Evaluation of the accomplishment of the Brazilian regulation “Portaria Nº 453/98” in mammography x-ray sets installed in the Sergipe state, Brazil.

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Abstract. In this work was done an evaluation of the accomplishment of the regulation “Portaria Nº 453/98” of the Ministry of Health in mammography machine installed in the Sergipe state, Brazil. The quality control procedures were carried out in 23 equipments currently used in clinical routine. The testing methodologies are described in documents of two Brazilian institutions: ANVISA and Brazilian College of Radiology. The following results are expressed on percentage of equipments that were in conformity with minimum requirement of the regulation, considering separately the three kinds of the tests above mentioned. About mechanical parts: compression force (70%), coincidence between the radiation field and the radiographic film (80%) and distortion of the plate compression (47%). About image analysis: performance and reproducibility of the automatic exposure control (54% and 63% respectively), and image quality (84%). In the item beam radiation quality: reproducibility and linearity of the air rate kerma (100% and 84% respectively). In the automatic processors were monitored the following parameters: temperature (70%), pH (65%) and dry-to-dry processing time (25%). The unsatisfactory test results of the plate compression and automatic exposure control jeopardize the expected balance between dose distribution and image quality. This unbalance has significant effects on image nonuniformity and/or a localized dose increment. Even though the results of the tests of image quality and air Kerma rate can be considered satisfactory they are not enough for a full evaluation because they do not take into account the interaction with the object of interest: the breast. The results of the time processing suggest that the operators must change the parameters of the technique employed, attempting to maintain the image quality without resulting in an increase of the absorbed dose.

1. Introduction

In 2005, malignant tumors were responsible for 13 per cent of the nearly 58 million deaths worldwide from all causes, of which 502 thousand were cases of breast cancer. In Brazil, estimates for 2008 are also valid for 2009, indicate that there will 466,730 new cases of cancer and the higher incidence will be breast cancer with 49 thousand cases. In our state, Sergipe, the numbers of occurrence are about 310 cases, a rate of 29.92 % which represents the second highest rate in the whole country [1]. Premature detection of breast cancer, specifically the discovery of even small tumors, restricted to the breast parenchyma, is essential in order to increase the probability of success in the treatment and cure. The strategies used for premature detection of breast cancer are: the breast self-examination, made by the woman, the clinical examination of the breasts, performed by trained health professional, held periodically to mammography, ultrasound and a biopsy. Recent recommendations from the Brazilian Ministry of Health specify that self-examination should be included as an action of health education, serving the body self-knowledge, but it should never replace the clinical breast examination, and it not be adopted as a strategy isolated to premature detection [2]. Mammography then arises as an important tool in the actions of systematic control of breast cancer in the early detection through screening programs for segments of population-risk group, with periodic examinations. When compared to other methods of conventional radiodiagnostic,
mammography can be considered one of the most complex examinations to performed, because in this case is required high-quality images of the breast tissue, which has very small structures (less than 1 mm) with very similar attenuation coefficients, all associated with the concern about the patient dose [3]. Besides, mammograms with reduced quality images can lead to incorrect diagnosis, generating unnecessary biopsies and increasing the costs, cases that cancer is not detected or delay in the detection, beyond do not justify the exposure of the patient in both cases. In this manner, it is of great importance the implementation of measures for monitoring the performance of equipment, accessories and technical routines, to guarantee the accomplishment of satisfactory images, exposing the patient to doses as the low as possible [4]. Each country has regulations in order to specify the operational and technical requirements necessary to perform mammography. In Brazil this requirements are defined in the “Portaria 453/98” of the Brazilian Ministry of Health [5]. The National Health Surveillance Agency (in Portuguese, ANVISA) is the brazilian agency responsible for the sanitary control over production and marketing of products and services subject to sanitary surveillance. In this case, this agency certified and accredited the legal performance of mammography equipments. The Quality Certification Program in Mammography of the Brazilian College of Radiology describes several tests in order to evaluate the mammography quality standards [6][7]. The aim of this work was to evaluate the operating conditions of mammographic equipments in use at health clinics in Sergipe State of Brazil and to compare the obtained values with those defined in the actual regulations.

2. Materials and Methods

2.1. The sample

On this study were collected data and performed tests on 23 health care establishments, which represents all the establishments providing the service of mammography in the Sergipe State, among breast specialized clinics, diagnostic radiology clinics, and hospitals with mammography service. In such services were evaluated 23 conventional mammography, the majority was model GE-SENOGRAPHE 600T. The tests were performed between August and December 2007.

