PREFACE

The Standards Program Committee (SPC) and the Perioperative Standards Committee (Periop SC) are pleased to present this 9th edition of *Standards for Perioperative Autologous Blood Collection and Administration (Perioperative 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 eight specialty program committees.

The Periop SC developed this 9th edition of *Perioperative Standards.* The Periop 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 *Perioperative 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 patients. In addition, *Perioperative 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 Periop SC also consulted the scientific literature on perioperative autologous blood management techniques and applications. Accordingly, *Perioperative 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 their foundation.

In addition, the SPC has made a clear distinction between standards and guidance. *Perioperative Standards* contains requirements that must be implemented by AABB-accredited facilities. Requirements are imperative statements, signified by the use of the term "shall." Guidance for the 9th edition of *Perioperative Standards can* 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 *Perioperative Standards* is found in the Standards Portal and is published in printed form. Guidance entries are crafted from Periop SC deliberations, member clarification requests, and approved variances.

The Periop SC has published a document providing informal responses to the comments received during the comment period explaining why the Periop SC adopted a suggestion, or did not. This document can be found on the AABB website.

It has been a pleasure to serve with the members of this Periop SC and I thank them for their dedication. The members volunteer their time to review each standard then revise or update as needed. The areas of expertise represented include blood bank, patient blood nanagement, accreditation, regulatory, and surgery (orthopedic, thoracic/cardiac, anesthesia, and perfusion/blood recovery). The roster of this committee included two past chairs (Dr. Berg and Dr. Puca) who gave historical perspective to many discusions.

I thank Christopher Bocquet and his staff who do an incredible job keeping us on task to meet the required timeline. The staff at the AABB Headquarters are truly unsung heroes devoted to transfusion safety of our patients worldwide, guiding us all in this journey to improve each edition of *Perioperative Standards.*

Theresa C. Stec, MT(ASCP)
Chair, Perioperative Standards Committee

INTRODUCTION

The *Standards for Perioperative Autologous Blood Collection and Administration (Perioperative Standards*) was prepared by the Perioperative Standards Committee (Periop SC) and the Standards Program Committee of the AABB. The goal of the *Perioperative Standards* is to maintain and enhance the quality and safety of perioperative autologous blood collection and administration 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 9th edition of *Perioperative Standards*:

When does this edition go into effect?

The effective date of this edition is January 1, 2021.

Are the standards requirements or recommendations?

The *Perioperative Standards* contains requirements implemented by AABB-accredited perioperative programs. 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 book relate to other laws and regulations?

The *Perioperative Standards* were 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 perioperative program located anywhere in the world, but they do not preempt federal, state, and/or local laws and regulations. Accredited facilities must follow the *Perioperative Standards* as written to ensure continued AABB accreditation in good standing. Although the majority of the standards here are intended to be consistent with applicable laws and requirements, no

assurances can be given that compliance with *Perioperative Standards* will result in compliance with all applicable laws and requirements. These *Perioperative Standards* are 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 the issues.

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

Yes. In many standards, the Periop SC chose to use the term "specified requirements." This phrase is defined in the glossary to include any applicable requirement under which a program 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, a record of that activity must be maintained 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, as well as the required record retention time.

What other tools are available to help me implement the *Perioperative 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 *Perioperative Standards*.
- A crosswalk that cross-references the standards in this edition of *Perioperative 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 to the 9th edition."
- Follow guidance to the 9th edition of *Perioperative Standards,* found in the AABB Standards Portal online, or in the printed publication. The guidance provides rationales behind significant changes to this edition of *Perioperative Standards*, and provides recommendations on how to meet the intent of certain standards.
- Contact the Standards Department (standards@aabb.org) to ask for interpretations or to submit a variance request. Variances to standards are effective for the edition of *Perioperative Standards* for which they are received. Request forms for variances can be found on the AABB website at http://www.aabb.org/sa/standards/Pages/Requesting-a-Variance.aspx. 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 new edition.