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RADIATION PROTECTION N° 162

Criteria for Acceptability of Medical Radiological Equipment used in Diagnostic Radiology, Nuclear Medicine and Radiotherapy

Directorate-General for Energy
Directorate D — Nuclear Safety & Fuel Cycle
Unit D4 — Radiation Protection
2012

This report was prepared by Quality Assurance Reference Centre for the European Commission under contract N°. ENER/10/NUCL/SI2.581655 and represents those organisations' views on the subject matter. The views and opinions expressed herein do not necessarily state or reflect those of the European Commission and should not be relied upon as a statement of the Commission's views. The European Commission does not guarantee the accuracy of the data included in this report, nor does it accept responsibility for any use made thereof.

Luxembourg: Publications Office of the European Union, 2012

ISBN 978-92-79-27747-4
doi: 10.2768/22561

Printed in Luxembourg

FOREWORD

Luxembourg, October 2012

The work of the European Commission in the field of radiation protection is governed by the Euratom Treaty and the secondary legislation adopted under it. Council Directive 97/43/Euratom (the Medical Exposure Directive, MED) is the legal act defining the Euratom requirements on radiation protection of patients and of other individuals submitted to medical exposure.

The MED requires the adoption of criteria of acceptability for equipment in order to indicate when remedial action is necessary (including, if appropriate, taking the equipment out of service).

In 1997 the Commission issued publication Radiation Protection 91 (RP91) containing a non-binding set of criteria for acceptability of radiological installations. Later Commission guidance on transposition of the MED into national legislation notes that RP91 "gives only the absolute minimum requirements" and that "holders of installations should make effort(s) to adopt more stringent criteria."

The present report (RP162) updates and considerably expands the scope of RP91. The recommended approach to the establishment and the use of criteria for acceptability of radiological equipment, as well as the technical parameters and values contained in the document, have been extensively reviewed and discussed between 2007 and 2012. This was done in many technical meetings involving specialists in different areas, through an open public consultation from January to June 2010 and in a dedicated workshop held in Dublin in September 2011. The final result is a quite extensive set of *non-binding* criteria that will help holders of radiological installations assess the (continuing) acceptability of the equipment they use and undertake appropriate remedial action, if indicated.

The report should also be useful for regulators when deciding on the adoption of national criteria for acceptability of radiological equipment. However, *the Commission* ***does not recommend*** *the direct adoption of the RP162 suspension levels in national regulations*, as this may pose unnecessarily stringent limitations on the use of equipment. The adoption of regulatory restrictions on equipment use should be based on careful and thorough evaluation of national circumstances. Hence, RP162 should be used by regulators only as an example of criteria to be considered.

While primarily intended for holders of radiological equipment in clinical use and for regulators dealing with safety of such equipment, this report could also be useful for wider audiences. These include designers, manufacturers and suppliers of equipment as well as other players involved in different stages of the equipment lifecycle.

The publication of this report in the Commission's Radiation Protection series of publications has been recommended by the Group of Experts established under Article 31 of the Euratom Treaty. It is our hope that it will contribute to a continuous improvement of the protection of the health of the European citizens against the risks accompanying the growing and generally beneficial use of ionising radiation in medicine.

Augustin Janssens
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CONTENTS

1 INTRODUCTION

This report provides a compendium of criteria which radiological, nuclear medicine and radiotherapy equipment in normal use ought to be able to pass. The most common form of criterion is a "suspension level" for a measurement of a performance or safety parameter. Failure to meet a suspension level will establish that the operation of the equipment involved is sufficiently poor to raise an alarm indicating action is required. The assessment up to this point will generally be a matter for the holder[1]. The equipment failing to meet the suspension level will have to be repaired, temporarily suspended from clinical service, designated usable for limited purposes, or completely suspended from service. This will have serious consequences for the practitioner(s) involved and for hospital/clinic management, particularly if the equipment has to be suspended or replaced.

Sets of suspension criteria for particular equipment types are provided with advice on the way they should be used. Particular emphasis is placed on the roles of the medical physics expert, the medical practitioner and the holder of the equipment who is generally represented by the management of the institution involved. The importance of the practitioner and the holder/management is considered further in sections 1.3, 1.7, 1.8 and 1.9. Regulators will also have an interest in both the suspension levels and their application.

The report provides about 347 suspension levels across all the types of radiological equipment. This may appear to be a large number, but it must be remembered they are applied across about 30 equipment types. In practice, except at the beginning and end of the life of equipment, a full set of suspension levels is unlikely to be used. Generally testing against criteria for acceptability is triggered by evidence that something is wrong. This may be, for example, deterioration in a quality assurance measure or an aspect of clinical performance. The response to such an event will normally be limited to testing against the criteria relating to the area of concern. The report presents a compendium of such criteria to be selected from, rather than a list to be followed slavishly. At the beginning of the life of equipment acceptance testing may well establish that most if not all of the suspension levels are met without the need for further testing. Similar considerations may apply when refurbished or second hand equipment is brought back into clinical use. Thus, in practice actions will be determined from testing against a limited number of the criteria.

1.1 Background and purpose

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 MED Directive (Council Directive 97/43/EURATOM (1997). Specifically the MED requires that medical exposures be justified and optimised. Optimisation includes satisfactory performance of the equipment used. To help give effect to this, the Directive stipulates that ***criteria of acceptability*** for radiological, nuclear medicine and radiotherapy equipment shall be adopted by Member States (see section 1.2 below)[2]. In 1997, the European Commission published Radiation Protection 91, proposing specific criteria for acceptability (RP 91, EC(1997b))[3] to help

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1 The holder is defined for the purpose of the MED (see page 9) as any natural or legal person who has the legal responsibility under national law for a given radiological installation (Council Directive 97/43/EURATOM (1997)), EC (1999)).

2 The terms ***Criteria of Acceptability*** and ***Criteria for Acceptability*** are both used in this report. ***Criteria of ----*** is used when specific reference is made to the MED in which it is employed. ***Criteria for*** ----- is generally used otherwise, as it was the title of RP 91 and is the form widely used in practice.

3 Herein after referred to as RP 91.

implement this requirement. Equipment performance not meeting the minimum standards specified in RP 91 is regarded as unacceptable. This publication has been used as guidance by individual professionals, particularly MPEs, and has also been incorporated into guidance or legislation throughout the Member States and elsewhere in the world. The criteria for acceptability apply to new equipment and to installed equipment, regardless of age. This revised report is intended to meet the objectives set out in the box.

Objectives of RP-162

1. Update existing criteria for acceptability.
2. Update and extend criteria for acceptability to new types of installations. In diagnostic radiology, the range of systems available has been greatly extended (e.g. computed radiography, digital radiography, digital fluoroscopy, multislice computed tomography (MSCT) and dual energy X-ray absorptiometry (DXA)). In nuclear medicine there are now positron emission tomography (PET) systems and combined modalities. In radiotherapy, there are linear accelerators with multileaf collimators.
3. Identify an updated and more explicit range of methods to better assess the criteria for acceptability.
4. Provide criteria for acceptability that are achievable throughout the Member States.
5. 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.
6. Deal, where practical, with the implications for screening techniques, paediatric examinations, high dose examinations and other special issues noted in the MED.
7. Promote approaches that are, as far as possible, consistent with those employed by the Medical Devices Directive (MDD) (Council Directive 93/42/EC (1993)), industry, standards organizations and professional bodies.

RP 91 considered diagnostic radiological installations including conventional and computed tomography, dental radiography and 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 are upheld. To give effect to this, the Commission, on the advice of the Article 31 Group of Experts, initiated a study aimed at reviewing and updating RP 91, which has led to this revised report. As with RP 91, this report is designed to ensure patient safety and efficacious diagnosis or treatment. Staff safety issues are not addressed here and are comprehensively addressed in the European Basic Safety Standards (BSS) (Council Directive (1996)) and its associated publications.

To achieve the objectives of RP 162, the development and review process has involved a wide range of individuals and organizations, including experts from relevant professions, professional bodies, industry, standards organizations and international organizations. It was easier to achieve the last objective (item 7 in the box) with radiotherapy than with diagnostic radiology. This is because of a long tradition of close working relationships between radiotherapy physics and the international standards organisations, which has facilitated the development and adoption of common standards in radiotherapy. An attempt

has been made, with the cooperation of the International Electrotechnical Commission (IEC), to parallel this approach in diagnostic radiology and to extend it, where it already exists, in nuclear medicine.

The *criteria for acceptability* developed generally fall into two categories, *qualitative and quantitative* (Table 1-1). Qualitative prohibitions 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 MED, the law or widely accepted norms of good practice. Methodology.

Table 1-1 Two Categories of Criteria for Acceptability

Category	Features
Qualitative Criteria	Qualitative prohibitions of some equipment types or features (e.g. direct fluoroscopy is not allowed by the MED).
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 suspension levels which must be met are provided. If these are not met, the equipment must be suspended from use and the poor performance must be investigated. The equipment may be returned to use following remedial action. Alternatively its clinical use may be restricted or terminated after a risk assessment, if satisfactory performance cannot be restored. The processes involved are more fully presented in sections 1.4 to 1.9.

It is important to bear in mind that the present report follows the precedent established in RP 91 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, and wider issues such as those associated with, for example, the requirements for suitable buildings/installations and information technology (IT) systems, such as picture archiving and communication systems (PACS), displays, radiological information systems (RIS) and radiotherapy networks.

1.2 Basis for criteria for acceptability in the European directives

1.2.1 Requirements of the Medical Exposure Directive (MED)

The work of the EC in the field of radiation protection is governed by the Euratom Treaty and the Council Directives made under it. The most prominent is the BSS for the protection of radiation workers and the public. This was originally adopted in 1959. The current version, Council Directive (1996), is presently being revised. Radiation protection of persons undergoing medical examination or treatment was first addressed in Council Directive 84/466/EURATOM. This was replaced by MED (Council Directive 97/43/EURATOM (1997))[4]. This prescribes a number of measures to ensure that medical exposures are delivered under appropriate conditions. It requires, among other things:

[4] Council Directives (1996) and the MED, Council Directive 97/43/EURATOM (1997), are at the time of writing, being incorporated into a single "recast" Directive which draws together the various European Radiation

- acceptance testing of new equipment,
- identification of criteria of acceptability for equipment safety and performance throughout its life, and
- establishment of quality assurance programmes.

This report addresses the second of these, criteria of acceptability, and updates RP 91, which addressed the same area (EC (1997)). However, some overlapping and confusion between these three areas above has arisen and this is addressed in sections 1.4 and 1.5 below.

The MED requires that all radiation doses arising from medical exposure of patients for diagnosis or health screening programmes shall be kept as low as reasonably achievable consistent with obtaining the required diagnostic information, taking into account economic and social factors (ALARA). Requirements in respect of dose monitoring systems are specified explicitly. These extend to all new equipment which: "shall have, where practicable, a device informing the practitioner of the quantity of radiation produced by the equipment during the radiological procedure."

Additionally Article 9 requires that: "Appropriate radiological equipment ----- and ancillary equipment are used for the medical exposure

- of children,
- as part of a health-screening programme,
- involving high doses to the patient, such as interventional radiology, computed tomography or radiotherapy."

and that: "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 8, for these practices."

The requirements in respect of ***criteria of acceptability*** are stated specifically in Article 8 as follows: "Competent authorities shall take steps to ensure that necessary measures are taken by the holder of the radiological installation to improve inadequate or defective features of the equipment. They shall also adopt specific **criteria of acceptability** for equipment in order to indicate when appropriate remedial action is necessary, including, if appropriate, taking the equipment out of service." This places responsibilities on both holders and competent authorities, and the Commission's guidance (EC (1999)) on transposition of the Directive into national legislation notes that the holder is responsible for ensuring these standards are drawn up and being used. It further notes that the "EC provide(s) guidance concerning criteria of acceptability for radiological and nuclear medicine equipment [RP 91]. However, this guidance gives only the absolute minimum requirements for equipment. Holders of installations should make effort(s) to adopt more stringent criteria."

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 91 (EC (1997b)). However, it is not intended to act as a guide to quality assurance and quality control programmes, which are comprehensively dealt with elsewhere (e. g. EC (2006); AAPM (2006b); IPEM (2005a), IPEM (2005b); AAPM (2002); BIR (2001); Seibert (1999); IPEM (1997a), IPEM (1997b), IPEM (1997c)).

Protection Directives including the MED and the BSS. It is not anticipated that the requirements in this area will change significantly.

Practical Consequences of the MED Directive

1. Acceptance testing must be carried out before the first use of the equipment for clinical purposes (MED 8.2).
2. Necessary measures must be taken by the holder of the radiological installation to improve inadequate or defective features of equipment (MED 8.3). Competent authorities must ensure the holders of equipment adopt and apply specific criteria of acceptability for equipment in order to indicate when intervention is necessary, including taking the equipment out of service (MED 8.3).
3. Quality assurance programmes including quality control measure must be implemented by the holder (MED 8.2).

1.2.2 Requirements of the Medical Devices Directives (MDD) and equipment standards

Since 1993, the safety aspects of design, manufacturing and marketing of medical devices, have been dealt with by the Medical Devices Directive (MDD) (Council Directive 93/42/EC (1993)). The MDD was substantially amended in 2007 by Council Directive 2007/47/EC (2007). This includes an obligation for "a post-market surveillance plan", which requires the manufacturers/suppliers to monitor and act on problems that emerge after installation of the device during its life in use.

