Radiation Protection Dosimetry (2012), pp. 1–4 doi:10.1093/rpd/ncs284

IMPLEMENTATION OF ACCEPTABILITY CRITERIA FOR DENTAL RADIOLOGY IN BELGIUM

Tom Clarijs[1,2,*]
[1]Department Health and Environment, Federal Agency for Nuclear Control (FANC), Ravensteinstreet 36, Brussels 1000, Belgium
[2]SCK•CEN Academy for Nuclear Science and Technology, Belgian Nuclear Research Centre (SCK•CEN), Boeretang 200, Mol 2400, Belgium

*Corresponding author: tom.clarijs@sckcen.be

The implementation of routine quality control (QC) tests in dental radiology in Belgium has been neglected for many years. In 2008, the (Belgian) Federal Agency for Nuclear Control determined acceptability criteria for X-ray equipment used for dentomaxillofacial imaging. An overview of the development of the criteria, together with implementation and the first results of dental QC in Belgium, is discussed.

Legislation on radiation protection of patients finds most of its origin in the recommendations of ICRP[1], and several safety standards[2–4]. On a European level, a legal obligation was formulated which imposes on the holder of a radiological installation the necessity of implementing appropriate quality assurance programmes including quality control (QC) 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]. Chapter VI of this Decree describes the regulation of radiation protection in medicine. A specific obligation for every radiological facility describes that a medical physics expert must perform QC of every X-ray equipment in the facility on a yearly basis. This QC part of the quality assurance programme verifies that acceptability criteria are met, to enable optimisation of the radiological practice according the ALARA principle.

DETERMINATION OF ACCEPTABILITY CRITERIA FOR DENTAL 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 dental X-ray equipment, but did not contain any criteria on digital detectors, or criteria for the evaluation of image quality for dental radiology. The successor document of Radiation Protection 91, Radiation Protection 162, will contain more criteria for these modalities[7].

Defining QC criteria

The FANC invited the Belgian Hospital Physicist Association (BHPA, www.BHPA.eu) to draft a document detailing the acceptability criteria for dentomaxillofacial imaging equipment. An open workgroup was created where commercial-based independent as well as hospital-associated physicists were represented, with FANC as an observer. Through literature research, various documents were gathered which served as a benchmark for Belgian criteria. These documents were mainly acceptability criteria from other radiation protection authorities, or industry standards. Some criteria were experimentally determined, or by statistical analysis of the few tested dental equipment in the past. The final document represented more than just acceptability criteria: for every dentomaxillofacial radiological modality, a set of features was determined to test, with a proposed testing methodology and the corresponding criteria. At the time of the determination of the criteria, dentomaxillofacial cone beam imaging was just introduced in Belgium. To avoid excluding this modality from QC testing, a minimal set of features were determined to test with each CBCT.

Transposing QC 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

dental sector, and some manufacturers, additional regulation was added to cope with unjustified practices (e.g. conical collimation on intra-oral equipment). The final document contained chapters on the definitions, graded application of the criteria, the criteria and test methodologies per imaging modality and extra rules of prohibition. The graded approach allows the identification of non-conformities with the criteria, in order to react appropriately according to the possible risks to the patient. For example, an inaccurate tube voltage requires a faster intervention than an artefact at the border of an image. The legislative document was published on 30 December 2008 as a FANC Decree laying down the acceptability criteria for dental radiology equipment[8]. This document is freely available in English, French and Dutch language on Jurion (www.fanc.fgov.be).

Evaluation and improvement of QC criteria

The FANC Decree was legally implemented from 1 January 2009 onwards. During the testing of various dental radiological equipment, it became clear that several criteria were prone to interpretation. Examples were the older AC generators which were equipped with a preheat mode for the cathode filament. These generators introduced measurable radiation quanta which, when not corrected for, negatively influenced factors such as exposure time and radiation output. With the increasing use of Cone Beam CT in dentomaxillofacial radiology, it became clear that specific criteria were needed for this modality. After more than 1 y of implementation, the Agency started up another consultation round to further improve the regulation to maintain an up-to-date document, which is practically implementable. A second version of the document is already drafted, yet needs to be finalised. 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.

IMPLEMENTATION OF ACCEPTABILITY CRITERIA

Since the implementation of the Belgian acceptability criteria for dentomaxillofacial radiological equipment, more than 10 000 installations were tested according to the document. Before 2009, the legal obligations on medical physics in dental radiology were not implemented in Belgium. With focused communication and intense stakeholder involvement, all dental practitioners in Belgium were reminded of their legal obligations, and were strongly advised to collaborate with a certified medical physicist for the QC of their radiological equipment. All dental radiological equipment in Belgium should have had at least one QC according to the defined acceptability criteria by the end of 2011.

The dental sector requested FANC for a detailed follow-up of the implementation of the criteria. Therefore, the Agency asked all certified medical physicists in Belgium to send the first results of the tested equipment on a voluntary basis, to allow a statistical analysis and evaluation. The Agency identified more than 10 000 units tested by the medical physics experts, but only a fraction of the detailed test data was exploitable for analysis. Tables 1–3 summarise these results per modality, with the

Table 1. First test results for intra-oral equipment.

