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Quality control of Cone Beam Computed Tomography (CBCT) equipment used in dental applications according to RDC 611

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Abstract: Cone Beam Computed Tomography (CBCT) is a powerful and a versatile tool that has revolutionized the way dentists plan and perform treatments. Several advantages are attributed to this modality, including: the equipment is compact, image acquisition is fast, it has high spatial resolution and produces detailed images. However, when compared to other imaging diagnostic methods used in dentistry, CBCT often administers higher doses, emphasizing the need for careful use and the application of radiation protection principles. For example, the effective dose of an intraoral radiograph is less than 1.5 μSv. The effective dose of a panoramic radiograph ranges between 2.7 and 24.3 μSv, while the effective dose of a CBCT scan ranges from 64 to 674 μSv. This study evaluated a CBCT device that underwent the tests recommended by current Brazilian regulations, assessed the doses generated by the device, and implemented a quality assurance program in a dental radiology service that uses this technology, to promote maximum efficiency, safety, and accuracy, optimizing the radiation doses administered and ensuring the quality of the images acquired. This is the first step in the development of a quality control (QC) protocol for the service under evaluation. It is part of the implementation of a certification program to be applied initially in the Galeão Air Force Hospital (HFAG) service, which will serve as a model for other radiology services of the Brazilian Air Force.

Keywords: CBCT, CQ protocol, Radiology Service, Dental Applications.

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Controle de qualidade de um equipamento de Tomografia Computadorizada de Feixe Cônico (TCFC) Odontológico de acordo com a RDC 611

Resumo: A Tomografia Computadorizada de Feixe Cônico (TCFC) é uma ferramenta poderosa e versátil que revolucionou a maneira como os dentistas planejam e realizam tratamentos. Várias vantagens são atribuídas a essa modalidade, entre elas: o equipamento é compacto, a aquisição de imagens é rápida, tem alta resolução espacial e produz imagens detalhadas. No entanto, quando comparado a outros métodos de diagnóstico por imagem usados na odontologia, a CBCT frequentemente administra doses mais altas, enfatizando a necessidade de uso cuidadoso e a aplicação de princípios de radioproteção. Como exemplo, a dose efetiva de uma radiografia intraoral é menor que 1,5 μSv. A dose efetiva de uma radiografia panorâmica varia entre 2,7 e 24,3 μSv, enquanto a dose efetiva de um exame de CBCT varia de 64 a 674 μSv. Este estudo avaliou um aparelho de TCFC que passou pelos testes recomendados pela regulamentação brasileira vigente, avaliou as doses geradas pelo aparelho e implementou um programa de garantia da qualidade em um serviço de radiologia odontológica que utiliza essa tecnologia, para promover a máxima eficiência, segurança e precisão, otimizando as doses de radiação administradas e garantindo a qualidade das imagens adquiridas. Este é o primeiro passo no desenvolvimento de um protocolo de controle da qualidade (CQ) para o serviço em avaliação. Faz parte da implementação de um programa de certificação a ser aplicado inicialmente no serviço do Hospital da Força Aérea do Galeão (HFAG), que servirá de modelo para outros serviços de radiologia da Força Aérea Brasileira.

Palavras-chave: CBCT, Protocolo de CQ, Serviço de Radiologia, Aplicações Odontológicas

