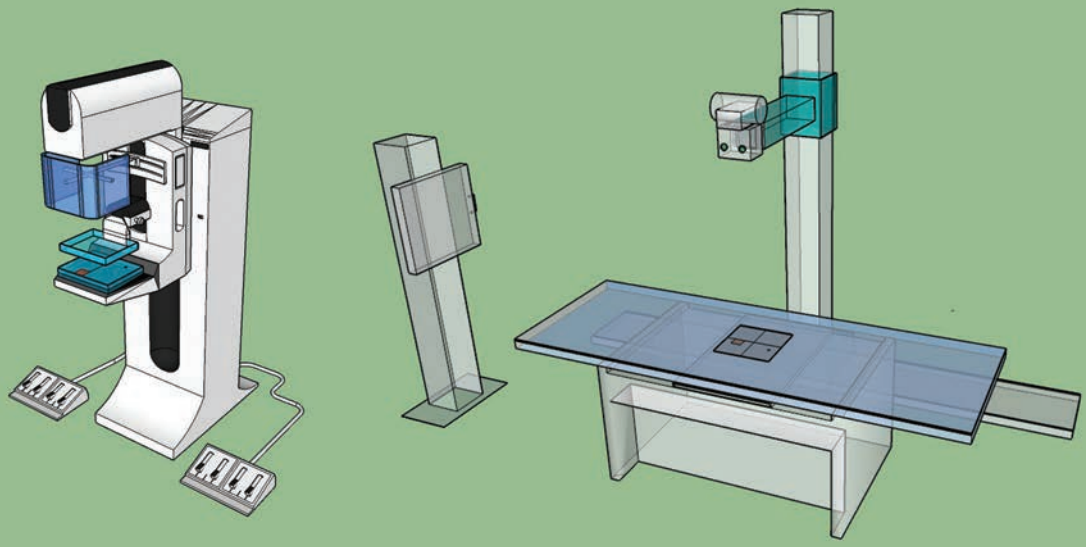

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No. 39

Implementation of a Remote and Automated Quality Control Programme for Radiography and Mammography Equipment

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IMPLEMENTATION OF A REMOTE AND AUTOMATED QUALITY CONTROL PROGRAMME FOR RADIOGRAPHY AND MAMMOGRAPHY EQUIPMENT

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IAEA HUMAN HEALTH SERIES No. 39

IMPLEMENTATION OF A REMOTE AND AUTOMATED QUALITY CONTROL PROGRAMME FOR RADIOGRAPHY AND MAMMOGRAPHY EQUIPMENT

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FOREWORD

Regular quality control (QC) testing of radiographic facilities has been largely overlooked throughout the world, even though it has been shown to reduce patient radiation exposure and improve image quality. This can be partially explained by the very large number of diagnostic radiology facilities and the lack of both appropriate testing equipment and staff qualified to effectively perform and analyse performance testing results.

In Member States, many radiology departments do not have access to on-site support by a clinically qualified medical physicist (CQMP) in diagnostic radiology, or visits by a CQMP may be limited owing to a lack of resources. Annual testing by a CQMP is inadequate to detect short term fluctuations in some critical components of the imaging chain. For these reasons, remote QC tools that facilitate daily or weekly testing are essential to ensure consistency between comprehensive annual evaluations. Remote testing tools, as presented in this publication, allow for central collection and analysis of data, strengthening the comparability and consistency of results from different centres. Additionally, automated QC tools may allow for more advanced analysis of images and image quality parameters. However, most existing efforts in automated QC generally involve complicated and expensive phantoms and infrastructure.

In response to Member State requests, investigation began on the topic of remote QC for consistency in radiology. The methodology proposed in this publication is based on simple, inexpensive test objects (one phantom for radiography and one for mammography) and modern methodologies exploiting the advantages of computer networking. The phantoms enable QC tests to be performed on a daily or weekly basis using a state of the art detectability index (d'), and accompanying software allows for complete and automated evaluation of the principal performance characteristics of the imaging chain. The phantoms can be built using simple, low cost materials that are widely available. They can be used together with the software either on a local basis by CQMPs in individual facilities or by groups of CQMPs responsible for networks of hospitals or other facilities, including smaller radiological facilities in remote settings.

The IAEA acknowledges the contribution of the drafting committee responsible for the development of this publication and the proposed methodology: H. Bosmans (Belgium), P. Mora (Costa Rica), and D. Pfeiffer and M. Arreola (United States of America). The automated tool for image analysis was developed by G. Zhang (Belgium) based on the recommendations of the drafting committee. The IAEA officers responsible for this publication were H. Delis and V. Tsapaki of the Division of Human Health.

EDITORIAL NOTE

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The supplementary material for this publication has not been edited by the editorial staff of the IAEA.

CONTENTS

1. INTRODUCTION

1.1. BACKGROUND

In many areas of the world, medical physics support is minimal or non-existent. This leaves many facilities with little or no guidance to implement a quality assurance (QA) programme in the medical imaging department. Under these conditions, imaging devices may go through their entire useful life without ever being tested for regulatory compliance or for radiation safety and image quality. Quality control (QC) functions may never evaluate whether or not a given image is actually of adequate diagnostic quality. Such a paradigm can lead to inadequate patient care and excessive radiation exposure.

Radiographic imaging makes up the bulk of imaging done throughout the world. Even with rapid development and deployment of advanced imaging modalities such as computed tomography and magnetic resonance imaging, radiography remains central to patient care. In spite of this, radiographic imaging systems receive some of the least QC effort of any imaging modality. This remains true even in facilities that have access to medical physics services.

However, it is in the core definition of a QA programme that it is "an organized effort by the staff operating a facility to ensure that the diagnostic images produced by the facility are of sufficiently high quality so that they consistently provide adequate diagnostic information at the lowest possible cost and with the least possible exposure of the patient to radiation" [1]. While regulatory requirements may typically enforce annual performance evaluations, the monitoring of the imaging equipment cannot be limited to these acts if the clinical goal is consistent and adequate diagnostic information.

To help mitigate these situations, the IAEA embarked on developing a programme through which QC measures can be made simply and inexpensively, based on a straightforward, yet data-rich phantom and a software tool for image analysis. Measurement data or images can be analysed by means of the software tool that will then allow trend analysis and data archiving. The analysis system will alert the responsible clinically qualified medical physicists (CQMPs) if any measured value is out of limits or if a worrisome trend is developing.

Depending on the infrastructure of the facility, different forms of implementation can be envisioned. If a facility has digital radiography (DR) and a good information technology infrastructure, images of the phantom can be uploaded to a central server for analysis and determination of image quality. Alternatively, in case of limited network or on-line capabilities, the images could be automatically analysed locally, and the results could be transmitted for analysis. Finally, if a facility uses only screen–film imaging and has a limited

infrastructure, the same phantom can be used and assessments can be made with simple optical density measurements, tracking of exposure parameters and artefact analysis. These results can then be entered into a database for analysis and CQMP oversight.

Through these measures, consistent system performance can be ensured, clinically adequate image quality can be maintained, patient safety can be increased, and overall patient care can be enhanced. In the long term, the data collected can be used to benchmark system quality performance between different systems also being monitored by this centralized programme.

Any well established QA programme involves both a comprehensive performance evaluation of the system, performed by a CQMP, and a less intensive QC test that could be performed by other assigned staff, such as a local medical radiation technologist, under the supervision of a CQMP.

Many Member States have established the regulatory framework and requirements for annual system performance testing by a CQMP. However, if frequent QC testing is missing from the QA programme, then the effectiveness of the programme is limited, as system deficiencies which may negatively impact image quality and patient care can arise in between such annual evaluations.

1.2. OBJECTIVE

The aim of this publication is to provide a framework for QC of radiographic and mammographic imaging systems with remote and automated tools. The methods described can facilitate frequent constancy testing without the need for on-site supervision by a CQMP. Instead, the CQMP will have overall remote supervision of the QC programme which will allow for a regular review of the collected data. Along these lines, these tests are not intended to replace annual comprehensive performance evaluations of the radiographic systems by a CQMP. They can however detect deficiencies in system performance before they become clinically significant. Furthermore, frequent QC testing promotes a culture of quality in imaging.

Guidance provided here, describing good practices, represents expert opinion but does not constitute recommendations made on the basis of a consensus of Member States.

1.3. SCOPE

This publication is directed towards the following groups of professionals, all involved in ensuring an environment of safety and quality in imaging:

— CQMPs in diagnostic radiology, who act or give advice on matters relating to radiation physics applied to medical imaging, including the issues of patient exposure to ionizing radiation and image QC. CQMPs are expected to do the following:
    - Promote, implement and support this framework of remote QC;
    - Train all staff members involved in image and data acquisition and upload, as described in this publication;
    - Supervise, review, interpret images and provide consistent feedback to the facility;
    - Initiate and verify implementation of corrective actions, if required.
— Medical radiation technologists, who have the primary responsibility for implementing this programme in the clinic, and who need to be adequately trained by a CQMP in the use of the proposed tools and be assigned specific time required to perform the tests.
— Radiologists, who are ultimately responsible for promoting a culture of safety and quality in radiology departments and, as such, can consider adopting this programme to ensure that the studies generated in the facility are of consistent high quality, and are acquired at safe, appropriate radiation doses.
— Regulatory authorities, who are responsible for establishing the environment for safety in imaging in Member States and can use this publication for the development of future regulations with regard to continuous safety and quality monitoring.
— Administrators, who are responsible for ensuring that adequate time and funds are made available for ensuring quality imaging and implementing this programme.

These guidelines are meant to be easy to implement, in order to support initiation of remote QC programmes. For this reason, they are limited to conventional planar imaging (radiography and mammography). Once a basic platform for remote QC has been established and implemented, similar tools can be developed for more advanced modalities.

This publication can be considered part of a comprehensive solution that can facilitate basic supervision of the equipment performance to be conducted remotely, under the guidance of a CQMP who is not present at the site. This comprehensive approach includes the following:

— The body of this publication, giving the technical details of the proposed methodology;
— An extended appendix (Appendix IV) on artefact evaluation, to be used for the evaluation of the images;

— Forms and tables generated based on the proposed methodology, which can be used for proper documentation of the results;
— Detailed characteristics and real size blueprints of the proposed phantoms, allowing users to accurately manufacture them;
— Dedicated software developed by the IAEA to automatically analyse the images generated by the proposed phantom and provide advanced and sophisticated measures of image quality.

Supplementary material that can be used in an electronic format can be downloaded directly from the IAEA Human Health Campus[1].

1.4. STRUCTURE

This publication begins with a brief overview of the QA and QC practices in different regions (Section 2), followed by a section (Section 3) on the requirements that need to be considered for the implementation of the proposed remote and automated methodology. The next two sections go into the details of the proposed methodology focusing on the testing (Section 4) and analysis (Section 5) procedures, which can also be used as guidelines for the institutional quality manual. The last section (Section 6) intends to clarify the potential contribution and responsibilities of different stakeholders in implementing a remote framework for the performance testing of equipment.

Several appendices are included in this publication, aiming to assist potential readers at different stages of implementing the proposed methodology. Specifically:

— Appendix I is a detailed description/user manual of automated software that can be used to facilitate accurate analysis of the images;
— Appendix II provides detailed information for the accurate manufacturing of the proposed phantoms;
— Appendix III gives a quick overview of the statistical tools that can be used for the QC;
— Appendix IV is intended to be used as an atlas for the identification of potential process failures and artefacts during testing;
— Appendix V provides the required background and additional information on the complicated image quality metrics used in the proposed methodology;
— Appendix VI gives additional information on the structure and available data in the Digital Imaging and Communications in Medicine (DICOM)

[1] The IAEA Human Health Campus can be found at https://humanhealth.iaea.org.

header that are an integral part of the image and can be used during the testing;
— Appendix VII summarizes the results of pilot testing;
— Appendix VIII provides templates that can be used by potential users to capture the results of testing in relevant equipment logbooks.

2. QUALITY ASSURANCE AND QUALITY CONTROL PRACTICES IN DIFFERENT REGIONS OF THE WORLD

2.1. STATUS OF COMPREHENSIVE QUALITY CONTROL

2.1.1. Asia and Pacific

The diversity in cultural and socioeconomic development in Asian countries has contributed to an unbalanced scenario in healthcare throughout the continent [2]. At present, only a few countries have in place national requirements for QC programmes for diagnostic radiology. These include Australia, India, Japan, the Republic of Korea, Malaysia, New Zealand, the Philippines and Thailand. This can be partially attributed to the lack of trained CQMPs who can initiate, organize and supervise a comprehensive training programme in diagnostic radiology. To tackle this fact, the IAEA, in collaboration with Member States, has initiated relevant projects on national and regional levels to (a) increase awareness of the need for and structure of organized quality practices in imaging and (b) strengthen the training of the CQMPs in the region.

The Asia–Oceania Federation of Organizations for Medical Physics and the South East Asian Federation of Organizations for Medical Physics, both founded in 2000, have been instrumental in stimulating professional practice of medical physics in the region. This is evident in the annual congress programme, which has featured regular QC symposia and workshops. The Association of Southeast Asian Nations (ASEAN) College of Medical Physics, founded in 2014, has been active in organizing workshops with hands-on practical training in QC.

A foundation for QC was firmly established with the release by the Asia–Oceania Federation of Organizations for Medical Physics of Policy Statement No. 1 describing the role, responsibilities and status of the CQMP in the federation's member organizations [3]. Some of the main functions and responsibilities of the CQMP are quality assurance, safety and supervision

of equipment maintenance. To date, this federation has published several policy statements on education, training, manpower, continuing professional development and career progression, among other topics, all contributing to the development of medical physics professionalism.

The successful implementation of routine QC also depends on the efforts of radiologists and medical radiation technologists. For this reason, the Asian chapter of the International Society of Radiographers and Radiological Technologists has been active in conducting QC workshops and training personnel in developing countries, while the Asian Oceanian Society of Radiology will add QC and safety to its educational and awareness objectives.

2.1.2. Europe

Since 1996, the European Commission has published several radiation protection guidelines [4–8] with the aim to optimize practice in the field of diagnostic radiology. The objective of Refs [4–8] was to provide image quality criteria and typical patient radiation dose values for adult and paediatric conventional X ray or computed tomography examinations. The guidelines resulted from the cooperative effort of radiologists and CQMPs with recognized experience in the respective diagnostic modalities, under the framework of European cross-national projects. In general, these guidelines do not address QC procedures to check technical aspects of the X ray imaging chain. In parallel to all these efforts to control the clinical image quality, technical QC protocols have also been developed.

The European Commission publication radiation protection series No. 162 (RP 162) [9] contains a non-binding set of criteria for acceptability of radiological installations. RP 162 updates and considerably expands on RP 91 [10], providing minimum requirements for radiological facilities. Acceptability is achieved if the results of several measurements are better than their ‘suspension level’. The suspension levels are limits (specified for several types of radiological equipment in normal use) that the equipment ought to be able to meet. Consequently, RP 162 constitutes major guidance for independent professionals and regulatory authorities. As a logical consequence at national or regional levels, QC protocols for compliance testing are based on the same text. Among others, proposed numerical values for the suspension levels were taken from documents published by the United Kingdom’s Institute of Physics and Engineering in Medicine and the International Electrotechnical Commission to ensure the reliability of the proposal values. RP 162 does not specify the frequency of the tests, although most countries aim for an annual compliance test.

The first QC protocol for mammography was published in 1993, and in 2003 the European Commission issued a recommendation to Member States to

offer evidence based cancer screening through a systematic population based approach with QA at all appropriate levels. The European guidelines for quality assurance in breast cancer screening and diagnosis [11] (now in their fourth edition) provide guidance for quality assessment of the entire range of activities in screening for and diagnosis of breast cancer. In this case, the guidelines contemplate QC procedures for the technical aspects of the mammographic systems intended for screening as well as diagnostic tasks, both for screen–film mammography and digital mammography. The guidelines include tests for acceptance testing, but also for daily quality supervision, to ensure the consistent production of mammograms of sufficient technical quality. Furthermore, they support central analysis of the results to improve the quality of the QC service and the comparability and consistency of the results.

The breast screening programmes presently implemented in Europe have diverse organizational settings and different QA schemes in place [9]. According to data from a study by Altobelli and Lattanzi [12], 22 out of 28 European countries have nationwide population based screening programmes. Most programmes developed at a regional level have their own screening information systems for running day to day operations, managing quality, and monitoring and evaluating services. However, the organization of physical and technical QA activities is often independent from the screening programme itself. Some countries (France, Norway, Spain and Sweden) have screening programmes organized at a regional level and QA activities organized at a national level. The scientific or professional societies for medical physics or radiation protection in some countries have developed national QC protocols for the technical aspects of mammography screening (Belgium, Finland, Germany, the Netherlands, Spain, etc.). Pioneer countries in the implementation of screening programmes (Denmark, Finland, Iceland, Norway, Sweden and the United Kingdom) had developed national QC protocols prior to the publication of the European Commission guidelines. Some other countries have also elaborated national protocols following the recommendations of the European guidelines but adapting testing frequencies and personnel to their human resources, personnel training and particular programme organization. In general, QC procedures in mammography are ahead of QC in general radiology.

2.1.3. Latin America

The development of well established QC programmes in Latin America has been hindered by limitations in three key areas: the ability to train CQMPs, the roles of medical societies, and the development and enforcement of strong regulatory requirements.

The number of CQMPs in Latin America is still insufficient to fully cover the needs of the region in terms of full QC coverage in diagnostic radiology, since most of them are associated with the practice of either radiotherapy or nuclear medicine medical physics [13]. Moreover, many CQMPs in diagnostic radiology lack the skills needed to implement QC programmes. Transitioning from conventional to digital equipment in general radiology, interventional radiology and mammography — each with its own specific characteristics — makes the implementation of QC particularly challenging. Strong academic and clinical training is needed in all aspects of radiology medical physics.

Further to the regulatory requirements for QC, the local improvement process has to start with the chief clinical physician recognizing the importance of QC and its contribution to improving diagnostic performance. Individuals of various disciplines (physicians, CQMPs, medical radiation technologists, engineers, etc.) must work together to ensure that the studies produced in a given facility have adequate image quality. Finally, the whole process benefits from the presence of strong regulatory authorities which mandate and enforce the implementation of QC programmes in radiology. All stages are important to solve the dose and quality problems in radiology today.

Some of the IAEA Member States in Latin America and the Caribbean were involved in the IAEA ARCAL agreement (Regional Cooperation Agreement for the Promotion of Nuclear Science and Technology in Latin America and the Caribbean) that initiated projects in the area of QC in diagnostic radiology in 1984. Through the regional project ARCAL XLIX (Implementation of Basic Safety Standards in Medical Practice) in 2001, a QC protocol in Spanish was developed for use in diagnostic radiology with help from CQMPs from Brazil, Chile, Colombia, Cuba, Mexico and Peru [14]. This first protocol covered basic QC tests for general radiology, dental radiology, mammography, fluoroscopy and computed tomography, and includes QC tests of darkrooms. This is still very much used by Member States, but it does not cover emerging digital technologies and has been revised under a regional IAEA project. This revision takes into account regional requirements, use of new digital technologies and increased availability of medical equipment. It focuses on QC tests for general, dental and interventional radiology, mammography, tomography, darkrooms, monitors and printers.

Later, under the regional IAEA project ARCAL LV (Quality Assurance in Mammography) in 2006, a dedicated protocol for screen–film mammography was published with contributions from the Plurinational State of Bolivia, Colombia, Costa Rica, Cuba, Dominican Republic, El Salvador, Guatemala, Nicaragua, Panama, Paraguay, Peru and the Bolivarian Republic of Venezuela. IAEA-TECDOC-1517 [15] on QC in mammography has been widely used in

the countries of the region and, owing to its great impact, a dedicated software package for easy implementation of the programme was developed in 2008.

Some of the larger Member States in the region have started to introduce some QC regulations in their respective legislations, with the support of regional medical physics societies. Given the requirements of IAEA Safety Standards Series No. GSR Part 3 [16], most Latin American countries are making it mandatory to have CQMPs in diagnostic radiology in charge of QC programmes, but in many cases these programmes are not yet implemented. The introduction of digital technologies is pressing an urgent need to redefine how to handle this situation in Latin America.

2.1.4. United States of America/Canada

In the United States of America, regulations and standards for performance of all medical X ray systems are under the jurisdiction of the Food and Drug Administration; medical X ray equipment manufacturers are subject to strict compliance with these standards. Specifically, the regulations governing performance and safety standards for radiographic systems were established decades ago based on recommendations by the Conference of Radiation Control Program Directors and the Center for Devices and Radiological Health and are contained in the Code of Federal Regulations 21 CFR 1020 [17]. These regulations cover all specific performance standards for X ray tubes and generators, the requirements for radiation protection and some basic guidance on dosimetry. These standards have been adopted by all individual states and are enforceable by each state's department of radiation protection or bureau of radiological health. However, these regulations do not include any specifics in terms of image quality metrics or any type of image QC or suggested performance standards. In more recent years, the Conference of Radiation Control Program Directors established task group H-33 for the development of an inspection protocol of diagnostic X ray facilities which use either computed radiography (CR) or DR systems clinically [18]. However, rather than a set of performance recommendations for both CR and DR systems, the document is meant to guide X ray inspectors as they survey medical X ray facilities.

In Canada, the Ministry of Health regulates the use of X rays in medicine. Two publications, Safety Procedures for the Installation, Use and Control of X ray Equipment in Large Medical Radiological Facilities [19] and the corresponding publication for smaller facilities, describe the need for annual assessments of parameters such as spatial resolution and low-contrast detectability only as part of the CQMP's annual testing for both CR and DR systems, but do not specifically describe a phantom or a procedure to perform these assessments.

In general, image quality performance standards and QC fall outside the scope of regulatory bodies, whose charters aim at radiation protection and the establishment of radiation safety processes for the benefit of patients, medical professionals and the general public. Thus, image quality assessment and QC have been undertaken by professional societies such as the Radiological Society of North America, the American College of Radiology, the Society for Imaging Informatics in Medicine and more specifically, the American Association of Physicists in Medicine (AAPM). Since the early days of clinical CR and DR implementation in the United States of America, facilities have adopted some QC procedures based purely on manufacturers' recommendations and protocols, but this has only been done by facilities which have either in-house or consultant CQMPs in diagnostic radiology overseeing such operations. In reality, it has to be noted that the vast majority of smaller stand-alone US imaging facilities do not follow any type of QC programme for CR or DR (not even manufacturers' recommendations), with obvious performance and clinical study quality consequences; this fact prompted the US Congress to pass a law which, starting in January 2018, steadily reduces federal government reimbursement payments to imaging departments that still use CR (and furthermore, those still using screen–film systems).

Meanwhile, the AAPM has formed, over the years, various task groups tasked with the development of acceptance testing and the establishment and implementation of QC protocols and procedures for CR and DR. Specifically, AAPM Task Group 10 published Report 93 [20], which describes the typical CR systems of the late 1990s/early 2000s from the three major worldwide manufacturers. Although the report includes descriptions on assessment of image quality parameters such as limiting spatial resolution, contrast detectability and noise, it is limited to those three manufacturers and does not recommend or adopt specific phantoms or test objects, and its implementation in the clinical setting was quite limited because of the lack of standardization. Two additional task groups were chartered several years ago to pursue development of meaningful QC procedures which could be easily implemented in any clinical setting. AAPM Task Group 151, Ongoing Quality Control in Digital Radiographic Systems [21], developed a clinical QC programme which can be carried out by a QC or lead medical radiation technologist under the supervision of a CQMP. The corresponding report includes detailed descriptions of an image reject analysis and a dose monitoring analysis programme, plus an artefact evaluation programme [21]. AAPM Task Group 116 has developed uniform exposure metrics for DR systems [22]. Lastly, AAPM Task Group 150 has been working on the development of acceptance testing and QC procedures for DR systems. It is expected that the report from this group will compile recommendations from all DR manufacturers regarding QC and image quality parameters for

clinical implementation to be performed (or at least monitored) by a CQMP in diagnostic radiology. As of 2018, the number of full time in-house CQMPs in diagnostic radiology in the United States of America appears to be only adequate in university and large scale metropolitan hospitals, while medium size hospitals and small clinics only have part time CQMPs or no CQMP services at all, making the implementation of QC programmes rather difficult. The possibility of remote QC will certainly facilitate the implementation of such programmes, promoting better and more efficient use of DR systems.

Unlike the case of general use CR and DR, QC programmes in mammography became mandatory in the United States of America for all facilities practising this modality as early as the mid-1990s with the enacting of the Mammography Quality Standards Act of 1992 [23]. These regulations, originally developed for screen–film mammography, included subjective (but well defined) assessments of limiting spatial resolution and low-contrast detectability, among others, as a function of entrance skin exposure (or the corresponding calculated average glandular dose) easily performed on a weekly basis. As mammography evolved into the digital realm, the act's regulations were modified to include DR systems, as only one CR based mammography device was ever cleared for clinical use by the Food and Drug Administration. Regulations in the Mammography Quality Standards Act adopt the manufacturer's image quality metrics and QC methodologies recommended by each manufacturer as an adequate standard to follow.

2.1.5. Africa

Only a small number of CQMPs are primarily involved in diagnostic radiology and nuclear medicine in Africa. This can be attributed to the lack of awareness of the need for CQMPs and of the importance of their role. Different surveys reported different numbers of CQMPs available, but the general consensus is that there is a critical shortage of suitably qualified medical physicists specialized in imaging in all countries of this region [24].

Most countries that do not yet have regulations in place are working on enacting them. Some countries do not require a CQMP to be involved in QA/QC (this may be because of the shortage of available CQMPs). The greatest challenge in addressing QA in imaging in Member States relates to human resource capacity building. Capacity building efforts are addressed through the strategy of assisting Member States to establish their own education programmes at the post-secondary education level. The African Regional Cooperative Agreement for Research, Development and Training Related to Nuclear Science and Technology (AFRA) adopted the first AFRA Regional Strategic Cooperative Framework at a high level policy review seminar in Aswan in November 2007.

The IAEA collaborates with AFRA. Some of the high priority areas of collaboration that support medical physics include the following:

— Enhancing human resource capacity in the AFRA Member States;
— Recognizing and regulating medical physics as a profession;
— Establishing and harmonizing education and training programmes throughout the continent;
— Implementing sustainable and comprehensive QA programmes.

The above priorities were and are currently being addressed by a number of IAEA technical cooperation projects. Some countries embraced the support from AFRA and the IAEA and have improved the status of medical physics in their countries or started to implement QA/QC. Successful initiatives in some countries are driven by individuals in specific departments, notwithstanding an absence of regulatory requirements. However, there are countries where any QC activities happen rarely and only in the form of regulatory inspections, supplier testing or outsourced services.

2.2. REMOTE AND AUTOMATED QUALITY CONTROL

Any medical institution, professional society, screening organization or properly trained CQMP can implement a remote QC programme. The best way to start a remote QC programme is to build on an ongoing (local) regular QC programme that has proven to be effective over time. Such a local programme will already be using a national or international protocol for the specific diagnostic area with the necessary test tools available to perform the tests on a regular basis, trained local personnel and access to a CQMP for the more comprehensive and sophisticated tests. If the facility has nurtured a culture of quality and safety, and given adequate information technology support, a remotely controlled version of the QC such as the one presented in this publication may even be easy to implement.

On the other hand, a facility with no background in QC programmes can easily get started establishing a remote QC programme if there is access to a remote QC process started by others. At the beginning, local funds need to be made available to buy QC equipment and train the local personnel. A CQMP has to be appointed from the beginning to supervise, monitor, provide support and follow up on the programme. Countries or regions where CQMPs in diagnostic radiology are scarce can benefit most from the implementation of remote QC programmes since the centralized analysis of the data can be handled by fewer expert professionals.

The first step is to decide which tests need to be performed and the corresponding data that will be acquired. It is crucial to collect relevant data consistently and correctly, and to evaluate the images for artefacts in a consistent manner. Responsibilities at the local level and the frequency of the tests need to be well defined. Documentation of these results is very important and has to be carried out in a clear manner that is easy to follow.

With remotely controlled QC established, data are sent to a central facility for analysis. Consistent, periodic data transfer is crucial. Different methods are available, and the one that suits the institution best can be chosen. For example, data can be sent via email, smartphone application or web page. Most importantly, the selected data transfer method should ensure that the integrity of the collected data is preserved and guaranteed. The CQMP has to be actively involved in the verification of data transfer integrity. Finally, at the central facility, a CQMP can analyse the data and compare them with tolerance criteria for each specific test and immediately generate a service call and report if any corrective action has to be taken.

The increase of digital equipment in radiology and the possible elimination of analogue equipment in the near future in many countries are also contributing to the development of remote QC, since the manipulation and transfer of information is much easier than in the past. The digital format can be taken advantage of to encourage remote QC programmes.

The overall framework consists of different components and responsibilities, as described in Fig. 1 and in the sections that follow.

