
PREFACE

The Standards Program Committee (SPC) and the Perioperative Standards Committee (Perioperative SC) are pleased to present this 11th 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, and the chairs of the 10 standards committees.

The Perioperative SC developed this 11th edition of *Perioperative 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 *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 donors and patients. In addition, the *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's recently updated quality system essentials as the foundation of the *Standards*. A facility will be assessed only on activities it performs.

Perioperative 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 Perioperative Autologous Blood Collection and Administration*, 11th edition, could be of assistance in understanding and implementing these requirements, but a facility will be assessed only upon the standards.

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Guidance for specific standards that appear in this edition of the *Perioperative Standards* will be published in the Standards Portal and in printed form. Guidance entries are crafted from the Perioperative SC, member clarification requests, and approved variances.

This 11th edition of *Perioperative 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 *Perioperative Standards* were presented since 2001 with the 1st edition. Since the year 2001, the quality requirements in the *Perioperative 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*, which was 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 merely 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 Perioperative SC feel that these updates across these *Perioperative Standards* (and all *Standards*) will provide a reset and upgrade on the previous version of the quality system essentials and will allow these *Perioperative Standards* to take the next step in quality.

The Perioperative SC has published a document providing informal responses to the comments received during the comment period,

explaining why the Perioperative 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 Perioperative SC for development of this 11th edition. These *Perioperative Standards* reflect the contributions of the committee members whose expertise included transfusion medicine/blood banking, patient blood management, accreditation, regulatory, and surgery (orthopedic, thoracic/cardiac, anesthesia, and perfusion/blood recovery). I would like to say a heartfelt thank you to every member of the Perioperative SC for their dedicated hours of work both individually and collaboratively to complete the 11th edition of the *Perioperative Standards* and its associated Guidance. 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. We hope that these *Perioperative Standards* will enable your organization to achieve and sustain the highest quality of care for the patients whom you serve.

Joseph Schwartz, MD, MPH, CABP, QIA(ASCP)
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 publication better understand the 11th edition of *Perioperative Standards*:

When does this edition go into effect?

The effective date of this edition is January 1, 2025.

Are the standards requirements or recommendations?

The *Perioperative Standards* contains requirements to be 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 publication relate to other laws and regulations?

The *Perioperative 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 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

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

Yes. In many standards, the Perioperative 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 *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 want to:

- Visit www.aabb.org for a document that details the disposition and resolution of all comments received for this edition, as well as significant changes. This document is titled “Significant Changes and Response to Comments” to this 11th edition of *Perioperative Standards*. When a public comment is the source of a change, or where the Perioperative Standards Committee did not make a change suggested by a comment, an explanation is provided.
- Guidance for the 11th edition of *Perioperative 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 *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. Request forms for variances can be found at www.aabb.org.