When a device is compliant with the Essential Requirements of the MDD, it can be "CE marked". This allows it to be marketed throughout the EU. Compliance with the MDD is often achieved, in practice, through conformity with the standards issued by the International Electrotechnical Commission (IEC) and/or the European Committee for Electrotechnical Standardization (CENELEC)[5]. Conformity with IEC or CENELEC standards is frequently included as part of the specification of equipment at the time of purchase and is generally confirmed during contractual acceptance (acceptance testing) by the purchaser. Many IEC standards are adopted and harmonized by CENELEC[6].

The MDD includes requirements for devices emitting ionising radiation. These do not override the requirements of Directives adopted under the Euratom Treaty and it is important to note that the Euratom Treaty Directives have precedence over other instruments in this area such as standards. Not withstanding this, care must be taken when transposing requirements arising from the MED into national legislation. It is essential that the need of end users and regulators are respected as well as those of industry and standard organisations. There is a need for harmonization and recognition of the global nature of the equipment supply industry.

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[5] The IEC is the world's leading organization involved in preparing and publishing International Standards for all electrical, electronic and related technologies. The standards cover a vast range of technologies, including power generation, transmission and distribution to home appliances and office equipment, semiconductors, fibre optics, batteries, and medical devices to mention just a few. Many, if not all, of the markets involved are global. Within the EU CENELEC is the parallel standards organization and in practice adopts many IEC standards and harmonises them within the European context.

[6] The complete list of harmonised standards is available at http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/medical-devices/index_en.htm.

1.3 To whom this document is addressed

Advice on good practice with respect to equipment performance is frequently addressed to or focused on the needs or responsibilities of a particular group. For example, the standards produced by IEC and CENELEC are primarily aimed at manufacturers and suppliers.

The primary audience to which this report is addressed is the holders and end-users of the equipment (specifically health care agencies and professionals, including hospitals, other institutions, medical physicists including MPEs[7], practitioners, radiographers, clinical technologists and other staff/agents including health service management professionals, 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 holders of radiological installations meet their obligations with respect to equipment performance under Article 8.3 of the MED. This is in keeping with the precedent implicitly established in the scope and format adopted for RP 91. This report addresses the needs of these groups while taking due account of the reality of globalization of the equipment industry, the associated standards and the harmonization objectives, viz a viz the MDD noted in 1.2.2.

The technical parts of sections 2, 3, and 4 assume that those reading and using them are trained to the level expected of an MPE or equivalent. They must be familiar with this Introduction and have a good working knowledge of the relevant types of equipment and appropriate testing regimes.

1.4 Clarification of terminology and equipment lifecycle

A critical reading of the MED, RP 91 and the professional literature demonstrates some variability in the meaning of terms such as remedial levels, suspension levels, acceptance testing, 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 1-2 and 1-3.

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 depart (Table 1-2). This report is concerned with ***suspension levels*** only. Remedial levels are, on the other hand, well described in numerous quality assurance publications (e.g. AAPM (2005); IPEM (2005a), IPEM (2005b); AAPM (2002); IPEM (1997a), IPEM (1997b), IPEM (1997c)). Failure to meet a suspension level requires that the equipment be taken out of service until it is restored to satisfactory performance or until its use is reviewed in a formal risk assessment. Following the risk assessment, the suspended equipment may be used in limited circumstances (Table 1-2 and sections 1.7, 1.8 and 1.9).

[7] Throughout the report, the term MPE is used as shorthand for an expert in medical physics who has competences and knowledge in diagnostic radiology, nuclear medicine or radiotherapy. This publication assumes that an MPE is an expert authorised to act independently. In some countries this may not yet be the case.

Table 1-2 Definitions and Actions associated with Satisfactory Performance, Remedial and Suspension Levels

State	Definition and / or Action
Satisfactory Performance	Operation of the equipment with all performance and safety criteria within the holder's 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 holder or his/her agent, e.g. an MPE, and take account of the clinical use of the equipment.
Suspension Level Contravened	Failure to comply with 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 maybe considered for use in limited circumstances. The holder and the operators must be advised in writing of the suspension and the related limitation(s) in use.[8] 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 lifecycle[9]. Thus they must be carefully distinguished from other formal assessments that occur particularly at the point where the equipment is accepted by the holder and then brought into clinical use (Table 1-3). In particular, suspension levels must be clearly distinguished from the levels set for acceptance tests (Table 1-3). The latter are used to establish that the equipment meets the supplier's specification and/or to verify contractual obligations have been met. The specification may demand, for example, 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 MED. 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. Quality assurance programmes involve many additional elements beyond the suspension levels presented here, and will inevitably involve the consideration of remedial levels.

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[8] Examples of how this might arise include the following: 1. In radiotherapy, a megavoltage unit with poor isocentric accuracy could be restricted to palliative treatment until the unit could 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.

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

Table 1-3 Usages of the Terms Acceptance Testing, Commissioning 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.
Establishing compliance with Criteria for Acceptability including suspension levels	As detailed in this report and applied as necessary throughout the life of the equipment.
Commissioning	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. clinical protocols), and will usually involve the radiological practitioner, technologists, MPE and the supplier's applications specialist.

1.5 Criteria for acceptability

1.5.1 Approaches to criteria

In Table 1-1 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. They include, for example, the requirements that:

- In the case of fluoroscopy, examinations without an image intensification or equivalent techniques are not justified and shall therefore be prohibited, and
- Fluoroscopic examinations without devices to control the dose rate shall be limited to justified circumstances,

both of which are from the MED.

Suspension levels, on the other hand, rely on measurements. They provide numerical limits for acceptable performance in respect of the parameters identified for each of the equipment types in sections 2, 3 and 4. Some organisations specify measurement methodologies without indicating the performance level to be achieved. This is not uncommon in many of the standards issued by, for example, IEC, CENELEC and some professional bodies. While this approach has the advantage that it is easier to get consensus on standards among the manufacturers, professions and others involved, it also has disadvantages. These include a lack of transparency, associated limitations on accountability and risk of misapplication in the hands of inexperienced users.

A wide ranging, consistent suite of approaches to performance and safety assessment of radiological equipment has been proposed by the UK Institute of Physics and Engineering in Medicine (IPEM (2005a), IPEM (2005b); IPEM (1997a), IPEM (1997b), IPEM (1997c), Report 32 Series). The American Association of Physics in Medicine (AAPM (2006b), AAPM (2005), AAPM (2002)) and British Institute of Radiology (BIR (2001)) have also published much useful material. Much of this material is for use in routine quality assurance programmes, and is reasonably based on the 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 physicists, it can prove unsatisfactory when used to provide suspension levels as understood in the MED. For example, if the baseline is, for some reason, unsafe or unsatisfactory, there is then no absolute safe standard against which performance can be measured. Consequently the approach using baseline performance as a benchmark has not been adopted in most instances in this publication Where possible, the emphasis has been to propose absolute suspension levels, taking account of the considerations in sections 1.7.2, 1.8 and 1.9 below. This is consistent with the approach adopted in many countries, including, for example, France, Germany, Belgium, Spain, Italy, and Luxembourg, which have adopted numerical limits for performance values based on RP 91 or other sources including the IPEM 32 series (IPEM (1995), IPEM (1997a), IPEM (1997b), IPEM (2010)).

1.6 Identifying and selecting suspension levels

With the exception of RP 91 there is no formal consolidated literature on criteria for acceptability of radiological equipment. The MED requires that criteria be established and available sources judged to be suitable were reviewed to identify potential criteria, principally as suspension levels. The most important primary source of suspension levels was IEC standards. In addition the recommendations of international organizations, professional bodies, and the scientific/medical literature all contain values for performance and safety that might be imported as 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 that 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 degrees of authority and consensus attaching to them. These are represented by grouping them under the headings A to D in order of preference (Table 1-4).

Table 1-4 Types of Suspension Level

Suspension Level	Definition
Type A	This is based on an international standard or a formal international or national regulation.
Type B	This is based on formal recommendations by scientific, medical or professional bodies.
Type C	This is based on material published in well-established peer reviewed scientific or medical journals and/or (exceptionally) based on reviewed recommendations from the drafting group. For Types A/C and B/C, see the text.
Type D	The need for a Type D suspension level arises when it has not been possible to make recommendations for explicit suspension levels (see text).

Type A

This type is based on an international standard or a formal international or national regulation.

Compliance with the relevant CENELEC/IEC or national 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 harmonization referred to above. In particular, agreed methodology is essential in any system of equipment testing. Standards organizations provide a useful role model in this regard, which this report has tried to emulate[10].

Type B

This type of criterion is based on formal recommendations of scientific, medical or professional bodies.

Where international or national standards are not available or are out of date, advice is often available from professional bodies, notably IPEM, AAPM, NEMA, BIR, ESTRO, EANM and ACR. Detailed advice on testing individual systems is available from the AAPM, earlier IPEM publications and a wide range of material published by many professional bodies and public service organizations. Much of the material is peer reviewed.

Type C

This type of suspension level is based on material published in well-established peer reviewed scientific or medical journals.

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.

Occasionally a Type A or B method/suspension level has been modified by the drafting group, and the resulting, revised method/suspension level is reached using the Type C process described here. Where this has occurred the suspension level is described as Type A/C or B/C as appropriate. This notation is also used, with the addition of an asterisk,C(see section 2.1), where the method is A or B but the test involves use of data from a patient protocol.*

Type D

The need for a Type D suspension level arises only when it has not been possible to make recommendations for explicit suspension levels.

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[10] When equipment standards are developed so that their recommendations can be addressed to and accepted by both "manufacturers and users", the question of establishing criteria of acceptability becomes much simplified. Highly developed initiatives in this regard have been undertaken in radiotherapy (see IEC (2007) and IEC (2008c)). These "provide guidance to manufacturers on the needs of radiotherapists in respect of the performance of MEDICAL ELECTRON ACCELERATORS and they provide guidance to USERS wishing to check the manufacturer's declared performance characteristics, to carry out acceptance tests and to check periodically the performance throughout the life of the equipment". This approach has much to offer to other areas.

This may occur for a variety of reasons. For example, where the technology involved is evolving rapidly, listing a value could be counterproductive because it could become out of date rapidly and/or it could act as an inhibitor of development. In such situations it is recommended that the suspension level should be determined by the holder based on the advice of the MPE in conjunction with the practitioner.

Each suspension level proposed in sections 2, 3 and 4 belong to one of these four categories. In each case, the category is identified and at least one reference to the primary source for the value and the recommended method of measurement is given. Test methods are not generally described in this report. They are generally those described in the reference provided.

1.7 Special considerations, exceptions and exclusions

1.7.1 Special considerations

The MED requires that special consideration be given to equipment in the following categories:

- Equipment for screening,
- Equipment for paediatrics and
- 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.

1.7.2 Old equipment

Exceptions to the recommended criteria may arise in various circumstances. These include cases where equipment has to be assessed that when installed was compliant 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 holder. These recommendations must take a balanced view of the overall situation, including the economic/social circumstances, older technology etc, and the purpose for which the equipment is deployed. It is possible that the MPE may recommend that the equipment be operated subject to restrictions on its use.

1.7.3 Rapidly evolving technologies

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. The suspension levels presented here are for well-established systems. When systems of novel design present themselves, the

MPE should agree suspension levels with the holder (EC (1999))[11]. The levels proposed by the MPE must be framed to be effective for new technology, take account of 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 replacing.

1.7.4 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 91 (EC (1997b)). It is important to be aware that treatment of the whole installation is outside the scope of this report. Thus, the requirements for an acceptable physical building with shielding that will adequately protect staff, the public and patients, power supplies and ventilation have not been addressed. However, these are areas of growing concern in which the requirements have changed considerably as both equipment and legislation have changed. In addition acceptable solutions to new problems, arising from equipment development, legislation, and dose limits/constraints are different in different parts of the world. Consequently, there are areas particularly shielding and IT that are now in urgent need of attention.

The contribution of IT networks to improving or compromising equipment functionality can bear on both justification and optimization. This can apply to both PACS or RIS networks 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. Likewise display monitors and viewing boxes are not treated here.

As already mentioned, this report focuses on qualitative criteria and suspension levels. It is not intended to provide a template for quality assurance programmes. 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, good 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 of these features can be incorporated into a quality management system.

With regard to wider equipment safety considerations, there are many national and international standards for medical devices, whose intention is to ensure the safety of equipment in respect of, for example electrical, mechanical, and software hazards. This report is not intended to duplicate these standards and processes. Where such standards and their relationship with radiation safety issues are sufficiently mature, their requirements have been referenced but not reproduced here. This is the case in many aspects of radiotherapy (Sections 1.5 and 4). Where the relationship is less mature, or there continues to be an overlap between safety standards and the performance issues that have become the main focus of this report, some of the basic safety issues are repeated in this report. For

[11] The holder of the equipment is accorded a clear role in this regard in the guidance for the transposition into national regulations (EC (1999)). In it, it is noted that the holder is responsible that the criteria are drawn up and being used. This is not surprising as it is also part of the responsibility of the holder in respect of all other types of equipment in the institution.

example, tube leakage, which is essentially a safety standards issue, continues to be present in the diagnostic radiology section of the report.

