

## The PROPOSED Quality Systems Framework

These Quality System Essentials form the foundation of AABB's Standards-setting. Based on the QSEs first articulated in 1997, the Quality Systems Framework are presented here as a streamlined and simplified approach to quality systems that can be implemented across a wide spectrum of settings.

Each quality element includes a short descriptive paragraph, a listing of key glossary terms, and the objective evidence that should be made available during an AABB assessment.

The Quality Systems Framework are presented here as stand-alone items to facilitate the review and consideration of the new template for comment purposes only. The 60 day comment period for this review takes place from September 21, 2021 to January 21, 2022.

AABB requests that all reviewers respond to questions regarding the PROPOSED Quality Systems Framework at the [survey here](#), as well as provide feedback on the content of the PROPOSED Quality Systems Framework.

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## QSE 1 – Organization

### Key Concepts:

This QSE describes the responsibilities of executive management, the nature of the quality system, and the need for ongoing attention to operational and quality issues through demonstrated management commitment.

Also included are risk assessments and disaster preparedness, as well as the authority of medical, technical or scientific leadership to approve exceptions to policies, processes, and procedures.

### Key Terms:

**Customer:** *The receiver of a product or service. A customer may be internal, eg, another organizational unit within the same organization, or external, eg, a patient, client, donor, or another organization.*

**Emergency Management:** *Strategies and specific activities designed to manage situations in which there is a significant disruption to organization operations or a significantly increased demand for the organization's products or services.*

**Executive Management:** *The highest level personnel within an organization, including employees, clinical leaders and independent contractors, who have responsibility for the operations of the organization and who have the authority to establish or change the organization's quality policy. Executive management may be an individual or a group of individuals.*

**Organization:** *An institution, or part thereof, that has its own functions and executive management.*  
**Policy:** *A set of basic principles or guidelines that direct or restrict the organization's plans, actions, and decisions.*

**Procedure:** *A defined series of tasks and instructions that specify how an activity is to be performed.*

**Process:** *A set of related activities that transform inputs into outputs.*

**Quality System:** *The documented organizational structure, responsibilities, policies, processes, procedures, and resources established by leadership to achieve quality.*

### Objective Evidence:

- All policies, processes and procedures
- Organogram or documents describing roles, responsibilities, and decision-making authority
- Evidence of executive management review of a quality system
- List of applicable federal, state and local laws and regulations and copies of any required certificates
- Defined quality system in a quality manual
- Process for approving exceptions to policies, processes and procedures and documented examples, if applicable
- Risk assessments and mitigation strategies
- Emergency operation and disaster continuity plan(s)
- Executive management review of customer feedback

## **1.0 Organization**

The **organization** shall define the parties responsible for the provision of products or services.

### **1.1 Executive Management**

The organization shall have a defined executive management. Executive management shall have:

- 1) responsibility and authority for the quality system and operations.
- 2) responsibility for compliance with these *Standards* and applicable laws and regulations.

### **1.2 Quality System**

The organization shall have a quality system. The organization's executive management shall ensure that this quality policy is implemented, and followed at all levels of the organization.

#### **1.2.1 Quality Representative**

The quality system shall be under the supervision of a designated person who reports to executive management.

#### **1.2.2 Management Reviews**

Management shall assess the effectiveness of the quality system at defined intervals.

### **1.3 Policies, Processes, and Procedures**

Policies, processes, and procedures shall be implemented and maintained to satisfy the applicable requirements of these *Standards*.

**1.3.1** The medical director shall approve all medical and technical policies, processes, and procedures.

**1.3.2** Any exceptions to policies, processes, and procedures shall require justification and preapproval by the medical director.

### **1.4 Assessment of Risk**

The facility shall have a process in place to perform risk assessments for activities at defined intervals.

**1.4.1** Mitigation strategies shall identify, assess, and address the level of risk associated with product quality and safety.

### **1.5 Operational Continuity**

The organization shall address continuity in the event that operations are at risk.

### **1.6 Emergency Preparedness**

The organization shall have emergency operation plan(s) to respond to the effects of internal and external disasters.

**1.6.1** The emergency management plan, including emergency communication systems, shall be tested at defined intervals.

### 1.7 Communication of Concerns

The organization shall have a process for personnel to anonymously communicate concerns about quality or safety. Personnel shall be given the option to communicate such concerns either to their organization's executive management, AABB, or both. AABB's contact information shall be readily available to all personnel.

### 1.8 Customer Focus

Executive management shall identify the organization's customers and their needs and expectations for products or services.

<b>Standard</b>	<b>Record to be Maintained</b>	<b>Minimum Retention Time<sup>1</sup></b>
1.2.2	Management review of effectiveness of the quality system	5
1.3	Policies, processes, and procedures	10
1.3.2	Exceptions to policies, processes, and procedures	10
1.6.1	Emergency operation plan tested at defined intervals	2

<sup>1</sup>Applicable state or local law may exceed this period.

## QSE 2 – Resources

**Key Concepts:** This QSE describes the need for resources - human, financial and otherwise - to support the work performed. It also describes personnel issues such as the qualification of staff, assessments of competence (including those performed under CLIA), and continuing education requirements.

