Significant Changes and Response to Comments Received to the 7th edition of Standards for Molecular Testing for Red Cell, Platelet, and Neutrophil Antigens

Please note that public comments that were submitted address the proposed 7th edition of Molecular Testing Standards, and not the final version. The committee has elected to make the substance of public comments that were submitted a part of this document. Guidance that appears with the 7th edition of Molecular Testing Standards in the Standards Portal provides a more in-depth look at the additions, deletions and changes and the rationales behind those decisions that appears below.

Standard	Significant Change (SC)/Response to Comment (RtC)	Comment	Change Made?	Outcome
General	SC	NA	NA	The 7th edition of Standards for Molecular Testing for Red Cell, Platelet, and Neutrophil Antigens has incorporated AABB's updated quality system essentials. The updated quality system essentials include the following updates: • All standards are written in the active voice. • Once a requirement has been stated, it is not repeated. • Each chapter begins with a description of what the standards therein cover. • Each chapter contains a list of key terms that relate to the content of the chapter, with their definitions. • Each chapter contains a list of examples of objective evidence that an assessor could look for during an on-site assessment; however, this list is not comprehensive, nor will it be assessed against by an assessor. It is merely for guidance purposes only. Each chapter now concludes with the record retention table for that chapter. Note that a comprehensive record retention table still exists at the end of Chapter 6.
1.0	SC	NA	NA	The committee revised standard 1.0 based on updates to the AABB Quality System Essentials. The standard reads as follows: **1.0 Organization**

				The organization shall define the parties responsible for the provision of products or services.
1.1, #2 (1.1, #3)	SC	NA	NA	The committee revised standard 1.1, #2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **1.1 Executive Management** The organization shall have a defined executive management. Executive management shall have: 2) Responsibility for compliance with these *MT Standards* and applicable laws and regulations, including all applicable current good manufacturing practice (cGMP) requirements.
1.1.1	RtC/SC	Please consider adding he following references to the standard: *42 CFR 493.1405, 42 CFR 493.1407, 42 CFR 493.1443, and 42 CFR 493.1445.	YES	The committee agreed with this comment and added the references to the CFRs as indicated in the comment.
1.2	SC	NA	NA	The committee revised standard 1.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **1.2 Quality System** The organization shall have a quality system. The organization's executive management shall ensure that this quality system is implemented and followed at all levels of the organization.
1.2.2	SC	NA	NA	The committee revised standard 1.2.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **1.2.2 Management Reviews** Management shall assess the effectiveness of the quality system at defined intervals.
1.3.1	SC	NA	NA	The committee revised standard 1.3.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: 1.3.1 The medical director and/or laboratory director (as applicable) shall approve all medical and

				technical policies, processes, and procedures.
1.4.1 (New)	SC	NA	NA	The committee added standard 1.4.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **1.4.1** Mitigation strategies shall identify, assess, and address the level of risk associated with quality and safety.
1.8 (New)	SC	NA	NA	The committee added standard 1.8 based on updates to the AABB Quality System Essentials. The standard reads as follows: **1.8 Customer Focus** Executive management shall identify the organization's customers and their needs and expectations for products or services.
1.9 (1.5)	SC	NA	NA	The committee added the clause "in electronic or written format" to the standard for clarity. The standard reads as follows: **1.9 Staffing Changes** The laboratory shall communicate to AABB in electronic or written format all initial appointments and changes for the laboratory director within 30 days of appointment.
1.10 (1.6)	SC	NA	NA	The committee added the clause "in electronic or written format" to the standard for clarity. The standard reads as follows: **1.10 Laboratory Status Changes** The laboratory shall communicate to AABB in electronic or written format within 30 days of the date the laboratory ceases or resumes all on-site testing.
2.1.1 (2.1)	SC	NA	NA	The committee revised the elements of standard 2.1.1 (which previously appeared as a part of standard 2.1) based on updates to the AABB Quality System Essentials. The standard reads as follows: **2.1.1 Job Descriptions** The organization shall establish and maintain job descriptions defining the roles and responsibilities for each job position related to the requirements of these *Perioperative Standards.*
2.1.2 (2.1.1)	RTC/SC	Please consider adding the following CFR	YES	The committee agreed with this comment and added the references to

		references to the standard: 42 CFR 493.1403, 42 CFR 493.1409, 42 CFR 493.1415, 42 CFR 493.1421, 42 CFR 493.1441, 42 CFR 493.1447. 42 CFR 493.1453, 42 CFR 493.1459 and 42 CFR493.1487.		the CFRs as indicated in the comment.
2.1.3.1 (New)	SC	NA	NA	The committee created new standard 2.1.3.1 for completeness. The content was initially included in the Standards for Cellular Therapy Services. The standard convers what should be included as a part of employee training. The standard reads as follows: **2.1.3.1** Training shall include: 1) Orientation. 2) Initial job specific training. 3) Quality-systems-related training. 4) Ongoing job-specific training.
2.1.3.2 (New)	SC	NA	NA	The committee created new standard 2.1.3.2 for completeness. The content was initially included in the Standards for Cellular Therapy Services. The standard convers what should be included as a part of employee training and the expectations of the qualifications of the individuals providing the training. The standard reads as follows: **2.1.3.2** The organization shall approve subject matter experts who provide training.
2.1.6 (2.1.4)	SC	NA	NA	The committee edited standard 2.1.6 (which previously appeared as standard 2.1.4) based on updates to the AABB Quality System Essentials. The standard reads as follows: **2.1.6 Continuing Education** The organization shall ensure that continuing education requirements applicable to these MT Standards are met when applicable.
2.2.1	RtC	We ask that the standard remain unchanged. In some instances, especially with RH phenotypes, previously	YES	Based on this comment, the committee reverted to the language of the proposed edition that previously existed in the 6th edition of MT Standards.

