IAEA-TECDOC-1447

Optimization of the radiological protection of patients: Image quality and dose in mammography (coordinated research in Europe)

Results of the Coordinated Research Project on Optimization of Protection in Mammography in some eastern European States

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FOREWORD

Mammography is an extremely useful non-invasive imaging technique with unparalleled advantages for the detection of breast cancer. It has played an immense role in the screening of women above a certain age or with a family history of breast cancer.

The IAEA has a statutory responsibility to establish standards for the protection of people against exposure to ionizing radiation and to provide for the worldwide application of those standards. A fundamental requirement of the International Basic Safety Standards for Protection Against Ionizing Radiation (BSS) and for the Safety of Radiation Sources, issued by the IAEA and co-sponsored by FAO, ILO, WHO, PAHO and NEA, is the optimization of radiological protection of patients undergoing medical exposure. In keeping with its responsibility on the application of standards, the IAEA programme on Radiological Protection of Patients attempts to reduce radiation doses to patients while balancing quality assurance considerations. IAEA-TECDOC-796, Radiation Doses in Diagnostic Radiology and Methods for Dose Reduction (1995), addresses this aspect. The related IAEA-TECDOC-1423 on Optimization of the Radiological Protection of Patients undergoing Radiography, Fluoroscopy and Computed Tomography, (2004) constitutes the final report of the coordinated research in Africa, Asia and eastern Europe.

The preceding publications do not explicitly consider mammography. Mindful of the importance of this imaging technique, the IAEA launched a Coordinated Research Project on Optimization of Protection in Mammography in some eastern European States. The present publication is the outcome of this project: it is aimed at evaluating the situation in a number of countries, identifying variations in the technique, examining the status of the equipment and comparing performance in the light of the norms established by the European Commission. A number of important aspects are covered, including:

— quality control of mammography equipment
— imaging techniques
— image quality
— differences in evaluation of image between internal and external experts
— patient dosimetry
— accuracy of dose assessment
— artefacts in image
— image viewing conditions.

The present publication is based on the results of the groups who participated in the coordinated research project. The IAEA wishes to acknowledge the contribution of the American College of Radiology and the European Commission, whose publications provided useful material for reproduction in this TECDOC. The IAEA officers responsible for this publication were M. Oresegun and M.M. Rehani of the Division of Radiation, Transport and Waste Safety.

EDITORIAL NOTE

The use of particular designations of countries or territories does not imply any judgement by the publisher, the IAEA, as to the legal status of such countries or territories, of their authorities and institutions or of the delimitation of their boundaries.

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CONTENTS

1. INTRODUCTION

The two basic principles of radiological protection of the patient as recommended by International Commission of Radiological Protection (ICRP) are justification of the practice and optimization of protection, including the consideration of reference levels. These principles are incorporated in the International Basic Safety Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources (BSS) [1], which sets currently internationally accepted requirements for radiation safety.

Justification is the first step in radiological protection. It is accepted that no diagnostic exposure is justifiable without a valid clinical indication, no matter how good the imaging performance may be. Every examination must result in a net benefit for the patient.

Once a diagnostic examination has been clinically justified, the radiological protection of the patient must be optimized, which means that the doses should be as low as reasonably achievable, consistent with obtaining the appropriate quality of image. However, insufficient attention has so far been given to this matter.

In the area of optimization of protection in diagnostic radiology and particularly in mammography there is considerable scope for both improvement of image quality and dose reductions. Simple, low-cost measures are available for reducing doses without loss of diagnostic information, but the extent to which these measures are used varies widely from country to country. The optimization of protection in diagnostic radiology does not necessarily mean the reduction of doses to the patient — it is paramount that the diagnostic confidence in the image is not compromised.

The BSS and ICRP advocate the use of reference or guidance levels as an aid to optimization of protection in medical exposure [2]. Guidance levels (GL) give an indication of the dose in good practice in performing a given X ray examination on an average patient, under normal clinical circumstances, using current imaging technology and techniques.

There is a need to evaluate the situation of optimization of protection in mammography in different countries, identify the points where action is needed and then document improvement after corrective actions are put in place. The lessons learnt from such an exercise, conducted in several countries, should give insight into the variation in practices, pattern of problems in optimization and, subsequently, inferences on how optimization can be effective. In this exercise conducted in 6 countries in eastern Europe, very useful and interesting observations were made, and ultimately it was possible to achieve, on an average, 25% reduction in dose while maintaining the image quality. It is hoped that this publication will prove useful to Member States in setting up a programme of optimization of radiological protection in mammography, using the experience of some countries in eastern Europe.

2. THE COORDINATED RESEARCH PROJECT

Previously concluded coordinated research projects (CRP) on radiological protection in diagnostic radiology organized by the IAEA have demonstrated the importance of implementing quality assurance and quality control programmes in radiology departments for purposes of radiological protection of the patient and improvement of quality of clinical images [3, 4].

Earlier CRPs did not include mammography. Knowing that such a radiographic technique is the highly appropriate technology for breast cancer detection and that suitable performance of mammographic imaging system can only be achieved through adherence to Quality Assurance (QA) guidelines and promotion of training initiatives, a CRP, of two years duration, was started in 1999 in some eastern European countries: Czech Republic, Hungary, Poland, Slovakia and Romania. Every country selected three mammographic facilities for data collection.

The primary objective of the current CRP was to have a situation analysis of the practice of optimization of protection in mammography in each of the participating countries and draw lessons which can be useful to many others. Dissemination of the results of such an exercise is the purpose of this document.

A secondary objective was to set up a radiological protection framework which could be expanded to a much wider range of countries and hospitals in order to facilitate a systematic approach to optimization of radiological protection for the patient in mammography. In this sense such activity served as a training tool and catalytic agent.

While the CRP involved only a few hospitals in each country, the collection of patient doses would be a first tentative step towards comparing local doses to the published reference values thus complying with the respective country regulations.

Finally, this publication could function as a template for the implementation of such an initiative in countries currently lacking a systematic approach to optimization of radiological protection for the patient in mammography.

3. METHODOLOGY ADOPTED FOR THE CRP

The CRP included two phases of work. The first phase dealt with the assessment of the existing status of radiological practice and equipment performance in a selected number of mammographic installations through the implementation of a quality control programme and corrective actions, where necessary. The second phase dealt with the same installations and reassessed the overall performance in terms of image quality and patient dose improvements. Five Member States of the IAEA as mentioned above were initially involved in the CRP, but one was not able to comply entirely with the programme work foreseen by the Agency, primarily due to local difficulties (retrieving of past clinical images).

Due to the practicality aspects of the CRP (image quality evaluation before and after the QC measurements), a close interaction and co-operation with radiology staff of each mammography centre was essential for the success of this project.

The IAEA's dosimetry laboratory undertook the calibration of dosimeters and intercomparison of dosimetry systems to be used for patient dose measurements.

3.1. INTERNAL AND EXTERNAL EVALUATION OF MAMMOGRAMS

A first set of 30 breast examinations (3 centres 10 patients) was retrieved in each country from the archived images produced within the last twelve months and assessed by the local radiologist of each installation before any QC tests were performed. The breast images were checked using the European guidelines on quality criteria for diagnostic radiographic images

[5, 6] employing the pre-designed standard forms made available by the laboratory that was in charge of the final central evaluation.

The radiologists in each country who evaluated the images are termed field radiologists in this report. They provided the internal evaluation. Furthermore, three independent expert radiologists were involved in the external evaluation of the quality of images. This required co-operation among three additional countries (Italy, France and Spain) from where the radiologists came.

All collected images were first sent to Madrid (Spain) where the first assessment was carried out by an expert radiologist in collaboration with a local medical physicist. A subsequent evaluation was made in Paris by a French expert radiologist and a medical physicist.

After the evaluation, the mammographic images were sent back to the respective mammography centre together with the scoring results. Furthermore, some of the breast images were digitized and put in a CD-ROM which was made available to all participating countries by the Centre at Madrid. The conclusions drawn from the analysis of the data were taken as educational material for training the local staff and as hint for corrective actions to be put in place in each participating centres.

Almost one year later, the same sequence was repeated and a second image evaluation was performed (Phase II) initially by the field radiologists in the same mammography centers and followed by an evaluation by the external experts. In the second phase one external expert radiologist was from France (same as in the 1st phase) and another from Italy. Two medical physicists were also involved in this second phase of the CRP.

Consequently, during each phase of the CRP, a given clinical image was checked as a minimum three times: once by a field radiologist and twice, separately, by two expert radiologists. The French radiologist, in particular, assessed both first and second phase films, thus allowing an intra-expert comparison to be made.

3.2. EVALUATION OF THE QUALITY OF CLINICAL IMAGES

Clinical images were evaluated in both phases according to the criteria recommended by the European Commission. These criteria are defined for cranio-caudal (CC) and medio-lateral oblique (MLO) projections separately.

The original forms published in the European document for checking the criteria were slightly adapted to the CRP purposes in the sense that they included an extra observation of breast composition (very dense, dense, normal, fatty). Modified forms used during the CRP are provided in the Appendix I, which contains this observation in the column below the dose column of each projection.

Four images (CC-right breast, CC-left breast, MLO-right breast, MLO-left breast) were collected and evaluated individually for each patient included in the CRP.

Each criterion was scored as ‘1’ if fulfilled, ‘0.5’ if doubtful, and ‘0’ if not fulfilled. A given film fulfilling all the criteria in MLO projection thus resulted in total score of 11 and in CC projection in a total of 10. The maximum possible score for the whole examination consisting of two MLO films (11+11=22) and two CC films (10+10=20) was 22+20=42.

During Phase I the Spanish radiologist expert, used a slightly different scoring procedure primarily due to practical reasons. Instead of assigning an individual score to each criterion on the proforma of each projection, a 'global' score of 10 was used for both films of the same projection. The European Quality Criteria were, however, taken into account during the evaluation procedure.

At the end of the first phase, it was therefore not easy to numerically compare the results obtained by the Spanish radiologist to those obtained by the French radiologist who did actually follow the individual criterion scoring system.

Such a 'global' approach unavoidably introduced an element of 'subjectivity' into the process of the image evaluation. Two main conclusions were drawn from the comparison of the two methods. First, there was a sort of 'similarity or vicinity' between the average scores given by the two experts to the same set of images. Second, the individual criteria scoring system was considered as the one to be applied during the subsequent Phase II of the CRP due to its clarity and reproducibility.

3.3. REJECT RATE ANALYSIS

As a first step of the QC programme, each participating mammography centre made an evaluation of rejected film rates and assessed the causes of rejection over a period of time ranging from 1 to 3 months. A list of possible causes of rejection was established allowing roughly to characterize the relative importance of the technical component on the observed reject rates. Five different categories were established: too light, too dark, positioning error, motion, and technical reasons. The number of films rejected by radiologists or by radiographers was also recorded.

3.4. PATIENT DOSIMETRY

3.4.1. Patient dose measurements

Several application specific quantities have been found useful in the past for measurements in diagnostic radiology. However, there has been ambiguity in the names of the quantities and their (sometimes incorrect) use. ICRU and IAEA [7] are developing two new recommendations on dosimetry in diagnostic radiology. Both documents provide a consistent set of application specific dosimetric quantities based on the air kerma. In addition, air kerma is the primary dosimetric quantity in the diagnostic energy range and all calibrations at national laboratories of dosimeters for use in diagnostic radiology are provided in terms of air kerma.

Each participating country evaluated the breast doses using local TLD read-out system. The dose responses as well as the energy characteristics of TLDs in use were known from national calibration results.

Entrance surface air kerma (ESAK) was measured using a TLD stuck on patient breast skin in the centre of the X ray beam. It may be mentioned that sticking the TLD chips on breast is not a recommended practice for routine breast dose measurements. It is primarily for research that this practice was adopted. Since most ESAK measurements were performed for patients with mean thickness of compressed breast close to 45 mm, the evaluation of average glandular dose (AGD) to patients was justified.

According to the dosimetry protocol described in the European document [8], the most relevant physical parameters such as kVp, mAs and thickness of compressed breast were recorded for each patient. The average glandular dose (AGD) was also computed for a 'standard breast' composition and compared to the limiting values of 2.3 mGy for a net film density of 1.0 O.D. Corrections were made for film densities different than 1.0 according to the European document.

3.4.2. Validation and comparison of dosimetric systems

In order to be able to compare dosimetry results obtained in different countries, an intercomparison of TL dosimetry systems used was organized by the IAEA dosimetry laboratory.

The European Protocol on Dosimetry in Mammography requires that the accuracy and precision of TL measurements of entrance surface air kerma on patients and phantoms are both better than ±10%. This criterion was therefore selected as a measure of a 'good dosimetry performance' of the participants. They were asked to send four sets (containing TLD chips) of non-irradiated dosimeters to the IAEA for the reference irradiation. Three dosimeter sets were irradiated at the IAEA dosimetry laboratory at radiation qualities representing the mammography beams used in clinical practice. One dosimeter set was used to assess a contribution of various environmental factors into the measured signal.

The irradiated dosimeters were mailed to the participants for their evaluation together with data sheets and information about irradiation conditions (date of irradiation, X ray target, filtration, tube potential, half value layer, irradiation geometry) excluding values of reference air kerma (blind test). The participants were asked to follow the European Protocol and calibrate their TLD systems in terms of air kerma free-in-air.

The beam from a molybdenum anode with a molybdenum filter generated at 28 kV was specifically recommended for the calibration. They were asked to apply all necessary corrections (energy dependence, fading, linearity of the system, individual sensitivity of detectors) to their readings and report the measured values of air kerma to the IAEA. Some more information on irradiation set-up can be found in [9].

The results of measurements were evaluated at the IAEA. Participants were informed about the results and they were given recommendations on how to improve their dosimetry.

3.5. QUALITY CONTROL TESTS

As frequently documented in the scientific literature, Quality Control (QC) tests are carried out to evaluate the performance level of radiographic systems in order to ensure that users are provided with the best achievable image quality while keeping patient doses as low as reasonably achievable.

As for mammography, such a general principle is essential since the imaging technique used (kV, exposure time, sensitivity class of film-screen combination etc.) may, much more than in general radiology, strongly affect the final outcome of the examination: the level of image information content as well as the patient dose.

Obviously, to practically implement QC tests proper measuring instruments and test-objects are required at the level of each mammography unit (Appendix II). Unfortunately, due to a

different type of measuring instrument available in the five participating countries, QC tests were carried out in a slightly different manner in different countries.

The following QC tests were performed twice, that is, after the first set (baseline data collection in Phase I) of both patient dose measurements and clinical image quality evaluation had been carried out and after the remedial actions had been implemented (beginning of Phase II):

- reproducibility and accuracy of kVp;
- alignment of X ray field/image receptor and tube output;
- measurement of focal spot size, source-to image distance;
- HVL determination;
- measurement of optical density control setting, thickness compensation, voltage compensation and reproducibility of AEC;
- measurement of compression force;
- bucky and image receptor: - anti-scatter grid,- screen-film;
- X ray film processor (sensitometry, temperature);
- darkroom;
- brightness and homogeneity of viewing boxes;
- dosimetry, phantom image quality.

The quality control tests methods used, as well as the criteria for scoring the results, were in full agreement with those specified in the European Protocol for the Quality Control of the Physical and Technical Aspects of Mammography Screening [6].

A breast phantom (the RMI 156 model) which is used worldwide for accreditation purposes of mammography units involved in breast screening cancer initiatives, was adopted as a standard image test-object for checking the level of the image quality produced in the participating mammography centres [10].

Phantom images were analyzed and scored by local physicists using viewing boxes with luminance level of as far as possible around 2000 cd/m^2 as required by the European quality criteria document [5]. However, not all centres could meet the requirement as stated in 5.7.1 and Figure 32. Acceptability thresholds specified by the phantom manufacturer (based on the American College of Radiology criteria) for contrast details and resolution inserts were applied.

3.6. REMEDIAL ACTIONS

The first set of QC tests (carried out after the patient dose measurements and clinical image quality evaluation) marked the beginning of the Phase I of the CRP. Appropriate corrective actions were then made on the basis of the corresponding results.

Some of them were mainly related to the radiographic techniques used (range of kVp, film-screen sensitivity etc) and required organizing training actions at the level of a given mammography centre in order to improve the local radiological practice. The educational material produced by the research group of the CRP (CD-ROM of digitized breast images) was used for this purpose.

Some other actions were more complex and called upon local maintenance services intervention as well as changes of pieces of equipment. Further changes were made, where indicated, as a result of the review of the protocols used for the projections under study.

These corrective actions and changes were constrained by the practical and economic considerations within each participating country.

Following the remedial actions further evaluations (film reject analysis, dose assessment and image quality) were repeated to determine the effectiveness of the changes in reducing patient doses without compromising on image quality.

4. RESULTS

4.1. THERMOLUMINESCENT DOSIMETER SYSTEM INTERCOMPARISON

To be meaningful, any measurement has to be traceable to the international measurement system and its uncertainty needs to be minimized. In order to provide comparison between various mammography units, an uncertainty of ±10% in measurement is sufficient.

The results of the first run of the comparison are given in Figure 1.

The results show that for nearly half of the diagnostic centres the reported values were outside of limits of ±10% and two centres had large deviations.

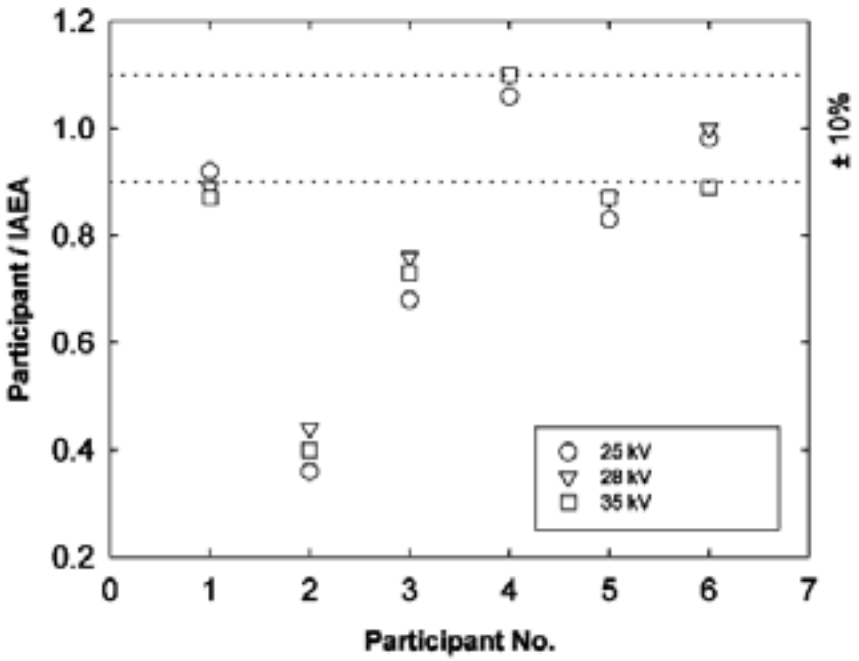


FIG. 1. Ratios of the air kerma stated by the participant to the reference value provided by the IAEA dosimetry laboratory for irradiation of thermoluminescent dosimeters (TLDs) in beams generated by a Mo/Mo anode filter combination during initial tests.

The analysis of the comparison showed that the main sources of discrepancies were:

- poor irradiation geometry during local calibration (backscatter from a phantom and scattering from surrounding materials);
- application of inadequate methods for local calibration (tungsten anode; comparison with a response to various other radiations);
- lack of traceability of local calibration (expired calibration; not traceable to a primary standard).

The participants were given instructions on how to improve their dosimetry and the follow-up of the exercise was organized.

The first follow-up resulted in about 20% of reported values of air kerma outside of ±10% margin. This was a considerable improvement compared with the first run but it also showed that the measurement problems were not completely corrected.

The participants were individually consulted with the aim to resolve the discrepancies. Their procedures were therefore carefully checked and adjusted.

The second follow-up was organized that resulted in all measurements being within acceptance limits ±10%. Dosimetric results of the CRP were then duly corrected.

The results of the follow-up tests are given in Figure 2.

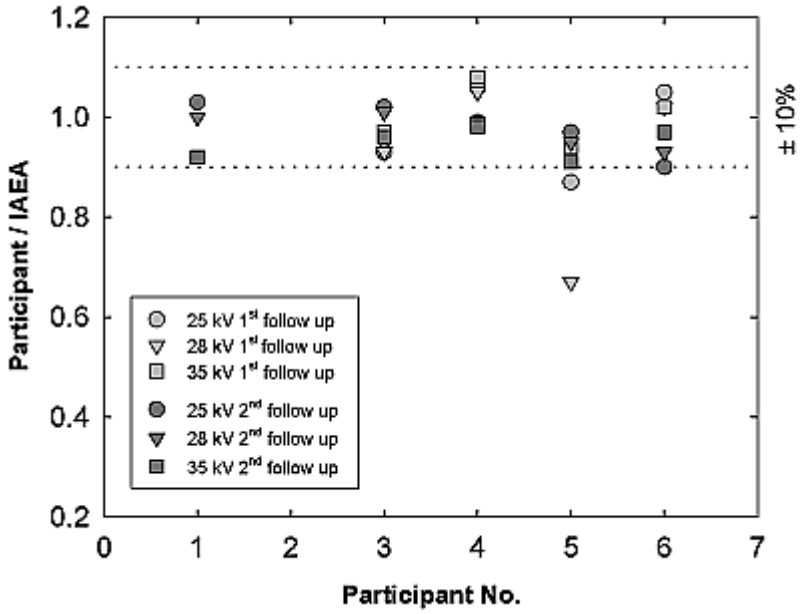


FIG. 2. Ratios of the air kerma stated by the participant to the reference value provided by the IAEA dosimetry laboratory for irradiation of TLDs in beams generated by a molybdenum anode with a molybdenum filter during the follow-up tests.

4.2. AVERAGE COMPRESSED BREAST THICKNESS

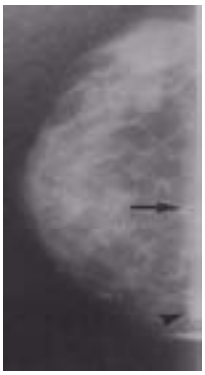
One of the most important factors that can significantly influence the absorbed dose to the breast is its volume and composition.

An 'optimal' contrast of the image while keeping the breast glandular dose as low as possible compatible with the radiographic technique in use can only be ensured if the breast is firmly compressed during the examination.

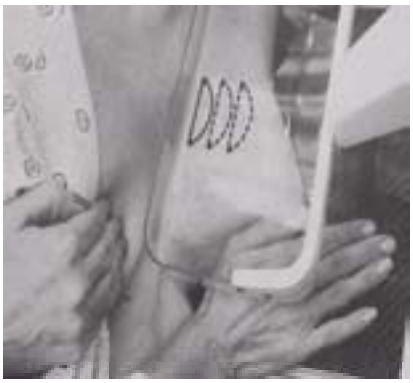
Depending on the radiographic projection considered, the thickness of the compressed breast may vary markedly from patient to patient. Furthermore, due to pectoral muscle, the MLO projection involves a thicker breast volume in comparison to the Cranio Caudal projection.

CRANIO-CAUDAL projection (CC)

CRANIO-CAUDAL VIEW



MEDIO LATERAL OBLIQUE (MLO)



MEDIO LATERAL OBLIQUE VIEW

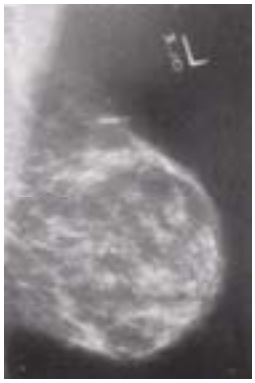


FIG. 3. Breast positioning (cranio caudal and medio lateral oblique projection).

Almost all participating countries were able to provide this information for each examination. Data collected during the two phases of the CRP allowed a comparison to be made among the participating mammography centres and for each radiographic projection considered.

The average compressed breast thickness for the Cranio-Caudal projection for all patients taken together was 52 ± 13 mm (minimum rounded value of 10 mm and a maximum value of 80 mm) and 56 ± 13 mm for the MLO projection (minimum rounded value of 30 mm and a maximum value of 80 mm) respectively.

As can be seen from the data and the figures below, depending on the projection considered, there were significant differences between the two phases of work. In the CC projection, the Phase I measured breast thickness values were statistically different from those measured during the Phase II ('T' Student test: p = 0.0049) while no significant differences were found for the MLO projection ('T' Student: p = 0.085) between the two phases of work of the CRP.

