Quality control tests of diagnostic radiology equipment in Hungary, and its radiation protection aspects

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Abstract. This paper gives a comprehensive outlook of history, present and probable future of quality control and safety testing of diagnostic radiology equipment in Hungary, with particular attention to its radiation protection aspects.

KEYWORDS: radiation protection of the patient; diagnostic radiology; quality control; acceptance testing

1. Introduction

1.2 Importance of equipment quality control

It is a general experience that optimum imaging with minimum patient and staff doses, moreover, safe operation and long life of X-ray equipment can be assured only by regular measurement of technical parameters and checking of their constancy (i.e. the so-called routine performance testing). These tests are generally known as quality control (QC), while together with the so-called corrective actions and its management it is called (physical-technical) quality assurance (QA) (of the equipment).

1.2 Radiation protection aspects of equipment quality control

Acceptable quality of equipment is necessary from the point of view of radiation protection of the patient. Minimizing of patient doses means at the same time minimizing of possible staff doses. Of course, QC is only the technical part of radiation protection; it must be accompanied by methodological radiation protection measures. Safety standards of diagnostic radiology equipment contain requirements for technical radiation protection, to be realized by manufacturers. Almost all measurements contained in acceptance and status testing have implications on radiation protection.

2. History and present status in Hungary

2.1 Preliminaries

In QC of diagnostic radiology equipment the first steps were taken in England in the 1960-es. Taking into account the first experiences, World Health Organization issued a guidance in 1982.

In Hungary – based on it – use of a limited number of homemade „QC-kits” was started in 1986-87 but, unfortunately, this attempt had a short life only.

QA has been a daily practice in radiation therapy and nuclear medicine for a long time. A National Patient Dose Assessment Programme has also successfully run since 1989, with co-ordination of NRIRR.

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Nowadays there is running technical QC in mammography screening centres, in some hospitals where a devoted engineer performs it, or where the service – within the framework of warranty or a lump-sum payment service contract – performs also QC tests, together with the maintenance. However, the latter does not contain daily testing of film developers, which is always task of the local staff.

2.2 Regulation

In the European Union (EU), Directive 97/43/EURATOM about radiation protection of patients [1] requires – among others – the good practice of (physical-technical) quality assurance. In Hungary, Decree No. 31/2001. (X.3.) of the Minister of Health harmonizes all of its requirements. Acceptance testing of new diagnostic X-ray equipment is assigned to NRIRR. Further full performance testing (status testing) is required yearly and after major servicing, it is task of accredited independent testing organizations. Simple daily checks (the so-called constancy testing) are the responsibility of users (licensees) themselves (see Table 1). QA programmes are under the surveillance of the radiation health authority (radiation health departments of State Public Health and Medical Officer Service).

According to this regulation, the running technical QC, mentioned in the previous section, may be considered as constancy testing only.

About an earlier stage of this topic we reported at the 14th International Conference of Medical Physics held in Nuremberg, Germany in 2005 [2].

### Table 1: Quality control and safety tests in diagnostic radiology

<table>
<thead>
<tr>
<th>Test</th>
<th>Regulation</th>
<th>It is obligatory for</th>
<th>Its characteristics, required frequency</th>
<th>It is made by</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acceptance test</td>
<td>Directive No. 31/2001. of the Minister of Health, 12.§ (2)</td>
<td>New X-ray equipment, except intraoral dental</td>
<td>QA: complete status evaluation, Before putting into use (single test)</td>
<td>NRIRR</td>
</tr>
<tr>
<td>Status test</td>
<td>Directive No. 31/2001. of the Minister of Health, 13.§ (2)</td>
<td>X-ray equipment after acceptance testing or QA programme started</td>
<td>QA: complete status evaluation, Yearly and after greater maintenance</td>
<td>Accredited independent bodies</td>
</tr>
<tr>
<td>Constancy test</td>
<td>Directive No. 31/2001. of the Minister of Health, 13.§ (2)</td>
<td>X-ray equipment after acceptance testing or QA programme started</td>
<td>QA: routine check, Daily, weekly, monthly etc.</td>
<td>Licensees (users)</td>
</tr>
<tr>
<td>Periodic safety check</td>
<td>Directive No. 16/2006. of the Minister of Health, 17.§ and Annex 13.</td>
<td>All functioning X-ray equipment, except computed tomography (CT)</td>
<td>Electrical, mechanical and radiation safety, Interventional X-ray: yearly, other: bi-yearly, and after greater maintenance</td>
<td>Notified bodies and bodies authorized by Authority of Medical Devices</td>
</tr>
</tbody>
</table>

