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CRITERIA AND SUSPENSION LEVELS IN DIAGNOSTIC RADIOLOGY

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The EC (European Council) Directive on radiation protection of patients requires that criteria for acceptability of equipment in diagnostic radiology, nuclear medicine and radiotherapy be established throughout the member states. This study reviews the background to this requirement and to its implementation in practice. It notes and considers parallel requirements in the EC medical devices directive and International Electrotechnical Commission standards that it is also important to consider and that both sets of requirements should ideally be harmonised due to the global nature of the equipment industry. The study further reviews the types of criteria that can be well applied for the above purposes, and defines qualitative criteria and suspension levels suitable for application. Both are defined and relationships with other acceptance processes are considered (including acceptance testing at the time of purchase, commissioning and the issue of second-hand equipment). Suspension levels are divided into four types, A, B, C and D, depending on the quality of evidence and consensus they are based on. Exceptional situations involving, for example, new or rapidly evolving technology are also considered. The publication and paper focuses on the role of the holder of the equipment and related staff, particularly the medical physics expert and the practitioner. Advice on how the criteria should be created and implemented is provided for these groups and how this might be coordinated with the supplier. Additional advice on the role of the regulator is provided.

INTRODUCTION

Since the European Commission report RP 91 was published, there have been a number of major developments in diagnostic radiology[(1)]. Key among these is the routine use of digital detectors (e.g. large-area flat detectors) in radiography and fluoroscopy, multiple slice computed tomography and in many instances an increasing dose per examination as well as an increase in the number of examinations. Manufacturers have incorporated many other new features into medical imaging systems. These have resulted in improved and more stable performance. For example, newer X-ray generators are more stable than their predecessors. However, in many rapidly evolving areas, acceptability criteria have not kept pace with technological development. There is a deficit in the availability of well-tested consensus-based criteria and suspension levels. All of this has created the need to revisit criteria for acceptability over and above the attention that may be required by routine quality assurance (QA) programmes.

Acceptability criteria for the range of diagnostic radiology equipment listed in Table 1 are presented in RP 162. The publication assumes that those using the tables and technical information in the document are familiar with the introduction to the document and have a good working knowledge of the relevant types of equipment and appropriate testing regimes.

Most of the suspension levels recommended are based on the physical or engineering performance or safety features. As mentioned elsewhere in these proceedings, a few qualitative criteria for acceptability are drawn from the sources such as statutory requirements or generally agreed norms for good practice[(2)].

Table 1. Systems included.

Type of system	Includes
X-ray generators and equipment for general radiography	Most systems including mobiles
Image receptors	Film, screens, CR, DR
Mammography	Screening and symptomatic diagnostic
Dental radiography	Intra-oral, extra-oral, CBCT
Fluoroscopic systems	General, cardiac, mobiles and other interventional
Computed tomography	All types
DXA	All types

The curve drawn from ref. (7).

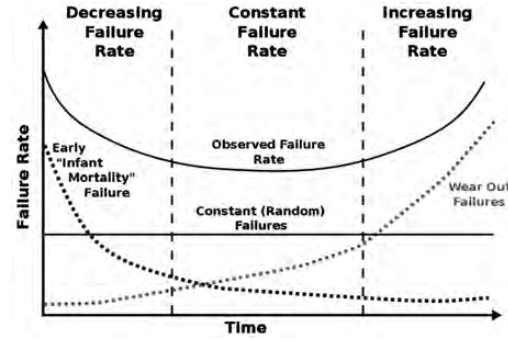

Figure 1. Bathtub curve for failure rate of equipment as a function of time[4].

Table 2. Comments received in diagnostic radiology.

Number of comments received		
Category	EC web-based public consultation	Post-Malahide workshop
Diagnostic radiology (DR)	723	406
DR as % of grand total of all comments received	63% of grand total	

In a small number of instances, including CT, the drafting teams were not satisfied that the available criteria based on the 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 (e.g. diagnostic reference levels, 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 RP 162. Nevertheless, ~10 suspension levels for DR (from a total of almost 200) are dependent on patient protocol doses. Failure to meet these levels must be viewed cautiously as it may reflect problems with the equipment or the protocol, or both. This will require a skilful interpretation and will almost inevitably give rise to the need for further investigation. Where the investigation reveals that equipment problems are responsible, RP 162 recommends proceeding within its framework. On the other hand, when the investigation reveals problems with the patient dose protocol, they should be addressed as part of the optimisation programme[3].