1. INTRODUCTION

Cone Beam Computed Tomography (CBCT) is a powerful and versatile tool that has revolutionized the way dentists plan and perform treatments. Unlike CT scanners, which have a narrow beam and are used in most medical procedures, cone beam equipment allows the acquisition of images of a larger anatomical region in a single exposure. This fact causes a significant reduction in radiation dose of the procedure [1]. The data is processed by a computer to generate detailed three-dimensional images of the areas examined and, for this reason, the technique has been widely used in dentistry. Several advantages are attributed to this modality, including: the equipment is compact, image acquisition is fast (which improves the efficiency of diagnosis and treatment planning), it has high spatial resolution, produces detailed images and generates lower radiation dose values, compared to those associated with medical computed tomography (which is a significant benefit for patients and professionals) [1]. It is difficult to establish how many times more radiation CBCT releases compared to intraoral and extraoral radiographs, because the radiation dose of CT varies according to the scanned area, the thickness of the slice, the adjustments of the device, as well as the type of CBCT machine [1]. However, when compared to other imaging diagnostic methods used in dentistry, CBCT often administers higher doses, emphasizing the need for careful use and the application of radiation protection principles. As an example, the effective dose of an intraoral radiograph is less than 1.5 μSv. The effective dose of a panoramic radiograph varies between 2.7 and 24.3 μSv, while the effective dose of a CBCT scan ranges from 64 to 674 μSv [1, 2, 3, 4, 5].

Quantifying the level of patient exposure in any medical procedure is complex due to the variation of several parameters, such as patient thickness, size of the irradiation field, etc. This quantification becomes even more complex in procedures that involve movement of the X-ray source and variable exposure times, as is the case with CBCT [5, 6].

To determine the levels of exposure in CBCT, kerma-length product (P_{KL}) or kerma-area product (P_{KA}) are normally used, thus determining dose indicators. This measurement requires some special care and precision in the measurement process.

1.1. Kerma-length product and kerma-area product:

The main quantities used to assess dosimetry in cone beam tomography are: kerma-length product (P_{KL}) and kerma-area product (P_{KA}), quantities derived from basic physical quantities. The kerma-length product (P_{KL}) is the quantity used in radiological physics, particularly in computed tomography (CT), to assess the amount of energy that is transferred to air by the x-ray beam over a specific length, z. The air kerma–length product is the integral of the air kerma free-in-air over a line L parallel to the axis of rotation of a CT scanner [7, 8]. Kerma is a quantity that measures the energy absorbed per unit mass, while length refers to the length of the x-ray beam used during the scan. It is defined by equation 1:

$$P_{KL} = \int_L k(z)dz \tag{1}$$

The SI unit of P_{KL} is Gy × m. Knowledge of the values of kerma-length products is important in assessing the risk of exposure to ionizing radiation and in optimizing the radiation dose in medical procedures.

The quantity air kerma–area product is the integral of the air kerma free-in-air over the area A of the x-ray beam in a plane perpendicular to the beam axis. (equation 2). It is a surrogate measurement for the entire amount of energy delivered to the patient by the X-ray beam [8].

$$P_{KA} = \iint_A k(x,y)dxdy \tag{2}$$

P_{KA} is the integral of the air kerma applied to the projection of the area of the X-ray beam onto the detector. The SI unit of P_{KA} is Gy×m^2. It is commonly used in diagnostic radiology to assess the radiation dose absorbed by patients during imaging exams, such as radiographs, computed tomography scans and fluoroscopy.

In Brazil, to comply with the requirements of ANVISA's Collegiate Board Resolution RDC 611 [9], published in 2021, many medical and dental radiology services have implemented Quality Assurance programs [10], like international practices [11]. Developing these Quality Assurance programs in Dental Radiology is essential in the current landscape of dental radiology services to ensure quality care, particularly in services that use ionizing radiation. This aspect must be closely monitored due to the risks involved [6].

Most CBCT equipment offers a standard dental protocol with acquisition parameters and voxel sizes suitable for an average patient. However, the operator can select, from a range of dental protocols, the most one appropriated based on the clinical needs and anatomical characteristics of each patient. Since the primary radiation dose received by the patient depends on the irradiated region and the selected exposure parameters, it is important to choose the dental protocol that provides the lowest dose while offering the necessary diagnostic information [12, 13], always respecting the ALARA principle ("As Low as Reasonably Achievable"). Protocols should, therefore, be created to reduce absorbed doses in dental exams, as radiosensitive structures, such as the thyroid, salivary glands, and eyes, may be within or near the primary radiation field.

