases presented in clinical practice.

30. The training in radiation protection shall also be encouraged and provided at the end of the preclinical period or during the clinical period.

A. Minimum specific training in radiation protection for interventional radiology

(1) As an example of usefulness of specific educational objectives in preparing training activity, training programmes shall present a few topics:
(2) X-ray systems for interventional radiology.

2.1 To explain the effect of a high additional filtration (for example copper filters) on conventional X-ray beams;

2.2 To explain the operation of continuous or pulsed X-ray emission modes;

2.3 To explain the benefits of the grid controlled X-ray tube when using pulsed beams;

2.4 To explain “road mapping”;

2.5 To explain temporal integration and its benefits in terms of image quality;

2.6 To analyse the changes on the dose rate when varying the distance from image intensifier to patient.

(3) Dosimetric quantities specific for interventional radiology.

3.1 To define the dose-area product (DAP) and its units;

3.2 To define entrance dose and entrance dose rate in fluoroscopy;

3.3 To discuss the correlation between surface dose and dose-area product;

3.4 To discuss the relationship between dose-area product and effective dose;

3.5 To correlate the dose upon entry into the patient with the dose at the exit surface and the dose at the intensifier entry surface.

(4) Radiological risks in interventional radiology.

4.1 To describe deterministic effects which may be observed in interventional radiology;

4.2 To analyze the risks of deterministic effects induction as a function of the surface doses received by the patient;

4.3 To analyze the relationship between received doses and deterministic effects in the lens of the eye;

4.4 To be aware of the likely time intervals between irradiation and occurrence of the different deterministic effects, the required follow-up and control of patients;

4.5 To analyze the stochastic risks in interventional procedures and their age dependence.

(5) Radiological protection of the staff in interventional radiology.

5.1 To comment on the most important factors which influence doses of occupationally exposed staff in the RI laboratories;

5.2 To analyze the influence of X-ray C arm positioning on the received doses by the occupationally exposed personnel;

5.3 To analyze the effects of using different fluoroscopic modes on occupational doses;

5.4 To analyze the effects of using personal protection (namely: lead aprons, gloves, eyeglasses, thyroid protectors, etc.);

5.5 To analyse the benefits and inconveniences of using articulated screen suspended from the ceiling;

5.6 To understand the importance of the suitable location of personal dosimeters.

(6) Radiological protection of patients in interventional radiology.

6.1 To analyse the correlation between fluoroscopy time and number of images taken in a procedure, with the dose received by patient;

6.2 To discuss the effects of the focus to skin distance and patient image intensifier input distance;

6.3 To analyze the dose reductions attainable by modifying the image rate in cine or in digital acquisition;

6.4 To give typical examples of patient entrance dose value per image in different procedures;

6.5 To analyze the effect of using different magnifications in the patient dose;

6.6 To discuss the parameters which shall be recorded in the patient history (or with reference to data on) regarding the received doses.

(7) Quality assurance (QA) in interventional radiology.

7.1 To discuss the difference between parameters that usually does not downgrade with time and those which can require periodical control;

7.2 To discuss the importance of establishing simple criteria to compare doses at the patient or intensifier entrance in different situations;

7.3 To note the importance in QA programs of the periodical control of patient dose and its comparison with reference dose levels.

(8) Local and international rules for interventional radiology.

8.1 To discuss the different regulations which apply in IR installations;

8.2 To describe the international recommendations for IR (WHO, IAEA, ICRP, EC, etc.);

8.3 To provide information on the international recommendations concerning the limitation of high-dose examinations.

(9) Procedure optimization in IR.

9.1 To note the importance of optimization in interventional radiology procedures;

9.2 To discuss the importance of reference levels related to the patient dose at local, national and international level.

9.3 To analyze the importance of periodical patient dose control in each room;

9.4 To discuss the possibility of using different C-arm orientations during long procedures in which the threshold for deterministic effects may be attained;

9.5 To analyze the importance of recording the dose distributed to every patient.

B. Minimum specific educational objectives for mammography

(1) Image systems and X-ray systems for mammography.

1.1 To discuss the effects of the generator in the quality and intensity of the X-ray beam (power, wave form, etc.);
1.2 To analyze the importance of the generator power in exposure times;
1.3 To describe the several focus sizes for the same X-ray tube and the differences between the power associated with each of them;
1.4 To discuss the focus size to be used with the conventional and magnification techniques;
1.5 To discuss the X-ray beam characteristics used in mammography;
1.6 To discuss the effect of the anode type on the quality and intensity of X-ray beam;
1.7 To discuss the effect of the filter type on the quality and intensity of the X-ray beam;
1.8 To describe the different anode/filter combinations that are available in modern X-ray mammography units;
1.9 To explain the use of different anode/filter combinations depending on breast features;
1.10 To describe the most important grid parameters (grid ratio, number of grid lines/cm, interspaced material and focus distance);
1.11 To discuss the use of the grid and its dependence on breast size and breast composition;
1.12 To describe the basic elements and performance of automatic exposure control (AEC);
1.13 To discuss the AEC sensor position with regard to breast size;
1.14 To analyze the most important problems related to the routine use of AEC;
1.15 To discuss the effect of breast compression on X-ray beam attenuation;
1.16 To describe the film parameters (base + fog, contrast, average gradient and latitude).

(2) Dosimetric quantities specific for mammography

2.1 To define the entrance surface air-kerma;
2.2 To define backscatter and the backscatter factor;

2.3 To define the entrance surface dose;
2.4 To define the average glandular dose;
2.5 To establish the relation between the entrance surface air-kerma and the average glandular dose;
2.6 To describe the breast features that affect the relationship between the entrance surface air-kerma and the average glandular dose;
2.7 To describe the X-ray beam parameters that affect the relationship between the entrance surface air-kerma and the average glandular dose;
2.8 To explain the methods for estimating the entrance surface air kerma and the average glandular dose.

(3) Radiobiology: risks in mammography

3.1 To describe the increment in the stochastic effects as a function of the average glandular dose;
3.2 To discuss the factors proposed by the ICRP-60 for stochastic effects in the breast (fatal and curable cancers);
3.3 To discuss the increment in organ dose with breast size and breastcomposition.

(4) Radiological protection for personnel occupationally exposed in mammography.

4.1 To comment on the most important factors that influence staff doses in mammography installations;
4.2 To analyse some typical values of occupational doses for mammography installations with and without protection screen;
4.3 To correlate the occupationally dose values with workload.

(5) Radiological protection of patients in mammography

5.1 To analyse the effect of mammography equipment (generator, focus-film distance, anode/filter combination, dose rate, etc.) on the dose to the patient;
5.2 To analyse the effect of the radiological technique (kV, grid, type of view, optical density of the film, exposure time, etc.) on the dose received by the patient;
5.3 To discuss the effect of breast compression on dose values;
5.4 To discuss the influence of the film-screen combination on dose values;
5.5 To discuss the influence of developer temperature and extended processing time on dose values;
5.6 To analyse the typical entrance surface air-kerma and the average glandular dose valuesfor an average breast;
5.7 To analyse the reference values for the entrance surface air-kerma and the average glandular dose;
5.8 To discuss the potential dose reduction in digital mammography.

