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# Radiation protection and quality control in radiography services: a comparative study between national and international standards

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**Abstract**: The creation of regulatory standards on radiation protection and quality control (QC) aims to establish a safety standard for services that use sources of ionizing radiation, seeking to guarantee the safety of those who may be exposed. In Brazil, the standard for radiation protection in x-ray imaging is the *Resolução da Diretoria Colegiada* No. 611 of the *Agência Nacional de Vigilância Sanitária* and in its Normative Instruction (NI) No. 90 are determined 33 QC tests for conventional medical radiography to be carried out periodically as part of the service's Quality Assurance Program. Internationally, the International Commission on Radiological Protection promotes the advancement of the science of radiation protection. Regarding QC, the tests are mainly established by the International Atomic Energy Agency, the American Association of Physicists in Medicine, the American College of Radiology, and the European Commission. This study aimed to perform a comparative analysis between national and international standards for radiation protection and QC in radiography services. For this, a survey was carried out on radiation protection and QC standards of several countries through documentary research. Differences were observed regarding radiation protection standards between Brazil and other countries. The comparative study demonstrated significant differences in ionizing radiation dose limits and the positioning of the individual dosimeter. The analysis also revealed that NI No. 90 lacks descriptions of QC testing methodologies compared to international ones. In conclusion, the inclusion of additional QC tests, and greater detailing of existing regulations are needed for improvements to NI No. 90. However, it should be noted that Brazil is on par with developed countries regarding radiation protection regulations.

**Keywords:** radiation protection, quality assurance, reference standards.

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# Proteção radiológica e controle de qualidade em serviços de radiografia: um estudo entre normas nacionais e internacionais

**Resumo**: As normas sobre radioproteção e controle de qualidade (CQ) tem como objetivo estabelecer um padrão de segurança em serviços de radiodiagnóstico, buscando garantir a segurança do trabalhador e demais indivíduos expostos. Atualmente, no Brasil, a Resolução da Diretoria Colegiada n° 611 da Agência Nacional de Vigilância Sanitária e na sua Instrução Normativa (IN) n° 90 discorrem respectivamente sobre aspectos de radioproteção e CQ. Em âmbito internacional, a International Commission on Radiological Protection fornece recomendações sobre os aspectos de radioproteção. Já em relação ao controle de qualidade, os testes são estabelecidos, principalmente, pela International Atomic Energy Agency, The American Association of Physicists in Medicine, American College of Radiology e European Commission. Diante do exposto, este estudo teve como objetivo realizar uma análise comparativa entre as normas nacionais e internacionais de radioproteção e CQ em serviços de radiografia. Para tanto, foi feito um levantamento por meio de pesquisa documental sobre as normas de proteção radiológica e CQ de diversos países destacando suas principais diferenças. Este demonstrou diferenças significativas em limite de doses de radiação ionizante e o posicionamento do dosímetro individual. Foi revelado ainda que a IN n° 90 carece de descrição nos testes de CQ quando comparada as internacionais. Em conclusão, o estudo destaca a necessidade de melhorias na norma brasileira, a inclusão de testes de CQ adicionais e maior detalhamento das regulamentações existentes. Entretanto, ressalta-se que o Brasil está equiparado a países desenvolvidos em relação as normativas de radioproteção.

**Palavras-chave:** radioproteção, garantia da qualidade, padrões de referência.

## 1. INTRODUCTION

Radiation protection can be defined as a set of measures aimed at protecting humans and the ecosystem from potential undesirable effects caused by ionizing radiation [1]. To reduce such effects, regulatory standards have been established for various practices involving ionizing radiation. The concepts, procedures, and dosimetric quantities in radiation protection are continuously detailed and updated in the International Commission on Radiological Protection (ICRP) and the International Commission on Radiation Units and Measurements (ICRU) publications. The concepts contained in these publications constitute international recommendations. Each country may or may not adopt them, partially or fully, when establishing its radiation protection standards. This depends on the country's stage of economic development and the capacity or feasibility of implementation in each area of application [2].