One of the fundamental steps in establishing a quality assurance program or even in certifying a service is to test the relevant parameters of the radiological equipment to correct possible inconsistencies in its operation. The values obtained in this first assessment will serve as a reference for monitoring its performance over time. Once the equipment reaches optimal operation by adapting all technical parameters, it will be possible to move forward in seeking quality certification.

This study aims to evaluate a CBCT device that has undergone the tests recommended by current Brazilian regulations, assess the doses generated by the device, and implement a quality assurance program in a dental radiology service that uses this technology, to promote maximum efficiency, safety, and accuracy, optimizing the radiation doses administered and ensuring the

quality of the images acquired. This is the first step in developing a QC protocol for the service under evaluation. It is part of the implementation of a certification program to be applied initially in the HFAG service, which will serve as a model for other radiology services of the Brazilian Air Force.

2. MATERIALS AND METHODS

The present study was developed in the dental radiology department of the Galeão Air Force Hospital (HFAG), located in Rio de Janeiro. The dental radiology department is equipped with 12 intraoral radiography devices, distributed across 12 consultation rooms, in addition to an Instrumentarium cone beam tomograph model Orthopantomograph OP300 (Figure 1).

Figure 1: Instrumentarium's Orthopantomograph OP300

Source: The authors

In addition to tomography, the device also allows for panoramic and cephalometric examinations, depending on the operator's initial selection. Despite being multifunctional, only the tomographic modality was evaluated in this study. The tomograph uses an X-ray tube with a nominal voltage of 90 kV. Parameters such as field of view (FOV - 3D area captured

by the scanner during the imaging process), current-time product, and nominal P_{KA} are variable and depend on the programs available for taking the exam (Table 1).

Table 1: Tomographic examination programs available on OP300

TUBE VOLTAGE (kVp)	FOV (mm^2)	DENTAL PROTOCOL	CURRENT (mA)	EXPOSURE TIME (s)	NOMINAL PKA ($mGy \times cm^2$)
90	61 x 41	1	3.2	1.2	29
		2	10	2.3	183
		3	8	6.1	382
		4	10	6.1	477
	61 x 78	1	3.2	2.3	59
		2	10	4.9	381
		3	6.3	13	623

In the present study, the quality control (QC) protocol proposed by Lisboa [6] was implemented, which provided a step-by-step guide for performing QC procedures in compliance with national legislation, using international documents as references [14, 15, 16]. The minimum instrumentation required for performance testing includes a solid-state detector capable of measuring parameters such as tube voltage, exposure time, air kerma (and air kerma rate), and half-value layer; an ionization chamber calibrated for air kerma or kerma- area product; an image quality phantom that allows for the measurement of image uniformity and the evaluation of CT numbers; and an image plate from a computed radiography system to measure the field of view.

The quality control tests on equipment, in tomographic mode, were conducted in accordance with the requirements outlined in the current Brazilian regulations — ANVISA's Collegiate Board Resolution (RDC) number 611 [9]. There are 18 evaluations established in Normative Instruction number 94, from May 2021 [17]. They are necessary to verify the proper functionality of the tomograph, all its components, and other procedures related to the safety of those involved in radiography and the assurance of diagnostic quality (Table 2).

Table 2: CQ tests established on ANVISA's Normative Instruction 94

QC TESTS		
X-Ray tube	1	Half value layer (HVL)
	2	Tube voltage accuracy
	3	Tube voltage reproducibility
	4	Exposure time accuracy
	5	Exposure time reproducibility
	6	Dose value (PKA)
	7	Dose indicator accuracy
	8	Air kerma rate accuracy
	9	Field of view
Physical space/Accessories	10	Radiometric survey
	11	Reporting room illuminance
	12	Monitor luminance for reports
	13	Integrity of radiation protection accessories
Tomographic image	14	Image artifacts
	15	Image uniformity
	16	CT number indicated value accuracy
	17	CT number uniformity
	18	Noise

2.1. X-Ray tube

The parameters related to the equipment's X-ray tube were evaluated using a Radcal Accu-Gold AGMS-D solid-state detector connected to a digitizer, which transmits the information to a computer (Figure 2).

