
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.

10.1.3.1 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.

Excerpt of Reference Standard 6.2.9A Relevant to Facilities and Safety

Standard	Record to Be Maintained	Minimum Retention Time (Years)*
10.1.3.1.1	Alarm investigation	2
10.2	Monitoring of biological, chemical, and radiation safety	2
10.3	Appropriate disposal of CGT products	2

*Applicable federal, state, or local law may exceed this period.