



SAMIRA Study on criteria for acceptability of medical radiological equipment

CARE ***(Criteria for Acceptability of Medical Radiological Equipment)***

Proposal for an Updated and Extended List of Acceptability Criteria

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List of Abbreviations

AAPM	American Association of Physicists in Medicine
ACR	American College of Radiology
AEC	Automatic exposure control
ATCM	Automatic tube-current modulation
BSSD	Basic Safety Standards Directive (Council Directive 2013/59/Euratom)
CBCT	Cone-beam computed tomography
CZT	Cadmium-zincum-telluride
DDR	Digital X-ray imaging detectors
DRL	Diagnostic reference level
DXA	Dual-energy X-ray absorptiometry
EANM	European Association of Nuclear Medicine
EC	European Commission
EIBIR	European Institute for Biomedical Imaging Research
EFOMP	European Federation of Organisations for Medical Physics
ESR	European Society of Radiology
ESTRO	European Society for Radiotherapy and Oncology
EU	European Union
FSRT	Fractionated stereotactic radiotherapy
FWHM	Full width at half maximum
HDR	High dose rate
HERCA	Heads of the European Radiological Protection Competent Authorities
HVL	Half-value layer
IAEA	International Atomic Energy Agency
IGRT	Image-guided radiotherapy
IPEM	Institute of Physics and Engineering in Medicine
LDR	Low dose rate
MPE	Medical physics expert
MRI	Magnetic resonance imaging
NEMA	National Electrical Manufacturers Association
PET	Positron-emission tomography
RP	EC Radiation Protection Series



RTPS	Radiotherapy treatment planning system
SAMIRA	Strategic Agenda for Medical Ionising Radiation Applications
SBRT	Stereotactic body radiotherapy
SDNR	Signal-difference-to-noise ratio
SPECT	Single photon emission computed tomography
SRS	Stereotactic radiosurgery
UQCM	User quality-control mode
WP	Work package



1. Introduction

Since the publication of Radiation Protection (RP) N° 162 in 2012, significant technological and regulatory changes for medical equipment have affected the criteria for acceptability of medical radiological equipment. Given changes in radiodiagnosis, hybrid imaging, radiotherapy and particle therapy, among other fields, an update to this publication is necessary to ensure it aligns with current standards and innovations. An update would be consistent with Council Directive 2013/59/Euratom (Basic Safety Standards Directive, or BSSD), which in Article 60, paragraph 2, mandates that Member States establish criteria for the acceptability of medical radiological equipment, indicating when intervention is required, including the removal of equipment from service. This consortium, combining experts from the European Institute of Biomedical Imaging Research (EIBIR), European Federation of Organisations for Medical Physics (EFOMP), European Association of Nuclear Medicine (EANM), and European Society of Radiology (ESR), will yield an updated publication to ensure that the criteria reflect the latest technological capabilities and regulatory requirements, maintaining high standards of safety and effectiveness in medical radiological practices.

To achieve the specific objectives, the project includes the following elements.

- A study of RP 162, review of relevant literature and international guidelines and recommendations, and survey of national standards regarding acceptability criteria of medical radiological equipment
- A proposal for an updated and extended list of acceptability criteria in line with the current state of technical and equipment standards, methods for assessing relevant technical parameters, and the applicable Euratom and European Union (EU) legal provisions
- A consultation with Member States and other stakeholders on the proposed updated and extended list of acceptability criteria
- A project workshop

Aided by the project's survey on the status quo of national regulations and guidelines on acceptability criteria and literature review, the deliverable proposes the acceptability criteria for medical radiological equipment in use in Europe to update the text of RP 162. The deliverable updates the methodology to update the text and then proceeds to describe proposed acceptability criteria for equipment in diagnostic and interventional radiology, nuclear medicine and radiotherapy according to the draft table of contents approved by the EC. Sources for changes to acceptability criteria and for new equipment are denoted throughout.



2. Methodology

2.1 Background

The purpose of this report is to provide advice and detailed guidance to responsible professionals in Member States on the implementation of part of the Council Directive 2013/59/Euratom (2013) that lays down the basic safety standards for protection against the dangers arising from exposure to ionising radiation. Specifically, the BSS requires that medical exposures be justified and optimised. Optimisation includes satisfactory performance of the equipment used. To help give effect to this, the BSSD stipulates that Member States (See section 2.2) shall adopt criteria for acceptability for radiological, nuclear medicine and radiotherapy equipment. In 2012 the European Commission published RP 162 (EC 2012), which in turn updated RP 91 (EC 1997), which proposed specific criteria for acceptability to help implement this requirement. Equipment performance exceeding the suspension levels specified in RP 162 is regarded as unacceptable. This publication has been used as guidance by individual professionals, particularly medical physics experts (MPE)¹, and has been incorporated into guidance or legislation throughout the Member States and elsewhere in the world. The suspension levels apply to new equipment and to installed equipment, regardless of age. This revised report is intended to meet the objectives listed below.

- Update existing suspension levels
- Update and extend suspension levels to new types of installations. In diagnostic radiology, the range of systems available has been greatly extended, e.g., digital radiography, dynamic X-ray imaging, digital breast tomo synthesis, dual energy and photon counting computed tomography. In nuclear medicine there are now digital positron-emission tomography (PET) systems combined in hybrid systems like PET-CT and PET-MR. Solid state detectors have been introduced in gamma cameras. In radiotherapy, linear accelerators are usually equipped with cone-beam computed tomography (CBCT) or magnetic resonance imaging (MRI), and accelerators can be used for particle therapy
- Identify an updated and more explicit range of methods to better assess the criteria for acceptability
- Provide suspension levels that are achievable throughout the Member States
- Provide advice on implementation and verification in practice, including advice on how to deal with situations where criteria for acceptability do not exist or where there is rapid innovation in equipment.
- Address, where practical, the implications for screening techniques, paediatric examinations, high-dose examinations and other special issues noted in the BSSD

Radiation Protection 162 considered diagnostic radiological installations including conventional and dental radiography, computed tomography, mammography, and, in a limited way, radiotherapy and nuclear medicine installations. However, development of new systems and technologies, improvements in traditional technologies and changing clinical needs have created situations where the criteria need to be reviewed to contribute to the standards of equipment performance being updated. To address this, the European Commission, based on the advice of the Article 31 Group of Experts, initiated a study aimed at reviewing and updating RP 162, which has led to this revised report. As with RP

¹ Throughout the report, the term MPE is used as defined in the BSSD as "An individual or, if provided for in national legislation, a group of individuals, having the knowledge, training and experience to act or give advice on matters relating to radiation physics applied to medical exposure, whose competence in this respect is recognised by the competent authority."



162, this report is designed to ensure patient safety and efficacious diagnosis or treatment.

To achieve the objectives of the new publication, the development and review process involved a wide range of individuals and organizations, including experts from relevant professions, professional bodies, industry, standards organizations and international organizations. The criteria for acceptability developed generally fall into two categories, qualitative and quantitative (Table 1). Qualitative criteria apply to certain equipment types or features, e.g., prohibition of direct fluoroscopy, or requirement for patient-dose indication systems. These generally arise from the BSSD, other laws or widely accepted norms of good practice.

Table 1: Two categories of criteria for acceptability

Category	Features
Qualitative criteria	Qualitative prohibitions of some equipment types or feature; e.g., direct fluoroscopy is not allowed by the BSSD
Quantitative criteria, also known as suspension levels	Based on quantitative indices, which must be met; e.g., leakage radiation from X-ray tube housing must be less than the prescribed value. The quantitative limit is generally described as a suspension level

Quantitative indices of performance can be measured, and the determined values must not meet the suspension levels that are provided. If these are reached or exceeded, the equipment must be suspended from use, and the poor performance investigated. The equipment may be returned to use following remedial action that results in the performance index value in question again being within the acceptable range. Alternatively, if satisfactory performance cannot be restored, its clinical use may be restricted or terminated after a risk assessment. The processes involved are more fully presented in sections sections 2.4–2.9.

It is important to bear in mind that the present report follows the precedent established in RP 162 and is limited to safety and performance issues with radiological, nuclear medicine and radiotherapy equipment. It does not address mechanical and electrical safety; standards of operation; or wider issues such as those associated with, e.g., requirements for suitable buildings/installations and information technology systems such as picture archiving and communication systems, radiology information systems and radiotherapy networks. Differently from RP 162, medical displays used for referral have been included in this publication since they are considered part of the chain of radiological imaging.

2.2 Basis for suspension levels in the European directives

2.2.1 Requirements of the BSSD

The work of the EC in the field of radiation protection is governed by the Euratom Treaty and the successive related Council Directives. The first EU basic safety standards for radiation protection were adopted in 1959 as a directive under the Euratom Treaty, establishing foundational rules to protect workers and the public from ionizing radiation. This framework has been continuously updated to align with science, with major revisions in 1996 and the most recent consolidated directive in 2013 and 14,, which draws together the various European radiation protection directives. It prescribes a number of measures to ensure that medical exposures are delivered under appropriate conditions. It requires, among other things, the following.



- Acceptance testing of new equipment
- Identification of criteria of acceptability for equipment safety and performance throughout its life
- Establishment of quality assurance programmes

This report addresses the second of these, criteria of acceptability, and updates RP 162, which addressed the same area. However, some overlapping and confusion between these three areas above has arisen, and this is addressed in sections 2.4 and 2.5 below.

The BSSD requires that all radiation doses arising from medical exposure of patients for diagnostic and interventional radiology, treatment planning, guiding and verification purposes shall be kept as low as reasonably achievable consistent with obtaining the required diagnostic information, taking into account economic and societal factors (ALARA). Requirements in respect of dose monitoring systems are specified explicitly in article 60. These extend to all new medical radiodiagnostic equipment producing ionising radiation, which shall “has a device, or an equivalent means, informing the practitioner of the relevant parameters for assessing the patient dose.”

Additionally, Article 61 requires:

“Appropriate medical radiological equipment, practical techniques and ancillary equipment is used in the medical exposure

- of children,
- as part of a health-screening programme,
- involving high doses to the patient, which may be the case in interventional radiology, nuclear medicine, computed tomography or radiotherapy.”

Special attention shall be given to the quality assurance programmes, including quality control measures and patient dose or administered activity assessment, as mentioned in article 56, for these practices.

The requirements in respect of **criteria for acceptability** are stated specifically in Article 60 as follows:

“Member States shall ensure that the competent authority takes steps to ensure that the necessary measures are taken by the undertaking to improve inadequate or defective performance of medical radiological equipment in use. They shall also adopt specific **criteria for the acceptability** of equipment in order to indicate when appropriate corrective action is necessary, including taking the equipment out of service.”

This places responsibilities on both undertaking and competent authorities.

Some practical consequences of these requirements are listed in the box below. This report deals only with the first and second points and concentrates primarily on the latter. It updates and extends the advice provided in RP 162. However, it is not intended to act as a guide to quality assurance and quality control programmes, which are comprehensively dealt with elsewhere.



Practical consequences of the BSSD

1. Acceptance testing must be carried out before the first use of the equipment for clinical purposes, and performance testing is carried out thereafter on a regular basis, and after any maintenance procedure liable to affect the performance. (BSSD art.60 1 d).
2. Necessary measures must be taken by the undertaking of the radiological installation to improve inadequate or defective features of medical radiological equipment in use. Competent authorities must ensure the undertaking of equipment adopt specific criteria for the acceptability for equipment in order to indicate when appropriate corrective action is necessary, including taking the equipment out of service (BSSD art. 60 2).
3. Quality assurance programmes including assessment of dose or verification of administered activity are implemented by the undertaking (BSSD art. 60 1 c).

2.3 To whom this document is addressed

Advice on good practice with respect to equipment performance is frequently addressed to or focused on the needs and responsibilities of a particular group. For example, the standards produced by IEC and the CENELEC are primarily aimed at manufacturers and suppliers. The primary audience to which this report is addressed is the undertaking and end-users of the equipment, specifically healthcare agencies and professionals, including hospitals, other institutions, MPEs, practitioners, radiographers, clinical and service engineers, clinical technologists and other staff and management, all of whom have a role in the deployment of equipment for use with patients.

In addition, it should be of value to regulators in assessing if undertakings of radiological installations meet their obligations with respect to equipment performance under article 60 of the BSSD. This is in line with the precedent implicitly established in the scope and format adopted for RP 162. This report addresses the needs of these groups while taking into account the reality of globalization of the equipment industry, associated standards and harmonization objectives.

The technical parts of sections 3–5 assume that those reading and using them are trained to the level expected of an MPE. They must be familiar with this introduction and have a good working knowledge of the relevant types of equipment and appropriate testing regimes.

2.4 Clarification of terminology and equipment lifecycle

A critical reading of the BSSD, RP 162 and the professional literature demonstrates some variability in the meaning of terms such as remedial levels, tolerance levels, action levels, suspension levels, acceptance and commissioning of equipment, and criteria for acceptability since they came into widespread use in the 1990s. In the interest of clarity, the relevant terms and how they are used in this report are set out in Tables 2 and 3.

The concepts of 'remedial' and 'suspension' levels for equipment performance are widely used in the quality assurance literature. To clarify how they are used here, the term **satisfactory performance** has been introduced to identify the state of the equipment from which suspension or remedial levels deviate (Table 2). This report is concerned with **suspension levels** only. On the other hand, remedial levels are well described in numerous quality control publications.



Table 2: Definitions and actions associated with satisfactory performance, remedial and suspension levels

State	Definition or Action
Satisfactory performance	Operation of the equipment with all performance and safety criteria within the prescribed values
Remedial level contravened	Poor performance sufficiently close to satisfactory performance that it will not reduce the clinical effectiveness or equipment safety but requiring remedial action to restore satisfactory performance as soon as the service availability permits it. Remedial levels are set by the undertaking or his/her agent, e.g., an MPE, and take account of the clinical use of the equipment.
Suspension level contravened	Meeting or exceeding one or more suspension levels. This requires immediate suspension of the equipment from clinical use and investigation of the cause of the unsatisfactory performance. Remedial action to restore satisfactory performance may be possible. Alternatively, following a documented risk assessment, prepared by the MPE and the practitioner, the suspended equipment may be considered for use in limited circumstances. The undertaking and the operators must be advised in writing of the suspension and the related limitation(s) in use ² . If neither of these actions is possible, the equipment must be suspended from use

Criteria for acceptability will be applied to equipment at various times throughout its lifecycle³. Thus, they must be carefully distinguished from other formal assessments that occur particularly at the point where the equipment is accepted by the undertaking and then brought into clinical use (Table 3). In particular, suspension levels must be clearly distinguished from the levels set for acceptance tests (Table 3). The latter are used to establish that the equipment meets the supplier's specifications and to verify that contractual obligations have been met. The specification may demand a higher level of performance than that required to meet the suspension levels set to verify compliance with the criteria for acceptability envisaged in the BSSD. However, on the other hand, new equipment meeting the requirements of acceptance testing should normally comply with criteria for acceptability including suspension levels. This is because the acceptance tests for modern equipment will often be more demanding, in terms of performance, than the criteria for acceptability, particularly if the equipment is supposed to be dedicated to special techniques requiring higher levels of performance. Quality assurance programmes involve many additional elements beyond the suspension levels presented here and will inevitably involve the consideration of remedial levels.

Table 3: Uses of the terms acceptance testing, commissioning, baseline levels and criteria of acceptability

Term	How and when Applied
Acceptance testing	To ensure compliance of new equipment with its specification on installation; generally involves the supplier, the MPE and users

² Examples of how this might arise include the following: 1) In radiotherapy, a megavoltage unit with poor isocentric accuracy could be restricted to simple direct fields or anterior-posterior/posterior-anterior techniques until the unit can be replaced; 2) In nuclear medicine, a rotational gamma camera with inferior isocentric accuracy could be restricted to static examinations; 3) In diagnostic radiology, an X-ray set with the beam-limiting device locked in the maximum field of view position might be used to obtain radiographs requiring that format in specific circumstances.

³ The criteria are applicable to refurbished and second-hand equipment, for which there is now a substantial market.



Commissioning	<p>Commissioning is generally done before the first use of equipment on a patient. It involves issues over and above those in acceptance testing (e.g., setting up clinical protocols), and will usually involve the radiological practitioner, technologists, MPE and the supplier's applications specialist.</p> <p>Commissioning of new radiological equipment is the process of fully characterising, validating, and optimising the equipment's performance for routine clinical use." It involves mainly MPEs, but also radiological practitioners and technologists. Usually, the supplier's applications specialist is only involved in the staff training and in some degree of equipment customization but always under the responsibility of the MPE</p>
Baseline levels	The set of reference measurements and documented performance parameters that define how the equipment should perform under normal, optimal conditions. It is established during commissioning and serves as the standard against which future quality assurance tests are compared
Establishing compliance with criteria for acceptability including suspension levels	As detailed in this report and applied as necessary throughout the life of the equipment

2.5 Approaches to criteria for acceptability

In Table 1 the criteria for acceptability were divided into two categories, **qualitative criteria** and **quantitative criteria**, also known as suspension levels. The qualitative criteria derive from legislation or widely accepted norms for good practice. For example, they include the following requirements, all of which are from the BSSD.

