
PREFACE

The Standards Program Committee (SPC) along with the Relationship Testing Standards Committee (RT SC) are pleased to present this 14th edition of *Standards for Relationship Testing Laboratories (RT 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, as well as the chairs of the eight specialty standards committees.

The RT SC consists of a chair; full members from the relationship testing field (including medical technologists, laboratory directors, medical and laboratory professionals, and quality experts); liaisons from other AABB task forces, committees, and work groups; representatives from other organizations; and an ethicist. The RT SC meets during the 2-year revision cycle and has frequent conference calls to discuss requests for variances from each edition of *RT Standards* and requests for standards interpretations.

The guiding principle of this document is to be consistent with available scientific information while focusing on patient advocacy and optimal care for clients. The requirements are intended to be simple, clear, and practical. The use of these *RT Standards* should aid materially in developing and maintaining policies, processes, and procedures that will contribute to acceptable results as well as a safe work environment for laboratory personnel.

Although the *RT Standards* provides a great amount of technical information concerning the relationship testing community, other AABB publications provide specific recommendations. During use of this edition of the *RT Standards*, having access to the current edition of the AABB *Technical Manual* and the *Guidance for Standards for Relationship Testing Laboratories* could be of service in understanding and implementing these requirements. Both the *Guidance for Standards for Relationship*

Testing Laboratories and the Standards Portal contain entries crafted from member clarification requests and approved variances.

The RT SC for the 14th edition grappled with two main issues. The first is the accreditation of forensic laboratories for relationship testing under these standards. The difficulty here is DNA forensic laboratories generally are not led by a laboratory director meeting the standard of having a doctoral degree. DNA forensic laboratories are led by a technical leader who, under forensic standards, is required to have only a master's degree. After much discussion within the committee and careful review of comments, the wording in the standard adopted appears to be a good compromise meeting the needs of the forensic community and maintaining the quality of the testing process. The second issue was reviewing and updating standards dealing with immigration testing. Representatives of the Department of State, Department of Homeland Security, and the United States Citizenship and Immigration Services also actively participated in the review process.

I would like to thank the committee members, general public, and the government agencies for their participation. I especially thank the AABB staff for their support in developing this 14th edition.

George C. Maha, JD, PhD, MT(ASCP)
Chair, Relationship Testing Standards Committee

INTRODUCTION

The *Standards for Relationship Testing Laboratories (RT Standards)* was prepared by the Relationship Testing Standards Committee (RT SC) and the Standards Program Committee of the AABB. The goal of the *RT Standards* is to maintain and enhance the quality and safety of services provided by relationship testing 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 14th edition of *RT Standards*:

When does this edition go into effect?

The effective date of this edition is January 1, 2020.

Are the standards requirements or recommendations?

The *RT Standards* contains requirements to be implemented by AABB-accredited relationship testing 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 *RT 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 relationship testing laboratory located anywhere in the world, but they do not preempt federal, state, and/or local laws and regulations. Accredited facilities must follow the *RT 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 *RT Standards* will result in compliance with all applicable laws and requirements. *RT Standards* is not intended as a sub-

stitute 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 RT 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. It should be noted that all records in this 14th edition must be kept for a minimum of 5 years.

What other tools are available to help me implement the *RT 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 *RT Standards*.
- A crosswalk that cross-references the standards in this edition of *RT 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. This document is entitled, “Response to Public Comments” to this 14th edition. When a public comment is the source of a change, or where the RT SC did

not make a change suggested by a comment, an explanation is provided.

- *Guidance for Relationship Testing Laboratories*, is available in hard copy; the same guidance is included in the online Standards Portal. The guidance provides rationales behind significant changes to this edition of *RT 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>.