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EFFICIENT QUALITY ASSURANCE PROGRAMS IN RADIOLOGY AND NUCLEAR MEDICINE IN ÖSTERGÖTLAND, SWEDEN

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Owners of imaging modalities using ionizing radiation should have a documented quality assurance (QA) program as well as methods to justify new radiological procedures to ensure safe operation and adequate clinical image quality. This includes having a system for correcting divergences, written imaging protocols, assessment of patient and staff absorbed doses and a documented education and training program. In this work we review how some aspects on quality assurance have been implemented in the County of Östergötland in Sweden and our efforts to standardize and automate the process as an integrated part of the radiology and nuclear medicine QA-programs. Some key performance parameters have been identified by a Swedish task group of medical physicists to give guidance on selecting relevant quality assurance methods. These include low-contrast resolution, image homogeneity, automatic exposure control, calibration of air kerma-area product meters and patient-dose data registration in the radiological information system, as well as the quality of reading stations and of the transfer of images to the picture archive and communication system. IT-driven methods to automatically assess patient doses and other data on all examinations are being developed and evaluated as well as routines to assess clinical image quality by use of European quality criteria. By assessing both patient absorbed doses and clinical image quality on a routine basis, the medical physicists in our region aim to be able to spend more time on imaging optimization and less time on periodic testing of the technical performance of the equipment particularly on aspects which show very few divergences. The role of the Medical Physics Expert is rapidly developing towards a person doing advanced data-analysis and giving scientific support rather than one performing mainly routine periodic measurements. We conclude that both the European Council directive⁽¹⁾ and the rapid development towards more complex diagnostic imaging systems and procedures support this changing role of the Medical Physics professional.

INTRODUCTION

The European Council directive⁽¹⁾ imposes on their member states that all medical radiation exposures of patients should be as low as reasonably achievable and clinical image quality consistent with obtaining the required diagnostic information. This process is often denoted optimisation and includes many aspects of quality assurance, QA. The objective for performing quality assurance on radiological equipment is to ensure that the quality of the clinical images is consistently sufficient for accurate diagnosis and at the same time minimizing patient and occupational absorbed doses. Examples of QA are justifications of imaging procedures, having written protocols for all standard imaging procedures, selection and acceptance testing of new imaging equipment, periodic equipment quality control, adequate training of staff, assessment of patient doses or administrated activities and methods to properly manage high risk patients such as foetus, children and patient undergoing high-dose procedures.

Sweden's radiation protection authority has issued several national regulations⁽²⁻⁶⁾ to meet the

European Council directive. However, the national regulations can never give advice on or regulate all aspects of radiological protection and therefore, since many years, regional radiation protection boards and Medical Physics Experts, MPE, are present within the organisation.

In the early 1980-ies, when regulations⁽⁷⁾ were first introduced in radiology, periodic testing of x-ray units was the primary work of the medical physicist. At that time QA in radiology for the medical physicist was to some extent synonymous with performing annual measurements on the equipment. Much has changed since then and the work description of the MPE have expanded considerably in accordance with the regulations.⁽⁴⁾ The role of the MPE today in radiology is being defined by professional bodies and his/her role should not be something separate but fully integrated in clinical practice and providing scientific support.

Almén and Cederlund⁽⁸⁾ suggests, that periodic testing of aspects which show very few divergences should be reduced in order to re-allocate resources to other more important aspects

of quality assurance. One such aspect where more resources are needed is clinical audit.^(9,10) This is a systematic process that seeks to review the radiological procedure to improve the practice, procedures and results by comparing them against agreed standards. Methods to assess clinical image quality on a routine basis are still developing and have been facilitated by the introduction of image criteria for common examinations⁽¹¹⁾ and methods for their efficient evaluation.⁽¹²⁾ Objective assessment of technical image quality in terms of for example low-contrast resolution of test-phantom images are important as subjective (human) evaluation often suffer from significant inaccuracy due to difficulties to define, maintain and communicate decision criteria for what is visible.⁽¹³⁾ Such test-phantom images can be useful in quality control in identifying deficiencies in the imaging equipment. However, until significant positive correlations can be established between physical and clinical image quality, optimisation should preferably be performed on images of patients or realistic anthropomorphic phantoms. A strategy for selecting the procedures to optimise is given by Hansson et al.⁽¹⁴⁾

