AABB Standards and Accreditation

Doug Padley, MT (ASCP)
Mayo Clinic
Rochester MN USA
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 (5th 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 1st Edition HPC Standards
- 2000 2nd Edition HPC Standards
- 2002 3rd Edition HPC Standards
- 2004-11 1st-5th Edition Cellular Therapy Stds
  Combined with 1st ed. cord blood (2001) and 3rd 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@aabb.org