Significant Changes and Response to Comments Received to the 1st edition of Cell and Gene Therapy Standards for Pharmacy

Please note that public comments that were submitted address the proposed 1st edition of *Cell and Gene Therapy Standards for Pharmacy (CGT Standards*), and not the final version. The Cell and Gene Therapy Pharmacy Standards Committee has elected to make the substance of public comments that were submitted a part of this document. Guidance that appears with the 1st edition of *CGT Standards* in the Standards Portal provides a more in-depth look at the additions, deletions and changes and the rationales behind those decisions that appear below.

Standard	Significant Change (SC)/Response to Comment (RtC)	Comment	Change made?	Outcome

Scope	SC	NA	NA	The Cell and Gene Therapy Standards for Pharmacy will include requirements for the receipt, handling, storage, dispensation, and/or discard of approved (e.g., FDA, Competent Authority, local, federal and regulatory body) cell and gene therapy products to maintain the product quality and safety while in possession of the pharmacy.
				However, the following are beyond the scope of these Standards and are not addressed in this 1st edition:
				• Products under IRB or Investigational New Drug Application
				• Products not approved for use by the appropriate Competent Authority
				  • Products deemed nonconforming but not approved for administration
				  • Compounding processes not included in the approved instructions for use
				• Collection of cellular starting material

				• CGT product manufacturing, characterization, or administration
Quality System Essentials	SC	NA	NA	The quality system essentials were updated and approved by the AABB Board of Directors in 2021, however, when created AABB had not considered a program designed for pharmacies providing cell and gene therapies. As such, some elements of the QSEs are not applicable to this defined space and therefore are deleted from this edition. However, most elements of the QSEs remain and those that were removed were intentional.
General	SC	NA	NA	The 11th edition of Standards for Cellular Therapy Services was used as the basis for this edition. Quality system standards or technical standards that were not altered are not included as significant changes below.
Scope	RtC	Overall, we feel as though this new standard is comprehensive, thorough, and will set the bar at a sufficient level to ensure that pharmacies who follow the standard will reliably deliver high quality CGT products to their patients. One concern that we have is the absence of reference to other best practice standards and regulatory requirements throughout. As suggested, pharmacy practice in general is subject to regulations put forth by the FDA, DEA, State Boards of Pharmacy and State Departments of Health which are generally referred to as "specified requirements". Though "specific requirements" are	No	The committee reviewed this comment but did not feel that a change was needed at this time. The term "specified requirements" is a hallmark of AABB standards allowing facilities and programs to meet the intent of a standard(s) in a way that supports their practices versus what the standard requires.

		referenced in specific sections of the standard related to procedures, there does not appear to be any reference to “specific requirements” with respect to staff or pharmacy spaces. It would be wise to expand references to “specific requirements” to include the staff that are working with these drugs in the pharmacy spaces. Additionally, pharmacy practice needs to follow best practice standards developed by The United States Pharmacopeia which in many cases is more conservative and intensive than those put forth is this standard or in the FACT standards. If pharmacy is truly going to take ownership of these products, the strictest of all best practice standards must be followed including but not limited to USP, FACT and AABB.		Of note, the guidance does provide a number of examples and ways to meet the standards as an assist to the users of this edition.
Chain of Identity	RtC	Can a universal change be made to “chain of identity” to appear as “chain of identity, if applicable” for clarity?	No	The committee reviewed the comment but did not feel that a universal change would be appropriate. In cases where “if applicable” is appropriate the committee has added it.
1.1, #2	SC	NA	NA	The committee removed the clause requiring that all applicable laws and regulations include those covered by the cGMPs. The committee noted that this does not apply in the pharmacy space.
1.1, #4 (New)	SC	NA	NA	The committee created subnumber 4 ensure that the executive management appoints a qualified pharmacist, the individual who serves in the management and lead role in the CGT space.
1.1, #4	RtC	What defines a "qualified responsible pharmacist"?	No	The committee noted this comment but did not feel that a change was needed at this time. Standard 1.1.2 does elucidate what the requirements are for the pharmacist.
1.1.1 (New)	SC	NA	NA	The committee created standard 1.1.1 to ensure that all CGT pharmacies maintain a licensure to conduct business with their relevant Competent Authority, which in most cases is typically a state regulator.
1.1.2 (New)	SC	NA	NA	The committee created standard 1.1.2 to detail the requirements for the individual that leads the