1.8 Establishing conformity with criteria for acceptability

Qualitative criteria and suspension levels will be applied by the holders in each Member State with appropriate oversight from the national competent authority(ies). It must be borne in mind that the competent authorities for the MED are generally not the same as those for the MDD. In addition the criteria for acceptability are introduced and applied in the context of increasing oversight in health care, for example, the developing requirements for clinical audit particularly in the radiological world. This is accompanied by an increasingly demanding environment for individual and institutional accreditation.

To verify that the criteria for acceptability are being met, the holder must appoint a competent person or persons. The person(s) appointed should be an MPE or have similar standing, whose role will include signing off on the protocols/tests to establish compliance. Who performs the tests in practice is a matter for local arrangements and may vary with the circumstances precipitating performance of the tests. For example, on 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 the tests, write them up, sign them off and report on them. Alternatively, he/she may accept and use results provided by the manufacturer's team. The test methods recommended in this report often rely on non-invasive measurements that would be available to the end user, but alternative approaches proposed by the manufacturer and agreed 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 or not the equipment performance is within suspension levels. 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 holder. In radiotherapy, this is well established, as illustrated by commonplace joint acceptance testing by the manufacturer's team and the holder'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[12].

When equipment fails to meet the criteria it must be suspended from use with patients. 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 practitioner(s) and, where necessary, representative(s) of the holder. The options include, for example, immediate suspension of the equipment, where the failure of compliance is serious enough to warrant it. They may also include assessment of the option that the equipment be replaced temporarily[13] 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

[12] An example of major maintenance would be replacement of an X-ray tube.

[13] Temporary replacement with mobile facilities for CT and vascular suites is not uncommon while new permanent replacements are planned. These involve additional risks.

communicated by the MPE, promptly and in writing, to senior management of the holder and 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.

1.9 Wider issues for the hospital, the MPE and the regulator

An MPE employed in a hospital will frequently have duties that embrace both facilitating the role and mission of the holder, and providing advice on compliance with these criteria. Good governance arrangements will ensure these responsibilities are exercised without coming into conflict with each other.

The hospital MPE's role, in identifying how one or more criteria are not met, is exercised alone. This is without prejudice to the unique responsibility medical/radiological practitioners hold in respect of the diagnosis and treatment of individual patients.

The advice given in this publication is directed toward the holder and the holder's staff and is consistent with the implementation advice given by the Working Party on the MED (EC 1999). It is also equivalent, in many respects, to advice and protocols on best practice that apply to almost every aspect of contemporary institutional medical practice. It is not envisaged that regulators will play a major role in implementing this advice on a day-to-day basis. In practice, it is expected that the holder will be responsible for implementing it. They will, in mature services, from within their own competence oversee the acceptability of their equipment. Where equipment fails to meet the criteria it will normally be removed from use and replaced, or services will be suitably altered, without involving regulators directly.

Regulators may become involved by adopting and/or making available criteria (or some suitable alternatives). Holders must in due course adopt the regulator's criteria and may or may not add to them. Regulatory inspections are likely to seek evidence of compliance with these or suitable alternative criteria. Where evidence is not available or where there is concrete evidence that the criteria (or suitable alternatives) are not complied with, regulators become an important agent for enforcement. In practice, in many institutions failure of compliance should already be known through internal advice from the MPE, clinical audit, or accreditation programmes. Where a problem exists and none of these approaches have identified it, there are likely to be many other serious problems in the institution.

1.10 Conclusions

The guidance provided in this introduction is crucial to the effective use of the sets of qualitative criteria and suspension levels for radiological, nuclear medicine and radiotherapy equipment to be found in sections 2, 3, and 4 of this report. Following this advice will ensure that the requirements of the MED are met in a way that is consistent with sound medical practice and the global harmonization of the radiological equipment industry.

2 DIAGNOSTIC RADIOLOGY

2.1 Introduction

Since RP 91 was published (EC (1997b)), there have been a number of major developments in diagnostic radiology. Perhaps key among these is routine use of digital detectors (e.g. large area flat panel detectors) in radiology and fluoroscopy, as well as multiple slice 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 IT 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 dose determination in radiology has contributed to this.

However, in rapidly evolving areas of radiology, such as CT scanning, acceptability criteria have not kept pace with technological developments. There is a deficit in the availability of well tested consensus-based criteria and suspension levels.

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. In a small number of instances, which includes CT scanners, the drafting teams were not satisfied that the available criteria based on equipment alone provided sufficiently robust reassurance of acceptability. In such cases a review of dose parameters or key patient dose protocols, and their comparison to accepted reference levels (eg., DRLs), can be meaningful, and represent the acceptability of the equipment as it is used in practice. However, such measurements are outside of the normal scope of this report. Nevertheless about 10 suspension levels in this section are dependent on patient protocol doses and they are duly flagged[14]. Failure to meet these levels must be viewed cautiously as it may reflect problems with the equipment or the protocol, or both. This will always require skilful interpretation and will almost inevitably give rise to the need for further investigation. If the investigation reveals that equipment problems are responsible, proceed within the framework of this document. If it reveals patient dose protocol problems they should be addressed within other areas in the optimisation programme.

2.2 X-ray generators and equipment for general radiography

2.2.1 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) or grids. Part of what is

[14] Each of these is accompanied by a short footnote drawing attention to the paragraph above and the suspension level type is distinguished by adding an asterisk (see section 1.6).

presented here is also applicable to generators for fluoroscopic equipment, dental CBCT and DXA systems. However, the criteria have not been developed with specialized X-ray equipment, such as mammographic, dental, and CT units in mind. These are covered in sections 2.4, 2.5, 2.7, and 2.8. Irrespective of the type of equipment, if there are obvious serious electrical or mechanical safety defects, then the system must be suspended from clinical use.

The criteria here refer to X-ray tube and generator, output, filtration and half value layer (HVL), beam alignment, collimation, the grid, AEC, 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, image quality, paediatric concerns, AEC, mobile devices, and spatial resolution. The equipment types listed in the box are not acceptable on the basis of the qualitative criteria stated.

Unacceptable X-Ray generators and equipment for general radiology

- Equipment without the ability to collimate the beam,
- Systems intended to include paediatric use, without the option to remove the grid, (for new equipment, specified more than one year after the publication of RP 162),
- Equipment without a device (where practicable) to show the quantity of radiation,
- Equipment without AEC devices (where practicable).

HVL/filtration

Total filtration in general radiography should not normally 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 2-2 or 2-3 in the next section, which depend on the year in which they were CE marked.

Paediatric Issues

Requirements for radiography of paediatric patients differ from those of adults, partly related to differences in size and immobilization during examination (EC 1999) IEC 2009) (see notes and suspensions level in Tables 2.1 and 2.18). Beam alignment and collimation are particularly important in paediatric radiology, where the whole body, 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 remove the grid from a radiography table/image receptor is essential in a system for paediatric use, as is the capacity to disable the AEC, use manual exposure factors, and where relevant 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 2-1: HVL or sufficient total filtration).

Image Quality and Spatial Resolution

There are 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 (Table 2-1). Both of these approaches may be augmented by

semi subjective assessments, or other quantitative assessments at the discretion of the MPE and the practitioner.

Automatic exposure control (AEC)

The AEC should ensure each patient receives the correct exposure. It is also necessary with modern generators that pre-programmed exposure systems be assessed based on the suppliers' specification and the MPE's evaluation. The optical density of the film or the receptor dose under AEC must be as detailed in Table 2-4 and 2-5. The option to manually override the AEC is essential.

IEC (2009) states that if the normal termination depends upon a radiation measurement, then the safety measure shall comprise means for termination of irradiation in the event of a failure of the normal termination. Either the product of X-ray tube voltage, X-ray tube current and loading time shall be limited to not more than 60 kWs per irradiation, or the current-time product shall be limited to not more than 600 mAs per irradiation (see Tables 2.4 and 2.5). The operation of a guard-timer must be checked for extreme situations. Compliance is checked by inspection and by the appropriate functional tests. It should be noted that the tube may be damaged if the test is done incorrectly (IPEM, 2005a).

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.

2.2.2 Suspension levels for X-ray generators and general radiography

The suspension levels for X-Ray generators and general radiography systems are provided in Tables 2-1 to 2-5.

Table 2-1 Suspension Levels for General Radiography Systems

Physical Parameter	Suspension Level	Reference	Type	Notes and Observations
X-RAY SYSTEM				
X-ray tube and generator				
Tube voltage				
Tube voltage accuracy	Deviation from set voltage > 10 % or 10 kV_p whichever is the greater	EC (1997) IPEM (2005a)	A	
X-ray tube output				
Magnitude of output (Y) at 1m	Y outside range of 25 to 80 µGy/mAs at 80 kV and total filtration of 2.5 mm Al	EC (1997) IPEM (1995) ICRU (2005)	A/C	Nearest nominal kV to 80
Repeatability of output for a Fixed setting	Deviation from mean value of measurements > 20 %	EC (1997) IPEM (2005a)	A	
Consistency of output in µGy/mAs for a range of mA and mAs values	Deviation from mean value of measurements > 20 %	IPEM (2005a)	B	Fixed kV
Half-value layer (HVL) /total filtration				
HVL or sufficient	HVL < values specified in	IEC (2008a)	A	Paediatric systems should

Physical Parameter	Suspension Level	Reference	Type	Notes and Observations
total filtration	Tables 2.2 and 2.3	IEC (1994) IEC (2009)		have optional additional Cu filtration of 0.1 or 0.2 mm (EC 1996) For newer paediatric equipment manufactured in compliance with IEC 60601-2-54 additional 0.1mm Cu or total 3.5mm Al is required (IEC, 2009)
Exposure time				
Accuracy of exposure time	Deviation from set time > 20 % (for times ≥ 100 ms). Deviation from set time > 30 % (for times < 100 ms).	IPEM (2005a)	B	Where shorter exposures are required in practice, they should be accurate , particularly for paediatrics (EC, 1996c)
Alignment				
X-ray/light beam alignment	Misalignment in any direction > 3 % of *focus-image receptor distance*	IPEM (2005a)	B	
Light beam/bucky centering	Alignment of crosswire with center of Bucky > 1% of *focus-image receptor distance*	EC (1997)	A	
Collimation				
Automatic collimation	X-ray beam outside the active area of the image receptor > 2% of *the focus-image receptor distance*	EC (1997)	A	Automatic collimation must allow smaller fields than the whole image receptor area
Grid				
Grid artefacts	If significant grid artefacts are visible	EC (1997)	A	See method in EC (1997)
Moving grid	If lamellae visible on image	EC (1997)	A	Should not be visible at the shortest exposure time used in clinical practice.
Focal Spot (FS) and Resolution				
Spatial resolution (as indicator of focal spot integrity)	< 1.6 lp/mm	JORF (2007)	A	Test to be performed with 20 cm of PMMA between test object and receptor. Resolution limited by focal spot size and detector characteristics.
Leakage radiation				
Leakage radiation	K_a(1 m) > 1 mGy in one hour at maximum rating specified by the manufacturer	IEC (2008a) EN (2008a) EC (1997) ICRU (2005)	A	

Physical Parameter	Suspension Level	Reference	Type	Notes and Observations
Dosimetry				
Integrated “dose indicator” calibration (DAP/KAP meter accuracy)	Overall uncertainty > ± 25 %	IEC (2000)	A	

Table 2-2 Suspension levels for minimum first HVL

Parameter	Suspension level	Reference	Type	Notes and Observations
X-ray Tube Voltage kV	**Minimum permissible first HVL mm Al**			
50	1.8	IEC (2008a) EN (2008a)	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			

Alternative means of demonstrating compliance consistent with the standard above are also acceptable.

Table 2-3 Suspension levels for minimum HVL for equipment CE marked pre-2012

Parameter	Suspension level	Reference	Type	Notes and Observations
X-ray Tube Voltage (see Note 1) kV	**Minimum permissible first HVL mm Al**			
From 30 upwards < 50	See "Notes and Observations"	IEC (1994) EN (1994)	A	Linear extrapolation used
50	1.5			
60	1.8			
70	2.1			
80	2.3			
90	2.5			
100	2.7			
110	3.0			
120	3.2			
130	3.5			
140	3.8			
150	4.1			
>150	See "Notes and Observations"			Linear extrapolation used

Table 2-4 AEC Suspension Levels for Film/ Screen systems

Physical Parameter	Suspension Level	Reference	Type	Notes and Observations
AEC verification				Further methodology in IEC (2009)
Limitation of overexposure	Focal spot charge > 600 mAs	EC (1997) IEC (2009) EN (2009)	A	
Verification of AEC optical density (OD) under reference conditions	OD outside of range 0.9 - 1.4	IPEM (1997a)	B	
Repeatability of OD	Film density > ±0.3 OD from mean value	IPEM (2005a)	B	
Verification of sensors of AEC	Film density for each sensor > ±0.5 OD from mean value	IPEM (2005a) BHPA (2008)	B	Exception when sensors are set up differently by design.
Verification of AEC	Film density for a phantom thickness > ±0.3 OD from mean value for all thicknesses	EC (1997)	A	

Table 2-5 AEC Suspension Levels for CR and DDR

Physical Parameter	Suspension Level	Reference	Type	Notes and Observations
AEC verification				Further methodology in IEC (2009)
Limitation of overexposure	Maximal focal spot charge > 600 mAs	EC (1997) IEC (2009) EN (2009)	A	
Verification of receptor air-kerma for CR and DDR Systems under AEC	≥ 10 µGy	Walsh et al (2008) Bowden et al (2011) IPEM (2010)	C	Suspension level for CR is double the maximum expected values mentioned by Walsh et al (2008) ie 3-5 µGy. Maximum expected dose for DDR may be marginally higher to take due account of geometry and presence or absence of grid (Walsh et al. 2008, Bowden et al, 2011). Alternative agreed methodologies are acceptable and may require adjustment in suspension level.
AEC device repeatability	DDI or measured kerma differs by > 40 % from mean value	IPEM (2010)	B	DDI as used in IPEM (2010). See also IEC (2009).
Verification of AEC at various phantom thicknesses	DDI or measured kerma for a given phantom thickness differs by > 40 % from mean value for all thicknesses	IPEM (2010)	B	

2.3 Radiographic image receptors

2.3.1 Introductory remarks

The Suspension Levels for screens, cassettes, CR and DDR are presented in Tables 2-6 to 2-9. They do not deal with the requirements for mammography or dental radiography. A wider approach which includes quality assurance of film, film processing and image receptors of all types is a critical part of an overall day to day quality system but is not addressed here (IPEM (2005a); BIR (2001); Papp (1998); IPEM (1997a)).

