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Optimisation of Radiological Protection in Digital Radiology Techniques for Medical Imaging

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CONTENTS

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OPTIMISATION OF RADIOLOGICAL PROTECTION IN DIGITAL RADIOLOGICAL TECHNIQUES FOR MEDICAL IMAGING

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Abstract– Use of medical imaging continues to increase, making the major contribution to population exposure from artificial sources of radiation world-wide. The principle of optimisation of protection is that 'the likelihood of incurring exposures, the number of people exposed, and the magnitude of their individual doses should all be kept as low as reasonably achievable (ALARA), taking into account economic and societal factors'. Optimisation for medical imaging requires more than ALARA, it implies keeping patient exposure to the minimum necessary to achieve the required medical objective. In other words, the number and quality of images must be adequate to obtain the information needed for diagnosis or intervention. Dose reductions for imaging or x-ray image-guided procedures should not be used if they degrade image quality to the point where it is inadequate for the clinical purpose. The move to digital imaging has provided versatile acquisition, post-processing, and presentation options, but because images are adjusted for optimal viewing, the appearance may not give any indication if the dose is higher than necessary. Nevertheless, digital images provide opportunities for further optimisation and offer the possibility of applying artificial intelligence methods in the future.

Optimisation of radiological protection for digital radiology of patients (radiography, fluoroscopy and computed tomography) involves selection and installation of equipment, design and construction of facilities, choice of optimal equipment settings, day-to-day methods of operation, quality control programmes, and ensuring that all personnel receive proper initial and career-long training. The radiation dose levels that patients receive also have implications for doses to staff. As new imaging equipment incorporates more options to improve performance, it becomes more complex and less easily understood, so operators have to be given more extensive training. Ongoing monitoring, review, and analysis of performance is required that feeds back into the improvement and development of imaging protocols. Several different aspects relating to optimisation of protection that need to be developed are set out in this report. The first is collaboration between radiologists/clinicians, radiographer/imaging technologists, and medical physicists, each of whom have key skills that can only contribute to the process effectively when individuals work together as a core team. The second is appropriate methodology and technology, with the knowledge and expertise required to use each effectively. The third relates to organisational processes that ensure required tasks, such as equipment performance tests, patient dose surveys, and review of protocols are carried out.

There is a wide range in equipment, funding, and expertise around the world, and the majority of facilities do not have all the tools, professional teams and expertise to fully embrace all the possibilities for optimisation. Therefore, this report sets out broad levels for aspects of optimisation that different facilities might achieve, and through which they can progress incrementally; D: Preliminary, C: Basic, B: Intermediate, and A: Advanced. Examples of systems and activities that should be in place to achieve different levels are set out. Imaging facilities can then evaluate arrangements they already have and use the document to guide decisions about the next actions to be taken in optimising their imaging services.

Keywords: Digital radiology; Optimisation; X-ray equipment; Image quality; Patient dose

MAIN POINTS

- **Optimisation of radiological protection in diagnostic imaging and image-guided procedures involves a balance between radiation dose and clinical information. It requires provision of clinical images for individual patients that are of sufficient quality to ensure an accurate and reliable diagnosis, thus enabling correct care decisions. The radiation dose used to achieve such clinical image quality should be adjusted to a level that is adequate and minimised according to the applied imaging technology.**

- **In medical imaging, optimisation of protection is at two levels 1) the design and construction of the equipment and the installation where it is used and 2) the day-to-day working procedures performed by the staff involved. Optimisation will only occur if all staff are properly trained in their roles, equipment operation is ensured through a comprehensive quality assurance programme, and there is ongoing monitoring, review, and analysis of performance that feeds back into continual development of protocols. This regular review of every aspect of the imaging process is key to the successful achievement of optimisation.**

- **Different aspects contribute to optimisation. Professionalism with optimisation teams comprising radiologists, radiographers, and medical physicists each using their unique sets of skills to improve imaging performance and address deficiencies; methodology and technology coupled with the necessary expertise to evaluate performance; and organisational processes to manage quality improvement within a structured framework, combining to steadily refine practice and performance.**

- **Complex digital x-ray equipment requires high levels of knowledge and skill from clinicians, radiographers and medical physicists. Features of the equipment allow dose levels to be reduced significantly without compromising image quality, but if used incorrectly patient doses can be unnecessarily high without this being apparent. For hospitals to implement optimisation successfully, all members of the multi-professional team must be given the necessary expertise through training and experience that is regularly updated, so they fully understand equipment operation.**

- **The degree to which an organisation has implemented optimisation will depend on the personnel, facilities, and level of knowledge and experience available. This document sets out broad categories within the aspects of professionalism, methodology and process for the systems that would be in place to achieve different levels of optimisation (C: Basic, B: Intermediate, A: Advanced) with an initial; level D (Preliminary) for those setting up a facility. Managers and staff of imaging facilities should use the document to guide their decisions about the next step to take as they continue actions to optimise their imaging services incrementally.**

EXECUTIVE SUMMARY

Optimisation is a key principle of radiation protection. Medical exposures are the most significant contributor to the exposure of the population world-wide from artificial sources of radiation, so optimisation is especially important in this field. Optimisation of radiological imaging requires that dose levels are reduced as much as possible, while providing images of sufficient quality and appropriate coverage with the information required for the diagnostic purposes. The emphasis on image quality has become crucial in digital radiology with more versatile image acquisition, post-processing, and presentation options. This requires a more rigorously defined optimisation process and awareness of underlying technical factors that are not always obvious. The clinical risk from an examination for which the dose has been reduced to the point at which changes in diseased tissue cannot be visualised because the level of image quality is insufficient are likely to be high, compared to any additional risk from a higher radiation exposure. However, cumulative radiation doses from the ever-increasing use of radiology may result in health consequences that, although not immediately apparent, could manifest at a later point in time. Thus, it is a question of balance between different types of risks (potential long-term effects from dose and more immediate clinical consequences). Uncertainties, which are specific to the procedure, make achieving this balance a challenging task for both technical and professional aspects.

In order to ensure that optimisation is carried out, a facility must have sufficient imaging equipment, and enough staff who have been adequately trained to use it. The optimisation process starts with specification of the equipment required to fulfil the clinical need, and continues through its purchase, installation, acceptance, and commissioning. It includes the maintenance and the quality assurance programme which continue throughout the life cycle of the equipment.

Optimisation requires the input of knowledge and skills on many different aspects of how radiological images are formed and so requires contributions from different healthcare professionals working together as a team. The radiologist or other clinician can judge whether the image quality is sufficient for the diagnostic purpose, the radiographer should know the practical operation and limitations of the equipment, and the medical physicist should understand the physical principles behind image formation and can perform and interpret measurements of dose and image quality. In order to achieve optimisation, the three specialities, together with other healthcare professionals who will sometimes be involved, must have mutual respect for their individual skills and work together as a cohesive group (i.e. professionalism). Unfortunately, the levels of knowledge and skills in many countries are often inadequate to achieve good optimisation on more complex digital radiology systems at the time of preparation of this report. Increasing technical and computational complexity in radiology equipment and applications underlines the importance of multi-professional collaboration and dependency on the combined knowledge of different professionals. Dedicated time must be made available for the professionals to work together to meet emerging challenges in optimisation as applications of new equipment are developed.

Digital imaging provides the potential for images to be obtained with lower exposures than previously possible using film screen combinations, enabling levels to be adapted to the diagnostic requirements of particular examinations. New techniques are continuously becoming available that can improve image quality and potentially enable diagnostic images

to be obtained with lower patient doses. As an example, automated exposure control systems are continuously developed to be more effective in ensuring consistent image quality while reducing patient dose by adapting the radiation level to each procedure and the patient. However, all of these features introduce additional complexities. If users do not deploy them effectively, because of limited awareness of their mode of operation, the doses received by patients will not be optimal, but this will not be apparent to the user. Therefore, more complex equipment requires knowledgeable staff with more extensive training for its operation. The knowledge and skills, in combination with the instruments and test objects to evaluate the performance of the equipment, form the basis of optimisation (i.e. methodology).

A key component of optimisation is keeping the radiation dose to the patient as low as practicable, while maintaining an adequate level of image quality and diagnostic information. At the basic level, this requires regular assessments of doses from groups of patients to determine the dose levels and comparisons with diagnostic reference levels to confirm acceptability. Evolving technical optimisation features and quality management systems will enable an extension of the optimisation process to individual patients and procedures based on clinical indication. However, if operators do not have the knowledge and skill to use such features, important opportunities will be lost. Such an indication and patient specific level of optimisation is a fundamental extension of the conventional optimisation principle (known as ALARA) as applied to patients, since indication-orientation and patient-specificity connect the optimisation process directly into the justification process, and enable them to be made mutually supportive, comprehensive and finally a unitary process for radiation protection.

Evaluation of image quality as part of quality assurance / quality control programmes typically involves evaluation of clinical images by an experienced radiologist against established good image quality criteria and/or objective analysis of phantom images by a medical physicist. Further net improvements could be gained in the future through automated image quality evaluation based directly on clinical patient images, and may involve artificial intelligence algorithms implemented directly into image archives or imaging modalities. Regardless of the present or future methodology, the process of measuring image quality involves many interdependent parameters and due to this comprehensive nature it is a pivotal part of the overall assessment of performance.

Results from clinical assessments, coupled with results from patient dose and image quality measurements feed into the development of examination protocols optimised for the clinical purpose. In order to ensure that optimisation processes are carried out consistently there need to be management systems in place to confirm that measurements and assessments are made, to ensure that available data from clinical use and performance measurements are used in making adjustments to protocols to address any deficiencies, and to monitor the progress that is made (i.e. process management).

The degree to which any organisation has implemented optimisation in digital radiology will depend on the personnel, facilities, and level of knowledge and experience available. Within the aspects of professionalism, methodology and process there will be different levels of performance that radiology facilities will have achieved. This document sets out broad categories for the systems that would be in place to achieve different levels of optimisation (C: Basic, B: Intermediate, A: Advanced) and it is hoped that evaluating arrangements that radiology facilities already have in place will provide a guide to decisions about what actions should be taken next to move along the road to improve optimisation of their imaging service.

It is also noted that these categories (C, B, A) with increasingly advanced optimisation methods also reflect the increasing capability to reach indication-oriented and patient-specific optimisation processes. As such, when radiology facilities move along to higher levels of optimisation, they are also strengthening their justification process which should fundamentally consider benefits and harm on both indication and patient levels.

There is a need for a cultural change in order to enable improvements and developments in optimisation methods and avoid key processes being overlooked. Optimisation will only be achieved through facilities investing in adequate staffing levels to operate their imaging equipment, and providing the appropriate training, together with professional development opportunities for their staff. Knowledge and understanding are key to successful optimisation of radiological imaging. The cultural shift towards multi-professionalism required can only occur if the professional roles and competences are built to support this fundamental shift.

This document provides guidance on the adaptation of levels of dose and image quality to clinical tasks, taking advantage of the wide dynamic range offered by digital imaging equipment. Practical aspects that depend on specific x-ray techniques will be covered in a separate document.

1. INTRODUCTION

(1) **Key points in this section:**

- **Implementation of optimisation requires frequent monitoring and analysis of performance, feedback of experience, and regular review to provide continual refinement of the service to the patient.**
- **Ensuring that patient doses are appropriate is an issue with images in digital form because the appearance can be adjusted for optimal viewing, so it may be difficult to determine whether the dose level is appropriate.**
- **Imaging equipment such as CT scanners has become more complex. Successful operation, making use of resources available to keep doses at a reasonable level, requires radiologists, radiographers and medical physicists with high levels of expertise, working together as a team.**
- **Image quality will affect diagnosis and so influence clinical risk, while radiation dose involves a small health risk. The clinical risk from having sub-optimal image quality because the dose used was too low is likely to outweigh the small additional risk from the extra radiation exposure.**
- **As more technical optimisation features and quality management systems evolve, the optimisation process will extend to focus more on individual patients and procedures, including artificial intelligence (AI), based on clinical indication.**

1.1. Background

(2) X-rays have been used for obtaining images of the body to aid in diagnosis of disease ever since their discovery by Roentgen in 1895. X-ray imaging has provided an invaluable aid in diagnosis, follow-up and management of patient treatments, and over the last few decades, with the rapid development of interventional techniques, it has allowed many complex procedures in cardiology and in specialities dealing with other parts of the body to be performed with reduced surgical intervention, improving patient comfort and survival. X-ray imaging procedures are the most widely used form of medical imaging and make the largest contribution to human exposure to ionising radiation from artificial sources. As such an x-ray examination carries an associated risk that, although not large, must be taken into account when patients are imaged.

(3) The benefits to the patient undergoing a radiological procedure that is going to influence management of their treatment or aid in diagnosis will almost always outweigh the risk resulting from the radiation exposure. However, if this is not the case, then performing the exposure is not justified. Awareness of associated risks has encouraged the development of facilities and tools on equipment to allow radiation doses to be kept as low as reasonably achievable (i.e. according to traditional ALARA principle). Those using x-rays need to understand the imaging process and the interplay between different factors, as well as being trained in the practical techniques, in order to ensure patient radiation doses are kept to a minimum to obtain the image quality required for the specific imaging task. The need for this understanding has become more crucial with the increased complexity of computed tomography, digital radiography, and interventional x-ray equipment, which can deliver significant radiation doses if used incorrectly. This need to manage the increased complexity of evolving medical imaging technology and applications reinforces the motivation for the

different optimisation categories (C, B, A) presented in this report, in order to elucidate the framework and processes to reach more advanced optimisation.

(4) The exercise of a) clinical judgement in justifying the need for imaging and of b) technical skills in the optimisation of radiological procedures directly reflect two of the fundamental principles of radiological protection. Optimisation is defined as the process of determining the level of protection and safety to make exposures ALARA with economic and societal factors being taken into account (ICRP, 2007b). However, evolving technical optimisation features and quality management systems will extend the optimisation process to focus more on individual patients and procedures based on clinical indication. This is an extension of the ALARA optimisation principle as applied to patients (Oenning et al., 2018), since indication-orientation and patient-specificity connect the optimisation process directly into the justification process, and enable them to be made mutually supportive, comprehensive, and finally a unitary process for radiological protection.

(5) Both justification and optimisation have become increasingly important with the passage of time as part of the effort to ensure that patients receive the best possible service from their imaging departments. The twin goals are to ensure that patient doses are not only low enough to justify the particular examination, but also through optimisation, are kept as low as reasonably achievable without being reduced to the extent that the level of image quality required for the clinical task is jeopardised. The mutual connection between optimisation and justification may be strengthened with more indication-oriented and patient-specific optimisation processes in the more advanced categories described in this report. Furthermore, increasing access to diagnostic and clinical data by evolving radiological information systems (RIS), picture archiving and communication systems (PACS), and hospital information systems (HIS) will help to implement a more advanced comprehensive process of justification and optimisation. The expansion in the use of radiological imaging worldwide in recent decades coupled with the introduction of new digital technologies that require higher levels of expertise to operate makes the effective practice of optimisation techniques more important than ever. The welfare of patients and the population at large will be enhanced if radiation exposures resulting from x-ray examinations can be kept to a minimum without reducing the medical benefits.

1.2. Justification and optimisation of medical exposures

(6) The three principles of radiological protection practice were set out in ICRP *Publication 105* (ICRP, 2007c). The first two of these, justification and optimisation, apply to medical exposures, while the third, dose limitation, does not. The patient should receive a dose from imaging that is consistent with the clinical questions that need to be answered. Instead of applying dose limits, radiology and other medical imaging facilities aim to keep doses at a reasonable level based on good practice and can use reference levels as a guide. The present publication is concerned with the optimisation processes important for maintaining acceptable dose levels. To achieve this requires input from different clinicians and healthcare professionals working together as a team within an organisation that provides a structure that facilitates the process.

(7) Before discussing optimisation in detail, it is worth saying something about justification, as the two principles operate together to reduce unnecessary exposure. Justification requires the radiologist / radiological practitioner to weigh the expected benefits from imaging against the potential radiation detriment, and to take into account available alternative techniques that do not involve exposure to radiation. For radiological practitioners to make such decisions, they

should understand the clinical indications and the health status of their patients in order to determine which imaging tests or fluoroscopically guided interventions (FGI) are appropriate. The process of justification in the medical context will not be considered here, except in relation to highlighting the need for radiological practitioners, whether they be radiologists or other healthcare professionals, to always be provided with the relevant clinical history for the patient who is to undergo the procedure, in order that the justification process can take place. The collaboration between the referring clinician providing the information about the patient's condition to the radiological practitioner is the first step in the process, but it is crucial for ensuring that the imaging task is adapted to the clinical need, so that optimisation is carried out satisfactorily.

(8) ICRP explained the concept and principle of optimisation as applied to medical exposures in *Publication 73* (ICRP, 1996). This publication identified that in medicine the optimisation of protection is usually applied at two levels: 1) the design and construction of equipment and installations, and 2) the day-to-day methods of working, which also include the quality assurance programme to maintain performance with audit of patient doses against diagnostic reference levels (DRLs) (ICRP, 2017). However, these are not sufficient to ensure that the radiological protection of procedures is optimal, as there will be continual development in both equipment facilities and the knowledge and skill of the operators that should feed into a process of steady improvement. Therefore, the proper training of operators with periodic sessions to update knowledge on new techniques and improved facilities on equipment is essential, as is the ongoing monitoring, review, and analysis of performance necessary to ensure continuing improvement in every aspect of the imaging process. Optimisation is not a static process to be ignored and forgotten once it has been achieved, it requires constant attention with frequent monitoring and analysis of performance, feedback of experience, and regular review to provide continual refinement of the service to the patient. This last component is key to achieving higher levels of optimisation.

(9) ICRP requires that in medicine, emphasis should be placed on the optimisation of protection in the working procedures (day to day practices and methods carried out by staff), as well as in the design of equipment, because both have a direct influence on the care of patients. *Publication 73* states that the basic aim of the optimisation of protection is to adjust the protection measures relating to the application of a source of radiation within a practice in such a way that the net benefit is maximised. It recognises that many features that influence the net benefit are outside the scope of radiological protection, including the management structure, financial provisions, and most aspects of building design and location.

(10) The concepts involved can be set out in simple terms, but their practical application can range from simple common sense to complex quantitative processes. In selecting the provisions for protection in relation to a source, there is always a choice of options. Some choices are between discrete options that can be adopted or not. For example, in radiography, use can be made of a grid or not, depending on the examination requirements. Other choices are more quantitative, for example, the choice of thickness of copper filtration in the x-ray beam or of the duration of a fluoroscopic examination.

(11) Subsequent to *publication 73*, ICRP prepared a publication dedicated to the topic of optimisation of protection (ICRP, 2006), but this did not consider issues of optimisation specific to medicine. The technical requirements for optimisation with regard to the various modalities used within radiology, namely radiography, fluoroscopy, and computed tomography (CT) are very different. ICRP has therefore, prepared publications that deal with practical aspects of optimisation of radiological protection in relation to the various medical imaging techniques. The content of these earlier publications will be described briefly in section 1.6. The present publication considers the overall approach to optimisation in relation to digital

radiology, rather than the application of specific technological knowledge and experience, and practical methodologies. The whole process requires clinicians and healthcare professionals to work closely together within an organisation structured to aid improvement in order to achieve a level of optimisation that is adequate for the purpose.

1.3. Risks from radiation exposure due to medical imaging

(12) Optimisation of radiological protection in diagnostic imaging and image-guided procedures entails the provision of image information that is of adequate quality for diagnosis (or guiding interventions), with a dose that is as low as reasonably achievable with the imaging facilities available. Thus, the aim is to maximise the benefit to the care outcome for the patient, while minimising any potential detriment from radiation exposure. Putting it the other way around, the aim is to minimise radiation dose without prejudicing the diagnostic utility of the procedure.

(13) At this point something should be said about risks from radiation in order to establish the context for optimisation. Potential effects of radiation exposure are tissue reactions (deterministic effects that occur in days, weeks, months following an exposure) and stochastic effects (risk of induced cancer or hereditary effects in the long term). Under normal circumstances there will only be a possible occurrence of tissue reactions from interventional cardiology or radiology for a very limited cohort of patients with serious medical conditions. However, there is also a risk of lens opacities from exposures of the eyes to doses over 500 mGy and these may develop with time (ICRP, 2012). Methods for the avoidance of tissue reactions are addressed in *Publications 85* and *120* (ICRP, 2000b, 2013a). In routine diagnostic imaging investigations, the main concern when using x-rays to image the body is the risk of stochastic effects, especially cancer. Our knowledge of the risks to human health from radiation exposure is derived from epidemiological studies of populations exposed to doses of radiation that are large compared to those from diagnostic imaging exposures (ICRP, 2007b). The populations that can be included in such studies are necessarily limited. The most important group is the surviving members of the Japanese population who received substantial whole-body radiation doses when atomic bombs were detonated over Hiroshima and Nagasaki. Over 100,000 of these individuals have been studied in detail, and excess numbers of cancers found. The group comprised a population of all ages and both genders, and the ICRP and other international organisations, such as the Biological Effects of Ionising Radiations (BEIR) Committee and the United Nations Scientific Committee of the Effects of Atomic Radiation (UNSCEAR), use epidemiological data derived predominantly from this group to estimate risks of cancer by extrapolating the dose-effect data down to the lower dose levels used in medical imaging (ICRP, 2005, 2007b, 2021). Results from studies on this group have shown that risks of cancer induction depend on the organ irradiated. They also indicate that the risks are generally greater for children and adolescents, and lower for those over 60-70 y, primarily because their expected life span is shorter.

(14) Although the evidence is derived predominantly from the Japanese survivor group, other studies on radiation workers in the nuclear industry, patients receiving high localised radiation doses from medical therapies, or exposure during radiation accidents, provide further evidence that the risk exists. It is often only through meta-analyses combining data from several studies that results for population sizes with sufficient statistical power to show a link between radiation and cancer are obtained. The epidemiological results are consistent with a linear dose-response relationship at low dose between the risk of cancer induction and mean absorbed organ doses below 100 mGy and, based on this, for purposes of radiological protection, a linear

no-threshold (LNT) model is used to extrapolate down to lower doses in order to estimate potential risks (ICRP, 2005). Recently NCRP has published a review of epidemiological studies, including those of the atomic bomb survivors, pooled results for nuclear industry workers, and data from other exposed populations, undertaken in order to assess the quality of the data and evaluate the support that they provide for the LNT model (NCRP, 2018; Shore et al., 2018). NCRP judged that, although the risks are small and uncertain, the available evidence provided broad support for a LNT model as the most pragmatic approach for radiological protection. Although the atomic bomb survivors received their radiation dose as a single exposure at one point in time, other populations such as nuclear industry workers were exposed to small doses incrementally over time, and the cumulative value was tens of mSv whole body dose. In addition, more evidence is emerging from recent reviews of epidemiological data that doses from exposures below 100 mSv are associated with cancer risks in both children and adults (Lubin et al., 2017; Little et al., 2018, 2022; Hauptmann et al., 2020; Rühm et al., 2022). It is within this context that the risks from medical exposures should be appraised.

(15) Medical exposures are designed to investigate conditions that generally only affect certain parts of the body and so regions of the body irradiated in any imaging procedure are localised. Moreover, the x rays are attenuated as they pass through the body, so superficial tissues receive higher radiation doses than ones deeper within the body. Therefore, the organs and tissues irradiated and the distributions of radiation dose within individual tissues are different for every type of examination, and also depend on the size and shape of the body for each patient. Since individual tissues also vary in their sensitivity to radiation, this means that the risk of any stochastic effect from every examination will be different and depend on the exact conditions of exposure, the age and the size of the patient (ICRP, 2021). The mean absorbed doses to organs and tissues from diagnostic medical exposures are generally in the range from fractions of a mGy to tens of mGy. The potential detriment to health from sequences of exposures performed for diagnosis and management of disease could be significant if dose levels are higher than they need to be, although patients form a sub-group of the general population who may have other competing morbidity.

1.4. Optimisation in the context of medical imaging

(16) Radiographic imaging is in essence a fairly simple procedure, with x rays being used to produce a ‘shadow’ image of tissues in the body. Since components of the tissue attenuate the x rays to different extents, structure can be visualised within tissues. The denser abdominal and pelvic tissues attenuate x-ray beams more than the lung tissue, but attenuation of the x-ray beams also depends on the energies of the x-ray photons. Any potential health detriment will depend on the tissues and organs irradiated, and the distribution of absorbed dose within them. Since attenuation in tissue means that organs closer to the surface receive higher doses, so chest x rays are performed with the patient facing away from the x-ray tube, so that the doses to the female breast and other more radiosensitive organs that are closer to the anterior surface are lower. Simple examples of poor optimisation are if a larger field size is used for a radiographic exposure than is necessary, or if a chest x ray is performed with a lower energy beam (e.g. 70-80 kV) from which little scattered radiation is generated, but an anti-scatter grid is inserted behind the patient, which also attenuates the primary beam, as these will increase the dose to the patient. The skill of the radiology professionals encompasses selection of the best imaging exposure factors, equipment, and technique available for each type of examination and personalised for each patient depending on their size and weight. Approaches have changed as techniques with digital equipment have evolved and become more sophisticated. For instance

the use of contact shielding for the gonads is no longer considered appropriate, as it is ineffective in reducing internal scatter that is the main source of radiation dose to the gonads and may obscure pathology or introduce artefacts that will degrade image quality (Hiles et al., 2021).

(17) The appearance of images recorded and stored in digital form can be adjusted through post-processing to give an acceptable range of grey levels for optimal viewing (ICRP, 2004). If a much higher dose is given than is appropriate, the image may appear slightly better or essentially the same, but this may be difficult to determine from simply viewing the image. A high dose in digital radiography will not produce a black image, as it would with film. However, digital images offer many advantages. Acceptable images can be achieved with lower dose levels when the radiological contrast is high. Thus, digital imaging has the potential to allow images to be obtained with lower exposures. In theory it will enable exposure levels to be adapted to the diagnostic requirements of particular examinations. However, this facility is often not considered and standard image detector exposure levels are often used for a wide variety of examinations. In addition, images can be processed to enhance features of relevance to diagnosis. The relevance of image processing in digital radiology is much more significant than anticipated from the first glance since the digital image data typically includes a range of thousands or even tens of thousands of greyscale values whereas the human eye can see less than a thousand separate greyscale levels even in optimal lighting conditions and when using advanced medical displays (Kimpe and Tuytschaever, 2007). This emphasises the potential of digital image processing in bringing the diagnostic features more clearly visible for human (radiologist) eyes in the final presented images. Achieving the correct balance between dose and image quality becomes a more complex task, but with proper application digital radiology should enable optimal image quality to be achieved, often with lower dose levels.

(18) As technology develops more sophisticated imaging equipment such as CT scanners are being purchased by countries that do not yet have the necessary level of professional expertise available locally that may exist in countries which have been operating such scanners for many years. CT scanners have become more complex and although they have more capabilities to enable doses to be kept at a reasonable level, achieving this requires a high standard of knowledge from clinicians, skill from the operators, and scientific expertise from medical physicists. If these are not in place, doses delivered to patients could be unnecessarily high without staff being aware that anything is wrong. Even in countries with highly developed healthcare systems, optimisation is frequently not fully implemented. For example, radiation accidents involving tissue reactions from CT scanners have been reported in the United States, where the necessary expertise might always have been expected to be available (ICRP, 2007a; Martin et al., 2017).

(19) There have been substantial developments in the application of fluoroscopically guided interventions (FGIs) during recent decades. These allow surgical procedures to be performed with less invasion of the body than is required by conventional surgery, resulting in lower risks, shorter recovery times, and lower costs (Maudgil, 2021). FGI is frequently the method of choice for complex interventions by a variety of medical specialists (UNSCEAR, 2008), so that numbers of procedures have increased substantially and these may be performed in a variety of settings and sometimes by clinicians with less training in radiological techniques and awareness of radiation exposure than radiologists. In addition, the increasing complexity of the procedures that are now possible means that longer exposure times may be required that carry a potential risk of radiation tissue reactions in the skin (ICRP, 2000b, 2010, 2013a; IAEA, 2010).

(20) As the level of sophistication develops, the variety and complexity of procedures that are possible increases (NCRP, 2019) and the level of optimisation should be increased in

parallel. Recent technological innovations that are now being implemented have the potential to provide a higher degree of optimisation through analysis of the levels of image quality necessary for imaging different organs, tissues, and pathologies, through the collation and analysis of image related data. However, effective use of these techniques requires that continual attention is paid to monitor the performance of equipment and develop examination protocols based on experience gained.

(21) Individual patients may undergo many imaging procedures from which they could receive effective doses reaching hundreds of millisievert (Brambilla, et al., 2020; Rehani et al., 2020). Although the majority of the patients who receive multiple exposures will be in the later stages of life, there are some children with particular health problems that require frequent follow-up with multiple imaging. Special attention should be paid to developing care plans for these individuals in which the frequency and performance of imaging is optimised.

1.5. Image quality levels and clinical diagnostic requirements

(22) Optimisation in simple terms involves achieving a balance between radiation dose and image quality. First and foremost, it requires provision of clinical images for individual patients that are of sufficient quality to ensure accurate and reliable diagnoses, in order to enable correct care decisions to be made. In addition, the radiation doses used in acquiring such clinical images should be adjusted so that, while being adequate to produce the images, they are minimised to the level appropriate to the applied imaging technology. Although many users may only have limited awareness of radiation doses for the examinations they perform, dose is a quantity that can be measured or calculated with relative ease. So, when optimisation programmes are set up, there can be a tendency to place undue emphasis on dose reduction, which can be quantified or read directly from the equipment, ignoring the potential detriment to the provision of clinical information, which in almost all cases is a far more important factor for the quality of care and effective clinical outcome.

(23) The level of image quality will affect diagnosis and the aim is to achieve a balance between the clinical and radiation risks in order to minimise the overall risk. In many imaging indications, the clinical risk related to possible sub-optimal image quality from an examination in which the dose is lower than the optimum is likely to outweigh the small additional risk from using a higher radiation exposure. A patient will not benefit from an examination that is incapable of visualising changes in the diseased tissue of interest. The main focus should therefore be on maximising the benefit-to-risk ratio. If the image quality is too low, the dose is wasted no matter how low it might be. There is a consequent clinical risk of misdiagnosis, which may increase as image quality declines (Fig. 1.1), and in such situations, there may be a need to increase the dose (Samei et al., 2018). Therefore, while in the general context of the system of radiological protection optimisation is understood as keeping doses ALARA, in the case of medical imaging this means delivering the lowest possible dose necessary to acquire adequate diagnostic images: this is best described as ‘managing the radiation dose to be commensurate with the medical purpose’ and may sometimes require the dose to be increased (ICRP, 2007a,c). Managing the radiation dose for any application requires an understanding of the way in which an image is formed and how different factors influence both the quality and the radiation dose received by the patient (Martin et al., 1999a).

(24) Ultimately, maximisation of the benefit-to-risk ratio for the patient involves the objective of measuring the image quality and the entire optimisation process in terms of clinical outcome. This objective is related to clinical effectiveness and, with more controlled scenarios, to clinical efficacy. Since clinical outcome depends on a very large number of factors and

clinical data types, such outcome quantification cannot be done with any simple model or modality. Therefore, a big data approach using methods related to artificial intelligence would seem to offer considerable potential for the handling of such multi-dimensional data, constructed from many clinical data types, and involving complex correlations and inter-dependencies, and is likely to become increasingly important in the future. This would enable indication-oriented and patient specific optimisation methodology to be implemented as an organisation-wide and consistent process, with measurable effectiveness and extensive use of other performance indicators.

