
PREFACE

The Standards Program Committee (SPC) along with the Relationship Testing Standards Committee (RT SC) are pleased to present this 15th 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.

While the *RT Standards* provides a great amount of technical information concerning the relationship testing community, other AABB publications provide specific recommendations. When using this edition of the *RT Standards*, having access to the current edition of the AABB *Technical Manual* and the 15th edition of *Guidance for Relationship Testing Laboratories* (available in the Standards Portal and as a standalone published document) could be of service in understanding and implementing these requirements. Guidance for specific standards that appear in this edition

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of the *RT Standards* will also be published in the Standards Portal and in the printed guidance. *Guidance* entries are crafted from member clarification requests and approved variances.

The 15th edition of the standard provides continued improvement on the changes implemented with the 14th edition. Clarification on the exception of the forensic Technical Leader to serve as a Laboratory Director for the purposes of relationship testing was added. This singular exception reinforces the high standard to which FBI QAS accredited laboratories are held, and is the only exception allowed outside of a Doctoral level degree. All other requirements of the Laboratory Director must be met.

Another significant clarification involves the continued requirement to provide identification of parties presenting for cases intended for immigration, visa, passport, and citizenship for the United States. Along with much appreciated input from the Department of State, these standards were strengthened to require documentation for the absence of these documents or photos, if not submitted with the samples.

A final significant change addressed the need for transparency in promotional materials. This standard makes it incumbent on the testing laboratory to implement the review of any third party materials to ensure all the information is in compliance with these RT Standards. It is in the best interest of the clients for all agencies operating alongside an accredited laboratory to uphold these standards.

In this year of adversity and remote work, I would also especially like to thank the AABB staff for their support and dedication to the committee. In addition, I am greatly appreciative of the diligent efforts of the committee in participating in many web-based meetings and for their unwavering support in developing this 15th edition.

Megan Shaffer, PhD,
Chair, Relationship Testing Standards Committee

INTRODUCTION

The *Standards for Relationship Testing Laboratories (RT Standards)* was prepared by the Relationship Testing Standards Committee 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 15th edition of *RT Standards*:

When does this edition go into effect?

The effective date of this edition is January 1, 2022.

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 15th 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, as well as significant changes. This document is entitled, “Significant Changes and Response to Public Comments” to this 15th 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* for the 15th edition of *RT Standards* is available both online and in a printed hard copy; the same guidance is included in the online AABB 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 <https://www.aabb.org>.