AABB BB/TS Standard 5.7.3.2.1 (New): Irradiation & Dose Delivery

The AABB Standards for Blood Banks and Transfusion Services (BB/TS), 35th Edition was effective April 1, 2026. Standard 5.7.3.2.1 is new to this edition.

> *5.7.3.2.1 The dose delivery shall be evaluated in accordance with the collection set manufacturer's written instructions (when specified) concerning irradiation of products and modifications made to expiration date based on the dosimetry results.*

The AABB BB/TS committee added standard 5.7.3.2.1 to the 35th edition for completeness. Per AABB, the related standards typically received many queries and the addition of this standard focused on dose delivery to address the most prevalent issue. So, while the Standard is new, it was not prompted by a recent change.

Vitalant became aware in 2015 that its Alyx® apheresis red blood cell sets with anticoagulant ACD-A and red cell additive solution AS-1 (i.e. ACD-A/AS-1), if **irradiated at or above 3000 cGy targeted to the central portion of the container, had to be relabeled to expire 28 days *after collection***. Units irradiated below 3000 cGy targeted to the central portion of the container**,** were not affected by this labeling restriction and would still expire as usual, 28 days *after irradiation* or 42 days after collection, whichever was sooner. This information had been previously communicated to hospital customers.

The Alyx® Operator's Manual and the package insert of the Alyx® 2RBC LR Kit both contain specific directions related to the irradiation and expiration dating of these products when the irradiation dose is 3000 cGy.

- ACD-A/ADSOL Red Cells may be irradiated. If irradiation dose is 3000 cGy, red cells should be transfused within 28 days from date of collection.
- Note: There is no restriction on red blood cells irradiated using 2500 cGy. The restriction to 28 days from collection is limited to red blood cells irradiated using 3000 cGy.

ACTION
If you irradiate ACD-A/AS-1 red blood cells at your facility, evaluate this information for potential impact because the requirements are more restrictive than those in the AABB Technical Manual (current edition).

PRODUCTS AND IRRADIATION DOSES TESTED
Performing *in vivo* red cell recovery studies for FDA review, Fenwal, a Fresenius Kabi company, tested its apheresis ACD-A/AS-1 collection sets at target doses of 2500 and 3000 cGy. Other doses were not tested. (Transfusion 2004;44(suppl s1):62A-63A.)

The manufacturer's identity and catalog numbers for the affected Fenwal collection sets are X4R5700, X4R5720, and X4R5730, and are printed on the manufacturer's base container label. However, the identity and catalog numbers may not be visible, depending upon the placement of the irradiating facility's final container label. More information is available from Fresenius Kabi at https://eifu.fresenius-kabi.com/medtech/. Search by Product Code (catalog numbers listed above) to view product inserts.

IMPACTED PRODUCTS
Affected apheresis ACD-A/AS-1 red blood cell products are collected using the Fresenius Kabi Alyx® System or the Fresenius Kabi Amicus® Separator.
Non-irradiated product codes for apheresis ACD-A/AS-1 red blood cells are: E4531, E4532 and E4533.
Irradiated product codes for apheresis ACD-A/AS-1 red blood cells are: E4526, E4527 and E4528.

WHAT TO EXPECT FROM YOUR BLOOD PROVIDER
Irradiated ACD-A/AS-1 products distributed since September 16, 2015 have been appropriately labeled.

- Units that we or one of our contracted irradiation facilities have irradiated at 3000 cGy or higher targeted to the central portion of the container are labeled to expire 28 days *from collection*.
- Units irradiated below 3000 cGy targeted to the central portion of the container are labeled as usual to expire 28 days from irradiation or 42 days from collection, whichever is sooner.

If you have any questions or concerns regarding ACD-A/AS-1 red blood cell products, please call your local blood center and ask to speak with a quality staff member. For more information regarding irradiation of ACD-A/AS-1 collection sets for Fresenius Kabi's Alyx® or Amicus® apheresis devices, please go to https://eifu.fresenius-kabi.com/medtech/.