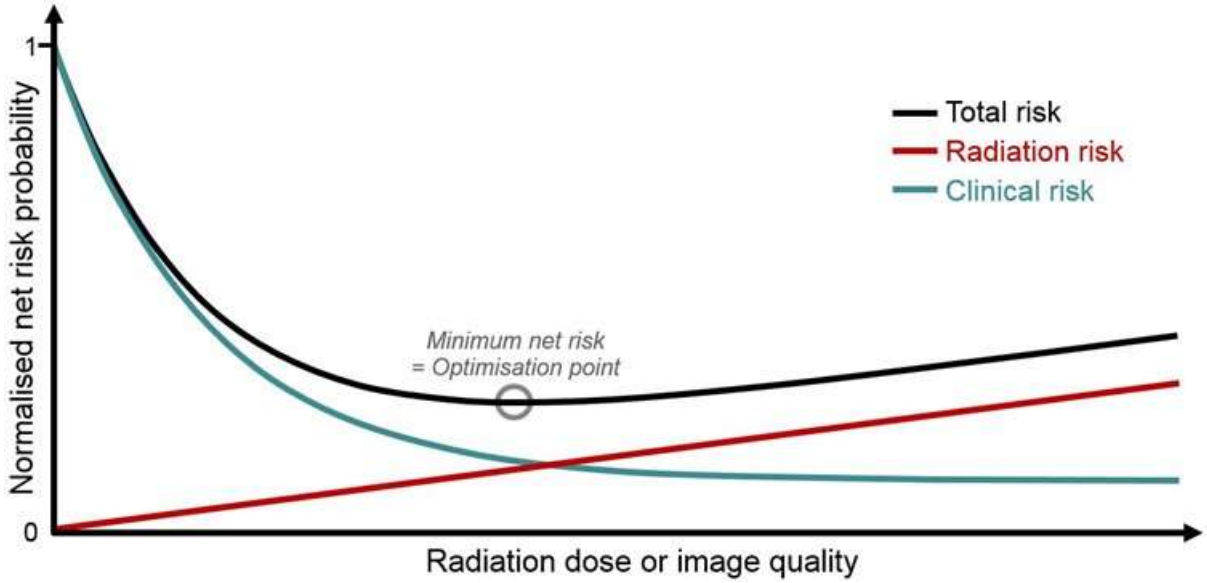

Fig. 1.1. The total net risk from radiological examination is a sum of radiation risk and clinical risk. The radiation risk is assumed to increase linearly with dose according to the LNT model. while clinical risk is assumed to decrease with dose as the image quality is improved to provide adequate clinical information. In this example the clinical risk decreases according to an exponential model, but there will be a lower limit where residual clinical risk is maintained regardless of the imaging method. The minimum net risk for the summed components will be the optimisation target point. (Adapted from Samei et al., 2018).

(25) This report addresses both radiation dose and image quality. Since adequate assessment of an image is both a clinical task and reader dependent it is not a trivial matter to decide what quality of image is adequate for the clinical task in hand (NCRP, 2015). Significant reliance is placed on the judgement made by the radiologist, but opinions vary among radiologists about image quality requirements and less experienced radiologists may in fact need a higher level of image quality in order to make a diagnosis. Thus, quantification that can aid in a decision about the appropriate level of image quality is difficult when it is based on subjective evaluation of image quality against quality criteria. The tools used for measurement of image quality for image receptors during performance tests relate to the ability to detect low contrast objects of varying size and shape within a uniform background and depend on the noise level and texture. These cannot easily be compared and translated into analogous clinical tasks. Research groups are investigating methods of image quality analysis that can be more closely allied with clinical tasks using simulations with model observers or by artificial intelligence-based methods. Although the field is developing, there is still some way to go before such methods provide solutions which can be implemented more widely in clinical practice, but their application is likely to be important in the future.

(26) The optimisation process may involve not only selection of the appropriate level of image quality but tailoring the examination protocol to the clinical need of each individual patient (Samei et al., 2018). Decisions may have to be made about the extent of the imaging required to answer the clinical question (e.g. this might include the possible need for rotational 3D-imaging in image-guided procedures). In some countries this option is included in the initial justification, but reasons for electing to carry it out are part of optimisation. As more technical optimisation features and quality management systems evolve, the optimisation process will extend to focus more on individual patients and procedures, including artificial intelligence (AI), based on clinical indication. Adapting the protocol to individual patients will also have to take their medical conditions/ limitations into account.

1.6. Coverage of optimisation in previous ICRP publications

(27) *Publication 34* was the first document published by ICRP on clinical radiology during the era of film screen radiography (ICRP, 1982). Since that time the field of radiology has become predominantly a digital medium and the variety of modalities and techniques for adjusting imaging parameters has increased substantially. *Publication 73* on radiological protection and safety in medicine (ICRP, 1996) included a section on optimisation and stressed the importance of adapting working procedures and subsequently *Publication 101b* 'The Optimisation of Radiological Protection: Broadening the Process' discussed optimisation of practices in general (ICRP, 2006). Operational procedures, good practices, and qualitative approaches were incorporated into optimisation, so that it became a more judgement based decision-making process and *Publication 105* expanded on the application in medicine (ICRP, 2007c). Since that time, there have been a series of ICRP publications on specific modalities within radiology that have included practical methodologies of optimisation produced to address the needs arising from the development of new technologies.

(28) *Publication 84* entitled 'Pregnancy and medical radiation' provided clarification on risks to the embryo and foetus from medical exposures (ICRP, 2000a). The transition from film/screen to digital radiography marked a significant change in practice and *Publication 93* 'Managing patient dose in digital radiology' was prepared to facilitate the transition (ICRP, 2004). In the meantime, the rapid development of fluoroscopically guided interventions had led to the first cases of tissue reactions in radiological imaging. A report on avoidance of radiation injuries was published in response to this (ICRP, 2000b). Other publications have since followed to provide guidance following the development in the use of fluoroscopically guided procedures by other specialities outside the imaging department (ICRP, 2010) and the increased use of interventions in cardiology (ICRP, 2013a). ICRP has two publications that cover optimisation in terms of managing patient dose in computed tomography (CT), an initial one from 2000 and a subsequent one on multi-slice CT (ICRP, 2000c, 2007a), and in addition a report on cone beam CT (ICRP, 2015). The specific needs and difficulties in diagnostic and interventional imaging of paediatric patients were addressed in *Publication 121* (ICRP, 2013b).

(29) An important component of the optimisation process is having information on doses that patients are receiving and a knowledge of whether these dose levels are reasonable. A tool that ICRP adopted over 20 years ago to aid in this is the DRL, the application of which is described in detail in *Publication 135* (ICRP, 2017). This reference level provides an indicative dose linked to requirements for good practice adopted among professional practitioners across the country or area. DRLs are a tool that can aid in the identification of x-ray facilities where dose levels for an examination are higher than is appropriate, through the making of comparisons between the median dose level in the facility and the DRL. Radiology facilities

should aim to keep their median dose levels for particular examinations below the relevant DRL. More guidance on use of the DRL tool, including information about how DRLs are derived and applied, as well as actions to be taken if they are exceeded is given in *Publication 135*. DRLs provide a step along the road to optimisation but are a tool and the establishment of DRLs is not an end in itself. The efficient way to use DRLs is in combination with patient radiation exposure monitoring systems, which have become available from several providers, either commercial or for free use. Exposure monitoring systems have also been actively developed to contain more features such as protocol management, and connections to other hospital systems (e.g. PACS) that can contribute to making optimisation a continual process of improvement.

1.7. The process of optimisation

(30) The present publication will aim to provide a general coverage of optimisation as a process and how this might be implemented in varying situations. The different components of optimisation discussed in section 1.2 are listed in Table 1.1. They relate to the basic radiology installation and the working methods, but these by themselves will not automatically lead to optimised imaging. More attention is given here to different aspects of the process of optimisation, as experiences have shown that there are several elements that need to be in place if optimisation is to be achieved. There is a need for individuals with professional skills of radiography, radiology and physics to work together. The skills will not be acquired without proper training.

Table 1.1 Components of optimisation.

Levels of optimisation
1) Design and construction of equipment and installations 2) Day-to-day methods of working including quality assurance programme and audit of patient doses
Essential aspects to ensure a successful optimisation process
• Proper training of radiographers, radiologists, medical physicists and other clinicians operating x-ray equipment in their areas of competence with respect to new equipment with improved facilities, and periodic training sessions to update their knowledge of new techniques • Ongoing monitoring, review, and analysis of performance feeding into continuing improvement in every aspect of the imaging process

(31) Since there are several groups of staff with different skill sets, optimisation also requires collaboration between the professional groups, and without this, progress is unlikely to occur. Performance tests on equipment may be carried out, but unless physicists feed back the information to users, assessments are made of the optimal equipment settings, and adjustments are made to clinical protocols, there will be little progress. Physicists might provide dose information from surveys and trace technical aspects related to image quality, but it is the radiographer and radiologist who can judge whether the quality of the clinical image is adequate. Unless the three groups work together to identify when doses for any procedure are

higher or substantially lower than expected, or that the image quality is higher than necessary or too poor for diagnosis there will not be any change in practice. The staff groups need the understanding from training and experience to be aware of dose levels and their dependence on different factors that affect image quality. They need to be able to make judgements and determine reasons for any deficiencies and be able to adjust protocols and procedures to address them. Encouraging staff engagement in these aspects enables optimisation to become a habit that is part of routine practice.

(32) There need to be systems in place to manage optimisation: ensure that monitoring, review, and analysis of performance are part of an ongoing process, that clinical protocols are established taking account of available data, and that results are applied across the whole organisation.

(33) This report considers how the different aspects of the optimisation process might be addressed by radiology services and countries with varying levels of infrastructure and optimisation tools. It will attempt to provide guidance across the full spectrum from countries with limited expertise through to advanced services with access to patient radiation exposure monitoring and image quality assessment software, taking into account the greater flexibility in image processing and presentation afforded through new techniques. Section 2 will deal with management of the x-ray equipment through its life-cycle, section 3 will examine the structure of the optimisation process, section 4 will review practices in measuring and analysing patient dose data, and section 5 will consider the assessment and requirements for image quality in more detail than in previous reports and section 6 will consider the requirements and provision of training, which is a key element in establishing a successful optimisation programme.

(34) The target audience for this publication includes not only radiologists, radiographers, medical physicists, and cardiologists and other clinicians and healthcare professionals operating x-ray equipment, who are deal directly with the processes described, but also managers involved in allocation of resources for equipment and training, x-ray equipment vendors, x-ray engineers, applications specialists, and regulators.

2. THE X-RAY INSTALLATION AND X-RAY EQUIPMENT LIFE CYCLE

(35) **Key points in this section:**

- **The equipment life cycle is a well understood concept, and describes medical equipment, including imaging equipment, from 'cradle to grave'. The stages in the life cycle of equipment are all important and include justification, acquisition, installation, acceptance, commissioning, user training, clinical use and disposal or alternative use.**
- **Professional skills, methodology and process all play a vital role in the management of the equipment life cycle; understanding and managing it appropriately is essential if optimisation is to be achieved.**
- **Optimisation is a continual process and is inextricably bound up with the minutiae of the imaging equipment life cycle. Each element of the life cycle contributes to successful optimisation. QA of the whole system helps to ensure this is achieved through focussing attention on the many different aspects of performance that need to be maintained.**

2.1. The life cycle of medical imaging equipment

(36) Setting up a new or replacing an existing x-ray imaging service requires careful planning by a team of radiological professionals. The equipment life cycle is a well understood concept, and describes medical equipment, including imaging equipment, from 'cradle to grave'. X-ray equipment is procured through a tender process wherein equipment suppliers are invited to submit a bid to supply the equipment or services. The team need to prepare a technical specification based on the clinical requirements, stating what the equipment is to be used for, where it is to be installed, the major system components, any accessories that might be required, and include the maintenance and repair arrangements. Once a contract has been agreed, the equipment will be installed according to agreed standards, personnel trained in its use, and a quality assurance (QA) programme put in place to ensure that standards are maintained.

(37) The initial conception of the clinical need for medical imaging must first be developed into a proper robust justification for purchase. This is the embryo stage of the life-cycle shown at the top of Fig. 2.1. The lifecycle of imaging equipment should be included in a healthcare organisation's planning process which should aspire to incorporate a systemic approach to the acquisition, deployment, maintenance, quality control, repair and disposal or alternative use of imaging equipment. Every stage in the life cycle is critical in terms of optimisation of patient protection. Professional skills, methodology and process all play a vital role in the management of the equipment life cycle; understanding and managing it appropriately is essential if optimisation is to be achieved.

(38) Fig. 2.1 shows the basic life cycle of x-ray equipment and how it involves a continual sub-cycle to maintain performance and improve optimisation, once the equipment is put into clinical use. It also shows the acquisition process in some detail; appropriate acquisition is essential if optimisation is to be achieved. The stages are described below; with an emphasis on relevance to optimisation.

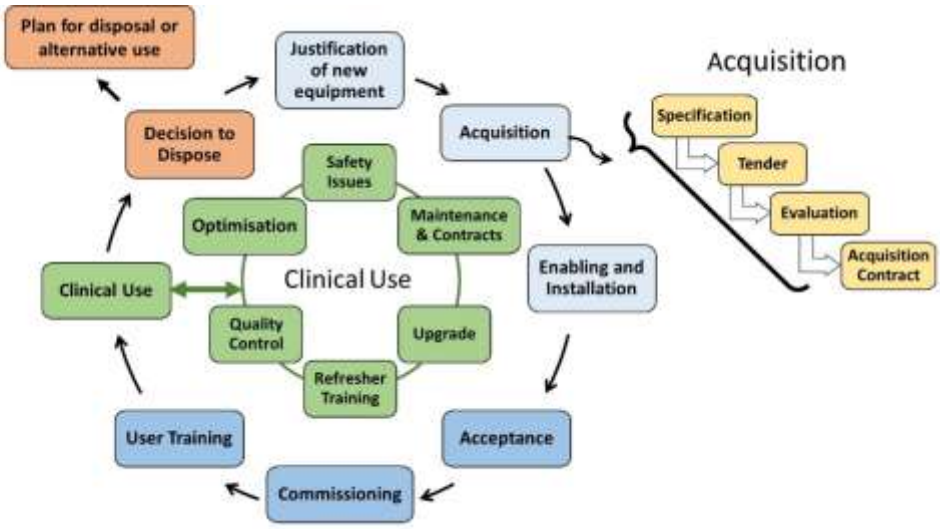

Fig. 2.1 The imaging equipment life cycle.

2.2. Acquisition of x-ray equipment

2.2.1. Justification of equipment

(39) The stages in the life cycle of equipment include justification, acquisition, installation, acceptance, commissioning, user training, clinical use and disposal or alternative use. The procurement of all medical imaging equipment should be justified, both in terms of clinical need and radiation dose. Justification should be evidence driven and take into account present and future clinical applications and revisions of workflow whilst ensuring that there is no unnecessary proliferation of equipment. Justification of new or replacement equipment requires the involvement of radiologists, radiographers / imaging technicians and medical physicists.

2.2.2. The acquisition and procurement process

2.2.2.1. Specification

(40) Once procurement of equipment has been justified, to reduce the possibility of inappropriate devices being purchased it is essential that a full performance specification of the entire system is established before any purchases are made. In the context of optimisation, the performance specification should include consideration of the intended clinical use of the equipment and also technical requirements relating to patient dose and image quality.

(41) The type and amount of training required should be specified as should the manner (e.g. procedures and their resulting technical documentation) in which the manufacturer / installer demonstrates that the equipment supplied actually does meet the performance specification and local regulatory requirements (see section 2.3.1). Maintenance requirements should also be included in the specification, as should detail of any regulatory requirements that the equipment will be expected to meet. Delivery timescales should also form part of the specification.

(42) Specification is a task that requires input from radiologists, radiographers / imaging technologists, radiology managers, medical physicists, Information and Communications Technology (ICT) professionals and procurement experts. The specification document should address the issue of enabling and infrastructure work required - for example, what level of

connectivity is required for the equipment to function appropriately, and how the vendor will address those requirements within the organisation's ICT infrastructure. Specifications should also include the resourcing and vendor activity involving the initial optimisation of equipment imaging or exposure protocols. This will ensure that the purchase not only includes the technology and applications, but also the correct setting of the technology that are appropriate for the first practical phase of optimisation. In our modern world with wide connectivity to networks, it is also important that data security and data safety issues are considered in the specification.

(43) In the case of used or refurbished equipment, the specification should be clear that the equipment should function as originally intended and meet all the performance and safety requirements that it did when new. IEC 63077 describes and defines the process of refurbishment of used medical imaging equipment. (IEC, 2019b).

2.2.2.2. Tender, evaluation and acquisition

(44) A tender comprises the specification and terms and conditions under which the equipment is to be purchased. Responses to the tender will form the basis for the evaluation process, so it is important that the questions posed by the specification document and stipulations regarding terms and conditions are correctly formulated. The tender may require the vendor to identify options for the disposal of redundant equipment.

(45) On receipt of tender returns a multi-disciplinary group comprising radiologists, radiographers / imaging technologists, radiology managers, medical physicists, biomedical engineers, ICT professionals and procurement experts should convene to consider the responses from those vendors offering their products. Evaluation should be carried out in an objective manner against predetermined criteria in order to maintain neutrality and to ensure that the most optimal equipment or system is actually chosen. After evaluation the acquisition contract can be placed, and lead in times identified. The contract should address all of the items included in the specification and the associated terms and conditions, including the initial optimised protocol settings.

2.3. Enabling and installation of x-ray equipment

(46) Enabling and installation are essential components of the equipment life cycle. Planning and construction of the x-ray room, protection, electrical and other services all need to be prepared beforehand, and consideration given to facilitating the appropriate movement of the patient and positioning of the attending staff. If the installation is not completed correctly or the correct infrastructure and building work is not carried out appropriately then at best delays will be encountered. There are likely to be ongoing issues throughout the life of the equipment. Basic connectivity issues and possible mitigation should be identified at this stage as should issues around licensing and registration (WHO, 2019).

2.3.1. Acceptance

(47) Acceptance testing is the process whereby the purchaser satisfies themselves that the equipment supplier has provided what has been ordered, that it is safe to use and that it functions according to the manufacturer's and purchaser's specification. This will involve both medical physicists and radiographers, in consultation with radiologists, and will include identifying the inventory and probably performing electrical and mechanical safety checks. Regulatory requirements may require demonstration of radiation safety, which should be carried out at this

stage. Acceptance tests often involve quantitative measurements to demonstrate that the equipment specification is met. These tests are vendor-specific and follow the vendor's methodology. IT connectivity and configurations to PACS and other relevant IT systems (such as image processing workstations and analysis servers) should also be verified at the acceptance.

(48) Depending on the complexity of the equipment and its specification the manufacturer / equipment supplier may be best placed to demonstrate conformity with certain aspects of the specification. For example, if the equipment specification quotes a Modulation Transfer Function (MTF) at a particular spatial frequency, then the installer can reasonably be expected to demonstrate this in some way, which may be by presenting the factory test sheet or may be by direct measurement. See section 2.2.2.1 on specification during the acquisition phase. The presence of operator and service manuals should be verified at this stage.

2.3.2. Commissioning

(49) In the commissioning phase, the purchaser should ensure that the equipment is ready for clinical use and establish baseline values against which the results of subsequent routine performance tests [constancy or quality control (QC) tests] can be made (IPEM, 2005). The set of QC tests should guarantee that the system parameters, modes and programmes are optimised for the intended clinical use and their deviations during the equipment life are within the acceptable limits. Protocols to be used for performance testing purposes should be identified - if clinical protocols are to be used for performance testing purposes, then commissioning should not take place until they have been installed.

(50) After any major work on the equipment the relevant baseline test may have to be repeated; for example, when a detector or x-ray tube is replaced. Commissioning should also address issues of interoperability in the case of highly complex digital imaging equipment (AAPM, 2019b).

(51) Clinical protocols for acquiring images should be evaluated at the commissioning phase and checked for consistency with other equipment operated by the healthcare organisation to ensure that to as great a degree as possible there is a systemic approach to imaging. In the case of digital radiography for example expected values of Exposure Index and technique factors should be established for routine examinations. Another example is that of CT, where all examinations for specific clinical indications in an organisation should be performed with similar protocols, or ones matched to give as similar a level of performance as equipment factors permit. As mentioned before, the purchase should not only include the technology and applications but also the optimised initial setting of the technology for clinical use.

2.3.3. User training for clinical use

(52) User training is critical for safe, optimised use of any imaging equipment. Organisations should have a policy for user training that should be part of the Quality Management Programme where it exists. Vendors have responsibility for providing users with training that includes a full understanding of imaging options available that can enable full optimisation. Initial user training should ideally be provided by the representative of the installer / manufacturer (applications specialist) following acceptance and before the equipment is put into clinical use. It is quite likely that not all end users of the equipment will be able to receive this initial training, which should also be given to anyone who is required to use it after installation. In this case, training should be delivered by an agreed cascade process. It is important that the most educated 'superusers' are identified for dissemination of the user

knowledge and provide practical guidance for subsequent refinement of protocol optimisation, as members of the local multi-professional team.

(53) Users need to understand the intended use and normal functioning of the device in order to use it effectively and safely. Training should cover requirements for equipment once in clinical use. For example, the UK Medicines and Healthcare products Regulatory Agency (MHRA, 2015) requires that where relevant, training should cover:

- Any limitations on equipment use;
- How to fit accessories and to be aware of how they may increase or limit use of the device;
- How to use controls appropriately;
- The meaning of any displays, indicators, alarms etc., and how to respond to them;
- Requirements for maintenance and decontamination, including cleaning;
- Recognise when the device is not working properly and know what to do about it;
- Understand the known pitfalls in use of the device, including those identified in safety advice from government, vendors and other relevant bodies; and
- Understand the importance of reporting device-related adverse incidents.

Training should be recorded for quality, continuing professional development (CPD) and safety purposes.

2.4. Operational requirements for x-ray equipment in clinical use

2.4.1. Quality control

(54) Quality control (QC) in medical imaging is a continual multi-disciplinary process and should not be confined to performance or compliance testing. QC involves collecting and analysing data, investigating results that are outside the acceptable tolerance levels for the QC programme, and taking corrective action to bring these results back to an acceptable level (Jones et al., 2015). The establishment of equipment performance and a QC programme constitute a tool in the process of optimisation of all radiology equipment. A QC programme should be structured and involve radiologists, radiographers / imaging technicians and medical physicist. A medical physicist, or in some cases a senior radiographer, should be appointed to supervise the whole programme, to oversee the records, and to review the data, especially in larger departments (IPEM, 2005). Ideally a QC programme should form part of a wider, managed, QA programme (see section 3.7).

(55) The move to digital imaging has resulted in a need to change the approach to QC in a radiology department, especially, but not only, in the field of plain film imaging. In traditional ‘pre digital’ imaging, the film itself acted as a final QC tool. Inappropriate exposure or processing would result in a film being marked as reject. This is no longer the case. However, standardised tools are now available to identify inappropriate exposures and should be put into routine use. Reject analysis and artefact identification should form an essential part of radiographer led QC.

(56) Some QC measurements may be undertaken by radiographers, but the programme, especially for more complex systems, should be performed under the supervision of a qualified medical physicist. They should understand how the system works, its characteristics, modes of operation and image acquisition, image quality requirements and image processing for different clinical programmes and clinical uses. They should be able to interpret test results and advise

on parameters to be measured. Close cooperation with the equipment vendor and service engineers is needed, as well as involvement of clinical staff operating and using the equipment.

(57) Routine performance testing should include task-specific evaluation of the imaging system, to reflect the intended clinical use of the equipment, and to guarantee production of required image quality at a reasonably low dose, commensurate with the desired clinical outcome. The test results should be compared with baseline performance values recorded at installation, and there should be criteria for acceptable changes in performance. These limiting values and the test frequency should be specific to the clinical task for which the equipment is used. If, during the equipment life, the clinical use of the equipment changes, that will require a change of the system settings and default programmes, and the QC baseline values and the QC programme will need to be modified accordingly. These tests should be carried out at regular intervals or after service or repair.

(58) The level of complexity of the performance test often dictates who performs it and how often it is performed. In some regions, performance testing is split into two levels 1 and 2. Level 1 tests are generally of a simple pass / fail nature and do not require sophisticated test equipment or analysis. They are performed by radiographers / imaging technologists at regular intervals that may be weekly or even daily depending on the equipment. Level 2 tests are carried out less frequently, perhaps at intervals of 6, 12 or even 24 months depending on the complexity of the system and require more resource and expertise. They are usually performed by a medical physicist, biomedical engineer, or vendor service engineer (IPEM, 2005; Jones et al., 2015) and results reported to radiology staff. Medical physicists should also undertake investigations when regular Level 1 QC tests identify performance factors that are out of tolerances and after any relevant changes in the system's acquisition (such an x-ray tube change) or major post-processing software updates.

(59) Simpler tests of image quality characteristics are based on observer evaluation using test objects (IPEM, 2005, AAPM, 2001) and the user should follow guidance on use of the specific object and be aware of its limitations. Reproducibility of the measurement conditions, including geometry, exposure settings, as well as the viewing conditions could have a significant impact on the results. More detailed image quality assessment may involve physical measurements to define conventional system characteristics like contrast, noise and resolution parameters represented objectively by technical parameters such as MTF (modulation transfer function), NPS (noise power spectrum), DQE (detective quantum efficiency) (Annex A). The future trend is towards more clinically realistic test objects that enable task-based evaluations of system imaging performance (see section 5.3.3 and Annexes B, C and D).

(60) Optimisation is a continual process and is inextricably bound up with the minutiae of the imaging equipment life cycle. Each element of the life cycle contributes to successful optimisation. QA of the whole system helps to ensure this is achieved through focussing attention on the many different aspects of performance that need to be maintained.

2.4.2. Upgrades and refresher training

(61) Upgrades occur at all points during the life cycle of imaging equipment. It is important that the purpose of an upgrade is understood by users and radiology management. It is equally important that appropriate commissioning tests are performed after an upgrade (software or hardware) and that staff groups are properly trained, either by an applications expert from the company or via cascaded documentation, as training is critical for safe, optimised use of any imaging equipment. Staff should be provided with refresher training throughout the life of the equipment and after any upgrade. All training should be recorded, which might be through a quality management system to provide ready access and traceability.

2.4.3. Safety issues

(62) An adverse incident is an event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of patients or other persons (MHRA, 2015). In the context of the optimisation of medical imaging, the definition of adverse incident could include exceeding a notification level for deterministic effects in FGI (NCRP, 2010; ICRP, 2013b). Equally, any overexposure to a patient (or staff member) that required reporting to a regulator would count as a safety issue. However, it is important to consider incidents with the potential to cause harm, so near miss evaluation and Local Adverse Event Reviews should be integral to the routine use of medical imaging equipment.

2.4.4. Contract management and maintenance

(63) All medical imaging equipment must be maintained appropriately. Often equipment comes with a limited warranty providing maintenance to vendors' specifications for a set time. Subsequent arrangements should be made using an evidence and risk-based approach to decision making – costs alone should not be the determining factor. Decisions about maintenance and contract management are often made by radiology management, and it is important that these key stakeholders have an understanding of the clinical implications of any decisions made. Maintenance contracts should be specific and auditable and those personnel (in-house or external) performing service and maintenance should be adequately trained and competent on the equipment they work with. Appropriate calibration of measuring equipment used in maintenance (to verify the performance or radiation output of the imaging equipment) should be a requirement of maintenance contracts. Contracts must ensure that schedules are available for planned preventative maintenance (PPM) and when equipment is returned to clinical use from either PPM or repair, service personnel should leave an indication of what changes they have made and whether those changes could impact on patient dose or image quality. If a repair or PPM has resulted in a potential change to image quality or dose, the radiographer / imaging technologist should perform a predetermined QC test in collaboration with or under the supervision of a medical physicist.

2.5. The end of clinical use and equipment disposal

(64) At some point during its life cycle, the equipment will become a candidate for disposal. This may be for example, because it can no longer be repaired or be brought economically back to acceptable specification by the manufacturer, it is no longer supported by the manufacturer, a lease has expired, it is obsolete, its clinical performance is no longer sufficient for the task, or repurposing is required. At that point, a decision to remove it from service might be made. However, a policy on removal from service is an essential part of device management (MHRA, 2015) and planning for replacement should be in hand before any decision is necessary. The planning cycle should include considerations on the justification for the new equipment that is to be obtained and go on to consider all of the other items in the equipment life cycle identified above. The cycle should take into account Health Technology Assessments where they exist.

(65) Because of their diversity and complexity, there are many ways that medical devices such as x-ray equipment can be disposed of. Options range from scrappage to resale for subsequent reuse. In most cases, consultation between the user and manufacturer or perhaps prospective reseller is critical especially for high-technology items in order to decide the best

way to dispose of them (WHO, 2017). No equipment should be scrapped without appropriate consideration of environmental impact and relevant regulatory controls.

(66) Charitable donations of x-ray equipment can be very helpful, may improve the efficiency of health facilities, may save costs of purchasing new equipment and may make some diagnoses or therapies accessible to patients, especially in resource-limited settings. Such donations can also cause health risks if their safety and performance are not verified prior to donation. They should also be furnished with full documentation sets in the correct language. The donor should also ensure that the infrastructure exists for appropriate and cost-effective maintenance and QC in the recipient country. As emphasised earlier, used or refurbished equipment, equipment should function as originally intended and meet all the performance and safety requirements that it did when new (IEC, 2019a).

(67) According to the World Health Organisation (WHO), quality problems associated with donated medical devices have been reported in many countries. These problems often result in receiving countries incurring unwanted costs for maintenance and disposal and may also create the impression that the equipment is ‘substandard’ and has been ‘dumped’ on a receiving country (WHO, 2017). Specific advice on the donation of medical imaging equipment can be found in WHO (2011) and THET (2013).

(68) All donated equipment should meet the suitability criteria defined by the WHO (WHO, 2011) namely:

- The equipment is appropriate to the setting
- The equipment is good quality and safe
- The equipment is affordable and cost-effective
- The equipment is easy to use and maintain
- The equipment conforms to the recipient's policies, plans and guidelines.

