

## PREFACE

**T**he Standards Program Committee (SPC) and the Cellular Therapies Standards Committee (CT SC) are pleased to present this 9th edition of *Standards for Cellular Therapy Services (CT 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 program units.

The CT SC developed this 9th edition of *CT Standards*. The CT SC used an evidence-based decision-making process, when possible, to modify existing requirements or to create new ones.

The CT SC consists of a chair; co-chair; full members from the cellular therapy field (including cord blood professionals, clinicians, medical and laboratory professionals, medical technologists, and quality experts); liaisons from other AABB task forces, committees, and work groups; and representatives from other organizations. The CT SC meets during the two-year revision cycle and has frequent conference calls to discuss requests for variance from each edition of *CT 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 donors and patients. The requirements are intended to be simple, clear, and practical. The use of *CT Standards* should aid materially in developing and maintaining policies, processes, and procedures that will provide safe and effective procurement, storage, processing, distribution, and administration of cellular therapy products, as well as a safe work environment for cellular therapy product service personnel.

The *CT Standards* is the 9th stand-alone edition of requirements for cellular therapy products and services. The changes in this edition reflect that relative maturity, and, for the most part, the changes in the

document reflect a response to the changing scientific and/or regulatory environment.

Although the *CT Standards* provide a great amount of technical information concerning the cellular therapy community, there are other AABB publications that provide specific recommendations. When using this edition of the *CT Standards*, having access to the current edition of the AABB *Technical Manual* and the current edition of the *Circular of Information for the Use of Cellular Therapy Products* could be of service in understanding and implementing these requirements. Guidance for specific standards that appear in this edition of the *CT Standards* is published in the AABB Standards Portal, the online home of the 9th edition of *CT Standards*.

The CT SC has published a document providing informal responses to the comments received during the comment period, explaining why the CT 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>.

I would like to thank all the members of the CT SC and my co-chair, Brenda Alder, for their hard work putting these standards together. Developing this edition would not have been possible without also the efforts of our AABB staff liaisons, Eduardo Nunes and Christopher Bocquet. We have tried to provide additional clarity and also relevant updates. As a reader, please continue to provide us with your comments and suggestions. They help us identify areas for modification and allow us to continue to improve these standards.

Richard L. Haspel, MD, PhD  
Chair, Cellular Therapies Standards Committee

## INTRODUCTION

**T**he *Standards for Cellular Therapy Services (CT Standards)* was prepared by the Cellular Therapies Standards Committee (CT SC) and the Standards Program Committee of AABB. The goal of the *CT Standards* is to maintain and enhance the quality and safety of procurement, processing, storage, and clinical administration of cellular therapy products and to provide a basis for the Accreditation Program of AABB.

The following frequently asked questions will help users of this book better understand this 9th edition of *CT Standards*:

### **When does this edition go into effect?**

The effective date of this edition is July 1, 2019.

### **Are the *CT Standards* requirements or recommendations?**

The *CT Standards* contains requirements to be implemented by AABB-accredited cellular therapy 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 book relate to other laws and regulations?**

The *CT 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 a cellular therapy facility located anywhere in the world, but they do not preempt federal, state, and/or local laws and regulations. Accredited facilities must follow the *CT Standards* as written to ensure continued AABB accreditation in good standing. Although the majority of the standards here are intended to be consistent with applicable laws and requirements, no assurances can be given that compliance with *CT Standards* will result in compli-

ance with all applicable laws and requirements. *CT 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 CT SC chose to use the term “specified requirements.” This phrase is defined in the glossary to include any applicable requirement under which a program 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, as well as the required record retention time.

### **What other tools are available to help me implement the CT 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 *CT Standards*.
- A “crosswalk” that cross-references the standards in this edition of *CT Standards* with those in the previous edition.

In addition, users of this edition may want to:

- Visit [www.aabb.org](http://www.aabb.org) for a document that details the disposition and resolution of all comments received to this edition. This document is titled “Response to Public Comments” to this 9th edition. When a

public comment is the source of a change, or where the CT SC did not make a change suggested by a comment, an explanation is provided.

- Consult guidance to the 9th edition of *CT Standards*, which can be found in the online AABB Standards Portal. The portal provides rationales behind significant changes to this edition of *CT Standards*, and provides recommendations on how to meet the intent of certain standards. A printed copy of the guidance is available as well from the online AABB Marketplace.
- Contact [standards@aabb.org](mailto: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. Requests for variance can be made online at the following address: <http://www.aabb.org/sa/standards/Pages/Requesting-a-Variance.aspx>.

