QSE 1 – Organization

Key Concepts

This quality system essential (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.

Key Terms

Customer: The recipient 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 a location or operational area within that organization; the entity assessed by the AABB and receiving AABB accreditation for specific activities.

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 Management System: The organizational structure, responsibilities, policies, processes, procedures, and resources established by executive management to achieve quality.

Examples of Objective Evidence

- Policies, processes, and procedures related to this chapter.
- Organizational charts or documents describing roles, responsibilities, and decision-making authority.
- Evidence of executive management review of a quality system.
- Applicable federal, national, state, and local laws and regulations, as well as copies of any required certificates.
- Defined quality system.
- Process for approving exceptions to policies, processes, and procedures, as well as documented examples, if applicable.
- Risk assessments and mitigation strategies.
- Emergency operation and disaster continuity plan(s).
- Executive management review of customer feedback.

1. Organization

1.0 Organization

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

Guidance

The primary purpose of this chapter is to ensure that a facility has statements of quality goals or objectives and that all parties involved in activities that affect quality understand these goals and objectives of the organization and their responsibility in fulfilling them. Another purpose is to ensure that management at the highest level of the facility is ultimately responsible and accountable for quality in the activities covered by the *BB/TS Standards*. Standard 1.0 requires that there be a structure that clearly identifies the parties who are responsible for providing blood bank/transfusion service activities covered by the *BB/TS Standards*. It also requires that the relationship of individuals who are responsible for key quality functions be defined. Each facility must evaluate and identify key quality functions within its own organization. An organizational chart would be one example of meeting this standard.

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 *BB/TS Standards* and applicable laws and regulations, including all applicable current good manufacturing practice (cGMP) requirements.
3) Authority to establish or make changes to the quality system.

Guidance

Although others in the facility may be more involved in carrying out the quality system, executive management is ultimately responsible and accountable for the quality of the activities covered by these *BB/TS Standards*. Executive management of the facility should take a visible role in supporting and implementing the quality system throughout the facility. Executive management is defined as the highest-level personnel within an organization, including employees who have responsibility for the operations of the organization and who have the authority to establish or change the organization's quality policy. Depending on the size and complexity of the facility, executive management may consist of only the facility supervisor, or a group consisting of the facility supervisor, an operations executive, customer service representatives, risk assessment managers, and representatives from other areas deemed appropriate by the facility. The facility must define the structure of executive management in its policies.

1.1.1 Medical Director Qualifications and Responsibilities

The blood bank or transfusion service (hereinafter referred to as the BB/TS) shall have a medical director who is a licensed physician, qualified by training, experience, and facility-defined relevant continuing education in activities required by these *BB/TS Standards* for which the facility is accredited. The medical director shall have responsibility and authority for all medical and technical policies, processes, and procedures—including those that pertain to laboratory personnel, operations, quality, and test performance—and for the consultative and support services that relate to the care and safety

of donors and/or transfusion recipients. The medical director may delegate these responsibilities to another qualified physician; however, the medical director shall retain ultimate responsibility for medical director duties.*

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.

Guidance

Standard 1.2 requires that each BB/TS have a quality system. Implicit in this requirement are development, documentation, and ongoing maintenance of the quality system. The quality system must, at a minimum, address the elements identified in Chapters 1 through 10 of the *BB/TS Standards*. A quality system consists of the policies, processes, and procedures that affect the quality of products, services, or reports. All requirements contained in *BB/TS Standards* can be assumed to affect quality. If the facility is a stand-alone facility (ie, functions independently from a hospital), it is expected to have its own quality system. If the facility is one of several operating departments or divisions in an AABB-accredited organization, such as a blood center, there is often a quality system that applies to all services, which would include the facility. Facilities currently implementing a quality system that satisfies AABB requirements can be assured that the requirements of this section are met.

1.2.1 Quality Representative

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

Guidance

Standard 1.2.1 requires that there be a designated individual within the organization who oversees quality system implementation. The designated individual may have other responsibilities, and ideally, they will not assess activities for which they are responsible. The individual designated to oversee the quality function must report to executive management; exercise control in all matters relating to compliance with these *BB/TS Standards* and federal, state, and local regulations; and have authority to recommend corrective action when it is appropriate.

1.2.2 Management Reviews

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

Guidance

Effectiveness of the quality system should be monitored through a documented program of internal and/or external audits with a schedule of activities described and appropriate follow-up and corrective actions. Management review should include all elements of the quality system; for example, emergency preparedness, training effectiveness, equipment issues, supplier and customer issues, quality control (QC), donor and patient adverse events, nonconformances, internal and external audits and assess-

*21 CFR 630.3(i), 42 CFR 493.1251, 42 CFR 493.1407, and 42 CFR 493.1445.