3. THE OPTIMISATION PROCESS

(69) **Key points in this section:**

- **The areas that need to be tackled first to improve optimisation in any facility depend heavily on the available tools, the technical infrastructure, and the multi-professional expertise available.**
- **The three aspects for developing goals and development steps in optimisation are:**
  - **Professionalism (professional skills and collaboration)**
  - **Methodology (methodology and technology)**
  - **Processes (organisational processes and documentation)**
- **The levels achieved within each component have been allocated gradings of A: Advanced, B: Intermediate, C: Basic, and a level D: Preliminary for centres that have been set up recently. The grades currently fulfilled and those that it is possible for different facilities to achieve will vary by facility type and by country.**
- **Each unit must decide on priorities, based on the level of performance (D, C, B or A), the equipment, tools available, staffing and level of expertise, prevalent disease issues, and budgets. The analysis should be used to set objectives that are achievable within the organisation.**
- **Professionalism covers the roles of management, radiologists, radiographers, medical physicists and supporting professionals. Through developing collaboration staff should aim to move away from traditional, hierarchical cultures to multidisciplinary approaches, with multi-professional teams to enable continuous improvement.**
- **Methodologies should move from basic performance tests and evaluations, to multi-modal monitoring of performance and functions, eventually using patient-specific parameters linked to care outcomes with more clinically relevant metrics for evaluating image quality and clinical information.**
- **Systematic processes with documentation should be implemented to ensure that results from performance testing, clinical surveys, and patient dose audits, are used in review of protocols, and aim eventually to achieve harmonisation of organisation wide protocols utilising the connectivity provided by IT systems.**
- **The Commission recommends that facilities analyse arrangements they have in place to identify which criteria set out in the Tables 3.1-3.3 they fulfil currently and use this to guide decisions about what actions need to be taken next to progress the optimisation process in their organisation.**
- **A quality management system can provide a framework to facilitate a systematic organisational approach, through aiding the identification of risks and possibilities for improvement, and so establishing a strategy to aid the achievement of optimisation.**

3.1. The status of optimisation and the challenges

(70) The areas that need to be tackled first to improve optimisation in any facility depend heavily on the available tools, the technical infrastructure, and the multi-professional expertise

available. At the present time, the majority of facilities around the world do not have the necessary tools, teams, nor expertise to fully embrace optimisation and take it forward to the same end-point. There are particular concerns when digital imaging equipment is introduced into centres for the first time. The replacement of older equipment with digital often creates a perception that the digital is 'intrinsically' better and safer just because it is newer or digital. However, the dose levels could be unreasonably high or too low without anyone realising, because the greyscale images are scaled based on the recorded data. What is important depends heavily on the available tools and expertise. Lower income countries with less developed facilities may not have the capability of making full use of methods that are accessible to them, considering the existing technical infrastructure and limited availability of multi-professional expertise.

(71) Access to diagnostic imaging facilities enables accurate diagnosis, treatment, management, and optimal outcomes, but this is limited in lower-income and low-middle income countries, and in some rural parts of high-income countries, due to a lack of adequate resources (DeStigter et al., 2021). However, access to imaging services needs to be developed, at every level of the health system. This includes provision of radiographic x-ray equipment for community primary healthcare services, as this is a mainstay for the investigation of common conditions such as pneumonia and fractures in many parts of the world, as well as the computed tomography and interventional equipment in specialised hospitals.

(72) This report attempts to address this range and prioritisation through separating requirements for optimisation into levels D to A, through which an imaging service would move as more aspects of optimisation were achieved. When a primary care radiography facility is set up, this would be at level D and basic prescriptive requirements in terms of staff and equipment would need to be put in place to achieve optimisation at level C. The majority of established x-ray facilities are likely to be at levels B and C, and the aim to achieve level A will require considerable development of multiple aspects of the service. Regardless of level, optimisation requires a continuous process of improvement through a quality dose management programme. The model of level-based imaging optimisation is designed to inform and guide policymakers and radiology managers in prioritising requirements and budgetary decisions.

3.2. Professionalism, methodology and processes in optimisation

(73) Optimisation depends on a comprehensive set of factors which have to work jointly together in order to reach a continuous and effective process. Continuous improvement and consistency of the outcome do not occur with separate functions in compartmentalised environments. The goals and development steps can be described in terms of three different perspectives or aspects:

- Professionalism (professional skills and collaboration)
- Methodology (methodology and technology)
- Processes (organisational processes and documentation)

(74) This is a development of proposals by Samei et al. (2018). Within each of these areas there are different levels of performance and optimisation that radiology facilities will have achieved. A combination of multi-professional skills, utilisation of clinically relevant parameters for measurement and evaluation, and integration with organisation wide processes with continuous monitoring are required to enable an effective optimisation process. Fig. 3.1

sets out broad categories for the system that would be in place to achieve different levels of optimisation.

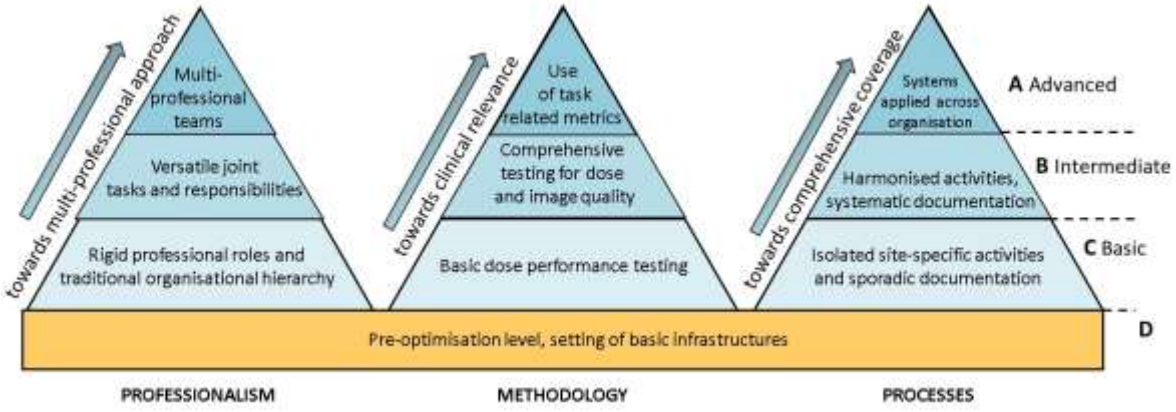

Fig. 3.1. The three main components in the development and maturation of optimisation. The levels represent different stages in achievement moving upward from D towards A. Level D represents a basic infrastructural level as a prerequisite for initiation of the optimisation process. A, B, and C set out the arrangements that will be in place for each component when that level is achieved.

(75) The first step is for facilities to evaluate the arrangements that are in place using this system to identify how much of each component they have in place, to guide them in decisions about what actions need to be taken. Use of the model can be flexible, in that it might potentially be applied either to x-ray rooms within a single hospital, or to several facilities that come under the management of one organisation. The levels achieved within each component have been allocated gradings of A: Advanced, B: Intermediate, C: Basic, and a level D: Preliminary for centres that have been set up recently. The grades currently fulfilled and those that it is possible for different facilities to achieve will vary by facility type and by country.

(76) Facilities may be at different levels in the three components in Fig. 3.1. For instance, medical physicists may undertake all the compliance testing needed to check dose and image quality performance is maintained, but communication channels with radiographers and radiologists may be limited, perhaps because testing is done by an external medical physics group, and arrangements may vary from one facility to another within a multi-site organisation. Thus, the levels within the model would be Professional skills C, Methodology B, Processes C. Taking another example, there may be a medical physicist based within the Radiology Department with regular communication with other specialities, but still undergoing training and accumulating experience, who has only limited equipment for testing x-ray equipment performance, and still developing arrangements with other sites. The levels for this organisation within the model would be Professional skills C, Methodology C, Processes C, but with the potential to move to B, B, B and onward over time.

(77) The next step in the improvement process in each aspect will depend on the level (C, B, or A) of performance for the facility, linked to the professional expertise, technical optimisation tools available, and the organisational infrastructure. Level C for each component represents the minimum level required simply to maintain a basic level of performance, and the starting blocks that need to be in place for the optimisation process to move forward. However, there are many centres throughout the world that will not be able to achieve this basic level at the present time, because of limited input or skills of professional groups, particularly medical physicist availability (professional skills), limited equipment and experience in performance testing (methodology), or an inadequate organisational support network with only ad hoc

arrangements to address failures (processes). For facilities in this preliminary stage (Level D), the personnel, tools, and structure will each need to be put in place to start the optimisation process.

3.3. Professional collaboration and the team approach

(78) Professionalism covers the roles of management, radiologists, radiographers, medical physicists and supporting professionals. Through developing collaboration staff should aim to move away from traditional, hierarchical cultures to multi-disciplinary approaches, with multi-professional teams to enable continuous improvement.

(79) This section will cover the main professional roles of those involved in optimisation, starting from management and including the radiologist, radiographer, medical physicist and supporting professionals such as nurses, vendor application specialists, biomedical engineers, data scientists, IT and informatics specialists. It will show the path from traditional and hierarchical organisational cultures to more multi-disciplinary and jointly organised tasks, finally reaching multi-professional teams to ensure continuous improvement of knowledge in the fast-developing field of medical imaging. A need for cultural change in order to enable other improvement and development in optimisation methods and processes should not be overlooked. Cultural shift towards multi-professionalism can only occur if the professional roles and competence is built to support this fundamental shift. Although much of this text refers to explicitly to radiologists as the predominant clinicians using x rays, similar principles of collaboration and a team approach apply to cardiologists and other clinicians involved with the operation and use of x-ray equipment.

(80) Features which may provide indicators for this evolving culture are consistency, systematic approach and coherence. Consistency means that tasks are performed according to the same set of rules and principles, regardless of time and location. It also refers to consistency of quality where the variation is reduced to produce more homogeneous outcomes. A systematic approach means that all operations are planned and can be described as processes, and also duty assignments and responsibilities are clearly determined. Coherence refers to the principle that ‘each piece of information is only stored in one location with regular back-ups of data’ aiming to avoid contradictory or overlapping information.

(81) However, these cultural and system aspects are dependent on more fundamental levels of safety and trust within an organisation. This can be seen as an aim to move towards an open and non-incriminating culture where faults and deviations do not lead to personal accusation, but to a search for any faults in the process, so that they can be fixed. Thus, any deviations are actively reported to enable corrective actions. Leadership commitment is a prerequisite for this cultural maturity which ultimately lays the foundation for other development areas of optimisation: methodology and processes.

(82) Management plays a key role in the organisation and staffing of the radiology service as a whole, and ensuring that staff are appropriately trained. This also involves decisions on equipment replacement including specification, procurement, installation, acceptance, commissioning into clinical use - and further to optional alternative use and finally decommissioning. The preparation of specifications, review of tenders and selection of imaging equipment requires input from all members of the imaging team, as well as bio-medical engineers. The operations undertaken to achieve optimisation require support from healthcare facility managers to ensure safe use and adequate training of staff.

(83) At the start of the referral process communication between the referring clinician and the radiologist is essential for appropriate justification. If radiologists do not have access to the

relevant aspects of their patients' clinical histories, they cannot determine what imaging is appropriate. Communication between medical physicists, radiographers, and radiologists, cardiologists and other clinical radiation practitioners is key to achieving optimisation of imaging and establishing and reviewing clinical protocols.

(84) In some countries where the process has not yet begun, the various tasks that contribute to optimisation can be undertaken by different groups that may not even communicate. For example, equipment testing can be done by government medical physics personnel, images are evaluated by radiologists and clinicians, dose audits may be undertaken by university researchers, and radiographers have responsibility for operating the equipment. If there is little communication between these groups, effective optimisation cannot take place. Practical advice is needed for all these groups on the importance of developing a team approach and pooling information. The communication channels between professional groups that would be in place to achieve various levels are set out in Table 3.1.

Table 3.1. Radiological professionals working in the facility and their communication at different levels. C, B, and A represent levels of service performance development, categorised as basic, intermediate, and advanced, respectively.

Performance level	Professional skills and staff communication
C Basic	Referring clinicians provide information on patient clinical histories to radiology department for most requests for imaging. Inappropriate referrals should be rejected but this may not always be so. Radiologists, radiographers, and medical physicists trained in diagnostic radiology perform roles separately and independent of each other. There is limited feedback of results from equipment performance tests to radiographers and radiologists.
B Intermediate	Regular feedback of information on testing and clinical performance between medical physicists, radiographers, and radiologists. Optimisation teams comprising radiographers, radiologists, and medical physicists established to review and optimise protocols for some modalities. Open communication between radiological professionals and other clinicians. Regular communication between radiology professionals, hospitals administrators and regulators on management of radiology services.
A Advanced	Radiographers, radiologists, and medical physicists are involved in periodic review of clinical protocols. Optimisation teams comprising radiographers, radiologists, and medical physicists have systematic collaboration, clear multidisciplinary roles in communication and they regularly review and optimise protocols for all modalities. Regular reporting and analysing of near misses and incidents, and acting to minimise the risk of recurrence in support of optimisation.

(85) Regulators, health authorities, and professional societies have important collaborative roles to play in setting acceptability criteria for equipment, staffing requirements, and other

aspects important for optimisation. Requirements for optimisation and radiological protection should be embedded into the quality requirements for medical practices developed by the health authorities and where appropriate linked to the rules of reimbursement for medical procedures.

(86) 'Optimisation teams' comprising radiologists, radiographers and medical physicists should be established to deal with each type of procedure. The preferred approach is for these multi-professional teams to focus on specific radiological areas (e.g. organ-specific sub-specialities in radiology practices). Ideally the leading expert available in each type of procedure should be utilised. This team-based process should be implemented consistently throughout the radiological organisation in order to achieve appropriate coverage for all relevant diagnostic and image-guided procedures. Building such teams also requires sufficient allocation of resources to make this team work effectively in routine practice, to support continuous improvement which is a built-in principle in optimisation.

(87) Advice is also needed for regulators and hospital administrators, as well as healthcare staff on how processes should operate, together with suggestions on how they might promote greater degrees of collaboration in practice. Finally, there needs to be communication between the radiologists and other clinicians, patients, and carers (outward facing) in conveying and following the appropriate processes for management of the patient's treatment. Everyone involved has a responsibility to understand the radiological protection requirements in medicine at some level. The groups and individuals involved will vary in different regions, so an approach of adopt and adapt by region is appropriate. Each unit must decide on priorities, based on their disease issues, and budgets, but guidance is required about the decisions to be made for those centres with more limited experience.

3.4. Methodology, technology, and expertise

(88) Methodologies should move from basic performance tests and evaluations, to multi-modal monitoring of performance and functions, eventually using patient-specific parameters linked to care outcomes with more clinically relevant metrics for evaluating image quality and clinical information.

(89) This component concerns the different levels of methodology used for optimisation, starting from the primary level with basic performance tests and evaluations, moving ahead to more inclusive and multi-modal monitoring of performance and functions, finally dealing with the care outcome and patient-specific parameters. Therefore, the methodology aims to utilise more clinically relevant metrics for evaluating image quality in order to provide more effective results.

(90) The practical process of optimisation begins with understanding equipment performance, and this requires both a necessary level of expertise and access to tools for testing the equipment. The next stage involves setting up clinical protocols using a team approach that includes communication between professionals working together each bringing their own expertise. The final stage is the analysis of results from surveys of dose and image quality which are then fed into the knowledge base to refine protocols. The main aspects of this are dependent on the skill of the operator, the influence of training (section 6), and methods of improvement through self-evaluation.

(91) The approaches and requirements for optimisation in centres and countries with varying levels of facilities, access to tools, and radiological and scientific expertise will differ. Steps in the optimisation process need to be prioritised in terms of increasing requirements for tools, facilities and expertise in practice, in order to set goals that can reasonably be achieved with the available resources. Steps will include, basic exposure factor optimisation, adjustments

to automatic exposure control devices (AECs), evaluations of equipment performance and patient dose, adjustments to equipment settings, through to software supported patient-specific optimisation using dose management systems.

Table 3.2. Aspects of methodology that should be in place to achieve different levels of optimisation.

Priority	Performance level	Practical tasks
1	C Basic	Acceptance testing and commissioning of equipment, including image quality and dose levels, and regular maintenance
2		Radiological evaluation of clinical image quality
3		Regular x-ray equipment QC and calibration
4	B	Patient dose audit - local
5	Intermediate	Evidence based preparation of protocols and choice of exposure factors
6	A	Analysis and evaluation of radiological images by professional team
7	Advanced	Improving protocols based on experience and/or comparison with benchmarks.
8		Patient radiation exposure monitoring using automatic systems (software) and its active use in continual review and optimisation.
9		Harmonising protocols and thus enabling not only an improvement in quality, but also the consistency of quality (reduced variation in quality and process steps)

(92) Examples of steps in the optimisation process that would be in place at the various stages include:

- C: Set the basic parameters (common to equipment type or modality (e.g. distance or projection direction);
- B: Adjust indication specific parameters to maximise image quality per dose unit (e.g. spectral optimisation); and
- A: Adjust patient-specific parameters (typically mAs by AEC) in individual exams to achieve diagnostic image quality with the lowest dose. Harmonise exposure parameters in order to achieve consistent image quality throughout the organisation.

(93) The practical tasks that would be implemented to achieve the various levels of performance in optimisation will depend on the equipment, facilities, and expertise available. The more important ones are listed in order of priority in Table 3.2, and where they would be expected to lie within the levels of expertise set out in Fig. 3.1.

3.5. Processes, control, and documentation

(94) Systematic processes with documentation should be implemented to ensure that results from performance testing, clinical surveys, and patient dose audits, are used in review

of protocols, and aim eventually to achieve harmonisation of organisation wide protocols utilising the connectivity provided by IT systems.

(95) This component concerns the means and motivation of systematic processes, process description, process flow and related documentation within the organisation. The stages in this component begin with isolated activities such as practical performance testing, developments of clinical protocols and performance of patient dose audits, but without a consistent approach across an organisation. This needs to be developed into a structured system that encourages, facilitates, and to some extent controls the regular performance of the various functions by different professionals within the imaging team. The input from the different groups then needs feed into a review and development process.

Table 3.3. Processes that should be in place for organisations at different levels in the optimisation.

Performance level	Processes
C Basic	System for selection and procurement of imaging equipment not standardised
	Ad hoc arrangements for equipment testing and patient dose audit (e.g. designed simply to meet the regulatory compliance level)
	Independent setting up of clinical protocols based on local experience
	Optimisation activities are site-specific and sporadic
	Limited documentation of procedures
B Intermediate	Involvement of trained professional team in selection and procurement of equipment
	Regular documented arrangements for equipment testing and patient dose audit
	Evidence based clinical protocols under regular review
	Harmonised activities and systematic documentation
	Some dose management software tools and/or facilities for download of patient exposure related data
	Established organisational links for implementation of optimisation
A Advanced	Systems for establishing clinical protocols, performance testing, dose surveys, etc. applied across whole organisation and monitored through quality system
	Continual live review and optimisation of imaging protocols based on analysis of procedure factors using dose management software or similar, where available and traceability of technical image quality measurements
	System to determine acceptable exposure based on requirements for specific clinical imaging tasks

(96) As the processes become more comprehensive, clinical protocols become harmonised and practical activities are managed as part of a quality agenda. The aim is to achieve

organisation wide systems and eventually connectivity through information technology (IT) systems with high levels of sophistication. This includes verification of the quality of archived data, and implementation, training, and assessment of changes to achieve optimisation. Some guidance on different aspects that would be expected linked to the level in the model are given in Table 3.3.

(97) Requirements for more advanced processes include modelling of the clinical task and observation in order to achieve image quality metrics (e.g. detectability of low contrast objects) which would be objective, quantitative, and standardisable and more relevant to clinical scenarios than the current metrics. Namely the development of image quality parameters bridging the gap from technical parameters to clinical parameters (i.e. describing in numerical terms what is needed to reach sufficient diagnostic accuracy for specific indications and diagnostic tasks).

(98) Acceptable differences in imaging parameters and patient doses relate to estimated uncertainty (accuracy and precision) of the objective image quality metrics. The aim is to reach not only sufficient diagnostic image quality but also to do it consistently.

3.6. Levels of performance and approaches required for optimisation

(99) Facilities should analyse arrangements they have in place to identify which criteria set out in the Tables 3.1–3.3 they fulfil currently and use this to guide decisions about what actions need to be taken next to progress the optimisation process in their organisation. Each unit must decide on priorities, based on the level of performance (D, C, B or A), the equipment, tools available, staffing and level of expertise, prevalent disease issues, and budgets. The analysis should be used to set objectives that are achievable within the organisation.

(100) Different levels of organisational and technical development (C, B and A) have been identified in Fig. 3.1, and in Tables 3.1, 3.2 and 3.3 examples of practical tasks and processes are given to help in ranking facilities based on the availability of multi-professional expertise and steps that have been achieved in developing the technical infrastructure. Sequences of actions setting out possible approaches that might be used to take the optimisation process forward are given here. These may be followed in order for particular components to be picked out to suit the situation. The aim is to provide guidance on the approach based on what might be achievable in different facilities.

(101) **D. Preliminary**: Isolated radiological professionals with little or no diagnostic radiology medical physics support and limited organisational structure for implementation of optimisation:

i. Set up links with professionals in larger hospitals to mentor and exchange ideas.
ii. Employ, educate, and train radiological staff in radiological imaging science, technology, and practice through attendance at external courses.
iii. Ensure access and sufficient allocation of medical physicist involvement in radiological protection, QC, dosimetry and optimisation.
iv. Prepare clinical protocols using evidence from professional societies with assistance of radiological colleagues from other facilities. Utilise web resources of professional societies.
v. Purchase equipment for measuring performance of x-ray equipment for individual facilities or groups of hospitals.

(102) **C. Basic**: Exposure factors based on historical practices with centres in initial stages of developing expertise in performance testing:

i. Review of protocols in the main centres by small team of national or international experts to assess level of optimisation for all types of x-ray procedures, especially CT.
ii. Initial small-scale survey of patient doses to establish level of optimisation already in place.
iii. Review of protocols in the main centres by groups of national or international experts with the aim of identifying where effort is required.
iv. Aim to train a multidisciplinary group of local professionals in optimisation requirements through visits to international centres, followed by joint visits to at last one centre within the country with a view to optimising protocols.
v. Provision of training courses in optimisation techniques for radiologists, radiographers and medical physicists at both local and national levels.
vi. National team of experts may be set up to visit some centres to optimise protocols, especially for CT, using results from dose surveys. These could be linked to any national training courses in optimisation.

(103) **B. Intermediate**: Knowledge of optimisation practices widespread but may not be put into practice in all centres:

i. National survey of patient doses, initially for CT and radiography to evaluate level of optimisation. Results can be used to identify broad needs for optimisation, and may also be applied in establishing DRLs that could be used in identifying target facilities where optimisation is required more urgently.
ii. Set up optimisation teams comprising radiographers, radiologists, and medical physicists for each modality with the aim of reviewing and optimising clinical protocols.
iii. Provision of advanced training courses in optimisation techniques for individual modalities for radiologist, radiographer, and medical physicist members of optimisation teams.
iv. Members of the optimisation teams provide cascade training for other members of the radiology department.

(104) **A. Advanced**: Optimisation undertaken routinely involving multidisciplinary teams:

i. National survey of patient doses for all types of x-ray procedures to establish DRLs and identify where further optimisation is required. Possible utilisation of national dose registries in large scale optimisation process, benchmarking, advanced data analytics (e.g. machine learning) and radiological research.
ii. Continual sharing of experiences in optimisation techniques in order to maintain the level of optimisation, and ensure procedures using new techniques are optimised as soon as they are introduced.
iii. Implementing more clinically relevant assessment of image quality by e.g. utilising clinical task models with model observers to achieve objective quantification of detectability for diagnostically meaningful contrast targets.
iv. Utilising exposure monitoring systems for wider scale determination of patient doses, including organ dose estimates.
v. Utilising integrated systems for protocol management and equipment management in order to enable more consistent quality from the technical to the clinical level, and to strengthen the harmonisation and standardisation of diagnostic and care processes.
vi. Utilising referral criteria integrated into hospital and radiological information systems (HIS/RIS) to implement clinical decision support (CDS) in order to enable correct examinations to be given to the right patients (based on indication) at the right time. CDS should optimally connect to modalities to take into account both the available access to different modalities and the queue status (length of worklists) with consequent delays in performance.

3.7. Quality systems

(105) A quality management system can provide a framework to facilitate a systematic organisational approach, through aiding the identification of risks and possibilities for improvement, and so establishing a strategy to aid the achievement of optimisation.

3.7.1. Quality Management

(106) If professionalism, methodology and process are to be harnessed in such a way that the optimisation goal is achieved, then there needs to be an underpinning framework that facilitates the systematic organisational approach to achieving that goal. This requires a system which ensures that all of the tasks, including QC tests, dose audits, investigation of failures to meet set standards, use of clinical and QC data in protocol optimisation, and communication of updated information are all carried out and recorded on an ongoing basis. Fig. 3.2 provides a diagrammatic representation of the relationships between quality management, QA and QC. One approach is through the adoption of Quality Management systems with that explicit aim.

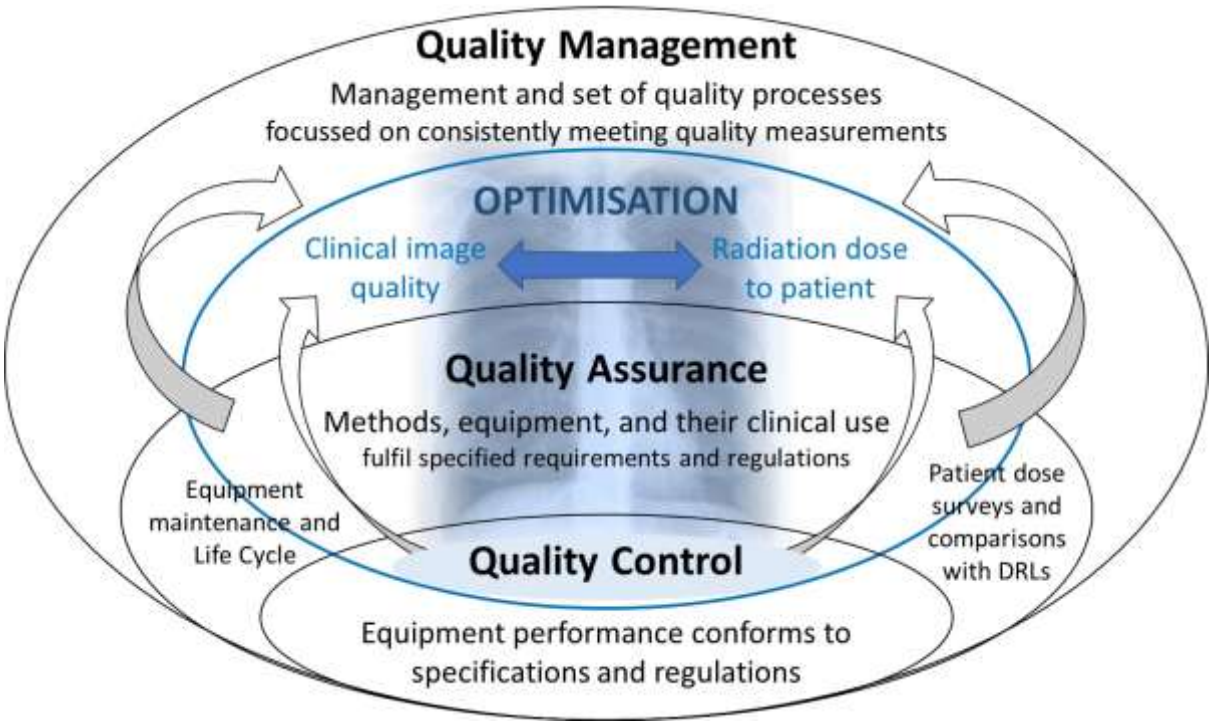

Fig. 3.2 Relationships between processes and tasks relating to optimisation within a quality system.

(107) The ISO publication ‘Quality management systems - Fundamentals and vocabulary’ (ISO, 2015a) defines a quality management system (QMS) as a suite of activities by which an organisation identifies its objectives and determines the processes and resources required to achieve desired results. A QMS can therefore be viewed as an enabler for identifying actions required to address both intended and unintended consequences encountered in the provision and development of a service. It can also be used as a tool to manage resources in both the long and the short term.

(108) Successful implementation of a QMS should enable an organisation to identify both risks and opportunities and identify possibilities for improvement and change. It will also give

the organisation the ability to demonstrate conformity with specified obligations, for example legislative requirements concerning radiological protection, provided they are incorporated within the objectives of the QMS. In this context, one of the requirements of a QMS might be the involvement or establishment of a working group to establish a vision and a strategy for optimisation. A QMS could also be used as the framework supporting the development of the levels of optimisation outlined in section 3.2 and depicted in Fig. 3.1.

(109) The successful execution of a QMS is dependent on the systematic definition and oversight of processes and adoption of the Plan - Do - Check - Act (PDCA) cycle (ISO, 2015b). The PDCA cycle is analogous to an audit cycle in which the steps are:

- Plan - define the objectives and the processes required to achieve those objectives;
- Do - implement the plan;
- Check - monitor /measure the outcomes against relevant comparators; and
- Act - take action where required to improve.

(110) To aid the process, there are seven key principles that should be used to support the development and subsequent maintenance of a Quality Management system. There is a focus on management responsibility, resource management, service realisation; and measurement, analysis and improvement. There is strong emphasis placed on providing high quality, reliable and consistent customer service as well as leadership. The seven principles are shown in Fig. 3.3, but are not depicted in any particular order. The relative importance of the principles will vary from organisation to organisation and will change over time (ISO, 2015c).

(111) Each of the seven principles in Fig. 3.3 will play a role to some extent in the progression from Level D to A in the professional, methodological and process elements of the optimisation strategy outlined in Fig. 3.1.

3.7.2. Quality Assurance

(112) Quality Assurance (QA) is an essential part of a QMS and is defined by the International Organisation for Standards (ISO) as being the part of quality management that is focused on fulfilling quality requirements. In essence this means the planning and documentation of policies, procedures and processes that underpin an organisation's approach to quality management. For example, suppose that one of the objectives specified by an organisation was the routine implementation of equipment performance testing for regulatory or optimisation purposes. This would be reflected in a written policy which would require the generation of procedures and work instructions relating to the operational implementation of equipment performance testing. This would include procedures concerned with what expectations there are on the equipment, when to test it, approaches to testing it and what to do with the results of the tests.

Fig. 3.3. The seven principles underpinning Quality Management and their interconnection.

3.7.3. Quality Control

(113) Quality Control (QC), also an essential part of a QMS, is defined as being the part of quality management focused on providing confidence that quality requirements will be fulfilled. Put another way, QC can be thought of as being the actual work done to meet the requirements of the QA programme. In the context of the example above it involves carrying out, recording and analysing the measurements performed in accordance with an equipment performance testing schedule. The American Association of Physicists in Medicine (AAPM, 2015) point out that QA is a proactive process that seeks to prevent defects in products or deliverables (e.g. medical images), while QC is a reactive process that seeks to identify defects in products or deliverables. QC is itself an essential part of the equipment life cycle (see section 2.4.1). Table 3.4 lists components of the quality system that would be regarded as QM, QA, and QC.

(114) Formal quality management systems under ISO standards can encourage the development and maintenance of an optimisation strategy by setting goals and monitoring performance. Large healthcare organisations with one or many radiology departments will find that appointing a member of staff to perform the role of quality manager, with clearly defined responsibilities and resources, is a definite advantage. This identifies an individual who is given the power and responsibility to ensure that the QA programme is kept up to date and evolves as circumstances require. There will be reassurance that changes in procedures and protocols are shared across all relevant facilities and staff within the organisation. Audits performed by the quality manager will ensure that regular QC tests are recorded and kept up to date. The quality manager can monitor planned developments in the optimisation programme and ensure that any incidents are followed up and appropriate actions taken to prevent reoccurrence in the future.

(115) However, formal quality management systems, such as those adhering to the International Standards Organisation procedures, are not essential. They are valuable aids in improving and developing the approach and continuing the optimisation of performance, but during the early stages of setting up and establishing procedures, organisations may find that it

is more cost effective in terms of staff time to concentrate on setting up individual components of the overall system, optimising protocols, and carrying out QC tests. These are the steps required in developing level D facilities to meet the basic level C and start on the road to optimisation. Once this has been achieved, then implementation of a QMS can ensure that optimisation is performed and progress in developing further improvements is maintained.

Table 3.4 Components of a radiology quality system.

