
PREFACE

The Standards Program Committee (SPC) and the Perioperative Standards Committee (Periop SC) are pleased to present this 8th 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 8th 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 the foundation of the standards.

In addition, the SPC has made a clear distinction between standards and guidance. *Perioperative Standards* contains requirements that must be implemented by accredited AABB facilities. Requirements are imperative statements, signified by the use of the term "shall." All guidance to *Perioperative Standards* is located in the version of the 8th 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

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provide rationales for standards or examples of how standards might be implemented. Along with this guidance, the Periop SC has provided rationales for any significant changes to this 8th edition of *Perioperative Standards*, which also exists in the Standards Portal. The Standards Portal can be accessed on the AABB website at the following address: <http://standards.aabb.org>.

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

Having been through this process a few times, I again am pleased to have the opportunity to express my thanks to the people involved in this project. The members of the Periop SC are volunteers who generously set aside their daily duties and donated their time and expertise to review, edit, and update *Perioperative Standards*. I am particularly grateful to the members who use such services on a regular basis and provided a practical perspective to our discussions. The members with quality or blood bank backgrounds are also appreciated for their unique perspectives, which resulted in thorough discussions on many topics.

The AABB staff members who participated in this project were Christopher Bocquet, Margaret Harper, and Karen Whilden. I thank them for their patience and insight and for keeping us on task. Special thanks to Mr. Bocquet for his diligence in steering the draft version of these *Standards* through the approval process.

Thanks also to all of the accredited perioperative programs for their commitment to quality and patient safety. As with previous editions, your feedback will help improve future editions of *Perioperative Standards*.

Mary P. Berg, MD
Chair, Perioperative Standards Committee

INTRODUCTION

The *Standards for Perioperative Autologous Blood Collection and Administration (Perioperative Standards)* was prepared by the Perioperative Standards Committee 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 book better understand this 8th edition of *Perioperative Standards*:

When does this edition go into effect?

The effective date of this edition is January 1, 2019.

Are the *Perioperative 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 your 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 these applicable laws and

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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. You therefore must make your 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 book require me to follow my own local laws and regulations?

Yes. In many standards, the Perioperative SC chose to use the term “specified requirements.” This phrase is defined in the glossary to include any applicable requirement under which your 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, you 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, 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 www.aabb.org for a document that details the disposition and resolution of all comments received to this edition. This document is entitled, “Response to Public Comments” to this 8th edition. When a public comment is the source of a change, or where the Perioperative SC did not make a change suggested by a comment, an explanation is provided.
- Guidance to the 8th edition of *Perioperative Standards* can be found in the AABB Standards Portal, available online. The portal provides rationales behind significant changes to this edition of *Perioperative 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. Requests for variance can be made online at the following address: [http:// www.aabb.org/sa/standards/Pages/Requesting-a-Variance.aspx](http://www.aabb.org/sa/standards/Pages/Requesting-a-Variance.aspx).