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Verification of absorbed dose in blood component cases using radiochromic film EBT3

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Abstract: Dosimetry of blood components is an essential practice to ensure the safety and efficacy of irradiation in blood products, serving as a fundamental measure to quantify and map the absorbed radiation doses. This study addresses dosimetric procedures using EBT3 radiochromic films according to ISO/ASTM 51939:2017 to ensure compliance with established dose standards. The methodology includes obtaining calibration curves for different absorbed dose values, mapping storage containers, and determining the optimal dose for irradiations using pre-calibrated radiochromic films with a margin of uncertainty of ±10%, based on the standards of the Gamma Irradiation Laboratory (LIG/CDTN). The irradiations were carried out in a Category II Multipurpose Panoramic Irradiator using a Cobalt-60 source. The films were positioned inside and outside the cases used for storing blood and components. The results demonstrate compliance with ISO/ASTM standards and ANVISA regulations, validating the efficacy of the quality assurance program, with a uniform distribution of absorbed doses in the analyzed containers. Data analysis shows that the absorbed dose variation is within established limits, ensuring that the components receive a minimum dose of 15 Gy and do not exceed the maximum dose of 50 Gy. Furthermore, the results indicate that the average absorbed dose was slightly below the fixed value of 25 Gy recommended by ANVISA, possibly due to the shielding effect of present materials. This study provides a solid basis for the continuous improvement of blood and blood component irradiation processes, ensuring that patients receive safe and effective treatments.

Keywords: radiochromic films, blood components, irradiation, blood.

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Verificação da dose absorvida em bolsas de componentes sanguíneos utilizando filme radiocrômico EBT3

Resumo: A dosimetria de hemocomponentes é uma prática essencial para garantir a segurança e eficácia das irradiações em produtos sanguíneos, sendo fundamental para medir e mapear as doses de radiação absorvidas. Este estudo aborda a aplicação de procedimentos dosimétricos utilizando filmes radiocrômicos, conforme a Norma ISO/ASTM 51939:2017, com o objetivo de assegurar a conformidade das doses absorvidas com os padrões estabelecidos. A metodologia inclui a obtenção de curvas de calibração, mapeamento dos recipientes de armazenamento e determinação da dose ideal para as irradiações, utilizando filmes radiocrômicos como dosímetros, previamente calibrados com uma margem de incerteza de ±10%, tendo como base os padrões do Laboratório de Irradiação Gama (LIG/CDTN). Os resultados demonstram conformidade com as normas ISO/ASTM e os regulamentos da ANVISA, validando a eficácia do programa de garantia de qualidade, com uma distribuição uniforme das doses absorvidas nos recipientes analisados. Por fim, este estudo demonstrou a eficácia dos procedimentos dosimétricos adotados, conforme as normas internacionais e regulamentos locais, fornecendo uma base sólida para a melhoria contínua dos processos de irradiação de sangue e hemocomponentes. Isso assegura a qualidade dos produtos irradiados, garantindo que os pacientes recebam tratamentos seguros e eficazes.

Palavras-chave: filmes radiocrômicos, hemocomponentes, irradiação, sangue.

1. INTRODUCTION

Radiation detectors, or dosimeters, can be classified into categories such as solid-state, including radiochromic films, thermoluminescent detectors, and semiconductors, or liquid-state, such as Fricke and alanine dosimeters [1,2]. In irradiation processes, dosimetry is an essential control to establish and verify parameters related to ionizing radiation. Dosimetry provides quantitative values for radiation-induced changes, ensuring that the irradiation process complies with normative specifications and that laboratory results are reproducible across different environments or industrial-scale irradiation facilities [1].

Dosimetry techniques are critically important in the irradiation of blood and blood components, ensuring that applied radiation doses strictly adhere to established parameters to guarantee both efficacy and process safety [3]. Dosimetry allows precise quantification of the absorbed dose by blood components, ensuring it is sufficient to inactivate T-lymphocytes, thus preventing complications such as Transfusion-Associated Graft Versus Host Disease (TA-GVHD) without compromising the integrity of other blood components [3,4]. Additionally, dosimetry techniques enable meticulous quality control and traceability of procedures in compliance with international [2] and national [5] standards, ensuring that the irradiation process is conducted consistently and safely, protecting patients.

The EBT3 radiochromic film is classified as a routine dosimeter used in the irradiation process of blood and components [2]. This film is designed with a polymer layer that changes color in response to ionizing radiation, allowing precise evaluation of the absorbed dose value. The degree of color change is quantitatively analyzed through high-resolution imaging and digital processing, enabling detailed mapping of absorbed dose distribution [6]. Its stability, precision, and high spatial resolution make the EBT3 an

invaluable tool for ensuring compliance with regulatory standards and conducting rigorous evaluations in laboratory and clinical settings [6].

