PREFACE

The Standards Program Committee (SPC) along with the Cellular Therapy Standards Committee (CT SC) are pleased to present this 8th edition of Standards for Cellular Therapy Services. 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 seven specialty program units.

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 2-year revision cycle and has frequent conference calls to discuss requests for variances 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 eighth 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 8th edition of *CT Standards*.

I would like to thank all the members of the Cellular Therapy Standards Committee and my co-chair Edwin Brindle for their hard work putting these *CT Standards* together. Developing this edition also depended on the efforts of our AABB staff liaisons, Eduardo Nunes and Christopher Bocquet. We are fortunate to have been able to build on the outstanding work of the former chair, Julie Allickson, and have tried to provide additional clarity and also relevant updates. For example, given the recent Zika virus outbreak, we now include a standard requiring that facilities have processes, policies, and procedures to address relevant emerging infectious diseases. 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.

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Chair, Cellular Therapy Standards Committee
INTRODUCTION

The Standards for Cellular Therapy Services (CT Standards) was prepared by the Cellular Therapy Standards Committee and the Standards Program Committee of the 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 the AABB.

The following frequently asked questions will help users of this book better understand this 8th edition of CT Standards.

**When does this edition go into effect?**
The effective date of this edition is July 1, 2017.

**Are the CT Standards requirements or recommendations?**
The CT Standards contains requirements implemented by AABB-accredited cellular therapy programs. 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 were 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 compliance with all applicable laws and requirements. These CT Standards are 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 book 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 (.pen) 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?
Several resources are available 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 also want to:

- Visit www.aabb.org for a document that details the disposition and resolution of all comments received about this edition. This document is entitled, “Response to Public Comments” to this 8th edition. When a public comment is the source of a change, or when the CT SC did not make a change suggested by a comment, an explanation is provided.

- Guidance to the 8th edition of *CT Standards* can be found in the AABB Standards Portal, available online. 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.

- 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. Requests for variance can be made online at the following address: http://www.aabb.org/sa/standards/Pages/Requesting-a-Variance.aspx.