

Quality-Specific Communication Skills

Definition: Skills and concepts used to convey information about a quality management system (QMS).

Level 4 Competency: Apply quality-specific communication approaches.

1. Level 5 Competency: Structure communication style to fulfill quality objectives.

Based on Level 5 competency – Not an all-inclusive list

BEHAVIORAL ANCHORS

1. The quality manager can incorporate a communication style that achieves quality objectives.
 - a. Shared information is organized with care
 - i. Uphold customer requirements
 - ii. Withhold confidential data until authorized to release
 - iii. Correct recipient(s)
 - b. Awareness of tone, body language and other non-verbal cues
 - c. Neutral language
 - d. Electronic transmissions meet quality requirements
 - e. Social media pros and cons
 - f. Maintain professionalism
 - g. Timing
 - h. Knowing when to withhold opinions/interpretations
 - i. Review information before distributing
 - i. Subject to pen records laws, such as Freedom of Information Act (FOIA).

2. Level 5 Competency: Apply communication tools to support quality objectives.

Based on Level 5 competency – Not an all-inclusive list

BEHAVIORAL ANCHORS

1. The quality manager can organize multiple sources of information to meet quality requirements.
 - a. Compile
 - b. Distribute
 - c. Retain
 - d. Retrieve.
2. The quality manager can schedule a laboratory quality meeting.

- a. Record attendance
 - b. Encourage participation from all
 - c. Manage time
 - d. Assign continuous improvement activities
 - e. Record critical information (objective evidence).
3. The quality manager can prepare communications in response to changes in laboratory requirements:
- a. Document control: Standard Operating Procedures (SOPs), forms, job aids, and reference documents
 - b. Quality checklists
 - c. Change in policy or regulation (agency, state, or federal)
 - d. Update quality standard with a newer version.
4. The quality manager can distinguish quality matters in the laboratory by active listening.
- a. Individuals feel they have been understood
 - b. Ask questions for clarification
 - c. Confirm understanding
 - d. Give full attention
 - e. Differentiate fact from opinion
 - f. Respond appropriately.

Quality-Specific Management Skills

Definition: Strategies to oversee quality requirements.

Level 4 Competency: Discuss oversight activities to accomplish quality management objectives.

1. Level 5 Competency: Describe the components of a QMS.

Based on Level 5 competency – Not an all-inclusive list

BEHAVIORAL ANCHORS

1. The quality manager can characterize each component of the laboratory quality system.
- a. Documents and records
 - i. SOPs
 - ii. Job aids

- iii. Document control
 - iv. Quality manual
 - v. Quality policy
- b. Organizational structure
 - i. Quality culture
 - ii. Resources
 - iii. Organizational chart
- c. Personnel
 - i. Follow procedures
 - ii. Hiring requirements
 - iii. Notification of duties, responsibilities, and authorities
 - iv. Training classes
 - v. Training requirements
 - vi. Competency verification
 - vii. Employee code of conduct training
 - viii. Ethics training
 - ix. Staff qualifications
 - 1. Recruitment (education, experience)
 - 2. Training
 - 3. Skills
 - 4. Certification/licensure
- d. Equipment
 - i. Maintenance
 - ii. Calibration
 - iii. Acquisition
 - iv. Qualifications plan
 - v. Decommissioning
- e. Purchasing
 - i. Procurement
 - ii. Inventory
 - iii. Evaluation
- f. Information management
 - i. Confidentiality
 - ii. Security
 - iii. Information integrity
- g. Occurrence management

- i. Nonconformances
 - ii. Laboratory environmental requirements
- h. Process control
 - i. Sample receipt
 - 1. Chain of custody
 - 2. Sample handling
 - 3. Sample collection
 - ii. Sample testing
 - 1. Traceability
 - 2. Verification and validation
 - 3. Measurement of uncertainty
 - 4. Quality control (QC)
 - iii. Reporting
 - 1. Root cause and corrective action
 - 2. Participate in root cause discussions
- i. Assessment
 - i. External and internal audits
 - ii. Proficiency testing
 - iii. Quality indicators
 - iv. Quality measures
- j. Process improvement
 - i. Constant improvement cycle
 - ii. Change management
 - iii. Management review
 - iv. Preventive actions
 - v. Opportunities for improvement
- k. Customer service and satisfaction
 - i. Customer feedback
 - ii. Meeting customer expectations
 - iii. Service standards
- l. Facilities and Safety
 - i. Workplace safety
 - ii. Waste management
 - iii. Emergency management
 - iv. Laboratory design.