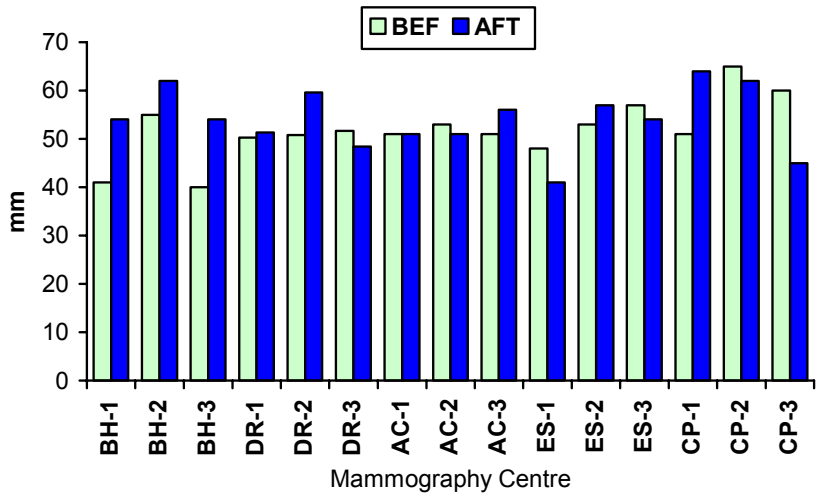


FIG. 4. Comparison of average compressed breast thickness (cranio-caudal projection) in different mammography centres.

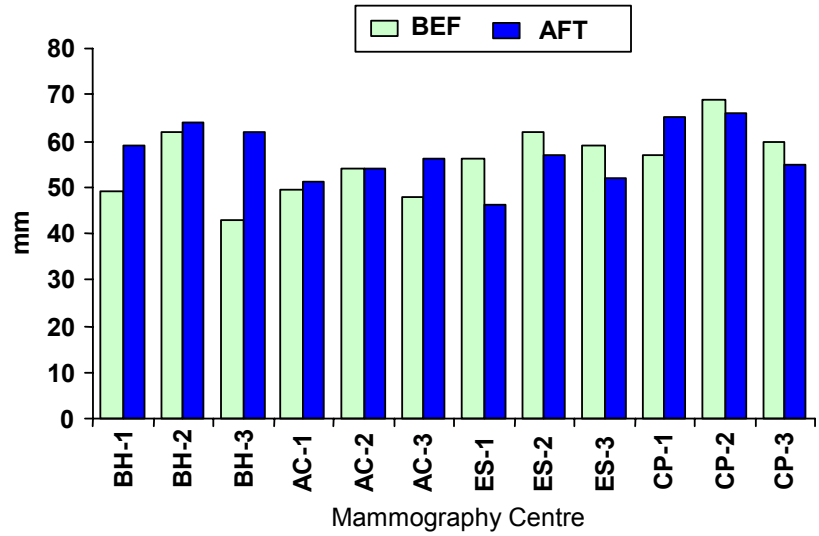


FIG. 5. Comparison of average compressed breast thickness (MLO projection) in different mammography centres.

4.3. ENTRANCE SURFACE AIR KERMA

In each participating country, 30 Entrance Surface Air Kerma (ESAK) values (3 centres × 10 patients × 1 projection) were measured, using TLDs stuck on the patient breast surface in the centre of the incident beam. The associated radiographic technique (kVp, mAs product), and breast thickness were also recorded.

According to the CRP work plan, measurements of ESAK were performed before QC tests and after the implementation of remedial actions. Depending on the availability of TLD systems and level of provision of each mammography centre, breast doses were estimated for the radiographic projections considered and for each patient.

Some centres were not readily equipped at the time of scheduled measurements and, therefore, they carried out some alternative incident air kerma measurements with a dedicated mammography ionization chamber. The measured dose values were then converted into ESAK by applying appropriate backscatter factors (typically 1.09 for X ray spectra used in mammography).

The vertical bar chart below (Figure 6) illustrates the variation of the average ESAK values in different mammography centres before and after the QC actions.

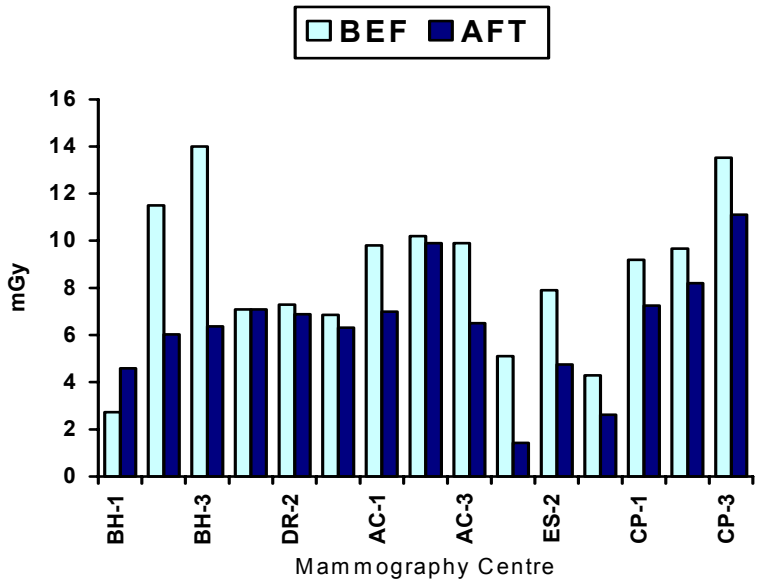


FIG. 6. Average Entrance Air Kerma (ESAK) in different mammography centres before and after the QC and remedial actions.

In all but one centres encouraging results were found demonstrating the efficacy of the remedial actions put in place between the two phases of work. Indeed, the 'before' ESAK values were systematically higher than the corresponding 'after' values which, in some centres, were twice as low.

Taking all breast thickness together, the 'before' ESAK average value (mean) was 8.6 ± 3.18 mGy with a minimum of 2.73 mGy and a maximum dose value of 14 mGy. The corresponding 'after' ESAK values were 6.4 ± 2.46 mGy, 1.43 mGy and 11.11 mGy respectively.

It is worth noting that the implementation of remedial actions leads to a dose reduction of about 25% thus keeping the majority of examinations below the ESAK reference value of 10 mGy for breasts of thickness between 4 and 6 cm.

4.4. AVERAGE GLANDULAR DOSE ESTIMATION

When analyzing differences between the AGD derived from the standard phantom and that from patient examinations, the contribution of patient age must be taken into account: the sample chosen for the evaluation may, for instance, consist of only women in a (lower) age group thus having on average denser breasts than the assumed average. It was therefore important to calculate the range and average of the measured breast thickness to get an indication of the appropriateness of compression.

Methodology described in the European protocol on dosimetry in mammography was followed to estimate the individual average glandular dose for the patients included in both phases of the CRP.

As one might expect, a similar trend of AGD values was found among the mammography centres as for ESAK. Indeed, an average conversion factor of 0.207 was applied to obtain the calculated values.

5. QUALITY CONTROL MEASUREMENTS

Quality Control tests were based on the European Protocol for the Quality Control of the Physical and Technical Aspects of Mammography Screening [6]. They involved local physicists and co-operation of local medical staff who made available the mammography equipment to be checked.

5.1. X RAY SOURCE (TUBE AND GENERATOR)

5.1.1. Focal spot size: star pattern method

Two different methods were followed to perform focal spot size measurement: a ‘star’ pattern resolution device, specially designed for mammography and a slit camera.

Although both of them are indirect measuring methods allowing derivation of actual focal spot dimensions by examining acquired images they provide valuable results allowing limiting values comparison to be made.

Results obtained on nine mammography units after the second round of measurements are illustrated in Figure 7. All dimensions measured in both parallel and perpendicular directions to the anode to cathode axes were in agreement with the required IEC/NEMA norm which limit an 0.3 focal spot to a width of 0.45 mm and to a length of 0.65 mm and an 0.4 focal spot to a width of 0.60 mm and to a length of 0.85 mm respectively.

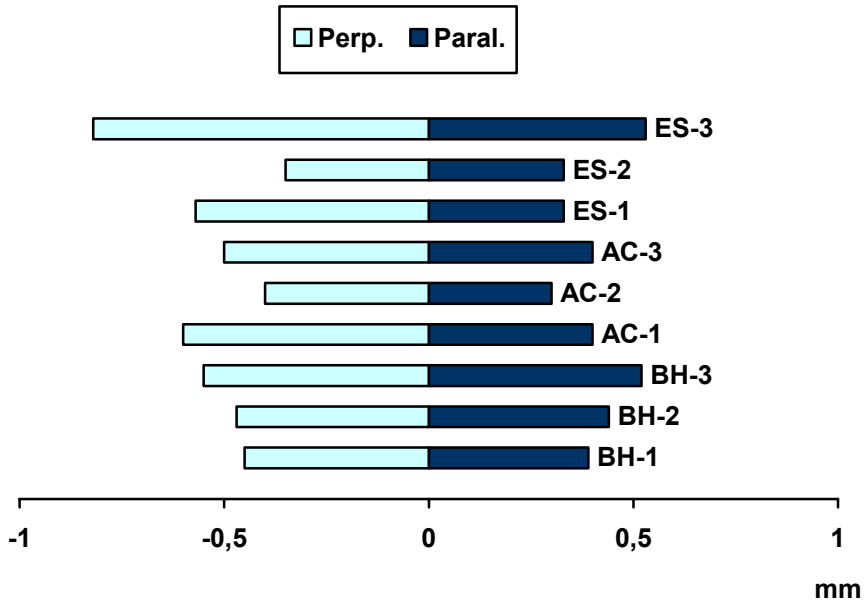


FIG. 7. Focal spot size.

5.1.2. Source-to-image distance

According to the European protocol measurements of distance between the focal spot indication mark on the tube housing and the image receptor were carried out taking into account thickness of the Bucky tray. All the installations were in agreement with the suggested limiting value, that is, a minimum source to image detector distance of 600 mm (see Figure 8).

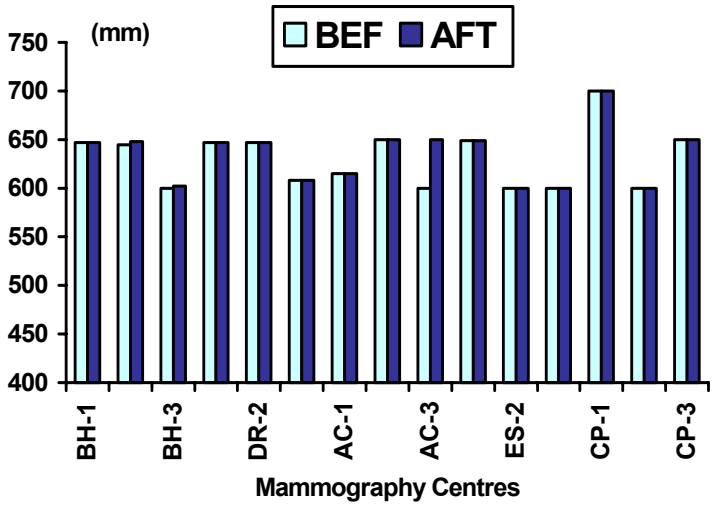


FIG. 8. Source to image distance (mm) in different mammography centres before and after the QC actions.

5.1.3. Alignment of X ray field/image receptor

The alignment of X ray with the image receptor is essential for an adequate imaging of the whole breast volume according to the chosen X ray projection. Any kind of misalignment (lateral or in the chest wall side) may result in a loss of information which might be relevant for the diagnosis. All sides: X rays must cover the film by no more than 5 mm outside the film. On chest wall edge: distance between film edge and edge of the bucky must be smaller than or equal to 4 mm.

The results of this QC test were all in agreement with the recommended limiting value (5 mm).

5.1.4. Tube output

A high X ray tube output is desirable in mammography since it allows to use shorter exposure times minimizing the effects of patient movement and ensures adequate penetration of large/dense breasts within the present back-up time. The results gathered from all countries are given in Figure 9. According to their clinical use, 5 mammography units out of 12 were clearly below of the typical values (40 to 75 μGy/mAs at 1 metre distance) all the others being closely in agreement with the suggested limits and accepting these giving higher output.

It is worth noting that the European document does not provide any information on tube-output values to comply with when using different anode and filter combinations such as Rh/Rh or Mo/Rh which are available on modern mammography equipment.

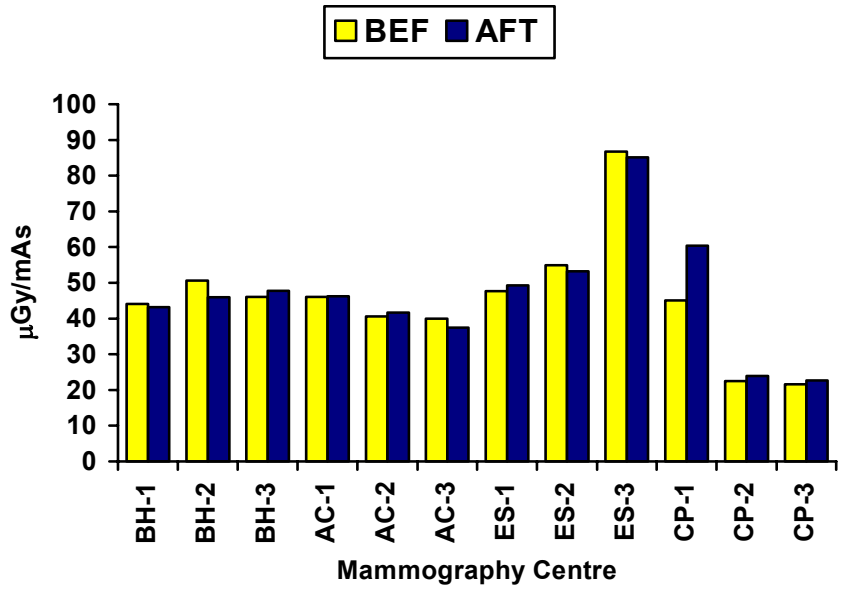


FIG. 9. X ray tube output (μGy/mAs at 1 metre) in different mammography units before and after the remedial actions.

5.1.5. Tube voltage reproducibility and accuracy

The reproducibility and accuracy of the tube voltage are essential in mammography. They guarantee a constant quality of image when repeating the exposure at same settings. This allows the practitioner to precisely select the appropriate kV value for the examination.

5.1.5.1. Reproducibility

In general, modern mammography equipments are capable of providing users with reproducible high tube voltage values. Deviations greater than 0.5 kV from the mean value are to be considered as unacceptable and need to be fixed.

The results obtained on the mammography units which could carry out the test are shown in Figure 10.

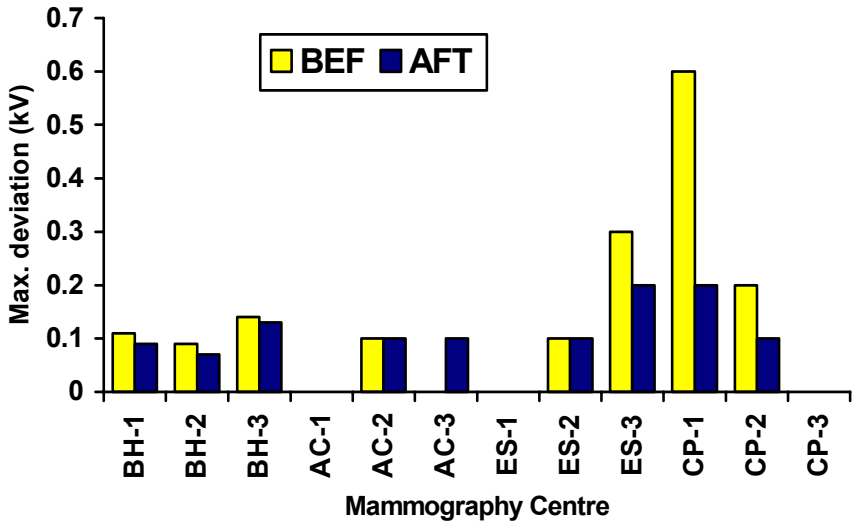


FIG. 10. Tube voltage reproducibility in different mammography units before and after remedial actions.

Before the action, all units except one had deviation more than 0.5 kV and the same were corrected, thus bringing all units within the range. Three units, namely AC-1, ES-1 and CP-3, showed no deviation at all.

5.1.5.2. Accuracy

As for the accuracy of the tube voltage, deviations greater than 1 kV over the whole range of the available kVp sets of the machine (25–31 kV) are to be considered as unacceptable and need to be fixed.

The results obtained on mammography units are shown in Figure 11. The data indicates that before the implementation of the corrective actions, seven mammography units out of twelve (58%) showed deviations greater than the recommended limiting values. Among those units deviations of up to 3 kVp were found.

After the QC exercise, the second round of kV measurements resulted in a general improvement of the accuracy except for two units, namely ‘BH-3 and ES-3’ which were still out of the limits (Figure 11).

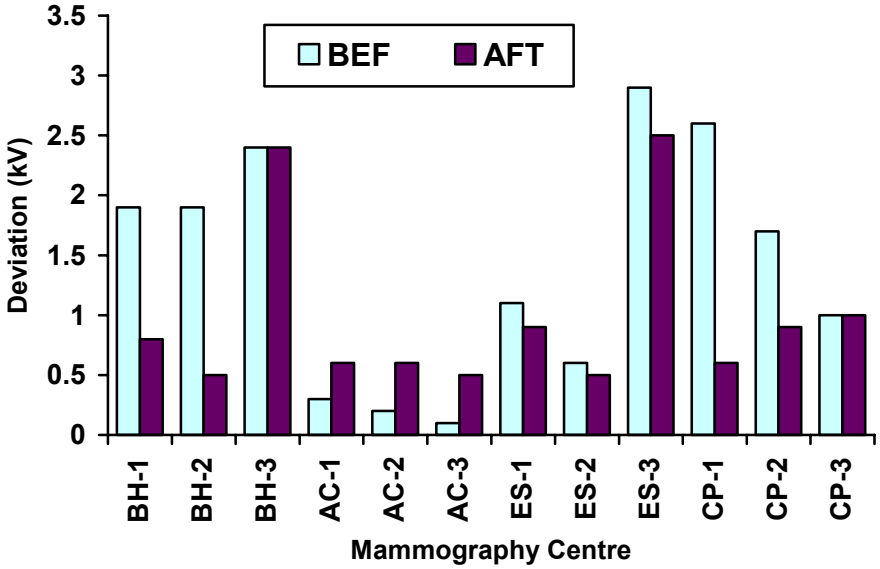


FIG. 11. Tube voltage accuracy in different mammography centres before and after the QC actions.

5.1.6. Half value layer at 28 kV Mo/Mo

According to the adopted protocol, the half value layer (HVL) was determined for each mammography units at 28 kV by adding thin aluminium filters to the X ray beam and measuring the attenuation in 'good geometry' i.e. for narrow beam conditions to minimize the influence of scattered radiation. A minimum total HVL value of 0.3 mm Al equivalent is the international recommendation for mammography equipment consisting of a Mo/Mo anode/filter combination and of a compression paddle thinner than 3 mm of PMMA. The results, presented in Figure 12, show that all mammography units considered were properly filtered.

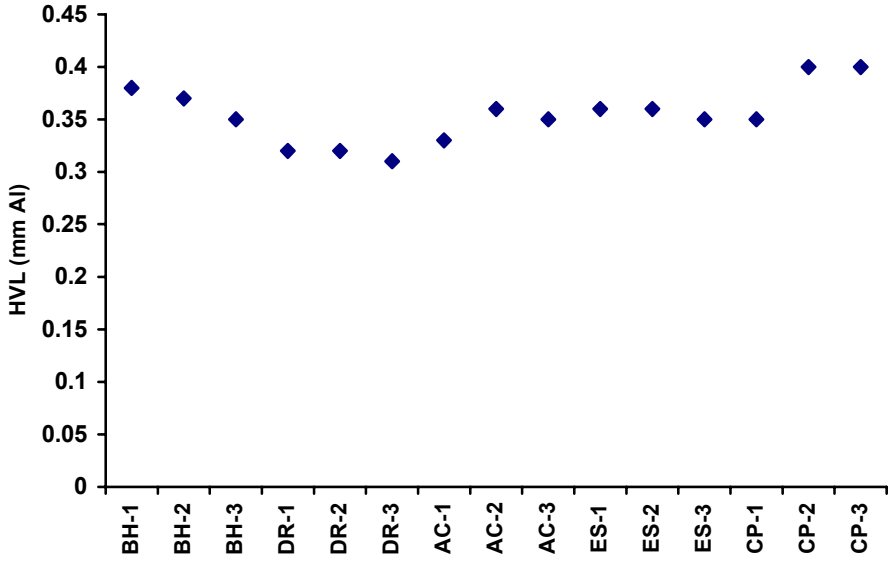


FIG.12. Half value layer of mammography units.

5.2. AUTOMATIC EXPOSURE CONTROL SYSTEM

The performance of the automatic exposure control (AEC) system can be described by the reproducibility and accuracy of the automatic optical density control under varying conditions, like different object thickness and tube voltages.

5.2.1. Optical density control setting: central value and difference per step

To compensate for the long-term variations in mean density due to possible AEC system drifting, the central optical density settings and the difference per step of the selector were assessed. Figure 13 illustrates this for the mammography centres which carried out such a test.

Considering the 'normal' range of optical densities recommended by the European document, namely 1.3 to 1.8, the vast majority of mammography units were found to be in compliance with these values before and after the implementation of the remedial actions.

In two mammography centres, ES-1 and ES-2 respectively, the central optical density values were either above the limiting values (ES-1) or below them (ES-2) before and after the implementation of the remedial actions.

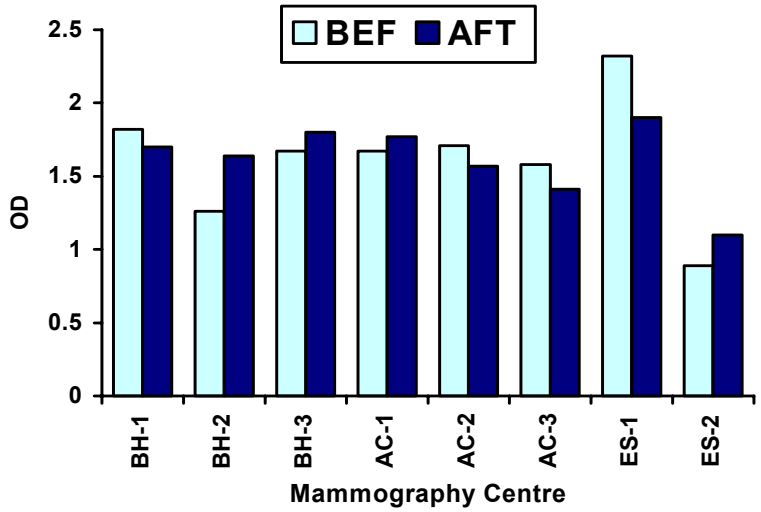


FIG. 13. Central Optical Density of AEC before and after the remedial actions.

As for the difference per step of AEC selector, the acceptable value for the range covered by full adjustment of the density control is >1 O.D. As shown in Figure 14, all mammography units were in agreement with the recommended limiting values.

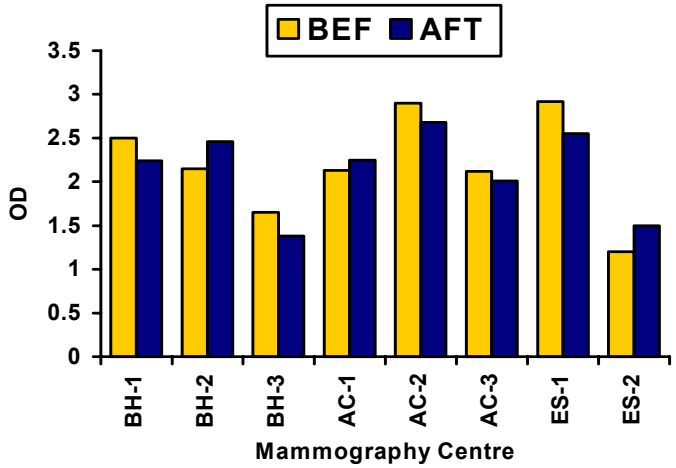


FIG. 14. Full range of AEC adjustment before and after the remedial actions.

5.2.2. Short-term reproducibility

The short-term reproducibility of the AEC is calculated by the deviation of the optical density of five routine exposures while using a breast phantom of 45 mm of PMMA. As shown in Figure 15, deviations of the mean values of exposures (optical density) were smaller than the limiting value of 5% for all the mammography units considered.

