AABB Accreditation: Evolution
ISQua Meeting 2015

Holly Rapp, Director
Accreditation and Quality
AABB

Way back when…

• 1956 – Accreditation program proposed to the AABB Board of Directors
• 1957 – Inspection & Accreditation Program is created
• 1958 – Publication of 1st edition of Standards for Blood Banks and Transfusion Services

Purpose of Accreditation

• Foster improvement of standards of practice as they relate to services affecting patients and donors
• Establish a basis for recognition of adherence to AABB Standards
• Provide proof of compliance, peer review and education

Participation

• All institutional members of AABB were required to participate in the I&A program
• Non-AABB members were encouraged to participate as well
• Program was pre-requisite for full participation in National Clearinghouse Program for exchange of blood products

Then (1950s,60s and 70s)…

• Volunteers
  – One National Chair
  – Five district &A chairs (around the US)
  – Inspectors (selected/ advanced degrees –MD, SBB)
• Inspection Form
  – Defined requirements for accreditation
    • Based on Standards for Blood Banks and Transfusion Services
  – Yes/No questions
• Deficiencies

1970’s

• Accreditation of SBB* Schools

* Specialist in Blood Bank
1980’s
- Clinical Laboratory Improvement Act (CLIA ‘88)
  - The United States Code of Federal Regulations (CFR) states the conditions that all laboratories must meet to be certified to perform testing on human specimens under the Clinical Laboratory Improvement Amendments 1988
- Accrediting organizations are granted “deemed status” to perform assessments for the government agency

Supporting Documents
- 1978 Inspection and Accreditation Policy & Procedure manual
- 1986 Accreditation Requirements Manual (ARM)
- 1987 Inspector’s Quarterly newsletter
- 1988 Inspector’s Handbook

Moving on…
- 1993 Inspection and accreditation of Parentage Laboratories (now Relationship Testing Laboratories)

Reform Era
- 1995 FDA* issued “Guidelines for Quality Assurance in Blood Establishments”
- AABB developed educational materials
- AABB Quality Plan produced
*Food and Drug Administration

Later (1996)…
- Volunteers
  - Chair
  - Four vice chairs
  - 27 area chairs
  - 800 inspectors

Now (21st century)…
- Volunteers
  - Accreditation Program Committee
  - 600 Volunteer assessors
- AABB Staff
  - National Office Accreditation Department
    - 5 lead assessors
    - 9 staff in the office
The Quality Era

- 1997 Quality System Essentials
- AABB Assessments
- AABB Assessors
- Assessment Tool
- System Audit

New Accreditation Programs

- Cellular Therapy 1998
- Immunohematology Reference Labs 2001
- Perioperative Services 2001
- Molecular Testing 2010

Deemed Status

- 1995 granted deemed status for CLIA – BBTS
- 2008 deemed status renewed for 6 years – BBTS – IRL
- 2014 deemed status renewed for 6 years – BBTS and IRL – Cellular Therapy and Molecular Testing added

Assessor Training

- New Assessor Training
- Assessor Day at the Annual Meeting
- Quarterly Assessor CE Update
- Assessor Continuing Education Report
- Assessor Competency

Assessors

- 600 Volunteers – 10 countries besides US
  - Variety of expertise
  - Volunteer > 24,000 hours per year
  - Perform between 600-700 assessments each year

Accreditation of the Accreditation Program

- ISQua (International Society for Quality in Healthcare)
- Accreditation program and Assessor training program are granted accreditation in 2009
- Accreditation renewed in 2013
Domestic and International
- AABB accredited facilities around the world
  - 22 countries

Summary
- Accreditation Program is over 50 years old
- Program is still growing
- Only ISQua accredited program in US

Questions?