
PREFACE

The Standards Program Committee (SPC) and the Blood Banks and Transfusion Services Standards Committee (BB/TS SC) are pleased to present this 32nd edition of *Standards for Blood Banks and Transfusion Services (BB/TS Standards)*.

The SPC is the umbrella committee whose primary role is to oversee the creation, development, and revision of all AABB standards to ensure harmonization and consistency in AABB's standard-setting activities. The SPC consists of a committee chair, the chair of the Standards Subcommittee for the Evaluation of International Variances, as well as the chairs of the individual standards committees.

The BB/TS SC developed this 32nd edition of *BB/TS Standards*, using an evidence-based decision making process, when possible, to modify existing requirements or to create new ones.

The process of developing the requirements in *BB/TS Standards* requires that the final publication reflects the concerns and priorities of several different aspects of the discipline, including the input of recognized experts in the field and the best interests of their donors and patients. In addition, *BB/TS Standards* was developed in the context of the global drive for quality in health care and internationally recognized principles of quality management. To this end, the BB/TS SC also consulted the scientific literature on blood bank and transfusion service techniques and applications including AABB Association Bulletins and AABB Risk-Based Decision-Making Reports. Accordingly, *BB/TS Standards* is based on input from a variety of sources, including member and public comments. In an effort to harmonize AABB publications, all standards have incorporated the AABB Quality System Essentials as the foundation of the standards. A facility is assessed only on those activities it performs.

BB/TS Standards contains requirements that must be implemented by accredited AABB institutions. Requirements are statements, signified by the use of the term, "shall." Guidance for the 32nd edition of *Standards for Blood Banks and Transfusion Services* could be of assistance in understanding and implementing these requirements but it is only the standards upon which a facility will be assessed. Guidance for specific standards that appear in this edition of the *BB/TS Standards* will be published in the Standards Portal and in printed form. Guidance entries are crafted from BB/TS SC deliberations, member clarification requests, and approved variances.

Preface

The BB/TS SC has published a document providing informal responses to the feedback received during the comment period explaining why the BB/TS SC adopted a suggestion, or did not. This document can be found on the AABB website at: <http://www.aabb.org/sa/standards/Pages/library.aspx>

It has been both an honor and a privilege to have been asked by AABB to chair the BB/TS SC. All of the committee members have many years of experience in their field and have volunteered to share their expertise. This publication sets the bar high enough to ensure that AABB accreditation remains internationally recognized and represents the utmost in quality of donor and patient care. *BB/TS Standards* is the product of those who truly believe in the value of evidence-based standards and will benefit any organization—from those seeking their initial AABB Accreditation to ones with well-established programs. It is meant to enhance and promote your facility on its journey from being a good program to becoming a great one.

Richard R. Gammon, MD
Chair, Blood Banks and Transfusion Services Standards Committee

INTRODUCTION

The *Standards for Blood Banks and Transfusion Services (BB/TS Standards)* was prepared by the Blood Banks and Transfusion Services Standards Committee and the Standards Program Committee of the AABB. The goal of the *BB/TS Standards* is to maintain and enhance the quality and safety of services provided by blood banks and transfusion services and to provide a basis for the AABB Accreditation Program.

The following frequently asked questions will help users of this publication better understand the 32nd edition of *BB/TS Standards*:

When does this edition go into effect?

The effective date of this edition is April 1, 2020.

Are the standards requirements or recommendations?

The *BB/TS Standards* contains requirements to be implemented by AABB-accredited blood banks and transfusion services. A requirement contains the word “shall,” which indicates that the statement is mandatory. Failure to meet the requirement would constitute a nonconformance under the AABB Accreditation Program. There are rare instances in which a standard uses the term “may.” A statement that uses “may” is not a requirement.

How does this publication relate to laws and regulations?

The *BB/TS Standards* was developed on the basis of good medical practice and, when available, scientific and evidence-based data. The requirements in this publication can be followed by a blood bank or transfusion service located anywhere in the world, but they do not preempt federal, state, and/or local laws and regulations. Accredited facilities must follow the *BB/TS Standards* as written to ensure continued AABB accreditation in good standing. Although the majority of the standards are intended to be consistent with applicable laws and requirements, no assurances can be given that compliance with *BB/TS Standards* will result in compliance with all applicable laws and requirements. *BB/TS Standards* is not intended as a substitute for legal advice and the content should not be relied upon for legal purposes. Users therefore must make their own determinations as to how best to ensure compliance with all applicable laws and requirements, including consulting legal counsel familiar with these issues.

Investigative studies may necessitate deviation from these *BB/TS Standards*. Such studies must 1) be performed under the direction of qualified individuals with consideration for the therapeutic requirements of the patient and the safety of the patient and donor, and 2) avoid supplanting or eliminating the requirements of these *BB/TS Standards* whenever possible. Scientific studies that modify or replace these requirements

must be approved by the Institutional Review Board Committee on Experimentation on Human Subjects or the equivalent peer-review group. The approval must be available in the blood bank or transfusion service.

Does this publication require me to follow my own local laws and regulations?

Yes. In many standards, the BB/TS SC chose to use the term “specified requirements.” This phrase is defined in the glossary to include any applicable requirement under which a service might operate. These could include, but are not limited to, a federal regulation, a customer agreement, a practice standard, the instructions for the intended use of a device, or a requirement of an accrediting organization.

What does the pen symbol (✍) mean?

When the pen symbol precedes a standard, users have to maintain a record of that activity in order to meet the standard. Readers should refer to the reference standard at the end of Chapter 6 to determine what that record must contain and the length of record retention.

What other tools are available to help me implement the *BB/TS Standards*?

There are several other resources to assist users. This publication also includes:

- A glossary, which reflects the usage of specific words or phrases in the context of these *BB/TS Standards*.
- A crosswalk that cross-references the standards in this edition of *BB/TS Standards* with those in the previous edition.

In addition, users of this edition may also want to:

- Visit www.aabb.org for a document that details the disposition and resolution of all comments received about this edition. This document is titled, “Response to Public Comments” to this 32nd edition. When a public comment is the source of a change, or where the BB/TS SC did not make a change suggested by a comment, an explanation is provided.
- Follow guidance to the 32nd edition of *BB/TS Standards*, found in the AABB Standards Portal online, or as a printed publication. The guidance provides rationales behind significant changes to this edition of *BB/TS Standards*, and provides recommendations on how to meet the intent of certain standards.
- Contact standards@aabb.org to ask for interpretations or to submit a variance request. Variances to standards are effective for the edition of *BB/TS Standards* for which they are received. Request forms for variances can be found at <http://www.aabb.org>. It should be noted that granted variances apply only to the edition of *Standards* for which they are requested. Renewals of previously granted variance requests must be submitted prior to the effective date of the subsequent edition, except in cases where the standard has been updated or the facility has reached compliance.