**Key Terms:**

**Competence:** *An individual's demonstrated ability to apply knowledge and skills needed to perform their job tasks and responsibilities.*

**Qualification (individuals):** *The aspects of an individual's education, training, and experience that are necessary for the individual to successfully meet the requirements of a position.*

**Objective Evidence:**

- Current job descriptions
- Evaluation of staffing levels and workload, if performed
- Process for recruiting and hiring
- Personnel records (e.g., certifications, qualifications, competence assessments, diplomas, transcripts)
- Training records
- Evaluations of competence records
- Evidence that job qualifications are met
- Continuing education records

## 2.0 Resources

The organization shall have adequate resources to perform, verify, and manage all the activities described in these *Standards*.

## 2.1 Human Resources

The organization shall employ an adequate number of individuals qualified by education, training, and/or experience.

### 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 *Standards*.

### 2.1.2 Training

The organization shall provide training for personnel performing critical tasks.

### 2.1.3 Competence

Evaluations of competence shall be performed before independent performance of assigned activities and at specified intervals.

**2.1.3.1** Action shall be taken when competence has not been demonstrated.

### 2.1.4 Personnel Records

Personnel records for each employee shall be maintained.

**2.1.4.1** For those authorized to perform or review critical tasks, records of names, signatures, initials or identification codes, and inclusive dates of employment shall be maintained.

### 2.1.5 Continuing Education

Requirements for relevant continuing education in activities performed by the organization as required by these *Standards* shall be met by all employees who perform critical tasks.

Standard	Record to be Maintained	Minimum Retention Time <sup>1</sup>
2.1.1	Job descriptions	5
2.1.2	Training records of personnel	5
2.1.3	Evaluations of competence	5
2.1.4	Personnel records of each employee	5 following conclusion of employment period
2.1.4.1	Records of names, signatures, initials or identification codes, and inclusive dates of employment for personnel who perform or review critical tasks	10
2.1.5	Continuing education requirements	5

<sup>1</sup>Applicable state or local law may exceed this period.

### QSE 3 – Equipment

**Key Concepts:** This QSE describes the selection, use, maintenance, and monitoring of equipment, including IT systems. It also describes the use and testing of alternative systems when primary systems fail.

**Key Terms:**

**Backup:** *Digital data and/or physical storage containing copies of relevant data.*

**Calibrate:** *To set or align measurement equipment against a known standard.*

**Corrective Action:** *Actions taken to address the root cause(s) of an existing nonconformance or other undesirable situation in order to reduce or eliminate recurrence.*

**Critical Equipment/Materials:** *A piece of equipment or material that can affect the quality of the organization's products.*

**Data Integrity:** *The accuracy, completeness and consistency of information resources*

**Equipment:** *A durable item, instrument, or device used in a process or procedure.*

**Installation Qualification:** - *Verification that the correct equipment is received and that it is installed according to specifications and manufacturer's recommendations in an environment suitable for its operation and use.*

**Operational Qualification:** *Verification that equipment will function according to the operational specifications provided by the manufacturer.*

**Performance Qualification:** *Verification that equipment performs consistently as expected for its intended use in the organization's environment, using the organization's procedures and supplies.*

**Validation:** *Establishing evidence that a process, executed by users in their environment, will consistently meet predetermined specifications.*

**Verification:** *Confirmation by examination and provision of objective evidence that specified requirements have been met.*

**Objective Evidence:**

- Processes for equipment selection, qualification, and maintenance
- List or tool used for critical equipment identification (manufacturer's serial number, date acquired and facility assigned identifier)
- Equipment calibration and maintenance records, if applicable
- Equipment qualification records
- Manufacturer's written instructions
- Records of investigation of equipment, malfunction, failure, repair and requalification, if applicable
- Alarm system testing and records of alarm management, if appropriate
- Evidence of information system backup and records of testing

### **3.0 Equipment**

The organization shall define and control critical equipment.

#### **3.1 Equipment Specifications**

Equipment specifications shall be defined before purchase.

#### **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.

##### **3.2.1 Installation Qualification**

Equipment shall be installed per manufacturer's specifications.

##### **3.2.2 Operational Qualification**

Each piece of equipment and component of an information system shall be verified before actual use.

##### **3.2.3 Performance Qualification**

Equipment shall perform as expected for its intended use.

#### **3.3 Use of Equipment**

Equipment shall be used in accordance with the manufacturer's written instructions.

#### **3.4 Unique Identification of Equipment**

Equipment shall have unique identification.

#### **3.5 Equipment Monitoring and Maintenance**

Equipment shall be monitored and maintained in accordance with manufacturer's written instructions.

##### **3.5.1 Calibration and Accuracy of Equipment**

Calibrations and/or adjustments shall be performed using equipment and materials that have adequate accuracy and precision. At a minimum, calibrations and/or adjustments shall be confirmed as described below unless otherwise indicated by the manufacturer:

- 1) before use.
- 2) after activities that may affect the calibration.
- 3) at prescribed intervals.

**3.5.1.1** Calibration of equipment shall include details of equipment type, unique identification, location, frequency of checks, check method, acceptance criteria, and limitations.

**3.5.1.2** Equipment used for calibration, inspection, measuring, and testing before initial use, after repair, and at prescribed intervals, shall be certified to meet nationally



recognized measurement standards. Where no such measurement standards exist, the basis for calibration shall be described and recorded.

**3.5.1.3** Equipment shall be safeguarded from adjustments that would invalidate the calibration setting.

**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 potential affected products or services, including those that have already been released or delivered shall be assessed.

**3.5.3** The organization shall:

- 1) define cleaning and sanitization 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 including communication 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.

