**Significant Changes and Response to Comments Received to the 35th edition of *Standards for Blood Banks and Transfusion Services***

Please note that public comments that were submitted address the proposed 35th edition of *Standards for Blood Banks and Transfusion Services (BB/TS Standards*), and not the final version. The Blood Banks and Transfusion Services Standards Committee has elected to make the substance of public comments that were submitted a part of this document. Guidance that appears with the 35th edition of *BB/TS 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** |
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| General | SC | NA | NA | Where appropriate, the phrase in bold below was added to all applicable standards that have CMS references:<br>***For accredited facilities that are assessed by AABB for conformance with the Clinical Laboratory Improvement Amendments (CLIA), refer to the Verification of CLIA Compliance Form before on-site assessment.*** |
| 1.1, #4 (deleted) | SC | NA | NA | Former subnumber 4 which read, "A participatory role in management review of the quality system." has been deleted as it was deemed redundant to standard 1.2.2. |
| 1.9 (New) | SC | NA | NA | Standard 1.9 is new to the 35th edition and was added to mirror a new standard in the 12th edition of Standards for Cellular Therapy Services. When originally proposed the content was not as specific and based on feedback subnumbers 1 – 5 were added for clarity. The 5 subnumbers mirror what an AABB assessor would expect to see on an assessment. The standard reads as follows:<br>**1.9 Facility Status Changes**<br>The facility shall communicate to AABB in electronic or written format within 30 days a change that impacts a facility's accreditation status, including:<br>1) Addition or discontinuation of AABB-accredited activities. |

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| | | | | 2) Premise, location, or contact information.<br>3) Organizational structure and management.<br>4) Appointment of or changes to the medical director.<br>5) Individual designated responsible for accreditation activities. |
| 1.9 (New) | RtC | We interpret these standards to be limited to communications to AABB for significant issues, e.g., serious issues with local/national health authority. However, ambiguity exists in what constitutes a change impacting accreditation vs. enforcement action. Furthermore, the current language in 1.9 lacks specificity regarding what constitutes a change that "directly or indirectly impacts accreditation." Further clarification would help standardize reporting thresholds and reduce variability in interpretation across facilities. | Yes | Based on this comment, the committee added subnumbers 1 – 5 in standard 1.9 to provide specifics as to what would constitute an impact on a facility's accreditation status. |
| 1.9 (New) | RtC | Please specify what changes must be communicated to AABB within 30 days as required by Standard 1.9. It is unclear what constitutes a change that indirectly impacts the facility accreditation status. The standard reads as though all changes would be reportable to AABB. We propose adding language that specifies that changes to ownership, medical director, location, or facility closure, would be reportable to AABB within 30 days. | Yes | Based on this comment, the committee added subnumbers 1 – 5 in standard 1.9 to provide specifics as to what would constitute an impact on a facility's accreditation status. |
| 1.9 (New) | RtC | Proposed Standard 1.9 is overly broad and out of the scope of AABB. The FDA already requires blood centers report these instances to the agency. We are not sure of AABB's intent with this Standard. Without a defined path of action from AABB following reporting, we question the need for a duplicated reporting effort and burdensome paperwork. Any such events and documentation can be reviewed by AABB during routine inspections. Additionally, as such an event may result in litigation for blood centers; involving AABB as an additional reporting step may result in additional issues, specifically as any reporting done to the AABB would be subject to discovery in litigation and AABB | No | The committee reviewed this comment but did not feel that a change was appropriate at this time. The intent of standard 1.9 is based on a requirement to maintain AABB accreditation.<br>The committee did elect to add new subnumbers 1 – 5 to provide more specificity however for ease of understanding and conformance. |

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| | | could be asked to become part of such litigation. | | |
| 1.9.1 (New) | SC | NA | NA | The committee created new standard 1.9.1 based on the same addition to the 12th edition of Cellular Therapy Standards. This standard now requires accredited programs contact AABB if they are under investigation by their relevant Competent Authority. This ensures AABB accreditation's department is aware of all issues that could potentially impact the program or AABB as an accreditation organization.<br>The standard reads as follows:<br>**1.9.1** If the organization is the subject of regulatory enforcement action by a relevant Competent Authority, the organization shall notify AABB within 7 days in electronic or written format.<br>The committee also added a new definition to the Glossary for "Regulatory Enforcement Action" for clarity which reads as follows:<br>**Regulatory Enforcement Action:** Measures taken by a Competent Authority that include, but are not limited to, progressive measures (eg, suspension or termination of operations, information notices requiring specific documentation or data, fines incurred) or critical triggers (eg, pattern of recurrent, unresolved issues; deficiencies in risk management systems). |
| 1.9.2 (deleted) | SC | NA | NA | The committee elected to delete a stand alone standard 1.9.2 that was a part of the proposed edition, as the core of the 5 subnumbers that appear in standard 1.9.1. This was based on comments received to the edition. |
| 1.9.2 (deleted) | RtC | Proposed Standard 1.9.2 is unneeded and burdensome. The Medical Directors for our facility (we have three) act as Laboratory Directors for CLIA purposes. Since we already report such changes to CLIA and maintain up to date documentation of all CLIA required personnel and delegations, we | No | The committee reviewed this comment and did not feel that a change was needed at this time. The committee does note that all accredited AABB facilities need to inform AABB if they have an acting medical director and that they are qualified to do so. |

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| | | question the purpose of additionally reporting changes to AABB. | | |
| 1.10 (New) | SC | NA | NA | The committee, when the proposed 35th edition was released for comment, had a version of standard 1.10 that was deemed vague. As a result, and with the desire to maintain the concept of the need to inform AABB in the case where a fatality that can be confirmed to be related to blood donation or a transfusion event.<br>The standard reads as follows:<br>**1.10 Unanticipated Event Notification**<br>The facility shall communicate to AABB in electronic or written format within 30 days any fatalities confirmed to be caused by blood donation or transfusion. Standard 7.4 applies. |
| 1.10 (proposed) | RtC | Please consider removing this requirement, since Transfusion service is reporting unexpected serious / potential serious events to the FDA within 45 days, which is required by the FDA. This is a duplicate to report the same events twice, and AABB can coordinate with the FDA to collect data anonymously. Furthermore, the wording of the standard does not specify to report events that are associated with issued products as the FDA requires. The wording of the standard is high level that encompasses potential serious that might not be associated with issued products, as they could have the potential of harming the patient.<br>Please consider the following rewrite:<br>1.10 Unanticipated Event Notification<br>Within 30 days, the organization shall notify AABB of the discovery of an event that has, is, or is likely to cause serious injury, harm, or death to an individual resulting from deviation(s) related to the scope of these BB/TS Standards | No | The committee reviewed this comment but did not feel that a change was needed at this time.<br>The committee wishes to share the following link to what is related to BPD reporting:<br>Biological Product Deviations \| FDA<br>https://www.fda.gov/media/70694/download?attachment<br><br>It should be noted that for facilities accredited by AABB, the following is required by the accreditation agreement:<br>AABB will require immediate corrective action and will notify CMS within 10 days if a facility has a nonconformance that has immediate severe adverse consequences to patient care or the public (immediate jeopardy). Immediate jeopardy is defined as a situation in which immediate corrective action is necessary because the laboratory's noncompliance with the requirement has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health or safety of the general public. |

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| 1.10 (proposed) | RtC | This proposed new standard is vague. Also, why has it been added to the Standards? What will accreditation do with the information? | Yes | The committee agreed with the intent of the comment and deleted the standard as originally written. The standard has been rewritten to focus on fatality reporting as a result of blood transfusion or blood donation to the AABB. |
| 1.10 (proposed) | RtC | Could a definition of serious injury and harm be added?<br>How is AABB notified? | Yes | The committee reviewed this comment and deleted the standard as written and replaced it with a standard focused on fatality reporting as a result of blood transfusion or blood donation to the AABB. |
| 1.10 (proposed) | RtC | Need to clarify "can cause" in the definition of an unanticipated event. This is too broad and may lead to unnecessary reporting. "Likely to cause" serious injury may be subjective. | Yes | The committee reviewed this comment and deleted the standard as written and replaced it with a standard focused on fatality reporting as a result of blood transfusion or blood donation to the AABB. It should be noted that, for facilities accredited by AABB, the following is required by the accreditation agreement:<br>AABB will require immediate corrective action and will notify CMS within 10 days if a facility has a nonconformance that has immediate severe adverse consequences to patient care or the public (immediate jeopardy). Immediate jeopardy is defined as a situation in which immediate corrective action is necessary because the laboratory's noncompliance with the requirement has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health or safety of the general public. |
| 1.10 (proposed) | RtC | Is AABB now saying that we need to notify AABB every time we file an FDA BPDR or fatality notice? If so, what is the benefit of AABB duplicating what the FDA already does? What mechanisms and protections are in place to support such notifications? Does the standard only apply to organizations outside the USA, or organizations using the AABB for their CLIA certification/recertification? | Yes | The committee reviewed this comment and deleted the standard as written and replaced it with a standard focused on fatality reporting as a result of blood transfusion or blood donation to the AABB. It should be noted that, for facilities accredited by AABB, the following is required by the accreditation agreement:<br>AABB will require immediate corrective action and will notify |