In Brazil, in 1998, the *Agência Nacional de Vigilância Sanitária* (ANVISA) published the *Portaria* No. 453 [3], which establishes the basic guidelines for radiation protection in medical and dental x-ray imaging, regulates the use of diagnostic x-rays throughout the national territory, and provides other provisions. In 2005, ANVISA published the guide *Radiodiagnóstico Médico: Desempenho de Equipamentos e Segurança* [4] that means to facility the uniformization of procedures to quality controls of equipments and safe tests of radiodiagnostic instalations. Then in 2019, ANVISA published, in the Official Gazette of the Union, the *Resolução da Diretoria Colegiada* (RDC) No. 330 [5], which revoked the *Portaria* No. 453, and two years later, RDC No. 611 [6], which establishes the sanitary requirements for the organization and operation of diagnostic or interventional radiology services and regulates the control of medical, occupational, and public exposures resulting from the use of these technologies throughout the national territory.

Given the importance of radiation protection, there arises the need for quality control procedures. These aim to evaluate the performance and safety of equipment used in practices

involving ionizing radiation. Quality control tests must be periodically conducted on the equipment as part of the Quality Assurance Program (QAP) [7].

In recent years, standards, recommendations, and laws have been developed to implement QAPs in x-ray imaging worldwide. Internationally, quality control procedures are primarily established by organizations such as the International Atomic Energy Agency (IAEA), the American Association of Physicists in Medicine (AAPM), the American College of Radiology (ACR), and the European Commission (EC). In Brazil, RDC No. 611 [6] defines the quality control tests through eight specific normative instructions for each imaging diagnostic technology and establishes that these must be conducted periodically as part of the QAP.

Thus, this work aimed to conduct a comparative study between the national standards (RDC No. 611 [6], RDC No. 330 [5], *Portaria* No. 453 [3], and *Instrução Normativa* (IN) No. 90 [8]) and the most recent international standards regarding radiation protection and quality control in radiography services, to perform a critical analysis of the current standards in Brazil.

## 2. MATERIALS AND METHODS

This article is qualitative and uses an exploratory-comparative approach. The methodology is both descriptive and evaluative, by identifying key components of each standard and critically assessing the alignment of Brazilian standards with international best practices.

Initially, the standards RDC No. 611 [6], RDC No. 330 [5], and *Portaria* No. 453 [3] were evaluated, and then the obtained information was compared with publications on the subject from the countries Algeria, Argentina, Australia, Bolivia, Bosnia and Herzegovina, China, Chile, Colombia, Croatia, El Salvador, Spain, United States, France, Guatemala, Indonesia, Italy, Mozambique, Nigeria, Portugal, and Uruguay.

Additionally, the 33 quality control tests for radiography equipment regulated by IN No. 90 [8] were also analyzed. These were compared with the tests established in the standards IAEA-TECDOC-1958 [9], AAPM No. 74 [10], and IAEA Human Health Series No. 47 [11]. The evaluation considered the tolerance limits, the periodicity of the tests, and the conditions under which they are performed. The information was analyzed using electronic spreadsheets.

## 3. RESULTS AND DISCUSSIONS

Among the parameters regarding radiation protection in X-ray imaging, some stood out, such as the annual equivalent dose to the eye lens for professionals. In Brazil, *Portaria* No. 453 [3] limited this value to 150 mSv. However, RDC No. 611 [6] reduced it to 20 mSv. In Argentina [12], Bosnia and Herzegovina [13], Croatia [14], El Salvador [15], France [16], Mozambique [17], and Uruguay [18], this dose limit is also 20 mSv, the same as the current limit in Brazil. In Algeria [19], Australia [20], Bolivia [21], China [22], Colombia [23], Spain [24], the USA [25], Guatemala [26], Italy [27], Nigeria [28], and Portugal [29], the limit value is 150 mSv. In this parameter, Indonesia and Chile stand out. In Indonesia [30], the average dose should be 20 mSv per year over 5 years, and should not exceed 50 mSv in any single year. Chile follows ICRP No. 60 from 1990 [31], which determines that the annual equivalent dose limit to the lens is 30 mSv.