Installation and calibration of a CR system is extremely important. It is also essential to note that the X-ray systems needs to be properly set up for use with CR/DDR systems. In particular, the AEC needs to be appropriately set up (AAPM (2006a); IPEM (2010)).

Details on desirable specifications and features of CR systems as well as their proper installation can be found in AAPM Report 93 (AAPM (2006a)). These guidelines should be

followed prior to acceptability testing. To date, unlike film systems, there are not many publications on the performance of CR systems. However, the recent publication in the IPEM Report 32 series provides useful guidance on quality assurance of these systems (IPEM (2010)). The suspension levels identified will almost inevitably need adjustment in line with future evidence and guidance (Table 2-8).

Likewise, with DDR systems, the tube, generator, workstation and/or laser printer must be known to be working properly. When testing the tube and generator, it is advisable to keep the detector out of the beam or protect it with lead. As with CR, few publications are available on suspension levels and the advice given above for CR, prevails (Table 2-9).

2.3.2 Suspension levels for image receptors

Table 2-6 Suspension Levels for screens (mammography and dental excluded

Physical Parameter	Suspension Level	Reference	Type	Notes and Observations
Screens and Cassettes	Significant visible artefacts present.	EC (1997) IPEM (2005a) BIR (2001) IPEM (1997a)	B	See also IEC (1993c).
Relative Speed of batch of Intensifying Screens	Deviations from mean relative speed > 20%	IPEM (2005a)	B/C	See also EC (1997).
Film Screen Contact	Non-uniform density or loss of sharpness.	IPEM (1997a)	B	See also IEC (1993c) and EC (1997).

Table 2-7 Suspension Levels for cassettes and CR Plates

Physical Parameter	Suspension Level	Reference	Type	Notes and Observations
Condition of cassettes and image plates	Damage to plate	IPEM (2005a)	B	See also Table 2.6.
Visual check of uniformity	Artefacts likely to affect clinical image quality	IPEM (2010)	B	

Table 2-8 Suspension Levels for CR readers [see notes 1 and 2]

Physical Parameter	Suspension Level	Reference	Type	Notes and Observations
Dark Noise	Agfa SAL>100 Fuji pixel value > 284 Kodak EI_{GP} > 80 Kodak EI_{HR} > 380 Konica pixel value < 3975	AAPM (2006a)	B/C	With new technologies, equivalent agreed values should be used.
Signal transfer properties (STP)	If relationship unknown or complex	IPEM (2010)	B/C	
Measured uniformity	Deviation from mean value of STP corrected ROI values > 20 %	IPEM (2010)	B	
Erasure cycle efficiency	> 1 %	IPEM (2010)	B	
Detector Dose Indicator (DDI) repeatability	Deviation from mean value of DDI > 20 %	IPEM (2010) AAPM (2006a)	B	
Scaling errors: (distance measurement)	Errors > 4%	IPEM (2010)	B/C	
Blurring	Clinically significant visible blurring present	IPEM (2010)	B/C	
Image quality: High Contrast Limiting Spatial Resolution	Spatial resolution < 2.8 lp/mm for dose ≤ 10 µGy. Spatial resolution < 2.4 lp/mm for dose ≤ 5 µGy.	DIN (2001)	A	Use phantom described in the standard or suitable equivalent, positioned at 45° to the edges of the CR plate. Also note AAPM (2006a), IPEM (2010) & Walsh et al. (2008).
Image Quality: Low Contrast Resolution	< 7 steps are visible	DIN (2001)	A	Use phantom described in the standard or agreed equivalent. Also note AAPM (2006a), IPEM (2010) & Walsh et al. (2008).
Laser beam function	Occasional jitter	IPEM (2010)	B/C	
Moiré Patterns	Moiré Patterns visible	IPEM (2010)	B/C	

1. The suspension levels quoted for Dark Noise are valid at the time of publication. However as CR is an evolving technology specification of dark noise may evolve also.
2. Signal transfer properties (STP) refers to a test to be done during the acceptance testing of the CR Reader in order to establish the relationship between receptor dose and pixel value.

Table 2-9 Suspension Levels for DDR systems [see notes 1, 2]

Physical Parameter	Suspension Level	Reference	Type	Notes and Observations
Dark Noise	Excessive noise in the system	IPEM (2010)	B/C	
Signal transfer properties (STP)	Relationship unknown or complex	IPEM (2010)	B/C	
Image retention	> 1 %	IPEM (2010)	B	
Detector Dose Indicator (DDI) repeatability	Deviation of the mean value of DDI > 20 %	IPEM (2010)	B	
Measured and visual uniformity	Deviation from mean value of STP corrected ROI values > 20 %	IPEM (2010)	B/C	
Scaling errors	Errors > 4 %	IPEM (2010)	B/C	
Blurring / line defects / stitching artefacts	Clinically significant visible blurring present or defective lines	IPEM (2010)	B/C	
Image quality: High contrast Limiting Spatial Resolution	Spatial resolution < 2.8 lp/mm for dose ≤ 10 µGy. Spatial resolution < 2.4 lp/mm for dose ≤ 5 µGy	DIN (2001)	A	Use phantom described in the standard, positioned at 45 ° to the edges of the DR detector. Also note AAPM (2006a), IPEM (2010) & Walsh et al.(2008).
Image Quality Low Contrast Resolution	< 7 steps are visible	DIN (2001)	A	Use phantom described in the standard or suitable equivalent. Also note AAPM (2006a), IPEM (2010) & Walsh et al. (2008) and new developments in the area.

1. System transfer properties refers to relationship established at acceptance test of the DDR system between receptor dose and pixel value.
2. It should be noted that a number of manufacturers have installed automatic QA software on their DDR equipment.

2.4 Mammography

2.4.1 Introductory remarks and qualitative criteria

Mammography involves the radiological examination of the breast using X-rays and is primarily used for the detection of breast cancer at an early stage. It is widely used in screening programmes involving healthy populations. 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 (IPEM (2005b); EC (2006)).

Mammography should be performed on equipment designed and dedicated specifically for imaging breast tissue. Either film/screen or digital detectors may be used. Tables 2-10 to 2-13 summarise the suspension criteria for conventional and digital mammography equipment. The qualitative criteria for mammography equipment are set out in the box

Unacceptable Mammography Equipment

- Equipment without AEC.
- Non digital equipment without a grid.
- Equipment with the focus-to- image receptor distance less than 60 cm.
- Equipment with a field of view less than 18 x 24 cm^2 (excluding stereotactic devices).
- Equipment without a foot pedal operated motorized compression plate and readout of compression thickness and force.

2.4.2 Suspension levels for mammograph

Table 2-10 Suspension Levels for Mammography

Physical Parameter	Suspension Level	Reference	Type	Notes and Observations
AEC short term Repeatability	Deviation from mean value of mAs > 15%	IEC (2011)	A	
X-ray/Image receptor Alignment	X-ray field extending beyond the image receptor > 5 mm on any side. Chest wall side: distance between image receptor and edge > 5 mm	EC (2006)	A	
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 (2011)	A	
Compression Force Consistency	Change in force > 20 N	IPEM (2005a)	B	Over 30s period
Tube voltage	Deviation of tube voltage > 2 kV_p from set value.	IPEM (2005a)	B	
Exposure Time	> 2 s for standard breast 4.5 cm PMMA	EC (2006)	A	Excluding slot scanning systems.
Specific radiation output	≤ 120 µGy/mAs @ 50cm for 28 kVp, Mo, Mo	EC (2006)	A	
Dosimetry (Average Glandular Dose, AGD)[15]	2 cm > 1 mGy 3 cm > 1.5 mGy 4 cm > 2 mGy 4.5 cm > 2.5 mGy 5 cm > 3 mGy 6 cm > 4.5 mGy 7 cm > 6.5 mGy	EC (2006)	A/C*	
HVL	< 0.28 mm Al @ 28 kVp for Mo, Mo	IEC (2011)	A	Or kVp/100 for some combinations of target/filter materials (IEC 2011).

[15] This suspension level is patient dose protocol dependent. Hence failure to meet it may reflect problems with the protocol, the equipment or both, and further investigation is necessary to establish if the problem lies in the equipment. See and follow advice in last paragraph of section 2.1.

Table 2-11 Suspension Levels for Film/Screen Mammography Systems

Physical Parameter	Suspension Level	Reference	Type	Notes and observations
Standard Film Density	OD < 1.3 or > 2.1	IPEM (2005a)	B	And if not correctable by AEC density control.
AEC Thickness Compensation	Deviation from mean value of OD > ±0.15 from standard breast (4.5 cm PMMA) for 2 cm to 7 cm of tissue-equivalent material.	EC (2006)	A	
Film/Screen Contact	>1 cm² of poor contact	EC (2006)	A	
High Contrast Resolution	< 12 lp/mm	EC (2006)	A	
Threshold Contrast	> 1.5% for 5-6 mm detail	EC (2006)	A	

Table 2-12 Suspension levels for Digital Mammography Systems

Physical Parameter	Suspension Level	Reference	Type	Notes and Observations
AEC Thickness Compensation	With CNR calculated from 5 cm of PMMA and 0.2 mm Al and X-ray exposure to just pass the contrast/detail criteria set as a reference, CNR at other thicknesses of PMMA acquired under clinical conditions should not be 2.0 cm < 115 % 3.0 cm < 110 % 4.0 cm < 105 % 4.5 cm < 103 % 5.0 cm < 100 % 6.0 cm< 95 % 7.0 cm< 90 %	EC (2006)	A	This test could be replaced by another validated equivalent test.
Threshold Contrast	With clinical exposure using an equivalent of 5cm PMMA > 0.85 % 5-6 mm > 2.35 % 0.5 mm > 5.45 % 0.25 mm > 23.0 % 0.10 mm	EC (2006)	A	Should be achievable at 3 mGy AGD; Images can be read by human observer or using tested software tools (Young et al, 2008). Test

Physical Parameter	Suspension Level	Reference	Type	Notes and Observations
				could be replaced by another validated equivalent.

Table 2-13 Suspension Levels for stereotactic biopsy tables

Physical Parameter	Suspension Level	Reference	Type	Notes
Threshold contrast	With clinical exposure using an equivalent of 5cm PMMA, contrast threshold value > 1.25 % for 5-6 mm details > 5 % for 0.5 mm details > 8 % for 0.25 mm details	NHS (2007)	A/C	Small field digital systems.
Accuracy of localization	Deviation in alignment > 1 mm in X and Y or > 3 mm in Z.	IPEM (2005b)	B/C	

2.5 Dental radiography

2.5.1 Introductory remarks and qualitative criteria

Dental radiography, though often delivering a low dose, is the most frequently conducted X-ray examination. The following are not acceptable for intra oral dental imaging:

Unacceptable Intra-oral Dental Equipment

- Film class lower than E for which special justification has not been made (EC (2004)).
- Non rectangular collimators on intraoral equipment, for which special justification has not been made (IEC (1994), EC (2004)).
- Rectangular collimation on intra oral equipment, resulting in a field size greater than 40 x 50 mm (IPEM (2005a)).

There are no specific qualitative criteria for dental extra-oral system systems.

Results of testing dental equipment are available in Gallagher et al. (2008), EC (1997), IEC standards, and the criteria for dental equipment adopted by EU member states (FANC besluit (2008); IPEM (2008); JORF (2007); IPEM (2005a); Directive R-08-05 (2005); SEFM-SEPR (2002); IEC (2000a)). Revised IEC standards for dental equipment are due to be issued at the time of finalizing this publication (IEC 60601-2-63 (draft, CDV, 2011), IEC 60601-2-65 (draft, CDV, 2011)).

Use of cone beam CT (CBCT)/ Dental Volumetric Tomography (DVT) for dental applications has risen steadily since its introduction about a decade ago. The design and specification of this types of equipment still varies considerably. The approach here (Table 2-16) is based on that recommended by the EC SEDENTEXCT project.