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| 1.10 (proposed) | RtC | Will AABB have a guidance document or form to assist facilities in determining when a notification/report is required to the AABB, what information to submit in the report and how to submit the report? | Yes | As issued with the proposed edition, the committee removed the initially shared standard. The committee has crafted a new standard focused on fatality reporting as a result of blood transfusion or blood donation to the AABB.<br>To the intent of the comment, guidance has been written to ensure the intent of the standard is understood. |
| 1.10 (proposed) | RtC | Clarify how this standard relates to Chapter 7 (Deviations, Nonconformances, and Adverse Events), the overlap creates confusion. Is the intent to notify the AABB of deviations/nonconformance and adverse events that are reportable to the FDA? Also, use of terms "likely," "can," and "serious" introduces subjectivity that may lead to inconsistent reporting. Perhaps expand on the standard to include examples or give some general reporting guidelines. | Yes | The committee reviewed this comment and deleted the standard as written and replaced it with a standard focused on fatality reporting as a result of blood transfusion or blood donation to the AABB. It should be noted that, for facilities accredited by AABB, the following is required by the accreditation agreement:<br>AABB will require immediate corrective action and will notify CMS within 10 days if a facility has a nonconformance that has immediate severe adverse consequences to patient care or the public (immediate jeopardy). Immediate jeopardy is defined as a situation in which immediate corrective action is necessary because the laboratory's noncompliance with the requirement has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the |

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| 1.10 (proposed) | RtC | As stated in the committee notes, this requirement mirrors requirements set forth by AABB's Accreditation Department. The committee should define what requirement correlates to this standard. It is also unclear as to AABB's intent to collect this information and how it will be utilized. This requirement seems redundant to Blood Product Deviation Reporting submitted to FDA CBER. This standard creates an undue, duplicative burden on blood bank organizations.<br><br>It is recommended that this standard be removed from the proposed edition.<br><br>However, if the standard remains in the proposed edition, it is recommended that additional guidance be provided as noted<br>• The statement "an event that has, is or is likely to" is open to subjectivity and should be clarified to ensure reporting consistency across all organizations.<br>• The statement "resulting from deviations to the scope of these standards" could require reporting that is not caused by the organization. For example, if the event is a result of a supply or equipment failure.<br>• The reporting process is not well defined. It is unclear if the notification would be written or electronic (e.g., via email, website portal, etc.)<br>• The reporting timeframe should be adjusted from 30 days to 45 calendar days to align with FDA CBER reporting timelines allowing blood banks to perform a more thorough investigation and confirm the likelihood of potential harmful events. However, if the 30-day notification remains in the standard, it should be well defined as it can be interpreted as<br>1) either calendar or business days<br>2) the start time of the 30-day notification could be when the issue is discovered or when the organization determines the event "has, is or is likely to cause serious harm". | Yes | The committee reviewed this comment and deleted the standard as written and replaced it with a standard focused on fatality reporting as a result of blood transfusion or blood donation to the AABB. It should be noted that, for facilities accredited by AABB, the following is required by the accreditation agreement:<br>AABB will require immediate corrective action and will notify CMS within 10 days if a facility has a nonconformance that has immediate severe adverse consequences to patient care or the public (immediate jeopardy). Immediate jeopardy is defined as a situation in which immediate corrective action is necessary because the laboratory's noncompliance with the requirement has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health or safety of the general public. |
| 1.10 (proposed) | RtC | Reporting unanticipated events falls outside the scope of accreditation and should not be required. Facilities should be required to report to regulatory entities when an unanticipated event occurs that can cause serious injury, harm, or death to an | Yes | The committee reviewed this comment and deleted the standard as written and replaced it with a standard focused on fatality reporting as a result of blood transfusion or blood donation to the |

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| | | individual. We think such reporting falls outside the purview of accrediting bodies. | | AABB. It should be noted that, for facilities accredited by AABB, the following is required by the accreditation agreement:<br>AABB will require immediate corrective action and will notify CMS within 10 days if a facility has a nonconformance that has immediate severe adverse consequences to patient care or the public (immediate jeopardy). Immediate jeopardy is defined as a situation in which immediate corrective action is necessary because the laboratory's noncompliance with the requirement has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health or safety of the general public. |
| 1.10 | RtC | We request the following edit to this standard, as well as the Glossary definition of "Unanticipated Event" to align with FDA's reporting requirements and definitions under 21 CFR 600.80 Postmarketing reporting of adverse experiences and 21 CFR 606.170 Adverse reaction file.<br>Further, 21 CFR 606.171(b)(1)(ii) and *Biological Product Deviation Reporting for Blood and Plasma Establishments, Guidance for Industry*, require reporting of product deviations that represent an unexpected or unforeseeable event that may affect the safety, purity, or potency of that product. Some of these Biological Product Deviation Reports (BPDRs) may fall under AABB's definition of and "Unanticipated Event" but not meet the FDA's definition for a Serious Adverse Event that requires submission of a MedWatch Form FDA 3500. Submitted BPDRs may already be reviewed by AABB, so we believe this clarification is necessary to mitigate overreporting, which would be burdensome to both blood centers as well as to AABB.<br><br>FDA Definitions:<br>21 CFR 600.80 includes definitions for Adverse experiences, or any adverse event associated with the use of a biological product in humans: | Yes | The committee reviewed this comment and deleted the standard as written and replaced it with a standard focused on fatality reporting as a result of blood transfusion or blood donation to the AABB. It should be noted that, for facilities accredited by AABB, the following is required by the accreditation agreement:<br>AABB will require immediate corrective action and will notify CMS within 10 days if a facility has a nonconformance that has immediate severe adverse consequences to patient care or the public (immediate jeopardy). Immediate jeopardy is defined as a situation in which immediate corrective action is necessary because the laboratory's noncompliance with the requirement has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health or safety of the general public. |

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| | | • 21 CFR 600.80(a) “Serious adverse experience”<br>• 21 CFR 600.80(a) “Unexpected adverse experience”<br><br>FDA Reporting Requirements:<br>21 CFR 600.80(c) requires that the applicant must submit to FDA postmarketing 15-day Alert reports (each adverse experience that is both serious and unexpected, whether foreign or domestic, as soon as possible but no later than 15 calendar days from initial receipt of the information by the applicant) and periodic safety reports pertaining to its biological product. Additionally, 21 CFR 606.170(b) requires that “When a complication of blood collection or transfusion is confirmed to be fatal, the Director, Office of Compliance and Biologics Quality, CBER, must be notified as soon as possible. A written report of the investigation must be submitted within 7 days after the fatality by the collecting facility in the event of a donor reaction, or by the facility that performed the compatibility tests in the event of a transfusion reaction.” | | |
| 2.1.3.1 (proposed) | RtC | Is a competency assessment required prior to "independent performance" as stated in 2.1.4? Or can personnel satisfactorily complete training and then work independently for a short time period before competency is assessed? | Yes | The committee reviewed this comment and agreed that the standard as proposed was redundant to standards 2.1.3 and 2.1.4. |
| 2.1.3.1 (proposed) | RtC | The new standard seems redundant with standard 2.1.4 that outlines competency. Is the intent of 2.1.3.1 to evaluate staff immediately following training? If retained, will this be a standard that will be added to all sets of standards for consistency? | Yes | The committee reviewed this comment and agreed that the standard as proposed was redundant to standards 2.1.3 and 2.1.4. |
| 2.1.3.1 (proposed) | RtC | Proposed Standard 2.1.3.1 is is overly broad and subject to interpretation. Critical Tasks as defined herein would encompass nearly every task performed within a blood center by testing and non-testing personnel. Training and its completion is already documented at our facility and therein, the trainer is required to sign that the employee meets the requirements of training and, where applicable, has passed a quiz. This Standard seems to be requiring that an additional step be performed for “critical tasks” and the use of “competent” implies the need to perform competencies consistent with CLIA Personnel Competencies. By CLIA definition, these are not required for | Yes | The committee reviewed this comment and agreed that the standard as proposed was redundant to standards 2.1.3 and 2.1.4. |