(6) Image quality in mammography

6.1 To discuss the more relevant features of a mammography image by comparing with the radiological images obtained from other types of examination;
6.2 To discuss the effects of X-ray equipment characteristics (generator, focus film distance, anode/filter combination, focus size, etc.) on the quality of the mammography image;
6.3 To point out the importance of “low exposure times”;
6.4 To analyse the effect of the radiological technique (kV, grid, type of view, optical density of the film, compression, patient positioning, etc.) on the image quality;
6.5 To discuss the influence of the film parameters (contrast, average gradient, latitude) on the image quality;

6.6 To discuss the influence of developer temperature and extended processing time on image quality;
6.7 To describe the several methods for evaluating image quality;
6.8 To discuss the limiting values proposed for the parameters associated with image quality;
6.9 To point out the image quality criteria for clinical mammography images;
6.10 To discuss the potential improvement in image quality to be obtained with digital mammography.

(7) Quality assurance in mammography

7.1 To discuss the difference between parameters that usually do not downgrade with the passing of time and those which may be downgraded and require periodical control;
7.2 To discuss the additional quality assurance requirements for mammography screening;
7.3 To analyse the importance of periodical control of all components of the X-ray system;
7.4 To analyse the importance of periodic control of the processor;
7.5 To analyse the importance of periodic control of the film/screen system;
7.6 To analyse the importance of periodic control of the viewing box;
7.7 To note the importance in the QA programmes of the periodical control of patient dose and its comparison with reference dose values;
7.8 To analyse the importance of periodical image quality control;
7.9 To analyse the importance of the periodical evaluation of image quality based on clinical criteria.

(8) Local and international rules and recommendations concerning mammography.

8.1 To discuss the national and European recommendations which apply in mammography installations;
8.2 To discuss some examples of accreditation programmes for mammography;
8.3 To analyse the content of the guidelines published by the European Commission which apply to mammography;

(9) Procedure optimization in mammography.

9.1 To note the importance of optimization in mammography;
9.2 To discuss the importance of using the reference dose values at the local, national and international level;
9.3 To analyse the importance of recording periodically the dose values and radiographic techniques;
9.4 To point out the need for frequently reviewing the tolerances or limiting values proposed in the quality control protocols.

C. Minimum specific educational objectives for pediatric radiology

(1) General considerations regarding the installation and the equipment.

1.1 To justify the requirements concerning the power of the generator and its relationship with the need for short exposure times (3 milliseconds);
1.2 To explain the advantage of high frequency generators in relation to the accuracy and reproducibility of exposures in pediatrics;
1.3 To discuss the advantages and limitations of automatic exposure control devices in pediatrics;
1.4 To justify the specific technical requirements of the automatic exposure control devices for pediatrics;

1.5 To explain that careful manual selection of exposure factors usually leads to lower doses;
1.6 To explain the design aspects to be considered in pediatrics X-ray rooms for improving the child's cooperation (control panel provided with easy patient visibility, etc.);
1.7 To discuss the advantages and limitations of fast film-screen combinations;
1.8 To discuss the advantages of using low-absorbing materials in cassettes, tables, etc.
1.9 To analyse the limited improvement of image quality when utilizing the anti-spreading grid in pediatrics and the increase of the patient's dose;
1.10 To analyse the limited technical requirements of antiscatter grids for pediatrics;
1.11 To explain how the antiscatter grid shall be removable in pediatric equipment, particularly for fluoroscopic systems;
1.12 To explain the advantages of using image intensifiers with high conversion factors for reducing patient dose in fluoroscopic systems;
1.13 To justify the advantage of the kV – mA dose rate curves for automatic brightness control in fluoroscopic systems used for pediatrics;
1.14 To explain why is it preferable not to use the automatic brightness control unless there is an automatic cut-off device;
1.15 To discuss the importance of using specific technical radiographic parameters for CT examinations in pediatrics (lower mAs than for adults and lower kV in some cases);
1.16 To analyse the special problems with the use of mobile X-ray units in pediatrics;
1.17 To explain the advantages and disadvantages of under-couch and over-couch fluoroscopic units with X-ray tube for pediatrics. To discuss the advantages and role of pulsed fluoroscopy;
1.18 To compare digital and conventional equipment and the role/use of (frame grab) technique in digital imaging;
1.19 To discuss value of cine playback (digital) and video playback (digital/conventional fluoroscopy) in screening examinations;
1.20 To discuss the role of additional tube filtration.

(2) Reduction of exposure

2.1 To analyse the most frequent causes of repeating the radiography in pediatrics – reject analysis, audit and feedback;
2.2 To discuss about the fact that the patient immobilization may cancel the repeating radiography;
2.3 To analyse the different immobilization devices for the available for pediatric radiology to make a traumatic examination. The role of simple aids such as sticky tape, sponge wedges and sand bags;
2.4 To explain how short exposure times can improve image quality and reduce the repetition of exposure;
2.5 To explain the inconvenience of using mobile X-ray units for pediatrics and the difficulty in getting short exposure times;
2.6 To explain the importance of existence of radiographers with specific training in pediatric radiology;
2.7 To discuss the importance of gonadal protection in pediatric radiology and necessity of having protection equipment for various sizes and types;
2.8 To analyse the importance of the collimation (in addition to the basic collimation corresponding to the film size) in pediatric patients, particularly protection for hips and lateral collimation devices for follow-up scoliosis;
2.9 To discuss the importance of the correct positioning and collimation, particularly for excluding the gonads from the direct beam;
2.10 To discuss the importance of establishing when adolescent girls might be pregnant, when abdominal examinations are contemplated;
2.11 To discuss use of the 10 and 28 days rule in children over 12 years old or younger if relevant;
2.12 To discuss the fact that motion is a greater problem in children, which may require a specific adjustment of radiographic techniques;

2.13 To discuss the importance of a proper consultative relationship between the referring physician and the radiologist. Role of agreed protocols and diagnostic pathways;
2.14 To discuss some examples of radiological examination of questionable value in children (like some follow-up chest radiographs in simple pneumonia, abdominal radiographs in suspected constipation);
2.15 To explain that the repetition of a radiological examination in pediatrics shall always be decided by the radiologist;
2.16 To discuss the advantage of using appropriate projections for minimizing dose in high risk tissues (where possible, Posterior Anterior (PA) projections shall replace Anterior Posterior (AP) projections for spinal examinations);
2.17 To discuss the advantage of having additional filters available to enable them to be easily changed (filters of 1 mm Al; 0.1 and 0.2 mm Cu shall be available);
2.18 To discuss the value of having dedicated pediatric room or complete sessions dedicated to pediatrics. Experienced staff who can obtain the child's confidence and cooperation in a secure and child-friendly are of paramount importance in reducing radiation doses in pediatrics;
2.19 To discuss the importance of having specific referral criteria, for example for head injuries where the incidence of injury is low;
2.20 To discuss referral criteria for all X-ray examination of children, especially those which may be age-related, for example non-ossified scaphoid, below age of 6, nasal bones cartilaginous below age of 3 years;
2.21 To discuss high kV techniques;
2.22 To explain the value of using long focus-patient distances;
2.23 To explain the importance of using the light beam diaphragm to move the patient into the correct position rather than screening during overcouch fluoroscopy procedures;
2.24 To discuss the role of audit and quality assurance in maintaining or improving image quality and dose.