				pharmacy that will be accredited. The term responsible pharmacist is one that is understood by the community, however, unlike medical director or laboratory director is not universal. For the responsible pharmacist, they typically have a designee, however, the responsible pharmacist maintains ultimate responsibility. The term is also defined in the glossary.
1.1.2 (New)	RtC	The responsible pharmacist should also maintain licensure with any relevant, competent authority and state licensing board.	No	The committee noted this comment and agreed with the intent. However, the committee feels that this is covered by standard 1.1, #2.
1.1.2 (New)	RtC	Can AABB expand on prior "experience" recommended for the Responsible Pharmacist role? Because the CGT market is still emerging, cell and gene subject matter experts with pharmacy operations experience is anticipated to be limited. We recommend relevant experience for the role including pharmacy operations management, quality system development, and/or supply chain management.	No	The committee noted this comment and agreed with its intent, however they did not feel that a change was appropriate at this time. As noted by the comment, with this space still evolving, to provide more specifics in this space would be inappropriate and limiting. However, the committee did provide guidance on the role to assist users in their understanding of the role.
1.1.2 (New)	RtC	Are there are considerations or crossover with FACT accreditation?	No	The committee reviewed this comment and noted that at this time such a crossover would be inappropriate.
1.2.1	SC	NA	NA	The committee edited existing standard 1.2 1 to mirror the pharmacy space requiring that the quality representative report on quality system activities on a quarterly basis.
1.2.3	SC	NA	NA	The committee edited existing standard 1.2.3 to add qualifications that fit the pharmacy space.
1.3.1	SC	NA	NA	The committee edited standard 1.3.1 by replacing the terms "medical director and/or laboratory director" with "responsible pharmacist" to mirror the pharmacy space. The roles removed from the standard do not exist in the pharmacy space.
1.3.2	SC	NA	NA	The committee edited standard 1.3.2 by replacing the terms "medical director and/or laboratory director" with "responsible pharmacist" to mirror the pharmacy space. The

				roles removed from the standard do not exist in the pharmacy space.
1.4, 1.6	RtC	The standards in question state that quality systems will undergo management review at defined intervals. We would suggest that the standard include a minimum frequency (i.e. every 2 years) for a review and renewal of policies governing quality systems.	No	The committee reviewed this comment but did not feel that a change to the standard would be appropriate at this time. Of note, all AABB Standards are updated and reassessed every two years at a minimum, which would include a review of all pharmacies policies, processes, and procedures.
1.6	SC	NA	NA	The committee added the clause "…and notify the appropriate personnel…" to the standard to ensure that employees are contacted in the case of an emergency.
1.6	RtC	Would it be appropriate to also ensure a contact list be made available to ensure appropriate personnel and not just functions be notified as per the emergency disaster recovery plan?	No	The committee reviewed this comment but did not feel that a change was needed at this time. The content of the comment's request best fits in the guidance document as an inclusion of these elements would limit the intent of the standard in a way that would be inappropriate.
2.1.2	RtC	I suggest adding, "licensure" as a basis for qualification.	No	The committee reviewed this comment but did not feel that a change was appropriate at this time. The committee notes that this change would be prove difficult to apply as not all individuals that perform a critical task can be licensed in all cases.
2.1.3	RtC	I believe it is important to include the element below as routinely pharmacists do not handle liquid nitrogen, also how to dispose liquid nitrogen left over from a dry shipper or dry ice from a container. I believe that this needs to be included. 2.1.3.1 This training shall include: 1) Orientation. 2) Initial job specific training. 3) Quality-systems-related training. 4) Safety training	No	The committee reviewed this comment but did not feel that the addition would be appropriate as it is felt that it is covered by standard 2.1.3.1.
2.1.3.1.1 (New)	SC	NA	NA	The committee created new standard 2.1.3.1.1 noting that training is of paramount importance in the pharmacy space. This new standard is focused on training within the defined scope of these Standards.

2.1.3.1.1	RtC	Please add “manipulation”, “preparation” and/or “compounding” to training list	No	The committee reviewed this standard but did not feel a change to the standard was appropriate at this time. The committee did edit the definition of “Handling” to include these terms.
2.1.3.2	SC	NA	NA	**The committee edited standard 2.1.3.2 to mirror the requirements in the pharmacy space.** The committee noted that in the CGT space, the term continuing education has a different meaning than what is understood by AABB’s traditional members. As such the committee updated Standard 2.1.3.2 to focus on ongoing job training, as opposed to traditionally understood CE/CMEs.
2.1.3.2	RtC	I would suggest that another section be added either under 2.1.3.2 outlining specific requirement for annual CE for different roles (responsible person, pharmacist, pharmacy technician, un-licensed technician, etc.) or you could simply defer to CE requirements of individual State Boards of Pharmacy	No	The committee reviewed this comment but did not feel that a change would be appropriate at this time. The feeling was that it would be problematic to define specific requirements that could be not applicable to all individuals seeking accreditation. The committee feels that this would be pharmacy defined and not universal.
2.1.4.2	RtC	Please add the following statement “at least annually… or more frequently based on other regulatory authority requirements”	No	The committee reviewed this comment but did not feel that a change would be appropriate at this time. The committee notes that annually as a minimum is the expectation and that any pharmacies that wish or are required by a Competent Authority to perform evaluations of competence more frequently, can.
3.0	RtC	We recommend narrowing the definition of “critical equipment/materials” to reflect equipment in direct contact (ultra-low freezers, shippers, etc.) with the CGT product. As a licensed pharmacy, there may be equipment within the pharmacy that does not pertain to CGT products.	No	The committee reviewed this comment but did not feel that a change would be appropriate at this time. The committee notes that the expectation is that all accredited pharmacies will share with AABB what they defined as critical in terms of equipment.

