

## PREFACE

**T**he Standards Program Committee (SPC) and the Global Standards Committee (GS SC) are pleased to present this 2nd edition of *Fundamental Standards for Blood Collection and Transfusion (Fundamentals)*.

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 11 specialty committees.

The GS SC developed this 2nd edition of *Fundamentals* as a tool to assist users and facilities as a first step of incorporating quality concepts and technical requirements in blood banking. This edition, unlike all other sets of AABB Standards, does not have an associated accreditation program; however, interested facilities can apply for AABB's Quality Certificate.

The AABB Quality Certificate is an internationally recognized distinction, acknowledging a facility's commitment to a culture of quality and excellence. This distinguished honor is achieved after an assessment process that validates compliance of interested facilities with established standards to continuously optimize their organizational outcomes, and ensure the highest levels of donor and patient safety.

The process of developing the requirements in *Fundamentals* 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, *Fundamentals* 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 GS SC also consulted the scientific literature on blood bank and transfusion service techniques and applications. Accordingly, the *Fundamentals* are based on input from a variety of sources, including member and public com-

ments. In an effort to harmonize AABB publications, such as the AABB Standards, the *Fundamentals* have incorporated the AABB Quality System Essentials (first identified in Association Bulletin #97-4) as the foundation of the Standards.

It has been a tremendous honor to serve as Chair of the AABB Global Standards Committee throughout the journey of compiling the second edition of the *Fundamental Standards for Blood Collection and Transfusion*. Over the past 3 years, our committee—an extraordinary assembly of dedicated global experts—has devoted countless hours, meeting monthly and often weekly, to craft these standards that meet the diverse needs of transfusion practices worldwide.

When the first edition was completed, I believed it would stand as a definitive guide for years. Yet, the rapid evolution of transfusion medicine across different countries—shaped by locally available resources, as well as geographic and cultural contexts—soon demonstrated the need for an updated, more contextually nuanced edition. The challenges we faced underscored the complexity of our mission and the importance of getting it right.

The collegiality and professionalism demonstrated by every member of the committee were truly exceptional. Each meeting, whether participants were animated in debate or meticulously focused on a single line of text, reflected the commitment to consensus, quality, and respect for differing viewpoints. This collaborative spirit is evident in the final document, which reflects both scientific rigor and a deep appreciation of local contexts.

I am deeply grateful to all committee members for their unwavering dedication, as well as those who provided thoughtful feedback during the public review. My special thanks go to AABB staff member Christopher Bocquet, whose tireless coordination and diligence were vital to this project's success, and to the AABB Board and members-at-large or their valuable input on the final draft.

This edition of the *Fundamentals* stands as a testament to what can be accomplished through global cooperation and shared vision. I trust it will serve the field and support the ongoing advancement of safe and effective transfusion medicine around the world.

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## INTRODUCTION

**T**he *Fundamental Standards for Blood Collection and Transfusion (Fundamentals)* was prepared by the Global Standards Committee (GS SC) and the Standards Program Committee of AABB. The goal of the *Fundamentals* is to maintain and enhance the quality and safety of services provided by blood banks and transfusion services.

The following frequently asked questions will help users of this publication better understand this edition of *Fundamentals*:

### **Are the standards requirements or recommendations?**

The *Fundamentals* contains requirements that can be implemented by interested blood banks and transfusion services. A requirement contains the word “shall,” which indicates that the statement is mandatory. 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 *Fundamentals* 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. The *Fundamentals* 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 these issues.

### **Does this publication require me to follow my own local laws and regulations?**

Yes. In many standards, the GS 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.