For accredited facilities that are assessed by AABB for conformance with the Clinical Laboratory Improvement Amendments (CLIA), refer to the Verification of CLIA Compliance Form before on-site assessment.

ments, process improvement, and facility issues. The format and frequency of management review should be determined by the facility. The review may take the form of a periodic (eg, quarterly) formal presentation to executive management, an annual formal report, or a compilation of ongoing reviews performed as part of daily/weekly monitoring.

✎ **1.3 Policies, Processes, and Procedures**

Policies, processes, and procedures shall be implemented and maintained to satisfy the applicable requirements of these *BB/TS Standards*. All such policies, processes, and procedures shall be in writing or captured electronically and shall be followed.

G u i d a n c e

Standard 1.3 requires that the facility develop and implement written quality and operational policies, processes, and procedures.

A **policy** is a documented general principle that guides present and future decisions. Policies are often generated as a result of standards, regulations, or an organization's "rules." A mission statement is generally understood to be at the level of a policy. A policy might also be a generally articulated "rule," such as a no-smoking policy.

A **process** is a description of a specific work goal and defines what is done and who does it. Processes are larger and more complicated activities than procedures. Processes usually involve more than one person, and often more than one department or work area within a facility. The responsibility of a particular person within a process may or may not involve performing a specific procedure. Although most facilities have documented their procedures, documentation of processes is less prevalent. A common way to describe a process in writing is by using a flow diagram with interconnected steps and branch points. Processes may also be described in tables or a narrative format. Documentation of all processes is required by Standard 1.3.

A **procedure** is a series of simple tasks that complete one piece of work. When written down, the procedure serves as a set of work instructions. Procedures typically are performed by one person, from beginning to end. Instructions for screening donors, performing phlebotomies, packing blood components, separating or filtering products, ABO/D typing, performing an adsorption, Donath-Landsteiner testing, and determining antibody titers are examples of procedures.

A way to think about the distinction among a policy, a process, and a procedure is that:

- Policies are rules.
- Processes are what we do.
- Procedures are how we do things.

1.3.1 The medical director and/or laboratory director (as applicable) shall approve all medical and technical policies, processes, and procedures. Standard 1.1.1 applies.*

✎ **1.3.2** Any exceptions to medical and technical policies, processes, and procedures shall require justification and preapproval by the medical director and/or laboratory director, as applicable. Standard 1.1.1 applies.*

*42 CFR 493.1251(d), 42 CFR 493.1407, and 42 CFR 493.1445.

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1.4 Risk Assessment

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

Guidance

This standard addresses the need for a facility to have a process in place for performance and review of risk assessments to evaluate the impact of any changes to critical tasks, materials, equipment, and personnel on the quality and safety of products and services. Risk assessment identifies factors that can contribute to outcomes other than those desired. Risk assessments are considered an essential element of change control processes, deviation management, developing corrective and preventive action plans as outcomes of reported events and audits, and general process improvement implementations. A risk assessment should be performed when implementing new processes. Mitigations should be incorporated into the processes to address identified risks. Mitigations can be prioritized for risks that are anticipated to have a high likelihood of occurrence or a potential high severity of harm. The effectiveness of mitigation strategies should be assessed through monitoring of deviations, incidents, nonconformances, and complaints, and/or by prospective audits. Risk assessments should be documented. The format, frequency, review, and assessment of risk evaluations should be determined by the facility.

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

1.5 Operational Continuity

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

Guidance

"Operational continuity" refers to the means of ensuring critical functions continue in settings that may hamper the ability to carry out those functions. This element of review is a key aspect of resolution and planning for individual organizations. The situations that would be covered by each facility would be different based on size, location, and scope of work. It should be noted that operational continuity would occur not only in the setting of a "disaster." For example, if 1) a key employee left a facility without notice and there was no immediate backup to perform their functions, 2) a critical piece of equipment were to fail, or 3) a facility is sold to another entity, there are policies, processes, and procedures in place to ensure critical operations function at a level needed to maintain key quality metrics.

It is not expected that a facility can anticipate every possible risk; however, standard operating procedures (SOPs) can be developed to address known common risks as well as procedures for unspecified, more unusual situations.

1.5.1 The BB/TS shall have a policy to address product inventory shortages.

Guidance

The policy should include strategies for addressing acute or short-term product shortages, as well as those that may be protracted and affecting a large portion of the industry (eg, limited availability of supplies or reagents as a result of disasters or recalls, changes in donor eligibility criteria, or implementation of new testing). The policy should include the identification and communication methods to include all