- The use of fluoroscopy equipment without a device to automatically control the dose rate, or without an image intensifier or equivalent device, is prohibited.
- Equipment used for external beam radiotherapy with a nominal beam energy exceeding 1 MeV has a device to verify key treatment parameters.
- Any equipment used for interventional radiology has a device or a feature informing the practitioner and those carrying out practical aspects of the medical procedures of quantity of radiation produced by the equipment during the procedure.
- Any equipment used for interventional radiology and computed tomography and any new equipment used for planning, guiding and verification purposes has a device or a feature informing the practitioner, at the end of the procedure, of relevant parameters for assessing the patient dose.
- Equipment used for interventional radiology and computed tomography has the capacity to transfer the information required under the previous requirement to the record of the examination.

Suspension levels, conversely, rely on measurements. They provide numerical limits for acceptable performance in respect of the parameters identified for each of the equipment types in sections 3–5. Some organisations specify measurement methodologies without indicating the performance level to be achieved.

A wide-ranging, consistent suite of approaches to performance and safety assessment of radiological equipment was proposed by the EFOMP as well as the American Association of Physicists in Medicine (AAPM) and Institute of Physics and Engineering in Medicine (IPEM). Much of this material is for use in routine quality assurance programmes and is based on the reasonable assumption that deviations from the baseline performance of



equipment at installation will provide an adequate means of detecting unsafe or inadequately performing equipment. While this approach may be reasonable in the hands of experienced medical physicist, it can prove unsatisfactory when used to provide suspension levels as understood in the BSSD. For example, if the baseline is, for some reason, unsafe or unsatisfactory, then there is no absolute safe standard against which performance can be measured. Consequently, the approach using baseline performance as a benchmark was not adopted in this publication. The emphasis has been to propose absolute suspension levels, taking into account the considerations in sections 2.7.2 and 2.8 below. This is consistent with the approach adopted by some EU countries, including, for example, Bulgaria, Estonia, Ireland Italy, Portugal and Slovakia, which have a direct or indirect reference in their legislation/regulation to RP 162. Another approach is adopted by other EU countries, including for example Belgium, Croatia, Netherlands, Poland and Spain, which have adopted numerical limits for performance values based on RP 162 and other sources. A small number of EU countries, including France, Germany, Luxembourg and Sweden, have set their own numerical limits for performance directly in their legislation.

2.6 Identifying and selecting suspension levels

With the exception of RP 162, there is no formal consolidated literature on criteria for acceptability of radiological equipment. The BSSD requires that criteria be established, and available sources judged suitable were reviewed to identify potential criteria, principally as suspension levels. The most important primary sources of suspension levels were IEC standards and IAEA publications. In addition, the recommendation of scientific, medical or professional bodies, national standards or formal national regulations, as well as the scientific/medical literature all contain values for performance and safety that might be used as suspension levels together with the methodology to determine the figures of merit to be confronted with the suspension levels. The levels recommended draw on all these sources and are, only exceptionally, new recommendations. Those selected and included are a subset of those available. As employed here, they are cautionary in the sense that they require both that the use of the equipment be stopped and a risk assessment be undertaken. They represent the minimum standard for the safety and performance acceptable in the EU identified by the expert judgement of the working group and reviewers. They are also informed by the social, legal and political circumstances that prevail in the EU.

The suspension levels identified have varying degree of authority and consensus attaching to them. These are represented in Table 4 by grouping them under the headings A–D in order of preference. See the text below for further clarification.

Table 4: Types of suspension levels

Suspension Level	Definition
Type A	Based on an international standard or a formal international publication
Type B	Based on formal recommendations by scientific, medical or professional bodies, national standards or a formal national regulation
Type C	Based on material published in well-established peer review scientific or medical journals
Type D	Reviewed recommendation from the drafting group, with methodology derived from Type A, B and C sources

Type A

Compliance with the relevant IEC/CENELEC standard can be taken as compliance with criteria that the industry has deemed to be essential for good performance and safety.



Development in this area is essential to the harmonisation referred to above. In particular, consistent methodology is essential in any systems or equipment testing. Standardization organisations provide a useful role model in this regard. Similar considerations apply to the technical reports issued by the IAEA, which has the key function to establish and promote international guidance for the safe and secure use of radiological equipment.

Type B

Where international standards or guidelines are not available or are out of date, advice is often available from scientific and professional bodies, notably AAPM, EANM, EFOMP, ESR, ESTRO or IPREM, which usually provide also the methodology to test specific figures of merit. Other sources of suspension levels are national standards, notably NEMA or DIN. Finally, some suspension levels are reported in formal national legislations/regulations, although usually without a reference methodology and a reference bibliography.

Type C

When neither standards nor recommendations issued by professional bodies are available, the published scientific literature was reviewed, and a recommendation was made by the drafting group and submitted to expert review. Where this process led to consensus, the suspension level and method of measurement has been adopted and is recommended in the relevant section.

Type D

This may occur for a variety of reasons, e.g., in type A, B or C publications the methodology for measuring a figure of merit is detailed, but any explicit suspension levels are not provided. For instance, this occurs in all the IEC standards related to nuclear medicine. Another circumstance is where the technology involved is recently new and there are yet not suspension levels published or agreed upon in international standards, but sufficient other evidence exists to allow for a suspension level to be recommended and the system characteristic to be tested was deemed of enough importance that a suspension level was deemed critical.

2.7 Special considerations, exceptions and exclusions

2.7.1 Special considerations

The BSSD requires that special consideration be given to equipment in the following categories.

- Equipment for screening
- Equipment for paediatrics
- High-dose equipment, such as that used for CT, interventional radiology or radiotherapy

The following chapters and sections address these issues where it is possible to do so.

Equipment used for paediatrics and in screening programmes is often similar or sometimes identical to general-purpose equipment. Where this is the case, additional guidance for the special problems of paediatrics, such as the requirement for a removable grid in general radiology or fluoroscopy, and the special needs with regard to CT exposure programmes are noted. The requirements for mammography are based on those appropriate to breast screening programmes.



2.7.2 Old equipment

Exceptions to the recommended criteria may arise in some circumstances. These include cases where the equipment to be assessed was compliant when installed with safety and performance standards that predate the criteria/suspension levels presented here. In such cases, the equipment must be reassessed according to the criteria of this report, including the risk assessment. Following that, the MPE must make a recommendation to the undertaking. These recommendations must take a balanced view of the overall situation, including the economic/social circumstances and the purpose for which the equipment is deployed. The MPE may recommend that the equipment be operated subject to restrictions on its use.

2.7.3 Rapidly evolving technologies

The suspension levels presented here are for well-established systems. Medical imaging and radiation therapy are areas in which many new developments are occurring. Encouraging development in such an environment is not well served by the imposition of rigid criteria. Such criteria, when rigorously enforced, could become obstacles to development and hence are not proposed here. When systems of novel design present themselves, the MPE should agree on the remedial levels to be considered with the undertaking. The levels proposed by the MPE must be framed to be effective for the new technology, considering related longer-established technologies, any CENELEC/IEC standards available, newly available test methods, the manufacturer's recommendations, related scientific and professional opinion/published literature, and the maxim that the new technology should aspire to be at least as safe as the technology it is intended to replace. A non-exhaustive list of technologies that can be considered rapidly innovating is presented below:

- Dual-energy computed tomography
- Photon-counting computed tomography
- 3D-rotational angiography
- Solid-state gamma camera
- Large-field-of-view PET
- MRI-LINAC

2.7.4 Exclusions

Within this report, the term 'equipment' has been interpreted to mean the main types of equipment used in diagnostic radiology, nuclear medicine and radiotherapy. This follows the precedent established in RP 162. It is important to be aware that treatment of the whole installation is outside the scope of this report, although there are areas particularly information technology, that are now in urgent need of attention.

Dose monitoring systems are essential for optimizing patient safety in medical imaging by automatically collecting, analyzing and reporting radiation exposure data. These systems assist in meeting legal requirements for recording patient doses and tracking diagnostic reference levels (DRLs), identify high-dose outliers and provide comprehensive data on dose variability, enabling the evaluation of imaging protocols, machine performance and staff training needs. Although acceptability criteria would be warranted, there are currently no recognized benchmark standards. A recent publication (IAEA 2025a) outlines the key quality control tests essential for optimal performance and provides information on the frequency of each test as well as the expected levels of accuracy to ensure the system's reliability and compliance with baseline values



established during commissioning. These levels, however, cannot currently be translated into suspension levels.

The contribution of information technology networks to improving or compromising equipment functionality can bear on both justification and optimization. This can apply to both picture archiving and communication or radiology information systems in diagnostic imaging and planning and treatment networks in radiotherapy centres. The requirements for acceptability of such networks are beyond the scope of this report.

In addition to the specified criteria, the equipment needs to be safe for the operator and to be operated competently. Neither of these issues is within the remit of this report, and both are equally important for good clinical practice. With regard to competent operation, the following need continuing attention: safety training, professional training, equipment supplier specific training, staff competency assessment, training records, equipment quality assurance, clear clinical protocols including patient identification, incident and accident reporting with active feedback, clinical audit, and clear employment policies utilising professional registers of qualified persons. All these features can be incorporated into a quality management system.

With regard to wider equipment safety considerations, many national and international standards apply to medical devices, whose intention is to ensure the safety of equipment in respect to, for example electrical, mechanical and software hazards. This report is not intended to duplicate these standards and processes. Where an overlap continues between safety standards and the performance issues that have become the focus of this report, some of the basic safety issues are repeated in this report. For example, tube leakage, which is essentially a safety standards issue, continues to appear in the diagnostic radiology section of the report.

2.8 Establishing conformity with criteria for acceptability

Qualitative criteria and suspension levels will be applied by the undertakings in each Member State with appropriate oversight from the national competent authority. In addition, the criteria for acceptability are introduced and applied in the context of increasing oversight in healthcare, e.g., the developing requirements for clinical audit, particularly in radiology.

To verify that the criteria for acceptability are being met, the undertaking must appoint a competent person or persons. The person(s) appointed should be an MPE, whose role will include certifying the protocols and tests to establish compliance.

Who performs the tests in practice is a matter for local arrangements and may vary based on the circumstances causing the tests to be performed in the first place. For example, upon receipt of new equipment, the MPE may choose to include tests for criteria for acceptability with the acceptance tests following discussion and agreement with the suppliers' engineers. In practice, the MPE may perform, document, certify and report on the tests.

The test methods recommended in this report rely on non-invasive measurements that would be available to the end user, but alternative approaches proposed by the manufacturer and agreed to in advance with the MPE may be acceptable. In these circumstances, results acquired during acceptance testing will often provide sufficient information for the MPE to make a judgement on whether the equipment performance reaches or exceeds suspension levels. In some cases the suspension level is linked with a specific testing method or a range of testing conditions and in unclear cases the original reference should be visited. Institutions should establish a local practice that enables compliance to be confidently verified, with minimum duplication of effort by a suitably



qualified person acting on behalf of the undertaking. In radiotherapy, this is well established, as illustrated by commonplace joint acceptance testing by the manufacturer's team and the undertaking's MPE.

Compliance with appropriate suspension levels should also be verified at times other than installation. Examples include after significantly reconfiguring or updating equipment, following major maintenance, following an alert raised during quality control measurements, before significant changes in intended use, and otherwise as required.

When equipment meets a suspension level, an investigation must be initiated. This must be undertaken in a way that is proportionate to the criteria that have not been met, the clinical needs in the institution, and national circumstances. A risk assessment of the various possible options must be prepared by the MPE in consultation with the relevant practitioners and, where necessary, representatives of the undertaking. The options include, for example, immediate suspension of the equipment, if the safety requirements in the relevant safety standards are not met. They may also include assessment of the option that the equipment be replaced temporarily or permanently. Alternatively, a phased suspension or limitations on the range of use of the equipment may be considered. In the latter case, the specific circumstances under which the equipment may continue to be used must be carefully defined and documented in the risk assessment. The risk assessment must be communicated by the MPE, promptly and in writing, to senior management of the undertaking and to the users of the equipment.

Finally, the judgement and advice of the MPE is critically important in establishing the basis on which acceptability should be determined when the recommended qualitative criteria and suspension levels are incomplete or lack precision, when the equipment is very old, when it involves an unanticipated new technology, or when it is subject to special arrangements or exemptions.

2.9 Conclusions

The guidance provided in this introduction is crucial to the effective use of the sets of qualitative criteria and suspension levels for radiology, nuclear medicine and radiotherapy equipment to be found in sections 3–5 of this report. Following this advice will ensure that the requirements of the BSSD are met in a way that is consistent with sound medical practice and the global harmonization of the radiological equipment industry.



3. Diagnostic and Interventional Radiology

3.1 Introduction

Since RP 162 was published, there have been a number of major developments in diagnostic radiology, including advancements in digital X-ray systems, 3D imaging, computed tomography, and interventional radiology techniques. Digital radiography has largely replaced traditional film-based X-rays, offering advantages like faster image acquisition, enhanced image quality, and reduced radiation exposure. Accordingly, suspension levels for film/screens systems are no longer reported in this publication.

Computed radiography is still in use, although it is not as prevalent as it once was due to the continuous rise of digital radiography. Still it remains a viable digital imaging option, particularly in certain settings or for specific applications where its unique advantages are beneficial. Suspension levels for computed radiography reported in RP 162 are unchanged. Key advancements in 3D imaging include digital breast tomosynthesis and 3D rotational angiography.

Computed tomography underwent rapid advancements focused on reducing radiation exposure, improving image quality, and enhancing clinical applications. Key innovations include wide-detector, ultra-high-resolution, iterative reconstruction, dual-energy and photon-counting computed tomography. These developments among others require revised and new acceptability criteria.

Manufacturers have incorporated many other new features into medical imaging systems; for example, those based on software and information technology innovations. These have resulted in improved and more stable performance. For example, newer X-ray generators are much improved when compared with their predecessors. These improvements also create the need to revisit criteria for acceptability.

The implementation of a quality culture within radiology departments and the evolution of quality assurance programmes have also had an impact on criteria and suspension levels. In part, the development and availability of relatively stable instrumentation for dosimetry in radiology has contributed to this. Acceptability criteria for all types of diagnostic radiology equipment are summarised in the following sections and are almost all based on physical or engineering performance or safety features.

3.2 X ray generators and equipment for general radiography

3.2.1 Introductory remarks and qualitative criteria

General radiographic systems still provide the great majority of X-ray examinations. They may be subdivided in practice into a number of subsidiary specialist types of system. This section deals with the suspension levels applicable to X-ray generators and general radiographic equipment. It also includes or is applicable to mobile systems, and system subcomponents/devices such as automatic exposure control (AEC), digital detectors or medical image display systems.

What is presented here is also applicable to generators for dynamic X-ray imaging systems, dental cephalometric, dental CBCT and dual-energy X-ray absorptiometry (DXA) systems.

However, the criteria do not apply to specialized X-ray equipment such as mammographic, dental intraoral and CT units. These are covered in sections 3.5, 3.6 and 3.8.



The criteria here refer to X-ray tube and generator, output, filtration and first half-value layer (HVL), beam alignment, collimation, anti-scatter grid, leakage radiation and dosimetry.

Suspension levels are specified in the tables below and should be used with due consideration for the remarks on HVL and filtration, focal spot, paediatric concerns, image quality and spatial resolution, AEC, and mobile devices.

The equipment types listed in the box below are not acceptable based on the qualitative criteria stated.

- Equipment without the ability to collimate the beam
- Systems intended to include paediatric use without the option to remove the grid
- Equipment without a device or an equivalent means, informing the practitioner of relevant parameters for assessing the patient dose
- Fluoroscopy equipment without AEC devices or without an image intensifier or equivalent device

HVL/filtration

Total filtration in general radiography should not be less than 2.5 mm Al. The first HVL is an important metric used as a surrogate measurement for filtration. It shall not be less than the values given in Tables 6 or 7 in the next section, which depend on the year in which they were CE marked.

Focal spot

International standard IEC 60336 (IEC 2020a) defines the test methods and criteria for determining the nominal focal spot dimensions of X-ray tube assemblies for medical diagnosis. The standard specifies procedures using pinhole cameras or slit cameras and digital detectors to ensure compliance with the specified focal spot size, which influences image resolution. The use of star-pattern test tools is no longer a normative procedure. Since most of the medical physics departments are not equipped with these instruments and are not routinely performing these measurements, the suspension levels related to focal spot dimensions were not addressed in the present document.

Paediatric issues

Requirements for radiography of paediatric patients differ from those of adults, partly related to differences in size and immobilization during examination (see notes and suspensions level in Tables 2.1). Beam alignment and collimation are particularly important in paediatric radiology, where the whole body, and individual organs and their separations are smaller. The X-ray generator and tube must have sufficient power and suitable range of timer settings to facilitate short exposure times. In addition, the option to disable the AEC is essential in a system for paediatric use, as is the capacity to use manual exposure factors, and set shorter exposures. Systems used with manual exposures (like dedicated mobile units for bedside examinations) should have exposure charts for paediatric patients.