Quality Management (QM)
Management of processes with: • Improved clinical outcome • Continual improvement of quality and safety [Plan-Do-Check-Act cycle (PDCA)] • Reviewing established quality criteria and policy • Ensuring adequate resources • Alignment with organisational purpose and strategy • Leadership commitment • Fostering no-blame culture
Quality Assurance (QA)
Planned and systematic procedures for: • Clinical image quality evaluation • Patient dose surveys and comparisons with DRLs • Image reject and retake analysis • Equipment maintenance and life cycle (incl. acceptance and commissioning) • QC and QA documentation • Test frequencies and tolerances • Self-evaluations and audits • Staff roles and responsibilities • Training and knowledge • Research and development aspects of quality
Quality Control (QC)
Planned and systematic procedures for: • Technical equipment performance tests including technical image quality tests and radiation output tests • Radiation safety tests • Technical safety tests

4. ANALYSES OF PATIENT DOSES

(116) **Key points in this section:**

- **The process of image interpretation is both task and reader dependent, so the choice of factors that influence both patient dose and image quality depend on the patient, the clinical question, the examination, the operator performing the procedure (radiographer, and/or radiologist, fluoroscopist) the equipment used to image the patient and the person interpreting the eventual image.**
- **Knowledge of the doses delivered to patients by imaging procedures is the first step in the optimisation process. This can only be gained by surveys of doses to real patients because of the nature of the distributions in dose. Patient dose surveys are essential in the development and implementation of an organisation's dose management strategy.**
- **Patient dose audit is the process whereby the results of a patient dose survey are compared against relevant standards - the most relevant current standard is the DRL.**
- **The use of radiology information systems (RISs) and patient radiation exposure monitoring / management systems for data retrieval enable large numbers of patients to be included in dose surveys.**
- **All personnel involved in x-ray imaging examinations should have a feeling of ownership or involvement in the process of dose audit and be familiar with the DRL concept. This multi-disciplinary team approach helps to ensure that results of dose surveys and any consequent changes that need to be made are fed back to equipment operators.**
- **When RIS and patient radiation exposure monitoring / management systems are used for data retrieval, task-based dose surveys are conceptually no more complex than anatomically based ones, provided that appropriate task related codes are in place.**
- **Patient dose audit against DRLs will only contribute to optimisation if action is taken to address doses levels that are high and any other deficiencies when they are identified.**

4.1. The influence of exposure factors on radiological images

(117) A key component of optimisation in medical imaging is keeping the radiation dose to the patient as low as reasonably achievable, while maintaining a level of image quality that is sufficient for the diagnostic purpose. The magnitude of the radiation dose is not immediately obvious from the appearance of an x-ray image, so assessments of doses from groups of patients perform an important role in demonstrating what the dose levels are so that they can be taken into account in the context of the optimisation process. The level of doses is determined by the exposure settings used for imaging and the optimum choices may not be immediately apparent.

(118) The process of image interpretation is both task and reader dependent, so the choice of factors that influence both patient dose and image quality depend on the patient, the clinical question, the examination, the operator performing the procedure (radiographer, and/or radiologist, fluoroscopist) the equipment used to image the patient and the person interpreting the eventual image.

(119) Exposure factors have a significant effect on patient dose and image quality. For example, an increase in mA (or mAs) without any adjustment to kV will result in an increased photon fluence at the image receptor and the patient entrance surface. There will be a consequent increased radiation dose to the patient and an improvement in Contrast to Noise Ratio (CNR, an indicator of image quality - see section 5.2) because of the Poisson nature of the image formation process. An increase in kV without adjusting the mA (or mAs) will cause an increased photon fluence at the image receptor and a higher patient dose but may also result in a potential reduction in CNR because of the variation in tissue mass attenuation coefficient with energy.

(120) In practice therefore, the outcome of an increase in mA (or mAs) will be increased CNR at the expense of increased patient dose. Use of a higher kV will result in a greater relative number of high energy photons reaching the image receptor and will therefore necessitate a reduction in mA (or mAs) to achieve the same dose to the image receptor. The net effect will be to reduce the patient entrance surface air kerma (ESAK or Ka,e) and also to some extent the radiation doses to the exposed organs, especially those nearer to the surface. There will be a consequent reduction in effective dose, E. This will be at the expense of a reduction in CNR.

(121) Other external factors such as the incorporation of anti-scatter grids into the imaging chain, field size, beam filtration, the use of differing focus to image receptor distances, different focal spot sizes and anode angulation all have well documented effects on patient dose and / or image quality. These are summarised in Table 4.1.

Table 4.1. Impact of basic factors on patient dose and image quality if kV is kept constant in conventional radiographic imaging.

Factor (single factorial)	Effect on Patient Dose (to maintain same Air Kerma at detector)	Image Quality
Increase field size	Increased P_{KA}; $K_{a,e}$ constant	Increase scatter
Introduce anti scatter grid	Increased P_{KA} ; $K_{a,e}$ increased	Decrease Scatter
Increase beam filtration	P_{KA} reduced; $K_{a,e}$ reduced	Reduce Contrast
Increase FID	None	Reduce unsharpness
Increase focal spot size	None	Increase unsharpness
Increase anode angle	None	Increase unsharpness, (increase useful FOV)
Decrease patient to detector distance	P_{KA} reduced; $K_{a,e}$ reduced*	Decrease unsharpness but increase scatter at detector

P_{KA} - kerma area product (KAP), $K_{a,e}$ – entrance surface air kerma (ESAK), FOV – field of view, FID - focus to image receptor distance

*Assumes field size remains the same at patient

4.2. Surveys and audit of patient doses

(122) Knowledge of the doses delivered to patients by imaging procedures is the first step in the optimisation process. This can only be gained by surveys of doses to real patients because

of the nature of the distributions in dose. Patient dose surveys are essential in the development and implementation of an organisation's dose management strategy.

(123) Correctly performed patient dose surveys will provide information about the range and distribution of doses delivered to real patients for each of a range of examinations at a facility. The use of phantoms as a surrogate for patients in a dose measurement programme is not appropriate since this approach effectively assesses machine output only. However, another important element of the optimisation process, that is understanding the performance characteristics of equipment, may well involve the use of phantoms to assess output. Examples would be the measurement of CT dose quantities or calibration of AEC devices.

(124) Patient dose audit is the process whereby the results of a patient dose survey are compared against relevant standards - the most relevant current standard is the DRL. Diagnostic Reference Levels (DRLs) that are used as the comparator in dose audits can be set at either national or local level (ICRP, 2017). An essential component of audit is that actions are assigned based on the outcome of the comparison. Depending on the complexity of the comparison task, the outcome will either be 'do something' or 'do nothing'. In either event it should be recorded, and if intervention is required it should be undertaken prior to the next audit being initiated. Audit is by nature a cyclical process and Fig. 4.1 shows an example of how the dose audit cycle can be carried out (ICRP, 2017). It is essential that the basis for any comparison should take into account the uncertainty budget associated with the physical measurements recorded during the dose survey.

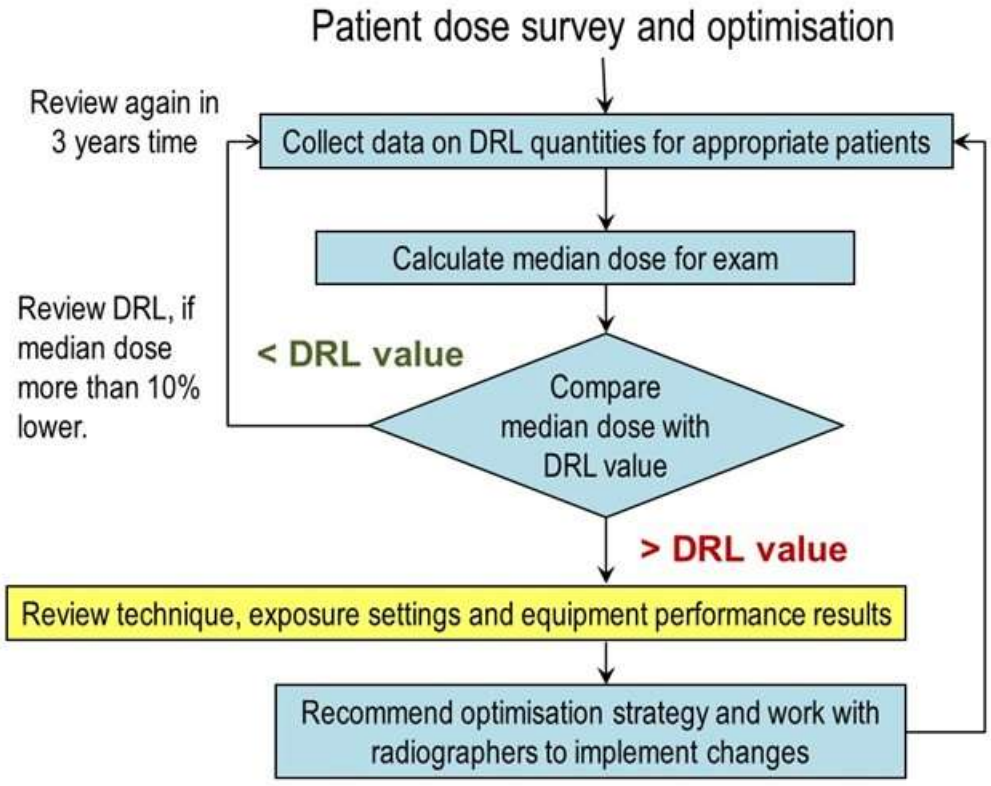

Fig. 4.1. The patient dose audit cycle (ICRP, 2017).

(125) Patient dose surveys and subsequent audit should be carried out in a scientifically justifiable manner. A full survey programme in a hospital should ideally cover representative examinations from all radiological tasks performed within the hospital, include equipment from across the hospital and work done by a range of operators. The programme should include work

done outside of the radiology department, for example in cardiology and theatres. Priority should result from consideration of the highest dose examinations, the most common examinations and the most relevant patient cohorts. Prior to surveys being initiated, the standard against which the results are to be compared at audit must be known.

(126) ICRP recommends that a survey of any particular examination should involve the collection of data from a minimum of 20 patients, and for diagnostic fluoroscopy, a group of at least 30 patients is preferable (ICRP, 2017). Sutton et al. (2021) have however suggested that the minimum sample size for patient dose audits should be 300 to 400. In practice many more will usually be included if the data is extracted from a Radiology Information System (RIS) or other information system. Any constraints on patient weight and age should ideally be those associated with the standard that is being used as a comparator. If this is not the case some attempt should be made to, at a minimum, understand the uncertainty budget (error) associated with the ensuing comparison against the standard. The clinical task associated with each procedure surveyed should be recorded in order to facilitate appropriate comparison.

(127) In regions with limited infrastructure for data collection, survey intervals of approximately three years will be appropriate for many diagnostic radiography and diagnostic fluoroscopy examinations provided that there are no substantial changes in equipment or software. Annual surveys are recommended for CT and image-guided procedures because they subject patients to higher doses of radiation. As automated systems for patient data collection and management become more widely available, the dose audit process may take the form of a regular review (ICRP, 2017).

4.3. Measurement and retrieval of patient dose data

(128) Metrics used in surveys should be representative of how the dose to the patient varies, so quantities such as air kerma-area product (KAP, PKA), entrance surface air kerma (ESAK, Ka,e), dose length product (DLP, PKL) and CT volume averaged dose index (CTDIvol, Cvol) are preferred. These tend to be those set as standards for comparative purposes. Abbreviations will be quoted in the text, but the symbols approved by ICRU should be used in equations. These are all measurable dose quantities and are not linked directly to doses to patients' organs which will not be considered in this publication.

(129) Ideally the metrics recorded should be transferred automatically to, and retrieved from, the RIS or other information system in order to avoid issues caused by transcription errors. In practice automatic transfer is in many situations aspirational, or even not possible in the case of the majority of CR installations. In this case relevant metrics need to be manually recorded in the RIS. In some cases, manual recording on paper may be the sole practical method of recording the data required for the survey. This may be the method used in the early stages of establishing a patient dose survey programme. Whatever the method by which information transfer or recording is performed, it is good practice to use standard examination codes for the different types and variants of radiological procedures so as to avoid introducing errors due to incorrect categorisation of examination types. It is often difficult to incorporate patient weight into the results of patient dose surveys since it is often not assessed in the first place. The caveat is that the assessment of patient size, whether using weight or some other metric, is of great importance if paediatric dose audit is to be undertaken (ICRP, 2017).

(130) The Digital Imaging and Communications in Medicine (DICOM) standard has defined the Radiation Dose Structured Report (RDSR) (IEC, 2014; Sechopoulos et al., 2015; DICOM, 2017; NEMA, 2020) to handle the recording and storage of radiation dose information from imaging modalities. Patient dose data monitoring is facilitated by transferring this

information to PACS, RIS/HIS, and dedicated vendor neutral electronic dose registries (AAPM, 2019a), interoperability among which is guided by the IHE (Integrating the Healthcare Enterprise) Radiation Exposure Monitoring (REM) Profile (IHE REM). Patient radiation exposure monitoring systems are now available and facilitate the establishment of databases as repositories of dosimetry data. These therefore have the potential to be used as a convenient way of carrying out patient dose surveys for those who have them.

(131) The use of radiology information systems (RISs) and patient radiation exposure monitoring / management systems for data retrieval enable large numbers of patients to be included in dose surveys. Commercial exposure monitoring systems or functionalities as integrated into PACS/RIS software provide access to substantial amounts of data and so enable an overview of the doses associated with particular examinations to be obtained more easily, and for example allow comparisons between different CT scanners (Nicol et al., 2016).

(132) A problem that might occur when downloading data for large numbers of patient examinations is the lack of a standard nomenclature for procedures. There may be variations in names for certain examinations used by different departments across an organisation, or even by different staff within the same department. There may also be variations in the interpretation of protocols by different radiographers and use of the same protocol for different clinical objectives. For example, a chest abdomen pelvis CT scan might be used for cancer staging or for follow-up of treatment - each require different levels of image quality.

(133) When dose data are continuously submitted to an automatic electronic database or registry, review of the registry data should be performed regularly and at least annually. When no automatic dose registry exists, audits could be performed by means of annual surveys, collecting data manually from dose displays, DICOM headers or PACS/RIS archives (ICRP, 2017; ACR, 2022).

(134) As optimisation is continued, all the protocols across different departments and hospitals coming under the same organisation should be aligned. This can only be achieved by establishing an agreed process for optimisation of protocols to which all radiologists agree, for judging the level of image quality that is appropriate for the various diagnostic purposes. Such developments may well form part of a quality management programme. The delivery of varying levels of image quality to cater for the preferences of individual radiologists cannot be justified.

(135) The calibration of equipment used in patient dose surveys should be verified regularly, preferably at intervals of no more than 1–2 years and should be traceable to national standards. Several studies have shown that KAP values indicated by x-ray unit consoles may deviate by 10–40% from the real value, and the variation in the calibration factor as a function of beam quality, for a given x-ray set-up, was typically within 10–20% (Vano et al., 2008; Jarvinen et al., 2015). Calibrations of meters and displays should be verified, preferably at intervals of no more than 1–2 years. IEC allow a tolerance of 25% for KAP meter calibration using a coverage factor of 2 (IEC, 2020). The results should be incorporated into the uncertainty budget associated with the survey, as should the results of radiological equipment QC tests.

4.4. Analysis and feedback of patient dose data

(136) Without sufficient feedback on doses from digital images, there is a risk of increasing dose over time or leaving doses at a high level in order to ensure that image quality is good. Such exposure creep will not be recognised unless dose levels are monitored.

(137) The comparator that is most often used when patient dose survey data is used in clinical audit is the DRL (ICRP, 2017). In general, the outcome of the comparison is a decision

on whether the radiation dose delivered for a particular examination exceeds that which the majority of radiologists agree will produce images that are sufficient for the clinical purpose. There is also an argument that patient dose survey data can be used to identify where patient doses are not high enough, as this may imply that adequate diagnosis cannot be achieved. However, patient dose survey data collection is predicated on the fact that only examinations with sufficient image quality to achieve a diagnosis should theoretically be entered into the survey in the first place; any non-diagnostic examination should be rejected after being taken (see section 2.4.1), included in the departmental review of practices, and excluded from the survey post hoc. This issue has added more complexity than was previously the case because of the wide dynamic range associated with digital imaging modalities. Previously, the image on a film acted as its own QC in that if it was overexposed the film was too black, and if it was underexposed the film was too light. The advent of digital radiography means that is predominantly no longer the case, and underexposed images may be considered to be diagnostic unless an appropriate QC regime involving the use of Exposure Indices (EIs) is in place along with a reject analysis programme (IEC, 2008; Jones et al., 2015; Dave et al., 2018). If such a QC programme is not in place it might not be possible to satisfy the underlying premise used in the setting of DRLs that all images must be diagnostic in the first place.

(138) DRLs are often referred to as being the first step on the path to optimisation; this is a reference to the action that should be taken if a dose survey does reveal doses that exceed the DRL. If this is so, an investigation should be undertaken to identify why it is the case for the examination in question and action taken to effect remediation if necessary. The investigation should include a review of equipment performance, the settings used, and the examination protocols. The factors most likely to be involved are survey methodology, equipment performance, procedure protocol, case mix, operator skill, and procedure complexity. Framing the bounds for and reflecting on the results of the investigation should be carried out in a multi-disciplinary manner and include input from appropriate professionals. For example, whilst a medical physicist may be able to comment on the performance of the measuring equipment used (and relate them to the results of QC performance tests), operator training issues or issues concerning patient case mix are more the remit of those clinical staff involved. The establishment of multi-disciplinary optimisation teams is of great value in this regard. Detail concerning setting up and reflecting on investigations was first developed by the Institute of Physics and Engineering in Medicine (IPEM, 2004) and subsequently extended by ICRP (ICRP, 2017).

(139) All personnel involved in x-ray imaging examinations should have a feeling of ownership or involvement in the process of dose audit and be familiar with the DRL concept. This multi-disciplinary team approach helps to ensure that results of dose surveys and any consequent changes that need to be made are fed back to equipment operators. Patient dose surveys and subsequent analysis should be performed with the collaboration of and input from these people, using readily understood aids, such as bar charts and tables. Dissemination of results should be similarly presented using easily accessible tools such as histograms of dose distributions. The process then becomes a natural part of clinical audit. These personnel are best placed to understand the clinical implications and reasons for any findings from a dose survey. They are also essential when it comes to the enactment of any clinical remediation that might be required as a result of the audit process - for example the adjustment of protocols or operator training.

4.5. The outcome of the audit process

(140) DRLs should not become or be thought of as dose limits. This is why they are considered the first step in the optimisation process and must be recognised in the audit process. The fact that doses are below a DRL should not mean that there is no further scope for optimisation. Median values of DRL quantities at a health facility that are above or below a particular value do not indicate that images are adequate or inadequate for a particular clinical purpose. Substituting compliance with national or local DRL values for evaluation of image quality is not appropriate.

(141) In this context, the concept of 'achievable dose' has been defined as a level of patient dose (metric) achievable by standard techniques and technologies in widespread use, without compromising adequate image quality. NCRP suggested that achievable dose values should be set at the median value of the distribution of a national DRL quantity (NCRP, 2012) and ICRP has concluded that this approach may be useful as an additional tool for improving optimisation. Local optimisation teams are ideally placed to consider adoption of this principle and to compare patient dose results with the 50th percentile value of the data used to derive national DRLs as well as with the DRL itself. Such a comparison is especially important since the median of the distribution used to derive the DRL value itself can also be considered to be that below which image quality should be regarded as being of greater priority than dose when additional optimisation efforts are performed (ICRP, 2017). Consideration of such issues make the use of patient dose surveys and audit an integral part of an organisation's dose management strategy.

(142) In situations where DRLs do not exist at a national level then local DRLs can be set using data from 10 to 20 x-ray rooms in a local area based on the third quartile of the distribution and the results obtained can be used as the basis for operation by local optimisation teams. For assessments on smaller numbers of rooms, 'typical values' based on the median values of a distribution might be used. These alternative local values are useful because they encourage users to identify units that require optimisation in the earlier stages of setting up programmes to survey patient doses, so that actions required can be investigated and taken soon after the survey has been completed. Alternatively, values from other centres, or ones reported in the scientific literature can be used as an initial guide. The adoption of DRL values from other countries should be done with great caution, given the potential for differences in technical aspects of practice. One example of the establishment of international DRLs in paediatric CT that can be used in countries without sufficient medical physics support to identify non-optimised practice is given in Vassileva et al. (2015).

(143) DRLs set at national level tend to be based on anatomical regions, such as thorax, pelvis and skull. The result of an investigation into why such a DRL is exceeded might reveal the cause to be case mix - for example the requirements for a chest x ray for a cohort of patients attending a chronic obstructive pulmonary disease (COPD) clinic are different from those for a chest x ray for the general population and may well result in higher patient doses. The result of the investigation might well be to establish a local indication specific DRL (comparator) for that particular patient cohort. There is no reason why other indication specific comparators cannot be developed, and this may well be more easily managed at a local level than a national one. One example of an examination suitable for an indication based DRL is the evaluation of cerebrospinal fluid shunt function in hydrocephalus using CT, where a lower dose of radiation is required than for a skull CT to achieve the required outcome. Another commonly quoted example is the use of imaging for the evaluation of renal stones. The identification of suitable examinations and consequent development of indication-based comparators is a task well suited to a multi-disciplinary optimisation team as described above and is a natural evolution

of the optimisation process. It represents a further stage in optimisation over and above the comparison with anatomically based DRLs. Values of indication specific DRLs have been proposed by some centres and work is on-going in this field (Treier et al., 2010; Jarvinen et al., 2015; Lajunen, 2015; Brat et al., 2019).

(144) When RIS and patient radiation exposure monitoring / management systems are used for data retrieval, task-based dose surveys are conceptually no more complex than anatomically based ones, provided that appropriate task related codes are in place. Task specific coding is an important step on the route to achieving a systematic optimisation process which may be targeted in a clear way at various types of procedures and enable benchmarking of results between examinations, examination groups, vendors, equipment models, organisations, regions and countries. However, it is very unlikely to be in place in the majority of healthcare facilities at the present time.

(145) Exceeding a DRL value should trigger investigation, and, if appropriate, corrective actions taken to optimise patient protection. This includes a review of equipment performance, the settings used, the examination protocols, and related procedural factors. In addition, if the median dose is substantially less than the DRL a check should be made to ensure that image quality is not adversely affected. One of the outcomes from a patient dose audit might be a desire to change a protocol associated with image acquisition. The effect on patient dose metrics of simple changes involving adjustments in kV and mA (mAs) can easily be determined experimentally or by calculation. More sophisticated dosimetry of any such proposed alteration can be assessed using patient dose modelling software based on anthropomorphic phantoms and Monte Carlo transport modelling. The effects of more subtle changes, such as those achievable by adjusting the performance of an AEC device or alteration to tube current modulation for CT, whilst being very important, are more difficult to accurately characterise because of the influence of individual patient anatomy. This can only be fully taken into account after the examination has been performed when patient specific estimates of organ and effective dose can be derived using the *a priori* information obtained from the examination itself. This approach requires sophisticated modelling and software as is provided in some patient radiation exposure monitoring software or other bespoke products. Patient specific dosimetry does not have a role in patient dose audit, other than in the widest sense. Patient dose audit against DRLs will only contribute to optimisation if action is taken to address doses levels that are high and any other deficiencies when they are identified.

4.6. Patient radiation exposure monitoring / management systems

(146) The process of dose audit based on analysis of downloads of patient dose data, followed by protocol adjustment and regular re-audit can make major contributions to optimisation. However, this is not the limit in improvement that could be made if data are analysed in greater detail. One possible next stage requires implementation of patient radiation exposure monitoring systems in which exposure data is fed in from the RDSRs linked to each imaging device. This can in theory provide a wealth of data, but in order to take advantage, examination protocols need to be standardised and systems set up to carry out the analyses, feedback results and implement changes to improve protocols at regular intervals.

(147) The analysis of dose data may often be done predominantly by medical physicists, but in order to take full advantage of the facilities offered, results need to be readily available to both radiographers and radiologists. To do so requires the establishment of methods to provide readily available feedback of information. This could be achieved for example through use of interactive dashboards that can provide fast access to enable analysis of data, as well as

allowing progress to be tracked. Whichever method is implemented, it needs to be easy to use and interrogate, and enable data to be easily found and shared, to encourage appropriate actions.

(148) Such systems make follow-up of patients conceptually easier, so that checks can be made readily to identify problems, trace them and find out whether the problems have been fixed. Processes could be set up to check protocol use, follow dose trends, provide current dose values, and identify outliers. Results could be highlighted in dose histograms showing dose distributions and allow individual examination data to be interrogated in order to allow investigation to determine possible causes of anomalies. Inclusion of the weight or patient dimensions in such a system would provide even more potential for analysis and improvement. They will however require increased human resource to adequately implement and will need to be subject to QC tests.

(149) Some of the steps discussed in this section are set out in Table 4.2 in terms of the levels of optimisation discussed in Section 3.

Table 4.2 Arrangements that should be in place for facilities at different levels.

D: Pre-optimisation level (Basic infrastructure)
• Availability of radiation instruments for measurement of radiation dose and exposure parameters. • Availability of simple protocols setting out measure equipment performance. • Purchase of range of instruments sufficient for carrying out QC tests on all imaging modalities. • X-ray equipment has displays of dose parameters (e.g. KAP for radiography and fluoroscopy and displays of $CTDI_{vol}$ and DLP on CT scanners)
C: Basic (Level D plus)
• Calibration of all KAP meters, and displays of $CTDI_{vol}$ and DLP • Dose audits performed every 3 years • Dose audit results fed back to radiographers and radiologists periodically • In process of developing national DRLs
B: Intermediate (Levels D and C plus)
• Standardisation of protocol names for procedures • Radiologists have agreed arrangement for development of examination protocols • Agreed codes for identifying more complex examinations • National DRLs established for a wide range of procedures • Annual survey of patient doses on wide range of procedures • Local DRLs and typical values set by organisation linked to local dose surveys • Results of patient dose audit included in annual review of examination protocols
A: Advanced (Levels D, C and B plus)
• Continual feedback and comparison of patient dose results with typical values • Application of dose management system software

- Comparison of $CTDI_{vol}$ values with other results at time of CT examinations
- Alignment of protocols for standard indications throughout organisation

1877

5. EVALUATION OF IMAGE QUALITY

(150) **Key points in this section:**

- **The image quality in medical imaging relates to the capability of providing anatomical or functional information that enables accurate diagnosis and informs care decisions or provides guidance for intervention.**
- **The clinical value of images is dependent on physical characteristics of the imaging method (role of the medical physicist), image capture and presentation system (role of the radiographer) and the interpreter who reviews the images (role of the radiologist).**
- **Basic image quality is characterised by contrast, resolution and noise. Contrast and resolution describe how different targets are represented in greyscale and sharpness. Noise represents a distractor that effects image texture and visual detection of features.**
- **In order to assess image quality in an arrangement that closely resembles the actual clinical setup, test objects should be used in combination with accessories to reproduce the total attenuation and/or shape of the patient to trigger the automatic mode in the imaging system.**
- **Subjective expert evaluation of clinical image quality by radiologists forms part of the routine self-assessment process included in the QA programme of the radiological department. The subjective evaluation of clinical image quality should be graded based on image quality criteria for each modality and clinical indication. Ideally this would be paired with patient dose audit.**
- **Anthropomorphic phantoms mimicking patient tissue attenuations, morphometry, organ distribution and tissue texture, can be used together with appropriate image quality metrics in protocol optimisation studies.**
- **The final stage of the optimisation process should be tailored to the clinical application and involve the multi-professional team of technicians / radiographers, medical physicists and radiologists.**
- **Artificial intelligence and its subsets, machine learning and deep learning, are developing quickly to provide versatile methods for a wide range of optimisation related tasks, and the image quality framework needs to evolve to address their impact in the image chain and patient outcomes.**

5.1. Introduction

(151) The image quality in medical imaging relates to the capability of providing anatomical or functional information that enables accurate diagnosis and informs care decisions or provides guidance for intervention. The provision of information is dependent on the image data itself but also concerns the interpreting observer who can be a doctor or a computer application. When ionising radiation is used for medical imaging as is done in radiological x-ray modalities, there is always a trade-off between the achieved image quality (in terms of noise) and radiation exposure. Thus, the optimisation task is characterised by balance between reaching an adequate image quality for diagnosis and avoiding excessive x-ray dose to the patient. The dose is not governed by strict limitation for any individual patient at a particular exposure. However, if adequate image quality is insufficient for adequate clinical interpretation,

the reliability of the diagnosis is at risk, and the correct care decision for that specific patient is jeopardised. In such a case, the radiation dose aspect becomes meaningless. Therefore, clinical image quality should be considered thoroughly in the overall optimisation process.

(152) The clinical value of images is dependent on physical characteristics of the imaging method (role of the medical physicist), image capture and presentation system (role of the radiographer) and the interpreter who reviews the images (role of the radiologist). One of the main reasons why optimisation has traditionally been focusing on the dose aspect (according to ALARA principle) is the ease of acquiring radiation dose information from x-ray equipment. The physical dose information is standardised and available through dose displays in most modern x-ray devices after the medical exposure has been made. On the other hand, image quality information is not given automatically by imaging equipment but has to be resolved separately and retrospectively, and this typically involves laborious evaluation by expert radiologists (clinical image quality, generally based on scoring patient images subjectively) and medical physicists (technical image quality based on objective phantom image analysis). Efforts to create automated objective methods, utilising model observers or artificial intelligence (AI) for clinical image quality measurement and monitoring are the subject of extensive research and development. These methods are expected to be important in the future, but such methods are not yet available on a wide scale for clinical application.

(153) From the physical imaging chain and parameter perspective, the image quality is further down the stream as compared to the radiation dose. Overall, the process of measuring image quality is more demanding, complicated and involves a larger amount of dependent and intertwined parameters as compared to standard physical radiation dose metrics in radiology. However, regular evaluation of clinical image quality is the backbone of a successful optimisation process and therefore it should be given sufficient resources, methods, references and tools to make it an on-going activity of the radiological department.

(154) For the sake of conciseness, more information about the image quality metric descriptors in the following sections can be found in Annex A.

5.2. General image quality metrics: Contrast, spatial resolution and noise

(155) Basic image quality is characterised by contrast, resolution and noise. Contrast and resolution describe how different targets are represented in greyscale and sharpness. Noise represents a distractor that effects image texture and visual detection of features.

5.2.1. Contrast

(156) In x-ray imaging techniques, contrast (or contrast resolution) is fundamentally based on the differences in x-ray attenuation between target and background materials, providing signals seen as differences in grey-scale in resulting images. Due to the characteristics of primary physical interactions (absorption and scattering) of x rays and human tissue materials, radiological contrast results from small naturally occurring variations in x-ray attenuation between pathological and normal (soft) tissue that only produce subtle differences (NIST, 2009). On the other hand, contrast between bone and soft tissue, and between soft tissue and air is far greater.

(157) The soft tissue contrast can be improved by using contrast agents injected into the blood stream (typically iodine). The use of lower kV in CT with iodine can improve the visualisation of the enhanced regions, due to the inherent increase in the attenuation coefficient of high atomic number elements as kV (and therefore quantum energy) decreases. Nonetheless,

the effect is highly dependent on patient size and the intended diagnostic task. A decrease in kV, would imply fewer penetrating photons and an increase in image noise and possible artefacts (such as beam hardening for larger patients). Thus, to guarantee an adequate image quality level, other acquisition parameters should be adjusted to compensate (typically an increase in tube current), when kV is decreased (Martin et al., 1999b; Bushberg et al., 2020).