2.5.2 Suspension levels for dental equipment

Suspension levels for various types of dental equipment are provided in Tables 2-14 to 2-16.

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. Image quality suspension levels for digital dental systems are not readily available, but where applicable, the provisions of Tables 2.7 to 2.9 can be used for guidance.

Table 2-14 Suspension Levels for Dental x-Ray Tubes and Generators (excluding CBCT)

Physical parameter	Suspension level	Reference	Type	Notes and Observations
X-ray tube and generator				
Tube voltage range, Intra Oral	Outside the range 60 to 90 kV_p	IEC (1994), EC (2004)	A	See also IEC 60601-2-63 (draft, CDV, 2011), IEC 60601-2-65 (draft, CDV, 2011).
Tube voltage range, Cephalometric and all others except CBCT	Outside the range 60 to 125 kV_p	IEC (1994), EC (2004)	A	
Tube voltagel accuracy	Deviation from set kV_p > 10 %	EC (1997)	A	
Exposure time accuracy	Deviation from set exposure time > 20 %	EC (1997)	A	
Exposure time precision	Deviation from measured value of time > 10 %	EC (1997)	A	
Repeatability of radiation output	Deviation from mean measured output > 20 %	EC (1997)	A	
FSD for Intra Oral Equipment	< 20 cm	IEC (1994)	A	
HVL	Operating voltage < 70 kVp, HVL < 1.5 mm Al. Other systems see Table 2.3	IEC (1994)	A	

Table 2-15 Suspension Levels for Dental CBCT Equipment

Physical parameter	Suspension level	Reference	Type	Notes and observations
X-ray tube and generator				
Tube and generator	See Table 2-1	SEDENTEXCT (2011)	A/C	Tube and generator tests as in Table 2.1 as far as applicable.
Dosimetry				
Integrated "dose indicator" calibration (DAP/KAP meter accuracy)	See Table 2-17	IEC (2000a) Toroi et al. (2009) IAEA (2011) SEDENTEXCT (2011)	A/C	Calibration as far as possible follows Table 2-1.
DAP/KAP[16]	Deviation > 2 x achievable dose	HPA (2010) SEDENTEXCT (2011)	A/C*	Achievable dose used pending the availability of DRLs.
CTDI – free in air	Does not meet manufacturer's specification or deviation from baseline > 40 %	IPEM (2005a) HPA (2010)	B/C	Use if CTDI is quoted by the manufacturers
Field of View and alignment				
Field of View	Field > size of the solid detector	HPA (2010) SEDENTEXCT (2011)	A/C	Film or suitable CR or DR detector. Protocol agreed with supplier. See also IEC 60601-2-63 (draft, CDV, 2011)
Image quality				
Image noise	*Deviation from baseline > 25 %*	*HPA (2010) IPEM (2005a)*	*A/C*	

[16] This suspension level is patient dose protocol dependent. Hence failure to meet it may reflect problems with the protocol, the equipment or both, and further investigation is necessary to establish if the problem lies in the equipment. See and follow advice in last paragraph of section 2.1.

Physical parameter	Suspension level	Reference	Type	Notes and observations
Spatial resolution	< 1 lp/mm (in high resolution mode)	Bundesregierung BRD (2004)	B	High contrast resolution bar pattern
Image density values	Deviation from manufacturer's specification > 25 %	HPA (2010) IPEM (2005a)	A/C	Quality Control phantom
Artefacts	Any artefacts likely to impact on clinical diagnosis		D	

Table 2-16 Suspension Levels for Dosimetry for dental systems excluding CBCT

Physical Parameter	Suspension Level	Reference	Type	Notes and observations
Intra-Oral				
Incident air kerma for mandibular lower molar tooth[17]	> 4 mGy	Napier (1999) EC (2004)	A/C*	Some authorities recommend a lower level. See JORF (2007)
Panoramic Systems				
Kerma area product of a typical clinical exposure or calculated kerma area product from dose width product or equivalent[17]	> 100 mGycm^2 or current national reference dose	IPEM (2005a)	B/C*	
Cephalometry Systems				
Incident air kerma for skull AP/PA[17]	> 3 mGy	EC (2004) Hart D, Hillier MC, et al. (1996)	A/C*	
Incident air kerma for skull lateral[17]	> 1.5 mGy	EC (2004) Hart D, et al. (1996)	A/C*	

[17] This suspension level is patient dose protocol dependent. Hence failure to meet it may reflect problems with the protocol, the equipment or both, and further investigation is necessary to establish if the problem lies in the equipment. See and follow advice in last paragraph of section 2.1.

2.6 Fluoroscopic systems

2.6.1 Introductory remarks and qualitative criteria

Fluoroscopic systems can be highly flexible and are open to a wide range of applications. They may offer a multiplicity of modes (and sub-modes) of operation. A set of the modes and submodes that represent the intended uses of the equipment should be identified for acceptability testing. For example, the main "cardiac mode(s)" and associated sub-modes might be tested in a unit whose intended application will be in the area of cardiac imaging. If the unit is later deployed for different purposes the need for new acceptance testing will have to be considered by the practitioner and the MPE.

In many cases fluoroscopic systems are supplied as dedicated units suitable for cardiac, vascular, gastrointestinal or other specific applications. Powerful mobile units are available and are generally flexible. In all cases the MPE will have to consider the intended application of the unit and the environment in which it will be installed and used. With respect to the X-ray generator, many of the criteria of acceptability are similar to those prevailing for general radiographic systems.

The following are not acceptable, in accordance with the MED, supported by requirements of IEC (2009):

Unacceptable Fluoroscopy Equipment

- Equipment without a device (where practicable) to show the quantity of radiation, Equipment using direct fluoroscopy.
- Equipment without a functioning audible 5 minute timer.
- Equipment without devices to control the dose rate in the absence of special justification.
- Systems intended to include paediatric use, without the option to remove the grid, (for new equipment, specified more than one year after the publication of RP 162).
- Equipment without beam collimation facilities.

2.6.2 Suspensions levels for fluoroscopy equipment

Table 2-17 Suspension Levels for Fluoroscopy and Fluorography Equipment

Physical Parameter	Suspension Level	Reference	Type	Notes
Collimation Limits	Deviation > 3 % of SID in either lateral or longitudinal directions or > 4 % for the sum of the two directions	IEC (2009) CFR (2010)	A	
Radiation/Image field size	Radiation area > 1.25 * image area	IEC (2009)	A	
Half-value layer	Tables 2-2 and 2-3 apply	IEC (2008a) IEC (1994)	A	

Physical Parameter	Suspension Level	Reference	Type	Notes
Patient Entrance Dose Rates (Fluoroscopy/normal mode)[18]	> 100 mGy/min at appropriate position	EC (1997) Martin (1998)	A/C*	Values include back scatter with grid in place
Patient Entrance Dose per frame (Normal digital fluorographic acquisition mode)[18]	> 2 mGy/frame For cardiac mode: > 0.2 mGy/frame	IPEM (2005a) Dowling et al (2008)	B/C*	See also Martin (1998) for method
Image receptor Air Kerma Rate (Fluoroscopy normal mode)	> 1 µGy/second	IPEM (1996) IPEM (2005a)	B	
Image receptor Air Kerma per frame. (Normal digital fluorographic acquisition mode)	> 5 µGy/frame For cardiac mode: > 0.5 µGy/frame.	IPEM (2005a) Dowling et al (2008)	B/C	
Integrated "dose indicator" calibration (DAP/KAP meter accuracy)	Deviation of the measured and indicated values > 35 %	IEC (2010) Toroi et al (2009)	A	35% accuracy only applies above 2.5 Gy cm^2 and 100 mGy and 6 mGy/min, respectively.
High contrast resolution	Spatial Resolution: < 0.8 lp/mm for field sizes > 25 cm < 1 lp/mm for field sizes ≤ 25	EC (1997)	A	
Low contrast sensitivity (Fluoroscopy mode)	Threshold Contrast: > 4 %	EC (1997)	A	
Radiation output using manual settings	Deviation of radiation output from values specified in Table 2.1	See Table 2.1	A	

[18] This suspension level is patient dose protocol dependent. Hence failure to meet it may reflect problems with the protocol, the equipment or both, and further investigation is necessary to establish if the problem lies in the equipment. See and follow advice in last paragraph of section 2.1.

2.7 Computed tomography

2.7.1 Introductory remarks and qualitative criteria

CT examinations are among the highest dose procedures encountered routinely in medical imaging and account for the largest single component of diagnostic medical irradiation in some countries (NCRP (2009)). Thus monitoring of CT equipment is important both in terms of individual examinations and population effects. The design, proper functioning, and the optimal use of equipment substantially influences CT dose. This can be particularly important when pregnant patients or children are involved. CT scanners are under continual technical development resulting in increasing clinical application (Nagel (2002)). In the last two decades the development of helical and multidetector scanning modes allowed greatly enhanced technical abilities and clinical application (Kalender (2011)).

CT scanners may be replaced for reasons that, in theory, include poor equipment performance as demonstrated by failure to meet acceptability criteria or suspension levels. In practice it is also likely that replacement is frequently with a view to meeting increased demands on the service, or to take advantage of new developments which enable improved diagnostics, faster throughput or other clinical benefits. In practice there are few (if any) examples of CT scanners being removed from use on the basis of their failure to meet criteria of acceptability/suspension levels and it is possible that more work in this area is necessary particularly in the area of image quality. In reality technological development by manufacturers is often the major consideration in equipment replacement. In this context particular attention is drawn to opportunities for evaluation that arise from testing involving patient dose protocols as mentioned in the last paragraph of section 2.1. Not withstanding the above there is a substantial market for used, refurbished or second hand CT scanners, and the criteria here apply to such equipment.

CT scanners are also a component of PET-CT systems. The CT acceptability criteria/suspension levels presented here can be applied to the CT component of these special equipment types. Suspension levels for CT scanners are provided in Table 2-18. CT scanners are increasingly utilised in radiotherapy in support of treatment planning (Mutic (2003); IPEM (1999)) and are further discussed in section 4. These criteria are not suitable for cone beam CT systems with 360˚ rotation time greater than 2 seconds (Bundesärztekammer (2007)).

The following are not acceptable:

Unacceptable CT Equipment

- Absence of automatic dose modulation in new equipment specified more than one year after the publication of RP 162 (IEC (2009a)).
- Lack of paediatric protocols in scanners used with children.
- Single slice CT scanners that have not been subject to a formal risk assessment in respect of the procedures for which they are being used.
- Scanners with artefacts likely to impact on clinical diagnosis.
- Absence of indication of CTDIw or CTDIvol in new equipment specified more than one year after the publication of RP 162 (IEC (2009a)).
- Absence of a DICOM structured dose report in new equipment specified more than one year after the publication of RP 162 (IEC (2009a)).

2.7.2 Suspension levels for CT scanners

Table 2-18 Suspension Levels for CT Scanners

Physical Parameter	Suspension Level	Reference	Type	Notes and Observations
Accuracy of indicated dose parameters (CTDIvol)	Deviation of measured dose from indicated dose> 20 %	IAEA (2011) IEC (2011d)	A/C	Display should be checked for standard head and body exams. For scanners with detector z-coverage > 40 mm see IEC (2009a).
Patient protocol doses (CTDIvol)[19]	Adult routine Head (acute stroke) > 80 mGy Adult Abdomen > 30 mGy Paediatric Abdomen (5 year old) > 25 mGy	ACR (2008) NRPB (2005) IEC (2004a)	A/C*	
CTDI free-in-air	Deviation of CTDI free-in-air from manufacturer's specifications > 20 %	IAEA (2011)	A/C	
Image noise	Deviation of noise from the specified values > 15 %	IEC (2004a) IAEA (2011)	A/C	
CT number accuracy	Deviation of CT number accuracy > 10 HU for water up to 30cm diameter	IAEA (2011) IPEM (2005a)	A/C	Different values will apply for other materials.
CT number uniformity	Deviation of CT number from specified value> 10 HU for water up to 20cm diameter Deviation of CT number from specified value > 20 HU for water above 20cm diameter	IAEA (2011) IPEM (2005a)	A/C	Different values will apply for other materials.
Image slice width	Deviation of image slice width from nominal value > 0.5 mm for < 1 mm ;	IEC (2004a) IAEA (2011)	A	

[19] This suspension level is patient dose protocol dependent. Hence failure to meet it may reflect problems with the protocol, the equipment or both, and further investigation is necessary to establish if the problem lies in the equipment. See and follow advice in last paragraph of section 2.1.

Physical Parameter	Suspension Level	Reference	Type	Notes and Observations
	> 50 % for slices of 1 to 2 mm; > 1 mm for slices above 2 mm			
Irradiated beam width	Deviates from manufacturers' specifications	IAEA (2011) IPEM (2005a)	A/C	
CT alignment lights	> ± 5 mm	IAEA (2011)	A	
Scan Projection Radiography (SPR) accuracy	> ± 2 mm	IAEA (2011) IEC (2004a)	A	
Spatial resolution	Deviation ≥ 10% from manufacturer's specification or 0.5 lp/mm whichever is greater	IAEA (2011) IEC (2004a)	A	Field test calibration method against manufacturer's method must be agreed IEC (2004a).
Couch top alignment and index accuracy	Deviation > 2 mm from specified distance	EC (1998) IPEM (2005a) IAEA (2011)	A/C	

2.8 Dual energy x-ray absorptiometry

2.8.1 Introductory remarks and qualitative criteria

Dual-energy X-ray absorptiometry (DXA) is a widely used method for quantifying bone mineral density (BMD) and body mass composition assessment (IAEA (2010)). Its application has more recently been extended to include estimation of body fat. It is performed on equipment specifically designed for and dedicated to these purposes. Similar examinations are performed with CT but give much higher doses (Kalender, 1995).