Figure 2: Detector Accu Gold AGMS-D positioned on the tomograph image receptor

Source: The authors

Once the detector is multiparametric, the parameters as voltage accuracy and its reproducibility, exposure time accuracy and its reproducibility, and half-value layer were evaluated in a single exposure. Six exposures were performed for the same program suggested by the equipment (which offered the longest exposure time — FOV 61 x 78 mm², current 6.3 mA, and 13 seconds of exposure time).

P_{KA} values were determined using a pencil-type ionization chamber, manufactured by Radcal, model 10X6-3CT, paired with an electrometer (Accu Dose 9095). This pencil-type ionization chamber was placed in the center of the image detector. An image plate (IP) from a CR radiography system was used to determine the actual field size, (i.e. area = length, b multiplied by height, h) employed during irradiations. Figures 3 and 4 illustrate the experimental setup. From the air kerma measurement, the kerma-length product was calculated using equation 3 (length of the chamber = 10 cm) and from this P_{KL} value, using equation 4, the P_{KA} value was calculated.

$$P_{KL} = 10\ (\text{cm}) \times \text{kerma}\ (\text{mGy}) \tag{3}$$

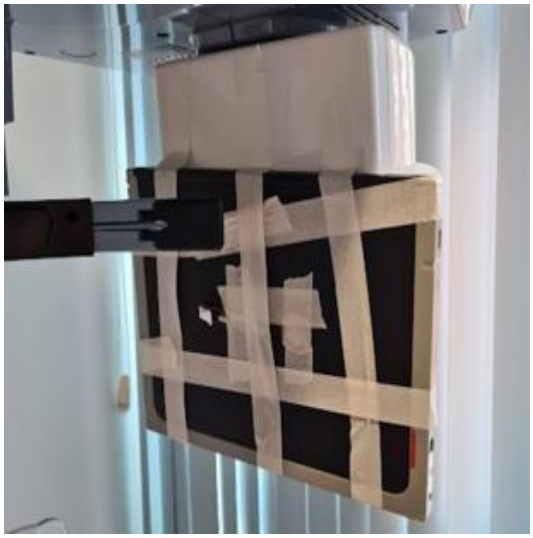
$$P_{KA} = P_{KL}\ (\text{mGy} \times \text{cm}) \times h\ (\text{cm}) \tag{4}$$

The parameters dose indicator accuracy and air kerma rate accuracy were analyzed using the Accu-Gold AGMS-D solid-state detector placed in the center of the CBCT equipment's imaging detector.

Figure 3: Ionization chamber and electrometer

Source: The authors

Figure 4: IP positioned on the image receptor to determine the field size used on irradiation



Source: The authors

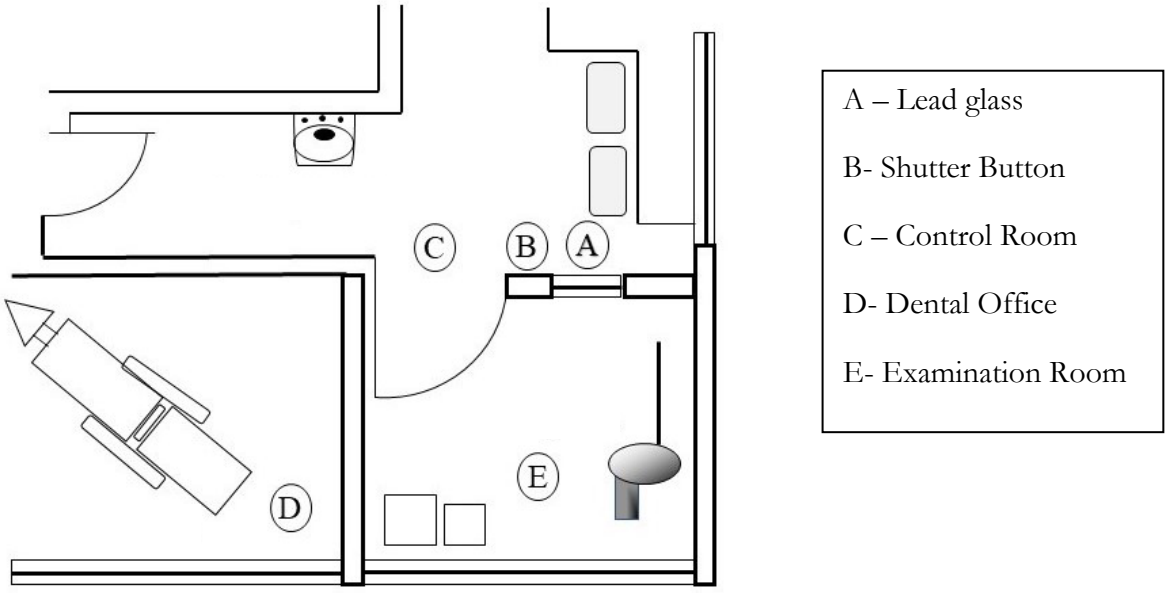
2.2. Physical space and radiation protection accessories

