
PREFACE

The Standards Program Committee (SPC) and the Blood Banks and Transfusion Services Standards Committee (BB/TS SC) are pleased to present this 34th 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 Variations, and the chairs of the eight standards committees.

The BB/TS SC developed this 34th 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 reflect 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 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's recently updated quality system essentials as the foundation of the standards. A facility will be assessed only on 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 Standards for Blood Banks and Transfusion Services*, 34th edition, could be of assistance in understanding and implementing these requirements, but a facility will be assessed only upon the standards. 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 the BB/TS SC, member clarification requests, and approved variances.

As mentioned, this 34th edition of *BB/TS Standards* implements AABB's updated quality system essentials. The quality system essentials were first introduced by AABB in Association Bulletin #97-04 and have served as the framework for which the *BB/TS Standards* have been presented since 2000 with the 20th edition. Since the year 2000, the quality requirements in the *BB/TS Standards* (and all sets of AABB *Standards*) have been updated on an as-needed basis, with changes occurring incrementally but not in a

universally applicable fashion. This updated version of the quality system essentials has been standardized in terms of language and style, and will be incorporated in all sets of AABB *Standards* beginning with the 16th edition of *Standards for Relationship Testing Laboratories*, effective January 1, 2024. The updated quality system essentials include the following updates:

- All standards are written in the active voice.
- Once a requirement has been stated, it is not repeated.
- Each chapter begins with a description of what the standards therein cover.
- Each chapter contains a list of key terms that relate to the content of the chapter, with their definitions.
- Each chapter contains a list of examples of objective evidence that an assessor could look for during an on-site assessment; however, this list is not comprehensive, nor will it be assessed against by an assessor. It is for guidance purposes only.
- Each chapter now concludes with the record retention table for that chapter. Note that a comprehensive record retention table still exists at the end of Chapter 6.

The AABB and the BB/TS SC feel that these updates across these *BB/TS Standards* (and all *Standards*) will provide a reset and upgrade on the previous version of the quality system essentials and will allow these *BB/TS Standards* to take the next step in quality.

The BB/TS SC has published a document providing informal responses to the comments 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 (<https://www.aabb.org/standards-accreditation/standards/about-aabb-standards/standards-library>).

It has been an honor and privilege to serve as chair of the committee for development of this 34th edition of the *BB/TS Standards*. These *BB/TS Standards* reflect the contributions of a large team of experts composed of members, liaisons, and representatives from other organizations and regulatory agencies. It has been a privilege to work with this team of professionals who share the goal of continuously advancing the quality of care to donors and patients. I would like to thank our workgroup chairs, Susan Noone, Susan Wilson, and Nina Sen, for their expertise and leadership in the development of proposed language and responses to comments. Our committee is greatly indebted to Chris Bocquet, AABB Senior Director of Standards Development and Quality Initiatives, whose background knowledge, guidance, and continuous support have been essential for achieving our goals. We are also indebted to Jason Silva, AABB Standards Development Manager, who provides the underlying organization for our committee work. I would like to express a special thanks to Karen Palmer, AABB Director of Regulatory Affairs, whose communication has been essential to ensure coordination of our committee's work with other AABB efforts during this year, particularly as we have incorporated the individual donor assessment approach to maximize blood safety more specifically and equitably. Finally, I would like to thank all individuals who have provided feedback and comments, which helps our committee to ensure that these *BB/TS Standards* are clear and operationally feasible. We hope that these *BB/TS Standards* will

enable your organization to achieve and sustain the highest quality of care to the donors and patients whom you serve.

Susan A. Galel, 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 Accreditation Program of the AABB.

The following frequently asked questions will help users of this publication better understand the 34th edition of *BB/TS Standards*:

When does this edition go into effect?

The effective date of this edition is April 1, 2024.

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 other 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 services 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 how best to ensure compliance with all applicable laws and requirements, including consulting legal counsel familiar with these issues.

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

Yes. In many standards, the Blood Banks and Transfusion Services Standards Committee 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 record retention tables at the end of each chapter and the complete reference standard at the end of Chapter 6 to determine what that record must contain.

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 to this edition, as well as significant changes. This document is titled “Significant Changes and Response to Comments” to this 34th edition. When a public comment is the source of a change, or where the Blood Banks and Transfusion Services Standards Committee did not make a change suggested by a comment, an explanation is provided.
- Guidance for the 34th edition of *BB/TS Standards* can be found in the AABB Standards Portal, available online and as a printed stand-alone copy of the published Guidance. 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 for interpretations or to submit a variance request. Variances to standards are effective for the edition of *Standards* for which they are received. Request forms for variances can be found at www.aabb.org.