Quality assurance and quality control in mammography: a review of available guidance worldwide

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Abstract

Objectives Review available guidance for quality assurance (QA) in mammography and discuss its contribution to harmonise practices worldwide.

Methods Literature search was performed on different sources to identify guidance documents for QA in mammography available worldwide in international bodies, healthcare providers, professional/scientific associations. The guidance documents identified were reviewed and a selection was compared for type of guidance (clinical/technical), technology and proposed QA methodologies focusing on dose and image quality (IQ) performance assessment.

Results Fourteen protocols (targeted at conventional and digital mammography) were reviewed. All included recommendations for testing acquisition, processing and display systems associated with mammographic equipment. All guidance reviewed highlighted the importance of dose assessment and testing the Automatic Exposure Control (AEC) system. Recommended tests for assessment of IQ showed variations in the proposed methodologies. Recommended testing focused on assessment of low-contrast detection, spatial resolution and noise. QC of image display is recommended following the American Association of Physicists in Medicine guidelines.

Conclusions The existing QA guidance for mammography is derived from key documents (American College of Radiology and European Union guidelines) and proposes similar tests despite the variations in detail and methodologies. Studies reported on QA data should provide detail on experimental technique to allow robust data comparison. Countries aiming to implement a mammography/QA program may select/prioritise the tests depending on available technology and resources.

Main messages

- An effective QA program should be practical to implement in a clinical setting.
- QA should address the various stages of the imaging chain: acquisition, processing and display.
- AEC system QC testing is simple to implement and provides information on equipment performance.

Keywords Mammography · Quality control · Quality assurance · Dose · Image quality

Introduction

To ensure the key goals of mammography are achieved, quality standards should be adopted. Ideally, these should be wide in scope and address the various aspects with impact on the mammography imaging process (e.g. technical, clinical and training).
A systematic approach for assessing critical performance indicators can be achieved through the implementation of a quality assurance (QA) program. QA provides a framework for constant improvement through a feedback mechanism. It allows the identification of deviations from optimum performance of mammographic equipment, suboptimal clinical practice and training needs [1–3].

An effective QA program should be practical to implement in a clinical setting. Adequate test equipment is necessary as well as standard methodology that provides ability to obtain the relevant objective, and subjective metrics of quality. Also, an effective QA program should be implementable at a low or moderate cost [4].

The testing of equipment should address the various critical stages of the imaging chain (acquisition, processing and display) and be implemented in a multidisciplinary team approach by trained staff (radiographer, medical physicist, radiologist) [3, 5].

In the past 20 years, several guidance documents have been developed nationally and internationally to promote quality in mammography. The scope of the guidance documents varies with some focused on technical aspects [4, 6–10], whereas others include also clinical aspects (e.g. epidemiology, interventional, pathology, surgery) [7, 11].

The developments in digital mammography over the last 10 years have resulted in developments in QA programmes and promoted the recommendation of new tests and procedures for quality control [12].

This study aimed to identify, analyse and compare selected protocols currently available for QA in mammography, and to discuss their contribution to harmonise practices in mammography worldwide.

This review aims to provide useful guidance to countries aiming to implement (or further develop) a QA program in mammography.

Methods

An extensive search was performed to identify guidance documents and protocols for QA in mammography. Sources used included scientific databases, organisations of national healthcare systems (hospitals, regulatory bodies, etc.), international agencies (e.g. International Atomic Energy Agency [IAEA], International Commission on Radiological Protection [ICRP]), professional colleges (e.g. American College of Radiology [ACR], Royal College of Radiologists [RCR]) and scientific associations (e.g. Institution of Physics and Engineering in Medicine [IPEM], American Association of Physicists in Medicine [AAPM]). The search returned various documents published in English, French, Portuguese, Spanish, German, Italian, Swedish and Dutch. Only documents published in English or French were considered for comparability issues, as other languages were not mastered by the team.

The guidance documents identified were reviewed and compared for structure, editorial details, target staff profiles, technologies addressed and type of guidance (technical and clinical). Comparative tables are presented summarising the most relevant findings.

Results

Guidance documents for QA and quality control (QC) in mammography

Fourteen guidance documents for QA and QC in mammography published between 1991 and 2011 were identified (Table 1). Two are recommended by European bodies (European Reference Organisation for Quality Assured Breast Screening and Diagnostic Services [EUREF] and European Commission [EC]), three are internationally proposed by the IAEA and ten have national or regional scope (United States of America [USA], Canada, Australia, United Kingdom [UK], Ireland, Nordic) by governmental bodies, professional and/or scientific organisations.

Guidance documents for QA and QC in mammography—scope and professional groups targeted

Four documents address both conventional and digital mammography. All documents are primarily focused on providing technical guidance. Three documents include both technical and clinical guidance.

Thirteen documents are targeted at medical physicists and nine also include guidance for radiographers and radiologists. One protocol is specifically targeted at radiographers (Table 2).

The EC protocol, Australian and Irish protocols are broader in scope and include guidance to epidemiologists, nurses, oncologists and surgeons.