Special radiation quality requirements are stated for paediatric applications (Table 5: HVL or sufficient total filtration).

Image quality and spatial resolution

Image quality evaluation in radiology is crucial for ensuring accurate diagnoses and optimizing patient care. It involves both objective and subjective assessments, focusing on parameters like spatial resolution, contrast resolution, noise, and artefacts. Quantitative methods such as measuring contrast-to-noise ratio and modulation transfer



function provide objective data, while subjective assessments rely on expert radiologist reviews and observer performance studies.

There are still unresolved difficulties in determining objective measures of image quality that are both reproducible and reflect clinical performance. Image quality must be sufficient for the diagnostic tasks that the system is used for. This may be subjectively assessed by, for example, an experienced practitioner. High-contrast bar patterns provide simple assessment that often proves valuable. Both of these approaches may be augmented by semi subjective assessments, or other quantitative assessments at the discretion of the MPE and the practitioner.

Mobile devices

With mobile devices, the criteria for equipment for general radiography are applicable except the requirements for the AEC, which cannot always be met in practice.

3.2.2 Suspension levels for X ray generators and general radiography

The suspension levels for X-ray generators and general radiography systems are provided in Tables 5–7.

Table 5. Suspension levels for general radiography systems

Physical Parameter	Suspension Level	Reference	Type	Notes and Observations
Tube voltage				
Tube voltage accuracy	Deviation from set voltage >8%	IEC (2022a)	A	Under any combination of loading factors
X-ray tube output				
Magnitude of output (Y) at 1 m	Y outside range of 25–80 $\mu\text{Gy/mAs}$ at 1 m from focal spot, 80 kV and total filtration of about 2.5 mm Al	IAEA (2023a)	A	Nearest nominal kV to 80
Repeatability of output for a fixed setting	Coefficient of variation >5%	IEC(2022a) IAEA (2023a)	A	Under any combination of loading factors
Output linearity	The quotients of the average of the air kerma values divided by the preselected values or the indicated values of current time product obtained shall not differ by more than 0.2 times the mean value of these quotients	IEC (2022a)	A	
HVL and total filtration				
HVL or sufficient total filtration	HVL < values specified in Table 6	IEC (2021a)	A	



Exposure time				
Exposure time accuracy	Deviation from set time > 10% (for times ≥ 100 ms). Deviation from set time >15% or 2 ms, whichever is greater (for times <100 ms)	IAEA (2023a)	A	
Exposure time repeatability	Coefficient of variation >5%	IAEA (2023a)	A	e.g., 80 kV 40 mAs
Alignment				
X-ray/light beam alignment	The maximum sum of misalignments >2% of the source-to-image detector distance between the light and radiation fields at two opposing field sides	IEC (2022a)	A	
Centering	Alignment of crosswire with X-ray beam centering $> \pm 1$ cm at focus-image receptor distance = 100 cm	IAEA (2023a)	A	
Collimation				
Correspondence between the X-ray field and effective image reception area	Image reception area circular: a) the X-ray field extends beyond the boundary of the effective image reception area by more than 2 cm b) <80% of the area of the X-ray field overlaps the effective image reception area	IEC (2024a)	A	a) Measured along a diameter in the direction of greatest misalignment with the image reception area b) Effective image reception areas smaller than 10 cm in diameter are exempted
	Image reception area non-circular: a) The total of the discrepancies between the edges of the X-ray field and the corresponding edges of the image reception area exceeds 3% of the indicated focal spot to image receptor distance b) The sum of the discrepancies on both axes exceeds 4% of the indicated focal spot to image receptor distance			a. along each of the two major axes of the image reception area b. when the image reception plane is normal to the X-ray beam axis
Grid				
Grid artefacts	Significant grid artefacts are visible	IPEM (2022)	B	
Oscillating grid	Grid lines visible on image	IPEM (2022)	B	



Leakage radiation				
Leakage radiation	Maximum air kerma at 1 m distance >1 mGy in 1 hour	IEC (2021a)	A	Collimation fully closed Detector with a 100 cm ² active area. Loading corresponding to the maximum specified tube potential (kVp) and current (mA) or specific "leakage technique factors" in 1 hour
Accuracy of dose display				
Integrated 'dose indicator' DAP/KAP meter accuracy	Deviation of displayed value from reference value > ±25%	IEC (2019)	A	The requirement is valid for field-class dose area product meters. Field size as at calibration. The requirement is limited to a range of IEC 61267 RQR radiation qualities 50–150 kV
Linearity	$(R_{\max}-R_{\min})/(R_{\max}+R_{\min}) \geq 0.05$	IEC (2019)	A	The response resulting from the minimum toward the maximum rated dose-area product rate, with measurements made at dose-area product rates in steps not greater than one order of magnitude

Table 6. Suspension levels for minimum first HVL

Physical Parameter	Suspension Level	Reference	Type	Notes and Observations
X-ray tube voltage (kV)	Minimum permissible first HVL (mm Al)			
50	1.8	IEC (2021a)	A	
60	2.2			
70	2.5			
80	2.9			
90	3.2			
100	3.6			
110	3.9			
120	4.3			
130	4.7			
140	5.0			
150	5.4			



Table 7. AEC suspension levels

AEC verification	Suspension Level	Reference	Type	Notes and Observations										
Limitation of overexposure	Maximal focal spot charge >600 mAs	IEC (2022a)	A											
AEC repeatability	The coefficient of variation for measured values (EI or measured air kerma) >5%	AAPM (2024a) ACPSEM (2024)	B	EI as defined in IEC (2008a)										
Verification of AEC at various phantom thicknesses	The image receptor dose (EI or measured air kerma) for each tube voltage/phantom thickness combinations $\geq 25\%$ of the average over all tested voltages	AAPM (2024a)	B	This only applies for AEC with a fixed signal-to-noise ratio at the detector, tube voltage range of 60–120 kV										
Verification of AEC at various tube voltage	The image receptor dose (EI or measured air kerma) for each tube voltage $\geq 25\%$ of the average over all tested voltages	AAPM (2024a)	B	<table border="1"> <thead> <tr> <th>Thickn ess (cm)</th> <th>Voltage (kV)</th> </tr> </thead> <tbody> <tr> <td>10</td> <td>60, 80</td> </tr> <tr> <td>15</td> <td>60, 80, 100</td> </tr> <tr> <td>20</td> <td>80,100, 120</td> </tr> <tr> <td>25</td> <td>100,120</td> </tr> </tbody> </table>	Thickn ess (cm)	Voltage (kV)	10	60, 80	15	60, 80, 100	20	80,100, 120	25	100,120
Thickn ess (cm)	Voltage (kV)													
10	60, 80													
15	60, 80, 100													
20	80,100, 120													
25	100,120													

3.3 Digital X-ray imaging detectors

3.3.1 Introductory remarks and qualitative criteria

Digital X-ray imaging detectors (DDR) are increasingly used in medical diagnosis and have widely replaced conventional (analogue) imaging devices such as screen-film systems or analogue X-ray image intensifier television systems. Therefore, it is necessary to update the suspension levels related to the specific imaging properties of these DDRs.

A tool that allows exporting images for processing in a DICOM format is essential to evaluate the physical characteristics of DDRs such as signal transfer properties, modular transfer function, noise power spectrum and detective quantum efficiency. Images for processing are not always accessible in the user mode or quality control mode.

When testing the tube and generator, it is advisable to keep the detector out of the beam or protect it, e.g., with lead.

Computed radiography is still in use, although it is not as prevalent as it once was due to the continuous rise of DDR. Still computed radiography remains a viable digital imaging option, particularly in certain settings or for specific applications where its unique advantages are beneficial. Suspension levels for computed radiography reported in RP 162 are unchanged.

The equipment listed in the box below is not acceptable based on the qualitative criteria stated.



- Systems that do not have an option in the user mode or quality control mode to export images for processing in DICOM format
- Presence of clinically significant blurring or defective lines or stitching (ACPSEM 2024; AAPM 2024a) – type B

3.3.2 Suspension levels for DDR systems

The suspension levels for DDR systems are provided in Table 8.

Table 8. Suspension levels for DDR systems

Physical Parameter	Suspension Level	Reference	Type	Notes and Observations
Signal transfer properties	The experimental data points shall be fitted by a model function. Relationship between image receptor incident air kerma and mean pixel value must be verified as simple (e.g., linear, log, or power). For the resulting fit: <ul style="list-style-type: none"> • Final $R^2 \leq 0.99$ • Individual experimental data point deviates from its corresponding fit result by more than 2% 	IEC (2015a)	A	
Lag effect (additive or multiplicative) (image retention, ghost)	$\geq 0.5\%$	IEC (2015a)	A	
Exposure index Accuracy	Deviation $> \pm 35\%$ Exposure indicator value deviates from exposure measurement within $> \pm 35\%$	AAPM (2024a)	B	Exposure index as defined in IEC (2008a)
Uniformity	Non uniformity $> 10\%$	EFOMP (2024) ACPSEM (2024)	B	
Scaling or distance accuracy	Errors $> \pm 4\%$	ACPSEM (2024)	B	

3.4 Medical image display systems

3.4.1 Introductory remarks and qualitative criteria

Medical image display systems are specialized systems designed for viewing and interpreting medical images. These systems must adhere to strict quality standards, and their key features include high resolution, consistent brightness and image quality, and DICOM compliance. Their role is of paramount importance since virtually all medical images are stored, viewed, and managed electronically.

Over the last decade and given the shift in display technology from cathode ray tube to liquid crystals, performance has improved dramatically, and higher performance characteristics should be expected, in particular regarding maximum luminance.

Primary monitors, also known as diagnostic monitors, are specialized display used by radiologists and other healthcare professionals for interpreting medical images. MPEs may also use the diagnostic display category when deciding how to characterize the desired



performance of any display that is used to perform primary interpretation or make routine medical diagnoses or decisions, e.g., modality displays for angiographic systems.

3.4.2 Suspension levels for diagnostic monitors

The suspension levels for diagnostic display systems are provided in Table 9.

Table 9. Suspension levels for diagnostic display systems

Physical Parameter	Suspension Level	Reference	Type	Notes and Observations
DICOM grayscale standard display function	Deviation >10% in either (just-noticeable difference)/(gray level) or dL/L per just-noticeable difference from DICOM grayscale standard display function	AAPM (2020) IEC (2021b)	B	Gray levels can be displayed in increments of 15, 5 or 1 using different digital patterns
Maximum luminance L_{max}	Non-mammography: $L_{max} < 300 \text{ cd/m}^2$ Mammography: $L_{max} < 350 \text{ cd/m}^2$	AAPM (2020)	B	Measured without ambient light
Minimum luminance L_{min}	Non-mammography: $L_{min} < 1 \text{ cd/m}^2$ Mammography: $L_{min} < 0.8 \text{ cd/m}^2$	AAPM (2020)	B	
Luminance ratio r	$r = L_{max}/L_{min} < 250$	AAPM (2020) IEC (2021b)	B	
Luminance uniformity	Max deviation > 30%	AAPM (2020) IEC (2021b)	B	Using the TG18-UNL80 test pattern
Luminance evaluation of multiple displays	$(L_{maxhighest} - L_{maxlowest})/L_{maxlowest} * 100 > 10\%$	IEC (2021b)	B	If multiple image-display devices are associated with the same image display system

3.5 Mammography

3.5.1 Introductory remarks and qualitative criteria

Mammography involves the radiological examination of the breast using X-rays and is primarily used for the detection and diagnosis of breast cancer at an early stage. It is widely used in screening programmes involving healthy populations. Screening for early detection of breast cancer in a healthy population places particular demands on radiological equipment as high quality images are required at a low dose. Symptomatic patients may also benefit from these considerations. Perhaps because of the exacting demands of mammography, acceptability criteria and suspension levels are well developed (IEC (2020a); IEC (2022a)).

Mammography should be performed on equipment designed and dedicated specifically for imaging breast tissue. Either film/screen or digital detectors may be used, although the use of film/screen has been practically discontinued, and is not considered in this



report. Furthermore, the use of computed radiography-based mammography systems is discouraged. Digital breast tomosynthesis has been also broadly introduced for breast imaging, although its use in screening programmes throughout the EU is currently limited while widespread in other environments. Therefore, this report includes suspension levels only for digital mammography and digital breast tomosynthesis. The former can be used for computed-radiography systems. Hence, Tables 10 and 11 summarise the suspension criteria for digital mammography, applicable also to computed radiography systems, and digital breast tomosynthesis equipment, respectively.

It is important to point out some criteria and considerations that were used when assembling these Tables. In the first place, any suspension criteria that involved solely comparison of obtained values to manufacturer specifications or to 'baseline' values obtained at acceptance, or similar, were excluded. This should not be understood to imply that these tests and criteria should be ignored. In addition, some criteria included in RP162 were excluded due to their referring to obsolete components, e.g., X-ray tube output for molybdenum-target tubes, and there being no updated general consensus on suspension levels that involve more current equipment components. Also, no threshold contrast or other image quality-related levels have been included given that there is a multitude of very different test phantoms, e.g., American College of Radiology (ACR) accreditation phantom, CDMAM and TORMAM, available, with no general consensus on which should be used, and with no single or set of metrics and corresponding suspension levels that should be adopted with their use. Finally, the suspension level for needle positioning accuracy for stereotactic biopsy systems was excluded from this report since it was deemed that this physical parameter is not usually measurable by medical physicists.

The equipment listed in the box below is not acceptable based on the qualitative criteria stated.

- Equipment without AEC
- Equipment with a focus-to-image receptor distance less than 60 cm
- Equipment with a field of view less than 18×24 cm², excluding stereotactic devices
- Equipment without a foot pedal-operated motorized compression plate and readout of compression thickness and force

3.5.2 Suspension levels for mammography systems

The suspension levels for mammography equipment are provided in Tables 10 and 11.

Table 10. Suspension levels for mammography systems

Physical Parameter	Suspension Level	Reference	Type	Notes and Observations
Tube voltage				
Tube voltage accuracy	Deviation from set voltage >5%	IEC (2022c)	A	Under any combination of loading factors
Tube voltage reproducibility	Coefficient of variation >5%	IEC (2022c)	A	Under any combination of loading factors



X-ray tube output				
Output linearity	Difference in air kerma per unit X-ray tube current time product >20% of the mean between the pair of 2 measurements results with different settings	IEC (2022c)	A	Determine average air kerma per unit x-ray tube current time product over 10 measurements at each setting. Number of settings should be such that span the available range of x-ray tube current time products.
Output reproducibility	Coefficient of variation >5%	IEC (2022c)	A	Over 10 measurements, under any combination of loading factors
Leakage radiation				
Leakage radiation	Maximum air kerma at 1 m distance >1 mGy in 1 hour	IEC (2021a)	A	Collimation fully closed. Detector with a 100 cm ² active area. Loading corresponding to the maximum specified tube potential (kVp) and current (mA) or specific "leakage technique factors" in 1 hour
First HVL				
HVL	HVL < V/100 + 0.03 OR HVL > V/100 + 0.03 + C, where C is: 0.12 for Mo/Mo; 0.19 for Mo/Rh; 0.22 for Rh/Rh; 0.30 for W/Rh; 0.32 for W/Ag; 0.25 for W/Al; and V is the nominal value of the tube voltage	IAEA (2023a) IEC (2022c)	A	For target/filter combinations not listed, HVL < V/100.
Exposure time				
Exposure time	>2 s for standard breast 40 mm PMMA	IEC (2022c)	A	Excluding slot-scanning systems
Alignment				
X-ray/light beam alignment	Misalignment >2% of focal spot-to-image receptor distance	IEC (2022c)	A	



Collimation				
X-ray/image receptor alignment	X-ray field not extending beyond the image receptor OR X-ray field extending beyond the image receptor >5 mm on chest wall side X-ray field extending beyond the edge of breast support >2 mm X-ray field extending beyond the image receptor >2% of focal spot-to-image receptor distance on other 3 sides Chest wall side: distance between image receptor and edge of support >5 mm	IEC (2022c)	A	
Breast compression				
Compression	No breast compression device shall be able to apply a force exceeding 300 N. For power-driven compression, the breast compression device shall be able to apply a force of at least 150 N, and it shall be unable to apply a force exceeding 200 N	IEC (2022c)	A	
Compression force consistency	Change in force >10 N	EFOMP (2023a)	B	Over 60 s period after achieving nominal force
Compression force accuracy	Deviation in displayed force >± 20 N	IEC (2022c)	A	
Compression paddle	Chest wall edge of the compression paddle >5 mm beyond the chest wall edge of the image receptor. Chest wall edge of the paddle is visible in the image	IAEA (2023a)	A	
Compression paddle motion	Minimum distance between compression paddle and breast support >10 mm	IEC (2022c)	A	
Grid				
Grid artefacts	If significant grid artefacts are visible	IEC (2022c)	A	
Focal spot				
Focal spot dimensions	Width [mm] × length [mm]: >0.15 × >0.15 for 0.1 mm nominal focal spot >0.45 × >0.65 for 0.3 mm nominal focal spot	IEC (2020b)	A	