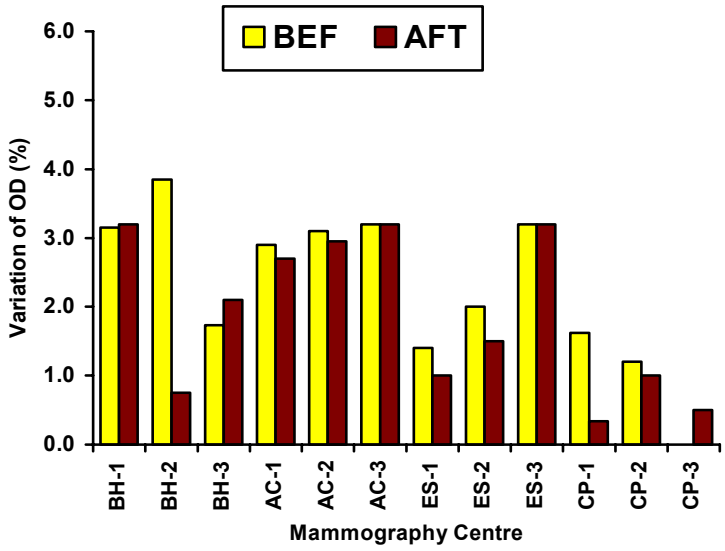


FIG. 15. AEC short-term reproducibility in different mammography centres before and after the QC actions.

5.2.3. Long-term reproducibility

The long-term reproducibility can be assessed from the measurement of the optical density and mAs product resulting from the exposure of the QC phantom (image phantom).

Deviations from baseline value (central optical density) greater than 0.2 optical density are to be considered as unacceptable. Due to feasibility and practicability reasons (lack of regular data collection, access to installations etc.) the long-term reproducibility was only assessed in few mammography centres.

As shown in Figure 16, no significant deviations from baseline values were observed among the mammography units studied after the first round of measurements. As one may notice, there was a significant improvement after the implementation of remedial actions in four mammography centres. In one centre, deviations were roughly reduced by a factor of two.

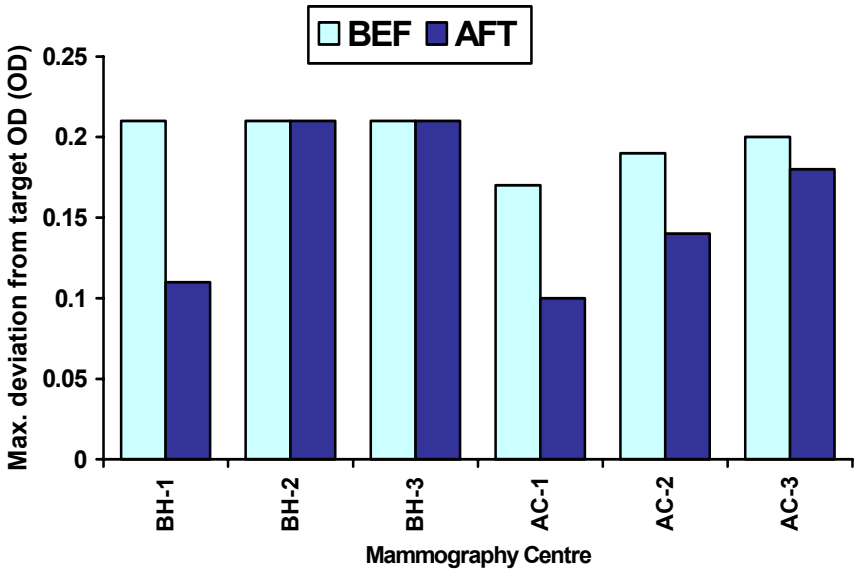


FIG. 16. Long-term reproducibility in different mammography centres before and after the QC actions.

5.2.4. Object thickness compensation

As per the European protocol, AEC compensation for the object thickness variation was measured by exposing different PMMA plates of thickness ranging from 20 to 70 mm, using the clinical settings. All optical density variations smaller than 0.2 0D in respect to the routine optical density are to be considered as acceptable.

Figure 17 illustrates the distribution of the results. As may be noted four centres had variation higher than tolerance at the beginning of the CRP exercise, although some equipment were newly installed. One reason associated with such a 'surprising' finding was the lack of object thickness compensation for very thick breasts such as those simulated by 70 mm of PMMA.

Such a thickness represents a very restrictive condition requiring a fine adjustment of the AEC device. The results obtained after the remedial actions point out varying degree of success, from slight improvement to no improvement and even increased variation in some cases. Three out of 14 installations were still not fulfilling the required percentage of variation of optical density.

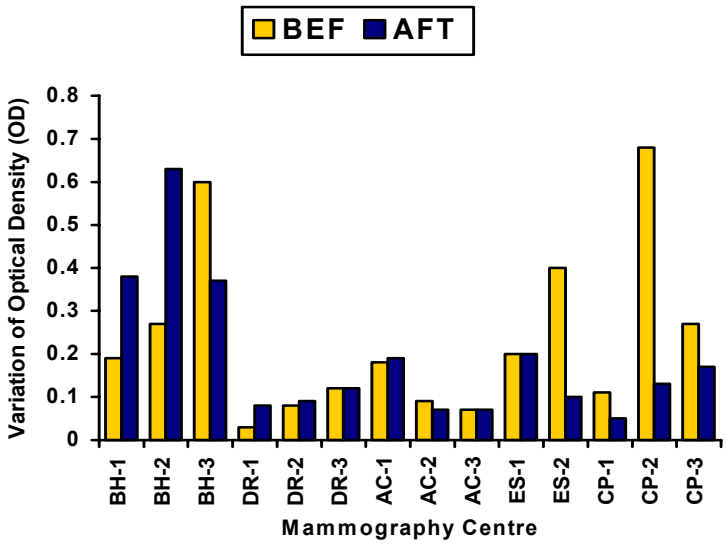


FIG. 17. Object thickness compensation in different mammography centres before and after the QC actions.

5.2.5. Tube voltage compensation

The AEC compensation for tube voltage variations is essential in mammography since it allows the user to adapt the energy of the X ray beam to the attenuation of the breast in particular the glandular breast tissue, while keeping the visual contrast optimized. It is important to remind that optical density variations greater than 0.2 OD are not considered as acceptable and need to be fixed. As recommended by the European protocol, measurements were carried out over the clinical range of kV for Mo/Mo anode/filtration combination.

The results obtained are shown in Figure 18. All mammography units but one were able to correctly compensate the film optical density while varying the kV.

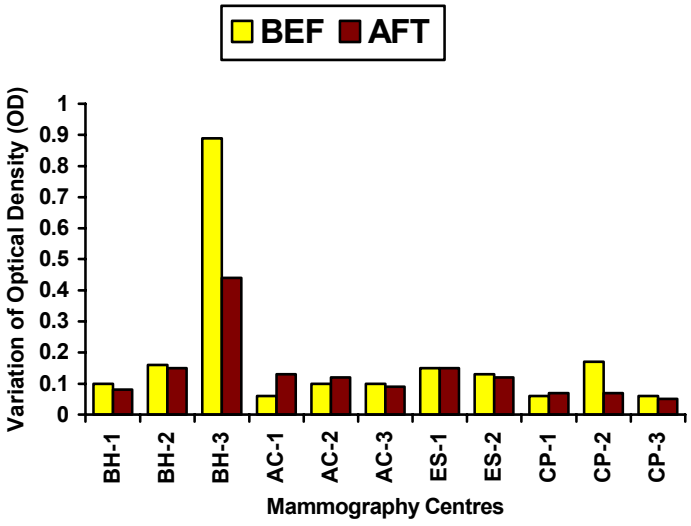


FIG. 18. Tube voltage compensation in different mammography centres before and after the QC actions.

5.3. COMPRESSION

5.3.1. Compression force

The compression of the breast tissue has to be tolerable but firm in order to improve the image contrast, reduce the breast dose and minimize the blurring of the image due to patient movement.

There is no optimal value known for the force, but attention to the applied compression and the accuracy of the indication is required. However, an applied compression force ranging from 140 Newton and 200 Newton is considered appropriate for mammography.

Due to a limited availability of the compression force test device, only eight mammography centres were able to carry out this test. Some alternative measuring instrument were used (bathroom scale for instance) to assess this parameter but their corresponding results were not reliable enough to be integrated in this report.

As can be seen in Figure 19, all but one mammography centre were found to be within the recommended range of compression force value. No significant differences were found between the two phases of the CRP.

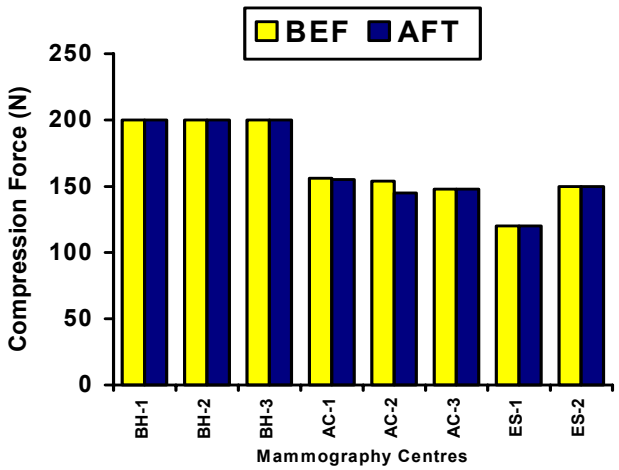


FIG. 19. Maximum applied compression force in Newton (N) in different mammography centres before and after the QC actions.

5.3.2. Compression plate alignment

The alignment of the compression device at maximum force was measured by using a piece of foam rubber. The distance between the bucky surface and the compression device on each corner was measured. The acceptable maximum misalignment is 15 mm for asymmetrical load and 5 mm for symmetrical load in the direction towards the nipple respectively. As shown in Figure 20 all the mammography units fulfilled the recommended misalignment limiting values for asymmetrical load. No data were provided by the participants for symmetrical load in the direction towards the nipple.

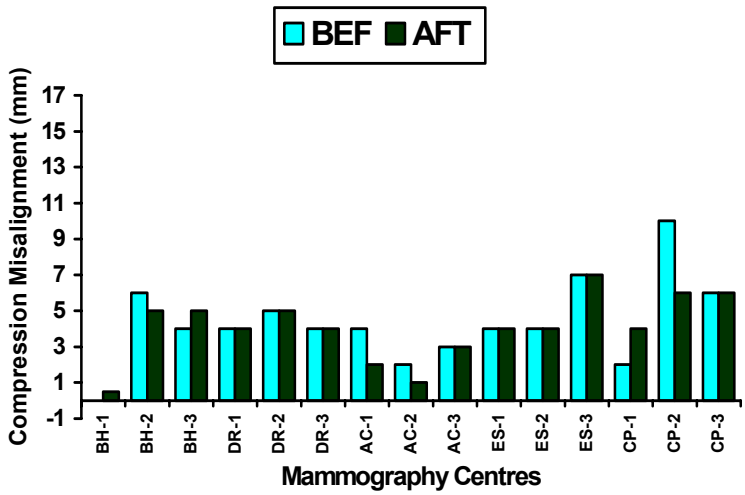


FIG. 20. Maximum misalignment of compression plates in different mammography centres before and after the QC actions.

5.4. BUCKY AND IMAGE RECEPTOR

The anti-scatter grid is composed of strips of lead and low-density interspace material which allow improvement of the image contrast by absorbing scattered photons. The grid system is composed of the grid, a cassette holder, a breast support table and a mechanism for moving the grid.

5.4.1. Grid system factor

To determine the grid system factor, two images of a PMMA 45 mm thick block were taken, one with and one without the grid system in place. The corresponding doses were measured with a dosimeter put on top of the PMMA block. The grid system factor was then calculated by dividing the obtained dosimeter readings, corrected for the inverse square law (the focal to detector distance being shortened while measuring without the grid system) and optical density differences. As recommended by the European protocol, the grid system factor has to be smaller than 3.

As shown in Figure 21, not all the mammography centres were able to perform such a quality control test, partly due to equipment related technical problems (some mammography equipment do not allow such measure to be made), partly due to unavailability of suitable dosimeters. As can be seen, consistent grid system factor values were obtained for both CRP phases for the different mammography units for which data was available.

5.4.2. Grid imaging

As a general rule, the homogeneity of the grid is essential since it allows producing an image without any artefact. To be estimated, such a parameter requires a subjective assessment of an image obtained at the lowest position of AEC-selector without any added PMMA thickness. Using this subjective approach, images from all the mammography units met this requirement.

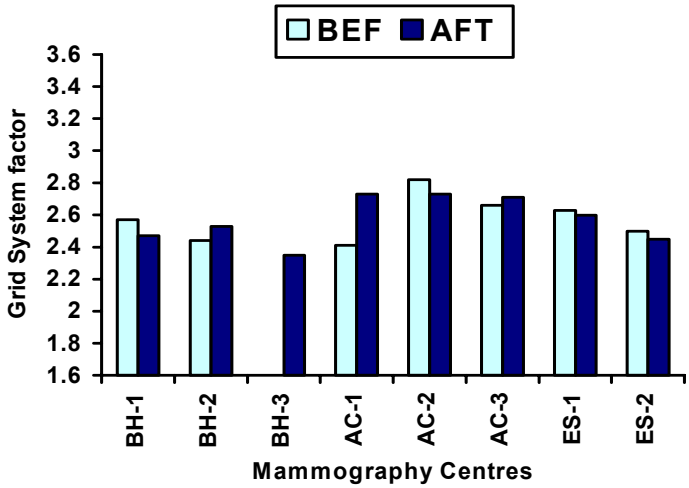


FIG. 21. Grid system factor in different mammography centres before and after the QC actions.

5.5. SCREEN-FILM

5.5.1. Inter-cassette sensitivity

The inter-cassette sensitivity is of a particular importance in mammography since it contributes to keep the quality of the produced image constant regardless of the detector (film) used. The sensitivity of all the cassettes of every participating mammography centre was assessed using European protocol by measuring the exposure parameter, mGy, mAs, and the optical densities of image of 45mm block of PMMA using a fixed tube voltage matching as close as possible to those used in clinical settings. The exposure variation within ±5% and 0.20 OD maximum difference for all cassettes are to be considered as acceptable. As shown in Figure 22, the inter-cassette sensitivity was not fully improved in all the mammography centres. Some exposure variations, which exceeded the recommended limiting values, were found to be related to the format of the cassette: the bigger the format, the larger the variations. The situation with regard to maximum difference in optical density for inter-cassette variations was much better (Figure 23).

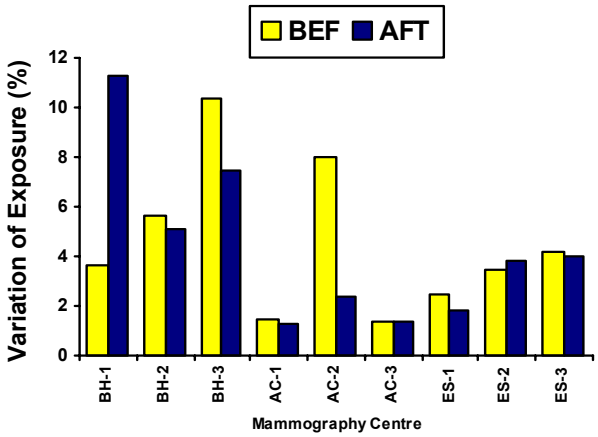


FIG. 22. Inter-cassette sensitivity (exposure variation) in different mammography centres before and after the QC actions.

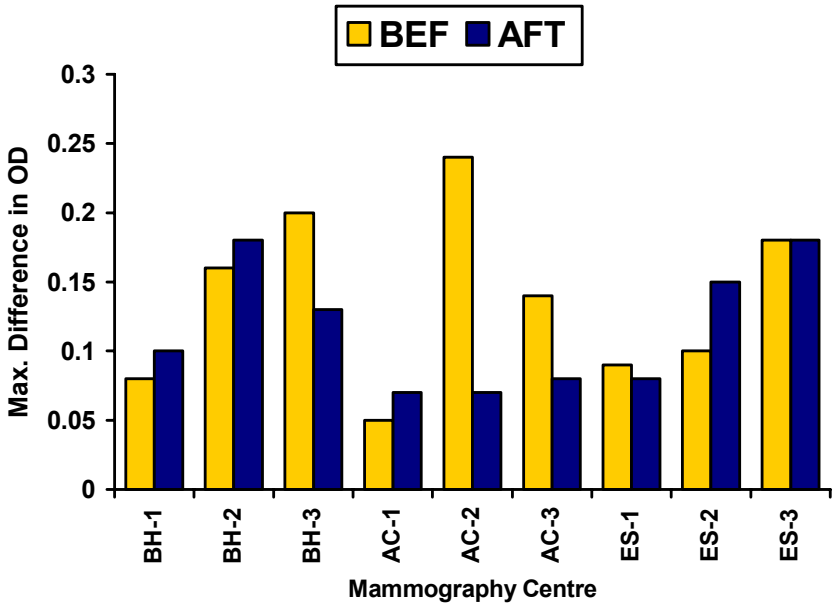


FIG. 23. Inter-cassette sensitivity (maximum difference in optical density) in different mammography centres before and after the QC actions.

5.5.2. Screen-film contact

A good mammography film contact with the intensifying screen within the cassette ensures an optimal image quality by reducing blurring and artefacts. Such a property has to be checked for each cassette and assessed through the use of a fine mesh which allows to locate the areas corresponding to a poor film-screen contact (Figure 24).

Although very subjective, the results of such a QC test are considered very relevant and significantly contribute to maintain the overall quality of mammography.

Figure 25 gives, for each mammography centre, the percentage of cassettes having an appropriate film/screen contact.

As can be seen, the results obtained after the second round of measurements show a significant improvement of this parameter in almost all the mammography centres considered.

5.6. FILM PROCESSING

The processor is often the most critical element in the imaging chain from the quality control point of view. During processing, the latent image captured on the film during the exposure is transformed into a visible, stable radiographic image.

With modern automated processors, the film is transported through the processing sequence: developing, fixing, washing and drying. The constancy of the processor performance in each stage of processing must be assured with the greatest care, in order to avoid rapid degradation of the image quality (loss of contrast, speed, and increase in base+fog, for example).

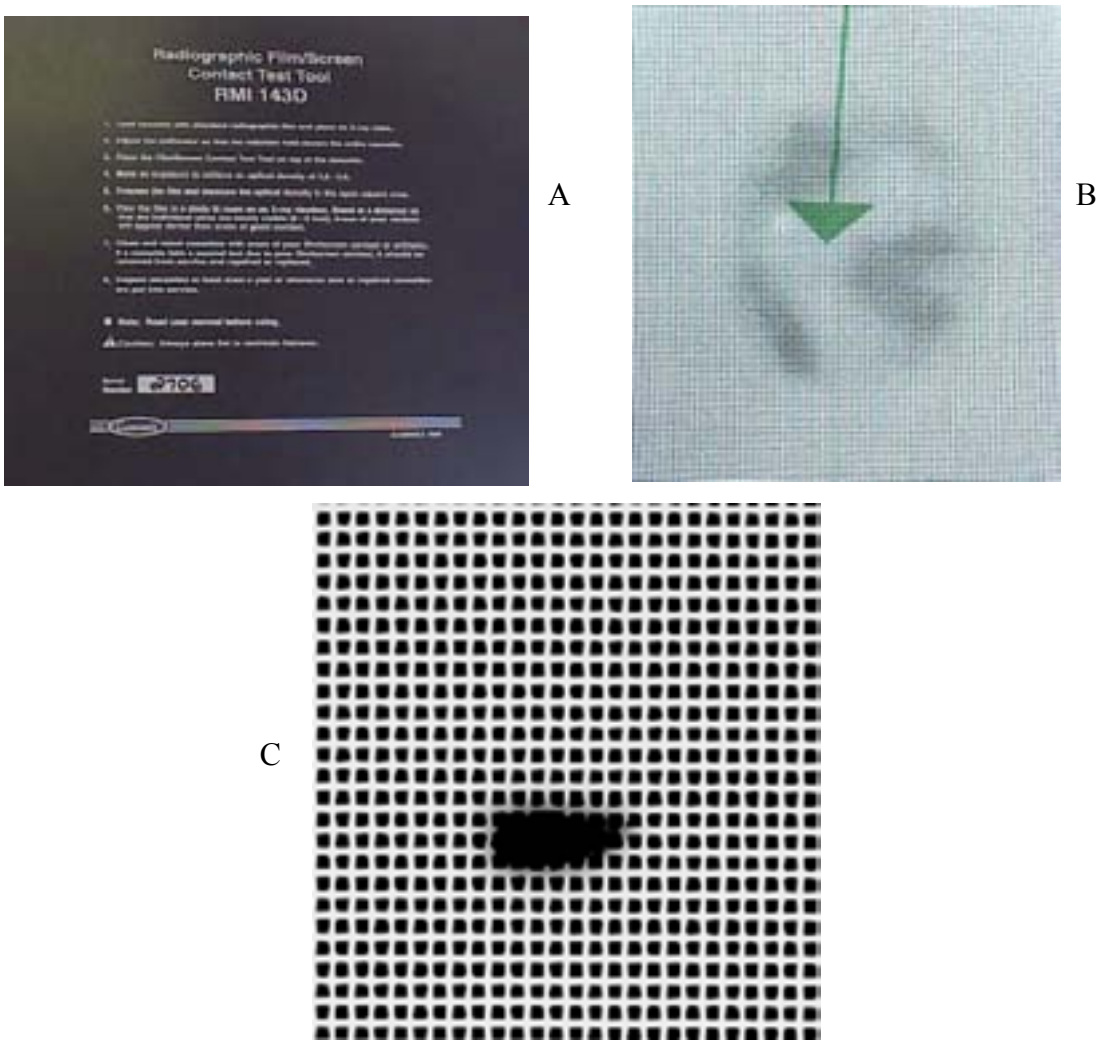


FIG. 24. Film-screen contact test tool (A) – Example of poor film-screen contact (B) – Magnified detail (screen scratch) (C).

An important aspect of quality control is, therefore, to maintain a record of the variations in these three parameters over time on a control chart. The use of sensitometry tests is the most effective method for measuring such variations.

5.6.1. Base line performance processor

In order to ensure the maximum image contrast the developer temperature and processing time needs to be consistent with the film manufacturer's recommendations. Figure 26 gives an indication of the variations of the developer temperature found among the mammography centres which kept a record of this parameter during the two CRP phases. Most of them seem to lie between 33–35°C.

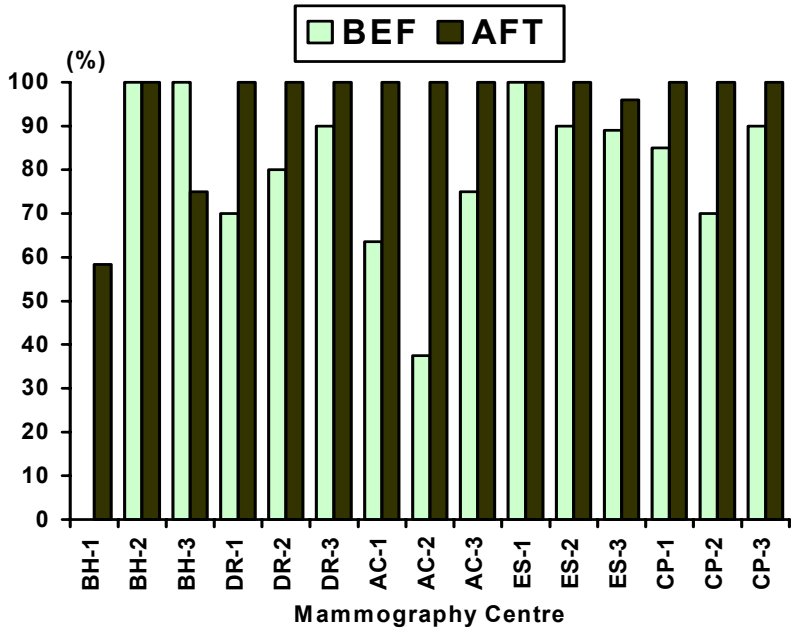


FIG. 25. Film/screen contact in different mammography centres before and after the QC actions.

In Figure 27 are illustrated the corresponding processing times.

As previously mentioned, due to difference in chemical types, the processing time and developer temperature vary but they are in a narrow range. Generally speaking, the higher the temperature, the shorter the processing time.

5.6.2. Film processor (sensitometry)

The light sensitometry is the most suitable method for measuring the performance of film processor. All quality control protocols strongly recommend performing such a QC test daily with a view to deriving, from the film characteristic curve, values such as base and fog, speed, mean gradient and maximum optical density. Such a test requires availability of sensitometer and densitometer, motivated personnel and competence at local level. Due to all these requirements, only few mammography centres were able to maintain a record of the sensitometry parameters over a meaningful period of time (several weeks) during the different phases of the CRP.