The aim of this study is not to give a comprehensive review of QA in radiology, but to give examples and some critical comments on the implementation of some key aspects on quality assurance in radiology in our region. The QA examples selected in this study are (1) acceptance testing, periodic quality control and rectification of imaging equipment, (2) teaching and training of staff and (3) assessment of patient doses.

Acceptance testing, periodic quality control testing, documentation, rectification and review

Equipment specification prior to purchase of new equipment is the first important step in achieving adequate quality of the images and patient doses that are 'as low as reasonably achievable'. When purchasing imaging equipment for use outside the radiology department, it is particularly important to involve the operators (surgeons and nurses) in the process and to assist them if needed in making a proper selection to fulfil their requirements. Prior to its first clinical use, the equipment should be tested on all aspects influencing image quality and radiation dose.⁽⁶⁾ Baseline or initial data should be established and if significant modifications to the equipment are done during its lifetime, new baseline values formed.

Radiological equipment should further be periodically controlled to ensure that the quality

is as good as it was when it was first installed. Recommended standards^(17,18) for such testing of x-ray imaging systems exist. The aspects to be tested and the frequency are specific to the particular equipment.^(5,6) In addition to controlling the imaging equipment, it is important to include also diagnostic viewing stations, dose-calibrators, protective shielding, image plate systems etc. It is important to decide on expected level of performance against which the equipment is evaluated. Consensus on such remedial or suspension levels must be found. Any non-trivial divergence from this expected level of performance should be recorded and a plan to correct the divergence initiated in collaboration with for example the hospital's engineering department or the manufacturer. A measurement document is signed and any changes or negative trends in the performance of the equipment should be pointed out to the staff operating the unit.

Following a national Swedish workshop in June 2006, on quality control in digital radiography, a task group was appointed by the Swedish Association of Medical Physics in order to give guidelines on which periodic quality control measurements should be performed and how often. The objective was not to copy the IPEM standard⁽¹⁷⁾ nor to strictly comply with national recommendations⁽⁴⁾ but to give advice on measurements that were relevant for constancy check on modern units.⁽²¹⁾ Almén and Cederlund⁽⁸⁾ found large variations in compliance with national regulation on quality control testing in 25 centres. They identified the need for revising the remedial or suspension levels, to introduce trend analysis or control charts and to develop systems for determining and follow-up the frequency of failing the quality control tests.

One of the major issues when purchasing nuclear medicine equipment such as gamma cameras and PET/CT systems is to ensure that the system fulfil the performance characteristics specified by the vendors, often measured following the NEMA (National Electrical Manufacturers Association) standard.^(15,16) These measurements are easy to perform for gamma cameras. However, our experience on the PET/CT system is different. These systems are much more complex and include corrections that are not always open for viewing. Furthermore, the NEMA measurements are very specific on what corrections to use and this leaves the user to either totally trust the vendors written NEMA protocol (if there are any) or to write their own protocol/reconstruction code in separate software. One condition on writing in-

house code is of course to have access to the raw data, which is not always the case. One solution is to do the testing together with the vendor but to keep in mind that it is not an independent third party measurement. There is certainly a need for defining strategies for easier independent commissioning measurements and a call for a national or international task group for the design of these strategies.

The medical physics department in Östergötland is bi-annually performing a questionnaire survey to review how their service at the radiology and clinical physiology department is perceived and what the benefits are and how it can be improved.

X-ray imaging. Ideally, the commissioning of new equipment should be performed after the vendor's application specialist has implemented the clinical examination protocols. This is sometimes a problem at our hospitals as the application specialist may arrive just in time for the clinical training of the staff commences. This training typically involves performing a limited number of patient examinations under supervision of the application specialist. A solution to this problem may be to first perform a limited safety inspection and the more rigorous commissioning measurements after the clinical protocols have been fully implemented.