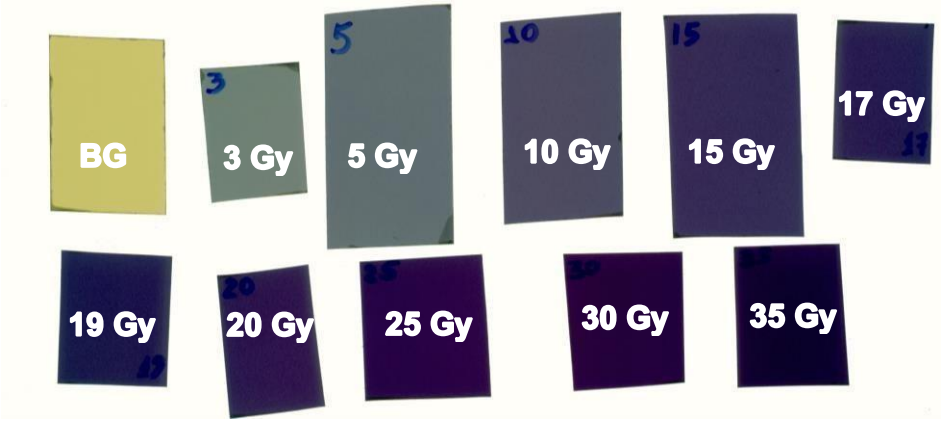
This study aims to develop and refine dosimetric techniques for precisely measuring radiation doses in blood irradiation and components using radiochromic film dosimeters following ISO/ASTM 51939:2017 standards. The study seeks to establish accurate calibration curves for radiochromic films through the correction of the aging of the EBT3 radiochromic film over six months. and optimize dosimetric practices to maintain high-quality assurance standards in blood irradiation procedures at LIG/CDTN.

2. MATERIALS AND METHODS

2.1. Dosimetry System And Calibration

The dosimetry system in this study is based on EBT3-type radiochromic film dosimeters. The film was calibrated for absorbed dose values of 3 Gy, 5 Gy, 10 Gy, 15 Gy, 17 Gy, 19 Gy, 20 Gy, 25 Gy, 30 Gy, and 35 Gy, as shown in Figure 1. The calibration was conducted at a distance of 1 meter from the source, with the films kept stationary and exposed to radiation until the absorbed dose of interest for the study was reached. The 1 meter distance is standardized by LIG/CDTN for all blood and blood component irradiations. The 10% uncertainty accounts for both the uncertainty of the radiochromic film and the uncertainty associated with the irradiation process at LIG/CDTN. Calibration was conducted following ISO/ASTM 51939:2017. The calibration values were chosen based on the absorbed dose interval stipulated by the standards for blood and component irradiation, ranging from 15 to 50 Gy. ANVISA specifies a fixed value of 25 Gy for blood component irradiation. All equipment used is traceable to recognized standards, and calibration was performed for each dosimeter batch in the blood irradiator.

Figure 1: Calibration of EBT3-type radiochromic films.



2.2. Irradiation Of Blood Components

The irradiations were conducted in a Category II Multipurpose Panoramic Irradiator, model/serial number IR-214, manufactured by MDS Nordion, equipped with a Cobalt-60 source with a maximum activity of 60,000 Ci (2.2 x 10^{15} Bq), as illustrated in Figure 2.

Figure 2: Cobalt-60 source installed at LIG/CDTN.

Previously, five different types of containers of varying sizes were used by companies sending blood and blood components for irradiation at LIG/CDTN. However, the laboratory has standardized the use of a single type of container, as shown in Figure 3.

Figure 3: Standardized case for blood component irradiation.

The exposure of the case containing the blood component occurs inside the irradiation chamber, positioned on a rotating table at 1 meter. The rotation of the table enhances the uniform distribution of the absorbed dose across the irradiated materials.

Consequently, radiochromic films were positioned both inside and outside the case to analyze the absorbed dose distribution. The film readings were performed using a transmission light scanner (HP ScanJet G4050), and the data were analyzed using ImageJ and OriginLab 2022b software, enabling the generation of calibration curves and detailed quantitative analyses.

3. RESULTS AND DISCUSSIONS

Based on the data obtained over the six-month period between July 2023 and December 2023, the following graphs and tables were prepared. During this period, the source activity decayed, ranging from 2.17×10^{15} Bq to 2.05×10^{15} Bq. However, to maintain the standardized irradiation dose of 25 Gy, the laboratory utilizes a dosimetry spreadsheet that accounts for source decay and other relevant parameters, ensuring that the absorbed dose to which blood and blood components are subjected remains consistent. As illustrated in Figure 4, the measurements conducted without correcting for the aging of the radiochromic film showed absorbed doses ranging from 20 Gy to 21 Gy, considering an associated uncertainty of up to 10%.