ARE NEW CRITERIA NECESSARY?

As stated in the section Introduction, new criteria are essential, arising from the changes and development in the technologies deployed in radiological imaging. However, at a deeper level, all equipment and devices are prone to failure to varying degrees during the useful life of the systems involved[4]. This is well illustrated in the *bathtub curve* (Figure 1), which indicates the rate of failure as a function of the age of the equipment.

The contributors to the bathtub curve are *early infant mortality* failures, constant *random failures* and finally, toward the end of the life of the equipment, *wear out* failures. These three components combined give the characteristic shape of the curve. The message of the curve is that failure can happen at any time during the life of the equipment. Thus, the equipment should be checked against the criteria for acceptability at any stage during its life. Clearly in the early phase, particularly around the time of acceptance, and toward the end of the life of the equipment are the critical times at which the equipment is most unreliable. However, even during the mid-phase of the equipment life significant failures can occur. One should be alerted to the possibility of these through QA programmes and/or significant changes in the clinical performance of the equipment.

The appropriateness of producing RP 162 at this time is well illustrated by the volume of comments received in diagnostic radiology area (Table 2).

Over 700 comments were received in response to the Commission's public web-based consultation. A further 400 were received in response to the invitation to comment extended by the Commission following the Malahide workshop. In total 63% of the comments received were attributable to diagnostic radiology, indicating a strong level of interest in this area. All of these comments were considered one by one by the drafting team. In consequence, it is felt that a high level of consensus has been achieved

and that the final result has been well adapted to the needs of the industry, standards organisations, medical physicists, technologists, practitioners, holders and regulators.

CRITERIA AND SOURCES OF GUIDANCE

The method of identifying criteria, assessing their suitability for the purpose of RP 162, grading them as A, B, C or D and the recommended approach to their deployment in practice are set out in the introduction to RP 162 and in other publications in this proceedings (RP 162)[2, 5].

The most common source for criteria for acceptability in diagnostic radiology was IEC standards. This was followed by the work from other international and national organisations, by professional bodies such as the IPEM and the AAPM (see box) and by a large number of individuals identified in an acknowledgment at the end of RP 162 and its references.

Diagnostic radiology: standards and guidance

- International Atomic Energy Agency (IAEA)
- International Electrotechnical Commission (IEC)
- European Commission (EC-CEC)
- Agence Française de Sécurité Sanitaire des Produits de Santé (F) (AFSSAPS)
- American Association of Physicists in Medicine (AAPM)
- Belgium Hospital Physicists Association (BHPA)
- British Institute of Radiology (BIR)
- Bundesregierung Deutschland BRD
- Bundesregierung (D) BRD
- Conference of Radiation Control Program Directors (US) (CRCPD)
- Deutsches Institut fur Normung e.V. (D) (DIN)
- European Society of Radiology (ESR)
- European Reference Organisation for Quality Assured Breast
- Screening and Diagnostic Services (EUREF)
- Health Protection Agency (UK) (HPA)
- Imaging Performance Assessment of CT Scanners (UK) (ImPACT)
- Institute of Physics and Engineering in Medicine (UK) (IPEM)
- Journal Officiel de la République Française (JORF)
- King's Centre for the Assessment of Radiological Equipment (UK) (KCARE)
- Ministry of Health Regulation, Luxembourg Annex 7 (LUX)
- Royal College of Radiologists (UK) (RCR)
- Sociedad Espanola de Fisica Medica and Sociedad Espanola de Proteccion
- Radiologica (SEFM-SEPR)
- Numerous other national professional bodies and peer-reviewed scientific or medical publications.

SOME SPECIAL ISSUES

With regard to implementation of the criteria in practice, the roles of the Medical Physics Expert (MPE) and other responsible persons have been treated in RP 162 in a way that offers new practical and well-grounded guidance on how they might be exercised. In particular, it offers guidance on the roles of the MPE, holder, regulators, suppliers, engineers and the practitioner which should help resolve confusion and provide a clearer way forward than has been available to date. It also offers guidance on dealing with new or rapidly evolving technologies, second-hand equipment and the areas that are outside the scope of the criteria.

The European Directive also requires that special attention be paid to examinations involving: exposure of children, health screening programmes, or involving high doses to the patient, such as interventional radiology, computed tomography or radiotherapy. The special requirements of these areas have been noted throughout RP 162.