Another relevant parameter in the comparison between countries was the use of personal dosimeters, which aim to determine the radiation dose received by professionals due to occupational exposure. In Brazil, according to *Portaria* No. 453 [3], the personal dosimeter should be worn over the lead apron at chest level, and a factor of 1/10 would be applied to the effective dose of an individual to correct the difference caused by the apron in the final dose. RDC No. 611 [6] states that the personal dosimeter should be used

according to the Radiation Protection Plan of the establishment. In practice, the dosimeter can be worn under or over the lead apron, depending on the determination of the establishment that performs the dosimeter reading. In Spain [32], the dosimeter must be worn over the lead apron. In Argentina [33], Guatemala [26], and El Salvador [34], their respective regulations do not specify how the personal dosimeter should be used, only mandating its use. In Italy [35] and Nigeria [36], their regulations state that the dosimeter should be worn at chest level without detailing its position relative to the lead apron. In Australia [37], Chile [38], China [39], France [40], and Uruguay [41], the dosimeter should be worn at chest level and under the lead apron. In Croatia [42], it is used the same as in the previously mentioned countries, and if necessary, another personal dosimeter should be worn at collar level, over the protective apron. In the USA [43], the dosimeter should be worn at collar level over the apron.

Since the dosimeter is used to assess effective dose and aprons do not cover the entire body, ideally, the dosimeter should be worn over this personal protective equipment. The use of the apron would only reduce the dose in covered regions. If the determination is to use it under the apron, the reading can be corrected due to the attenuation by the apron; however, the dose would be higher in regions not covered by the apron. In such situations, a specific methodology for calculating the effective dose can be established, but it would depend on the model of the apron used.

The use of the anti-scatter grid, which functions to reduce scattered radiation from the beam before it reaches the receptor (to improve image contrast) [44], also showed significant differences between countries. In Brazil, *Portaria* No. 453 [3] did not specify whether the grid should be removable or not. RDC No. 611 [6] states that the anti-scatter grid must be removable but does not mention its removal in equipment specified for pediatric applications. In Croatia [45], Spain [46], Nigeria [47], and Uruguay [41], the grid must be removable in pediatric radiology. In Italy [48], the regulation states that the grid

should be removable if possible. In El Salvador [49], their regulation says that digital radiography (DR) receptors are not affected by incident radiation scatter by design, thus not requiring the use of a removable grid.

Regarding quality control tests, Table 1 (Parts 1-5) presents the comparison results concerning the limits of tests on radiography equipment between IN No. 90 [8] and the international protocols IAEA-TECDOC-1958 [9], AAPM Report No. 74 [10], and IAEA Human Health Series No. 47 [11]. In addition to tolerance limits, IN No. 90 [8] also establishes restriction limits for some tests. According to RDC No. 611 [6], if the parameters are within restriction levels, the legal representative of the service must immediately suspend the use of the equipment or allow temporary operation only for urgent or emergency care, based on the assessment of the technical manager and the radiation protection supervisor, when applicable.

As shown in Table 1, most tests are comparable in their respective standards regarding their tolerance limits, particularly IN No. 90 [8] and IAEA-TECDOC-1958 [9], which even specify the same limit values for the evaluation of some test results. Thus, it is observed that Brazil considers the IAEA-TECDOC-1958 [9] standard to determine its tolerance limits in its regulations.

The compared standards provide the frequency at which tests should be conducted and generally determine an annual periodicity and after repairs for most tests. However, IAEA Human Health Series No. 47 [11] presents differences in test periodicity, recommending that some should have a periodicity of less than a year.

**Table 1:** Comparison of Tolerance Limits for Quality Control Tests on Radiography Equipment (Part 1).

| TESTS | IN No. 90 (2021) | AAPM REPORT No. 74 (2002) | IAEA-TECDOC-1958 (2021) | IAEA HUMAN HEALTH SERIES No. 47 (2023) |
|---|---|---|---|---|
| **Accuracy of focus-to-receptor distance indicators** | ≤ 5%. | N/A[1]. | N/A. | The difference between the ruler or tape measure and the FID[2] reading indicator should not exceed ± 1.5 cm. |
| **Accuracy of the light field indicator** | Tolerance: ≤ 2%. Restriction: ≤ 4% of FID. | The individual X-ray field and the edges of the light field should be within ± 2% of the FID. | The maximum difference between the light and radiation field values at the edge must be > 2% and the total sum of the difference on the four sides must be > 4% of the FID used. | ≤ 2% of FID. |
| **Alignment of the central axis of the X-ray beam** | Tolerance: ≤ 3º. Restriction: ≤ 5º relative to the axis perpendicular to the receptor plane. | The beam alignment should be within 2 degrees relative to the perpendicular axis of the table. | ≤ 3º relative to the axis perpendicular to the receptor plane. | N/A. |
| **Integrity of the chassis and cassettes** | Intact grids and cassettes. | N/A. | There should be no dirt or damage. | There should be no dirt or damage. |
| **Reproducibility of exposure time** | Tolerance: ≤ 10%. Restriction: > 20%. | The reproducibility of the exposure time should have a coefficient of variation < 0.05 | ≤ 10%. | Coefficient of variation <0,05. |
| **Automatic Exposure Control compensation for different thicknesses** | Tolerance: ≤ 20%. Restriction: > 40%. | Routine radiographic systems should be able to maintain an OD[3] of 1.0 ± 0.3 above base plus fog in the clinical operating range. Chest radiography systems should maintain an OD of 1.5 ± 0.1 OD above base plus fog. | DR[4] systems: ≤ ± 30%. CR[5] systems: < ± 0.2 OD. | ≤ ± 40%. |