2.3 Benefits of acceptance testing

According to generally accepted definitions, the main aim of acceptance testing is checking the compliance of the equipment with the contract and/or manufacturer’s specifications (and local regulations, if applicable). It is the first benefit of the user. In the – very unlikely but in principle
possible – case of non-compliance the user can successfully complain using the test report. Testing activity of NRIRR is independent from manufacturers, it is run within the frame of an accredited testing laboratory, using calibrated measuring instruments, performed by highly qualified personnel and based on valid international standards (which are identical with European and also with Hungarian standards). The other benefit for the user is the measuring of the so-called base levels for further QA, i.e. initializing of a QA programme assuring long, safe and optimum performance of equipment.

2.4 Practice and experiences of acceptance testing

Acceptance (and also status) testing is based on EN/IEC 61223-3 standard series. The needed universal X-ray parameter measuring devices and other test devices were bought with the financial support of the EU, before full membership of Hungary. Acceptance testing has been continuous since May 2002. During the first six years about 200 acceptance tests were performed. This number includes radiography, tomography and fluoroscopy equipment, mobile radiography equipment, surgical image intensifiers, digital subtraction angiography (DSA) and interventional radiology equipment, mammography equipment, dental panoramic and cephalometric equipment, and – started in 2006 – CT equipment, too. Almost in every third case some need for servicing or adjustment was detected. The most frequent problems are the improper adjustment of beam limiting devices and automatic exposure control. These are recorded not only in the test reports but also in official letters written to the competent leaders of the health institutions. As it always happens in the warranty period, these servicing or adjustments are free of charge for them. We mention that with our measuring instruments we could detect differences between specified and actual filtration or between displayed and actual X-ray tube current. Acceptance tests are always non-invasive.

2.5 Difficulties in acceptance testing

Modern X-ray equipment have the general characteristics that the possibility of operator errors is minimized by their construction. These equipment are called user-friendly. In contrary of it, they are not “measurement-friendly”. Taking into account the non-invasive character of the tests, it is not possible to go into a so-called “service mode” if no authorized service personnel is present. Some examples for the difficulties arisen from it: we have to remove and take back cassette or enter “patient data” before every exposure. In some cases there was impossible to measure tabletop attenuation, as without the presence of a radiographic cassette an exposition is not possible. Moreover, many times only the current time product can be selected, the tube current is not independent. For digital equipment, it is not possible to determine constancy of film density (in automatic exposure control [AEC] mode) but constancy of dose only.

At the beginning, acceptance testing was not known very much by radiological personnel although in every case we have sent an information leaflet in advance. In many cases the cost of the tests was the main problem for hospitals. Although we insist on the presence of the representative of the customer – mainly from the point of view of avoiding later legal disputes, we do not “use” their equipment – personnel often say that we can perform measurements without them. Measurements on DSA equipment are performed always with the aid of a service engineer of the manufacturer, while in case of CT testing presence of an experienced CT-operator is absolutely necessary. Further, mostly organizational problems occur in testing surgical image intensifiers in operating theatres.

Radiographers often do not know how to use fluoroscopy or tomography equipment so we had to rely on the accompanying documents. In general, knowledge of radiographers is very different, so improving the education and training of radiographers as well as training them on QA is a very urgent and necessary task. It is extremely important also from radiation protection point of view.

2.6 Status testing

A status test means a full performance measurement equivalent to an acceptance test, although some simplifications are possible. (E.g. checking of documents and measurement of leakage radiation or tabletop attenuation can be omitted.)
Accreditation of NRIRR – besides acceptance testing – contains also status testing. During 2006-2007 two further testing laboratories got accreditation for status testing from the Hungarian National Accreditation Body, and the number of accredited testing laboratories probably will grow further.

These laboratories are fully equipped with calibrated measuring instrumentation and work with highly qualified personnel.

We hope that they will start the work in the near future.

As total replacement of the equipment park is likely needs more than 15 years, initializing QA programmes on existing equipment is a longer process.

2.7 Constancy testing

We are of the opinion that – at least in the first some years – the extent of constancy testing has to be restricted to the simplest checks, both for financial and professional skill reasons. NRIRR elaborated a guidance booklet for constancy testing film development and conventional radiographic and fluoroscopic equipment. It was confirmed by the Hungarian National Board of Radiology and then issued by NRIRR; it can also be read on the website of the institute [3]. In its elaborating we relied upon experiences of other counties, above all England [4].