#### **3.5.4 Investigation and Follow-up**

Investigation and follow-up of equipment malfunctions, failures, or adverse events shall include:

- 1) assessment of products or services provided since the equipment was last known to be functioning per manufacturer's written instructions, or organization defined specifications.
- 2) assessment of the effect on the safety of individuals affected.
- 3) removal of equipment from service.
- 4) investigation of the malfunction, failure, or adverse event, and a determination if other equipment is similarly impacted.
- 5) requalification of the equipment.
- 6) reporting the nature of the malfunction, failure, or adverse event to the manufacturer, when indicated.

### **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 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:

- 1) numerical designation of system versions with inclusive dates of use.
- 2) validation/verification/qualification of system software, hardware, databases, and user-defined tables prior to implementation.
- 3) fulfillment of life-cycle requirements for internally developed software.
- 4) defined processes for system operation and maintenance.
- 5) defined process for authorizing and documenting modifications to the system.
- 6) system security to prevent unauthorized access.
- 7) policies, processes, and procedures and other instructional documents developed using terminology that is understandable to the user.
- 8) functionality that allows for display and verification of data before final acceptance of the additions or alterations.
- 9) defined process for monitoring of data integrity for critical data elements.
- 10) system design that establishes and maintains unique identity of donor, product or service, and recipient (as applicable).
- 11) training and competency of personnel who use information systems.
- 12) procedures to ensure confidentiality of protected health information.

### 3.7.1 Alternative Systems

An alternate 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 Personnel responsible for management of information systems shall be responsible for compliance with the regulations that affect their use.

3.7.3 The organization shall support the management of information systems.

3.7.4 A system designed to prevent unauthorized access to computers and electronic records shall be in place.

3.7.5 The organization shall have measures in place to minimize the risk of an internal or external data breach.

<b>Standard</b>	<b>Record to be Maintained</b>	<b>Minimum Retention Time<sup>1</sup></b>
3.2	Equipment qualification	10 after retirement of the equipment
3.4	Unique identification of equipment	5
3.5.1	Equipment calibration activities	5
3.5.2	Equipment found to be out of calibration	5
3.5.3	Equipment monitoring, maintenance, calibration, and repair	5
3.6	Equipment traceability	5
3.7	Implementation and modification of software, hardware, or databases	2 years after retirement of system

<sup>1</sup>Applicable state or local law may exceed this period.

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## QSE 4 – Supplier and Customer Agreements

**Key Concepts:** This QSE describes the need for agreements between the organization and its customers and suppliers. The agreements define expectations between both parties and measures taken when one entity fails to meet the expectations of an agreement.

### Key Terms:

**Agreement:** *A contract, order, or understanding between two or more parties, such as between an organization and one of its customers.*

**Agreement Review:** *Systematic activities carried out before finalizing the agreement to ensure that requirements are adequately defined, free from ambiguity, documented, and achievable.*

**Customer:** *The receiver of a product or service. A customer may be internal, eg, another organizational unit within the same organization, or external, eg, a patient, client, donor, or another organization.*

**Qualification (materials):** *For materials that come into contact with the product, verification that the materials are sterile, the appropriate grade and suitability for the intended use and, whenever possible, approved for human use by the United States Food and Drug Administration (FDA) or relevant Competent Authority.*

**Quality:** *Characteristics of a product or service that bear on its ability to fulfill customer expectations. The measurable or verifiable aspects of a product or service that can be used to determine if requirements have been met.*

**Quality Control:** *Testing routinely performed on materials and equipment to ensure their proper function.*

**Supplier:** *An entity that provides a material, product, or service.*

**Supplier Qualification:** *Evaluation of a potential supplier to assess its ability to consistently deliver products or services that meet specified requirements.*

### Objective Evidence:

- Processes for defining and updating or changing agreements
- Process for recording verbal agreements, if practiced
- Agreement records
- Agreement review records
- Supplier qualification records
- Supplier evaluation records
- Supplier selection process
- Evidence of action taken when supplier fails to meet expectations, if applicable
- Evidence of receipt of product(s) as stipulated in agreements
- Records of inspection and testing

#### 4.0 Supplier and Customer Agreements

The organization shall ensure that agreements to provide or receive products or services are reviewed and approved.

#### 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** 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.

**4.1.2** When a supplier fails to meet specified requirements, it shall be reported to the management with contracting authority.

#### 4.2 Agreements

Agreements and any incorporated changes shall be reviewed and communicated.

**4.2.1** Agreements shall be reviewed at defined intervals.

**4.2.2** Changes to agreements shall be communicated to affected parties.

**4.2.3** The responsibilities for activities covered by these *Standards* when more than one organization is involved shall be specified by agreement.

#### 4.3 Incoming Receipt, Inspection, and Testing

Incoming products or services, equipment and materials shall be received, inspected, and tested, as necessary, before acceptance or use.

<b>Standard</b>	<b>Record to be Maintained</b>	<b>Minimum Retention Time<sup>1</sup></b>
4.1	Evaluation and participation in selection of suppliers	5
4.2	Agreements	5
4.2.1	Agreement review	5
4.2.4	Agreements concerning activities involving more than one organization	5
4.3	Inspection of incoming critical materials	10

<sup>1</sup>Applicable state or local law may exceed this period.

## QSE 5 – Process Control

**Key Concepts:** This QSE covers the organization’s operations and production functions. It describes the need to ensure that this work is controlled, that processes function as expected, and that expected outcomes are met. This QSE encapsulates what occurs in each organization and forms the basis of their accreditation.

