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# The REVISION OF RP 91 ON CRITERIA FOR ACCEPTABILITY OF RADIOLOGICAL (INCLUDING RADIOTHERAPY) AND NUCLEAR MEDICINE INSTALLATIONS

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**In 1997 the European Commission published Radiation Protection 91: 'Criteria for acceptability of radiological (including radiotherapy) and nuclear medicine installations'[(1)]. This document specified the minimum criteria for acceptability. It has been used to this effect in legislation, codes of practice and by individual professionals. In a single document, it defined a level of performance at which remedial action was required. The document specified a series of parameters which characterised equipment performance and acceptable levels of performance. In its time it proved to be a useful document which was applied in member states to various degrees. Since the publication of Report 91 in 1997[(1)], a series of weaknesses emerged over time. Development of new radiological systems and technologies, as well as improvements in traditional technologies, has created circumstances where the acceptability criteria were in need of review. These weaknesses were recognised by the European Commission and a tender for its revision was issued. The criteria were developed by a team drawn from a broad range of backgrounds including hospitals, industry, government bodies, regulators and standardisation organisations. Representatives were mainly from Europe, but individuals from the American Association of Physicists in Medicine and International Atomic Energy Agency were included in the drafting process. This study describes the process employed in developing the revised document and the consultation process involved. One of the major difficulties the revision team encountered was related to an understanding of the actual meaning of the EC Directive[(2)]. The view taken by the revision team was that Article 8, paragraph 3 places responsibilities on both the holders of radiological equipment and competent authorities. The acceptability criteria have been produced consistent with the European Commission's Medical Exposures Directive[(2)], which requires that patient exposures are optimised and justified.**

## INTRODUCTION

The original report on 'Criteria for acceptability of radiological (including radiotherapy) and nuclear medicine installations equipment[(1)]' was an attempt to specify the minimum standards of performance. The document was intended for member states to provide them with the implementation guidance. In a single document, it defined a level of performance at which remedial action was required. The document specified a series of parameters, which characterised equipment performance and acceptable levels of performance. In its time, it proved to be a useful document that was applied in member states to various degrees.

Since the publication of Report 91 in 1997[(1)], a series of weaknesses in the original document have emerged over time. These weaknesses relate to the following:

- New quality assurance approaches have developed.
- Tolerances and remedial action levels have evolved as equipment design has improved.
- Certain types of radiological and nuclear medicine installation were not included (e.g. computed radiography, digital radiography, digital fluoroscopy, multislice computed tomography (CT), combined position emission tomography (PET)/CT scanners, combined and PET/CT scanners) to name a few.
- New techniques have been introduced that have implications for equipment performance.
- Specialised techniques, such as paediatric and interventional radiology, are poorly addressed in Radiation Protection (RP) 91. The Medical Exposures Directive[(2)] places special emphasis on radiation protection in paediatric radiology, mammography and interventional radiology.

The acceptability criteria required revision to reflect the improvements in testing methodologies, which have resulted, in many instances, in the improvement in the accuracy of measurement methods. This has an impact on the acceptability criteria as it enables tolerances to be revised. Knowledge and practices have also evolved since the publication of RP 91. The European Commission recognised these weaknesses and placed a tender for its revision.

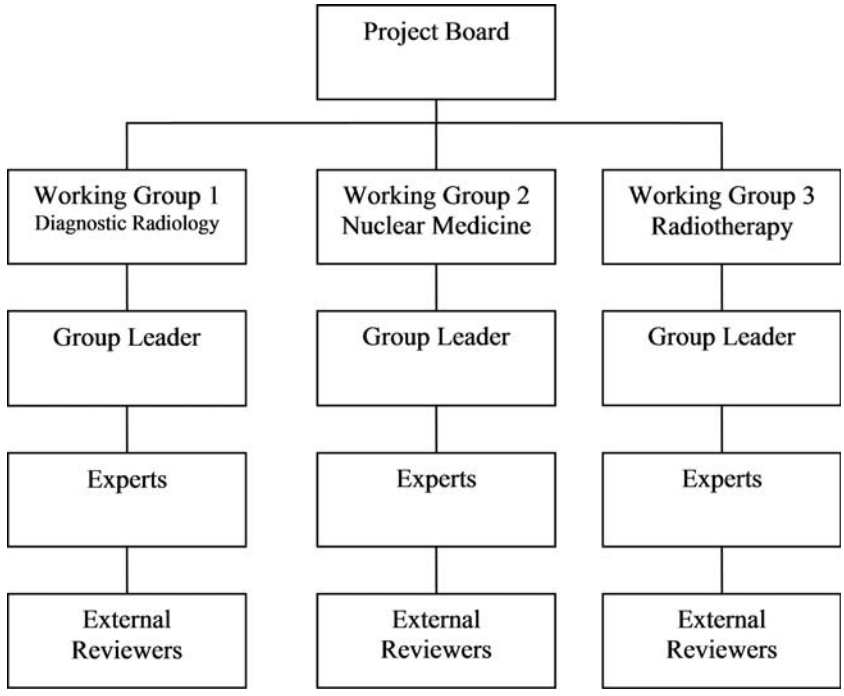


Figure 1. Establishment of the review teams and the process for external review.