2.2. Materials used in realization the tests

For the tests were used materials and equipment listed below:

a) Radiographic Simulator, Model Phantom Mama. Made in acrylic, with three plates homogeneous 10x120x160 mm and a plate of wax 20x120x160 mm, which are implanted test structures such as fiber, microcalcifications, tumors mass, low levels of contrast and spatial resolution;

b) Densitometer, Mark VICTOREEN, Model 07-443;

c) Balance for compression test in mammography, common model;

d) Chassis and films in use in services;

e) Two coins of same radius;

f) Foam rubber;

g) Thermometer, Digital Multimeter, Model MD-380, Mark INSTRUTHERM;

h) Conjoint Dosimeter: Ionization chamber / Electrometer, Mark RADCAL CORP, Model 2025C;

i) Especial pH tape, Mark MHCHEREY - NAGEL, Ref 921.10;

j) Acrylic plates of different thicknesses.

2.3. Methods

The data were collected during regular inspections of the inspector’s teams of the Aracaju Municipal and Sergipe State Departments of Health.

2.3.1. Testing the equipment performance

It was evaluated the performance of devices and accessories that influence directly and indirectly in image quality in mammographic. The aim of any radiodiagnostic procedure is to obtain a high quality image while keeping the dose to the patients as low as practicable. Significant problems and wide
variations in the current mammography practice could be avoided by performing regularly a quality control programme (QCP) [8]. The following items were measured: the collimation system, the performance of automatic exposure control, the compression force, the compression plate alignment, the reproducibility and linearity of the air kerma rate, the image quality and the processing system. All these tests are described in the instructions for conducting the tests on image quality and guidelines for the Quality Certification Program in Mammography of the Brazilian College of Radiology (BCR) [4] and the document “Radiodiagnosis medical: Performance of Equipment and Safety of the National Agency of Sanitary inspection” [5]. In the next subsections a brief description of each executed test and the acceptance criteria are presented.

2.3.1.1. Collimation system

After inserting a film inside the chassis in the bucky, a second chassis was plated on the platter support projected about 3 cm in the direction of the thorax wall. Two overlapping coins, with the same ratio, were positioned at 3 cm from the second chassis. The films were sensitized using the manual mode at 28 kV and 20 mAs. After processing, the images of coins in each film were used to estimate the coincident between them. It is accepted deviations lower than 1% of DFF (distance source-film) for the difference between the radiation field and the film.

2.3.1.2. Performance of Automatic exposure control (AEC)

A series of expositions using several acrylic plates with thickness from 2 to 5 cm simulating different breasts were made. The equipment operating in the semi-automatic mode at one fixed tube voltage normally used clinically (28 kV) and AEC enabled was made each exposition. The Optical Density (OD) values were measured in the processed film. The maximum acceptable variations in the OD values must be in ±20% when compared to the first value found with the image related to thickness of 5 cm.

2.3.1.3. Compression force

The force applied by the compression device was measured positioning the balance on the breast support and making the compression. To be qualified, the value measured should be between 11 and 18 kg.

2.3.1.4. Compression device alignment

After positioning a foam rubber on the support of the breast, the pedal of compression was moved to compress the maximum of force in which the equipment was selected. The distortion that the platter made in the foam on all four corners was registered in millimeters. The difference between the highest and lowest value found to be less than 5 mm indicating platter alignment.

2.3.1.5. Reproducibility and Linearity of the air kerma rate

While the equipment in manual mode, tube voltage of 28 kVp, it was defined three different values of mAs according to the types of breasts exposed clinically: fine, medium and dense. The ionization chamber was positioned on the breast support, centered at a distance of approximately 4 cm from the thorax wall. Selected each mAs, four repeated expositions were done. To be reproducible the value of the coefficient of variation (CV) found had to be less than 10% and linearity (L) less than 20%, these values are found from the equations 1 and 2 respectively.

\[ CV = \frac{\sigma}{k_{\text{mean}}} \]  

\[ L(\%) = 100 \cdot \frac{R_1 - R_2}{(R_1 + R_2)/2} \]
In the equation 1, $\sigma$ is the standard deviation, $k_{\text{mean}}$ the average rate of air kerma. In the equation 2, from the relationship between average reading of values of exposure and the value corresponding of each mAs, the lower and higher values found are related to the R1 and R2 respectively.

### 2.3.1.6. Processing System

In order to evaluate this system, the items temperature, processing time (dry to dry) and pH were checked. The pH measurement was carried out in the mean components (revealing, fixative and water) of the three stages of the revelation process. We considered a satisfactory value when it was in the range defined by the film processor manufacturer.

### 3. Results and Discussion

#### 3.1. Performance of equipment valued

The results will be presented in the percentage term of the amount of equipment that are in conformity and not conform to the values permitted and required by the brazilian regulations.