				The guidance does share this expectation as well.
3.5.1	RtC	Calibrations of equipment used in compounding or preparation must be conducted at least as required by United States Pharmacopeia, as well as state and local requirements and this should be made clear.	No	The committee reviewed this comment but did not feel that a change was needed at this time. The committee feel that this element is covered by standard 3.5.1.2 which speaks to the need follow requirements set forth by nationally recognized measurement standards.
3.5.2 #7 (New)	SC	NA	NA	The committee created new subnumber 7 to ensure that all accredited pharmacies have a plan in place to review the impact of the recall of equipment has on a facility and what steps to take as necessary.
3.5.3.1	SC	NA	NA	The committee added a clause to the standard to ensure that the standard contained the terms "receipt, handling, storage, dispense and/or disposal" for consistency with similar requirements in other AABB sets of Standards. A crossreference to standard 7.2.3 to was also added which focuses on the recall of products that are determined to be nonconforming.
3.5.3.1	RtC	When product(s) may have been affected by faulty equipment, the organization should have a mechanism for recalling any products released/delivered and informing both the patients who received those products, their healthcare providers as well as any applicable regulatory bodies, and this should be made clear.	Yes	The committee reviewed this comment and agreed with its intent. The committee felt that adding a crossreference to standard 7.2.3, which discusses the recall of products that are nonconforming would be appropriate.
3.6	SC	NA	NA	The committee added a clause to the standard to ensure that the standard contained the terms "receipt, handling, storage, dispense and/or disposal" for consistency with similar requirements in other AABB sets of Standards.
3.6	RtC	Can AABB further expand on requirements for equipment traceability, provide examples or specific deliverables/documentation, and/or include a definition for "equipment traceability"?	Yes	The committee reviewed this comment but did not feel that a change was needed at this time. The committee notes that the guidance does

				provide examples of what is included as it relates to traceability.
3.7	RtC	Information systems used to store patient specific, privileged and/or confidential information should be 21 CFR Part 11 compliant.	No	The committee reviewed this comment but did not feel that a change was needed at this time. The committee did not feel that a citation would be appropriate with the expectation that all users follow all appropriate existing federal regulations.
3.7, #10	SC	NA	NA	The committee edited entry #10 in standard 3.7 to mirror the pharmacy space by replacing the term “recipient” with “patient.”
3.7, #10	RtC	Please note this includes not only identity, but privacy and security concerns (e.g., HIPAA).	No	
3.8 – 3.8.2	SC	NA	NA	The committee added standards 3.8 – 3.8.2 for completeness. These standards require that all accredited pharmacies have an evaluate their alarm systems at defined interval to ensure that conditions to allow for proper action to be taken if CGT products reach unacceptable conditions.
3.8.1	RtC	How are "unacceptable conditions" defined? Understanding that each therapy has differing conditions, is this dictated by the manufacturer and therapy?	No	The committee reviewed this comment and noted that these conditions would be defined by the manufacturer and it would be the responsibility of the pharmacy to follow them, and monitor them accordingly.
3.8.2	RtC	With whom does this immediate action lie? The responsible pharmacist?	No	The committee reviewed this comment and noted that in this case the immediate action would need to be defined by the pharmacy in question. If the pharmacy set that to be the responsible pharmacist, that would be the expectation of the assessor onsite.
4.2.2, 4.2.4	RtC	I suggest that these standards should be combined into one as they seem similar.	No	The committee noted this comment but did not agree with the note that the standards should be merged. However, the committee did moved

				standard 4.2.2 to appear as standard 4.2.4.1. The contents of the standard have not changed.
4.2.2.1	RtC	Suggest adding, “Chain of condition is maintained” to the standard list.	No	The committee reviewed this comment but did not feel that this addition would be appropriate for the standard.
4.2.2.1, #1	SC	NA	NA	The committee added the clause, “…the applicable Standards and/or…” for completeness. This mirrors the language in the *Standards for Cellular Therapy Services*.
4.2.2.1, #1	SC	NA	NA	The committee has added a reference to section 582(d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee-1(d)), as added by the Drug Supply Chain Security Act (DSCSA) (Title II of Public Law 113-54) for completeness.
4.2.2.1.1 (New)	SC	NA	NA	The committee removed the clause “compounding” from the standard as this is not typically allowed for biologics particularly for licensed products.
4.2.2.1.1 (New)	SC	NA	NA	The committee created this new standard to ensure that facilities that receive and manipulate the CGT product before dispensation.
4.2.2.2.2	RtC	If all parties mutually agree, and approved labeling of product allows, chain of condition may be satisfied using a validated and qualified shipping container, removing the need for continuous temperature monitoring.	No	The committee reviewed this comment but did not feel that a change would be appropriate at this time. The committee noted that the guidance to this section does touch on expectations as it relates to continuum of care.
4.2.2.2.2	SC	NA	NA	The committee added a clause to the standard to ensure that the standard contained the terms “receipt, handling, storage, dispense and/or disposal” for consistency with similar requirements in other AABB sets of Standards.