We aim to perform periodic tests on a yearly basis and after scheduled technical maintenance in order to assure proper operation and to minimise the time that the equipment is out of clinical operation. After unscheduled repair by the engineering department or by the vendor, the medical physicist negotiates a time slot for a specific, limited QC-test depending on the type of divergence or service. This was implemented after an accident where a vendor, after scheduled maintenance, set the automatic exposure control (AEC) dose on a radiography unit to seven times higher dose than expected. Specific QC-tests are performed after replacement of x-ray tube, flat-panel detector, AEC, or anti-scatter grid etc. but not yet after software updates and alterations in image post-processing. After completion of the QC-tests, the medical physicist or engineer reports any divergence in the hospital maintenance system database (Medusa v5.3). In doing this, we can directly communicate any specific problems to an assigned local engineer who has access to the test report. If the problem is judged to be minor, the equipment is put back into clinical use, but the clinical staff is informed that it might have limited performance. After major problems, the equipment is suspended from

further clinical use until it is properly serviced. A control chart is updated on key aspects of the equipment, for example automatic exposure control dose or dose rate and technical image quality such as low- and high-contrast resolution. An annual QC-report is written to the senior radiologists where all non-trivial divergences are reported, with sample control charts (figure 1).

Figure 1a shows the increase in required air kerma rate to maintain the level of the automatic brightness control system. It has increased by approximately 10% per year and indicates that the sensitivity of the image intensifiers has decreased during the period of operation. Figure 1b shows low-contrast detection index, LDI⁽²¹⁾ with identical image acquisition conditions over a period of two and a half years. Changes in LDI during this period are in some cases significant and conclude that the objective LDI method has superior precision ($\pm 2\%$ SD) to our previous visual (subjective) low-contrast resolution assessment tests.

Figure 1

A review of the last six years QC on digital radiography systems in our region show that most divergences are found (% of reported divergences) on the alignment and centring of radiation field size and position (37%), automatic exposure control, AEC (24%), grid related problems (16%) and image artefacts (12%). Aspects that generate very few divergences are for example tube voltage, filtration, dose-linearity, instruction manual and mechanical failures (1%). A large majority of the divergences would therefore be found testing the AEC-system and taking a few test-phantom images. These tests could then be performed more quickly and more frequently in order to identify problems at an earlier time.

Nuclear Medicine. In nuclear medicine the dose calibrator,⁽⁵⁾ should be controlled at least once a month. Other equipment in nuclear medicine should be tested periodically. Besides this there are no national guidelines on how often QC should be done on a PET or gamma camera system. In the literature there are recommendations⁽¹⁹⁾ for which measurements that should be done and how often. Zanzonico et al.⁽¹⁹⁾ has given an overview for dose calibrators, gamma cameras and PET systems and give many useful references.

However, there is a divergence between the nuclear departments in Sweden on how and how

often QC is to be performed on gamma cameras.⁽²⁰⁾ The QC routine on each particular nuclear medicine department is probably dependent on old habits, the specific vendor's recommendations and the education of the staff. There is an old guideline for QC on gamma cameras, printed 1980 in a booklet by the Swedish association for radiation physics (SFFR), describing in detail how and how often a QC procedure should be performed. However it is strongly in need of an update, as it for instance does not contain any information on tomography, SPECT and PET. There is a need of discussion on strategies for a common QC performance in Sweden and a call for national guidelines.

The Nuclear medicine department in Linköping follows QC procedures that are recommended by the vendor. Daily stability control and function tests are done on the dose-calibrators. We also control the linearity of the radioactivity quarterly. Gamma camera daily QC is performed by the technologists, including tests of extrinsic uniformity, energy peak and energy resolution using a ^{57}Co flood field. These measurements are followed up in a control chart where the mean value from the five measurements for every week is calculated (figure 2a). One problem is that the vendor's daily QC procedure only offers calculation of uniformity for the centre field of view (CFOV). Therefore it is important for the staff to also check the uniformity image visually, otherwise artefacts caused by a PM-tube out of range can pass the daily check, as shown in figure 2b. This image passed the daily control for some time.