(3) Risk factors

3.1 To discuss the fact that longer life expectancy in children means a greater potential for the manifestation of possible harmful effects of radiation;
3.2 To consider that the radiation doses necessary to examine young children shall generally be smaller than those employed in adults;
3.3 To explain that the risk factor for cancer induction of in children is between two and three times higher than for adults, with emphasis on the developing breast and gonads and the more widespread distribution of red bone marrow in the developing skeleton;
3.4 To discuss the risk factors for genetic effects in children;
3.5 To compare the risk factors for radiological examination in children with other common risks like traveling by air or by car;
3.6 To correlate with the natural occurrence of congenital abnormalities;
3.7 To correlate with the natural incidence of cancer.

(4) Patient dosimetry. Reference dose values.

4.1 To explain the specific difficulties of measuring patient doses in pediatrics;
4.2 To discuss the dosimetric techniques available for patient dosimetry in pediatrics;
4.3 To discuss the fact that patient dose values are related to patient size.
4.4 To analyse some typical patient reference dose values in pediatrics and their relation with patient size;
4.5 To analyse the reference dose values available for pediatrics;
4.6 To discuss how to use reference dose values in pediatric radiology;

(5) Protection of medical personnel and parents.

5.1 To analyse the possibility of parents cooperating in the radiological examination for their children and the precautions to be taken;
5.2 To clarify whether the parent's exposure in this situation can be considered as a medical exposure so that optimization criteria must be applied;
5.3 To highlight the fact that parents and helpers shall know exactly what is required of them;
5.4 To explain that pregnant woman shall not be allowed to help during pediatric examinations;
5.5 To explain the importance of using lead aprons and lead gloves (if the hands are in the direct radiation field) in these situations.

(6) European guidelines and international recommendations

6.1 To explain the content of European Guidelines on Quality Criteria for Diagnostic Radiographic Images in Pediatrics;
6.2 To take into consideration the existence of relevant documents published by the ICRP, NCRP and WHO concerning radiation protection in pediatric radiology.

D. Addendum for pediatric nuclear medicine

Some of the previous objectives can also be of interest for specialists performing pediatric procedures. Some additional actions proposed by the EANM are as follows:

(1) General considerations

1.1 To explain the importance of having nuclear medicine technologistes with specific training in pediatric radiology;
1.2 To discuss the fact that motion is a greater problem in children and it can require specific adjustments of nuclear medicine techniques;
1.3 To discuss the importance of a proper consultative relationship between the physician prescriber and the nuclear medicine specialist;
1.4 To explain that the repetition of a nuclear medicine examination in pediatrics shall always be decided by the nuclear medicine specialist.

(2) Risk factors

2.1 To compare the risk factors for nuclear medicine examinations in children with other risks like traveling by air or by car.

(3) Patient dosimetry. Reference dose values.

3.1 To discuss how to use the reference dose values in pediatric nuclear medicine.

(4) Protection of personnel and parents

4.1 To explain the radioactivity problem in the human body fluids, especially in urine.

(5) Reduction of exposure

5.1 To discuss how to determine the amount of activity to be administered to a pediatric patient;
5.2 To discuss how to enhance elimination of radiopharmaceuticals in order to reduce exposure.

E. Minimum specific educational objectives for radiotherapy

The radiotherapy practice encompasses the clinical care of patients as well as the technical aspects of radiotherapy. Benefits to patients accruing from radiotherapy depend upon the accurate administration of high doses to the tumour with doses to normal tissues being kept to a minimum level.

In addition to these patient-centred aspects of radiation protection, appropriate measures must also be taken to reduce the amount of radiation to staff and the general public to as low a level as is reasonable attainable.

In order to achieve these aims, a broad basic training is required in all of the categories of staff involved in the delivery of ionising radiation. The European Society for Therapeutic Radiology and Oncology has recommendations for each core curricula for the involved disciplines and this summary contains the elements from these curricula which relate to radiation protection.

It is important to emphasize that the extent of training required will depend upon the levels of knowledge and training of different groups of professional in physics, radio-biology, etc..

(1) Radiotherapy equipment – safety and accuracy

1.1 To show that the principles of operation and constructive details of therapy X-ray generators, including treatment head, are designed for safe and accurate delivery of radiation to the target volume with minimal collateral radiation dose;
1.2 To discuss how filtration and factors affecting the beam characteristics determine the radiation dose to skin and target volume;
1.3 To discuss how the construction of cobalt 60 units and methods of safety control minimize the risk of radiation accidents;
1.4 To describe the production of high-energy X radiations in linear accelerators and measurements for limiting X ray head leakage;
1.5 To describe the X-ray applicators, electron applicators, conventional linear accelerators collimators, multi-leaf collimators, the effect of collimators on penumbra size, shielding materials and dose after the passage of beam through shielding materials and the relevance in restricting radiation dose to the target volume;
1.6 To describe equipment control and interlock systems and select/confirm systems and their role in hazard control;
1.7 To explain the role of commissioning measurements and quality control checks in determining the accuracy of radiation dose delivered to the patient;
1.8 To discuss the qualities of equipment referring to the information necessary to provide an accurate and safe administration of the radiation in the irradiated volume;
1.9 To discuss the importance of verification of information in order to ensure safe and accurate administration of radiation to the treatment volume.

(2) Geometric and dosimetric quantities for accuracy in radiotherapy.

2.1 To discuss the use of percentage depth dose curves (outputs), backscatter and peak-scatter factors, tissue phantom ratios, tissue standard factors and equivalent squares in determining the radiation dose delivered to a patient;
2.2 To discuss the role of beam geometry, magnification and beam penumbra in determining the extent of the radiation field used for a patient treatment;
2.3 To explain the definition of field dimension and its use in ensuring a correct coverage of the target volume;

2.4 To explain the variation of depth-dose with the energy and to correlate it to the optimal selection of energy in the administration of radiation to a patient;
2.5 To explain the general features of isodose charts and their dependence upon FSD and energy with regard to ensuring the adequate and homogenous irradiation of the target volume;
2.6 To describe the acquisition and the use of beam data for radiotherapy treatment planning and to analyse the limitations of the algorithms used;
2.7 To explain calibration protocols and the uncertainties in the calibration process and to correlate these to the overall uncertainty of patient radiation dosage.