4.2.2.2.3, 4.2.2.2.5	RtC	I suggest that these standards should be combined into one as they seem similar.	No	The committee noted this comment but did not agree that these standards were similar to the point of combination.
4.2.2.2.4	SC	NA	NA	The committee created the new standard to ensure that receipt of incoming products is a key component to the CGT Standards.
4.2.4	SC	NA	NA	The committee added the clause "and accompanying materials" to standard 4.2.4 for completeness. This ensures that the agreements between the manufacturer and the pharmacy covers not only the CGT product but any accompanying materials (test kits, syringes, etc) as well. The committee added the clause "site of" to the standard to ensure that there is an understanding that this is a step in the overall process of moving the product along to the administration site.
4.2.4	RtC	This standard contains the concept of "administration", should this be included in this edition per the scope?	No	The committee noted this comment but did not think a change was appropriate at this time. The element of administration while not covered in the edition, is an element of agreement between a pharmacy and the administration site.
5.1.2	SC	NA	NA	The committee added crossreferences to standards 2.1.3 and 2.1.4 (focused on training and competence) to standard 5.1.2 for completeness.
5.1.4.1	SC	NA	NA	The committee edited standard 5.1.4.1 by replacing the term "actual results" with "validation results" as this better reflects the scope of the Standards.
5.1.9	SC	NA	NA	The committee has added a reference to section 582(d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee-1(d)), as added by the Drug Supply Chain Security Act

				(DSCSA) (Title II of Public Law 113-54) for completeness.
5.1.9.1	SC	NA	NA	Standard 5.1.9.1 appears in chapter 4 of the Standards for Cellular Therapy services, however, the CGT Standards Committee felt that this standard would be more appropriate for their purposes to appear in chapter 5. To ensure parallel structure with the rest of the edition, subnumber 3 concerning "chain of condition" was added to the standard.
5.2	SC	NA	NA	The committee edited standard 5.2 by replacing the term "and utilization" with "dispensing, and/or disposal" for accuracy as this reflects the scope of the CGT Standards.
5.2.1	SC	NA	NA	The committee edited the title of standard 5.2.1 to read, "Receipt of and Qualification of CGT Products" to better reflect the scope of the Standards.
5.2.1.1, #1	SC	NA	NA	The committee created subnumber 1 to ensure that accredited pharmacies focus on the dose of the product, focusing on concentration and quantity where applicable.
5.2.1.1,#1	RtC	Noting variations for doses whether it be multiple injections and weight-based dosing for the CGTs themselves. In addition, are there inspection requirements needed for drugs co-infused alongside the CGT (e.g., IL-2).	No	The committee reviewed the comment but did not feel that a change was appropriate to make at this time. The committee noted that most pharmacies do not maintain the information noted, and would be outside their scope. The goal of leaving this subnumber broad allows pharmacies to have different ways to meet this requirement based on what they receive.
5.2.1.1, #3	SC	NA	NA	The committee added new subnumber 3 to this standard, ensuring that accredited pharmacies maintain purchase orders as an element of unique identifiers to be retained.

5.2.1.1, #8	SC	NA	NA	The committee added new subnumber 8 to this standard to include chain of condition, including results of visual inspection and all that is required as a part of that.
5.2.1.1, #8	RtC	In the event of international manufacture for chain of condition, we recommend requiring customs documentation.	No	The committee reviewed this comment but did not feel that a change was needed at this time. The committee feels that this concept is covered by subnumber 11.
5.2.1.1, #11	SC	NA	NA	The committee created subnumber 11 to ensure that all accompanying documents and materials are provided a space for programs that receive documents along with the product, while recognizing that this is not the case in all pharmacies.
5.2.1.1, #11	RtC	CGTs may have administration kits or co-infused drug requiring inspection that should be considered.	No	The committee reviewed this comment and did not feel that a change was needed at this time. This documentation could be included as a part of the facilities information to share with the assessor on site.
5.3.1	RtC	Can AABB further define "Handling: The act of moving a cell and gene therapy product through the supply chain for pharmacy dispensing"? We feel that this should be more narrowly defined, as there are critical differences in handling product without removing it from the original manufacturer packaging compared to removing product from original manufacturer packaging or manipulating product.	No	The committee reviewed this comment but did not feel that a change was needed at this time. The committee feels that this would be determined by each specific pharmacy for the specific examples they provided. The standard was written in a manner to allow for variance among pharmacies.
5.3.1	RtC	Should product handling reporting requirements to the manufacturer be included?	No	The committee reviewed this comment but did not feel that a change was appropriate at this time. The committee noted that this would be product dependent and that it is required to be detailed to the manufacturer. Any and all reporting requirements should be addressed in the agreements.

5.3.1	RtC	Are there specific documentation or standards consideration for if a patient's treatment is delayed, and thus impacts ability to administer within a specific timeframe? Standards due to patient expiry?	No	The committee reviewed this comment but did not feel that a change was appropriate at this time. The committee noted that this would be covered by the agreements between parties and that any return process would be covered therein.
5.3.1	RtC	We recommend the development of specific standards around CGT dose thawing. From our experience, there is severe variation in this process.	No	The committee reviewed this comment but did not feel that a change would be appropriate at this time. The committee feels that this request is too specific, and would depend on the type of product in question. It would be difficult to write a specified process for every product that could be covered by these CGT Standards.
5.3.1, #1	SC	NA	NA	The committee added subnunmber 1 to the edition to ensure that pharmacy staff consider risk when handling CGT products, which can be quite delicate in nature.
5.3.1, #1	RtC	Storage of CGT while onsite, to ensure the therapy stays within condition requirements (e.g., temp & noting storage location & log).	No	The committee reviewed this comment but did not feel that a change would be appropriate at this time. The committee feels that this concept is already covered by standard 5.7.
5.3.1, #2	SC	NA	NA	The committee added subnumber 2 to the standard to stress the importance of staff training, especially as it pertains to the handling of these products.
5.3.1, #2	RtC	HIPAA considerations for the handling of patient-specific CGTs should be included here as well.	No	The committee reviewed this comment but did not feel that a change would be appropriate at this time. The committee feels that this concept would be covered by standard 2.1.3 which focused on training.
5.3.1, #3	RtC	We recommend adding the additional underlined language to the following: "Staff attire, gowning, and use of appropriate personal protective equipment and environmental controls relevant to the task performed pertaining to the CGT product and its hazardous risk."	Yes	The committee reviewed this comment, and agreed with its intent and made the addition to the proposed language that was provided with the edition that was submitted for public comment.

