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ON THE ACCEPTABILITY OF FLUOROSCOPIC SYSTEMS FOR CLINICAL USE

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The proposed European commission report radiation protection 162 (EC RP 162) provides a set of tests and reference criteria that reflect European Union requirements for the acceptability of fluoroscopy X-ray systems. The report updates and expands on the current criteria established in report radiation protection (RP) 91 (1997). There is no universally accepted set of test methods due to differing national regulations and professional opinions. This paper provides a sample of such differences in the context of the proposed RP 162 criteria. A review of some fundamental fluoroscopic tests from both an Irish European Union and a US perspective is presented. The criteria proposed in EC RP 162 provide sufficient information about basic acceptability of interventional fluoroscopes and ideally, evaluations should be extended further to include specific clinical requirements.

INTRODUCTION

Fluoroscopic equipment is manufactured to meet a wide range of intended uses. The goal of acceptability testing is that of establishing whether or not a specific fluoroscope is fit for its intended range of clinical uses. In some cases, the equipment may only be suitable for some of the procedures in the proposed range. When necessary, the Medical Physics Expert's (MPEs) report should define an appropriately limited range of acceptable procedures for that instrument.

Testing the dosimetric and imaging performance of a fluoroscope is a necessary part of an acceptability evaluation. There is no universally accepted set of suspension criteria or even of the test methods themselves. This discordance comes from differing national regulations and professional opinions. This paper provides a sample of such differences by reviewing some basic fluoroscopic tests from both an Irish and a US perspective.

The draft report European commission report radiation protection 162 (EC RP 162) provides a set of tests and reference values that reflect European Union (EU) requirements[(1)]. It will replace the existing criteria set out in report EC RP 91[(2)]. In the context of the EU, fluoroscopes not meeting the published requirements should be suspended from clinical use. MPEs in other regions of the world may find the RP 162 materials useful as well. Depending on the circumstances, the MPE should consider alternative and additional tests as part of a auality assurance (QA) programme.

RP 162 REQUIREMENTS

This section outlines the proposed RP 162 requirements for fluoroscopic systems in the context of an interventional C-arm system. Single test methods are based on EU practice. Where applicable, contrasting US and EU test methods are discussed. Table 1 outlines the range of suspension items included in RP 162.

Generally unacceptable characteristics

The following items are below any reasonable level of acceptability for fluoroscopes used for clinical purposes:

(1) Direct fluoroscopy (using an unamplified fluoroscopic screen).
(2) Lack of a functional 5 min fluoroscopic timer.
(3) Equipment without any indication of delivered radiation dose.
(4) Equipment where the dose rate is only controlled manually is acceptable under a few rare justified circumstances.

Collimator functionality

The beam must be limited so that it does not exceed the active size of the image receptor by $>3\%$ of the source to image receptor (SID) in one direction or by $>4\%$ in both directions. As an alternative, the irradiated area should be $<1.15\times$ the imaged area. Irradiated areas larger than the image receptor can only be tested using film or its equivalent.

When possible, the collimator might be configured so that the maximum irradiated area is always confined within the imaged area. As shown in Figure 1, this permits a visual check of collimator performance at any time and without tools.

Table 1. Fluoroscopic suspension items[1].

(i) Generally unacceptable characteristics
(ii) Collimator functionality
(iii) Radiographic performance
(iv) Automatic dose rate control
(v) High- and low-contrast imaging performance

Table 2. Measured kVp and HVL on a fluoroscope running under ADRC control using an electronic dosemeter.

Mode	kVp	HVL (mm Al)
Fluoro	82	5.66
Cine	91	3.85
Cine	80	4.54

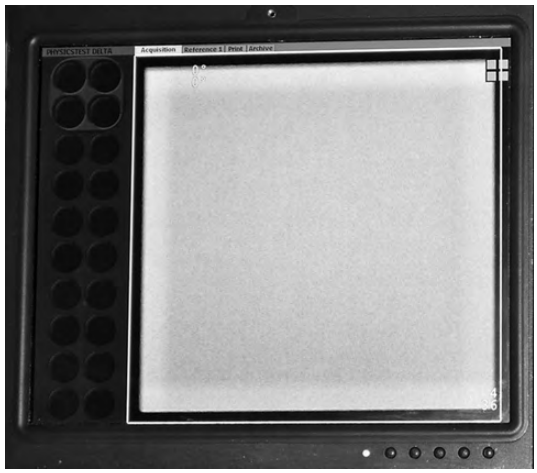

Figure 1. Beam confined to less than the maximum permitted by the selected field-of-view. The white square in the photograph is the system's calculated nominal field. The actual irradiated area was configured to 97% of nominal.