##### 3.1.1. Collimation system

The test has the objective to verify the coincidence between the real and the expected radiation field. The last is defined by the collimator adjustment to film dimensions. The result shows that 15% of the equipment the field of X-ray exceeds the margin of the chest wall of the film in more than 1% of DFF. Figure 1 shows the relationship between the percentages of conformity of equipment with the non-conform.

![Figure 1](image_url)  
**Figure 1**: Results obtained in the evaluation of the alignment between the radiation field and the film.

The X-ray field larger than the size of the film means one larger patient exposure, especially when the field is advanced in the border concerning the chest wall. This unnecessary exposure increases the scatter radiation that sensitizes the film increasing background blackening in the image, reducing therefore the contrast.

##### 3.1.2. AEC performance

It were evaluated 20 equipments, 3 of the 23 mammography did not have automatic exposure control. The results show, according to the figure 2, that 38% of the equipment presented an unsatisfactory performance in this module.
With this test can guarantee that the system of automatic exposure control maintain the optical density of the film within a range enabling to reach blackening and contrast necessary in the image with the minimum exposure time. The use of the AEC in these equipments that do not follow the regulations has as consequence the lack of reproducibility in the applied dose.

3.1.3. Compression force

The adequate breast compression is one of the most important pre-requisites for obtaining a mammographic image of good quality. A compression less than 11 kg does not provide adequate uniformity of breast tissue and some structures are overlapped in the image, on the other side a compression greater than 18 kg cause discomfort over the patient. Figure 3 illustrates the situation found in the evaluated devices. In 40% of equipment the intensity of compression had considered out of range appropriate for the compression of the breast.

3.1.4. Compression device alignment

The platter that compresses the breast should be constructed and installed so that after the process of compression, it is aligned parallel to the support of the breast, making the breast tissue a uniform object.
A inclination greater than the acceptable limits (5 mm) means that the breast has a thick irregular in the platter and this manner the image does not present with uniform optical density. Figure 4 shows the results obtained in this test.

![Figure 4: Result of the evaluation of the compression device alignment](image)

The results show a worrying situation because, more than half, 55% of equipment presents with the compression platter desalinated. We believe that the main possible causes are prolonged use, little handling care and low quality of material components.

3.1.5. Reproducibility and Linearity of the air kerma rate

This test evaluates the performance of the X-ray tube through the reproducibility and linearity of exposure. The results show, according to the figure 2, that 95% of the equipment can be considered as reproducible and 85% linear, related to X rays exposure. Only one equipment had a coefficient of variation of 0.08 attributed to 8% that is a value below of the 10%, tolerance value established by ANVISA, but above the 5% value that is recommended by the same law.

![Figure 5: Reproducibility of the air kerma rate](image)
3.1.6. Processing System

The processing of radiographic film is a very important stage in obtaining an image of quality. The automatic processing should be evaluated daily to testify if parameters such as temperature, processing time and pH are within the permitted range. Analyzing the figures 7, 8 and 9, is perceptible a large quantity of automatic processing operating outside the standards required by manufacturers, principally with regard to processing time, where only 35% of processing showed satisfactory results.

Figure 6: Linearity of the air kerma rate

Figure 7: Temperature
The Figure 10 shows the relationship between the evaluated equipments and the conformity indicator for the proposed tests. The results show that only one equipment fulfils all items that are part of the tests regulated by ANVISA, 8 equipments (34%) fulfill eight items, and 4 equipments (43.47%) fulfill six tests. Therefore, it can evaluate that taking into account the 13 tests proposed by ANVISA [5], the 4 equipments (43.47%) related to the six items is a number too high for the quality standard that the examination of mammography requires. This fact should be directly related to equipment’s age, where 85% of them have more than ten years of manufacturing, beyond the lack of a continuous programmer of quality control, coupled with a lack of regular maintenance.
4. Conclusions

The evaluation of the technical situation of mammographic equipment currently in use in the Sergipe State, Brazil showed that many of them need maintenance. Important parameters that act directly on the quality of the image are outside the range required for its adequate functioning. The most common defect is in the compression device, where more than half are desalinated decreasing the uniformity of breast tissue and thus contributing to an unsatisfactory image quality. A similar situation have the processing time of the films in processing machines, where 65% of equipment process the film at different times those recommended by manufacturers. To optimize the quality of the images and minimize the doses in patients in those services of mammography is necessary to implement routines of work, improving the technical operators and consciousness of its directors about the importance of periodic quality control tests in the equipments. Other measurements using a phantom are being realized by our group to evaluate the effects of these factors in the image quality and dose.

5. References