5.2.2. Spatial resolution

(158) Spatial resolution describes the level of detail which can be observed on a medical image. It may concern boundaries between tissue types or structural patterns within tissue such as bone fractures. Comprehensive methods to determine spatial resolution span a continuous range of object dimensions in order to evaluate image system performance not only with the smallest details but also all other spatially distributed features in the image. Traditional spatial resolution measurements have been made using high contrast target and high radiation dose exposure level where the effect from image noise is minimal, enabling higher precision of the assessment method.

(159) In digital radiology, images are comprised of discrete picture elements where the pixel size sets a clear boundary on what can be resolved spatially in the image. However, if a very small object has high enough contrast to boost the integrated signal within a pixel to make that pixel stand out among neighbouring pixel grey-scale background, it is still possible to detect such an object even if it is smaller than a pixel.

(160) On the other hand, there are many relevant object features that are significantly larger than the pixel dimension. Typical digital radiography detector pixel size is in the order of 150 microns which is small enough for many clinical imaging purposes, if the other imaging factors are optimal. Also, the image (2D or 3D) dimensions vary significantly from around 5 cm in spot mammography and limited field-of-view in cone-beam CT to about an order of magnitude more in chest radiography or multi-slice CT. Imaging detector resolution capabilities are rapidly changing, enabling the visualisation of smaller structures, for instance with photon counting techniques or smaller detector elements.

(161) At a physical level, spatial resolution is fundamentally described as the spread of the image signal about the true original location corresponding to a signal source object. This spread is referred to as a point-spread function (PSF) and theoretically it is determined for an infinitesimally small point high-contrast source (i.e. impulse response function). If the PSF does not vary according to location within the image, it is said to be stationary or shift-invariant. In other words, the resolution is expected to be the same in all parts of the image. Basically, the PSF describes the blurring of an image due to all relevant factors in the imaging chain. The same blurring occurs with line objects, contrast edges and tissue textures in the image. Therefore, spatial resolution does not only affect the sharpness of small focal details but, together with contrast and noise characteristics, effects the overall appearance of the image.

(162) Physical sources of blurring involve many factors starting from x-ray tube focus size where a smaller focus point enables higher precision according to basic optical principles. Patient movements (even involuntary movements such as heartbeat and vessel or digestive movement) add motion blurring to the attenuated signal distribution. Therefore, any avoidable movements should be prevented, for instance by training the patient in breath hold technique prior to imaging, when possible. The thickness of an imaging detector poses the next level of potential blurring because the original location of x-ray absorption is not kept within that point on the detector, but instead the signal (typically in a form of light photons) is spread across the thickness of the detector. As a result, part of the signal may also be detected in neighbouring detector locations and pixel elements, causing blurring. Still the final level of blurring may

occur at the image processing steps where the image signal is mathematically processed or reconstructed, in order to formulate the final 2D or 3D image appearance for presentation.

(163) Therefore, the practical spatial resolution of an imaging system is a combination of several technical factors and mathematical operations. Spatial resolution may be described in the spatial domain (e.g. in the form of high-contrast line pair-patterns as seen in Fig. 5.1) or in the frequency domain. In the frequency domain, the modulation transfer function (MTF) provides a comprehensive description of contrast representation with a continuous range of spatial frequencies. The spatial frequencies can be thought as a visual line-pair pattern of white and black lines next to each other where the density of the lines increases at higher frequencies (e.g. 10 line pairs per cm) until the imaging system starts to lose the original black and white contrast and eventually just becomes grey as white and black parts are averaged. A line-pair pattern can also be described as a sinusoidal contrast signal with a wavelength corresponding to the visual line-pair pattern size.

5.2.3. Noise

(164) Small details and lower contrast structures may be hidden under the noise texture which is seen as the graininess of the image. The main component of image noise is provided by quantum noise. Quantum noise is governed by Poisson statistics, stating that the observed noise defined as the standard deviation of the grey-scale pixel values in a certain homogeneous part of the image is inversely proportional to the square-root of the dose. Therefore, by lowering the dose to a quarter of the original level, the image noise is doubled. This gives a fairly simple rule for predicting the effect on image noise if there is a change in the radiation dose level:

$$\text{Noise} = 1/\text{Dose} \qquad (5.1)$$

which applies in a roughly similar manner for all x-ray modalities (and may not apply with iterative or AI-based reconstruction is used). This relationship is visually demonstrated in Fig. 5.2.

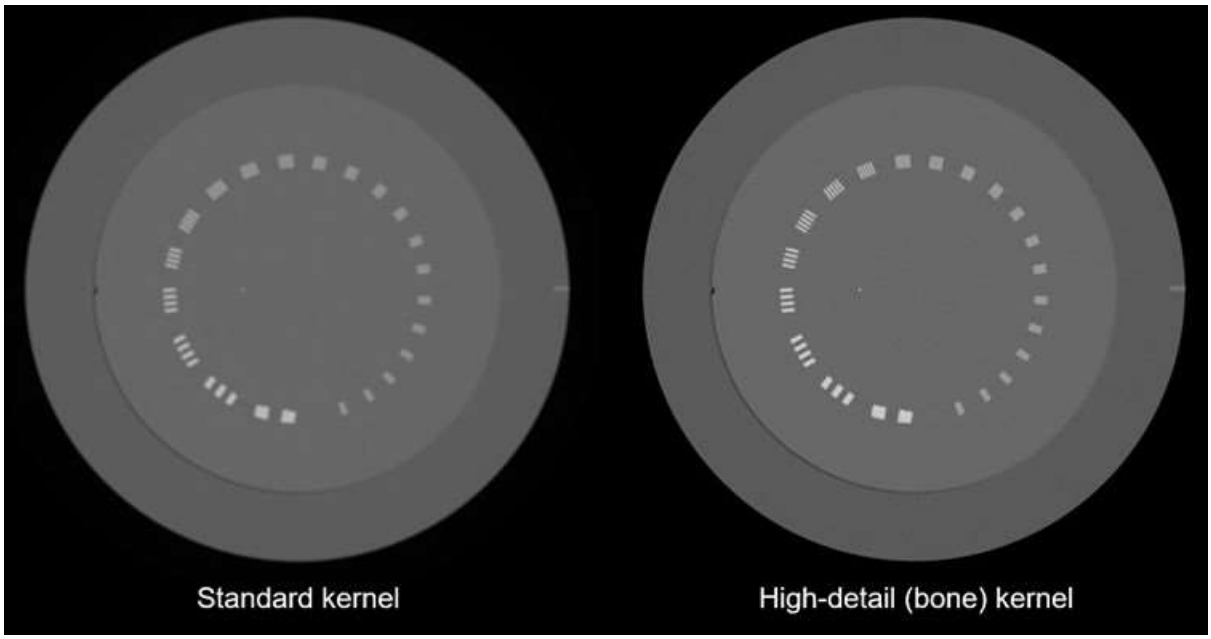

Fig. 5.1. Examples of spatial resolution line-pair patterns with varying spatial frequency presented in CT images reconstructed with a standard reconstruction kernel (left) and a high-detail kernel (right). The image pair demonstrates the significant effect of image reconstruction on the sharpness/blurring of the final axial image. Images have been acquired with 64-slice CT

using a commercially available image quality phantom and the same raw data were used in both images. On the standard kernel image, the visually limiting spatial resolution is around 8 lp/cm (about 0.63 mm) whereas for the high-detail images it is around 11 lp/cm (0.46 mm). Although not apparent from the image, the image noise is significantly increased in the high-resolution image on the right which may limit the use of this option especially in low-contrast diagnostic tasks. The high-contrast point-source for frequency domain analysis of spatial resolution (by MTF) is shown in the central part of both images. Mika Kortesniemi: Finland.

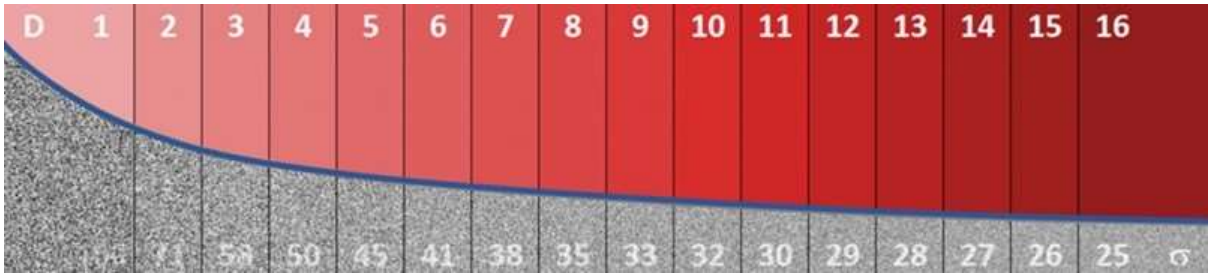

Fig. 5.2. Schematic picture of image quantum noise values described in terms of grey-scale standard deviation σ measured from a homogeneous region, ranging from 100 (left) to 25 (right) in parallel with the corresponding exposure level (relative dose D, ranging from 1 to 16) used in x-ray imaging. The noise in the image decreases as the exposure level increases, and vice versa. The relationship follows the inverse square-root law. One of the most effective optimisation steps in x-ray imaging is the definition of appropriate balance between image noise and radiation dose. Image: Mika Kortesniemi, Finland.

(165) There are also other noise components in addition to quantum noise which play a role in x-ray imaging modalities such as electronic noise (especially with low-dose scanning where the electronic component can be more prominent due to a lower level of integral x-ray signal) and anatomical noise (interference of anatomical structures and tissue textures in an image).

(166) As with spatial resolution, noise can also be presented in the frequency domain by determining the noise power spectrum (NPS) which can be thought of as the grain size distribution of the noise. The NPS is an important descriptor of image quality because it represents the image texture (the noise structure of homogeneous parts of the image). The human visual system is fairly sensitive to differences in noise textures. This may become relevant with image post-processing in digital radiography and fluoroscopy, and with iterative reconstruction methods in CT where the traditional texture appearance of images may be altered to a ‘plastic’-like appearance when lower-frequency (more blotchy) noise components become more emphasised. NPS can be calculated in 2D or in 3D (the latter when the imaging modality allows for volumetric images, provides additional system performance information). Patient lesions and structures are 3D and most (non anthropomorphic) image quality phantoms tend to only carry test objects for 2D analysis (Fig. 5.1) but NPS can usually be calculated also in the third dimension in such phantoms. The NPS has an especial importance in CT, due to the available options in terms of reconstruction methods.

5.2.4. Combined effects of basic parameters

(167) The main image quality descriptor may be used in combination to provide more comprehensive estimation parameters for the observed image quality. The contrast-to-noise ratio (CNR) can be used as a simple measurable physical image quality parameter to describe how a certain level of contrast may be detected by the signal level as compared to the noise. As such, it provides the simplest type of observer model, trying to estimate the level of contrast

detection with only two measurable parameters. However, as anticipated, the actual observed clinical image quality is a much more complicated entity which entails many more image quality related features. Such additional and clinically relevant object (e.g. lesion) features include target size, shape, texture, edge profile, etc. An example demonstrating different levels for visualisation of circular objects depending on object contrast, dimension, and image noise is shown in Fig. 5.3.

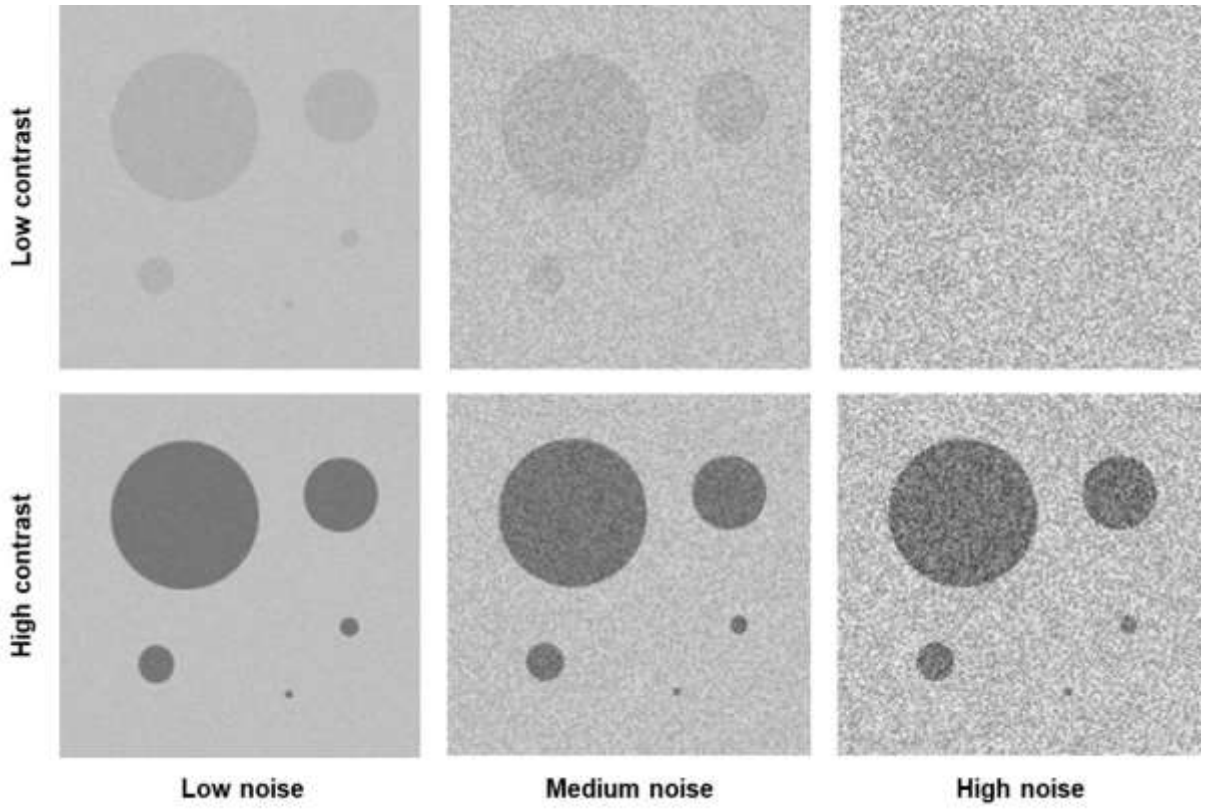

Fig. 5.3. Example of circular contrast targets with two different contrast levels (stronger contrast on lower row images) and varying noise level (increasing noise from left to right images). Each image includes five targets with varying target size and random positions in the field-of-view. The images demonstrate the different visibility of targets and how smaller targets are harder to detect despite the same CNR as in the larger targets in the same image frame. Images: Mika Kortesniemi, Finland.

(168) In addition to fundamental contrast, spatial resolution and noise evaluation, other factors are also relevant for traditional image quality assessment, such as image uniformity and image artefacts. Image uniformity describes the ability of the imaging chain to keep the contrast representation constant (i.e. no additional contrast gradients or alteration to the background signal level) in the entire image field-of-view. Image artefacts refer to additional contrast features in the image which are not present in the imaged object. There are many types of artefacts in the imaging systems and they vary between radiological modalities (e.g. radiography plates may have scratches and punctate densities that mimic stones while CT images may present ring artefacts if detector air-calibration has not been successfully performed). Artefacts may also be caused by physiological and non-physiological patient motion, or medical devices that are inside, on, next to, or under a patient. Overall, image non-uniformities and artefacts should be monitored and avoided as they interfere with the image review regardless of the x-ray modality.

(169) The preceding image quality description concerns the technical imaging chain. On the image review and observer level, there are still more parameters such as room illumination, display monitor performance, display viewing distance and even operator noise (concerning inter and intra observer variability) which eventually have an effect on the image quality optimisation. Because of those aspects, a comprehensive evaluation of clinical image quality for optimisation is a highly challenging task. In order to develop the optimisation process and methods further, specifically in order to move further from the traditional image quality parameters and utilise more clinically relevant image quality metrics, model observer methods are introduced in section 5.3.3 and expanded in Annex B.

5.3. Objective technical image quality assessment: metrics and phantoms

5.3.1. Geometric image quality phantoms: requirements

(170) The three x-ray modalities: digital radiography, fluoroscopy and CT have in common certain basic tests and hence phantom design requirements to measure the technical performance of the systems in terms of image quality (Mah et al., 2001; Xu and Eckerman, 2009; DeWerd and Kissick, 2014; Hernandez-Giron et al., 2016). The phantoms used should contain patterns or test objects to enable measurement of uniformity, noise level, spatial resolution, low contrast detectability (threshold for the smallest object and or contrast level of similar attenuation to the surrounding background) in terms of CNR, and the presence of possible artefacts in the images (an example for fluoroscopy is shown in Fig. 5.4). These basic image quality parameters do not require sophisticated tools for quantification but they still reflect the most important features contributing to technical image quality. Therefore, they will define the level C methods.

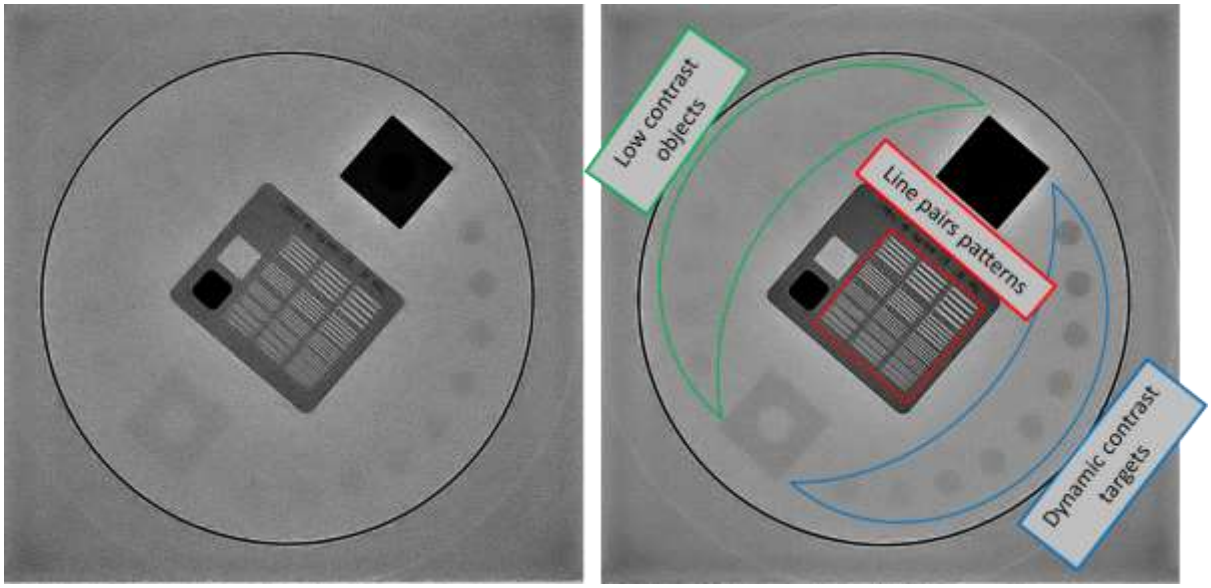

Fig. 5.4. Fluoroscopy images of an image quality phantom containing two radial distributions of low contrast targets (highlighted in green) and dynamic contrast targets (highlighted in blue) and spatial resolution patterns (middle square). The selected abdominal protocol offered a low dose (left) or high dose (right) setup. The low dose protocol provided less X-ray quanta reaching the detector and hence a lower image quality level as can be seen in this image pair. Images: Irene Hernandez-Giron, The Netherlands.

(171) Image quality evaluation may cover an extensive set of methods beginning from the signal generation of the imaging modality, and ending up with the diagnostic task using clinical data. An example of the fundamental technical level is the testing of the calibration curves used to translate the signal reaching the detector into the grey values in the images. For instance, a technical CT image quality phantom with a set of materials with well described attenuation for the applied x-ray energy can be used (Fig. 5.5, left) to test the correct contrast performance of the scanner. This is done in conformance with the guidelines and specifications of the phantom providing the tolerance values for reference. These tests would guarantee the correct representation of CT numbers (depending on the x-ray energy spectrum) for different tissues in the patient as these phantoms usually cover a wide range of tissue equivalent attenuations, ranging from dense bone, through various types of soft tissue (e.g. muscle and fat) to air.

(172) There are numerous commercial phantoms that are widely accepted worldwide for these tasks by medical physics organisations and used as standard in guidelines for QA. These phantoms are usually called 'geometric phantoms', because they have simple geometric shapes (such as cylinders, squares, lines, line-pairs, and points). They contain patterns of objects in a uniform material background to measure the aforementioned image quality metrics. The vendors of imaging devices often have their own basic phantoms that can be used to quickly check most of these parameters, if the specifications of such phantoms are known (Fig. 5.5, right).

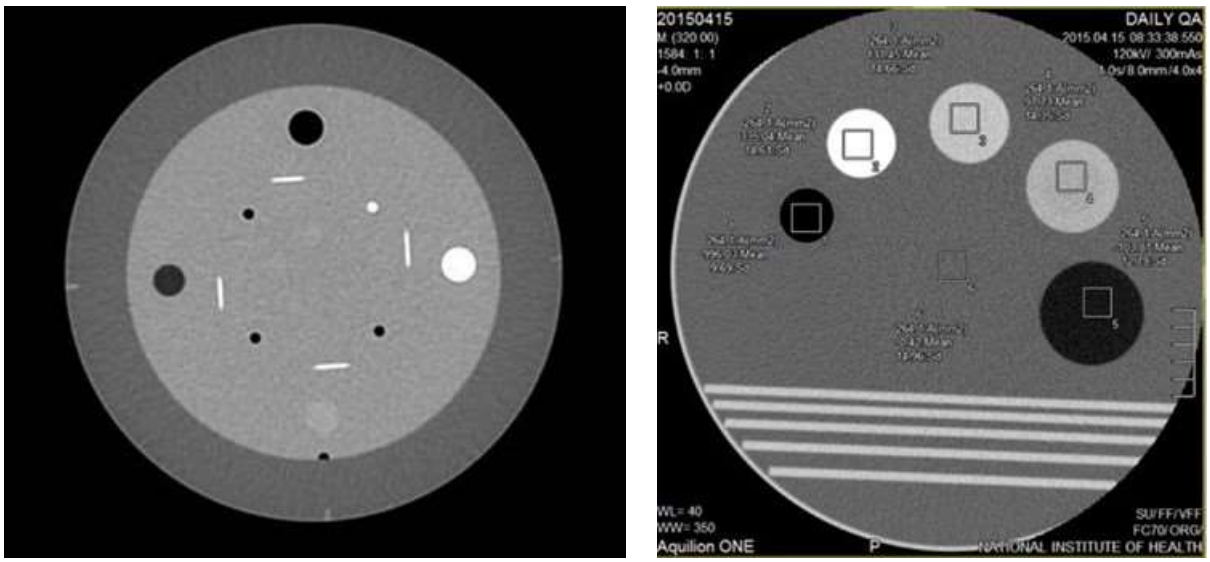

Fig. 5.5. CT image of a commercial phantom used to measure linearity, containing different materials with known attenuation properties (left). On the right, an example of a CT vendor specific phantom, used in their regular testing. Images: Irene Hernandez-Giron, The Netherlands.

(173) For all three modalities, especially for optimisation of clinical protocols, it is recommended to mimic (at least) the total attenuation of the patient. In the case of digital radiography and fluoroscopy, commercial phantoms are usually thin and do not reproduce the total attenuation of the patient head or body. They should be combined with Polymethyl methacrylate (PMMA) blocs or copper plates placed at the x-ray tube exit to reach an equivalent total attenuation to a patient and hence enable the imaging system to perform in automatic mode as it would in clinical use and measure image quality and dose closer to the clinical setup. If such an attenuator is not available, even a simple water container may be used to create the relevant net attenuation. In the case of CT, the phantoms used for protocol optimisation should

not only reproduce the total attenuation of the patient, but also their shape and overall size in the x-y direction for the investigated indication (body region). This is especially crucial in CT protocols combined with automatic exposure control. Some commercial phantoms have external rings that can be bought separately for this purpose (Fig. 5.6). As an alternative for soft tissue, water slabs or bolus can be used to increase the diameter and attenuation of the phantoms to make them closer to the desired patient size (Gardner et al., 2014).

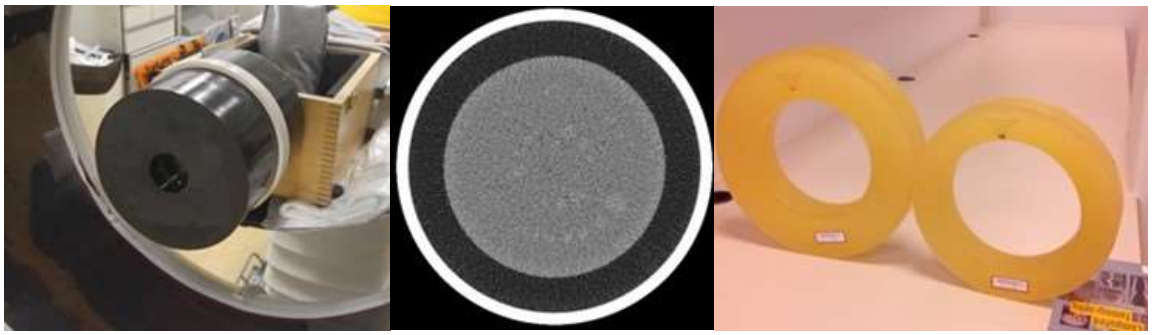

Fig. 5.6. External Teflon ring to mimic the attenuation of the skull (left) placed around the Catphan phantom low contrast module, CT image of this configuration and the effect on low contrast detectability (centre) and two abdominal rings of different sizes (right). Images: Irene Hernandez-Giron, The Netherlands.

5.3.2. Low contrast detectability

(174) Low contrast detectability (LCD) is frequently assessed by human observers estimating the number of objects (with a similar attenuation to the surrounding background) that can be detected in the images for CT (Fig. 5.7), digital radiography and fluoroscopy. The patterns and object distribution are frequently known beforehand by the observers, which introduces a bias in the results.

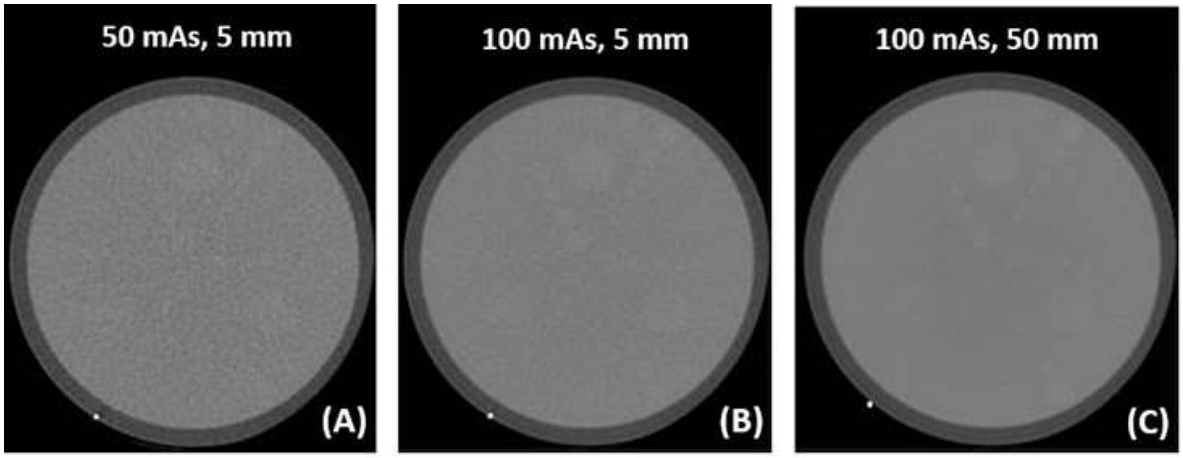

Fig. 5.7. Examples of the improvement in low contrast detectability in CT phantom images with round contrast targets. Different visualisation of LCD is apparent and improves when dose is increased (between A and B) and slice thickness (between B and C). Images: Irene Hernandez-Giron, The Netherlands.

(175) If the same observer is asked to score the same set of images in different sessions, differences in the responses might appear (intra-observer variability) and also when compared to other observers (inter-observer variability). This is the only technical image quality metric

that is still assessed mostly visually. As an alternative to this subjective method, model observers (section 5.3.4) have been successfully applied to assess LCD in an objective and repeatable manner, but still showing comparable metrics and trends similar to human observers for different imaging modalities in combination with simple uniform background phantoms (Hernandez-Giron et al., 2011; Vaishnav et al., 2014; Racine et al., 2016; AAPM, 2019e). These methods will be covered in the next sub section.

5.3.3. Model observers

(176) Human observer studies are generally applied to validate and optimise the image quality of novel imaging systems before entering into routine clinical use. Such observer studies are performed by radiologists and based on the scoring of geometric or anthropomorphic phantoms, sometimes containing lesion-like objects. This approach is time consuming, complex and expensive. A simplified version with skilled observers for instance medical physicists performing simple detection tasks, such as the assessment of low contrast detectability of targets (surrounded by uniform backgrounds) in geometric phantoms is widely used. The results of these perception studies are constrained to the range of conditions and type of images analysed, which rarely represent all the available options in the imaging device. Besides this, a wide intra- and inter-observer variability may appear, as will be discussed in the next section. Thus, alternative objective and reproducible methods are needed to avoid these bottlenecks of human observer studies.

(177) Consequently, there is a growing trend to use statistical decision theory for image quality assessment in medicine. Model observers are mathematical algorithms that were first introduced into medical imaging as surrogates of human observers for the detection and discrimination tasks of simple objects. As such, they are not a substitute for the clinical validation of protocols or systems, which is still crucial and needs the intervention of radiologists scoring patient images (Hernandez-Giron, et al., 2011; Solomon et al., 2016; Ba et al., 2018; Viry et al., 2021). Furthermore, model-observers cannot currently be regarded as routine tools for optimisation, but as a more advanced methodology which requires specific image processing or medical physicist knowledge for successful implementation. Nevertheless, model observers provide valuable tools as they pursue the characterisation of image quality in diagnostic tasks in an objective way, although in an approximate manner and are likely come into regular use by medical physicists in the future. Moreover, some medical imaging manufacturers use model observers to support their claims regarding low contrast detectability in phantoms, with the acceptance of regulatory organisations, in particular for CT imaging (COCIR, 2016).

(178) Model observers have two main applications in medical imaging that will influence which model to select and how it should be implemented. The simplest application is to evaluate and optimise the acquisition performance of the medical imaging system. In this case, it may be sufficient for the ideal model observer to approximate a human observer, although it will overestimate the practical diagnostic performance (Barrett et al., 1993; He and Park, 2013). The second application is to test the image reconstruction process. This is a more demanding task especially with modern CT scanners that include more complex image reconstruction algorithms which bypass the physical image quality parameters used for traditional estimates (i.e. non-linear, frequency-dependent, and locally variable noise distributions). More complex model observers have to be applied in this case, leading to anthropomorphic model observers.

(179) The anthropomorphic model observers include approximations to certain aspects of the visual perception process and its frequency dependence in their implementation, expressed

in mathematical form. These aspects can be related to the way the human eye filters the frequencies present in the images or how the detection process is triggered in the human visual cortex. Two main subclasses of anthropomorphic model observers are used in medical imaging: the non-prewhitening matched filter with an eye filter (NPWE) and the Channelised Hotelling model observer (CHO). One example of application of model observers is the assessment of low contrast detectability of simple objects, such as those present in commercial phantoms for QC. More detailed information about the model observers' implementation can be found in the Annex B.

