

QSE Organization and Leadership (OR)—Gap Analysis Tool

Use this gap analysis tool to help assess the status of your current QSE Organization and Leadership initiatives.

Gap Analysis Element		Status					
		0%	≈ 20%	≈ 40%	≈ 60%	≈ 80%	≈ 100%
OR-01	Laboratory leadership has set the expectation that quality is the laboratory’s foundation for work performed and has defined the scope of applicability of the QMS. Comments:						
OR-02	Laboratory leadership has accepted responsibility for the design, implementation, maintenance, and improvement of the QMS. Comments:						
OR-03	Laboratory leadership has a process to develop, implement, and maintain a quality policy, which includes at minimum: <ul style="list-style-type: none"> • Scope of service the laboratory intends to provide to meet customer expectations • Laboratory’s commitment to ethical practice • Laboratory’s commitment to good professional practice • Quality of laboratory examinations • Compliance with the laboratory’s QMS Comments:						
OR-04	The laboratory has a process to train laboratory personnel on ethics. Comments:						

QSE Customer Focus (CF)—Gap Analysis Tool

Use this gap analysis tool to help assess the status of your current QSE Customer Focus initiatives.

Gap Analysis Element		Status					
		0%	≈ 20%	≈ 40%	≈ 60%	≈ 80%	≈ 100%
CF-01	The laboratory has identified its external and internal customers to include: <ul style="list-style-type: none"> • Physicians • Other health care professionals • Other organizational departments • Patients and/or their advocates • Other laboratories • Other organizations for which it provides services (eg, nursing homes) • Personnel Comments:						
CF-02	The laboratory has a process to determine the expectations of its external customers (eg, physicians, other laboratories, patients) for elements such as: <ul style="list-style-type: none"> • Examinations and examination frequency • Collection and transport of samples • Desired turnaround times • Mechanisms for reporting results, including critical values • Consultation needs • Patient wait times Comments:						

QSE Facilities and Safety Management (FS)—Gap Analysis Tool

Use this gap analysis tool to help assess the status of your current QSE Facilities and Safety Management initiatives.

Gap Analysis Element		Status					
		0%	≈ 20%	≈ 40%	≈ 60%	≈ 80%	≈ 100%
FS-01	<p>The laboratory has assessed its needs and resources, and space has been allocated with consideration given to each of the following:</p> <ul style="list-style-type: none"> • Comfort, privacy, and facility access for all persons, including accommodation for those with disabilities • Protection of patients, personnel, and visitors from recognized safety hazards • Unidirectional workflow, where applicable • Separation of work areas to minimize contamination, laboratory errors, or other incompatibilities (eg, noise, interruptions, temperature, vibration) • Design for adequate emergency systems that meet applicable requirements (eg, placement of eye washes, sinks, fire extinguishers, evacuation routes, emergency power supply) • Safe and adequate building utilities (eg, energy sources, lighting, temperature control, ventilation, water, waste disposal) • Adequate storage that meets required environmental conditions (eg, temperature, humidity, biosecurity) for samples, slides, histology blocks, retained microorganisms, equipment, reagents, laboratory supplies, documents, files, manuals, records, and results • Adequate information technology infrastructure to meet the needs of the laboratory and its customers <p>Comments:</p>						
FS-02	<p>The organization or laboratory maintains a process to design and modify facilities.</p> <p>Comments:</p>						