(3) Radiobiology and radiation risks

3.1 To discuss the justification and use of radiotherapy in malignant and benign disease;
3.2 To contrast the use of external beam therapy with brachytherapy in the treatment of disease and to discuss the relative benefits of both modalities to the patient;
3.3 To relate the response to radiation at the molecular and cellular level, including cellular injuries and cell survival curves, to the macroscopic response of tissue to radiation;
3.4 To discuss the response of tumours and normal tissue to the therapeutic levels of radiation, including dependence on fractionation, dose rate, radiosensitisation, re-oxygenation;
3.5 To consider radiation reactions – early and late;
3.6 To discuss the role of radiobiological modelling including the linear-quadratic model in explaining the effects of radiation injuries to tissues;
3.7 To discuss therapeutic ratio and its role in optimising dose administered to patient;
3.8 To discuss the effects of radiation on the embryo and fetus, leukaemogenesis and carcinogenesis, somatic and genetic hazards for exposed individuals and population;
3.9 To explain the assessment of the efficacy of radiotherapy and its role in the justification of radiation treatment.

(4) Radiation treatment planning for optimising administration of radiation dose.

4.1 To describe the delimitation of interest volumes according to ICRU 50 and ICRU 62 and the role of this delimitation in optimising radiation treatment;
4.2 To compare fixed-SSD and isocentric radiotherapy, and to discuss the benefits of the two methods.
4.3 To describe beam modifications of in case of oblique incidence, inhomogeneities, use of wedge filters, compensators and interface effects in the context of achieving an accurate and homogenous irradiation of the target volume;
4.4 To discuss the combination of fields in order to accomplish a homogenous irradiation of the target volume;
4.5 To discuss how the elaboration of a 3D treatment planning and optimization can be used to limit the radiation exposure of normal tissues;
4.6 To discuss how the use of conformal radiotherapy can optimize the irradiation of the target volume related to normal tissues;
4.7 To explain how treatment verification and *in vivo* dosimetry can enhance the accuracy of the dosage and targeting of the radiation beam;
4.8 To explain how Intensity Modulated Radiotherapy (variable) – IMRT, can be used to limit the radiation dose delivered to vulnerable organs;
4.9 To explain how stereotactic radiotherapy can limit collateral radiation damage;
4.10 To explain the role of using Monte Carlo method in treatment planning, in enhancing the accuracy of dose estimation;
4.11 To discuss the role of different imaging modalities in radiotherapy including CT – computed tomography and RMN – nuclear magnetic resonance in enhancing the accuracy of target volume delimitation;

4.12 To describe methods of patient alignment and immobilization and their role in enhancing the geometric accuracy of dose administration to the patient;
4.13 To discuss the risks and benefits of special techniques: total-body Irradiation (TBI), intra-operative radiotherapy (IORT) total-skin electron irradiation (TSEI).

(5) Optimal and safe use of radionuclides in radiotherapy.

5.1 To discuss the types of sources used in radiotherapy and their construction, with regard to their efficacy in irradiating target volumes;
5.2 To relate the connection between the source intensity and the radiation dose administered to patient;
5.3 To discuss the hazards of specific sources;
5.4 To discuss the principles of clinical use and the associated radiation hazards;
5.5 To discuss the control and testing of sealed sources in relation to the radiation hazard;
5.6 To discuss the use of brachytherapy equipment as well as the benefits and risks involved;
5.7 To discuss the use of unsealed sources for radiotherapy and radiation protection requirements.

(6) Radiation hazards in radiotherapy facilities.

6.1 To discuss current national legislation;
6.2 To discuss the design of treatment rooms, including primary and secondary shields and the effects of scatter radiation and leakage radiation;
6.3 To discuss the design of sealed sources storage and modalities of dispensing as radioactive waste;
6.4 To discuss the radiation measurements around the treatment chambers.

F. Training modules in radiation safety

For medical physicists all modules are recommended. For medical doctors and paramedical personnel, all the modules are recommended apart from points 15, 16 and 20.

1. Basic physics, mathematics and biology for radiation protection.
2. Radiation sources of exposure.
3. Interaction of radiation with matter.
4. Dosimetric quantities and units.
5. Theory of radiation detection and measurements.
6. Dosimetric calculations and measurements.
7. Biological effects of ionising radiation.
8. External dose assessment.
9. Internal dose assessment.
10. The role of international organisations in radiation protection (not essential).
11. The concept of radiation protection.
12. Occupational radiation protection.
13. Radioactive waste safety.
14. Physical protection and security of sources.
15. Transport of radioactive materials.
16. Public exposure control.
17. Intervention for protection of the public in chronic and acute exposure situations.
18. Medical exposures.
19. Regulatory control.
20. Communication on radiation sources transport and radioactive waste safety.
21. Emergency preparedness and response. Accident analysis.

22. Safe use of radiation sources in specific practices.

Table IV.1

TRAINING AREA	**DR/ MD**	**RT/ MD**	**NM/ MD**	**CD/ MD**	**DT**	**MD**	**RD**	**NU**	**ME**
Atomic structure, production and interaction of radiation	m	h	h	l	l	l	m	l	m
Nucleus structure and radioactivity	m	h	h	l	-	-	m	l	m
Radiological quantities and units	m	h	h	m	l	l	m	l	m
Physical characteristics of the X-ray or therapy equipments	m	h	l	m	l	m	m	l	h
Fundamentals of radiation detection	l	m	h	l	l	l	m	l	h
Fundamentals of radiobiology. Biological effects of radiations.	m	h	h	m	l	m	m	l	l
Radiation protection. General principles.	h	h	h	h	m	m	h	l	m
Operational radiological protection	h	h	h	h	m	m	h	m	m
Particular patient radiation protection aspects	h	h	h	h	m	h	h	m	m
Particular staff radiation protection aspects	h	h	h	h	m	h	h	m	m
Quality control and quality assurance	m	h	h	m	l	l	m	l	h
National and European regulations and standards	m	m	m	m	m	m	m	l	h
Minimum number of training hours	30-50	40-60	30-50	20-30	10-15	15-20	40-100	10-15	40-60

RD/M = Diagnostic Radiology Specialists (Medical Doctors)
RT/M = Radiotherapy Specialists (Medical Doctors)
MN/M = Nuclear Medicine Specialists (Medical Doctors)
One additional training area on Radiopharmaceuticals: Handling, quality control and detection (h level) shall also be considered.
CD/M = Interventional Cardiology Specialists (Medical Doctors)
DT = Dentists
MD = Other Medical Doctors using X-ray systems
RD= Radiographers (medical assistants: radiodiagnostic, radiotherapy or nuclear medicine)
NU = nurses (some specific training is necessary in Nuclear Medicine and Radiotherapy)
ME = Maintenance engineers

For the other groups of practitioners, training shall be adapted in a similar framework.
Level of knowledge : l = low level
m = medium level
h = high level

APPENDIX No. 5
of the norms

CRITERIA FOR ACCEPTABILITY OF RADIOLOGICAL INSTALLATIONS

I. General provisions

1. The present criteria for acceptability of radiological installations are established according to the Recommendations of the European Commission, Radiation protection series no. 91/1997.