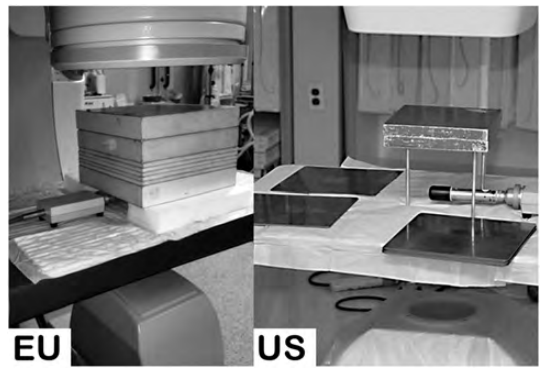

Figure 2. Patient entrance dose rate testing. Typical EU and US geometries are shown. US practice is to test under relatively low scatter conditions 30 cm from the face of the image receptor and at minimum source to image receptor (SID). EU practice approximates clinical backscatter. EU geometry often varies.

Radiographic performance: manual technique and half value layer

Fluoroscopes with manual control of technical factors must meet RP 162 radiographic acceptability criteria for accuracy and minimum half value layer (HVL) when used in the manual mode. Many newer fluoroscopes use additional fixed or variable copper filters. If the filter is in the beam, the measured HVL will be substantially higher than the nominal minimum. Measured HVLs will change in response to changes in both X-ray tube voltage (kVp) and filter. Table 2 is an example of such measurements.

Special techniques are needed to measure the HVL of a system without manual technique controls. One of these is the substitution method (maintaining the same total test filter thickness while moving layers of attenuator from above to below the measuring instrument). The second is to rely on the HVL function of an electronic dosemeter. This may be a problem for copper-filtered beams if the test instrument is unable to properly characterise such a beam.

Automatic dose-rate control (ADRC)

Most fluoroscopes automatically adjust the output of the system to maintain a constant image-receptor dose rate that is independent of patient size. This results in a size-dependent patient input dose rate. The measuring technique itself differs between EU and USA practice. Figure 2 illustrates the two setups. Figure 3 illustrates the results using the US protocol and test points specified by New York City Regulations[3]. These rules specify testing fluoroscopy at all points and acquisition modes at points up to and including 2-mm Cu. Maximum acquisition air kerma rates are often substantially greater than those measured at the 2-mm Cu test point (Figure 3).

US regulatory requirements are based on limiting fluoroscopy patient-entrance air kerma rates (without scatter). EU practice (including RP 162 regulations) defines acceptability based on fluoroscopic entrance air kerma rates using a defined thickness phantom representing an average patient[1–4]. Testing all modes at maximum output can often supply surprising results.

Image-receptor input air kerma measurements

EU practices for both radiation measurements and image quality have focused on the image-receptor

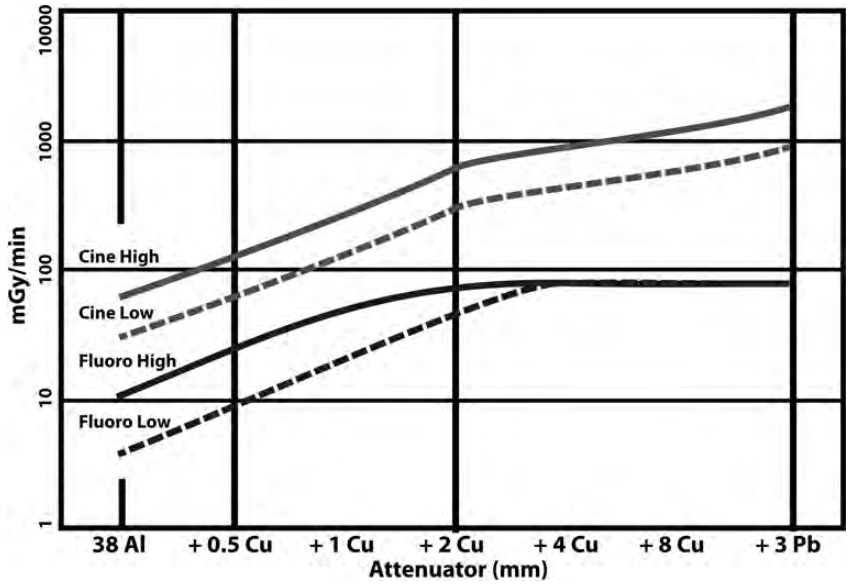

Figure 3. Typical patient entrance air kerma rates obtained using US geometry and New York State specified attenuators. This system has two fluoroscopy and two cinefluorography dose rate modes. Both fluoro modes converge at 88 mGy min^{-1} (US regulatory limit). Note that the high cine mode produces a maximum air kerma rate of almost 2 Gy min^{-1}.