### Key Terms:

**Change Control:** *A structured method of revising a policy, process, or procedure, including hardware or software design, transition planning, and revisions to all related documents.*

**Critical Equipment/Materials/Tasks:** *A piece of equipment, material, service, or task that can affect the quality of the organization’s products.*

**Executive Management:** *The highest level personnel within an organization, including employees, clinical leaders and independent contractors, who have responsibility for the operations of the organization and who have the authority to establish or change the organization’s quality policy. Executive management may be an individual or a group of individuals.*

**Process Control:** *Activities designed to ensure that processes are stable and consistently operate within acceptable limits of variation in order to produce predictable output that meets specifications.*

**Product:** *A tangible output from a process.*

**Reference Standard:** *Specified requirements defined by the AABB. Reference standards define how or within what parameters an activity shall be performed and are more detailed than quality system requirements.*

**Service:** *An intangible output of a process.*

**Standard:** *A set of specified requirements upon which an organization may base its criteria for the products, components, and/or services provided.*

**Validation:** *Establishing evidence that a process, executed by users in their environment, will consistently meet predetermined specifications.*

**Verification:** *Confirmation by examination and provision of objective evidence that specified requirements have been met.*

### Objective Evidence:

- Change control records
  - Example of a new or revised process, procedure or product
- Implementation records
- Records of a completed traceability investigation (e.g., tracer audits – an audit that traces a product and all related samples from their initial source to their final disposition and allow the identification and traceability of each product and all related samples from their final disposition, through all processing and/or testing steps, to their source)
- Storage records
- Quality control records
- Process validation records

- Evidence of process planning, if applicable
- Records of material storage, handling and use
- Records of inspection of materials
- Product inspection records
- Testing records

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## **5.0 Process Control**

The organization shall ensure the quality of products or services.

## **5.1 General Elements**

The organization shall ensure that processes are carried out under controlled conditions.

### **5.1.1 Change Control**

The organization shall develop new processes or procedures or change existing ones. Before implementation, the new or changed processes or procedures shall be validated.

### **5.1.2 Quality Control**

A program of quality control shall be established that is sufficiently comprehensive to ensure that products, equipment and materials perform as expected.

**5.1.2.1** Quality control failures shall be investigated before release of test results, products or services.

**5.1.2.2** 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 Process Planning**

Quality requirements shall be incorporated into new or changed processes, products or 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 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 re-validation depending on the level of risk and impact of the new or changed products or services.



#### 5.1.4 Process Validation

Before implementation, the new or changed processes and procedures shall be validated.

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.

#### 5.1.5 Process Implementation

The implementation of new or changed processes and procedures shall be planned and controlled.

5.1.5.1 Postimplementation evaluations of new or changed processes and procedures shall be performed.

#### 5.1.6 Use of Materials

All materials shall be stored and used in accordance with the manufacturer's written instructions.

#### 5.1.7 Inspection

The **organization** shall ensure that products or services are inspected at organization-defined stages.

#### 5.1.8 Identification and Traceability

The organization shall ensure that all products or services are identified and traceable.

#### 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.

Standard	Record to be Maintained	Minimum Retention Time <sup>1</sup>
5.1.1	Validation of new or changed processes and procedures	5
5.1.8	Identification and traceability of products	5

<sup>1</sup>Applicable state or local law may exceed this period.

## QSE 6 – Documents and Records

**Key Concepts:** This QSE focuses on the need to maintain all documents and records in a manner that ensures their confidentiality, traceability, completeness, uniformity, and ability to retrieve and locate in a time deemed adequate. This QSE also includes the need to ensure data integrity and that all data can be backed up and retrieved.

### Key Terms:

**Backup:** *Digital data and/or physical storage containing copies of relevant data.*

**Confidentiality:** *The protection of private, sensitive, or trusted information resources from unauthorized access or disclosure*

**Data Integrity:** *The accuracy, completeness and consistency of information resources.*

**Document (noun):** *Written or electronically generated information and work instructions. Examples of documents include quality manuals, procedures, or forms.*

**Document (verb):** *To capture information through writing or electronic media.*

**Label:** *An inscription affixed or attached to a product for identification.*

**Labeling:** *Information that is required or selected to accompany product, which may include content, identification, description of processes, storage requirements, expiration date, cautionary statements, or indications for use.*

**Master List of Documents:** *A reference list, record, or repository of an organization's policies, processes, procedures, forms, and labels related to the Standards which includes information for document control.*

**Record (noun):** *Information captured in writing or through electronically generated media that provides objective evidence of activities that have been performed or results that have been achieved, such as test records or audit results. Records do not exist until the activity has been performed and documented.*

**Record (verb):** *To capture information for use in records through writing or electronic media.*

### Objective Evidence:

- Records of activities performed
- Record system
- Master list of documents
- An electronic record system, if applicable
- Uniform storage media and ability to track newer technologies to older ones as needed
- Evidence of document and record review
- Evidence of standardized formats for all documents and records
- Record retention periods
- Record traceability
- Data back up plans
- Record change process

- Obsolescence of records and disposition
- Record destruction

## **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 Document Control**

The organization shall control all documents that relate to the requirements of these *Standards*. Documents shall be protected from unauthorized access and accidental or unauthorized modification, deletion, or destruction.

#### **6.1.1 Format**

Documents shall be in standardized formats. Additional policies, processes, and procedures (such as those in an operator's manual) may be incorporated by reference.

#### **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 *Standards* are performed.
- 5) invalid or obsolete documents are not used.
- 6) any archived or obsolete documents are identified as such.

