



# AABB Standards and Accreditation Programs

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# Overview

- AABB Standards for Cellular Therapy Services
  - Includes cord blood standards
- AABB Accreditation Program
- Collaborations and Partnerships

# AABB Mission and Core Values

*AABB advances the practice and standards of transfusion medicine and cellular therapies to optimize patient and donor care and safety.*

- Professional and standards setting organization since 1947
- 1,800 institutional members
- 8,000 individual members
- Successful history of working with regulatory agencies in various countries
- **Proven track record of international technical assistance and close collaborations with government agencies**

# Standards and Accreditation

- **Cellular Therapy Services**
- Blood Bank/Transfusion Service
- Relationship Testing
- Immunohematology Reference Laboratories
- Perioperative Autologous Blood Collection
- Molecular Testing for Red Cell, Platelet, and Neutrophil Antigens

# Cellular Therapy Accredited Facilities

| Type of Facility                              | US | International |
|---|----|---------------|
| HPC   | 85 | 5             |
| Cord Blood                                    | 29 | 44            |
| Somatic (Includes pancreatic islets and MSCs) | 3  | 3             |

| <b>Country</b>       | <b>Facilities</b> |
|----------------------|-------------------|
| United States        | 102               |
| Canada               | 7                 |
| India                | 5                 |
| Taiwan               | 5                 |
| Singapore            | 4                 |
| Brazil               | 4                 |
| Hong Kong            | 3                 |
| China                | 3                 |
| Greece               | 2                 |
| Hungary              | 1                 |
| Cyprus               | 1                 |
| Argentina            | 1                 |
| Belgium              | 1                 |
| Israel               | 1                 |
| Japan                | 1                 |
| Netherlands          | 1                 |
| Panama               | 1                 |
| Poland               | 1                 |
| Portugal             | 1                 |
| Saudi Arabia         | 1                 |
| South Africa         | 1                 |
| Thailand             | 1                 |
| United Arab Emirates | 1                 |

