# 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.

**G u i d a n c e**

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 program is ultimately responsible and accountable for quality in the activities covered by these *CT Standards*.

Standard 1.0 requires that there be a structure that clearly identifies the parties who are responsible for providing cellular therapy products covered by the *CT Standards*. It also requires that the relationship of individuals who are responsible for key quality functions be defined. Each program 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 *CT 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.

**G u i d a n c e**

Although others in the facility may be more involved in implementing the quality system, executive management is ultimately responsible and accountable for the quality of the activities covered by these *CT Standards*. Executive management of the facility should have an understanding of the scope of activities performed and what laws and regulations are applicable to those activities. Executive management must then have a visible role in supporting and implementing the quality system throughout the facility that ensures adherence to those requirements. Executive management is defined as the highest-level personnel within an organization, including employees who have responsibility for the organization's operations 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 laboratory director or may involve 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.

Executive management also holds ultimate responsibility for implementation of a plan or policy for management of information technology (IT) systems at the organization, pertaining to IT systems and equipment owned by the organization or on its network, including servers and equipment systems connected through a wired or wireless connection, or a virtual private network (VPN) connection. The plan should address policies for network monitoring, malware protection, password and network management,

remote access, server and workstation security, access authorization and termination, and secured disposal of retired IT equipment or devices.

**1.1.1** The facility shall demonstrate institutional support for the cellular therapy program.

**Guidance**

Good quality practices come from the top levels of executive management all the way down to personnel who perform, verify, and manage daily operations. Institutional support is necessary for a successful cellular therapy (CT) program; all of the human and financial resources needed to operate in compliance with the *CT Standards* should be provided. Safety of products and quality care for donors and recipients are essential for improved patient outcomes.

Standard 10.0 is also relevant, which indicates the facility should establish and maintain policies, processes, systems, and procedures designed to minimize risks to the health and safety of employees, donors, patients, volunteers, and other persons affected within the work environment. This includes having the institutional support needed to provide suitable quarters, environment, and equipment in order to maintain safe operations, and periodic evaluation to ensure ongoing functionality and adequacy. Objective evidence that the facility is meeting this standard could include the results of all recent audits by accreditors or regulatory agencies such as the US Food and Drug Administration (FDA) or Occupational Safety and Health Administration (OSHA). Additional subjective evidence could include executive management's participation in CT program meetings and data review of results of internal audits.

**1.1.2** The facility shall register for all applicable products and activities with the Food and Drug Administration (FDA) or relevant Competent Authority. When applicable, the facility shall obtain regulatory approval for all products and activities.

**Guidance**

This standard acknowledges that regulation of cell therapy products may differ by country or region. The facility is responsible for identifying the relevant regulatory agency or Competent Authority and for understanding applicable regulations and mechanisms for obtaining approval. For example, this involves evaluation of how unmanipulated, minimally manipulated, or more-than-minimally manipulated products, and products intended for autologous or allogeneic use, may be regulated differently. Generally, facilities that house activities related to any aspect of cell therapy activity (eg, procurement, processing, storage, and distribution) will be expected to be registered with relevant authorities. AABB accreditation does not replace the requirement to obtain regulatory approval where warranted.

**1.1.3** **Procurement Facilities**
The procurement facility shall have a medical director who is responsible for ensuring that the determination of donor eligibility and medical suitability was performed, when applicable.

**Guidance**

The medical director is required to participate in the development of policies, processes, and procedures related to the procurement facility. These policies and procedures should include medical director involvement with reports of adverse events, reporting to required authorities, and donor eligibility.

**1.1.3.1 Procurement Medical Director**

The procurement medical director shall be a member of executive management and shall be a licensed physician with relevant experience, and qualified by training. The procurement medical director shall participate in continuing education relevant to the activities performed by the facility as required by these *CT Standards*. The procurement medical director shall have ultimate responsibility and authority for medical activities related to the procurement of cellular therapy products and related services. When the medical director delegates these responsibilities to another qualified medical professional (designee), the medical director shall retain ultimate responsibility.

**G u i d a n c e**

Continuing education (CE) refers to adult learning and training after a degree of higher education has been granted. CE consists of educational activities that serve to enhance professional development by maintaining, developing, or increasing the knowledge and skills of an individual relevant to the responsibilities of the position. CE is a critical component of maintaining competence. Proof or evidence of this education should be provided along with a certificate of attendance *and* the actual number of contact hours spent learning or training.

**1.1.3.1.1** The procurement medical director shall have at least 1 year of experience in the scope of procurement activities performed by that facility.

**G u i d a n c e**

The facility should define how the medical director will gain this experience to ensure the individual will be able to take on the responsibility of the position and maintain ongoing competency, whether it is by a combination of direct observation, record review, and participation in after-action reviews or by some other means. Proof or evidence of this experience should be provided. Examples of how this can be accomplished include real-world experiences such as shadowing of experienced personnel performing critical procedures, simulation training for hands-on experience, and participating in after-action reviews and regular review of records so that a medical director can anticipate common issues and how those issues may be resolved as part of risk management and corrective and preventive action. These types of activities to gain experience coupled with maintaining competency reinforce accountability of the director.

