
Preface

The AABB is proud to present these *Quality System Essentials* (QSEs), developed with input from the AABB Standards Program Committee (SPC); Accreditation Program Committee (APC); quality experts in every field for which AABB sets voluntary standards; AABB assessors; and AABB staff with quality, regulatory and standards expertise.

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.

These QSEs were developed by members of the SPC and APC. The process included an open comment period as well as vetting and approval by AABB's Board of Directors twice during development. The QSEs were written to apply to all disciplines for which AABB sets voluntary Standards but can be applied to any field where quality systems are implemented.

The framework for these QSEs were developed from AABB Association Bulletin #97-04, which laid out the 10 quality system essentials that form the basis of all 10 chapters of this document.

Features include:

- All standards 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 for guidance purposes only.
- Each chapter concludes with the record retention table for that chapter. Note that the comprehensive record retention table can be found at the end of this book, just before the Glossary.

In the future, the QSEs will be managed by the Quality System Essentials Committee and will be updated on a defined basis. This will include input from the public to ensure that the voice of the community is included and represents the will of quality experts.

AABB believes that these QSEs are a step forward in the constantly evolving field of quality standards and hopes that you agree.

INTRODUCTION

The *Quality System Essentials* was prepared by the Standards Program Committee of the AABB. The goal of the quality system essentials (QSEs) is to maintain and enhance the quality and safety of services provided by an organization, facility, or program wishing to ensure that 1) the quality of its products and services is maintained and 2) the affected individuals are sure that the highest standard of care is maintained throughout the entire process.

The following frequently asked questions will help users of this book better understand the QSEs.

Are the QSEs requirements or recommendations?

AABB standards contain requirements to be implemented by organizations wishing to maintain the highest level of quality. A requirement contains the word “shall,” which indicates that the statement is mandatory. Failure to meet the requirement would constitute a nonconformance.

How does this publication relate to other laws and regulations?

The AABB QSEs 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 facility located anywhere in the world, but they do not preempt federal, state, and/or local laws and regulations. Although the majority of the QSEs here are intended to be consistent with applicable laws and requirements, no assurances can be given that compliance with the QSEs will result in compliance with all applicable laws and requirements. The QSEs 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.

Do the QSEs require me to follow my own local laws and regulations?

Yes. In many standards, the AABB 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 QSE, users have to maintain a record of that activity in order to meet the requirement. Readers should refer to the record retention tables at the end of each chapter and the comprehensive reference standard at the end of the book to determine what that record must contain. The time for which a record would need to be maintained would depend on the activity performed and any appropriate Competent Authority regulations.

What other tools are available to help me implement the QSEs?

There are resources to assist users.

- This publication includes a glossary, which reflects the usage of specific words or phrases in the context of these QSEs.
- Contact standards@aabb.org to ask for interpretations.