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| | | non-testing personnel. We feel that if this Standard were added, AABB assessors would inconsistently interpret our training program and the type of competency assessments required. | | |
| 2.1.6.1 (proposed) | RtC | "Overseeing" is broad. What type of competency is required for "overseeing" staff and what level of staff that "oversee" others, e.g., direct supervisors, team or shift leads, managers, directors, how far up? Continuing education is not uncommon for some positions, e.g., laboratory testing or medical but this will be a new concept for some facilities when considering critical tasks in donor management, blood collection, manufacturing, distribution, supply or inventory management, etc. Is this warranted? The note states this "closes a potential loophole" what is the loophole? I agree that training for critical tasks (2.1.3) is necessary for anyone doing those critical tasks. I am not certain I agree with con ed for anyone performing any critical task. | Yes | The committee reviewed this comment and based on the content did not feel that this standard should remain in the 35th edition. |
| 2.1.6.1 (proposed) | RtC | The word "minimum" is a nebulous term; an organization could establish zero (O) as their continuing education requirement. | Yes | The committee reviewed this comment and based on the content did not feel that this standard should remain in the 35th edition. |
| 2.1.6.1 (proposed) | RtC | While Continuing Education (CE) is critical for clinical and technical roles, its applicability to donor-facing or logistical roles (e.g., donor screening, product distribution) is less clear. These roles may benefit more from targeted competency assessments than formal CE hours. We recommend this standard be removed or clarified. Applying to roles beyond the laboratory seems overly burdensome and unnecessary.<br>Additional clarification regarding what constitutes a critical task and continuing education will be helpful to ensure the appropriate staff are identified as well as determining the applicable on-going education classes. For example:<br>• Define "critical tasks" with examples (e.g., crossmatching, donor eligibility determination).<br>• Allow flexibility in meeting CE requirements through internal training, competency assessments, or manufacturer-led sessions.<br>• Clarify whether CE must be accredited or if informal education (e.g., SOP reviews, in-service training) qualifies. | Yes | The committee reviewed this comment and based on the content did not feel that this standard should remain in the 35th edition. |

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| | | In addition, the term "overseeing" in reference to critical tasks, as currently written, is broad and could be interpreted in various ways depending on the organizational level. It would be helpful to specify whether this refers to immediate supervisors, managers, directors, or executives, as each may have different scopes of responsibility. We suggest the removal of the term "overseeing" if the standard is retained. | | |
| 2.1.6.1 (proposed) | RtC | This standard is preceded by 2.1.6 Continuing Education which states "the organization shall ensure that continuing education requirements applicable to these BB/TS Standards are met when applicable." The only standard that refers to continuing education (CE) is under Standard 1.1.1 Medical Director Qualifications and Responsibilities which states the medical director must have facility-defined relevant continuing education.<br><br>By adding 2.1.6.1 without additional guidance, AABB's expectation of continuing education is open to subjectivity. Since continuing education is not defined in the glossary, it can be interpreted to mean education/training from a formal CE program (i.e., an organization accredited by state agencies or another organization) or an internal education program. Also, additional guidance should be provided for "employees performing or overseeing critical tasks" as all employees performing collection, preparation, processing, QC testing, etc. of blood and blood products would be subject to this standard. | Yes | The committee reviewed this comment and based on the content did not feel that this standard should remain in the 35th edition. |
| 2.1.6.1 (proposed) | RtC | This standard reads as though continuing education will be required for all employees performing or overseeing critical tasks. Standard 2.1.4 already requires evaluation of staff competence before staff perform tasks independently and at defined intervals. This is in addition to Standard 2.13 that requires the organization to provide training for personnel performing critical tasks. We think the requirement for continuing education for any employee that performs a critical task as specified in 2.1.6.1 is redundant and should not be included in the Standards. | Yes | The committee reviewed this comment and based on the content did not feel that this standard should remain in the 35th edition. |

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| 2.1.6.1 (proposed) | RtC | The introduction of Standard 2.1.6.1 appears to differ somewhat from the overarching Standard 2.1.6, which notes, "The organization shall ensure that continuing education requirements applicable to these BB/TS Standards are met when applicable," while also stating that accredited organizations shall define requirements as a matter of course. The committee did not adopt the proposed change to the 34th edition, which suggested that continuing education should be demonstrated as relevant to the BB/TS, explaining that the phrase "when applicable" is intended to provide flexibility for facilities to determine which continuing education requirements apply to specific individuals.<br>21 CFR 606.20(b) requires that "*The personnel responsible for the collection, processing, compatibility testing, storage or distribution of blood or blood components shall be adequate in number, educational background, training and experience, including professional training as necessary, or combination thereof, to assure competent performance of their assigned functions, and to ensure that the final product has the safety, purity, potency, identity and effectiveness it purports or is represented to possess*." It does not stipulate that these individuals maintain "minimal continuing education," nor that these be defined by the organization.<br>Additionally, under 21 CFR 630.5, "*the responsible physician may delegate… activities to a physician substitute or other trained person.*" Delegated persons need not maintain "minimal continuing education" for such tasks.<br>We might interpret this new Standard 2.1.6.1 to include the personnel that are included under the two referenced CFRs because these tasks could be considered to be "critical tasks." Therefore, we request that "critical tasks" be further defined, and that this Standard 2.1.6.1 align directly to the FDA regulations outlined in 21 CFR 606.20(b) and 21 CFR 630.5, so that minimum continuing education requirements do not need to be defined for such personnel. | Yes | The committee reviewed this comment and based on the content did not feel that this standard should remain in the 35th edition. |
| 2.1.6.1 (proposed) | RtC | We object to this Standard in its entirety. All blood bank employees are performing critical tasks. These employees already receive annual competency evaluations as well as | Yes | The committee reviewed this comment and based on the content did not feel that this standard should remain in the 35th edition. |

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| | | annual safety and annual cGMP training. Continuing education is not well defined outside of testing personnel requirements and is too broad in this context. The existing 2.1.6 seems adequate as it implies that continuing education is required when applicable, which we interpret to mean applicable to meet that employee's external licensure requirements. It is not intended to require that facilities must create and maintain continuing education libraries and assessments not already in existence for front-line staff who collect, process, or ship blood (which are critical tasks with quality components) or those who manage those employees. | | |
| 3.5.4.1 (New) | SC | NA | NA | The committee created new standard 3.5.4.1 for clarity. This new standard clarifies that not all equipment has to be reviewed when it is known that one piece of equipment is at the root of the nonconformance.<br>The standard reads as follows:<br>**3.5.4.1** When a nonconformance cannot be attributed to a specific piece of equipment, all pieces of equipment potentially involved in the nonconformance shall be evaluated<br>to determine if expected performance criteria are met based on the manufacturer's written instructions. |
| 3.5.4.1 (New) | RtC | This new standard seems unnecessary. Parent standard 3.5.4, is for investigation and follow-up for equipment malfunctions, failures, or adverse events. Presumably if you are applying this standard, you know the equipment involved. Whether one device or multiple devices, the subparts 1) through 6) apply. Specifically, item 4) requires a determination if other equipment is affected. The explanation for 3.5.4.1 states that it clarifies that not all equipment has to be reviewed when it is known that one piece of equipment is at the root of the conformance. The standard (3.5.4.1) does not explicitly state this. | Yes | The committee noted this comment and agreed with much of the intent but determined that an edit to the standard for clarity would be appropriate. The standard now reads as follows:<br>**3.5.4.1** When a nonconformance cannot be attributed to a specific piece of equipment, all pieces of equipment potentially involved in the nonconformance shall be evaluated<br>to determine if expected performance criteria are met based on the manufacturer's written instructions. |
| 3.6 (deleted) | SC | NA | NA | Based on a review of chapter 3, it was deemed that this standard is redundant to many standards in chapter 3, specifically the 3.5 |