Performance testing of mammographic systems and breast dose assessment

Most documents (exceptions are the European Protocol [EP] and IAEA-D protocols) recommend performance testing of the three main stages of the mammography imaging chain (Tables 3, 4, 5, 6 and 7):

1. Image acquisition (the stage with more intensive testing)
2. Image processing (following the manufacturers’ recommendations)
3. Image display (includes monitor and printer testing)
Table 1  Guidance documents for quality assurance and quality control in mammography

| Edition | Publisher | Country | Title                                                                 | Short title<sup>a</sup> | Status                      | Scale          | Reference<sup>b</sup> |
|---------|-----------|---------|----------------------------------------------------------------------|--------------------------|----------------------------|-----------------|------------------------|
| 2011    | IAEA      | Various | Quality assurance programme for digital mammography                   | IAEA-DM                  | In use                     | Worldwide      | [4]                    |
| 2009    | IAEA      | Various | Quality assurance programme for screen film mammography               | IAEA-SF                  | In use                     | Worldwide      | [10]                   |
| 2007    | IAEA      | Various | Dosimetry in diagnostic radiology: an international code of practice | IAEA-D                   | In use                     | Worldwide      | [13]                   |
| 2006    | European Commission/EUREF | Various | European guidelines for quality assurance in breast cancer screening and diagnostic 4th edition | EC                       | In use/update in progress | Europe         | [14]                   |
| 1996    | EP European Commission | Various | European protocol on dosimetry in mammography                        | EP                       | In use                     | Worldwide      | [6]                    |
| 1991/1994 | Swedish Radiation Protection Institute | Denmark, Finland, Iceland, Norway, Sweden | Report on Nordic radiation protection Co-operation– Number 1-mammography | Nordic Protocol          | Supersed by the European Protocol | Nordic Countries | [17]                   |
| 2009    | NHSBSP    | UK      | Commissioning and routine testing of full field digital mammography systems | NHSBSP/UK                | In use                     | National       | [18]                   |
| 2009    | RANZCR    | Australia and New Zealand | Mammography quality assurance program: guidelines for quality control testing for digital (CR & DR) mammography | RANZCR                   | In use                     | National       | [19]                   |
| 2008    | The National Cancer Screening Service Board | Ireland | Guidelines for quality assurance in mammography screening             | Irish Protocol           | In use                     | National       | [11]                   |
| 2008    | NQMCBASA  | Australia | Breast screen Australia Quality improvement program                    | Australian Protocol      | In use                     | National       | [20]                   |
| 2005    | IPEM      | UK      | The commissioning and routine testing of mammographic X-ray systems   | IPEM/UK                  | In use/update in progress  | National       | [8]                    |
| 1999    | ACR       | USA     | Mammography quality control manual for radiologists, medical physicists and technologists | ACR                      | In use/update in progress  | National       | [9]                    |
| 2006    | Ministère de la Santé-Québec | Canada (Québec) | Manuel de contrôle de la qualité pour la mammographie et la biopsie guidée par stéréotaxie, Volume 2–physicien biomédical | Canadian Protocol         | In use                     | Regional       | [21]                   |
| 2001    | Ministère de la Santé-Québec | Canada (Québec) | Manuel de contrôle de la qualité, Volume 1-technologie en radiologie | Canadian Protocol         | In use                     | Regional       | [22]                   |

<sup>a</sup> Short title used as reference in this manuscript  
<sup>b</sup> Listed on the reference list
Testing the image acquisition system

X-ray production system All documents recommend testing the generator and X-ray source, the Automatic Exposure Control (AEC) and the breast compression systems. Recommended tests include (1) alignment of X-ray field/light field/image receptor area, (2) repeatability and accuracy of tube output exposure, (3) half-value layer (HVL), (4) AEC response versus breast thickness and tube voltage compensation and (5) alignment of the compression plate.

Breast dose Table 6 reviews the guidance for dosimetry testing. All guidance documents provide recommendations for assessment of breast dose and two (i.e. EP; IAEA-D) are dedicated to this topic and include detailed methodology.

The mean glandular dose (MGD) is the recommended parameter for assessing the risk of radiation-induced cancer in mammography. Proposed methodologies for MGD assessment (reviewed in Table 6) include:

- Measurements on patients using a thermoluminescent dosimeter (TLD) (a minimum of ten patients is recommended)
- Dose estimation from clinical exposure data (10–60 patients recommended)
- Dose estimation using test objects/phantoms (the entrance surface air kerma without backscatter (ESAK) should be measured and multiplied by a conversion factor, which compensates for X-ray beam quality, breast thickness and composition (percentage glandularity)

The ESAK is required to calculate MGD and can be measured with a calibrated ionisation chamber (IC), semiconductor dosimeter or TLD material (Table 6). If measurements include the effect of backscatter (e.g. TLDs), an appropriate correction factor should be applied [6]. The recommended phantoms to perform dosimetry testing vary between the protocols (Table 6).

Also, the various protocols propose different methodologies to measure the required data for MGD calculation (e.g. the ACR, Canadian and UK/IPEM propose measurements to be performed at 40 mm from the chest wall edge, whereas the EP recommends 60 mm).

Since the conversion factors used to estimate the MGD from the incident air kerma depend on the X-ray beam quality, it is necessary to keep track of the target/filter (T/F) combination and tube voltage used in the experimental procedure, as well as the half-value layer (HVL) of the X-ray beam.