2.2.1. Framework of remote quality control

Remote QC uses images that are locally acquired in a standardized manner, using either simple or sophisticated phantoms, focusing on the consistency of performance and complementing the regular comprehensive QC testing performed by the CQMP. The images are acquired by on-site personnel such as medical radiation technologists who have also been trained in uploading the images to the central system, which may or may not be located at the facility.

Advanced processing of the uploaded images is performed centrally by the CQMP using appropriate software (either an automated tool for image analysis (ATIA) or other relevant software; see Appendix I) to extract quantitative indices related to noise, uniformity and artefact detection. Clearly, a system has to be in place to generate immediate feedback routed to the facility and the responsible CQMP regarding any inadequate performance of the system and the need for follow-up or corrective actions.

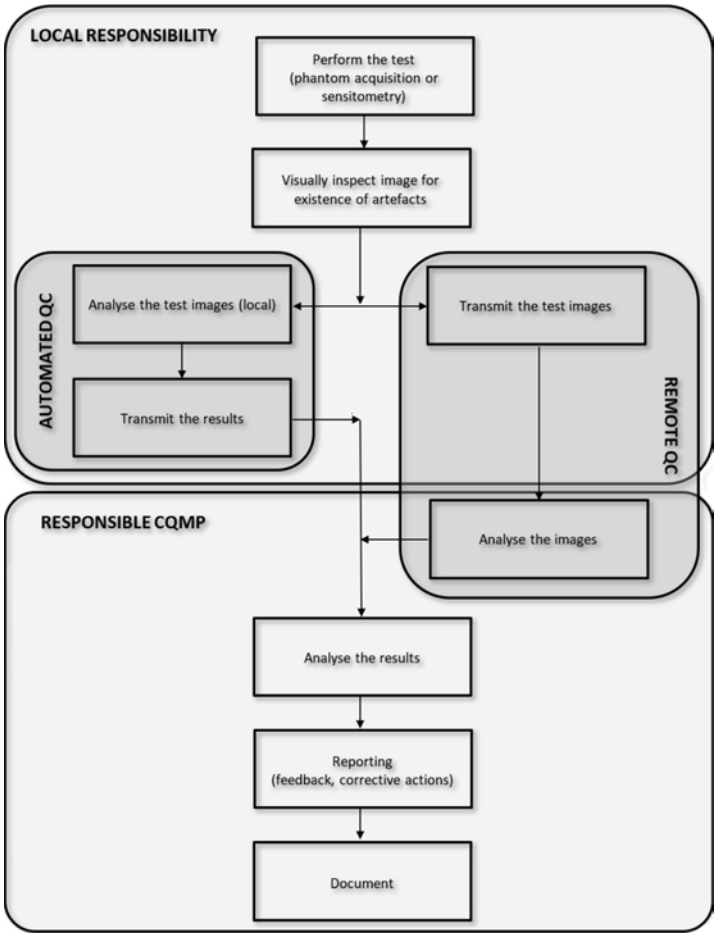

FIG. 1. Basic concept of remote and automated QC.

Remote QC consists of the following major components:

— Local image acquisition;
— Local image verification and artefact analysis;
— Image upload;
— Centralized image analysis and results analysis;
— Reporting and feedback.

Alternatively, if information technology and network infrastructures are lacking locally, or if the department is based on screen–film systems, a different

kind of remote QC can be established with the transmission of discrete point measurements, as also described in this publication.

2.2.2. Framework of automated quality control

Automated QC consists of the following major components:

— Local data acquisition;
— Local image verification and artefact analysis;
— Local automated image analysis;
— Data upload;
— Centralized results analysis;
— Reporting and feedback.

Data are acquired in a standardized manner using simple phantoms focusing on the consistency of imaging systems' performance and complementing the regular comprehensive QC testing performed by the CQMP. The measurements required for the automated QC are meant to be performed automatically (e.g. via an ATIA) on images acquired by the local personnel, who are also expected to be trained in the use of the automated QC tools. This process does not require the CQMP to be regularly on the site. Data are uploaded for centralized analysis and review by the CQMP.

2.2.3. Need for remote and automated quality control

Regular QC testing of radiographic facilities has been largely ignored throughout the world. However, QC guidelines published by the IAEA, American College of Radiology, European Commission and other authorities have demonstrated that effective QC programmes involving daily or weekly tests contribute to reduced patient radiation exposures while improving image quality. Specific examples of failures intrinsic to modern technology include miscalibration and drift of the automatic exposure control (AEC), artefacts, and failures resulting from the limited lifespan of detectors.

In Member States, many departments have neither access to on-site support by a CQMP in diagnostic radiology nor regular visits by a CQMP, owing to lack of personnel or the travel distances involved. As annual testing is not designed to detect short term fluctuations of some critical components of the imaging chain, more frequent testing is required. Remote QC for general diagnostic radiographic and mammographic equipment is a practical solution to ensure consistency between the comprehensive evaluations performed by the CQMP. Remote QC allows for central collection and analysis of data, making it possible

to perform comparisons and evaluate consistency of results from different centres. Additionally, automated QC tools may allow for more advanced analysis of images and image quality parameters. Most existing efforts in automated QC generally involve the use of complicated and expensive phantoms, software and infrastructure.

In response to the need to advise Member States, and as a result of a recommendation made through the Scientific Committee of the IAEA/WHO Network of Secondary Standards Dosimetry Laboratories in 2014 [25], a committee was formed to investigate this topic.

In this publication, the proposed methods are based on simple and inexpensive phantoms and modern methodologies exploiting the advantages of computer networking. These methods can facilitate remote QC applications and can promote collection of data in a harmonized manner allowing for comparison and benchmarking.

2.3. IMPORTANCE OF SUPPORT FROM CLINICALLY QUALIFIED MEDICAL PHYSICISTS

CQMPs have training and experience in image production, formation and characterization, as well as expertise in radiation physics, understanding of how radiation interacts with human tissues and understanding of the complex technology involved in modern imaging equipment. They are essential to the successful application of medical imaging [26]. Because of their training and experience, CQMPs are needed to provide oversight of a QA programme in radiological imaging. They can assist staff members to understand the implications of the QC test results and identify and initiate corrective actions when the results indicate a problem.

3. RESOURCES AND NEEDS

While quality practices can be proven to be cost effective in the long term (e.g. minimizing the downtime of the equipment through early detection of problems and failures), they require resources in terms of staff time, infrastructure and capital investment in order to be implemented.

3.1. TIME COMMITMENTS

The implementation of a QC programme based on the guidelines in this publication requires a certain amount of staff time both during the initiation phase and during the running of the programme. During the initial phase, the major components requiring staff time are the following:

— Adapting and adopting the remote QC protocols to reflect and cover the local needs, and relevant translation of the protocols to develop the local test procedures;
— Setting up the data and software infrastructure (by information technology experts) for the storage, data integrity and analysis of the images and the transmission of the results and images;
— Training the corresponding professionals (mainly by the responsible CQMP) to properly perform the test — for example image acquisition or densitometry — and to transmit the required results or images.

During the running of this remote QC programme, a dedicated amount of time will be required by the medical radiation technologist on the site and by the CQMP. For the medical radiation technologists, this mainly includes the time required to acquire the necessary images, perform the automated analysis (if part of the implementation) and subsequently transmit either the results or the image itself. The CQMP, on the other hand, has to devote some time to collecting, analysing and evaluating the results or images received and, as needed, to preparing, implementing and documenting corrective actions.

3.2. HUMAN RESOURCES

A comprehensive QA programme is composed of multiple elements, including both technical and human resources. Each participating institution needs to have a well defined QA team that will oversee activities and processes. Evaluation of all activities and follow-up corrective actions by responsible individuals are key elements of an effective QA programme.

The main personnel and their responsibilities for a QA team implementing this remote and automated QC programme for radiography and mammography are the following:

— Medical radiation technologist: Located on the site, this person is responsible for acquiring the images of the phantoms with a pre-established testing frequency, recording information on data forms as needed, sending the data

or images to the processing server and, in some cases, analysing the images with the ATIA. The medical radiation technologist is also responsible for methodically identifying artefacts and reporting any deviation of image quality as soon as it occurs, to implement corrective actions.

— CQMP: This person is responsible for training all appropriate staff in the facility to produce images of the phantoms; the CQMP performs data collection and image analysis as needed and sends images for remote and automated analysis. The CQMP understands and works with the ATIA. He or she is responsible for establishing baseline values of the various metrics that will be monitored over time and has to be available to review the data from various imaging facilities to provide oversight and recommend follow-up and corrective measures in a timely manner. The CQMP may be on the site, but is usually remote from the actual imaging rooms in the facility.
— Radiologist: This person is responsible for the implementation of radiation protection policies and procedures for patients. This includes responsibility for the appropriateness of the examination. The radiologist needs to be available to discuss artefacts in the QC images and is alerted to report artefacts observed during the clinical practice and seek corrective actions.
— Administrative head of the department: Responsible for assigning dedicated time to personnel to perform the necessary QC activities, this person also secures the funds needed to keep the QC programme running. When corrective actions are needed, it is important that administrative personnel cooperate to bring the solutions, such as to secure technical service as soon as needed.
— Information technology specialist or engineer: This person is responsible for correct installation of the ATIA, Internet access and bandwidth issues, lossless transmission of data and images, and maintenance of the information technology and network infrastructure.
— Service engineer: This person is responsible for preventive and corrective maintenance issues that are identified by the QC programme. He or she needs to ensure access to the required images and assist in their correct transmission, as well as helping to identify the cause of problems identified by the QC programme.

3.3. INFORMATION TECHNOLOGY

The following subsections describe the needs which relate to information technology, depending on the level and model of remote or automated QC that is implemented.

3.3.1. Local infrastructure and personnel support

3.3.1.1. Facilities without image transmission capabilities

The simplest model for implementing a remote QC programme is through the transmission of numerical data obtained from measurements, without the need to transmit the associated images. In this case, the analysis of the images and the collection of relevant data take place locally (e.g. with the ATIA). The results obtained from those measurements are transmitted to the CQMP in order to analyse the system performance over time at the pre-established testing frequency. The forms included in Appendix VIII can be used for proper data collection and local maintenance of the results.

The important points that need to be considered in the design and implementation of such a system include the following:

— Access to 'for processing' (raw) images for best results and most advanced analysis. Access may require coordination with the equipment manufacturers. If 'for processing' images are not available, then 'for presentation' (processed) images could be used, which would also be useful to track the consistency of the processing.
— Installation of the ATIA software on the site to allow image measurements. The ATIA is an application without special installation requirements that is typically easily installed on any Windows based system.
— Central on-line system for data collection that can be implemented on a site-wide or even regional basis, either using a central storage or cloud solution.
— Internet access in the facility and the remote site, or a smartphone app developed by the facility for data transmission. Interim solutions such as emails or text messages could be considered, if needed, although such solutions might prove inefficient and time consuming in the long term.
— A unique facility and system identification scheme for the transmitted data in order to ensure consistency and accuracy of data transmission and to avoid confusion regarding the results.
— Storage for maintaining QC records, images (either in film or digital form) and associated results locally for a reasonable time (as determined by the facility and the CQMP, unless local regulations mandate a minimum time) and the ability to make these readily accessible for future reference (e.g. for periodic review or academic/scientific purposes).

3.3.1.2. Facilities with image transmission capabilities

Actual transmission of the QC images to a remote site or a central repository is certainly a much more complicated task, but it also provides a more comprehensive and sustainable solution when compared with the transmission of numerical data only. Access to the image itself is obviously always preferable as this allows the CQMP to perform more comprehensive analysis of the image, review the DICOM information, or refer to the image for information in case of unexpected results. It can be implemented in different ways depending on the available information technology infrastructures in the remote facility. For example, with a central picture archiving and communication system (PACS) in place at the remote facility, it is adequate to agree on a system of proper image identification and storage, granting the CQMP secure remote access rights to the PACS and to the QC results database. A more robust and automated solution would be for the autosend function to be enabled in the PACS with routing set to transfer the images to a remote server at the CQMP's facility on which the ATIA exists. The receipt of the image triggers the automated analysis.

If a PACS is not available and the imaging systems are not connected to external networks (e.g. for institutional or security reasons) then the following can be considered:

— Coordinate with the system vendor and local information technology support during the design and planning period (e.g. prior to installation) to identify and set up the most convenient and stable way to export images.
— Address bandwidth issues at both the sending and receiving points to avoid making the transmission slow, unreliable and inefficient as medical images can be rather large. Interim solutions such as attaching images to emails could be considered if needed, although in the long term these solutions might prove inefficient and time consuming.
— Organize an external central image repository where the images can be archived for extended periods of time (e.g. FTP, SharePoint, Dropbox). The chosen location should meet security requirements of the health institution.

3.3.2. Protection of data

As in all applications that involve distribution of data, especially in digital form, data protection is essential. Although QC images and results cannot be considered sensitive information, as patient data are, they also need to be handled very carefully as they contain information with regard to the performance of radiographic systems in the department. Nevertheless, the exchange of information is necessary for the existence of a remote or automated

QC programme, and careful evaluation is required to verify adequate data protection and to ensure that unauthorized access to the data by outside users is strictly blocked. Access to detailed test data for each facility, either in the form of comprehensive QC reports or stored records of recent images or results, should only be granted to the CQMP and to staff members designated by the department. It is evident that, even though the CQMP might have access to the performance results from equipment in different facilities, each department needs to have access only to its own data and not to the detailed data of other departments or facilities.

When properly generated and documented, and if required by the administrative levels of a facility, summary reports of data can be disseminated as evidence of good practice and can be provided to the regulatory authority for compliance and licensing purposes.

In principle, a system of remote QC can produce a very large amount of results in a very short period of time. These results can be useful to the scientific and professional community, and therefore they could be shared for professional/scientific purposes. However, it is important that personnel at the various facilities secure adequate permission prior to the use of any relevant data. Furthermore, provisions need to be made to ensure that the identity of the originating department and the type or manufacturer of the equipment are protected during such data sharing; in other words, a process similar to that of anonymization of clinical images needs to be in place for these purposes. In no instance are these data to be used for commercial, advertisement purposes; neither are they to be used for comparison of performance between vendors.

3.3.3. Central data repository

The purpose of implementing a remote and automated QC programme such as the one described in this publication is to provide Member States and imaging facilities with an alternative for those institutions where access to a CQMP is insufficient to implement a complete QC programme in a formal manner. A central data repository supervised by a CQMP can help individual institutions with little access to CQMPs to track image quality and equipment performance parameters over time.

This central data repository can function at the following levels:

— Small scale: The CQMP can monitor system performance for one individual hospital with several X ray rooms, including both radiography and mammography;
— Medium scale: The CQMP can monitor performance at several facilities simultaneously;

— Large scale: With adequate medical physics support, a remote QC programme can run on a national or regional level (e.g. covering several screening programmes or multiple countries or regions).

The central data repository has to be equipped with a platform that allows for proper receipt, analysis and monitoring of incoming data generated from participating institutions for both radiography and mammography. It should be able to receive both numerical and image data. Its platform has to allow for the structure of a unique identification scheme for each system for simple recognition of the origin of all received data and images and their corresponding collation and sorting. In a large programme, the system can be set in such a manner that the analysis of the incoming data and the corresponding alerts for non-compliance are automatically generated and routed to the supervising CQMP. Finally, the system can be configured to automatically populate a database to document that the supervising CQMP has reviewed the data or that corresponding notifications are in place.

An advanced imaging centre or hospital could aim to also develop an automated system for performing trend analysis on QC data. This is certainly a more challenging goal from a statistical perspective, and the assistance of qualified consultants may be required. Such an advanced centre would also have the ability to aggregate the data from a variety of widespread imaging facilities for comparative purposes and for the development of performance standards.

3.4. FINANCIAL CONSIDERATIONS

One of the main objectives of this publication is to help facilities implement remote, reliable QC programmes that require a minimum of equipment as well as human and financial resources. However, it needs to be clear that the implementation of any QC efforts requires a commitment from the department management in terms of making such resources available. Often, management fails to understand that budgeting for these necessary QC resources is an investment which will have medium term and long term returns as the quality of the studies and the professional reputation of the facility improve steadily over time. Certainly, the application of relevant QA and QC practices as outlined here is associated with a number of increased costs, during both the planning and implementation phases. During planning and design, typical identifiable costs include the following, among others:

— Fabrication of the phantom, including acquiring the required materials (see Appendix II).

— Information technology costs, determined by the complexity of the department and institution, which may cover:
    - On-site computers;
    - Data lines/connections/Internet services;
    - Hardware for the central data repository;
    - Development or purchase of software packages, such as a database utility (the IAEA ATIA application is free);
    - Data storage.
— Dedicated, assigned time for local staff to perform the tests and transfer numerical data or images, as applicable.
— Services of the CQMP to analyse the results.

In the most fundamental financial terms, even if one were to neglect the obvious contribution to patient health and safety which results from the implementation of a QC programme, the development of such a programme will prove to be quite cost effective from the very first day of implementation, bringing the following benefits to the department and facility:

— Decreased imaging equipment downtime, by timely identification of problems and potential failures;
— Increased patient and study throughput, by routinely ensuring the clinical availability of the imaging system, through the frequent monitoring of its performance and minimizing study/image rejects and retakes due to technical issues;
— Improved diagnostic accuracy, by ensuring that the established levels of image quality are continuously met and identifying immediately any slow deterioration that would otherwise go unnoticed in between annual tests;
— Compliance with regulatory requirements that mandate documented regular and frequent testing (as, for example, for the enrolment of a facility or department in a multicentre or regional breast screening programme);
— Decreased travel time and expenses for the CQMP to visit remote areas in order to monitor system performance (these savings alone, both in terms of time and money, can compensate for the cost of dedicated staff time required for implementation; this could be more evident in small departments with equipment of low complexity);
— Support for licensing procedures, providing regular and concrete evidence of QA and QC practices in the department and thus commitment to quality;
— Retrospective evaluation for medical–legal defence in extreme cases of unforeseen events that might be linked with the performance of the imaging equipment.

4. TESTING AND REPORTING

It is important to note that the programme presented here is for QC, ensuring that the system is performing stably over time. It does not determine whether or not a system is functioning optimally or even properly. Ideally, QC using this programme will be initiated when a new system is commissioned. For existing units, it is essential to ensure that the system is well calibrated and optimized. Before beginning the programme, it is helpful for the system to be fully calibrated by a service engineer and tested by the CQMP. During this testing, or during the commissioning testing for a new unit, the CQMP will establish the operating levels and control limits for the system.

The following procedures assume that the imaging system under consideration possesses the ability to generate and transfer unprocessed (i.e. 'for processing') QC images; this refers to images for which only basic dead pixel, flat field and similar implicit correction algorithms have been applied, but no frequency based or look-up table mapping of any kind has been used. If 'for processing' images are not available, then 'for presentation' (processed) images could be used, which would also be useful to track the consistency of the processing.

4.1. REMOTE QUALITY CONTROL

4.1.1. Description of phantoms

Phantoms for both radiography and mammography are described in this section. These simple phantoms generate a large, uniform field for artefact analysis by means of a uniform attenuator. Each phantom also has simple square targets in a target plate (explicitly described in Appendix II) that allow for densitometric evaluation of analogue films and for advanced analysis of digital images. The components of the phantom do not have specific tolerances associated with them. However, note that if tight tolerances are not held, then comparison with other systems not imaging that specific phantom cannot be made.

In the radiographic phantom, the uniform attenuator is a 10 cm × 10 cm square sheet of copper, 2 mm thick. If it is more cost effective, this sheet may be composed of thinner sheets stacked together totalling 2 mm, such as two sheets each 1 mm thick. The target plate is a 28 cm × 28 cm, 5 mm thick polymethyl methacrylate (PMMA) sheet. Two rectangular inserts are placed on this piece as described in detail in Section 4.2.1.3. The first target is a 5 cm × 5 cm copper square, 2 mm thick. This copper piece is used for densitometry measurements in

analogue systems and for modulation transfer function (MTF) and detectability index (d') analysis in digital systems. Therefore, it is critical that the copper square rest flat on the PMMA target plate, angled 2–5° from the edge of the target plate (and therefore, angled 2–5° from the digital image matrix) for accurate MTF determinations. The second target is a 1 cm × 1 cm square of aluminium, 4 mm thick. This is used for densitometry measurements in analogue systems and for contrast to noise ratio (CNR), signal difference to noise ratio (SDNR), and d' analysis in digital systems.

In the mammography phantom, the uniform attenuator is a 24 cm × 30 cm slab of PMMA, 40 mm thick, which is a common attenuator provided with most digital systems. If it is more cost effective, this slab may be composed of several thinner slabs stacked together totalling 40 mm, such as four slabs each 1 cm thick. The target plate is a 5 mm thick PMMA piece. Two targets are placed on this piece as described in detail in Section 4.2.2.3. The first target is a 5 cm × 5 cm copper square, 1 mm thick. This copper piece is used for densitometry measurements in analogue systems and for MTF and d' analysis in digital systems. Therefore, it is critical that the copper square rest flat on the PMMA target plate, angled 2–5° from the edge (and therefore, angled 2–5° from the digital image matrix) for accurate MTF determinations. The second target is a 1 cm × 1 cm square of aluminium, 0.2 mm thick. This is used for densitometry measurements in analogue systems and for CNR, SDNR, and d' analysis in digital systems.

As stated earlier, access to the ‘for processing’ image is ideal for analysis. However, this is not always possible. Some DR systems allow this image to be accessed along with the processed, ‘for interpretation’ image. On a CR system, it is necessary to select an acquisition protocol with the least image processing applied, such as those labelled as ‘pattern’, QC or ‘test mode’ [27, 28]. These options produce an image with no edge enhancement or smoothing applied, and a linear response look-up table. These selections have to be done prior to exposing the CR plate.

When imaging the phantom, the following points are also essential:

— The phantom needs to be positioned consistently and reproducibly every time;
— The phantom needs to be positioned correctly, with particular attention to ensuring that the phantom is not rotated relative to the edge of the radiation field;
— The same kilovoltage peak (kVp) needs to be used every time (for example, 80 kVp for radiographic systems and 28 kVp for mammographic systems);
— The radiation field needs to be collimated to include the entire phantom and needs to be approximately consistent between exposures;

— For screen–film and CR systems, a test cassette needs to be designated, labelled and used each time (this cassette may be used clinically as well, if needed);
— Two-detector DR systems with an upright bucky detector and a table bucky detector require test images for each of the detectors;
— For CR and DR systems, the same exam and view selection needs to be made every time (e.g. anteroposterior abdomen, medium adult);
— The same image processing selections need to be chosen every time (e.g. flat field, QC, unprocessed);
— The technical parameters that were used need to be accurately recorded.

It is essential to note that it is also necessary for the phantom itself to undergo the process of commissioning by a CQMP on each specific system that is part of the programme to ensure proper use, provide the required training to staff, and establish the baseline values for the system.

4.1.2. Guidelines for facilities without test image transmission capabilities

A remote QC programme in radiology can be started in a very simple way by identifying the basic numerical data that can be collected and transmitted to a central facility for analysis. These data will be collected by local personnel with the help of easy test tools and without the need to manipulate the whole image.

For analogue equipment (in use in many Member States), digitizing the hard copy image may not be feasible or recommended, as most film scanners do not offer an ‘unprocessed’ or ‘raw scanned image’ capability. Basic values that need to be measured are determined at the imaging facility and entered into a standardized data form (see Appendix VIII). These data are then sent to a central facility for remote analysis and oversight by the CQMP.

For digital equipment, images may be uploaded to a central facility for automated analysis and CQMP oversight. If this is not possible, the local staff at the imaging facility may make simple region of interest (ROI) measurements and enter the values into a standardized data form (see Appendix VIII). It is also possible for imaging facilities to analyse the images using the ATIA and enter the results into the standardized data form for oversight by the CQMP.

For analogue imaging in both conventional radiography and mammography, the monitoring of sensitometric parameters of the film processor is the starting point for any QC programme. Ideally, the imaging facility will have a digital thermometer, as well as a sensitometer and a densitometer. The parameters to measure every day are the temperature of the developing solution, the base plus fog optical density, the mid-density and the density difference. Because these devices can be expensive and are prone to failure, a simplified method

for film processor QC using the phantoms described above is provided. In any case, the CQMP has to be consulted to establish the proper operating levels and control limits.

For digital imaging using hard copy, laser printers are subject to monitoring on a regular basis. QC of a wet laser printer is performed in a manner practically identical to the one described above for film processors. Many dry laser printers have automated calibration and QC functions. If available, these could be incorporated into the QC procedure and used consistently. If these are not available, the QC described above for film processors could also be used.

Interpretation (or 'reading') workstation screens and monitors are clearly central to any digital imaging facility; QC of these monitors is vital. Most medical display manufacturers have automated calibration and QC functions available which are simple to use. These functions generally run in the background and are automatically performed at intervals specified by the manufacturer. At the initiation of a QC programme, the CQMP needs to ensure that these functions are enabled and working correctly. Beyond these functions, it is essential that imaging facilities perform basic periodic QC evaluations using images of the described phantoms and a standardized test pattern, such as the test patterns proposed by the Society of Motion Picture and Television Engineers [29] or AAPM Task Group 18 [30].

The specific procedures for acquiring the test images and making the corresponding measurements are provided in Section 4.2.

4.1.3. Guidelines for remote quality control for facilities with image transmission capabilities

Image transmission simplifies QC testing for the facility and allows for a more scientifically rigorous evaluation of the images. Both CR and DR, being digital modalities, allow for uploading of the test images and for automated analysis.

DR systems also provide the advantage that all technical parameters used to acquire an image are included in the DICOM header and no manual processing is required once the phantom image has been acquired.

In both CR and DR, it is necessary for the medical radiation technologist to review the test images and verify their validity before uploading them. This review is needed both to ensure that the exposure was performed properly and to perform an initial assessment of artefacts that might be severe enough to have an immediate clinical impact. In such a case, the medical radiation technologist on the site will have to alert both the radiologist and the CQMP immediately to have them review the test images and existing artefacts so that a decision regarding clinical use of the X ray system may be made.

After the initial artefact analysis is completed, images are sent to the central facility for in depth analysis and oversight by the CQMP. The specific details regarding the process for uploading images are specific to the infrastructure of the facility and cannot be further described within this publication. For best results and most advanced analysis, it is necessary that 'for processing' (raw) images be available, which may require coordination with the equipment manufacturers. If 'for processing' images are not available, then 'for presentation' (processed) images could be used, which would also be useful to track the consistency of the processing.

4.2. PROCEDURES FOR REMOTE QUALITY CONTROL

4.2.1. Radiography

4.2.1.1. Scope of remote quality control for radiography

The scope of the procedure is to evaluate the ability of the system to consistently generate images of a simple test object by determining the consistency of both acquisition technical parameters and image quality indicators and metrics (e.g. tube load in mA·s, optical density, exposure index, incident air kerma (K_i), pixel value, uniformity, signal to noise ratio (SNR), MTF, air kerma–area product (KAP)) and artefacts.

4.2.1.2. Frequency of remote quality control for radiography

Given the simplicity and time required for the tests proposed, it is suggested that they be performed weekly or, optionally, daily.

4.2.1.3. Description of radiographic phantom

A very simple radiographic phantom that can be easily built locally (see Appendix II) is comprised of two parts:

(1) A target plate made of a 28 cm × 28 cm × 0.5 cm sheet of PMMA. The targets are a 5 cm × 5 cm × 0.2 cm copper square and a 1 cm × 1 cm × 0.4 cm aluminium square which lie flat on the target plate. The positions of both test objects can be seen in Fig. 2. The copper square has to be angled 2–5° with respect to the edge of the target plate to be able to measure MTF. Specific details for the manufacturing of the phantom, as well as a relevant blueprint, can be found in Appendix II.

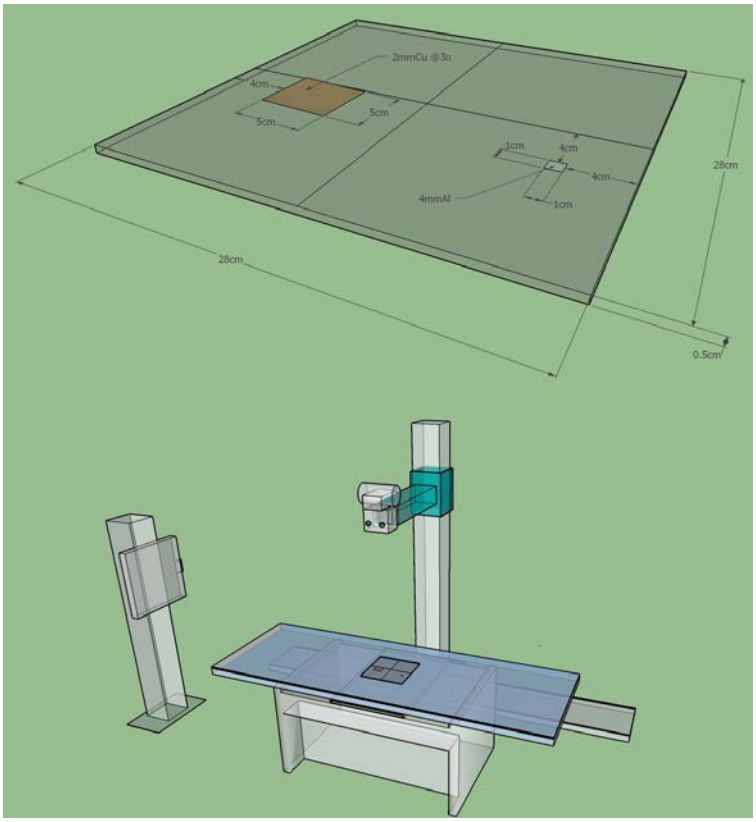

FIG. 2. Radiography phantom (top) and set-up (bottom).