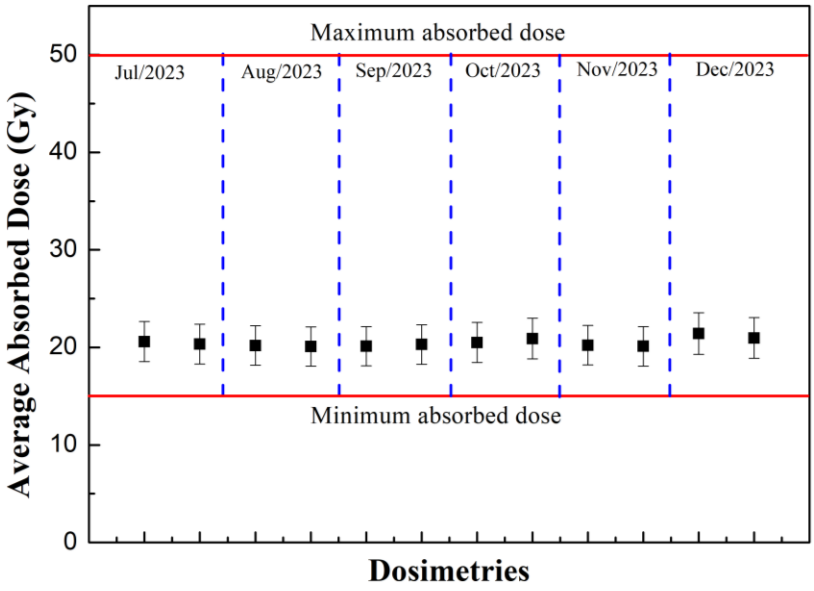
Table 1 summarizes the dosimetric data obtained during the analyzed period, highlighting the average absorbed dose in each measurement and the uncertainty associated with the irradiation process.

Table 1: Dosimetric data without correction for the aging of the radiochromic film.

Dosimetry date	Mean absorbed dose (Gy)	Uncertainty associated with irradiation (Gy)
07/17/2023	20.60	± 2.06
07/31/2023	20.35	± 2.04
08/16/2023	20.20	± 2.02
08/30/2023	20.10	± 2.01
09/07/2023	20.12	± 2.01
09/24/2023	20.30	± 2.03
10/02/2023	20.50	± 2.05
10/19/2023	20.90	± 2.09
11/06/2023	20.23	± 2.02
11/21/2023	20.11	± 2.01
12/05/2023	21.42	± 2.14
12/18/2023	20.97	± 2,10

The average absorbed dose values remained consistent within the expected range, showing slight variability over the period. Despite this variability, the data confirms compliance with the previously established uncertainty limits (±10%), highlighting the reproducibility and reliability of the dosimetric system.

Figure 4: Graph showing dosimetric data without correction for the aging of the radiochromic film.



The measurements corrected for the aging of the radiochromic film, represented in Figure 5 and Table 2, indicate a consistent increase of approximately 2 Gy compared to the measurements without correction. This variation reflects the direct impact of the adjustment to compensate for the reduced sensitivity of the radiochromic material over time.

For the correction of the radiochromic film response, the Fading Correction (Decay of Film Response) was taken into account. An initial calibration was performed upon the arrival of the films, followed by monthly recalibrations under the same conditions to assess the darkening of the film over time. Additionally, tests were conducted to correct for Saturation Effects, as the film's darkening necessitates verifying whether the absorbed dose remains within the linear response range of the film. A correction factor was established and applied to the obtained values.

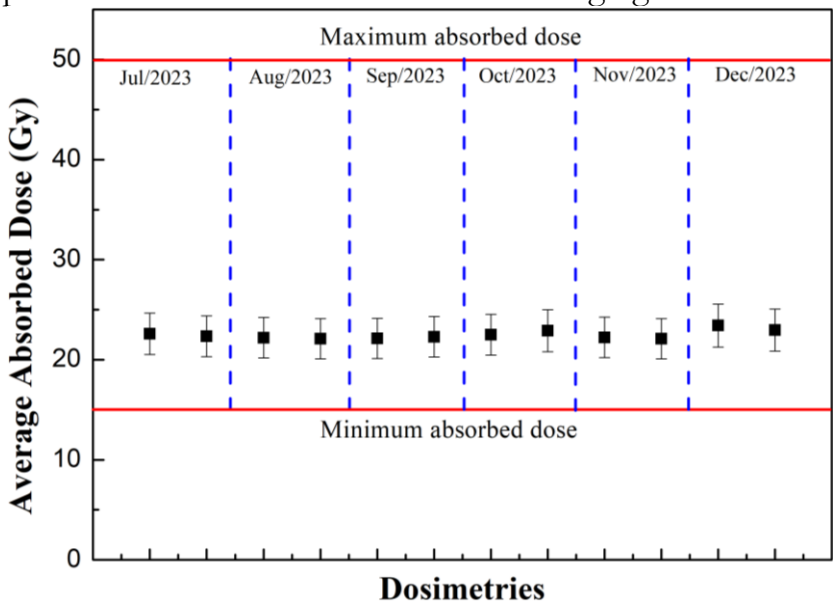
The corrected data show absorbed doses ranging from 22.10 Gy to 23.42 Gy, with the highest doses observed at the end of the analysis period, on 12/05/2023 and 12/18/2023. This trend reaffirms the importance of accounting for film aging when evaluating the uniformity and accuracy of dose values.