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| | | | | thread. This standard was also deemed redundant per standard 6.2.2. |
| 3.6 (deleted) | RtC | The reasoning for the removal of 3.6 Equipment Traceability is unclear. After the removal of 3.6, the only mention of traceability in QSE 3 is the reference to 5.1.8.2 Traceability which does not mention equipment but is only inferred due the tie back to 3.4 Unique Identification of Equipment. If removed, we recommend modifying 5.1.8.2 to explicitly include equipment traceability. | No | The committee reviewed this comment but did not feel that the rationale to retain the standard was sufficient.<br>The content of 3.5.4.1 and 6.2.2 cover the requirements that previously existed in this standard. |
| 3.6.1 | RtC | Given the recent surge in cybersecurity attacks across our industry. Should AABB strengthen Standard 3.6.1 on Alternative System? Currently, the standard requires maintaining a backup system for continuous operation when computerized functions fail, with mandatory testing and disaster recovery plans. However, many blood banks and transfusion services seem to treat "downtime" casually. With increasing digital risks, we should consider a more comprehensive approach to ensure robust alternative systems that protect our critical operations and patient safely. | No | The committee noted this comment but did not feel that an edit to standard 3.6.1.<br>The committee feels that new standard 3.7 and the content contained in the 3.6 flow of the standards are sufficient. |
| 3.7 (New) | SC | NA | NA | The committee created new standard 3.7 to ensure that facilities monitor their critical technology infrastructure and that they function as expected. This standard requires that there are defined checks to monitor that technology is working as intended and expected. The standard reads as follows:<br>**3.7 Technology Infrastructure**<br>The organization shall have an ongoing program to ensure that critical technology and communication infrastructures function as intended, including risk-based monitoring or testing at organization-defined intervals. Standards 1.4, 1.5, and 1.6 apply. |
| 3.7 (New) | RtC | Scope of standard is not clear. Does this encompass cybersecurity, software, telecommunications, etc. Also, the term "critical technology and communication infrastructures" is vague. Does it include, cybersecurity protocols, emergency communication systems, etc. Recommend detailed guidance be provided. | No | The committee reviewed this comment but did not feel that a change was needed at this time. The committee has created comprehensive guidance to assist in the implementation of this standard. |

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| 3.7 (New) | RtC | Standard 3.7 seems too nebulous, can more specifics be added? | No | The committee reviewed this comment but did not feel that a change was needed at this time. The committee has created comprehensive guidance to assist in the implementation of this standard. |
| 3.7 (New) | RtC | Proposed Standard 3.7 is an overreach by AABB and also overly broad. AABB standard 1.5 and 1.7 already require operational continuity and emergency preparedness which we believe covers the intent of this proposed standard as it relates to cybersecurity and communication infrastructure. We also believe it is outside of the scope and skill of AABB inspection staff to assess the adequacy of such risk-based monitoring. | No | The committee reviewed this comment but did not feel that a change was needed at this time. The committee has created comprehensive guidance to assist in the implementation of this standard. |
| 3.8.2.1 (New) | SC | NA | NA | The committee added new standard 3.8.2.1 for completeness, reflecting a gap in the standards where assessors did not have the ability to cite a specific standard related to the expected quality control testing needed of temperature recording devices.<br>The standard reads as follows:<br>**3.8.2.1** The organization shall perform quality control testing of automated temperature recording devices at facility-defined intervals to verify accuracy of recordings. Standards 3.5.1 and 5.1.2 apply. |
| 3.8.2.1 (New), 3.9.1.1 (New) | RtC | Quality Control (QC) testing needs further detail. Lack of clarity regarding what QC entails can lead to over-interpretation beyond manufacturer recommendations. Quality control of a validated automated temperature monitoring system seems unnecessary. Calibration checks as required by the manufacturer seems more appropriate.<br>The requirement for quality control (QC) testing of validated automated systems may be redundant and burdensome. Clarify whether QC refers to functional checks beyond manufacturer-recommended calibration. Also, consider exempting validated systems from additional QC if performance checks are performed on a regular basis. | No | The committee reviewed this comment but did not feel that a change would be appropriate at this time. The committee has created new guidance to assist in the implementation of this standard. |
| 3.9 | SC | NA | NA | The committee added the term "Storage device" to the title of this standard for clarity, recognizing that the focus of this section is on |

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| | | | | storage devices. Note the content of the standard has not changed.<br>The standard title now reads as follows:<br>**✎3.9 Storage Device Alarm Systems** |
| 3.9.1.1 (New) | SC | NA | NA | In conjunction with the addition of standard 3.8.2.1, standard 3.9.1.1 has been added to this edition for parallel construction and completeness.<br>The standard reads as follows:<br>**3.9.1.1** The organization shall perform quality control testing of alarm activations at facility-defined intervals to verify alarms are activated when the temperature-sensing device/probe detects an unacceptable temperature. Standards 3.5.1 and 5.1.2 apply. |
| 3.10 | SC | NA | NA | The committee added the term "Bedside" to the title of standard 3.10 for clarity, recognizing that the focus of this section is on where the warming devices are used and in place. Note the content of the standard has not changed.<br>The standard title now reads as follows:<br>**✎3.10 Bedside Warming Devices for Blood and Blood Components** |
| 3.10.1 (New) | SC | NA | NA | In conjunction with the addition of standards 3.8.2.1 and 3.9.1.1, standard 3.10.1 has been added to this edition to ensure parallel construction and completeness.<br>The standard reads as follows:<br>**3.10.1** The organization shall perform quality control testing of the warning system at facility-defined intervals to verify warnings are activated when the temperature-sensing device detects an unacceptable temperature. Standards 3.5.1 and 5.1.2 apply. |
| 5.1.1.1 | SC | NA | NA | For completeness, the committee as added a reference to "42 CFR 493.1253" which focuses on the establishment and verification of performance specifications. |
| 5.1.2.4 | RtC | We are requesting further guidance from the AABB on the expectations based on 42 CFR 493.1281 referenced in the Standard. Are | No | The committee reviewed this comment but did not feel that a change was appropriate at this time. |

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| | | facilities expected to perform method comparison studies for every test that is performed by different methods, instruments, and sites or the only the ones that are CLIA "regulated" analytes? | | The committee noted that this standard was added to the 34th edition based on feedback from representatives from CLIA. The committee has added guidance to this edition for clarity. |
| 5.1.8.3 | RtC/SC | Note that the requirements in 21 CFR 606.120 do not seem to have been incorporated fully in the Standards. We may want to suggest that the AABB add the following (unless it is elsewhere in the standards and not in this section):<br>• 21 CFR 606.120(a) – labeling operations shall be separated physically or spatially from other operations.<br>• 21 CFR 606.120(b)(1) – labels shall be held upon receipt, pending review and proofing to ensure accuracy (or the firm can use an "on-demand" printer)<br>• 21 CFR 606.120(b)(2) – each type of label shall be stored separately to prevent mix-ups; obsolete labels shall be destroyed. | Yes | The committee reviewed this comment and agreed with its intent. To meet the intent of the comment, the committee has added a crossreference to 21 CFR 606.120 to the standard. |
| 5.1.8.4 | SC | NA | NA | The committee added two CFR crossreferences to the standard for completeness and clarity. The additions are to 21 CFR 606.160(b)(l)(vii) and 21 CFR 630.10(g)(1).<br>21 CFR 606.160(b)(l)(vii) is focused on records that relate the donor with the unit number of each previous donation from that donor, while 21 CFR 630.10(g)(1) is focused on donor proof of identity and postal address. |
| 5.1.9 | RtC | We are requesting AABB clarify what constitutes transport versus storage - particularly in cases where portable coolers are used. For example, if a validated cooler has arrived at its intended location, at what time would the cooler no longer be considered a "transport" container? | No | The committee reviewed this comment but did not feel that a change would be appropriate at this time. The committee notes that the comment in question is defined by the Food and Drug Administration. The committee has added guidance to the standard for clarity purposes. |
| 5.1.9.1 (deleted) | SC | NA | NA | The committee elected to delete former standard 5.1.9.1 which formerly appeared as a title only and provided no value to the Standards. ~~**5.1.9.1 Inventory Management**~~ |
| 5.1.9.3 (New) | SC | NA | NA | The committee created new standard 5.1.9.3 to focus on storage |

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| | | | | devices with electronic capabilities that do allow for continuous monitoring for clarity.<br>The new standard reads as follows:<br>🖉**5.1.9.3** Storage areas and devices for blood and blood components shall be monitored: |
| 5.1.9.3.1 (5.1.9.3) | SC | NA | NA | The committee edited standard 5.1.9.3.1 (formerly 5.1.9.3) for clarity. The edits mirror the language and tone of the edits to the section.<br>The standard now reads as follows:<br>**5.1.9.3.1 Electronic** storage **devices** for blood and blood components shall be monitored continuously and **the temperature** recorded at least every 4 hours. **Standard 1.5 applies.** |
| 5.1.9.3.1 (5.1.9.3) | RtC | Please clarify whether these standards apply to electronic monitoring systems. | No | The committee reviewed this comment but did not feel that a change was needed at this time. The standard details the focus of "electronic storage devices" which would include "electronic monitoring systems." |
| 5.1.9.3.1 (5.1.9.3) | RtC | For standard 5.1.9.3.1 can "Electronic storage devices" be revised to state "Electronically enabled storage devices"? | No | The committee reviewed this comment but did not feel that a change was needed at this time. The committee notes that the term "electronic storage device" has been in use in the standards and has become understood in the community and to update it at this time would not prove beneficial for the users of the *Standards*. |
| 5.1.9.3.2 (New) | SC | NA | NA | The committee has added new standard 5.1.9.3.2 to the 35th edition to ensure that all requirements surrounding temporary storage containers are covered in the edition, and what is expected with regard to the maintenance of viability of blood and blood components is taken into consideration by the accredited facility.<br>The standard reads as follows:<br>**5.1.9.3.2** Temporary storage containers shall be qualified and validated to store blood and blood components to ensure that they maintain temperature within the acceptable range for the defined duration of storage. |