5.3.1, #10	SC	NA	NA	The committee elected to include the clause, "quarantine (if applicable) and handling" to the content of subnumber 10 for completeness and to mirror the title and content of the standard.
5.3.1, #11	SC	NA	NA	The committee added new subnumber 11 to the standard for completeness. The addition of the concept was added recognizing that the element of return of a CGT product in the supplier and customer agreements.
5.3.2	RtC	We recommend the scope of this standard (Aseptic Methods) to be limited to facilities that perform intermediate steps (e.g., compounding, dose preparation) or that manipulate (e.g., compounding, thawing, diluting) CGT products.	No	The committee noted this comment but did not feel that a change was needed at this time. The scope does reflect the request made.
5.3.2, #5	SC	NA	NA	The committee added subnumber 5 to the edition to ensure that sterility of the CGT product is maintained when they are handled.
5.3.2, #7	SC	NA	NA	The committee added subnumber 7 ensure that when handling CGT products, facility staff are following all applicable requirements set forth by the Competent Authority.
5.3.3, #2, 3	SC	NA	NA	The committee added the term "spatial" to subnumbers 2 and 3 as it relates to segregation of equipment and materials to ensure that the standard mirrors the scope of the Standards.
5.3.3, #5	SC	NA	NA	The committee edited subnumber 5 to mirror the pharmacy space to include the appropriate cleaning of all equipment and spaces between each individual CGT product.
5.3.3, #5	RtC	For bullet point (5), would it be appropriate to include confirm line clearance, thus serving as an additional step for preventing contamination/errors. Additionally, this would need to be documented as such as well.	No	The committee reviewed this comment but did not feel that a change would be appropriate at this time. The committee noted that the need to clean/cleanse between patients is of utmost importance, however the suggested language would be too specific and would narrow the scope too far.

5.3.3, #6	SC	NA	NA	The committee edited subnumber 6 for clarity. The committee added the term "appropriate" to the beginning of the subnumber recognizing that there are different labeling requirements for each state and facility.
5.3.3, #7	SC	NA	NA	The committee elected to edit subnumber 7 for clarity. The committee updated the subnumber in order to reflect the step in which the pharmacist will review the product to ensure that there are no errors or potential contamination.
5.3.3, #7	RtC	For CGTs with international supply chains, keep in mind language requirements in labeling.	No	The committee reviewed this comment but did not think that a change would be appropriate at this time. The committee feels that this would be pharmacy specific.
5.4	SC	NA	NA	The committee edited standard 5.4 to mirror the pharmacy space with the inclusion of "chain of condition" and "dispensing and/or disposal."
5.4	RtC	Please keep in mind HIPAA considerations with Chain of Identity in particular with regard to this standard.	No	The committee reviewed this comment but did not feel that a change was appropriate at this time. The committee noted that this would be pharmacy specific
5.5	SC	NA	NA	The committee elected to edit standard 5.5 for completeness. The committee added new subnumbers 1 – 5 that focus specifically on the labeling of the CGT product.
5.5.1 (New)	SC	NA	NA	The committee created new standard 5.5.1 to ensure that in the case where a facility that may perform an intermediate step on a CGT product (e.g., manipulation) that there traceability maintained to ensure a complete picture of the CGT product exists.
5.5.2 (New)	SC	NA	NA	The committee created new standard 5.5.2 to ensure that all CGT product shipping containers

				are labeled as per the requirements set forth by the appropriate Competent Authority.
5.6	SC	NA	NA	The committee created a mirrored standard with the 11th edition of CT Standards. This standard focuses on product transport and shipping with the added inclusion of "packaging" to the title of the standard itself. The committee also added the clause "chain of condition" to the standard for completeness, mirroring the addition throughout this 1st edition.
5.6.1	SC	NA	NA	The committee created a mirrored standard with the 11th edition of CT Standards. This standard focuses on the inclusion of the clause, "…including the package insert and additional product labeling and guidance." to ensure that packing requirements of CGT products are in conformance with the package insert.
5.6.1	RtC	We recommend the following updates to the language "All parties, including the manufacturer and facilities should agree and the facility shall control packaging to ensure conformance with specified requirements including the package insert included with the CGT product."	No	The committee reviewed this comment but did not feel that a change was needed at this time. The committee noted that this concept is covered by elements in chapter 4 and others throughout.
5.6.2	SC	NA	NA	The committee added a crossreference to standard 3.3, which focuses on the use of equipment and that all equipment be used in accordance with manufacturer's written instructions.
5.6.3	SC	NA	NA	The committee created a mirrored standard with the 11th edition of CT Standards. This standard is focused on product transport and shipping with the added inclusion of maintenance and monitoring of the product.
5.6.3	RtC	We recommend eliminating the requirement for continuous temperature monitoring during transport or shipping if the shipping container is validated	No	The committee reviewed this comment but did not feel that a change was needed at this time.

