PREFACE

The Standards Program Committee (SPC) along with the Immunohematology Reference Laboratories Standards Committee (IRL SC) are pleased to present this 13th 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 Subcommittee for the Evaluation of International Variances, and the chairs of the nine specialty standards committees.

The IRL SC developed this 13th 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.

This 13th edition of *IRL Standards* implements AABB's updated quality system essentials. The quality system essentials were first introduced by AABB in Association Bulletin #97-04 and have served as the framework for which the *IRL Standards* were presented since 2001 with the 2nd edition. Since 2001, the quality requirements in the *IRL Standards* (and all sets of AABB *Standards*) have been updated on an as-needed basis, with changes occurring incrementally but not in a universally applicable fashion. This updated version of the quality system essentials has been standardized in terms of language and style, and will be incorporated in all sets of AABB *Standards* beginning with the 16th edition of *Standards for Relationship Testing Laboratories*, effective January 1, 2024. The updated quality system essentials include the following updates:

- All standards are 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 merely for guidance purposes only.
- Each chapter now concludes with the record retention table for that chapter. Note that a comprehensive record retention table still exists at the end of Chapter 6.

The AABB and the IRL SC feel that these updates across these *IRL Standards* (and all *Standards*) will provide a reset and upgrade on the previous version of the quality system essentials and will allow these *IRL Standards* to take the next step in quality.

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." *Guidance for Standards for Immunohematology Reference Laboratories* (available in the Standards Portal and as a published document) could be of service in understanding and implementing these requirements. Guidance entries are crafted from member clarification requests and approved variances.

The IRL SC has published a document providing informal responses to the feedback 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 (https://www.aabb.org/standards-accreditation/standards/about-aabb-standards/standards-library).

As we conclude work on the 13th edition of the *IRL Standards*, it is a moment to reflect on the immense effort put forth by our dedicated committee of volunteers. Their feedback, opinions, and professional debates have been invaluable in shaping this edition. This edition stands out from its predecessors due to the unique challenge we faced: incorporating the new quality system essentials. We strove to reduce unnecessary repetition but also ensure that additional clarity was added when the committee deemed it of importance. IRLs hold a unique position in laboratory medicine. Unlike when a physician orders most tests (like glucose or total protein), which follow a predefined method, a serologic investigation is often more dynamic. The observed reactions guide the subsequent steps, which can change during the course of the testing. Sometimes, these

steps cannot be completed without adaptations to testing or without rare cells and antisera. The committee has always strived to be prescriptive enough, but to allow for flexibility because we understand the complexity and challenges that occur. I am grateful for being a part of the very special IRL community and having been able to serve leading this committee.

Michael Gannett, MLS(ASCP)^{CM}, SBB^{CM}
Chair, Immunohematology Reference
Laboratories Standards Committee

INTRODUCTION

The *Standards for Immunohematology Reference Laboratories* (*IRL Standards*) was prepared by the Immunohematology Reference Laboratories Standards Committee 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 13th edition of *IRL Standards*:

When does this edition go into effect?
The effective date of this edition is April 1, 2024.

Are the 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 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 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 Immunohematology Reference Laboratories Standards Committee 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 complete 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 to this edition, as well as signifi-

cant changes. This document is titled "Significant Changes and Response to Comments" to this 13th edition. When a public comment is the source of a change, or where the Immunohematology Reference Laboratories Standards Committee did not make a change suggested by a comment, an explanation is provided.

- Guidance for the 13th edition of *IRL Standards* can be found in the AABB Standards Portal, available online and as a printed stand-alone copy of the published Guidance. 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 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 www.aabb.org.