#### **6.1.3 Document Changes**

Changes to documents shall be reviewed and approved by an authorized individual.

**6.1.3.1** The organization shall track changes to documents.

#### **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 *Standards*.

#### **6.1.5 Review of Policies, Processes, and Procedures**

Review of each policy, process, and procedure shall be performed at a minimum every 2 years.

#### **6.1.6 Document Retention**

The organization shall determine which documents shall be archived, destroyed, or made obsolete.

### **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 is accessible and retrievable.

### **6.1.8 Document Retrieval**

The organization shall ensure that documents are retrievable in a timely manner.

## **6.2 Record Control**

The organization shall maintain a system for identification, collection, indexing, accessing, filing, storage, maintenance, and disposition of original records.

### **6.2.1 Records**

Records shall be complete, retrievable in a period of time appropriate to the circumstances and protected from accidental or unauthorized destruction or modification.

### **6.2.2 Record Traceability**

The records system shall ensure traceability of:

- 1) critical activities performed.
- 2) the individual who performed the activity.
- 3) date the activity was performed.
- 4) time the activity was performed, if applicable.
- 5) results obtained.
- 6) method(s) used.
- 7) equipment used.
- 8) critical materials used.
- 9) the organization where the activity was performed.

### **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.

### **6.2.4 Legibility**

All records shall be legible and indelible.

### **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.

**6.2.6** Records shall be created concurrently with performance of each critical activity.

### **6.2.7 Copies**

Copies of records shall be verified as containing the original content and shall be legible, complete, and accessible.

### **6.2.8 Confidentiality**

The organization shall ensure the confidentiality of records.

### **6.2.9 Retention**

Records required by these *Standards* shall be retained for a period of time indicated in the record retention table at the end of each QSE.

### **6.2.10 Record Review**

Records shall be reviewed for accuracy, completeness, and compliance with applicable standards, laws, and regulations.

### **6.2.11 Storage of Records**

Records shall be stored to:

- 1) preserve record legibility and integrity for the entire retention period.
- 2) protect from accidental or unauthorized access, loss, deterioration, damage, destruction, mix-up, or modification.
- 3) permit ready identification
- 4) allow retrieval in a defined timeframe.

### **6.2.12 Destruction of Records**

Destruction of records shall be conducted in a manner that protects the confidential content of the records.

## **6.3 Electronic Records**

The organization shall support the management of information systems.

### **6.3.1 Access to Data and Information**

Access to data and information shall be controlled.

**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** Electronic records shall include the date and identity of the person making a change.

### **6.3.2 Data Integrity**

Data integrity shall ensure that data are retrievable and usable.

**6.3.2.1** Data shall be accurately, reliably, and securely sent from the point of entry to final destination.

**6.3.2.2** Data shall be retrievable for the entire retention period.

**6.3.2.2.1** The organization shall archive records or data from media and platforms no longer in use.

**6.3.3 Storage Media**

Data storage media shall be protected from damage or unintended access and destruction.

**6.3.4 Back-Up Data**

The organization shall back up all critical data.

**6.3.4.1** Back-up data shall be stored in a secure off-site location.

**6.3.4.2** Back-up data shall be protected from unauthorized access, loss, or modification.

**6.3.4.3** The ability to retrieve data from the back-up system shall be tested at defined intervals.

<b>Standard</b>	<b>Record to be Maintained</b>	<b>Minimum Retention Time<sup>1</sup></b>
6.1.2	Document control, including review and approval of all documents before use	5
6.1.3	Review and approval of changes to documents	5
6.1.4	List of all active policies, processes, procedures, labels, and forms	5
6.1.5	Biennial review of each policy, process, or procedure	5
6.1.6	Documents that are archived, destroyed, or made obsolete	5
6.2.5	Record change	5
6.2.7	Verification that copies of records contain the original content and are legible, complete, and accessible before the original records are destroyed	5
6.2.10	Review of records for accuracy, completeness, and compliance with applicable standards, laws, and regulations	5
6.3	Electronic records	5
6.3.1.1.1	Date and identity of person making change(s) to electronic records	5

<sup>1</sup>Applicable state or local law may exceed this period.

## QSE 7 – Deviations, Nonconformances and Adverse Events

**Key Concepts:** This QSE focuses on the need to ensure to capture, manage, and respond to deviations, nonconformances or adverse events. This also includes the need to maintain records of resolution.

**Key Terms:**

**Adverse Event:** *A complication in an individual. Adverse events may occur in relation to organization-defined activities.*

**Conformance:** *Fulfillment of requirements. Requirements may be defined by customers, practice standards, regulatory agencies, or law.*

**Deviation:** *A departure from policies, processes, procedures, applicable regulations, standards, or specifications.*

**Disaster:** *An event (internal, local, or national) that can affect the safety and availability of the product or of individuals.*

**Near-Miss Event:** *An unexpected occurrence that did not adversely affect the outcome but could have resulted in a serious adverse event.*

**Nonconformance:** *Failure to meet requirements.*

**Root Causes:** *The underlying cause(s) of an event or nonconformance that, if eliminated, would prevent recurrence.*

**Traceability:** *The ability to follow the history of a product or service from source to final distribution or disposition using records.*

**Objective Evidence:**

- Records and evaluation of deviations, nonconformances and adverse events
- Notification to customer(s) following investigation, if appropriate
- Records of evidence that measures were taken to ensure deviations, nonconformances and adverse events do not recur.
- Planned deviation records, if any
- Records of deviation reporting to appropriate parties (e.g FDA)

## 7.0 Deviations, Nonconformances, and Adverse Events

The organization shall capture, assess, investigate, and monitor failures to meet specified requirements. The responsibility for review and authority for the disposition of nonconformances shall be defined. These events shall be reported in accordance with specified requirements and to outside agencies as required.