AEC				
AEC short-term reproducibility	Deviation from mean measured value >15%	IEC (2022c)	A	Measured value can be current-time product, air kerma output, or linearized pixel value in image ROI
AEC signal-difference-to-noise ratio (SDNR) short-term reproducibility	CV of SDNR >5%	IAEA (2023a)	A	
AEC security cut-off	Exposure is not terminated after pre-exposure	EFOMP (2023a)	B	
AEC thickness compensation	SDNR relative to SDNR for 45 mm of PMMA: <0% for 20 mm PMMA <0% for 30 mm PMMA <0% for 40 mm PMMA <-15% for 50 mm PMMA <-30% for 60 mm PMMA	EFOMP (2017)	B	Calculated as $\Delta\text{SDNR} = (\text{SDNR}_i - \text{SDNR}_{45}) / \text{SDNR}_{45}$ for any thickness i
Image receptor performance				
Image receptor response function	$R^2 < 0.99$ when fit according to manufacturer's response function	IAEA (2023a)	A	Usually a linear function
Image receptor response function	CV of mean pixel value per unit air kerma or x-ray tube current time product across measurements spanning the available x-ray tube current time product range >10%	EFOMP (2017)	B	After linearization, if manufacturer's response function is non-linear
Image receptor uniformity	Local uniformity >5% Global uniformity >10%	IAEA (2023a)	A	
Ghosting	Ghost image SDNR >2.0	IAEA (2023a)	A	
Radiation dose				
PMMA-based mean glandular dose	>1.0 mGy for 20 mm PMMA/21 mm equivalent breast thickness >1.5 mGy for 30 mm/32 mm >2.0 mGy for 40 mm/45 mm >2.5 mGy for 45 mm/53 mm >3.0 mGy for 50 mm/60 mm >4.5 mGy for 60 mm/75 mm >6.5 mGy for 70 mm/90 mm	IAEA (2023a)	A	

Table 11. Suspension levels for digital breast tomosynthesis, in addition to those of Table 10

Physical Parameter	Suspension Level	Reference	Type	Notes and Observations
Exposure time				
Exposure time	>±15% of measured value	EFOMP (2023a)	B	Individual projection time
AEC				
AEC short-term reproducibility	CV of signal-to-noise ratio >10%	IEC (2020b)	A	Tested on the first projection image



Image receptor performance				
Image receptor uncorrected defective detector elements	Any pixel with value $>\pm 20\%$ from average pixel value in surrounding 5 mm \times 5 mm ROI	IEC (2020b)	A	Tested on projection images after using the system's software to correct for defective elements
Reconstructed image				
Reconstructed volume coverage	Any high-contrast object below and above a breast phantom does not appear in focus in at least one of the reconstructed slices	IEC (2020b)	A	
In-plane geometric distortion	Measured distance between objects $>5\%$ of actual distance	IEC (2020b)	A	Distance between objects should be between 40 and 60 mm
Display				
Displayed breast thickness	>5 mm difference from measured	EFOMP (2023a)	B	

3.6 Dental radiography

3.6.1 Introductory remarks and qualitative criteria

Dental radiographs are, together with chest radiographs, the most frequent X-ray examination worldwide. Despite the relatively low dose per examination, the high frequency of paediatric examinations and the increasing use of CBCT warrant attention.

The list of unacceptable intraoral dental equipment from EC (2012) is maintained.

- Film class lower than E for which special justification has not been made
- Non-rectangular collimators on intraoral equipment, for which special justification has not been made
- Rectangular collimation on intra oral equipment, resulting in a field size greater than 40 \times 50 mm

For handheld intraoral equipment, its use should align with the statements by the European Academy of DentoMaxilloFacial Radiology (Berkhout 2015) and Heads of the European Radiological Protection Competent Authorities (HERCA) (2014); their suspensions levels are the same as for other intraoral equipment, with a few specific requirements as shown in Table 12.

3.6.2 Suspension levels for dental equipment

Suspension levels for dental equipment are provided in Tables 12 and 13. Where exposure settings or pre-programmed exposure protocols are provided with the equipment, their appropriateness should be checked as part of the confirmation that the equipment is acceptable. A distinction should be made between exposure settings for adults and children.

Suspension levels for dental CBCT listed in (EC 2012) have been largely replaced or removed in favour of levels listed in the (IEC 2021d) and (IEC 2021e) standards.

Image-quality suspension levels are not included. Whereas (EC 2012) included image quality suspension levels for CBCT, there is insufficient evidence regarding the



applicability of image quality-based suspension levels in CBCT. Naturally, for any dental equipment, the presence of severe consistent artefacts or other severe image quality degradations impeding diagnosis can be cause for suspension.

In terms of dose, suspension levels listed in (EC 2012) are kept, despite some of them being determined over 20 years ago. For CBCT, no absolute or relative suspension levels for dose are defined, as this would require more efforts in the establishment and application of diagnostic reference levels (Trindade 2025). In future documents, suspension levels relative to a protocol-specific diagnostic reference level can be defined.

Table 12. Suspension levels for intraoral equipment

Physical Parameter	Suspension Level	Reference	Type	Notes and Observations
Tube voltage				
Tube voltage range	Indicated setting <60 kV	IEC (2021c)	A	A distinction is made between the 'indicated tube voltage setting' (the displayed/selectable value on the equipment) and the measured tube voltage (to which the suspension level for tube voltage accuracy below applies).
Tube voltage accuracy	Deviation from set voltage >10%	IEC (2021c)	A	
Tube current and exposure time				
Tube current accuracy	Deviation from set current >20%	IEC (2021c)	A	
Exposure time accuracy	Deviation from set exposure time >5% or >20 ms (whichever is larger)	IEC (2021c)	A	Does not apply for exposure times <0.1 s for one-peak (self-rectified AC) generators.
X-ray tube output				
Dose accuracy	Deviation of air kerma from set value >50%	IEC (2021c)	A	The manufacturer shall also provide a method to calculate the dose-area product in the accompanying documents
Incident air kerma for mandibular lower molar tooth	> 4 mGy	EC (2004) & EC (2012)	A	
HVL and total filtration				
HVL or sufficient total filtration	≤70 kV: <1.5 mm Al-equivalent filtration >70 kV: see Tables 2.2 and 2.3	IEC (2021c) IEC (2021a)	A	



Collimation and focus–skin distance				
Maximum field size	Exit field size >6 cm diameter. For digital receptors: no rectangular collimation used OR field size exceeds receptor by >1 cm in the diagonal.	IEC (2021c)	A	
Focus–skin distance	<20 cm	IEC (2021c) IAEA (2018)	A	
Protection against stray radiation				
Leakage radiation	Hand-held equipment: >0.05 mGy/h at outer surface in loading state. Other equipment: >0.25 mGy/h at 1m in loading state.	IEC (2021c)	A	
Backscatter shield thickness for handheld equipment	<0.25 mm Pb-equivalent at 70 kV	IEC (2021c)	A	The shield should be non-removable

Table 13. Suspension levels for extraoral equipment and dental CBCT

Physical Parameter	Suspension Level	Reference	Type	Notes and Observations
Tube voltage				
Tube voltage range	Indicated setting <60 kV	IEC (2021d)	A	A distinction is made between the indicated tube voltage setting (displayed/selectable value on the equipment) and the measured tube voltage (to which the suspension level for tube voltage accuracy applies).
Tube voltage accuracy	Deviation from set voltage >10% or increment or decrement of tube voltage outside of 50–150% of indicated change.	IEC (2021d)	A	
Tube current and exposure time				
Tube current accuracy	Deviation from set current >20%	IEC (2021d)	A	



Exposure time accuracy	Deviation from set exposure time > (5% + 50 ms)	IEC (2021d)	A	If the exposure time varies throughout the irradiation, the manufacturer must instruct users how to measure it. If pulsed exposure is used, the manufacturer must document the pulse pattern and duration in the instructions.
Tube current time product	Deviation from set tube current time product > (10%+0.2 mAs)	IEC (2021d)	A	
X-ray tube output				
Dose accuracy	Deviation of air kerma / dose-area product from set value >50%	IEC (2021d)	A	
Repeatability of radiation output	Coefficient of variation of air kerma >5%	IEC (2021d) IEC (2021e)	A	
Output linearity	Difference in air kerma per tube current time product for two settings >20% of average air kerma per tube current time product for these two settings	IEC (2021d)	A	
Incident air kerma (cephalometric radiography)	Skull AP/PA: >3 mGy Skull lateral: >1.5 mGy	EC (2004) EC (2012)	A	
HVL and total filtration				
HVL or sufficient total filtration	See Tables 6 and 7	IEC (2021d)	A	
Collimation and focus-skin distance				
Field size (narrow-beam equipment)	Field exceeds effective reception area perpendicular to the scanning direction or >1 mm on either side parallel to the scanning direction	IEC (2021d)	A	
Field size (CBCT)	For active receptor width ≥ 8 cm: field exceeds receptor by >2% of focal spot-receptor distance in one direction, or >3% in both directions. For active receptor width <8 cm: field exceeds receptor by >1% of focal spot-receptor distance in one direction or >2% in both directions.	IEC (2021d) IEC (2021e)	A	
Focus-skin distance	<15 cm	IEC (2021d)	A	



3.7 Dynamic X ray imaging systems

3.7.1 Introductory remarks and qualitative criteria

With respect to the X-ray tube/generator and system subcomponents/devices such as AEC, digital detectors, or medical image display systems of dynamic x-ray imaging systems, many of the criteria of acceptability are the same to those prevailing for general radiographic systems.

In fluoroscopy and interventional radiology equipment, the technological evolution has led to automatic control loops that control all the exposure parameters through an AEC. This clinical modality can potentially interfere with performing quality control measurements, as well as with assessing acceptability of the equipment. The availability of the user quality-control mode (UQCM) in X-ray equipment for interventional procedures (NEMA 2019) should be viewed as a performance requirement necessary to fulfill the obligations that stems from the BSS in this class of radiological equipment. UQCM allows the medical physicist to operate under open-loop control logic to manually set the irradiation parameters before the exposure. This, in turn, makes possible checking the accuracy and reproducibility of the tube voltage, HVL, kerma linearity, etc. Moreover, UQCM allows exporting images for processing in a DICOM format, and this is essential to evaluate the physical characteristics of the DDR such as modular transfer function, noise power spectrum and detective quantum efficiency. In addition, access and the possibility to export the electronic documentation of system configuration allows the end user to monitor and analyze the exposure parameters and protocol settings. Strictly speaking, the availability of UQCM cannot be regarded as a qualitative criterion for acceptability of dynamic X-ray imaging systems. Instead, it should be considered as a performance criterion to be required in the procurement phase.

High-contrast resolution is the most sensitive to magnification, focal spot size and pixel size. The settings used for fluoroscopy, fluorography and cine modes are vastly different; therefore, different results are expected for the different modes. Similarly, low contrast detectability or threshold-contrast detail detectability is typically used more as an optimization test than as an acceptance test. Moreover, different methods coexist for its estimation and there is not a consensus on suspension levels. Therefore, the suspension levels related to these quantities, which were still reported in RP 162 although originating from EC (1997), were removed from the present report.

Qualitative criteria

The following are requirements in accordance with the BSSD supported by IEC (2002) and IEC (2022b).

- The use of fluoroscopy equipment without a device to automatically control the dose rate, or without an image intensifier or equivalent device, is prohibited (BSSD).
- Any equipment used for interventional radiology has a device or a feature informing the practitioner and those carrying out practical aspects of the medical procedures of quantity of radiation produced by the equipment during the procedure. Equipment installed prior to 6 February 2018 may be exempted from this requirement (BSSD).
- Any equipment used for interventional radiology has a device or a feature informing the practitioner, at the end of the procedure, of relevant parameters for assessing the patient dose (BSSD).
- The interventional X-ray equipment shall create radiation dose structured reports (RDSR) (IEC 2022b) as defined in IEC (2014a)



- Equipment used for interventional radiology has the capacity to transfer the information required in the previous point to the record of the examination. Equipment installed prior to 6 February 2018 may be exempted from this requirement (BSSD)
- Systems intended to include paediatric use shall have means to easily remove the anti-scatter grid without the use of tools (IEC 2022a, IEC 2022b).
- For interventional X-ray equipment, the selection of pulse rate must be independent from selection of the dose per pulse. (IEC2022b)

3.7.2 Suspensions levels for dynamic X ray imaging systems

The suspension levels for dynamic X-ray imaging imaging systems are provided in Table 14.



Table 14. Suspension levels for dynamic X ray imaging systems

Physical Parameter	Suspension Level	Reference	Type	Notes and Observations
Tube voltage				
Tube voltage accuracy	Deviation from set voltage >8%	IEC (2022a)	A	Under any combination of loading factors
X-ray tube output				
Magnitude of output (y) at 1 m	Y outside range of 25–80 µGy/mAs at 1 m from focal spot, 80 kV and total filtration of 2.5 mm Al	IAEA (2025b)	A	Nearest nominal tube voltage to 80 kV
Repeatability of output for a fixed setting	Coefficient of variation >5%	IAEA (2025b)	A	
Output linearity	The ratio mGy/mAs for any two adjacent stations $\geq \pm 10\%$	IAEA (2025b)	A	The two mAs settings differ by less than a factor of 2
First HVL and total filtration				
HVL or sufficient total filtration	See Table 6	IEC (2021a)	A	
Collimation				
Correspondence between the X-ray field and effective image reception area	Regardless the shape of the image reception area when the X-ray beams is perpendicular to the image receptor plane a) The X-ray field measured along a diameter in the direction of greatest misalignment with the image reception area extends beyond the boundary of the effective image reception area by more than 2 cm b) <80% of the area of the X-ray field shall overlap the effective image reception area	IEC (2024a)	A	For interventional X-ray equipment Effective image reception areas smaller than 10 cm in diameter are exempted
Dosimetric settings				
Range of air kerma rates in fluoroscopy	For radioscopy, the modes of operation provided for normal use shall include two modes, designated normal and low, respectively, producing different reference air kerma rates, such that the value for the low mode exceeds 50 % of the value for the normal mode.	IEC (2022b)	A	For interventional X-ray equipment



Patient entrance surface air kerma rate	normal mode ≥50 mGy/min High dose rate ≥100 mGy/min	IAEA (2025b)	A	With 20 cm PMMA
Limiting air kerma rate (fluoroscopy)	≥88 mGy/min for fluoroscopy normal mode ≥176 mGy/min for high-level control fluoroscopy	IAEA (2025b)	A	High level control fluoroscopy mode, ensuring the radiographic factors have reached maximum value
X-radiation pulse repetition frequency during radioscopy	If the radioscopy pulse rate is selectable minimum pulse rate is ≥4 pulse/s	IEC (2022a)	A	For interventional X-ray equipment
Accuracy of dose display				
Integrated "dose indicator" calibration (DAP/KAP meter accuracy)	Deviation of the measured and indicated values >35%	IEC (2022b)	A	35% accuracy only applies above 2.5 Gy·cm ² and 100 mGy and 6 mGy/min

3.7.3 Suspension levels for three-dimensional imaging systems

Both the AAPM (AAPM 2023a) and a joint EFOMP–IAEA–ESTRO working group (EFOMP 2021) have recently released quality control protocols for CBCT, including 3D rotational angiography. The present publication does not intend to introduce any new suspension level specifically linked to this modality, as this technology is probably too recent and there is currently no established consensus on this matter within the medical physics community (IAEA 2025b).

3.8 Computed tomography

3.8.1 Introductory remarks and qualitative criteria

Computed tomography is currently the major contributor to the collective population radiation dose both because it is a relatively high dose examination (BSS) and an increasing number of people are subjected to either a single computed-tomography examination (UNSCEAR 2019) or many times during their lifetime (Brambilla 2020). Thus monitoring of computed-tomography equipment is important in terms of both individual examinations and population effects. This can be particularly relevant when pregnant patients or children are involved.

Computed tomography has advanced significantly over the last decade. Key advances included the refinement of dual-energy computed tomography and the introduction of photon-counting computed tomography, which can be grouped under the name of multi-energy computed tomography. This technique offers the opportunity for advanced visualization, detection, and quantification of select elements, e.g., iodine or calcium, or materials, e.g., fat, beyond the capability of standard single-energy computed tomography. Other key advances include much faster scanning time and reduced radiation doses through iterative reconstruction techniques.

Qualitative criteria

The following are unacceptable equipment in accordance with the BSSD.



- Any computed tomography equipment that does not have a device or a feature informing the practitioner at the end of the procedure of relevant parameters for assessing the patient dose.
- Any computed-tomography equipment that does not have the capacity to transfer the information required in the previous point to the record of the examination. Equipment installed prior to 6 February 2018 may be exempted from this requirement.

Automatic exposure control

Automatic tube-current modulation (ATCM) is a computed-tomography technique that automatically tailors a system's radiation output to the specific body regions and parts being imaged in order to manage the radiation delivered to obtain the desired level of diagnostic quality.

ATCM is based on software algorithms that are validated during a computed-tomography scanner validation and manufacture and are not subject to wear or deterioration. In addition, because there are currently no widely used and accepted Phantoms for ATCM testing or established criteria for ATCM evaluation, ATCM was not considered in the required suspension levels.