# AABB Standards

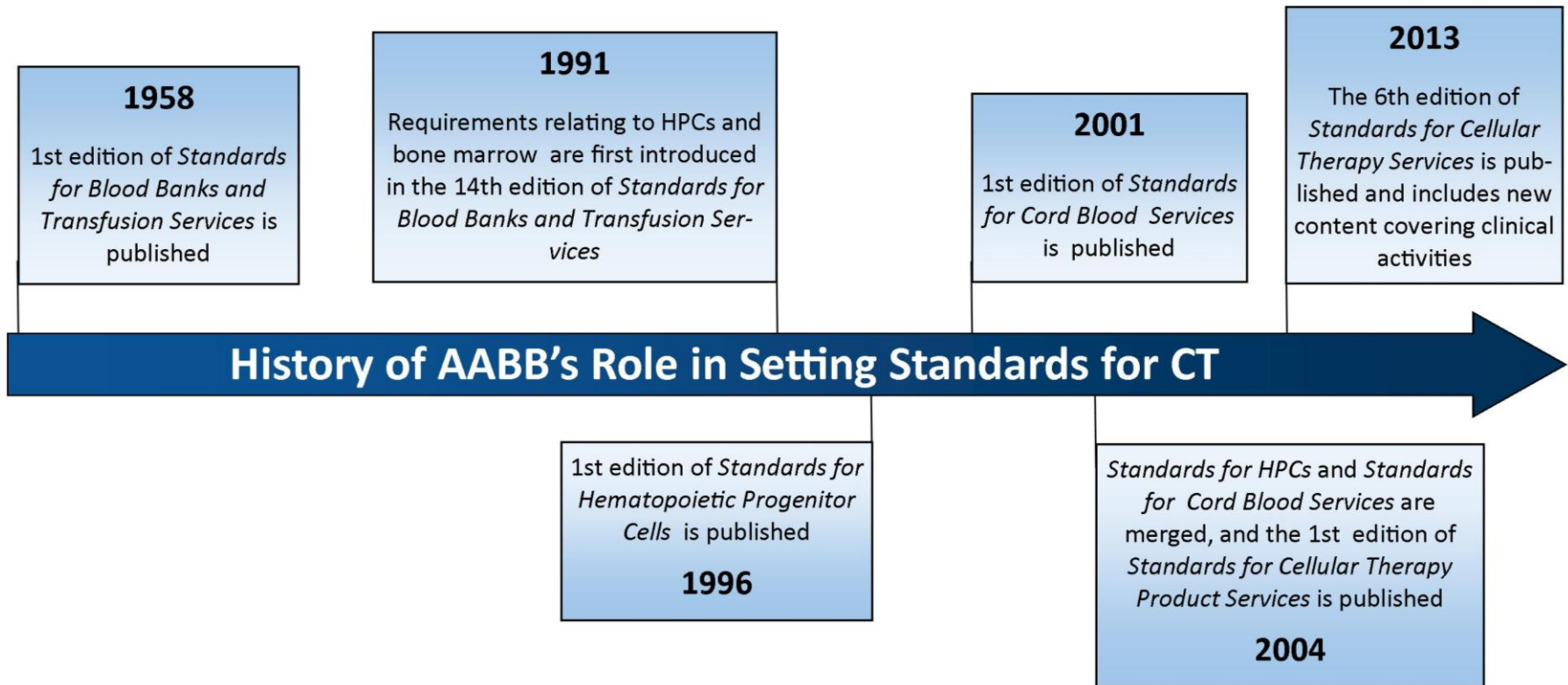
# Standards Program

- Standards developed by committee of technical and clinical experts, ethicists, public members and external representatives (e.g., CIBMTR and NMDP)
- Public comment period
- Revised on a 24-month cycle
- Process for interim and emergent standards
- Policy to manage conflicts of interest