Figure 2

The monthly QC contains control of centre of rotation (COR) for all collimators used in SPECT, the intrinsic uniformity and the energy peak for $^{99\text{m}}\text{Tc}$. The measurements are monitored with control charts as in Figure 2a. Calibrations are only performed if the parameters are out of range. Once a year the sensitivity (cps/MBq) is measured for each gamma camera and for the isotopes of interest for quantification ($^{99\text{m}}\text{Tc}$, ^{123}I and ^{151}I).

The PET QC is a maintenance procedure performed daily to normalize variations in PET detector responses. The results produced determine the readiness of the system for scanning or whether service is needed. The procedure includes daily normalisation based on a homogeneously filled ^{68}Ge phantom scan, computation and verification of the PET calibration factor (ECF), normalisation results

display and sinogram inspection. A cross calibration between the dose calibrator and the PET scanner is done every time the ^{68}Ge phantom is exchanged i.e. once a year. This will assure that the standard uptake values (SUV) measured with the scanner are aligned with the activity measured by the dose calibrator. Periodical controls of the image performance in terms of contrast and resolution are not performed. The control of the registration between SPECT and CT imaging respectively PET and CT is done once a year with the phantom recommended by the vendor.

Teaching and training of staff

International bodies (ICRP, WHO, IAEA, EU) recognise the importance of specific training in radiological protection, as it is fundamental for optimisation programmes in medical imaging.⁽²²⁾ The routines for such training should be documented as well as the signed certificate after the training. Such training should be a routine part of the introduction program for new staff and part of the continuous professional development program for all staff. It should be both theoretical and practical and performed on the equipment used by the staff. Special training emphasis should be made for staff performing examinations of children, screening and high-dose examinations such as computed tomography, PET and interventional radiology. It is important to recognise that medical physicists and engineers, who sometimes act as teachers for clinical staff, also need training, particularly when new equipment is purchased. Due to our and other centre's inquiry, such training is now available from the vendors.

X-ray imaging. In our county, the staff is divided into five subgroups depending on their type of work and responsibility. Staff that do not handle the imaging equipment themselves but take part in the examination or intervention only need basic radiation protection training. Staff that handle the imaging equipment or are responsible for the procedure (typically a physician) require specific practical hands-on training on the particular equipment. For staff involved in interventional radiology and residents in radiology, we also require that they take part in a practical session in a fluoroscopy room where many aspects of patient- and occupational doses are studied using anthropomorphic phantoms and hand-held dose rate survey meters. At the surgery department, the mobile x-ray unit is only one of many technical items that the staff need to manage. Our experience is that persuading physicians to take part in radiation protection training can be

challenging, whereas nurses usually are keener to attend. Audits performed by the Swedish Radiation Safety Authority (SSM) frequently reveal non-compliance with legal requirements for training and education of physicians at Swedish hospitals, in particular of orthopaedic surgeons (Torsten Cederlund, SSM, private communication). We therefore try to follow the regular methods to maintain sufficient training on medical equipment by using professional interactive learning systems such as TILDA (Tool for Interactive Learning and Daily Assistance) so that the staff can annually update and check their knowledge on a particular x-ray unit.

Nuclear medicine. All staff starting at the nuclear medicine department must take part in a theoretical introductory lecture about handling radioactive nuclides. This also includes medical and technologist students placed at the department for more than two weeks. We also offer a practical exercise in decontaminating a small "accident" with ^{99m}Tc . This will also give experience in working with radiation safety and survey instruments.