(180) Besides the basic image metrics already mentioned, there is a more complex level related to the individual diagnostic tasks that will be dependent on the indication, disease and patient variability. This would be related to applying model observers to anthropomorphic phantoms containing lesions or even patient images, and is an active field of research. In future, model observers are expected to be applied in connection with AI-based image quality assessment methods, in order to provide these new methods with a well-established reference (ground truth) for training, validation, and testing.

5.4. Subjective evaluation of image quality

5.4.1. Evaluation of clinical image quality

(181) Subjective evaluation of clinical image quality by an expert reviewer is a cornerstone of practical radiological optimisation. Judgements of image quality must be made by professionals with appropriate training and experience, primarily radiologists. Regular and systematic clinical image quality evaluation has been undertaken as a part of QA, or in a part of that process referred to as self assessment. Clinical image quality evaluation is also an on-going task of the technologist/radiographer during the normal clinical workflow, in cooperation with medical physicists when required (for instance when a previously unseen or unknown artefact appears). For example, in projection radiography this will be done immediately after the image acquisition, in order to verify that the image has been successfully produced with appropriate projection, collimation and post-processing. Clinical image quality evaluation should also be an integral part of radiologist image review, with prompt feedback to those involved in image acquisition if sufficient image quality is not achieved due to technical or procedural reasons.

(182) Subjective expert evaluation of clinical image quality by radiologists forms part of the routine self-assessment process included in the QA programme of the radiological department. The subjective evaluation of clinical image quality should be graded based on image quality criteria for each modality and clinical indication. Ideally this would be paired with patient dose audit. With that said, determination of good image quality should never be based on just an ad hoc expert judgement. It should always be based on consistent and systematic good image quality criteria which describe explicitly the anatomical features that should be seen in a patient image, the coverage or projections that should be included, and how the patient should be aligned to secure a reliable and reproducible appearance of possible pathological findings. Eventually, this diagnostic quality and reliability can be described by sensitivity, specificity, accuracy and predictive value related to specific clinical indications. In practice, for a sample of patient images, assessment of clinical image quality is typically based on numerical scorings with respect to applied good image quality criteria.

(183) To illustrate good image quality criteria with an example, a regular chest x-ray PA (posterior anterior) projection will be used. Many professional societies in medical imaging

have offered guidelines for this traditional projection radiography view. Hereafter, the European guidelines that have already been in use for over two decades are summarised (EC, 1996a). These still encapsulate the essential role of clinical image quality aspects in general radiographic acquisitions and there is a companion set of guidelines for paediatric radiography (EC, 1996b).

(184) According to these guidelines the PA chest radiograph (e.g. Fig.5.8) diagnostic requirements should fulfil the image criteria shown in Table 5.1. The diagnostic requirements in any modality and examination should be accompanied by criteria for patient dose in terms of DRLs (and possible local DRLs), and recommended criteria for exposure or acquisition technique applied to the available imaging equipment.

Table 5.1. Overview of diagnostic quality image criteria for PA chest radiography based on current guidelines (in brief), together with a patient image fulfilling them (EC, 1996a).

General image criteria for PA chest radiography
i. Image acquired (typically) in full inspiration with symmetrical reproduction of the thorax. ii. Medial border of the scapulae excluded from the lung fields iii. Showing the whole rib cage above the diaphragm iv. Sharp representation of the vasculature in the whole lung region with particular emphasis on the small vessels in peripheral parts v. Clear visualisation of trachea and proximal bronchi, borders of the heart and aorta, diaphragm and lateral costo-phrenic angles vi. Clear visualisation of the retrocardiac lung, mediastinum and spine through the heart shadow
Specific image criteria for PA chest radiography
In addition to these general image criteria, the PA chest image should also conform to appearance of specific details entailing reliable visualisation of: i. Small round details in lung area, also including the retrocardiac areas (high contrast details down to 0.7 mm diameter and low contrast down to 2 mm diameter) ii. Linear and reticular details towards the lung periphery (high contrast details down to 0.3 mm in width and low contrast down to 2 mm in width).
An example of a clinical image quality scoring card according to these PA chest x-ray image quality criteria is provided in EC (1996a).

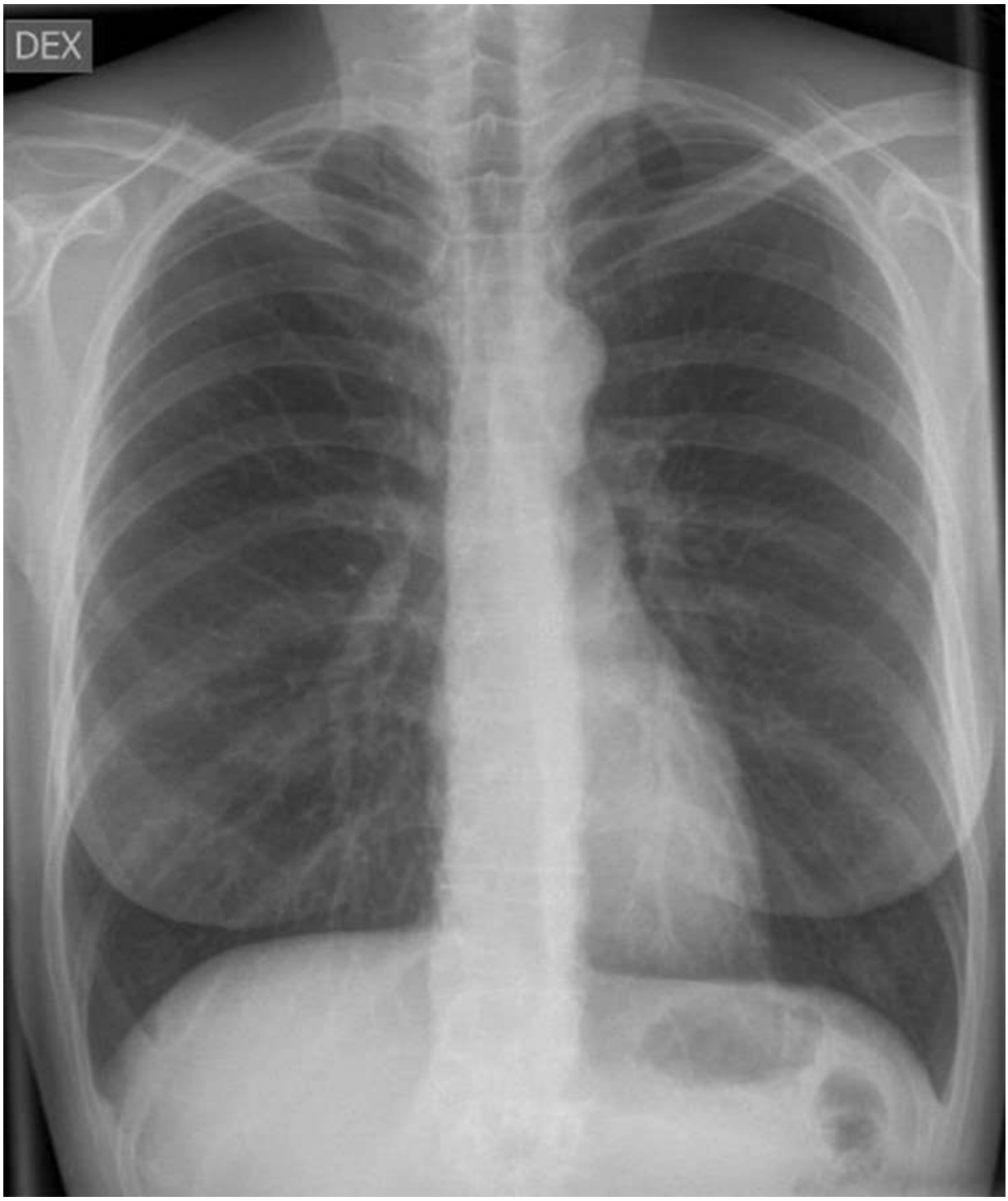

Fig. 5.8 An example x-ray chest PA projection produced according to the image quality criteria. Image courtesy of HUS Diagnostic Centre, Finland.

(185) Establishment of simple image quality scoring criteria for subjective evaluation of clinical images for a range of scenarios, based on adequate visualisation of pertinent anatomical structures and the usefulness of the image, could be used to assess images in busy departments and help to reduce variability between observers. An example of this approach using image quality scoring criteria developed for paediatric CT images has been reported by Padole et al. (2019). Simple (and practical) scoring criteria of this type should be 'indication-based' and radiologists participating in the evaluations should first ensure that the criteria are applied

consistently, as discussed earlier in this section. More detailed assessment criteria for CT images have been published by the European commission which can provide information about essential features that can be used for evaluating CT images (EC, 1998).

(186) Subjective image quality evaluation also links to the concept of visual grading characteristics (VGC) analysis, in which the main task is to score or grade how well relevant anatomical structures are reproduced in the images for a given indication. For example, several sets of images of the same patient (with varying acquisition and/or reconstruction parameters) can be presented to the radiologists who have to determine if the relevant anatomical or pathological structures are adequately represented (Båth and Månsson, 2007; Verdun et al., 2015). Another approach can be to ask the observers to pick the image set they prefer in terms of diagnostic image quality. These studies can be carried out also with anthropomorphic phantoms at the early stages of the optimisation process but always taking into consideration the anatomical differences (especially in terms of tissue or organ texture complexity and composition) between phantoms and patients. The outcomes of the optimisation based on the scoring of patient images based on VGC, will be highly dependent on the selected patient cohort characteristics. This cohort should be representative of the general target population for the indication being studied. The final stage of the optimisation process should be tailored to the clinical application and involve the multi-professional team of technicians / radiographers, medical physicists and radiologists.

(187) The organised and systematic cooperation of technicians / radiographers, medical physicists and radiologists is crucial. These studies are usually based on the selection of a cohort of patients for which certain acquisition or reconstruction parameters in the imaging protocols will be changed, within reasonable values that can be setup beforehand using anthropomorphic phantoms or even cadaver images. Thus, different image sets will be ready to be scored subjectively by radiologists (and potentially analysed in parallel by medical physicists applying objective image quality metrics, as seen in sections 5.2 and 5.3).

(188) This approach to protocol optimisation, though necessary, is complex, expensive and time consuming. As an alternative in some cases, anthropomorphic phantoms, represent to some extent the patient normal anatomy and even disease stages (for instance, different types of lung nodules or liver lesions, with varying composition and shape) and can be used for concrete task-oriented protocol optimisation. Though these phantoms mimic patient anatomy and attenuation and are realistic for dosimetric purposes, some of them lack certain relevant tissues (such as lung parenchyma), realistic tissue texture, or enough variability in terms of pathology distribution or characteristics (Gavrielides et al., 2017; Hernandez-Giron et al., 2019). Though they are a good starting point for clinical protocol optimisation and testing of artefacts and are more realistic than the traditional geometric phantoms, the extrapolation of the outcomes of such phantom studies for patients has to be done with caution.

(189) The recent developments in 3D printing, as a customisable and low-cost alternative to create image quality phantoms will likely improve the ability of phantoms to replicate tissue characteristics and widen the range of patient and disease variability that can be used in evaluations (Filippou and Tsoumpas, 2018). An example of such phantoms for CT, in particular mimicking a small section of the lung vessel distribution, and combined with nodule surrogates (whose detectability can be analysed with model observers as a function of the selected protocol) is shown in Fig. 5.9 (Hernandez-Giron et al., 2019; Zhai et al., 2019).

(190) Various techniques can be useful in the detection of features or abnormalities and these are described in more detail in the Annexes to this report. Receiver operating characteristic (ROC) analysis can be used for comparing performance between observers or between two imaging protocols in detection tasks involving decisions as to whether a case is ‘normal’ or ‘abnormal’ (Annex C). Multi-alternative forced choice study, consists of several

images displayed simultaneously containing different alternatives from which the observer is forced to choose one of the images as being 'abnormal' (Annex D).

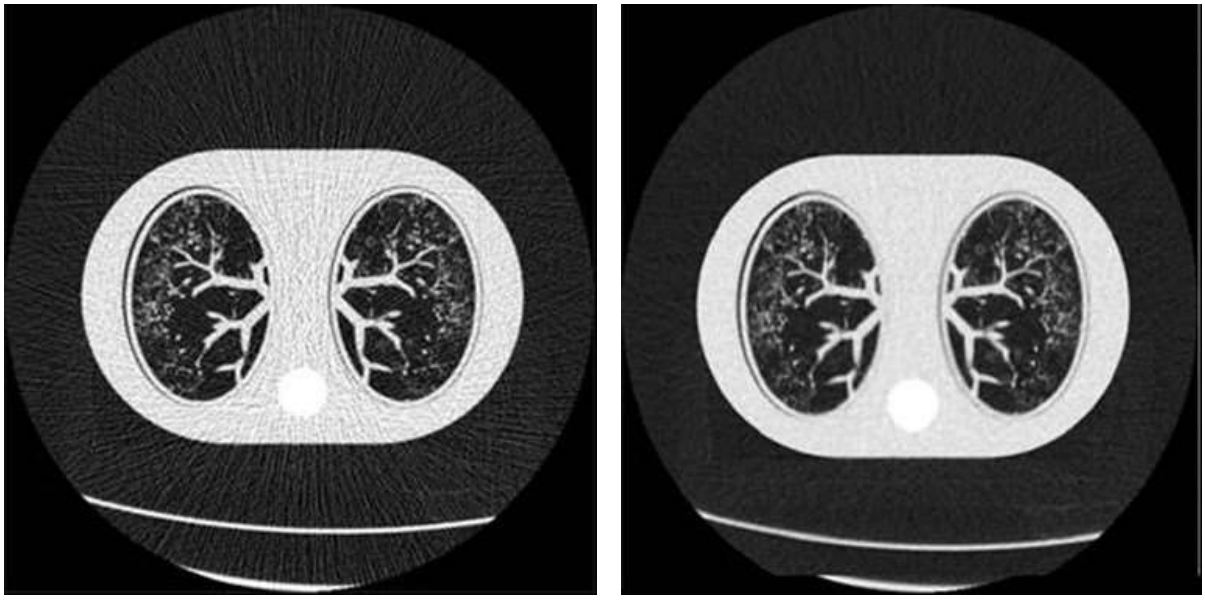

Fig. 5.9. CT images of a thorax phantom with two 3D printed inserts mimicking lung vessels, combined with lung nodule surrogates. For an Ultra-low dose CT protocol (dose equivalent to a chest x ray), on the left the images were reconstructed with filtered-back projection and on the right with iterative reconstruction. Images: Irene Hernandez-Giron and Wouter J.H.Veldkamp, The Netherlands. CLUES project (CLUES, 2021).

5.4.2. Role of display monitors and their performance in the image quality chain

(191) The scoring of medical images should be performed following internationally recommended visualisation conditions in a darkened room appropriate for diagnostic purposes (AAPM, 2019d). Monitors have to be calibrated to visualise DICOM images and comply with the requirements of pixel size related to the desired imaging modality. For instance, the requirements for mammography images in terms of the pixel size are more demanding than for CT or digital radiography. The most widely used criteria are those proposed by the AAPM task group 270 related to medical displays (AAPM, 2019d). AAPM also released a set of test images (phantom and patient) that can be used to check monitor performance. The visualisation settings for window level and window width should be tuned to the clinical task at hand. In fluoroscopy rooms, where the image visualisation has to be done in real time, the monitors should also be adequate for the diagnosis and properly calibrated. For the protocols where low contrast tissues need to be accurately visualised, the interventional room lights can be partially dimmed (when it is safe during the procedure) to enhance the interventionist's grey level perception of the images.

(192) In the last few years, the use of mobile devices, such as cell phones and tablets has been proposed as an alternative for the visualisation of medical images. The lifespan and performance of these types of screen have not been thoroughly studied so far, and with the current available technology, they should never replace a calibrated diagnostic monitor. In the coming years, these mobile devices might be given clearance to be used for medical applications, but they should always be calibrated to display medical images and also used in the correct ambient luminance conditions. Owing to the shortage of radiologists worldwide, and to a greater extent in the low- and middle-income countries, wide expansion of the

utilisation of mobile phones has already started and is expected to increase markedly in the next few years, therefore concurrent evidence-based research studies are required to ensure the best performance of the mobile screens to be used in medical diagnostic applications (AAPM, 2018).

5.5. Future aspects of Radiomics and Artificial Intelligence in determining image quality

(193) Artificial intelligence (AI) and its subsets, machine learning and deep learning, are developing quickly to provide versatile methods for a wide range of optimisation related tasks, and the image quality framework needs to evolve to address their impact in the image chain and patient outcomes.

(194) AI had originally been defined as an area of science where machines perform tasks which typically require human thinking (Boden, 1977). Within the concept of AI, machine learning (ML) is seen as a subset of AI methods aiming towards data-driven decisions via models created from large-scale training data (Natarajan et al., 2017). As such, ML may provide outcome prediction on new unseen data based entirely on earlier training data without previous programming or hand-crafted models. Therefore, ML methods learn from experience (Meyer et al., 2018). Further in the hierarchy of ML methods, deep learning (DL) forms a subset of ML with a gradually increasing level of abstraction as the data are fed through several data processing layers in a neural network architecture, providing higher abstraction level features from the original input data (Krizhevsky et al., 2012; Adam et al., 2017; Meyer et al., 2018). The hierarchy of these methods is presented in Fig. 5.10.

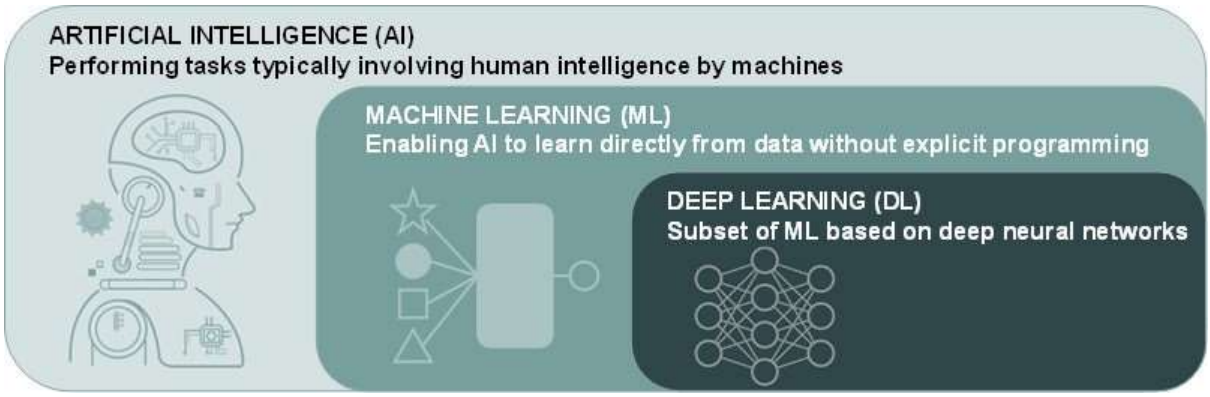

Fig. 5.10. Hierarchial concepts from artificial intelligence to machine learning, and to deep learning. Methods of artificial intelligence cover a wide range of applications where the availability of big data and increased computing power has enabled the rapid development of machine learning. As a subset of machine learning, deep learning has demonstrated versatility in application to a number of tasks also related to optimisation.

(195) Various methods related to AI, ML and DL are developing fast around healthcare as in all sectors of science and industry (Ranschaert et al., 2019). As shown before, DL is already being used in CT image reconstruction. Increasing interest has been shown in ML for radiology because typical imaging objects such as lesions and organs appearing in medical images are in practice far too complex to be described by a simple equation or hand-crafted model as used in conventional computer aided diagnostics (Litjens et al., 2017; Suzuki, 2017). The DL methods, especially convolutional neural networks (CNN) and its variants have already shown convincing results in medical imaging related to many diagnostic tasks traditionally handled

by human experts. Such tasks include lesion or tissue localisation, segmentation, classification and clinical outcome prediction (Litjens et al., 2017).

(196) The main challenge in AI methods has been in the access to a sufficient amount of annotated and representative training and validation data, which is a fundamental prerequisite to achieve sufficient robustness in making AI methods more generally applicable to clinical regimes (Adam et al., 2017; Litjens et al., 2017; Meyer et al., 2018). This robustness must also be proven with retrospective and prospective clinical validation trials extending to varying multi-centre data before such methods can be safely applied in wider clinical routine. These further steps take time and are still lacking in many of the current early-stage diagnostic AI research studies.

(197) AI methods can also be applied directly in the optimisation of the radiological chain. Image quality classification and grading, in addition to patient specific dosimetry, may be realised with a ML/DL approach (Samei et al., 2018). These fast-developing objective and efficient AI algorithms may complement and ultimately replace traditional methods such as model observers for image quality assessment and Monte Carlo simulations for dosimetry calculations (Lee et al., 2018; Maier et al., 2018). The first attempts to develop model observers to deal with patient images were based on deep learning to tackle the variability of anatomical background and its influence in low contrast detectability (Gong et al., 2019). The principle of optimisation goes much further than just balancing image quality and dose. In medical imaging, it should finally lead to objective and reliable quantification of diagnostic value in terms of care outcome. Therefore, the final conceptual level of optimisation should concern risk vs benefit assessment performed for individual patients and clinical procedures (Samei et al., 2018). In order to achieve such a comprehensive level of optimisation, many types of clinical and healthcare data are likely to be needed in combination with the diagnostic imaging data to produce adequate clinical metrics and multi-dimensional features used for clinical outcome classification and prediction models (Esteva et al., 2019).

(198) In general, AI in healthcare can develop in synergy with the exponential growth of available curated data to create possibilities for better-informed decisions. Finally, these developments are expected to improve quality and safety of healthcare, and also reduce costs by enabling more preventive and personalised care (Adam et al., 2017; Mollura et al., 2020).

5.6. Overview of stages of development

(199) Some of the steps discussed in section 5 are set out in Table 5.2 in terms of the levels of optimisation discussed in Section 3. More information on implementation of image quality assessment relating to different modalities in terms of levels is given in Annex E.

Table 5.2. Classification of image quality metrics and methods linked to the implementation levels.

D: Pre-optimisation level (basic infrastructure)
• Availability of vendor phantom for basic image quality assessment for all imaging modalities

- Availability of simple protocols to test system performance with such phantoms, following the vendor guidelines, simple visual scoring, use of vendor software or freeware for basic image analysis.
- Purchase of phantoms for image quality evaluation

C: Basic (level D, plus)

- Availability of simple protocols to test system performance with vendor phantoms, following the guidelines provided, simple visual scoring, use of vendor software or freeware for basic image analysis.
- Evaluation of clinical images through regular reporting by trained radiologist
- Subjective clinical image quality evaluation should be a part of routine self-assessment and paired with patient dose audits.
- Utilisation of clinical image data in simple assessments by using contrast and noise measurements from regions of interest, enabling CNR level image quality assessment from image data.
- Using specific geometric phantoms (if possible, recommended in international guidelines to favour benchmarking between systems and hospitals) for image quality assessment in the image domain – contrast, noise, spatial resolution, artefacts, uniformity, geometry, image collimation and centring, detector exposure index (EI) – as measured manually and evaluated visually.

Diagnostic monitor QC in the form of a visual test image review, based on SMPTE (Society of Motion Picture and Television Engineers) or preferably more versatile test patterns, such as TG18-QC (AAPM Task Group 18-QC) (AAPM, 2019d).

B: Intermediate (levels C and D, plus)

- Expansion of image quality evaluation to more versatile phantoms – geometric phantoms that mimic the total attenuation and/or shape of the patient. This may be through specially designed phantoms or through use of test objects in combination with external rings/supplements for different body parts (such as head or abdomen) to test IQ closer to the clinical situation.
- Comprehensive and systematic QA programme for IQ covers all imaging modalities. Image quality and dose measurements combined together using anthropomorphic phantoms for selected clinical protocols.
- Comprehensive display monitor and illumination measurements: visual evaluation of test patterns, monitor DICOM greyscale standard display function (GSDF) contrast and luminance response and uniformity measurements with luminance meter. Verification of monitor consistency in a multivendor setup.

Optional progressive steps towards A level:

  - Simple model observer evaluations – detectability of low contrast objects in phantoms- in selected optimisation tasks involving image quality assessment.

A: Advanced (levels B, C and D, plus)

- Use of anthropomorphic phantoms as consistent patient surrogates in terms of dose and if possible, containing anatomical structures and organs, for visual IQ tests and clinical image quality self-assessment, artefact check, protocol dose check compared to standard patients, and basic IQ tests in the image domain.
- Systematic and wide scale monitoring of image quality measured on phantom images acquired in radiological QA programme for the main imaging modalities, covering also display monitors for primary diagnostics and secondary use. Image quality monitoring combined with radiation exposure monitoring.

Optional (A+):

- Application of model observers, based on indication specific task functions. These models should be used in combination with anthropomorphic phantoms mimicking typical patient and organ representation. Images of these complex anthropomorphic phantoms could also be scored subjectively by radiologists during the optimisation process.
- IQ metrics applied directly from patient clinical image data possibly AI/ML/DL based methods.
- Further development: Connection of objective and quantitative IQ follow-up applications with comprehensive and on-line quality management and patient safety monitoring system, and linked to continuous hospital wide audit process (also accounting for management and systematic continuous improvements at an organisational level).

2461

6. EDUCATION AND TRAINING OF CLINICAL STAFF IN OPTIMISATION METHODS

(200) **Key points in this section:**

- **Investment in an adequate staffing level, with trained healthcare staff and a commitment to their continuous professional development (CPD) are essential when considering investment in new imaging equipment and software.**
- **Key professional groups each need a specific set of knowledge, skills and competencies (KSC) to ensure their effective contribution and participation as a team in the optimisation process. These KSCs are obtained and maintained during university education, and throughout their careers during periods spent in training positions, residencies, and through focused courses for CPD.**
- **Training plans should be established with well-constructed programme delivery tailored to the needs of the local facility and staff, dependent on resources available.**
- **Medical physicists have a key role in optimisation, ensuring a link between the equipment and its clinical users. The ICRP strongly recommends that their education and clinical training be adequate for performing this role and for educating others in radiological protection.**
- **X-ray equipment is becoming more complex, so operators require higher levels of knowledge and skill. If features that could potentially reduce dose are set up incorrectly, they can have the opposite effect, so the need for careful, continuous efforts in training staff has never been more crucial than it is now.**
- **Optimisation training is more effective when provided by a multi-disciplinary core team. This will improve mutual understanding, build a team culture, and promote effective communication. Regular reflective meetings on optimisation and review of lessons learned from safety and near-miss events will support on-going education.**
- **Professional societies should provide training programmes, and regulatory and health authorities should encourage medical facilities to implement training in optimisation.**
- **Virtual and on-demand web-based packages can improve access to training and enable review of material independent of time and location. Online training materials could play a significant role for facilities in developing countries with fewer resources by reducing the demands of travelling and scheduling, and improve overall cost-efficiency.**
- **Vendors of imaging equipment and software should produce updated training material in parallel with the introduction of new systems to promote optimisation.**

6.1. Introduction

(201) The use of radiation in medicine may result in unnecessary radiation exposure where equipment is in the hands of untrained or undertrained operators. But this could be largely avoided if the operators were adequately trained in techniques for the optimisation of protection (Bor et al., 2008). Although the delay in manifestation of long-term health effects resulting from exposure to ionising radiation makes the associated risks difficult to comprehend or

monitor, the overarching requirement 'to do more good than harm' makes radiological protection of patients an important ethical duty (ICRP, 2018). Education and training in radiological protection can enhance personnel understanding, foster the development of a culture of safety, teamwork, and professionalism, and improve workers' satisfaction and commitment to radiological protection principles (ICRP, 2018). Investment in an adequate staffing level, with trained healthcare staff and a commitment to their continuous professional development (CPD) are essential when considering investment in new imaging equipment and software.

(202) ICRP *Publication 113* sets out a comprehensive discussion of the basic education and ongoing training of all stakeholders in radiological protection in medicine, including suggested content, objectives, management approaches, and the approximate minimum time needed for this training (Table 3.1 in ICRP, 2009). The recommended knowledge content about radiological protection and dosimetry is important, but effective optimisation also requires other critical skills, namely building a strong team and safety culture based on mutual respect and effective interaction and collaboration between the professional groups. This becomes ever more important with the increasing complexity of modern x-ray equipment. Radiologists and radiographers need to work closely with medical physicists to ensure the operation of dose reduction features are understood and facilities are used properly. Professional links and mutual understanding should be developed from the start through collaborative training and continuing dialogue, with regular reviews and update training focused on maintaining and developing competencies in optimisation through a team approach.

6.2. Professionals with a role in the optimisation process

(203) Key professional groups each need a specific set of knowledge, skills and competencies (KSC) to ensure their effective contribution and participation as a team in the optimisation process. These KSCs are obtained and maintained during university education, and throughout their careers during periods spent in training positions, residencies, and through focused courses for CPD.

(204) Education and training of health professionals involved in medical imaging should provide the KSCs needed for them to perform optimisation effectively as part of their role. This is not constrained to only radiology, radiography and medical physics professionals but applies to the full range of professionals involved in medical imaging, as exemplified in Table 6.1. The training of these individuals needs to be built on throughout their careers, the level and detail being dependent on their role. For technologically biased roles, it will include new protocols, software, imaging methods and technologies as they become available. For other roles such as those of the anaesthesiologist and management, simple awareness of the issues may be enough. To facilitate targeted and appropriate delivery of training, up to date and training plans should be developed based on assessment of the needs of the local facility and staff (e.g. infrastructure, staffing, clinical workload and available optimisation options).

(205) A core team for optimisation should include the medical physicist, the radiologist, and the radiographer/technologist. It is imperative that an appropriate training regime is developed for this core group. Team members once they have become familiar with the new technology and appropriate settings, will be more responsible and prudent, more productive, and able to fine tune equipment settings to achieve better results.

(206) Each of the professionals shown in Table 6.1 has an important role to play in optimisation, but due to the specific education as a healthcare scientist, the Medical Physicist has a key role in ensuring a link between the equipment/software and its clinical users. In many

circumstances, the lack of access to a Medical Physicist qualified in medical imaging is an obstacle to optimisation, a problem that is of special importance for rural/small facilities or low- or middle-income countries where the profession does not exist or is not recognised as a healthcare profession. In addition to being responsible for the technical QC and dosimetry, clinically qualified Medical Physicists have specific skills and competencies in optimisation. The Commission recommends that access to Medical Physicists qualified in medical imaging is ensured in all activities related to diagnostic and interventional radiology, and that their education and clinical training be adequate for performing their role in optimisation.

Table 6.1. Health care professionals with a role that affects patient doses.

