AABB Standard Setting and the AfSBT Standards

Eduardo Nunes
Senior Director of Policy, Standards, and Global Development
AABB

www.aabb.org
Overview

- History of AABB standards-setting
- Overview of AABB-AfSBT process and other administrative considerations
- Quality System Essentials
What is a Standard?

- Standards are imperative scientifically-based statements, often stated as positives rather than negatives
  - The list of what NOT to do is too long
- Minimal and unambiguous requirements that may be exceeded in practice
What is NOT a Standard?

- Legal framework of Ministry of Health
- *Recommendations* for specific methodologies
- Statements that cannot be verified through direct observation
History of AABB Standards

- First edition 1958
- In 1976 the 8th edition included a requirement for each facility to have, “program of quality control”
Quality continues

- Association Bulletin #97-4 identified the 10 Quality System Essentials (QSEs) as the minimum elements that must be addressed in a quality system.
QSEs in the AABB Standards

- Listed in the “General Policies” section of the 18th edition (1997)
- Each QSE became a standard in “General Policies” section of the 19th edition (1999)
AABB – AfSBT Project Timeline

- November 2010: AfSBT representatives visit AABB
- December 2010 – May 2011: Skype conference calls, email
- June-August 2011: Public comment period
- Review of comments
# Quality System Essentials in AABB and AfSBT Standards

<table>
<thead>
<tr>
<th>AABB QSE</th>
<th>AfSBT Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Organization</td>
<td>1.1 Organization &amp; Structure</td>
</tr>
<tr>
<td>Resources</td>
<td>1.3 Resources</td>
</tr>
<tr>
<td>Equipment</td>
<td>1.7 Equipment</td>
</tr>
<tr>
<td>Supplier and Customer Issues</td>
<td>1.5 Suppliers and Service Providers</td>
</tr>
<tr>
<td>Process Control</td>
<td>1.12 Process Control</td>
</tr>
</tbody>
</table>
QSEs in AfSBT Standards, continued

<table>
<thead>
<tr>
<th>AABB QSE</th>
<th>AfSBT Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>Documents &amp; Records</td>
<td>1.4 Documents &amp; Records</td>
</tr>
<tr>
<td>Nonconforming Products and Services</td>
<td>1.10 Non-conformances</td>
</tr>
<tr>
<td>Assessments: Internal &amp; External</td>
<td>1.9 Internal &amp; External Audits</td>
</tr>
<tr>
<td>Corrective &amp; Preventive Action</td>
<td>Under 1.10</td>
</tr>
<tr>
<td>Facilities &amp; Safety</td>
<td>1.8 Work Environment &amp; Safety</td>
</tr>
</tbody>
</table>
Shall vs. Should

- Standards vs. guidance
  - A Standard is a goal (what)
  - Guidance contains methods of meeting that goal (how)
  - Assessors assess against Standards only. Did the facility meet the goal?
Role of should’s

- AfSBT includes a few “should” statements
- Signal future directions or areas where consensus is still emerging
- Guidance
Emphasis on validation

- Assessor: “Show me how you know that this transport cooler maintains the unit at the right temperature.”

- If the *Standards* does not say *how*, then each facility must decide what works for them, keep records of data supporting the decision, and reflect it in their policies, processes and procedures
How is a Standard created?

- A number of sources of input are considered, including:
  - New data
  - Existing policies and guidelines
  - Input from the users
Input from the users

- Includes:
  - Requests for clarification of a standard
  - Requests for variance from a standard
  - Feedback obtained during the comment period
  - Feedback from assessors

- The process for supporting Standards-setting should include mechanisms for this type of feedback
Standards in detail

- General statements appear in section 1, Quality System
- Sections 2-10 follow donation to transfusion workflow
- Each chapter modeled after workflow for that topic (eg, crossmatch precedes issue for transfusion)
- Section 11 covers National Blood Service Accreditation Requirements
Case Study

- How Section 1 was impacted by comments
- Examples of actions taken are illustrative of the relationship between Standards and satellite documents
Comment on scope

- If a blood transfusion centre does not routinely cross-match and issue units directly to patients, then sections 7 (ordering), 8 (compatibility testing) and 9 (haemovigilance and clinical interface) apply?

- What about hospital blood banks that do not collect their own blood donations but rely on central facility for all donor activities
Brilliant!

IDEA CAT LOOKS FOR MORE GOOD IDEAS
We clearly needed a better idea

- Introduction: “These Standards apply to blood services or individual facilities that perform any or all of the following functions...”
- Donor activities, and processing up until distribution
“Exceptions warranted by clinical situations shall require justification and pre-approval by the medical director on a case-by-case basis.”

Comment: Should there be requirement for keeping record of approval?
Change made!

WHO’S AWESOME?
You’re Awesome!

www.aabb.org
How?

- 1.1.3.1 now includes the pen symbol (_pen_
- Item 2 in Record Retention Table
Comment: Supervision

- 1.3.2: “The facility shall have sufficient, trained personnel, working under supervision, to perform its activities.”
- Comment: ‘Supervision’ should be defined (direct, telephonic)
Guidance added!
Guidance

- Guidance document outlines differences between direct and indirect supervision, and provides examples of the kinds of functions and employees that are candidates for indirect supervision
Release of untested units

- 1.10.4.1.1 addresses release of units with incomplete compatibility and/or infectious disease testing

- Comment: Disagree with standard. Each facility should have an emergency stock available to meet any urgent requirement.
Outcome
Why?

- We do not disagree with commenter
- Certainly this is good practice
- BUT – we did not want to write a standard that limits ability of BTS to respond to disasters and emergencies
Last example: Records

- Proposed Standards: INDEFINITE retention of records of donor consent and of look-back to identify recipients of units from a blood donor who is later found to be positive or reactive for HIV, HBV, or HCV
Comment

Are you sure you mean “indefinite”? Like, FOREVER?
We say: great catch!
Change made

- Both record retention periods changed to 10 years
- National regulations may exceed timeframes in retention tables
Not everything is a Standards issue

Different comments can be addressed in different ways

- Change to Standards
- Change to satellite document (intro, guidance)
- No change
Conclusion

- Standards-setting is a journey, not a destination
- Improved by active input from users
- We look forward to continuing the trip
Thanks!
If you have questions...

- eduardo@aabb.org
- standards@aabb.org