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| 5.1.9.3.2 (New) | RtC | The term "temporary storage container" is vague. A definition or example will help distinguish a "temporary storage container" from a "transport container" if one exists. | No | The committee noted this comment but did not feel that a change was needed at this time.<br>The committee felt that the issue should not be about the terminology but the temperature at which the products are being maintained in, essentially their storage condition. |
| 5.1.9.3.2 (New) | RtC | Recommend that the new standard, 5.1.9.3.2 be revised to allow the use of validated shipping containers to temporarily maintain products within the acceptable shipping range.<br>While it is understood that these products are not being shipped, only temporarily stored, this new standard places additional burden on facilities to now meet the smaller storage range of 1 to 6C. This could require additional validation studies of the same shipping containers, or require facilities to purchase additional storage equipment, both of which pose unnecessary financial burdens. The other option would be to pack the products in the shipping containers and ship the products to another facility, causing additional work for staff and unnecessary transport and handling of the products. | No | The committee reviewed this comment but did not feel that a change was needed at this time.<br>The committee noted that this standard does not state that one has to go beyond the storage temp requirements. In terms of temperature, whether 1-6, or 1-10 is based on the product either being shipped or transported. |
| 5.1.9.5.1 (5.1.9.2.1) | SC | NA | NA | The committee edited standard 5.1.9.5.1 for clarity, updating the language by adding the clause, "and validated" and replaced the term "expected" with "defined."<br>The standard reads as follows:<br>**5.1.9.5.1**Transport containers shall be qualified and validated to transport blood, blood components, tissues, and derivatives to ensure that they maintain temperatures within the acceptable range for the defined duration of transport or shipping. |
| 5.1.9.5.1 (5.1.9.2.1) | RtC | Please revise wording of 5.1.9.5.1 to match 5.1.9.3.2 using Transport containers in place of storage containers and removing the example (eg, portable coolers) as some places may use coolers for storage.<br>Suggested wording.<br>"Transport containers shall be qualified and validated to store blood, and blood components, tissues, and derivatives to ensure they maintain temperature within the acceptable range for the defined duration of transport or shipping." | Yes | The committee reviewed this comment and agreed that a change was needed. Based on the comment, the committee added the term "Transport" to the beginning of the standard.<br>The standard reads as follows:<br>**5.1.9.5.1**Transport containers shall be qualified and validated to transport blood, blood components, tissues, and derivatives to ensure that they maintain temperatures within the acceptable range for the |

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| 5.1.10 | SC | NA | NA | The committee added the following CFRs, “42 CFR 493.857 and 42 CFR 493.959” to the standard for completeness. 42 CFR 493.857 focuses on proficiency testing around immunohematology, and 42 CFR 493.959 focuses on immunohematology reference laboratories. |
| 5.2.4 | RtC | I am writing to request that the patient alloantibodiy standard be aligned with the donor antibody standard to support better understanding of RBC alloantibody potential impact on the patient, as we already do for autologous donors (who are patients).<br>The recommendation is to add the clause that appears for the autologous donor antibody receives (who is themselves a patient) to the patient standard: "the referring physician shall also be notified. Appropriate education, counseling, and referral shall be offered.”<br>The wording may need some minor editing, such as "recommendation for education, counseling and referral" instead of directly offering it.<br>Reason: RBC alloantibodies can cause future patient implications, particularly for those who may become pregnant. Failure to refer women with alloantibodies to be properly educated and referred can significantly harm their pregnancies and is entirely preventable with proper referral. | No | The committee noted this comment but did not feel that a change would be appropriate at this time.<br>This level of a change as suggested would not be appropriate to edit without feedback from the community. As a result, the committee will take this information and include it as a proposed standard in the 36th edition of BB/TS Standards when they are released for comment. |
| 5.3.3 (5.3.3, 5.3.3.1, 5.3.3.2) | SC | NA | NA | The committee elected to merge standards 5.3.3.1 and 5.3.3.2 into a new version of standard 5.3.3 which previously only appeared as a title. As previously written, standards 5.3.3.1 and 5.3.3.2 appeared virtually identical.<br>The standard now reads as follows:<br>**5.3.3 Postphlebotomy Instructions**<br>The collection facility shall provide the donor with written instructions for postphlebotomy care, and actions to take concerning adverse events that may occur after donation. Standard 7.3.3. applies. |
| 5.4.2.1 | SC | NA | NA | The committee edited standard 5.4.2.1 to continue to require that all donor followup when needed occur within 24 hours, while citing the existing FDA Guidance which |

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| | | | | allows for the this to occur within 72 hours when approved. The citation of the Guidance will allow facilities to maintain the 72 hour eligibility requirements so long as they have approval from the FDA. The standard now reads as follows: **5.4.2.1** If the collection facility determines that additional clarification or information is needed to evaluate donor eligibility, this information shall be obtained within 24 hours or as approved by FDA or relevant Competent Authority regulations.* ***21 CFR 630.10(c). FDA Guidance for Industry: Compliance Policy Regarding Blood and Blood Component Donation Suitability, Donor Eligibility and Source Plasma Quarantine Hold Requirements (October 2023).** |
| 5.4.2.1 | RtC | As indicated in the committee notes, the 72-hour timeframe is supported by current FDA enforcement discretion; specifically, FDA's Compliance Policy Regarding Blood and Blood Component Donor Suitability, Donor Eligibility, and Source Plasma Quarantine Hold Requirements- Guidance for Industry, October 2023. By separating "per FDA" and "within 72 hours of collection" by the word OR, it can be perceived that FDA has different requirements.<br>It is recommended that the standard be revised to state "If the collection facility determines that additional clarification or information is needed to evaluate donor eligibility, this information shall be obtained within 72 hours of collection or per relevant Competent Authority." It is also recommended that FDA's Guidance for Industry indicated above is referenced under the standard. | Yes | As issued for comment, standard 5.4.2.1 was written in a way that allowed facilities to have 72 hours to perform follow up as the standard which would run contrary to the existing FDA language. Based on the feedback, the committee edited the standard to retain the previous language with the added clause of "…within 24 hours or as approved by.." to ensure that facilities that do have approval for a 72 hour follow up by their Competent Authority are covered. |
| 5.4.2.1 | RtC | If the collection facility determines that additional clarification or information is needed to evaluate donor eligibility, this information shall be obtained within 24 hours of collection (21 CFR 630.10 (c)(2)), or as otherwise described by FDA (see https://www.fda.gov/media/158608/download) or relevant Competent Authority regulations. | Yes | As issued for comment, standard 5.4.2.1 was written in a way that allowed facilities to have 72 hours to perform follow up as the standard which would run contrary to the existing FDA language. Based on the feedback, the committee edited the standard to retain the previous language with the added clause of "…within 24 hours or as approved |

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| | | | | by..” to ensure that facilities that do have approval for a 72 hour follow up by their Competent Authority are covered. |
| 5.5.2.2.1 | RtC/SC | Recommend adding 21 CFR 640.65(b)(8). | Yes | The committee agreed with the comment received and added a reference to the cited CFR for completeness. |
| 5.5.3.4.3 | RtC/SC | Recommend adding 21 CFR 640.21(d)(2). | Yes | The committee agreed with the comment received and added a reference to the cited CFR for completeness. |
| 5.6.5.2.1 | SC | NA | NA | The committee removed the clause “blood and..” from the standard as it is strictly focused on apheresis platelets.<br>The standard reads as follows:<br>**5.6.5.2.1** If the apheresis product intended for cold storage without pathogen reduction will arrive at the processing facility within 4 hours of collection, the product may be transported in a manner intended to cool the Apheresis Platelets toward a temperature range of 20 to 24 C. |
| 5.7.3.2.1 (New) | SC | NA | NA | The committee has added standard 5.7.3.2.1 to the 35th edition for completeness.<br>Standards 5.7.3.2 and 5.7.3.2.2 typically receive many queries and the addition of this standard focused on dose delivery addresses the most prevalent issue.<br>The standard reads as follows:<br>**5.7.3.2.1** The dose delivery shall be evaluated in accordance with the collection set manufacturer’s written instructions (when specified) concerning irradiation of products and modifications made to expiration date based on the dosimetry results. |
| 5.7.3.2.1 (New) | RtC | We reviewed the manufacturer’s instructions for the two whole blood collection sets utilized and neither set of instructions references irradiation. What are the expectations when the manufacturer’s written instructions lack information related to the irradiation of products? | Yes | Based on the content of this comment, the committee added the clause “…when specified…” in parentheticals recognizing that there are instances where the manufacturer’s written instructions may not contain the requested information. In the case where this information is not available, the committee expects that the users of the Standards refer back to standard 5.7.3.2. |