Personnel	**Role in the optimisation process**
Referring Physicians	Should precisely formulate in the request for an imaging procedure the clinical question to be answered by the procedure and should provide all relevant documentation and information that will support the imaging specialist in selecting the best image acquisition approach (justification and optimisation).
Radiologists	Involved in the decision-making process on the appropriateness of the examination (justification), in patient protocol development and selection, and in interpreting images and reporting results. This specialist takes the main responsibility for patient protection, including optimisation, and also have responsibility for the protection of staff members assisting in fluoroscopic procedures.
Other physicians	Performing image-guided procedures (e.g. cardiologists, orthopaedists, neurosurgeons, gastroenterologists, others), who take the responsibility for selecting optimal acquisition protocols, interpreting images and reporting results. They take responsibility for patient protection and should also play a role in the protection of staff members assisting in the procedures.
Radiographers or Imaging Technologists	In most cases, the operator of digital radiography and CT equipment and the main persons interacting with patients. This specialist is responsible for using the most appropriate acquisition protocols tailored to the patient size and conditions that will provide the diagnostic content needed at the lowest possible dose. Effective interaction with a patient plays a key role in achieving the best results and care. Radiographers will also carry out some QC measurements to ensure constancy of performance is maintained, as part of the QA programme.
Medical Physicists Qualified in Medical Imaging	Apply their scientific knowledge as part of the optimisation team in creating and optimising clinical protocol needs for the many complex CT, digital radiography, fluoroscopy, and fluoroscopically-guided procedures in modern imaging facilities. In addition, the medical physicist duties relate to defining and supervising the QC and QA programmes, which include patient

	dose monitoring, and dose audits for comparison with DRLs. In some countries medical physicists making QC measurements are not facility staff, but employed by independent companies or government institutions and in these cases need to be brought into the optimisation teams to work with other professionals.
Any other staff involved in preparing patients or performing procedures	For example, anaesthesiologists, speech therapists, and nurses, should also have knowledge and skills to support the optimisation process and protect themselves, comforters and carers, and their patients during imaging procedures. An important group here are the clerical staff who make patient bookings and may well have a role in patient identification.
Medical Physicists and Biomedical Engineers involved in specification	Who are involved in the development of technical specifications for purchasing imaging equipment play an important role in ensuring that the x-ray equipment characteristics and the performance requirements are correctly formulated including dose management related requirements.
Maintenance engineers and service specialists	Although not directly involved in the clinical process play an important role in ensuring optimal setting of all equipment parameters and constant performance of the imaging system. These specialists / engineers provide equipment maintenance, install software upgrades, and carry out QC measurements to confirm performance in relation to equipment maintenance and repair. They have responsibility for providing sufficient information and training to the users of imaging equipment on the system features thus helping them define optimal performance.
Facility Managers	Take overall responsibility for the radiological protection programme and resources, for quality and dose management, for staff adequacy and competence, and for building a strong safety culture.
Equipment and software vendors	Although not directly involved in the clinical process, vendors should understand the importance of connectivity to existing systems, providing a plan for initial cascade training, and instruction for a facility's users of new equipment and/or software. Training modules could be provided on their web sites.
Regulators	Regulators should have an understanding of doses, dose units, and both the potential benefits and radiation health risks with each imaging modality for proper RP oversight.

6.3. Understanding requirements of equipment operation for optimisation

6.3.1. The two pillars of optimisation

(207) There are many aspects to optimisation for building quality and safety in diagnostic imaging (see section 1.2), these come under the two pillars of optimisation from *Publication 73* (ICRP, 1996). The first is concerned with facility and equipment and the second with the overall competence of those personnel carrying day to day operational tasks (Fig. 6.1). The personnel need the KSCs to select the appropriate imaging exam, optimise the exam, and protect both the patients and the workers in the room during these exams. In order to acquire the KSC they require to be provided with ongoing training mechanisms through their employer, CPD/CME (continuing medical education), their professional organisation, or government. Inadequate KSCs may result in failure to adjust imaging protocols to the clinical question. This could result for example in not taking into account patient size with the potential result of unnecessarily high (or low) doses and/or poor image quality (ICRP, 2000b,c, 2004, 2007a,c, 2010, 2013a, 2015).

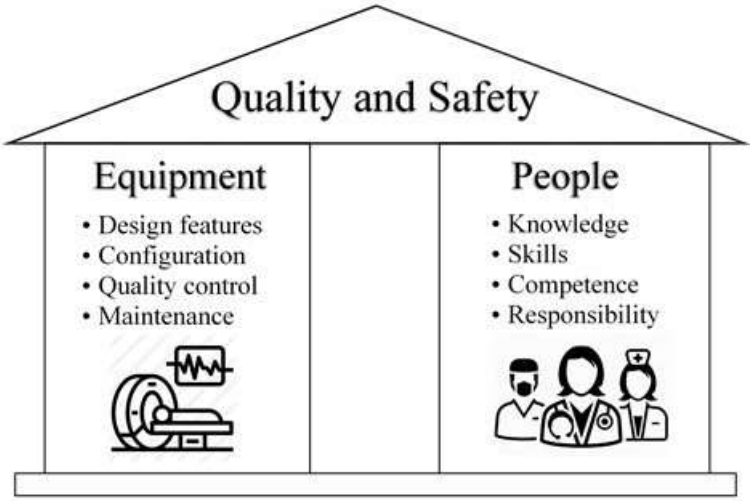

Fig. 6.1. Two foundational pillars of optimisation on which quality and safety in diagnostic imaging are built: the facility design, equipment, and software on the left; and the trained professionals performing the workflow process and imaging protocols on the right.

(208) It is important that training reinforces the principle that optimisation is iterative in that it requires ongoing monitoring, team review, and analysis of performance to maintain and improve protocols, dose reduction, or dose increase when image quality is not adequate, aided by continuous learning and feedback.

6.3.2. Training Issues arising from the complexity of digital imaging equipment

(209) In response to increased awareness of the need for patient radiation exposure management, vendors of medical imaging equipment have developed many technological solutions to improve image quality and reduce patient dose (AAPM, 2019c; Balter, 2019). Modern imaging equipment has more automatic and user-friendly control functions allowing for easier day to day operation and improved optimisation. However, this can create a false perception that the equipment almost works by itself (rather analogous to the driverless car) in acquiring perfect images at the lowest possible doses for patient and staff, but this is far from

the reality. Moreover, vendor pre-set protocols are often not adequately set up to fully provide the best optimisation.

(210) The automated systems to reduce patient dose in modern digital imaging equipment are complex. If they are set up correctly, they will provide a much better service with lower doses, but if they are set up incorrectly, features that could potentially reduce dose can have the opposite effect. Staff may be unaware because the images are good and the dose reduction tool has been switched on (Trianni et al., 2005). Therefore, more complex equipment requires more knowledgeable and skilled users behind the machine, so the need for careful continuous efforts at training staff has never been more crucial than it is now.

(211) Facility managers and clinical stakeholders may be keen to invest in purchasing expensive, high-profile, imaging equipment, but if they do this, they must also support appropriate training programmes tailored to the imaging device for all the staff involved. An efficient strategy may be one of 'cascade training' where a few staff learn more deeply how to optimise the new device / software in order that they can then pass on their knowledge to more staff internally. Otherwise, the full potential of the equipment will not be realised, and patient doses could be increased rather than reduced. Radiology professionals responsible for management, quality and patient and staff safety have a responsibility to ensure that facility management are aware of, and support, the need for the provision of adequate training. The same is true of vendors and their representatives. In this context, vendors also have a responsibility for provision of tools and support to implement such specific end-user training.

(212) Developments in application and use of Artificial Intelligence, notably machine learning, relating to optimisation of imaging are expanding rapidly and have in some cases demonstrated improvements in standardisation and optimisation of protocols when compared to expert radiologists (Mukherjee et al., 2020; Pinto et al., 2021). As this rapidly expanding field moves forward further developments will require validation, policy, and ethical oversight. This will in turn have particular implications for staff training, with a need for teamwork to achieve implementation and establish adequate quality assurance processes. (Levenson, 2012; Li et al., 2020). The associated investment in training needs to be made now- to avoid future clinical errors with potentially catastrophic consequences.

6.3.3. Understanding the concept of optimisation and the team approach

(213) Basic medical education complemented with specific clinical and imaging knowledge is assumed for medical imaging specialists and such education is available from many sources. In addition to this basic and specialist education, imaging professionals must learn the RP principle of optimisation, why they should care about it and how they can work as a member of the core team to implement it across a growing variety of imaging modalities, complex protocols, and patient sizes, and be engaged in it. These are important goals of the training for the core team professionals in optimisation that should be considered when developing learning objectives.

(214) For best results, optimisation education and training should aim to improve patient care and optimise clinical outcome rather than focus on ALARA or dose reduction alone. This is an iterative process (ICRP, 2006, 2017) and strongly related to quality improvement as well as linked to the principles of biomedical ethics (ICRP, 2018; Beauchamp et al., 2019). In this context, training on optimisation should include means to improve professional knowledge, skills and attitudes and develop the competencies needed to effectively implement optimisation, which will also contribute to building stronger teams. Regular reflective meetings on optimisation and review of lessons learned from safety and near-miss events will support on-going education.

(215) When training on optimisation is provided by a multi-disciplinary team, members will complement each other, improve mutual understanding and foster a team culture. Multiple studies show that one of the obstacles for optimisation is the limited appreciation by different professionals of their respective roles and competencies. This creates a barrier to effective communication which leads to delays, protocol errors, sometimes repeat imaging, and patient safety concerns (Hyer and Novello, 2006; EPA, 2007; Lau et al., 2011a,b).

6.4. Provision of training

6.4.1. Ways of sharing information for learning

(216) Guidance on radiological protection education and training of healthcare professionals has been developed for example, by ICRP and the EC, including optimisation among the list of essential learning topics (ICRP, 2009; EC, 2014). Other professional organisations have developed a variety of learning resources on efficient approaches for optimisation (IAEA, 2021a,b).

(217) Knowledge (theoretical basis), skills (ability to apply this knowledge) and attitudes (the personal and interpersonal behaviour needed to perform duties with high quality and safety), as components of a person's KSCs, relevant to optimisation, are obtained and maintained during university education, post-graduate training and residencies, and focused courses for CPD. Depending on the scope and purpose, these courses could either be targeted to one specific group of healthcare providers or encompass a broader multi-disciplinary group of professionals. The latter is particularly important for optimisation, so staff members can better understand and appreciate their respective roles and the roles of other professional groups. Radiology and facility management should make attendance at such courses accessible to all, and not just specific staff groups.

(218) Training on optimisation can be provided in structured courses and shorter focused sessions to stimulate interaction and knowledge / opinion sharing between professionals with different roles. Refresher courses and special focused sessions organised during professional congresses and scientific conferences as well as learning initiatives from professional societies, vendors or other organisations have an important role in updating about new technological developments and sharing optimisation experiences.

(219) Records should be kept of training provided and organisations that provide formal courses should be accredited. More information on methods for accreditation of courses, certification of individuals, evaluation of knowledge gained, and obtaining feedback from course participants is given in ICRP (2009).

(220) A combination of lectures, practical training, and hands-on sessions in a hospital environment in small groups have proved to be effective learning approaches for optimisation. Other options include using simulators, video tutorials and e-learning tools. Some student radiology learning includes cartoon self-study and others use competitive 3D gaming virtual worlds 'Second Life' (Rudolphi-Solero et al., 2020). This can be complemented with on-the-job training through scientific visits to imaging facilities with recognised good practice, (Vassileva et al., 2012, 2013; Rastogi et al., 2020).

(221) Regular departmental meetings provide opportunities for imaging team members (i.e. radiologists, radiographers and medical physicists) to discuss optimisation and quality improvement, identify priority actions and distribute roles. Each facility should assess the training needs taking into account the local conditions, and more information on training plans,

the design of programmes and different formats that that might be considered for provision of training is discussed in ICRP (2009).

6.4.2. Improving teamwork skills

(222) Fostering multi-disciplinary teamwork is an essential component of optimisation training, and staff should receive instruction on team building and communication with other disciplines. The trainers themselves should be role models for proper teamwork and this can be facilitated by cascade training activities on optimisation involving multidisciplinary teams. This approach will support team culture and safety culture through improving mutual understanding and respect for others.

(223) Building a teamwork atmosphere as part of training on optimisation can be achieved by sharing activities, dividing the responsibility between team members and allocating multiple tasks so that individuals can substitute for each other whenever possible, and can easily relocate, sharing rewards and accountability, encouraging positive competition between the team members, and helping new members through the sharing of experiences within the team itself.

(224) Working in a team will make physicians, radiographers, medical physicists, and nurses work efficiently, with better mindsets, in an innovative atmosphere, freely sharing their mistakes, showing themselves capable of positive criticism, and thus improving the performance of the team and its results.

6.5. Knowledge content adaptation as a basis for optimisation

(225) Each of the key professional groups needs a specific set of knowledge, skills and attitudes / behaviours and related competencies (KSCs) essential for their effective participation in the optimisation process. Competencies define the application of the knowledge, skills, and behaviours in the setting of daily practice.

(226) Current thinking would suggest that education and training in optimisation in medical imaging should be based on Bloom's taxonomy of learning. It has long been recognised that learning takes place at an increasing level of complexity from the simple recall of facts to the process of analysis and evaluation (Fig. 6.2). This ascending order of complexity was first described by Benjamin Bloom, an American educationalist (Bloom and Krathwohl, 1956) and has since been revised to reflect more current approaches to teaching, learning, and evaluation (Anderson and Krathwohl, 2001). The taxonomy classifies forms and levels of learning based on the premise that an individual cannot apply or evaluate something until it is understood and that learning at the higher level is dependent on having acquired the prerequisite knowledge and skills at lower levels. This is the basis for qualifications frameworks for lifelong learning worldwide (EPC, 2008; UNESCO, 2018; ACGME, 2019). Educational curricula that use the Bloom taxonomy should be applied throughout the radiological protection worker's career to ensure lifelong learning. Modules have been created entitled entrustable professional activities (EPAs) which provide measurable assessment of individual KSCs (AAMC, 2014).

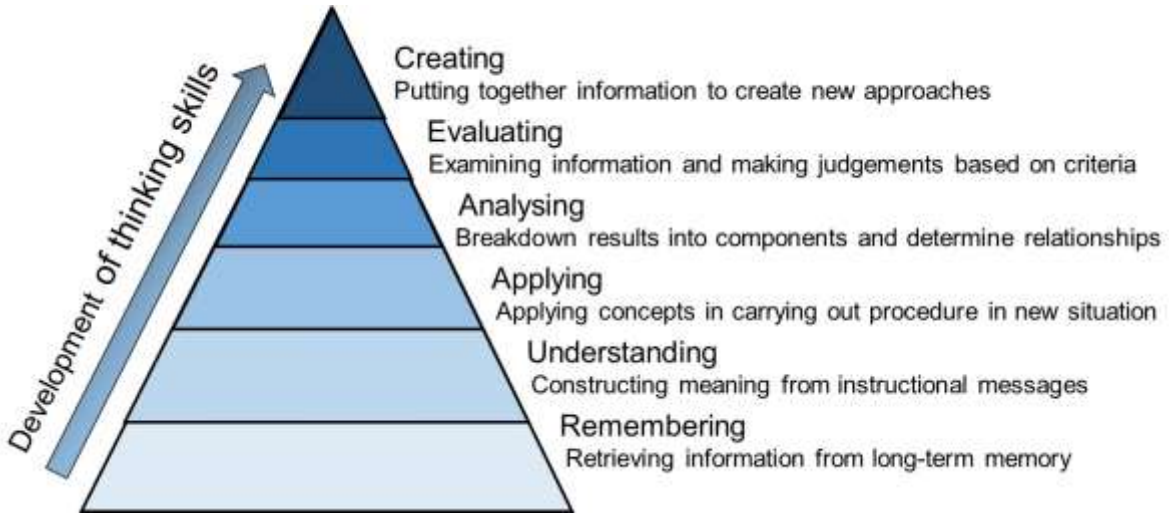

Fig. 6.2 The forms and levels of learning identified in Bloom's Taxonomy, with brief description of the processes to which they might apply in the context of optimisation.

(227) This model enables the educator to define the student learning outcomes based on the knowledge, skills and competences that are necessary for RP professionals to apply to optimisation at various levels in the clinical setting. Most of the topics are common for all groups, but the content may need to be adapted to the basic knowledge of each professional group. Examples of key knowledge, skills and competencies that enable the development of training modules on optimisation as part of a radiological protection education and training programme are given in Annex F, and more comprehensive lists have been published elsewhere (ICRP, 2009; EC, 2014).

6.6. Responsibility for training

(228) Earlier recommendations of the Commission define responsibilities of different parties in respect of the RP education and training, apply also to training related to optimisation (ICRP, 2009). Organisations highlighted in particular are: universities, training institutions, and scientific societies; RP regulatory bodies and health authorities; international organisations; and radiology equipment vendors.

(229) Professional societies should provide training programmes, and regulatory bodies and health authorities have a critical role in requiring that training providers authorised to give certification for medical professionals have sufficient infrastructure and qualified staff for organisation of the training programmes. In addition, regulatory officers need to have a basic knowledge about optimisation approaches in different modalities understand and appreciate the importance of optimisation. They need to understand the concept of DRLs and dose audits and require their implementation during authorisation and inspection processes.

(230) The Bonn Call for Action jointly issued by the IAEA and WHO in 2012 identified the need to enhance implementation of the principle of optimisation of protection and safety and the need to strengthen radiological protection education and training of health professionals as two of the ten priority actions to improve Radiological Protection in Medicine in the Next Decade (IAEA/WHO, 2012). An online Bonn Call for Action implementation toolkit has recently been published by the IAEA, including on-line resources for training in optimisation in several languages (IAEA, 2021a). Virtual and on-demand web-based packages can improve access to training and enable review of material independent of time and location. Online

training materials could play a significant role for facilities in developing countries with fewer resources by reducing the demands of travelling and scheduling, and improve overall cost-efficiency. Annex C of the ICRP *Publication 113* gives examples of some sources of training material provided by different international organisations (IAEA, ICRP, IRPA, EC), professional societies, alliances like Image Gently, Image Wisely, EuroSafe Imaging and some universities, in different formats (online resources for basic or continuing training, like e-learning, webinars and others).

(231) Equipment vendors have an important role to play in providing training for new technologies that is relevant to optimisation. Training materials should be produced in parallel with the introduction of new imaging technology and software. Emphasis should be placed on the correct use of new equipment features that have the potential to reduce patient doses, the understanding of settings so that system features function correctly, adaptations for different patients and imaging tasks, and an appreciation of the significance of displays of dose quantities.

(232) Healthcare facility and Radiology management have an important responsibility for ensuring sufficient human and financial resources for optimisation and associated training of staff (ICRP, 2007c). They should understand that investing in an adequate staffing level, staff training, and professional development helps to minimise errors and risks, and improve clinical results, and this applies to training in optimisation. Improvements in patient care and staff satisfaction that result, increase the standing of the medical facility. Hospital management need to be made aware of training requirements linked to medical imaging and the roles and responsibilities of different staff members, and allocate staff sufficient time to enable them to achieve and maintain competences.

(233) Healthcare professionals performing medical imaging have to assume their own responsibility for acquiring and maintaining their knowledge, skills and competencies, including those in respect of their role in optimisation, as a basic requirement to practice their profession, and to keep themselves updated throughout their professional careers. Equal opportunities should be given for education and training to all staff, and this applies to training in optimisation. All trainers and staff should be treated equitably relative to training and in-services without regard to gender, seniority, ethnicity or familial relationships.

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ANNEX A. DESCRIPTORS OF IMAGE QUALITY

A.1. Noise

(A 1) Stochastic fluctuations of pixel values around the average measurement in a region of interest on the image, given by the standard deviation (σ) of said values. For x-ray based imaging modalities, the number of photons reaching the detector *(N)* follows Poison's law and $\sigma \propto \sqrt{N}$. This relationship may not be applicable when iterative or more complex reconstruction methods are used to generate the images.

A.1.1. Visual noise

(A 2) Amount of 'graininess' observed in the image that can hinder relevant anatomical features or lesions. The noise texture, or appearance of the noise distributed in blob or cluster-like structures can also be visually assessed. The latter is more relevant in imaging modalities such as CT, where different reconstruction methods [filtered back projection (FBP), iterative, deep-learning based] and reconstruction kernels (soft, sharp, etc.) can be selected to enhance structures and greatly affect the noise texture.

A.1.2. Signal to noise ratio (SNR)

(A 3) Quotient between the signal (*S*, measured as the mean pixel value) and the noise (σ, standard deviation of pixel values), in a region of interest. SNR is proportional to the square root of the number of photons reaching the detector in x-ray imaging, when they follow Poisson's law.

$$SNR \propto \frac{S}{\sigma} = \frac{N}{\sqrt{N}} = \sqrt{N}$$

A.1.3. Noise equivalent quanta (NEQ)

(A 4) In a real imaging detector, there exists a certain loss or inefficiency in the process of collecting the photons reaching the detector and not all of them will contribute to the final image generation ($N_{real}<N_{ideal}$), which is represented by the NEQ and linked to the SNR.

$$NEQ = N_{Real} = SNR^2_{Real}$$

A.1.4. Noise Power Spectrum (NPS)

(A 5) Distribution of the noise amplitude for each frequency value in an image, related to the observed noise texture. It is usually measured on images of a uniform phantom in selected and limited regions of interest (ROIs). It can be measured in 2D or 3D for volumetric imaging. The definition of the NPS in 2D is as follows:

$$NPS_{2D}(f_x, f_y) = \frac{\Delta_x \Delta_y}{L_x L_y} \frac{1}{N_{ROI}} \sum_{i=1}^{N_{ROI}} |FT_{2D}\{ROI_i(s,y) - \overline{ROI_i}\}|^2$$

where Δ_x, Δ_y are the pixel sizes in the x and y dimensions, L_x, L_y are the ROI's lengths (expressed in pixels) for both dimensions, N_{ROI} is the number of ROIs used in the average operation and $\overline{ROI_i}$ is the mean pixel value of the ith ROI.

(A 6) The NPS can be easily extended to 3D, when the imaging modality requires so, such as in CT. The NPS represents the decomposition of noise (σ) over the spectral frequencies and a fast approximation of noise is measuring the area under the NPS. The equation by which they are related is:

$$\sigma^2 = \iint NPS_{2D}(f_x, f_y) df_x \, df_y$$

A.2. Contrast (C)

(A 7) Intensity difference between an object (target, *T*) and the surrounding material (background, *Bg*) in the image. It is recommended take ROIs of the same size over the object and the background and measure respective mean pixel values (MPV), and subtract them to obtain the contrast. Contrast can be negative or positive (for instance with hypodense and hyperdense liver lesions, respectively in CT) and sometimes the absolute value is taken. It is also common the relative contrast (C_{rel}, which is often expressed as a %) in which a reference object is used to normalise the measured intensity difference between object and background.

$$C = MPV_T - MPV_{Bg} \qquad C_{rel} = \frac{MPV_T - MPV_{Bg}}{MPV_{ref}}$$

A.3. Contrast to noise ratio (CNR)

(A 8) Quotient between the contrast and the noise (σ) measuring the later usually in the background sample.

$$CNR \propto \frac{C}{\sigma} = \frac{NMPV_T - MPV_{Bg}}{\sqrt{N}}$$

A.4. Detective Quantum Efficiency (DQE)

(A 9) The detectors of medical imaging systems are not ideal and this leads to a certain waste of the number of photons that will not contribute to image formation. The efficiency of a device can be determined as the ratio between the real number of photons contributing to image formation (NEQ) and the ideal number of photons reaching the detector N_{ideal}:

$$DQE = \frac{SNR^2_{Real}}{SNR^2_{Ideal}} = \frac{NEQ}{N_{Ideal}}$$

A.5. Spatial resolution

(A 10) Ability of a medical imaging system to reproduce small features in the image slice plane and through the z-axis along the patient. Different descriptors can be used for this image quality metric.

A.5.1. Visual spatial resolution

(A 11) Subjective measure of spatial resolution in which human observers assess phantom images containing groups of line pair patterns [identified each by the number of line pairs per

mm (lp mm^{-1}) that they contain]. They have to determine the number of these groups that can be clearly resolved inspecting the images, ideally in a diagnostic displayed monitor and darkened diagnostic equivalent visualisation conditions.

A.5.2. Point spread function (PSF)

(A 12) Spread of a high contrast small point-like object of known dimensions in the image [impulse response function or Dirac's delta δ (x,y)], used as a measure of the blurring introduced by the imaging system. This small object is made of different materials depending on the imaging modality (metal bead in x-ray imaging). Profiles are drawn at different angles centred on it (XY plane) and through it (Z-direction, in 3D imaging modalities). These profiles can be fitted to Gaussian functions and averaged to get the in plane and longitudinal PSF. The full width half maximum (FWHM) of the profile relates to the spread (σ) of the Gaussian fit, as:

$$FWHM = 2\sqrt{2ln2}\,\sigma \approx 2.355\,\sigma$$

A.5.3. Line spread function (LSF)

(A 13) Response of an imaging system to a line-like object which can be a phantom containing a very thin slit or high contrast line-like objects, usually placed at different orientations. Profiles are drawn at a 90º angle from the line and fitted in a similar fashion as with PSF measurements. The LSF can be considered like a group of PSF measurements taken along the same direction.

$$LSF(x) = \int_{-\infty}^{+\infty} PSF(x,y)dy$$

A.5.4. Edge spread function (ESF)

(A 14) Response of the imaging system to a sharp edge, which is placed at different slanted positions with regard to the detector. The mathematical expression of an edge is the Heaviside function [H(x,y)] and it is related to the PSF and LSF.

$$H(x) = \begin{cases} 1, & x > 0; \\ \frac{1}{2}, & x = 0; \\ 0, & x < 0. \end{cases}$$

$$\frac{d(H(x))}{dx} = \delta(x)$$

$$LSF(x) = \frac{\partial \mathrm{ESF(x)}}{\partial \mathrm{x}}$$

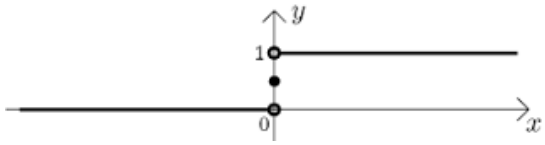

Fig. A.1. Representation of an edge spread function.

A.5.5. Modulation Transfer function (MTF)

(A 15) The MTF specifies the response of the imaging system as a function of its spatial frequency response. It allows the threshold frequency beyond which structures in the image will not be captured to be measured. In other words, MTF represents the system capacity to transfer the modulation of the input signal for each of the spatial frequencies present in the output image. In practice, the MTF can be obtained based on images of a point (PSF), a line or line patterns (LSF) and an edge (ESF). As these three quantities (PSF, LSF and ESF) are related,

they can be calculated not only in the spatial domain but also in the frequency domain, applying the Fourier Transform (FT) properties. For instance:

$$MTF_{1D} = \left| \frac{FT\{LSF(x)\}}{\int_{-\infty}^{+\infty} LSF(x)dx} \right|$$

A.5.6. Task transfer function (TTF)

(A 16) Also known as target transfer function, introduced by Richard et al. (2012), is an evolution on the MTF concept that is applied when the spatial resolution depends on the target contrast (for instance in CT, especially with iterative reconstruction). Whereas MTF has traditionally been measured with high contrast objects (usually made of metal or highly attenuating materials), in patients there are many different tissues with a wide range of x-ray attenuations. Iterative reconstruction algorithms in CT, introduce non-linear effects in the images (for instance dose and noise do not have a linear dependence anymore) and thus measuring MTF for a given contrast level and assuming that the observed trends can be extrapolated for all sorts of materials is not valid. In practice, the TTF is determined using several targets (usually cylinders) of a varied range of materials, for which the MTF is calculated based on profiles drawn at several directions. TTF can also be extended to 3D objects, such as spheres.

(A 17) More information on the various quantities used for evaluation of image quality can be found in Verdun et al. (2015).

A.6. References

Richard, S., Husarik., D.B., Yadava, G., et al., 2012. Towards task-based assessment of CT performance: system and object MTF across different reconstruction algorithms. Med. Phys. 39(7), 4115-4122.

Verdun, F.R, Racine, D., Ott, J.G., et al., 2015. Image quality in CT: From physical measurements to model observers. Physica Medica 31, 823-843.

ANNEX B. MODEL OBSERVERS

B.1. Introduction

(B 1) The anthropomorphic model observers include approximations to certain aspects of the visual perception process and its frequency dependence in their implementation, expressed in mathematical form. These aspects can be related to the way the human eye filters the frequencies present in the images or how the detection process is triggered in the human visual cortex, for instance. There exist two main subclasses of anthropomorphic model observers used in medical imaging: the non-prewhitening matched filter with an eye filter (NPWE) and the channelised hotelling model observer (CHO). One example of application of model observers is the assessment of low contrast detectability of simple objects, such as those present in commercial phantoms for QC.

(B 2) The implementation of model observers for detection or discrimination tasks consists of different stages for which the classes of images compared (abnormality present, $\boldsymbol{I_1}$ and abnormality absent, $\boldsymbol{I_2}$) undergo certain transformations that lead to the calculation of decision variables and usually the comparison to a threshold to determine for instance if certain object is visible or not. A template ($\boldsymbol{w}$, which represents the strategy of the model observer to detect the objects) is applied to the two classes of images under study, as shown in the equation:

$$T_i = w^t I_i = \sum_{n=1}^{N^2} w_n I_n \qquad with\ i = 1(signalpresent), 2(signalabsent)$$

Where w^t I_i is an inner product between the column vectors of the template (w) and the image (I) and N^2 is the number of pixels in the image. From the resulting distribution test statistics, a detectability index (d') can be obtained as follows:

$$d' = \frac{\langle T \rangle_1 - \langle T \rangle_2}{\sqrt{\frac{1}{2}(\sigma_1^2 + \sigma_2^2)}}$$

where <·> represents the mean of the decision variables, σ is the standard deviation and sub-indexes 1, 2 represent each image class.

B.2. Non-prewhitening matched filter with an eye filter model observer

(B 3) The non-prewhitening matched filter with an eye filter model observer (NPWE) model observer is based on the simpler NPW with the addition of an eye filter (E) which is a mathematical function representing the contrast sensitivity function in humans (Pelli, 2013). There are several equations for the eye filter in the literature, based on experimental studies usually with monitors that did not have the technical specifications of those currently available, in terms of pixel size and luminance, so they have to be used with certain precaution. In these studies, patterns such as grids of different contrasts were shown to the observers to measure the contrast detectability threshold for a range of spatial frequencies. Fig. B.1. shows a flowchart with a possible implementation for the NPWE when analysing the presence of lesions in two image classes.

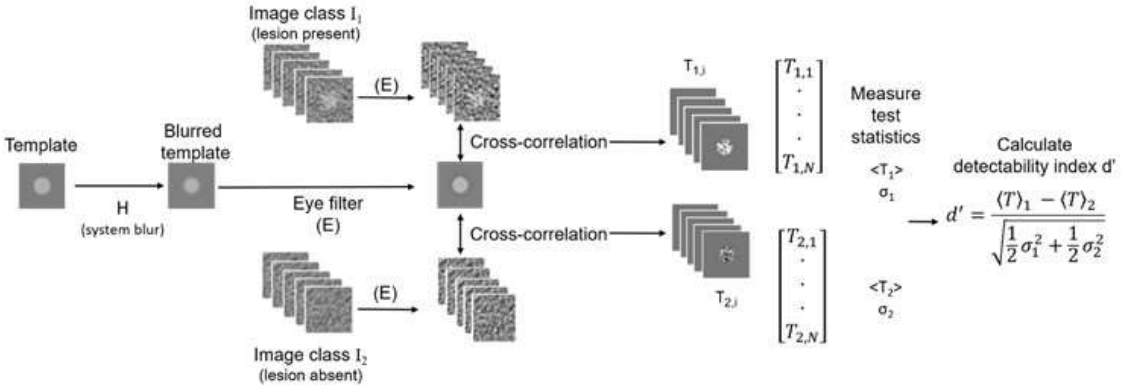

Fig. B.1. Flowchart with a possible implementation of the NPWE model observer applied to a detection task between two image classes (lesion present/lesion absent). The system blur (H) is used to get a more accurate representation of the expected signal (template), and an eye filter (E, a function representing the contrast sensitivity function of the human eye at a given eye-monitor distance) is applied to the template and both classes of images. Afterwards, the output images are cross-correlated by the template, and from the test statistic distributions, the mean <·> and the standard deviation σ calculated to be combined in a detectability index (d'). Images: Adapted from Wouter J. H. Veldkamp by Irene Hernandez-Giron, The Netherlands.

