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.

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.

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

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.

1.1.3 Procurement Facilities

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

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 responsibility and authority for the scope of accredited medical activities related to the procurement of cellular therapy products and services under these *CT Standards.* When the medical director delegates these responsibilities to another qualified medical professional (designee), the medical director shall retain ultimate responsibility.

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.

C **1.1.3.1.2** The procurement medical director shall have had active oversight of a minimum of 10 cell product procurement procedures related to their scope of responsibilities throughout the preceding 2-year accreditation cycle. Standard 2.1.2 applies.

1.1.4 Processing Facilities

The processing facility shall have a laboratory medical director and a laboratory director who will 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 the scope of accredited medical activities related to the processing and provision of cellular therapy products and services under these *CT Standards*. When the medical director delegates these responsibilities to another qualified medical professional (designee), the medical director shall retain ultimate responsibility.*

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.†

C **1.1.4.1.2** The laboratory medical director shall have had active oversight of a minimum

*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.
†42 CFR 493.1443.
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