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| 5.7.3.2.1 (New) | RtC | Please clarify the intent of this standard. Collection set manufacturers do not have written instructions concerning irradiation and the expiration is not based on dosimetry results. It is unclear what issue this standard addresses. | Yes | Based on the content of this comment, the committee added the clause "…when specified…" in parentheticals recognizing that there are instances where the manufacturer's written instructions may not contain the requested information. In the case where this information is not available, the committee expects that the users of the Standards refer back to standard 5.7.3.2. |
| 5.7.4 - Platelets | RtC | The requirements for pH, dose, and residual WBC are lumped together in the same standards. Some of the requirements are from guidance (e.g., dose) and some are from regulation (e.g., pH) [and they can have different QC requirements (95/75 and 95/95)]. When the regulation is cited (21 CFR 640.25(b)), it may imply we have regulations for dose and WBC count. We think these standards could be separated and the reg and guidance citations split accordingly as well. Otherwise, it can be made clearer when the reg vs guidance is being used to support each requirement. | No | The committee reviewed this comment but did not feel that a change would be appropriate at this time. The committee feels that this edit should be circulated as a part of the proposed 36th edition of BB/TS Standards to ensure that members would have an ability to opine on any such edit. |
| 5.7.4.3.1 | RtC | What is the rational requiring red blood cells be frozen within 6 days of collection unless rejuvenated when rare red blood cells can be frozen without rejuvenation up to the date of expiration? | No | The committee reviewed this comment but did not believe a change was needed at this time. The committee has conducted a literature review and will consider any potential update for the 36th edition of BB/TS Standards. |
| 5.7.4.20 (New) | SC | NA | NA | The committee elected to add a new standard focused on Pathogen Reduced Cryoprecipitated Fibrinogen Complex. The product in question previously appeared as a part of reference standard 5.1.9A in the previous edition. The standard reads as follows:<br>**5.7.4.20 PATHOGEN REDUCED CRYOPRECIPITATED FIBRINOGEN COMPLEX**<br>Pathogen Reduced Cryoprecipitated Fibrinogen Complex shall be prepared as per the manufacturer's written instructions. |
| 5.7.4.27 (5.7.4.26) | SC | NA | NA | For completeness the committee added a crossreference to this FDA Guidance document.<br>**FDA Guidance for Industry: Manufacture of Blood Components Using a Pathogen** |

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| | | | | **Reduction Device in Blood Establishments: Questions and Answers (November 2021).** |
| 5.7.4.27.1 (5.7.4.26.1) | RtC | We recommend including the reference to FDA Guidance for PRT platelets: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/manufacture-blood-components-using-pathogen-reduction-device-blood-establishments-questions-and | Yes | The committee agreed with the intent of this comment and added a crossreference to the December 2007 FDA Guidance regarding the collection of platelets by automated methods. |
| 5.8.2 | SC | NA | NA | The committee edited standard 5.8.2 (and other subsequent standards related to D variants) for clarity and to mirror language in the community currently. The intent of the standard has not changed.<br>The standard reads as follows:<br>**5.8.2 Determination of Rh Type for All Collections**<br>The Rh type shall be determined for each collection with anti-D reagent. If the initial test with anti-D is negative, **further testing shall be performed to screen for D variants**. When either test is positive, the label shall read "Rh POSITIVE." When **all testing is** negative, the label shall read "Rh NEGATIVE." |
| 5.8.2 | RtC | I am reaching out with concerns to changes in standards 5.8.2 and 5.12. I am questioning why we are removing the requirement for weak D testing. Our healthcare system just recently discovered that our blood supplier is sending out certain testing to CTS. CTS is not performing actual weak D testing instead they are using a combination of Anti-D reagent that detects most weak D variations. Our medical director has advised that we start performing weak D testing on all Rh-negative units that we receive from our blood supplier in order to protect Rh negative patients from D alloimmunization. If you could provide some guidance or education about why the changes to no longer require weak D were chosen that would be appreciated. | Yes | As proposed the standard included a requirement to use initial and indirect antiglobulin tests (IAT) however, based on this feedback (and others from the community) the requirement was removed. Noting that the standard now merely has to label all negative tests accordingly. |
| 5.8.2 | RtC | The committee stated the intent of the standard has not changed; however, the specific wording appears otherwise. Please clarify if an automated microplate analyzer that does not use a traditional IAT method but is approved to label blood components as | Yes | As proposed the standard included a requirement to use initial and indirect antiglobulin tests (IAT) however based on this feedback (and others from the community) the requirement was removed. Noting that the standard now merely |

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| | | Rh negative, requires additional IAT testing to label the unit Rh negative. | | has to label all negative tests accordingly. |
| 5.8.2 | RtC | Standard 5.8.2, This platform is using different anti D reagents for labeling: Rh GROUPING<br>The determination of D antigen status is accomplished by testing the donor's red blood cells only. If it is intended that Rh negative donors be labeled from testing on the PK7300 and/or PK7400 then a combination of two Anti-D reagents must be used, one of which must be Anti-D. Anti-D (PK 1) and/or Anti-D (PK 2) must be used as the second source of Anti-D reagent. Anti-D is capable of giving a positive reaction with most weak D cells and partial D Category VI cells. If this combination is not used, then the Rh-negative status must be confirmed by testing the donor's red blood cells with a method and Anti-D reagent recommended for the detection of weak D cells and partial D Category VI cells.<br>A positive test with either Anti-D, Anti-D (PK 1), or Anti-D (PK 2) indicates that the red blood cells being tested are D positive (+). A negative test with Anti-D (PK 1) and/or Anti-D (PK 2) and a positive test with Anti-D is indicative of a weak D or partial D Category VI sample.<br>A negative test with Anti-D and Anti-D (PK 1) and/or Anti-D (PK 2) usually indicates that the red blood cells being tested are D negative (-).<br>However, recognition of all the rare, weak or variant antigen motifs cannot be guaranteed with any of the Anti-D reagents.<br>Wanted to bring this up to see if this would be acceptable with the way the standard is currently written. Had a facility as if they would need to perform IAT D typing on their units. Not sure if they submitted the comment. | Yes | As proposed the standard included a requirement to use initial and indirect antiglobulin tests (IAT) however based on this feedback (and others from the community) the requirement was removed. Noting that the standard now merely has to label all negative tests accordingly. |
| 5.8.2 | RtC | Please clarify whether the standard now requires initial and indirect antiglobulin tests (IAT). | Yes | As proposed the standard included a requirement to use initial and indirect antiglobulin tests (IAT) however based on this feedback (and others from the community) the requirement was removed. Noting that the standard now merely has to label all negative tests accordingly. |
| 5.8.2 | RtC | See suggested revision below for clarity and consistency with CFR, and allow flexibility | Yes | As proposed the standard included a requirement to use initial and |

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| | | for tests that may be acceptable for use in the future:<br>The Rh type shall be determined for each collection with anti-D reagent. If the initial test with anti-D is negative, further testing shall be performed to detect variant expression of D. When further testing is positive, the label shall read "Rh POSITIVE." When further testing is negative, the label shall read "Rh NEGATIVE." | | indirect antiglobulin tests (IAT) however based on this feedback (and others from the community) the requirement was removed. Noting that the standard now merely has to label all negative tests accordingly. |
| 5.12 | SC | NA | NA | In conjunction with the edits made to standard 5.8.2 above, the committee edited standard 5.12 to reflect the edit in terms of language to use the term "D variants."<br>🖊**5.12 Serologic Confirmation of Donor Blood ABO/Rh (including autologous units)**<br>Before transfusion, the ABO group of each unit of Whole Blood, Red Blood Cell, and Granulocyte component and the Rh type of such units labeled as Rh negative shall be confirmed by a serologic test from an integrally attached segment. **Further testing for D variants** is not required. |
| 5.12 | RtC | Please clarify if an automated microplate analyzer that does not use a traditional IAT method but is approved to label blood components as Rh negative, requires additional IAT testing to label the unit Rh negative. | Yes | When the standard was released for public comment the term "serological weak" was included in the standard. Based on this comment, the term has been removed and the standard updated. |
| 5.14.2 | SC | NA | NA | In conjunction with edits made to standards 5.8.2 and 5.12 to reflect the edit in terms of language to use the term "D variants."<br>The standard reads as follows:<br>🖊**5.14.2 Rh Type**<br>Rh type shall be determined with anti-D reagent. **Testing for D variants** is optional when typing the patient. If a discrepancy is detected and transfusion is necessary before resolution, only Rh-negative Red Blood Cells shall be issued to patients of childbearing potential. |
| 5.14.4 | RtC | We are requesting AABB consider adding situations when patients have a positive antibody screen or history of red cell alloantibodies to the criteria when the Type and Screen sample expiration is 3 | No | The committee reviewed this comment but did not feel that a change was needed at this time. Such a change would be too large to make at this time and would require |

