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).

**Creation Date:** June 30, 2021
**Revision Date:** No revisions to date.

---

# Module 2
# Blood Establishment Computer Software (BECS)

**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.

**Centers for Medicare & Medicaid Services**

- Are You a Covered Entity? https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/HIPAA-ACA/AreYouaCoveredEntity

**International Society of Blood Transfusion (ISBT)**

- ISBT Guidelines for Validation of Automated Systems in Blood Establishments http://www.isbtweb.org/fileadmin/user_upload/guidelines-Validation-Automated-Systems-in-Blood-Establishments.pdf

**U.S. Department of Health & Human Services**

- Summary of the HIPAA Privacy Rule https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html

**U.S. Food & Drug Administration (FDA)**

- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices https://www.fda.gov/media/119933/download
- Cybersecurity https://www.fda.gov/medical-devices/digital-health/cybersecurity

- Design Control Guidance For Medical Device Manufacturers
  https://www.fda.gov/regulatory-information/search-fda-guidance-documents/design-control-guidance-medical-device-manufacturers

- 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: Deciding When to Submit a 510(k) for a Change to an Existing Device
  Reference: https://www.fda.gov/media/99812/download

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
  https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-medical-devices

- Identifying an MDDS
  https://www.fda.gov/medical-devices/medical-device-data-systems/identifying-mdds

- Medical Devices: How to Register and List
  https://www.fda.gov/medical-devices/device-registration-and-listing/how-register-and-list

- Quality System Inspection Technique: Guide to Inspections of Quality Systems
  https://www.fda.gov/media/76038/download

- Quality System (QS) Regulation/Medical Device Good Manufacturing Practices
  https://www.fda.gov/medical-devices/postmarket-requirements-devices/quality-system-qs-regulationmedical-device-good-manufacturing-practices

- When is a 510(k) needed?
  https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k

- Medical Device Exemptions 510(k) and GMP Requirements
  https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/315.cfm

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

21 eCFR Part 11: Electronic Records; Electronic Signatures
https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=ae155e4f81721d356edf17f302890a27&ty=HTML&h=L&mc=true&r=PART&n=pt21.1.11

21 eCFR Part 201: Labeling
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=201

21 eCFR Part 211: Current Good Manufacturing Practice for Finished Pharmaceuticals
https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=ae155e4f81721d356edf17f302890a27&ty=HTML&h=L&mc=true&r=PART&n=pt21.4.201

21 eCFR 211.68: Automatic, mechanical, and electronic equipment

https://www.ecfr.gov/cgi-bin/text-idx?SID=51a2ce0e01e9baf7570cb2e5afba5446&mc=true&node=se21.4.211_168&rgn=div8

21 eCFR 211.68(b)
https://www.ecfr.gov/cgi-bin/text-idx?SID=51a2ce0e01e9baf7570cb2e5afba5446&mc=true&node=se21.4.211_168&rgn=div8

21 eCFR 606: Current Good Manufacturing Practice for Blood and Blood Components
https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=ae155e4f81721d356edf17f302890a27&ty=HTML&h=L&mc=true&r=PART&n=pt21.7.606

21 eCFR 606.100(b)
https://www.ecfr.gov/cgi-bin/text-idx?SID=51a2ce0e01e9baf7570cb2e5afba5446&mc=true&node=se21.7.606_1100&rgn=div8

21 eCFR 606.160(b)(7)(iv)
https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=51a2ce0e01e9baf7570cb2e5afba5446&mc=true&n=pt21.7.606&r=PART&ty=HTML#se21.7.606_1160

21 eCFR 606.60: Equipment
https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=51a2ce0e01e9baf7570cb2e5afba5446&mc=true&n=pt21.7.606&r=PART&ty=HTML#se21.7.606_160

21 eCFR 801.4: Meaning of *intended uses*
https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=ae155e4f81721d356edf17f302890a27&ty=HTML&h=L&mc=true&r=SECTION&n=se21.8.801_14

21 eCFR 803.18: What are the requirements for establishing and maintaining MDR files or records that apply to me?
https://www.ecfr.gov/cgi-bin/text-idx?SID=51a2ce0e01e9baf7570cb2e5afba5446&mc=true&node=se21.8.803_118&rgn=div8

21 eCFR 820.181: Device master record
https://www.ecfr.gov/cgi-bin/text-idx?SID=51a2ce0e01e9baf7570cb2e5afba5446&mc=true&node=se21.8.820_1181&rgn=div8

21 eCFR 820.30: Design Controls
https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=51a2ce0e01e9baf7570cb2e5afba5446&mc=true&n=pt21.8.820&r=PART&ty=HTML#se21.8.820_130

21 eCFR 820.30(a)1
https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=ae155e4f81721d356edf17f302890a27&h=L&mc=true&n=pt21.8.820&r=PART&ty=HTML#se21.8.820_130

21 eCFR 820.70(i): Production and process controls

https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=ae155e4f81721d356edf17f302890a27&h=L&mc=true&n=pt21.8.820&r=PART&ty=HTML#se21.8.820_170

Other References:

- Compliance Program Guidance Manual, Chapter 42 – Blood and Blood Components: Inspection of Licensed and Unlicensed Blood Banks, Brokers, Reference Laboratories, and Contractors, June 1, 2016.