		characterized samples are selected based on presence of rare genetic variants in the absence of phenotype information and when antisera cannot distinguish variant antigens		However, based on the feedback, the committee did edit the standard to include the clause “all results shall”
2.2.1	SC	NA	NA	The committee elected to edit the standard to require that all results are concordant, along with molecular methods. This clarifies the intent of the standard. The standard reads as follows: **2.2.1** Previously characterized samples shall have been tested by available serologic and/or molecular methods and all results shall be concordant.
Reference Standard 2.2A	SC	NA	NA	The committee expanded reference standard 2.2A adding new columns for “The NCBI Reference Sequence”, and the “rs Number.” The committee also replaced the title of the “antigen” column with “Comment Antigen(s)”. The committee also completed the table to include all known 45 DNA resources for Red Blood Cells.
Reference Standard 2.2B	SC	NA	NA	The committee expanded reference standard 2.2B adding new columns for “The NCBI Reference Sequence”, and the “rs Number.” The committee also replaced the title of the “Antigen” column with “Comment Antigen(s)”. The committee also completed the table to include all known 35 DNA resources for Platelets.
Reference Standard 2.2C	SC	NA	NA	The committee expanded reference standard 2.2C adding new columns for “The NCBI Reference Sequence”, and the “rs Number.” The committee also replaced the title of the “Antigens” column with “Alleles”.
3.0	SC	NA	NA	The committee revised standard 3.0 based on updates to the AABB Quality System Essentials. The standard reads as follows:

				3.0 Equipment The organization shall define and control critical equipment.
3.1	SC	NA	NA	The committee revised standard 3.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **3.1 Equipment Specifications** Equipment specifications shall be defined before purchase.
3.2	SC	NA	NA	The committee revised standard 3.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **3.2 Qualification of Equipment** All critical equipment shall be qualified for its intended use. Equipment shall be requalified, as needed, after repairs and upgrades.
3.2.2	SC	NA	NA	The committee revised standard 3.2.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **3.2.2 Operational Qualification** Each piece of equipment and component of an information system shall be verified before actual use.
3.3 (New)	SC	NA	NA	The committee added standard 3.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **3.3 Use of Equipment** Equipment shall be used in accordance with the manufacturer's written instructions.
3.5	SC	NA	NA	The committee revised standard 3.5 based on updates to the AABB Quality System Essentials. The standard reads as follows: **3.5 Equipment Monitoring and Maintenance** Equipment shall be monitored and maintained in accordance with the manufacturer's written instructions.
3.5.1.1 (3.4.1.2)	SC	NA	NA	The committee revised standard 3.5.1.1 based on updates to the AABB Quality System Essentials. The standard appears as follows: **3.5.1.1** Calibration of equipment shall include details of equipment type, unique identification, location, frequency of checks, check method,

				acceptance criteria, and specified limitations.
3.5.1.2 (New)	SC	NA	NA	The committee added standard 3.5.1.2 based on updates to the AABB Quality System Essentials. The standard appears as follows: **3.5.1.2** Equipment used for calibration, inspection, measuring, and testing shall be certified to meet nationally recognized measurement standards. Certification shall occur before initial use, after repair, and at prescribed intervals. Where no such measurement standards exist, the basis for calibration shall be described and recorded.
3.5.2 (New)	SC	NA	NA	The committee added standard 3.5.2 based on updates to the AABB Quality System Essentials. The standard appears as follows: **3.5.2** When equipment is found to be out of calibration or specification, the validity of previous inspection and test results and the conformance of potentially affected products or services (including those that have already been released or delivered) shall be verified.
3.5.3 (New)	SC	NA	NA	The committee added standard 3.5.3 based on updates to the AABB Quality System Essentials. The standard appears as follows: **3.5.3** The organization shall: 1) Define cleaning and sanitation methods and intervals for equipment. 2) Ensure that environmental conditions are suitable for the operations, calibrations, inspections, measurements, and tests carried out. 3) Remove equipment from service that is malfunctioning/out of service and communicate to appropriate personnel. 4) Monitor equipment to ensure that defined parameters are maintained. 5) Ensure that the handling, maintenance, and storage of equipment are such that the equipment remains fit for use. 6) Ensure that all equipment maintenance and repairs are performed by qualified individuals

				and in accordance with manufacturer's recommendations. 7) Ensure that all critical equipment is stored in accordance with the manufacturer's written instructions.
3.5.4, #2 (3.5.2, #2)	SC	NA	NA	The committee revised subnumber 2 of standard 3.5.4 based on updates to the AABB Quality System Essentials. The subnumber previously read, "Assessment of the effect on donor eligibility and donor and patient safety." The standard now reads as follows: **3.5.4 Investigation and Follow-up** Investigation and follow-up of equipment malfunctions, failures, or adverse events shall include: 2) Assessment of the effect on the safety of individuals affected. The wording related to Perioperative specific activities has been changed to more general language in the new QSE. The intent of the Standard has not changed.
3.5.4, #3 (3.5.2, #3)	SC	NA	NA	The committee revised standard 3.5.4, #3 based on updates to the AABB Quality System Essentials. The previous wording read, "Investigation of the malfunction, failure, or adverse event, and a determination if other equipment is similarly affected." The standard now reads as follows: **3.5.4 Investigation and Follow-up** Investigation and follow-up of equipment malfunctions, failures, or adverse events shall include: 3) Removal of equipment from service, if indicated.
3.5.4, #4 (3.5.2, #4)	SC	NA	NA	The committee revised standard 3.5.4, #4 based on updates to the AABB Quality System Essentials. The previous wording read, "Investigation of the malfunction, failure, or adverse event, and a determination if other equipment is similarly affected." The standard now reads as follows: **3.5.4 Investigation and Follow-up** Investigation and follow-up of equipment malfunctions, failures, or adverse events shall include:

				4) Investigation of the malfunction, failure, or adverse event, and a determination if other equipment is similarly affected, as applicable.
3.5.4, #5 (3.5.2, #5)	SC	NA	NA	The committee revised standard 3.5.4, #5 based on updates to the AABB Quality System Essentials. The previous wording read, "Investigation of the malfunction, failure, or adverse event, and a determination if other equipment is similarly affected." The standard now reads as follows: **3.5.4 Investigation and Follow-up** Investigation and follow-up of equipment malfunctions, failures, or adverse events shall include: 5) Ensure that the handling, maintenance, and storage of equipment are such that the equipment remains fit for use.
3.6 (New)	SC	NA	NA	The committee added standard 3.6 based on updates to the AABB Quality System Essentials. The standard reads as follows: **3.6 Equipment Traceability** The organization shall maintain records of equipment use in a manner that permits: 1) Equipment to be uniquely identified and traceable. 2) Tracing of any given product or service to all equipment associated with the procurement, processing, storage, distribution, and administration of the product or service.
3.7, #2 (3.6.1, #1)	SC	NA	NA	The committee updated standard 3.7, #2 based on updates to the AABB Quality System Essentials. The committee expanded the clause to include "verification" and "qualification" beyond "validation" which appeared in the 6th edition. The standard reads as follows: **3.7 Information Systems** The organization shall have controls in place for the implementation, use, ongoing support, and modifications of information system software, hardware, and databases. Elements of planning and ongoing control shall include:

				2)Validation/verification/qualification of system software, hardware, databases, and user-defined tables before implementation.
3.7, #6 (New)	SC	NA	NA	The committee added new subnumber 6 to standard 3.7 based on updates to the AABB Quality System Essentials. The standard reads as follows: **3.7 Information Systems** The organization shall have controls in place for the implementation, use, ongoing support, and modifications of information system software, hardware, and databases. Elements of planning and ongoing control shall include: 6) System security to prevent unauthorized access. This expands the content of the standard.
3.7, #7 (New)	SC	NA	NA	The committee added subnumber 7 to standard 3.7, #7 based on updates to the AABB Quality System Essentials. The standard reads as follows: **3.7 Information Systems** The organization shall have controls in place for the implementation, use, ongoing support, and modifications of information system software, hardware, and databases. Elements of planning and ongoing control shall include: 7) Policies, processes, and procedures and other instructional documents developed using terminology that is understandable to the user.
3.7, #9 (3.6.1, #4)	SC	NA	NA	The committee added subnumber 9 to standard 3.7 based on updates to the AABB Quality System Essentials. The standard reads as follows: **3.7 Information Systems** The organization shall have controls in place for the implementation, use, ongoing support, and modifications of information system software, hardware, and databases. Elements of planning and ongoing control shall include: 9) Defined process for monitoring of data integrity for critical data elements.

3.7, #10 (New)	SC	NA	NA	The committee added subnumber 10 to standard 3.7 based on updates to the AABB Quality System Essentials. The standard reads as follows: **3.7 Information Systems** The organization shall have controls in place for the implementation, use, ongoing support, and modifications of information system software, hardware, and databases. Elements of planning and ongoing control shall include: 10) System design that establishes and maintains unique identity of the donor, the product, or service, and the recipient (as applicable).
3.7, #11 (New)	SC	NA	NA	The committee added subnumber 11 to standard 3.7 based on updates to the AABB Quality System Essentials. The standard reads as follows: **3.7 Information Systems** The organization shall have controls in place for the implementation, use, ongoing support, and modifications of information system software, hardware, and databases. Elements of planning and ongoing control shall include: 11) Training and competency of personnel who use information systems.
3.7, #12 (New)	SC	NA	NA	The committee added subnumber 12 to standard 3.7 based on updates to the AABB Quality System Essentials. The standard reads as follows: **3.7 Information Systems** The organization shall have controls in place for the implementation, use, ongoing support, and modifications of information system software, hardware, and databases. Elements of planning and ongoing control shall include: 12) Procedures to ensure confidentiality of protected information.
3.7.1 (3.6.2)	SC	NA	NA	The committee revised standard 3.7.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **3.7.1 Alternative Systems** An alternative system shall be maintained to ensure continuous

				operation in the event that computerized data and computer-assisted functions are unavailable. The alternate system shall be tested at defined intervals. Processes and procedures shall address mitigation of the effects of disasters and include recovery plans.
3.7.2 (3.6.3)	SC	NA	NA	The committee revised standard 3.7.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **3.7.2** Personnel responsible for management of information systems shall be responsible for compliance with the regulations that affect the use of the system.
4.0	SC	NA	NA	The committee revised standard 4.0 based on updates to the AABB Quality System Essentials. The standard reads as follows: **4.0 Suppliers and Customers** The organization shall ensure that agreements to provide or receive products or services are reviewed, approved, and meet supplier and customer expectations.
4.1	SC	NA	NA	The committee revised standard 4.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **4.1 Supplier Qualification** The organization shall evaluate the ability of suppliers of critical materials, equipment, and services to meet specified requirements.
4.1.1 (4.0, 4.1)	SC	NA	NA	The committee revised standard 4.1.1 (which previously appeared as a part of standard 4.1) based on updates to the AABB Quality System Essentials. The standard reads as follows: **4.1.1** The organization shall evaluate and participate in the selection of suppliers. If executive management is not included in the selection process, there shall be a mechanism to provide feedback to management with contracting authority.
4.2	SC	NA	NA	The committee revised standard 4.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **4.2 Agreements**

				Agreements and any incorporated changes shall be reviewed and communicated.
4.2.1	SC	NA	NA	The committee revised standard 4.2.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **4.2.1** Agreements shall be reviewed at defined intervals to ensure that the terms of agreement continue to meet requirements.
4.2.2 (New)	SC	NA	NA	The committee added new standard 4.2.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **4.2.2** Changes to agreements shall be communicated to affected parties.
4.2.3 (New)	SC	NA	NA	The committee added new standard 4.2.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: ✎ **4.2.3** The responsibilities for activities covered by these *MT Standards* when more than one organization is involved shall be specified by agreement.
4.3	SC	NA	NA	The committee revised standard 4.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: ✎**4.3 Incoming Receipt, Inspection, and Testing** Incoming products or services, equipment, and materials shall be received, inspected, and tested, as necessary, before approval for use.
5.0	SC	NA	NA	The committee revised standard 5.0 based on updates to the AABB Quality System Essentials. The standard reads as follows: **5.0 Process Control** The organization shall ensure the quality of products or services.
5.1	SC	NA	NA	The committee revised standard 5.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **5.1 General Elements** The organization shall ensure that processes are carried out under controlled conditions.