The EC protocol proposes conversion factors by Dance et al. (1990) and Dance et al. (2000), whereas the ACR uses factors by Dance et al. (1990); Wu et al. (1991) and Sobol et al. (1997) [9], the Canadian protocol uses Stanton et al. (1984) and Wu et al. (1991) [13] and the Nordic protocol propose conversion of Rosenstein et al. (1985) [14].

Image receptor The most frequently recommended tests for digital mammography include (1) the system’s response function, (2) image noise, (3) missed tissue at chest wall edge, (4) signal homogeneity and (5) image artefacts (Table 3).
| X-ray generation | Test type | Target parameter to assess | International | National | Regional | Frequency |
|-------------------|-----------|---------------------------|---------------|----------|----------|-----------|
| X-ray source      | Focal spot size | EC (2006) | Y | N | N | Y | Y | Y | N | Y | N | Y | 5 |
|                   | Source-to-image distance | IAEA-SF (2009) | Y | N | N | N | Y | Y | N | N | Y | Y | 5 |
|                   | Alignment of X-ray field/image receptor | IAEADM (2011) | Y | Y | Y | Y | Y | Y | N | N | Y | Y | 9 |
|                   | Radiation leakage | ACR (1999) | Y | Y | N | N | Y | Y | Y | Y | N | Y | 7 |
|                   | Tube output | Ireland (2008) | Y | Y | Y | Y | Y | Y | N | Y | Y | 8 |
| Tube voltage and beam quality | Reproducibility and accuracy | UK/IPEM (2005) | Y | Y | Y | Y | Y | Y | N | Y | Y | 9 |
| AEC system performance | Half value layer (HVL) | Ireland (2008) | Y | Y | Y | Y | Y | N | Y | Y | 9 |
|                   | Optical density control setting: central value and difference per step | UK/NHSBSP (2009) | Y | Y | N | N | Y | N | N | N | Y | 7 |
|                   | Back-up timer and security cut-off | Canada (Quebec) (2001/2006) | Y | N | N | N | Y | Y | Y | N | Y | N | 5 |
|                   | Short term reproducibility | Canada (Quebec) (2001/2006) | Y | N | N | N | Y | Y | Y | Y | R | 8 |
|                   | Long term reproducibility | Canada (Quebec) (2001/2006) | Y | N | Y | N | N | N | Y | N | N | R | 4 |
|                   | Object thickness and tube voltage compensation | Canada (Quebec) (2001/2006) | Y | Y | Y | Y | Y | Y | Y | Y | Y | 10 |
|                   | Correspondence between AEC sensors | Canada (Quebec) (2001/2006) | Y | N | N | N | Y | N | Y | Y | R | 5 |
| Compression       | Compression force | Canada (Quebec) (2001/2006) | Y | N | Y | Y | Y | N | Y | N | Y | 7 |
| Bucky and image receptor | Compression plate alignment | Canada (Quebec) (2001/2006) | Y | Y | Y | Y | Y | Y | N | Y | N | 8 |
| Anti-scatter grid | Grid system factor | Canada (Quebec) (2001/2006) | Y | N | N | N | Y | Y | N | N | Y | 4 |
| Screen-film      | Grid imaging | Canada (Quebec) (2001/2006) | Y | N | N | N | Y | Y | N | N | Y | 4 |
|                   | Inter cassette sensitivity and attenuation variation and optical density range | Canada (Quebec) (2001/2006) | Y | Y | N | Y | Y | N | N | N | Y | 6 |
|                   | Screen-film contact | Canada (Quebec) (2001/2006) | Y | Y | Y | Y | N | Y | N | N | Y | 6 |
| Image receptor response (digital) | Response function | Canada (Quebec) (2001/2006) | Y | N | Y | N | N | Y | Y | N | Y | R | 6 |
| Missed tissue at chest wall edge (digital) | Noise | Canada (Quebec) (2001/2006) | Y | N | Y | R | Y | Y | N | Y | Y | 7 |
| Image receptor homogeneity and stability (digital) | Image receptor homogeneity | Canada (Quebec) (2001/2006) | Y | N | N | Y | N | Y | N | N | Y | 8 |
|                   | Detector element failure (DR systems) | Canada (Quebec) (2001/2006) | Y | N | N | N | Y | N | N | N | N | 4 |
|                   | Uncorrected defective detector elements (DR systems) | Canada (Quebec) (2001/2006) | Y | N | N | N | Y | N | N | N | N | 2 |
| Inter-plate sensitivity variation (CR) | Image receptor homogeneity | Canada (Quebec) (2001/2006) | Y | N | N | N | Y | N | N | Y | N | 5 |
| Other sources of radiation (CR) | Detector element failure (DR systems) | Canada (Quebec) (2001/2006) | Y | N | N | N | Y | N | N | N | Y | 2 |
| Fading of latent image (CR) | Uncorrected defective detector elements (DR systems) | Canada (Quebec) (2001/2006) | Y | N | N | N | Y | N | N | N | Y | 4 |
Some protocols propose specific tests for CR systems, namely (1) inter-plate sensitivity variations, (2) image artefacts, (3) evaluation of the influence of secondary sources of radiation and (4) fading of the latent image signal. Guidance is also included for testing the scanning mechanism of the CR plate and the efficiency of the erasure cycle. Specific tests for SFM are proposed in the older protocols (EC protocol, UK/IPEM, Canada, IAEA-SF) (Table 3).

