PREFACE

The Standards Program Committee (SPC) and the Cellular Therapies Standards Committee (CT SC) are pleased to present this 12th 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, and the chairs of the ten standards committees.

The CT SC consists of a chair; co-chair; full members representing 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 meetings 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 12th 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.

This 12th edition of *CT Standards* implements AABB's updated quality system essentials. The quality system essentials were first introduced by AABB in Association Bulletin #97-04 and have served as the framework on which the *CT Standards* have been presented since 2000, when the *CT Standards* previously appeared as the *Standards for Hematopoietic Progenitor Cells*. Since the year 2000, the quality requirements in the *CT Standards* (and all sets of AABB *Standards*) have been updated on an as-needed basis, with changes occurring incrementally but not in a universally applicable fashion. This updated version of the quality system essentials has been standardized in terms of language and style and incorporated in all sets of AABB *Standards* as they are updated, beginning with the 16th edition of *Standards for Relationship Testing Laboratories,* effective January 1, 2024. The updated quality system essentials include the following updates:

- All standards are written in the active voice.
- Once a requirement has been stated, it is not repeated.
- Each chapter begins with a description of what the standards therein cover.
- Each chapter contains a list of key terms that relate to the content of the chapter, with their definitions.
- Each chapter contains a list of examples of objective evidence that an assessor could look for during an on-site assessment; however,

this list is not comprehensive, nor will it be assessed against by an assessor. It is merely for guidance purposes only.

- Each chapter now concludes with the record retention table for that chapter. Note that a comprehensive record retention table still exists at the end of Chapter 6.

The AABB and the CT SC feel that these updates across these *CT Standards* (and all *Standards*) will provide a reset and upgrade on the previous version of the quality system essentials and will allow these *CT Standards* to take the next step in quality.

I would like to acknowledge and thank all the members of the CT SC. Keeping the *CT Standards* relevant and up to date in a field that rapidly evolves is no small endeavor. Each member brings deep subject matter expertise and consistently puts forth their best effort, volunteering their time and experience as we have delved into questions, reviewed comments, and worked towards consensus on revising or creating new standards for this 12th edition. As we concluded our in-person meeting prior to AABB's annual meeting, we collectively acknowledged how much we each learn about different facets of cellular therapy during the 2-year revision cycle. Working in partnership with this committee has been an honor and a privilege, allowing me to gain valuable experience and broaden my understanding of the field. I would especially like to thank Dr. Kevin Land for his laughter and humor during our meetings and Dr. Wanxing Cui for introducing us to new tools while ensuring we had relevant data points from other sources during our discussions.

The work of the CT SC is a collaborative effort, and I greatly appreciate the valuable input from our liaisons at other AABB committees and representatives from other organizations. Their contributions allow us to achieve a holistic view while looking forward and anticipating emerging trends and relevant initiatives from other entities.

I also extend my appreciation to the many professionals and stakeholders who provided insightful feedback during the public comment periods. Public comment periods are invaluable. Your comments help us view proposed revisions with fresh eyes and are instrumental in refining the standards to meet the needs of our diverse and advancing field.

Lastly, I would like to express my personal gratitude to Chris Bocquet, our AABB staff liaison. It has been a pleasure to collaborate with Chris on this and other AABB initiatives. Chris is always available to offer advice specific to our CT SC, as well as insights from across the AABB Standards committees to ensure that our group is successful. He provides structure and forward momentum to the committee's work, balanced with humor and levity. It takes a special talent to encourage and shape volunteer experiences into meaningful opportunities that make a difference. Being a part of the CT SC and getting to know Chris and the other committee members with whom I have served on this and prior editions has been a truly impactful part of my professional journey.

Katherine Brown, PhD
Chair, Cellular Therapies Standards Committee

INTRODUCTION

The 12th 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 the 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 12th edition of *CT Standards*:

When does this edition go into effect?

The effective date of this edition is July 1, 2025.

Are the *CT Standards* requirements or recommendations?

The CT Standards contains requirements 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 these 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 record retention tables at the end of each chapter and the comprehensive 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 and Response to Comments" to the 12th edition.
- Follow guidance to the 12th 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.
- Requests for renewal of previously granted variance requests must be submitted prior to the effective date.