Evaluation of blood irradiation indicators for dose verification and FDA recommendation compliance

Justin Czerniawski PhD, Vice President – R&D and Peter Daniel

Authors are employees of Rad Source Technologies, manufacturer of the RS 3400 and AccuTag

Background and Objective

Irradiation of cellular blood components is performed to prevent transfusion-associated graft-versus-host disease (TA-GVHD). FDA recommendations specify a minimum dose of 15 Gy and target dose of 25 Gy for all irradiated blood products intended for transfusion.[1,2] While irradiation indicators are routinely used as part of quality assurance programs, many are designed only to indicate exposure and not to verify a specific delivered dose.[3,4] The objective of this study was to compare the response of three commercially available blood irradiation indicators across clinically relevant dose levels and assess their ability to visually differentiate delivered dose.

Materials and Methods

AccuTag™ (15 Gy), Rad-Sure™ (15 Gy), and RAD-CONTROL (15 Gy) blood irradiation indicators were irradiated using a calibrated RS® 3400 X-ray blood irradiator at doses of 10, 15, 25, 50, and 75 Gy and unirradiated control (0 Gy). For each dose level, a single unirradiated indicator of each type was placed at evenly spaced locations within the central region of a blood phantom. Immediately following irradiation, indicators were visually evaluated by primary researchers under fluorescent light for dose-dependent visual response and their ability to differentiate between irradiation dose levels.

Results

AccuTag exhibited a progressive dose-dependent visual response across the evaluated dose range. Color changes were distinguishable between under-irradiation (10 Gy), FDA-recommended dose range (15 Gy minimum and 25 Gy target), and higher-dose conditions (50-75 Gy). **Response enabled visual identification of the FDA-recommended dose under the conditions tested.**[1,2,5] In contrast, Rad-Sure and RAD-CONTROL confirmed irradiation exposure but did not provide distinguishable dose-level verification.

Conclusions

Under the conditions tested, AccuTag exhibited a dose-dependent visual response across the evaluated dose range.[5] Rad-Sure and RAD-CONTROL confirmed irradiation exposure but did not provide distinguishable dose-level verification, consistent with their intended design and labeling.[3,4]

Dose-responsive indicators such as AccuTag may provide additional quality assurance information beyond confirmation of irradiation exposure and support verification of target dose delivery during blood irradiation in accordance with FDA recommendations for blood products intended for transfusion.[1,2,5]

Clinical Relevance

Effective prevention of TA-GVHD depends on delivery of the intended irradiation dose. Dose-responsive indicators may provide additional quality assurance information by helping verify that irradiation targets have been achieved and may support compliance with FDA blood irradiation recommendations.[1,2]

References

1. FDA. Medical Devices; Radiology Devices; Classification of Blood Irradiators. *A Proposed Rule by the Food and Drug Administration on 03/18/2026*
2. AABB. Standards for Blood Banks and Transfusion Services. 35th ed.; 2026
3. Directions for Use RAD-CONTROL LBL-00563.8
4. Use Instructions Rad-Sure rev. 0 January 2023
5. AccuTag Validation Guide (v1.01 updated 01 Oct 2025)

Visual Comparison of Indicator Response Across Clinically Relevant Irradiation Doses