2. The present criteria represent Minimum operational requirements for the radiological installations that, if they are not achieved, urgent corrective measures shall be taken.

3. The proposed criteria shall not be used as recommended values for the quality control.

4. The proposed criteria do not apply to digital radiological installations.

5. The present criteria for acceptability are applied to installations used in diagnostic radiology, radiotherapy and nuclear medicine:

a) general X-ray-diagnostic installations (radiography and radioscopy);
b) X-ray-diagnostic installations with conventional tomography;
c) computed tomography installations;
d) installations for dental X-ray-diagnostic;
e) installations for mammography X-ray-diagnostic;
f) radiotherapy installations;
g) nuclear medicine installations;

II. The criteria for acceptability for general X-ray-diagnostic installations are as follows:

1. High voltage accuracy of X-ray tube (kilovoltage)

- Dial calibration:

The maximum deviation of the indicated value from the real value shall be less than ±10%.

- Variation in case of modification in tube current:

The maximum variation shall be less than 10%.

- Precision of tube voltage:

For all generators: for repeated measurements the deviation in the tube voltage shall be less than ± 5% from the mean value.

2. Total filtration

- The total filtration in the useful beam shall be equivalent to not less than 2.5 mm of aluminum.

3. Exposure time

- For exposure times greater than 100 ms, the real exposure time shall be within the limits of ± 10% of the indicated exposure time.

4. X-ray tube output

- Magnitude:

With a total filtration of 2.5 mm Al, the tube output shall be greater than 25 μGy/mAs at 1 m for 80 real kV operation.

- Tube output reproducibility:

The tube output shall be constant within the limit of ± 20% compared to the mean for repeated exposures, for a given tube voltage and filtration taken from the range used in practice, such as for example a tube voltage of 80 kV with a filtration of 2.5 mm Al.

- Variation at the modification in indicated current:

The variation shall be less than 15%.

- Variation depending upon in indicated tube current - exposure time product:

The variation shall be less than 20%.

5. Alignment

- The alignment of X ray beam with the light beam:

The sum of distances between the limit of X-ray area and the limit of light field on a direction in each of the principal directions shall not exceed 3% of the focus field distance and the sum of the distances on the two perpendicular directions shall not exceed 4%.

- Field alignment:

When the axis of the X ray beam is perpendicular to the plane of the image receptor, the centre of the X ray field and the centre of the image receptor shall be aligned within the limit of 2% of the focus-image receptor distance.

- X ray/light beam centreing:

The alignment of the light beam diaphragm cross-wire with the X ray beam centre shall not differ by more than ±1% of the focus to-film distance.

- Light beam/Bucky device centreing:

The alignment of the light beam diaphragm cross-wire with the centre of the film in the Bucky device shall not differ by more than ±1% of the focus to film distance.

- Orthogonality of X ray beam and the plane of the image receptor:

The angle between the central axis of X ray beam and the plane of the image receptor shall be equal to 90 degrees, with a maximum tolerance of ± 1.5 degrees.

6. Collimation

- The X ray beam shall be collimated in such a way that the total exposed area for fixed focus image receptor distance shall remain within the borders of the selected image receptor.

- Automatic collimation

At any side of the image receptor, the separation of the X ray beam shall not exceed by more than 2% of the focus-image receptor distance. The operator shall be able to use smaller fields than the whole image receptor area.

7. Focal-spot size

- In the absence of specification of an absolute standard, focal spot size determinations shall be carried out throughout the working life of a tube as part of the quality control procedure to indicate the extent of any deterioration and enable determining whether it is possible to continue with the use of the tube.

8. Grid

- Artefacts

An X-ray image of the grid to the tube voltage of 50 kV shall be made. No parasite artifacts shall be visible.

- Moving grid

The moving grid network shall not be visible on the image achieved at the shortest exposure time used in practice.

9. Automatic exposure control (AEC)

- Limitation of overexposure:

The load corresponding to the maximal focal spot shall be less than 600 mAs (not in the case of fluoroscopy and tomography).

- Limitation of exposure time (single exposure):

The exposure time for a single exposure shall be limited to a maximum of 6 seconds.

- The difference in optical densities between two exposures at the same automatic exposure control settings, one with a short exposure time and the other with a long exposure time, shall be less than 0.3 OD.

- For a fixed attenuator thickness the maximum difference in test image optical density, when varying the voltage in the field used in practice, shall not exceed ± 0.3 OD.

- For a fixed X-ray tube voltage, the maximum difference in test image optical density, when varying the attenuator thickness, shall not exceed ± 0.3 OD of the average value of test image optical density taken over attenuator thickness covering the patient thickness range met in practice at this tube voltage.

10. Leakage (leakage) radiation

- The leakage (leakage) radiation from the cupola of the X-ray tube, measured at a distance of 1 m from the focus shall not exceed 1 mGy per hour, at the maximum rating of the X-ray tube specified by the manufacturer for the tube in that cupola.

III. Film processing, properties of image receptors and viewing conditions.

In this chapter criteria are described in order to ensure that necessary conditions are maintained for producing an adequate quality of radiographs on photographic and radiographic materials.

1. Intensifying screens and cassettes

- Sheets and cassettes status and cleanliness:

No important artefacts shall be exist on exposed films.

- Cassette light-proofness:

No black edges shall be visible on an unexposed film to X-ray, but exposed in the cassette during two times (meaning both sides) for 10 minutes each on a viewing box (viewing screen) with a brightness of at least 1000 cd/m^2.

- Film-screen contact:

The cassette shall not create areas of visible differences of density or unsharp areas on the radiograph. This can be checked, for instance, with a metal mesh placed on the cassette.

- Relative sensitivity of film-screen combinations of the same speed class:

The film densities obtained at identical exposure conditions (same: dose, tube voltage, filtration, etc.) shall not differ by more than 0.3 OD for film-sheet combinations of the same type.

2. Film processing

- Base and fog:

The film base and fog shall be less than 0.30 OD

- Speed index:

Deviation from the baseline value of the speed index shall be less than 0.2 OD.

- Contrast index:

Deviation from the baseline value of the contrast index shall be less than 0.2 OD.

3. Darkroom

- Light leakage:

After adaptation of the eyes for at least 5 minutes in the dark with safelights and other lights off, no appreciable light leaks shall be visible.

