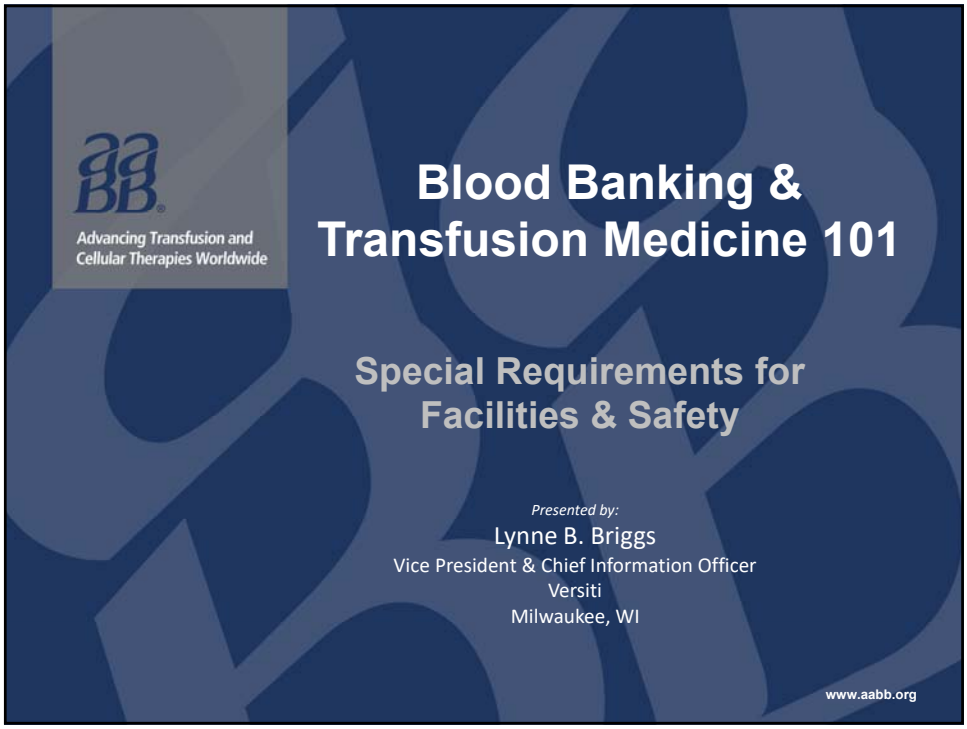

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Learning Objectives

After participating in this program you should be able to….

- Describe the unique requirements for computer systems in hospitals and blood centers.
- Define and explain the organizations that provide oversight and standards for computer use.
- Describe the unique issues with cybersecurity in the medical laboratory and blood centers.

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Agenda

- Some Basics
- Why are Blood Establishment Computer Systems (BECS) Unique
- What are the Rules/Standards, and Who Makes Them
- How Does This Influence Management of a BECS
- What About Cybersecurity in Blood Centers and Hospitals

3

Some Basics

Important in Framing Everything Else…

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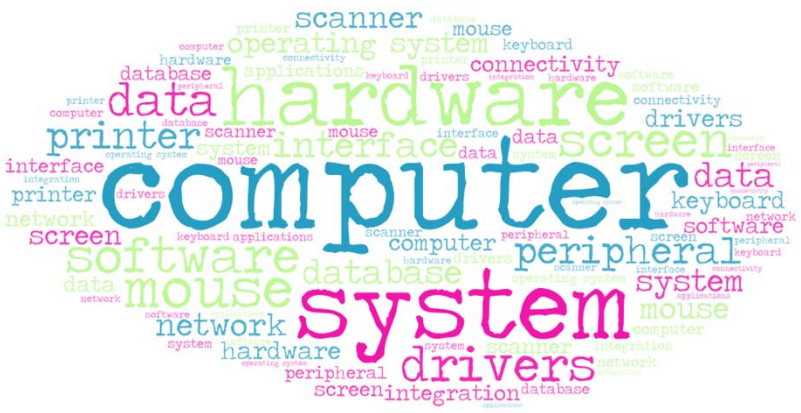
What Is a Computer "System"?