Table 3. RP 162 acceptability limits for fluoroscopic image receptor dose rates.

>1 μGy s^{-1} for fluoroscopy
>0.5 μGy $frame^{-1}$ for cardiac cine
>5 μGy $frame^{-1}$ for digital subtraction angiography
Measurements are made through a standard phantom at the largest available FOV

entrance surface for decades. Because of regulatory requirements on patient-entrance measurements, US practice regarding detector input is less formal. The RP 162 acceptability limits for the image-receptor input are shown in Table 3. The test geometry is shown in Figure 4.

Integrated reference point dose and KAP meters

All fluoroscopes compliant with RP 162 have cumulative air kerma reference point indicators, Kerma area product (KAP) indicators or both. Depending on the model, these indicators may be driven by calculations, physical measurements or combinations. The RP 162 and current International Electrotechnical Commission (IEC) specification are an absolute accuracy of within $\pm 35\%$[1, 5]. There is no generally accepted test protocol for making these measurements on an installed system (The American Association of Medical Physics) is developing such a protocol.

The author's (S.B.) experience using a simplified protocol is that individual systems can be found with correction factors over most of this range (and a few exceeding the range). The stability of individual systems relative to their own mean values is typically a few per cent over a time span of several years. Improvements in this situation are needed as fluoroscopic dose reporting enters the mainstream.

Figure 5 illustrates the simplified measurement protocol. The dosemeter is placed at isocenter and the beam rotated to a horizontal direction. All removable attenuators (mattress and table top) are removed from the beam. The field is collimated to within a medium field-of-view (FOV) of the image receptor. A 4-mm Cu attenuator is placed on the image receptor. Data are collected at the isocenter and adjusted to the dose reference point using the source-isocenter distance of the system under test (reference point is 15 cm from isocenter towards the X-ray tube). When dose measurements are complete, the measuring plate replaces the chamber at the isocenter. The image on the monitor defines the field size at isocenter.

High- and low-contrast imaging performance

Acceptability of high-contrast spatial resolution and low-contrast detectability is included in RP 162[1]. Current test procedures rely on human observers. Analytic evaluation of digital images can be

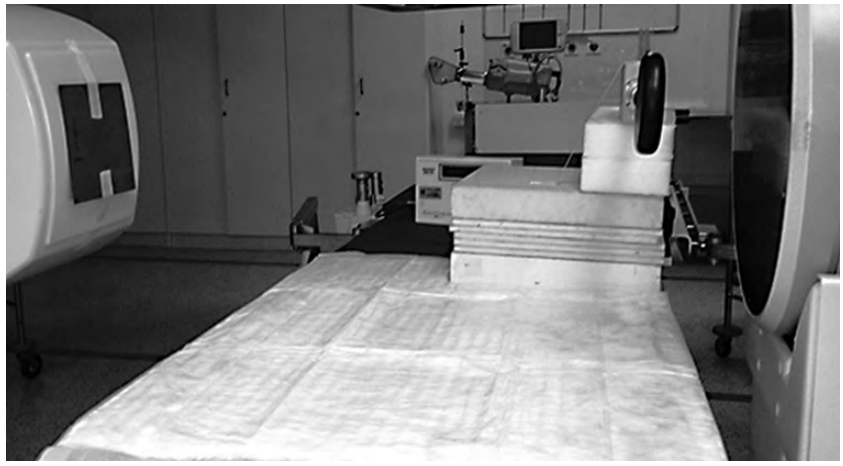

Figure 4. Geometry for measuring image receptor entrance dose rates. The attenuator is taped to the collimator. An inverse square factor is used to transform the data to the image receptor entrance.