(2) A 10 cm × 10 cm × 0.2 cm copper plate that serves as the main attenuator for the phantom. Several thinner sheets of copper may be combined for a total thickness of 0.2 cm if this is more cost effective.

4.2.1.4. Instrumentation for remote quality control of radiography

The following components are needed:

— Radiographic phantom:
  - Attenuator plate;
  - Target plate.

— Densitometer for film measurements (if screen–film system).

— Acquisition workstation with image analysis tools available, such as ROI mean and standard deviation tool, or software such as ImageJ (if digital image upload is not available).
— ATIA (if local advanced image analysis will be performed).
— Data form (see Appendix VIII).

4.2.1.5. Methodology for remote quality control of radiography

(a) Image acquisition

For remote QC of radiography, images are acquired with analogue or CR equipment, or with DR equipment, as explained below.

To acquire images with analogue or CR equipment, the steps are as follows:

(1) Select a 24 cm × 30 cm cassette and label it as 'QC cassette'. The testing needs to be done consistently using only the labelled QC screen–film or CR cassette (although not preferred, the QC cassette can also be used clinically if the number of cassettes for clinical use is low).
(2) Place the QC test cassette in the bucky tray (if available), using consistent orientation for each test.
(3) Position the X ray tube so that the field is centred on the image receptor; set the focus to detector distance to 1 m.
(4) Place the target plate on the table, centring it to the X ray field and the image receptor.
(5) Carefully collimate the beam to the edges of the target plate. Do not fully open the collimators.
(6) Attach the copper plate at the bottom of the collimator, using the light field to ensure that it is covering the entire field.
(7) For CR, create a test patient record for the image.
(8) Use 80 kVp (or the closest value possible).
(9) Select the mA·s setting:
    — If the system has AEC capability, select the clinical setting used for anteroposterior abdomen views, with only the central cell (AEC detector) selected;
    — If the system has no AEC capabilities, manually select 20 mA·s (or the closest value possible).
(10) Make the exposure.
(11) Record all exposure parameters (mA·s and exposure index, if available) on the data form (see Appendix VIII).
(12) Process and display the image.

To acquire images with DR equipment, the steps are as follows:

(1) Place the target plate on the table, centring it to the X ray field and the image receptor.
(2) Set the focus to detector distance to 1 m.
(3) Collimate the beam to include the entire target plate.
(4) Attach the copper plate at the bottom of the collimator, using the light field feature to ensure that it is covering the entire field.
(5) Create a test patient record for the image.
(6) Use 80 kVp (or the closest value possible).
(7) Select the mA·s setting:
    — If the system has AEC capability, select the clinical setting used for anteroposterior abdomen views, with only the central cell (AEC detector) selected;
    — If the system has no AEC capabilities, manually select 20 mA·s (or the closest value possible).
(8) Make the exposure.
(9) Record all exposure parameters (mA·s, exposure index, K_i and KAP, if available) on the data form (see Appendix VIII).
(10) Process and display the image.

(b) Image analysis

For remote QC, radiography images are analysed in four ways, depending on whether they are analogue or digital, and whether the facility is able to upload images or conduct advanced analysis.

Analogue images are analysed as follows:

(1) Review the image for artefacts.
(2) Zero the densitometer and measure the optical density at the following points:
    — Centre and four corners of the film, positioned 2 cm in from each edge of the film;
    — Inside the aluminium square;
    — Adjacent to the aluminium square;
    — Inside the copper square.
(3) Calculate the difference between the optical density adjacent to the aluminium square and inside the aluminium square.
(4) Record the results on the data form (see Appendix VIII).

Digital images from equipment without image upload capability are analysed as follows:

(1) View the 'for processing' image, if possible.
(2) Adjust the window width and level to review the image for artefacts. Keep in mind that using too small a width may overemphasize artefacts that are not clinically significant, while too large a width may hide significant artefacts.
(3) At the acquisition or image interpretation workstation, use the image analysis tools to place ROIs (approximately 1 cm^2) at the following points:
    — Centre and four corners of the image, positioned 2 cm in from each edge of the image;
    — Inside the aluminium square;
    — Adjacent to the aluminium square. Note: Some CR systems will modify the image data, truncating bits of it, if the image is modified at the acquisition station. All ROI measurements need to be performed at an interpretation workstation using PACS tools.
(4) Record the mean pixel value and the standard deviation for each ROI.
(5) Record the results on the data form (see Appendix VIII).

Digital images from equipment without image upload capability, but with advanced analysis capability, are analysed as follows:

(1) View the image.
(2) Adjust the window width and level to review the image for artefacts. Keep in mind that using too small a width may overemphasize artefacts that are not clinically significant, while too large a width may hide significant artefacts.
(3) Save the image to the computer that has the ATIA.
(4) Run the ATIA and open the QC image.
(5) Verify that the ROIs have been automatically placed in the correct positions. If they have not, move them to the correct positions.
(6) Click the appropriate icon to complete the analysis.
(7) Record the results on the data form: CNR, SDNR, MTF (20%) and d' (diameter $D = 4$) or export the .csv file for further analysis.

Digital images from equipment with image upload capability are analysed as follows:

(1) View the image.
(2) Adjust the window width and level to review the image for artefacts. Keep in mind that using too small a width may overemphasize artefacts that are not clinically significant, while too large a width may hide significant artefacts.

(3) Upload the image to the processing server.

4.2.1.6. Corrective actions for radiography

Several issues may be identified during testing. This subsection addresses corrective actions for radiography artefacts and system inconsistencies.

The following corrective actions are applicable if the medical radiation technologist observes an artefact:

— Acquire a second image but rotate the phantom (both the target and attenuator plates) by 90°. If the artefact moves, then it is in the phantom and the phantom may need to be replaced or repaired.
— For analogue and CR images, acquire a second image using a different cassette. If the artefact goes away, then the problem is in the cassette/screen and the cassette/screen may need to be cleaned or replaced.
— Send the image to the CQMP (if possible).
— Discuss the artefact with the radiologist to decide if it could negatively impact image interpretation (owing to its size, position, shape, etc.). If the artefact may mimic or disguise pathology, repairs need to be completed prior to resuming clinical use.
— Contact service as necessary after discussion with the CQMP.

The following corrective actions are applicable if the remote analysis by the CQMP or the automated system reveals any inconsistency:

(1) Investigate the cause, under supervision of the CQMP.
(2) Decide whether the equipment can be used clinically, following the CQMP's suggestions.

4.2.2. Mammography

4.2.2.1. Scope of remote quality control for mammography

The scope of the procedure is to evaluate the ability of the system to consistently generate images of a simple test object by determining the consistency of both acquisition technical parameters and image quality indicators as well as metrics (e.g. mA·s, optical density, exposure index, K_i, pixel value, uniformity, SNR, MTF) and artefacts.

4.2.2.2. Frequency of remote quality control for mammography

Given the simplicity and time required for the tests proposed, it is suggested that they be performed weekly or, optionally, daily.

4.2.2.3. Description of mammography phantom

A very simple mammography phantom is described that can be easily built locally (see Appendix II). It comprises the following two parts:

— A target plate made of a 24 cm × 30 cm × 0.5 cm sheet of PMMA, with test objects being a 5 cm × 5 cm × 0.1 cm copper square and a 1 cm × 1 cm × 0.02 cm aluminium square which lie flat on the target plate. The positions of both test objects can be seen in Fig. 3. The copper square is angled 2–5° with respect to the edges of the target plate for an accurate determination of the MTF.
— A 24 cm × 30 cm × 4 cm PMMA plate that serves as the main attenuator for the phantom. This base plate may consist of multiple thinner plates stacked together if that is more cost effective (as shown in Fig. 3, top).

4.2.2.4. Instrumentation for remote quality control of mammography

The following components are needed to complete the instrumentation:

— Mammographic phantom:
  - Base attenuator;
  - Target plate.
— Densitometer for film measurements (if analogue system).
— Acquisition workstation with image analysis tools, for example tools to identify ROI, mean pixel value and standard deviation, or software such as ImageJ (if digital image upload is not available).
— ATIA (if local advanced analysis will be performed).

4.2.2.5. Methodology for remote quality control of mammography

(a) Image acquisition

For remote QC of mammography, images are acquired with analogue or CR equipment, or with DR equipment, as explained below.

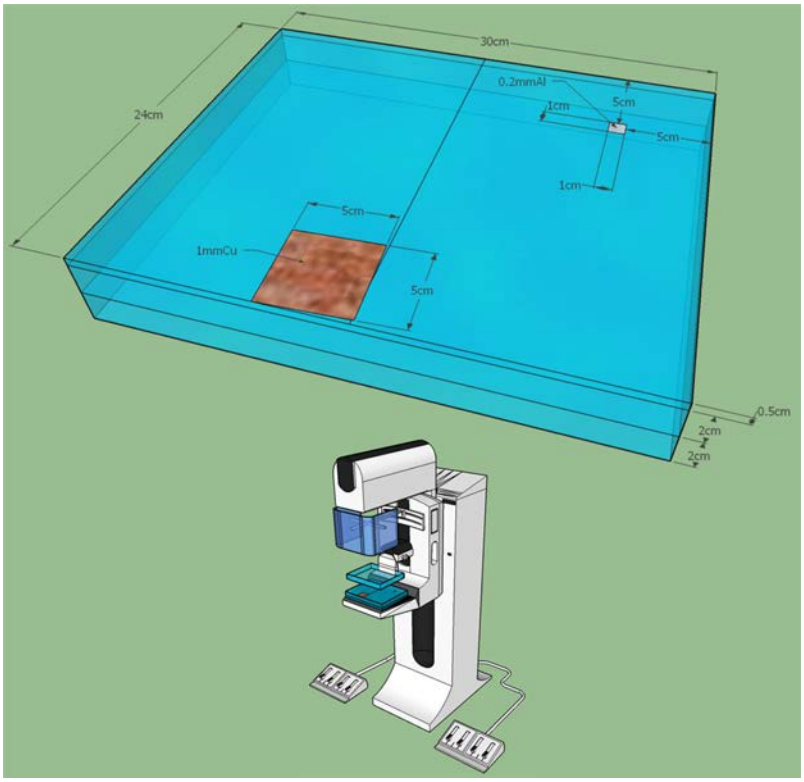

FIG. 3. Mammography phantom (top) and set-up (bottom).

To acquire images with analogue or CR equipment, the steps are as follows:

(1) Using the large image receptor, select a cassette which will be designated/labelled as the 'QC test cassette' and used each time. If necessary, the QC cassette may also be used clinically.
(2) Place the cassette in the bucky.
(3) Position the phantom aligned with the chest wall. Always place the target plate on top of the 4 cm attenuator.
(4) Position the AEC detector farthest from the chest wall, ensuring that it is not under the copper target.
(5) Compress to 5 daN.
(6) Use fully automated exposure; if not available, use 28 kVp, Mo/Mo combination, zero density setting.
(7) For CR, create a test patient record for the image.
(8) Make the exposure.

(9) Record all exposure parameters (kVp, mA·s, anode/filter, compressed breast thickness, mean glandular dose, and exposure index, if available) on the data form (see Appendix VIII).
(10) Process the image.

To acquire images with DR equipment, the steps are as follows:

(1) Create a test patient record for the image.
(2) Select the left craniocaudal view.
(3) Position the phantom aligned with the chest wall. Always place the target plate on top of the 4 cm attenuator.
(4) If the system uses a movable AEC detector, position it farthest from the chest wall, ensuring that it is not behind the copper target.
(5) Compress to 5 daN.
(6) Acquire an image.
(7) Record all exposure parameters (kVp, mA·s, anode/filter, compressed breast thickness, K_i, and mean glandular dose, if available) on the data form (see Appendix VIII).
(8) View the image.

(b) Image analysis

For remote QC, mammography images are analysed one of the following four ways, depending on whether they are analogue or digital and whether or not the facility is able to upload images.

Analogue images are analysed as follows:

(1) Review the image for artefacts.
(2) Zero the densitometer and measure the optical density at the following points:
    — Centre and four corners of the film, positioned 2 cm in from each edge of the film;
    — Inside the aluminium square;
    — Adjacent to the aluminium square;
    — Inside the copper square.
(3) Calculate the difference between the optical density adjacent to the aluminium square and inside the aluminium square.
(4) Record the results on the data form (see Appendix VIII).

Digital images from equipment without image upload capability are analysed as follows:

(1) View the image.
(2) Adjust the window width and level to review the image for artefacts. Keep in mind that using too small a width may overemphasize artefacts that are not clinically significant, while too large a width may hide significant artefacts.
(3) At the acquisition or image interpretation workstation, use the image analysis tools to place ROIs (approximately 1 cm^2) at the following points:
    — Centre and four corners of the image, positioned 2 cm in from each edge of the image;
    — Inside the aluminium square;
    — Adjacent to the aluminium square. Note: Some CR systems will modify the image data, truncating parts of it, if the image is modified at the acquisition station. All ROI measurements need to be performed at an interpretation workstation using PACS tools.
(4) Record the mean pixel value and the standard deviation for each ROI.
(5) Record the results on the data form (see Appendix VIII).

Digital images from equipment without image upload capability, but with advanced analysis capability, are analysed as follows:

(1) View the image.
(2) Adjust the window width and level to review the image for artefacts. Keep in mind that using too small a width may overemphasize artefacts that are not clinically significant, while too large a width may hide significant artefacts.
(3) Save the image to the computer that has the ATIA.
(4) Run the ATIA and open the QC image.
(5) Verify that the ROIs have been automatically placed in the correct positions. If they have not, move them to the correct positions.
(6) Click the appropriate icon to complete the analysis.
(7) Record the results on the data form: CNR, SDNR, MTF (20%) and d' (diameter $D = 0.1$) or export the .csv file for further analysis.

Digital images from equipment with image upload capability are analysed as follows:

(1) View the image.
(2) Adjust the window width and level to review the image for artefacts. Keep in mind that using too small a width may overemphasize artefacts that are not clinically significant, while too large a width may hide significant artefacts.

(3) Upload the image to the processing server.

4.2.2.6. Corrective actions for mammography

Several issues may be identified during testing. This subsection addresses corrective actions for mammography artefacts and system inconsistencies.

The following corrective actions are applicable if the medical radiation technologist observes an artefact:

— Acquire a second test image, but rotate the phantom (both the target and attenuator plates) by 180°. If the artefact moves, then the problem is in the phantom and the phantom may need to be replaced or repaired.
— For analogue and CR images, acquire a second test image but use a cassette different from the QC cassette. If the artefact goes away, then the problem is in the cassette/screen and the cassette/screen may need to be cleaned or replaced.
— Send the image to the CQMP (if possible).
— Discuss the artefact with the radiologist to decide if it could negatively impact image interpretation (size, position, shape, etc.).
— If the artefact may mimic or disguise pathology, the repairs have to be completed prior to further clinical use of the equipment.
— Contact service as necessary after discussion with the CQMP.

The following corrective actions are applicable if the remote analysis by the CQMP or the automated system reveals any inconsistency:

(1) Investigate the cause, under supervision of the CQMP.
(2) Decide whether the equipment can be used clinically, following the CQMP's suggestions.

4.2.3. Sensitometry

4.2.3.1. Scope of sensitometry

The scope of sensitometry is to evaluate the ability of the film processor to deliver images with consistent optical density and contrast.

4.2.3.2. Frequency of sensitometry

Daily.

4.2.3.3. Description of sensitometry

Sensitometric performance of the film processor is tracked through the optical density measurements of the background, the aluminium square and the copper square. Operating limits for these values are established by the CQMP. See Appendix II and Appendix VIII.

4.2.3.4. Corrective actions related to sensitometry

In all instances where optical density values fall outside acceptable limits, the first step is to repeat the QC process. If the second film is acceptable, then clinical use may continue as normal. If the deficiency persists, then corrective action is needed.

Changes in sensitometric performance may indicate contaminated chemistry, elevated chemical solution temperatures or outdated (expired) film. Further, the processor may not be replenishing the chemicals properly or transporting the films though the system properly.

4.2.4. Interpretation monitors

4.2.4.1. Scope of quality control for interpretation monitors

The scope of QC for interpretation monitors is to ensure that they are:

— Clean and free from dust, fingerprints, and other marks that may interfere with clinical information;
— Calibrated correctly, and the brightness and contrast settings are set correctly;
— Producing images as part of the image acquisition chain that are of adequate quality, they are working consistently and there are no obvious artefacts;
— Meeting manufacturer specifications — via the performance of medical display manufacturer automated tests (if available).

4.2.4.2. Frequency of quality control for interpretation monitors

Monthly.

4.2.4.3. Instrumentation for quality control of interpretation monitors

The following are required to perform QC of interpretation monitors:

— Dry, soft, lint-free cloth or cleaning tissue recommended by the workstation's manufacturer;
— Acquired phantom image;
— Standardized test pattern (from the Society of Motion Picture and Television Engineers [29], AAPM Task Group 18 [30] or similar source).

4.2.4.4. Methodology for quality control of interpretation monitors

Display calibration consists of the following two steps:

(1) Set up the monitors to automatically run any calibration and test protocols at the manufacturer defined frequency.
(2) Verify that tests and calibrations have been automatically performed and that all measurements are acceptable.

4.2.4.5. Tests for quality control of interpretation monitors

QC tests for interpretation monitors cover the medical display condition and a visual inspection.

The steps for conducting the QC of the medical display condition are as follows:

(1) Check the surface of the monitors for dust, scratches, defects, fingerprints, shiny patches (from grease or gel) and other foreign material (e.g. pen marks). If dirt, fingerprints, or other foreign material are present, wipe the monitor gently using a soft lint-free cloth, dampened with water, paying particular attention to the problem areas. Then wipe with a dry, soft, lint-free cloth. A special purpose screen cleaning tissue or cloth recommended by the monitor's manufacturer may also be used. After drying, recheck the monitor to be sure the problems were eliminated. If they were not, clean it again.
(2) Record data and significant findings.

The steps for conducting the visual inspection are as follows:

(1) Display the phantom image and inspect it for any significant artefacts, adjusting window width and window level to those values established by the CQMP. Keep in mind that using too small a width may overemphasize

artefacts that are not clinically significant, while too large a width may hide significant artefacts.

(2) Display the test pattern on the monitor.

(3) Without adjusting the window width and window level, evaluate the test pattern for the following visible targets (see Appendix VIII):
   — Are the 0–5% contrast boxes visible?
   — Are the 95–100% contrast boxes visible?
   — Are the line pair images at the centre and four corners visible and clearly distinguishable?

4.2.4.6. Corrective actions for interpretation monitors

Ideally, medical display screens have to be free of dust, fingerprints and other marks. Similarly, there should be no shiny patches or obvious non-uniformities on the surface. Significant blemishes that interfere with the interpretation or QC of images have to be corrected. If there are questions regarding the significance of a blemish, the interpreting physician or CQMP needs to be consulted.

Most problems can be corrected by cleaning as per the manufacturer's instructions. Physicians could also be encouraged to remove promptly any significant dirt from their workstation. However, if cleaning does not correct the problem, the manufacturer might need to be contacted to evaluate and correct the problem. Abrasive materials or alcohols are not to be used on medical display faces, since the antiglare surface on the display might be destroyed.

In most cases, automated tests and control limits are available in manuals or other documents published by the manufacturer. These tests are extremely valuable in maintaining quality and are specific to each manufacturer. If such automated testing is available, the CQMP can assist the facility in verifying that the automated system is set up and functioning properly.

The interpretation monitors have to be free of artefacts and non-uniformities that could interfere with proper interpretation of images. All such artefacts need to be discussed with the CQMP for guidance.

The 5% and 95% patches have to be visible. If they are not, calibration or adjustment of the medical display is needed. It is suggested to run all manufacturer calibrations for the interpretation monitors and review the test pattern. If inadequate visualization of the targets remains, it may be necessary to adjust the brightness and contrast of the interpretation monitor itself. Consult the CQMP for guidance. If it is impossible to correct the image, the replacement of the interpretation monitor may be necessary.

4.2.5. Dosimetry

4.2.5.1. Scope of quality control for dosimetry

Patient dose is an important consideration in the justification of X ray imaging for medical purposes. At the installation of a system, the level of exposure to the image receptor has to be optimized to properly balance radiation dose and image quality. While it is most common to discuss patient dose, it is the dose to the image receptor that actually determines image quality and it is that value that is established when commissioning the system. Subsequently, while patient dose will be dependent upon such factors as patient size, dose to the image receptor for a given examination should remain constant. A good QC programme will ensure that this calibration is maintained. Note that different procedures have different image quality requirements and therefore will require different image receptor doses in a digital system. In an analogue system, the appropriate dose to the image receptor is determined by the small range of usable optical densities (i.e. the latitude) in the film.

Patient dose estimates are typically compared to national diagnostic reference levels. The use of patient dose monitoring platforms is becoming more common. These systems provide insight on both dose level and deviations from normal or expected values. They also allow for comparison between systems.

The use of a simple test object does not allow a complete patient dose assessment. Proper application of radiographic techniques (including selection of modality, selection of preprogrammed procedures, correct focus–detector distance, collimation and patient–detector distance) and patient related factors (patient habitus, positioning and basic instructions) cannot be controlled by a periodic test. However, periodic testing with a consistent test object can verify the stability of many components that may impact patient dose — for example, X ray exposure, dose measuring devices (such as a KAP meter), the functioning of the collimator, the AEC system and the exposure indicator in the detector.

Patient dose is determined in part by the technical factors — anode/filter selection, tube voltage, mA·s — and, most importantly, by patient size. Stability of the technical factors, verified through imaging of the phantom, is a first indicator of stable patient exposure. These factors are available in the DICOM header of the images or can be noted from the control console for tracking. Most digital mammography systems also estimate the mean glandular dose. This value represents the dose to the tissue of interest for patient risk assessment. It uses the reported value of compressed breast thickness, anode/filter and tube load, and assumes breast glandularity. Assessment of stability requires, then, that the test object image acquisition be performed with a consistent compression force and indicated breast thickness for mammography systems. If the dose is reported in

the DICOM header, the ATIA will extract the value and report it. If the CQMP has verified the accuracy of the reported values, those can then be used to track consistency of dose along with the other parameters.

The AEC is a critical component in X ray imaging. This system ensures that a target air kerma level is reached at the detector, regardless of patient size. Reproducible functioning of the AEC can be tested from periodic acquisitions of images of a simple test object, the exposure of which will have to result in the same entrance dose or KAP value, yielding the same exposure to the detector. Digital systems have exposure indicators that relate the incident air kerma to an index value. While manufacturers have historically been free to define their own exposure indices, the exposure index has recently been standardized. Exposure indices may be available in the DICOM header of the image. If they are present, the ATIA will extract and report them. Periodic testing of exposure to the detector can also be based on tracking the mean pixel value in the 'for processing' images (see subsections 4.2.1 and 4.2.2). The use of the exposure index is preferred, as it allows for comparisons among systems. The mean pixel value could be calibrated to reflect detector air kerma, but this is not a common procedure.

Proper function of the collimator is tested indirectly by tracking KAP values. If manual collimation is used, then the KAP values can be used to verify that collimation is consistent. In both cases, it must be known that the tube output is acceptably stable and reproducible.

Stability of X ray exposure also requires an X ray tube and generator that are functioning properly. These are evaluated via the exposure factors of anode/filter, tube voltage, and tube load (mA·s).

4.2.5.2. Instrumentation for dosimetry

There is no need for any extra instrumentation beyond that described in subsections 4.2.1.4 and 4.2.2.4. Basically, exposure parameters, measured or calculated KAP value (if available), indicated patient dose indicators (if available) and exposure index or mean pixel value in a ROI are tracked over time. Most of these data can be retrieved from the DICOM header of the image or can be noted at the time of data acquisition.

4.2.5.3. Methodology for dosimetry

Some KAP meters may require an explicit and manual reset prior to test object image acquisition. While most KAP meters are fully integrated into the modality and are reset automatically at the start of a registration or image acquisition, in some older systems the KAP meter is a separate unit without

the integration required to automatically reset it. In such cases a manual reset is needed.

4.2.5.4. Dosimetry measurements

X ray exposure parameters (anode/filter, kVp and mA·s, KAP) are available at acquisition or in the DICOM header of the test object image. These need to be recorded at the time of the exposure if they are not included in a DICOM header.

Mean pixel value tracking can be used as a surrogate for an exposure indicator if no system-defined indicator is present. However, if the exposure indicator is easily available, this value can be used.

Oversight by the CQMP will include trend analysis, which involves an analysis of the stability of the data over time. It can often happen that only very small deviations appear from week to week but, over a longer period of time, such minor deviations can accumulate into a large divergence that requires follow-up.

4.2.5.5. Corrective actions related to dosimetry

Deviations made evident by trend analysis need to be carefully investigated. First, it has to be determined if operator errors caused the deviations. If the phantom is not positioned properly or if the technical parameters are not consistently selected, errors may occur.

Assuming that human error is not the cause, system function is suspected. The following situations can be imagined:

— The dose indicator display can fail, while the exposure is stable. While a standard regarding necessary accuracy for the patient dose indication or the exposure index has not been formally established, 20% is typically used.
— If further investigation demonstrates that the dose indication is correct, drifts can be due to instability of the AEC, KAP meter, X ray detector, or X ray tube or generator. Typical corrective actions are to request the calibration of the AEC or the KAP meter first. Instability of the X ray tube or generator and detector are less frequent and could be considered when operator error and instability of the AEC and KAP have been excluded. In any case, such evaluation needs to be carried out in consultation with the CQMP, who will ideally be on the site for this detailed troubleshooting.

As stated above, applications that monitor actual patient doses over time are very useful and should be used in conjunction with a phantom QC programme. If the dosimetric evaluation of the test object image acquisition points to a stable

X ray system while patient doses are drifting, and problems with the imaging system have been ruled out, other causes such as human error may be investigated.

4.3. FOLLOW-UP FOR REMOTE QUALITY CONTROL

Various levels of reporting are required for a remote and automated QC system to function properly. The structure of the reporting depends upon the QC system implemented at a particular facility. In any case, the first level of reporting is local to the facility. After the phantom has been exposed, the resultant image can be reviewed by the medical radiation technologist for gross artefacts or other obvious problems. If any are detected, the issue has to be immediately reported to the CQMP providing oversight for the QC programme. Note that the first step after a problem is identified is to acquire a second test image to determine if the problem persists. If the issue is still present, under the direction of the CQMP, the facility supervisor as well as the service engineer need to be notified (as necessary) so that appropriate corrective action can be initiated. If the problem disappears after repeating the exposure, this could be noted in the QC documentation while notifying the CQMP.

After images or measurements are uploaded to the QC system, analysis is performed automatically. If any parameter falls outside of the control limits, the system needs to notify both the facility and the overseeing CQMP automatically. Upon reviewing the results, the CQMP determines the appropriate action and gives direction to the facility. Depending upon the severity of the problem, the CQMP and the facility decide whether the system can be used clinically. After following the directions of the CQMP, the facility needs to notify the CQMP of the status of the system. The event, follow-up actions and resolution need to be recorded in the QC documentation.

It might happen that a facility neglects to perform the QC testing for a number of days. Ideally the QC system can be set up to automatically send reminders if this happens to both the facility and the overseeing CQMP that QC data are missing.

The QC system can provide quarterly summaries to the overseeing CQMP. The CQMP has the responsibility to review these reports for trends in the data that might indicate a potential problem otherwise missed by the QC system. This can also reveal issues with data collection or image acquisition which may go undetected by the automated QC programme. The CQMP can then report to the facility any findings from this quarterly review.

Finally, it is appropriate for the QC system to provide an annual summary to both the CQMP and the facility. This summary could be used as an educational tool regarding performance of QC functions. Additionally, the annual summary

can provide insight into the health of the imaging system and help facilities plan for replacement of the system once the QC data indicate end-of-life issues.

