**Significant Changes the 9th edition of Standards for Perioperative Autologous Blood Collection and Administration**

| Standard | Outcome |
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| 1.0 | The committee has added the component, "red blood cells" to standard 1.0 as the Perioperative Standards encapsulate this component and therefore needed to be included. |
| 1.0 | The committee added the term "Whole" to the second sentence considering "Whole blood" is the component that perioperative programs work with most frequently. It should be noted that the components listed in the sentence would include "blood" as well. |
| 1.1.1 | The committee added the term "education" to the standard to match the same language that appears in other sets of AABB Standards. This ensures that the standard captures that the medical director is qualified by "education" as well. |
| 1.4 (New) | The committee added new standard 1.4 to the Standards to match this same inclusion across all sets of AABB Standards. This standard is now considered a core quality principle for AABB's purposes. The standard reads as follows:<br>**1.4 Operational Continuity**<br>Executive management shall ensure that the facility has policies, processes, and procedures that address continuity for potential events that put operations at risk. |
| 3.3 | The committee added a reference to 21 CFR 211.68 to this standard for completeness. |
| 3.5.2 | The committee added a reference to 21 CFR 803.30 to this standard for completeness. |
| 3.7 | The committee added the clause, "…and prevent hemolysis or other damage to perioperative blood components." for completeness. This addition matches the language in the 32nd edition of Standards for Blood Banks and Transfusion Services. The committee also added a cross reference to standard 3.5 which focuses on equipment monitoring and maintenance. |
| 3.8.1 | The committee added a reference to 21 CFR 211.68 for completeness. |
| 3.8.2 | The committee elected to remove the former third sentence that appeared in this standards as it was deemed a better fit for guidance. The sentence previously read, "Processes and procedures shall address mitigation of the effects of disasters and recovery plans." |
| 4.2 | The committee elected to add the terms "and services", "processing" and "administration" to the standard for completeness. The committee also removed the term "transfusion services" with the inclusion of the new terms noted above.<br>The standard now reads as such,<br>Agreements, or changes to agreements, to obtain or provide critical materials **and services** for perioperative collection, **processing**, storage, and **administration** ~~transfusion services~~ shall define supplier and customer expectations. The agreement shall reflect that both parties have accepted the terms therein. |
| 5.1.2.1 | The committee added a cross reference to standard 8.2, #5 to standard 5.1.2.1 for completeness. 8.2, #5 requires that quality control records be monitored as a part of a perioperative program's utilization review. |
| 5.1.5 | The committee re-titled the standard as "Prevention of Contamination", replacing "Sterility" to better match the content of the standard, and the subsequent substandards. |
| 5.1.6.2 | The committee added the clause, "…including review of patient identification before the label is applied." for completeness. This addition ensures that the Perioperative Standards match current practice. |
| 5.2.1, #1 | The committee added the term "procedure" to subnumber 1 for completeness. The subnumber now reads as such, "A description of the **procedure**, risks, benefits, and treatment alternatives. |

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| 5.2.2 | The committee replaced the term "surgery" with the clause, "the use of perioperative blood components" for clarity. Surgery is not an accurate representation of what occurs in all situations covered by these Perioperative Standards. |
| 5.4.1.1 | The committee added the term, "qualified" standard 5.4.1.1 to ensure any individual positively identifying the patient is qualified to do so. |
| 5.4.3.1 | The committee rewrote standard 5.4.3.1 for accuracy. The committee replaced the clause "…direct patient…" with "…patient requires a direct…". |
| 5.4.4, #1 | The committee added the clause, "…or Competent Authority" to the end of subnumber 1 to expand the standard beyond only FDA requirements. |
| 6.1.3 | The committee added the clause, "…by an authorized individual…" for completeness ensuring that any record review is done by an individual allowed to do so. |
| 6.2.1 | The committee edited the standard to include the phrase, "The perioperative program shall have a process to ensure that…"<br>This better matches the language that exists throughout the Standards. The standard now reads as such, "**The perioperative program shall have a process to ensure that** records are ~~shall be~~ complete, retrievable in a period of time appropriate to the circumstances and protected from accidental or unauthorized destruction or modification. |
| 7.1.1 | The committee added record retention requirement to standard 7.1.1 to ensure users knew that a record was required in each instance. The cascading pen symbol from 7.1 was not something the committee wanted to assume users understood. |
| 7.1.2 | The committee added record retention requirement to standard 7.1.2 to ensure users knew that a record was required in each instance. The cascading pen symbol from 7.1 was not something the committee wanted to assume users understood. |
| 7.1.3 | The committee added record retention requirement to standard 7.1.3 to ensure users knew that a record was required in each instance. The cascading pen symbol from 7.1 was not something the committee wanted to assume users understood. |
| 7.2.2 | The committee re-wrote standard 7.2.2 to match the style of the language in standards 7.2.1 and 7.2.3. The intent of the standard has not changed. The standard now reads as such, "**7.2.2** Nonconforming perioperative blood components and critical materials shall be retrieved, quarantined, and recalled." |
| 7.3.1.1 (New) | Standard 7.3.1.1 is new to the edition and was included to ensure that the chapter contained the necessary steps that take place in an adverse event for completeness. The new standard now reads as such:<br>**7.3.1.1** Discontinue the administration of any perioperative blood components. |
| 7.3.1.2 (7.3.1.1) | The committee added the clause standard 7.3.1.2, "Compare and verify…" to the standard for accuracy and flow. The intent of the standard has not changed. |
| 7.3.1.3 (7.3.1.2) | The committee edited standard 7.3.1.3 has been edited for flow purposes, however the intent of the standard has not changed. The standard now reads as such, "**7.3.1.3** ~~The perioperative program shall~~ Discontinue the use of any processing devices and materials involved in immediate complication and ~~shall~~ examine ~~them~~ for evidence of nonconformance(s) (eg, malfunction or bacterial contamination). Standard 3.5.2 applies." |
| 7.3.1.4 (7.3.1.3) | The committee edited standard 7.3.1.4 has been edited for flow purposes. The changes have been expanded to match current practice of work. The expansion of the standard should assist in the assessment process as well. The standard now reads as such, "**7.3.1.4 Assess the need for additional testing, including collection of specimens, materials, and/or supplies, if applicable.** ~~The perioperative program shall have a process for indicating the~~ |

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| | ~~circumstances under which additional testing will be performed and what will be tested. Standard 4.1.2 applies.~~" |
| 7.3.3.1 | The committee edited standard 7.3.3.1 for accuracy and to expand the standard. The committee removed the term "appropriate" as it is difficult to assess and replaced the clause "appropriate outside" with "internal and external." The standard now reads as such, "7.3.3.1 Fatalities associated with perioperative services shall be reported to **internal and external** ~~appropriate outside~~ authorities." |
| 8.0 | The committee edited standard by removing the parenthetical "(i.e., inspections and survey)" from the standard as it was deemed unnecessary. The committee noted that this information is already covered in the guidance. |
| 8.2, #3 | The committee edited subnumber 3 of standard 8.2 for completeness. The subnumber now reads as such, "3) Sample **and product** collection and labeling." |
| 8.3.1 (New) | The committee created new standard 8.3.1 requiring that perioperative programs provide all quality indicator data to personnel who have responsibility for oversight of that area. The standard mimics a standard in the Standards for a Patient Blood Management Program. The standard now reads as such:<br>**8.3.1 The perioperative program shall provide quality indicator data to the personnel with responsibility for oversight including third-party providers.** |
| 9.2.1 | The committee added a crossreference to new standard 8.3.1 for completeness. The intent of the standard has not changed. |