



# AABB Standards and Accreditation

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# Objectives

- Review AABB standard setting process
- Describe accreditation program

## What is AABB?

- International association
  - Dedicated to transfusion medicine and cell therapy
- Standard setting / accreditation for 50 yrs.
- 8,000 individual members
- 1,800 institutional members
- 50 states 80 countries



# Standards Overview

- Based on ISO and Quality Systems
- Include Quality System and Technical standards
- Standards not prescriptive
  - Flexible
  - Allow for innovation and technology
  - Facilities must meet all requirements
- 18 month cycle for new editions
  - To keep up with rapidly changing science and technology
- Tools
  - Assessment tools (guidance/inspection preparation)
  - Commendable practice on web (examples of SOPs, forms, etc)

# AABB Standards Chapter Titles (5<sup>th</sup> Edition)

- Organization,
- Resources
- Equipment
- Agreements
- Process Control
- Documents and Records
- Deviations and Nonconforming Products or Services
- Internal and External Assessments
- Process Improvement

# Standards Review and Updates


- Based on new evidence
- Changes in regulations
- Changes in standard of care
- Input from membership, SPU members, and accredited facilities
- CT SPU has a defined algorithm for changing standards
- AABB has mechanism for public/membership notification



# The Evolution of AABB Cellular Therapy Standards

- 1991-96 Part of BB TS Standards
- 1996 1<sup>st</sup> Edition HPC Standards
- 2000 2<sup>nd</sup> Edition HPC Standards
- 2001 1<sup>st</sup> Edition Cord Blood Standards
- 2002 3<sup>rd</sup> Edition HPC Standards
- 2004-11 1<sup>st</sup> -5<sup>th</sup> Edition Cellular Therapy Stds  
Combined with 1<sup>st</sup> ed. cord blood (2001) and 3<sup>rd</sup> edition HPC

# Format of AABB CT Standards

- Cascading pattern:
  - General quality standards
    - Technical standards that apply to all cellular therapy products
      - Technical standards that are specific to the type of product or donor
        - Reference standards (most detailed requirements in book)
- **C or F  = Corresponding record required**
  - **Refer to retention time for records (6.2.10)**
    - **From Creation or Final Disposition**



- 5.0: Process Control
  - 5.7 Verification of Donor Eligibility
    - ✍ 5.7.2 Donor identity: *Requires 2 identifiers at procurement*
      - 5.7.2.1 Additional requirements for cord blood: *requires identification of the birth mother before procurement.*
        - Reference standard 5.7.1.A
        - Contains more detail about donor eligibility requirements

# The Standards Program Unit

- **Content experts**
  - Technical
  - Scientific
  - Regulatory
- **An ethicist (may also serve as public rep)**
- **Physicians**
  - Lab Directors
  - Clinicians
- **Representative from AABB accreditation program unit**
- **Representatives from other organizations (AATB, ACOG, ASBMT, ASFA, ASH, FACT, FDA, ISCT, NMDP)**

# AABB Accreditation Program

- Based on *Standards*
- Program has policies regarding:
  - Conflict of interest
  - Confidentiality
  - Assessor technical expertise
  - Organization of accrediting body
  - Impartiality
- Internal and external validation of assessments



# The Process

- Assessment team and duration of assessment based on services and volume
  - Team includes AABB staff assessor plus others
- Either facility or assessor may decline
- Not same assessor for sequential cycles
- Unannounced (within an approved date range)
- Written policies and procedures
- Dispute process (Accreditation Review Cmte)
- Assessor CE requirements (content and quantity)
- Variance process
  - Facility can request variance from standards, reviewed by CT SPU

# Accreditation Spans Entire Process

- Collection sites
- Testing sites
- Processing sites
- Storage sites
- Infusion sites
- Off-site collection facilities (incl UCB)
  - Physically assess minimum of one site or 10% (greater of the two – since 1998)

# International Accreditation

- Allows accreditation with “variances” from certain standards
  - Infectious disease testing kits in some countries may not be US FDA approved
  - Country specific Government/Health Ministry Policies that are not compliant with AABB standards
  - International Accreditation is noted on AABB web site.



# Efforts Towards Harmonization of Cellular Therapy Standards

- AHCTA, A formal worldwide group with broad representation
- The Circular of Information- new revision in early development
- The ISBT 128 working group

***Mission statement:***

- Harmonisation of respective standards
- Ultimately achieve a single set of quality, safety and professional requirements for cellular therapy including haematopoietic stem cell (HSC) transplantation.
- All aspects of the process from donor recruitment to transplantation and clinical outcome.
- Supported by
  - complementary standards and guidelines,
  - promotion of the concept of a global set of standards
- Inform and support authorities in the area of cellular therapy regulation: *minimum requirements*

Questions...

Contact us at [standards@abb.org](mailto:standards@abb.org)