5. DATA ANALYSIS REQUIREMENTS

5.1. ALGORITHMS

Traditional image quality metrics, such as the use of line pair patterns and the visibility of low contrast objects, are inherently subjective. Additionally, these measurements can be time consuming. This makes their use in a robust QC programme problematic and unreliable. Many facilities have limited time to devote to QC, and in many instances, there is not a designated QC person, meaning that different people perform the QC each time. It was therefore necessary to develop a tool that is user independent and can be used quickly. The tool described in this publication allows for simple analysis by the facility, advanced analysis using generic or dedicated applications, and remote analysis of images.

To counter the subjective nature of traditional metrics, advanced metrics such as SDNR, MTF and d' are calculated by the ATIA. None of these metrics is dependent upon the observer, so the impact of different individuals performing the QC tests is negligible.

In a broad sense, the MTF relates the ability of the system to image fine detail. While multiple methods for determining MTF exist, one of the most robust and easiest to implement automatically is using the Fourier transform of the image of a sharp edge [31]. The copper square in the described phantoms is positioned and used for this purpose.

Contrast is the ability of a system to discern an object with a small signal difference from the background. An object with a smaller signal difference is more difficult to see than one with a larger signal difference. Furthermore, greater noise in the background will make it harder to visualize an object with a given signal difference. This task is often described by the SDNR. To calculate the SDNR, the difference in mean signal values between a ROI in the target and a ROI in the background is determined. This difference is then divided by the noise in the background. A larger SDNR indicates that a system has a greater ability to allow visualization of a target. In the two phantoms, the small aluminium squares are used for SDNR determination.

Even though the MTF and the SDNR, as determined in this algorithm, remove subjectivity from the analysis, they still suffer from the reality that their

clinical relevance is somewhat limited. They grossly simplify the challenges of interpreting diagnostic radiological images. To help overcome this, a newer 'detectability index' has been developed: *d′*. This index relates subjective measurements such as the SDNR and the MTF to actual, clinical interpretation tasks. Through *d′*, a simple phantom can be directly linked to clinical imaging performance.

While extremely valuable, *d′* is not the only metric important to image quality in a radiographic image. Artefacts or non-uniformities in the signal can make an otherwise excellent image useless. It is therefore essential to include artefact and uniformity analysis in any QC programme. The ATIA includes a function for highlighting artefacts and areas of non-uniformity. This function may be run on the image with the target plate, recognizing that the test targets will be identified by the application, or it can be run on a separate, uniform image with only the base attenuator. In either case, images need to be visually reviewed by either the facility QC staff or the CQMP to ensure that artefacts and non-uniformities highlighted by the application are not objectionable. Details of the image quality metrics used in this publication are described in detail in Appendix V.

5.2. CONTROL LIMITS AND AUTOMATED NOTIFICATIONS

A QC programme is not effective if it merely records values for each measurement but does not compare them to some standard. The goal of any QC programme is to ensure consistent performance. It is therefore necessary to establish baseline performance for each system, along with upper and lower control limits. Measurements will typically show some small deviation around the baseline, but they should not go beyond the control limits if the system is performing correctly.

In most cases, control limits are set at approximately two standard deviations from the baseline. However, in the initial phase of implementation, some arbitrary values can be defined (e.g. ±10% of the baseline) that can be tracked over time in order to better associate the control limits with the system fluctuation as the programme matures. Appendix III has more detail regarding QC statistics and can guide the user in defining the control limits.

For example, a study has shown that MTF normally varies about 5% from a baseline value over the long term in mammography units [32]. A facility may choose to track a specific value, for example, at 20% MTF over time. Given this, it would be reasonable to establish control limits at ±10% of the baseline value for the 20% MTF for such a system. Variation within those limits would be

considered normal and acceptable. Variation outside those limits would require some follow-up activity.

Another approach to establishing control limits is performance based. What metric value is required for a system to generate images of adequate quality? In this case, a minimum value is established based on historical and evidence based data, and the system must demonstrate performance above that target value. Falling below the minimum acceptable target value would require follow-up activity.

It is important to note that a QC programme can only be successful if there are mechanisms in place that trigger corrective actions. A disadvantage of a remote and automated QC programme is that the facility may be performing the QC functions but not receiving any feedback for deficient images. Identified problems might remain unaddressed and corrective action might not be taken if the notification process between the facility and the CQMP is not working. Regardless of how the measurements are made, it is essential that the facility and the CQMP be made aware of any problems in a timely manner. Ideally, the QC system will send automatic notifications in the form of email or other electronic alert to the appropriate individuals when a potential problem is discovered. Automated notifications remove the possibility that problems will simply be neglected or forgotten by the facility. When working properly, they also allow facilities to continue with routine clinical work with the knowledge and assurance that the system is functioning properly when no notification has been received. Owing to the differences between and necessities of local infrastructures, facilities and Member States will establish these automatic alert systems at whatever level is deemed appropriate.

5.3. TREND ANALYSIS

In a system operating under acceptable performance, measurements of any given metric are expected to fluctuate somewhat randomly around the baseline value owing to statistical variation. If the plot of a given metric shows non-random tendencies and variations, this is evidence that there is an underlying problem with the system, which needs to be addressed. For example, the plot of a metric might show it decreasing nearly linearly over time. While it might still be within the control limits, a trend of three or more points moving in the same direction is evidence of a problem that requires investigation.

As described in Appendix III, trend analysis can be much more advanced than this simple example. In any case, it is not simply enough that measurements of a particular metric remain within the control limits or above the par value. Trends and tendencies need to be identified and corrected.

6. IMPLEMENTING A REMOTE QUALITY CONTROL FRAMEWORK

6.1. ROLES AND RESPONSIBILITIES

Implementing a remote QC framework at a national level is always highly encouraged and preferred. However, regional collaborations and programmes are also acceptable approaches.

6.1.1. Role of national or local authorities

A quality and safety culture can be defined as the set of core values and behaviours resulting from a collective commitment by leaders and staff at all levels in an institution to emphasize and focus on safety and quality over competing financial and performance goals to ensure the protection of employees, patients and the public in general in an environment where image quality and radiation dose are clinically optimized. Within Member States, such a culture has to be promoted and supported by the top regulatory authorities.

The need for regular QC as part of a comprehensive QA programme is clearly highlighted in GSR Part 3 [16] as a basic requirement for medical imaging facilities. While a valuable requirement, it does not specify the frequency at which QC activities need to be performed, stating only that the "frequency is in accordance with the complexity of the radiological procedures being performed and the associated risks." In radiology, it is often considered that the risks of performing radiological procedures are very small, which is only true where the risk of the radiation exposure to the patient is concerned. However, other medical risks may arise from studies with a poor image quality, and those risks can become very high if an important clinical finding is missed or if a false positive diagnosis leads to inappropriate or unnecessary medical treatment and intervention.

Typically, it is left to the local regulatory authorities to define the required frequency of QC testing. For the most part, these same regulatory authorities do a very good job in terms of conducting inspections for licensing purposes. It is thus in the best interest of Member States to promote the implementation of QA programmes that include frequent testing, as proposed herein. This publication provides a methodology to support such programmes even in underserved areas, where the requirements of GSR Part 3 are often left unaddressed owing to the limited availability of required qualified personnel.

According to GSR Part 3, "Registrants and licensees shall ensure that programmes of quality assurance for medical exposure include…[m]easurements of the physical parameters of medical radiological equipment made by, or

under the supervision of, a medical physicist" [16]. However, the lack of CQMPs in certain countries, regions and areas makes the implementation of these requirements difficult. Nonetheless, local authorities can make sure that proper procedures for adequate QA and medical physics support are in place. The scope of the methodologies described in this publication does not intend to replace or minimize the need for the on-site support of CQMPs or to replace the requirements for frequent comprehensive QC. The aim is to provide an additional tool for the CQMP and optimize the use of resources, especially in underserved areas.

The guidelines in this publication can be used by Member States as a starting point to develop structured regulatory requirements for evaluating and monitoring the performance of imaging equipment. For example, evidence of regular QC could be required as part of the licensing process. The methodology presented in this publication, or a similar method, can be used for this purpose. At the same time, national authorities could acknowledge the efforts of a department to develop regular QC procedures as evidence of good practice; when a CQMP cannot be physically present, remote and automated QC is a feasible option.

6.1.2. Role of professional societies

Further to the use of the existing methodologies for remote and automated QC, professional societies can play a vital role in developing a general quality and safety culture in Member States. National or regional societies of radiologists, medical radiation technologists (radiographers) and medical physicists can promote and support the following:

- The need for and advantages of a quality and safety culture, reflecting it in all programmes and activities;
- Education, in terms of continued professional development workshops and seminars which can be frequently organized to introduce members to this model framework of QC and disseminate the benefits expected from the implementation of a comprehensive QA programme;
- Dissemination of the framework described in this publication;
- Uniform QC processes, programmes and testing, allowing for comparison and establishment of performance standards;
- Research into clinically relevant QC testing.

6.1.3. Role of the manufacturer

Although this publication is mostly aimed at imaging facilities and their supporting CQMPs, the importance of the imaging equipment manufacturers

cannot be underestimated. The successful implementation of a programme of this type is highly dependent upon the tools made available in the marketplace.

Of primary importance are the availability and accessibility of 'for processing' images. Without access to these images, many QC functions cannot be adequately established or performed. The most important aspects of the standard unprocessed image are that the signals are proportional (either directly or logarithmically) to the detector pixel exposure, and that no edge enhancement, smoothing, frequency based processing or averaging has been applied to the file. It is important to note that it is acceptable for the following to have been applied to the unprocessed image [22]:

— Data replacement for defective pixels;
— Flat field correction;
— Pixel gain and offset corrections;
— Geometric distortion correction.

Any other corrections or modifications can yield faulty results in QC tests. Manufacturers are encouraged to remember that QC is nearly as important as the clinical imaging. Just as appropriately processed images are necessary and beneficial for clinical imaging, images without processing are necessary and beneficial for QC of imaging.

Basic image analysis tools are usually also provided at the acquisition workstation. Window width and level adjustment is needed to be able to verify that the exposed image is diagnostically acceptable. Simple ROI statistics and measurement tools allow the medical radiation technologist to make elementary QC tests at the workstation.

Additionally, the importance of implementing a standardized exposure index [22] is emphasized by this publication. This standardized system makes it much easier for imaging facilities to implement uniform imaging protocols and QC measures, especially when equipment from different manufacturers is installed within the same facility.

This publication suggests a framework for advanced, comprehensive image QC evaluation. It would be very helpful for manufacturers to include the ATIA, or an equivalent providing similar evaluations, on their workstations. It is to the manufacturer's benefit to provide tools to ensure that their equipment is operating optimally. Including such software on the acquisition unit would also make it easier for facilities to work towards optimizing their imaging protocols, as d' relates directly to some of the clinical imaging tasks. Facilities could experiment with additional filtration and technical settings to optimally balance dose and d' for their practice.

Along with the ATIA or an equivalent, it is advisable that manufacturers provide the simple test tool described in subsections 4.2.1.4 and 4.2.2.4 with their imaging systems, or one providing equivalent capabilities. The phantom test tool is inexpensive and simple to construct, but some facilities may have challenges in acquiring the necessary parts or getting the edges of the copper MTF target fine enough for proper analysis. Imaging equipment manufacturers have access to much better fabrication facilities than do most medical institutions. Further, manufacturers benefit from significant cost savings due to economies of scale, making it even less expensive for them to produce the test tool than for the users to do so. Manufacturers of test tools are encouraged to produce this phantom, as it may be to the advantage of many facilities to be able to purchase such a test tool independently for their installed systems, recognizing that many may not have the ability to fabricate the tool themselves.

The manufacturers of PACSs also have a role to play in implementing the guidelines in this publication. PACSs are ideal for the central storage, analysis and database platform that is called for. They already generally have the ability to accept and store sent images, provide analysis tools and notify individuals when certain conditions are met. Few additional functions are needed to implement the guidelines in this publication. PACS providers are encouraged to consider incorporating the functionality to implement this programme within their structure. Similarly, it is conceivable that many dose monitoring packages would be easily capable of implementing this QC framework.

6.2. FUTURE DIRECTIONS

It is recognized that a comprehensive QA programme and its associated QA testing can be time consuming for both medical radiation technologists and medical physicists. This framework for remote and automated QC has been designed with the intent that it be implemented efficiently. As with any new programme, it is likely that potential for improvement exists. As implementation of the programme grows, the additional experience will help illuminate where such improvements are possible. It is hoped that future refinements and optimizations will be made.

As implementation grows to a wide scale, it is expected that the use of this unified programme will soon result in a large database of performance results. A collective meta-analysis of these data could yield important results regarding the performance of systems throughout the Member States. Such an analysis can help to establish performance standards, control limits and point to areas where improvements in imaging protocols can be made. There are only a handful of examples of such programmes being implemented on a wide scale, making it

difficult to predict the many ways in which the data might be used. It is hoped that researchers throughout the Member States will make use of these data.

Beyond the scope of such large research projects, it is easily envisioned that much benefit can be derived from collaboration between facilities and institutions using this QC framework. Such collaboration can be as simple as the sharing of troubleshooting techniques or helping with the development of imaging protocols. These collaborations can be encouraged through the establishment of user groups, both on-line and at face to face meetings. User groups can provide an informal venue for the exchange of ideas and methods along with group discussion of problems and resolutions.

This publication only addresses the modalities of radiography and mammography. It is clear that many other X ray based imaging modalities could benefit from a similar framework. It would be desirable to develop such a programme for them. As demonstrated here, the test tools do not need to be complicated or expensive, though it is recognized that some modalities such as computed tomography may present complications not encountered with either planar radiography or mammography. Nonetheless, efforts are needed to extend this framework to computed tomography, fluoroscopy and dental imaging in whatever manner possible.

As stated in subsection 6.1.1, the role of regulatory authorities cannot be overstated. It is often only with a regulatory mandate and enforcement that some facilities will initiate a programme such as this. Continuing effort has to be made to encourage regulators to put a requirement for QC testing such as this remote and automated framework into their rules, and to look for appropriate documentation at inspection. Facilities could be given credit for using this programme under the mandates of GSR Part 3 [16].

Appendix I

MEDICAL PHYSICS TOOLBOX

I.1. DESCRIPTION OF AUTOMATED TOOL FOR IMAGE ANALYSIS

The ATIA was developed in order to facilitate the analysis of radiography and mammography phantom images described in this publication. It is available for download by all Member States via the IAEA Human Health Campus[2]. This tool will automatically calculate the following variables: SDNR, CNR, MTF and *d'*. Each variable can later be tracked over time to see its behaviour in order to take corrective actions as needed. At the same time, the ATIA can extract and report relevant tags (e.g. kVp, mA, s, exposure index) from the DICOM header of the image that can be used to supplement the information from the QC image.

After the software is installed, the main dashboard is displayed (Fig. 4).

FIG. 4. The main dashboard of the automated tool for image analysis (ATIA) application available from the IAEA Human Health Campus.

[2] The IAEA Human Health Campus can be found at https://humanhealth.iaea.org.

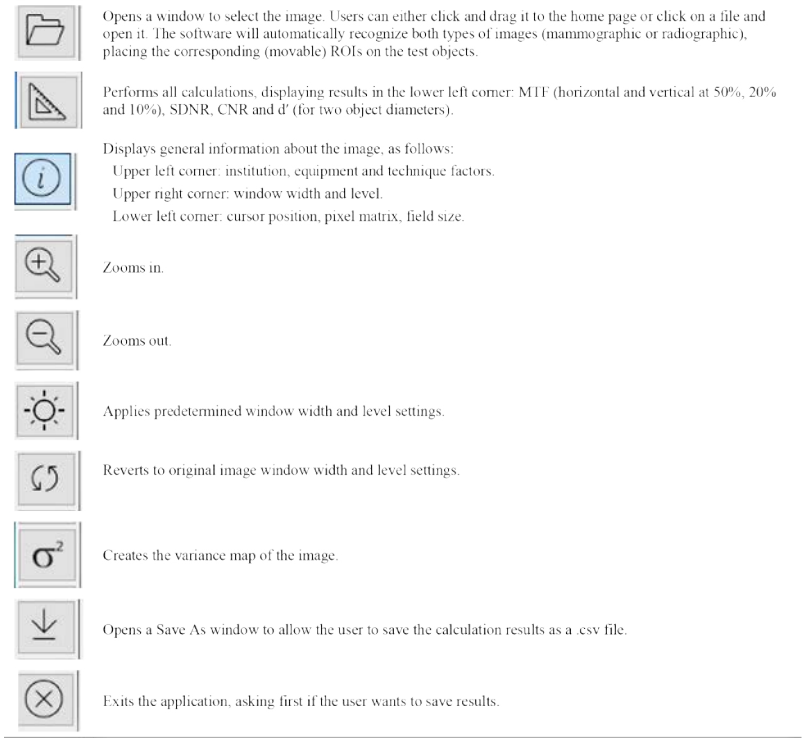

FIG. 5. Automated tool for image analysis (ATIA) application icons. CNR — contrast to noise ratio, MTF — modulation transfer function; ROI — region of interest, SDNR — signal difference to noise ratio.

The main control buttons of ATIA are described in Fig. 5, while Figs 6 to 9 show a radiology phantom image loaded onto the system and the corresponding variance maps (Figs 6, 8) and .csv files (Figs 7, 9).

I.2. CONTROL CHARTS FOR RESULTS FROM AUTOMATED TOOL FOR IMAGE ANALYSIS

An Excel template has been developed to facilitate the analysis of data produced by the ATIA over time. The data are loaded in the file with just a few clicks and individual control charts are displayed for the following metrics: mA·s, kVp, SDNR, CNR, organ dose, entrance dose, exposure index, MTF and *d′*. Figure 10 shows one of the sheets with the summary of control charts and then, specifically, the SDNR results.

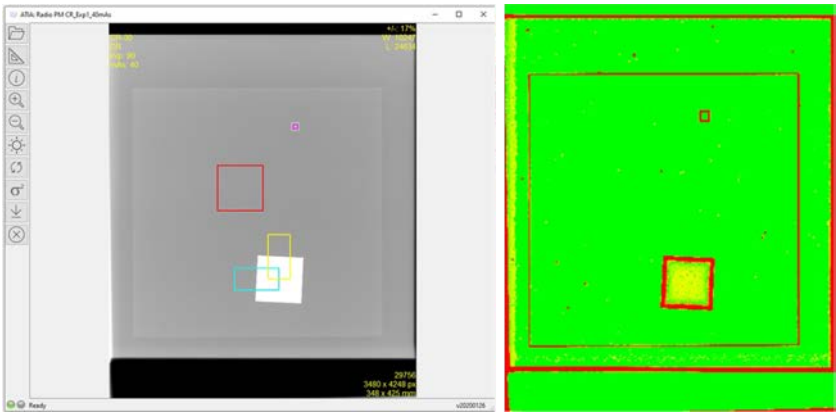

FIG. 6. A radiography phantom image loaded into the automated tool for image analysis (ATIA) (left) and the corresponding variance map (right) produced by the ATIA.

A2

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q
1	CR																
2																	
3	CR-30																
4	20160304																
5																	
6	Signal		Backgroud						MTF 50%	MTF 20%	MTF 10%			d'			
7	Mean	SD	Mean	SD	SDNR	SNR		Horz (/mm	0.929889	1.92086	2.64436		D=0.3mm	7.63121			
8	22351.4	33.038	23425.7	38.071	28.2198	615.316		Vert (/mm	0.798238	1.72049	2.2783		D=4mm	156.981			
9																	
10	Horizontal			Vertical			NNPS					DICOM TAG					
11	/mm	MTF		/mm	MTF		/mm	Horz	Vert	Rad		Name	Key	Value			
12	0	1		0	1		0	1.56E-05	1.56E-05	1.56E-05		Institutior	(0008	008 DR FAYLAN ESQUIVEL S.			
13	0.25	0.786556		0.25	0.775274		0.039063	6.48E-06	1.75E-05	6.51E-06		Institutior	(0008	104 IMAGENES MEDICAS			
14	0.5	0.683401		0.5	0.653848		0.078125	1.93E-06	7.16E-06	1.86E-06		StationNa	(0008	101 CR-30			
15	0.75	0.576098		0.75	0.532225		0.117187	1.09E-06	1.81E-06	6.10E-07		PatientNa	(0010	001 ^PROTOTIPO RAYOS X			
16	1	0.467259		1	0.422363		0.15625	7.68E-07	1.19E-06	3.67E-07		DeviceSer	(0018	100 PB517500033808			
17	1.25	0.37461		1.25	0.33331		0.195312	5.50E-07	8.79E-07	2.83E-07		PlateID	(0018	100 B1WNMT0085			
18	1.5	0.299178		1.5	0.24615		0.234375	3.97E-07	1.36E-06	3.20E-07		TargetExp	(0018	141 2281			
19	1.75	0.239639		1.75	0.194231		0.273437	5.59E-07	9.14E-07	2.87E-07		Deviation	(0018	141 6			
20	2	0.182889		2	0.142983		0.3125	1.33E-07	8.13E-07	2.36E-07		StudyDate	(0008	002 20160304			
21	2.25	0.148686		2.25	0.10743		0.351562	2.29E-07	3.02E-07	2.34E-07		SeriesDat	(0008	002 20160304			
22	2.5	0.114924		2.5	0.080283		0.390625	5.11E-07	3.14E-07	1.95E-07		Acquisitio	(0008	002 20160304			
23	2.75	0.098269		2.75	0.062642		0.429687	1.09E-07	5.05E-07	2.23E-07		Modality	(0008	006 CR			
24	3	0.083027		3	0.052939		0.46875	1.11E-07	7.43E-07	1.97E-07		Presentat	(0008	006			
25	3.25	0.06526		3.25	0.036098		0.507812	1.90E-07	3.80E-07	1.94E-07		Manufacti	(0008	007 Agfa			
26	3.5	0.05836		3.5	0.027779		0.546875	9.65E-08	6.54E-07	1.81E-07		FieldOfVi	(0018	114			
27	3.75	0.042023		3.75	0.014205		0.585937	1.99E-07	1.18E-07	1.63E-07		Exposure1	(0018	115			
28	4	0.038055		4	0.016438		0.625	2.33E-07	2.70E-07	1.75E-07		XRayTube	(0018	115			
29	4.25	0.034173		4.25	0.015871		0.664062	4.26E-07	1.24E-07	1.65E-07		ImagerPix	(0018	116 0.1			
30	4.5	0.02918		4.5	0.014402		0.703125	1.22E-07	1.70E-07	1.49E-07		AnodeTar	(0018	119			
31	4.75	0.032878		4.75	0.012494		0.742187	1.19E-07	1.03E-07	1.33E-07		Manufacti	(0008	007 Agfa			
32	5	0.021279		5	0.008867		0.78125	1.96E-07	2.32E-07	1.41E-07		KVP	(0018	006 90			
33	5.25	0.019185		5.25	0.007609		0.820312	8.32E-08	1.80E-07	1.29E-07		FilterMate	(0018	705			
34	5.5	0.025449		5.5	0.005302		0.859375	1.55E-07	1.14E-07	1.21E-07							
35	5.75	0.009126		5.75	0.003914		0.898437	1.45E-07	5.17E-08	1.06E-07		Exposure	(0018	115 40			
36	6	0.010208		6	0.010323		0.9375	1.20E-07	1.32E-07	1.16E-07		ImageAnd	(0018	115			
37	6.25	0.01224		6.25	0.002413		0.976562	2.18E-07	1.77E-07	1.03E-07		EntranceD	(0040	830			
38	6.5	0.005119		6.5	0.005818		1.01562	2.15E-07	2.55E-07	1.02E-07		Exposure	(0018	141 9117			

Test_CR-30_20160304

FIG. 7. The .csv file of the radiography phantom image presented in Fig. 6 opened as a spreadsheet containing all the important information and measurements.

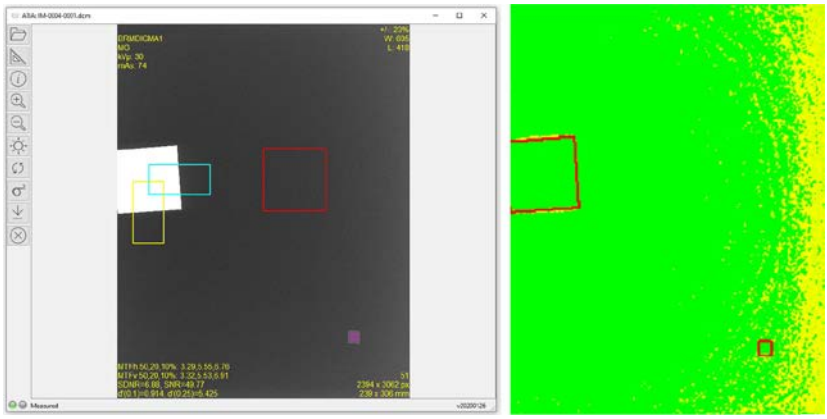

FIG. 8. A mammography phantom image loaded into the automated tool for image analysis (ATIA) (left) and the corresponding variance map (right) produced by the ATIA.

A1 MG

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R
1	MG																	
2	BCH - Medical Imaging Center																	
3	BRMDIGMA1																	
4	20170718																	
5																		
6	Signal		Backgroud						MTF 50%	MTF 20%	MTF 10%			d'				
7	Mean	SD	Mean	SD	SDNR	SNR		Horz (/mm	3.28942	5.54824	6.75791		D=0.1mm	0.914393				
8	491.915	9.33945	570.783	11.468	6.87719	49.7718		Vert (/mm	3.31645	5.53055	6.90888		D=0.25mm	5.42507				
9																		
10	Horizontal			Vertical			NNPS					DICOM TAG						
11	/mm	MTF		/mm	MTF		/mm	Horz	Vert	Rad		Name	Key	Value				
12	0	1		0	1		0	0.000227	0.000227	0.000227		Institutior	(0008|008	BCH - Medical Imaging Center				
13	0.25	0.847613		0.25	0.831246		0.039063	0.000229	2.96E-05	6.88E-05		Institutior	(0008|104					
14	0.5	0.841777		0.5	0.822979		0.078125	3.69E-05	7.51E-06	1.31E-05		StationNa	(0008|101	BRMDIGMA1				
15	0.75	0.814774		0.75	0.801455		0.117188	2.15E-05	9.56E-06	7.87E-06		PatientNa	(0010|001	Physicist^IAEA Mamm Phantom				
16	1	0.799647		1	0.77569		0.15625	2.70E-05	3.01E-06	6.11E-06		DeviceSer	(0018|100	2.08E+11				
17	1.25	0.766416		1.25	0.744223		0.195313	1.66E-05	6.96E-06	5.63E-06		PlateID	(0018|100					
18	1.5	0.742405		1.5	0.727279		0.234375	9.51E-06	7.27E-06	4.01E-06		TargetExp	(0018|141					
19	1.75	0.713416		1.75	0.698732		0.273438	7.27E-06	4.70E-06	4.59E-06		Deviation	(0018|141					
20	2	0.689737		2	0.664565		0.3125	9.56E-06	5.67E-06	4.73E-06		StudyDate	(0008|002	20170718				
21	2.25	0.658879		2.25	0.63585		0.351563	3.92E-06	6.40E-06	3.70E-06		SeriesDat	(0008|002	20170718				
22	2.5	0.609681		2.5	0.608466		0.390625	6.07E-06	3.13E-06	3.61E-06		Acquisitio	(0008|002	20170718				
23	2.75	0.577475		2.75	0.587852		0.429688	7.90E-06	4.02E-06	3.44E-06		Modality	(0008|006	MG				
24	3	0.539822		3	0.538297		0.46875	2.59E-06	1.01E-06	3.36E-06		Presentat	(0008|006	FOR PROCESSING				
25	3.25	0.507426		3.25	0.512554		0.507813	4.94E-06	2.73E-06	3.57E-06		Manufacti	(0008|007	GE MEDICAL SYSTEMS				
26	3.5	0.4759		3.5	0.474861		0.546875	4.91E-06	2.35E-06	3.26E-06		FieldOfVi	(0018|114	306				
27	3.75	0.431712		3.75	0.431522		0.585938	4.12E-06	3.84E-06	3.58E-06		Exposure1	(0018|115	1200				
28	4	0.406621		4	0.401481		0.625	4.42E-06	3.09E-06	3.55E-06		XRayTube	(0018|115	61				
29	4.25	0.367167		4.25	0.376002		0.664063	5.72E-06	2.81E-06	3.43E-06		ImagerPix	(0018|116	0.1				
30	4.5	0.331436		4.5	0.334694		0.703125	2.04E-06	3.89E-06	3.44E-06		AnodeTar	(0018|119	RHODIUM				
31	4.75	0.30907		4.75	0.298176		0.742188	2.93E-06	3.24E-06	3.14E-06		Manufacti	(0008|007	GE MEDICAL SYSTEMS				
32	5	0.274369		5	0.280221		0.78125	3.29E-06	3.67E-06	3.76E-06		KVP	(0018|006	30				
33	5.25	0.243242		5.25	0.231797		0.820313	3.33E-06	3.58E-06	3.22E-06		FilterMate	(0018|705	RHODIUM				
34	5.5	0.214692		5.5	0.206686		0.859375	1.56E-06	4.54E-06	3.03E-06								
35	5.75	0.179506		5.75	0.197769		0.898438	2.78E-06	3.35E-06	3.19E-06		Exposure	(0018|115	74				
36	6	0.165464		6	0.157523		0.9375	1.92E-06	3.12E-06	3.26E-06		ImageAnc	(0018|115					
37	6.25	0.13296		6.25	0.141691		0.976563	9.75E-06	4.29E-06	3.62E-06		EntranceC	(0040|830	8.058				
38	6.5	0.125085		6.5	0.1127		1.01563	4.48E-06	2.51E-06	3.46E-06		Exposurel	(0018|141					

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FIG. 9. The .csv file of the mammography phantom image presented in Fig. 8 opened as a spreadsheet containing all the important information and measurements.