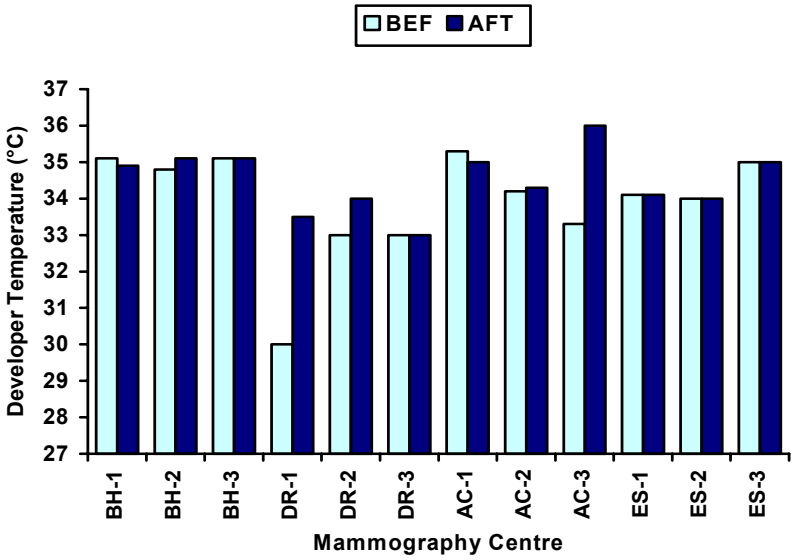


FIG. 26. Film developer temperature in different mammography centres before and after the QC actions.

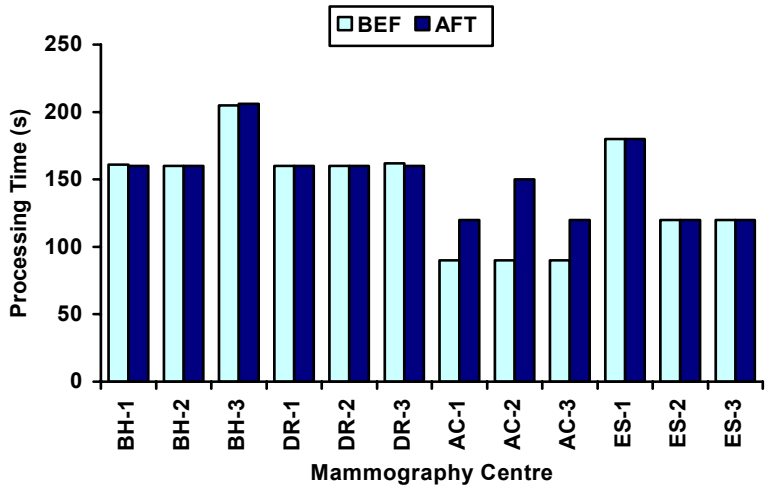


FIG. 27. Film processing time in different mammography centres before and after the QC actions.

5.6.3. Artefacts

An image of a standard test PMMA block obtained daily, using a routine exposure, should show a homogenous density, without scratches, shades or other marks indicating artefacts. Figures 28 and 29 illustrate the distributions of the artefacts before and after the implementation of remedial actions respectively.

As can be seen, the overall percentage of artefacts due to film processing was significantly reduced between the two phases of the CRP (from 21% to 16% respectively). Conversely, artefacts due to absence of cassettes cleaning were found to be increased over the same period of time: from 20% to 25% respectively. Finally, grid artefacts were found to be of minor importance.

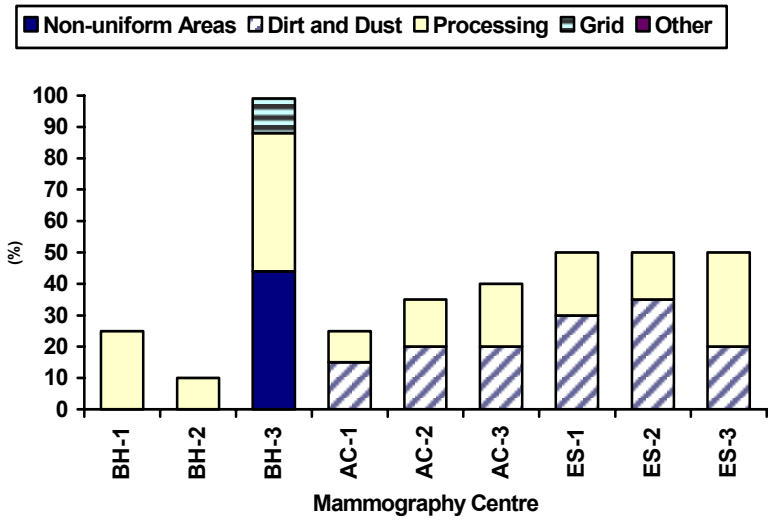


FIG. 28. Artefacts distribution in different mammography centres (before remedial actions).

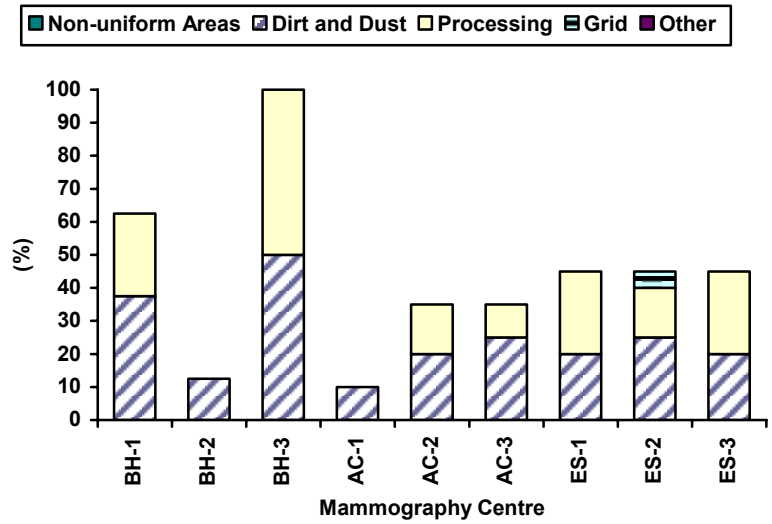


FIG. 29. Artefacts distribution in different mammography centres (after remedial actions).

5.6.4. Darkroom

5.6.4.1. Light leakage

Light leakage of the darkroom should be verified since the intrinsic characteristics of all films handled in such a place (fog, speed and contrast) must not be affected by any source of external light. An extra fog greater than 0.02 OD after 2 minutes of exposure is to be considered as unacceptable and should be fixed.

As shown in Figure 30, such a lack of tightness (resulting in light leakage) was found either before or after the remedial actions were put in place. Darkroom light tightness, being a good example of a QC parameter, needs to be constantly checked in order to avoid any unwanted degradation of the image quality.

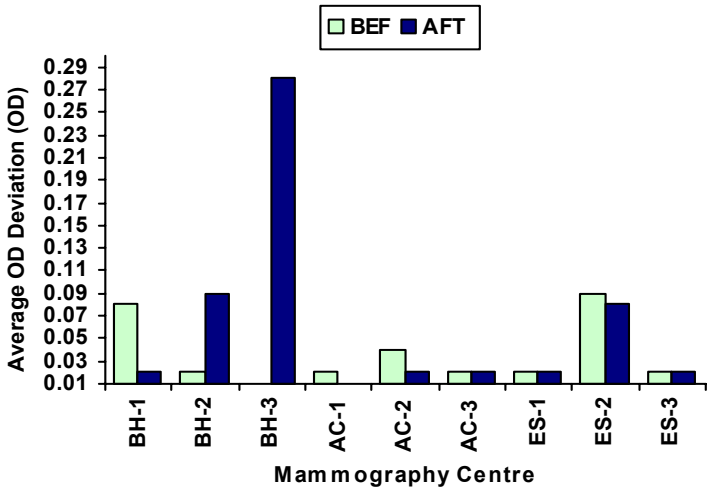


FIG. 30. Darkroom light tightness in different mammography centres before and after the QC actions.

5.6.4.2. Safelights

Another relevant physical factor that can significantly affect the image quality is the condition of the safelight. Extra light should increase fog on the film. An extra fog greater than 0.05 OD after 2 minutes of exposure is to be considered as unacceptable and should be fixed.

Different reasons may lead to an extra fog to the film: the power of the bulb, the light (colour), the filter of the safelight box, the distance from the workbench and the direction toward which the safelight is oriented. All these factors were included in study and the results obtained are shown in Figure 31. As can be seen very few mammography centres were able to achieve the required limiting value, some of them were still far from this even after the remedial actions were implemented.

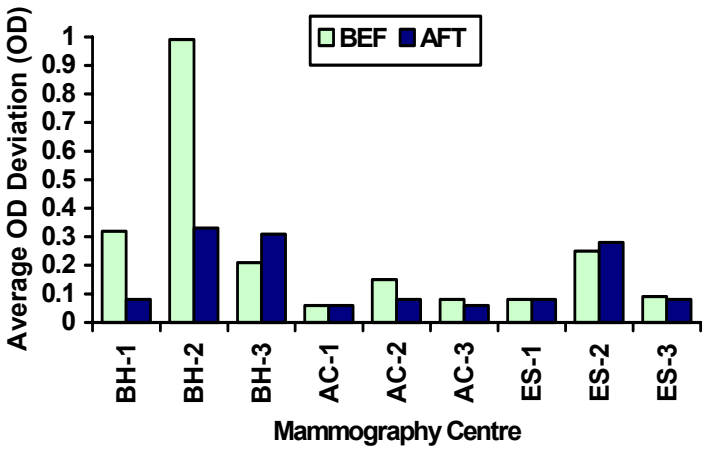


FIG. 31. Safelights in darkrooms in different mammography centres before and after the QC actions.

5.6.4.3. Film hoppers and cassettes

All the film hoppers and the cassettes used during the CRP were controlled and found to be light tight in all the mammography centres.

5.7. VIEWING CONDITIONS

Viewing conditions are very important for the correct interpretation of the diagnostic information content of the image. They may greatly influence the degree of perception of low contrasted details, which, in mammography, represent one of the major issues.

Although the need for relatively bright viewboxes is generally appreciated, the low level of ambient lighting is also essential, consistent with EC guidelines.

5.7.1. Viewing box

5.7.1.1. Luminance and homogeneity

The tendency to use sensitive films in mammography resulting in high optical density demand that one must ensure that the luminance of the viewbox is adequate. A luminance level ranging from 2000 to 6000 (cd/m^2) is to be considered as acceptable knowing that the upper limit provided is to minimize glare where films are imperfectly masked and lower level affects the diagnostic information.

The homogeneity of a single viewing box is also a condition for good imaging interpretation and high quality mammography. Gross mismatch between viewing boxes or between viewing conditions used by the radiologists and others interpreting the image can become a cause of error, and this too was studied.

The distribution of luminance of viewing boxes measured during the CRP is shown in Figure 32. It is worth noticing that only few mammography centres were close to the upper limiting value (mainly new equipment), some of them were in the middle range of luminance and almost 50% of the centres were below the lower limiting value required even in Phase II.

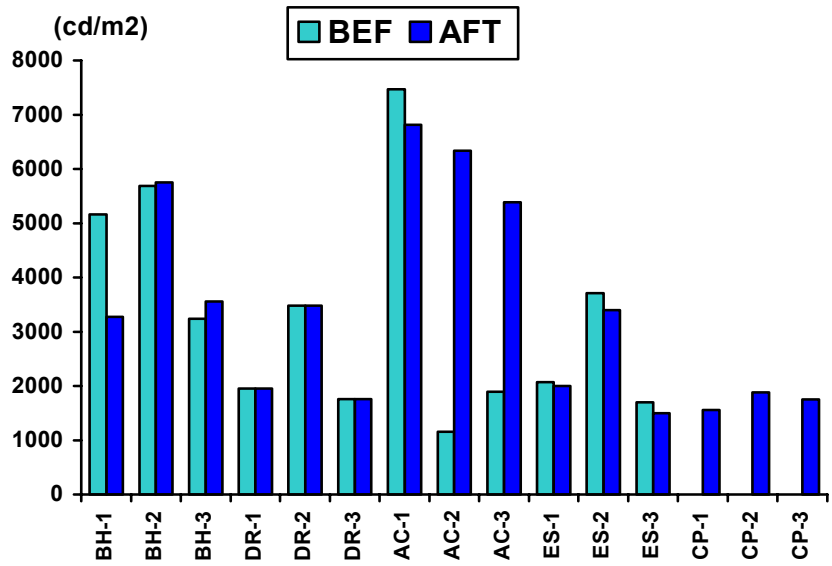


FIG. 32. Distribution of luminance of viewing boxes (cd/m^2) in different mammography centres before and after the QC actions.

Figure 33 illustrates the results for homogeneity in different mammography centres. As can be seen, all but one mammography centre were in agreement with the recommended limiting values.

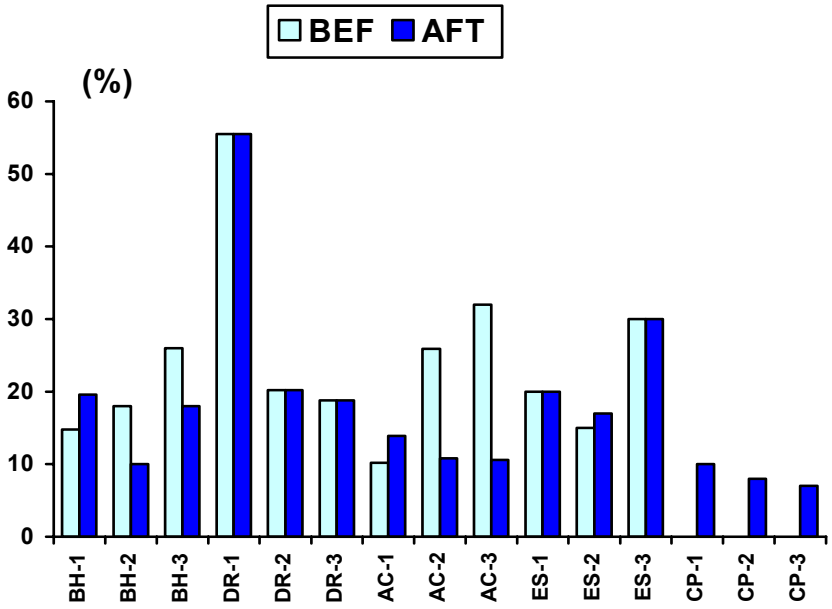


FIG. 33. Homogeneity of viewing boxes in different mammography centres before and after the QC actions.

5.7.2. Ambient light level

As shown in Figure 34, an overall reduction of ambient light level was achieved after the implementation of remedial actions in all but one mammography centre.

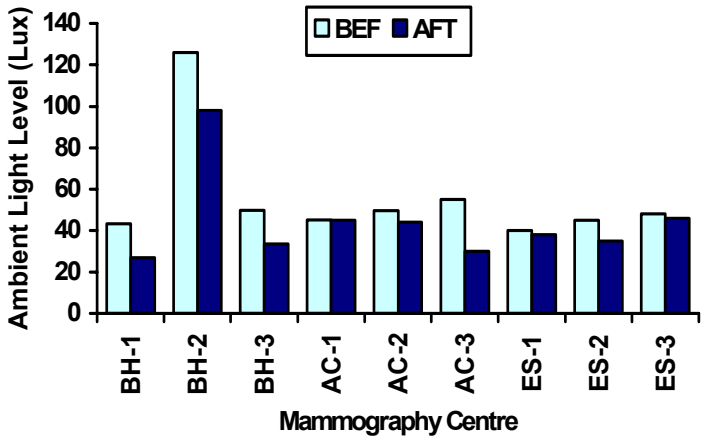


FIG. 34. Ambient light level in different mammography centres before and after the QC actions.

5.8. PHANTOM IMAGE QUALITY EVALUATION

In order to estimate the quality of the images produced in different participating mammography centres, while integrating the diversity of radiographic techniques and of equipment in use, the RMI 156 mammography accreditation phantom was chosen (Figure 35). This phantom assures optimum imaging performance of a mammographic system by providing a baseline from which one can easily monitor units' performance.

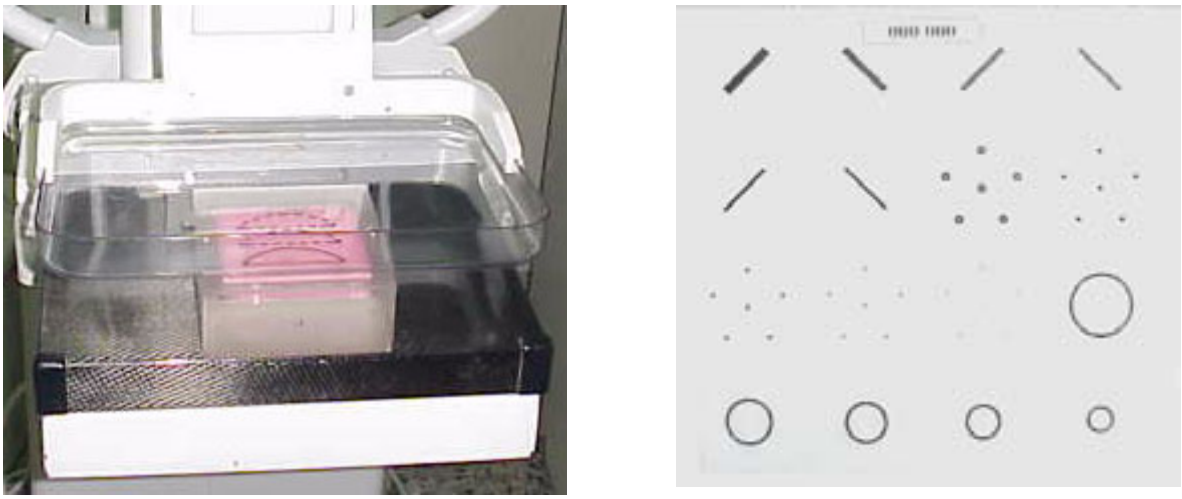


FIG. 35. RMI 156 mammography accreditation phantom.

The Accreditation Phantom contains test objects which simulate small structures seen in the breast (microcalcifications, fibrils, and tumor like masses). All the test objects are contained in a single wax block, which is enclosed in an acrylic base.

The phantom is designed to simulate a 4.0 to 4.5 cm compressed breast. Included with the phantom is a 4 mm acrylic disk for making density difference measurements as required by the American College of Radiology (ACR).

The following physical parameters were assessed by exposing the phantom according to the manufacturer instructions: the mean optical density, the optical density difference and the global score.

5.8.1. Mean optical densities

In order to allow the user to approach the optimal detectability of the phantom inserts, the mean optical density level of the breast phantom image should be about 1.3 (accepted range from 1.05 to 1.6 OD).

Figure 36 shows the distribution of the mean optical densities measured during the two phases of the CRP. As a consequence of remedial actions, the overall optical density was increased from 1.49 to 1.55 over the time of CRP exercise. Unfortunately, the results obtained show that six mammography centres out of fifteen were still producing too light images, i.e. potentially under informative images and four others were above the upper limiting value thus producing darker images.

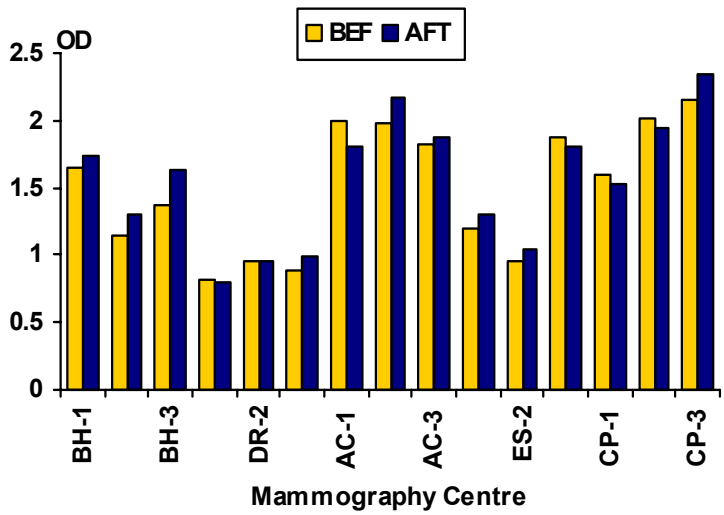


FIG. 36. Mean Optical Densities (O.D.) of the phantom images in different mammography centres before and after the QC actions.

5.8.2. Optical density differences

The density difference due to a 4.0 mm acrylic disc should be at least 0.40 and should not vary by more than ±0.05 from the established operating level. Figure 37 shows the results obtained. Few mammography centres were above the limiting value recommended by the ACR. Three mammography units, which at the time of study were not in good order of operation, indicated much smaller density difference from the mean optical density point of view. Only one mammography centre reported marked change in the optical density difference between the two phases of the CRP.

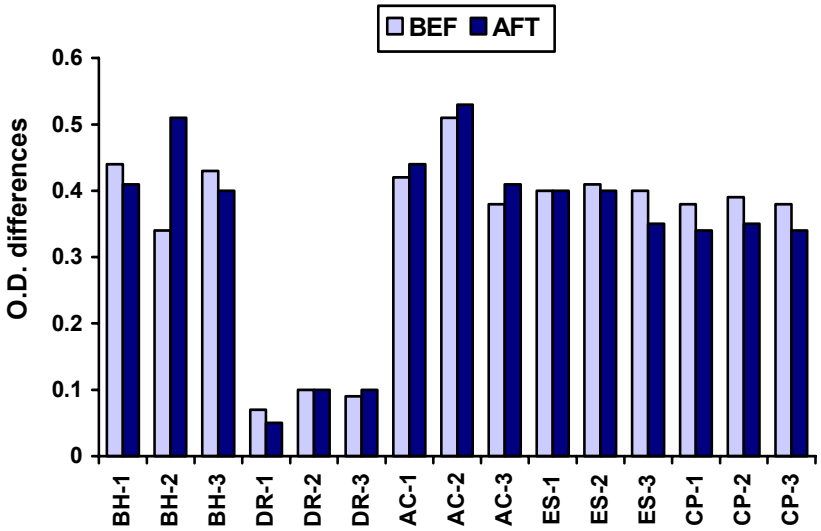


FIG. 37. Optical density differences in accreditation phantom in different mammography centres before and after the QC actions.

5.8.3. Global scores

In order to test imaging performance of the mammographic X ray system, the phantom, with image quality evaluation objects, should be used at least monthly. A minimum of the four largest fibres, the three largest speck groups and the three largest masses must be visible. Within the framework of the CRP such a regular assessment was not possible and only few images were collected at the level of each mammography centre. Images were scored by the local medical physicists before and after the implementation of remedial actions. As shown in Figure 38, all mammography centres but one improved their image score between the two phases of the CRP (the average score increased from 10.2 to 10.8). As can be seen, two mammography centres out of twelve were not able to achieve the minimum required score of 10 neither before nor after the remedial actions were put in place.

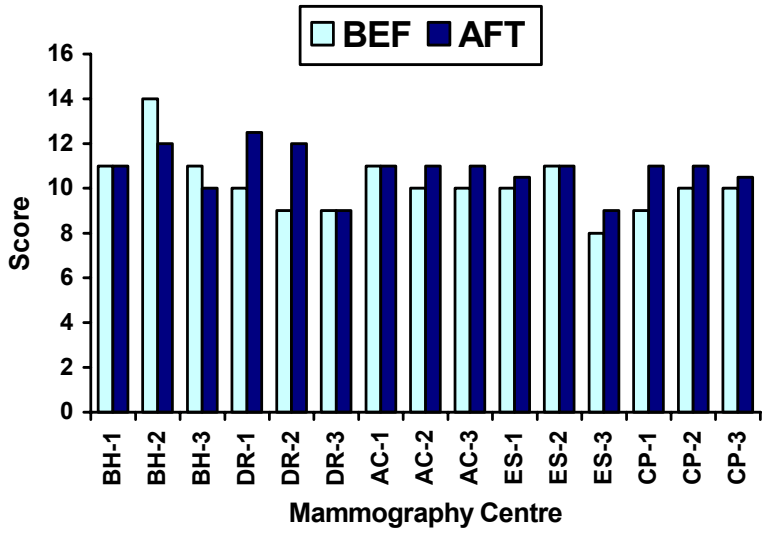


FIG. 38. Global scores of phantom images.

6. FILM REJECT ANALYSIS

6.1. THE OVERALL REJECT RATE

The overall reject rate was estimated from a set of a minimum 1000 radiographic films collected in each mammography centre. The category of personnel who rejected the film (radiologist or radiographer) and the causes of rejection were recorded.

Figure 39 gives the results obtained in each mammography centre and allows estimating the impact of the QC exercise carried out within the framework of the CRP.

Besides the variations of film reject rates from centre to centre, the average film rejection rate was significantly decreased between the two phases of the CRP, from 4.8% to 3% with the highest rejection rate value reduced from 18% to 8%. Although the retake rate of 18% is relatively high, it can be found in the absence of any previous QC activity.

6.2. REJECT RATES BY CAUSES OF REJECTION

According to the CRP methodology, five different categories of causes of film rejection were defined: too light, too dark, positioning error, motion, and technical reasons. As shown in Figure 40, before the implementation of remedial actions, two major causes were responsible for more than 50% of rejected films (too light and too dark films). Inadequate positioning of the breast was found to be the third cause of rejection in almost all mammography centres.