*C* **1.1.3.1.2** The procurement medical director shall have actively managed and reviewed a minimum of 10 cell product procurement procedures throughout the preceding 2-year accreditation cycle.

**G u i d a n c e**

The minimum of 10 product procurement procedures to be overseen includes at least one for each activity performed by the facility over the accreditation cycle. If a procedure occurs relatively rarely, the medical director may oversee the procedure(s) performed by the staff to maintain competency. Such procedures should be identified in a standard operating procedure (SOP) and should be documented. The objective is to ensure the medical director is engaged in the management and review process of

activities for which the facility is covered. Examples of active management for a procurement medical director may include direct involvement in donor eligibility determination to ensure criteria are met, overseeing the procurement of material from a donor to ensure procedures are followed, and review and management of a process deviation and implementation of corrective actions.

### 1.1.4 Processing Facilities

The processing facility shall have a laboratory medical director and a laboratory director who will ultimately be responsible for the processing, storage, and/or provision of the product under their responsibilities.

#### 1.1.4.1 Laboratory Medical Director

The laboratory medical director(s) shall be a member of executive management and shall be a licensed physician with relevant experience, and qualified by training. The processing laboratory medical director shall participate in continuing education in activities performed by the facility as required by these *CT Standards*. The laboratory medical director(s) shall have responsibility and authority for medical activities related to the processing and provision of cellular therapy products and related services. When the medical director delegates these responsibilities to another qualified medical professional (designee), the medical director shall retain ultimate responsibility.*

**Guidance**

The purpose of these standards is to ensure that the laboratory medical director can delegate their responsibilities to a designee even though the laboratory medical director retains ultimate responsibility. The standards do not explicitly stipulate whether the designee must have either a doctoral degree or a physician's license; however, relevant standards in Chapter 2, Resources, would apply. For example, Standards 2.1.1 and 2.1.2 require the facility to identify job qualifications based on education, training, and/or experience. Standard 2.1.3 requires the facility to establish policies for training all personnel. Also, initial and annual competency evaluations must be performed for defined tasks and activities (Standard 2.1.4), as well as relevant continuing education (CE) for all relevant employees (Standard 2.1.6). Therefore, the facility should define in written policies what training, competency, and CE the designee needs to have documented and how the facility determines that the designee has the appropriate qualifications.

Also, there must be written documentation of the actual training, competence, and CE on file for the designee in addition to the laboratory medical director. One example of a situation in which the designee may not need a doctoral degree or physician's license is when the laboratory medical director has already approved policies that define the acceptable criteria for the release of cell therapy products. Then, when the release criteria are met for a product before distribution, a nonphysician individual with documentation of qualifications, training, competency, and CE may be delegated as designee for that review step, as long as the release criteria are met.

Alternatively, some situations require the same type of physician's license for a designee, such as when the procuring facility must obtain a physician's order before the procurement procedure. In order to meet this standard, any designee should be a physician with documentation of relevant and appropriate

*42 CFR 493.1405, 42 CFR 493.1407, 42 CFR 493.1443, and 42 CFR 49.1445.
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.

qualifications, training, competency, and CE that makes them qualified to write a physician's order for procurement.

CE refers to adult learning and training after a degree of higher education has been granted. CE consists of educational activities that serve to enhance professional development by maintaining, developing, or increasing the knowledge and skills of an individual relevant to the responsibilities of the position. CE is a critical component of maintaining competence. Proof or evidence of this education should be provided along with a certificate of attendance *and* the actual number of contact hours spent learning or training.

**1.1.4.1.1** The laboratory medical director shall have at least 1 year of experience in the scope of processing activities performed by the facility.*

**Guidance**

The facility should define how the laboratory medical director will gain this experience to ensure the individual will be able to take on the responsibility of the position and maintain ongoing competency, whether it is by a combination of direct observation, record review, and participation in after-action reviews or by some other means. Proof or evidence of this experience should be provided. See guidance to Standard 1.1.3.1.1.

*C* **1.1.4.1.2** The laboratory medical director shall have actively managed or reviewed a minimum of 10 cell product processing procedures throughout the preceding 2-year accreditation cycle.

**Guidance**

The laboratory medical director has to have overseen a minimum of 10 product processing procedures, including at least one for each activity performed by the facility over the term of its accreditation cycle. If a procedure occurs relatively rarely, the medical director may oversee the procedure(s) performed by the staff to maintain competency. Such procedures should be identified in SOPs and should be documented. See guidance to Standard 1.1.4.2.

**1.1.4.2 Laboratory Director**

The laboratory director shall be a member of executive management and have a relevant doctoral degree, with relevant experience, and who is qualified by training. The laboratory director shall participate in continuing education for the specific cellular therapy products being produced. The laboratory director shall be responsible for all technical aspects of the facility that are related to the processing and provision of cellular therapy products and services under these *CT Standards*. When the laboratory director delegates these responsibilities to a designee, the laboratory director shall retain ultimate responsibility.†

*42 CFR 493.1443.
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