
PREFACE

The Standards Program Committee (SPC) and the Blood Banks and Transfusion Services Standards Committee (BB/TS SC) are pleased to present this 35th 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, and the chairs of the 10 specialty standards committees.

The BB/TS SC consists of a chair, members providing full representation of the blood banking and transfusion field (including medical laboratory scientists, laboratory directors, medical and laboratory professionals, and quality experts), liaisons from other AABB committees, and representatives from other organizations. The BB/TS SC meets during the 2-year revision cycle and has frequent conference calls to discuss requests for variances from each edition of *BB/TS Standards* and requests for standards interpretations.

Although the *BB/TS Standards* provides a great amount of technical information concerning immunohematology reference laboratories, other AABB publications provide specific recommendations. When using this edition of the *BB/TS Standards*, having access to the current edition of the AABB *Technical Manual* and the 35th edition of *Guidance for Standards for Blood Banks and Transfusion Services* (available in the Standards Portal and as a stand-alone published document) could be of service in understanding and implementing these requirements. *Guidance* entries are crafted from member requests for clarification and approved variances.

This 35th edition of *BB/TS Standards* maintains the AABB's quality system essentials updated in 2023. The quality system essentials were first introduced by AABB in Association Bulletin #97-04 and have served as the framework by which the *BB/TS Standards* has been presented since 2000 with the 20th edition.

It has been a great honor and privilege to serve as chair of the committee responsible for developing the 35th edition of the *BB/TS Standards*. This edition reflects the collective expertise and dedication of a broad team of professionals, including committee members, liaisons, and representatives from partner organizations and regulatory agencies. It has been a pleasure to collaborate with this distinguished group, united by a shared commitment to advancing the quality of care for donors and patients. Sincere appreciation is extended to our workgroup chairs, Alexandra Jimenez, Nina Sen, and Susan Wilson, for their leadership, technical insight, and thoughtful contributions in developing proposed revisions and responses to public comments. The committee is deeply grateful to Chris Bocquet, AABB Senior Director of Standards Development and

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Quality Initiatives, whose knowledge, guidance, and steadfast support were vital to achieving our goals. Special thanks are also extended to Karen Palmer, AABB Director of Regulatory Affairs, for ensuring alignment with other AABB initiatives throughout this revision cycle. Finally, the committee wishes to thank all individuals who provided feedback and comments. Your perspectives help us ensure that the *BB/TS Standards* remains clear, practical, and relevant. We hope that this 35th edition supports your organization in achieving and sustaining the highest quality of care for the donors and patients you serve.

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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 (BB/TS SC) 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 book better understand this 35th edition of *BB/TS Standards*.

When does this edition go into effect?

The effective date of this edition is April 1, 2026.

Are the *BB/TS 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 book 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 laboratories must follow the *BB/TS Standards* as written to ensure continued AABB accreditation in good standing. Although the majority of the standards here are intended to be consistent with these 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. Therefore, users 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.

Does this edition 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 reg-

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ulation, 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 comprehensive reference standard at the end of Chapter 6 to determine what that record must contain, as well as the required record retention time.

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 the AABB website for a document that details the significant changes to this edition. This document is titled “Significant Changes and Response to Comments” to the 35th edition of *BB/TS Standards*.
- Follow guidance to the 35th edition of *BB/TS Standards*, found in the AABB Standards Portal online or in the printed *Guidance for Standards for Blood Banks and Transfusion Services*. 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 on the AABB website (<https://www.aabb.org/standards-accreditation/standards/about-aabb-standards/requesting-a-variance>). Requests for renewal of previously granted variance requests must be submitted before the effective date.