### 7.1 Deviations

The organization shall capture, assess, investigate, and report events that deviate from accepted policies, processes, or procedures. The evaluation shall include an assessment of the patient and shall not delay proper clinical management of the patient.

### 7.2 Nonconformances

Upon discovery, nonconforming products or services shall be evaluated and their disposition determined.

7.2.1 Nonconforming products or services shall be quarantined and/or destroyed.

7.2.2 The unintended distribution or use of products or services that do not conform to specified requirements shall be prevented.

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 Released Nonconforming Products or Services

Products or services that are determined after release not to conform to specified requirements shall be evaluated to determine the effect of the nonconformance on the quality and/or safety of the product or service.

7.2.4.1 Records shall include the disposition of the product or service, the rationale, and the name(s) of the individual(s) responsible for the decision.

### 7.3 Adverse Events

The organization shall detect, monitor, evaluate, manage and report adverse events related to safety and quality.

7.3.1 Records of adverse events and the related investigations, evaluations, and notifications shall be maintained.

7.3.2 Investigation results and analysis shall be communicated among all facilities involved as appropriate.

Standard	Record to be Maintained	Minimum Retention Time <sup>1</sup>
7.1	Deviations	10 years after any impacted product is used or discarded



7.2	Nonconformances	10 years after any impacted product is used or discarded
7.2.4	Nature of nonconformances discovered after release and subsequent actions taken, including acceptance for use	10
7.2.4.1	Disposition of the nonconformance	10

<sup>1</sup>Applicable state or local law may exceed this period.

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## QSE 8 – Assessments: Internal and External

**Key Concepts:** This QSE addresses the organization’s internal quality assessment functions as well as processes to support external assessments by accreditors, health authorities, etc. This chapter also describes the need for the organization to engage in ongoing quality monitoring and utilization review.

### Key Terms:

**Adverse Event:** *A complication in an individual. Adverse events may occur in relation to organization defined activities.*

**Assessment:** *A systematic examination to determine whether actual activities comply with planned activities, are implemented effectively, and achieve objectives. Types of assessments include external assessments, internal assessments, peer review, and self-assessments.*

**Competence:** *An individual’s demonstrated ability to apply knowledge and skills needed to perform their job tasks and responsibilities.*

**Competent Authority:** *The agency responsible under its national law for regulations applicable to organization.*

**Conformance:** *Fulfillment of requirements. Requirements may be defined by customers, practice standards, regulatory agencies, or law.*

**Corrective Action:** *Actions taken to address the root cause(s) of an existing nonconformance or other undesirable situation in order to reduce or eliminate recurrence.*

**Deviation:** *A departure from policies, processes, procedures, applicable regulations, standards, or specifications.*

**Nonconformance:** *Failure to meet requirements.*

**Preventive Action:** *An action taken to reduce or eliminate the potential for unexpected deviations, nonconformances or other undesirable situations.*

**Quality Indicator Data:** *Information that may be collected and used to determine whether an organization is meeting its quality objectives as defined by top management in its quality policy. Indicators are measured by data for movement or regression with regard to those quality intentions. The data used for monitoring a quality indicator may consist of single-source data or multiple-source data, as long as it is clear how the data will come together to define the indicator.*

**Root Causes:** *The underlying cause(s) of an event or nonconformance that, if eliminated, would prevent recurrence.*

### Objective Evidence:

- Records of internal assessments scheduled and conducted
- Records of evidence that deficiencies discovered during assessments and inspections have been addressed, including changes to quality or operational functions.
- Records of external assessments being conducted
- Quality indicator data collection and review

**8.0 Internal and External Assessments**

The organization shall conduct internal assessments of operations and quality systems.

**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 External Assessments**

The organization shall participate in an external assessment program applicable to the activities performed in the organization.

**8.3 Management of Assessment Results**

The results of assessments shall be:

- 1) reviewed by the personnel having responsibility for the area assessed.
- 2) evaluated to determine the need for corrective and preventive action.
- 3) communicated to the appropriate staff.
- 4) reported to executive management.

**8.4 Quality Monitoring**

The organization shall collect and evaluate quality indicator data on a scheduled basis, including adverse events.

**8.4.1** The organization shall provide data generated to the personnel who have responsibility for the quality indicator data collected.

<b>Standard</b>	<b>Record to be Maintained</b>	<b>Minimum Retention Time<sup>1</sup></b>
8.1	Internal assessments	5
8.2	External assessments	5
8.3	Management of assessment results	5

<sup>1</sup>Applicable state or local law may exceed this period.

## QSE 9 – Process Improvement

**Key Concepts:** This QSE focuses on the use of corrective and preventive actions to drive process improvement. It describes measures to ensure that the root cause of nonconformances are effectively addressed.

