

PREFACE

The Standards Program Committee (SPC) and the Cellular Therapies Standards Committee (CT SC) are pleased to present this 11th 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 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 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, as well as a safe work environment for cellular therapy product service personnel.

The CT SC developed this 11th edition of *CT Standards* using an evidence-based decision making process, when possible, to modify existing requirements or to create new ones. The changes in this edition reflect a response to the changing scientific and/or regulatory environment. Although the *CT Standards* provides a great amount of technical information concerning cellular therapy activities, 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 *Guidance for Standards for Cellular Therapy Services*, available as part of the AABB Standards Portal and in print.

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>.

As one of my committee colleagues remarked at the completion of our edits, “This was a project to remember!” In the spirit of remembering how this project came to be, I would like to say thank you to the many people involved. First, on behalf of the committee I would like to acknowledge all of those who provided feedback during the open comment periods—both pre-draft and proposed new edition. Your input was incredibly valuable throughout the process.

I would like to say a heart-felt thank you to the entire CT Standards Committee. Every single member spent their time and energy helping to refine this edition of the *CT Standards*. Your involvement as subject matter experts was critical throughout the process and the (seemingly) countless hours spent on virtual calls are a testament of your dedication to the cellular therapy field.

Katherine Brown, PhD
Chair, Cellular Therapies Standards Committee

INTRODUCTION

The 11th edition of *Standards for Cellular Therapy Services (CT Standards)* was prepared by the Cellular Therapies Standards Committee (CT SC) 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 11th edition of *CT Standards*:

When does this edition go into effect?

The effective date of this edition is July 1, 2023.

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* 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. Therefore, users 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 edition 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 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, as well as the required record retention time.

What do the “C” and “F” next to the pen symbol mean?

The “C” designation means that the record retention period follows the creation of the cellular therapy product associated with the record. The “F” designation means that the record retention period follows the final disposition of the cellular therapy product associated with the record.

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 also want to:

- Visit the AABB website for a document that details the significant changes to this edition. This document is titled, “Significant Changes to the 11th edition.”
- Follow guidance to the 11th edition of *CT Standards*, found in the AABB Standards Portal online, or in the printed *Guidance for Standards for Cellular Therapy Services*. The guidance provides rationales behind significant changes to this edition of *CT Standards*, and provides recommendations on how to meet the intent of certain standards.
- Contact the Standards Department (standards@aabb.org) to ask for interpretations or to submit a variance request. Variances to standards are effective for the edition of *CT Standards* for which they are received. Request forms for variances can be found on the AABB website at <http://www.aabb.org/sa/standards/Pages/Requesting-a-Variance.aspx>. Requests for renewal of previously granted variance requests must be submitted before the effective date.