Iterative reconstruction

Iterative reconstruction is a set of algorithms developed by medical imaging companies to improve image quality and reduce radiation dose. It is based on software algorithms that are validated during a computed-tomography scanner validation and manufacture and are not subject to wear or deterioration. Therefore, iterative reconstruction was not considered in the required suspension levels.

Low-contrast resolution

The evaluation of low-contrast resolution involves assessment of the minimum detectable size of an object, for a given low contrast value, and given radiation dose. This is a subjective task; different responses are likely for different observers. Additionally, because there are currently no widely used and accepted phantoms for low contrast resolution testing or established criteria for low contrast resolution evaluation, low contrast resolution was not included in the required suspension levels.

3.8.2 Suspension levels for computed tomography scanners

The suspension levels for computed tomography scanners are provided in Table 15.

Table 15. Suspension levels for computed tomography systems

Physical Parameter	Suspension Level	Reference	Type	Notes and Observations
Tube voltage accuracy	Deviation from set voltage >±5%	AAPM (2019a)	B	kV meter calibrated for CT



CTDI _{vol}	The calculated CTDI _{vol} values deviate by more than $\pm 20\%$ or ± 1 mGy, whichever is larger, from the CTDI _{vol} values displayed on the control panel.	IEC (2019b) IAEA (2012)	A	The CTDI _{vol} shall be evaluated for four test cases as follows: <ul style="list-style-type: none"> • Typical adult body CT • Typical adult head CT • Typical paediatric head CT • Typical paediatric body CT
CTDI free-in-air	The measured CTDI free-in-air values deviate $> \pm 20\%$ compared with manufacturer's specification	IEC (2019b) IAEA (2012)	A	The CTDI _{free-in-air} shall be evaluated for the test cases as follows: <ul style="list-style-type: none"> • All nominal beam collimations • All selectable tube potential settings • Typical adult head CT • Typical paediatric head CT • Typical paediatric body CT
Image noise	The measured value of the magnitude of the noise shall not deviate from the specified value in the accompanying documents by more than $\pm 15\%$ or ± 0.75 HU, whichever is larger.	IEC (2019b)	A	Two cylindrical phantoms containing a uniform medium, shall be used for image noise and CT number uniformity and accuracy: <ul style="list-style-type: none"> • A "small phantom," with an outside diameter of 16–20 cm and a total attenuation equivalent to at least 16 cm H₂O • A "large phantom," with an outside diameter of 30–35 cm and a total attenuation equivalent to at least 30 cm H₂O <p>The magnitude of the noise is measured by the standard deviation of the CT numbers in the central ROI</p>



CT number accuracy	<p>Maximum deviation in mean CT numbers in a water phantom is:</p> <ul style="list-style-type: none"> • >4 HU for adult head and all paediatric head and body protocols using the small phantom • >6 HU adult body protocols using the large phantom and using the small or large phantom with varied tube voltage • >6 HU paediatric body protocols using the small phantom with varied tube voltage 	IEC (2019b) IAEA (2012)	A	The CT number is measured by the mean of the CT numbers in the central ROI
CT number uniformity	<p>Maximum difference in mean CT numbers in a water phantom:</p> <ul style="list-style-type: none"> • >4 HU for adult head and all paediatric head and body protocols • >8 HU adult body protocols • >8 HU for paediatric body protocols with variation of tube voltage 	IEC (2019b)	A	<p>4 uniformity values shall be determined by calculating the absolute values of the difference between the mean CT number of the ROI in the central position and those in each of the four peripheral positions.</p> <p>The maximum of these four uniformity values shall be compared to the given specification</p>
Reconstructed section thickness	<p>Maximum difference between measured reconstructed slice thickness and nominal value:</p> <ul style="list-style-type: none"> • $>\pm 1.0$ mm for nominal slice thickness >2 mm • $>\pm 50\%$ for nominal slice thickness of 1–2 mm • $>\pm 0.5$ mm for sub-millimetre slices 	IEC (2019b) IAEA (2012) AAPM (2019a)	A	
Patient table indexing accuracy (actual table motion to gantry-displayed distance)	Deviation ± 1 mm	IEC (2019b) AAPM (2019a)	A	
CT alignment lights	$>\pm 5$ mm	IAEA (2012)	A	
Scan Projection Radiography (SPR) accuracy	$>\pm 2$ mm	IEC (2019b) IAEA (2012)	A	



High-contrast spatial resolution	The measurement of the 50% point and 10% point of the MTF curve shall not be ± 0.75 lp/cm or $\pm 15\%$ of the baseline values	IEC (2019b)	A	
Material density quantification accuracy	Iodine density: Absolute density error $\leq 20\%$ or ≤ 0.5 mg/mL, whichever is greater Calcium density: Density error $\leq 10\%$	AAPM (2024b)	B	For multi-energy CT

3.9 Dual-energy X ray absorptiometry

3.9.1 Introductory remarks and qualitative criteria

Dual-energy X-ray absorptiometry is a procedure that uses two different energy levels of X-rays to measure bone density in various anatomic sites, allowing for the diagnosis of osteoporosis and assessment of fracture risk. It is also used to perform whole body composition analysis by measuring fat, muscle and bone tissue in specific regions of the body and can track changes over time in response to treatments or lifestyle changes (Aparisi 2025).

3.9.2 Suspension levels for DXA systems

Table 16. Suspension levels for DXA systems

Physical Parameter	Suspension Level	Reference	Type	Notes and Observations
Entrance-air-kerma (in air value without adjustment to include backscatter)	Outside manufacturer's specification by $> 30\%$	Thomas (2022)	C	
Features of X-ray generator	Use Table 6 as appropriate			



Changes in BMD or area metrics	<p>DXA equipment should be suspended if any of the following are measured:</p> <ol style="list-style-type: none"> 1. A phantom BMD value differing from the established average value by more than three standard deviations (SD). 2. Two consecutive phantom BMD values differing from the established average value by more than two SD and on the same side of the average. 3. Two consecutive phantom BMD values differing by more than four SD. 4. Four consecutive phantom BMD values differing from the established average value by more than one SD and all are on the same side of the average. 5. Ten consecutive phantom BMD values falling on the same side of the average regardless of their distances from the average 	AAPM (2024b) Lewiecki (2016)	B	
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3.10 Dosimetry equipment

3.10.1 Introductory remarks and qualitative criteria

Dosimeters in diagnostic radiology are crucial for measuring radiation exposure, playing a key role in patient safety and quality assurance. Dosimeters help determine the radiation dose received by patients during procedures like X-rays, computed-tomography scans, and fluoroscopy. This is vital for optimizing imaging protocols and minimizing radiation risks. Dosimeters allow assessing the performance of X-ray equipment and ensure that it is delivering consistent and accurate radiation output. This helps maintain image quality and minimizes unnecessary radiation exposure. Various types of dosimeters are used in diagnostic radiology, including ionization chambers and semiconductor detectors. Reference class kerma-area product meters, according to the definition of IEC (2019a), are used to test the accuracy and calibration of radiation output indicators integrated in the radiological equipment. Therefore, suspension levels are provided in this section while the corresponding suspension levels for field class KAP meters are provided in the respective sections 3.1 for general radiography and 3.7 for dynamic X-ray equipment.



3.10.2 Suspension levels for dosimeters used in X-ray diagnostic imaging

The suspension levels for dosimeters used in X-ray diagnostic imaging systems are provided in Table 17.

Table 17. Suspension levels for dosimeters used in X-ray diagnostic imaging

Physical Parameter	Suspension Level	Reference	Type	Notes and Observations
Energy dependency of response	>5%	IEC (2024b)	A	Over a range of reference radiation qualities defined in IEC 61267
Linearity of air kerma rate	$(R_{max}-R_{min})/(R_{max}+R_{min}) > \pm 2\%$	IEC (2024b)	A	Over the whole rated range of air kerma rate; measurements made at air kerma rates in steps not greater than one order of magnitude.
Stabilization time	$\Delta = \text{ABS}[R(15\text{min})-R(1\text{h})]/R(1\text{h}) > 2\%$	IEC (2024b)		R is measured 15 min after switching on the instrument and after 1 h (steady state)
Repeatability of air kerma in the attenuated beam	CV>1%	IEC (2024b)	A	with $K \geq 10 \mu\text{Gy}$
Repeatability of air kerma rate in the attenuated beam	CV>3%	IEC (2024b)	A	with $K_{\text{rate}} \geq 1 \mu\text{Gy/s}$
Repeatability of air kerma in the primary beam and in mammography	CV>1%	IEC (2024b)	A	with $K \geq 1000 \mu\text{Gy}$
Repeatability of air kerma rate in the primary beam and in mammography	CV>3%	IEC (2024b)	A	with $K_{\text{rate}} \geq 100 \mu\text{Gy/s}$
Repeatability of air kerma length product in the primary and in the attenuated beam	CV>1%	IEC (2024b)	A	Approximately 50% of the rated length should be irradiated
Resolution	>1%	IEC (2024b)	A	Resolution represents the smallest significant change in the dosimeter indication, within the whole effective range of indicated values
Long-term stability	Limits of variation of response $> \pm 2\%$ per year	IEC (2024b)	A	Detector assembly is irradiated in a reproducible field
DAP/KAP meter accuracy	Accuracy $> \pm 15\%$	IEC (2019a)	A	Reference class dose area product meters



DAP/KAP Linearity	$(R_{\max} - R_{\min}) / (R_{\max} + R_{\min}) \geq 0.05$	IEC (2019a)	A	The response resulting from the minimum to the maximum rated dose-area product rate, with measurements made at dose area product rates in steps not greater than one order of magnitude.
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4. Nuclear Medicine

4.1 Introduction

Innovations in nuclear medicine in the last decade focused on enhancing diagnostic precision through advanced imaging technologies like solid-state gamma camera, digital PET-CT and hybrid PET-MRI. The development of higher-resolution and more sensitive imaging instruments is increasing the ability to detect and quantify diseases faster and more accurately.

Another area of development is related to theranostics, an innovative approach to nuclear medicine, especially in oncology, that uniquely combines the diagnosis and treatment of a disease. It uses radiopharmaceuticals that bind to specific molecular targets on diseased cells, allowing for tumour visualization (diagnosis) and, almost simultaneously, the administration of therapeutic radiation to destroy it, all with great precision and minimal effects on healthy tissue. If the equipment is used for modern image-based dosimetry studies before, during and after radionuclide therapy, particular criteria of acceptability are needed concerning the accuracy of quantification.

The objective of this section is to specify the suspension levels for the equipment used in Nuclear Medicine procedures. It sets out criteria for acceptability for radionuclide calibrators, well counters and probes, gamma cameras, SPECT and PET systems. Differently from radiology and radiotherapy, IEC standards related to nuclear medicine do not set standards for the criteria of acceptability of medical radiological equipment. Therefore type A criteria are only based on IAEA publications, while most of the suspension levels are of type B or C.

Although the quality assurance of radiopharmaceuticals is an important process, it is not an objective of this report. Neither is the in-house production of radiopharmaceuticals, often established in connections with PET installations, utilising either self-shielded cyclotrons or cyclotrons in specially designed bunkers. This activity is regarded as a radiopharmaceutical manufacturing activity and therefore also outside the scope of this document.

For all imaging modalities, important qualitative criteria apply, i.e., visual inspection for artefacts. Equipment must be suspended if artefacts are expected to have an impact on clinical diagnosis.

4.2 Radionuclide calibrators

4.2.1 Introductory remarks

Radionuclide calibrators, also referred as activity meters, are well-type ionisation chambers that provide direct activity readout for syringes and vials. Acceptance testing follows the (IEC 1994) performance standard that specifies how to characterise intrinsic precision, linearity and accuracy. Routine tests, including background, constancy, linearity, geometry and high-voltage stability, are described in (IEC 2019c). Accuracy should be verified using at least two long-lived, traceable reference sources (AAPM 2012). The results should agree with the certified values within the combined measurement uncertainty. Because a well-type chamber's response depends on container shape and volume, geometry dependence must be established for all clinically used syringes and vials; site-specific correction factors should be derived when necessary. Dial settings or calibration factors should be checked periodically against national metrology recommendations, e.g., (NPL 2006 and Bergeron 2018), for clinically used nuclides such



as ^{99m}Tc , ^{18}F , ^{68}Ga , ^{177}Lu and ^{90}Y . Where IEC and IAEA publications primarily describe test methods, the numerical thresholds below follow guidance from professional societies (AAPM 2012) or national metrology institutes (NPL 2006). The suspension levels defined in this section apply to commonly used clinical radionuclides measured in standard reference geometries. Extension to all possible radionuclide–geometry combinations is neither practical nor intended and is addressed through acceptance testing and routine quality assurance.

The qualitative criteria for radionuclide calibrators are set out in the box below.

- Equipment damaged or showing self-test failure that compromises safety, e.g., cracked liner, loose shielding and unstable readout
- Equipment where background count rate increases significantly above baseline, e.g., >20% of normal background or trending beyond statistical control limits, indicating contamination or shielding fault

4.2.2 Suspension levels for radionuclide calibrators

Table 18. Suspension levels for radionuclide calibrators

Physical Parameter	Suspension Level	Reference	Type	Notes and Observations
Accuracy	$\pm 5\%$	IAEA (2006) AAPM (2012)	A	Measured with at least two traceable reference sources of activity >3.7 MBq The activity value of 3.7 MBq is indicated as an order of magnitude to ensure adequate counting statistics during performance testing. Lower activities may be used, provided that equivalent measurement uncertainty and repeatability can be demonstrated
Reproducibility	CV>1%	IAEA (2006) AAPM (2012) NPL (2006)	A	At least 10 measures with test source of activity >3.7 MBq. Please see row above
Linearity	Measurements outside $\pm 5\%$ of the expected values	IAEA (2006) AAPM (2012) NPL (2006)	A	Using the decaying source method or the shield method, or the graded source method



Constancy (daily test)	Measurements outside $\pm 5\%$ of the decay-correct initial values	AAPM (2012)	B	With a long-lived test source such as ^{57}Co , ^{133}Ba , ^{137}Cs or ^{68}Ge . If a standard source is used rather than a test source, the measurement obtained on the setting for the source radionuclide can also serve as an accuracy test
Geometry dependence	Non-correctable geometry bias (e.g., difference $>5\%$ between clinically used containers)	IAEA (2006)	A	New calibration factors must be determined when effect of geometry is $>5\%$

The suspension levels given in Table 18 are for instruments used for the measurement of the activity of gamma emitting sources with energies above 100 keV. If these instruments are calibrated to measure isotopes emitting low gamma ray energies (below 100 keV) or beta or alpha emitting sources special measures need to be taken in order to overcome vial and geometry dependent readings. This could be achieved, e.g. by measuring a calibrated source in various vials and geometries for setting up individual calibration factors. In these cases, the suspension levels in Table 18 might be exceeded

4.3 Well counters and probes

4.3.1 Introductory remarks

Well counters are NaI(Tl) well detectors used for highly sensitive in-vitro counting of patient samples and standards. Routine tests per IEC (2016a) include background, energy calibration (peaking), constancy, count-rate performance and verification of counting statistics (χ^2 test). Efficiency (counts per second, cps per Bq) should be established at installation and checked at least annually with traceable sources. Count-rate behaviour should be checked over the expected clinical range to assess dead-time losses. Energy resolution, expressed as a percent of the full width at half maximum (FWHM), is tracked against the acceptance baseline or manufacturer specification.

Parameters such as cross-calibration factors, absolute sensitivity and count-rate performance are routinely assessed during acceptance testing and quality assurance. As they are not uniformly defined as suspension levels in international standards, they are not included as absolute criteria for acceptability.

Non-imaging counting probes includes organ uptake probes, e.g., thyroid uptake systems, and intraoperative gamma probes. These probes use NaI(Tl) or similar scintillation detectors with collimators, connected to portable counting systems. Routine tests (IEC 2016a) include background count rate, energy peaking, constancy, and for uptake systems sensitivity verification against an independent activity standard. Mechanical integrity and collimation should be verified regularly because damage directly affects sensitivity and angular response. As in the previous sections, (IEC 2016a) and (IAEA 1991) define the test methods for probes.

The qualitative criteria for well-counters and probes are set out in the box below.



- Energy peaking. Equipment unable to peak to nominal photo peak or outside manufacturer-specified peaking tolerance
- Energy resolution. Significant degradation of FWHM compared with acceptance baseline and outside manufacturer specification
- Background count rate. Equipment where background count rate increases significantly above baseline, e.g., >20% of normal background or trending beyond statistical control limits, indicating contamination or shielding fault

4.3.2 Suspension levels for well-counters and probes

Table 19. Suspension levels for well-counters and probes

Physical Parameter	Suspension Level	Reference	Type	Notes and Observations
Constancy (daily)	Deviation exceeds $\pm 10\%$ from baseline after re-peaking and retesting	EANM (2017) Zanzonico (2008)	B	Long-lived radionuclides such as ^{57}Co , ^{68}Ge and ^{137}Cs can be used as reference sources for well-counter constancy determination
Short-term reproducibility (χ^2 test) ⁴	χ^2 test fails the 95% confidence criterion on two successive days	IAEA (1991)	A	For radionuclide calibrators

4.4 Gamma camera systems

4.4.1 Introductory remarks

The conventional gamma camera is currently available in a number of configurations capable of not only performing planar imaging (section 4.4.2) but also whole-body imaging (section 4.4.3) and SPECT (section 4.4.4). SPECT technology has evolved significantly over the past decade, with major advances including the following.

