
INTRODUCTION

The 14th edition of *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 book better understand this 14th edition of *IRL Standards*.

When does this edition go into effect?

The effective date of this edition is April 1, 2026.

Are the *IRL Standards* requirements or recommendations?

The *IRL Standards* contains requirements to be implemented by AABB-accredited immunohematology 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 book can be followed by an immunohematology reference laboratory located anywhere in the world, but they do not preempt federal, state, and/or local laws and regulations. Accredited laboratories must follow the *IRL Standards* as written to ensure continued AABB accreditation in good standing. Although the majority of the standards here are intended to be consistent with these applicable laws and requirements, no assurances can be given that compliance with *IRL Stan-*

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ards will result in compliance with all applicable laws and requirements. *IRL Standards* is 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 edition 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 (✍) 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 comprehensive reference standard at the end of Chapter 6 to determine what that record must contain, as well as the required record retention time.

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 the AABB website for a document that details the significant changes to this edition. This document is titled “Significant Changes and Response to Comments” to the 14th edition of *IRL Standards*.

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- Follow guidance to the 14th edition of *IRL Standards*, found in the AABB Standards Portal online or in the printed *Guidance for Standards for Immunohematology Reference Laboratories*. The guidance 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 to ask for interpretations or to submit a variance request. Variances to standards are effective for the edition of *IRL Standards* for which they are received. Request forms for variances can be found on the AABB website (<https://www.aabb.org/standards-accreditation/standards/about-aabb-standards/requesting-a-variance>). Requests for renewal of previously granted variance requests must be submitted before the effective date.