The radiometric survey was conducted using a Radcal 9095 electrometer and an 1800 cm^3 ionization chamber, model 10X6-1800 (Figure 5). Measurements were taken at the points indicated in the room diagram (Figure 6). The areas that were analyzed were those surrounding the exam room. The measurements were made in places where there is a greater presence of people. Points A, B and C refer to the control room, where the exam is performed. Point D refers to the dental office that is located next to the exam room (point E).

Figure 5: Ionization chamber positioned to perform the radiometric survey

Source: The authors

Figure 6: Diagram of the room with the points monitored during the radiometric survey



Source: The authors

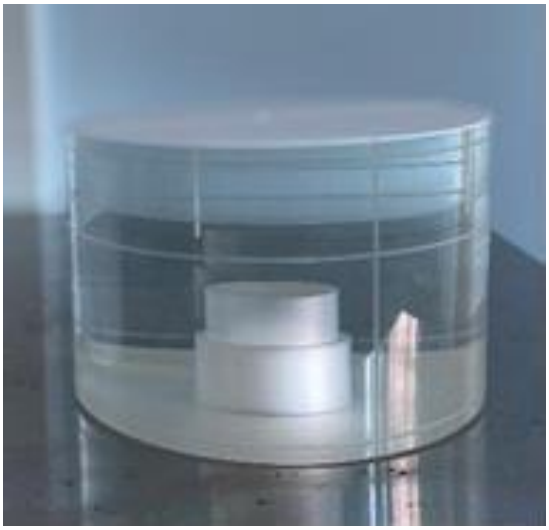
To evaluate the illuminance of the reporting room and the luminance of the primary and secondary monitors, a lux meter, model Light-o-meter P10 by Unfors, was used. The device was operated in ambient lighting mode.

The integrity of accessories and personal protective equipment was assessed through visual inspection.

2.3. Tomographic image

To evaluate the tomographic image, a phantom made of polymethyl methacrylate (PMMA) was exposed. The phantom consists of a homogeneous region — used for assessing image uniformity — and another region used to evaluate the indicated value and uniformity of CT numbers, with structures equivalent to materials such as air, PMMA itself, and polytetrafluoroethylene (PTFE), commonly known as Teflon. The phantom, supplied by the X-ray equipment manufacturer, is shown in Figure 7.

Figure 7: PMMA phantom for image quality control



Source: The authors

Next, a visual inspection of the phantom's tomographic images was performed using software integrated into the tomographic system, as recommended by the European Protocol [15] and the Spanish Quality Control Protocol in Diagnostic Radiology [16]. The evaluation included the presence or absence of artifacts in the image, the indicated value and uniformity of the CT number, and noise.

3. RESULTS AND DISCUSSIONS

3.1. X-ray Tube

Table 3 presents a comparison between the results obtained from measurements of the parameters related to the X-ray tube voltage and exposure time, and the tolerances established by IN 94/RDC 611 [9].

