Association for the Advancement of Blood & Biotherapies

AABB Information Technology in Blood Banking and Transfusion Services Training Modules & Certificate Program

References

Purpose: this resource is being provided by AABB to use for future reference after you complete this educational module. AABB will periodically review this document for accuracy. Please submit any broken links to eLearning@aabb.org (please include a subject line of AABB IT Certificate Reference Document).

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Module 1
Overview of Blood Collection, Manufacturing, and Transfusion

Please note: BECS stands for blood establishment computer software. Blood establishment computer systems may be abbreviated with the same letters, but the FDA uses the term BECS to refer to software.

AABB

- www.aabb.org
- AABB Standards for Blood Banks and Transfusion Services, current Edition. This program is based on the 31st edition. References to this source material may be applicable with future editions of the AABB Standards.
- AABB Technical Manual, Methods section, current Edition.
- Patient Blood Management: https://www.aabb.org/news-resources/resources/patient-blood-management

AACC

- https://labtestsonline.org/articles/patient-blood-management

Centers for Disease Control and Prevention

- https://www.cdc.gov/
- National Healthcare Safety Network Biovigilance Component Hemovigilance Module Surveillance Protocol https://www.cdc.gov/nhsn/pdfs/biovigilance/bv-hv-protocol-current.pdf

ICCBBA

- https://www.iccbba.org/
- United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using ISBT 128, Version 3.0.0: https://www.iccbba.org/uploads/4a/e3/4ae3b3fd95bae57d4ee0f58ab6c5874f/IG-002-US-Consensus-Standard-Blood-v3.0.0.pdf

- ISBT 128 Standard Technical Specification
  https://www.iccbba.org/tech-library/iccbba-documents/technical-specification

ISBT (International Society of Blood Transfusion)

- Standard for Surveillance of Complications Related to Blood Donation (Donor Reaction Definition)
  https://www.isbtweb.org/fileadmin/user_upload/Donor_Standard_Definitions_Final_2014.pdf
- Proposed Standard Definitions for Surveillance of Non Infectious Adverse Transfusion Reactions
  https://www.isbtweb.org/fileadmin/user_upload/Proposed_definitions_2011_surveillance_non_infectious_adverse_reactions_haemovigilance_incl_TRALI_correction_2013_TACO_correction_2018.pdf
- Transfusion-Associated Circulatory Overload (TACO) Definition (2018)
  https://www.isbtweb.org/fileadmin/user_upload/TACO_2018_definition_March_2019.pdf

Medscape

- Crossmatching
  https://emedicine.medscape.com/article/1731279-overview

National Institutes of Health (NIH)

- Granulocytes by Apheresis
  https://clinicalcenter.nih.gov/blooddonor/donationtypes/granulocytes.html

The Joint Commission

- https://www.jointcommission.org/
- https://www.jointcommission.org/assets/1/6/Bloodmanagementbrochure_2016_web.pdf

U.S. Food & Drug Administration (FDA)

Blood & Blood Products
https://www.fda.gov/vaccines-blood-biologics/blood-blood-products

Blood Donor Screening
https://www.fda.gov/vaccines-blood-biologics/licensed-products-blas/blood-donor-screening

General Principles of Software Validation; Final Guidance for Industry and FDA Staff
https://www.fda.gov/media/73141/download

Guidance for Industry: Blood Establishment Computer System Validation in the User's Facility
https://www.fda.gov/media/72533/download

Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion
https://www.fda.gov/media/84460/download

Requirements for Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use
https://www.federalregister.gov/documents/2015/05/22/2015-12228/requirements-for-blood-and-blood-components-intended-for-transfusion-or-for-further-manufacturing

Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture, Guidance for Industry
https://www.fda.gov/media/86137/download

Guidance for Industry and Food and Drug Administration Staff: Medical Device Accessories – Describing Accessories and Classification Pathway for New Accessory Types (issued December 30, 2016)
https://www.fda.gov/media/90647/download

Compliance Program Guidance Manual Chapter 42 - Blood and Blood Components Inspection of Licensed and Unlicensed Blood Banks, Brokers, Reference Laboratories, and Contractors-7342.001Fr
https://www.fda.gov/media/84887/download

Electronic Code of Federal Regulations (eCFR) Title 21: Food and Drugs:

21 eCFR 211.188(b)(11): Batch production and control records
https://www.ecfr.gov/cgi-bin/text-idx?SID=5e69a06ab494dbd48696091c076dc74c&mc=true&node=se21.4.211_1188&rgn=div8

[21 CFR 606.121(c)(8)(v)(B)] Container Label
https://www.ecfr.gov/cgi-bin/text-idx?SID=2185be94ebdb3052208589969fb70d8f&mc=true&node=pt21.7.606&rgn=div5#se21.7.606_1121

21 eCFR 606.121(c)(13): Bar Code Label Requirement for Human Drug Products and Biological Products https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=94f12d288c2d6c26b0328b3fb052df88&h=L&mc=true&n=sp21.7.606.g&r=SUBPART&ty=HTML

21 CFR Sec. 606.160 (a) (1): Records
https://www.ecfr.gov/cgi-bin/text-idx?SID=2185be94ebdb3052208589969fb70d8f&mc=true&node=pt21.7.606&rgn=div5#se21.7.606_1160
21 eCFR 606.160(e): Records
https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=aec66b81474b44f28cb8fd8077a9fbfb&ty=HTML&h=L&mc=true&n=pt21.7.606&r=PART#se21.7.606_1160

21 eCFR 610.40: Test Requirements
https://www.ecfr.gov/cgi-bin/text-idx?SID=5e69a06ab494dbd48696091c076dc74c&mc=true&node=se21.7.610_140&rgn=div8

21 eCFR 630.10: General donor eligibility requirements
- 21 CFR 630.10(a)(1)
- 21 CFR 630.10(a)(4)(e)
- 21 CFR 630.10(f

https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=8f41355aef50ecae7fcfa37467543f13&mc=true&n=sp21.7.630.b&r=SUBPART&ty=HTML#se21.7.630_110

21 eCFR 630.40: Requirements for notifying deferred donors
https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=94f12d288c2d6c26b0328b3fb052df88&ty=HTML&h=L&mc=true&r=SECTION&n=se21.7.630_140

21 eCFR 640.5: Testing the blood
https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=94f12d288c2d6c26b0328b3fb052df88&h=L&mc=true&n=pt21.7.640&r=PART&ty=HTML#se21.7.640_15

21 eCFR 807.20: Who must register and submit a device list?
https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=94f12d288c2d6c26b0328b3fb052df88&ty=HTML&h=L&mc=true&r=SECTION&n=se21.8.807_120

21 eCFR 807.92(a)(3): Content and format of a 510(k) summary
https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=94f12d288c2d6c26b0328b3fb052df88&ty=HTML&h=L&mc=true&r=SECTION&n=se21.8.807_192

21 eCFR 864.9245: Automated blood cell separator
https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=94f12d288c2d6c26b0328b3fb052df88&ty=HTML&h=L&mc=true&r=SECTION&n=se21.8.864_19245

21 eCFR 880.6310: Medical device data system & 21 eCFR 880.6310(a)
https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=94f12d288c2d6c26b0328b3fb052df88&ty=HTML&h=L&mc=true&r=SECTION&n=se21.8.880_16310

Reference Articles

- Schreiber, George and Simone, Glynn, Transfusion, “Increasing Blood Availability by Changing Donor Patterns,” Transfusion, 43, May 2003, 591-597)

- Heinrich, Janet, GAWHEHS-99-187R, Availability of Blood