- Solid-state cadmium-zincum-telluride (CZT) detectors were initially introduced in dedicated systems such as cardiac CZT cameras and have more recently been integrated into general-purpose cameras with specific gantry designs that enable 3D SPECT acquisitions
- The integration of computed tomography used for attenuation correction or diagnostic purposes
- The development of advanced reconstruction algorithms, improving image quality and quantitative accuracy
- The implementation of absolute quantification with the fast development of new ^{177}Lu therapies, enabling improved therapy monitoring and dosimetry
- There is no single universal 'standard' for quality control in SPECT; instead, a framework of guidelines and protocols from organizations such as the AAPM, IAEA, National Electrical Manufacturers Association (NEMA) and EANM is used to ensure instrument performance and data accuracy. In addition, there are a number of publications on SPECT absolute quantification that provide a wealth of useful

⁴ Short-term reproducibility reflects detector and electronics stability, and failure of the χ^2 test on successive days indicates systematic instability that may compromise quantitative reliability.



background material and detailed accounts of test methods to calibrate the SPECT cameras

4.4.2 Suspension levels for gamma cameras used for planar scintigraphy

Gamma cameras are operated with collimators appropriate to the study being performed. Tests performed with collimators mounted are termed 'system' tests. Tests performed without collimators are 'intrinsic' tests. Since there is a large range of different types of collimators in use and their characteristics vary from type to type and from manufacturer to manufacturer, the MPE should be closely involved when deciding on system tests for a particular collimator. It is important to perform system non-uniformity tests on all collimators in clinical use in order to detect collimator damage. Suspension levels for key performance parameters are given in Table 20.

Table 20. Suspension levels for gamma cameras used for planar scintigraphy

Physical Parameter	Suspension Level	Reference	Type	Notes and Observations
Intrinsic energy resolution	>11%	AAPM (2019b)	B	For ^{99m} Tc
Intrinsic/system flood field uniformity	>5%	AAPM (2019b)	B	For 5 million count floods over the UFOV
Intrinsic spatial resolution	>4 mm FWHM	AAPM (2019b)	B	For ^{99m} Tc
System spatial resolution	>8 mm FWHM at 10 cm	AAPM (2019b)	B	For ^{99m} Tc with LEHR parallel hole collimator – without scatter
System planar sensitivity	>10% deviation from the manufacturer's specification	IAEA (2009)	A	
Detector to detector sensitivity variation (system with multiple detectors)	>5% for a pair of detectors	AAPM (2019b)	B	For each detector per radionuclide and collimator combination

4.4.3 Suspension levels for gamma cameras used for whole-body imaging

The NEMA Standard NU-1 2018 (NEMA 2018) contains an additional test for whole-body systems. Before performing this test, it is advisable that the basic tests for the planar gamma camera are performed for each detector head. A suspension level for a key performance parameter is given in Table 21.

Table 21. Additional suspension levels for gamma cameras used for whole-body imaging

Physical Parameter	Suspension Level	Reference	Type	Notes and Observations
Whole-body spatial resolution without scatter	Degradation >10% of the planar spatial resolution	AAPM (2019b)	B	

4.4.4 Suspension levels for gamma cameras used for SPECT imaging

The basic tests for planar gamma-camera systems should be performed on each detector head used for SPECT before proceeding with tests specific to SPECT. It has also been noted that suspension levels defined for SPECT imaging can be applied to 3D solid-state



CZT cameras. With respect to the computed tomography component of SPECT-CT systems, many of the criteria of acceptability are the same as those prevailing for computed-tomography systems, employed in diagnostic radiology. Suspension levels for key performance parameters are given in Table 22.

Table 22. Additional suspension levels for gamma cameras used for SPECT imaging

Physical Parameter	Suspension Level	Reference	Type	Notes and Observations
SPECT spatial resolution	Reconstructed FWHM >10% of the planar spatial resolution or >2 mm, whichever is less	IAEA (2009)	A	
Centre of rotation (CoR) and detector head tilt	Offset >1 pixel	EC (2012)	C	Pixel size as in clinically used protocols
SPECT-CT image registration	Mean deviation along any axis >5 mm	AAPM (2019b)	B	

4.4.5 Suspension levels for gamma cameras used for SPECT quantitative imaging

A prerequisite for scanner calibration is a robust measurement of activity in a radionuclide calibrator. Activities must be traceable to national and international standards. International guidelines recommend accuracies of 5–10% for diagnostic and 5% for therapeutic radionuclides.

We recommend evaluating the radioactivity concentration calibration for all SPECT radionuclides used in imaging and for which absolute quantification is applied in clinical routine.

Table 23. Additional suspension levels for gamma cameras used for SPECT quantitative imaging

Physical Parameter	Suspension Level	Reference	Type	Notes and Observations
Radioactivity concentration calibration	Deviation from known activity concentration >10%	Tran-Gia (2019) Danieli (2023) D'Arienzo (2016) Uribe (2017)	C	For all radionuclides with absolute quantification used in clinical routine; scan of a uniform phantom

4.5 Positron emission tomography

4.5.1 Introductory remarks

Positron emission tomography is a nuclear medicine imaging technique that utilizes positron-emitting radionuclides, normally produced in a cyclotron or radionuclide generator. PET is based on the coincidence detection of two oppositely directed 511 keV photons emitted from the annihilation of a positron with an electron. The detection of such events is used for the reconstruction of an image describing the in vivo distribution of a positron emitting radiopharmaceutical. The most frequent clinical indication for a PET study today is in the diagnosis, staging, and monitoring of malignant diseases as well as



other indications including assessment of neurological and cardiological disorders. It is expected that the utilization of PET will continue to increase significantly in the future.

The PET technology has evolved rapidly in the past decade with the following technological advances greatly improving the accuracy of PET imaging.

- The introduction of time-of-flight PET to improve image quality by measuring the time difference in detection of the two photons generated by positron annihilation. Use of this information localizes the event more precisely along the line of response, improving signal-to-noise and lesion detectability, especially in larger patients
- The use of digital PET detectors, typically based on silicon photomultipliers, to provide higher sensitivity and allow for better timing resolution, which is critical for time-of-flight PET
- The combination of a PET with a computed tomography or MRI scanner such that only hybrid PET-CT or PET-MR scanners are commercially available. The suspension levels for the individual modalities are valid for the combined modalities as well. The suspension level specifically related to this combination regards uniquely image registration between the two systems
- The extension of the axial PET detector coverage to more than 1 m such that these long-axial field-of-view PET scanners can detect much more photons, thus enabling ultra-fast, ultra-low-dose and dynamic whole-body PET imaging.
- There is no single, universal standard for quantification in PET; instead, a framework of guidelines and protocols from organizations like the IAEA, NEMA, AAPM and EANM is used to ensure instrument performance and data accuracy. These guidelines cover equipment calibration, specific quantitative methods like standardized uptake value, and procedures for quality assurance and control to address factors that limit quantitative reliability in PET imaging.

4.5.2 Suspension levels for PET systems

Table 24. Suspension levels for PET systems

Physical Parameter	Suspension Level	Reference	Type	Notes and Observations
Radioactivity concentration calibration	Deviation from known activity concentration >10%	EANM (2023) EFOMP (2023b) FANC (2020)	B	For all radionuclides used; scan of a uniform phantom using a multi-bed scan protocol when appropriate
Uniformity	Non-uniformity >10%	EANM (2023) EFOMP (2023b) FANC (2020)	B	Scan of a uniform phantom using a multi-bed acquisition protocol when appropriate; check both uniformity within slice and across slices
Image registration	>1 PET voxel size	AAPM (2019c)	B	Clinically used PET voxel size



Contrast recovery	NEMA IEC phantom spheres		Maximum voxel-based CRC range for ^{18}F		EANM/SNMMI/ARTNet (2025)	B	<p>Recommended maximum voxel-based CRC acceptability range (contrast 1:8) for PET scanner with PSF reconstruction (Sunderland 2025).</p> <p>In case of scanner without PSF reconstruction use the table for RCs 1 published at https://earl.eanm.org/accreditation-specifications/</p>
	Diameter (mm)	Volume (mL)	min	max			
	37	26.52	1.06	1.33			
	28	11.49	1.01	1.30			
	22	5.57	1.01	1.37			
	17	2.57	1.00	1.43			
	13	1.15	0.83	1.25			
	10	0.52	0.45	0.86			



5. Radiotherapy

5.1 Introduction

The purpose of this section is to list performance parameters and their tolerances for radiotherapy equipment, namely linear accelerators, computed-tomography simulators, kilovoltage units, particle therapy systems, brachytherapy, treatment planning systems and dosimetry equipment. Specific reference is not made to safety requirements, but these need to be checked at acceptance and after maintenance and upgrades and would result in suspension of the equipment during operation if not met.

These mechanical, dosimetrical and safety performance tolerances reflect the need for precision in radiotherapy and the knowledge of what can be reliably achieved with radiotherapy equipment.

Suspension levels are expressed in the same format with the same measurement uncertainties as originally given in the quoted standards and guidance documents. All test equipment used in measuring functional performance must be well maintained, regularly calibrated and traceable (where appropriate) to national or international standards laboratories. For radiotherapy equipment not mentioned in this section the suspension levels should be applied accordingly.

5.2 Linear accelerators

5.2.1 Introductory remarks

The publication (IEC 2020c) is the standard which identifies those features of design that are regarded as essential for the safe operation of the equipment and places limits on the degradation of the performance beyond which a fault condition exists. These include protection against electrical and mechanical hazards and unwanted and excessive radiation hazards, i.e., dose monitoring systems, selection and display of treatment related parameters, leakage radiation and stray radiation.

On the other hand, (IEC 2007), which is also being revised, is the performance standard related to (IEC 2020c). The technical report (IEC 2008b) provides proposed values for the functional performance characteristics described IEC (2007). The former (IEC 2007) specifies test methods and reporting formats for performance tests of medical electron accelerators for use in radiotherapy, with the aim of providing uniform methods of doing so. The latter (IEC 2008b) is not a standard but suggests values measured by the methods specified in IEC (2007) that are achievable with present technology.

The values given in Tables 26–29 are a summary of the tolerance values in (IEC 2008b) and are based on the methodology in (IEC 2007). These values are broadly consistent with the tolerances specified in (IPEM 1999), (AAPM 1994), (CAPCA 2005a), (AAPM 2009), (AAPM 2017a), (COMP 2018a), (COMP 2018b), (AAPM 2021a) and (AAPM 2023b). For a detailed description of test methods, conditions, and applicability, please refer to the IEC, IPEM, AAPM and COMP documents. A list of suggested test equipment is included in (IEC 2008b). The Tables are intended to include the performance parameters of all treatment devices incorporating a linear accelerator. Where tests are performed routinely for quality control, suggested frequencies of testing are given in (IEC 2008b), (IPEM 1999), (AAPM 1994), (CAPCA 2005a), (AAPM 2009), (AAPM 2017a), (COMP 2018a), (COMP 2018b), (AAPM 2021a), (AAPM 2021b), (AAPM 2023b) and other national quality-assurance protocols or standards. (AAPM 2009), (AAPM 2017a), (COMP 2018a), (COMP



2018b), (AAPM 2021a), (AAPM 2021b) and (AAPM 2023b) have detailed quality assurance recommendations for devices not covered in (AAPM 1994).

Megavoltage imaging and cone beam computed tomography are covered in their own subsection (5.2.3.1 and 5.2.3.2). Stereotactic radiotherapy, covered in subsection 5.2.3.3, with its definitions summarized in (ESTRO 2025), requires more stringent suspension levels and dedicated tests routinely performed for quality control and suggested frequencies of testing are given in (IEC 2008b), (IPEM 1999), (IAEA 2017), (AAPM 2017b), (DGMP 2020) and (AAPM 2025a) as well as (COMP 2018c), (COMP 2018d), (AAPM 2011) and (AAPM 2025b) for the most used stereotactic radiotherapy-dedicated devices.

In the subsections 5.2.3 and in tables 25–27, 'IEC' refers to (IEC 2007) and (IEC 2008b), and the numbers in the Reference column refer to the clauses in these publications.

Tables 25–28 is a limited summary of the tolerance values in these publications and greater detail is contained in the publications. 'See IEC' in the tables indicates that greater detail concerning the tolerances, e.g., dependence on field size, is contained in the IEC documents. Hybrid systems, e.g., MR- or PET-guided linear accelerators, are not specifically covered in this report due to lack of dedicated tolerance values for these systems at the time.

5.2.2 Suspension levels for linear accelerators

Table 25. Suspension levels for linear accelerators

Physical Parameter	Suspension Level	Reference ⁵	Type
Dose monitoring system		7	
Weekly calibration check	>2.0%		A
Reproducibility	>0.5%		A
Proportionality	>2.0%		A
Dependence on angular position of gantry and beam limiting device	>2.0%		A
Dependence on gantry rotation	>2.0% – electron radiation >2.0% – X radiation		A
Stability throughout the day	>2.0%		A
Uniformity of radiation fields		9	
<u>X radiation</u>			
Flatness of square X-ray fields with flattening filter (max/min ratio)	>1.06		A
Symmetry of square X-ray fields (max/min ratio)	>1.03		A
<u>Wedge fields</u>			
Maximum deviation of wedge factor with all angular positions of the gantry and beam limiting system	2.0%		A
Maximum deviation of wedge angle	2.0°		A
<u>Multileaf collimators</u>			

⁵ (IEC 2007 and 2008b), clause numbers unless another reference is cited



Leaf transmission	>2.0%	COMP (2018b)	B
Dosimetric leaf gap (Varian systems)	>0.3 mm	COMP (2018b)	B
Leaf position accuracy	>0.5 mm	AAPM (2023b)	B
Sliding window/VMAT holistic test	>2.0 mm	AAPM (2023b)	B
<u>Electron radiation</u>			
Maximum deviation of dose distribution of electron fields with angular position	3.0%		A
Symmetry of electron fields (max/min ratio)	>1.05		A
Maximum ratio of absorbed dose (max/min ratio)	1.09		A
Maximum deviation of dose distribution of electron fields with angular position	3.0%		A
Depth dose characteristics		8	
<u>X radiation</u>			
Penetrative quality	>3.0% or 3.0 mm		A
Depth dose and profiles	>2.0% relative to baseline	AAPM (2023b)	B
<u>Electron radiation</u>			
Minimum depth of dose maximum	>1.0 mm		A
Ratio of practical range at 80% absorbed dose	>1.6		A
Deviation of actual value of penetrative quality	>3.0 % or 2.0 mm		A
Maximum relative surface dose	100 %		A
Stability of penetrative quality	>1.0 % or 2.0 mm		A
Indication of radiation fields		10	
<u>X radiation</u>			
Numerical field indication	>3.0 mm or 1.5%		A
For MLCs	>3.0 mm or 1.50%		A
Light field indication	>2.0 mm or 1.0%		A
Maximum distance between the centres of radiation and light fields	2.0 mm		A
Maximum distance between the centres of radiation and light fields for MLCs	2.0 mm		A
Reproducibility	>2.0 mm		A
<u>Electron radiation</u>			
Light field indication	>2.0 mm		A
<u>Geometry of adjustable BLDs</u>			
Maximum angular deviation from parallelism of opposing edges	0.5°		A
Maximum angular deviation from orthogonality of adjacent edges	0.5°		A



Maximum displacement of the radiation field from symmetry when rotating the beam limiting system	2.0 mm		A
Illuminance and penumbra of the light field			
Illuminance (minimum)	25 lux		A
Edge contrast ratio (minimum)	4.0		A
Indication of the radiation beam axis		11	
<u>On entry</u>			
X-rays	>2.0 mm		A
Electrons	>4.0 mm		A
<u>On exit</u>			
X-rays	>3.0 mm		A
Isocentre		12	
Maximum displacement of radiation beam axis from isocentre	2.0 mm		A
Mechanical isocentre	>2.0 mm	COMP (2018b)	B
Indication of the isocentre	>2.0 mm		A
Maximum displacement of radiation beam axis from isocentre	2.0 mm		A
Indication of distance along the radiation beam axis		13	
Maximum difference for isocentric equipment	2.0 mm		A
Maximum difference for non-isocentric equipment	5.0 mm		A
Zero position of rotational scales		14	
Gantry rotation	>0.5°		A
Roll and pitch of radiation head	>0.1°		A
Rotation of beam limiting system	>0.5°		A
Isocentric rotation of the patient support	>0.5°		A
Table top rotation, pitch and roll	>0.5°		A
Accuracy of rotation scales	>0.5°	AAPM (2023b)	B
Congruence of opposed radiation fields		15	A
Movement of patient support		16	
Vertical movements	>2.0 mm		A
Longitudinal and lateral movements	>2.0 mm	AAPM (2023b)	B
Isocentric rotation axis	>2.0 mm		A
Parallelism of rotational axes	>0.5°		A
Longitudinal rigidity	>5.0 mm		A
Lateral rigidity	>0.5° and 5.0 mm		A



5.2.3 Suspension levels for systems and methods connected with linear accelerators

Table 26. Suspension levels for megavoltage imaging systems

Physical Parameter	Suspension Level	Reference	Type
Electronic imaging devices		IEC 2007 and 2008b, clause 17	
Minimum detector frame time	0.5 s		A
Corresponding maximum frame rate	2 / s		A
Minimum signal-to-noise ratio	50		A
Maximum imager lag			
Second to first frame	5.0%		A
Or fifth to first frame	0.3%		A
Minimum spatial resolution	0.6 lp/mm		A

Table 27. Suspension levels for CBCT systems

Physical Parameter	Suspension Level	Reference	Type
Maximum difference for isocentric equipment	2.0 mm	IEC (2007, 2008b), clause 13	A
kV/MV/laser alignment	>2.0 mm	COMP (2018a)	B
Image quality: high-contrast resolution	>2.0 mm	COMP (2018a)	B

In table 28 stereotactic radiosurgery (SRS) refers to intracranial single fraction stereotactic radiotherapy, while fractionated stereotactic radiotherapy (FSRT) refers to intracranial multi-fraction stereotactic radiotherapy and stereotactic body radiotherapy (SBRT) refers to any fraction extracranial stereotactic radiotherapy (ESTRO 2025).