5.1.1	SC	NA	NA	The committee revised standard 5.1.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **5.1.1 Change Control** When the organization develops new processes or procedures or changes existing ones, they shall be validated before implementation.
5.1.2 (5.1.4)	SC	NA	NA	The committee revised standard 5.1.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **5.1.2 Quality Control** A program of quality control shall be established that is sufficiently comprehensive to ensure that products, equipment, materials, and analytical functions perform as intended.
5.1.2.1 (5.1.4)	SC	NA	NA	The committee updated standard 5.1.2.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **5.1.2.1** Quality control results shall be reviewed and evaluated against acceptance criteria.
5.1.2.2 (5.1.4.2)	SC	NA	NA	The committee updated standard 5.1.2.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **5.1.2.2** Quality control failures shall be investigated before release of test results, products, or services.
5.1.2.3 (5.1.4.1)	SC	NA	NA	The committee updated standard 5.1.2.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **5.1.2.3** The validity of test results and methods and the acceptability of products or services provided shall be evaluated when quality control failures occur.
5.1.3 (New)	SC	NA	NA	The committee added standard 5.1.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **5.1.3 Process Planning** Quality requirements shall be incorporated into new or changed processes, products, services, and novel methods. Planning and

				implementation activities shall include the following: 1) Evaluation of accreditation, regulatory, and legal requirements related to the new or changed process, product, or service. 2) Review of current available knowledge (eg, review of medical practice and/or literature). 3) Evaluation of risk. 4) Identification of affected internal and external parties and mechanism to communicate relevant information. 5) Identification of performance measures applicable to the new or changed process, product, or service. 6) Evaluation of resource requirements. 7) Evaluation of the impact of the new or changed process, product, or service on other organization (or program) processes. 8) Evaluation of the need to create or revise documents for the new or changed process, product, or service. 9) Review and approval of the output of process development and design activities (eg, pilot or scale-up study results, process flow charts, procedures, data forms). 10) Evaluation of the extent and scope of process validation or revalidation depending on the level of risk and impact of the new or changed products or services. The committee noted that program have processes to meet these requirements already.
5.1.4.1 (New)	SC	NA	NA	The committee added standard 5.1.4.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **5.1.4.1** Validation activities shall include the following: 1) Identification of objectives, individual(s) responsible, expected outcomes, and/or performance measures. 2) Criteria for review of outcomes. 3) Approval of validation plan. 4) Review and approval of actual results.

				5) Actions to be taken if objectives are not met. The committee noted that programs have processes to meet these requirements already.
5.1.5 (New)	SC	NA	NA	The committee added standard 5.1.5 based on updates to the AABB Quality System Essentials. The standard reads as follows: **5.1.5 Process Implementation** The implementation of new or changed processes and procedures shall be planned and controlled.
5.1.5.1 (New)	SC	NA	NA	The committee added standard 5.1.5.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **5.1.5.1** Postimplementation evaluations of new or changed processes and procedures shall be performed. The committee noted that programs have processes to meet these requirements already.
5.1.6 (5.1.5)	SC	NA	NA	The committee revised standard 5.1.6 based on updates to the AABB Quality System Essentials. The standard reads as follows: **5.1.6 Use of Materials** All materials shall be stored and used in accordance with the manufacturer's written instructions and shall meet specified requirements.
5.1.6.2	SC	NA	NA	The committee elected to edit standard 5.1.6.2 for clarity. The committee replaced the term "performed" with "tested". The intent of the standard has not changed.
5.1.6.3 (5.1.5.3)	SC	NA	NA	The committee elected to edit standard 5.1.6.3 for clarity. The committee replaced the clause, "…or using unlicensed" with "…including the use of FDA cleared or approved tests…" This change does not alter the intent of the standard.
5.1.8.3 (5.1.6.4)	SC	NA	NA	The committee revised standard 5.1.8.3 for clarity. The inclusion of the clause, "if applicable", recognizes that there are instances where a molecular testing laboratory does not

				have the responsibility for labelling blood components.
5.1.9 (5.1.8)	SC	NA	NA	The committee revised standard 5.1.9 based on updates to the AABB Quality System Essentials. The standard reads as follows: **5.1.9 Handling, Storage, and Transportation** The organization shall ensure that products or services are handled, stored, and transported in a manner that prevents damage, limits deterioration, and provides traceability.
5.1.10.1 (New)	SC	NA	NA	The committee created new standard 5.1.10.1 for completeness. The standard ensures that the MT Standards mirror the requirements set forth by CMS in July 2022 with an effective date of 2024. The requirements address proficiency testing referrals and what communication is and is not allowed until the results of proficiency testing are complete and submitted. The standard reads as follows: **5.1.10.1** Laboratories shall ensure that no interlaboratory communications pertaining to proficiency test events occur until after the submission deadline.* *42 CFR 493.801(b)(4).
5.1.10.2 (New)	SC	NA	NA	The committee created new standard 5.1.10.2 for completeness. This addition was made in conjunction with the addition of the CFR cited, which requires that laboratories that perform proficiency testing to show that they can successfully perform the act. Laboratories that attempt to have their samples outsourced would not meet the requirements in the CFR. The standard reads as follows: **5.1.10.2** The laboratory shall ensure that no portion of a proficiency testing sample is sent to another laboratory for analysis.* *42 CFR 493.801(b)(4).
5.1.10.3 (New)	SC	NA	NA	The committee added new standard 5.1.10.3 to the edition for completeness. This addition was made in conjunction with the addition of the CFR cited, which requires that