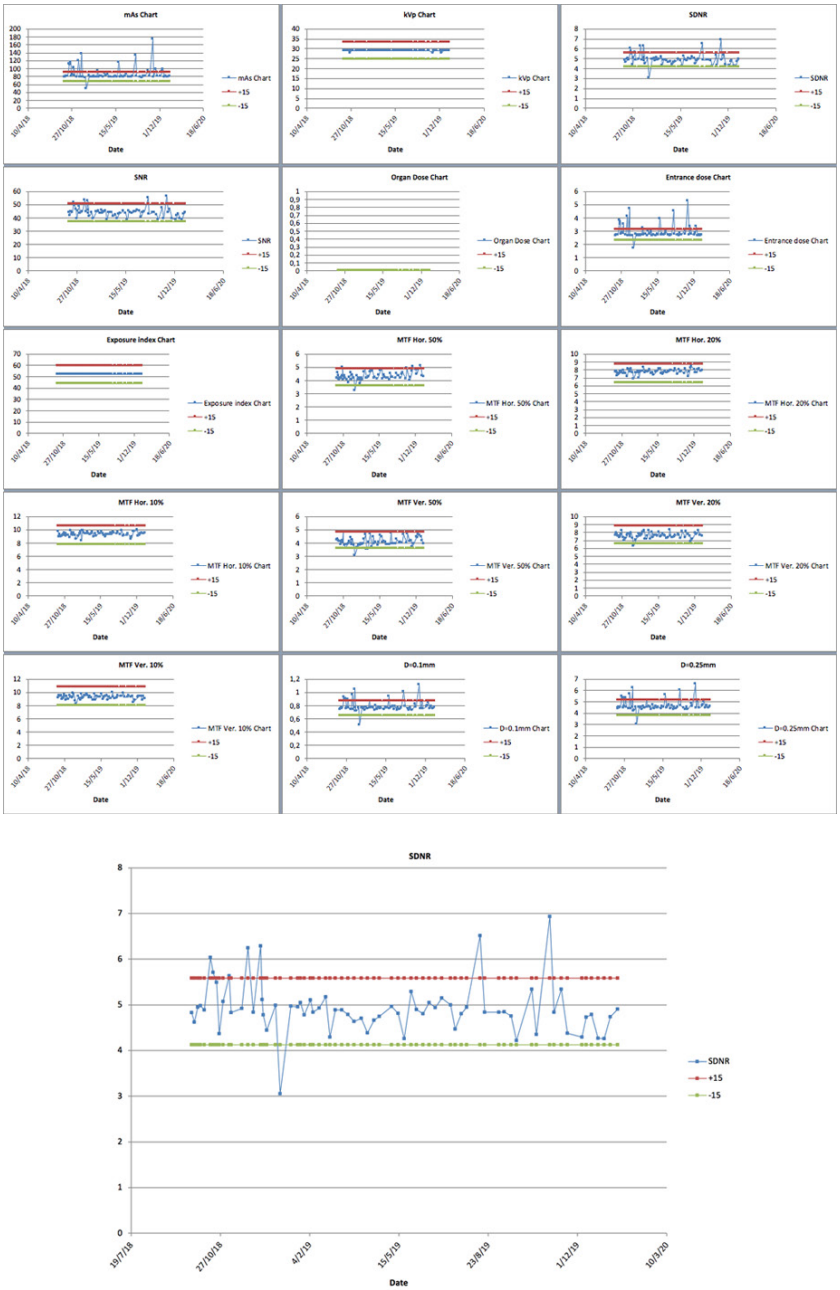


FIG. 10. Overview results page (top) and signal difference to noise ratio (SDNR) running chart (bottom), as created automatically by the Excel file.

Using the proposed methodology, the following measures of performance and consistency can be assessed for the system:

— AEC performance in terms of:
  - Applied kVp;
  - Applied mA·s setting;
  - Resulting mean pixel value;
  - Dose level;
  - Dose to the detector (exposure index).
— SNR.
— SDNR.
— MTF in both directions.
— Normalized noise power spectrum.
— *d'*.
— Image artefacts.
— Variance maps.

It is important to note that in CR systems (both radiographic and mammographic), there is no direct communication interface between the X ray generator and the CR processing station, and the generator parameters (kVp and mA·s) are not populated in the CR image DICOM header and are, therefore, not extractable by the ATIA.

The variance map can provide a valuable visual of the uniformity of the image. It is important to note that the variance analysis provides adjustable limits for the colour range relative to the background (Fig. 11). With a wider window, more subtle non-uniformities may not be visible. Too narrow a range might overemphasize non-uniformities that are not clinically important.

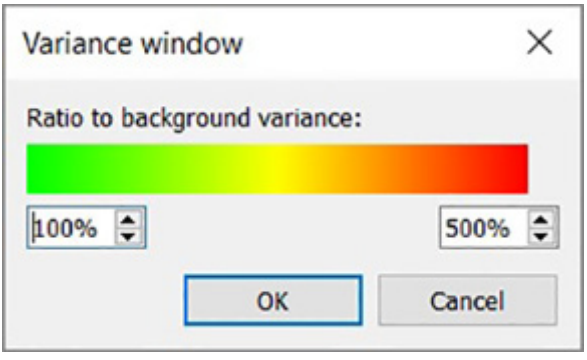


FIG. 11. Variance analysis setting window showing minimum width.

I.3. OTHER TOOLS FOR IMAGE ANALYSIS (IMAGEJ)

The ATIA previously described has been specifically designed for the needs of the automated and remote QC as described in the context of these guidelines. However, in the current era of digital imaging there are a large number of both free and commercial software packages that can be used for QC and image analysis. One of the most popular freely available tools is ImageJ, which has been extensively used by the scientific community for the measurement and analysis of medical images. It can display, edit, analyse, process, save and print 8 bit, 16 bit and 32 bit images and can read many image formats (e.g. TIFF, GIF, JPEG, BMP, DICOM, FITS). It can calculate area and pixel value statistics of user defined selections. It can measure distances and angles and create density histograms and line profile plots. It also supports standard image processing functions such as contrast manipulation, sharpening, smoothing, edge detection and median filtering. Users can also create their own plug-ins specific to their needs.

Extensive documentation exists on the use of the software, which can be also used for the some of the measurements described in these guidelines. An example of the use of ImageJ for the measurement of grey level values in an image of the suggested mammographic phantom is demonstrated in Fig. 12, and calculation of MTF using COQ (an ImageJ plug-in) is shown in Fig. 13 [33].

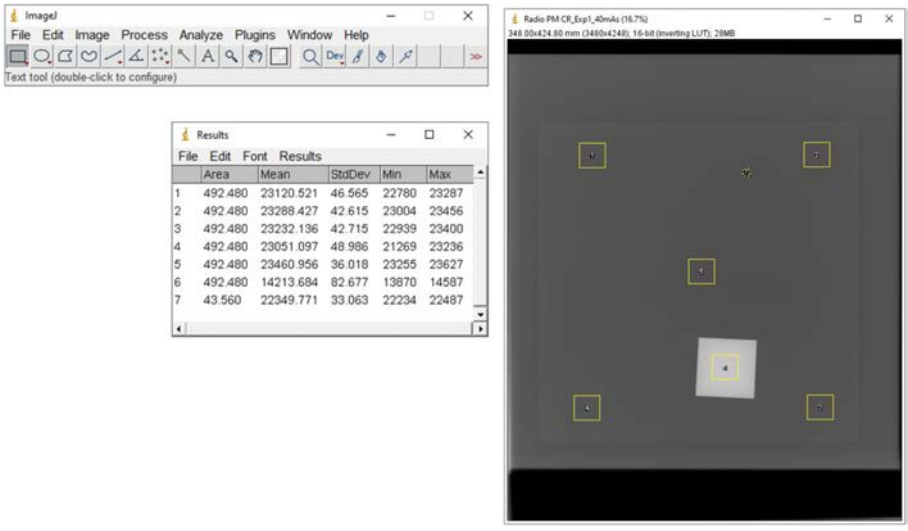


FIG. 12. Screenshot of grey level and noise measurements with ImageJ and corresponding results for region of interest (ROI) measurements.

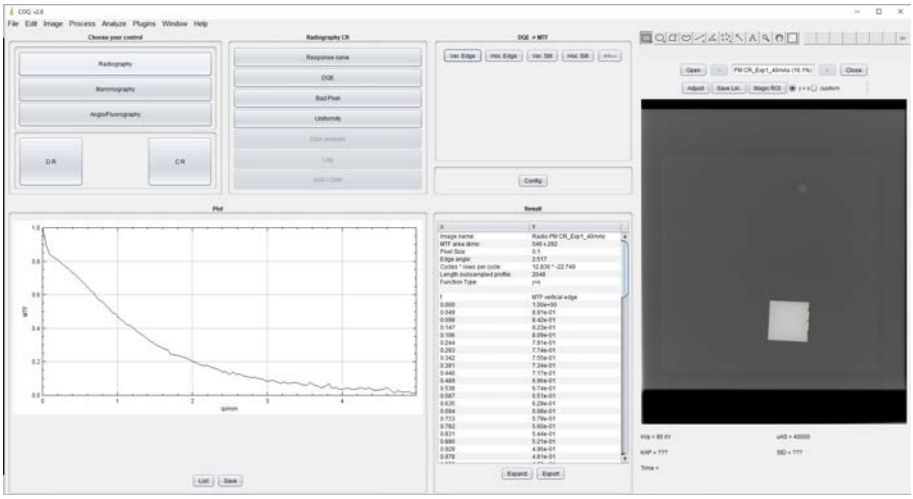


FIG. 13. Screenshot of the modulation transfer function (MTF) measurement with COQ (ImageJ plug-in) and corresponding results from COQ [33].

Appendix II

PHANTOM SPECIFICATIONS

The phantoms proposed for QC are very simple and relatively inexpensive, as they use materials which can be purchased and manufactured locally.

II.1. RADIOGRAPHY

The subsections that follow provide instructions to create a radiographic phantom.

II.1.1. Materials required

The following materials are required to create the attenuator plate and target plate for a radiographic phantom:

— Attenuator plate of 2 mm thick copper (10 cm × 10 cm);
— Target plate consisting of a carrier and inserts:
  - 5 mm thick PMMA (28 cm × 28 cm);
  - 4 mm thick aluminium (1 cm × 1 cm);
  - 2 mm thick copper (5 cm × 5 cm).

II.1.2. Geometry

The geometry of the phantom is presented in Fig. 14. For the convenience of end users, a printable blueprint is also provided in PDF format via the IAEA Human Health Campus[3] (Radiography_Blueprint.pdf).

II.1.3. Tips for manufacturing the phantom

The following tips may be helpful in manufacturing the phantom:

— The phantom blueprint (Radiography_Blueprint.pdf) needs to be printed at actual size on A3 size paper (without scaling). The scale of printing can be verified in the printout before use, with the help of the corresponding

[3] The IAEA Human Health Campus can be found at https://humanhealth.iaea.org.

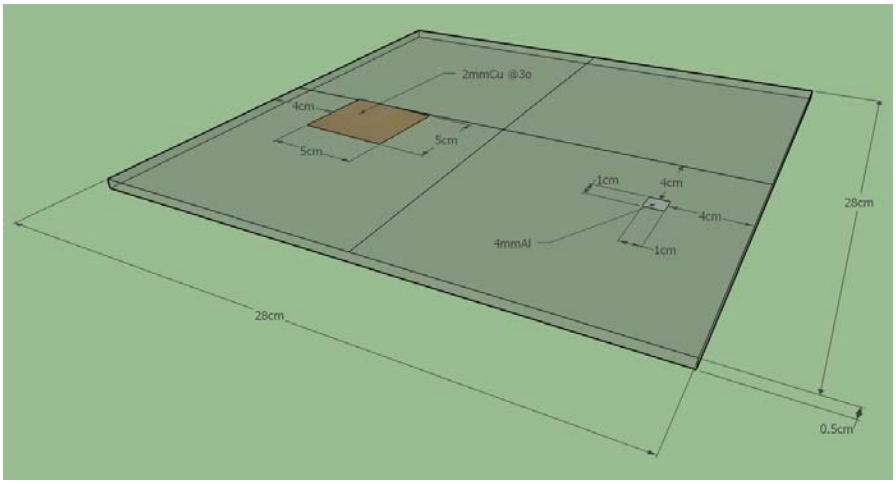


FIG. 14. Dimensions of the target plate for a radiography phantom. An additional attenuator of 2 mm Cu is required for proper use.

graphic scale line. The printout can be placed above or below the 5 mm PMMA plate and serve as a guide for the correct placement of the copper and aluminium inserts in terms of proper size, positioning and angulation.

— It is important that the lines indicating the two axes and the centre of the phantom (as shown in the blueprint) be marked (for example, with a permanent marker) on the target plate, as this is essential for the reproducible positioning of the phantom with the light field.
— Unlike in the case of commissioning and acceptance testing, the purity of the inserts (aluminium, copper) is not of primary importance.
— It is necessary to verify (under radiographic imaging prior to assembly of the phantom) that all elements have the necessary uniformity to ensure proper imaging.
— Care is required to create sharp edges on the copper plate insert to allow proper evaluation of the MTF. The International Electrotechnical Commission standard is that the image of the edge shall show no ripples larger than 5 μm, although it has been found that the ATIA can tolerate a slightly rougher edge.
— The vertical edge of the MTF insert needs to be positioned at an angle of 2–5° and close to the central axis of the phantom.
— Inserts need to be glued carefully on the 5 mm PMMA plate, preferably using instant adhesive glues or superglues.
— The 2 mm copper plates have to be free of scratches and bends.

II.2. MAMMOGRAPHY

The subsections that follow provide instructions to create a mammography phantom.

II.2.1. Materials required

The following materials are required to create the attenuator plate and target plate for a mammography phantom:

— Attenuator plate of 4 cm thick PMMA (24 cm × 30 cm);
— Target plate consisting of a carrier and inserts:
  - 5 mm thick PMMA (24 cm × 30 cm);
  - 0.2 mm thick aluminium (1 cm × 1 cm);
  - 1 mm thick copper (5 cm × 5 cm).

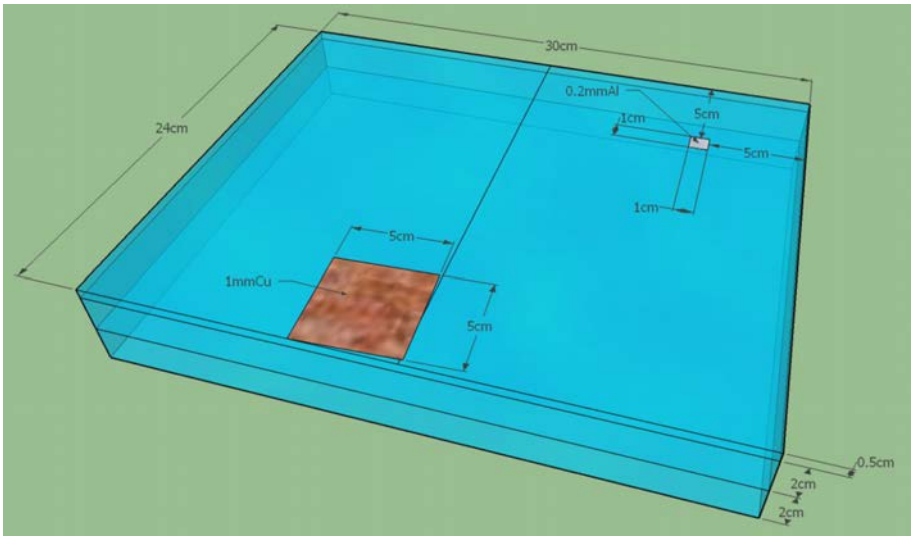


FIG. 15. Dimensions of the mammography phantom and attenuator.

II.2.2. Geometry

The geometry of the phantom is presented in Fig. 15. For the convenience of end users, a printable blueprint is also provided in PDF format via the IAEA Human Health Campus[4] (Mammography_Blueprint.pdf).

II.2.3. Tips for manufacturing the phantom

The following tips may be helpful in manufacturing the phantom:

— The phantom blueprint (Mammography_Blueprint.pdf) needs to be printed at full scale on A3 size paper (without scaling). The scale of printing can be verified in the printout before use, with the help of the corresponding graphic scale line. The printout can be placed above or below the 5 mm PMMA plate and serve as a guide for the correct placement of the copper and aluminium inserts in terms of proper size, positioning and angulation.
— It is important that the line indicating the central axis of the phantom (as shown in the blueprint) be marked (for example, with a permanent marker) on the target plate, as this is essential for the reproducible positioning of the phantom with the light field.
— Unlike in the case of commissioning and acceptance testing, the purity of the inserts (aluminium, copper) is not of primary importance.
— It is necessary to verify (under mammographic imaging prior to assembly of the phantom) that all elements have the necessary uniformity to ensure proper imaging.
— Care is required to create sharp edges on the copper plate insert to allow proper evaluation of the MTF. This will preferably be done using a computer controlled digital manufacturing process such as laser cutting and not regular scissors. The International Electrotechnical Commission standard is that the image of the edge shall show no ripples larger than 5 μm, although it has been found that the ATIA can tolerate a slightly rougher edge.
— The vertical edge of the MTF insert needs to be positioned at an angle of 2–5° and close to the central axis of the phantom.
— Inserts need to be glued carefully on the 5 mm PMMA plate, preferably using instant adhesive glues or superglues.
— The 4 cm PMMA plate has to be free of scratches and nicks.

[4] The IAEA Human Health Campus can be found at https://humanhealth.iaea.org.

Appendix III

BASIC STATISTICAL TOOLS

As already mentioned in this publication, QC tests do not necessarily need to be complicated or time consuming. Certainly, a minimum level of competence is required to perform the tests, and this increases with the complexity of such tests, but even simple and quick tests can reveal problems with the equipment and can thus be used to monitor system performance.

Simple measurements performed occasionally and sporadically can only rarely reveal issues with the equipment. On the other hand, a series of consistent, periodic measurements which are properly documented and tracked can yield useful conclusions. The management and documentation of simple performance testing requires knowledge of basic statistical tools, which are addressed in this Appendix.

III.1. BASIC STATISTICS

Although a single number is often used to express the value of a given physical quantity (e.g. it takes 32 s to read this paragraph), such measurements are not exactly true. It is due to the nature of the measurement that the exact value of any physical quantity can never be known; it can only be approximated with increasing accuracy depending on the measuring process. Typically, if a reproducible procedure is used to repeat the same measurement, the result will not be the same every time. Thus, if several measurements were made of the time it takes to read this paragraph, the results would likely vary, owing to the inexact nature of such measurements. For the majority of the physical quantities and parameters of interest in this publication, one can consider that they follow a normal, or Gaussian, probability distribution, indicating that the chance of getting a certain result follows a bell shaped distribution function.

III.1.1. Average

When considering a set of measurements for a given quantity, and assuming that no significant, systematic cause of error exists, the best approximation to the actual value of the quantity is the average of all measurements. Although there are some more statistics behind the concept of the average, the basic idea is that if only minor random variations exist, these will result in differences in the individual measurement results. Therefore, an increased number of repeated

measurements would nearly eliminate their effect. Obviously, the larger the number of repeated measurements, the better the approximation to the actual (but still unknown) value will be.

III.1.2. Standard deviation

The standard deviation is used as a guide to the spread of measurements; it is a measure of the variability, expressed in the same units as the data. It is defined as the square root of the variance, which in turn is a measure of the deviations of individual measurements from the mean. In other words, the standard deviation in a normal Gaussian distribution demonstrates the confidence that all the results of the measurements are included within a range.

III.2. CONTROL CHARTS

Although medical equipment is designed to operate with a high degree of stability, as discussed above, any measurement of a parameter associated with the performance of the equipment will have a certain amount of variation. Furthermore, the equipment itself will not provide an identical performance each time it generates an image. This contributes to what is referred to as background noise.

Control charts (see Fig. 16) are one of the seven basic tools of statistical process control. These graphs were first introduced by W.A. Shewhart (for this reason they are sometimes called Shewhart charts) [34], and they can help to identify whether a process, in our case any of the imaging processes tested, is performing as expected and under control or if a thorough examination is required to identify possible problems related to quality. It is important to note that the use of control charts is not sufficient to reveal the cause of a process or parameter not being under control; they merely reveal that there is a problem with the consistency of the process. It is also important to note that the charts do not indicate that a system is functioning optimally, only whether it is functioning consistently. When an indication exists that the process is outside statistical control, a more thorough investigation is required on-site by a CQMP to investigate possible causes.

A typical control chart is a graph of the quantity being monitored over time, with the horizontal axis indicating the time and date of the measurement. The measurements, represented by individual points on the graph, are usually connected with a line for easier visualization of trends. The central line represents the average, target or baseline value of the monitored quantity. These baselines are defined during the comprehensive testing done by the CQMP (e.g. during

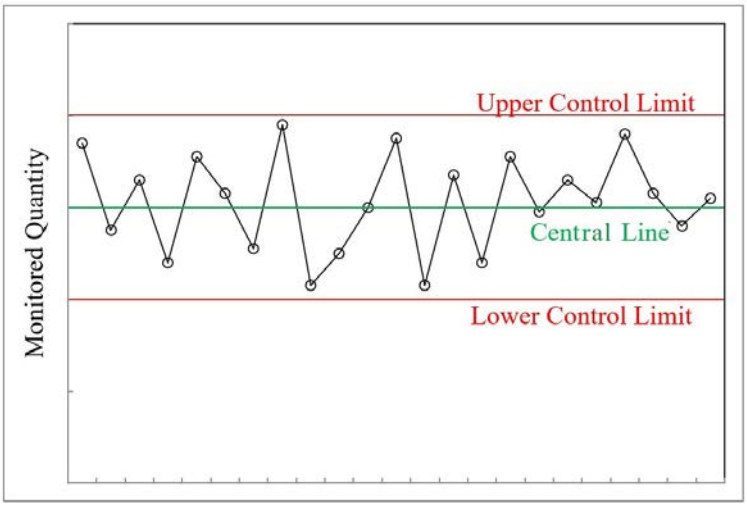


FIG. 16. Sample control chart.

commissioning). Two control limits are also set: the upper control limit and the lower control limit, as shown in Fig. 16. As long as the monitored quantity falls between these limits, the process is considered to be under control and performing satisfactorily. A measurement outside these limits indicates that the process might be out of control and corresponding investigation and corrective actions may be required. However, there are cases when even with all the measured data falling within the control limits, the process might require investigation; this is the purpose of trend analysis, which is discussed later.

When control charts are used, it is important that they be trustworthy. This means that when the system is operating within the defined limits, no underlying problems are expected and full confidence in the clinical use of the system is assumed; on the other hand, when the limits are exceeded, there is an underlying cause that needs to be addressed. The efficacy of this chart largely depends on the proper definition of the central line, the upper control limit and the lower control limit. For example, a narrow range of limiting values (representing perhaps an unrealistic expectation of the capabilities of the system) would cause false positive alarms, indicating a measured value outside statistical control even though the process is actually functioning properly. Conversely, a wide control range (unrealistically neglecting the importance of the parameter being monitored) can cause false negative events, hiding problems.

For these reasons, correct establishment of the baseline value and its control limits is crucial for the proper use of the control charts and needs to be performed carefully by the CQMP in charge of the QC programme. There are

several ways to establish the control limits of a control chart. The main ones are based on: (a) the confidence intervals required and the standard deviation, or (b) the regulatory or manufacturer's requirements.

A typical value used for the control limits is two standard deviations from the average value. Although this is a good approach, it needs to be noted that setting control limits at two standard deviations will result in 95% of the results of a normal distribution falling within this range, resulting in 5% of the results falling outside the control limits owing only to statistical fluctuation, without there being an underlying cause.

In some situations, it may be considered appropriate to establish two different sets of control limits: A set of outer limits (for example at three standard deviations from the central line) could be established as the 'action limits' outside of which a measurement will initiate a proper detailed investigation and corrective actions, as necessary. A second set of inner limits (for example at two standard deviations from the central line) could be established as the 'warning limits', that will initiate increased awareness of that parameter and its impact on the performance of the system.

There are additional rules that apply when using control charts, even in cases where all measurements fall within the control limits, as there may be certain indications that may trigger further investigation (sensitizing rules) [34], such as the following:

— Several points (e.g. six points) steadily increasing or decreasing;
— Several consecutive points (e.g. more than eight) falling on one side of the central line;
— Unusual or non-random patterns in the chart.

Appendix IV

PROCESS CONTROL FAILURES AND ARTEFACTS

IV.1. PROCESS CONTROL FAILURES

The framework presented in this publication evaluates the complete imaging chain: end point measures like SDNR and d' include all the properties and components of the system. The supervising CQMP receives and evaluates the data through trend analysis and inspection of images as needed. Periodic monitoring of these data has the potential to detect image quality and dose deficiencies and facilitate their remediation. This is extremely important as problems can develop gradually or occur suddenly.

While all components can deviate from their initial performance, in digital radiology, the AEC, the KAP meter, the automatic collimator system (positive beam limitation) and the detector have been found to be most vulnerable to changes over time. In addition, dust or dirt can be present everywhere and negatively impact the quality of the image. Software upgrades can also (unexpectedly) influence dose and quality settings.

The DICOM header tags and all other parameters calculated from the image (mean pixel value, SDNR, MTF and d') result from the integrated use of tube, filter, collimator, AEC and detector. Deviations in exposure or imaging performance in general need to be closely monitored to ensure that image quality or patient dose do not start changing significantly.

Not all deviating parameters point to serious issues, but it is very important to carefully check all of them, find the component causing the problem and initiate corrective action as required. Correction may require expert knowledge to trace the exact cause of a deviation. Ultimately, when severe deviations happen, it is possible that major components of the system will need to be serviced or replaced.

The cycle of process control can be summarized as follows:

(i) Perform periodic data acquisition and analysis;
(ii) Note relevant alerts;
(iii) Determine cause of alert;
(iv) Formulate remedial action;
(v) Return to (i).

IV.1.1. Background

Deviations in exposure related DICOM tags, as well as in the calculated mean pixel values, SNR, SDNR and *d′*, may relate to problems with different components of the imaging chain: X ray tube and generator, automatic collimator (if used), AEC and how it is programmed, KAP meter, filter, grid and detector. The analysis of a problem must consider all potential factors. The phantom has been conceived to test as many factors as possible. By dissecting the data, one may be able to determine likely causes of a deficiency, or at least be able to rule out problems with certain components of the imaging chain. The following non-comprehensive list describes some common scenarios:

— Observed changes in mean pixel value, SNR and *d′*: If the indicated kVp and mA·s are stable and the KAP value is also stable, then it can be concluded that the tube, filter, collimator and AEC are performing in a stable manner. Therefore, the cause is almost certainly with the detector.
— The kVp is consistent and stable, possibly confirmed by a contrast measure, but all other parameters (mA·s, KAP, mean pixel value, SNR, SDNR and *d′*) have suddenly changed: The system seems to be operating at a different working point; possibly a tube or detector replacement has taken place or the AEC has been reprogrammed or recalibrated (during service).
— A gradual mA·s increase is observed over time while the kVp, mean pixel value, SNR and SDNR appear stable: This may indicate that the tube is deteriorating. If the KAP value, evaluated as a function of time, changes with mA·s, there may be a sensitivity problem in the detector.

IV.1.2. Case studies of process control failures

The following examples describe actual problems that were revealed through an established regular QC programme. Although they have not been generated with the ATIA, the results are typical of what the ATIA would provide in similar cases.

IV.1.2.1. Case study 1 (impact of a new detector)

This example (Fig. 17) demonstrates the possible impact of a new detector on the tube load (mA·s) being applied, and its consequences on mean pixel value and standard deviation. The DICOM tag 0018,700 A contains the detector ID. It is important to track this DICOM tag: while the local personnel will certainly know about detector replacement, the CQMP in charge of remote supervision may not be aware of this.