**Table 1:** Comparison of Tolerance Limits for Quality Control Tests on Radiography Equipment (Part 2).

| TESTS | IN No. 90 (2021) | AAPM REPORT No. 74 (2002) | IAEA-TECDOC-1958 (2021) | IAEA HUMAN HEALTH SERIES No. 47 (2023) |
|---|---|---|---|---|
| **Grid alignment** | No artifacts, visible blades, or image non-uniformity. | Misalignment of the X-ray beam with the grid in either dimension can result in image artifacts. The time between grid movement and exposure duration can also cause artifacts. Therefore, the acceptable misalignment will vary with the relationship between the grid in use and the FID. | N/A. | N/A. |
| **Radiometric survey** | Free Area. Tolerance: ≤ 0.5 mSv/year; Restriction: > 1.0 mSv/year. Controlled Area. Tolerance: ≤ 5.0 mSv/year; Restriction: > 10.0 mSv/year. | N/A. | Controlled Area: 0.10 mSv/week or 5.0 mSv/year. Free Area: 0.01 mSv/week or 0.5 mSv/year. | N/A. |
| Exposure time accuracy | Tolerance: ≤ 10%. Restriction: > 30%. | Coefficient of variation < 0.05. | ≤ 10%. | For exposure times longer than 100 ms, ± 10% of the nominal value; For exposure times shorter than 100 ms, ± 15% or ± 2 ms of the nominal value, whichever is greater. |
| **Sensitivity difference between phosphor plates for same-sized image receptors** | Tolerance: ≤ 20%. Restriction: > 40%. | N/A. | <20%. | ≤ 20%. |

**Table 1:** Comparison of Tolerance Limits for Quality Control Tests on Radiography Equipment (Part 3).

| TESTS | IN No. 90 (2021) | AAPM REPORT No. 74 (2002) | IAEA-TECDOC-1958 (2021) | IAEA HUMAN HEALTH SERIES No. 47 (2023) |
|---|---|---|---|---|
| Tube potential accuracy | Tolerance: ≤ 10%. Restriction: > 20%. | ± 5%. Older generators may not be able to meet this specification. In this case, a maximum absolute tolerance of ±4 kVp should be used. | Deviation ≤ ± 10%. | Deviation ≤ ±5% or ±5 kVp, whichever is greater. |
| **Tube potential reproducibility** | Tolerance: ≤ 5%. Restriction: > 10%. | N/A | Coefficient of variation ≤ ± 10%. | N/A. |
| **Automatic Exposure Control reproducibility** | Tolerance: ≤ 10%. Restriction: > 20%. | N/A. | < 10%. | The recorded exposure index and, mAs values should be ± 25% of their respective baseline values for DR[3] systems and ± 30% for CR[4] systems. |
| **Tube head leakage radiation** | Tolerance: ≤ 1.0 mGy/h at 1 m. Restriction: > 2.0 mGy/h at 1 m. | N/A. | N/A | The maximum air kerma ≤ 1 mGy/h 1 meter in any direction. |
| **Tube output (R)** | Tolerance: 30 ≤ R (μGy/mAs) ≤ 65, at 1 m for 80 kVp and total filtration between 2.5 mm Al[6] and 5 mm Al. Restriction: < 20 μGy/mAs and R > 80 μGy/mAs. | For single-phase generators, it should be 4 ± 0.8 mR/mAs, 80 kVp, 100 cm of DFR1 with total filtration of 2.5 mm Al. For all other types of generators, it should be 6 ± 1 mR/mAs, 80 kVp, 100 cm FID with a total filtration of 2.5 mm Al. | > 25 μGy/mAs at 1 m for 80 kVp and total filtration of 2.5 mm Al. Between 30 and 65 μGy/mAs at 1 m and total filtration between 2.5 and 5 mm Al. If annual output measurements are made, the variation from the reference value should be less than 25%. | The radiation output for 2.5 mm Al total filtration and 80 kV exposures should be in the range of 25 μGy/mAs to 80 μGy/mAs. |

