The Standards Program Committee (SPC) and the Blood Banks and Transfusion Services Standards Committee (BB/TS SC) are pleased to present this 31st 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 Interpretation Committee, as well as the chairs of the seven specialty committees.

The BB/TS SC developed this 31st edition of BB/TS Standards. The BB/TS SC used 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. 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 (first identified in Association Bulletin #97-4) as the foundation of the standards.

In addition, the SPC has made a clear distinction between standards and guidance. BB/TS Standards contains requirements that must be implemented by accredited AABB institutions. Requirements are imperative statements, signified by the use of the term “shall.” All guidance to BB/TS Standards is located in the version of the 31st edition that exists in the AABB Standards Portal. Guidance is provided to clarify the difference between requirements and recommendations. The intent of guidance is to provide rationales for standards or examples of how standards might be implemented. Along with this guidance, the BB/TS SC has provided rationales for any significant changes to this 31st edition of BB/TS Standards, which also exist in the Standards Portal.

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 at the following address: http://www.aabb.org/sa/standards/Pages/library.aspx.

It has been my distinct honor and privilege to serve as chair of the BB/TS SC. Walt Disney once said, “Of all the things I’ve done, the most vital is coordinating those who work with me and aiming their effort at a certain goal.” This sentiment certainly applies to the BB/TS SC. In creating this 31st edition, I am grateful to have worked with a strong team of experts and blood bank leaders. The work of the committee is accomplished through its members, not the chair. My heartfelt thanks to each committee member, liaison, and organizational representative for volunteering their time and wisdom in the development of this new edition. A special recognition is offered to our workgroup chairs: Richard R. Gammon, MD; Kaaron Benson, MD; and Susan M. Wilson, BS, MT(ASCP)SBB. These three individuals led their teams in developing proposed language and revisions as well as evaluating each public comment. Well done!

The journey of standards development begins well in advance of the effective date, with countless hours of review, research, editing, debate, more editing, and yes, more debate. The BB/TS SC thoughtfully considers advancements in the industry, developing issues, and the impact of potential changes to donors, patients, and the membership of AABB. Public feedback is vital, and I thank each individual and institution that provided comments on our draft version. Your voice truly helped shape the final edition and ensured the creation of standards that are clear, meaningful, and accessible.

Most importantly, I cannot express enough gratitude to the AABB National Office staff and the AABB leadership. The Standards Department—Eduardo Nunes, Christopher Bocquet, and Margaret Harper—work tirelessly on our behalf and have an infinite well of patience. Not every issue is easily resolved, and many are shrouded in controversy, yet common sense, principle-based leadership, and unending support made my role as chair exceedingly simple. Thank you.

Thank you to those who read this preface! To paraphrase Jedi master Obi-Wan Kenobi: “The Standards will be with you. Always.”

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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 (BBTS SC) and the Standards Program Committee of 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 AABB.

The following frequently asked questions will help users of this publication better understand the 31st edition of BB/TS Standards:

When does this edition go into effect?
The effective date of this edition is April 1, 2018.

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 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 Stan-
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dards 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 BBTS 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 want to:
• Visit www.aabb.org for a document that details the disposition and resolution of all comments received to this edition. This document is titled “Response to Public Comments” to this 31st edition. When a public comment is the source of a change, or where the BBTS SC did not make a change suggested by a comment, an explanation is provided.
• Guidance to the 31st edition of BB/TS Standards can be found in the AABB Standards Portal, available online. The portal 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 http://www.aabb.org.