Table 2: Dosimetric data corrected for the aging of the radiochromic film.

Dosimetry date	Mean absorbed dose (Gy)	Uncertainty associated with irradiation (Gy)
07/17/2023	22.60	± 2.26
07/31/2023	22.35	± 2.23
08/16/2023	22.20	± 2.22
08/30/2023	22.10	± 2.21
09/07/2023	22.12	± 2.21
09/24/2023	22.30	± 2.23
10/02/2023	22.50	± 2.25
10/19/2023	22.90	± 2.29
11/06/2023	22.23	± 2.22
11/21/2023	22.11	± 2.21
12/05/2023	23.42	± 2.34
12/18/2023	22.97	± 2.29

These results demonstrate that aging correction significantly improves the accuracy of the measurements and ensures a more reliable estimate of the absorbed doses over the period. This underscores the importance of including this step in the analysis process to achieve greater uniformity in the dosimetry of blood components.

Figure 5: Graph of dosimetric data corrected for the aging of the radiochromic film.



The data presented in Table 1 and Figure 4 show a consistent variation in absorbed doses throughout the measurement period, with average values ranging from 20.10 Gy to 21.42 Gy. This variation is within the expected range, considering the associated uncertainty of up to 10%.

Although the values remain within the uncertainty range, certain measurements, such as those taken on 12/05/2023 and 12/18/2023, exhibited higher doses, reaching 21.42 Gy and 20.97 Gy, respectively. The data still require correction related to the aging of the radiocrhromic film, as the actual irradiation dose at the Gamma Irradiation Laboratory was 25 Gy.

The data do not account for corrections related to the aging of the radiocrhromic film, which may contribute to the observed variations when using the 25 Gy value as a reference. Aging may reduce the sensitivity of the radiocrhromic material, introducing bias into the results. Therefore, implementing a correction for this effect could enhance the measurement accuracy, particularly in long-term studies that demand greater reproducibility.

Analysis of the data corrected for the aging of the radiocrhromic film reveals a consistent increase of approximately 2 Gy in the absorbed doses compared to the results obtained without this correction when we consider the fadding and saturation factors. This increment highlights the importance of considering the aging effect in the radiocrhromic film response, especially in long-duration studies. The correction ensures greater accuracy in determining the absorbed dose, reducing the impacts of potential deviations associated with the film's sensitivity degradation.

The corrected values remained within a range of 22.10 Gy to 23.42 Gy, exhibiting stability within the expected limits even after the adjustment. However, it is noted that higher doses, such as those recorded on 12/05/2023 (23.42 Gy) and 12/18/2023 (22.97 Gy), are concentrated at the end of the analysis period. This trend may be attributed to operational factors, such as variations in the positioning of the hemocomponent container within the irradiation chamber or the positioning of the films.

The consistency in the corrected values, combined with the reduction of previously observed variations, reinforces the effectiveness of the aging correction method. This approach is particularly useful in applications where small discrepancies in absorbed doses may impact the uniformity and safety of the process, such as in the irradiation of blood components.

Finally, considering the effect of film aging and its correction process, the hypotheses proposed within the defined objectives are validated. The absorbed dose values comply with the standards set by ANVISA, as well as the regulations outlined in ISO/ASTM 51939:2017, confirming that the blood components are being irradiated within the predetermined dose range. Thus, the irradiation procedure for blood and blood components is being carried out in accordance with the established guidelines.

4. CONCLUSIONS

The results obtained with the correction for aging of the radiocrhromic film demonstrated absorbed doses ranging from 22.10 Gy to 23.42 Gy, approaching the recommended average value of 25 Gy for inhibiting T lymphocyte proliferation, in accordance with ANVISA guidelines. This consistency highlights that the irradiation processes are aligned with the safety and quality requirements for blood products. Additionally, the corrected values remain within the 15 Gy to 50 Gy range stipulated by ISO/ASTM 51939:2017, ensuring that the blood components are irradiated safely and effectively, minimizing the risks of adverse reactions in transfusions. These findings reinforce the reliability of the dosimetric method employed and the process's compliance with regulatory standards, ensuring the quality and safety of irradiated blood for clinical use.

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CONFLICT OF INTEREST

All authors declare that they have no conflicts of interest.

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