

PREFACE

The Standards Program Committee (SPC) and the Cellular Therapies Standards Committee (CT SC) are pleased to present this 10th 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 10th 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>.

I would like to express my genuine appreciation to all the members of the CT Standards Committee. They bring a tremendous amount of insight, knowledge, compassion, and best practices in their areas of expertise that together make this a valuable tool and resource. The committee members were tireless in their efforts to discuss, review, research, and define all the many aspects of the *CT Standards* that are involved in each cycle review. I would especially like to acknowledge: Wade Atkins for always thinking of crucial aspects and all the time he spent on doing extra tasks; Elina Linetsky for her valuable insights in her areas of expertise and her candid insights; Kate Brown as co-chair; Kathy Fortune for her humor and ability to simplify seemingly complicated concepts; and the AABB Board for their support with the mission of the *CT Standards*.

I would be remiss to not acknowledge the representatives from other organizations. These representatives are amazingly valuable resources who in the course of developing this edition of *CT Standards* proved to be true assets to the committee. In particular, I'd like to mention Patricia A. Shi, MD, from ASFA; Jelani R. Sanaa, MS, MLS^{CM}(ASCP)SBB^{CM}, SH^{CM} from CMS, and Hanh M. Khuu, MD, from the FDA.

Due to the COVID-19 pandemic, all of our meetings were held virtually during intense and busy times for health-care professionals as we sought to learn to work in more creative ways. The committee mem-

bers are amazing individuals and I am grateful to have the opportunity to work with and learn from them.

We have worked to more clearly define standards pertaining to the growing field of immune effector therapies, and many other items that are detailed in the “Significant Changes to the 10th edition.”

We were able to build on the outstanding work of our amazing former chair, Richard Haspel, MD, PhD.

I have worked with our AABB staff liaison, Christopher Bocquet, for over 20 years with AABB committees, and Chris deserves many accolades for his patience, wisdom and humor in working with the committee. His wealth of knowledge of the standards and AABB as an entity are invaluable. I am proud of our team and all their efforts and do not want to forget to thank all those that submitted comments to help us dig deeper to deliver this new edition.

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