Table 28. Suspension levels for stereotactic radiotherapy systems

Physical Parameter	Suspension Level	Reference	Type
Small field dosimetry			
Beam profile and output constancy	>2.0% from baseline	AAPM (2025a)	B
Relative output factors for >1.0 cm apertures	>2.0% from TPS	AAPM (2025a)	B
Relative output factors for ≤1.0 cm apertures	>5.0% from TPS	AAPM (2025a)	B
Indication of radiation fields			
Maximum distance between the centres of radiation and light fields for SRS	0.5 mm	IEC (2007, 2008b), clause numbers 10	A
Maximum distance between the centres of radiation and light fields for FSRT/SBRT	1.0 mm	AAPM (2025a)	B
Alignment of a stereotactic frame for SRS	>0.5 mm	IEC (2007, 2008b), clause number 10	A



Indication of the radiation beam axis			
<u>On entry</u>			
SRS	>0.5 mm	IEC (2007, 2008b), clause number 11	A
FSRT/SBRT	>1.0 mm	AAPM (2025a)	B
<u>On exit</u>			
SRS	>0.5 mm	IEC (2007, 2008b), clause number 11	A
FSRT/SBRT	>1.0 mm	AAPM (2025a)	B
Isocentre			
Indication of the isocentre for SRS	>0.5 mm	IPEM (2019)	B
Indication of the isocentre for FSRT/SBRT	>1.0 mm	AAPM (2025a)	B
Coincidence of radiation and mechanical isocentre	>1.0 mm	AAPM (2025a)	B
Radiation isocentricity test for SRS (3D displacement)	>1.0 mm	AAPM (2025a)	B
Radiation isocentricity test for FSRT/SBRT (3D displacement)	>1.5 mm	AAPM (2025a)	B
Treatment couch			
Indication of the couch position (relative over the maximum clinical range)	>1.0 mm or >0.5°	AAPM (2025a)	B
Couch positioning accuracy for SRS (absolute)	>1.0 mm	AAPM (2025a)	B
Couch positioning accuracy for FSRT/SBRT (absolute)	>2.0 mm	AAPM (2025a)	B
Surface guidance systems			
Reproducibility of localization	>1.0 mm after stabilizing	AAPM (2025a)	B
Drift over time	>2.0 mm over 1 h	AAPM (2025a)	B
End-to-end test for complete treatment chain, including planning imaging and additional linear accelerator equipment			
Maximum 3D displacement for SRS	1.00 mm	AAPM (2025a)	B
Maximum 3D displacement for FSRT/SBRT in static delivery mode using non-moving phantoms	1.25 mm	DGMP (2020)	B
Maximum 3D displacement for SBRT with passive or active motion compensation in moving phantoms	1.50 mm	DGMP (2020)	B
Gamma knife			
Timer check on dual timer difference	>1.0 s	IPEM (2019)	B
Timer linearity	>1.0%	AAPM (2025b)	B
Stability of timer	> 0.01 min	IEC (2008b)	A
Shutter correction	>2.0%	IPEM (2019)	B
CyberKnife			
Iris collimator field size verification	>0.5 mm	COMP(2018b)	B



MLC Leaf position test	>5% deviations with >0.5 mm	COMP(2018b)	B
MLC leaf transmission	>1.0%	COMP(2018b)	B
Imager alignment center	>1.0 mm	COMP(2018b)	B
Second order path calibration	RMS >0.50 mm	AAPM (2025b)	B

5.3 Computed tomography simulators

5.3.1 Introductory remarks

Computed tomography simulators usually comprise a wide-bore computed tomography scanner, together with an external patient positioning and marking mechanism using projected laser lines to indicate the treatment isocentre. This is often termed 'virtual simulation.' Quality assurance of the scanner and alignment system is essential to ensure that the isocentre is accurately located in the treatment volume for subsequent treatment planning and treatment, the computed tomography image is not spatially distorted, and the Hounsfield numbers are accurate for attenuation corrections. The established standards for computed-tomography scanners (See section 3.8) for good image quality and optimum patient radiation dose apply. Quality assurance regimes are therefore based upon good clinical practice. The most recent works are (AAPM 2003b), (IAEA 2012) and (COMP 2017). The tolerance limits in these reports are designed to satisfy the accuracy requirements for conformal radiotherapy and have been shown to be achievable in a routine clinical setting. Further guidance is contained in IPEM Report 81 published in 1999 (IPEM 1999). The guidance in Table 29 is based on these three reports. (IPEM 1999) suggests that the tests are done under the same scanning conditions as those used clinically. Checks on image quality should also be done after software upgrades in case they affect the calibration of the Hounsfield units.

5.3.2 Suspension levels for computed tomography simulators

Table 29. Suspension levels for computed tomography simulators

Physical Parameter	Suspension Level	Reference	Type
Alignment of computed-tomography gantry lasers			
With centre of the imaging plan	>2.0 mm	AAPM (2003)	B
Parallel & orthogonal over length of laser projection	>2.0 mm	AAPM (2003)	B
Alignment of wall lasers			
Distance to scan plane	>2.0 mm	AAPM (2003)	B
With imaging plane over length of laser projection	>2.0 mm	IPEM (1999)	B
Alignment of ceiling laser			
Orthogonal with imaging plane	>2.0 mm	AAPM (2003)	B
Orientation of scanner table top			
Orthogonal to imaging plane	>2.0 mm	AAPM (2003)	B
Scales and movements			
Readout of longitudinal position of table top	>1.0 mm	IAEA (2012)	A
Table top indexing under scanner control	>2.0 mm	IAEA (2012)	A
Gantry tilt	>1.0° from vertical	IAEA (2012)	A
Scan position			
Scan position from pilot images	>1.0 mm	IPEM (1999)	B



Image quality			
Left & right registration	None	IPEM (1999)	B
Image scaling	>2.0 mm	IPEM (1999)	B
CT number/electron density verification	> 20 HU (all materials)	IAEA (2012)	A
Motion (4D CT)			
Amplitude of moving target(s)	>2.0 mm	COMP (2016)	B
Spatial integrity and positioning of moving target(s) at each 4D respiratory phase	>2.0 mm (from baseline)	COMP (2016)	B
4D-CT intensity projection image reconstruction	>2.0 mm (from baseline)	COMP (2016)	B

5.4 Kilovoltage units

5.4.1 Introductory remarks

The publication (IEC 2015b) is the standard which identifies those features of design that are regarded as essential for the safe operation of the equipment and places limits on the degradation of the performance beyond which a fault condition exists. These include protection against electrical and mechanical hazards and unwanted and excessive radiation hazards. Tests are based upon (IPEM 1999), which is based on a survey of UK practice in 1991. Where recommendations from other bodies are adopted, they are indicated in Table 30. For a detailed description of test methods and conditions, please refer to (IPEM 1999) and (CAPCA 2005b). This section does not cover the use of X-ray tubes with point-source field characteristic or for intraoperative radiotherapy.

5.4.2 Suspension levels for kilovoltage units

Table 30. Suspension levels for kilovoltage units

Physical Parameter	Suspension Level	Reference	Type
Output calibration	>3.0%	IPEM (1999)	B
Monitor chamber linearity (if present)	>2.0%	IPEM (1999)	B
Timer end error	>0.01 min	IPEM (1999)	B
Timer accuracy	>2.0%	IPEM (1999)	B
Coincidence of light and X-ray beams	>5.0 mm	CAPCA (2005b)	B
Field uniformity	>5.0%	IPEM (1999)	B
HVL constancy	>10.0%	IPEM (1999)	B
Measurement of HVL	>10.0%	IPEM (1999)	B
Applicator output factors	>3.0%	IPEM (1999)	B

5.5 Particle therapy

5.5.1 Introductory remarks

The publication RP 162 lacked a dedicated section to particle therapy, although at that time there were particle therapy facilities in operation. Presently, particle therapy is recognized as a well-established therapeutic option in the radiotherapy field, and the number of installations of machines able to provide particle therapy treatments is continuously growing. In the last 10–15 years there have been a number of major developments in particle therapy medical equipment, both for what concerns delivery techniques and machine design, and further developments are ongoing.



The publication (IEC 2017) outlines testing methodologies and disclosure protocols for the performance of light ion equipment utilized in radiotherapy. This standard facilitates direct performance comparison among equipment from various manufacturers. Its publication followed (IEC 2014a), which describes several concepts relevant to (IEC 2017).

The publication (IEC 2014a) indeed sets the requirements for manufacturers regarding the design and construction of light ion beam equipment for radiotherapy applications. It does not, however, define optimal performance criteria. Its primary objective is to identify essential design features for the safe operation of such equipment and to establish thresholds for performance degradation. Exceeding these thresholds is presumed to indicate a fault condition, triggering an interlock to prevent continued operation. Clause 201.10 in particular specifies limits beyond which interlocks activate to prevent, interrupt, or terminate irradiation, thereby ensuring essential performance and preventing unsafe conditions. Both type tests, conducted by the manufacturer or an accredited laboratory, and site tests, not necessarily conducted by the manufacturer, are specified for each requirement. It is important to note that a manufacturer can only provide a compliance certificate related to type tests prior to installation. Data obtained from site tests should be integrated into the accompanying documentation, typically as a site test report, by those responsible for equipment testing during installation.

The values given in Table 31 are a summary of the tolerance values in (IEC 2014a) and are based on the methodology reported in (IEC 2017). These values are consistent with the ones present in the subsequent publications from scientific societies, e.g., AAPM, and available in literature. For a detailed description of test methods, conditions and applicability, and verification frequencies, please refer to the IEC and AAPM documents. A list of suggested test equipment is included in (IEC 2017).

Table 31 is intended to include the performance parameters of the treatment devices incorporating a medical light ion treatment machine.

5.5.2 Suspension levels for particle therapy accelerators

The suspension levels for particle therapy equipment are provided in Table 31, regarding all the three delivery techniques currently in use, i.e., pencil beam scanning, uniform scanning and passive scattering delivery modes.

Table 31. Suspension levels for particle therapy accelerators

Physical Parameter	Suspension Level	Reference	Type	Notes and Observations
Beam delivery				
<u>Energy</u>				
Method of selection of energy per nucleon or light ion beam range	Depth dose >10% or 0.25 Gy, whichever is greater from the intended depth dose or range >1 mm from the intended range	IEC (2014b)	A	If these conditions are not met irradiation shall be terminated before an additional dose of 0.25 Gy is delivered
Range verification	Deviation > 1mm	AAPM (2019d)	B	Tolerance valid for scattering, uniform scanning and pencil beam scanning
<u>Gantry</u>				
Gantry angle readout	>0.5°	IEC (2014b)	A	



Gantry isocentricity	>2 mm	AAPM (2019d)	B	
Gantry angle accuracy	>1°	AAPM (2019d)	A	
Gantry X-ray isocentricity	>2 mm	AAPM (2019d)	B	
Emergency interruption during rotation	>5°	IEC (2014b)	A	
Snout extension accuracy	>10 mm	AAPM (2019d)	B	
Snout rotational accuracy	>1°	AAPM (2019d)	B	
Compensator placement accuracy	>2 mm	AAPM (2019d)	B	
<u>Leakage radiation</u>				
Leakage of light ions through BLDs	>0.75% of the delivered dose on the central axis and >2% at any point in the patient (See IEC)	IEC (2014b)	A	It does not apply to radiation heads that do not use beam limiting devices
Non primary radiation outside the projection of the radiation field	In the patient plane, off axis between 150 and 500 mm beyond the irradiated field: <ul style="list-style-type: none"> >0.5% of the dose delivered at the equipment reference point on the central axis of the field In the patient plane, off axis between 500 and 2000 mm beyond the irradiated field: <ul style="list-style-type: none"> >0.1% of the dose delivered at the equipment reference point on the central axis of the field 	IEC (2014b)	A	
Neutron non-primary radiation outside the projection of the radiation field	>0.08% of the dose delivered at the equipment reference point on the central axis of the field	IEC (2014b)	A	
Non primary radiation outside the patient plane	>0.5% of the dose at the equipment reference point	IEC (2014b)	A	
Non primary radiation under fault conditions	>0.25 Gy of additional absorbed dose outside of the projection of the radiation field in the plane containing the equipment reference point	IEC (2014b)	A	
Emission of ionizing radiation after termination of irradiation due to induced radioactivity	H*(10)>10 μSv at any readily accessible place 5 cm from the surface of the enclosure or >1 μSv at	IEC (2014b)	A	H*(10) is accumulated over a period of 5 minutes



	1 m from the surface of the enclosure. Alternatively, an ambient dose rate >200 µSv/h at any readily accessible place 5 cm from the surface of the enclosure or >20 µSv/h at 1 m from the surface of the enclosure			
Dose monitoring system				
Reproducibility of MU delivery	>2%	AAPM (2019d)	B	
Proportionality of MU delivery	>1%	AAPM (2019d)	B	
Dependence of MU delivery on angular position	>2%	AAPM (2019d)	B	
Output constancy	Deviation >2% (relative to baseline) Deviation >3% (relative to one consistent field)	AAPM (2019d)	B	
Standard output calibration	>2%	AAPM (2019d)	B	
Dose monitoring systems common elements	Failure of any common element that could change the radiation response of either dose monitoring system by more than 5% shall stop irradiation	IEC (2014b)	A	
Monitoring of absorbed dose distribution	>10% of the intended dose value or >0.25 Gy, whichever is greater	IEC (2014b)	A	
Termination of irradiation by dose monitoring system	>110% of the intended dose value	IEC (2014b)	A	
Independent termination system	>120% of the intended dose or an additional dose of 0.5 Gy, whichever is greater	IEC (2014b)	A	The independent termination method shall be analysed through a risk management process



Dose monitor unit rate	<p>If, under any fault conditions, the light ion beam equipment can deliver a dose monitor unit rate of more than twice the maximum specified value, means shall be provided to terminate irradiation when the dose monitor unit rate exceeds a value of not more than twice the maximum specified.</p> <p>If, under any fault conditions, the light ion beam equipment can deliver a dose monitor unit rate of more than ten times the maximum specified value, the dose monitor unit rate monitoring system shall limit the excess absorbed dose at any point in the radiation field to <4 Gy. The value of the excess absorbed dose shall be given in the technical description.</p>	IEC (2014b)	A	
Depth dose characteristics				
Range uniformity	>0.5 mm	AAPM (2019d)	B	Corresponding to depth of 90% dose at points off axis. Tolerance from baseline
Depth dose verification	>2%	AAPM (2019d)	B	Tolerance valid both for scattering and uniform scanning delivery modes
Spread-out Bragg peak width	>2%/2 mm	AAPM (2019d)	B	Tolerance valid both for scattering and uniform scanning delivery modes
Lateral profiles of light ion portals				
Spot position	Deviation (absolute) >1 mm Deviation (relative) >0.5 mm	AAPM (2019d)	B	Tolerance valid for scanning delivery modes. See AAPM 2019d for details about tolerances for checks on different time scales, e.g., daily vs. annual
Spot size	Deviation >10%	AAPM (2019d)	B	Tolerance valid for pencil beam scanning delivery mode. Test to be performed at different gantry angles



Flatness of light ion portals	Deviation >2%	AAPM (2019d)	B	Test to be performed at different gantry angles
Symmetry of light ion portals	Deviation >1% (>2% for uniform scanning depending on the machine model)	AAPM (2019d)	B	Test to be performed at different gantry angles
Lateral profile penumbra	>2 mm	AAPM (2019d)	B	
Lateral profiles of light ion portals for systems that use modulated scanning	>2 mm	AAPM (2019d)	B	
Indication of radiation fields				
X-ray isocentre vs. laser isocentre	>2 mm	AAPM (2019d)	B	
Imaging and treatment coordinate coincidence	>2 mm	AAPM (2019d)	B	See table III of AAPM (2019d)
Mechanical Coincidence of particle and X-ray fields	>1 mm	AAPM (2019d)	B	See table IV of AAPM (2019d)
Coincidence of particle and light field	>1 mm	AAPM (2019d)	B	If light field is used for setup
Applicator carriage extension indicator	>10 mm	AAPM (2019d)	B	
Patient support				
Overshoot for linear and rotational movements	>5 mm (linear) >2° (rotational)	IEC (2014b)	A	For automatic set-up and for the checks of pre-programmed movements before treatment
Speed for rotational movements	>1°/s (minimum speed available) >7°/s (maximum speed. Unless the manufacturer's risks management document identifies it as an acceptable risk)	IEC (2014b)	A	See IEC
Speed for linear movements	>10 mm/s (minimum speed available) >100 mm/s (maximum speed. Unless the manufacturer's risks management document identifies it as an acceptable risk)	IEC (2014b)	A	See IEC
Isocentric rotation of the patient support	>2 mm	AAPM (2019a)	B	Also known as couch isocentricity
Accuracy of patient support translational motions	>1 mm	AAPM (2019a)	B	Applies to all axes



Accuracy of patient support rotational motions	>1°	AAPM (2019a)	B	
Emergency interruption – rotational displacement	>5°	IEC (2014b)	A	
Emergency interruption – linear displacement	>10 mm	IEC (2014b)	A	

5.5.3 Suspension levels for systems connected with particle therapy accelerators

Both planar and volumetric imaging systems using kilovoltage play a crucial role in particle therapy through image-guided radiotherapy (IGRT). The recommendations, including tolerances, valid for IGRT systems used in radiotherapy holds and applies to IGRT system used in particle therapy, as reported by (AAPM 2019d) and (AAPM 2020b). More information on kilovoltage radiographic systems performances can be found in section 2. (IEC 2014c) and recent update address such IGRT systems. In general, evaluating the IGRT systems' geometric accuracy relative to the particle beam is fundamental.

