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ACCEPTANCE TESTING OF FLUOROSCOPY SYSTEMS USED FOR INTERVENTIONAL PURPOSES

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This study presents the results of acceptance testing on 18 interventional fluoroscopy systems in Ireland. Acceptance testing and routine quality assurance (QA) of X-ray systems are the requirements of the EU Medical Exposures Directive (MED) and these requirements were subsequently implemented into Irish legislation. The MED states that special consideration should be given to the QA and dose assessment of high dose procedures such as interventional fluoroscopy. Owing to the advances in fluoroscopy technology, it has been found that comprehensive testing of interventional systems proves challenging in a busy hospital environment. A number of recurrent problems have been identified and are presented.

INTRODUCTION

Acceptance testing and routine quality assurance (QA) of X-ray systems are the requirements of the EU Medical Exposures Directive (97/43/EURATOM). These requirements were implemented into Irish legislation in 2002, and it states that special consideration should be given to the QA and dose assessment of high dose procedures such as interventional fluoroscopy.

International[1] and European[2–7] guidance documents are available, detailing testing methodologies and criteria of acceptability against which equipment performance may be judged. These guidelines have been used to develop in-house protocols for testing fluoroscopy/digital acquisition systems. Protocols are reviewed on a regular basis as part of the overall QA programme to take into account the new guidelines and changes or advancement in technology.

New developments in diagnostic imaging technology are creating challenges for those performing fluoroscopy QA and the technology is developing faster than the published criteria of acceptability. Flat-panel detector (FPD) digital fluoroscopy systems are beginning to replace image intensifier (II) technology and mobile C-arm II/TV systems are becoming increasingly more complex. The time required to perform comprehensive testing, analysis and reporting of all variables on complex fluoroscopy systems is a real challenge in a busy hospital environment. This study compares the results of acceptance testing for several fluoroscopy configurations and highlights some recurring problems.

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METHODOLOGY

The Medical Physics and Bioengineering Department (MPBE) of St James's Hospital is responsible for providing radiation protection (RP) and QA services to a large asset base of radiology facilities throughout Ireland. MPBE performed acceptance testing on 18 fluoroscopy installations (interventional II/TV, interventional FPD, mobile C-arm II/TV) in a number of Irish hospitals from 1999 to date. The tests done on the installations included:

- tube and generator performance;
- automatic exposure control (AEC) entrance doses;
- image quality;
- electrical safety;
- mechanical safety;
- RP and equipment design.

AEC dose rates and image quality were assessed in fluoroscopy and digital acquisition modes.

Testing was performed using calibrated ionisation chambers (6 cm^3 and 180 cm^3), calibrated peak tube voltage (kV) and exposure time meter, patient-equivalent water phantoms, copper filters, standard Leeds image quality test objects, calibrated electrical safety test equipment and other standard physics test tools.

RESULTS

Eighteen systems of varying configuration were tested (Figure 1). All systems were found to have failed one or more acceptance tests. Dose rate, image quality and RP issues were identified on the majority of systems tested (Figure 2).

About 50% of systems tested were found to have significant issues requiring action by equipment suppliers prior to the system going into clinical use.

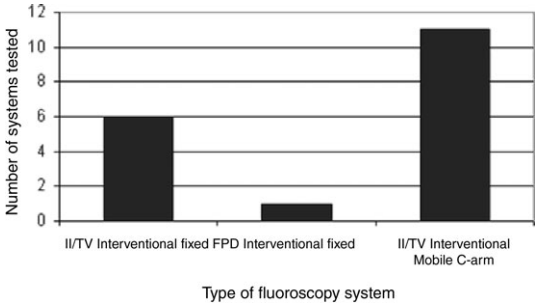

Figure 1. Number and type/configuration of fluoroscopy systems tested.