		and qualified to maintain the conformance with specific requirements, including the package insert included with the CGT product, and it has been agreed upon by all parties.		The committee notes that the standard contains the clause, "where applicable" recognizing that there are CGT products that do not have to be continuously monitored.
5.6.4	SC	NA	NA	The committee created a mirrored standard with the 11th edition of CT Standards. This standard now includes the addition of "chain of condition" to parallel the inclusion thereof throughout the edition. The committee also added a reference to section 582(d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee-1(d)), as added by the Drug Supply Chain Security Act (DSCSA) (Title II of Public Law 113-54) for completeness.
5.6.4	RtC	Where / how are records kept? As part of the EMR? Or as part of a secure drive within the health system?	No	The committee reviewed this comment but did not feel that a change was appropriate at this time. The committee feels that the way in which a pharmacy retains records should be defined by them within the parameters set forth by the standard, understanding that not every pharmacy will do things in the same exact way.
5.6.4	RtC	Please kind in mind HIPAA compliance considerations in record keeping.	No	The committee reviewed this comment but did not feel that a change was needed at this time. It was noted that the concept of confidentiality is covered by standards 3.7 and 6.2.8 and in training by the personnel.
5.7	SC	NA	NA	The committee created a mirrored standard from the 11th edition of CT Standards. The committee felt it important to include the concept of "dispensing" which is the final element of the scope of this proposed 1st edition.
5.7	RtC	For facilities that do not compound or manipulate CGT products, can you confirm that contamination is prevented by not opening manufacturer	No	The committee reviewed this comment but did not feel that a change was needed at this time. The committee did not feel it would be

		packaging or tamper seals? Can AABB consider adding this clarification to the definition of "contamination"?		appropriate to create a blanket requirement as this would be pharmacy defined in most cases.
5.7.2	SC	NA	NA	The committee created a mirrored standard from the 11th edition of CT Standards. The committee added the clause "…if applicable…" to the standard recognizing that there are circumstances where pharmacies do not record and determine appropriate humidity ranges.
5.7.2.1	SC	NA	NA	The committee created a mirrored standard from the 11th edition of CT Standards. The committee added the clause "..continuously monitored…" recognizing that there are pharmacies that do maintain CGT products at room temperature which do have to be monitored continuously.
5.7.2.1	RtC	Should humidity be added here or better yet chain of condition be expanded to not only include humidity but also lighting and other applicable items?	No	The committee reviewed this comment but did not feel that this change was appropriate at this time. The committee noted that humidity monitoring is not required for all products and not standard as yet in terms of monitoring in all pharmacies which would be difficult to enforce without a standard practice.
5.7.4.1	SC	NA	NA	The committee created a mirrored standard from the 11th edition of CT Standards. The committee felt that having this standard in an edited format recognizing that there are CGT products immersed in liquid nitrogen and need to have their temperature or levels recorded at least every 24 hours.
5.7.4.2	SC	NA	NA	The committee created a mirrored standard from the 11th edition of CT Standards. The committee felt that having this standard in an edited format recognizing that certain CGT products are not immersed in liquid nitrogen and thusly have to have the temperature of refrigerator or freezers be recorded every 4 hours at a minimum.
5.7.4.1, 5.7.4.2	RtC	We recommend clarifying if temperature and/or liquid nitrogen recording requirements are only applicable when the product is stored within the	No	The committee reviewed this comment but did not feel that a change was needed at this time.

		pharmacy prior to dispensing, or if this is also a requirement while the product is in transport and shipping from the pharmacy?		The committee reviewed this comment and noted that there are different requirements for different CGT products themselves. There are different transport times for different CGT products and writing a standard that is broad enough to accommodate all possible CGT standards would not be appropriate.
5.7.5.1 (New)	SC	NA	NA	The committee elected to add standard 5.7.5.1 to this edition for completeness. This ensures that when pharmacies have CGT products that exceed their defined temperature ranges, they have a policy to take corrective action in that case.
5.7.5.1	RtC	This standard discusses temperature excursions but should other environmental excursions such as humidity and lighting chain of condition.	No	The committee reviewed this comment but did not feel that this change was appropriate at this time. The committee noted that humidity monitoring is not required for all products and not standard as yet in terms of monitoring in all pharmacies which would be difficult to enforce without a standard practice.
5.8	SC	NA	NA	The committee created a mirrored standard from the 11th edition of CT Standards. This standard is focused on verification, and the step that take place prior to dispensing in the scope of these Standards.
5.8, #2	SC	NA	NA	The committee created subnumber 2 as a part of standard 5.8 to ensure that product administration are included as a part of the verification of the prescription of the CGT product.
5.8, #4	RtC	For cryopreserved products, bullet point (4), could it be confirmed if label verification on the cassette associated with cryopreserved CGT products would be sufficient or would it be suggested that cassette be opened to confirm label associated with the CGT product?	No	The committee reviewed this comment but did not believe that a change was needed at this time. The committee noted that enacting a blanket statement on validation that would be