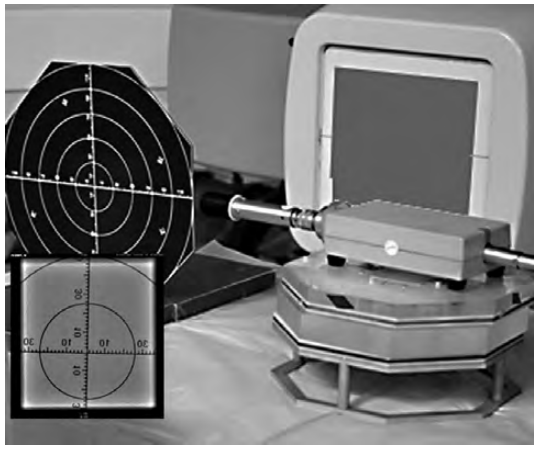

Figure 5. An informal working geometry for calibrating internal 'dose' indicators. See text for details.

Figure 6. Representative US IQ test geometry. The test-objects are placed on the Al attenuator which is at 30 cm from the image receptor. Magnification is approximately 1.5 for this interventional C-arm. Additional HC testing is done at maximum SID (Mag. ≈2.0) to further investigate the effects of the focal-spot.

expected to reduce observer variability. Fully integrated test-objects and software will provide direct measurements of modulation transfer function, contrast to noise ratio and signal to noise ratio in the future.

As noted above, most aspects of EU fluoroscopic testing are at the image receptor's input surface. These are typically done using Leeds Test Objects for low contrast and a Hüttner plate for high contrast (HC)[6]. Focal-spot size and geometric magnification of the test-object do not influence the results with the tool directly attached to the receptor.

The US practice is quite variable with regard to test geometry. One author's (S.B.) practice (a hybrid of published protocols) is reported in this paper. Tests are performed under low-scatter conditions that otherwise simulate clinical geometry (Figure 6). The patient-entrance dose-rate geometry (minimum SID with the test-object approximately 30 cm from the image receptor) is used. This yields a geometric magnification factor of approximately 1.5. Testing is performed with the beam collimated to the test feature being investigated and using all available FOVs of the image receptor. Fluoroscopic runs should be stored for later analysis whenever possible. In all cases, it is important to validate the imaging monitor performance prior to testing fluoroscopic image quality (IQ).

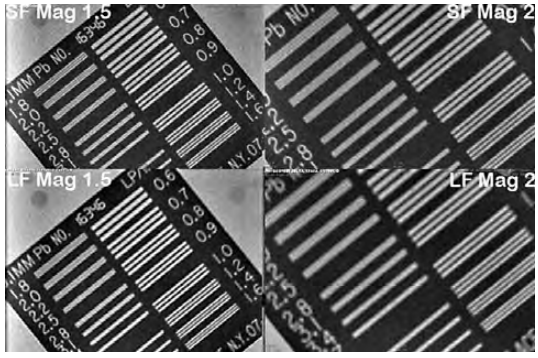

Figure 7. Effects of focal-spot size and geometric magnification on high-contrast resolution. The small-focus images are fluoroscopic last image hold, the large-focus images are single cine frames. All images were acquired using the 15-cm FOV of this image receptor.

Low-contrast testing is conventionally performed using a 1-mm Al plate (with 2.4, 3.2, 4.8, 7.1 mm holes) placed on top of a 38-mm attenuator. The physical contrast is approximately 2.6%. This target no longer challenges image receptors. The author (S.B.) uses a locally made 0.5-mm thick plate with rows of holes ranging from 0.5 to 5 mm. Including magnification, an acceptably performing image receptor will easily resolve the 2-mm row when imaged at the smallest FOV and the system's lowest dose-rate mode.

High-contrast tests are performed with a lead bar phantom initially placed on a 19-mm Al block. Because focal spots are asymmetric, the pattern must always be placed in the same orientation. All available combinations of available focal spots and FOVs are tested using minimum SID. Supplemental images are produced at maximum SID and smallest FOV. The effects of focal-spot size and magnification are clearly seen in Figure 7.

CAUSES OF UNACCEPTABILITY

The collimator assembly is not protected from mechanical impact in C-arm systems and is the leading reason for unacceptability in the short time frame. Deteriorating image receptors or video systems can usually be identified (using image receptor input dose rates and IQ test results) and repaired, while the system remains in an acceptable status. Integrated dose displays should be verified as part of each QA session. Changes in the calibration factor of $>5\%$ should be investigated.

CONCLUSIONS

The proposed report EC RP 162 provides sufficient information about the basic acceptability of interventional fluoroscopes. Ideally, the MPE's evaluation should be extended to include specific clinical requirements. Many of the tests proposed in RP 162 can be performed using alternative protocols. The selection of actual testing methods is based on a combination of regulatory requirements, local standards and the availability of test equipment.

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