Patient doses, assessment of fluoroscopy time and feedback to operators

Diagnostic standard doses, DSD, should be measured for a set of specific examinations for which the Swedish Radiation Safety Authority has established diagnostic reference levels.^(2,3) There should always be a documented valid standard dose measurement available. A new measurement should be initiated if new equipment is being used, if the method of operation is revised or if the previous measurement is over three years old. If the standard dose exceeds the reference level, an investigation should be conducted in order to possibly reduce the standard dose. In addition, for all fluoroscopy units outside the radiology department and all interventional radiography units, the fluoroscopy time and preferably also the air kerma-area product, P_{KA} should be recorded, analysed and fed back to the individual operators, clinical staff and hospital management.

X-ray imaging. As of 2009 a majority of the x-ray rooms in our county are equipped with licenses for modality performed procedure step (MPPS) that report air kerma-area product, P_{KA} for the complete examination to the radiological information system (RIS) (Sectra RIS v.4.1). If not, the radiographer is asked to manually type the displayed P_{KA} in the RIS. On request, administrative staff sends the relevant patient

dose information to the medical physicist in excel spread sheets for further analysis via pivot tables where data is sorted by examination room and type of examination and fed back to the radiology departments in terms of periodic reports. This option has been operational for two years but the data is still not managed optimally as it is prone to errors in the data. For example if a patient is registered at one modality but moved and examined elsewhere, the patient dose data is still registered on the first modality. Also the handling of data from computed tomography systems is not optimal as no standard for computed tomography dose index, C_{vol} and dose-length product, $P_{KL,CT}$ is available. Our overall experience with MPPS reports is however positive, but the dose data needs to be quality controlled as pointed out by Axelsson et al.⁽²¹⁾ Figure 3a shows the diagnostic standard doses in all ten chest x-ray rooms in our region at two separate occasions.⁽²³⁾ They both comply with the national diagnostic reference level ($0.60 \text{ Gy}\text{cm}^2$), but still show some variation. The present DSD (2008-2009) and also its standard deviation ($0.22 \pm 0.07 \text{ Gy}\text{cm}^2$) are however lower than in the previous compilation during years 2005-2007 ($0.29 \pm 0.13 \text{ Gy}\text{cm}^2$). Similar results were found in the Swedish national survey⁽²⁴⁾ and is a good example of useful quality assurance and first step in optimisation. Information technology applications to identify erroneous data are being established at some hospitals.⁽²⁵⁾ For example, Källman et al.⁽²⁶⁾ have reported on automatic daily collection, analysis and reporting of patient dose and other exposure related factors through analysis of the DICOM header stored in a DICOM metadata repository. This system show promising features and enables direct feedback on any deliberate or non-deliberate action in the x-ray room.

Since 2000 we have collected fluoroscopy time, T, and P_{KA} -values systematically. Rooms with interventional radiology report to the RIS, but data from mobile C-arm units are manually recorded by the clinical staff and emailed to the medical physics department on request. The data is then sorted per type of procedure and all procedures that were performed more than ten times per year and x-ray unit were analysed. The median and 95-percentile value of T and P_{KA} were computed and reported to the operators. The example below indicates the importance of assessing the trends over time and not just each year by itself. For the ESWL (Extra corporal Shock Wave Lithotripsy) intervention (figure 3b), the average fluoroscopy time was reduced by 6% between the years 2007 and 2008 but still the P_{KA} was doubled as new imaging equipment was

installed in January 2008. The reasons for the increase are being investigated and some corrective actions taken. The main reasons for increasing P_{KA} include lower total filtration and larger field of view compared to the old equipment. Assessing the P_{KA} without reference to previous data or assessing fluoroscopy time only would possibly overlook this problem.

Figure 3

The individual operators are annually presented with his or her T and P_{KA} -value and the corresponding values for the clinic as a whole as reference. If the operator's T and P_{KA} -value exceeds the corresponding values for the clinic by more than 50%, he or she is asked to contact senior radiologist and submit an explanation. Since 2005 approximately 35 individual operators were analysed each year and 14% and 22% of these exceeded the 50% threshold for the T and P_{KA} -value, respectively. A majority of these operators was working at the larger University hospital where most of the new and more complex procedures are performed and not at the neighbouring smaller hospitals.

