The Standards Program Committee (SPC) and the Immunohematology Reference Laboratories Standards Committee (IRL SC) are pleased to present this 10th edition of *Standards for Immunohematology Reference Laboratories (IRL 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 Interpretation Committee, as well as the chairs of the seven specialty program units.

The IRL SC developed this 10th edition of *IRL Standards*. The IRL 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 *IRL 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, *IRL 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 IRL SC also consulted the scientific literature on immunohematology laboratory techniques and applications. Accordingly, *IRL Standards* is based on input from a variety of sources, including comments from members and the public. 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. *IRL Standards* contains requirements that must be implemented by accredited AABB institutions. Requirements are imperative statements, signified by the use of the term, “shall.” All guidance to *IRL Standards* is located in the version of the 10th 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 provide rationales for standards or examples of how standards might be implemented. Along with this guidance, the IRL SC has provided rationales for any significant changes to this 10th edition of *IRL Standards*, which also exists in the Standards Portal.

The IRL SC has published a document providing informal responses to the comments received during the comment period explaining why the IRL 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

It’s hard to believe that we have completed the 10th edition of the *IRL Standards*. Writing this almost 18 years to the day from the effective date of the very first edition, I am amazed at how far we have come. Advances in molecular testing, laboratory information systems, and interfering therapeutic agents have necessitated many changes during the past 10 editions. I would like to thank Helene, Michael, Joanne, Nancy, Cami, Sandy, Jansen, Laurie, Pat and Dr. Yazer for their commitment of time and their many years of knowledge to this process. I would also like to thank Christopher Bocquet for his energy as he attempted to keep us focused—it was sometimes a daunting task!

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INTRODUCTION

The Standards for Immunohematology Reference Laboratories (IRL Standards) was prepared by the Immunohematology Reference Laboratories Standards Committee (IRL SC) and the Standards Program Committee of the AABB. The goal of the IRL Standards is to maintain and enhance the quality and safety of services provided by immunohematology reference laboratories 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 10th edition of IRL Standards:

When does this edition go into effect?
The effective date of this edition is January 1, 2018.

Are the standards requirements or recommendations?
The IRL Standards contains requirements to be implemented by AABB-accredited reference laboratories. 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 IRL Standards 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 reference laboratory located anywhere in the world, but they do not preempt federal, state, and/or local laws and regulations. Accredited facilities must follow the IRL Standards as written to ensure continued AABB accreditation in good standing. Although the majority of the standards are intended to be consistent with applicable laws and requirements, no assurances can be given that compliance with IRL Standards will result in compliance with all applicable laws and requirements. IRL Standards is not intended as a
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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 IRL 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 (_pen_) 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.

**What other tools are available to help me implement the IRL 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 *IRL Standards*.
- A crosswalk that cross-references the standards in this edition of *IRL 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 about this edition. This document is titled, “Response to Public Comments” on this 10th edition. When a public comment is the source of a change, or where the IRL SC did not make a change suggested by a comment, an explanation is provided.
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• Guidance to the 10th edition of *IRL Standards* can be found in the AABB Standards Portal, available online. The Portal provides rationales behind significant changes to this edition of *IRL 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 http://www.aabb.org.