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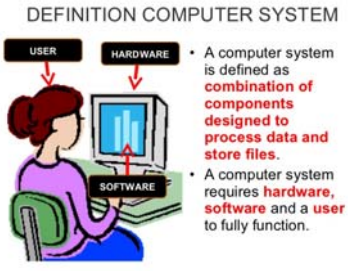
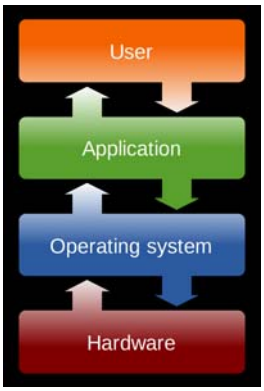
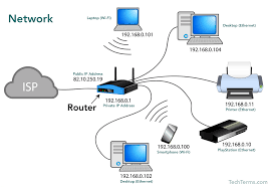
What is a Computer "System"







Think of "system" in the broadest sense of all the parts that create a harmonized person/machine interaction to solve a problem, perform a task…

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What's Unique for a Blood Center or Transfusion Service?

From purely an IT perspective….

NOTHING!

That's why this can be confusing…..

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So, why are we in this session?

A Blood Establishment Computer System (BECS) is unique….

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Why a BECS is Unique

INTENDED USE – IT'S A MEDICAL DEVICE

The BECS makes "decisions", which has donor and patient safety implications. It maintains critical traceability records and process controls about the donor, donation, manufacturing, storage, and transfusion (donor/patient "match").



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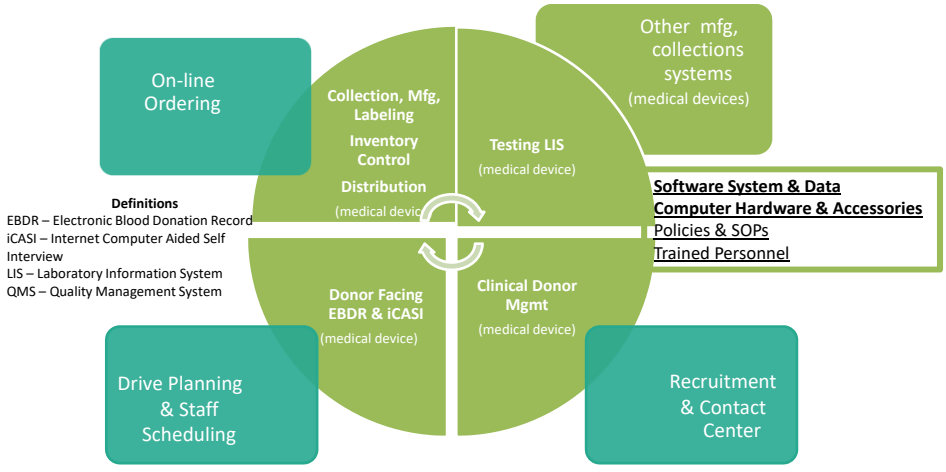
Functions that Make Up a BECS – Blood Center



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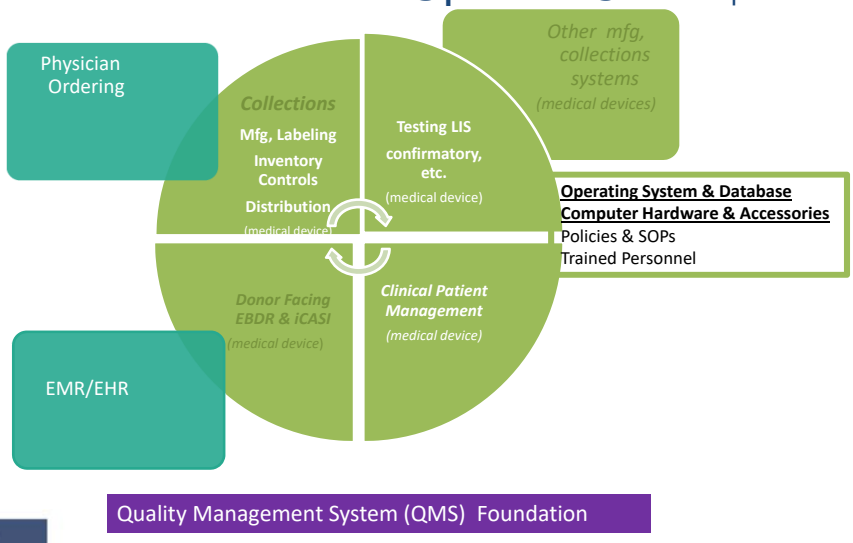
Functions that Make Up a BECS - Hospital