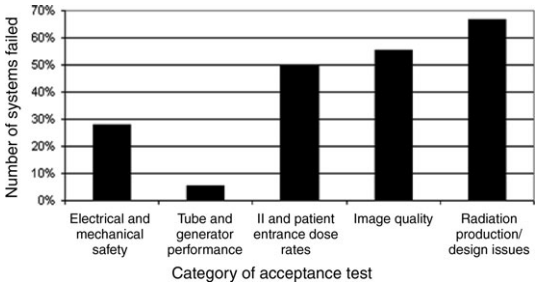

Figure 2. Acceptance test carried out and number of systems failing test.

Examples of commonly failed tests include: high entrance dose rates (EDRs), electrical safety measurements exceeding limits, significant S-distortion, accuracy of dose-area product meter and no audible indication of X-ray screening.

Entrance doses (FPD vs. fixed II/TV)

A comparison of entrance doses from a new vascular interventional FPD system vs. two conventional vascular II/TV systems is presented (Table 1). All three systems are from the same manufacturer. Entrance dose measurements were performed in line with IPEM protocols[5].

The results for doses in the fluoroscopy mode show that patient EDRs (PEDRs) made with a 20 cm water phantom are similar for all three systems (full field setting, normal fluoro mode). Detector EDR is highest on the FPD system.

In the digital acquisition mode, the dose per frame at the FPD entrance was greater than that at the majority of interventional systems (data not shown) and greater than both conventional II/TV systems (on the same default clinical 'dose' setting).

Table 1. A comparison of doses from a vascular FPD interventional system and two conventional II/TV vascular systems.

System	Fluoroscopy		Digital acquisition	
	PEDR (mGy/min)	Detector EDR (μGy/s)	Patient entrance dose (mGy/frame)	Detector entrance dose (μGy/frame)
FPD	4.6	0.6	0.4	2.6
II/TV (i)	4.3	0.2	0.3	1.1
II/TV (ii)	3.5	0.2	0.2	0.7

Image quality (FPD vs. fixed II/TV)

Results from subjective image quality tests using standard Leeds test objects were comparable between the FPD and conventional II/TV fixed systems (noise, threshold contrast detail detectability and limiting spatial resolution). Spatial resolution was observed to be slightly greater on the FPD system (1.4 lp/mm vs. 1.25 lp/mm on both II/TVs). The FPD has a full field size diagonal of 48 cm and the II/TV systems have a field diameter of 40 cm.

Mobile C-arm II/TV systems

A significant number (61%) of installations tested were modern mobile C-arm II/TV systems. The use of mobile C-arm systems for interventional purposes is growing and they are often used for very high dose angiography procedures. The systems tested as part of this study were found to have a wide variety of user-selectable acquisition modes and filtration options, many of which had noticeable impact on dose measurements and image quality.

It was found that if acceptance testing is performed following software configuration by the applications specialist, the number of options available to the clinical users is greatly reduced; therefore, testing of system options may be completed in a more efficient manner. Conversely, it was noted that if the physicist performs acceptance testing prior to software configuration, the amount of options available can be significant; however, many of these options may be deactivated by the applications specialist and may never be available to the clinical users.

User awareness issues

A consistent outcome from acceptance testing was that many 'user awareness' issues were identified,

whereby users were notified of significant operating features of the fluoroscopy system, for example:

- where varying the software filters had a considerable impact on image quality and/or radiation dose;
- where the selectable dose options had either no impact or a major impact on measured dose;
- where there was no audible indication of X-ray generation except in the high-dose fluoroscopy mode.

DISCUSSION

This study highlights the importance of comprehensive acceptance testing for complex modern fluoroscopy systems. The authors have found that it is beneficial to liaise with both the system applications' specialist and the clinical users prior to acceptance testing, to ascertain user's requirements and clinical settings. This will assist with the efficient testing of relevant modes of operation. The default clinical 'dose' setting should be optimised to ensure that it is as low as reasonably achievable. Comparative studies of new systems will assist the on-going development of testing guidelines and the criteria of acceptability for modern fluoroscopy equipment.

FUNDING

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