2.8.2 Suspension levels for DXA systems

Table 2-19 Suspension Levels for DXA Equipment

Physical Parameter	Suspension Level	Reference	Type	Notes and Observations
Entrance surface air-kerma (incl. backscatter)[20]	> 500 µGy, (spine examination) or outside manufacturer's specification by > 35 %	Larkin et al (2008) Njeh et al (1999) Sheahan et al (2005)	C*	Based on upper level of dose from equipment type with highest dose.
Other features of x- ray generator	Use Table 2-1 as appropriate			
BMD precision of an individual machine	Deviation of measured BMD > 3 % from manufacturer's specification	Larkin et al (2008) Sheahan et al (2005) BIR (2001) IAEA (2010)	C	For other phantoms see IAEA (2010).

[20] This suspension level is patient dose protocol dependent. Hence failure to meet it may reflect problems with the protocol, the equipment or both, and further investigation is necessary to establish if the problem lies in the equipment. See and follow advice in last paragraph of section 2.1.

3 NUCLEAR MEDICINE

3.1 Introduction

The safe, efficient and efficacious practice of nuclear medicine involves the integration of a number of processes. The quality of each process will have an impact on the overall quality of the clinical procedure and ultimately on the benefit to the patient. It is important, therefore, that each process be conducted within the framework of a quality assurance programme that, if followed, can be shown to achieve the desired objectives with the desired accuracy (EANM (2010)).

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 activity meters, well counters and probes, gamma cameras, SPECT and PET systems. 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.

The suspension levels stated are intended to assist in the decision making process regarding the need for recalibration, maintenance or removal from use of the equipment considered. For all imaging modalities important qualitative criteria apply: visual inspection for artefacts. Equipment must be suspended if artefacts are expected to have an impact on clinical diagnosis.

It should be noted, however, that for radiotherapeutic applications, relevant suspension levels may well be different from the ones suggested in this section. This would be the case if the equipment is used for modern image-based dosimetry studies before, during and after radionuclide therapy. Special considerations apply in these situations and an MPE should be consulted in this case. Each part of this section is comprised of a brief introduction and a list of relevant equipment. For each piece of equipment, a brief introduction, a table with the critical performance parameters and the suspension levels are given. References to recommended test methods for each parameter are also given. This section considers:

1 Activity meters[21]

2 Well counters and probes

3 Gamma camera systems

4 Positron emission tomography

5 Combined modality systems

[21] Often referred to as dose or radionuclide calibrators.

3.2 Activity meters

3.2.1 Introductory remarks

Activity meters are used to measure the radioactivity to be administered to patients for diagnosis or therapy.

The activity levels of clinically administered radiopharmaceuticals for diagnosis are governed primarily by the need to balance the effectiveness and the safety of the medical procedure, i.e. optimising the amount of administered activity to the patient to achieve the required objective e.g. diagnostic image quality, while maintaining a justifiable radiation risk.

Unsealed radioactive sources are also administered to patients orally, intravenously or injected into various parts of the body for curative or palliation purposes. The treatment of the patient depends on the activity and radionuclide used to give the prescribed absorbed dose to target tissue (IPEM (2011); EANM (2011); EANM (2008)).

Various radionuclides are used for Nuclear Medicine procedures. Activity meters must be capable of measuring the activity of a particular radionuclide (gamma or beta emitting) accurately over a wide range of energies for correct determination of the radioactivity to be administered to the patient. They must also be capable of measuring accurately over a wide range of activities.

The performance of activity meters must be assured through a quality assurance programme conforming to international, European or national standards (NPL (2006); EC (1997)). The suspension levels are given in Table 3-1 for each critical parameter together with the type of criterion used and a reference to a recommended test method.

3.2.2 Suspension levels for activity meters

Table 3-1 Suspension Levels for Activity Meters

Physical Parameter	Suspension Level	Reference	Type	Notes and Observations
Accuracy	> 5 %	NPL (2006)	A	
Linearity	> 5 %	NPL (2006)	A	
System reproducibility	> 1 %	NPL (2006)	A	

The suspension levels given in Table 3-1 are for instruments used for the measurement of the activity of gamma emitting sources with energies above 100keV. If these instruments are calibrated to measure isotopes emitting low gamma ray energies (below 100 keV) or beta or alpha emitting sources (Siegel et al. (2004)) 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 3-1 probably cannot be met. If the instrument is suspected of malfunctioning a test with a relevant source needs to be carried out to confirm the suspicion using the values in Table 3-1 (EANM (2008)).

3.3 Well counters and probes

3.3.1 Introductory remarks

Multiple or single “well type” gamma counters are used for in-vitro diagnostic procedures involving the assessment of radioactivity in samples of body fluids. Similarly probes are used for a variety of *in-vivo* measurements, such as those used for iodine uptake measurements, and therefore, the same suspension criteria apply.

The performance of well counters and probes must be assured through a continuous quality assurance programme conforming to international standards (IEC (2001a)). The suspension levels are given in Table 3-2 for each critical parameter.

With respect to intra-operative probes, they should have appropriate collimation and be of appropriate sensitivity (NEMA (2004)).

3.3.2 Suspension levels for well counters and probes

Table 3-2 Suspension Levels for Well Type Gamma Counters and Probes

Physical Parameter	Suspension Level	Reference	Type	Notes and Observations
Count rate performance	> 5 %	IEC (2001a)	C	
Energy resolution	> 10 %	IEC (2001a)	C	
Counting precision	Within the 95 % confidence limits of a chi square test	IEC (2001a)	C	

3.4 Gamma camera systems

3.4.1 Introductory remarks

The gamma camera is currently available in a number of configurations capable not only of performing simple planar imaging (Section 3.4.2) but also whole body imaging (Section 3.4.3) and Single Photon Emission Computed Tomography (SPECT) (Section 3.4.4). Some dual headed gamma cameras with appropriate coincidence circuits and software are also capable of performing Positron Emission Tomography (Section 3.4.5). However, PET systems, dealt with in section 3.5, are rapidly replacing such systems.

The IEC standards (IEC (2004d); IEC (2004b), IEC (1998a), IEC (1998b)) and the National Electrical Manufacturers Association (NEMA) (NEMA (2007a)) in the USA have published relevant standards. These are almost identical with respect to many test procedures, test objects and radioactive sources and have been used extensively. The IEC and NEMA standards were aimed primarily at manufacturers but are now more orientated towards user application than previous publications making it easier to test for compliance in the field. The NEMA Standard also includes directions for the testing of Gamma Cameras with discrete Pixel Detectors.

In addition to the standards, there are a number of publications on quality control that provide a wealth of useful background material and detailed accounts of test methods and phantoms for routine assessment which must be undertaken on a regular basis according to national and international protocols (IPEM (2003); AAPM (1995); IAEA (2009b)).

3.4.2 Suspension levels for planar gamma camera

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 collimator 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 at the earliest opportunity (IEC (2004d), IAEA (2009a)). Suspension levels for key performance parameters are given in Table 3-3.

Table 3-3 Suspension Levels for Gamma Camera Systems

Physical Parameter	Suspension Level	Reference	Type	Notes and Observations
Intrinsic Spatial Resolution	> 6 mm	NEMA (2007a), IEC (2005)	C	
Intrinsic energy resolution	> 15 %	NEMA (2007a), IEC (2005)	C	
Multiple window spatial registration (for systems used for dual isotope studies)	> 1 pixel	NEMA (2007a), IEC (2005)	C	Pixel size as in clinically used protocols. Clinically relevant isotopes should be used.
Differential and Integral System/Intrinsic Non-uniformity	> 7 %	NEMA (2007a) IEC (2005) for method	C	
Detector to detector sensitivity variation (systems with opposing detectors)	Variation > 10 %	NEMA (2007a)	C	
System alignment (systems with opposing detectors)	Misalignment > 1 pixel	NEMA (2007a)	C	Pixel size as in clinically used protocols

3.4.3 Suspension levels for whole body imaging system

The NEMA Standard NU-1 (NEMA (2007a)) 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 (Table 3-3).

Table 3-4 Additional Suspension Level for Whole Body Imaging Systems

Physical Parameter	Suspension Level	Reference	Type	Notes and Observations
Whole Body Spatial Resolution Without Scatter	> 10 mm at 10 cm	NEMA (2007a)	C	

3.4.4 Suspension levels for SPECT systems

IEC standard (IEC (1998a)) and NEMA Standard (NEMA (2007a)) both contain a section devoted to SPECT systems. The basic tests for Planar Gamma Camera systems should be performed on each detector head used for SPECT before commencing with the tests specific for SPECT.

Table 3-5 Additional Suspension Levels for SPECT Systems

Physical Parameter	Suspension Level	Reference	Type	Note
Centre of Rotation (CoR) and Detector Head Tilt	Offset > 1 pixel	IEC (2004d), IEC (1998a), NEMA (2007a) IAEA (2007b)	C	Pixel size as in clinically used protocols.
SPECT System Spatial Resolution	FWHM > 15 mm	IEC (2004d), IEC (1998a), NEMA (2007a)	C	Collimation as in clinically used protocols.

3.4.5 Gamma cameras used for coincidence imaging

The tests described in Tables 3-3 and 3-5 for gamma cameras should be performed. However, the thicker crystals required for these cameras do not perform as well with respect to intrinsic spatial resolution as the thinner crystals intended mainly for use with Technetium-99m based radiopharmaceuticals. It should be noted that gamma camera based coincidence imaging systems are inferior to dedicated PET systems and the latter should be preferred in all circumstances.

3.5 Positron emission tomography

3.5.1 Introductory remarks

Positron Emission Tomography (PET) is a nuclear medicine imaging technique that utilises positron-emitting radionuclides, normally produced in a cyclotron or radionuclide generator. The most frequent clinical indication for a PET study today is in the diagnosis, staging, and monitoring of malignant diseases as well as tissue delineation for radiotherapy treatment planning. Other indications include assessment of neurological and cardiological disorders.

The PET technology has evolved rapidly in the past decade. Two significant advances have greatly improved the accuracy of PET imaging:

(i) the introduction of faster scintillation crystals and electronics which permit higher data acquisition rates, and,

(ii) the combination, in a single unit, of PET and CT or MRI scanners ("multi-modality" scanners, see section 3.6).

It is expected that the utilisation of PET will increase dramatically in the future.

PET is based on the coincidence detection of two oppositely directed 511 keV photons emitted from the annihilation of a positron with an atomic electron. The detection of such events is used for the reconstruction of an image describing the *in vivo* distribution of a positron emitting radiopharmaceutical.

Suspension levels are given in Table 3-6 for the key performance parameters of PET systems (IEC (2008c); NEMA (2007b); IEC (2005), EANM (2010), IAEA (2009a)). The table is less comprehensive than it should be due to a lack of consensus and peer reviewed evidence.

Parameters depending on reconstruction settings should be evaluated with the optimized settings for clinical applications (EANM (2010)). This will guarantee that the parameters reflect image quality in practice.

3.5.2 Suspension levels for PET systems

Table 3-6 Suspension Levels for PET Systems

Physical Parameter	Suspension Level	Reference	Type	Notes and Observations
Spatial Resolution	> 7 mm	IAEA (2009a) for method	C	
Sensitivity	< 1 cps/kBq for 2D imaging and < 4 cps/kBq for 3D imaging	IAEA (2009a)for method	C	

3.6 Combined modality systems

3.6.1 Introductory remarks

A combined modality diagnostic system is defined as the combination of two diagnostic modalities into one system. Examples of such systems are PET-CT, SPECT-CT, PET-MRI, etc. Usually one modality presents functional (molecular) images and the other anatomic images. The fusion (combination) of their images gives a higher diagnostic value than the individual images alone.

The quality control procedures of each individual modality comprising the combined modality system are well established and if followed as recommended, the combined modality system will operate optimally. The suspension levels for the individual modalities are valid for the combined modality systems as well. The main concern with combined modality systems is the registration of the imaging modalities. Here it is recommended that an independent image registration test, using a phantom in the place of a patient, be used at regular intervals to assure the image registration of the modalities comprising the combined modality system (NEMA (2007b); IAEA (2009a)).