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How Was This Managed Before Computers?

- WWII is the starting point of today's large-scale blood programs
- Before computers - manual records, signatures….paper and extensive human intervention
- Foundational regulations were created, and remain in effect – also evolve with new clinical, scientific discovery….(1980's, AIDS crisis and discovery of HIV virus), and use of new technologies - computers

NOT prescriptive as to HOW – Allowing for Technology Changes

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Why Managing a BECS is Unique

Technology has made many blood center and hospital transfusion functions a "black box", creating great efficiency.

But, the same decades-old foundational regulations must be met, while managing the unique risks introduced by that same technology

=

REGULATIONS (must be met by the BECS and how it is managed)
GUIDANCE DOCUMENTS (help with "how")
STANDARDS (make it easier to work together)
SOPs (organization's working policies and processes)

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What ARE the Rules?

Regulations
Guidance Documents, and
Standards
Organization SOPs

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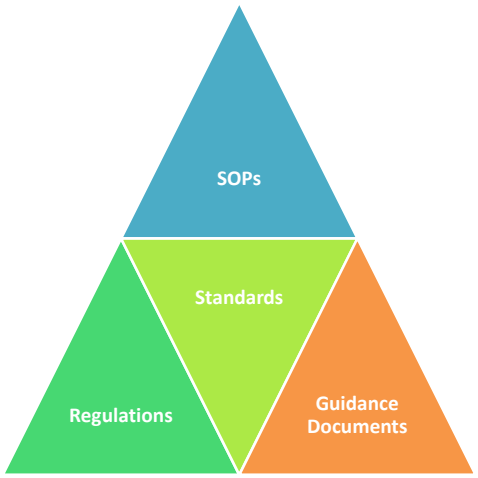
How the Rules Fit Together



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FDA and CFRs - Regulations

- FDA – Food and Drug Administration
  - ✓ Legal authority over biologic products like blood and how they are managed, (not just the milk in the grocery store….), and
  - ✓ Legal authority to regulate both medical devices and electronic radiation-emitting products (tongue depressors, ventilators, MRI devices….and BECS)
- CFR – Code of Federal Regulation (a REALLY big book)
  - ✓ The CFR is where the FDA writes down their rules…what has to be done.
  - ✓ The BECS has to fulfill the CFRs if its managing the blood, and
  - ✓ The BECS itself is a medical device and must meet the medical device CFRs in how it is designed, built, tested, and controlled/managed each day as a medical device

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Applicable CFRs, at a Glance

- 21 CFR 864 –

Defines BECS as a class II medical device, specifically lists the computer environment, and notes requirements for testing, controlling the system, risk/hazard analysis

- 21 CFR 606s

BECS is part of the cGMP for Blood and Components. If the computer system is performing a function (irradiation…do you have record on that for labeling) that needs records/controls…then it needs to meet and be managed under this CFR – functions of the BECS…are they compliant broadest sense of the "system"

- 21 CFR 211, subpart D

BECS is part of the "equipment" in blood and transfusion operations which needs to be managed

- 21 CRF, part 11

Management of electronic records and signatures (if you keep electronic records…about donor, blood products, patient transfusions, test results…need to meet this (includes decommissioning systems, and retaining access to those records).