**Key Terms:**

**Adverse Event:** *A complication in an individual. Adverse events may occur in relation to organization defined activities.*

**Assessment:** *A systematic examination to determine whether actual activities comply with planned activities, are implemented effectively, and achieve objectives. Types of assessments include external assessments, internal assessments, peer review, and self-assessments.*

**Corrective Action:** *Actions taken to address the root cause(s) of an existing nonconformance or other undesirable situation in order to reduce or eliminate recurrence.*

**Deviation:** *A departure from policies, processes, procedures, applicable regulations, standards, or specifications.*

**Near-Miss Event:** *An unexpected occurrence that did not adversely affect the outcome but could have resulted in a serious adverse event.*

**Nonconformance:** *Failure to meet requirements.*

**Preventive Action:** *An action taken to reduce or eliminate the potential for unexpected deviations, nonconformances or other undesirable situations.*

**Root Causes:** *The underlying cause(s) of an event or nonconformance that, if eliminated, would prevent recurrence.*

**Objective Evidence:**

- Records of collected data, analysis and corrective action taken when near misses, deviations, or adverse events discovered
- Tracking of relevant data that impacts the organization’s current and future operations
- Records that corrective and preventive action is taken
- Records that corrective and preventive action taken was effective and is monitored
- Documentation that process improvement data is included in executive management review

## 9.0 Process Improvement

The organization shall collect data, perform analysis, and follow-up of issues requiring corrective and preventive action, including near-miss events.

### 9.1 Corrective Action

Corrective action shall include:

- 1) investigation of the root cause of nonconformances relating to the product or service the process, and the quality system.
- 2) investigation of complaints.
- 3) determination of the corrective action needed to eliminate the cause of nonconformances.
- 4) ensuring that corrective action is reviewed and found to be effective.

### 9.2 Preventive Action

Preventive action shall include:

- 1) analysis of appropriate sources of information to detect, analyze, and eliminate potential causes of nonconformances.
- 2) determination of steps needed to address any problems requiring preventive action.
- 3) initiation of preventive action and application of controls to ensure that it is effective.

### 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.

Standard	Record to be Maintained	Minimum Retention Time <sup>1</sup>
9.0	Implementation of changes to policies, processes, and procedures resulting from corrective and preventive action	5
9.1	Corrective action	5
9.2	Preventive action	5

<sup>1</sup>Applicable state or local law may exceed this period.

## QSE 10 – Facilities and Safety

**Key Concepts:** This QSE addresses the safety and adequacy of areas where the work required by these Standards is performed. This includes occupational safety, biohazardous materials disposal, environmental monitoring and compliance with applicable local and national regulations.

**Key Terms:**

***Environmental Monitoring:*** Policies, processes, and procedures used for monitoring any or all of the following: temperature, humidity, particulates, and microbial contamination in a specific area. Where appropriate, the program shall include sampling sites, frequency of sampling, and investigative and corrective actions that should be followed when specified limits are exceeded.

***Executive Management:*** The highest level personnel within an organization, including employees, clinical leaders and independent contractors, who have responsibility for the operations of the organization and who have the authority to establish or change the organization's quality policy. Executive management may be an individual or a group of individuals.

***Organization:*** An institution, or part thereof, that has its own functions and executive management.

**Objective Evidence:**

- Safe environmental conditions for all individuals in the organization
- Local, state, and federal regulations being followed
- Proper discard of hazardous and potentially hazardous materials
- PPE is available and in use available

**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 federal regulations.

**10.1 Safe Environment**

The organization shall minimize and respond to environmentally related risks to the health and safety of all individuals and products or services. Suitable quarters, environment, and equipment shall be available to maintain safe operations.

**10.2 Biological, Chemical, and Radiation Safety**

The organization shall monitor adherence to biological, chemical, and radiation safety standards and regulations.

**10.3 Discard of Products**

Products shall be handled and discarded in a manner that minimizes the potential for human exposure to infectious agents.

<b>Standard</b>	<b>Record to be Maintained</b>	<b>Minimum Retention Time<sup>1</sup></b>
10.2	Monitoring of biological, chemical, and radiation safety	5
10.3	Appropriate discard of products	10

<sup>1</sup>Applicable state or local law may exceed this period.

## Glossary

**Adverse Event:** A complication in an individual. Adverse events may occur in relation to organization defined activities.

**Agreement:** A contract, order, or understanding between two or more parties, such as between an organization and one of its customers.

**Agreement Review:** Systematic activities carried out before finalizing the agreement to ensure that requirements are adequately defined, free from ambiguity, documented, and achievable.

**Assessment:** A systematic examination to determine whether actual activities comply with planned activities, are implemented effectively, and achieve objectives. Types of assessments include external assessments, internal assessments, peer review, and self assessments.

**Backup:** Digital data and/or physical storage containing copies of relevant data.

**Calibrate:** To set or align measurement equipment against a known standard.

**Change Control:** A structured method of revising a policy, process, or procedure, including hardware or software design, transition planning, and revisions to all related documents.

**Competence:** An individual's demonstrated ability to apply knowledge and skills needed to perform their job tasks and responsibilities.

**Competent Authority:** The agency responsible under its national law for regulations applicable to organization.

**Compliance:** See Conformance.

**Confidentiality:** The protection of private, sensitive, or trusted information resources from unauthorized access or disclosure

**Conformance:** Fulfillment of requirements. Requirements may be defined by customers, practice standards, regulatory agencies, or law.

**Corrective Action:** Actions taken to address the root cause(s) of an existing nonconformance or other undesirable situation in order to reduce or eliminate recurrence.

**Critical Equipment/Materials/Tasks:** A piece of equipment, material, service, or task that can affect the quality of the organization's products.

**Customer:** The receiver of a product or service. A customer may be internal, eg, another organizational unit within the same organization, or external, eg, a patient, client, donor, or another organization.