Table 3: Comparison between the results and the tolerances established by IN 94/RDC 611

	NOMINAL VALUE	MEASURED VALUE	DEVIATION	IN 94 TOLERANCE
Half Value Layer (HVL)	**> 3.2 mm Al**	**5.78 mm Al equivalente**	-	**3.0 mm Al equivalent for three-phase equipament at 90 kVp**
Tube voltage	**90 kVp**	**90.80 kVp** **90.90 kVp** **90.80 kVp** **90.90 kVp** **90.60 kVp** **90.60 kVp**	**Accuracy: 0.85 %** **Reproducibility: 0.33%**	**Deviation ≤ 10%** **Deviation ≤ 5%**
Exposure time	**13s**	**10.53s** **10.53s** **10.53s** **10.53s** **10.53s** **10.53s**	**Accuracy: 19%** **Reproducibility: 0%**	**Deviation ≤ 10%** **Deviation ≤ 10%**

The results show that the HVL, the accuracy and the reproducibility of the tube voltage comply with the tolerances established in the norm. The measured voltage showed minimal variation from the nominal value, indicating that the system was stable and delivered the nominal voltage value (accuracy deviation less than 1%). When evaluating the consistency of the results, the system also demonstrated high reproducibility, as the maximum deviation among the six readings was less than 0.5%.

The six-time readings were found to be inaccurate, with an accuracy deviation of 19%. However, the readings presented no variation. Although the measured values deviated by 19% from the protocol value, there was no variation among the obtained results, demonstrating measurement stability. Despite this non-compliance, the restriction threshold

established in the IN was not exceeded (20%). The technical support service needs to be contacted to adjust the X-ray equipment to comply the normative indices, ensuring its full functionality and preventing it from impacting other parameters, especially the patient dose, given the direct relationship between these two parameters.

To verify the reproducibility of the air kerma, six exposures were also performed using the same program suggested by the equipment (with the longest exposure time: FOV 61 x 78 mm², current 6.3 mA, and exposure time of 13 seconds), resulting in a reproducibility of 0.08%, demonstrating compliance with the legislation. According to IN 94, air kerma reproducibility must be ≤ 10%.

The height of the radiation field (h) was measured with a cassette used in computed radiography (CR) positioned at the detector entrance, yielding a result of (10.3 ± 0.1) cm. A radiopaque object was used as a reference to correct the image magnification effect. The field size was measured with a calibrated ruler in centimeters with a precision of 1 mm. According to the manufacturer's manual, the image detector area is 100 x 68.2 mm, confirming that the radiation field is confined to the device's detector.

The CBCT dental equipment studied in this work provides a dose estimate for each suggested technique before exposure. The calculated P_{KA} values were obtained by multiplying the measured P_{KL} values by the height of the irradiation field. However, the results showed that the nominal P_{KA} values were underestimated by up to 34% compared to the calculated P_{KA} values. In other words, the value indicated by the equipment is up to 34% lower than the measured representative dose value.

Table 4 shows the obtained results.

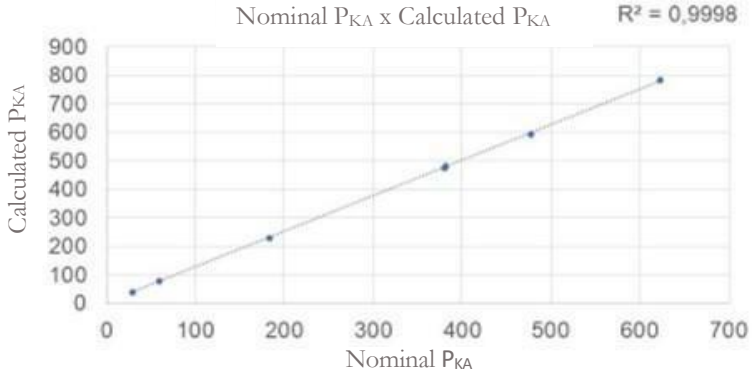
Table 4: Comparison between nominal and calculated P_{KA} values. The last column shows the percentage difference between these values