**Table 1:** Comparison of Tolerance Limits for Quality Control Tests on Radiography Equipment (Part 4).

| TESTS | IN No. 90 (2021) | AAPM REPORT No. 74 (2002) | IAEA-TECDOC-1958 (2021) | IAEA HUMAN HEALTH SERIES No. 47 (2023) |
|---|---|---|---|---|
| **Half-Value Layer (HVL)** | The value of the HVL varies depending on the equipment voltage (from 50 to 130 kVp). If single-phase, it should be between 1.5 and 3.5, and if three-phase, between 1.6 and 4.1. | N/A. | The value of HVL varies depending on the equipment voltage (from 70 to 130 kVp). For single-phase, it should be between 2.1 and 3.5, and for three-phase, between 2.3 and 4.1. | If the requirements are not available in national standards, international standards should be used. For example, IEC 60601-1-3 recommends that at 80 kV, the HVL for systems sold before 01/06/2012 should not be less than 2.3 mm Al; for systems sold after that date, the recommended value is 2.9 mm Al. |
| **Spatial resolution** | Tolerance: ≥ 2.5 lp/mm. Restriction: < 1.5 pl/mm. | N/A. | ≥ 2.4 lp/mm for DR and CR. | N/A. |
| **Screen-film contact** | Without loss of uniformity. | N/A.. | N/A. | No artifacts should be observable. |
| **Image artifacts** | The presence of marks in the image is not acceptable. | N/A. | The presence of artifacts in the image is not acceptable. | No visible artifacts or grossly inhomogeneous areas should be observable. |
| **Darkroom integrity** | No entry of external light. | N/A. | N/A. | The light sources should not produce unacceptable fogging on the films. |
| **Image uniformity** | Tolerance: ≤ 10%. Restriction: > 20%. | N/A. | CR systems: < ±10%. DR systems: < ±5%. | ≤ 20%. |
| **Accuracy of detector dose indicator (when available)** | Tolerance: ≤ 20%. Restriction: > 40%. | N/A. | The difference between the calculated dose value and the initial baseline dose should be < 10 μGy. | ≤ 20%. |

**Table 1:** Comparison of Tolerance Limits for Quality Control Tests on Radiography Equipment (Part 5).

| TESTS | IN No. 90 (2021) | AAPM REPORT No. 74 (2002) | IAEA-TECDOC-1958 (2021) | IAEA HUMAN HEALTH SERIES No. 47 (2023) |
|---|---|---|---|---|
| **Erasure cycle effectiveness** | Absence of residual image. | N/A. | N/A. | Absence of a ghost image (CR only). |
| **Monitor luminance for diagnosis or reporting** | ≥ 170 cd/m². | N/A. | ≥ 170 cd/m². | ≥ 350 cd/m². |
| **Negatoscope luminance for diagnosis or reporting** | ≥ 1500 cd/m². | N/A. | ≥ 1800 cd/m². | N/A. |
| **The luminance uniformity of monitors and negatoscopes for diagnosis or report** | ≤ 30%. | N/A. | ≤ 30%. | N/A. |
| **Reporting room illuminance** | ≤ 50 lx | N/A. | 15 - 50 lx. | 15 - 50 lx. |

Subtitle:

1: N/A = not applicable.

2: FID: focus-to-image receiver distance.

3: OD = optical density.

4: DR = digital radiography.

5: CR = computed radiography.

6: Al = aluminum.