EXAMPLES

General radiographic systems still provide the great majority of X-ray examinations. They include the widely used general-purpose equipment, chest rooms, mobile systems and system subcomponents/devices such as automatic exposure control (AEC) or grids. All of these are treated in RP 162. In addition, sections are devoted to specialised X-ray equipment, such as mammographic, dental, fluoroscopic, CT and dual-energy X-Ray absorptiometry (DXA).

The general X-ray criteria refer to well-established requirements for X-ray tubes and generators, output, filtration and half-value layer (HVL), beam alignment, collimation, grids, AEC, leakage radiation and dosimetry. In addition, account is taken of image quality, paediatric concerns and mobile devices where possible.

Examples to illustrate the qualitative criteria and suspension levels, taken directly from RP 162, are provided in the box and table below.

Table 3. Suspension levels for fluoroscopy and fluorography equipment.

Physical parameter	Suspension level	Reference	Type[a]	Notes
Collimation limits	Deviation >3% of SID in either lateral or longitudinal directions or >4% for the sum of the two directions	IEC (2009); 21CFR (2010)	A	
Radiation/image field size	Radiation area >1.25 [a]image area	IEC (2009)	A	
HVL	Tables 2-2 and 2-3 apply	IEC (2008a); IEC (1994)	A	
Maximum patient entrance dose rates (fluoroscopy/ normal mode)[b]	>100 mGy min^{-1} at appropriate position	EC (1997b); Martin (1998)	A/C[a]	Values include back scatter with grid in place. In most cases 30 cm (maximum) water phantom is adequate
Patient entrance dose per frame (normal digital fluorographic acquisition mode)[b]	>2 mGy $frame^{-1}$; For cardiac mode: >0.2 mGy $frame^{-1}$	IPEM (2005a); Dowling *et al.* (2008)	B/C[a]	See also Martin (1998) for method
Image receptor air kerma rate (fluoroscopy normal mode)	>1 μGy s^{-1}	IPEM (1996); IPEM (2005a)	B	
Image receptor air kerma per frame. (normal digital fluorographic acquisition mode)	>5μGy $frame^{-1}$; For cardiac mode: >0.5 μGy $frame^{-1}$	IPEM (2005a); Dowling *et al.* (2008)	B/C	
Integrated 'dose indicator' calibration (DAP/KAP meter accuracy)	Deviation > ± 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^{-1}, respectively
High contrast resolution	Spatial resolution: <0.8 lp mm^{-1} for field sizes >25 cm; <1 lp mm^{-1} for field sizes ≤25	EC (1997b)	A	
Low contrast sensitivity (fluoroscopy mode)	Threshold contrast: >4%	EC (1997b)	A	
Radiation output using modes of operation controlled by manually setting	Output outside suspension level in section 2.2 above	See also Section 2.2	A	

[a]See RP 162.
[b]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 text.

Unacceptable X-ray generators and equipment for general radiology

- Equipment without the ability to collimate the beam.
- Equipment for paediatric use without the facility for grid removal specified after the publication date of RP 162.
- Equipment without a device to show the quantity of radiation (where practicable).
- Equipment without AEC devices (where practicable).

The qualitative criteria are for general radiography equipment and provide a list of types of radiology equipment that are unacceptable in practice by virtue of the MED Directive or widely accepted good practice. Table 3 provides the suspension levels recommended for fluoroscopy. Note that rows 4 and 5 in the table are based on patient dose protocols and hence the cautions mentioned above apply to them.

CONCLUSIONS

The background and framework for implementation of the revised RP 162 criteria for acceptability of diagnostic radiology equipment are described in a

summary form. The advice provided in the introduction to RP 162 is crucial to the effective use of the qualitative criteria and suspension levels for radiological equipment. Following this advice will ensure that the requirements of the MED are met in a way that is consistent with good medical practice and with the requirements for global harmonisation of the radiological equipment industry[6].

A comprehensive schedule of critical performance parameters, each with a suspension value, has been developed from international standards, national professional guidance and peer-reviewed scientific or medical literature. Its regular use should help ensure acceptable standards of medical radiological equipment performance and the limitation in use or withdrawal of sub-standard equipment. The MPE has an important role in establishing and monitoring equipment performance against the RP162 criteria and in identification of criteria/suspension levels when none are available.

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