# Milestones in AABB CT Standards



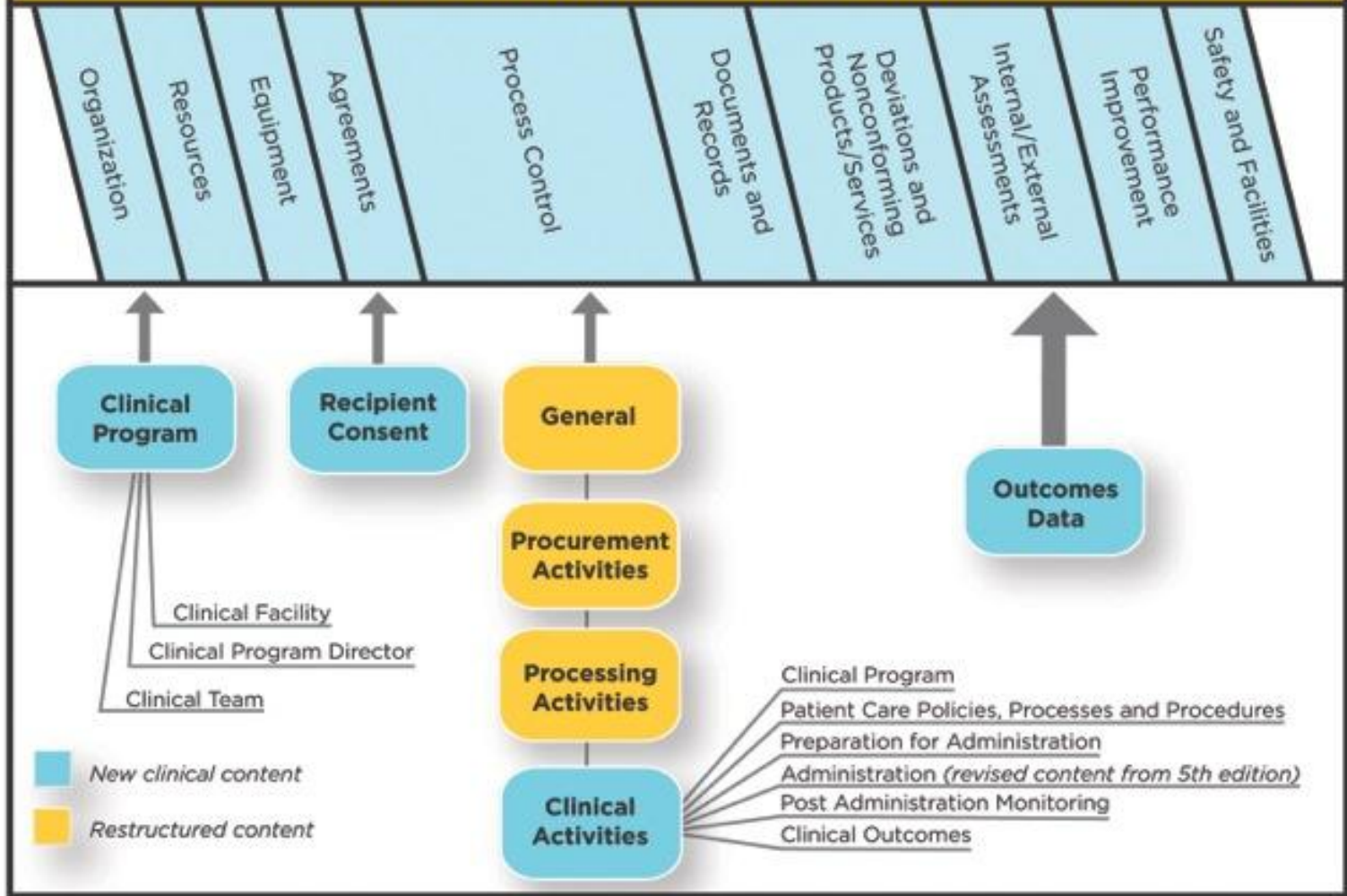
# Standards

- Chapters match AABB's 10 Quality System Essentials
  - Begins with high-level quality system requirements
  - Technical requirements cascade from quality system requirements
- Process for interim and emergent standards allows response to emerging issues
- Process for request for clarification from committee
- **Variance process allows for differences in regional regulations and recognition of innovative practices while preserving quality and safety**

# Scope

- AABB Standards are broadly applicable to virtually any cellular therapy product
  - All aspects of procurement, processing, and transplantation
  - International transfer of products
- Continued evolution and expansion to address novel cellular therapies
- **New clinical standards also cover clinical use of these products and patient care**

# Selected Clinical Content in the 6th Edition of CT Standards



# AABB Accreditation Program

# Accreditation Program

- Designed to operate in a regulated environment
- Unannounced assessments
- International assessments – coordinated in advance
- 2 year renewal cycle
- Systems approach
  - Reviews objective evidence
  - Verifies operations over time (not snapshot in time)
  - Robust auditing techniques

# International Recognition



- **Both** Accreditation program and assessor training program are accredited by ISQua
  - International Society for Quality in Health Care
  - ISQua accredits accrediting organizations worldwide
- AABB is one of only three accredited organizations in North America
  - Assessor training program is one of eleven accredited globally

# Translation Requirements

- Only documents sent to AABB as part of pre-assessment and follow up/corrective action must be translated into English
- English translator required during the on-site assessment.



# Assessment Team

- Volunteer assessors as content experts
  - Possess technical and clinical expertise
  - Receive training in auditing and assessment process
  - Continuing education requirements
  - Participate in AABB assessor competence program
  - Rigorous conflict of interest policy
    - Facility or assessment team member may decline assignment
- AABB Staff lead assessor serves on each team for consistency and to minimize conflict of interest

***Team size and length of assessment based on facility size and scope of services***

# Assessment Summary

- Delivered to key facility representatives at exit session
  - Assessment objective restated
- Acknowledge facility accomplishments
- Nonconformances are based on objective findings – shared and explained during exit session
  - Facility verifies understanding of the issue presented
- Copy of summary report left at facility
- Corrective action due within 30 days
  - Reviewed by AABB staff to determine acceptability

# Collaborations and Partnerships

# Collaborations and Partnerships

- Work with US HRSA and CMS to add additional assessment verification
- Global Services: International technical assistance programs (e.g. PEPFAR)
- Partner with ABHH (Brazilian Association for Hematology, Hemotherapy and Cellular Therapy) to build joint standards and accreditation program
  - AABB Standards translated and licensed to ABHH
  - Brazil developed mirror accreditation program
    - AABB oversight and shared policies
  - Accreditation certificate issued by AABB/ABHH
  - Applies to transfusion medicine and cellular therapy facilities

# Other Options

- Collaborate with health ministries to develop standards for their country in any area of AABB standards
  - Used to develop the first cellular products regulations in India
- Collaborate with regional consortiums to accredit multiple centers:
  - Increases value with standardization between centers and offers optimal use of resources
  - Custom packages may include other member services as well

Obrigado  
Muchas Gracias  
Thank you!

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