DENTAL PROTOCOL	NOMINAL P_{KA} (mGy×cm²)	CALCULATED P_{KA} (mGy×cm²)	DEVIATION (%)
1	29	38 ± 2	31
2	183	228 ± 12	25
3	382	482 ± 25	26
4	477	593 ± 30	24
1	59	79 ± 4	34
2	381	473 ± 24	24
3	623	784 ± 40	25

It is possible to see that the equipment does not provide accurate information about the exposure in patients. This fact may be directly related to the results obtained in the exposure time accuracy test. Therefore, adjustments in the equipment are necessary. Similar results can be found in the literature, such as those obtained in this study [18, 19, 20], which allows us to infer that most commercial brands provide underestimated doses. It is necessary to perform the necessary adjustments on the equipment to correct these underestimations.

Consequently, it was immediately requested that the representative dose values be adjusted through a correction factor. Figure 8 shows the linear adjustment used. The measured P_{KA} values are plotted on the y-axis, while the nominal P_{KA} values are on the x- axis.

Figure 8: Linear adjustment plotted to determine the equation that allows the correction of the calculated P_{KA} value.



Source: The authors

The correlation between both quantities was determined to be linear, because its R^2 is approximately 1. This relation was given by equation 5.

$$\text{Corrected } P_{KA} = (1{,}248 \text{ x Nominal } P_{KA}) + 2{,}26 \quad (5)$$

The equation 5 must be used to correct the equipment's P_{KA} values and, with these results, should be established a dose reference level (DLR), aiming to know those doses applied on the service. The knowledge of the doses received by the patients will allow us to go forward at a practice optimization, inside of a set of action proposed at a QC program that we intend to implement.

3.2. Physical Spaces and radiation protection accessories

The radiometric survey was done using the parameters that produce the highest dose. It was also considered a workload of 50 weeks per year. The limits established at IN 94 [17], for free areas are 0.5 mSv/year, while at controlled areas are 5 mSv/year. The results showed that the calculated value was below those limits, showing that the wall's shielding is protecting the external areas from unacceptable dose rate levels. All measurements performed at each monitored point were satisfactory, demonstrating that the shielding is within the established limits.

The illuminance of the reporting room was measured under conditions that replicate the professionals' working environment, yielding a result of 8 lux in front of the monitor. According to IN 94 [17], the tolerance value for the illuminance of the reporting room should be less than 50 lux, indicating that the room meets the ideal conditions.

The luminance of the reading monitor was measured using a radiography image from the computer's memory. This was done because the evaluated service's monitor is not specialized for this function. Measurements were taken in both bright and dark areas. The bright area presented a luminance of (42.5 ± 0.1) cd/m², while the dark area presented a luminance of (10.5 ± 0.1) cd/m². According to IN 94 [17], the luminance should be greater than or equal to

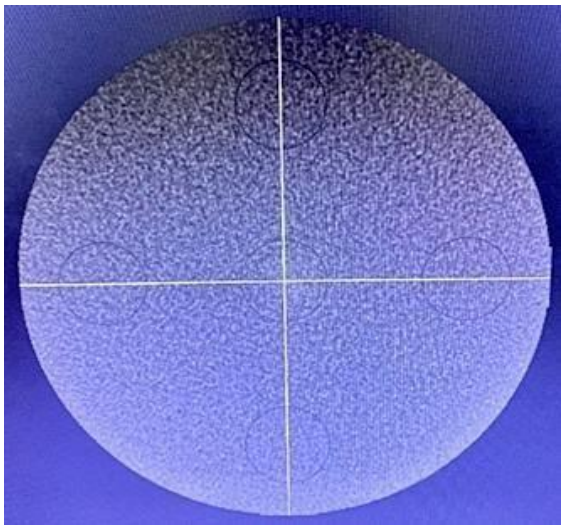
170 cd/m², indicating that the results were below expectations or that the applied methodology at is not ideal for this evaluation.