3.6.2 Suspension levels for combined modality systems

Table 3-7 Suspension Level for the Image Registration of Combined Modality Systems

Physical Parameter	Suspension Level	Reference	Type	Notes and Observations
Image registration	> 1 SPECT or PET pixel size	IAEA (2009b) for method	C	Clinically used pixel size

4 RADIOTHERAPY

4.1 Introduction

The purpose of this section is to list performance parameters and their tolerances for radiotherapy equipment, namely linear accelerators, simulators, CT simulators, Cobalt-60 units, kilovoltage units, 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 functional performance tolerances reflect the need for precision in radiotherapy and the knowledge of what can be reliably achieved with radiotherapy equipment. The tolerances presented must be used as suspension levels at which investigation must be initiated, according to the definition in section 1.4. Where possible, it will be necessary to adjust the equipment to bring the performance back within tolerance limits. If adjustment is not possible, e.g. loss of isocentric accuracy, it may still be justified to use the equipment clinically for less demanding treatments. Such a decision can only be taken after careful consideration by the clinical team (responsible medical physics expert and radiation oncologist) and must be documented as part of an agreed hospital policy. Alternatively it should be suspended from use until performance is restored. Suspension from use is also required if the safety requirements in the relevant safety standards are not met.

In the following text the performance tolerances are referred to as tolerance values, as this is the terminology used in the quoted IEC standards. However, in the Tables these levels are listed as suspension levels as they correspond also with the definition of suspension level in section 1.4 and used in the other sections of this report.

The tolerance values quoted in this section have been extracted mostly from international and national standards (category type A), supplemented by guidance from national professional bodies (category type B) (see section 1.5). Tolerances are expressed in the same format (e.g. or maximum deviation) as originally given in the quoted standards and guidance documents. In radiotherapy, all tests form part of acceptance testing.

All test equipment used in measuring functional performance must be well maintained, regularly calibrated and traceable (where appropriate) to national standard laboratories.

Particle therapy is not considered in this report.

4.2 Linear accelerators

4.2.1 Introductory remarks

IEC 60601-2-1 (2009b) 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).

IEC 60976 (IEC (2007)), and IEC 60977 (IEC (2008c)) are closely related to this standard. The former 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 is not a standard per se but suggests tolerance values, measured by the methods specified in IEC (2007) that are achievable with present technology.

The values given in Table 4-1 are a summary of the tolerance values in IEC (2008c) and are based on the methodology in IEC (2007). These values are broadly consistent with the tolerances specified in IPEM (1999), AAPM (1994), AAPM (2009) and CAPCA (2005a). For a detailed description of test methods, conditions and applicability, please refer to the IEC, IPEM and AAPM documents. A list of suggested test equipment is included in IEC (2008c). The Table is 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 (2008c), IPEM (1999), AAPM (1994), AAPM (2009), CAPCA (2005a) and other national QA protocols. AAPM (2009) has detailed quality assurance recommendations for devices not covered in AAPM (1994).

In Table 4.1, "IEC" refers to IEC (2007) and IEC (2008c) and the numbers in the Reference column refer to the clauses in these publications. "IPEM (1999)" refers to tables in its section 5.2. Table 4-1 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.

4.2.2 Suspension levels for linear accelerators

Table 4-1 Suspension Levels for Linear Accelerators

Physical Parameter	Suspension Level	Reference (IEC (2007, 2008c) clause numbers unless stated)	Type
Uniformity of radiation fields		9	
X-radiation			
Flatness of square X-ray fields (max/min ratio)	> 1.06 See IEC		A
Symmetry of square X-ray fields (max/min ratio)	> 1.03		A
Deviation of dose distribution of square X-ray fields with angular positions	See IEC		A
Maximum ratio of absorbed dose (beam flatness at d_{max})	See IEC		A
Wedge fields			
Maximum deviation of wedge factor with all angular positions of the gantry and beam limiting system	2 %		A
Maximum deviation of wedge angle	2°		A
IMRT	See IEC		A
Electron radiation			
Flatness of electron fields	See IEC		A
Maximum deviation of dose distribution of electron fields with angular position	3 %		A

Physical Parameter	Suspension Level	Reference (IEC (2007, 2008c) clause numbers unless stated)	Type
Symmetry of electron fields (max/min ratio)	>1.05		A
Maximum ratio of absorbed dose (max/min ratio)	1.09 See IEC		A
Dose monitoring system		7	
Weekly calibration check	>2 %		A
Reproducibility	>0.5 %		A
Proportionality	>2 %		A
Dependence on angular position of gantry and beam limiting device	>3 %		A
Dependence on gantry rotation	>2 % - electron radiation >3 % - X-radiation		A
Stability throughout the day	>2 %		A
Stability in moving beam radiotherapy	See IEC		A
Depth dose characteristics		8	
X-radiation			
Penetrative quality	>3 % or 3 mm.		A
Depth dose and profiles	>2 %	IPEM (1999)	B
Electron radiation			
Minimum depth of dose maximum	>1 mm		A
Ratio of practical range at 80% absorbed dose.	>1.6		A
Deviation of actual value of penetrative quality	>3 % or 2 mm		A
Maximum relative surface dose	100 %		A
Stability of penetrative quality	>1 % or 2 mm		A
Indication of radiation fields		10	
X-radiation			A
Numerical field indication	>3 mm or 1.5 % See IEC		A
For MLCs	>3 mm or 1.5 % See IEC		A
Light field indication	>2 mm or 1 % See IEC		A
Maximum distance between the centres of radiation and light	2 mm See IEC		A

Physical Parameter	Suspension Level	Reference (IEC (2007, 2008c) clause numbers unless stated)	Type
fields			
Maximum distance between the centres of radiation and light fields for MLCs	2 mm See IEC		A
Maximum distance between the centres of radiation and light fields for SRS/SRT	0.5 mm See IEC		A
Reproducibility	>2 mm		A
Alignment of an SRS stereotactic frame	>0.5 mm See IEC		A
Electron radiation			
Light field indication	>2 mm		A
Geometry of adjustable BLDs			
Maximum angular deviation from parallelity 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 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	
On entry			
X-rays	>2 mm		A
Electrons	>4 mm		A
SRS	>0.5 mm		A
On exit			
X-rays	>3 mm		A
SRS	>0.5 mm		A
Isocentre		12	
Maximum displacement of radiation beam axis from isocentre	2 mm		A
Mechanical isocentre	>1 mm	IPEM (1999)	B
Indication of the isocentre	>2 mm		A
Indication of the isocentre for SRS	>0.5 mm	IPEM (1999)	B

Physical Parameter	Suspension Level	Reference (IEC (2007, 2008c) clause numbers unless stated)	Type
Indication of distance along the radiation beam axis		13	
Maximum difference for isocentric equipment	2 mm		A
Maximum difference for non-isocentric equipment	5 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	>.5°		A
Table top rotation, pitch and roll	>0.5°		A
Accuracy of rotation scales	>0.5°	IPEM (1999)	B
Congruence of opposed radiation fields	> mm	15	A
Movements of patient support		16	
Vertical movements	>2 mm		A
Longitudinal and lateral movements	>2 mm	IPEM (1999)	B
Isocentric rotation axis	>2 mm		A
Parallelism of rotational axes	>0.5°		A
Longitudinal rigidity	>5 mm		A
Lateral rigidity	>0.5° and 5 mm		A
Electronic imaging devices		17	
Minimum detector frame time	0.5 s		A
Corresponding maximum frame rate	2 / s		A
Minimum signal-to-noise ratio	50 See IEC		A
Maximum imager lag			
Second to first frame	5 %		A
Or fifth to first frame	0.3 %		A
Minimum spatial resolution	0.6 lp/mm		A

Detachable devices can be attached to either the treatment head or the couch. The former include shadow trays and micro-MLCs, and the latter include devices such as stereotactic frames, head shells, bite-blocks, etc. Where reproducible immobilisation and positioning of the patient is required, the positional tolerance of these devices should be less than 2 mm in general use and 0.5 mm for SRS.

It is recognised that planar and volumetric imaging using both kilovoltage and megavoltage radiation is playing an increasing part in radiotherapy through image guided radiotherapy (IGRT). The tolerances above apply only to planar electronic imaging devices. More

information on checking kilovoltage radiographic systems can be found in section 2. There is an IEC standard under development addressing IGRT systems. Where tests of planar electronic imaging devices are performed routinely for quality control, suggested frequencies of testing are given in CAPCA (2005c).

4.3 Simulators

4.3.1 Introductory remarks

IEC 60601-2-29 (IEC (2008b)) 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. In a similar way to IEC (2007) and IEC (2008c) for linear accelerators, IEC 61168 (IEC (1993a)) and IEC 61170 (IEC (1993b)) specify test methods and functional performance values for radiotherapy simulators. The functional performance requirements of radiotherapy simulators are directly related to the radiotherapy equipment being simulated. The performance tolerances must therefore be at least equal to those considered appropriate for the radiotherapy equipment and in many instances must be better in order not to add to the total positioning errors. There are some differences from recommendations published by national physicists' associations (IPEM (1999), AAPM (1994) and CAPCA (2005b)). Where recommendations from these bodies are adopted, they are indicated in Table 4-2.

The values given in Table 4-2 are a summary of the tolerance values in IEC (1993b) and are based on the methodology in IEC (1993a). Where additional tolerances (e.g. for MLC simulation) have been suggested in the more recent linear accelerator standards IEC (2007) and IEC (2008c) and IPEM (1999), these are indicated in the Table. For a detailed description of test methods and conditions, please refer to the IEC and IPEM documents.

Where tests are performed routinely for quality control, suggested frequencies of testing are given in IEC (1993b), IPEM (1999), AAPM (1994), CAPCA (2005b) and other national QA protocols.

In the table, "IEC" refers to IEC (1993a) and IEC (1993b).

4.3.2 Suspension levels for radiotherapy simulators

Table 4-2 Suspension Levels for Radiotherapy Simulators

Physical Parameter	**Suspension Level**	**Reference** (IEC (1993a,b) unless stated)	**Type**
Indication of radiation fields			
Numerical field indication	>2 mm or 1.0 % See IEC		A
Numerical field indication for MLCs	>2 mm or 1.0 %	IEC (2008c,) IEC (2007)	A
Light field indication	>1 mm or 0.5 %		A

Physical Parameter	Suspension Level	Reference (IEC (1993a,b) unless stated)	Type
	See IEC		
Maximum distance between the centres of radiation and light field	>1 mm or 0.5 % See IEC		A
Maximum distance between the centres of radiation and light field for MLCs	>1 mm or 0.5 %	IEC (2008c,) IEC (2007)	A
Reproducibility	>1 mm		A
Delineator geometry			
Angular deviation from parallelity of opposing edges	>0.5°		A
Angular deviation from orthogonality of adjacent edges	>0.5°		A
Displacement of the radiation field from symmetry when rotating the beam limiting system	>2 mm	IEC (2008c,) IEC (2007)	A
Light field			
Field size (10x10 cm^2)	>1 mm		A
Minimum illuminance	50 lux		A
Minimum edge contrast ratio	4.0		A
Indication of the radiation beam axis			
On entry	>1 mm	IPEM (1999)	B
On exit	>2 mm		A
Isocentre			
Displacement of radiation beam axis from isocentre	>1 mm See IEC		A
Mechanical isocentre	>1 mm	IPEM (1999)	B
Indication of the isocentre	>1 mm	IPEM (1999)	B
Indication of distance along the radiation beam axis			
From isocentre	>1 mm		A
From radiation source	>2 mm		A
Image receptor to isocentre	>2 mm		A
Zero position of rotational scales			
Gantry rotation	>0.5°	IPEM (1999)	B
Roll and pitch of radiation head	>0.1°	IEC (2008c)	A
Rotation of delineator	>0.5°	IPEM (1999)	B
Isocentric rotation of the patient support	>0.5°	IEC (2008c)	A
Table top rotation, pitch and roll	>0.5°	IEC (2008c)	A
Accuracy of rotation scales	>0.5°	IPEM (1999)	B
Congruence of opposed radiation fields	>1 mm		A

Physical Parameter	Suspension Level	Reference (IEC (1993a,b) unless stated)	Type
Movements of patient support			
Vertical movements	>2 mm		A
Longitudinal and lateral movements	>2 mm	IPEM (1999)	B
Isocentric rotation axis	>1 mm		A
Parallelism of rotational axes	>0.5°		A
Longitudinal rigidity	>5 mm		A
Lateral rigidity	>0.5° and 5 mm		A
Electronic imaging devices			
Minimum detector frame time	0.5 s	IEC (2008c,) IEC (2007)	A
Corresponding maximum frame rate	2 / s	IEC (2008c,) IEC (2007)	A
Minimum signal-to-noise ratio	50	IEC (2008c,) IEC (2007)	A
Maximum imager lag			
Second to first frame	5 %	IEC (2008c,) IEC (2007)	A
Or fifth to first frame	0.3 %	IEC (2008c,) IEC (2007)	A
Minimum spatial resolution	0.6 lp/mm	IPEM (1999) 10.2.6	B
Radiographic QC			
Alignment of broad and fine foci images	>0.5 mm	IPEM (1999)	B
Fluoroscopic QC			
Full radiographic and fluoroscopic tests		IPEM (1999)	B
Alignment of Shadow Trays	>1 mm	IPEM (1999)	B

4.4 CT simulators

4.4.1 Introductory remarks

CT simulators usually comprise a wide bore CT 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”. There is an IEC safety standard (IEC (2009)) under development reflecting this application of CT scanning. 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 CT image is not spatially distorted and the Hounsfield numbers are accurate for attenuation corrections. The established standards for CT scanners (see section 2.7) 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 “Quality assurance for computed-tomography simulators and the computed-tomography-simulation process”: (AAPM (2003)) and “Quality assurance programme for computed tomography: Diagnostic and therapy applications”: (IAEA (2011)). 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 4-3 is based on these three reports. IPEM Report 81 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. Where tests are performed routinely for quality control, suggested frequencies of testing are given in AAPM (2003), IPEM (1999), CAPCA (2007b), IAEA (2011) and other national QA protocols. The IEC standard under development will also give some guidance on tolerance values.