				applicable to all CGT products would not be possible as this is defined on a CGT product by CGT product circumstance. Of note, the committee felt that requiring that a cassette be opened in all cases would not be appropriate, and should only be done so when the instructions indicate this requirement.
5.8, #5	SC	NA	NA	The committee edited subnumber 5 to include the term "patient" recognizing that the patient is the individual that would be receiving the CGT product for administration.
5.8, #7	SC	NA	NA	The committee edited subnumber 7 to include the need to maintain the identification of the pharmacist that is performing the verification of CGT product to the appropriate patient.
5.8, #8	SC	NA	NA	The committee added the term "verification" to subnumber 8 for the purpose of mirroring the title of the standard, and the step in the process of receiving a CGT product.
5.9 (New)	SC	NA	NA	The committee created new standard 5.9 focused on the dispensing of the CGT product. The subnumbers describe what is required to be reviewed at the time of dispense with all Competent Authority regulations.
5.10	SC	NA	NA	The committee created a mirrored standard from the 11th edition of CT Standards. The standard, focused on "disposal" was edited in a manner to meet the requirements of disposal of a CGT product.
6.2.2	SC	NA	NA	The committee edited the opening sentence of standard 6.2.2 with the addition of the clause, "the following as applicable" recognizing that in some instances all 9 elements in the standard would not be applicable to the pharmacy space.

6.2.2, #2	RtC/SC	Please make an addition to subnumber 2 to include any additional reviewer associated with confirming executed activity.	Yes	The committee reviewed this comment and edited subnumber 2 recognizing that there are instances where there is a supervisory role in some cases for the individual performing the activity as defined by the pharmacy.
6.2.5.1	SC	NA	NA	The committee elected to include the clause "…by an authorized individual" to the end of standard 6.2.5.1 to mirror the pharmacy space. The addition of the clause to the standard ensures that the individual who makes changes to records is allowed to do so.
6.2.7	RtC/SC	I suggest adding the clause, "identified as such and" before "verified" in the standard.	Yes	The committee reviewed this comment and agreed with its intent. The addition was made as suggested.
6.2.9.1	SC	NA	NA	The committee created a mirrored standard from the 11th edition of CT Standards. Recognizing that in the pharmacy space, record retention time periods are defined by the pharmacy or local regulatory body, that having a minimum of a two year retention period mirror the time between AABB assessments would be appropriate.
6.2.9.2 (New)	SC	NA	NA	The committee added new standard 6.2.9.2 to the edition to ensure that documentation related to the elements in the DSCSA are covered and that the DSCSA is followed in all cases. This has been added as a specific reference to the Act to ensure users are aware of its relevance to the edition and their responsibilities under it.
Chapter 7	SC	NA	NA	Based on the reality of the the pharmacy world, the term "adverse event" has been removed from this chapter and this edition. The pharmacy world has a very specific patient centered definition of this term that does not coincide with how AABB defines it in the Standards. As these Standards do not reflect pharmacies that

				have patients, the committee felt it would be appropriate to adjust the terminology to allow for the concept of the standards (7.3 – 7.3.2) to be included in the document while recognizing the space these Standards will be accredited in.
7.1	SC	NA	NA	The committee edited standard 7.0 for clarity. Specifically, the committee replaced the term "recipient" with "patient." This better reflects the scope of the Stnadards and the individual that will be receiving the CGT product. The committee also added a crossreference to standard 7.2.6.1 ensuring that any CGT product considered nonconforming is handled appropriately and per defined agreements.
7.1.3 (New)	SC	NA	NA	The committee added new standard 7.1.3 to the edition recognizing that when a deviation occurs, that there are steps needed to be taken concerning the reporting of a deviation. This can include executive management, the product manufacturer, or Competent Authority.
7.1.3.1	SC	NA	NA	The committee created a mirrored standard from the 11th edition of CT Standards. The content of the standard was shifted to focus on the pharmacy space with the inclusion of the terms "responsible pharmacist" and the term "dispensing."
7.1.3.2	SC	NA	NA	The committee created a mirrored standard from the 11th edition of CT Standards. The focus of this standard however is focused on the approval for release of CGT products that may be listed as deviations are done so by the responsible pharmacist.
7.1.3.3	SC	NA	NA	The committee created new standard 7.1.3.3 to ensure that in the case where the prescribing physician should be informed of a deviation, the standards would reflect that.
7.2.1	SC	NA	NA	The committee edited the content of standard 7.2.1 to mirror the expectations one would

