

# DEVELOPMENT AND IMPLEMENTATION OF ACCEPTABILITY CRITERIA FOR MEDICAL RADIOLOGICAL EQUIPMENT IN BELGIUM

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**Routine quality control in medical diagnostic radiology necessitates up-to-date working methodologies and criteria adapted to the current technology and standards. In Belgium, acceptability criteria for x-ray equipment were determined by medical physics experts which required broad benchmarking and stakeholder involvement. These were published in 2011 as a Decree of the (Belgian) Federal Agency for Nuclear Control. An overview of the development and its implementation are discussed.**

Key words: quality control, quality assurance, acceptability criteria, radiology, medical physics

Legislation on radiation protection of patients finds most of its origin in the recommendations of ICRP, and several safety standards. (1,2,3,4) On a European level, a legal obligation exists which imposes the holder of a radiological installation to implement appropriate quality assurance programmes including quality control measures and patient dose assessments. Furthermore, acceptance testing should be carried out before the first use of the equipment for clinical purposes, and thereafter performance testing on a regular basis, and after any major maintenance procedure.

In Belgium, the current general legislation on radiation protection is the Royal Decree of 20 July 2001 (5). In this Decree, Chapter VI is describing the regulation of radiation protection in medicine. A specific obligation for a holder of a radiological facility describes that a medical physics expert performs quality control of every x-ray equipment in the facility on a yearly basis. This quality control is to verify that acceptability criteria are met, to enable optimization of the radiological practice according the ALARA principle.

## 1. DETERMINATION OF ACCEPTABILITY CRITERIA FOR MEDICAL RADIOLOGY

Since 2001, the (Belgian) Federal Agency for Nuclear Control (FANC), the competent authority in Belgium for radiological protection and nuclear safety, referred to the European guidance document Radiation Protection 91 for acceptability criteria. (6) These criteria, published in 1997, included criteria for general x-ray equipment, but did not contain any criteria on digital detectors, nor specific criteria for the evaluation of image quality.

### 1.1 Defining quality control criteria

The FANC invited the Belgian Hospital Physicist Association (BHPA – [www.BHPA.eu](http://www.BHPA.eu)) to draft a document containing the acceptability criteria for medical radiological equipment. An open workgroup was created where independent as well as hospital-associated and commercial-based physicist were represented, with FANC as an observatory role. Through literature research, various documents were gathered which served as a benchmarking for Belgian criteria. Some criteria were

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experimentally determined, or by statistical analysis of the tested medical radiological equipment in the past. Next to specifications for the X-ray tube, particular criteria were included on the performance of the detector dose. Despite current efforts of standardization of the exposure index in digital imaging by international organizations, criteria were drafted which allow to measure the performance of digital detectors.

The 26-page final document represents more than just acceptability criteria, but also measurement objectives, measurement method, geometrical setup, acceptability criteria (suspension, remedial) and calculation methods when appropriate. The first version of this document was published by the BHPA in 2007.

### **1.2 Transposing quality control criteria into regulation**

The final document which contained the features to test, together with a testing methodology was redrafted into a regulatory format by the FANC. During that process, which contained various consultation rounds with the Belgian medical physics experts, the representatives from the professional sector of radiology, and some manufacturers, additional recommendations were exchanged for a qualitative implementation. A chapter was added on the evaluation of conformity, which provided a graded approach in relation with the risk of the non-conformity. Depending on the severity of the non-conformity, the delay on implementing corrective actions is adapted according to the radiological risk it represents. This allows a reasonable methodology to implement corrective actions in order to remediate the sub-level of performance, without putting the equipment out of order immediately.

The final document contains chapters on the definitions, graded application of the criteria, and the criteria and test methodologies for general diagnostic X-ray equipment, such as tele-operated tables, ceiling mounted systems and mobile systems. The legislative document was published on 24 August 2011 as a FANC Decree laying down the acceptability criteria for medical radiology equipment. (7)

## **2. IMPLEMENTATION OF ACCEPTABILITY CRITERIA**

The FANC Decree was legally implemented from 3<sup>rd</sup> September 2011 onwards. Every medical radiological equipment needs to be verified against these criteria at least once a year by a nationally certified medical physics expert.

Appropriate communication was sent to the involved stakeholders (people responsible of authorized medical radiological installations, medical physics experts, professional bodies) informing them about the Belgian acceptability criteria and advising them to closely collaborate with a certified medical physicist for the quality control of their radiological equipment.

Since the publication of the Belgian acceptability criteria, the Federal Agency for Nuclear Control systematically verifies its implementation in their regular inspections in the medical radiology sector. Through the working group Radiology of the BHPA, feedback is generated on the efficiency of implementation, which will allow to further improve the existing acceptability criteria to maintain an up-to-date status.

As a conclusion, the determination of acceptability criteria was an extensive process which involved a broad benchmarking and stakeholder involvement. The implementation of these criteria represent an improvement for the radiation protection of the patient and by consequence operator.

During the last years, the working groups of the Belgian Hospital Physicist Association drafted documents containing acceptability criteria for several modalities (e.g. general radiological equipment, fluoroscopy systems, CT), which will all be transposed into legislation. The Federal Agency will, together with the certified medical physicists, continue to strive towards optimization in Belgium for medical radiological equipment.

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