				if a laboratory receives samples for proficiency testing from an outside source that they immediately contact CMS who will instruct them on how to move forward. The standard reads as follows: **5.1.10.3** Any laboratory that receives a proficiency testing sample from another laboratory for testing shall notify CMS of the receipt of the sample.* *42 CFR 493.801(b)(4).
5.1.10.3.1(New)	RtC/SC	Should there be a standard included here that when there are PT failures the testing provided around the time of PT failure must be evaluated as those are the CMS recommendations. Similar to the standard below from the CT Standards.	YES	The committee agreed with this comment and created new standard 5.1.10.3.1 to address this feedback. The standard reads as follows: **5.1.10.3.1** Proficiency testing shall be successful. Failures shall be investigated and corrective actions taken, including notification to potentially impacted parties and appropriate regulatory bodies, as applicable.† Standard 1.4 applies. †42 CFR 493.803 and 42 CFR 493.1236(b).
5.2.3.2 (New)	SC	NA	NA	The committee created new standards 5.2.3.2 to the 7th edition of MT Standards in recognition that there are molecular testing laboratories that perform testing in the biotherapies area and the sample collection methods described in the standard would allow for that expanded scope for the MT Standards and users. The standard reads as follows: **5.2.3.2** Test methods shall be validated for each specimen type (eg, buccal swab, peripheral blood).
5.2.3.2.1 (New)	SC	NA	NA	The committee created new standards 5.2.3.2.1 to the 7th edition of MT Standards in recognition that there are molecular testing laboratories that perform testing in the biotherapies area and the sample collection methods described in the standard would allow for that expanded scope for the MT Standards and users. The standard reads as follows: **5.2.3.2.1** If the laboratory performs the same test method on more than one specimen type, equivalency shall be demonstrated.

5.2.3.2.2 (New)	RtC/SC	We ask that you consider that in some instances, the only available sample may be a type not commonly received and not validated for every test performed in the laboratory, but that genomic DNA is easily obtained from the specimen using standard techniques and the quantity and quality can be assessed by standard techniques.	YES	The committee noted this comment and agreed with its intent. As a result, the committee added new standard 5.2.3.2.2 to this edition based on feedback from the membership. This standard was added in recognition that there are instances where a sample available is for a type not commonly received and as a result, not validated for every test that a laboratory may be performing. However, the genomic DNA can be more easily acquired and tested via standard methods. This addition closes the loop created with the inclusion of standard 5.2.3.2.1 in the proposed edition. The standard reads as follows: **5.2.3.2.2** Results obtained using DNA isolated from a specimen type not validated for the test method shall be reported with a disclaimer that the results are for investigational use only.
5.3.1 (New)	SC	NA	NA	The committee elected to create new standard 5.3.1 for completeness. The focus on FDA cleared or approved tests kits is being put in place for facilities that follow FDA regulations. This standard supplements the content of standard 5.3 which is focused on testing validation. The standard reads as follows: **5.3.1** The laboratory shall validate FDA-cleared or -approved test kits in accordance with specified requirements.
5.3.2 (New)	SC	NA	NA	The committee created new standard 5.3.2 for completeness. With the understanding that more laboratories are using LDTs and RUO, the committee felt it important to create a standard around the need to follow the pertinent standards that populate this edition. The standard reads as follows: **5.3.2** Use of laboratory-developed tests (LDTs) or commercial research use only (RUO) kits shall comply with the following standards.
5.3.2.1 (5.3.1)	SC	NA	NA	The committee edited former standard 5.3.2.1 (formerly 5.3.1) for readability and accuracy. The

				committee replaced the term “test” system” with “genotyping system” and the clause, “or a test for variant” was deleted.
5.3.2.2 (New)				The committee created new standard 5.3.2.2 based on the updates to made to standard 5.3.2.1. The committee created this new standard to focus on sequence based typing. The standard reads as follows: **5.3.2.2** To implement a sequence-based typing system, the validation protocol shall demonstrate: 1) Gene-specific alignment. 2) Ability to detect and annotate previously characterized variant(s). 3) For next-generation sequencing (NGS), the bioinformatics pipeline functions as intended.
5.3.2.3 (New)	SC	NA	NA	The committee created new standard 5.3.2.3 for clarity. The addition of the new standard ensures that products for investigational use are labeled accordingly and appropriately. The standard reads as follows: **5.3.2.3** Results for analytes for which a second method has not been used to confirm the minor allele shall be reported with a disclaimer that they are for investigational use only. Reference Standard 2.2A, Minimum DNA Resources – Red Blood Cells; Reference Standard 2.2B, Minimum DNA Resources – Platelets; and Reference Standard 2.2C, Minimum DNA Resources – Neutrophils apply.
5.3.2.3 (New)	RtC	Please confirm the correctness of the statement. Should the standard require that results for analytes for which a second method has not been used to confirm the minor allele shall be reported with a disclaimer that they are for investigational use only.	YES	The committee noted this comment and agreed with the query. The standard was adjusted in its language as written in the proposed for clarity.
5.3.2.3 (New)	RtC	Does this standard pertain only to Standards 2.2B and	YES	The committee noted this comment and states that all three reference standards in chapter 2 would apply to the standard in question.