- Safe light (inactinic):

A adequate pre-exposed film of unit optical density equal to one unit, exposed at normal working distance for 4 minutes in darkness conditions with safelights (inactinic) on and lights on in surrounding rooms, there shall not show an increase of density by more than 0.10 OD compared to a different part of the same film not exposed under darkness conditions.

4. Viewing conditions

- Viewing box (viewing screen):

Brightness shall be at least 1700 cd/m^2. Inhomogeneity shall be less than 30%.

- Environment

Background roomlight at 1 m distance from viewing box shall be less than 50 lux.

IV. Radioscopy

In this chapter additional criteria are formulated compared to the ones in point II and point III.

1. Dose rate
At least one of the following criteria shall be fulfilled:

a) The maximum dose rate at the entrance screen without grid (diameter 25 cm) of a conventional image intensifier shall not exceed 0.8 μGy/s for exposure of an appropriate phantom (namely a phantom of PMMA of 25 cm) with automatic dose rate control and automatic brightness control.

For special high dose rate applications, for example in interventional radiology, the maximum dose rate shall not exceed 1.0 μGy/s.

For other sizes of screens, the dose rate may be calculated taking into account the fact that the dose rate is in inverse-proportion to the square of the diameter.

b) The maximum dose rate of the useful beam including backscatter at the level of patient skin or at the surface of some form of patient substitute (for example a 25 cm PMMA phantom) on the side facing X-ray tube shall not exceed 100 mGy/min.

2. Resolution

- The resolution of the image intensifier-TV chain combination shall be of at least 0.8 line pair per millimeter, at a field size of 30 – 35 cm; this resolution is evaluated by the use of a specified testing object (for example grid of resolution Hüntter type 18 resolution grating or Leeds-type test object).

  For field sizes of 23 – 25 cm and 15 – 18 cm, these values are 1.0 l.p./mm and 1.4 l.p./mm respectively.

  In a spot image, the resolution shall be at least 2.0 l.p./mm.

3. Threshold contrast

- The threshold contrast under automatic operation, estimated from the TV monitor image shall be 4% or less.

4. Timer

- An irradiation interruption system shall operate immediately at the expiry of the time period pre-selected for fluoroscopy, not exceeding 10 minutes. An acoustic signal shall warn of the imminent termination at least 30 seconds in advance to enable the system to be reset if exposure needs to be prolonged.

5. Cinematography

- For adequate cine studies using a 23 cm diameter image intensifier the entrance dose rate shall be less than 0.20 μGy/frame. Typical patient entrance dose rates are 0.10 – 0.30 Gy/min for 25 frames/second with a 25 cm PMMA phantom.

6. Radiation/image field size

- The ratio between the areas of the radiation field and the image intensifier entrance surface shall not exceed 1.15. It is considered good practice if the edges of the collimators are visible on TV image.

V. Computed and conventional tomography

In this chapter additional requirements for computed and conventional tomography are formulated.

1. Conventional tomography

1.1 Cut height level

- The concordance between the cut height level and the indicated one shall be within ± 5 mm.

1.2 Cut plane incrementation

- In incrementing from one tomographic cut plan to the next, the cut height shall be reproducible within ± 2 mm.

1.3 Exposure angle

- The exposure angles, the measured one and the indicated one, shall coincide to within the limits of ± 5º for units operating at angles greater than 30º; for smaller angles, the concordance shall be better.

1.4 Cut height uniformity

- The density of the image of the hole in a lead sheet shall be nearly uniform, or shall vary in uniformity according to the structure of the particular tomographic unit. The image shall not indicate unexpected overlaps, inconsistency of exposure or asymmetries in motion.

1.5 Spatial resolution

- The tomographic unit shall provide a resolution of 1.6 l p/mm.

2. Computed tomography

2.1 Image noise

- The standard deviation of the CT numbers in the central 500 sq. mm region of interest for a water or tissue equivalent phantom shall not differ more than 20% from the baseline value.

2.2 CT numbers values

- The deviation in the CT number values for water or tissue-equivalent material and materials of different densities, in the same position in the field shall be less than ± 20 HU or than 5%.

2.3 CT numbers uniformity

- The standard deviation of the CT number averaged on the central interest region of 500 sq. mm region of interest for water or tissue equivalent material at the centre and around the periphery of phantoms, shall be less or equal to 1.5% of the base line value.

2.4 Computed tomography dose index (CTDI)

- The measurements of CTDI for a single slice for each beam shaping filter of the beam and for each available slice thickness shall not deviate more than ± 20% from the baseline value.

2.5 Irradiated slice thickness

- The full width at half-height of the dose profile shall not differ more than ± 20% from baseline value.

2.6 High contrast resolution (spatial resolution)

- The measurements of full width at half-height of the point spread function of a pin, or the edge response function of an edge shall not differ more than ± 20% from baseline value.

2.7 Low contrast resolution

- Polystyrene pins of 0.35 cm diameter inserted in a uniform body water phantom shall be visible in the image.

VI. Dental radiography

In this chapter additional requirements for dental radiography equipment are formulated. The criteria in this chapter are valid for the dental radiographic equipment using an intra-oral or extra-oral film, but are not valid for the panoramic dental radiographic equipment. Users may apply these criteria to panoramic dental radiographic equipment as well, but they shall take care that the chosen criterion shall be adequate to that application.

1. Radiation quality

- The X-ray tube voltage shall be at least 50 kV.

2. Filtration

- The filtration in the useful beam shall be equivalent to at least 1.5 mm Al at X-ray tube voltages of up to 70 kV and 2.5 mm for voltages in excess of 70 kV.

3. Focus-skin distance

- The focus-skin distance shall be at least 20 cm for equipment with selectable X-ray tube voltages in excess of 60 kV and at least 10 cm for equipment with X-ray tube voltages equal to or lower than 60 kV.

4. Beam size

- The field diameter shall be at maximum 60 mm at the outer end of the beam applicator.

5. Timer

- The accuracy shall be at maximum 20%
- The precision shall be at maximum 10%

6. Tube output

- For tube voltages in the range of 50 ÷ 70 kV, the tube output shall be 30 – 80 µGy/mAs at 1 m from the focus.

VII. Mammography

1. Generation and control of X-ray beam.

X ray source

1.1 Dose rate

- The dose rate at a distance equal to the film focus distance (FFD) shall be at least 7.5 mGy/s.

1.2 Source-to-image distance

- The source-to-image distance shall be according to the manufacture's specification and typically is ≥ 600 mm.

1.3 Alignment of X ray field with the image receptor.

- Thorax side: X-rays field shall not exceed the film by more than 5 mm outside. Lateral sides: X-rays field shall cover the film to the edges.

Tube voltage

1.4 Accuracy and precision

- Accuracy for tube voltages in the range 25 to 31 kV shall be less than ± 1 kV; the precision shall be less than 0.5 kV.