Quality of the acquired image Table 7 summarises eight groups of tests for assessment of IQ recommended in the guidance documents reviewed. The tests address technical and clinical IQ criteria using test objects and phantoms.

Phantoms and test objects The recommended phantoms to produce the images for low contrast IQ assessment vary between the protocols. CDMAM is frequently recommended in Europe (EC PROTOCOL, UK/IPEM, UK/NHSBSP and Ireland) whereas the ACR phantom is the standard in use in the US and Canada.

IAEA does not recommend a particular phantom but highlights the importance of using a phantom that contains structures able to mimic those typically found in the breast.

For high-contrast IQ assessment the MTF is the key recommended parameter. The MTF bar pattern method is more straightforward to implement than the calculation of the MTF using the edge phantom.

Image processing Image quality is affected by the processing stage. For SF systems the guidance reviewed recommends testing the performance of the chemical processor (e.g. time, temperature, base and fog levels). The EC guidelines highlight the importance of testing image processing. For digital mammography systems, the manufacturer’s guidance should be followed because image-processing algorithms are manufacturer-specific.

Artefacts Artefact analysis is an important test recommended in all guidelines reviewed. For SFM it focuses on artefacts resulting from the chemical processing or from the degradation of the screen-film detector characteristics. In digital systems, artefact analysis is focused on investigating problems originating in the image acquisition system and during plate handling and processing (CR systems). Testing includes assessment originated by printing devices (e.g. laser printers). A clinical evaluation protocol (type testing) is available in the EUREF website (www.euref.org) and repeated/rejected analysis is recommended on the IAEA-DM protocol.

Image display QA guidelines for testing image display systems (Table 5) refer to the AAPM report Task Group 18 [15].
for testing electronic monitors and printers. The testing of light boxes is included in the QC guidance for SFM systems [11, 12, 16].

Test frequency and reference (or limiting) values

All guidance documents provide recommendations on the frequency of the tests (Table 1). A number of tests are recommended at acceptance only. Others should be performed periodically (yearly, 6-monthly, monthly, weekly or daily). Intermediate testing should be performed when necessary (e.g. following major equipment repair).

The guidance documents also provide reference values and pass/fail criteria. These originate from manufacturer recommendations, expert knowledge, survey QC data, baseline values and national policies (e.g. existing dose reference levels). A critical aspect is to ascertain when the measured (including uncertainties) is substantially lower than the reference/limiting value. As an example, UK/IPEM guidance recommends that measured values for the relevant performance indicators not exceed one-third of the range proposed for the limiting or remedial values.

Discussion

The study showed that in the last 20 years comprehensive guidance documents have been developed worldwide to support the implementation of QA in mammography.

Target technology

The IAEA-DM protocol (edited 2011) is the most up-to-date guidance and is dedicated to digital mammography. The UK/IPEM, EC, IAEA-SF and ACR protocols are well-established documents originally developed for SFM that have been adopted in many countries worldwide. The EC guidelines were updated and an addendum on digital mammography was included [1, 17]. At the date of submission of this paper, an updated version of the ACR protocol is known to be in progress to include guidance specifically targeted at digital mammography. Also, as per information available on the EUREF website, a revised edition (5th) of the EC Guidelines is in development [18].