**Data Integrity:** The accuracy, completeness and consistency of information.

**Deviation:** A departure from policies, processes, procedures, applicable regulations, standards, or specifications.



**Disaster:** An event (internal, local, or national) that can affect the safety and availability of the organization's products or the safety of individuals.

**Document (noun):** Written or electronically generated information and work instructions. Examples of documents include quality manuals, procedures, or forms.

**Document (verb):** To capture information through writing or electronic media.

**Equipment:** A durable item, instrument, or device used in a process or procedure.

**Emergency Management:** Strategies and specific activities designed to manage situations in which there is a significant disruption to organization operations or a significantly increased demand for the organization's products or services.

**Environmental Monitoring:** Policies, processes, and procedures used for monitoring any or all of the following: temperature, humidity, particulates, and microbial contamination in a specific area. Where appropriate, the program shall include sampling sites, frequency of sampling, and investigative and corrective actions that should be followed when specified limits are exceeded.

**Establish:** To perform all of the activities required to plan, validate, and implement a system or process.

**Executive Management:** The highest level personnel within an organization, including employees, clinical leaders and independent contractors, who have responsibility for the operations of the organization and who have the authority to establish or change the organization's quality policy. Executive management may be an individual or a group of individuals.

**Organization:** An organization, or a location or operational area within that organization; the entity assessed by the AABB and receiving AABB accreditation for specific activities.

**Installation Qualification:** - Verification that the correct equipment is received and that it is installed according to specifications and manufacturer's recommendations in an environment suitable for its operation and use.

**Label:** An inscription affixed or attached to a product for identification.

**Labeling:** Information that is required or selected to accompany the product, which may include content, identification, description of processes, storage requirements, expiration date, cautionary statements, or indications for use.

**Maintain:** To keep in the current state; to preserve or retain; to keep in a state of validity.

**Master List of Documents:** A reference list, record, or repository of an organization's policies, processes, procedures, forms, and labels related to the Standards which includes information for document control.

**Material:** A supply item used in a process or procedure.

**Near-Miss Event:** An unexpected occurrence that did not adversely affect the outcome but could have resulted in a serious adverse event.

**Nonconformance:** Failure to meet requirements.

**Operational Qualification:** Verification that equipment will function according to the operational specifications provided by the manufacturer.

**Operational Systems:** Processes, resources, and activities that work together to result in a product or service.

**Organization:** An institution, laboratory, or program that has its own functions and executive management.

**Performance Qualification:** Verification that equipment performs consistently as expected for its intended use in the organization's environment, using the organization's procedures and supplies.

**Policy:** A set of basic principles or guidelines that direct or restrict the organization's plans, actions, and decisions.

**Preventive Action:** An action taken to reduce or eliminate the potential for unexpected deviations, nonconformances or other undesirable situations.

**Procedure:** A defined series of tasks and instructions that specify how an activity is to be performed.

**Process:** A set of related activities that transform inputs into outputs.

**Process Control:** Activities designed to ensure that processes are stable and consistently operate within acceptable limits of variation in order to produce predictable output that meets specifications.

**Product:** A tangible output from a process.

**Qualification (individuals):** The aspects of an individual's education, training, and experience that are necessary for the individual to successfully meet the requirements of a position.

**Qualification (materials):** For materials that come into contact with the product verification that the materials are sterile, the appropriate grade and suitability for the intended use and, whenever possible, approved for human use by the United States Food and Drug Administration (FDA) or relevant Competent Authority.

**Quality:** Characteristics of a product or service that bear on its ability to fulfill customer expectations. The measurable or verifiable aspects of a product or service that can be used to determine if requirements have been met.

**Quality Control:** Testing routinely performed on materials and equipment to ensure their proper function.

**Quality Indicator Data:** Information that may be collected and used to determine whether an organization is meeting its quality objectives as defined by top management in its quality policy. Indicators are measured by data for movement or regression with regard to those quality intentions. The data used for monitoring a quality indicator may consist of single-source data or multiple-source data, as long as it is clear how the data will come together to define the indicator.

**Quality Management System:** The organizational structure, responsibilities, policies, processes, procedures, and resources established by leadership to achieve quality.

**Record (noun):** Information captured in writing or through electronically generated media that provides objective evidence of activities that have been performed or results that have been achieved, such as test records or audit results. Records do not exist until the activity has been performed and documented.

**Record (verb):** To capture information for use in records through writing or electronic media.

**Reference Standard:** Specified requirements defined by the AABB. Reference standards define how or within what parameters an activity shall be performed and are more detailed than quality system requirements.

**Regulation:** Rules promulgated by federal, state, or local authorities to implement laws enacted by legislative bodies.

**Release:** Removal of a product from quarantine or in-process status for the purpose of distribution.

**Root Causes:** The underlying cause(s) of an event or nonconformance that, if eliminated, would prevent recurrence.

**Service:** An intangible output of a process.

**Shall:** A term used to indicate a requirement.

**Standard:** A set of specified requirements upon which an organization may base its criteria for the products, components, and/or services provided.

**Supplier:** An entity that provides a material, product, or service.

**Supplier Qualification:** Evaluation of a potential supplier to assess its ability to consistently deliver products or services that meet specified requirements.

**Traceability:** The ability to follow the history of a product or service from source to final distribution or disposition using records.

**Validation:** Establishing evidence that a process, executed by users in their environment, will consistently meet predetermined specifications.

**Verification:** Confirmation by examination and provision of objective evidence that specified requirements have been met.