The integrity of accessories was visually assessed and found to be in compliance.

3.3. Tomographic Image

For the assessment of the tomographic image (image uniformity, indicated CT number value in three distinct materials – water, Teflon and air, CT number uniformity and noise). Figure 9 shows the image for the evaluation of image uniformity and noise.

Figure 9: PMMA image obtained by tomographic acquisition. It is possible to see the regions of interest (ROIs)



Source: The authors

The presence or absence of artifacts in the image was visually evaluated, and no artifacts were identified, in accordance with IN 94 [17]. The results of the indicated CT number values for each element of the phantom were in agreement with the values established in the reference (equipment user manual). Regarding the uniformity of the CT number, the values also presented within the expected range, indicating that the generated image has an adequate signal, in addition to being uniform and having low noise (Table 5).

Table 5: Quantitative results of image quality evaluation

TEST	MATERIAL	MEASURED VALUE	STANDARD DEVIATION (NOISE)
Indicate CT Number Value (HU)	PMMA	192	75
	Teflon	814	94
	Air	-980	3
Uniformity of CT Number (HU)	-	73	-

According to IN 94 [17], the CT number should not vary by more than 10% from the reference values established by the manufacturers, and the noise levels should be less than 15% of the reference value.

Based on the results obtained from the 18 evaluations established in IN 94 [17], we verified that most parameters are complying (14 tests), and only 4 tests presented results outside the established tolerances: exposure time accuracy, dose representative values (PKA), dose indicator accuracy, and monitor luminance for radiological reports.

The tests recommended in the normative configure a minimum set of evaluations to comply with legal requirements, but they are not the only ones that can be performed. A medical physicist responsible for quality control can and should expand the set of evaluations to optimize protection for all those involved in radiation exposure and improve image quality, thereby facilitating radiographic diagnosis. A quality assurance program should not be limited to only legal requirements, and the more evaluations performed, the easier it will be to ensure quality, safe, and efficient service in its processes. This would be the first step towards developing a certification program to be implemented, with subsequent reflections on professional training, process standardization, and automation of administrative procedures, seeking management professionalization, cost reduction, and consequently, excellence.

4. CONCLUSIONS

High-quality CTFC examinations are vital for accurate diagnoses, effective treatment planning, error reduction, and safe and efficient patient experience. The synergy of advanced technology and technical expertise is critical to optimize the benefits of this imaging modality, highlighting the need for established protocols.

The tube voltage and the half value layer presented stable and compliant with the established normative. However, the exposure time values were found to be non-compliant. Similarly, the representative dose values were outside the expected values determined by the Normative Instruction, but still within the tolerance limit. Therefore, although within tolerance levels, the equipment can be used. The radiometric survey of the installation was found to be compatible with the applied doses in the service, since the dose levels in each evaluated area are in accordance with the established normative for each type of area.

The equipment needs to be adjusted so that the parameters related to exposure time, dose representative values, and dose indicator accuracy are exact. It is also recommended that the radiological report monitors be specific for this purpose, aiming for excellence in image evaluation. The quality control tests of the equipment must be repeated periodically in accordance with the established normative

Equipment quality control allowed the characterization of its performance and dosimetry parameters, as well as the identification of indicators that require adjustments and the establishment of baseline values for future quality control tests. The next steps in establishing a certification program, the ultimate goal of this project, will involve conducting a rigorous evaluation that encompasses aspects such as professional qualification, radiological safety procedures, quality management, and other aspects related to service delivery. This will be an important indicator that a healthcare institution meets established standards and is committed to continuous improvement of quality and patient safety.

The implementation of a QC program would therefore enable the strengthening of respect and positive image of the service before patients, collaborators, and society, in addition to its operational efficiency serving as a quality reference to be followed.

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CONFLICT OF INTEREST

All authors declare that they have no conflicts of interest.

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