As new techniques in digital mammography are becoming widespread, it is expected that revised versions of the existing protocols will be produced, including guidance for testing the capabilities of state of the art technology (e.g. tomosynthesis, dual-energy contrast-enhanced digital subtraction mammography).
| Test type       | Target parameter/characteristic to assess | EC (2006) | IAEA-SF (2009) | IAEA-DM (2011) | ACR (1999) | UK/IPEM (2005) | Ireland (2008) | Australia (2008) | RANZCR (2009) | UK/NHSBSP (2009) | Canada (Quebec) (2001/2006) | Total (10) |
|----------------|------------------------------------------|-----------|----------------|----------------|------------|----------------|---------------|------------------|---------------|------------------|-------------------------------|------------|
| Viewing condition | Viewing box                             | Y Y Y Y Y | Y Y Y Y N Y Y | Y N Y N Y N | N Y Y N | Y Y Y N Y N Y | Y Y N N N Y N | Y N N N Y N N | Y N N N N N N | Y N N N N N N |                                   |            |
|                | Homogeneity                              | Y Y Y Y Y | Y Y Y N Y N Y | N Y Y N Y N | Y Y Y N | Y N Y N Y N Y | Y Y Y Y N N Y | Y N N N N N N | Y N N N N N N | Y N N N N N N |                                   |            |
|                | Ambient light                            | –         | Y Y Y Y Y Y Y | Y Y Y N N N | Y N Y N | Y Y Y N N N | Y Y Y Y N N Y | Y N N N N N N | Y N N N N N N | Y N N N N N N |                                   |            |
| Monitors       | Ambient light (CRT displays)             | Y N Y N R | Y Y Y Y Y Y Y | N N N N N N | Y Y Y N | Y Y Y Y N N Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y |                                   |            |
|                | Geometrical distortion (CRT displays)    | Y N Y N R | Y Y Y Y Y Y Y | N N N N N N | Y Y Y N | Y Y Y Y N N Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y |                                   |            |
|                | Contrast visibility                      | Y N Y N R | Y Y Y Y Y Y Y | N N N N N N | Y Y Y N | Y Y Y Y N N Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y |                                   |            |
|                | Resolution                               | Y N Y N R | Y Y Y Y Y Y Y | N N N N N N | Y Y Y N | Y Y Y Y N N Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y |                                   |            |
|                | Display artefacts                        | Y N Y N R | Y Y Y Y Y Y Y | N N N N N N | Y Y Y N | Y Y Y Y N N Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y |                                   |            |
|                | Luminance range                          | Y N Y N R | Y Y Y Y Y Y Y | N N N N N N | Y Y Y N | Y Y Y Y N N Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y |                                   |            |
| Printers       | Greyscale display function               | Y N Y N R | Y Y Y Y Y Y Y | N N N N N N | Y Y Y N | Y Y Y Y N N Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y |                                   |            |
|                | Luminance uniformity                     | Y N Y N R | Y Y Y Y Y Y Y | N N N N N N | Y Y Y N | Y Y Y Y N N Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y |                                   |            |
|                | Geometrical distortion                   | Y Y Y Y N | Y Y Y Y Y Y Y | N N N N N N | Y Y Y N | Y Y Y Y N N Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y |                                   |            |
|                | Contrast visibility                      | Y Y Y N R | Y Y Y Y Y Y Y | N N N N N N | Y Y Y N | Y Y Y Y N N Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y |                                   |            |
|                | Resolution                               | Y Y Y N R | Y Y Y Y Y Y Y | N N N N N N | Y Y Y N | Y Y Y Y N N Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y |                                   |            |
|                | Printer artefacts                        | Y Y Y N R | Y Y Y Y Y Y Y | N N N N N N | Y Y Y N | Y Y Y Y N N Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y |                                   |            |
|                | Optical density range (optional)         | Y Y Y Y N | Y Y Y Y Y Y Y | N N N N N N | Y Y Y N | Y Y Y Y N N Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y |                                   |            |
|                | Greyscale display function               | Y Y Y Y N | Y Y Y Y Y Y Y | N N N N N N | Y Y Y N | Y Y Y Y N N Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y |                                   |            |
|                | Density uniformity                       | Y Y Y Y N | Y Y Y Y Y Y Y | N N N N N N | Y Y Y N | Y Y Y Y N N Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y |                                   |            |
| Other Electrical tests | –                                   | N N Y Y Y Y Y Y Y | N N N N N N | Y Y Y N | Y Y Y Y N N Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y |                                   |            |
| Mechanical tests | –                                    | N Y Y Y Y Y Y Y | Y Y Y Y Y Y | Y Y Y Y N N | Y N N N | Y Y Y Y N N Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y |                                   |            |
| Repeat image analysis | –                                  | N Y Y Y Y Y Y Y | Y Y Y Y Y Y | Y Y Y Y N N | Y N N N | Y Y Y Y N N Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y | Y Y Y Y Y Y Y |                                   |            |

Y yes/exists, N no/not provided, R referred without detail on the methodology

*(Total refers to the total number of guidance documents that recommend the test)
| Protocol ID | Technical (with test objects/phantom) | Test equipment (dosimeters) | Quantities and units | AGD estimation | Conversion factors | Reference dose per projection |
|------------|---------------------------------------|-----------------------------|---------------------|----------------|-------------------|-----------------------------|
| Nordic     | Standard breast model 45 mm PMMA equivalent to average breast (50% adipose + 50% glandular) | NA                          | Clinical (with patient data) | Test equipment (dosimeters) | Quantities and units | AGD estimation | Conversion factors | Reference dose per projection |
| EP         | Standard breast model 45±5 mm PMMA | TLD or other dosimeter with a dynamic range 0.5–100 mGy | 10 patients with a compressed breast thickness between 40 to 60 mm for dose measurements on patients with TLD | ESAK (mGy), AGD or MGD (mGy) | AGD = ESAK × gPB | Dance (1990) | 2.3 mGy for a standard phantom |
| ACR        | (1) Blocks of PMMA (20, 40, 60 and 80 mm) (2) Standard breast model 40-mm PMMA equivalent to 42 mm 50/50 mixture | NA                          | Entrance Exposure estimated from technical factors recorded and tube output (mR/mAs) and MGD (mGy) | AGD = ESD × conversion factors | | | |
| IPEM       | (1) Blocks of PMMA (20-80 mm) (2) Standard breast model 45-mm PMMA, equivalent breast thickness 55 mm with 30% glandularity | NA                          | AGD for a series of breast examinations on each mammography system periodically. Data collection: breast thickness; kVp; mAs. Accuracy: ±2 mm | ESAK(K), AGD or MGD (mGy) | D = Kgs | Dance (2000) for two age ranges 40–60 to 50-64 | 2 mGy (40 mm compressed breast thickness) |
| EC         | (1) Blocks of PMMA (20-80 mm) (2) Standard breast model 45-mm PMMA, equivalent breast thickness 53 mm | NA                          | AGD for a series of breast examinations on each mammography system. Data collection: breast thickness; kVp; mAs. Accuracy: ±2 mm | ESAK(K); AGD or MGD (mGy) | D = Kgs | Dance (2000) for two age ranges 40–60 to 50-64 | 2.5 mGy for 45 mm compressed breast thickness |
| PQDCS      | (1) Standard breast model 40-mm PMMA, equivalent to 42 mm 50/50 mixture | NA                          | Entrance Surface Dose (ESD) (mR); AGD or MGD (mrad/R) | AGD = ESD × conversion factors | | | |
| IAEA-D     | 45-mm thick PMMA phantom equivalent to 'standard' breast of thickness 50 mm and glandularity 50% | A range of 10–50 patients. Reference requires that the compressed breast is between 40 and 60 mm thick, with a mean value of 50 ± 5 mm | IC or semiconductor Dosimeter or TLD | Incident air kerma, (mGy); Entrance surface air kerma (mGy); AGD or MGD (mGy) | | | |
| BC NBSP    | Blocks of PMMA (20–70 mm) | Based on IPSM89 (2005) and the European Protocol in Dosimetry in Mammography (1996) | IPSM89 (2005) and the European Protocol in Dosimetry in Mammography (1996) | ESAK(K); AGD or MGD (mGy) | D = Kgs | Dance (2000) for two age ranges 40–60 to 50-64 | 2.5 mGy for 45 mm compressed breast thickness |