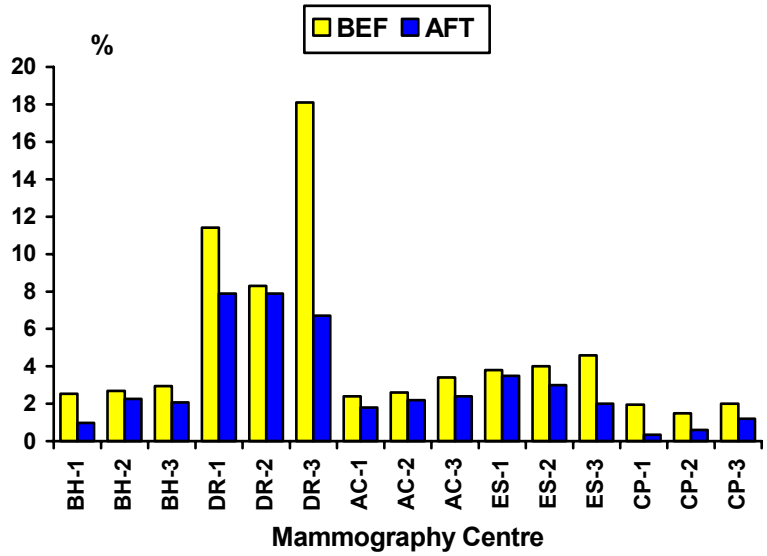


FIG. 39. Overall film rejection rate.

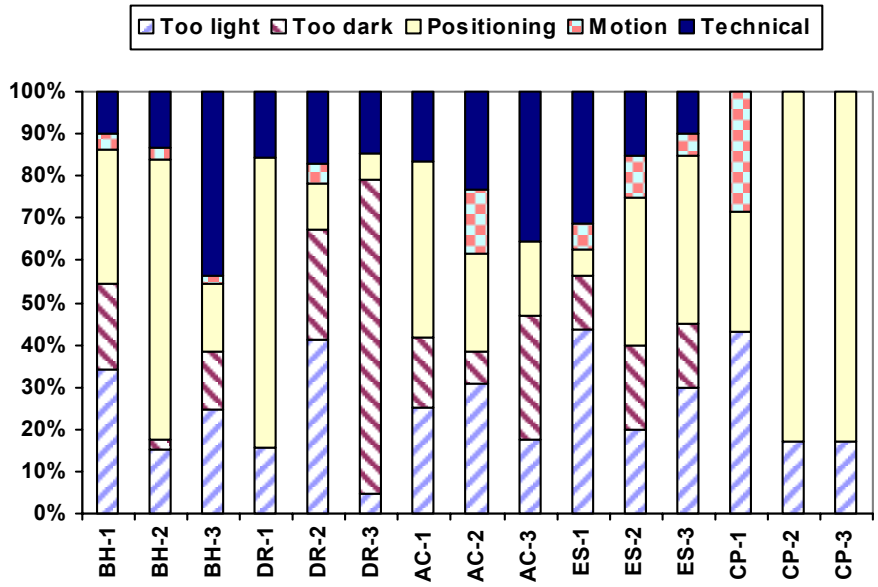


FIG. 40. Film reject rate per cause of rejection (Phase I results).

Figure 41 illustrates, for Phase II, the results obtained after the implementation of technical remedial actions. In this case, the main cause of rejection (40% of rejected films) was, not surprisingly, found to be the inadequacy of breast positioning which, obviously, relates rather on skill of personnel than on technical factors. The percentage of too light and too dark films was found to be less important (24% and 18% respectively) than at the end of the Phase I of the CRP, thus demonstrating a significant improvement due to the remedial actions put in place.

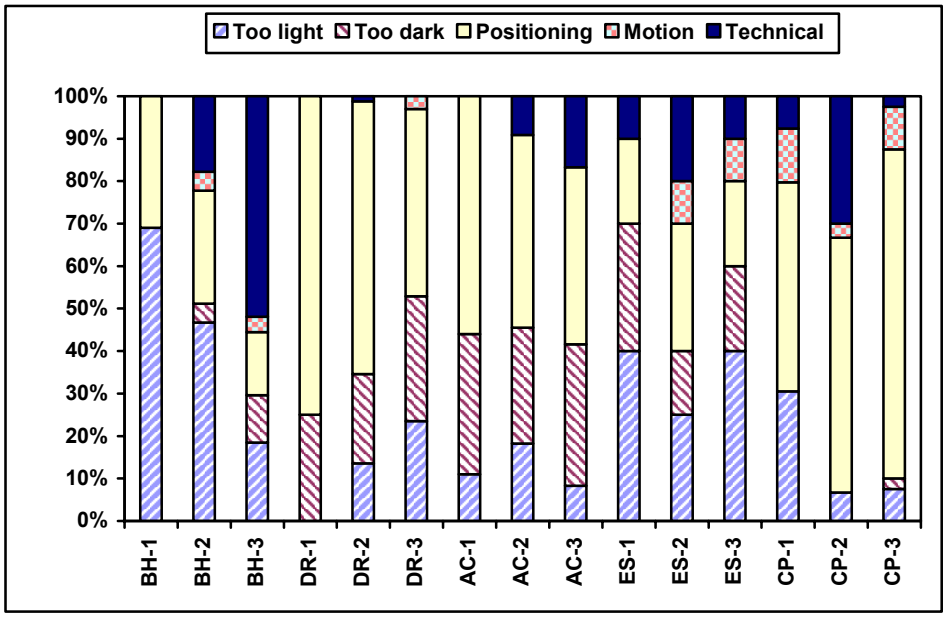


FIG. 41. Film reject rate per cause of rejection (Phase II results).

7. IMAGE QUALITY

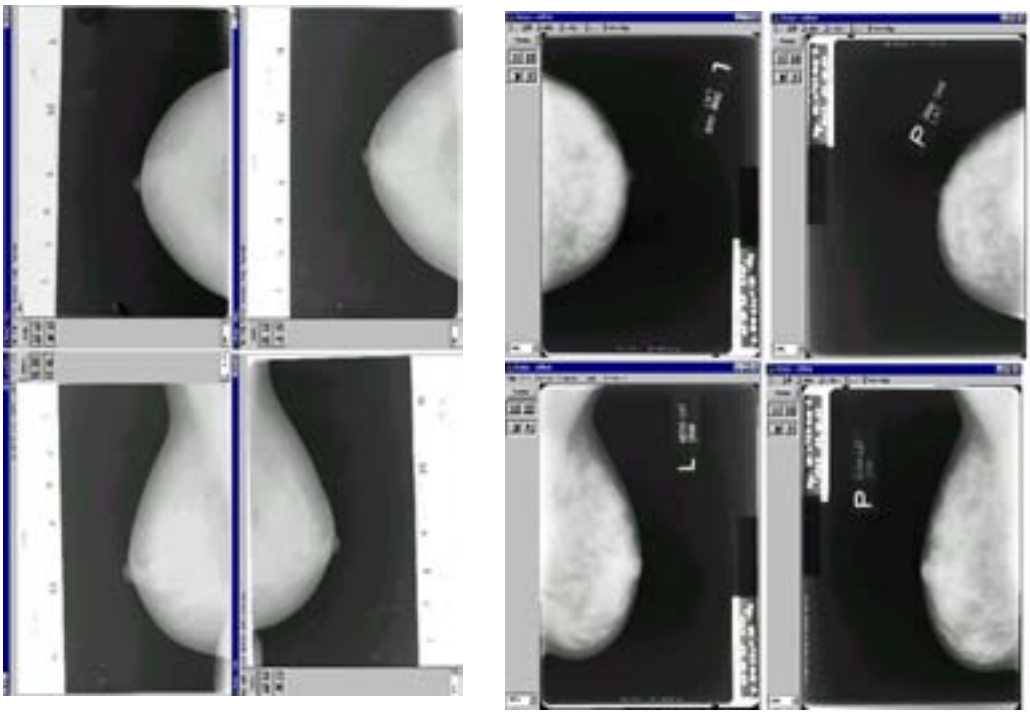
Before going into more detailed discussion on image criteria, it is important to stress that the overall quality of the images collected during the CRP was rather acceptable although some centres provided films with lower diagnostic informative contents. Figure 42 illustrates some examples of 'poor' quality images.

In addition to that, it is also important to know whether or not the assessment and scoring of images by the external panel of radiologists (see Section 3.1) was based on the common criteria for images viewed by them independently (inter-viewer reliability). Also, it is important to compare the average response rate of the external panel of radiologists to those of the field radiologists (inter-group reliability).

These considerations are fundamental in attempting to define relevant and universally applicable criteria. Perfect agreement between the panel and field radiologists would indicate that both groups define and apply the same criteria in the same way. It would also demonstrate that both groups see the criteria in the same manner, a matter of experience and training.

On the other hand, disagreement between the two groups may indicate:

- there is some disagreement about the actual understanding of one or more criteria;
- judgment is subjective rather than according to stable decision rules common to all;
- one group has insufficient experience or training in scoring criterion.



(A) **(B)**

FIG. 42. Example of images collected during the CRP. (A) Image is too white, there is no contrast. (B) Bad positioning of the breast and missing compression.

7.1. EVALUATION BY FIELD RADIOLOGISTS

As mentioned in the methodology earlier, four images (Cranio-caudal: (CC) right breast, CC: left breast, Medio lateral oblique (MLO): right breast, MLO: left breast) were evaluated individually for each patient through the questionnaire (the same as used by external experts) completed by local radiologists. In order to get a general idea on the degree of fulfilment of image criteria, the results gathered for each radiographic projection are shown in Figure 43 and Figure 44 respectively.

7.1.1. Cranio-caudal projection images

As can be seen in Figure 43, the percentage of image criteria met by films in each mammography centre varied markedly, from 69% to 92%. In all mammography centres together, the average compliance rate achieved during the Phase I of the CRP was 82% while the corresponding value for the Phase II was 88%, thus reflecting a slight improvement of the image quality.

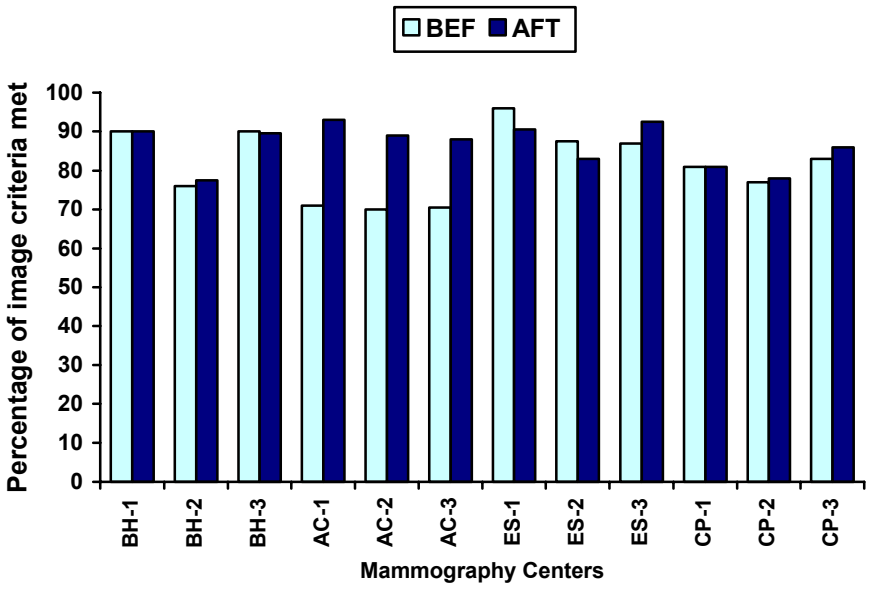


FIG. 43. Fulfilment rates of the image criteria (%) — Field radiologist (CC projection).

7.1.2. Medio lateral oblique projection images

As often recognized, to be able to achieve an adequate breast positioning in a MLO projection is more difficult than in a Cranio-caudal view. Figure 44 shows the results provided by the field radiologists for the MLO projection. The overall average image criteria fulfilment rate for this projection was 78% for Phase I and 85% for Phase II.

The situation can be summarized as:

- the average fulfilment rate of image criteria for MLO projection for Phase I was lower as compared to the corresponding Cranio-Caudal value : 78% and 82% respectively;
- there were larger variations in fulfilment rate in MLO projection than in CC projection from 59% to 90%.

7.2. EVALUATION BY EXTERNAL EXPERTS

Using the scoring system described in Section 3.2, a given clinical image was separately assessed by two external radiologist experts.

Different types of analysis of the results are made in the following paragraphs:

The comparison between the results provided by experts and those given by local radiologists during the phase II of the CRP.

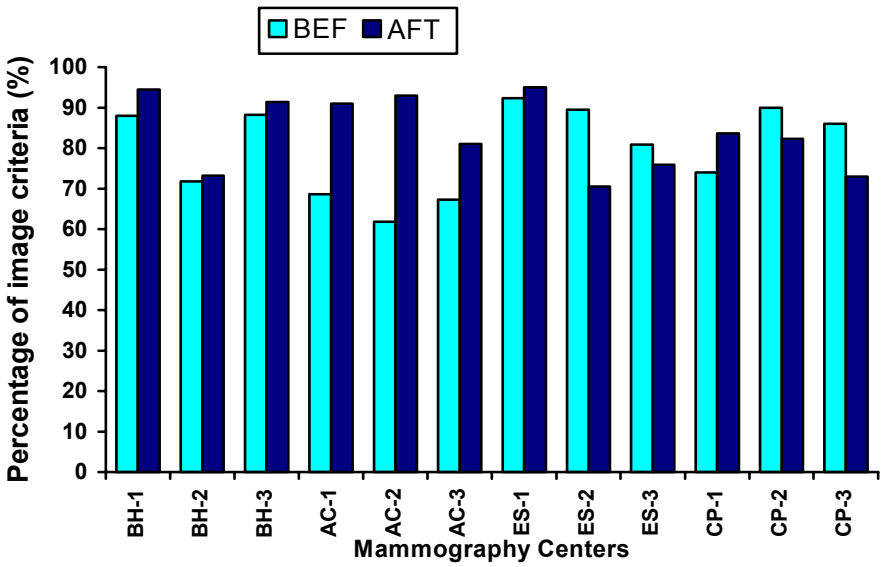


FIG. 44. Fulfilment rates of image criteria — Field radiologist (MLO projection).

The comparison between the opinions of the two experts who saw the same set of mammography images during the phase II (inter-viewer variability).

The comparison between the opinions of one of the two experts provided during phase I and phase II.

7.2.1. Comparison between expert and field radiologists (phase II)

In this comparison, the score of left and right breast for each patient were summed. This was done separately for CC and MLO projection. As mentioned in Section 3.2, the maximum possible score thus becomes 20 for CC projection and 22 for MLO projection.

Summed scores are represented in Figure 45 for CC projection giving bars representing score given by field radiologist and external radiologist (expert). Similarly Figure 46 gives image score for MLO projection.

One major observation can be made from Figures 45 and 46 when comparing the height of the vertical bars of the two categories of viewers. The scores given by the field radiologist for each mammography centre were systematically greater than those given by the experts. This is in fact a very well known attitudinal issue towards images generated by self or by someone else, in addition to higher expectation of quality by expert radiologists. Even a quantitative judgment in such a situation (a numerical score for example) cannot be neutral and would tend to overestimate the actual result, hence the higher scores of the field radiologists. Both CC and MLO projections clearly show such a trend and confirm the above explanation.

Further, the scores allotted by the field radiologist for CC projection lie within narrower (and upper) range of 15.9 to 18.5 (mean 17.2) as compared to those of expert 11.9 to 17.1 (mean 14.6).

Similar is the situation for the MLO projection (Figure 46). The expert's scores (out of 22 in this case) varied from 12 to 17.2 (mean 15.2) for the field radiologists it was 16 to 21 (mean 19).

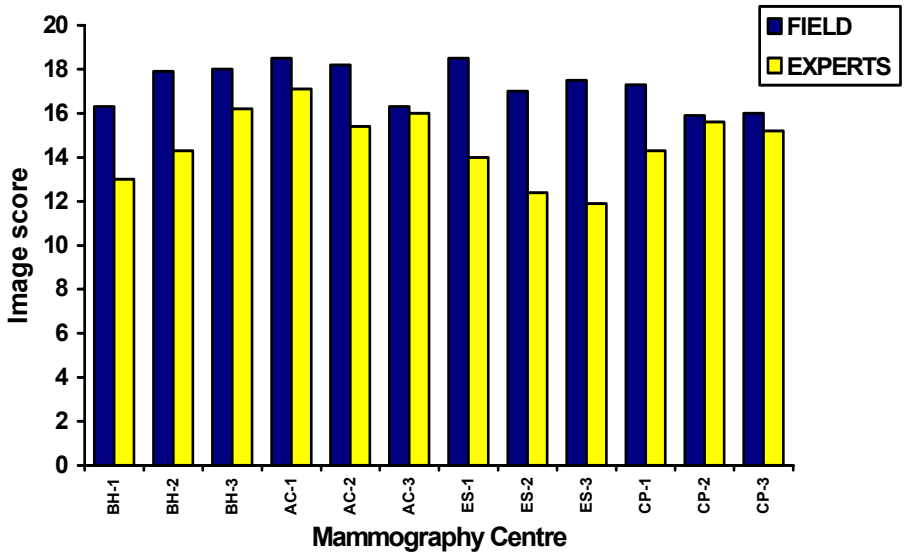


FIG. 45. Image score by field radiologists and expert for Cranio-Caudal (CC) projection (Phase II).

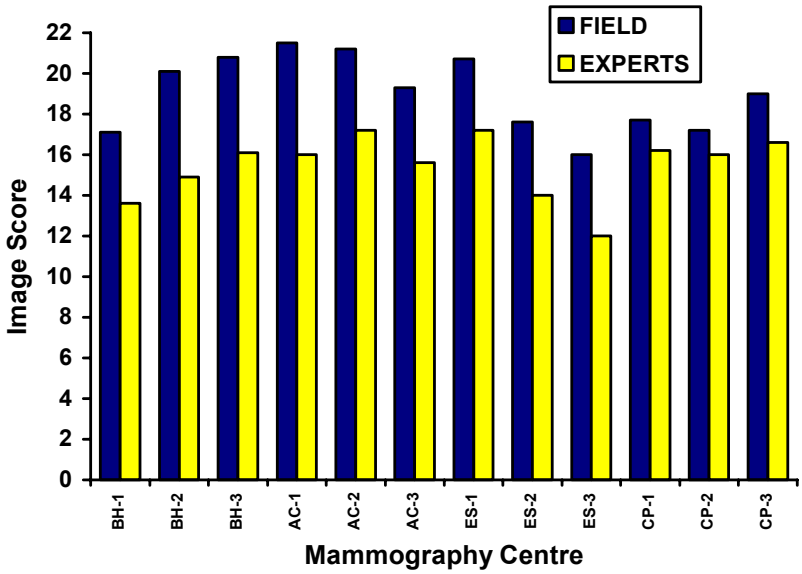


FIG. 46. Image score assigned by field radiologists and expert for MLO projection (Phase II).

7.2.2. Comparison of experts' judgment (inter-viewer variability)

As described earlier, during the CRP Phase II, the two experts worked independently and reviewed the same set of mammography films. For each film and each reading by an expert, the points assigned were summed to create the total score.

Ideally, to have least inter-viewer variability, identical methodology should be used by different viewers, which was the case during the Phase II of the CRP. Secondly, the viewers should be trained to apply the criteria. Furthermore, it must be possible to apply the criteria to the films, that is, the technical environment necessary to rating should be provided and be of a high quality. In this case, new viewboxes were used.

The data presented in Figure 47 is expressed as a percentage of maximum possible score given to the radiographic projections (CC + MLO) averaged over all the patients examined in a given mammography centre. This is a simple method to achieve direct comparison of two situations with different total score. For example, comparison of score of CC projection out of 10 (or 20 for both breasts) with score of 11 for MLO projection (or 22 for both breasts). Figure 47 allows such a comparison to be made and illustrates the relative score of the two external experts.

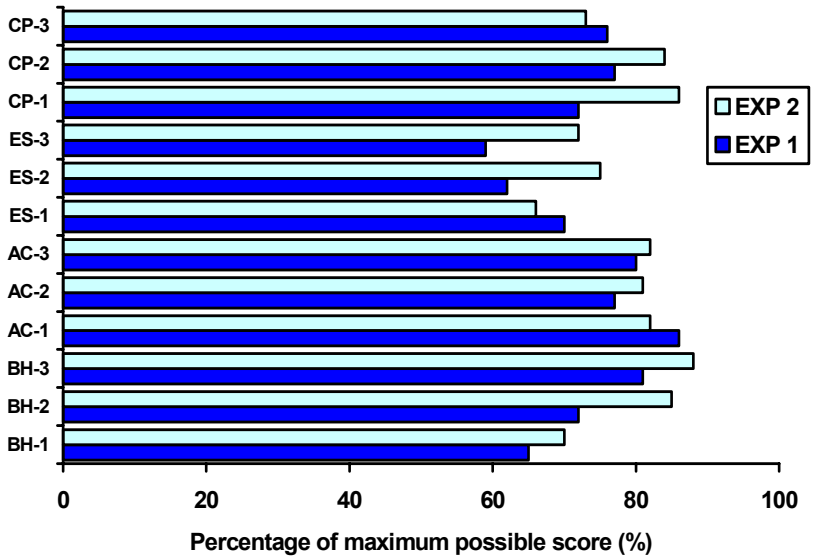


FIG. 47. Inter-viewer comparison.

As per Figure 47, in 6 centres out of 12, there was a close agreement of the experts' opinion (less than 5% of difference of their relative score), that is, a very little inter-viewer variability. There was no systematic trend to under or overestimate. There were only 2 centres out of 12 where experts' opinions were clearly discordant (more than 10% of difference of their relative score), namely ES-2 and CP-1.

7.2.3. Comparison between phases I and II (same expert)

Considering all the remedial actions put in place as well as the improvements of the mammography equipment made, Phase II results would, implicitly, provide a better scoring than the Phase I. With the view of checking such an expected improvement the same expert was involved in a double reading exercise which consisted in comparing phase I and phase II image quality. Although not the same patients were included in both phases, the opinion of the

same expert would, potentially, represent a consistent basis for evaluating the actual improvement achieved through the CRP.

The overall results shown in Figure 48 do not confirm the expected trend. Depending on the mammography center, Phase I scores were some times higher than for Phase II. However, the Phase I average score was 14.4 and the corresponding Phase II score was 14.6, which is not much different.

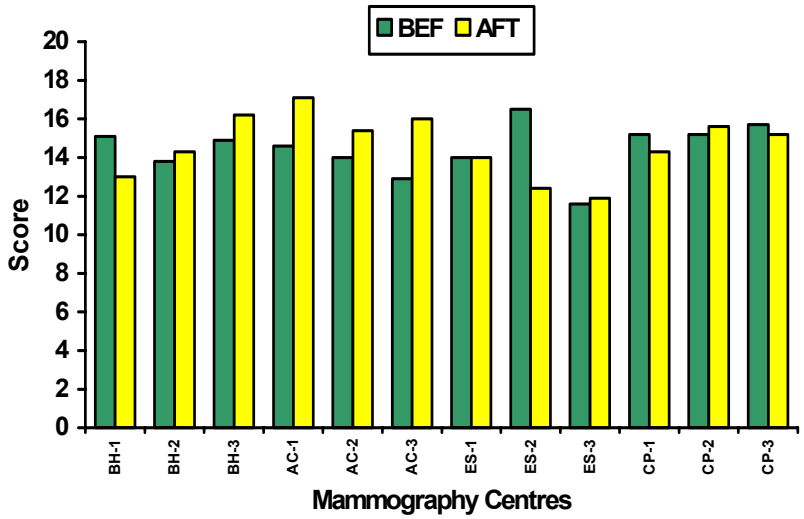


FIG. 48. Comparison of scores provided by the same expert — cranio-caudal projection.

The results shown in Figure 49 for the MLO projection correlate better with the expected trend. In all mammography centres but one, Phase II expert scores were higher than the corresponding Phase I values. The average Phase I score was 14.5 while the Phase II value was 15.5.