Nuclear medicine. A major impact on the final image quality in nuclear medicine examinations is the total number of registered counts. The administrated activity and the imaging time together with a QC assured system give the total number of counts that the system is able to detect which is correlated to the final image quality. The guidelines given by European Association in Nuclear Medicine (EANM), Society in Nuclear Medicine (SNM) and technical leaflet for nuclear medicine examinations are, however, mainly focusing on the administrated activity to the patient and also show a wide divergence. The Swedish radiation safety authority (SSM) also gives diagnostic reference levels (DRN) for some examinations as a measure of administrated activity. It would however be of more clinical importance to state all these reference levels and guidelines in terms of collected counts for different nuclear medicine examinations. This is further confirmed by a recent survey study for whole body bone scintigraphy in Sweden,⁽²⁷⁾ showing a relation between number of collected counts and visually evaluated clinical image quality. Furthermore, in Sweden there is a large diversity in how same type of examinations are performed. There was a national clinical survey in Sweden for myocardial perfusion where all the 30 nuclear medicine departments participated.⁽²⁰⁾ The results show a large difference in the final image

quality and deviating diagnostic answers on the simulated studies.

Consequently there is a real need of co-operation on protocol optimisation to give a sufficient image quality and a correct diagnostic answer. One feasible solution is the newly started cooperation between the Swedish Society in Nuclear Medicine (SFNM) and the External Quality Assurance in Laboratory Medicine In Sweden (EQUALIS). An expert group has been assigned in the nuclear medicine area that will focus on survey studies and establish quality criteria for examinations adequate for diagnosis.

CONCLUSIONS

It is the responsibility of the medical physics community to identify problem-areas, review and find consensus on remedial levels and develop efficient QC-measurement strategies. If such consensus were formed, the QC-measurement in an individual hospital would be of global and not just local interest. Objective, automated QC-methods on assessing for example low-contrast resolution is needed as several reports has shown subjective visual assessment is not reliable.^(13,28) The time for each medical physics or engineering department to focus strictly on their own 'problems' has passed. We have basically the same problems and need to join effort to solve them. We therefore welcome any initiative to redefine the role²⁹ for the Medical Physics Expert (MPE) in the modern radiology department to make better use of the enormous data flow in need of automated analysis. Justification and optimisation of radiological procedures are key aspects of quality assurance. More time need to be spent on these tasks by the MPE compared to for example periodic testing of imaging equipment, particularly on aspects that show very few divergences. The MPE needs to take more part in research and to adapt scientific advances into clinical application to promote health and disease management, thus being a Medical Physics Researcher.²⁹

