

PREFACE

The Standards Program Committee (SPC) and the Global Transfusion Services Standards Committee (GS SC) are pleased to present this 1st edition of *Fundamental Standards for Blood Banks and Transfusion Services (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 seven specialty committees.

The GS SC developed this 1st 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. The purpose of this document is to serve as a resource only and introduction to AABB standards setting.

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 comments. In an effort to harmonize AABB publications, like 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.

This effort was truly an international collaborative effort to bring tools to regions currently without minimum standards for blood transfusion. Representatives from international blood banking organizations contributed over many years to try to create a set of standards that are achievable with limited resources, at the same time ensuring safe blood transfused in a safe fashion. These standards are not intended to replace or substitute for Standards and guidelines currently in existence. Specifically, for those institutions able to achieve accreditation conforming with current AABB standards (including those with variances for international sites that need not adhere to FDA requirements) we continue to encourage assessment and accreditation through the current pathway. For institutions eligible to use the Stepwise Standards co-developed by the African Society for Blood Transfusion and the AABB, these Standards do not replace and are not a substitute for the current standards. Rather, this effort is to provide a first step for institutions that are not eligible to use the stepwise standards to help ensure quality by embarking on a process improvement journey. We look forward to dialogue with various international groups and organizations as to what the next steps should be, such as developing an intermediate and more advanced international version. Similarly, for those organizations hoping to move towards some sort of accreditation process, how can organizations work together to establish affordable yet robust assessment process that results in some sort of regionally recognized accreditation. Thanks to AABB staff for their dauntless pursuit of this international goal and to the myriad contributing individuals and organizations.

Jed Gorlin, MD, MPH
Chair, Global Standards Committee

INTRODUCTION

The *Fundamental Standards for Blood Banks and Transfusion Services (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 the 1st 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. 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.

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.