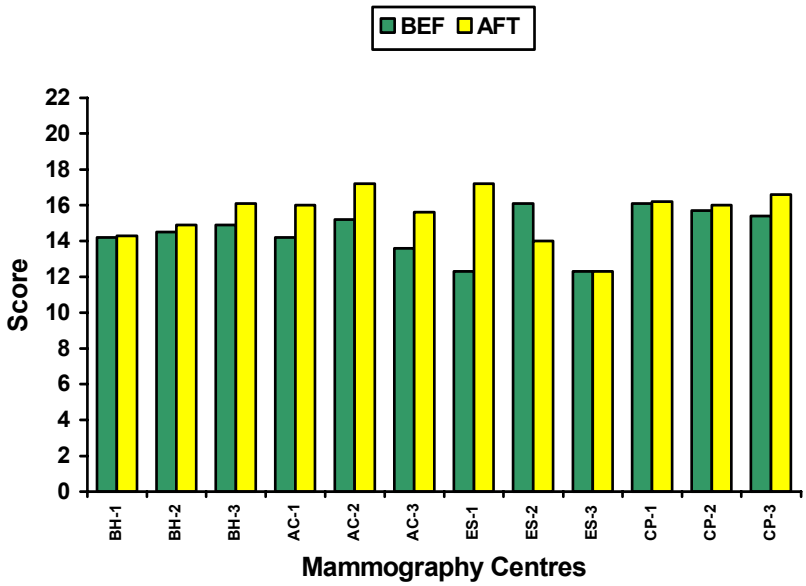


FIG. 49. Comparison of scores provided by the same expert— MLO projection.

7.3. DETAILED COMPARISON BETWEEN EXPERT RADIOLOGIST'S OPINION

Phase II scores given to each image by the two independent radiologist experts were compared criterion-by-criterion to assess their degree of agreement. The results obtained are detailed in the following tables and figures, for each criterion separately and for each radiographic projection. In total, 652 mammography films (326 CC views and 326 MLO views) collected in different countries were scored by each radiologist during this phase of the CRP.

By construction, each table allows a cross comparison of experts' opinion to be made. Each element of the diagonal of the table expresses the degree of agreement (yes, yes) or disagreement (no, no) of both experts. The sum of the diagonal terms gives the level of concordant answers, either positive or negative.

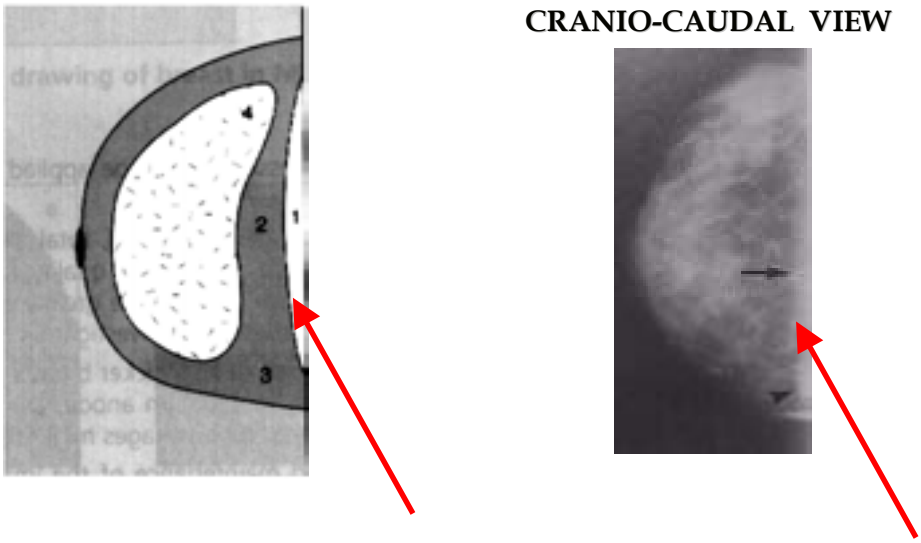


FIG. 50. Visually sharp reproduction of pectoral muscle at image margin.

7.3.1. Criterion 1: visually sharp reproduction of pectoral muscle at image margin (cranio-caudal projection)

Figure 51 gives the histogram of the answers provided by the two experts to the criterion "Visually sharp reproduction of pectoral muscle at image margin" (Figure 50). The experts had to answer in "yes" or "no". Agreement is plotted in Figure 51. It is important to remember that the visual sharp reproduction implies that the relevant anatomical detail(s) are clearly defined and visible.

Table I numerically represents the crossed judgment by two experts. The last column gives the ratings of expert 1 and the last row gives the ratings of expert 2. The central part of the table (rows and columns 2 and 3) are the cross-comparison between the "yes" and the "nos"of both experts. Agreement on "yes" refers to the percentage of cases that both experts coincide in appreciating that the criterion was met. Agreement on "no" corresponds to the percentage of cases in which neither of the experts felt that the criterion was met. The quality criterion No. 1 has been evaluated by the two experts (Table I.A). Column 4 shows the results of the evaluation by Expert 1, who considers that the criterion is fulfilled in 22.7% of the cases and not fulfilled in 77.3% of the cases. The lower row shows the results of the evaluation of Expert 2, who considers that the criterion is fulfilled in 34.1% of the cases and not fulfilled in 65.9% of the cases. The 'common' agreement with the 'yes' is in 20.2% of the cases. The

common agreement with the 'no' is in 63.4% of the cases. The 2.5% and the 13.9% are discrepancies between experts. A similar approach is used in subsequent tables.

The graph values allow making a better assessment of the level of agreement by summing the diagonal terms: e.g. 83.6% in this particular case. The higher the value, the better the agreement among the experts.

TABLE I. DESCRIPTION OF CROSSED JUDGMENT BY TWO EXPERTS

Quality Criterion	Yes (expert 2)	No (expert 2)	Expert 1
Yes (expert 1)	% Agreement between experts "yes-yes"	% Discrepancy between experts "yes-no"	%
No (expert 1)	% Discrepancy between experts "no-yes"	% Agreement between experts, "no-no"	%
Expert 2	%	%	100%

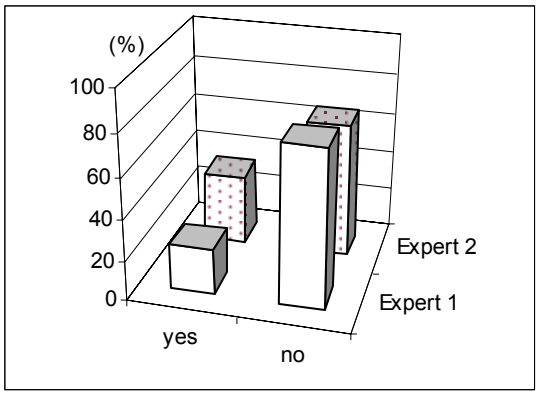


FIG. 51. Level of agreement on Criterion 1 between two experts (CC projection).

As can be deduced from Table I, both experts mainly agreed on "not seen" for the criterion "sharply visualized the pectoral muscle" by providing the same negative answer (63.4% of all answers). However, there was also a slight agreement on "seeing" since 20.2% of all answers were positive for both of them. The experts' opinion reflects here the degree of difficulty in technically achieving the criterion, sharp visualization of the pectoral muscle being affected by the blurring due to the patient movement, the choice of adequate radiographic setting is of great importance in this particular case.

TABLE I.A. CROSSED JUDGMENT BY EXPERTS (%) (CRITERION 1 – CC PROJECTION)

CC 1	**Yes**	No	Expert 1
Yes	20.2	2.5	22.7
No	13.9	63.4	77.3
Expert 2	34.1	65.9	100.0

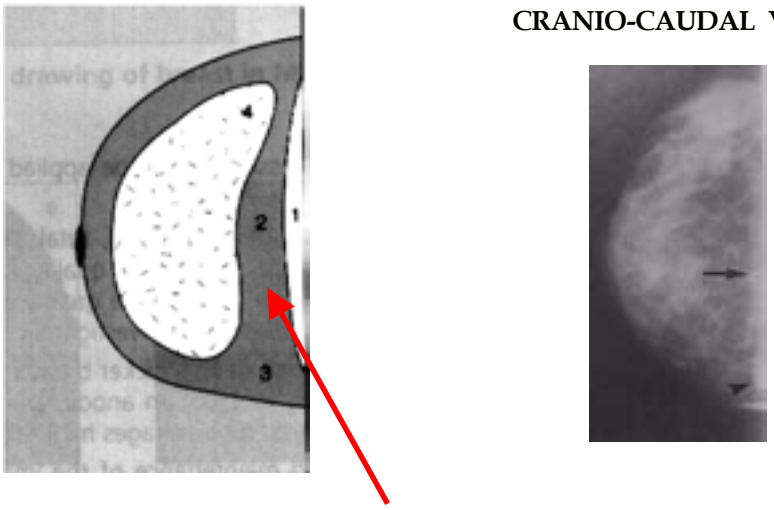


FIG. 52. Visually sharp reproduction of retroglandular fat tissue.

7.3.2. Criterion 2: visually sharp reproduction of retroglandular fat tissue (cranio-caudal projection)

As shown in Figure 53, the criterion "visually sharp reproduction of retroglandular fat tissue" (Figure 52) was easily met by both experts.

Their level of agreement was very high, 89.1% of all answers, thus indicating that the criterion definition was clear and that the great majority of mammography films were capable of showing such an anatomical part of the breast without any ambiguity.

TABLE II. CROSSED JUDGMENT BY EXPERTS (%) (CRITERION 2 – CC PROJECTION).

CC2	**Yes**	No	Expert 1
Yes	84.9	5.9	90.8
No	5.0	4.2	9.2
Expert 2	89.9	10.1	100.0

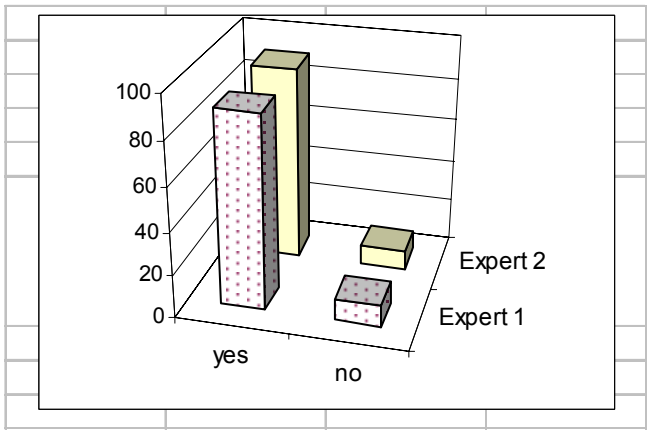


FIG. 53. Level of agreement on Criterion 2 between both experts (CC projection).

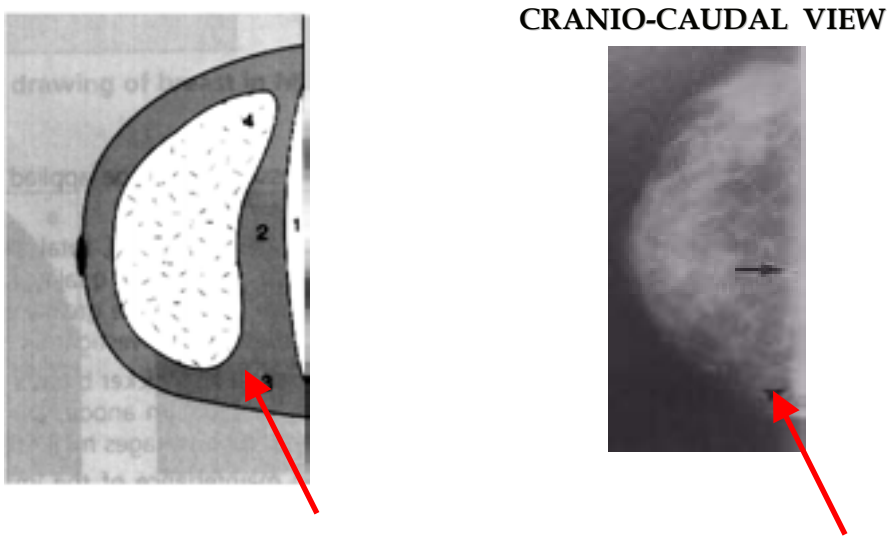


FIG. 54. Visually sharp reproduction of medial breast tissue.

7.3.3. Criterion 3: visually sharp reproduction of medial breast tissue (cranio-caudal projection)

As in the case of Criterion 2, the "visually sharp reproduction of medial breast tissue" in Figure 54 was very frequently seen by both experts (Figure 55) (90.3% of common positive answers) and their level of agreement was even higher, that is 91.6% of total answers.

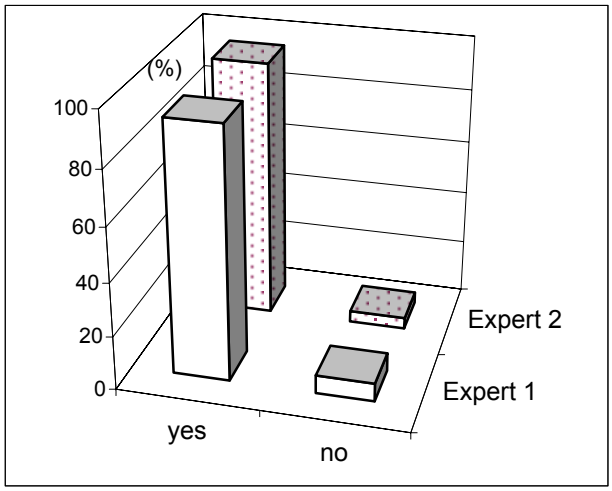


FIG. 55. Level of agreement on Criterion 3 between both experts (CC projection).

TABLE III. CROSSED JUDGMENT BY EXPERTS (%) (CRITERION 3 – CC PROJECTION)

CC 3	**Yes**	No	**Expert 1**
Yes	90.3	2.9	93.2
No	5.5	1.3	6.8
Expert 2	95.8	4.2	100.0

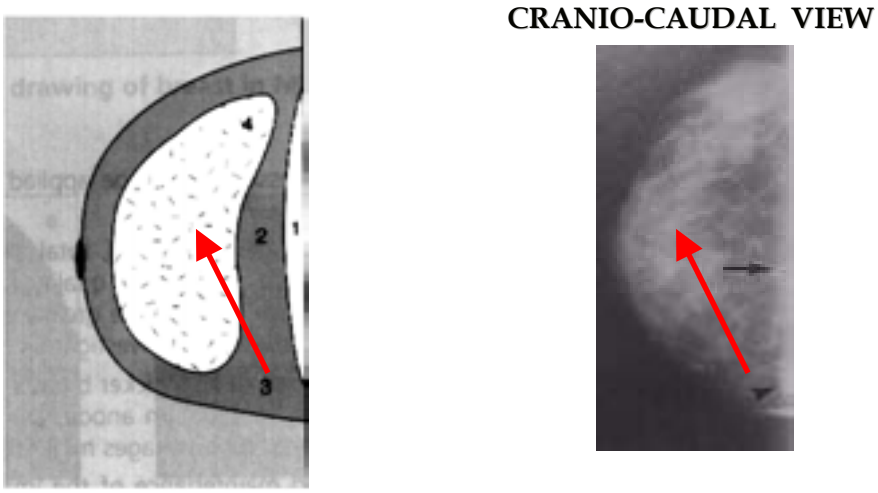


FIG. 56. Visually sharp reproduction of lateral glandular tissue.

7.3.4. Criterion 4: visually sharp reproduction of lateral glandular tissue (cranio-caudal projection)

Here again, as shown in Table IV, there is similarity of the answers provided by the experts. A common agreement was reached in 87.4% of all answers and about 10% were common negative answers. There was no clear disagreement between the experts on the visibility of the criterion either when they negatively answered or when they positively answered.

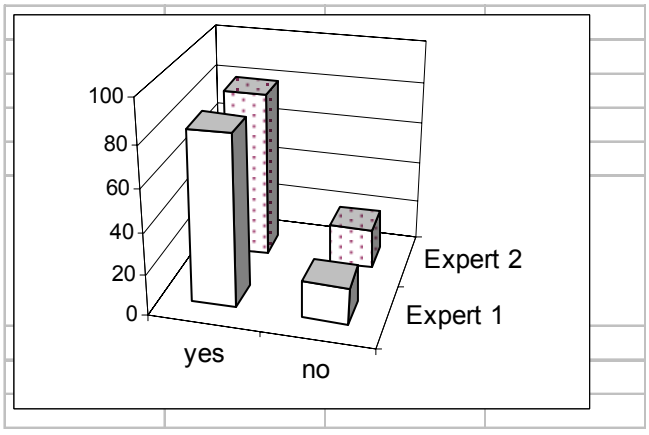


FIG. 57. Level of agreement on Criterion 4 between both experts (CC projection).

TABLE IV. CROSSED JUDGMENT BY EXPERTS (%) (CRITERION 4 – CC PROJECTION)

CC 4	**Yes**	No	Expert 1
Yes	75.2	7.1	82.3
No	5.5	12.2	17.7
Expert 2	80.7	19.3	100.0

7.3.5. Criterion 5: no skin folds seen (cranio-caudal projection)

The perception of the presence of skin folds on a mammography image has a higher subjective component and may significantly differ from one viewer to another. This is what is shown on Figure 58 where the percentage of both positive and negative opinions of the experts is significantly different.

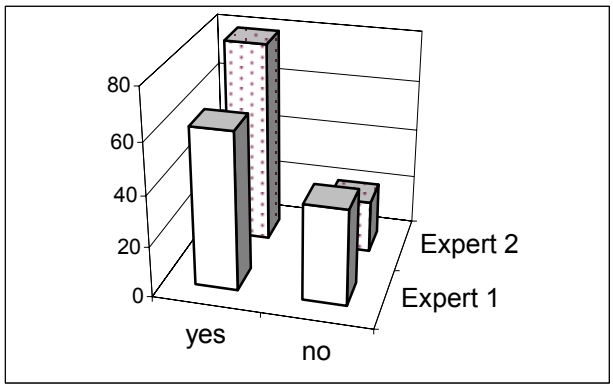


FIG. 58. Level of agreement on Criterion 5 between both experts (CC projection).

From a more detailed analysis of Table V, one may deduce that the experts disagreed in about 40% of total answers (sum of the negative diagonal terms being 39.7) and that their individual opinions were really different.

In fact, 74% of the total number of negative answers (28.2 divided by 37.9) provided by Expert 1 were considered as positive by Expert 2 while only 50% (10.9 divided by 20.6) were considered as positive by Expert 1 when Expert 2 answered negatively.

TABLE V. CROSSED JUDGMENT BY EXPERTS (%) (CRITERION 5 – CC PROJECTION)

CC5	**Yes**	No	Expert 1
Yes	51.3	10.9	62.1
No	28.2	9.7	37.9
Expert 2	79.5	20.6	100.0

7.3.6. Criterion 6: symmetrical images of left and right breast (Cranio-Caudal projection)

This is really a very technical image criterion which slightly includes a subjective component.

Ideally, the symmetry of the left and right breast can be ensured through good positioning of patient and appropriate compression with respect to the radiographic projection. However, the perception of the degree of achieved symmetry relies on viewer's personal judgment and may not always coincide with a pure geometrical concept. Furthermore, breasts, by nature, are not necessarily symmetrical organs.

As shown in Figure 59, the two experts were not at all consistent in their findings concerning this criterion.

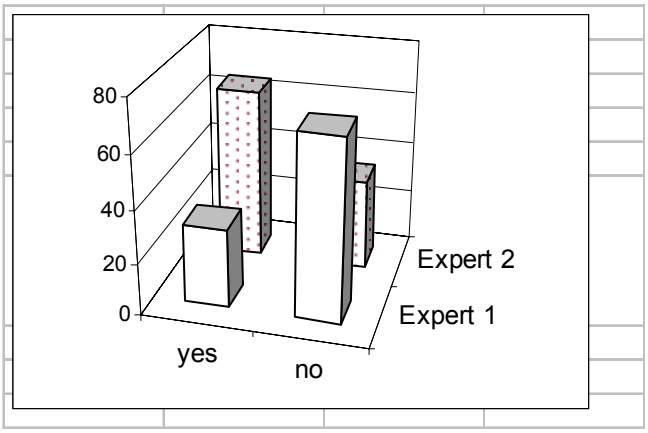


FIG.59. Level of agreement on Criterion 6 between both experts (CC projection).

Indeed, the two experts agreed on 50% of the images and disagreed on 50%.

Their individual opinions were very diverging. As illustrated by Table VI, 61% of Expert 1's negative answers were considered as positive by Expert 2, while only 21% of Expert 2's negative answers were considered as positive by Expert 1.

As to the extent of meeting of this criteria, Expert 2 said yes more often than Expert 1, 65.3% and 30.5% respectively.

Such results suggest, therefore, a need for a better definition of symmetry to be considered as a possible improvement of the image criteria system.

TABLE VI. CROSSED JUDGMENT BY EXPERTS (%) (CRITERION 6 – CC PROJECTION)

CC6	**Yes**	No	Expert 1
Yes	22.9	7.6	30.5
No	42.4	27.1	69.5
Expert 2	65.3	34.7	100.0

7.3.7. Criterion 7: visualization of skin outline with bright light (but barely without it) (cranio-caudal projection)

In order to be able to meet this criterion, an appropriate technical environment is needed. As already mentioned such a requirement was fulfilled but, obviously, this was just a necessary condition and not a sufficient one to be able to actually see the criterion.

As shown in Figure 60, both experts answered more than 60% of time positively but their level of agreement was not so good. As detailed in Table VII, both experts mainly disagreed on being able to visualize skin outline with bright light, that is 53.3% of total answer (negative diagonal values 27.7 + 25.6).

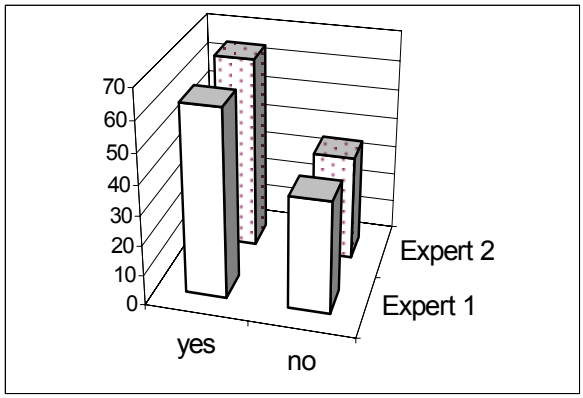


FIG.60. Level of agreement on Criterion 7 between both experts (CC projection).

TABLE VII. CROSSED JUDGMENT BY EXPERTS (%) (CRITERION 7 – CC PROJECTION)

CC7	**Yes**	No	Expert 1
Yes	37	25.6	62.6
No	27.7	9.7	37.4
Expert 2	64.7	35.3	100.0

7.3.8. Criterion 8: reproduction of vascular structures seen through most dense parenchyma (cranio-caudal projection)

The required degree of visibility for this criterion to be seen, that is reproduction of a vascular structure, is less constraining than a sharp visualization or even a simple visualization. However, use of inadequate technical factors such as long exposure times can make difficult the fulfilment of this criterion.

As illustrated by Figure 61, there was a very high level of agreement achieved by both experts concerning this criterion, almost 95% of the total answers.

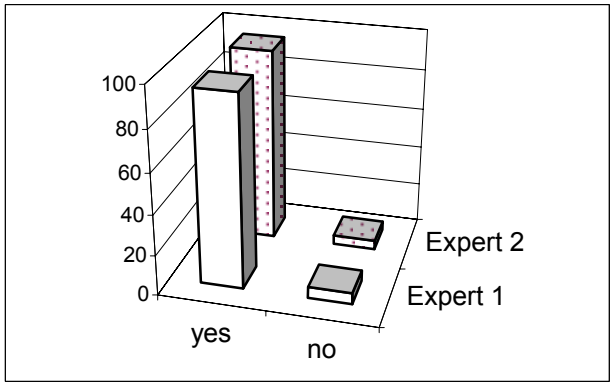


FIG. 61. Level of agreement on Criterion 8 between both experts (CC projection).

TABLE VIII. CROSSED JUDGMENT BY EXPERTS (%) (CRITERION 8 – CC PROJECTION)

CC8	**Yes**	No	Expert 1
Yes	92	2.5	94.5
No	3.4	2.1	5.5
Expert 2	95.4	4.6	100.0

7.3.9. Criterion 9: visually sharp reproduction of all vessels and fibrous strands and pectoral muscle margin (absence of movement) (cranio-caudal projection)

Despite the intrinsic difficulty of meeting this criterion, which requires sharp visualization of low contrasted tiny vessels, very similar findings to those discussed above for Criterion 8 were obtained.

Both experts recognized Criterion 9 "Visually sharp reproduction of all vessels and fibrous strands and pectoral muscle margin (absence of movement)" as easily observable. Their average positive answer rate was 92% and their disagreement rate was on only 8% of total answers. (Figure 62)

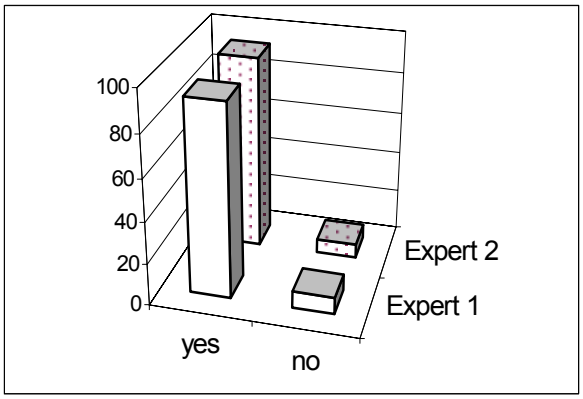


FIG. 62. Level of agreement on Criterion 9 between both experts (CC projection).