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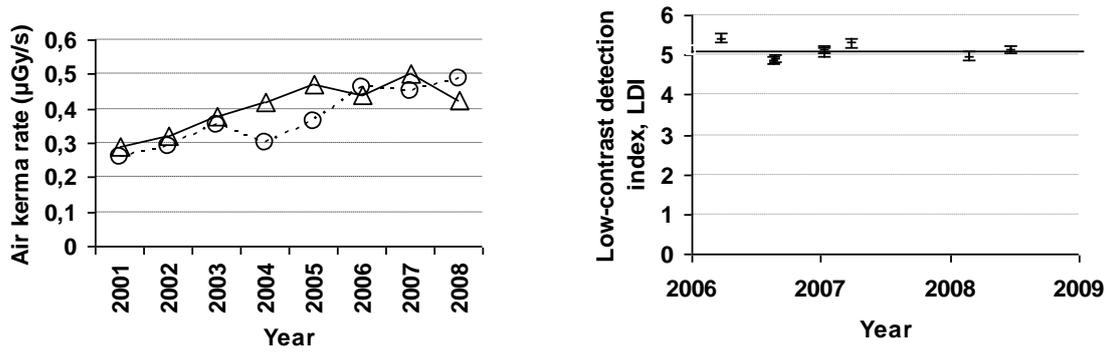
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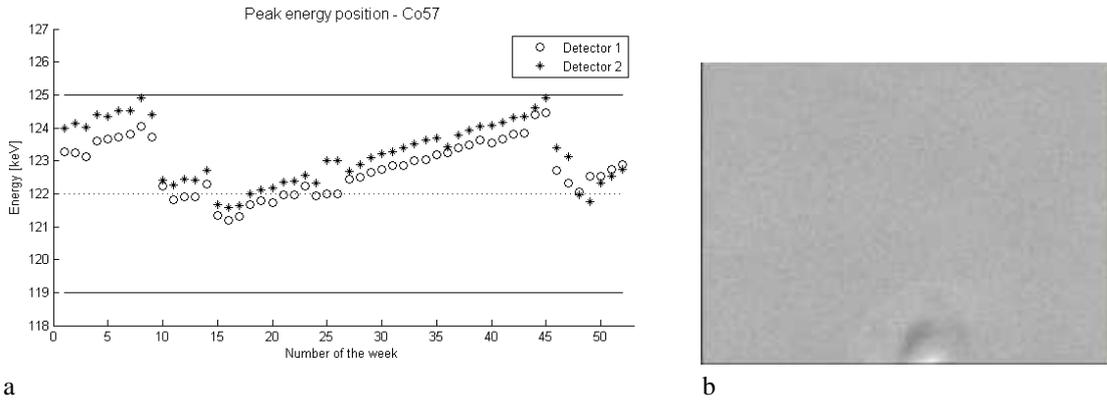
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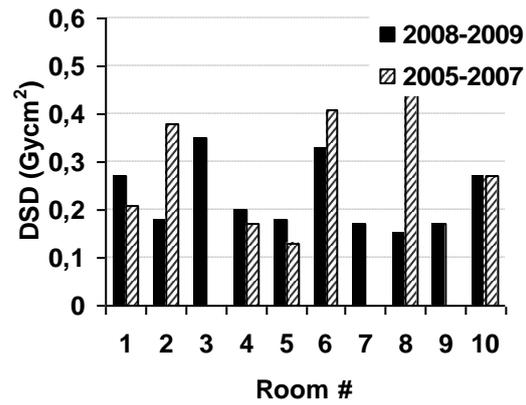


a b
 Figure 1. Control charts of (a) the entrance air kerma rate at the two image intensifiers with 2 mm Cu filtration on the x-ray tube (Swemac Biplan 400) and (b) low-contrast detection index, LDI, for a Philips Digital Diagnost.

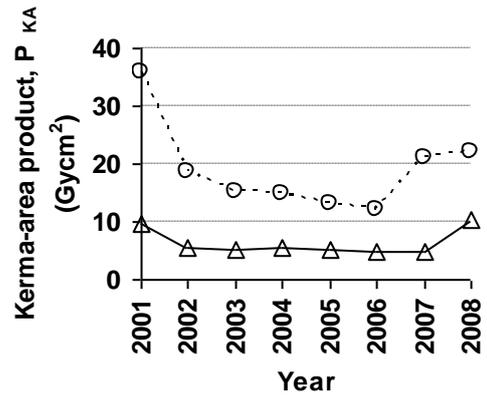


a b
 Figure 2. The control chart (a) from the daily control of the energy peak using a ⁵⁷Co flood field phantom for the year of 2008. The diamonds shows the peak value for head 1 and the rings shows the peak value for head 2. The upper limit (125 keV) and the lower limit (119 keV) are shown by the continuous lines. Week number 10 and 46 a new energy calibration was done. (b) show the uniformity map from a daily control on a gamma camera. In the lower central part there is an artefact caused by a PM-tube out of range.

Figures for Sandborg et al (paper 26)



a



b

Figure 3. Diagnostic standard doses, DSD (a) in all chest x-ray rooms in our region at two time periods. The air kerma-area product, P_{KA} for Extra corporal Shock Wave Lithotripsy interventions (b) at the urology clinic in Östergötland; o: 95th percentile and Δ: median values.