		2.2C but not 2.2A? Please clarify.		
5.3.3 (5.3.2)	SC	NA	NA	The committee edited standard 5.3.3 (formerly standard 5.3.2) for readability and clarity. The structure of the standard was made to mimic the other standards in this section. When the standard was issued for comment, individuals felt that as written it would require laboratories to validate 20 samples for entries 2, 3 and 4. This would make it near impossible for laboratories to implement novel test methods as a result of that reading. As such, the committee added the clarifier that "at least 1 sample" would be sufficient to ensure that any novel methods implemented using items 2 – 4 would be sufficient to ensure that they meet the standard. The standard reads as follows: **5.3.3** To implement a novel test method, the validation protocol shall require the analysis of at least 20 biological test samples, including: 1) Homozygous wild-type samples. 2) Heterozygous sample(s): at least one sample. 3) Homozygous variant sample(s): at least one sample, when available. 4) Hemizygous sample(s): at least one sample, when applicable.
5.3.3 (5.3.2)	RtC	This standard requires that to implement a novel test method, the validation protocol shall require the analysis of at least 20 biological test samples. It is my understanding (as written) that the requirement for 20 biological test samples is also applicable to 3) homozygous variant sample(s) (when available) or 4) hemizygous sample(s) (when applicable)? Is the 20 samples requirement "easily"	YES	The committee noted this comment and agreed that as written when the standards were issued as proposed this misunderstanding could become prevalent. As such subnumbers 2 – 4 were updated to only require "one sample" be tested.

		achievable for 3) and 4) or am I misinterpreting the clause? Or a lesser number of samples for 3 and 4 would be acceptable and would not prevent a lab from implementing a novel test method.		
5.3.4 (5.3.1)	SC	NA	NA	The committee created new standard 5.3.4, however the content of the standard previously appeared as part of former standard 5.3.1. The standard reads as follows: **5.3.4** Test results shall show consistency within the laboratory (precision) and concordance with results from another method or another laboratory (accuracy). The validation protocol shall define acceptable results.
5.4.1, #1 (New)	SC	NA	NA	The committee added new subnumber 1 to the edition and was included to ensure that testing done through next generation sequencing and serologic testing which is being performed currently by AABB accredited molecular testing laboratories. The standard reads as follows: **5.4.1 General Test Criteria** Test criteria shall be incorporated into the testing processes to ensure accurate results. 1) The assay shall interrogate the region(s) of interest.
5.4.2	SC	NA	NA	The committee edited standard by adding the term “analytic” to appear before “algorithms.” The committee removed the clause “in genotype prediction are maintained” for clarity.
5.6.1, #9 (New)	SC	NA	NA	The committee added new subnumber 9 to the edition for completeness. The new subnumber has been included in the edition to ensure that facilities under US FDA regulations are labeling finalized test reports using investigational methods appropriately. The standard reads as follows: **5.6.1** Interpretations of investigations shall contain the following information*:

				9) For laboratories operating in the United States using test method(s) and/or reagent(s) that are not FDA-cleared or -approved, a statement such as the following shall be included in the report: "This test was developed, and its characteristics determined by [insert laboratory name]. It has not been cleared or approved by the US FDA." *42 CFR 493.1291(c).
5.6.2 (New)	SC	NA	NA	The committee created new standard 5.6.2 as a first step towards full ISBT nomenclature implementation in accredited laboratories. This style of standard is written in a similar fashion to how similar standards first appeared in the BBTS and CT Standards when they began the process for implementation of IBST nomenclature and ISBT 128 labeling implementation. The standard reads as follows: **5.6.2 ISBT Nomenclature** The laboratory shall have a plan for the implementation of ISBT nomenclature for antigens and alleles.
6.0	SC	NA	NA	The committee revised standard 6.0 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.0 Documents and Records** The organization shall ensure that documents and records are created, stored, and archived in accordance with record retention policies.
6.1	SC	NA	NA	The committee revised standard 6.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.1 Document Control** The organization shall control all documents that relate to the requirements of these Molecular Testing Standards. Documents shall be protected from unauthorized access and accidental or unauthorized modification, deletion, or destruction.
6.1.1 (6.1.2)	SC	NA	NA	The committee revised standard 6.1.1 based on updates to the AABB Quality System Essentials. The standard reads as follows:

				6.1.1 Format Documents shall be in standardized formats. Additional policies, processes, and procedures (such as those in an operator's manual or published in the AABB Technical Manual) may be incorporated by reference.
6.1.2 (New)	SC	NA	NA	The committee added standard 6.1.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.1.2 Document Review, Approval, and Distribution** The document control process shall ensure that documents: 1) Are reviewed by personnel trained and/or qualified in the subject area. 2) Are approved by an authorized individual. 3) Are identified with the current version and effective date. 4) Are available at all locations where operations covered by these MT Standards are performed. 5) Are not used when deemed invalid or obsolete. 6) Are identified as archived or obsolete when appropriate.
6.1.3 (New)	SC	NA	NA	The committee added standard 6.1.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.1.3 Document Changes** Changes to documents shall be reviewed and approved by an authorized individual.
6.1.3.1 (New)	SC	NA	NA	The committee added standard 6.1.3.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.1.3.1** The organization shall track changes to documents.
6.1.4 (6.1.1)	SC	NA	NA	The committee revised standard 6.1.4 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.1.4 Master List of Documents** The organization shall maintain complete lists of all active policies, processes, procedures, labels, forms, and other documents that relate to the

				requirements of these *Perioperative Standards*.
6.1.6	SC	NA	NA	The committee revised standard 6.1.6 based on updates to the AABB Quality System Essentials. The standard reads as follows: ✎**6.1.6 Document Retention** The organization shall determine which documents shall be archived, destroyed, or made obsolete.
6.1.7	SC	NA	NA	The committee revised standard 6.1.7 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.1.7 Document Storage** Documents shall be stored in a manner that preserves integrity and legibility; protects from accidental or unauthorized access, loss, destruction, or modification; and ensures accessibility and retrievability.
6.1.8 (New)	SC	NA	NA	The committee revised standard 6.1.8 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.1.8 Document Retrieval** The organization shall ensure that documents are retrievable in a timely manner.
6.1.9 (6.1.5)	SC	NA	NA	The committee revised standard 6.1.9 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.1.9** The organization shall use only current and valid documents. Applicable documents shall be available at all locations where activities essential to meeting the requirements of these *MT Standards* are performed.
6.2	SC	NA	NA	The committee revised standard 6.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.2 Record Control** The organization shall maintain a system for identification, collection, indexing, accessing, filing, storage, maintenance, and disposition of original records.
6.2.2, #3 (6.2.4, #3)	SC	NA	NA	The committee revised standard 6.2.2, #3 based on updates to the AABB Quality System Essentials. The standard reads as follows:

				6.2.2 The records system shall ensure traceability of: 3) Date the activity was performed.
6.2.2, #4 (6.2.4, #3)	SC	NA	NA	The committee revised subnumber 4 to standard 6.2.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.2.2** The records system shall ensure traceability of: 4) Time the activity was performed, if applicable.
6.2.3 (New)	SC	NA	NA	The committee added standard 6.2.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.2.3 Information to Be Retained** Records shall demonstrate that a material, product, or service conforms to specified requirements and that the quality system is operating effectively.
6.2.5 (6.2.6, 6.2.6.1, 6.2.6.2)	SC	NA	NA	The committee revised standard 6.2.5 based on updates to the AABB Quality System Essentials. The standard reads as follows: **🖉 6.2.5 Record Change** The organization shall establish processes for changing records. The date and identity of the person making the change shall be recorded. Record changes shall not obscure previously recorded information.
6.2.5.2 (New)	SC	NA	NA	The committee added new standard 6.2.5.2 to the edition for completeness. This standard also appears in the Standards for Relationship Testing Laboratories and is based on that language. **6.2.5.2** If an amended report is issued, the original report shall be maintained. Standard 6.2.1 applies.
6.2.7 (6.2.1.2)	SC	NA	NA	The committee revised standard 6.2.7 based on updates to the AABB Quality System Essentials. The standard reads as follows: **🖉 6.2.7 Copies** Before destruction of original records, copies of records shall be verified as containing the original content and shall be legible, complete, and accessible.
6.2.9 (6.2)	SC	NA	NA	The committee revised standard 6.2.9 based on updates to the AABB

				Quality System Essentials. The standard reads as follows: **6.2.9 Retention** Records required by these *Perioperative Standards* shall be retained for a period indicated in the record retention table at the end of each chapter.
6.2.10 (New)	SC	NA	NA	The committee added standard 6.2.10 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.2.10 Record Review** Records shall be reviewed for accuracy, completeness, and compliance with applicable standards, laws, and regulations.
6.2.11, #1 (6.2.8, #1)	SC	NA	NA	The committee revised subnumber 1 of standard 6.2.11 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.2.11 Storage of Records** Records shall be stored to: 1) Preserve record legibility and integrity for the entire retention period.
6.2.11, #2 (6.2.8, #2)	SC	NA	NA	The committee revised subnumber 2 of standard 6.2.11 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.2.11 Storage of Records** Records shall be stored to: 2) Protect from accidental or unauthorized access, loss, deterioration, damage, destruction, mix-up, or modification.
6.2.11, #3 (New)	SC	NA	NA	The committee added subnumber 3 to standard 6.2.11 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.2.11 Storage of Records** Records shall be stored to: 3) Permit ready identification.
6.2.11, #4 (6.2.9, #3)	SC	NA	NA	The committee revised subnumber 4 of standard 6.2.11 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.2.11 Storage of Records** Records shall be stored to:

				4) Allow retrieval in a defined time frame.
6.2.13 (6.2.3)	SC	NA	NA	The committee elected to edit standard 6.2.13 for clarity. The committee added the clause, "…and review…" to the standard which allowed for the removal of the clause, "…~~and to review the interpretation of test records applying to the specific sample, report, or service.~~" as it was deemed redundant. The standard reads as follows: **6.2.13** The record system shall make it possible to trace and review any sample, report, or service from its source to final disposition.
6.3 (New)	SC	NA	NA	The committee added standard 6.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.3 Electronic Records** The organization shall support the management of information systems.
6.3.1 (New)	SC	NA	NA	The committee added standard 6.3.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.3.1** Access to Data and Information Access to data and information shall be controlled.
6.3.1.1 (New)	SC	NA	NA	The committee added standard 6.3.1.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.3.1.1** The authorization to access and release data and information shall be defined, and individuals authorized to enter, change, and release results shall be identified.
6.3.1.1.1 (New)	SC	NA	NA	The committee added standard 6.3.1.1.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.3.1.1.1** Electronic records shall include the date and identity of the person making a change.
6.3.2 (New)	SC	NA	NA	The committee added standard 6.3.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.3.2 Data Integrity** Data integrity shall ensure that data are retrievable and usable.

6.3.2.1 (New)	SC	NA	NA	The committee added standard 6.3.2.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.3.2.1** Data shall be accurately, reliably, and securely sent from the point of entry to final destination.
6.3.2.2 (6.2.7.1.2)	SC	NA	NA	The committee revised standard 6.3.2.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.3.2.2** Data shall be retrievable for the entire retention period.
6.3.2.2.1 (New)	SC	NA	NA	The committee added standard 6.3.2.2.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.3.2.2.1** The organization shall archive records or data from media and platforms no longer in use.
6.3.3 (New)	SC	NA	NA	The committee added standard 6.3.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.3.3 Storage Media** Data storage media shall be protected from damage or unintended access and destruction.
6.3.4 (6.2.7.1)	SC	NA	NA	The committee updated standard 6.3.4 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.3.4 Backup Data** The organization shall back up all critical data.
6.3.4.2 (New)	SC	NA	NA	The committee added standard 6.3.4.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.3.4.2** Backup data shall be protected from unauthorized access, loss, or modification.
6.3.4.3 (New)	SC	NA	NA	The committee added standard 6.3.4.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.3.4.3** The ability to retrieve data from the backup system shall be tested at defined intervals.
7.1 (New)	SC	NA	NA	The committee added standard 7.1 based on updates to the AABB