In the revised document the development of new techniques has been addressed. For example, direct digital radiography detectors had not been commercially exploited for imaging purposes when RP 91 was published in 1997. In addition, new techniques such as the multi-slice CT have the acceptability criteria specific to their application. Most areas of equipment testing of radiological equipment have been refined and revised since the publication of the original document (CEC, 1997). The implications of new installations were excluded.

In addition to extending the range and scope of the document, it was important to regularise the approaches to the assessment of the acceptability criteria. Where possible it was decided to refer to previously published protocols to harmonise the assessment and practice in different member states. As a consequence the revised document represents a novel approach to the development of the acceptability criteria. Given that the current advice on the acceptability criteria is spread over a very large number of publications, reviewing and collating these published criteria into a single document is intended to promote consistent application and usage across member states.

In summary, the objectives of the revision were to address the above weaknesses by:

- updating the existing acceptability criteria (though specific details of test approaches and methodologies are not included);
- updating and extending the acceptability criteria to new techniques;
- specifically dealing with the implications of paediatrics and interventional radiology;
- using the existing consensus achieved with industry, standards organisations and professional bodies to strengthen the acceptability criteria;
- dealing with the variation in practice across member states for all aspects of radiological installations.

## REVISION PROCESS

Three revision teams were established to deal with diagnostic radiology, nuclear medicine and radiotherapy. To undertake the task, key individuals were identified who had between them the necessary experience and availability to be able to undertake this revision competently. These key individuals were assigned to revision teams dealing with the criteria in diagnostic radiology, nuclear medicine and radiotherapy, based on their expertise. Where cross-expertise was available it was used, consequently some individuals contributed to more than one

section of the document. In addition, a number of experts were identified, external to the revision teams, based on particular expertise these individuals have (see Figure 1).

A two-stage review process for the document was envisaged for the initial draft of the document. The intial draft was sent to a panel of external reviewers, proposed by the revision team to the Commission as part of the original tender process, for comment. A meeting of the working groups was convened to review the comments by the external reviewers proposed by the tenderer and to produce a revised document.

The revised document was then submitted to the European Commission. At this stage there was an external on-line consultation process facilitated by the European Commission with industry (through standards organisations), European professional bodies as well as national professional societies. The Commission placed the draft document on its website for comments and interested parties were invited to comment on the draft by 30 June 2010. A second separate tender was issued by the Commission to address the comments received which was awarded to the same group who undertook the initial drafting.

In response to this second tender, a process for addressing the comments was identified. For each of the comments received, the revision team was required to complete a pro-forma itemising whether it was accepted or rejected, how the comments have been dealt with in the revised text or why the comment was rejected. This process is similar to the one established by the International Electrotechnical Commission for the development of International Standards.

A revised document was produced in time for circulation to the delegates at a workshop in Malahide, Ireland in September 2011. At the workshop the main issues arising from the consultation process were to be discussed. In addition, the workshop enabled evidence for acceptability criteria in the form of reviews and case studies to be discussed and debated in a suitable scientific form to assist in developing a more mature document. Sessions were devoted to specific key topics, which had emerged following the consultation exercise undertaken by the European Commission. Rapporteurs were used to synthesise the results of the discussions and to provide the revision teams with guidance on how to further revise the document.

Following the discussion at the meeting, the Commission's project official issued a further call for public consultation on the document presented at the Malahide workshop.

## SCOPE OF ACCEPTANCE CRITERIA TO BE DEVELOPED

The range of radiological systems for which acceptance criteria were to be developed was agreed with the European Commission as part of the process of responding to the tender. Clearly, there is a very large range of different devices in diagnostic radiology from relatively simple dental systems to extremely complex CT or interventional systems. In addition, the technology involved ranges from traditional analogue and film-based devices to modern digital flat panel detectors and associated display monitors. The range of devices is smaller in both radiotherapy and nuclear medicine. In radiotherapy, whilst the radiation doses may be much larger and correspondingly greater attention is required, there is a more developed culture of rigorous acceptance testing and quality assurance in many countries when compared with diagnostic radiology and nuclear medicine.

One of the major difficulties the revision team encountered related to an understanding of the actual meaning of the EC Directive (EC 1997). Critical to the development and implementation of the acceptability criteria is the interpretation of Article 8—Equipment, and in particular paragraph 3 which states '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 where appropriate remedial action is necessary, including, if appropriate, taking the equipment out of service'. The key part of this paragraph is the word 'They' and the difficulty in determining to whom it refers. It was clear from the feedback received during the consultation process that this paragraph was capable of interpretation in different ways and the responses reflected this perception. For example, 'they' could be interpreted as relating to the competent authority or the holder or both. The exact meaning of this was debated at length by the revision team, as the scope and nature of the document is inevitably determined by its audience. In view of the comments received, the revision team decided to investigate the precise meaning of this paragraph. In summary, the view taken by the revision team was that this paragraph places responsibilities on both the holders of radiological equipment and competent authorities. The Commission's guidance[3] on transposition of the Directive into national legislation notes that 'the holder is responsible for ensuring these standards are

drawn up and being used'. This guidance also notes that 'In some Member States competent authorities provide examples of these standards to the holder' (EC 1999).

## SUMMARY

The acceptability criteria have been revised to address the weaknesses in the existing document described above. Report 91 has been revised and a draft document produced, which is to be published as Radiation Protection 162: 'Radiation Criteria for Acceptability of Medical Radiological Equipment used in Diagnostic Radiology, Nuclear Medicine and Radiotherapy'.

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