TABLE IX. CROSSED JUDGMENT BY EXPERTS (%) (CRITERION 9 – CC PROJECTION)

CC9	**Yes**	No	Expert 1
Yes	88.7	3.4	92.1
No	4.6	3.4	8.0
Expert 2	93.3	6.8	100.0

7.3.10. Criterion 10: visually sharp reproduction of skin structure (rosettes from pores) along the pectoralis muscle (cranio-caudal projection)

This is a criterion which mostly relates to viewing conditions but also to viewers' expertise and attraction for such an imaging detail (rosettes from pores). Breast composition may also influence the degree of visibility of this criterion.

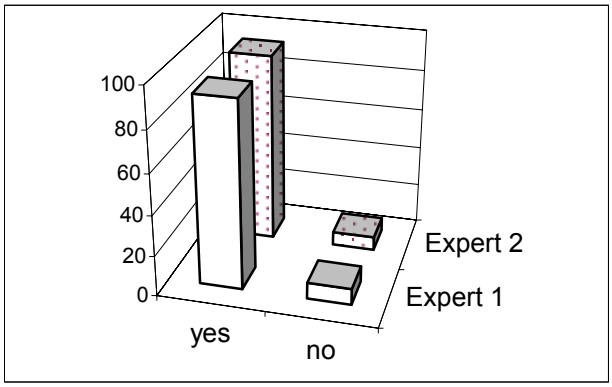


FIG. 63. Level of agreement on Criterion 10 between both experts (CC projection).

As shown in both Figure 63 and Table X, a good agreement was achieved by the two experts with a marginal preference of Expert 1 in seeing more frequently the considered criterion than Expert 2: 96.3% and 88.7% respectively.

TABLE X. CROSSED JUDGMENT BY EXPERTS (%) (CRITERION 10 – CC PROJECTION)

CC10	**Yes**	No	Expert 1
Yes	86.6	9.7	96.3
No	2.1	1.7	3.8
Expert 2	88.7	11.4	100.0

7.3.11. Criterion 1: pectoral muscle at correct angle (medio lateral oblique projection)

As already said, the proper performance of the MLO projection intrinsically requires much more care than the CC projection due to breast positioning problems.

This can easily affect the degree of visibility of a given image criterion and may result in diverging opinions when different viewers are involved. A good illustration of this will be Criterion 2, which will be discussed below.

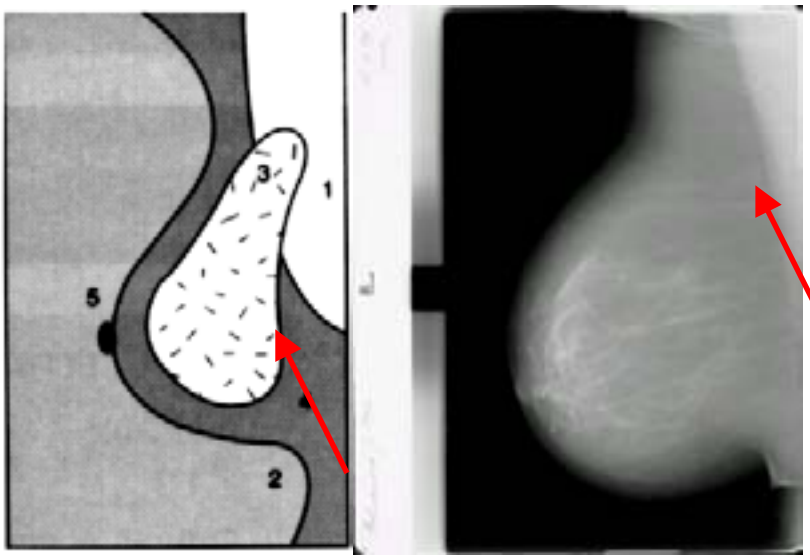


FIG. 64. Pectoral muscle at correct angle.

As for criterion 1, Figure 65 shows the results provided by both experts. As can be seen, the criterion was met very frequently by the experts, the expert 2 saw it in 92.4% of cases while the positive answer rate of expert 1 was 81.5%.

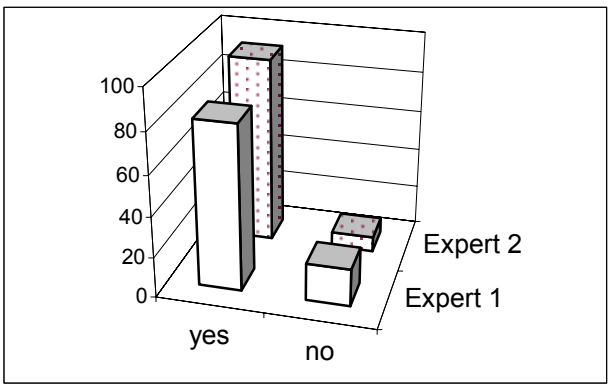


FIG. 65. Level of agreement on Criterion 1 between both experts (MLO projection).

Looking to more detailed information provided in Table XI, one may notice that both experts disagreed on about 16% of answers and that Expert 2 was a little more frequently in disagreement than Expert 1.

TABLE XI. CROSSED JUDGMENT BY EXPERTS (%) (CRITERION 1 – MLO PROJECTION)

MLO 1	**Yes**	No	Expert 1
Yes	79	2.5	81.5
No	13.4	5	18.4
Expert 2	92.4	7.5	100.0

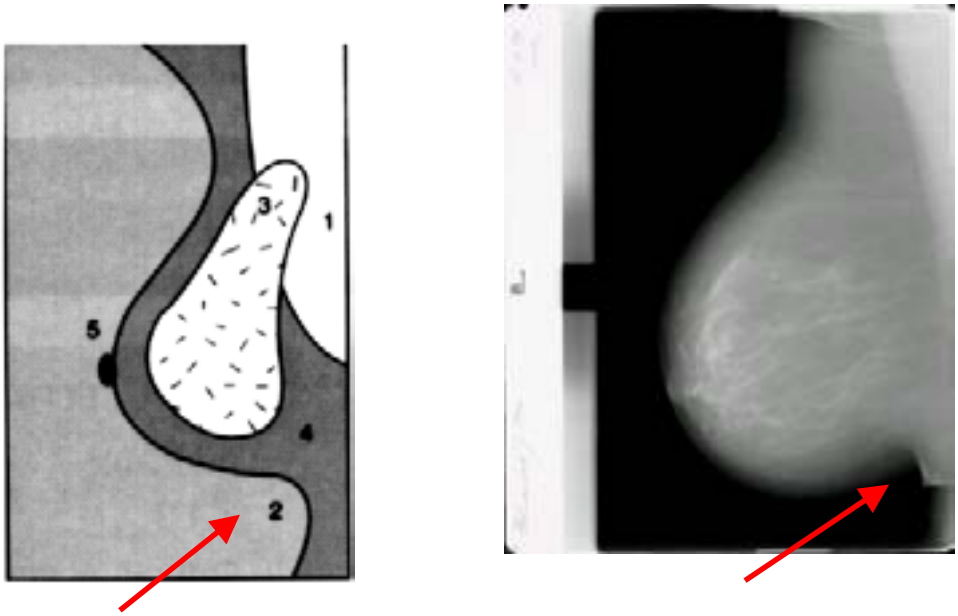


FIG. 66. Infra mammary angle visualized.

7.3.12. Criterion 2: infra-mammary angle visualized (medio lateral oblique projection)

The visualization of the infra-mammary angle is strongly related to the breast positioning. However, the extent to which such an anatomical part may be considered as fully or partly represented on the mammography film also depends on breast size.

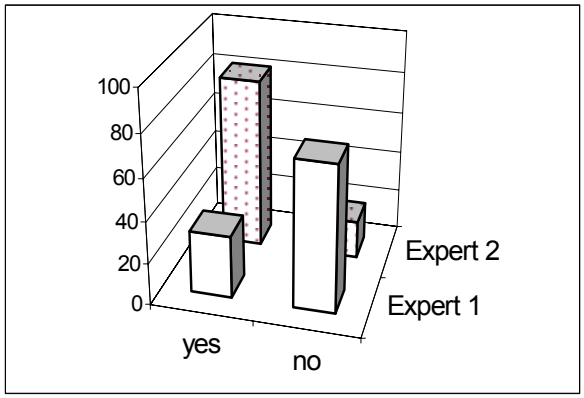


FIG. 67. Level of agreement on Criterion 2 between both experts (MLO projection).

As clearly illustrated by Figure 67, the two experts did not meet the criterion to the same level. One saw it in more than 80% of cases while the second did see it in only 30% of cases.

Table XII allows a more thorough analysis of the experts' answers.

Both experts disagreed mainly on the visibility criterion (55.5% of total answers) and their individual opinions were particularly discordant. Indeed, among the negative answers provided by Expert 1, 75% were considered as positive by Expert 2, while only 9% of the negative answers of Expert 2 were considered as positive by Expert 1. Expert 1 found that criterion was not met in 70% of films while Expert 2's answer was negative in only 18% of films.

This degree of discordance demonstrates the incompleteness of the criterion definition and calls for more objectivity to better describe the visualization of the criterion.

TABLE XII. CROSSED JUDGMENT BY EXPERTS (%) (CRITERION 2 – MLO PROJECTION)

MLO 2	**Yes**	No	Expert 1
Yes	28.2	1.7	29.9
No	53.8	16.4	70.2
Expert 2	82	18.1	100.0

7.3.13. Criterion 3: visually sharp reproduction of cranio-lateral glandular tissue (medio lateral oblique projection)

This is an easily achievable criterion and the said tissue was sharply seen by both experts very frequently; their positive agreement reached 91% of films. The experts were mostly in agreement.

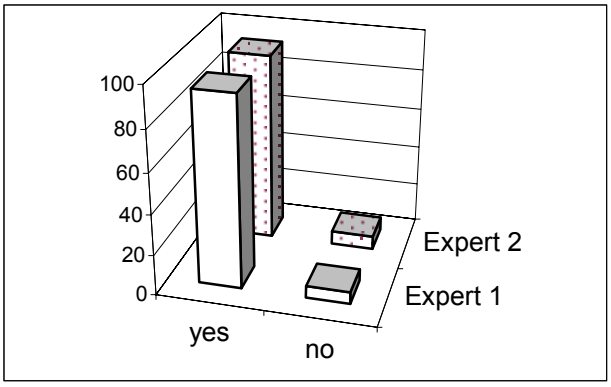


FIG. 68. Level of agreement on Criterion 3 between both experts (MLO projection).

TABLE XIII. CROSSED JUDGMENT BY EXPERTS (%) (CRITERION 3 – MLO PROJECTION)

MLO 3	**Yes**	No	Expert 1
Yes	89.5	4.6	94.1
No	3.8	2.1	5.9
Expert 2	93.3	6.7	100.0

7.3.14. Criterion 4: visually sharp reproduction of retro glandular fat tissue (medio lateral oblique projection)

As in the case of the the cranio-caudal projection, the Criterion 4 (Visuallly sharp reproduction of retro glandular fat tissue) was a criterion with high degree of agreement among both experts. (Figure 69)

As shown in Table XIV, there was a high level of agreement among the experts who commonly answered positively in about 90% of cases. Less than 10% of discordant answers was found, of which 65% were by Expert 1.

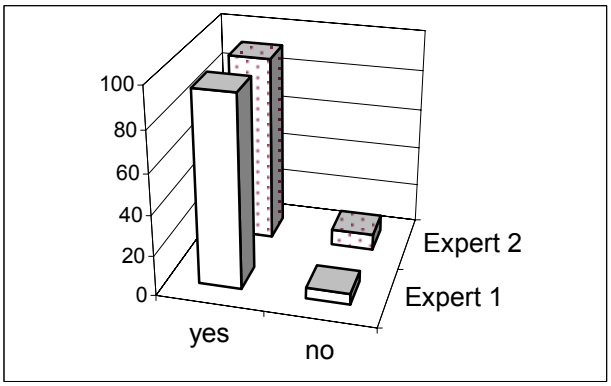


FIG. 69. Level of agreement on Criterion 4 between both experts (MLO projection).

TABLE XIV. CROSSED JUDGMENT BY EXPERTS (%) (CRITERION 4 – MLO PROJECTION)

MLO 4	**Yes**	No	Expert 1
Yes	89.1	5.5	94.6
No	2.9	2.5	5.4
Expert 2	92	8	100.0

7.3.15. Criterion 5: nipple in full profile, clear of overlying breast tissue and/or indicated by marker

This is an image criterion for which the fulfilment is affected by the viewer's subjectivity and good breast positioning. It requires precise definition of "full profile" to be unambiguous. The results shown in Figure 70 confirm the relative low positive answer rates provided by both experts, 63% on average.

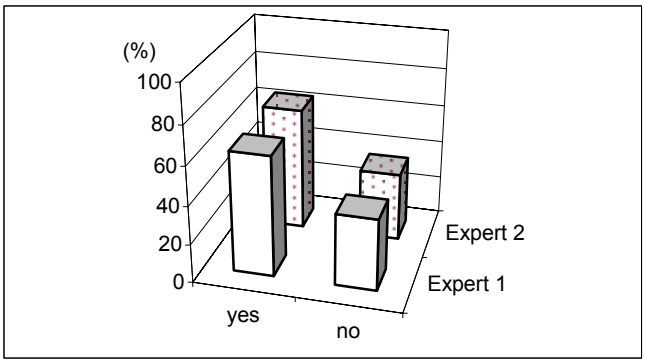


FIG. 70. Level of agreement on Criterion 5 between both experts (MLO projection).

TABLE XV. CROSSED JUDGMENT BY EXPERTS (%) (CRITERION 5 – MLO PROJECTION)

MLO 5	**Yes**	No	Expert 1
Yes	50.4	12.2	62.6
No	13.9	23.5	37.4
Expert 2	64.3	35.7	100.0

7.3.16. Criterion 6: no skin folds seen

As in the case of the cranio-caudal projection, this criterion was differently met by both experts who gave almost opposite answers about the presence of skin folds on the mammography images they have seen. One possible reason could be the negative form of the criterion, which may confuse the viewer who, in the case of skin folds absence, would logically tend to answer negatively instead of positively, to be consistent with the negative question.

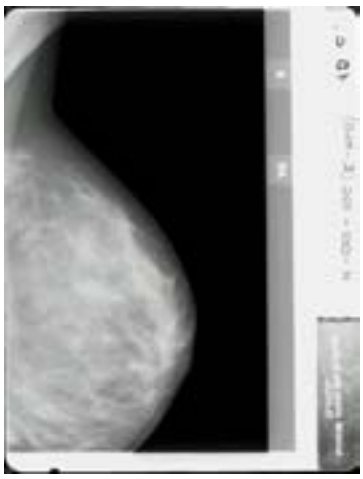


FIG. 71. Example of MLO view showing skin folds, the inferior part of the breast is missing in the picture and the pectoral muscle is not at a correct angle.

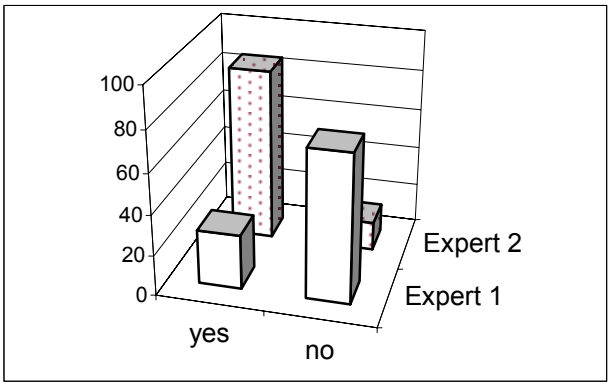


FIG. 72. Level of agreement on Criterion 6 between both experts (MLO projection).

TABLE XVI. CROSSED JUDGMENT BY EXPERTS (%) (CRITERION 6 – MLO PROJECTION)

MLO 6	**Yes**	No	Expert 1
Yes	25.6	1.3	26.9
No	60.1	13	73.1
Expert 2	85.7	14.3	100.0

7.3.17. Criterion 7: symmetrical images of left and right breast (medio lateral oblique projection)

The same considerations made for Criterion 7 on cranio-caudal projection apply. The individual opinions of both experts were also very diverging. As illustrated by Table XVII, 55% of the negative answers of Expert 1 were considered as positive by Expert 2, while only 27% of the negative answers of Expert 2 were considered as positive by Expert 1.

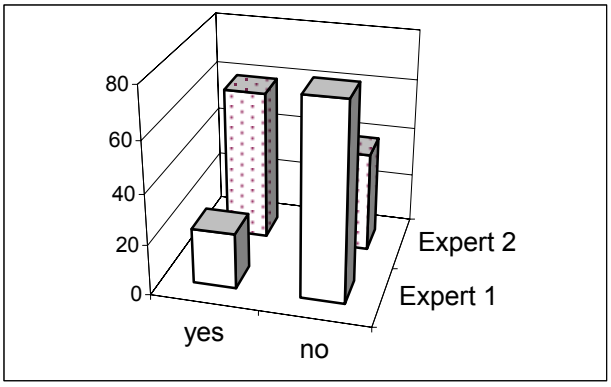


FIG. 73. Level of agreement on Criterion 7 between both experts (MLO projection).

On the other hand, Expert 2 did see more frequently than Expert 1 the feature of this criterion: 59.7% and 21.9%, respectively.

TABLE XVII. CROSSED JUDGMENT BY EXPERTS (%) (CRITERION 7 – MLO PROJECTION)

MLO 7	**Yes**	No	Expert 1
Yes	16	5.9	21.9
No	43.7	33.6	77.3
Expert 2	59.7	39.5	100.0

7.3.18. Criterion 8: visualization of skin outline with bright light (but barely without it) (medio lateral oblique projection)

Almost the same results were found concerning this criterion as for the cranio-caudal projection. The answer profiles of both the experts compared rather well with those obtained for this criterion, that is, the agreement rate and the overall percentage of positive and negative answers.

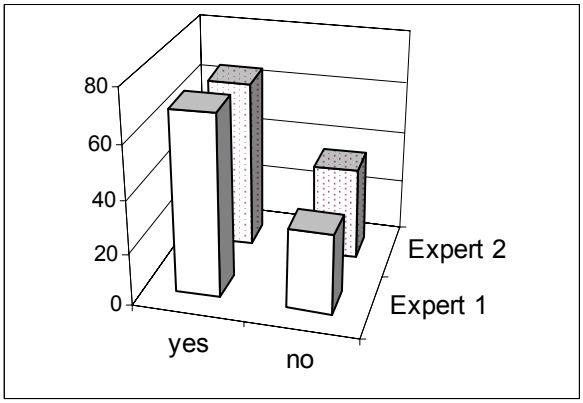


FIG. 74. Level of agreement on Criterion 8 between both experts (MLO projection).

TABLE XVIII. CROSSED JUDGMENT BY EXPERTS (%) (CRITERION 8 – MLO PROJECTION)

MLO 8	**Yes**	No	Expert 1
Yes	39.9	29.8	69.7
No	24.8	5.5	30.3
Expert 2	64.7	35.3	100.0

7.3.19. Criterion 9: reproduction of vascular structures seen through most dense parenchyma

This image criterion obtained the highest agreement rate from both experts. It was, on average, seen on 95% of films by both of them and found to be met commonly in 92.4% of the cases.

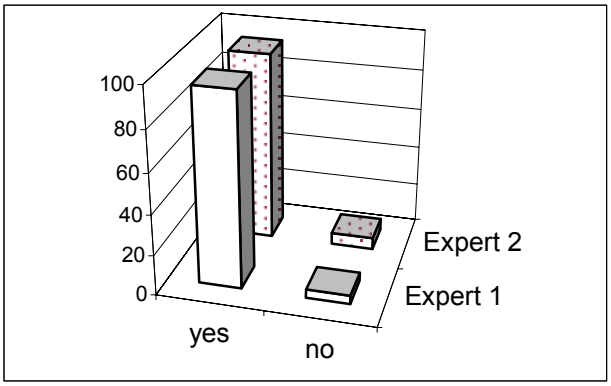


FIG. 75. Level of agreement on Criterion 9 between both experts (MLO projection).

TABLE XIX. CROSSED JUDGMENT BY EXPERTS (%) (CRITERION 9 – MLO PROJECTION)

MLO 9	**Yes**	No	Expert 1
Yes	92.4	3.4	95.8
No	1.7	2.5	4.2
Expert 2	94.1	5.9	100.0

7.3.20. Criterion 10: visually sharp reproduction of all vessels and fibrous strands and pectoral muscle margin (medio lateral oblique projection)

No different remarks than for the same criterion discussed in cranio-caudal projection. Both experts were in agreement on about 95% of films and found the criterion easy to be fulfilled in 91.6 % of films.

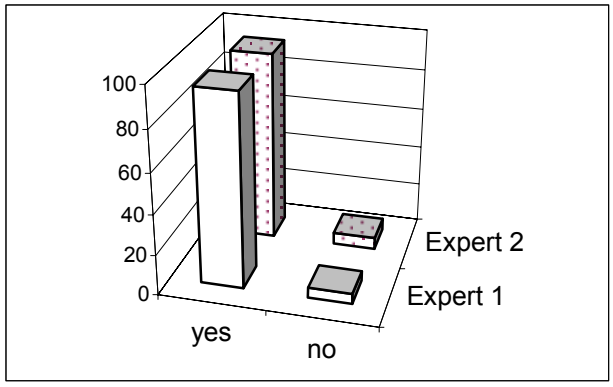


FIG. 76. Level of agreement on Criterion 10 between both experts (MLO projection).

TABLE XX. CROSSED JUDGMENT BY EXPERTS (%) (CRITERION 10 – MLO PROJECTION

MLO 10	**Yes**	No	Expert 1
Yes	91.6	3.4	95.0
No	2.5	2.5	5.0
Expert 2	94.1	5.9	100.0

7.3.21. Criterion 11: visually sharp reproduction of skin structure (rosettes from pores) along the pectoral muscle (medio lateral oblique projection)

As shown in both Figure 77 and Table XXI, a good agreement was achieved by the two experts with a slight preference of Expert 1 in seeing more frequently the structure in this criterion than Expert 2: 96.6% and 91.6%, respectively.

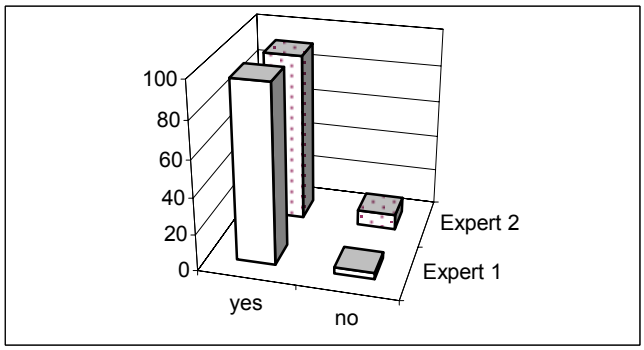


FIG. 77. Level of agreement on Criterion 11 between both experts (MLO projection).

TABLE XXI. CROSSED JUDGMENT BY EXPERTS (%) (CRITERION 11 – MLO PROJECTION

MLO 11	**Yes**	No	Expert 1
Yes	91.6	5	96.6
No	0	3.4	3.4
Expert 2	91.6	8.4	100.0

7.4. HIERARCHY BETWEEN CRITERIA

A first attempt was made to establish a hierarchical list of image criteria which might be considered as “sine qua non” criteria mainly underpinning the process of rejecting the image, if not fulfilled. In other terms, image criteria were studied from their relevance point of view as they individually contribute to the final judgment concerning the acceptability of the image.

To be able to carry out such an analysis, images judged as unacceptable by the strictest expert were chosen. Such a choice was dictated by the consideration of getting the maximum number of rejected films as compared to the number of films rejected by the expert who was more flexible.

The analysis of the selected films was done by sorting in descending order the frequency of the image criteria which were not fulfilled.

The higher the frequency, the higher the contribution of the criterion to the process of rejecting the image.

Since the rejection of the film (rather than acceptance) is the main issue under consideration, for an image to be considered as unacceptable, the most relevant criterion will have the highest frequency (%) of fulfilment or least frequency (percentage) of non-fulfilment.

Tables XXII and XXIII give the relative frequency of non-fulfilment of individual criteria.