Some tests included in IN No. 90 [8] are not found in the other standards: integrity of accessories and personal protective equipment; representative dose values; image quality; geometric distortion; reproducibility of air kerma; linearity of air kerma with the product of current and exposure time. The same representative dose values can be found in IAEA's safety guide No RS-G-1.5 [55]. Image quality test must be performed based on the established specific parameters, on a reference image obtained with the calibrated equipment, and on the specifications of the test tool. This test tool must verify, as a minimum, spatial resolution and low contrast resolution [8].

On the other hand, the international standards present a considerably greater number of tests that are not carried out in Brazil. IAEA HUMAN HEALTH SERIES n°47 [11], for example, has four tests for automatic exposure control, while IN No. 90 [8] has only two of these. Furthermore, IAEA HUMAN HEALTH SERIES No. 47 [11] and IAEA-TECDOC-1958 [9] present a test on the sensitivity of automatic exposure control sensors, a test not present in IN No. 90 [8]. This has the function of checking the consistency between the automatic exposure control sensors, considering that not all sensors in the system have the same sensitivity. Furthermore, IN No. 90 [8] presents the dose indicator accuracy test, while IAEA-TECDOC-1958 [9] has a test to evaluate the accuracy of the dose indicator and another to evaluate its reproducibility. The latter can be defined as the ability to agree on results when the instrument is applied uniformly and repeatedly to invariant objects [53]. Therefore, the reproducibility test of the dose indicator is also important, as it guarantees that it will always reproduce the same values for the same objects.

In addition to the tests mentioned, the IAEA HUMAN HEALTH SERIES No. 47 [11] and the IAEA-TECDOC-1958 [9] standards have a greater emphasis on the issue of image quality. In these publications, the low contrast detectability test is presented, which provides a more elaborate analysis of the image, revealing the presence of visible low-contrast details. Both standards also present the kerma-area product accuracy test. This test is

performed to ensure the accuracy of the product kerma-area meter, which shows an indication of the patient's input dose. Another test that stood out in the comparison was the precision test of the measured dimensions, present only in the IAEA HUMAN HEALTH SERIES No. 47 [11]. This test can be used to ensure that the distances measured from the image by the software distance indicators match the actual distances.

Unlike the other standards, IN No. 90 [8] does not detail how the tests should be conducted or the materials to be used, only citing the periodicities and limits. ANVISA published the testing methodologies for *Portaria* No. 453 in 2005 [3]; however, several tests have since been added or updated in subsequent INs. Therefore, a new publication of these methodologies is necessary, with a priority on quantitative methods.

In the comparison between radiation protection standards and quality control tests analyzed, the greater level of detail in the IAEA HUMAN HEALTH SERIES standard no. 47 [11] is noticeable, as in addition to presenting a greater number of tests, it describes in more detail the methodologies to carry them out. IAEA-TECDOC-1958 [9] is similar to IN No. 90 [8] concerning which tests must be carried out. However, unlike IN No. 90 [8], IAEA-TECDOC-1958 [9] presents brief methodologies for testing.

Even though Brazil is on par with developed countries in terms of radiation protection, it is still possible to advance further about the details of the tests already established and also with the implementation of other tests, such as the one that evaluates the sensitivity of automatic exposure control sensors, which does not exist in the current Brazilian standard, IN nº 90 [8]. Given the possibility of contributing to the improvement of the QAP with the implementation of more quality control tests, studies are therefore needed to include these in IN nº 90 [8], to make this normative instruction an even broader reference on the subject of radiation protection.

## 4. CONCLUSIONS

This work aimed to perform a comparative analysis between national and international standards for radiation protection and quality control in radiography services. Initially, the legislation governing the application of ionizing radiation for medical diagnosis and national and international quality control tests were identified with the main objective of making a comparison between these standards. With this, the positive and negative points between the compared standards were shown. The importance of certain tests in IN No. 90, which are not included in the international standards, should be reassessed, while the incorporation of tests found only in international standards could also be beneficial. It is important to emphasize that IN No. 90 is a norm, not a protocol as the international publications used in this comparative. Therefore, there is a difference in their formality, obligatory nature, and context of application. In this work, we suggest a new Brazilian publication to provide clear guidance on the correct procedures for conducting all tests. Despite this, Brazil is on par with developed countries when it comes to aspects of radiation protection in x-ray imaging.

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## CONFLICT OF INTEREST

All authors declare that they have no conflicts of interest.

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