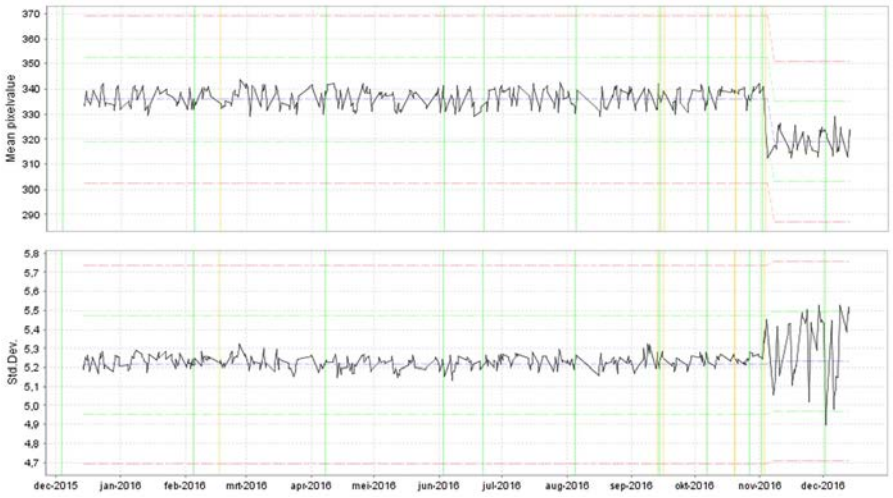


FIG. 17. Run charts of mean pixel value and standard deviation indicating an incident that needs to be further investigated (courtesy of J. Binst, UZ Leuven).

Such a performance change raises further questions: Is the sensitivity of the new detector greater, allowing lower mA·s to be used, or do the exposure settings need to be increased to the original level? Is the increased fluctuation in the noise acceptable, or is it an indication of a further problem? In this case, the annual test of the system has been replanned to an earlier time point. Subsequent to the testing, the AEC was adjusted to increase the mA·s back to the original level, restoring the original image quality.

IV.1.2.2. Case study 2 (intervention effects)

This example (Fig. 18) shows that it is important to monitor a system after any major intervention. In this case, the tube load (mA·s) changes as a function of time. Other parameters are behaving as expected, with higher mA·s leading to lower standard deviations, and so on. The intrinsic performance of the system is not changed. In Fig. 18, the three red arrows point to routine service being performed on the system. The longer blue arrow refers to the date when service engineers were asked to reset the dose settings to the original value. Finally, the green lines indicate the time of intervention by the service engineers.

Service engineers can modify the settings of a system without appropriate notification to the facility. Dose levels set to the requirements of the local team may be deleted with software upgrades or when the settings behind specific programmes have changed or been set back to default.

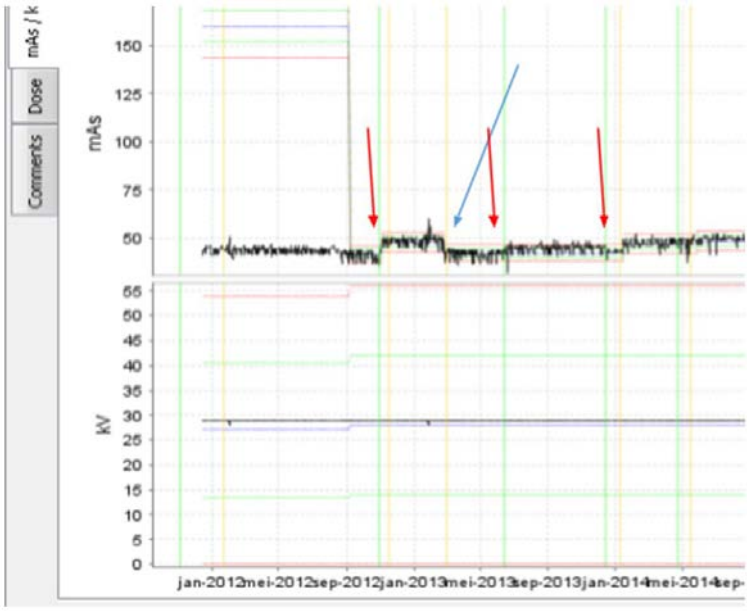


FIG. 18. Run charts of the mA·s used for standard phantom exposure, indicating several changes in the system performance (courtesy of J. Binst, UZ Leuven).

This case study, among others, indicates that the interventions of service engineers can impact the control charts. It is essential to perform any QC procedure very carefully after each intervention.

IV.1.2.3. Case study 3 (gradual degradation)

Figure 19 presents an example of a gradual degradation of the X ray tube over time, demonstrated with a daily QC procedure. It was observed that the mA·s gradually increased while the mean pixel value remained constant.

The mean pixel value is the result of different steps performed by the detector, from capturing the X rays to their conversion into a signal. The pixel value defines the performance level of a certain system. The AEC ensures the proper amount of radiation to provide constant pixel values. In this case, the AEC is correctly compensating for decreasing tube output, as the mean pixel value is constant. Such variations in tube output are rarely observed with feedback controlled systems in modern use.

This case shows that it is important to track many different factors to be able to differentiate between tube and detector problems. Any error in the interpretation

of these data could have financial consequences. This also demonstrates the need for organized and complete trend analysis over a longer time period.

IV.1.3. Guidance for process control failures

In situations where there is a clear deviation in the data, the first thing to exclude is human error both in the measurement and in the processing of the data. If the problem is sudden, the first step is to repeat phantom image acquisition and data analysis. Local personnel may need additional training and guidance to ensure that QC is performed correctly. It is extremely important that the same imaging conditions be used consistently.

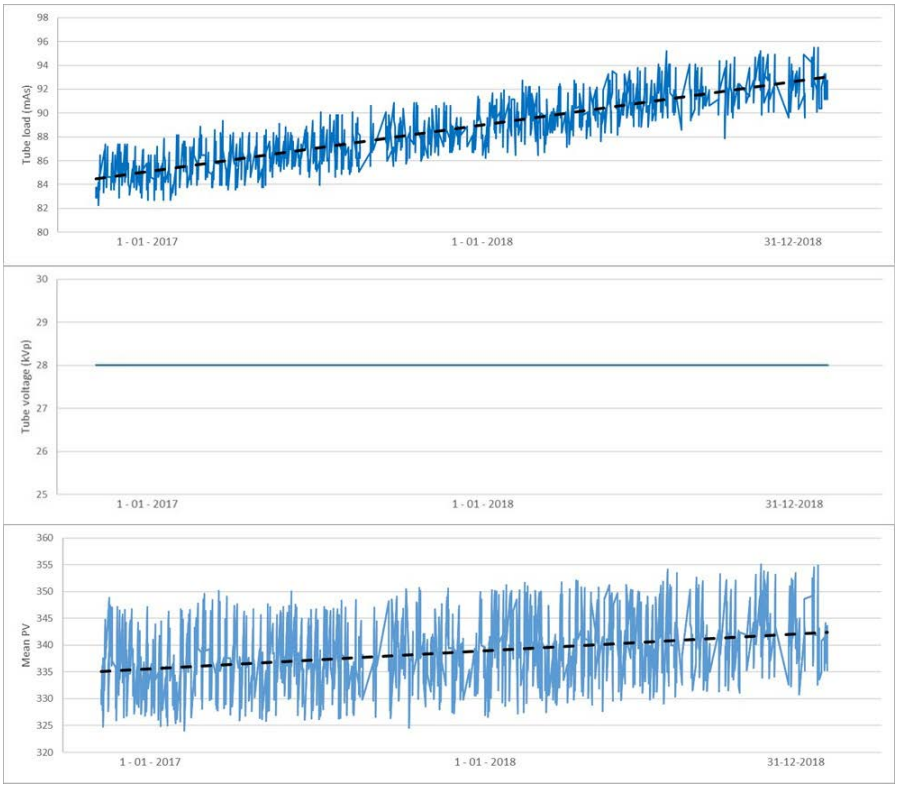


FIG. 19. Run charts of the tube load in mA·s (top), tube voltage in kVp (middle) and mean pixel value (bottom) of a system, indicating a gradual degradation of the system performance. The automatic exposure control compensates for a gradual degradation of either tube or detector by increasing the tube load. The tube load increase is larger than the mean pixel value increase (courtesy of J. Binst, UZ Leuven).

In situations where there is a sudden change in the values of a measurement, the obvious step is to verify whether any service or replacement of the system's components has taken place. Software upgrades or maintenance of the system may result in different settings with imaging suddenly taking place at a different performance level.

Gradual changes over time are generally identified through trend analysis.

Most components of modern imaging equipment are very stable. Generators are self-monitoring and self-regulating; errors in kVp, mA and exposure time are rarely observed in modern equipment. Focal spots fail catastrophically rather than slowly changing over time. Of all system components, the AEC is probably most prone to deterioration. Older systems, however, might demonstrate issues with these factors, so close attention needs to be given to them.

IV.2. IMAGE ARTEFACTS

The subsections that follow describe several types of image artefacts that might be observed.

IV.2.1. Background

Both screen–film and digital systems are sensitive to artefacts, although the appearance of these artefacts and their causes are distinctly different. While nominally specific to mammography, Ref. [35] is a valuable resource regarding artefacts in both mammography and radiography, as many of the causes and appearances are similar.

For screen–film and CR imaging, dust and dirt on the screens are frequent causes of artefacts. Screen cleaners and bad cleaning practices can also lead to significant artefacts. Blotchiness due to thickness variations in the filter, or dirt or corrosion on the filter are also common in screen–film and CR imaging, especially in mammography. Grid non-uniformities can cause blotchiness or generalized non-uniformity in the image. A malfunctioning bucky can cause an unacceptable structured background of grid lines in any system.

Artefacts specific to DR imaging, both in radiographic and mammographic systems, include signal non-uniformities due to a bad flat field calibration file, stitching artefacts, electronic clipping, noise, bad pixels appearing as either white or black specks, and lines of dropped pixels. Examples of some of these artefacts are given in the case studies that follow. Ghost images may arise from previous exposures that have not been fully erased. Detectors that are sensitive to ghost artefacts may from time to time show a shadow of a structure (for example, a

breast) on top of the homogeneous image. Changes in the sensitivity of one of the detector materials may show up as a permanent artefact.

IV.2.2. Case studies of image artefacts

The following case studies describe actual instances of image artefacts observed during an established regular QC programme in a DR system.

IV.2.2.1. Case study 4 (digital radiography system: dust or debris)

This case examines the impact of dust or debris on the system or phantom and its effect on the homogeneity of a DR image. Like a dead pixel, a dust particle creates a local drop in signal. While a dead pixel is less sensitive to radiation, a dust particle deprives the detector of a part of the radiation. The effects of dust and dead pixels on the pixel values are generally very small, however the variance map reveals the artefact. In the case of dust, successive QC acquisitions show the artefact in slightly different positions, making the hypothesis of a dead pixel improbable.

The remedial actions consist in eliminating the dust particle. As dust can be present in many parts of the imaging chain, eliminating it can be a cumbersome task, often requiring the help of a service engineer if the accessible parts such as outer tube housing, compression paddle (in case of mammography), phantom and bucky seem to be dust free.

Differentiating between dust and dead pixels is facilitated if a second QC acquisition is performed with a different phantom position, as the latter is the most likely source of dust. The added value of a second QC acquisition with a phantom rotated over 180° is shown in Fig. 20: Different orientations of the ‘dust phantom’ result in a shift in the location of the artefact on the image.

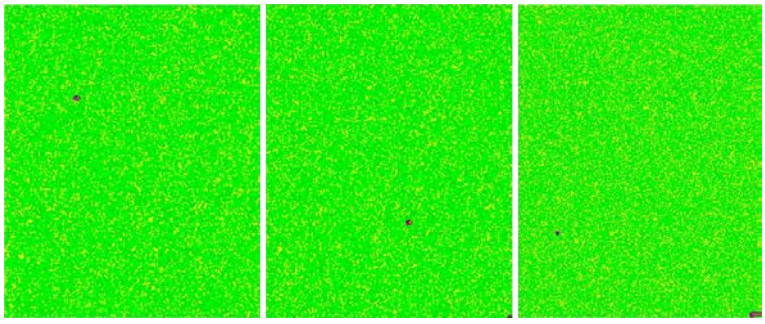


FIG. 20. Example of the appearance of dust in the bucky tray on three consecutive images of a uniformity phantom. Note that the artefact rotates together with the phantom.

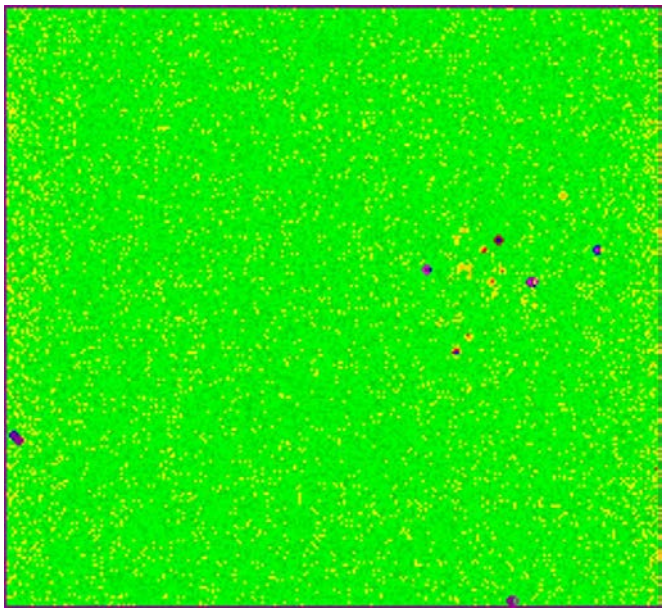


FIG. 21. Example of an image with dust or debris particles, as they appear in the variance image.

IV.2.2.2. Case study 5 (digital radiography system: accumulated dust)

A common example of accumulated dust in the DR detector is shown in this case. Unlike the case presented earlier where the dust was on the phantom, in this case the artefact on the variance map (Fig. 21) did not change orientation together with the phantom. In slot scan systems, dust usually shows up as lines in the image.

IV.2.2.3. Case study 6 (digital radiography system: calibration)

Examples of incorrect application of detector calibration are presented in this case study. Detector calibration is a frequent procedure that is most often done by the local personnel adhering to the instructions of the manufacturer, or by service engineers. Occasionally the procedure can go wrong. Examples of detector calibration problems include (i) the acquisition of the flat field images too quickly after a patient exposure, such that the remaining signal, the so-called lag, is being engraved into the flat field map and from there applied to all successive cases (Fig. 22 (top left)); (ii) debris on the calibration test block that enters in the same way as (i) into the calibration file (Fig. 22 (top middle and right)); or (iii) an incorrect procedure applied.

It can be difficult to differentiate between a problem due to lag and a long lasting effect from a long series of acquisitions that result in changes to the detector's sensitivity (or ghost effect). The ghost effect on the pixel value can be overcome by means of flat fielding. Lag, on the other hand, can be corrected with a new calibration procedure. The lag problem of a particular system is illustrated in two clinical cases shown in Fig. 22 (bottom).

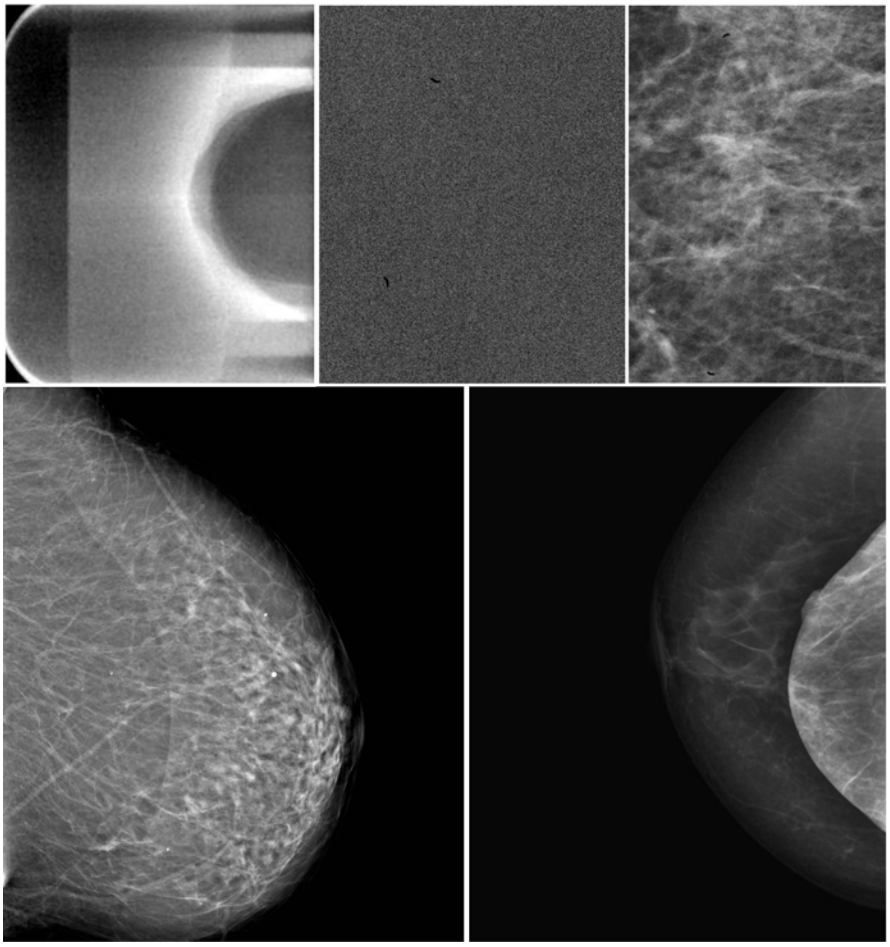


FIG. 22. Examples of artefacts attributed to incorrect detector calibration, as they appear in phantom (top) and clinical (bottom) images (courtesy of J. Jacobs, UZ Leuven).

IV.2.2.4. Case study 7 (digital radiography system: dead pixels or clusters of dead pixels)

This case demonstrates the example of a dead pixel or a cluster of dead pixels. A localized pixel value that deviates from its neighbours and is always in exactly the same location of the detector is commonly caused by a dead pixel detector element. A dead pixel can show up as signal void (Fig. 23 (top)), or have a more complicated appearance, like the bull's eye example shown in Fig. 23 (bottom).

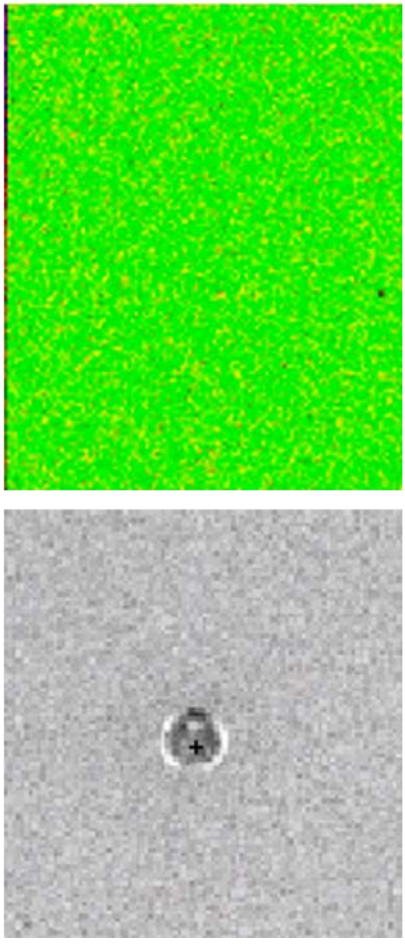


FIG. 23. Examples of dead pixels on a digital detector. Dead pixels can show up as a signal void (top) or in the shape of a bull's eye (bottom).

Differentiation between a dead pixel and simple debris is possible from a series of successive QC test images (see also case study 4). Localized deviating pixel values that are in similar positions during successive acquisitions may be due to dust in one of the several parts of the imaging chain, including the detector housing, even if that is sealed. Dead pixels have a fixed position and may show up as white dots (or whiter than normal dots) in the image. It must be acknowledged that 'near dead' pixels have been observed that switch from normal to dead signals from time to time. Dead pixels can mimic microcalcifications and can therefore impact diagnostic performance. However, as a single microcalcification will not lead to the diagnosis of a malignant cluster and subsequent referral for biopsy, and as several solutions for dead pixel masking are available, the detection of a single dead pixel does not automatically lead to a recommendation to replace a detector. Rather, either the local personnel or the service engineer could be asked to perform a dead pixel masking procedure. It is advisable to make sure that not too many dead pixels are clustered together (Fig. 23). The CQMP could verify the impact of successive dead pixel masking on the bad pixel map that might be available on the system, which is sometimes only retrievable with the help of the service engineer. If dead pixels or dust are a frequent problem in the facility, it is advisable to try to organize more frequent testing (daily rather than weekly).

IV.2.2.5. Case study 8 (digital radiography system: dead columns)

This case study relates an example of dead columns — wherein a whole column of pixels is dead, as shown in Fig. 24 (left). While a single dead column is not necessarily problematic (after masking), clustered dead columns, such as those shown in Fig. 24 (right), may be unacceptable.

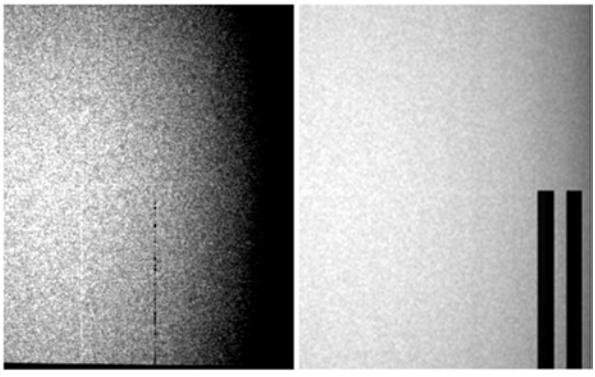


FIG. 24. Example of the appearance of dead columns in digital detectors, single (left) and multiple (right) (courtesy of K. Lemmens, Leuven).

Dead columns will not lead to an incorrect diagnosis, and after masking, they may not even be detectable in the clinical images. However, when not corrected, these lines may show up as artefacts. They are very visible in a homogeneity map or thumbnail image: they are precisely straight and in the same place on successive days. As in the case with the dead pixels, the dead pixel map needs to be inspected to see whether dead lines cluster. In most detectors, dead columns span only half of the detector. This is related to the stitching of detector elements.

IV.2.2.6. Case study 9 (digital radiography system: grid problems)

Examples of grid problems detected in QC procedures are presented in this case study. Horizontal lines or moiré patterns in larger parts of the image may point to problems with the antiscatter grid. Gridline removal is essential and artefacts due to incomplete removal have to be corrected. This applies to moving as well as static grids. Figures 25 and 26 present an example of a grid artefact, visualized in several types of thumbnail images. Figure 25 presents the thumbnail images (values and deviation) of mean pixel values (top row), the SNR (centre row) and the variance (bottom row), quantities that can also be derived by the ATIA application. Figure 26 shows another grid problem: the grid is not aligned with the chest wall position. After being serviced, this problem was overcome.

Grid pattern artefacts can be very subtle. They can, depending on the conditions, affect the quality locally or over the complete image. If moiré patterns are observed in thumbnail images, the original (full size) image has to be inspected. It may also be helpful to inspect noise power images, ideally from conditions with and without the artefact. Noise power spectra are also generated in the ATIA application. Image acquisitions obtained with different exposure times and PMMA attenuator thicknesses may show under which conditions grid problems are apparent and which routine clinical images might thus be affected too. Gridline problems need to be discussed with the service engineer. It is important to have the use of the grid included in the test set-up if the grid is used clinically.

IV.2.2.7. Case study 10 (digital radiography system: pinholes)

The effects of subtle pinholes in the filter of the X ray tube are demonstrated in this case study. As already mentioned, dust or debris on the filter may show up as large artefacts in the image, owing to magnification. For the same reason, extremely small holes can produce a coherent pattern, similar to the output of a pinhole camera for focal spot measurements (Fig. 27).

The pinholes in the filter generate actual images of the focal spot at several points on the detector. A filter specific flat field calibration file could overcome the effect, but in practice there was no such filter specific file. The effect on clinical images was very limited.

For a long time, this artefact had not been noticed, as the pinholes were present in a filter that was only used for extremely large breasts. This filter was not used in the daily QC test procedure. The presence of this artefact indicates that all filters need to be included in the QC tests.

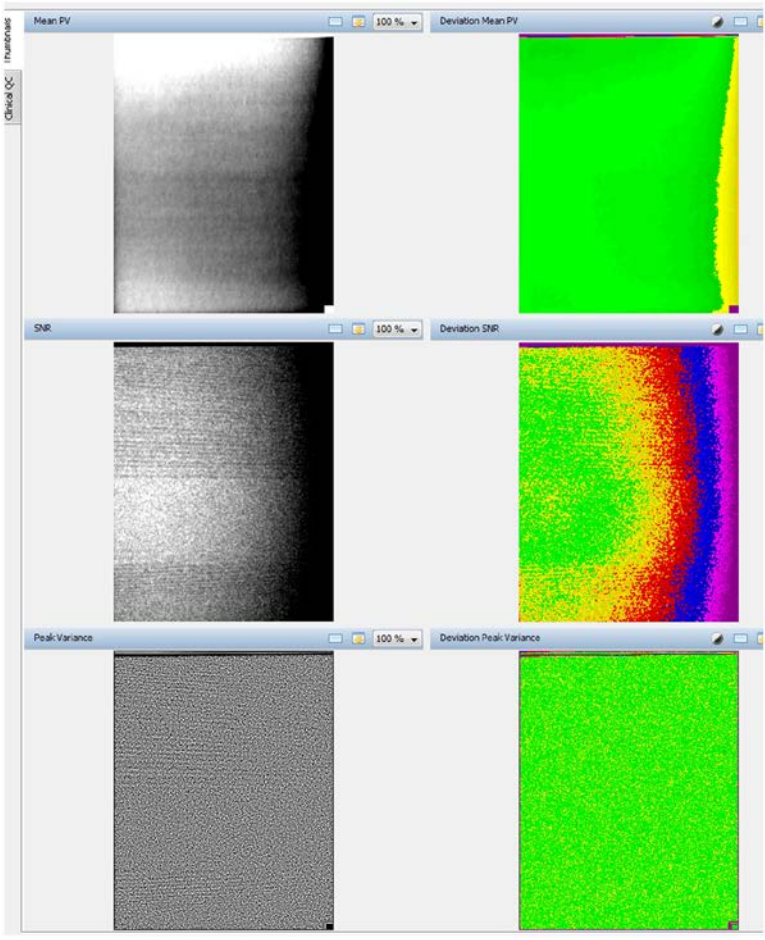


FIG. 25. These images demonstrate the effect of grid problems on mean pixel values (top row), the signal to noise ratio (SNR) (centre row) and the peak variance (bottom row).

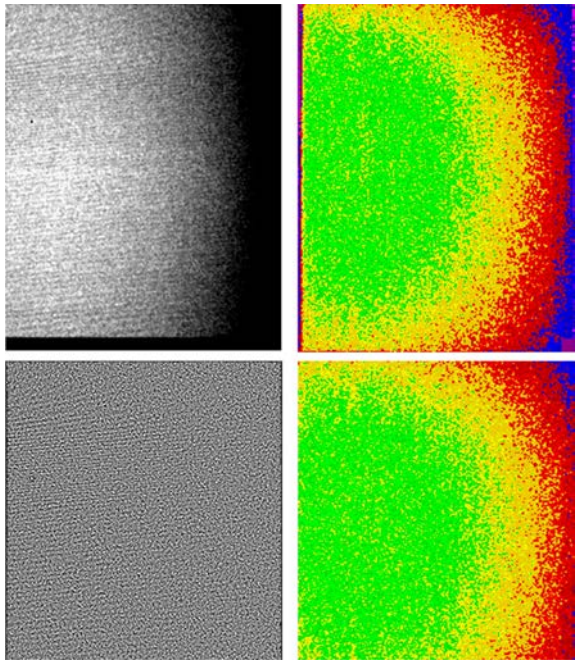


FIG. 26. Image demonstrating a grid misalignment, as shown in the image and in the variance map, before (top row) and after (bottom row) service (courtesy of K. Lemmens, Leuven).

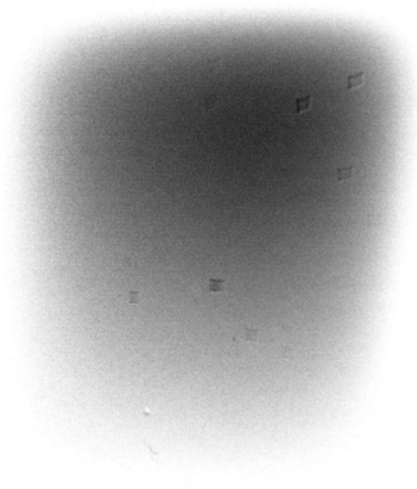


FIG. 27. The effect of small holes in the external filter (courtesy of N. Marshall, UZ Leuven).

