
QSE 10 – Facilities and Safety

Key Concepts

This QSE addresses the safety and adequacy of areas where the work required by these *CGT Standards* is performed. This includes occupational safety, biohazardous material 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.

Examples of Objective Evidence

- Policies, processes, and procedures related to this chapter.
- Safe environmental conditions for all individuals in the organization.
- Local, state, and national regulations being followed.
- Proper disposal of hazardous and potentially hazardous materials.
- Personal protective equipment (PPE) is available and in use.

10. Facilities and Safety

10.0 Facilities and Safety

The organization shall ensure safe environmental conditions. The work area shall be suitable for the activities performed. Safety programs shall meet local, state, and national regulations.

Guidance

This standard requires that the facility ensure safe and adequate environmental conditions in the workplace. Specifically, this standard requires that the facility have a program that is designed to minimize risks to the health and safety of its employees, donors, volunteers, and patients. Implicit in this standard is the requirement that suitable quarters, environment, and equipment be available to maintain safe operations. The standard specifically requires processes for biological, chemical, and radiation safety, where applicable, as well as a system for monitoring training and compliance with those processes.

The standard also requires that products be handled and disposed of in a manner that is designed to prevent the potential for human exposure to infectious agents. Documentation of disposal of unused products should be maintained.

10.1 Safe Environment

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

10.1.1 Policies, processes, and procedures shall identify and address the hazards present in the facility—including biological, chemical, and, where applicable, radiation safety—and appropriate intervention to limit exposure. The facility shall maintain a system for monitoring training and compliance.

10.1.1.1 The facility shall post signage reflecting the hazards present that pose a risk to health and safety.

Guidance

Adverse health effects begin when the oxygen level of air reaches “oxygen-deficient” levels of below 19.5% oxygen. Between 16% and 19.5%, symptoms can include increased breathing rates, accelerated heartbeat, impaired thinking, and poor coordination.

To be effective, the system should monitor continuously and activate both audible and visual alarms under conditions that will allow action to be taken before adverse consequences to humans in the area.

Refer to regulations defined by the local Competent Authority.

10.1.2 Biohazardous or hazardous materials shall be handled and/or disposed of according to safety data sheets, in a manner that minimizes the potential for human and environmental exposure to infectious agents.

10.1.3 Where liquid nitrogen is present, specific hazards shall be addressed. Standard 2.1.3 applies.

10.1.3.1 The facility shall have a system in place to monitor oxygen levels and an alarm system set to activate under conditions that will allow action to be taken.



10.1.3.1.1 Alarm activation shall require personnel to investigate and document the condition activating the alarm and to take immediate corrective action as necessary.



10.2 Biological, Chemical, and Radiation Safety

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



10.3 Handling and Disposing of Biological Materials

Biological materials shall be handled and/or disposed of in a manner that minimizes the potential for human and/or environmental exposure to biohazardous agents and in keeping with the relevant Competent Authority requirements.

10.4 General Operational Controls

Access to facilities used for dispensing shall be limited to authorized individuals.