B.3. Channelised Hotelling model observer (CHO)

(B 4) The channelised Hotelling observer mathematical implementation originates from perception studies carried out in the 1950s and 1960s, where the responses of observers to different luminance or grating patterns (sinusoids, saw-tooth, rectangular waves, among others) were studied. From the results, the visual interpretation in the human visual cortex was modelled as a group of independent receptors (channels), sensitive only for a narrow spatial frequency range window. Thus, the visual stimulus, decomposed into its frequencies was only detected by one of the channels if a certain threshold was hit. Based on this, the CHO is a mathematical expression of the channels that are used to filter the images (abnormality present and absent for instance). There exist multiple implementations of these channels in the literature and they have to be adapted to the characteristics of the lesions and the background under study (Petrov et al., 2019). In Fig. B.2. some examples of the appearance of different types of channels in the image domain are shown.

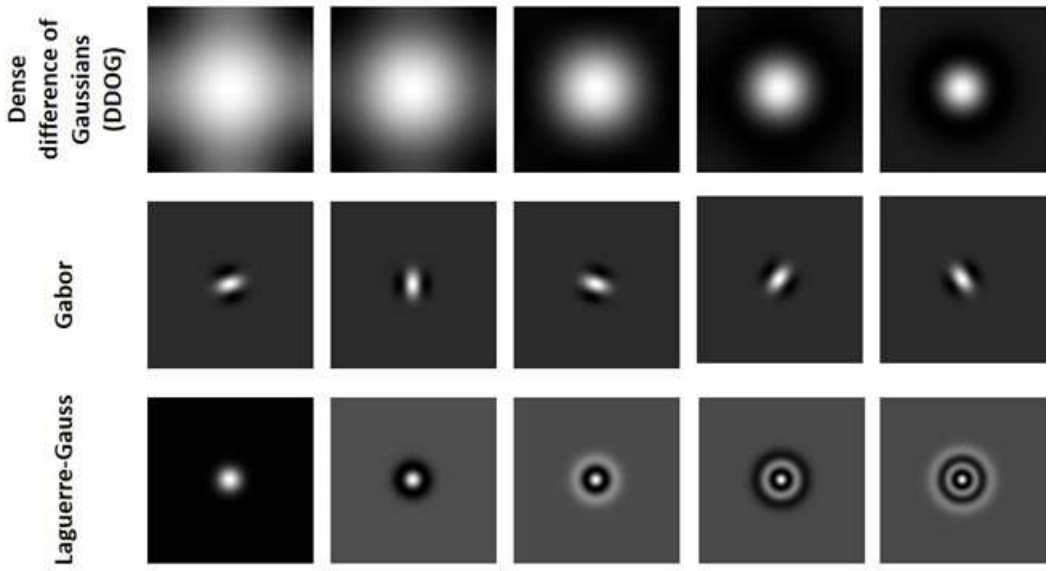

Fig. B.2. Some examples of channels (in the image domain) used with the channelised hotelling observer depicting the different appearances: Dense difference of Gaussians (DDOG, top row), Gabor (middle row) and Laguerre-Gauss (bottom row). Images: Irene Hernandez-Giron, The Netherlands.

(B 5) The use of model observers has extended in the past few years and they have even been applied to sustain low contrast detectability claims by CT vendors. There is a need for standardisation of these methods and there are some initiatives to benchmark the implementation of model observers for simple detection tasks in uniform phantoms, involving research groups in different countries (Ba et al., 2018). This initiative established a simple setup of images and a basic model observer that can be implemented by anyone interested in these image quality metrics. They can start to get familiar with them and tinker with the implementation, with the option of benchmarking the results to the outputs of groups that use model observers regularly for research.

(B 6) Besides the basic image metrics already mentioned, that characterise technical aspects of the image acquisition and relate to the x-ray tube output, there is a more complex level related to the individual diagnostic tasks that will be dependent on the indication, disease and patient variability. This would be related to applying model observers to anthropomorphic phantoms containing lesions or even patient images and is an active field of research. Model observers may also be applied in connection with the new AI-based image quality assessment methods, in order to provide these new methods a well-established reference (ground truth) for training, validation and testing.

B.4. References

Ba, A., Abbey, C.K., Baek, J., et al., 2018. Inter-laboratory comparison of channelized hoteling observer computation. Med. Phys. 45(7), 3019-3030.

Pelli, D.G., Bex, P., 2013. Measuring contrast sensitivity. Vision Res. 20(90), 10-14.

Petrov, D., Marshall, N.W., Young, K.C., et al., 2019 Systematic approach to a channelized Hotelling model observer implementation for a physical phantom containing mass-like lesions: Application to digital breast tomosynthesis. Physica Medica 58, 8-20.

ANNEX C. RECEIVER OPERATING CHARACTERISTIC STUDIES

(C 1) Signal detection theory, the basis of receiver operating characteristic (ROC) analysis, started in World War II to detect signals in a noisy environment in radar communications (for instance objects such as flocks of birds or enemy planes in the vicinity of aircraft), applying mathematical methods. ROC analysis represents the performance of human observers in detection or classification tasks to decide if the case under study is 'normal' or 'abnormal' (Samei and Krupinski, 2018; Metz, 2000). ROC studies have applications for qualitative performance comparisons, between observers, or between two imaging protocols or even imaging modalities for certain indications.

(C 2) The basis of ROC studies is to decide if the case under study is 'normal' or 'abnormal' in a binary approach, which can be represented in a 2×2 matrix containing all possible outcomes, as shown in Table C.1.

Table C.1. ROC study decision matrix for the classification of normal and abnormal cases.

Diagnosis	**Abnormality present**	**Abnormality absent**
Abnormal	True Positive (TP)	False Positive (FP)
Normal	False Negative (FN)	True Negative (TN)

(C 3) Based on these outcomes, two quantities are calculated, the true-positive fraction (TPF) or sensitivity and the false positive fraction (FPF), with the following equations:

$$TPF = \frac{TP}{TP + FN} = Sensitivity (1) \qquad FPF = \frac{FP}{TN + FP} = 1 - \frac{TN}{TN + FP} = 1 - Specificity (2)$$

(C 4) The ROC curve represents the TPF (sensitivity) versus the FPF (1-specificity) for the studied cases, and an example is given in Fig. C.1 The summation of the observer sensitivities for all specificity values is the area under the ROC curve (AUC) and can be interpreted as the accuracy of the observer or the imaging system to perform or image, respectively, the assigned detection or discrimination task.

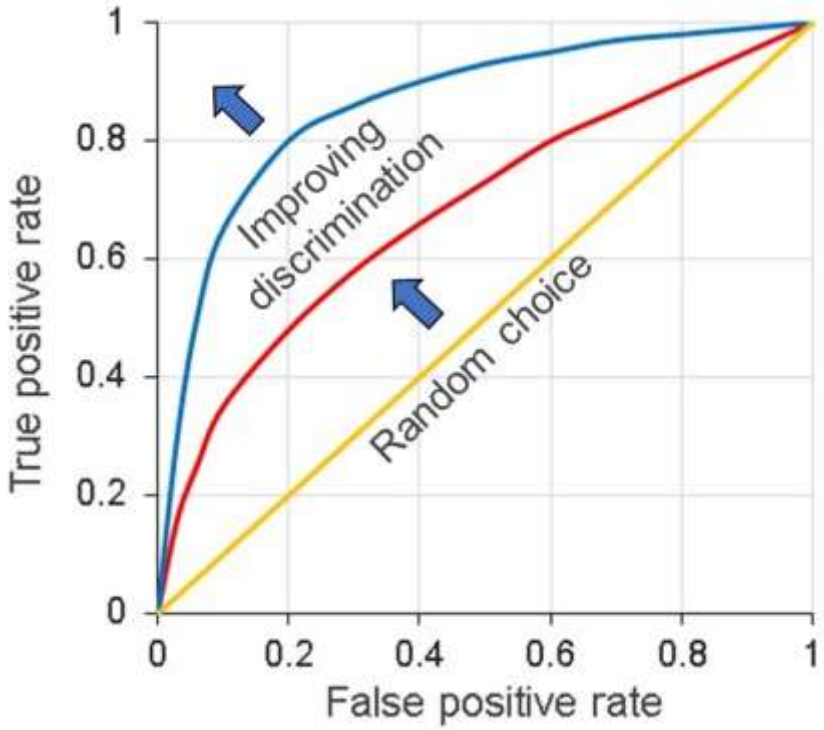

Fig. C.1. ROC curves that can be used in evaluating and comparing the performance of diagnostic tests in predicting clinical outcomes.

C.2. References

Metz, C.E., 2000. Fundamental ROC analysis. In: Van Metter, R.L., Beutel, J., Kundel H.L. (Eds.), Handbook of medical imaging. Physics and psychophysics. Vol. 1.: SPIE-The International Society for Optical Engineering, Bellingham, WA, pp. 751-771.

Samei, E., Kruipinski, E., (Ed.), 2018. The handbook of medical image perception and techniques, 2nd ed. Cambridge University Press, New York.

ANNEX D. MULTI-ALTERNATIVE FORCED CHOICE EXPERIMENTS

(D 1) The classical multi-alternative forced choice study, consists of several images displayed simultaneously containing different alternatives (for instance one image showing abnormality and the others normal cases) 'forcing' the observer to choose one of the images as 'abnormal'. An example of a 4-alternative forced choice (AFC) study is shown in Fig. D.1, for a signal known exactly and background known exactly (SKE/BKE) task. Usually, the 'abnormality' target size, contrast… and other characteristics are displayed for reference. The number of correct decisions the observer makes, divided by the total number of displayed cases is the so-called Proportion Correct (PC).

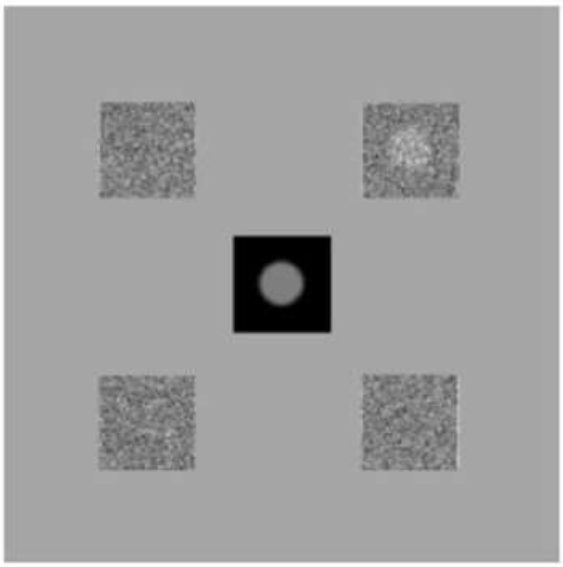

Fig. D.1. Example of interface for 4-AFC experiments with human observers, showing the target lesion (centre) and four images, one containing the lesion in this case. The observer would have to select the lesion present and the number of correct scores would be stored. Images: Irene Hernandez-Giron, The Netherlands.

(D 2) This type of study is usually applied to compare human and model observer performance. M-AFC studies aim at quantifying the observers' capacity to discern two distributions (abnormality present and abnormality absent), using as a parameter the 'detectability' (d'), already mentioned in the model observer section (Hernandez-Giron, 2015; Ba et al., 2018; Samei and Krupinski, 2018). The observer makes a decision, applying certain criteria to determine to which image class distribution each of the scored images belongs. Mathematically, this process can be modelled by applying statistical decision theory, assuming that the observer assigns a certain decision value, λ, to each image (Fig. D.2). The detectability index represents the distance between the probability functions of the abnormality absent (which only contains 'noise', anatomical or another) and the abnormality present (which contains 'noise' and 'lesion or signal'). The closer the two distributions are the more difficult the lesion is to detect, and the lower the detectability index (Verdun et al., 2015).

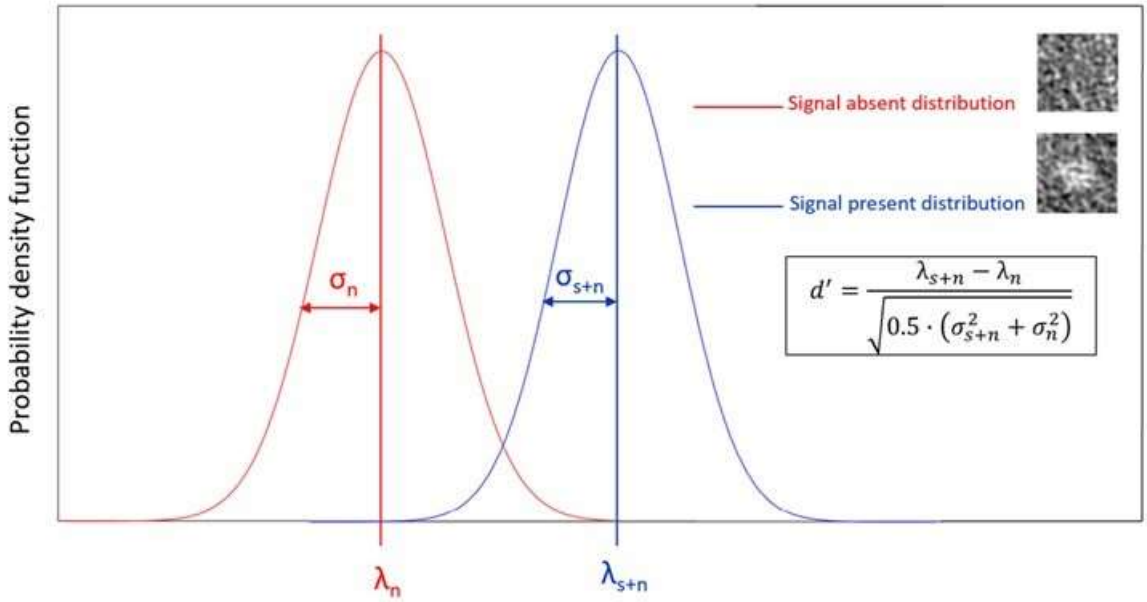

Fig. D.2. Probability density functions of two image classes: One with a signal present (signal + noise (s+n); with mean λ_{s+n} and standard deviation σ_{s+n} for the related distribution) and one with signal absent (noise, n; with mean λ_n and standard deviation σ_n for the related distribution). The closer the distributions are together, the more similar the image classes and the more difficult the lesion is to detect (lower d'). Images: Irene Hernandez-Giron, The Netherlands.

(D 3) A link can be made between d' and ROC studies, making the assumption that the decision variables follow Gaussian distributions (often, this assumption is laxly made and certain properties of the imaging system noise and anatomical background have to be checked). For 2-AFC studies (where the observer only has to perform a binary task and select which image contains an abnormality, in a pair), the Proportion Correct (PC) represents the area under the ROC curve (AUC). In turn, the AUC can be transformed into a detectability index:

$$d' = 2erf^{-1}[2(AUC) - 1]$$

where $erf^{-1}(\cdot)$ is the inverse error function.

(D 4) In the literature similar equations can be found for 4-AFC human observer experiments or even with a higher number of displayed images (Ba et al., 2018). To compare results for different human observers, either the detectability indexes can be compared, or their respective area under the curve.

D.2. References

Ba, A., Abbey, C.K., Baek, J., et al., 2018. Inter-laboratory comparison of channelized hoteling observer computation. Med. Phys. 45(7), 3019-3030.

Hernandez-Giron, I., Calzado, A., Geleijns, J., et al., 2015. Low contrast detectability performance of model observers based on CT phantom images: kVp influence. Physica Medica 31(7), 798-807.

Samei, E., Kruipinski, E., (Ed.), 2018. The handbook of medical image perception and techniques, 2nd ed. Cambridge University Press, New York.

Verdun, F.r., Racinea, D., Otta, J.G., et al., 2015. Image quality in CT: From physical measurements to model observers. Physica Medica 31, 823-843.

ANNEX E. IMPLEMENTATION OF IMAGE QUALITY ASSESSMENT

(E 1) This Annex provides a guide to systems that might be expected to be in place for the development of optimisation in radiology facilities. This takes the form of measurements that would be performed to assess image quality, types of phantoms and test objects that would be required, methodologies that would be used, and systems that would be in place to facilitate the inclusion of evaluations of image quality in the optimisation process.

E.1. D level: Preliminary

(E 2) This level applies to radiology facilities that are being set up and are about to put the processes required for optimisation in place.

- Purchase of test objects and phantoms to enable measurement of image quality to commence.
- Measurement of image quality performance during commissioning of x-ray equipment and setting baseline values against which future measurements can be compared.
- Basic assessments of clinical image quality performed by radiologists.
- Preparations to put in place basic Level C requirements (see below).

E.2. C level: Basic

- Radiography measurements: contrast range, low-contrast resolution, high-contrast (spatial) resolution, uniformity, artefacts, image collimation and centring, detector exposure index (EI) - with constant exposure (mAs, kV).
- Fluoroscopy measurements: basically the same as above. The minimum level involves the use of simple fluoroscopy test object with basic contrast range and resolution targets (enabling simple contrast-detail analysis).
- CT measurements: CT-numbers of water and other reference materials (CT#-linearity), slice sensitivity profile (slice width), spatial resolution (visual line pair-patterns, optionally MTF), low-contrast resolution, noise (determined as SD of pixel values, optionally NPS), uniformity, artefacts, geometry and centring – with constant exposure settings.
- Display monitor measurements: visual evaluation of SMPTE or preferably more versatile test pattern such as AAPM TG18-QC (AAPM, 2018).
- Utilisation of clinical image data in simple image quality assessment by using contrast and noise measurements from regions of interest, enabling CNR level image quality assessment from image data.
- Basic self-assessments of clinical image quality performed by radiologists based on established clinical image quality criteria for most essential imaging studies.

E.3. B level: Intermediate

(E 3) Level C, plus:

- Additional aspects such as anthropomorphic phantoms in addition to traditional IQ, 3D printed phantoms as an affordable way to obtain specific / anthropomorphic phantoms, need for tissue structure like objects in phantoms. Utilisation of these targets in more objective image quality evaluation with range of imaging protocols.
- Comprehensive display monitors and illumination measurements: visual evaluation of test patterns; monitor DICOM GSDF contrast & luminance response and uniformity measurements with luminance meter, optionally also all other AAPM TG18 tests.
- Implementation of automated analysis methods for selected imaging modalities and tests in order to make IQ measurement more efficient and objective within QA programme.
- Systematic programme for self-assessment of clinical image quality be radiologists supplemented by optional VGA studies for selected targets for optimisation. Connection of IQ evaluation in self-assessment with internal and external audits.
- Use of model observer approach in selected optimisation tasks involving image quality assessment.

E.4. A level: Advanced

(E 4) Levels C and B, plus:

- Systematic and wide-scale use of automated IQ measurements and analysis of phantom images acquired in radiological QA programme for all imaging modalities, covering also display monitors for primary diagnostics and secondary use.
- Use of versatile model observers in IQ assessment, based on clinically relevant and indication specific task functions/templates, accounting for variability and range of object appearance.
- Development and implementation of AI methods for image quality measurements, classification and grading for wide range of imaging modalities and clinical indications, validated by retrospective and prospective data trials.
- Connection of objective and quantitative IQ follow-up applications with comprehensive and on-line quality management and patient safety monitoring system, and linked to continuous hospital wide audit process (also accounting for the aspect of management and systematic continuous improvement in organisational level).

N.B. Since particular image quality test objects tend to be produced by individual companies, none are specifically recommended here in order to avoid commercial bias.

E.5. Reference

AAPM, 2005. Assessment of Display Performance for Medical Imaging Systems. AAPM Report No.3. American Association of Physicists in Medicine, New York.Report of AAPM Task Group 18. https://deckard.duhs.duke.edu/~samei/samei_tg18/index.html. Test patterns can be downloaded at http://www.gradllc.com/testpaterns.htm. (Both websites were accessed in August 2021).

ANNEX F. KNOWLEDGE, SKILLS, AND COMPETENCIES (KSC)

F.1. Examples of KSCs required for optimisation of x-ray imaging procedures

Knowledge	Skills (ability to apply knowledge)	Competencies, (Attitudes/Behaviours)
Clinical aspects		
• Define the principle of optimisation • Understand advantages and disadvantages of different x-ray imaging options for clinical investigations • Understand the image quality needed for different clinical questions and related range of imaging protocols • Recognise the level of image noise required for diagnosis in the full range of x-ray procedures	• Able to evaluate clinical image quality • Able to identify the level of image quality required for different types of x-ray imaging procedures • Able to undertake subjective evaluations of clinical images for the purpose of comparing protocols • Able to distinguish when the image quality level provided by a protocol is inappropriate (too poor or too good) • Able to compare and contrast optimised protocols for different patient populations • Able to select the parameters that influence automated adjustments to dose and image quality levels	• Ensure that the process of optimisation of clinical protocols is embedded in the department procedures • Ensure results of patient dose audit are taken into account in protocol review and revision • Ensure that there is a system to determine the correct exposure parameters are selected for every patient • Able to collaborate with fellow professionals, and acknowledge and respect skills of individuals from all disciplines • Able to establish agreement among clinicians about appropriate image noise levels required for different procedures
Physical aspects		
• Describe the influence of exposure parameters on patient dose for a range of modalities • Recognise the various measurements that can be made to evaluate image quality • Define and understand the influence of noise on the ability to perceive objects	• Able to measure x-ray exposure variables linked to patient dose • Able to perform physical measurements to make objective assessments of image quality • Able to perform measurements to assess patient dose for a range of x-ray equipment	• Set up a programme for QC with appropriate frequencies for testing a range of equipment • Establish a system for setting DRLs at institution level

• Define and understand the parameters used to measure image quality • Define and understand dose quantities used to describe patient exposure for different imaging modalities • Identify which exposure parameters to change when adjustments in patient dose or image quality are required • Describe how systems for carrying out automatic adjustments to exposure parameters function • Define and understand advantages and disadvantages of different x-ray imaging options	• Able to carry out audits of patient doses and compare results with DRLs • Able to select exposure variables that affect the automated adjustments to dose and image quality • Able to communicate advantages of different imaging options to clinical colleagues • Estimate radiation doses to be delivered to patients for a range of different imaging procedures.	• Analyse results of patient dose audit and identify where corrective action is required • Identify changes needed to exposure settings to optimise protocols when dose or image quality levels are inappropriate based on QC measurements • Able to establish research / development projects to improve optimisation practices

3476

ABBREVIATIONS

AAMC	American Association of Medical Colleges
AAPM	American Association of Physicists in Medicine
ACGME	Accreditation Council for Graduate Medical Education.(US)
ACR	American College of Radiology
AEC	Automatic exposure control
AFC	Alternative Forced Choice
AI	Artificial intelligence
ALADAIP	As low as diagnostically acceptable being indication-oriented and patient-specific
ALARA	As low as reasonably achievable
AUC	Area under curve
BEIR	Biological Effects of Ionising Radiation
BKE	Background known exactly
CDS	Clinical decision support
CHO	Channelised hotelling model observer
CLUES	Clinical image quality assessment project
CME	Continuing Medical Education
CNN	Convolutional neural networks
CNR	Contrast-to-noise ratio
COCIR	European Coordination Committee of the Radiological Electromedical and Healthcare IT Industry
COPD	Chronic obstructive pulmonary disease
CPD	Continuous Professional Development
CT	Computed tomography
CTDI	Computed tomography dose index
$CTDI_{vol}$	Volume averaged CTDI
DICOM	Digital Imaging and Communications in Medicine
DIMITRA	Dentomaxillofacial paediatric low-dose imaging project (European).
DL	Deep learning
DLP	Dose Length Product
DQE	Detective quantum efficiency
DRL	Diagnostic reference level
EC	European Commission
EI	Exposure index
EPA	Entrustable Professional Activities
EPA	Environmental Protection Agency (US)
EPC	European Parliament and Council
ESAK	Entrance surface air kerma. (also $K_{a,e}$) (ICRP Glossary - Air-kerma, entrance surface)
ESF	Edge spread function

3516	FGI	Fluoroscopically guided intervention
3517	FID	Focus to Image receptor Distance
3518	FN	False negative
3519	FOV	Field of view
3520	FP	False positive
3521	FWHM	Full width half maximum
3522	GSDF	Greyscale standard display function
3523	HIS	Hospital information system
3524	IAEA	International Atomic Energy Agency
3525	ICRU	International Commission on Radiation Units and Measurement
3526	ICT	Information and communications technology
3527	IEC	International Electrotechnical Commission
3528	IHE	Integrating the Healthcare Enterprise
3529	IPEM	Institute of Physics and Engineering in Medicine (UK)
3530	IQ	Image quality
3531	IRPA	International Radiological Protection Association
3532	ISO	International Standards Organisation
3533	IT	Information technology
3534	KAP	Kerma-area product (also P_{KA}) (ICRP Glossary - Air-kerma, product)
3535	KSC	Knowledge, skills and competences
3536	LCD	Low contrast detectability
3537	LNT	Linear non-threshold (dose-effect model)
3538	LSF	Line spread function
3539	M-AFC	Multi-alternative forced choice
3540	MHRA	Medicines and Healthcare products Regulatory Agency (UK)
3541	ML	Machine learning
3542	MPV	Mean pixel value
3543	MTF	Modulation transfer function
3544	NCRP	National Council on Radiation Protection and Measurement (US)
3545	NEMA	National Electrical Manufacturers Association (US)
3546	NEQ	Noise equivalent quanta
3547	NIST	National Institute of Standards and Technology
3548	NPS	Noise power spectrum
3549	NPW	Non-pre whitening (model observer)
3550	NPWE	Non-pre whitening with eye filter (model observer)
3551	PA	Postero-anterior (projection)
3552	PACS	Picture archiving and communication system
3553	PC	Proportion correct
3554	PDCA	Plan - do - check - act
3555	PMMA	Polymethyl methacrylate
3556	PPM	Planned preventative maintenance

PSF	Point spread function
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management System
RDSR	Radiation dose structured report
REM	Radiation exposure monitoring
RIS	Radiology information system
RLI	Radiology Leadership Institute
ROC	Receiver operating characteristics
ROI	Region of interest
SD	Standard deviation
SKE	Signal known exactly
SMPTE	Society of Motion Picture and Television Engineers
SNR	Signal to noise ratio
SPECT	Single photon emission tomography
THET	Tropical Health and Education Trust
TN	True negative
TP	True positive
TTF	Task transfer function
UNESCO	United Nations Educational, Scientific and Cultural Organisation
UNSCEAR	United Nations Scientific Committee on the Effects of Atomic Radiation
VGA	Visual grading analysis
VGC	Visual grading characteristics
WHO	World Health Organisation
2D, 3D, 4D	2-, 3- or 4- dimensional

GLOSSARY

Only terms not included in the ICRP main Glossary are included here. The ICRP Glossary can be viewed at the website address: http://icrpaedia.org/ICRP_Glossary.

CNR, Contrast-to-noise ratio

CNR is the contrast divided by the noise. Contrast means the difference between pixel values of any two regions in the image. Noise means the graininess of the image which is typically described by a single value representing the standard deviation of pixel values within a (homogeneous) region in the image. Note: This quantity needs to be introduced because attention only to the 'contrast' has often resulted in images of higher quality than needed for confident diagnosis. Noise is also a measure of image quality. Images having higher noise levels do not necessarily undermine diagnostic accuracy; rather, the contrast-to noise ratio may be similar or improved.

DICOM-Digital Imaging and Communications in Medicine

Digital imaging standard describing a set of protocols describing how radiology images are identified in a structured way, formatted and communicated. DICOM is manufacturer-independent and was developed by the American College of Radiology and the National Electronic Manufacturers Association. Provision of an agreed structured format facilitates the exchange of files between devices that have the capability of accepting image and patient data in DICOM format. DICOM 3.0 is the current version. http://medical.nema.org/

Iterative reconstruction

CT image reconstruction technique which typically applies repeated iterative loops of forward projection (producing simulated projection raw data) and back-projection (creating image from projections). Thus, the image reconstruction happens by several iteration cycles where the iterated image gradually approaches the final image result converging either by CT image pixel values or by the difference between the simulated and true (measured) raw data projections. Iterative methods may apply different levels of physical modelling of the CT scan where increased modelling may enable higher image quality while also adding to the computational complexity and calculation time.

Noise

Noise means the graininess of the image which is typically described by a single value representing the standard deviation (1SD) of pixel values within a (homogeneous) region in the image. Noise can also be described by noise-power-spectrum (NPS) which describes the spatial frequency distribution of the noise. This can also be described as the grain size distribution of the image noise, or noise texture. Therefore, NPS is more comprehensive description of the noise compared to single value noise determined from pixel standard deviation.

Patient radiation exposure monitoring

Components, mechanisms, and operational processes related to recording, collecting, and analysing patient radiation exposure data associated with clinical imaging operation. Here monitoring refers to capturing and meaningfully evaluating patient radiation exposure data and not the actions for quality improvement, an ultimate goal undertaken by managing patient radiation exposure data.

Radiation Dose Structured Report

Part of the DICOM standard defining the set of DICOM objects providing the radiation dose related parameters by hierarchical description of the irradiation event (e.g. within entire CT examination or pulsed fluoroscopy image series).

Radiology information system (RIS)

A system that supports the information processing and business requirements of radiology departments and freestanding image centres.

Signal to noise ratio (SNR)

Signal-to-noise ratio (abbreviated SNR or S/N) is a measure that compares the level of a desired signal to the level of background noise. Closely related to CNR but instead of contrast as in CNR the signal is involved in SNR.

Spatial frequency

Any signal can be composed of a series of harmonic (sine and cosine) waves. An image can be interpreted as a composition of an infinite number of periodic sine and cosine waves. A short wavelength (equivalent to high spatial frequency) corresponds with small detail, whereas a long wavelength (equivalent to low spatial frequency) corresponds with large objects in the image. The relationship between spatial frequency and detail size is inversely proportional. In order to avoid confusion with the term time frequency, spatial frequency is used. A common unit is line pairs per millimetre (lp mm^{-1}).

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Although ICRP has produced documents on the general principles of optimisation and their application in medicine, and on its application in different medical imaging modalities. However, these publications have not considered practical arrangements for implementation in medicine in detail. The range in the types of medical facility using digital radiology equipment is vast with tremendous variation in the levels of imaging expertise within these organisations. This publication sets out guidance on different aspects of the optimisation process that should be considered and the organisational arrangements needed to ensure that optimisation takes place at all levels. Since image quality is of crucial importance in obtaining the clinical information from images, a section has been included on methods for evaluation of image quality that should be considered in parallel with dose assessments. The Commission established Task Group 108 on Optimisation of digital radiography, fluoroscopy, and computed tomography in Medical Imaging in 2018 lead by members of ICRP Committee 3. It was apparent that attempting to set out general guidance on optimisation methods, as well as application to different modalities, was too much to include in a single document. This report is the first part dealing with the general principles of optimisation and a second report dealing with practical application to individual radiology imaging modalities will follow.

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