IV.2.2.8. Case study 11 (computed radiography system: poorly maintained plate)

This case demonstrates local pixel value inhomogeneities. Classical flat field and dead pixel correcting pre-processing is not possible on the majority of the CR systems available in the market. This is due to the fact that the plates cannot be reproducibly positioned in the reader system within the accuracy of one pixel. As a consequence, CR images may be hampered by more inhomogeneities than normal DR systems. In addition to inhomogeneities in the phosphor layers (having a direct impact on the sensitivity of the detector), artefacts can also be due to dust on the plates or on the various optical components of the plate reader (Fig. 28). It has to be noted that newer CR systems which use needle structured phosphors already include some flat fielding corrections.

The relevance of these artefacts has to be evident and proven crucial from clinical images before any major remedial action is taken. When detecting many CR artefacts, the first step is always to clean the cassette and instruct the personnel on the proper cleaning procedure and the products to use. The phosphor screens used are coated with a protective layer that must be treated very carefully. No abrasive or corrosive cleaners should be used; if cost effective and at all possible, only the manufacturer's recommended cleaning solution should be used. Careful in depth cleaning will allow the user to distinguish dust from inhomogeneities on the plate.

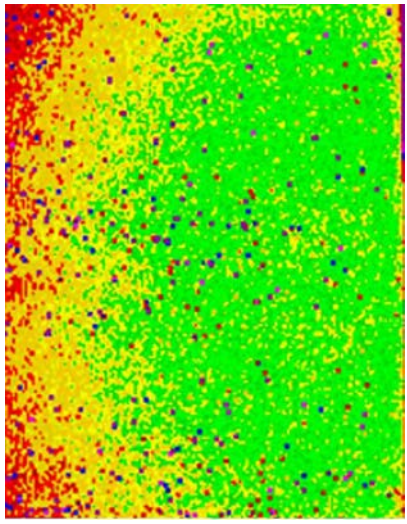


FIG. 28. A poorly maintained computed radiography plate created this variance map, as produced by the automated tool for image analysis (ATIA).

IV.2.2.9. Case study 12 (computed radiography system: dust versus scratches)

Examples of typical artefacts attributed to the CR technology are presented in this case study. Most artefacts in CR imaging are the consequence of dust in the reader and the various optical devices linked to this: a dust particle on one of the reader elements may result in signal void at the level of that reader element. With readers that scan over the plate, such a signal void will produce a straight line, a so-called scan line, over the image. Figure 29 shows examples of scan line artefacts due to a problem with a reading element in the CR plate reader (top) and resulting from a scratch on a CR plate (bottom). Scan line artefacts can be easily retrieved from the QC test. The artefact will also show up in clinical images, as CR systems will typically not compensate for this effect with calibration files (as would be the case in DR).

Differentiating between a scan line and a scratch is simple: a scratch will never be straight within a pixel over the complete column or row of an image. This artefact can be corrected by the service engineer by simple cleaning. If these artefacts re-appear very frequently, extra effort will be needed in order to make the environment of the reading system free of dust.

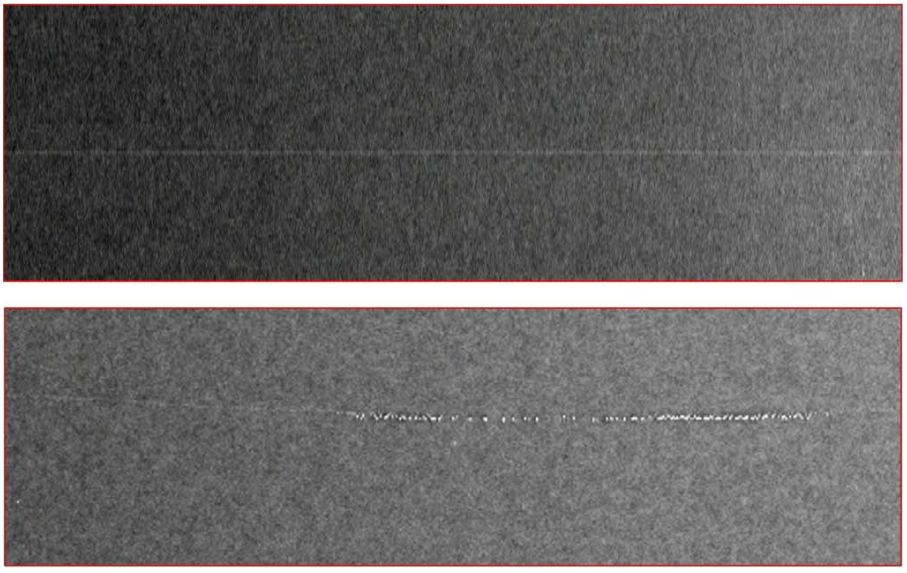


FIG. 29. Examples of computed radiography errors in the reading element (top) or due to a scratch (bottom).

IV.2.2.10. Case study 13 (computed radiography system: plate ageing)

Another source of artefacts in all technologies, but especially in CR systems, is the ageing of the plates. The number of clinical acquisitions over which manufacturers can guarantee adequate performance for a CR plate is not predefined in all cases. In some countries, the regulator fixes this number. Phosphor damage may be an indication for replacement (Fig. 30). While lag and ghosting are usually linked with DR systems, they can also occur in CR when the reader system is not capable of releasing all trapped ionization effects efficiently. Sudden failure can cause lag and, in the long run, a permanent ghost image, as in the case of Fig. 30 (right).

Dirt and scratches can reach an unacceptable level, suggesting plates should be replaced rather than cleaned. It is good practice to consult the manufacturer's specifications in terms of number of exposures per plate.

A facility will typically have a number of CR plates used per X ray tube. While this publication suggests always performing the QC tests with the same cassette, it may be good practice to also test all clinical cassettes from time to time to verify the status of their cleanliness.

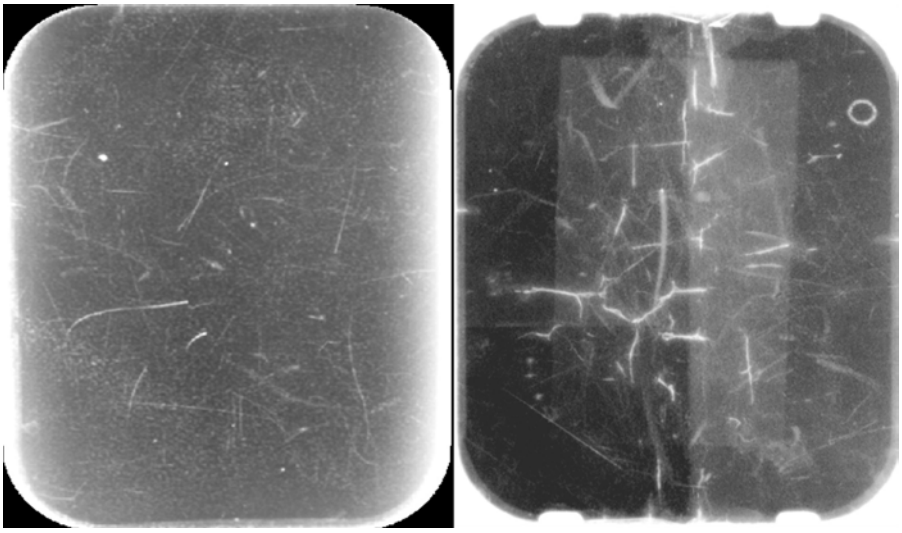


FIG. 30. Artefacts attributed to the age and poor maintenance of computed radiography plates resulting in a permanent ghost image (right) (courtesy of A. Jacobs, Leuven).

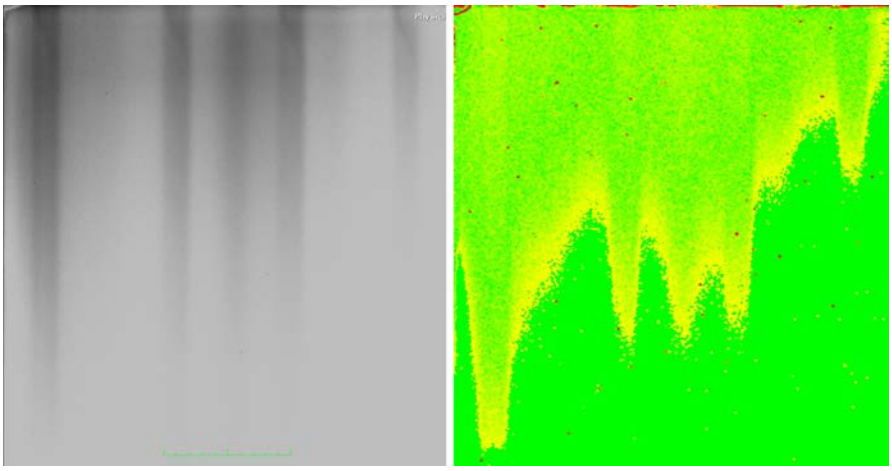


FIG. 31. Severe streak artefacts caused by damage to the phosphor screen by the rollers in the computed radiography reader, as they appear in a uniform image (left) and in the corresponding variance map (right). Note that the variance range in the automated tool for image analysis (ATIA) was set to 10% and 110% to generate this image.

IV.2.2.11. Case study 14 (general radiography — computed radiography system: significant streak artefacts)

This example shows significant streak artefacts in a CR image. Such streaks have two possible sources: the CR reader or the cassette. It is possible to differentiate between the two by analysing other cassettes. If the artefact is present on other cassettes, then it is caused by the CR reader. If it is only found on one cassette, then there is a fault with that cassette. In this case (Fig. 31), the streak was only seen on a single cassette. The phosphor was removed and inspected, showing that the phosphor had been permanently damaged by the rollers in the CR reader. The only solution is to replace the cassette.

Cleaning of CR cassettes and screens is extremely important, but needs to be done very carefully.

IV.2.3. Guidance for correcting image artefacts in computed radiography and digital radiography systems

In the case of an observed image artefact, the first variable to eliminate in the analysis is human error in either the measurements or the data processing. If the problem shows up suddenly, always repeat the phantom image acquisition and data analysis. If needed, guide the local personnel to ensure images are

being acquired correctly. It is extremely important that the same parameters and processing programmes be chosen on the system every time.

The next step is to ensure the integrity and adequate condition of the test objects, making sure that no damage or variation has occurred, including verifying whether the proper phantom has been used. For evaluation of localized problems, it is very important that the phantom be clean.

In the case of sudden changes in the values of more than one parameter, the first step is to verify that no major service, calibration, hardware upgrade or replacement of components has happened on the system. Software upgrades or maintenance of the system may also result in different settings affecting QC results.

There are several types of image artefacts that may show up during QC activities. The ATIA application and the phantom have been set up to show problems. The ATIA produces thumbnail images that, via the calculation of the variance of small ROIs in the original image, enhance the appearance of the artefacts. These images can be colour coded with each colour representing a predetermined percentage deviation from the variance in a reference position. If a suspicious artefact is found, the original image needs to be inspected (and perhaps clinical images need to be inspected as well).

Image quality artefacts can have many causes, and the remedies can be quite different. Determining the cause of image artefacts can be challenging, but the following guidelines can help to narrow down the possibilities:

— Most apparent (global) image artefacts are probably due to changes in the noise properties. In depth noise investigations require extra testing, usually on-site.
— Sudden changes in overall spatial resolution, as detected with an MTF measurement, are rare in digital imaging. While an edge-based MTF cannot be measured in all locations of the detector, localized noise measurements are also expected to point to this artefact.
— Large areas of non-uniformity may be due to ghosting or detector lag. Sensitivity variations in the detector due to repeated use are defined as ghosting. Effects caused by residual signal from previous exposures are defined as lag. Both artefacts can happen in digital imaging. Rather than replacing a detector when an artefact has been detected and identified, other remedies always need to be considered first; a recalibration of the detector (flat fielding) or fixing dead pixels may solve the situation.
— Localized image quality problems can be frequent and disruptive for the overall image quality. They are usually either detector related such as dead pixels or due to dust or dirt anywhere in the system. Dust or dirt can be found on the filter, on the tube housing, in and under the compression

paddles (in case of mammography), on the test object, in a (CR) cassette, on top of the bucky and even in the bucky. It may be very difficult to eliminate a dust related problem. At first, the nature of the apparent artefacts has to be recognized. To do so, it is recommended to verify whether the artefact is present in every successive image and whether it is always in the same place in the image. Artefacts that are very local but not found in exactly the same position may be due to dust or dirt on the phantom, which can easily move or float around inside the cassette. This can be verified with a second phantom exposure in which the phantom is rotated 90°. If rotation of dust on the phantom is confirmed, remedial action is straightforward: clean the phantom. A typical procedure to remove localized dead pixels consists of replacing the pixel value in the dead pixel by the average value of surrounding pixels. Manufacturers typically have procedures in place to do so. Physics testing ensures that this process of fixing clusters of dead pixels does not result in large parts of the image being blurred.

The types of localized artefacts that can be encountered are obviously different between DR and CR systems. DR technology has clearly defined pixel elements, with pixel values at specific image coordinates always coming from the same physical detector element. Dead pixels can be removed with a calibration procedure. The manufacturers specify the level of remedial action for their systems. In CR systems, a plate and reading system is involved; in this case, the coordinates in an image cannot be linked to the specific position on the plate and calibration cannot remove very localized artefacts. Before a localized problem leads to a recommendation to replace a detector, the clinical impact of the artefact has to be evaluated. Remedial action is more stringent if there is a possible repercussion on clinical performance.

In the approach outlined in this publication, image artefacts are evaluated from acquisition of images of the phantom as described in the sections above. The phantom includes an edge test object and a small piece of aluminium. At the location of the artefacts, the homogeneity or uniformity of the image cannot be evaluated. A second test acquisition with the phantom rotated or an acquisition of a completely homogeneous block can be made for this purpose. The ATIA can also be applied on a completely homogeneous image.

Appendix V

IMAGE QUALITY METRICS

Image quality metrics include SNR, SDNR and *d'*, as explained in this Appendix.

V.1. SIGNAL TO NOISE RATIO (SNR)

The pixel SNR compares the signal level at a given location within the image to a measure of the noise at the same location. The signal is calculated as the mean pixel value (PV) from a ROI. The standard deviation (stdev) from the same ROI is used as a very simple estimate of the noise. SNR is the ratio of these two values (Eq. (1)):

$$\mathrm{SNR} = \frac{\mathrm{Mean}(\mathrm{PV})}{\mathrm{stdev}(\mathrm{PV})} \tag{1}$$

For periodic testing, the ROI should always have the same size and be located in the same position. The ROI could be sized to contain a sufficient number of pixels to ensure that a repeatable value is obtained, but small enough to avoid any heel effect or other large area of inherent non-uniformity that may influence the measurement. In a typical radiographic or mammographic image, a ROI of 5 mm × 5 mm is sufficiently large. Likewise, the ROI should not be placed in a region that includes local artefacts. In the ATIA, the ROI is placed in a uniform area of the phantom. If the user notes local artefacts in the ROI, the ROI position needs to be moved away from the artefact.

The calculation is done on 'for processing' images that present a linear response with respect to dose and are corrected for the offset value. Linearization and offset correction begins with determining the response of the system to different levels of detector air kerma. Traditionally, it has been recommended to use a recurrence quantification analysis 5 (RQA5) beam for radiography for this measurement [22] which specifies the use of 0.5 mm of copper and added aluminium filtration to obtain a nominal half value layer of 6.8 mm, and RQA M2 for mammography with an additional filtration of 2 mm aluminium to obtain a first half value layer of 0.60 mm aluminium [36]. A minimum of five images with increasing detector air kerma values are acquired (from 0.5 μGy to 20 μGy, for example). Pixel values are averaged in a fixed ROI (typically 100 × 100 pixels) in the image. The curve fit between mean pixel value and detector

air kerma allows for calculation of the offset value — meaning the (theoretical) pixel value at 0.0 μGy. The inverse of the same curve fit can be applied on all the pixel values in the image to obtain the linearized image. The pixel value in the linearized image (PV_{lin}) will now have the value of detector air kerma — this is a useful check on the linearization step. Many DR systems have a linear response and have zero offset value, in which case this process is not needed. More care is required for CR systems, which often present a logarithmic response or have a power law relationship between pixel value and detector air kerma. When the goal is to monitor the performance of a system over time as part of a QC programme, this linearization is not needed. This is the case in the programme described in this publication.

V.2. SIGNAL DIFFERENCE TO NOISE RATIO (SDNR)

The SDNR is a simple measure of how discernible the target is, which has been shown to correlate with more complex detectability measures [37] for circular objects in homogeneous backgrounds. In the proposed phantom, an object consisting of a 1 cm × 1 cm aluminium square with a thickness of 0.2 mm (mammography) or 4 mm (radiography) is used.

Two ROIs are used, one positioned within the aluminium square and one in the local background. The mean pixel value from the ROI in the aluminium square (PV_{Al}) and from the ROI in the background (PV_{bg}) are measured. The noise is taken to be the standard deviation of the pixels within the background ROI. SDNR is then calculated as shown in Eq. (2):

$$\mathrm{SDNR} = \frac{\mathrm{Mean}\left(\mathrm{PV}_{\mathrm{bg}}\right) - \mathrm{Mean}\left(\mathrm{PV}_{\mathrm{Al}}\right)}{\mathrm{stdev}\left(\mathrm{PV}_{\mathrm{bg}}\right)} \tag{2}$$

For periodic testing, the ROIs should always have the same size and be located in the same position. The size of the ROI is again a trade-off between a size large enough to give a repeatable measurement and one small enough to avoid bias from large scale non-uniformities. In the phantom described in this publication, the 10 mm × 10 mm size of the aluminium square target was chosen to allow easy positioning of a ROI of 5 mm × 5 mm. Positioning of ROIs in SDNR is as critical as in the SNR calculation.

Whereas SNR requires linearized and offset corrected images, calculation of SDNR is less stringent because the offset is subtracted in the numerator and does not affect the standard deviation value in the denominator. SDNR is not suitable for making comparisons of ‘imaging performance’ between different imaging systems. Furthermore, even within one imaging system, SDNR must be

interpreted with caution. For example, blurring within the X ray detector will reduce standard deviation ('image noise') and thus increase the SDNR; however, blurring will decrease small detail detectability, potentially influencing diagnostic performance of the system. Thus, when tracking the SDNR, cases of systematic SDNR increase or decrease need to be investigated [38].

V.3. DETECTABILITY INDEX (d′)

Model observers are a mathematical means of estimating a measure of target detectability from images. They overcome many of the drawbacks of human detectability studies, such as inter-reader variability, difficulty in finding the required number of observers and the time consuming nature of the readings. The non-pre-whitening model observer with eye filter (NPWE) used in this publication calculates the SNR for a specific detection task using technical parameters of the imaging system. The NPWE observer is a version of the original non-pre-whitening model (NPW) observer proposed by Wagner et al. [39], modified to include the human visual transfer function [40]. NPW and NPWE observers have been used to describe object detectability, for example in contrast-detail test objects, for both screen–film systems and for digital detectors [41–43]. The NPWE has been proposed for quality specifications, QC, and optimization of digital mammography systems [37] and general X ray systems [44]. The NPWE d' expresses the detectability of objects for some given geometry, object size and shape, and for a measure of large area image contrast.

The approach by Monnin et al. [37] has been adopted in which NPWE d' is calculated as shown in Eq. (3):

$$d' = \frac{\sqrt{2\pi}C\int_0^\infty S^2(u)\mathrm{MTF}^2(u)\mathrm{VTF}^2(u)u\,\mathrm{d}u}{\sqrt{\int_0^\infty S^2(u)\mathrm{MTF}^2(u)\mathrm{VTF}^4(u)\mathrm{NNPS}(u)u\,\mathrm{d}u}} \tag{3}$$

where

C is the measured contrast;

S is the Fourier transform of the object (i.e. a task function);

MTF is the pre-sampling modulation transfer function of the detector;

NNPS is the normalized noise power spectrum for the image of interest; and

u is the spatial frequency in a visual transfer function (VTF).

Contrast (C) is measured using the aluminium square described above. The use of a 5 mm thick PMMA target plate results in nearly scatter free conditions in radiography. While some scatter is present from the 4 cm thick PMMA attenuator in the mammography phantom (for the grid in imaging), the impact of this in a QC situation is minimal. In this publication, a circular object is assumed with contrast equal to that of the aluminium square. The Fourier transform of a disc-like object with radius R is a first order Bessel function (Eq. (4)):

$$S(u) = \frac{R}{U} J_1(2\pi R u) \tag{4}$$

The visual transfer function (VTF in Eq. (5)) was implemented using a nominal image magnification of 1.5 and a viewing distance of 400 mm [37]. Explicitly,

$$\mathrm{VTF}(u) = 29.5u^2 \exp(-4u) \tag{5}$$

The normalized noise power spectrum was estimated from a region of 512 pixels × 512 pixels in a homogeneous area of the phantom image. Half-overlapping 256 pixel × 256 pixel ROIs were then extracted for 2-D noise power spectrum calculation. In line with International Electrotechnical Commission guidance [45], a surface can be fitted to and subtracted from the region prior to the extraction of the ROIs. This is to remove or suppress the influence of background trends on the noise power spectrum. A standard formula is used to calculate it. The axial (0° and 90°) and radial noise power spectrum curves were sectioned from the 2-D spectra, using seven spatial frequency bins on either side of the axes for the axial spectra. The on-axis data (0° and 90°) were excluded from all three curves. The normalized noise power spectrum was formed by dividing the noise power spectrum by the squared mean pixel value of the large region in the linearized image.

The pre-sampling MTF was measured using a version of the edge method [31, 47], in which a small object is inserted in the phantom. A 50 mm × 50 mm copper square 1 mm thick (mammography) or 2 mm thick (radiography) with machined straight edges was placed at the centre of the detector and rotated slightly to give an angle between 2° and 5° with respect to the pixel matrix. A finely sampled version of the edge spread function is formed from which the

pre-sampling MTF is calculated. The edge spread function is generated from a ROI positioned on the edge, and the size of this ROI influences the magnitude of the measured MTF at low spatial frequencies. Large ROIs will characterize the long distance scattering, either arising from X ray scattered radiation or from detector signal scattered from the X ray detector, and this results in a reduction in MTF at low frequencies. Hence, the ROI needs to be large enough to obtain a reasonably accurate estimate of this scattering. Furthermore, the ROI size has to be held constant over time. Given these constraints, there is some freedom of choice in ROI selection. For the 50 mm × 50 mm edge described here, the ROI could be 50 mm × 25 mm (i.e. ~50 mm/2 extending under the edge). Alternatively, a square ROI of 40 mm × 40 mm could be used. The edge spread function is calculated using two orthogonal edges in the edge test object, resulting in two MTF curves, one for each direction across the detector. For convenience, the MTF curves are binned to 0.25 mm^{-1} frequency intervals at output. In the final d' calculation, the two orthogonal MTF curves are averaged and evaluated at the same frequencies as the normalized noise power spectrum (by interpolation) to give a single MTF.

Note that the d' measurements and calculations need to be performed on 'raw' or 'for processing' images that are linearized and offset corrected. If these images are not available, the assumptions in the calculation of d' are not valid. As stated previously, most DR systems demonstrate a linear response to air kerma. They also typically have very small offset values. The response curve for CR systems is generally non-linear with significant offset values. In this case, the calculated d' may be used for QC purposes — remaining constant over time — but it does not have the same broad detectability significance that it would otherwise have. In no case can d' be calculated from a fully processed image.

Appendix VI

BASIC INFORMATION ON DICOM

VI.1. BACKGROUND

The earliest digital medical imaging devices were both proprietary in nature and designed to provide an output in the form of printed film. Users had no expectations that those early digital images would be extracted from such devices, or that they could be exchanged between devices or software from different manufacturers. Manufacturers developed practical solutions for transferring, storing and remotely displaying images electronically. These were initially in proprietary forms, and different systems would not communicate (i.e. they were not 'interoperable'). One could, for example, equip an entire hospital with X ray, computed tomography and magnetic resonance acquisition devices as well as a PACS and review workstations, but these would only work together if everything was purchased from one vendor, or if custom interfaces were developed for each acquisition device. This approach was neither scalable nor affordable, and it quickly became crucial to develop open standards to promote interoperability between equipment from different manufacturers [47].

The first open standard effort for medical imaging was the ACR-NEMA standard published in 1985, jointly sponsored by the American College of Radiology (representing the users) and the National Electrical Manufacturers Association (representing the manufacturers) [48]. This standard defined a mechanism for encoding the pixel data of the images themselves, together with information about the images in the form of a list of data elements and a set of commands, and a means of exchanging these data over a point to point connection between two devices using a 50 pin parallel interface. There was little adoption of this standard at the time, and it was not until 1993, when an extensively revised version of the standard was produced and renamed DICOM [49], that significant progress was made. A key feature of DICOM that distinguished it from its predecessor was the use of evolving computer networks and Internet technology and protocols. Today, the use of DICOM is ubiquitous, and no manufacturer would be able to market a device that did not conform to the standard. The standard is not static, but rather evolves through extension with additional features as new imaging and communication technology is developed. Although DICOM is ubiquitous in medical imaging, two 'DICOM conformant' devices may or may not be able to completely and perfectly interoperate, depending on the specific details of how the standard has been implemented in each device.

Although initially targeted towards radiology applications, today the DICOM standard is not so restricted in scope and includes support for many other medical specialties such as radiotherapy, cardiology, dentistry, endoscopy, dermatology and pathology. DICOM has also been extended beyond the scope of medicine to include non-destructive testing of aircraft parts (digital imaging and communication in non-destructive evaluation, or DICONDE) as well as baggage screening and other security applications (digital imaging and communications in security, or DICOS).

VI.2. COMPOSITE INFORMATION MODEL AND INFORMATION OBJECTS

A primary purpose of DICOM is the interchange of images and their accompanying information. To this end, the standard describes information object definitions, each of which is specific to a type of image produced by a particular modality but shares a common structure. For example, there is an information object definition for computed tomography and another for ultrasound. What these have in common is the same set of information about the patient and the management of the study. They differ in their acquisition technique, spatial and temporal relationships, and encoding of the pixel data. Accordingly, DICOM describes this information in modules that are either general or specific to a modality. The patient module, for example, includes the patient's name, birth date and identifier (i.e. characteristics of the patient that are fixed). The patient study module contains information about the patient that may vary over time but is important to the interpretation of the study, such as weight and height. In addition to information about the patient, additional information required to manage the study is included, such as the date and time that the study was started, the identifiers of the request and the study itself, and descriptors of the type of procedure. This additional information may be found in the general study module. All DICOM images of patients contain such modules, regardless of the type of acquisition device.

Different modalities contain additional modules specific to them. For example, in mammography, information on breast compression such as compression force and thickness is included along with information on the X ray technique, which contains specific attributes that describe the characteristics of the beam and its production, including the tube current, exposure time, filtration (Fig. 32). Ultrasound images on the other hand include relevant information about the type of transducer used and the transducer frequency.

FIG. 32. Sample Digital Imaging and Communications in Medicine (DICOM) header with unique identifiers in left hand column followed by a description and value.

Modules not only describe information that is either general or modality specific, but also information that is shared between multiple images during the same procedure. This commonality is defined in a DICOM information model, which describes entities such as patients, studies, equipment, series and images, and the relationships between them. Hence, all images that are acquired as

part of the same procedure will contain exactly the same information about the patient and the study. If the procedure is performed on the same device, then the information about the equipment will be identical in all such images. Multiple images may be grouped into the same series if they have something in common, such as if they were acquired in a single run of the computed tomography gantry. When images are encoded, however, all this common information is replicated into each instance; that is, every image will contain a full set of information. For this reason, they are referred to as composite instances (as opposed to normalized instances in which the information about each entity would be managed and transmitted separately). The intent is that a single image may be separated from other images on the system on which it is produced or stored, yet it will still contain the full set of information necessary to identify and interpret it.

The standard describes modules as consisting of attributes (and defines the meaning of each attribute in the context of its use in that module) as well as the sets of values that may be used for each attribute, whether an attribute has a single or multiple value and any requirements or conditions on the presence of the attribute. Attributes are defined to be Type 1 (shall be present with a value), Type 2 (shall be present but may be empty if the value is unknown) and Type 3 (optional). In certain cases, manufacturers choose not to fill Type 3 attributes.

Appendix VII

PILOT STUDY RESULTS

In order to evaluate the ability of the proposed methodology to produce accurate and reproducible results and to capture the system fluctuations that can indicate a performance issue, phantoms were manufactured at four institutions independently (Fig. 33) and were used to test the constancy of several radiographic and mammography systems.

FIG. 33. Photos of the radiography (top) and mammography (bottom) phantoms, positioned with respect to the light field. For the radiography phantom, note the use of the absorber, positioned at the collimator exit (top right).

The following paragraphs present some of the results obtained in this test and indicate the advantages and the points that need to be considered during the implementation of the QC methodology.