Reference: Dance (2000) for two age ranges 40–49 and 50-64.
| Phantom Type | Description | Dosimetry | Dose |
|-------------|-------------|-----------|------|
| NQMCBSA     | Standard phantom 42 mm 50% adipose, 50% glandular breast (i.e. ACR accreditation phantom) | – | ≤2.0 mGy for exposures made using typical clinical settings |
| NHSBSP      | (1) Blocks of PMMA (20–70 mm) | 50 patients recommended with a compressed breast thickness of 55±5 mm; 10 patients should be included in the dose sample | – | ESAK(K); AGD or MGD (mGy); D = Kgcs; Dance (2000) |
|             | (2) Standard breast model 45-mm PMMA, equivalent breast thickness 53 mm | | | 1 mGy for 20 mm PMMA; 2.5 mGy for 45 mm PMMA; 6.5 mGy for 70 mm PMMA |
| IAEA-SF     | Standard breast model 45-mm PMMA, equivalent breast thickness 53 mm | NA | ESAK(K); AGD or MGD (mGy); D = Kgcs; Dance (2000) |
|             | | IC | Achievable: 2.0 mGy; Acceptable: 2.5 mGy |
| IAEA-DM     | Blocks of PMMA (20, 45, 70 mm) | NA | ESAK(K); AGD or MGD (mGy); D = Kgcs; Dance (2000) |
|             | | Calibrated detector at appropriated mammographic energies | | 1 mGy for 20 mm PMMA; 2.5 mGy for 45 mm PMMA; 6.5 mGy for 70 mm PMMA |