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| | | days. Extending the Type and Screen sample expiration in patients with a positive antibody screen or history of red cell alloantibodies can be a patient safety issue as there is the possibility to miss an evanescent antibody. | | comment from the community, but this will be considered for the 36th edition of BB/TS Standards. Of note, facilities can be more strict than the Standards as written if appropriate. |
| 5.16.2.3 | SC | NA | NA | The committee elected to edit standard 5.16.2.3 for completeness. These edits ensure that the standard is focused on both an electronic system or a facility defined method to transfer ABO/Rh and antibody screen data. The updated standard reads as follows: **5.16.2.3** A **validated interface shall be used to transfer ABO/Rh and antibody screen data from an instrument to the information system, or a facility-defined** method exists to verify correct entry of data before release of blood or blood components. |
| 5.19.7 | SC | NA | NA | The committee added the reference to the FDA guidance focused on the use of cold stored platelets for completeness. The standard reads as follows: **5.19.7 Specially Selected Platelets** The BB/TS shall have a policy regarding indications for specially selected platelet requirements, where applicable, including but not limited to: 1) HLA-matched, crossmatch-compatible, HLA antigen-negative, and HPA antigen-negative platelets. 2) The use of cold-stored platelets.* ***FDA Guidance for Industry: Alternative Procedures for the Manufacture of Cold-Stored Platelets Intended for the Treatment of Active Bleeding When Conventional Platelets Are Not Available or Their Use Is Not Practical (June 2023).** |
| 5.27.3 | SC | NA | NA | The committee elected to add an additional crossrefernce to standard 5.15.4 for completeness. Standard 5.15.4 is focused on a policy for transfusion of significant volumes of plasma containing incompatible |

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| | | | | ABO antibodies or unexpected red cell antibodies. |
| 5.27.6 | RtC | Emergency release should be a clinical decision made by a licensed independent provider - including NPs and PAs. Stating that only a physician can order emergency release is not reflective of today's healthcare structure. A Licensed Independent Practitioner (LIP) is a healthcare professional, such as a physician, nurse practitioner, or physician assistant, who is permitted by law and their organization to provide patient care services independently, without direct supervision or direction, within the scope of their license and granted clinical privileges.<br>I propose that the standard read: The records shall contain a signed statement from the requesting "licensed independent provider" or "ordering provider" indicating that the clinical situation was sufficiently urgent to require release for blood before completion of compatibility testing or infectious disease testing. The signature can occur before or after the release/issue of blood. | No | The committee reviewed this comment but did not feel that a change was appropriate at this time. It should be noted that the ask in question focuses on issues regulated by the Food and Drug Administration. |
| 5.30 | SC | NA | NA | In conjunction with edits made to standards 5.8.2, 5.12 and 5.14.2 standard 5.30 has been edited for clarity.<br>The standard reads as follows:<br>**5.30 Rh Immune Globulin**<br>The transfusion service shall have a policy for Rh Immune Globulin prophylaxis for Rh-negative patients who have been exposed to Rh-positive red cells. ~~The results of weak D testing and/or RHD genotyping, if performed, shall be evaluated when determining Rh Immune Globulin prophylaxis.~~<br>Standard 5.14.2 applies. |
| 5.30.2 | SC | NA | NA | In conjunction with edits made to standards 5.8.2, 5.12, 5.14.2, and 5.30 to reflect the edit in terms of language to use the term “D variants.”<br>The standard reads as follows:<br>**5.30.2** Individuals who are pregnant or who have been pregnant recently shall be considered for Rh Immune Globulin administration when all of the following apply: |

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| | | | | 1) The individual's initial test for D antigen is negative.<br>2) The individual is not known to be actively immunized to the D antigen.<br>3) The RhD type of the fetus/neonate is unknown, or the fetus/neonate initial test for D antigen or screen for D variants is positive. Screening for D variants is required when the initial test for D is negative. |
| 5.1.8A, #12 | RtC | They do not require the name of the drug ingested on the platelet label if a donor has recently taken aspirin/derivative and the donation (Platelets) are included in a pool. 21 CFR 640.21(c) states the unit must be labeled if Whole Blood is used as the source for platelets and donor has recently ingested aspirin, the regulation does not exclude pooled platelets. | Yes | The committee agreed with the intent of this comment and adjusted the entry in the "Pooled" column to have an "R" (required) in place of "NR" (not required) based on the evidence presented. |
| 5.1.9A, 5.1.9B, 5.1.9C (5.1.9A) | SC | NA | NA | The committee elected to divide Reference Standard 5.1.9A into three separate reference standards to focus three separate products. Reference standard 5.1.9A on cellular components (whole blood, RBCs, platelets, etc.); Reference standard 5.1.9B on acellular components (fresh frozen plasma, thawed plasma, plasma pathogen reduced, etc.); and reference standard 5.1.9C on other products such as recovered plasma, tissue and derivatives.<br>This allows for readability and to ensure that all like products are maintained on the same row with expanded columns.<br>Along with the changes cited above, reference standards 5.1.9A and 5.1.9B include columns expanded beyond storage, transport and expiration. These columns still exist, however specific entries within expiration include leukoreduction, and irradiation recognizing the specific components that previously had appeared as separate rows. |
| 5.1.9A, B, C (5.1.9A) | RtC | While we understand dividing the reference standards, it is difficult to read and follow. With increasing use of electronic versions, we have found the formatting makes it very | Yes | The committee noted this comment and understands the request. The Standards, when published will be legible from what appears in the MS |

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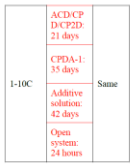
| | | difficult to read and discern the line items within each column. Additionally, the draft version cuts off every column after "Expiration," leaving the reader with a significant amount of missing information (almost 4 full columns) from this modified table (see pages 115-125). We offer the following suggestions:<br>1. Optimize formatting for electronic versions<br>2. Ensure that words are formatted so that partial words are not displayed on several lines, for example, the Storage column content on page 117 of the draft:<br>  <br><br>  <br><br>3. Consider formatting the table with merged rows for identical content (e.g., "Maintain frozen state or "1-10C, as noted in the "Transport" column) but split columns for different content so that a separation is easier to read (e.g. split the cells in the row for Item #2, Expiration)<br>  <br><br>  <br> | | Word or PDF that was available online when the Standards were released for comment.<br>The committee does feel that the split of former reference standard 5.1.9A into three separate reference standards should help with the legibility of the reference standards. |
| 5.1.9A, footnote 4 (New) | SC | NA | NA | The committee added footnote 4 to the edition (which has been applied to the expiration columns) understanding that the majority of the expiration times for the products in the reference standard are set by the FDA or a relevant Competent Authority outside the US (eg, Ministries of Health, etc) that may have different expiration times.<br>The new footnote reads as follows: "As defined by the FDA or relevant Competent Authority" |
| 5.1.9A, #2 (5.1.9A, #4) | RtC | The formatting of this reference standard is difficult to read. Additionally, for item #2, the standard requires a change in the expiration date of ACD-A/ADSOL units irradiated ≥3000cGY to 28 days from the date of collection. This requirement would | No | The committee reviewed this comment but did not feel that a change would be appropriate at this time.<br>These requirements are set forth by the manufacturer of the product and |