Regarding the ability of the proposed methodology to capture the system performance, Figs 34 and 35 present the control charts of the application of the methodology in one mammography (Fig. 34) and one radiography (Fig. 35) unit over a period of a few weeks. The control limits in these charts have been set at an indicative level of 15% from the baseline value, set by the CQMP during the comprehensive QA and commissioning of the phantom. However, these values can be revised to reflect vendor or regulatory requirements or reconsidered and defined at lower values in the case of stable systems.

Figure 36 presents a control chart of the mA·s results for one mammography unit included in the test. It can be seen that the wide variability of the results indicates a problem and does not allow an accurate trend analysis of the data. This was investigated and was found to be due to the inconsistent positioning of the phantom, which significantly affected (due to the MTF copper plate) the system's AEC performance. The procedure was corrected and the results were improved.

In terms of the ability of the proposed phantom and the software to accurately generate the MTF, the results produced were compared to the MTF values generated utilizing the Leeds DMAM2 mammography phantom and analysed with independent software. The results, presented in Fig. 37, indicate that a properly manufactured phantom, with the automated analysis of the ATIA, can correctly measure the system MTF. This underscores the significance of well manufactured copper plates with sharp edges. As mentioned in the description of the phantoms, professional support in this process might be required, as rough edges could result in non-accurate and non-reproducible results for the MTF, making the methodology unsuitable both for acceptance and consistency measurements.

In terms of calculating d', results are presented in Fig. 38, confirming the expected linear response of d' with respect to the AEC setting in a DR unit.

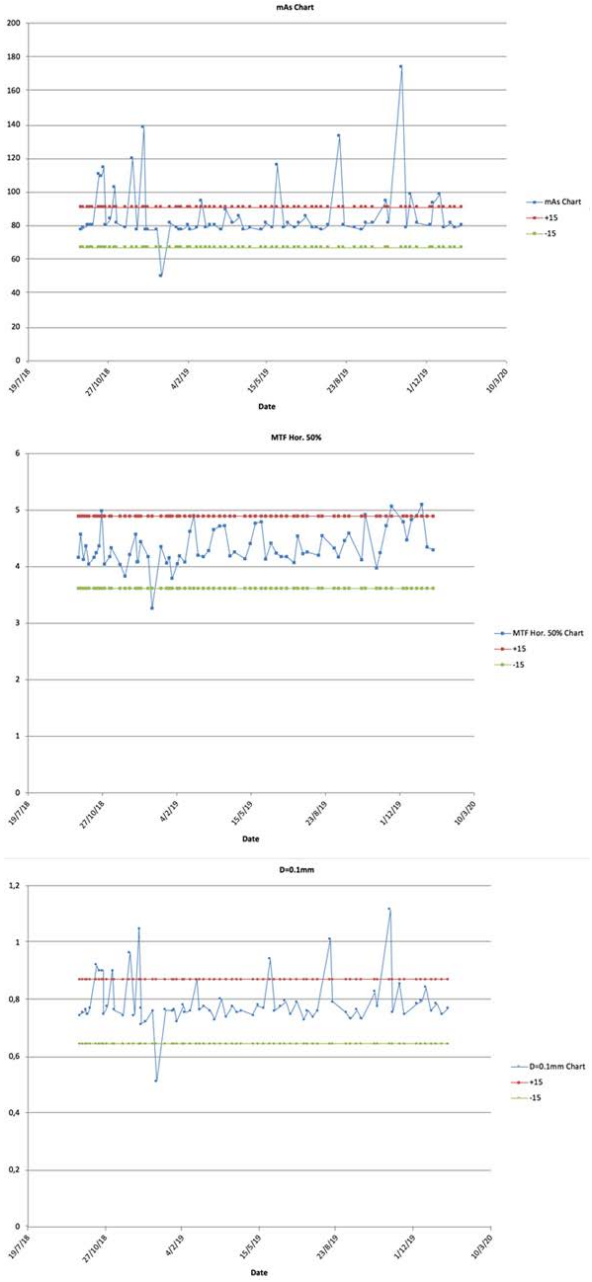


FIG. 34. Control charts produced with the proposed methodology for some of the main performance parameters (mA·s, modulation transfer function (MTF), d') of one mammography unit during an 18 month period.

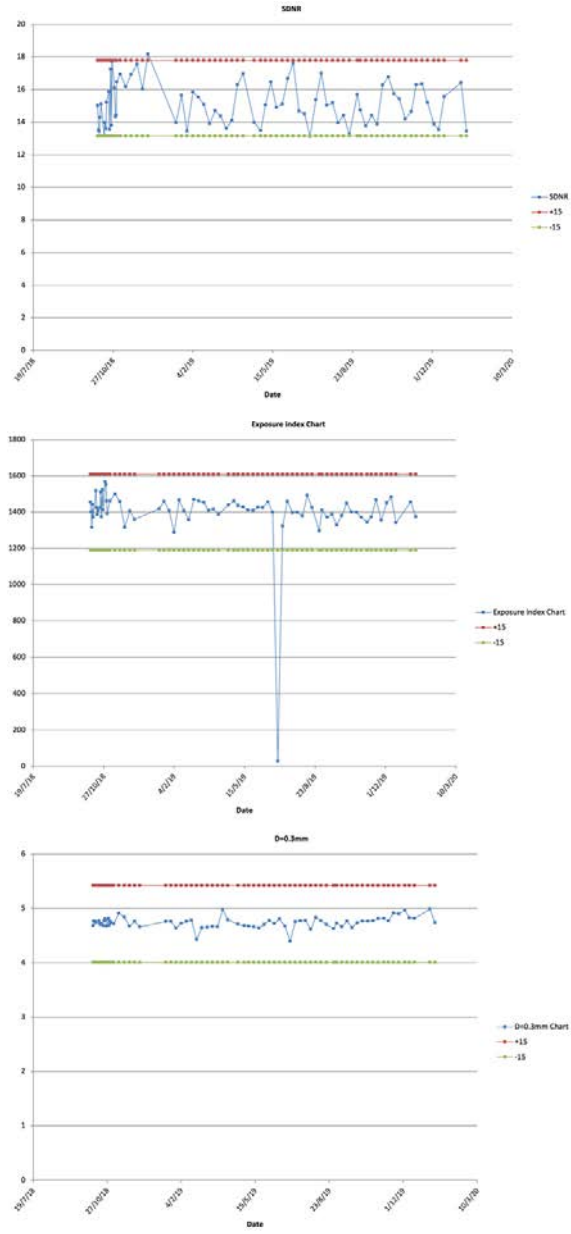


FIG. 35. Control charts produced with the proposed methodology for some of the main performance parameters (signal difference to noise ratio (SDNR), exposure index, d') of one radiography unit during an 18 month period.

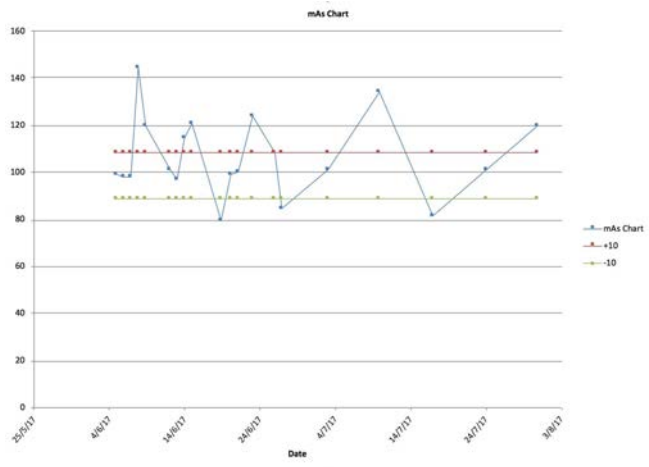


FIG. 36. Control chart of the mA·s results for one mammography unit demonstrating wide fluctuations, due to inconsistent positioning of the phantom affecting the automatic exposure control.

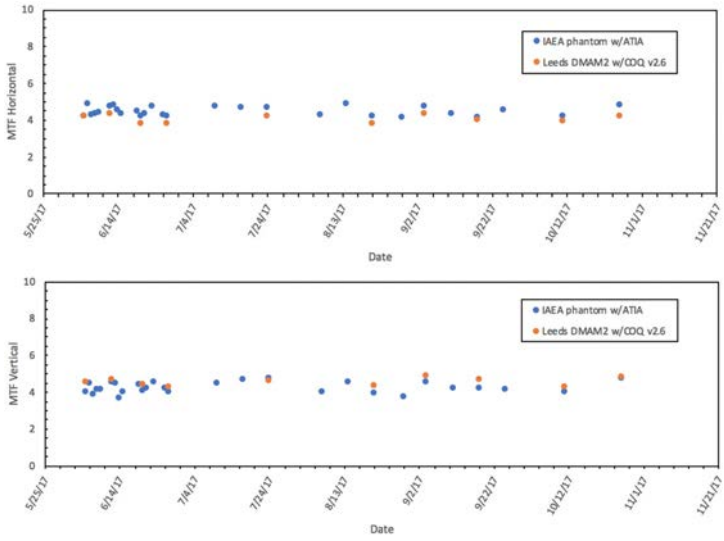


FIG. 37. Graphs demonstrating the modulation transfer function (MTF) performance over time. The blue points come from the IAEA phantom and the automated tool for image analysis (ATIA) application. The orange points are from the Leeds DMAM2 phantom analysed with an ImageJ plugin (COQ v2.6) [32]. MTF data in both the horizontal and vertical directions are presented. The two sets of data in each direction are identical with the student's t-test result $p < 0.01$.

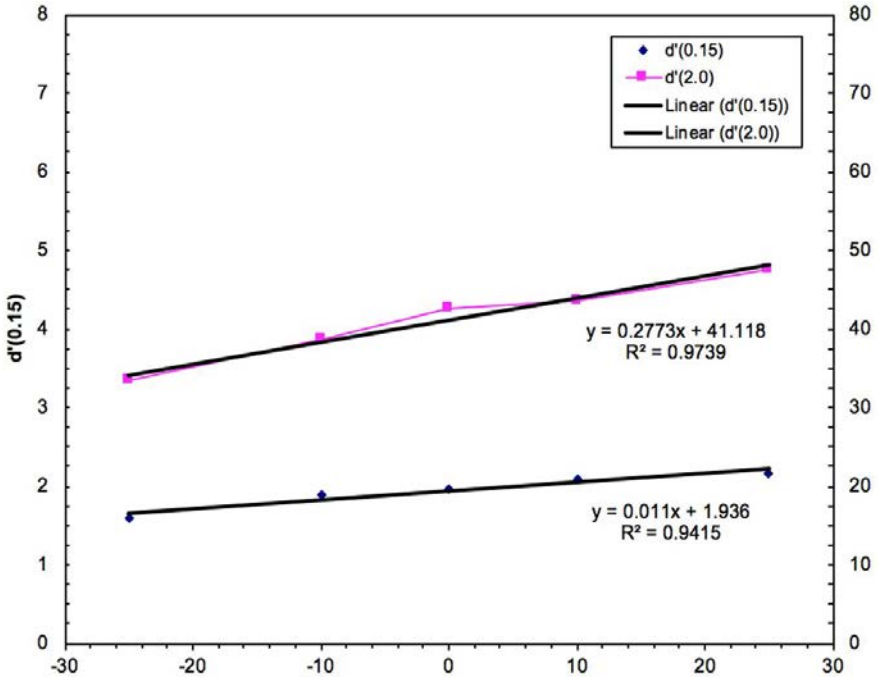


FIG. 38. Sample d' results of a digital radiography unit, confirming the expected linear response of d' with respect to the automatic exposure control setting in a digital radiography unit.

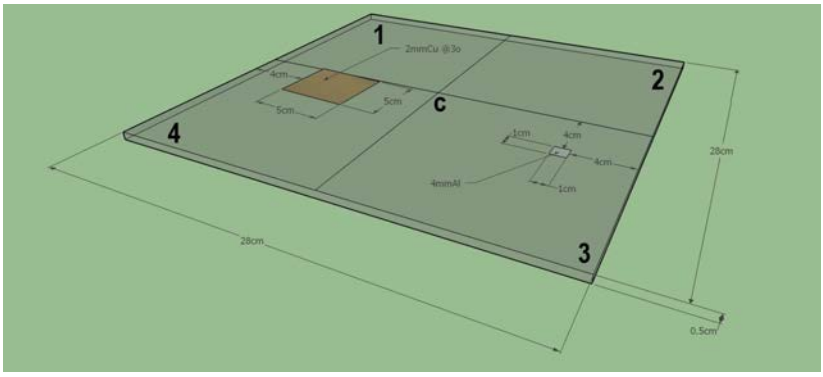
Appendix VIII

DATA FORMS

This Appendix contains templates for the tests proposed in this publication. These pages can be printed separately from the publication and can be used as part of the documentation of the results of the tests in a hospital/department. The images included help to standardize (as much as possible) the measuring conditions and positions, following the methodology described in Section 4.

VIII.1. RADIOGRAPHY — SCREEN–FILM SYSTEMS

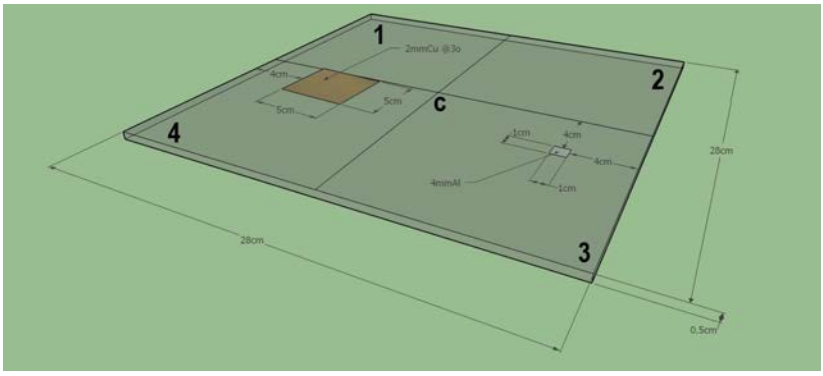
X ray manufacturer:
Model and serial number:
Room:
Date:



Acquisition parameters, at 80 kVp and 0 AEC setting							
mA·s							
Image measurements							
OD at centre							
OD at corner 1							
OD at corner 2							
OD at corner 3							
OD at corner 4							
OD inside Al							
OD outside Al							
OD inside Al – OD outside Al							
OD inside Cu							
Note: AEC — automatic exposure control, OD — optical density.							

VIII.2. RADIOGRAPHY — COMPUTED/DIGITAL RADIOGRAPHY EQUIPMENT WITHOUT LOCAL AUTOMATED TOOL FOR IMAGE ANALYSIS (ATIA)

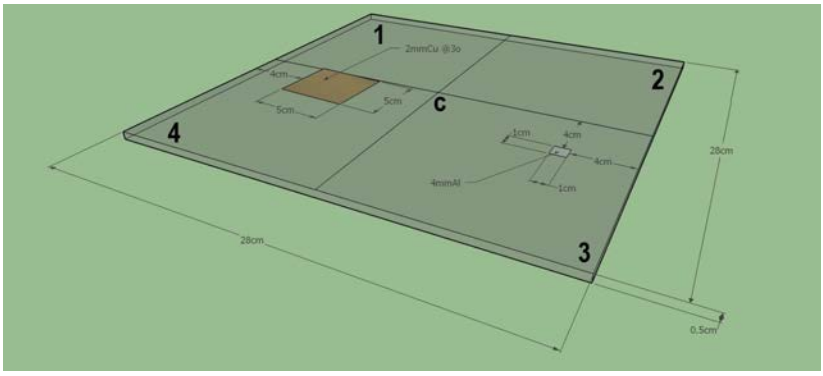
X ray manufacturer:
Model and serial number:
Room:
Date:



Acquisition parameters, at 80 kVp and 0 AEC setting							
mA·s							
Exposure index							
Air kerma–area product							
Image analysis							
MPV at centre							
SDV at centre							
MPV at corner 1							
SDV at corner 1							
MPV at corner 2							
SDV at corner 2							
MPV at corner 3							
SDV at corner 3							
MPV at corner 4							
SDV at corner 4							
MPV inside Al							
SDV inside Al							
MPV outside Al							
SDV outside Al							
Note: AEC — automatic exposure control, MPV — mean pixel value, SDV — standard deviation.							

VIII.3. RADIOGRAPHY — COMPUTED/DIGITAL RADIOGRAPHY EQUIPMENT WITH LOCAL AUTOMATED TOOL FOR IMAGE ANALYSIS (ATIA)

X ray manufacturer:
Model and serial number:
Room:
Date:

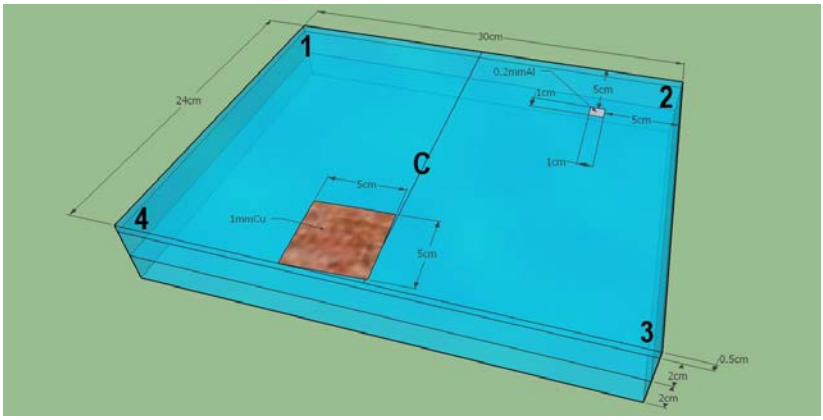


Acquisition parameters, at 80 kVp and 0 AEC setting							
mA·s							
Exposure index							
Air kerma–area product							
Image analysis							
SDNR							
CNR							
H MTF at 20%							
V MTF at 20%							
$d'(R = 2)$							

Note: AEC — automatic exposure control, CNR — contrast to noise ratio, H — horizontal, MTF — modulation transfer function, SDNR — signal difference to noise ratio, V — vertical, R — radius.

VIII.4. MAMMOGRAPHY — SCREEN–FILM SYSTEMS

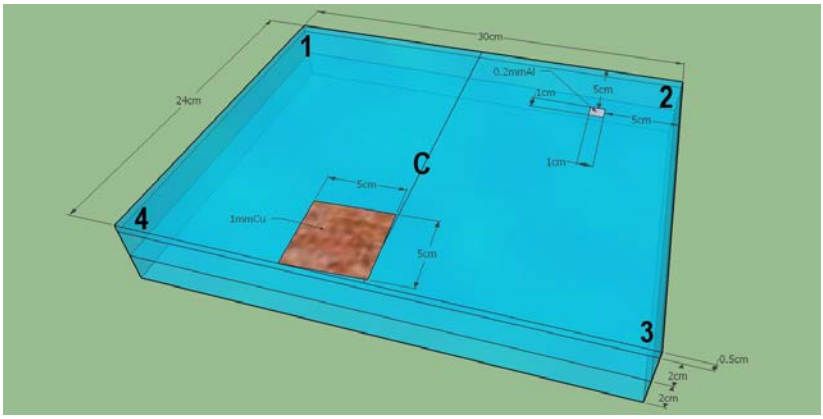
X ray manufacturer:
Model and serial number:
Room:
Date:



Screen–film and computed radiography unit acquisition parameters If not fully automated use Mo/Mo, 28 kVp and 0 AEC setting							
Anode/filter							
kVp							
mA·s							
Compressed thickness (cm)							
Image analysis							
OD at centre							
OD at corner 1							
OD at corner 2							
OD at corner 3							
OD at corner 4							
OD inside Al							
OD outside Al							
OD inside Al − OD outside Al							
OD inside Cu							
Note: AEC — automatic exposure control, OD — optical density.							

VIII.5. MAMMOGRAPHY — COMPUTED/DIGITAL RADIOGRAPHY EQUIPMENT WITHOUT LOCAL AUTOMATED TOOL FOR IMAGE ANALYSIS (ATIA)

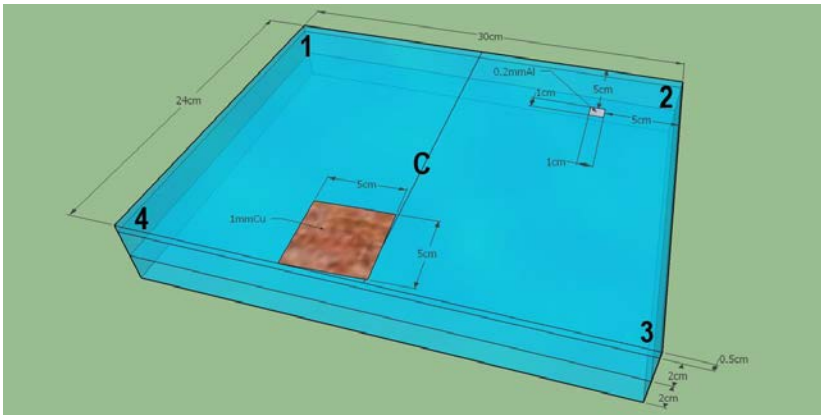
X ray manufacturer:
Model and serial number:
Room:
Date:



Acquisition parameters If not fully automated use Mo/Mo, 28 kVp and 0 AEC setting					
Anode/filter					
kVp					
mA·s					
Compressed thickness (cm)					
Exposure index					
Image analysis					
MPV at centre					
SDV at centre					
MPV at corner 1					
SDV at corner 1					
MPV at corner 2					
SDV at corner 2					
MPV at corner 3					
SDV at corner 3					
MPV at corner 4					
SDV at corner 4					
MPV inside Al					
SDV inside Al					
MPV outside Al					
SDV outside Al					
Note: AEC — automatic exposure control, MPV — mean pixel value, SDV — standard deviation.					

VIII.6. MAMMOGRAPHY — COMPUTED/DIGITAL RADIOGRAPHY EQUIPMENT WITH LOCAL AUTOMATED TOOL FOR IMAGE ANALYSIS (ATIA)

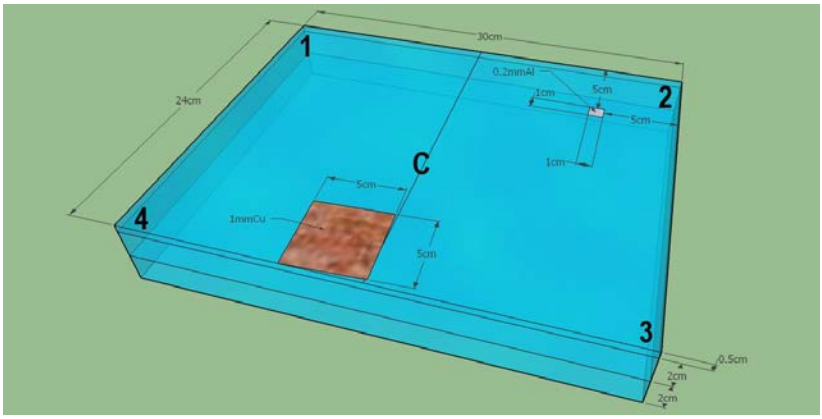
X ray manufacturer:
Model and serial number:
Room:
Date:



Acquisition parameters If not fully automated use Mo/Mo, 28 kVp and 0 AEC setting							
Anode/filter							
kVp							
mA·s							
Compressed thickness (cm)							
Exposure index							
Image analysis							
SDNR							
CNR							
H MTF at 20%							
V MTF at 20%							
$d'(R = 0.125)$							
Note: AEC — automatic exposure control, CNR — contrast to noise ratio, H — horizontal, MTF — modulation transfer function, SDNR — signal difference to noise ratio, V — vertical, R — radius.							

VIII.7. MAMMOGRAPHY — DIGITAL RADIOGRAPHY EQUIPMENT WITHOUT LOCAL AUTOMATED TOOL FOR IMAGE ANALYSIS (ATIA)

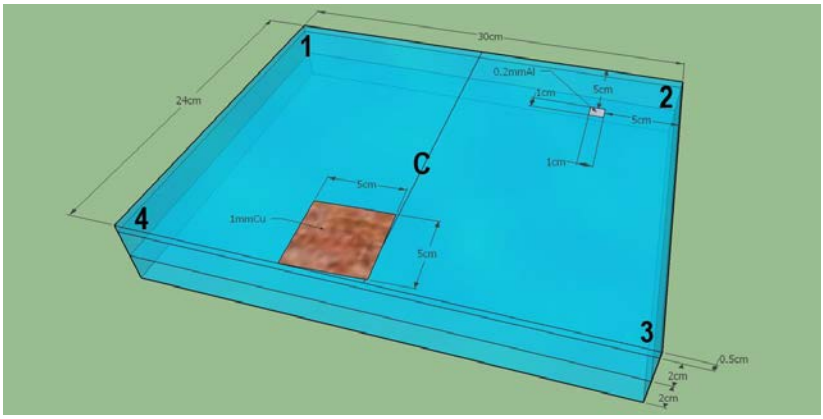
X ray manufacturer:
Model and serial number:
Room:
Date:



Acquisition parameters							
Anode/filter							
kVp							
mA·s							
Compressed thickness (cm)							
K_i							
MGD							
Image analysis							
MPV at centre							
SDV at centre							
MPV at corner 1							
SDV at corner 1							
MPV at corner 2							
SDV at corner 2							
MPV at corner 3							
SDV at corner 3							
MPV at corner 4							
SDV at corner 4							
MPV inside Al							
SDV inside Al							
MPV outside Al							
SDV outside Al							
Note: MGD — mean glandular dose, MPV — mean pixel value, SDV — standard deviation.							

VIII.8. MAMMOGRAPHY — DIGITAL RADIOGRAPHY EQUIPMENT WITH LOCAL AUTOMATED TOOL FOR IMAGE ANALYSIS (ATIA)

X ray manufacturer:
Model and serial number:
Room:
Date:

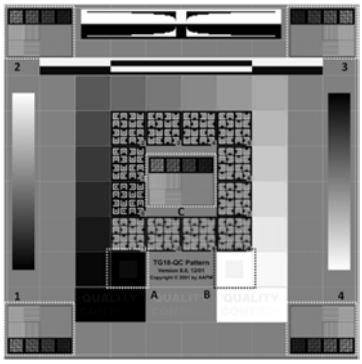


Acquisition parameters							
Anode/filter							
kVp							
mA·s							
Compressed thickness (cm)							
K_i							
MGD							
Image analysis							
SDNR							
CNR							
H MTF at 20%							
V MTF at 20%							
$d'(R = 0.125)$							

Note: CNR — contrast to noise ratio, H — horizontal, MGD — mean glandular dose, MTF — modulation transfer function, SDNR — signal difference to noise ratio, V — vertical, R — radius.

VIII.9. MONITORS

X ray manufacturer:
Model and serial number:
Room:
Date:



Evaluation of test pattern (enter pass/fail)						
Geometrical distortion						
0%–5% contrast boxes visible (A)						
95%–100% contrast boxes visible (B)						
(enter value)						
High contrast line pairs visible (centre)						
Low contrast line pairs visible (centre)						
High contrast line pairs visible (corner 1)						
Low contrast line pairs visible (corner 1)						
High contrast line pairs visible (corner 2)						
Low contrast line pairs visible (corner 2)						
High contrast line pairs visible (corner 3)						
Low contrast line pairs visible (corner 3)						
High contrast line pairs visible (corner 4)						
Low contrast line pairs visible (corner 4)						

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ABBREVIATIONS

AAPM	American Association of Physicists in Medicine
AEC	automatic exposure control
AFRA	African Regional Cooperative Agreement for Research, Development and Training Related to Nuclear Science and Technology
ATIA	automated tool for image analysis (application)
CNR	contrast to noise ratio
CQMP	clinically qualified medical physicist
CR	computed radiography
d′	detectability index
DICOM	digital imaging and communications in medicine
DR	digital radiography
KAP	air kerma–area product
MTF	modulation transfer function
NPWE	non-pre-whitening model observer with eye filter
PACS	picture archiving and communication system
PMMA	polymethylmethacrylate
PV	pixel value
QA	quality assurance
QC	quality control
ROI	region of interest
SDNR	signal difference to noise ratio
SNR	signal to noise ratio

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Regular quality control (QC) testing of radiographic facilities has been largely overlooked throughout the world, even though it has been shown to reduce patient radiation exposure and improve image quality. Furthermore, many radiology departments do not have access to on-site support by a clinically qualified medical physicist, and relevant QC testing may be limited owing to lack of resources.

The methodology proposed in this publication is based on simple, inexpensive test objects and exploits the advantages of digital imaging. It can facilitate remote and automated QC applications and can promote collection of data in a uniform, harmonized manner allowing for intercomparison and benchmarking.

The proposed methodology is not intended to replace or minimize the need for on-site medical physics support, or replace requirements for comprehensive QC. The aim is to provide an additional tool for the everyday clinical routine and optimize use of resources.

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