TABLE XXII. RELEVANCE OF IMAGE CRITERIA FOR REJECTED FILMS IN THE CRANIO-CAUDAL PROJECTION

Image Criteria (Cranio-Caudal projection)	% of non fulfilment
1. Pectoral muscle – visually sharp reproduction	10.6
2. Retroglandular fat tissue – visually sharp reproduction	68.9
3. Medial breast tissue – visually sharp reproduction	76.5
4. Lateral glandular tissue – visually sharp reproduction	40.9
5. No skin folds seen	62.9
6. Symmetrical images of Lt & Rt	16.2
7. Skin outline visualization by bright light	66.6
8. Vascular structures (seen through most dense parenchyma)	81.8
9. All vessels and fibrous strands, pectoral muscle margin – visually sharp reproduction	75.1
10. Skin structure (rosettes from pores) along pectoralis muscle – visually sharp reproduction	86.4

Four major criteria in order of hierarchy were identified as being the most relevant in the process of rejecting the image: Criteria 10, 8, 3 and 9. All of them are very much radiographic technique related and constitute the frame of the basic diagnostic information content of a mammography image: the skin and vascular structure, the medial breast tissue and all vessels. Criterion 10 is most common one among rejected images but is strongly related to the subjectivity of the observer, Criterion 8 seems more consistent with the importance of the information that it conveys (the visualization of vascular structure), Criteria 3 and 9 represent the major part of the image information content that is always sought in a mammography film and cannot be missed. Therefore, any image that would miss such parameters could not be

considered as informative enough to be acceptable and, to some extent, should have to be rejected. A more thorough analysis (cluster analysis for instance) of the individual weight of each image criterion might help to better understand the complex decision process that underpins the rejection of a film.

As for the MLO projection, two major image criteria were found to be very often not fulfilled: Criteria 11 and 10.

They were followed by two others (Criteria 3 and 4), which dealt with the visualization of the lateral glandular tissue and the retroglandular tissue, respectively. As previously, these four criteria should be considered as essential and be present on an image in order for the image to be accepted.

TABLE XXIII. RELEVANCE OF IMAGE CRITERIA FOR REJECTED FILMS MLO PROJECTION

Image Criteria (MLO projection)	% of non fulfilment
1. Pectoral muscle at correct angle	59.1
2. Infra-mammary angle visualized	18.2
3. Cranio-lateral glandular tissue – visually sharp reproduction	71.6
4. Retroglandular fat tissue – visually sharp reproduction	69.3
5. Nipple in full profile	46.6
6. No skin folds seen	36.3
7. Symmetrical images of Lt & Rt breast	9.5
8. Visualization of skin outline with bright light	6.2
9. Vascular structures (seen through most dense parenchyma)	7.5
10. All vessels and fibrous strands & pectoral muscle margin-visually sharp reproduction	79.5
11. Skin structure (rosettes from pores – visually sharp reproduction	88.6

8. CONCLUSIONS

Despite some practical limitations within the CRP and obvious difficulties connected with the implementation of a new programme in different countries, the results of this project have shown that it is possible to implement a programme of optimization of protection in mammography.

Considerable reductions in dose were achieved at low cost while keeping the image quality at the highest level compatible with diagnostic requirement. The methodology, based on patient dose measurements, comparison with reference values, assessment of image quality, the introduction of QC and corrective actions, if needed, and re-evaluation of breast doses and image quality, has demonstrated the effectiveness for this kind of optimization programme.

The programme has proved to be valuable as a learning process for those taking part and has also provided them with tools and practical protocols which can be used in the implementation of a national QC programme in mammography in the future.

It was evident from some of the country reports that there were inadequacies or deficiencies in experimental technique, and in understanding how to perform some of the measurements and what instrumentation to use in given situations. This in turn highlights the need for adequate training to be given to participants in future initiatives of this type. This may be all the more important in the more specialized areas of quality control and dosimetry in interventional radiology and CT.

The implementation of this study has confirmed the need for calibration and intercomparison of participants' dosimetric practice. In this project the use of TL dosimeters made it easy to perform calibration and intercomparison exercises, providing an assurance on the accuracy of the reported results for patient doses. For a country's TLD system to meet accepted dosimetric performance criteria, it is essential that an appropriate quality control programme be in place.

Evaluation of image quality in mammography using the clinical criteria of the EC has been shown to be a sound method of confirming an adequate level of diagnostic information in the images. The main advantage of the criteria has to be seen in its educational value in reducing the inter-viewer variation rather than in quantifying image quality. It was helpful in identifying differences in perception by different observers and in realizing the components of the criteria where the differences are more. The training in familiarity with each component of the criteria is what matters. The importance of adequate training of local practitioners is highlighted while applying such an approach in many different countries.

This programme demonstrates the usefulness of the quality criteria in day-to-day assessment of mammographic images, as part of a QC programme.

8.1. POINTERS FOR FUTURE PROGRAMMES AIMED AT OPTIMIZING RADIOLOGICAL PROTECTION IN DIAGNOSTIC RADIOLOGY OR IN INTERVENTIONAL RADIOLOGY

The experience gained from this multi-national and multi-centric coordinated research and lessons drawn can be useful, in particular with regard to the following:

1. Use of image quality criteria such as those established by the European Communities forms a sound basis for starting the process of optimization.
2. Inter-observer variations while evaluating images using the EC quality criteria are large.
3. Without an appropriate quality assurance programme covering image quality and patient assessment, there are a number of problems which can lead to increased patient doses.
4. Adequate training of participants is necessary on quality criteria and on relevant quality assurance programmes.
5. Calibrations and inter-comparisons prove useful for improving the accuracy of dosimetry.
6. Evaluation of interim results together with feedback is needed periodically throughout the programme.
7. Evaluation by external expert(s) needs to be encouraged.

APPENDIX I

FORM FOR DATA COLLECTION AT EACH FACILITY

CENTRE/ROOM: (VERSION 04.2000)

IMAGE IDENTIFICATION (PATIENT INITIALS): AGE:

FILM-SCREEN COMBINATION USED:

AUTOMATIC EXPOSURE DEVICE USED: YES / NO

DATE: kV: mAs: Focus-skin distance: cm
Thickness of compressed breast: cm

RADIOLOGIST WHO ASSESSED THE IMAGE:

RADIOGRAPHER WHO DID THE EXAMINATION:

IMAGE ACCEPTABLE FOR DIAGNOSIS: YES / NO

IMAGE REJECTED BY: RADIOGRAPHER / RADIOLOGIST

CAUSE OF REJECTION:

IMAGE QUALITY CRITERIA (**MAMMOGRAPHY**) MLO (MEDIO-LATERAL OBLIQUE) PROJECTION		YES	NO	DOUBT-FUL	PATHOLOGY THAT AVOIDS THE VISUALIZATION
1. Pectoral muscle at correct angle	R				
	L				
2. Infra-mammary angle visualized	R				
	L				
3. Visually sharp reproduction of cranio-lateral glandular tissue	R				
	L				
4. Visually sharp reproduction of retroglandular fat tissue	R				
	L				
5. Nipple in full profile, clear of overlying breast tissue and/or indicated by marker (5 in fig. 1)	R				
	L				
6. No skin folds seen	R				
	L				
7. Symmetrical images of left and right breast					
8. Visualization of skin outline with bright light (but barely without it)	R				
	L				
9. Reproduction of vascular	R				

structures seen through most dense parenchyma	L				
10. Visually sharp reproduction of all vessels and fibrous strands and pectoral muscle margin (absence of movement)	R				
	L				
11. Visually sharp reproduction of skin structure (rosettes from pores) along the pectoral muscle	R				
	L				
Blackening of the image		optimum		too light	too dark
DOSE (mGy) AT THE ENTRANCE: (reference 10 mGy; 28 kV; FFD >60 cm)					
OBSERVATIONS: BREAST VERY DENSE / DENSE / NORMAL / FATTY					

CENTRE/ROOM:

IMAGE IDENTIFICATION (PATIENT INITIALS): AGE:

FILM-SCREEN COMBINATION USED:

AUTOMATIC EXPOSURE DEVICE USED: YES / NO

DATE: kV: mAs: Focus-skin distance: cm
Thickness of compressed breast: cm

RADIOLOGIST WHO ASSESSED THE IMAGE:

RADIOGRAPHER WHO DID THE EXAMINATION:

IMAGE ACCEPTABLE FOR DIAGNOSIS: YES / NO

IMAGE REJECTED BY: RADIOGRAPHER / RADIOLOGIST

CAUSE OF THE REJECTION:

IMAGE QUALITY CRITERIA (**MAMMOGRAPHY**). CC (CRANIO-CAUDAL) PROJECTION		YES	NO	DOUBT-FUL	PATHOLOGY THAT AVOID THE VISUALIZATION
1. Visually sharp reproduction of pectoral muscle at image margin	R				
	L				
2. Visually sharp reproduction of retroglandular fat tissue	R				
	L				
3. Visually sharp reproduction of medial breast tissue	R				
	L				
4. Visually sharp reproduction of lateral glandular tissue	R				
	L				
5. No skin folds seen	R				
	L				
6. Symmetrical images of left and right breast					
7. Visualization of skin outline with bright light (but barely without it)	R				
	L				
8. Reproduction of vascular structures seen through most dense parenchyma	R				
	L				
9. Visually sharp reproduction of all vessels and fibrous strands and pectoral muscle margin (absence of movement)	R				
	L				

10. Visually sharp reproduction of skin structure (rosettes from pores) along the pectoralis muscle	R				
	L				
Blackening of the image		optimum		too light	too dark
DOSE (mGy) AT THE ENTRANCE: (reference 10 mGy; 28 kV; FFD >60 cm)					
OBSERVATIONS: BREAST VERY DENSE / DENSE / NORMAL / FATTY					

APPENDIX II

EQUIPMENT USED FOR THE CONDUCT OF THE QUALITY CONTROL TEST

The agreed CRP work plan required the following equipment to carry out the Quality Control test:

- sensitometer
- densitometer
- thermometer
- PMMA plates (6 plates of 1 cm thickness)
- image phantom for constancy test (RMI 156)
- dosimeter specific for mammography (optional)
- TLD system (TL material, TL reader, accessories)
- kVmeter specific for mammography (optional)
- light meter (for the evaluation of viewing boxes)
- aluminium sheets (3 plates of 0.1 mm, 1 plate of 0.2 mm)
- star pattern for mammography (optional)
- film screen contact device for mammography.

Action limits adopted for the most significant parameters (or function) are listed below.

Parameter/function	Action Limit
kVp accuracy	Differences>± 1 kV
kVp reproducibility	Coefficient of variation>0.02
HVL (28 kVp)	HVL<0.31 mm Al or HVL>0.40 mm Al
AEC: compensation of kVp	Maximal difference>±0.1 mean O.D.
AEC: compensation of thickness	Maximal difference>±0.1 mean O.D.
AEC reproducibility	Coefficient of variation>0.05
ESAK reproducibility	Coefficient of variation>0.05
Film/screen contact	Visible areas of poor contact on the film
Uniformity of compression force	Difference of distances>1% SID
Luminance of viewing boxes	Luminance<2000 cd/m^2

RMI 156 Phantom: An accreditation phantom was used as standard object: RMI 156 was recommended by the CRP research group. Besides RMI 156 is commonly used in a number of mammo-units worldwide.

This phantom is designed to test the performance of a mammographic system by a qualitative evaluation of the system's ability to image small structures similar to those found clinically. Identification of these structures is important in the early detection of breast cancer. The phantom includes 16 various sets of test objects: six different size nylon fibers simulate fibrous structures in ducts (from 0.4 mm to 1.56 mm), five groups of simulated micro-calcifications (from 0.16 mm to 0.54 mm), and five different size tumor-like masses (from 0.25 mm to 2.0 mm). All the objects are insert in wax block. RMI 156 phantom approximates a 40 to 45 mm compressed breast. Exposure parameters of the phantom were similar to those for breast in CC projection. The scheme of RMI 156 is given below.

APPENDIX III

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REFERENCES

[1] FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, WORLD HEALTH ORGANIZATION, International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, Safety series No. 115, IAEA, Vienna (1996).

[2] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Radiological Protection and Safety in Medicine, ICRP Publication 73, Pergamon Press, Oxford and New York (1996).

[3] INTERNATIONAL ATOMIC ENERGY AGENCY, Radiation Doses in Diagnostic Radiology and Methods for Dose Reduction, IAEA-TECDOC-796, Vienna (1995).

[4] INTERNATIONAL ATOMIC ENERGY AGENCY, Optimization of the Radiological Protection of Patients undergoing Radiography, Fluoroscopy and Computed Tomography (Final Report of a Coordinated Research Project in Africa, Asia and Eastern Europe), IAEA-TECDOC-1423, Vienna (2004).

[5] EUROPEAN COMMISSION, European Guidelines on Quality Criteria for Diagnostic Radiographic Images, Rep. EUR 16260 EN, Luxembourg (1996).

[6] EUROPEAN COMMISSION, The European Protocol for the Quality Control of the Physical and Technical Aspects of Mammography Screening. In: European Guidelines for Quality Assurance in Mammography Screening, 3d Edition, Office for Official Publications of the European Communities, Luxembourg (2001).

[7] ZOETELIEF, J., PERNIČKA, F., ALM CARLSSON, G., DANCE, D.R., DeWERD, L.A., DREXLER, G., JÄRVINEN, H., KRAMER, H.-M., NG, K.-H., Dosimetry in diagnostic and interventional radiology – International Commission on Radiation Units and IAEA activities (IAEA-CN-96/39), Proceedings of the International Symposium on Standards and Codes of Practice in Medical Radiation Dosimetry, Vienna, 25-28 November 2002. IAEA, Vienna (2003), 387-404.

[8] EUROPEAN COMMISSION, European Protocol on Dosimetry in Mammography, Rep. EUR 16263 EN, Luxembourg (1996).

[9] PERNIČKA, F, DANEŠ, J., GICZI, F., MILU, C., NIKODEMOVÁ, D., STANISZEWSKA, M.A., ORESEGUN, M., MACCIA, C., PADOVANI, R., VAÑÓ, E., Comparison of air kerma measurements in mammography using thermoluminescent dosimeters ((IAEA-CN-96/47)), Proceedings of the International Symposium on Standards and Codes of Practice in Medical Radiation Dosimetry, Vienna, 25-28 November 2002. IAEA, Vienna (2003), 449-456.

[10] AMERICAN COLLEGE OF RADIOLOGY, Mammography Quality Control for Medical Physicists, ACR, Reston, VA (1992).

DEFINITIONS

The following definitions apply for the purposes of the present publication only:

Absorbed dose

Absorbed dose, D = dE/dm, where dE is the mean energy imparted by ionizing radiation to matter in a volume element and dm is the mass of matter in the volume element.

Accuracy

The closeness of an observed value of a quantity to the true value.

Anti-scatter grid

Device to be placed before the image reception area in order to reduce the incidence of scattered radiation upon that area and thus increase the contrast in the X ray pattern.

Artefact

Any unwanted structure or pattern visible in an image, not including noise.

Automatic exposure control (AEC)

A device which determines and provides automatically the exposure needed to produce an image of adequate optical density, by sampling the X ray intensity at the image receptor.

Average glandular dose

Reference term (ICRP 1987) for radiation dose estimation for X ray mammography, i.e. the average absorbed dose in the glandular tissue (excluding skin) in a uniformly compressed breast of e.g. 50% adipose, 50% glandular tissue composition.

Base density

The optical density due to the supporting base of the film alone.

Base plus fog density

The optical density of a film due to its base density plus any action of the developer on the radiographically unexposed emulsion.

Baseline value

Reference value of a functional performance characteristic, which is obtained immediately following an acceptance test in one or a series of constancy tests and used as a base for comparisons for the evaluation of results of consecutive constancy tests.

Beam alignment

The degree of overlap between the X ray beam and the image receptor such that the whole X ray field is both centred and contained within the image receptor.

Beam limiting device

Device to limit the extent of the radiation beam.

Breast compression device

A radiotransparent paddle used to help hold the breast stationary and eliminate blurring due to motion, to help separate structures within the breast and to decrease the thickness of breast tissue, minimizing the amount of radiation used and the amount of scattered radiation reaching the film.

Brightness

Quantity of light emitted by or reflected from any surface.

Characteristic curve

A graph of the relationship between the optical density of the X ray film (ordinate) and the logarithm of the exposures given to the film (abscissa).

Consistency of output

The variation in measured X ray output when a number of measurements are performed on an X ray tube and generator with a dosimeter capable of demonstrating a high degree of precision and the radiographic factors remain constant.

Consistency

The degree of variation of a measured parameter when a number of measurements under identical conditions are performed with an instrument capable of demonstrating a high degree of precision.

Constancy test

Quality test, repeated at specific intervals, to establish and document changes of the initial status of a piece of equipment or its components, described by baseline values.

Contrast detail phantom

A test object used in the assessment of imaging systems, which employs details of different sizes and contrasts.

Cranio-caudal projection

One of the routine views for mammography. The detector system is placed caudal (below the breast) and the vertical X ray beam is directed from cranial to caudal (downward through the breast).

Density control setting

The control which enables the optical density which is produced by an AEC system to be varied in discrete steps.

Diagnostic reference levels

Dose levels in medical radiodiagnostic practices or, in the case of radiopharmaceuticals, levels of activity, for typical examinations for groups of standard-sized patients or standard phantoms for broadly defined types of equipment. These levels are expected not to be exceeded for standard procedures when good and normal practice regarding diagnostic and technical performance is applied.

Entrance surface air kerma

The air kerma measured free-in-air (without backscatter) at a point in a plane corresponding to the entrance surface of a specified object, e.g. a patient's breast or a standard phantom.

Entrance surface dose

Absorbed dose in air, including the contribution from backscatter, assessed at a point on the entrance surface of a specified object, e.g. a patient's breast or a standard phantom.

Equivalent dose

The equivalent dose (H_T) is the absorbed dose, in tissue or organ T weighted for the type and quality of radiation R. It is given by: $H_{T,R} = w_R D_{T,R}$, where $D_{T,R}$ is the absorbed dose averaged over tissue or organ T, due to radiation R, w_R is the radiation weighting factor.

Exposure factors

The settings of X ray tube voltage (kV), tube current (mA) and exposure time (s).

Film gamma

The gradient of the “straight line” portion of the characteristic curve of an X ray film.

Filtration

Modification of characteristics of ionizing radiation on passing through matter.

Fog

The density added to a radiographic image due to unwanted action of the developer on the radiographically unexposed film emulsion or by light, ionizing radiation or heat exposure during storage, handling and processing.

Guidance level for medical exposure

A value of dose, dose rate or activity selected by professional bodies in consultation with the Regulatory Authority to indicate a level above which there should be a review by medical practitioners in order to determine whether or not the value is excessive, taking into account the particular circumstances and applying sound clinical judgment.

Half-value layer

Thickness of a specified material which, under narrow beam conditions, attenuates photon radiation according to its energy spectrum to an extent that the kerma rate, exposure rate or absorbed dose rate is reduced to one half of the value that is measured without the material.

Inherent filtration

The filtration provided by permanent materials through which the radiation beam must pass before emerging from the radiation source. For X ray tubes it is the filtration inherent in the structural components of the X ray tube head: the glass of the X ray tube, the insulating oil, the seal of the X ray port.

Kerma

Kinetic energy released in material by ionizing radiation. Kerma is determined as a quotient of dEtr by dm where dEtr is the sum of the initial kinetic energies of all the charged ionizing particles liberated by uncharged ionizing particles in a material of mass dm

Kilovoltage (kV) compensation

The ability of an AEC to maintain constant optical density on the films when the kV setting has been changed

Limiting value

Value of a parameter which, if exceeded, indicates that corrective action is required.

Medical exposure

Exposure applying to the following groups: patients as part of their own medical diagnosis or treatment; individuals as part of occupational health surveillance; individuals as part of health screening programmes; healthy individuals or patients voluntarily participating in medical or biomedical, diagnostic or therapeutic, research programmes; individuals as part of medico-legal procedures.

Medical physics expert

An expert in radiation physics or radiation technology applied to exposure, whose training and competence to act is recognized by the competent authorities, and who, as appropriate, acts or gives advice on patient dosimetry, on the development and use of complex techniques and equipment, on optimization, on quality assurance, including quality control, and on other matters relating to radiological protection, concerning exposure.

Medio-lateral projection

One of the routine views for mammography. The detector system is placed lateral to the breast and the horizontal X ray beam is directed from medial to lateral aspect through the breast.

Net optical density

Total film density minus base plus fog density.

Object contrast

The inherent differences in X ray attenuation in the object being imaged.

Optical density

The degree of blackening of processed X ray or photographic film. Numerically equal to the decadal logarithm of ratio of light incident on the film to that transmitted through the film.

Optimization

Any process or procedure which ensures that doses due to appropriate medical exposure for radiological purposes are kept as low as reasonably achievable (ALARA) consistent with obtaining the required diagnostic information, taking into account economic and social factors.

Organ dose

Average absorbed dose in a specified tissue or organ of the human body.

Phantom

Used to absorb and/or scatter radiation equivalently to a patient, and hence to estimate radiation doses and test imaging systems without actually exposing a patient. It may be an anthropomorphic or a physical test object.

Precision

The variation, usually relative standard deviation, in observed values.

Qualified expert

Person having the knowledge and training needed to carry out physical, technical or radiochemical tests enabling doses to be assessed, and to give advice in order to ensure effective protection of individuals and the correct operation of protective equipment, whose capacity to act as a qualified expert is recognized by the competent authorities. A qualified expert may be assigned the technical responsibility for the tasks of radiological protection of workers and members of the public.

Quality assurance

All those planned and systematic actions necessary to provide adequate confidence that a structure, system, component or procedure will perform satisfactorily complying with agreed standards.

Quality control

Part of quality assurance. The set of operations (programming, coordinating, implementing) intended to maintain or to improve quality. It covers monitoring, evaluation and maintenance at required levels of all characteristics of performance of equipment that can be defined, measured and controlled.

Quality criteria

Criteria which characterize a level of acceptability for radiological images which could answer to any clinical indication. The characteristics include diagnostic requirements (image criteria, important image details), criteria for radiation dose to the patient (reference dose value), and examples of good imaging technique.

Quality management

All activities of the overall management function which determine the quality policy, objectives and responsibilities, and implement them by such means as quality planning, quality control, quality assurance and quality improvement within the quality system.

Radiation output (X ray output)

The air kerma measured free-in-air (without backscatter) per unit of tube loading at a specified distance from the X ray tube focus and at stated radiographic exposure factors.

Radiographic contrast

The difference of optical density between two adjacent elements of a radiographic image.

Reference dose value

Value of a specific dose quantity obtained by patient dose evaluation, which may be used to quantify the diagnostic reference level.

Reproducibility

Indicates the reliability of either a measuring method or test equipment. The results under identical conditions should be constant.

Resolution

The degree to which fine detail of an object can be reproduced in a radiographic, fluoroscopic, television or other image. The smallest object or highest spatial frequency of a given contrast that is just perceptible.

Safe light

Source of illumination which provides visibility in a darkroom without modifying appreciably the optical density of the film.

Screen film contact

The close proximity of the intensifying screen to the emulsion of the film, necessary to reduce blur.

Screen film sensitivity

The sensitivity S is equal to the quotient Ko/Ka where Ko = 1mGy and Ka is the air kerma free-in-air for the net density D = 1.0, measured in the film plane.

Secondary standard

Standard whose value is assigned by comparison with a primary standard of the same quality.

Standard breast

A model used for calculations of glandular dose consisting of a 40 mm thick central region comprising a 50: 50 mixture by weight of adipose tissue and glandular tissue surrounded by a

5 mm thick superficial layer of adipose tissue. The standard breast is semi-circular with a radius of >80 mm and a total thickness of 50 mm.

Standard breast phantom

A PMMA (polymethylmethacrylate) phantom to represent approximately the average breast (although not an exact tissue-substitute) so that the X ray machine operates correctly under automatic exposure control and the dosimeter readings may be converted into dose to glandular tissue.

Standards dosimetry laboratory

A laboratory designated by the relevant national authority for the purpose of developing, maintaining or improving primary or secondary standards for radiation dosimetry.

Thermoluminescent dosimeter (TLD)

A radiation dosimeter which contains a substance that, when properly annealed and exposed to ionizing radiation, emits light after thermal stimulation in proportion to the radiation dose received.

Tolerance

The maximum allowed variation in a measured value expressed as a fraction of a mean value of an appropriate number of measurements.

Total filtration

The sum of effective thickness of materials traversed by the primary X ray beam before it enters the patient.

Note: The sum of effective thickness is the sum of aluminum equivalent thickness of inherent and additional filtration.

Tube potential

The potential difference (kilovolt, kV) applied across the anode and cathode of the X ray tube during a radiographic exposure.

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Rehani, M.M.	International Atomic Energy Agency
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Wrixon, A.D.	International Atomic Energy Agency

Consultants Meetings

Prague, Czech Republic: November 1999
Vienna, Austria: December 2000