QUALITY ASSURANCE IN DIAGNOSTIC RADIOLOGY IN HUNGARY – FIRST EXPERIENCES IN ACCEPTANCE TESTING

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Introduction: The importance of technical quality assurance

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

Regulation

In the European Union, Directive 97/43/EURATOM about radiation protection of patients 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 NPHC-NRIRR. Further full performance testing (*status testing*) is required yearly and after major servicing, it will be the task of accredited 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).

Preliminaries

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. We had, however, only few preliminaries in QA in diagnostic radiology in the second half of the eighties. Nowadays there are running QA programmes in some hospitals and mammography centres.

Start and 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). It is the first benefit of the user. In the – unlikely but in principle possible – case of non-compliance the user can successfully complain using the test report. The testing activity of our institute is independent from manufacturers, it is run within the frame of an accredited testing laboratory, using calibrated measuring instruments and based on valid international 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.

Table 1: QUALITY CONTROL AND SAFETY TESTS IN DIAGNOSTIC RADIOLOGY

Test	Regulation	It is obligatory for	Its characteristics, required frequency	It is made by
Acceptance test	Decree No. 31/2001. of the Minister of Health, 12.§ (2)	New X-ray equipment	QA: complete status evaluation, Before putting into use (single test)	NPHC-NRIRR
Status test	Decree No. 31/2001. of the Minister of Health, 13.§ (2)	X-ray equipment after acceptance testing or QA programme started	QA: complete status evaluation, Yearly and after greater maintenance	Bodies to be accredited
Constancy test	Decree No. 31/2001. of the Minister of Health, 13.§ (2)	X-ray equipment after acceptance testing or QA programme started	QA: routine check, Daily, weekly, monthly etc. (under elaboration)	Licensees (users)
Periodic safety check	Decree No. 47/1999. of the Minister of Health, 17.§ and Annex 13.	All functioning X-ray equipment, except CT and dental equipment	Elecrical, mechanical and radiation safety, Interventional X-ray: yearly, other: bi-yearly, and after greater maintenance	Notified bodies and bodies authorized by decision of Authority of Medical Devices
Radiation protection test (till full EU-membership only)	Decree No. 16/2000. of the Minister of Health, 4-5.§ and Annex 3.	Every X-ray equipment type	Single (type) test, Before the first installation	NPHC-NRIRR

Status testing and constancy 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.) We hope that first accredited bodies will start their work in the next few months. In an intermediate phase status testing is likely to be performed mostly by service firms as nowadays only they possess the required test devices. The long-term aim is to organize – and provide with test devices – an independent testing network, based on medical physicists, similarly to Great Britain or Sweden. 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. The elaboration of QA programmes for diagnostic radiology is in progress, with the co-operation of NPHC-NRIRR and National Board of Radiology. As total replacement of the equipment park is likely to need more than 15 years, initializing QA programmes on existing equipment is also to be solved.

Periodic safety checks

A special requirement in Hungary – originating not from the EU but similar to the system in Germany – is that medical devices are to be checked periodically from the point of view of electrical, mechanical and radiation safety. For X-ray equipment it is required biannually 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. After overcoming some initial difficulties this system has been functioning successfully for three years. This check is independent from QA testing although they are overlapping to some extent.

Radiation protection testing of equipment

It is a type test which is, by regulation, a necessary condition for selling an equipment type in Hungary. After the full EU-membership of Hungary it will be stopped as CE-marking certifies also radiation protection aspects of conformance to Annex I of EU Medical Devices Directive. Table 1 outlines all QA and safety tests in diagnostic radiology.

Practice and results of acceptance testing

Acceptance 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. Acceptance testing has been continuous since May 2002. During the first year about 35 acceptance tests were performed. From them 2 were mammography equipment,

the others are radiographic and fluoroscopic equipment, including tomographic and mobile equipment and surgical image intensifiers. About in every third case some need for servicing or adjustment was detected. These were recorded not only in the test reports but also in official letters written to the competent leaders of the hospitals. As it always happens in the warranty period, these servicing or adjustments are free of charge for the hospital. 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. Tests are always non-invasive.

Objective difficulties

Modern X-ray equipment have the general characteristics that the possibility of operator errors are minimized by their construction. 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 exposition is not possible. Moreover, many times only the current time product can be selected, the tube current is not independent.

Subjective difficulties

As everything at the beginning, acceptance testing is not known very much by radiological personnel although in every case we send an information leaflet in advance. In most cases the cost of the tests is 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 – personnel often say that we can perform measurements without them.

Radiographers often did not know how to use fluoroscopic or tomographic equipment so we had to rely on their documents. In general, knowledge of radiographers is very different; in many cases they do not know even the type and speed of the intensifying screens used by themselves. So improving the education and training of radiographers as well as training them on QA is an absolutely urgent and necessary task. Further, mostly organizational problems occurred in testing surgical image intensifiers in operating theatres.

Conclusions

So the started way of implementing QA in diagnostic radiology needs a lot of further efforts, adapting experiences of other countries, and also some financial help to reach an acceptable level in the EU.