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So, What Does That Mean to Me

SYSTEM SELECTION OR DEVELOPMENT

- BECS (computer software system used), must meet the basic blood requirements for any area it claims to manage (intended use)…blood collection, manufacturing, record keeping, matching blood product to patient

- There must be documentation that proves the BECS has been designed and validated to meet stated intended use requirements, and known risks identified and mitigated. Clear installation instructions and requirements (e.g., operating system and data base versions, validated peripherals , and versions (drivers)) and configurations identified.

An FDA 510K clearance helps buyers of systems know if these basics have been met, and a 510K must be granted for sale/production use of such a system.

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So What Does That Mean To Me?

SYSTEM LIFECYCLE MANAGEMENT

1. Install the system and be able to prove (document) it has been installed in compliance with manufacturers specifications – IQ (Installation Qualification) - Unit Testing

2. Setup and test (document) the system is working with the organization's specific settings, operational assumptions, on its equipment.. – OQ (Operational Qualification) – Systems and Integration Testing

3. The combination of the technology, trained staff, processes (SOPS), must be shown to work together (that harmony), to achieve the expected results - PQ (Performance Qualification) – User Acceptance Testing

4. Must lock down and control that validated state. Changes require a disciplined and well documented Change Management Process.

MEDICAL DEVICES

Don't change scanner, PC O/S, Tablet O/S, printer, database version/type, WITHOUT change control, validation, verifying it meets the manufacturers stated versions

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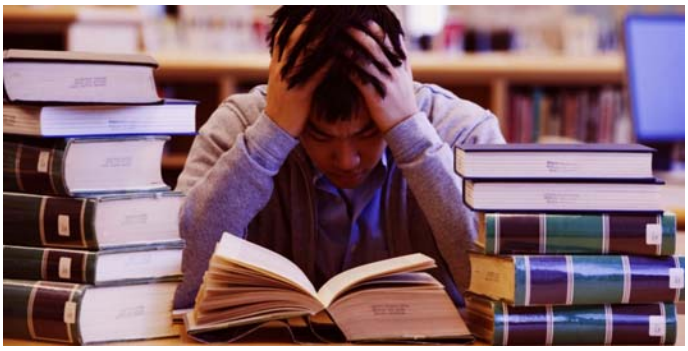
Well That Feels Overwhelming!!!



I read the CFRs, but I'm still not sure what to do…, and if the FDA thinks its okay

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Guidance Documents

- After a regulation is issued, the FDA may determine that it needs to provide industry, academia, and other stakeholders with more information on how the FDA intends to exert (or decline to exercise, as the case may be) its regulatory authority.
- The FDA does this through issuing what it has termed 'Guidance' documents.

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Applicable Guidance at a glance…

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- General Principles of Software Validation
- Blood Establishment Computer System Validation in the User's Facility
- Part 11 Electronic Records; Electronic Signatures - Scope and Application
- Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices

As more computer technology was introduced…how do we know its meeting its intended use and protecting the safety of the donor and patient

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Standards - More Clarity and Focus

Provide more industry specific guidelines and interpretation of the CFRs and/or "hows"

AABB – "American" Association of Blood Banks (international, so now AABB)

ISBT – International Society of Blood Transfusion

ICCBBA - International Council for Commonality in Blood Banking Automation

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AABB – Standards

- Currently active 31st Edition Published 2018 – always evolving
- Upcoming 32nd Edition – April 2020
- Blood centers and transfusion Services can be accredited by AABB, based on bi-annual inspections based on these more specific standards and CFR interpretations
- Specific standards provided from what viral tests are run, to how long specific records must be retained, information systems, are addressed
- If there is a disagreement between the AABB Standards and a CFR/Guidance – the more conservative of the 2 is used.