				expect in a pharmacy, replacing the term "destroyed" with "disposed of."
7.2.2	SC	NA	NA	The committee edited the content of standard 7.2.2 to mirror the expectations one would expect in a pharmacy, replacing the term "distribution or use" with "dispensing."
7.2.3	RtC	Items 1 and 2 seem to be discussing the same concept, should they both exist.	Yes	The committee noted this comment and agreed with its intent. As presented in the proposed edition, there were two subnumbers but after a review of their content they were merged into one that requires that nonconformances once identified be quarantined, retrieved, recalled, and the disposition of nonconforming CGT products and critical supplies determined.
7.2.3, #1	RtC	Is this inclusive of administration kits and co-infused drug?	No	The committee noted this comment but did not feel that a change was needed at this time.
7.2.4	SC	NA	NA	The committee edited standard 7.2.4 to ensure that the content mirrored the pharmacy space.
7.2.4.1	SC	NA	NA	The committee edited standard 7.2.4.1 based on what is expected of a pharmacy. The term "disposition" was deemed as inappropriate in the pharmacy space and felt that the term "assessment" was more appropriate.
7.2.5	SC	NA	NA	The committee created a mirrored standard from the 11th edition of CT Standards. The committee felt that the notification requirements surrounding nonconformances needed to be adjusted to mirror the pharmacy space. In this case, in the pharmacy space the individual notified is determined to be either, the manufacturer, or the administration facility. The committee also replaced the term "dispense" has replaced "release" for accuracy.

7.2.5	RtC	More guidance is needed around what is considered the appropriate party in this case. We assume it is the manufacturer.	No	The committee reviewed this comment but did not feel that a change was needed at this time. The committee noted that this would be defined by the pharmacy in question.
7.2.6	SC	NA	NA	The committee edited standard 7.2.6 to ensure that the content mirrored the pharmacy space.
7.2.6.1	SC	NA	NA	The committee created a mirrored standard from the 11th edition of CT Standards. This standard was created to articulate the requirements of what should occur when a nonconforming CGT product is found. Those being that the CGT product could be dispensed, or that the CGT product could be deemed appropriate Competent Authority requirements or disposed of.
7.2.6.2	SC	NA	NA	The committee created a mirrored standard from the 11th edition of CT Standards. The standard is focused on the requirement to ensure the authorized release of CGT products; including the approval that would come from three sources, the manufacturer, ordering provider, and responsible pharmacist, dependent upon who has authorization.
7.3	SC	NA	NA	The committee edited standard 7.3 to ensure that the content mirrored the pharmacy space and to mirror the changes made throughout the chapter.
7.3.1	SC	NA	NA	The committee edited standard 7.3.1 to ensure that the content mirrored the pharmacy space and to mirror the changes made throughout the chapter.
7.3.1	RtC	Similar to record questions above in standard 7.2.5, are there record-keeping time limitations expected? Where and how are records stored?	No	The committee reviewed this comment but did not feel that a change was needed at this time. The committee noted that this would be defined by the pharmacy in question.

9.1, #2	SC	NA	NA	The committee edited standard 9.1, #2 to ensure that the content mirrored the pharmacy space.
9.1, #5 (New)	SC	NA	NA	The committee, with standard 9.1 focused on corrective action, has added subnumber 5 to the standard for completeness. This new subnumber requires that the manufacturer of any CGT product be consulted before any process improvements are implemented to ensure their conformance with the update.
10.1.1.1 (New)	SC	NA	NA	The committee created new standard 10.1.1.1 to ensure that the pharmacy in questions has adequate signage in its facility to ensure that all relevant hazards are noted for the health and safety of all individuals that could be impacted.
10.1.2	SC	NA	NA	The committee created a mirrored standard from the 11th edition of CT Standards updated to mirror the pharmacy space.
10.1.3	SC	NA	NA	The committee added a crossreference to standard 2.1.3, the standard focused on training, to ensure that individuals charged with handling liquid nitrogen are trained to do so.
10.1.3.1, 10.1.3.1.1	SC	NA	NA	The committee created two mirrored standards from the 11th edition of CT Standards updated to mirror the pharmacy space.
10.3	SC	NA	NA	The committee created a mirrored standard from the 11th edition of CT Standards updated to mirror the pharmacy space.
Glossary – Chain of Condition	SC	NA	NA	The committee created a new glossary definition for chain of condition to provide clarity of the term for users of the Standards.
Glossary - Compounding	SC	NA	NA	The committee created a new glossary definition for compounding to provide clarity of the term for users of the Standards.
Glossary – Critical	RtC/SC	Can AABB provide a definition for “critical calculations”?	Yes	The committee reviewed this comment and agreed with the request. The committee created a new glossary definition for critical calculations

Calculations				to provide clarity of the term for users of the Standards.
Glossary - Disposal	SC	NA	NA	The committee created a new glossary definition for disposal to provide clarity of the term for users of the Standards.
Glossary – Handling	SC	NA	NA	The committee created a new glossary definition for handling to provide clarity of the term for users of the Standards.
Glossary – Human Prescription Labeling	SC	NA	NA	The committee created a new glossary definition for human prescription labeling to provide clarity of the term for users of the Standards.
Glossary – Pharmacy (Activity)	SC	NA	NA	The committee created a new glossary definition for pharmacy (activity) to provide clarity of the term for users of the Standards.
Glossary – Pharmacy (Facility)	SC	NA	NA	The committee created a new glossary definition for pharmacy (facility) to provide clarity of the term for users of the Standards.
Glossary – Pharmacy Label	SC	NA	NA	The committee created a new glossary definition for pharmacy label to provide clarity of the term for users of the Standards.
Glossary – Responsible Pharmacist	SC	NA	NA	The committee created a new glossary definition for responsible pharmacist to provide clarity of the term for users of the Standards.