*NA not applicable, – not available/not accessible

Mo/Mo is the conversion factor of incident air KERMA (K) to MGD for Mo/0.030 mm Mo at 28 kVp, c is a factor that corrects for glandularity different from 50% and s corrects for any anode/filter material combination, other than the Mo/Mo at 28 kVp only. The coefficient cDG,g,DG50 converts MGD for a 50% glandular breast to the MGD for a breast of glandularity, g, and of the same thickness.
| Test                                                                 | Guideline                      | Materials                                                                 | Comments and reference values                                                                 |
|----------------------------------------------------------------------|--------------------------------|---------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|
| Positioning                                                          | ACR EC Ireland, Australia, IAEA-SF | NA                                                                        | Subjective evaluation using clinical criteria                                                  |
| Compression                                                          | ACR EC Ireland Australia, IAEA-SF | Compression force device, foam rubber, tape measure, Force measuring device (e.g. analogue bathroom scales) | Display force = measured force ± 20 N. Max motorised force = 130–200 N. Subjective evaluation using clinical criteria. |
|                                                                   | Ireland                         | Scales, compressible material                                              | Display force = measured force ± 20 N. Max misalignment <5 mm for symmetric load.              |
|                                                                   | Australia                       | Force measuring device (e.g. analogue bathroom scales)                     | Maximum motorised force between 150–200 N                                                    |
|                                                                   | IAEA-DM                         | Scales (e.g. analogue bathroom scales), foam, PMMA slabs                  | Test motorised and manual compression. Max motorised force = 150 N-200 N.                   |
| Contrast resolution and visualisation of breast lesions (in phantom) | ACR, Canada, Australia, RANZCR   | ACR accreditation phantom. Canada (alternative phantoms are RMI 156 or NA 18–220 or CIRS 015) | CANADA: provides reference values for SFM and DR. ACR, Australia: RANZCR provides minimum threshold for visible details |
|                                                                   | EC                              | CDMAM                                                                     | ACR, Australia: RANZCR provides minimum threshold for visible details                         |
|                                                                   | UK/IPEM, UK/NHSBSP              | TOR (MAM) or CDMAM                                                        | IPEM: recommend remedial values for low contrast detail detectability                         |
|                                                                   | Ireland                         | CDMAM, PMMA blocks, CDOM software, TORMAX                                 | NHSBSP: recommend acceptable and achievable values.                                         |
|                                                                   | IAEA-DM                         | Not specified (phantom should mimicking breast structures)                 | IQ assessed for digital system should be as good as, or better than, that expected with high quality SF mammography |
| Spatial resolution                                                   | UK/IPEM                         | TOR(MAX)                                                                  | Recommends remedial value                                                                   |
|                                                                   | EC                              | MTF test tool, software to calculate MTF                                   | Recommends considering the acceptance value as reference                                     |
|                                                                   | Ireland                         | MTF edge phantom, ImageJ software                                          | Recommended considering the acceptance value as reference                                    |
|                                                                   | Canada                          | 2 test patterns; PMMA                                                      | Minimum threshold for broad                                                                  |
|                                                                   | ACR                             | Bar pattern                                                                | Recommended values for perpendicular and parallel MTF                                       |
|                                                                   | IAEA-DM                         | MTF test tool-metal foil with straight edges (e.g. copper, stainless steel, brass, etc.) PMMA to support the MTF test tool and MTF software | Acceptable values are presented for all available manufactures.                               |
|                                                                   | UK/NHSBSP                      | Bar pattern                                                                | Recommended values presented according manufactures (should be at least <70 % of Nyquist frequency of the detector) |
| Noise                                                               | UK/IPEM                         | TORMAX                                                                    | Remedial and suspension values provided                                                      |
|                                                                   | EC                              | NPS phantom (standard test block), optional software to calculate NPS     | Manufacturer’s specifications                                                               |
|                                                                   | Ireland                         | Standard PMMA test block dosimeter                                         | Consider acceptance values as reference.                                                     |
|                                                                   | Canada                          | PMMA blocks with various thickness and 0.1 mm of aluminium                | Acceptable values are presented for all types of breast tissue.                             |
|                                                                   | ACR                             | NA                                                                        | Subjective evaluation using clinical criteria                                                 |
Professional targets

The EC and Irish protocols are wider in scope and may be useful to a broader range of healthcare professionals. Other protocols focus on dosimetry and IQ assessment and are targeted at medical physicists, radiographers and breast radiologists. Hendrick et al. [5] showed that the profile of staff performing QA testing differs between countries. Often, radiographers are in charge of the most frequent tests (daily, weekly), whereas medical physicists perform in-depth technical performance assessment (e.g. collimation, X-ray tube output, and AEC testing). In Japan, radiographers perform all QC testing, whereas in Finland, Iceland and Hungary the service engineers tend to be in charge of the QC tasks. As highlighted in the IAEA-DM protocol a critical aspect is that QC testing is delegated to staff holding appropriate expertise and training [4].

QA testing of mammographic systems and breast dose assessment

Image detection and acquisition system

All protocols reviewed recommend testing the X-ray source (tube voltage and HVL) and the AEC system. AEC testing is one of the most important procedures due to its direct impact on IQ and breast dose [19]. It should consider the effects of variations in object/attenuator thickness and radiation beam quality. Hendrick et al. [5] compared QC practices in 22 countries (affiliated with the International Breast Cancer Screening Network) and concluded that this test that was performed in all countries.

Breast dose

The recommended methodologies for breast dose estimation vary (Table 6). Measurements using test objects and breast phantoms are frequently recommended and more practical to implement than measurements based on TLD techniques.

Dose assessment with a standard test object/phantom facilitates the comparison of different mammographic techniques and the investigation of the impact of technical settings on breast dose [20, 21]. Clinical dose assessment (using clinical exposure data) provide valuable information on the clinical practice and takes into account the influence of breast thickness and composition on dose [6].

Variations in dosimetry techniques in mammography may prevent a robust comparison of breast dose in mammography between countries and between radiology departments [22–24].

Dance et al. [16] also highlighted that national protocols adopt different phantoms, optical densities, measurement points and conversion factors, which make it difficult to compare the doses estimated with different protocols.
Hemdal et al. [23] measured the impact of variations in experimental technique (e.g., positioning of the dosimeter, compression plate in or out of the beam) on MGD values and found noticeable variations.

When the European protocol was used, the value of the MGD increased by 5±2 % (total variation 0–9 %) at clinical settings and by 9±3 % (4–17 %) compared with the use of the Nordic protocol [21]. The same authors also compared measurements with different dosimeters (ionisation chambers vs solid-state detectors) [23]. They concluded that HVL measurements can be performed accurately with a sensitive solid-state detector and a collimated radiation field, correcting for energy dependence.

This review showed variations in the conversion factors used in the estimation of breast dose (to account for X-ray spectrum characteristics and breast composition) amongst the guidance documents.

Zoetelief and Jansen [25] compared protocols for dosimetry in mammography and concluded that the use of different radiation transport codes and different spectra could cause differences in the conversion factor g by up to about 7 %. They also showed that inclusion of the compression plate in the beam results in a 4.5±1.5 % smaller g value for the same HVL. Also, when breast thickness increases from 2 cm to 8 cm, the g value decreases by a factor of 4.