The automatic exposure control system (AEC system)

1.5 Optical density control setting

- The optical density (including base and fog) at the reference point of the developed film shall remain within the limits of ± 0.15 OD compared to the target value. Target value is typical in the ranged between 1.3 up to 1.8 OD, base and fog included.
- The optical density control step-size shall be in the range of 0.10 – 0.20 OD.

1.6 Short-term precision

- The deviation of the mean value of exposures shall be less than 5%.

1.7 Long-term precision

- The long-term precision shall be better than ± 0.20 OD compared to the baseline optical density value.

1.8 Object thickness compensation

- All object density variations shall be within the range of ± 0.15 OD, compared to the current optical density.

1.9 Tube voltage compensation

- All optical density variations shall be within the range of ± 0.15 OD.

2. Compression

2.1 Compression force

- The compression of the breast tissue shall be firm but tolerable (bearable). There is no optimal value known for the force, but attention shall be given to the applied compression and the accuracy of the indication. The maximum automatically applied force shall be in the range of 130 to 200 N (13 – 20 kg).

2.2 Compression plate alignment

- Minimal misalignment is allowed, less than 15 mm is acceptable for asymmetrical load and in direction towards the nipple and less than 5 mm for symmetrical load.

3. Image receptor and Bucky device

3.1 Antiscatter grid

- The grid system exposure factor shall be ≤ 3.

3.2 Inter cassette sensitivity and variation in optical density range when exposed with the same settings of the X-ray equipment with automatically exposure control

- The exposure range, in mGy (or mAs) shall be within the limit of ± 5% for all exposures.
- The maximum difference in optical density between all cassettes shall be less than 0.20 OD.

4. Film processing and viewing

4.1 Film processing

- Base and fog (D_{min}): D_{min} shall be 0.2 OD.
- Speed index: deviation from the baseline value shall be ± 10%.
- Contrast: mean gradient (Mgrad) shall be > 2.8.
- Daily performance: the daily operation of the processor can be assessed by sensitometry. Sensitometry is carried out daily after the processor has been used for about one hour each morning and at approximately the same hour daily. The variability of parameters can be calculated over a period of time, for example one month. The variability for all parameters shall be less than ± 10%.

4.2 Darkness conditions

- Compared to the criteria at point II, the following additional criterion is applied:

Cassettes and film hopper: no extra fogging.

4.3 Viewing conditions

Viewing box:

- The brightness shall be in the range of 2000 – 6000 cd/m^2. The ambient light level shall be below 50 lux.

5. System properties

5.1 Reference dose

- The entrance surface air kerma shall be ≤ 10 mGy for a 40 mm PMMA phantom of, ≤ 12 mGy for 45 mm phantom and ≤ 20 mGy for a 50 mm phantom.

5.2 Image quality

- Spatial resolution:

In both directions the resolution shall be over 12 pl/mm for measurements with a test object placed at 4 cm above table (on a phantom) and on midline 6 cm in from chest-wall side of film.

- Threshold contrast visibility

For measurements of contrast of large details with a test object inside a 45 mm thickness PMMA phantom, a limiting value of < 1.3 % contrast for 6 mm detail is recommended.

5.3 Exposure time

- The exposure time shall be less than 2 s when an image of 45 mm thickness PMMA phantom is formed.

VIII. Radiotherapy

These criteria are applied in case of normal clinical use of radiation therapy equipment, but not those for brachytherapy, interoperative radiotherapy, dynamic, palliative or radiotherapy of the whole body. The radiation therapy treatment simulators are excluded from this study. As it is presented in the Introduction, the criteria presented may be used as remedial levels at which corrective measures are convenient to be applied. In a very few occasions, the clinical use of an equipment can be justified even if the remedial level has been exceeded. For example, curative treatment demands a high stability of the treatment table height, especially during lateral irradiation. If due to mechanical tolerances reasons the table height cannot be adjusted within the tolerance limits, it still may be justified to perform palliative posterior-anterior or anterior-posterior treatments, if no solution exists at all. The values given in Table V.1 below are based on recommendations of the OMS (1988) and NCS (1995) with some modifications.

1. Treatment planning system (ICRU, 1986)

1.1 A computerized dose distribution can be considered as sufficiently accurate if calculated and measured doses differ by less than 2% at pertinent points for the treatment.
1.2 In regions involving very steep dose gradients, the observed position of a given isodose curve shall differ by less than 0.3 cm from its calculated position.

IX. Nuclear medicine

The criteria indicated here have been selected as ones to tests that can fairly easily be done on a regular basis in departments of nuclear medicine. Failure to observe the criteria can mean the need to undertake new investigations to establish the causes and to help decide on remedial actions. The criteria for gamma camera for planar and gamma emission tomography (SPECT) and isotope calibrator are derived from IPSM Report 65 (IPSM, 1992).

1. Gamma camera (high-resolution collimator – Tc^{99m})

1.1 Uniformity

- The variation shall be less than ± 10% within used field. The test shall be performed with and without collimator and at specified energy windows (E ± 10%).

1.2 Sensitivity

- The sensitivity (ability to detect the gamma rays emitted from a radioactive source in cps/MBq) shall differ less than 20% from baseline value.

1.3 Centre of rotation center shall not get farther within more than a half a pixel.

2. Multi-headed camera

2.1 Sensitivity

- The differences in sensitivity between any of the heads shall be less than 10%.

2.2 Geometry

- Pixel by pixel correspondence of opposite clichés shall be within a half a pixel.

3. Isotopes calibrator

3.1 Linearity

- Linearity shall be less than ± 5% over the range of activity used.

3.2 Reproducibility

- The reproducibility shall remain within the limits of ± 5%.

3.3 Accuracy

- The instrument accuracy shall remain within the limits of 5% for gamma emitters with energy superior to 100 keV and within the limits of 10% for beta emitters and low energy gamma emitters.