For stereo X-ray imaging, refer to what has been described in the dedicated sections 5.2.2 for linear accelerators, 3.3.2 for digital X-ray imaging detectors and 3.2.2 for X-ray generators. As a general consideration, the suspension level concerning the maximum difference for isocentric stereo X-ray imaging systems serving a radiation therapy machine should be set at 2 mm in accordance with (IEC 2008b), as reported in Table 25.

For CBCT using linear accelerators, refer to what has been described in the dedicated section 5.2.3.2. The tolerance requested for CBCT isocentricity, as reported in (AAPM 2019), is set to 2 mm.

5.6 Brachytherapy

5.6.1 Introductory remarks

For brachytherapy, many standards are described in (IEC 2013), (IAEA 2023b) and several GEC-ESTRO guidelines. These identify those features of design that are regarded as essential for the safe operation of the equipment and place limits on the degradation of the performance beyond which a fault condition exists. Important issues are dosimetry of low-dose-rate (LDR) and high-dose-rate (HDR) photon-emitting sources, and other parameters are related to the remote after loading device.

The suspension levels given in Table 32 are based on the performance tolerance values in the (ESTRO 2004), (IAEA 2023b), (GEC-ESTRO 2019), (GEC-ESTRO 2020) and (GEC-ESTRO 2022) guidelines and the (COMP 2018e) report. For a detailed description of test methods and conditions, refer to the documents above. Brachytherapy has greatly developed in the past years. Several add-on systems have been designed and used in the clinics. For ultrasound systems in combination with stepping devices, mostly used in LDR and HDR prostate brachytherapy treatment, (GEC-ESTRO 2020) recommendations were published, including tolerance tables, and are listed in table 32.

Brachytherapy treatment planning systems are covered as well but are shown in section 5.7 of treatment planning systems of this report. A quite new device is the moveable



CBCT for brachytherapy. To find tolerances for CBCT in radiotherapy, please refer to Table 27 of this report.

No clear quality control guidelines exist for electronic brachytherapy sources. Some models are on the market, but the quality control and suspension levels are often unclear and manufacturer specific, so they are not considered here. Also for brachytherapy beta sources or in-vivo dosimetry systems, no clear quality control guidelines exist.

5.6.2 Suspension levels for brachytherapy units

The suspension levels for particle therapy equipment are provided in Table 32.

Table 32. Suspension levels for brachytherapy units

Physical Parameter	Suspension Level	Reference	Type
Source calibration			
Single source (HDR)	>3%	GEC-ESTRO (2022)	B
Mean of batch (LDR permanent implant)	>5%	IAEA (2023b) GEC-ESTRO (2019)	A
Individual sources (LDR temporary implant)	>5%	GEC-ESTRO (2019)	B
Source position	>2 mm	IAEA (2023b)	A
Controlling timer	>1% or 100 ms, whichever is greater	IEC (2013)	A
Transfer tubes and applicator length	>1 mm	ESTRO (2004) COMP (2018e)	B
Ultrasound system and stepping device			
Scaling	>1 mm	GEC-ESTRO (2020)	B
Volume	>5%	GEC-ESTRO (2020)	B
Offset for biplane probe	>1 mm	GEC-ESTRO (2020)	B
Stepping device	>1 mm (longitudinal) or 0.5% (rotational)	GEC-ESTRO (2020)	B

5.7 Treatment planning systems

5.7.1 Introductory remarks

The report (IEC 2001) is the standard that identifies those features of design for radiotherapy treatment planning systems (RTPSs) that are regarded as essential for the safe operation of the equipment. It states:

The output of a RTPS is used by appropriately qualified persons as important information in radiotherapy treatment planning. Inaccuracies in the input data [Note: This includes image information], the limitations of the algorithms, errors in the treatment planning process, or improper use of output data, may represent a safety hazard to patients should the resulting data be used for treatment purposes.

It is principally a software application for medical purposes and a device that is used to calculate the dose distribution in the patient for a proposed radiotherapy treatment. Workstations attached to RTPSs for volume definition shall be of high quality. The user shall be made aware of any software change that has the potential to alter the dose calculation or distribution.



The report (IAEA 2004) is a comprehensive guideline to the procedures to be used for the quality assurance of modern RTPSs. The accuracy requirements for commissioning of external-beam RTPSs is published in (AAPM 2015). IMRT and VMAT commissioning and RTPS performance should lead to the accuracy requirements published in (AAPM 2018). For SRS and SBRT treatments RTPSs should lead to the accuracy requirements stipulated in (AAPM 2025a).

Brachytherapy RTPS requirements are based on (GEC-ESTRO 2025) guidelines for commissioning and quality assurance of TG-43-based brachytherapy treatment planning systems. Particle-therapy RTPS requirements are described in (AAPM 2020b), the report of Task Group 185 on clinical commissioning of intensity-modulated proton therapy systems.

5.7.2 Suspension levels for treatment planning systems

The suspension levels for treatment planning systems are provided in Table 33 and are based on a comparison of measurements and treatment planning system data. It is important to stress that treatment planning system performance strongly depends on beam modelling and the commissioning process.

Table 33. Suspension levels for treatment planning systems

Physical Parameter	Suspension Level	Reference	Type	Notes and Observations
Homogeneous phantom (H₂O) tests for square and rectangular photon beams				
Output at reference condition at calibration point	>0.5%	AAPM (2015) AAPM (2019e)	B	
PDD (for the range of field sizes)	>2%	AAPM (2015) AAPM (2019e)	B	
Output factors (for the range of field sizes)	>2%	AAPM (2015) AAPM (2019e)	B	
Beam profiles (for the range of field sizes)	>2%	AAPM (2015) AAPM (2019e)	B	
Distance to agreement difference in penumbra of beam profiles	>2 mm	IAEA (2004) AAPM (2019e)	A	
Complex geometry tests for photon beams				
One complex geometry condition (dose difference)	>2%	AAPM (2015) AAPM (2019e)	B	
Combination of two or more complex geometry conditions (dose difference)	>5%	AAPM (2015)	B	
Combination of two or more complex geometry conditions (distance to agreement difference)	>3 mm	AAPM (2015)	B	
Outside the field edge (up to 5 cm)	>3% of max dose	AAPM (2015)	B	



Heterogeneous medium tests for photon beams				
Dose on CAX distal to lung tissue	>3%	AAPM (2015)	B	Field size 5×5 cm ² , measure and calculate dose ratio above and below heterogeneity, outside of build-up area
IMRT/VMAT tests for photon beams				
Range of clinical cases (gamma pass rate for 3% G, 2 mm criteria, threshold 10%)	<90%	AAPM (2018)	B	
External end-to-end audit	>5%	AAPM (2015)	B	
SRS/SBRT tests for photon beams				
Range of clinical cases (gamma pass rate for 5% G, 1 mm criteria, threshold 10%)	<95%	NCS (2018)	B	
Range of clinical cases (gamma pass rate for 3% G, 1 mm criteria, threshold 10%)	<90%	AAPM (2015)	B	
MLC transmission	>5%	AAPM (2015)	B	
External end-to-end audit	>5%	AAPM (2015)	B	
Tests for electron beams				
Standard applicators on standard or extended SSD (homogeneous phantom)	>3%, 3 mm	AAPM (2015)	B	
Reference applicator oblique incidence on standard SSD (homogeneous phantom)	>5%	AAPM (2015)	B	
Reference applicator on standard SSD (heterogeneous phantom)	>7%	AAPM (2015)	B	
Tests for brachytherapy (based on TG43 formalism)				
Distance between known reference points	>1 mm (CT) >2 mm (MRI) >1 mm (US)	GEC-ESTRO (2025)	B	
Volumes from physical and numerical phantoms	>5%	GEC-ESTRO (2025)	B	
Difference of reference dose rate vs along-away table	>2%	GEC-ESTRO, (2025)	B	



Source half-life and decay for permanent sources	>1%	GEC-ESTRO, (2025)	B	
DVH calculation ⁶	>2%	GEC-ESTRO, (2025)	B	Isotropic source: isodose volume vs mathematical volume of sphere (seed), Anisotropic source: volume of cylindrical isodose volume (multiple sources), Anisotropic source: isodose to structure conversion
Applicator visibility for tip reconstruction	>2 mm	GEC-ESTRO (2025)	B	
Tests for proton therapy beams				
Difference in the spot fluence profile sigma values	>5%	AAPM (2020b)	B	
CT number to Relative Linear Stopping Power conversion (near water like materials)	±2%	AAPM (2020b)	B	
Agreement for uniform field in homogeneous media	2%, 2 mm >98% of point	AAPM (2020b)	B	
Test for IMPT fields	3%, 3 mm >95% of point	AAPM (2020b)	B	

5.8 Dosimetry equipment

5.8.1 Introductory remarks

The quality assurance of dosimetry equipment used for quality control and commissioning of treatment machines is described in (IEC 2016b). For a detailed description of test methods and conditions, please refer to this document.

The international standard (IEC 2016b) divides dosimeters into three classes.

1. Field-class dosimeter: dosimeter whose performance and stability are sufficient for it to be used to make ordinary routine measurements
2. Reference-class dosimeter: dosimeter whose performance and stability are sufficient for it to be used to calibrate other dosimeters
3. Scanning-class dosimeter: dosimeter whose performance and stability are sufficient for it to be used to measure relative dose distributions in connection with a scanning system.

⁶ Complex geometry includes the combination of the following conditions: presence of wedges, small MLC-shaped field, asymmetrical field at minimal anticipated SSD, off-axis MLC-shaped field with maximum-allowed MLC over travel, field with extensive blocking and oblique incidence.



Since all beam-scanning phantom vendors specify their electrometers to be at least field-class dosimeters, scanning-class dosimeters are combined with field-class, and the requirements for the latter apply to both.

5.8.2 Suspension levels for dosimetry equipment used in radiotherapy

The suspension levels for dosimetry equipment used in radiotherapy are provided in Table 34. No detector arrays or other detector types are included.

Table 34. Suspension levels for dosimetry equipment

Physical Parameter	Suspension Level	Reference	Type	Notes and Observations
Field-class air-filled ionisation chamber				
Leakage current	±0.5%	IEC (2016b)	A	Of ionization current produced by minimum rated or effective dose rate
Post-irradiation leakage	±1.0%	IEC (2016b)	A	Within 5 s after the end of a 10 min irradiation
Long-term stability	±1.0%	IEC (2016b)	A	Of response per year for ⁶⁰ Co, ⁹⁰ Sr or ¹³⁷ Cs gamma radiation
Accumulated dose stability	±1.0%	IEC (2016b)	A	Of response per 10 ⁴ Gy for any radiation quality in the rated range.
Measurement assembly				
Repeatability	±0.5%	IEC (2016b)	A	Relative standard deviation at minimum effective indicated value
Long-term stability	±1.0%	IEC (2016b)	A	Of response per year to input charge or current in the rated or effective range
Response time	<3 s	IEC (2016b)	A	
Reference-class air-filled ionisation chamber				
Leakage current	±0.5%	IEC (2016b)	A	Of ionization current produced by minimum rated or effective dose rate.
Post-irradiation leakage	±0.5%	IEC (2016b)	A	Within 5 s after the end of a 10 min irradiation
Long-term stability	±0.5%	IEC (2016b)	A	Of response per year for ⁶⁰ Co, ⁹⁰ Sr or ¹³⁷ Cs gamma radiation
Accumulated dose stability	±1.0%	IEC (2016b)	A	Of response per 10 ⁴ Gy for any radiation quality in the rated range.
Measurement assembly				
Resolution	±0.25%	IEC (2016b)	A	Of minimum effective reading



Repeatability	±0.25%	IEC (2016b)	A	Relative standard deviation at minimum effective indicated value
Long-term stability	±0.5%	IEC (2016b)	A	Of response per year to input charge or current in the rated or effective range.
Zero drift – dosimeter	±0.5%	IEC (2016b)	A	Of rate of change of indicated value produced by minimum rated input current.
Non-linearity – dosimeter	±0.5%	IEC (2016b)	A	Of response at 0.5 full reading on each range
Response time	<3 s	IEC (2016b)	A	

Physical Parameter	Suspension Level	Reference	Type	Notes and Observations
Limits of variation				
Post-irradiation leakage	±1.0%	IEC (2016b)	A	
Polarity of polarizing voltage	1.0%	IEC (2016b)	A	
Ionic recombination	1.0%	AAPM (2020b)	B	
Cylindrical ionisation chamber				
Energy dependence (70–250 kV X-ray)	±2.0%	IEC (2016b)	A	
Energy dependence (250 kV X-ray, ⁶⁰ Co)	±1.0%	IEC (2016b)	A	
Energy dependence (25 MV X-ray, ⁶⁰ Co)	±2.0%	IEC (2016b)	A	
Energy dependence (100–450 MeV/u light ion beams)	±2.0%	IEC (2016b)	A	
Angular dependence – rotation	±0.5%	IEC (2016b)	A	
Angular dependence – tilt	±1.0%	IEC (2016b)	A	
Plate-parallel ionisation chamber				
Energy dependence (12–70 kV X-ray)	±2.0%	IEC (2016b)	A	
Energy dependence (5–25 MeV electron beams)	±2.0%	IEC (2016b)	A	
Energy dependence (50–250 MeV proton beams)	±2.0%	IEC (2016b)	A	
Energy dependence (100–450 MeV/u light ion beams)	±2.0%	IEC (2016b)	A	
Angular dependence - tilt	±1.0%	IEC (2016b)	A	By tilting the chamber by 5°



Physical Parameter	Suspension Level	Reference	Type
Field-class measuring assembly			
Repeatability	±0.5%	IEC (2016b)	A
Long-term stability	±1.0%	IEC (2016b)	A
<u>Dosimeter</u>			
Zero drift	±1.0%	IEC (2016b)	A
Non-linearity	±0.5%	IEC (2016b)	A
Dead time	±0.5%	IEC (2016b)	A
Dose rate dependence	±0.5%	IEC (2016b)	A
<u>Battery-operated measuring assemblies</u>			
Battery condition	±0.5%	IEC (2016b)	A
<u>Mains-operated measuring assemblies</u>			
Mains voltage (Variation)	±0.5%	IEC (2016b)	A
Reference-class measuring assembly			
Repeatability	±0.25%	IEC (2016b)	A
Long-term stability	±0.5%	IEC (2016b)	A
<u>Dosimeter</u>			
Zero drift	±0.5%	IEC (2016b)	A
Non-linearity	±0.5%	IEC (2016b)	A
Dose rate dependence	±0.5%	IEC (2016b)	A
<u>Battery-operated measuring assemblies</u>			
Battery condition	±0.5%	IEC (2016b)	A
<u>Mains-operated measuring assemblies</u>			
Mains voltage (variation)	±0.5%	IEC (2016b)	A

Physical Parameter	Suspension Level	Reference	Type
Beam scanning system positioning accuracy	<1 mm	AAPM (2020b)	B
Barometer accuracy	>0.1 kPa	IPEM 1999	B
Thermometer calibration	>0.5°C	IPEM 1999	B
Detectors used for small photon field output determination should have a correction factor	<5%	IAEA (2017)	A



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