4.4.2 Suspension levels for CT simulators

Table 4-3 Suspension Levels for CT Simulators

Physical Parameter	Suspension Level	Reference (AAPM,2003a) unless stated)	Type
Alignment of CT Gantry Lasers			
With centre of the imaging plane	> 2 mm		B
Parallel & orthogonal over length of laser projection	> 2 mm		B
Alignment of Wall Lasers			
Distance to scan plane	> 2 mm		B
With imaging plane over length of laser projection	>2 mm	IPEM (1999) 1°	B
Alignment of Ceiling Laser			
Orthogonal with imaging plane	> 2 mm		B
Orientation of Scanner Table Top			
Orthogonal to imaging plane	> 2 mm		B
Scales and Movements			
Readout of longitudinal position of table top	> 1 mm	IAEA (2011)	A
Table top indexing under scanner control	> 2 mm	IAEA (2011)	A
Gantry tilt	> 1° from vertical	IAEA (2011)	A
Scan Position			
Scan position from pilot images	> 1 mm	IPEM (1999) 1 mm	B
Image Quality			
Left & right registration	None	IPEM (1999)	B
Image scaling	>2 mm	IPEM (1999)	B
CT number/electron density verification	> 20 HU (all materials)	IAEA (2011)	A

4.5 Cobalt-60 units

4.5.1 Introductory remarks

IEC 60601-2-11 (IEC (2004b)) 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. controlling timer, selection and display of treatment related parameters, leakage radiation and stray radiation). IEC (2004b) also includes requirements for multi-source stereotactic radiotherapy equipment.

The IEC has not published performance tolerances for cobalt-60 units. The functional performance characteristics and tolerance values in Table 4-4 are based on those for linear accelerators in IEC (2008c), IEC (2007) with some changes for cobalt-60 units. The Table does not address multi-source stereotactic radiotherapy equipment. There are some differences in the recommendations published by national associations (IPEM (1999), AAPM (1994) and CAPCA (2006a)). Where recommendations from these bodies are adopted, they are indicated in the Table. For a detailed description of test methods and conditions, please refer to the documents indicated.

Where tests are performed routinely for quality control, suggested frequencies of testing are given in IPEM (1999), AAPM (1994), CAPCA (2006a) and other national QA protocols.

4.5.2 Suspension levels for Cobalt-60 units

Table 4-4 Suspension Levels for Cobalt-60 Units

Physical Parameter	Suspension Level	Reference (IEC (2008c) unless stated)	Type
Uniformity of radiation fields			
Flatness of square fields (max/min ratio)	>1.06		A
Symmetry of square fields (max/min ratio)	>1.04	IPEM (1999)	B
Deviation of dose distribution of square fields with angular positions.	See IEC 60976/7		A
Wedge fields			
Maximum deviation of wedge factor with gantry angle	2 %	IPEM (1999)	B
Maximum deviation of wedge angle with all angular positions of the gantry and beam limiting system	2°		A
Source position (when applicable)	>3 mm	AAPM (1994)	B
Controlling Timer and Output Checks			
Timer check on dual timer difference	>1 s	IPEM (1999)	B
Weekly calibration check	>2 %		A
Reproducibility	>0.5 %		A
Proportionality	>2 %		A
Dependence on gantry rotation	>1 %	IPEM (1999)	B

Physical Parameter	Suspension Level	Reference (IEC (2008c) unless stated)	Type
Stability in moving beam radiotherapy	See IEC 60976/7	IEC (2008C) IEC (2007)	A
Timer linearity	>1 %	AAPM (1994)	B
Stability of timer	> 0.01 min		A
Output vs field size	>2 %	IPEM (1999) AAPM (1994)	B
Shutter correction	>2 %	IPEM (1999)	B
Depth dose characteristics			
Penetrative quality	>1 %	IPEM (1999)	B
Depth dose and profile	>2 %	IPEM (1999)	B
Indication of radiation fields			
Numerical field indication	>3 mm or 1.5 %	IPEM (1999) 2 mm	A, B
Light field indication	>2 mm or 1 %		A
Maximum distance between the centres of radiation and light field	>2 mm or 1 %	AAPM (1994) 3 mm	A, B
Reproducibility	>2 mm		A
Collimator geometry			
Angular deviation from parallelity of opposing edges	>0.5°		A
Angular deviation from orthogonality of adjacent edges	>0.5°		A
Displacement of the radiation field from symmetry when rotating the beam limiting system	>2 mm		A
Light field			
Field size (10x10 cm^2)	>2 mm	IPEM (1999)	B
Minimum illuminance	25 lux		A
Minimum edge contrast ratio	4.0		A
Indication of the radiation beam axis			
On entry	>2 mm		A
On exit	>3 mm		A
Isocentre			
Displacement of radiation beam axis from isocentre	>2 mm	IPEM (1999) 3 mm AAPM (1994) 2 mm	A, B
Mechanical isocentre	>2 mm	IPEM (1999)	B
Indication of the isocentre	>2 mm		A
Indication of distance along the			

Physical Parameter	Suspension Level	Reference (IEC (2008c) unless stated)	Type
radiation beam axis			
Maximum difference for isocentric equipment	2 mm	IPEM (1999) 3 mm AAPM (1994) 2 mm	A, B
Maximum difference for non-isocentric equipment	5 mm		A
Zero position of rotational scales			
Gantry rotation	>0.5°	IPEM (1999)	B
Roll and pitch of radiation head	>0.1°		A
Rotation of beam limiting system	>0.5°	IPEM (1999)	B
Isocentric rotation of the patient support	>0.5°		A
Table top rotation, pitch and roll	>0.5°		A
Accuracy of rotation scales	>1°	IPEM (1999)	B
Congruence of opposed radiation fields	>2 mm		A
Movements of patient support			
Vertical movements	>2 mm		A
Longitudinal and lateral movements	>2 mm	IPEM (1999)	B
Isocentric rotation axis	<1 mm		A
Parallelism of rotational axes	>0.5°		A
Longitudinal rigidity	>5 mm		A
Lateral rigidity	>0.5° and 5 mm		A

4.6 Kilovoltage units

4.6.1 Introductory remarks

IEC 60601-2-8 (IEC (1997b) 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 4-5. For a detailed description of test methods and conditions, please refer to the IPEM (1999) and CAPCA (2005d). This section does not cover the use of X-ray tubes with point source field characteristic and /or for IORT (Intraoperative radiotherapy). Where tests are performed routinely for quality control, suggested frequencies of testing are given in IPEM (1999) and CAPCA (2005d).

4.6.2 Suspension levels for kilovoltage units

Table 4-5 Suspension Levels for Kilovoltage Units

Physical Parameter	Suspension Level	Reference (IPEM, 1999) unless stated)	Type
Output calibration	>3 %		B
Monitor chamber linearity (if present)	>2 %		B
Timer end error	>0.01 min		B
Timer accuracy	>2 %		B
Coincidence of light and X-ray beams	>5 mm	CAPCA (2005d) 2 mm	B
Field Uniformity	>5 %		B
HVL constancy	>10 %		B
Measurement of HVL	>10 %		B
Applicator output factors	>3 %		B

4.7 Brachytherapy

4.7.1 Introductory remarks

IEC 60601-2-17 (IEC (2004c) 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. controlling timer, selection and display of treatment related parameters and leakage radiation). This safety standard requires in the technical description the statement of tolerances for brachytherapy source positioning, transit time and dwell time.

The values given in Table 4-6 are based on the performance tolerance values in ESTRO Booklet No. 8 (2004b), AAPM (1994) and CAPCA (2006b) for radioactive sources.

For a detailed description of test methods and conditions, please refer to the documents above. Where tests are performed routinely for quality control, suggested frequencies of testing are also given in the documents above.

4.7.2 Suspension levels for brachytherapy equipment

Table 4-6 Suspension Levels for Brachytherapy Equipment

Physical Parameter	Suspension Level	Reference (ESTRO, 2004b)	Type
Source calibration			
Single source when only one source is used (e.g. HDR)	>3 %	AAPM (1994)	B
Individual source in a batch Mean of batch (e.g. LDR or permanent implant)	>5 % >3 %		B
Linear source uniformity of wire sources	>5 %		B
Source position	>2 mm		B
Applicator length	>1 mm		B
Controlling timer	>1 %	AAPM (1994)	B
Transit dose reproducibility	>1 %	CAPCA (2006b)	B

4.8 Treatment planning systems

4.8.1 Introductory remarks

IEC 62083 (IEC (2001b)) “Requirements for the safety of radiotherapy treatment planning systems” (RTPS) is the standard which identifies those features of design that are regarded as essential for the safe operation of the equipment. It states that “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 is a device that is used to simulate the application of radiation to a 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 which has the potential to alter the dose calculation or distribution.

The report IAEA (2004a) “Commissioning and quality assurance of computerized planning systems for radiation treatment of cancer” is a comprehensive guideline to the procedures to be used for the quality assurance of modern RTPSs. Two subsequent documents providing practical guidance for implementation of this report have been published by the IAEA. The first document, IAEA (2007a), addresses specification and acceptance testing of RTPSs, using the IEC (2001b) document as a basis. This document gives advice on tests to be performed by the manufacturer (type tests) and acceptance tests to be performed at the hospital (site tests). The second document, IAEA (2008a), addresses the commissioning of RTPSs using a range of test cases described in IAEA (2004a). These two IAEA TECDOCs are restricted to photon beam planning and issues related to IMRT or other specialized techniques such as stereotactic radiosurgery are not included. Criteria for the acceptability of performance tolerances of IMRT plans, e.g. based on gamma calculations, are an area of development and are not considered.

The IEC has not published performance tolerances for RTPSs, and the tolerance values for RTPS for photon beams in Table 4-7 are taken from IAEA (2008a), where descriptions of test methods and conditions can be found.

4.8.2 Suspension levels for treatment planning systems

Table 4-7 Suspension Levels for External Beam Radiotherapy Treatment Planning Systems for Photons

Physical Parameter	Suspension Level	Reference (IAEA, 2008a)	Type
Output factors at the reference point	>2 %		A
Homogeneous, simple geometry			
Central Axis data of square and rectangular fields	>2 %		A
Off-axis data	>3 %		A
Complex geometry			
Wedged fields, inhomogeneities, irregular fields, asymmetric collimator setting; Central and off-axis data	>3 %		A
Outside beam edges			
In simple geometry	>3 %		A
In complex geometry	>4 %		A
Radiological field width 50% - 50% distance	>2 mm		A
Beam fringe / penumbra (50% - 90%) distance	>2 mm		A

Quality assurance for treatment planning systems is also described in AAPM (1998), ESTRO Booklet No 7 (2004a) for photon beams and ESTRO Booklet No 8 (2004b) for brachytherapy, and the national protocols IPEM (1999) and CAPCA (2007a). Quality assurance for treatment planning for IMRT is discussed in AAPM (2003b), ESTRO Booklet No 9 (2008) and AAPM (2011), for stereotactic body radiotherapy in AAPM (2010a) and for helical tomotherapy in AAPM (2010b).

4.9 Dosimetry equipment

4.9.1 Introductory remarks

The quality assurance of dosimetry equipment used for quality control and commissioning of treatment machines is considered by AAPM (1994), IPEM (1999) and CAPCA (2007c). The CAPCA standard is largely based upon AAPM (1994), but with some local measurements. IPEM (1999) has the most quantitative measures. The tests from all reports are set out in Table 4-8. For a detailed description of test methods and conditions, please refer to these documents. Where tests are performed routinely for quality control, suggested frequencies of testing are also given in these documents.

4.9.2 Suspension levels for dosimetry equipment

Table 4-8 Suspension Levels for Dosimetry Equipment

Physical Parameter	**Suspension Level**	**Reference** (IPEM, 1999)	**Type**
Ionisation Chambers			
Leakage current	>0.1 %	AAPM (1994)	B
Linearity	>0.5 %	AAPM (1994)	B
Radionuclide stability check	> 1 %		B
Calibration against secondary standard	>1 %		B
Beam Data Acquisition Systems			
Positional accuracy	>1 mm	CAPCA (2007c)	B
Linearity	>0.5 %	AAPM (1994)	B
Ion recombination losses	>0.5 %		B
Leakage current	>0.1 %	AAPM (1994) 0.5 %	B
Effect of RF fields	>0.1 %		B
Stability of compensated signal	>0.2 %		B
Standard percentage depth dose plot	>0.5 %		B
Constancy of standard percentage depth dose plot	>0.5 %		B
Standard profile plot: flatness	>3 %		B
Standard profile plot: field size	>2 mm		B
Accessories			
Thermometer Calibration	>0.5 °C	AAPM (1994) 0.1 °C	B
Barometer calibration	>1 mbar		B
Linear rule calibration	>0.3 %	AAPM (1994)	B

Performance characteristics of radiation detector matrices are not considered.

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ACKNOWLEDGEMENTS

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