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| | | create an unnecessary burden for establishments to remain compliant. | | cannot be adjusted through the Standards. |
| 5.1.9A, #4 (New) | SC | NA | NA | The committee added new entry, row #4 for completeness.<br>The addition of buffy coat platelets was included for completeness and in recognition of the fact that many member facilities are using these products and that the requirements surrounding them exist and are being followed.<br>The entry reads as follows:<br>  |
| 5.1.9B, footnote 2 (New) | SC | NA | NA | The committee added a new footnote #2 focused on convalescent plasma recognizing that there are future uses of plasma products and should those emerge after the Standards become effective, having a requirement to follow the manufacturers written instructions that emerge with the product.<br>The footnote reads as follows:<br>**[2]Convalescent plasma product storage, transport, and expiration times conform to manufacturer's written instructions.** |
| 5.1.9B, footnote 2 (New) | RtC | Recommend removing the second sentence "Therapeutic convalescent plasma needs to be distinguished from nontherapeutic plasma | Yes | The committee reviewed this comment and agreed with its intent. When submitted as proposed, the footnote included the second sentence noted in the comment, and as result, the committee removed it. |
| 5.4.1A, #8 (New) | SC | NA | NA | The committee elected to add a new entry in the reference standard surrounding platelet count. This is included as an element of donor qualification appearing in the Standards, as a result, the committee felt it appropriate to reproduce the content in the specific donor qualification reference standard for completeness.<br>The entry reads as follows:<br>**8) Platelet Count** \| **For plateletpheresis collections, the donor** \| |

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| | | | | | **platelet count, if available, shall be ≥150,000/µL (Standard 5.5.3.4.3 applies)** | |
| 5.4.1A, #8 (New) | RtC | In accordance with AABB Standard 5.5.3.4.3 and FDA Guidance for Industry and FDA Review Staff Collection of Platelets by Automated Methods, December 2007, the blood establishment should defer from platelet pheresis donation donors whose platelet counts are LESS THAN platelets/uL. It is recommended that the criteria should be revised to state "For plateletpheresis collections, the donor platelet count, if available, shall be >/= 150,000/µL (i.e., greater than or equal to 150,000/µL). | Yes | The committee reviewed this comment and agreed with its intent. Based on the comment the entry was edited to appear as "≥" as opposed to ">" | | |
| 5.4.1A, #8 (New) | RtC | As written, the requirement for platelet count indicates greater than 150,000/µL. However, the requirement for platelet count as stated in "FDA Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods (December 2007)" is "at least 150,000 platelets/µL." We propose a revision to this standard to read that the platelet count shall be ≥ 150,000 platelets/uL. | Yes | The committee reviewed this comment and agreed with its intent. Based on the comment the entry was edited to appear as "≥" as opposed to ">" | | |
| 5.4.1A, #15 (New) | SC | NA | NA | The committee elected to add the Chikungunya vaccine for to the reference standard for completeness. The entry appears as follows: | | |
| | | | | 15) Immunizations and Vaccinations | Receipt of recombinant vaccine [eg, RSV, HPV, Zoster Recombinant, Adjuvanted (Shingrix), and **Chikung** | None |

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| | | | | | **unya Vaccine]** | |
| 5.4.1A, #15 (New) | RtC | "CBER's benefit-risk analysis broadly shows the vaccine does not have benefits outweighing risks, under most plausible scenarios. For these reasons, CBER believes this vaccine is not safe and that continued administration to the public would pose a danger to health."<br>For discussion:<br>The BBTS may want to reconsider its addition to the 35th edition.<br>Also, they may want to consider marking Association Bulletin #24-03 as obsolete. Ixchiq may continue to be approved for use outside of the US which may be a consideration for our international members. Does BBTS only include vaccines approved by FDA? | Yes | The committee agreed with the intent of the comment and adjusted the entry surrounding this and updated the entry accordingly. | | |
| 5.4.1A, #15 (New) | SC | NA | NA | The committee added the trivalent MMR vaccine to the deferral period associated with measles based on a request from AABB's TTD Committee.<br>The entry reads as follows | | |
| | | | | 15) Immunizations and Vaccinations | Receipt of live attenuated viral and bacterial vaccines [German measles (rubella), **Trivalent measles-mumps-rubella (MMR) vaccine**, Quadrivalent measles-mumps-rubella-varicella (MMRV) vaccine, Chicken pox/Shin | 4 Weeks |

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| | | | | | gles (varicella zoster), Chikungunya] | |
| 5.4.1A, #15 (New) | SC/RtC | As the Trivalent vaccine is defined as measles-mumps-rubella (MMR), the quadrivalent vaccine MMRV should also be defined. | Yes | The committee agreed with the intent of the comment and made the change requested.<br>The entry reads as follows:<br>15) Immunizations and Vaccinations \| Receipt of live attenuated viral and bacterial vaccines [German measles (rubella), Trivalent measles-mumps-rubella (MMR) vaccine, **Quadrivalent measles-mumps-rubella-varicella (MMRV) vaccine,** Chicken pox/Shingles (varicella zoster), Chikungunya] \| 4 Weeks | | |
| 5.4.1A, #15 (New) | SC | NA | NA | The committee added the deferral period for the Ebola vaccine to the reference standard for completeness. This request was heard from members during the lifecycle for the 34th ed of BB/TS Standards.<br>The entry reads as follows:<br>**15) Immunizations and Vaccinations** \| **Ebola Vaccine** \| **6 weeks** | | |

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| 5.4.1A, #16 | RtC | I believe that the proposed change of wording from "a donor's open wound" to "an open wound" does not accurately reflect the intention of the FDA May 2023 HIV guidance, which states (on page 11): "A history in the past 3 months of contact with blood of another individual through percutaneous inoculation such as a needle stick or through contact with a donor's open wound or mucous membranes." The FDA guidance makes it clear, I think, that the contact requiring deferral involves someone else's blood contacting the DONOR's NON-INTACT skin or the DONOR's mucous membranes. Contact of someone else's blood with a donor's INTACT skin does not require deferral, as I understand the FDA guidance. I believe that the proposed change would cause confusion and would cause blood banks to unnecessarily defer donors who contacted someone else's open wound when the donor's skin was intact. | Yes | The committee noted this comment and agreed with its intent. When the proposed edition was released for comment the entry in question was updated but based on this feedback the language was included in the 34th edition was reinserted. |
| 6.0 | SC | NA | NA | The committee added a crossreference to the following CFRs to the standard for completeness.<br>***21 CFR 606.160, 42 CFR 493.1105** |
| 6.2.9A | RtC | The table "Excerpt of Record Retention 6.2.9A requires updates to accurately reflect the correct record categories. The categories should be revised to reflect proper classification. Specifically, for records related to donor information and individual donation units and records pertaining to patient care and treatment. | Yes | The committee noted this comment and reviewed the placement of "X"s for accuracy and appropriateness. |
| 7.3.4.2, #2 | SC | NA | NA | For completeness, the committee added the clause, "authorized health professional" standard 7.3.4.2, #2 recognizing that there are instances where an individual contacted that is not the recipient's physician due to the need to contact an individual immediately.<br>The standard reads as follows:<br>**7.3.4.2** When the transfusion is discontinued, the following shall be performed immediately:<br>2) The recipient's physician or **authorized health professional** shall be notified. |

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| 7.3.4.2, #2.<br>7.3.5.3,<br>7.3.6 | RtC | Using the AABB Glossary definition for Authorized Health Professional, "A person permitted to perform certain tasks in accordance with regulations and based on their credentials, qualification, education, training and experience", it is our understanding that our organization can define what roles would be considered an Authorized Health Professional, correct? | Yes | The committee noted this comment and while they did not think that a change was needed at this time, they do agree with the query.<br>In this situation, this is typically impacted by the local, state or federally appropriate regulations. |
| 7.3.5.1, #1 | RtC | It doesn't seem logical to require a comparison of a patient's pretransfusion sample to the post transfusions sample for hemolysis, if the post transfusion sample does not show evidence of hemolysis. | | |
| 7.3.5.3 | SC | NA | NA | For completeness, the committee added the clause, "authorized health professional" standard 7.3.4.2, #2 recognizing that there are instances where an individual contacted that is not the recipient's physician due to the need to contact an individual immediately.<br>The standard reads as follows:<br>**7.3.5.3** Interpretation of the evaluation shall be recorded in the patient's medical record and, if suggestive of hemolysis, bacterial contamination, pulmonary reactions, or other serious adverse event related to transfusion, the interpretation shall be reported to the patient's physician or **authorized health professional** immediately. Standard 7.3.5.4 applies. |
| 7.3.6 | SC | NA | NA | For completeness, the committee added the clause, "authorized health professional" standard 7.3.4.2, #2 recognizing that there are instances where an individual contacted that is not the recipient's physician due to the need to contact an individual immediately.<br>The standard reads as follows:<br>**7.3.6 Delayed Transfusion Reactions (Antigen-Antibody Reactions)**<br>If a delayed transfusion reaction is suspected or detected, tests shall be performed to determine the cause. The results of the evaluation shall be reported to the patient's physician or **authorized health professional** and recorded in the |

Commented [SN1]: 7.3.5.1 #1 Needs an outcome response

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| | | | | patient’s medical record. Standard 7.3.5.4 applies. |
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