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ISBT - Standards

- Create international “consensus” standards, guidelines, and promote best practices
- Publish International Standards and Guidelines– per the international working parties, with strong consideration of the FDA position, as well as all other IT standards bodies (ISO, GAMP, etc.)
  - IT: Integration, validation, new technology (RFID) guidelines
  - Detailed and comprehensive set of computer system standards

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ICCBBA - Standards

- ISBT-128: Information Standard for Blood and Transplant.
  The number 128 reflects the 128 characters of the ISO/IEC 646 7-bit character set.
- Blood product code, labeling, bar code and data exchange standard

NOTE:
The FDA refers/defers to this standard – fully acceptable to meeting US blood product labeling, etc. requirements

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SOPs – How Your Organization Codified the Rules and Standards

- Every blood center and hospital transfusion service has its own quality "system"
- Policies and Procedures are provided to employees as their working instructions
- These policies and process/procedure documents take in all the CFRs, guidance documents, and standards to provide specific "how to"
- The FDA and AABB will audit to these, and sometimes they need to be adjusted
  - PC install and validation SOPs
  - Scanner installation and validation
  - Error tracking
  - Tablets (attached to our EBDR medical device)
  - System back ups and recovery
  - Record retention
  - Infrastructure change control and validation
  - Software development and validation
  - IT separation of duties and walkthrough/reviews
  - Maintaining and environmental manual

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Cyber Security

Some Basics…

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What is Cyber Security

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What is Cyber Security

Computer security, cyber security or information technology security (IT security) is the protection of computer systems from the theft of or damage to their hardware, software, or electronic data, as well as from the disruption or misdirection of the services they provide.

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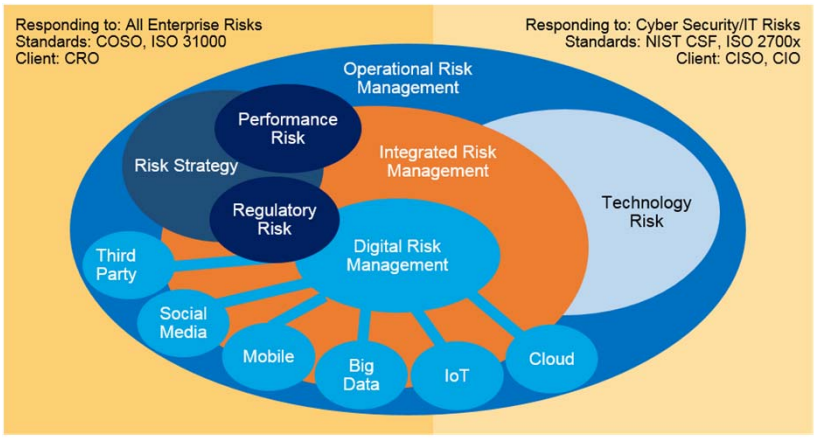
What is Cyber Security – Part of Enterprise Risk Management



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Why Is This Different…?

Two Reasons…

1. Healthcare (blood center or hospitals) are often targeted
   a. We cannot be down for extended periods – Ransomware
   b. We have a lot of personal information – Ripe for identify theft. High value
   c. Stakes are high if our data integrity is lost
2. Medical device software/systems
   a. Vendors often behind and/or have not applied latest patches
   b. Internal IT handicapped in applying some of the same technology protections (patching, monitoring tools) onto a medical device

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How Does the FDA Address This?

- Risk-based approach - state that they expect blood centers and hospital transfusion services to take appropriate precautions
- Also expect manufacturers of our systems to take precautions, but the FDA does not test for this
- It is a myth, that manufacturers, *and to some degree*, that the blood center or hospital cannot patch systems to make them more secure
- FDA does not consider itself cyber experts. They work and cooperate with other industry groups
- FDA expects to be informed of cyber vulnerabilities and/or breaches to medical devices
- Issued Guidance documents to help

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Cyber Guidance at a Glance

- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices
- Postmarket Submissions for Management of Cybersecurity in Medical Devices
- Cybersecurity for Networked Medical Devices Containing Off the Shelf (OTS) Software (older, combined above)

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Questions?

Contact
AABB eLearning Team
eLearning@aabb.org

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