Test feature	Subtest	Intra-oral	
		Valid data	Percentage of units fail
Voltage	Accuracy	1244	10
	Variation mA	205	2
	Variation ms	1276	1
	Reproducibility	1285	1
HVL		1284	8
Timer	Accuracy	1179	16
	Reproducibility	1227	1
Tube output	Quantity	1269	19
	Short-term reproducibility	1279	1
	Variation mAs	1205	12
	Variation mA	138	1
Dosimetry	Molar adult programme	1274	13
	Maximum programme	1157	7
Image quality	Resolution	1217	1
	Contrast	1151	3
	Optical density	277	8
	Base + fog	449	21
	Dynamic range	1195	9
	Homogeneity and artefacts	1243	5
Focus-skin distance		1260	1
Collimation		1150	2

The total number of units is provided which had valid data points to include in the analysis, together with the total percentage of units violating the acceptability criteria. Different test features are provided, together with the respective sub-parts within each feature. For further details on the testing methodology, reference is made to the FANC- Decree[8].

percentage of X-ray units violating the acceptability criteria. Owing to the low number of tested Cone Beam CT units, no data are provided for this modality.

The analysis of these data showed that the acceptability criteria are feasible to apply in practice. Furthermore, many test results showed great potential for optimisation, in particular dosimetry and image quality. Through this data collection, it is possible to determine preliminary Belgian dose reference levels for dental radiological equipment. Table 4 provides the 75th percentile of the measured dose for each modality. The violation of the acceptability criteria for image quality was mainly due to the use of film screen.

In conclusion, the determination of acceptability criteria was an extensive process which involved broad benchmarking and stakeholder involvement. Although the implementation of the criteria represents a large workload for all certified medical physicists in Belgium, >90 % of the dental radiological equipment is now periodically monitored. A close follow-up of the first test results proved to be very useful in the evaluation of the acceptability criteria and the status of the dental radiological equipment. The Federal Agency will, together with the certified medical physicists, continue to strive towards optimisation in Belgium for dental radiological equipment.

Table 2. First test results for panoramic equipment.

Test feature	Subtest	Panoramic	
		Valid data	Percentage of units fail
Voltage	Accuracy	493	12
	Variation mA	299	2
	Reproducibility	495	0
HVL		493	8
Tube output	Quantity	496	35
	Short-term reproducibility	496	2
	Variation mAs	68	1
	Variation mA	326	5
Dosimetry	Adult programme	437	17
Image quality	Resolution	232	1
	Contrast	373	34
	Isocentre	130	1
	Homogeneity and artefacts	423	7
Collimation		412	14

The total number of units is provided which had valid data points to include in the analysis, together with the total percentage of units violating the acceptability criteria. Different test features are provided, together with the respective subparts within each feature. For further details on the testing methodology, reference is made to the FANC- Decree[8].

Table 3. First test results for cephalometric equipment.

Test feature	Subtest	Cephalometric	
		Valid data	Percentage of units fail
Voltage	Accuracy	84	6
	Variation mA	55	0
	Reproducibility	82	0
HVL		83	2
Tube output	Quantity	84	47
	Short-term reproducibility	82	0
	Variation mAs	31	3
	Variation mA	60	14
Dosimetry	Adult programme	86	20
Image quality	Resolution	57	0
	Contrast	79	24
	Homogeneity and artefacts	83	6
Focus-skin distance		78	7
Collimation		82	15

The total number of units is provided which had valid data points to include in the analysis, together with the total percentage of units violating the acceptability criteria. Different test features are provided, together with the respective sub-parts within each feature. For further details on the testing methodology, reference is made to the FANC- Decree[8].

Table 4. 75th percentiles of measured dose for the different modalities.

Modality	Programme	75th percentile	Unit
Intra-oral	Maxillary molar adult patient	1.9	mGy
Panoramic	Adult patient	12	cGy cm^2
Cephalo	Adult patient	23	mGy cm^2

The dose values are measured in entrance dose at the end of the position indicating device for intra-oral equipment and dose area product for panoramic equipment and cephalometric equipment.

ACKNOWLEDGEMENTS

The author would like to thank all medical physicists of the Belgian Hospital Physicists Association who actively participated in the elaboration and implementation of the acceptability criteria. Gratitude

is also expressed to the professional organisations representing the dental sector in Belgium, for their efforts of communication to their members.

REFERENCES

1. International Commission on Radiological Protection (ICRP). *Recommendations of the International Commission on Radiological Protection*. ICRP Publication 60 (1990).
2. International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources. IAEA Safety Series No. 115 (1996).
3. Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation.
4. Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure.
5. Royal Decree of 20 July 2001 laying down the general regulations on the protection of the public, the workers and the environment against the hazards of ionizing radiation. (ARBIS/RGPRI) Official Gazette 30 August 2001, available at www.jurion.fanc.fgov.be.
6. Radiation Protection 91. *Criteria for acceptability of radiological (including radiotherapy) and nuclear medicine installations.* European Commission, Directorate-General Environment, Nuclear Safety and Civil Protection (1997).
7. Radiation Protection 162. *Criteria for acceptability of radiological (including radiotherapy) and nuclear medicine installations.* European Commission, Directorate-General for Energy, Directorate Nuclear Energy, Unit Radiation Protection (to be published).
8. *FANC Decree of 12 December 2008 laying down the acceptability criteria for dental radiological equipment*. Official Gazette 30 December 2008, available at http://www.jurion.fanc.fgov.be/jurdb-consult/consultatieLink?wettekstId=7705&appLang=fr&wettekstLang=en.