2.8 Periodic safety checks

A special requirement in Hungary – originating not from the EU but to achieve a minimum technical surveillance also in cases where there is no service contract – is that medical devices are to be checked periodically from the point of view of electrical, mechanical and – if applicable – radiation safety. For X-ray equipment it is required bi-annually and after major servicing, except in case of interventional equipment for which it is required yearly. This checking is performed by organizations authorized by the Authority of Medical Devices and under its surveillance. This system – after overcoming some initial difficulties – has been functioning successfully since about 2001. There are about ten authorized organizations for performing periodic safety checks on diagnostic radiology equipment in Hungary.

This check is independent from QA testing although they are overlapping to some extent.

3. Contents and possible future of acceptance and status testing

Acceptance as well as status testing based on standard series EN 61223-3 series (equivalent to IEC 61223-3 series). Detailed information about the required measurements and measuring instrumentation is given in the Annex. Measurement of leakage radiation is a direct radiation protection measurement but on user’s request we sometimes measure scattered radiation and shielding, too.

Standards of this series are issued between 1996 and 1999, except standard for CT, which is from 2004. Standard for mammography equipment has a recent second edition, which is, however, is not harmonized till now in the EU. The older standards are not applicable to the newest equipment so their revision would be needed.

It is not known yet, whether the other three standards (radiography/radioscopy, DSA, dental equipment) will be renewed or only withdrawn. (Decision in the IEC is under preparation.) Namely, some countries have own independent QA regulation, while others use a European document, the so-called RP91 („Criteria for acceptability of radiological (including radiotherapy) and nuclear medicine installations”), first edition of which was issued in 1997. A second edition is now under elaboration, with the aim of reaching the possible widest consensus, including also manufacturers. In case of lack of new international standards a new regulation may be based on this EU document, which probably will be issued in 2009.
4. Conclusions

The started way of implementing QC in diagnostic radiology needs a lot of further efforts and adapting experiences of other countries to reach an acceptable level in the EU.

REFERENCES


ANNEX

Measurements on radiography (and tomography) equipment

1. Radiation output
2. Leakage radiation
3. Tube voltage and irradiation time accuracy
4. Dose linearity
5. Dose reproducibility
6. Total filtration
7. Dimensions of the X-ray beam
8. Coincidence of X-ray beam and light beam
9. Attenuation between X-ray source assembly and patient
10. Stability of AEC (automatic exposure control) density (with different phantom thicknesses)
11. Reproducibility of AEC dose
12. AEC backup timer
13. At tomography units: Testing with a tomographic test object

Measurements on fluoroscopy (and DSA) equipment

1. Leakage radiation
2. Tube voltage at 25 mm Al phantom in AERC (automatic exposure rate control) mode
3. Total filtration
4. Testing of AERC with different phantom thicknesses, at all magnifications
5. Coincidence of X-ray beam and image reception area
6. Patient input dose rate at 25 mm Al phantom in AERC mode
7. Image intensifier input dose rate at 25 mm Al phantom in AERC mode
8. Line pair resolution
9. Low contrast resolution
10. At digital units: dose per frame
11. At DSA units (with a DSA test object):
   a) Dynamic range
b) DSA contrast sensitivity

c) Artefacts

d) Compensation for attenuation non-linearity

**Measurements on mammography equipment**

1. Radiation output
2. Leakage radiation
3. Tube voltage and irradiation time accuracy
4. Dose linearity
5. Dose reproducibility
6. Total filtration (based on half value layer measurement)
7. Dimensions and centring of the X-ray beam
8. Coincidence of X-ray beam, light beam and image reception area
9. Attenuation between X-ray source assembly and patient
10. Smallest current time product in AEC mode
11. Stability of AEC density (with different phantom thicknesses)
12. Reproducibility of AEC dose
13. AEC backup timer
14. Testing of compression device by force measurement

**Measurement devices used**

1. Universal X-ray parameter meter
2. Radiation protection dosimeter
3. Radiographic and fluoroscopic test object
4. Line pair resolution test object
5. X-ray beam and light beam coincidence testing device
6. Tomographic test object
7. DSA test object
8. Fimdensitometer
9. Aluminium and PMMA phantoms