				Quality System Essentials. The standard reads as follows: **7.1 Deviations** The organization shall capture, assess, investigate, and report events that deviate from accepted policies, processes, or procedures. The assessment shall ensure timely and appropriate clinical management of the recipient, if applicable.
7.2.1 (New)	SC	NA	NA	The committee added standard 7.2.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **7.2.1** Nonconforming products or services shall be quarantined and/or destroyed.
7.2.3 (New)	SC	NA	NA	The committee added standard 7.2.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **7.2.3** The organization shall: 1) Identify, quarantine, retrieve, recall, and determine the disposition of nonconforming products or services. 2) Identify and manage nonconforming products or services.
7.2.4.1 (7.2)	SC	NA	NA	The committee revised standard 7.2.4.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **7.2.4.1** Records shall include the disposition of the nonconforming product or service, the rationale, and the name(s) of the individual(s) responsible for the decision.
7.2.4.2 (New)	SC	NA	NA	The committee added new standard 7.2.4.2 to ensure that individuals identified as a customer to the laboratory would be informed of any nonconformance that could affect quality. This standard also appears in other sets of AABB Standards. The standard reads as follows: **7.2.4.2** In cases where quality may have been affected, the nonconformance shall be reported to the customer.
7.3 (New)	SC	NA	NA	The committee added standard 7.3 based on updates to the AABB

				Quality System Essentials. The standard reads as follows: **7.3 Adverse Events** The organization shall detect, monitor, evaluate, manage, and report adverse events related to safety and quality.
7.3.1 (New)	SC	NA	NA	The committee added standard 7.3.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **7.3.1** Records of adverse events and the related investigations, evaluations, and notifications shall be maintained.
7.3.2 (New)	SC	NA	NA	The committee added standard 7.3.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **7.3.2** Investigation results and analysis shall be communicated among all facilities involved, if applicable.
8.0	SC	NA	NA	The committee added standard 8.0 based on updates to the AABB Quality System Essentials. The standard reads as follows: **8.0 Internal and External Assessments** The organization shall conduct assessments of operations and quality systems.
8.1 (New)	SC	NA	NA	The committee added standard 8.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **8.1 Internal Assessments** The organization shall conduct internal assessments. Internal assessments shall be performed by personnel independent of those having direct responsibility for the activity being assessed.
8.2 (New)	SC	NA	NA	The committee added standard 8.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **8.2 External Assessments** The organization shall participate in an external assessment program applicable to the activities performed in the organization.

8.3, #2, (New)	SC	NA	NA	The committee added new subnumber 2 to standard 8.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **8.3 Management of Assessment Results** The results of assessments shall be: 2) Evaluated to determine the need for corrective and preventive action.
8.3, #3 (New)	SC	NA	NA	The committee added new subnumber 3 to standard 8.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **8.3 Management of Assessment Results** The results of assessments shall be: 3) Communicated to the appropriate staff.
8.4 (8.2)	SC	NA	NA	The committee revised standard 8.4 based on updates to the AABB Quality System Essentials. The standard reads as follows: **8.4 Quality Monitoring** The organization shall collect and evaluate quality indicator data on a scheduled basis, including adverse events.
8.4.1 (New)	SC	NA	NA	The committee added standard 8.4.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **8.4.1** The organization shall provide data generated to the personnel who have responsibility for the quality indicator data collected.
9.0	SC	NA	NA	The committee revised standard 8.4 based on updates to the AABB Quality System Essentials. The standard reads as follows: **9.0 Process Improvement** The organization shall collect data, perform analysis, and follow up on issues requiring corrective and preventive action, including near-miss events.
9.1, #2	SC	NA	NA	The committee revised subnumber 2 to standard 9.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **9.1 Corrective Action** The organization shall have a process for corrective action that includes:

				2) Investigation of the root cause(s) of nonconformances relating to the product or service, the process, and the quality system.
9.1, #3	SC	NA	NA	The committee revised subnumber 3 to standard 9.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **9.1 Corrective Action** The organization shall have a process for corrective action that includes: 3) Determination of the corrective action needed to eliminate the cause of nonconformances, as applicable.
9.1, #4 (9.1, #5)	SC	NA	NA	The committee revised subnumber 4 to standard 9.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **9.1 Corrective Action** The organization shall have a process for corrective action that includes: 4) Ensuring that corrective action is reviewed and found to be effective.
9.1.1 (New)	SC	NA	NA	The committee added standard 9.1.1 based on updates to the AABB Quality System Essentials, which includes some verbiage from standard 9.1 in the previous edition. The standard reads as follows: **9.1.1** Investigation and corrective action shall include consideration of deviations, nonconformances, and complaints.
9.2, #1 (9.2.1)	SC	NA	NA	The committee revised subnumber 1 to standard 9.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **9.2 Preventive Action** The organization shall have a process for preventive action that includes: 1) Analysis of appropriate sources of information to detect, analyze, and eliminate potential causes of nonconformances.
9.2, #2 (9.2.2)	SC	NA	NA	The committee revised subnumber 2 to standard 9.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **9.2 Preventive Action** The organization shall have a process for preventive action that includes:

				2) Determination of steps needed to address any problems requiring preventive action.
9.2, #3 (9.2.3)	SC	NA	NA	The committee revised subnumber 3 to standard 9.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: ✎**9.2 Preventive Action** The organization shall have a process for preventive action that includes: 3) Initiation of preventive action and application of controls to ensure that it is effective.
9.3 (New)	SC	NA	NA	The committee added standard 9.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **9.3 Performance Improvement** The organization shall track and identify trends in information related to its operational and quality system performance to identify opportunities for improvement.
10.0	SC	NA	NA	The committee revised standard 10.0 based on updates to the AABB Quality System Essentials. The standard reads as follows: **10.0 Facilities and Safety** The organization shall ensure safe environmental conditions. The work area shall be suitable for the activities performed. Safety programs shall meet local, state, and national regulations.
10.3 (New)	SC	NA	NA	The committee added standard 10.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: ✎**10.3 Handling and Discarding of Biological Materials** Biological materials shall be handled and discarded in a manner that minimizes the potential for human exposure to infectious agents.