Tsai et al. [15] showed that the MGD calculated using Dance’s method is 9–21 % higher than that using Wu’s method. Jamal et al. [24] also compared MGD per film considering eight different studies using different protocols and conversion factors and found MGD values with noticeable variations for a same breast thickness.

The MGD critically depends on the X-ray spectrum generated by the TF combination and tube voltage used. Modern digital mammography systems offer innovative TF combinations (e.g., W/Ag, W/Al) and new conversion factors have been developed [24, 26, 27]. The protocols reviewed do not yet include the most recent published data.

Quality of the acquired image All guidance reviewed recommends performing low-contrast threshold detection testing, breast lesion visualisation (e.g. simulated in phantoms) and artefact analysis. Compression force, image noise and spatial resolution testing are also recommended with variations in the proposed methods and test materials.

The EC protocol recommends assessment of image quality of digital mammographic systems using images produced with a specific low-contrast-detail test object (CDMAM) [28, 29], which is a costly tool not readily available in all imaging departments. The UK/IPEM and ACR protocols recommend alternative test objects to CDMAM, namely TOR (MAM) and the ACR accreditation phantom, respectively. The choice of a suitable IQ phantom should take into consideration the technology to be tested (screen-film of digital). Huda et al. [30] examined the effectiveness of the ACR phantom to assess image quality in digital mammography and concluded that it is unsatisfactory due to an inappropriate range and sensitivity to characterise simulated breast lesions.

Variations in recommended test objects originate differences in reference/tolerance values (Table 7). The number and type of recommended IQ tests varied (between 1 and 9) as well as the recommended methodologies. Examples of methods found in the guidance for rating IQ include absolute, or relative, scales (e.g. five-step scale, 1 (worst) to 5 (best); two-step scale with 1 (criterion was fulfilled) and 0 (criterion was not fulfilled); four-step scale as designed by PGMI scale (perfect, good, moderate and inadequate).

The guidance documents reviewed do not include recommendations on observer training for IQ assessment. This could be useful to reduce inter-observer variability in the assessment of IQ.

Also, breast compression force is influenced by breast thickness and composition. However, no recommendations are provided to promote the optimisation of compression force according to individual characteristics of the breast (compressibility, composition and thickness) [31, 32]. Maximum values for compression in mammography are recommended [7, 11, 33, 34].

The composition of breast tissue is an important issue because increased breast density is known as a risk factor for developing breast cancer [35]. Nevertheless, in the reviewed QA guidance for IQ assessment breast density was not used as a standard.

In 2011, an addendum to the EC protocol, containing guidance for clinical evaluation of mammographic images, was published promoting harmonisation in image quality analysis. Clinical IQ assessment conducted by experienced radiologists is important because it takes into account the effects of image processing which may directly affect the visibility of relevant features and the subsequent diagnostic outcome [36].

Image display/presentation and processing

All protocols including guidance for digital mammography recommend testing monitor displays and printers (Table 2). No recommendations are provided regarding the format for delivering mammography examinations/images to the patient and practices vary—some healthcare institutions deliver the examination in hardcopy (paper or film), whereas others provide digital images on CD.

Despite the potential critical impact of image processing in the quality of the final image the testing of image processing tools in still at early states (compared with testing of hardware). Most protocols for testing digital mammography
systems recommend testing based on raw image data and do not include recommendations for testing post-processing algorithms used in clinical images. Establishing testing protocols for post-processing tools in digital mammography is a challenging task as performance tests for image acquisition, processing, and display systems were discussed and compared. Noticeable variations exist in the proposed methods, test objects and phantoms. Also, reference values and acceptability criteria vary between protocols, which raises the question of whether it would be possible to have a mammography system complying with a test procedure and acceptability criteria, whereas using another test procedure the system would fail.

Harmonisation and best practices in mammography would benefit from more detailed guidance on the experimental methods for QC testing and recommendations of more affordable test equipment and materials that could be acquired by the majority of X-ray departments.

When a recommended protocol cannot be implemented in full, a selection of tests may be adequate. Selection criteria should take into consideration resources and expertise available and the relevance of the tests to local practices. It should be noted to highlight the value of testing the AEC system, which is a simple procedure to implement that provides valuable information on the overall performance of the mammography system.

A key factor to promote the success of a QA program for mammography is teamwork and the collaboration of all key staff (e.g., radiographers, radiologists, medical physicists and healthcare managers). Training and continuous feedback mechanisms are essential to improve the testing procedures and strengthen the outcomes of the program.

Also, the use of professional networks and special interest groups to exchange experiences with colleagues worldwide can be of great value in the initial phases of implementation of a mammography QA program.

Conclusion

In this study the published guidance for QA in mammography was reviewed. The recommended performance tests for image acquisition, processing and display systems were discussed and compared. Noticeable variations exist in the proposed methods, test objects and phantoms. Also, reference values and acceptability criteria vary between protocols, which raises the question of whether it would be possible to have a mammography system complying with a test procedure and acceptability criteria, whereas using another test procedure the system would fail.

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