X. Definition of terms

The definitions given here are not universally applicable but indicate the meaning of terms as used in this Appendix.

a) Basis and fog (D_{min})

- The optical density of a non exposed film after developing.

b) Radiation quality

- A measure of the penetrating power of an X-ray beam, usually characterized by X-ray tube voltage and the half-attenuation layer.

c) Breast compression

- The application of pressure to the breast during mammography so as to immobilize the breast and to present a more uniform breast thickness to the X- ray beam.

d) Established criteria

- In a quality assurance program, acceptable variations in results of a constancy test which indicate satisfactory functional performances of the equipment tested.

e) Optical density (OD)

- The logarithm of the ratio between the intensity of perpendicularly incident light on a film and the light intensity transmitted by the film.

f) Net optical density

- Optical density excluding basis and fog.

g) Deviation

- Percentage of difference between measured value (m) and prescribed value (p) according: (m/p – 1) x 100%.

h) D_{min}

- See Base and fog

i) Absorbed dose

- The quantity of the mean energy imparted by ionizing radiation to the matter in an infinitesimally small volume element by the mass of matter in this volume element (adapted from ICRU 1980).

j) Radiation dose

- A generic term for a variety of quantities related to the absorbed dose, such as air kerma, entrance dose, exit dose, etc.

k) Entrance surface dose

- The absorbed dose in air including the contribution from backscatter, measured at a point on the entrance surface of a specified object, for example a patient's thorax or a standard phantom.

l) Accuracy

- The closeness of an observed value of a quantity to the true value. The percentage of difference between measured value (m) and true value (r) according:
  100 x (m-r) / r.

m) Conversion factor

- The ratio of two quantities, usually expressed as a multiplying factor (except for a contrary indication) used for converting the value of one quantity into the other.

n) Grid exposure factor

- The ratio between the incident air kerma in air with grid and the air kerma without grid. The grid exposure factor is dependent on the type of grid, radiation quality, field size and object thickness. It is recommended to measure at 28 kV and use a 4 cm thick PMMA phantom.

o) Grid

- A device positioned close to the entrance surface of an image receptor to reduce the quantity of scattered radiation reaching on the receptor.

p) Contrast index

- The difference between density control steps determined between the step nearest to the speedpoint and the step nearest to a density at 2.0 above base and fog.

q) Computed tomography dose index CTDI

- The integral of a dose profile D (z), divided by the nominal section (slice) thickness T:

CTDI = 1 / T $\int$D(z) dz, D(z) being the dose profile as a function of coordinate z perpendicular to the tomographic plane.

r) Mammography

- The X-ray examination of breasts. This may be undertaken for health screening or for studying symptoms of a breast disease (symptomatic diagnosis).

s) Mgrad (average gradient)

- The property expressing the film contrast in the diagnostic range. This is calculated as the slope of the line through the points D_1 = D*min* + 0.25 *DO* and $D_2 = D_{min}$ + 2.00 *DO*.

t) PMMA

- Polymethylmethacrylate. Trade names include Lucite, Perspex and Plexiglas.

u) Threshold contrast

- The contrast that produce a just visible difference between two optical densities.

v) Precision

- The variation (usually relative standard deviation) in observed values, usually for a set of measurements made at about the same time.

w) Tube (Radiation) output

- The air kerma measured free-in-air (without backscatter) per unit of tube loading at a specified distance from the X-ray tube focus and at stated radiographic exposure factors.

x) Speed

- Sensitivity; the property of the film emulsion directly related to the dose. The speed is the value on the x axis corresponding to an optical density of 1.00+ D_{min} (speedpoint). The higher the value speed, the more dose is needed to obtain the right optical density. The blackening curve of a film is constructed starting with a limited number of points, the speed must be interpolated. Linear interpolation will provide sufficient accuracy.

y) Reproducibility

- See Precision, the measurements are often made over a period of time.

z) Automatic exposure control system (AEC)

- A mode of operation of an X- ray equipment allowing the automatic control of the tube loading and to interrupt it when a pre-set radiation exposure value to the image receptor is reached. The tube potential may or may not be automatically controlled.

aa) Half-value layer

- The thickness value for an absorber attenuating the air kerma of a collimated X-ray beam by half under conditions of limited scatter.

bb) Tube potential

- The potential difference (kilovolt, kV) applied between the anode and the cathode of the X-ray tube during a radiographic exposure.

cc) Constancy tests

Each of series of tests carried out:

- to assure that the functional performances of equipment correspond established criteria; or
- to enable the early recognition of changes in the properties of component of the equipment.

dd) Status tests

- Tests carried out to establish the functional status of equipment at a given moment.

ee) Baseline value (a reference value of a functional parameter)

- either the value obtained for this parameter in the initial constancy test immediately following a status test;
- either the mean values obtained in a series of initial constancy test assembly immediately following a status test, in case of a description in an adequate particular norm.

ff) Variation

- The absolute difference of two individual measurements (a and b) divided by the mean of those figures, according: (1-b)/(1/2a + 1/2b) x 100%.

XI. Abbreviations

- FFD – Focus- film distance
- OD – Optical density
- FSD – Focus-skin distance
- ICRU – International Commission on Radiological Units and Measurements
- CTDI – Computed Tomography Dose Index
- IPSM – Institute of Physical Sciences in Medicine
- HU – Hounsfield Unit, HU = $1000/(\mu/\mu_0-1)$, where μ is the linear attenuation coefficient for the respective tissue and μ_0 is the linear attenuation coefficient for water. The CT number for air is about 1000 and the CT number for water is 0 and 1HU being equivalent to about 0.1% of the linear attenuation coefficient for water.
- NCS – Nederlandse Commissie voor Stralingsdosimetrie
- SPECT – Single Photon Emission Computed Tomography
- WHO – World Health Organization

Table V.1 Tests related to mechanical and geometrical performances, beam quality and light field accuracy and acceptability criteria (remedial action level) of those

Test	**Acceptability criteria**
- Rotation system supporting the irradiation probe (gantry)	±1º
- Pivoting outside the normal rotation plan (yoke)	±0.2º
- Isocentre	± 2 mm
- Source distance indicators	± 2 mm
- Beam axis indicators	± 2 mm
- Numerical field indicators	± 2 mm
- Light field indication	± 2 mm
- Collimation system rotation	±1º
- Treatment couch: • lateral and longitudinal scales • vertical scales • vertical deflection (under the patient's load)	 2 mm 2 mm 5 mm

Test	**Acceptability criteria**
- Treatment verification systems according to the manufacturer's specifications (gantry angle, field size, collimator rotation, treatment time or monitor units, beam energy, etc.)	± 2 mm
- Immobilization devices (moulds, breast bridges, head supports, arm or leg supports, bite-blocks, etc.)	± 2 mm
- Patient alignment devices	± 2 mm
Beam quality and light- field accuracy	
- Light field indicator (density units)	± 1 mm per edge
- Central axis dose calibration at reference position in phantom:	± 3 % (photons) ± 4 % (electrons)
- Constancy tests: cobalt – 60 units classic X-ray units accelerators	 ± 2 % ± 2 % ± 2 %
- Linearity of monitor	± 1 %
- Timer of cobalt – 60 unit	± 0.01 min
- Check electrons/photons radiation type of radiation shall be selected properly	
- X ray beam beam flatness beam symmetry	 ± 3 % ± 3 %
- Cobalt – 60units beam symmetry	 ± 3 %
- Roentgen-therapy units beam symmetry	 ± 6 %
- Electron beams flatness and symmetry	 ± 3 %
- Transmission factor OF wedges and compensators	± 2 %
- Dose monitoring system precision linearity dose rate effect stability gantry angle	 ± 0.5 % ± 1 % ± 2 % ± 2 % ± 3 %