2. Level 5 Competency: Discuss approaches for meeting quality expectations.

Based on Level 5 competency – Not an all-inclusive list

BEHAVIORAL ANCHORS

1. The quality manager can create a quality manual.
 - a. Policies/procedures (e.g., document control, analytical testing, occurrence management, sample collection, sample accessioning, chain of custody, reporting)
 - i. Initiate
 - ii. Review
 - iii. Approve
 - iv. Update
 - b. Define quality elements.
 - i. Say what we do, do what we say
 - ii. Write a quality policy
 - iii. Define quality control (QC)
 - iv. Define quality assurance (QA).
 - c. Identify roles and responsibilities
 - i. Staff roles
 - ii. Demonstrate commitment of upper management to the QMS.
2. The quality manager can describe how the laboratory integrates quality into their processes.
 - a. Domains of the quality system that apply to laboratory activities
 - b. Range of testing activities from sample receipt to sample disposal
 - c. Generate objective evidence that is critical to the quality of test results
 - d. Continuous operation of the QMS to maintain accreditation.
3. The quality manager can collaborate in laboratory strategic planning.
4. The quality manager can prepare to add methods to the scope of accreditation.
5. The quality manager can act on identified gaps.
 - a. Recommend updates to infrastructure
 - b. Formulate input on laboratory purchases
 - c. Edit written procedures to include improvements
 - d. Assign quality improvement tasks to others
 - e. Perform quality training.

3. Level 5 Competency: Ensure laboratory personnel implement strategies to meet regulations, standards, and programs (RSP) requirements.

Based on Level 5 competency – Not an all-inclusive list

BEHAVIORAL ANCHORS

1. The quality manager can verify that laboratory personnel comply with administrative requirements for testing.
 - a. Clinical Laboratory Improvement Amendments (CLIA) licensure, certification maintenance
 - b. Select Agent Alternate Responsible Official (ARO)
 - c. Security clearance/background check
 - d. Certification
 - e. Continuing education
 - f. Financial disclosures required by state.
2. The quality manager can verify compliance to laboratory safety requirements:
 - a. To the extent auditable to the QMS
 - b. To ensure appropriate environmental conditions and facilities for testing activities
 - c. To ensure compliance to applicable federal and state requirements
 - i. Bloodborne pathogens
 - ii. Biosafety officer
 - iii. Chemical safety officer
 - iv. Occupational Safety and Health Administration (OSHA) requirements
 1. Right to know law
 2. Use of respirators
 3. Hazard communication – globally harmonized system.
 - v. Emergency evacuations
 - vi. Active Shooter.
3. The quality manager can evaluate safety during sample disposal.
 - a. To the extent auditable to the QMS
 - b. Personal protective equipment is donned and used where required by the method or other authority
 - c. Materials submitted to appropriate area (hazardous waste, autoclave, etc.)
 - d. Waste directed to an appropriate area (hazardous waste, autoclave, etc.)
 - e. Sample disposal which are hazardous are disposed according to chemical hygiene requirements
 - f. Disposal of controlled substances.
4. The quality manager can verify compliance to laboratory waste management requirements.
 - a. To the extent auditable to the QMS
 - b. To ensure compliance to applicable federal and state requirements.

Quality-Specific Leadership Skills

Definition: Strategies to promote a culture of quality in the laboratory.

Level 4 Competency: Apply leadership practices in support of a laboratory QMS.

1. **Level 5 Competency:** Discuss how professional organizations are a resource to expand the capabilities of the quality manager.

Based on Level 5 competency – Not an all-inclusive list

BEHAVIORAL ANCHORS

1. The quality manager can choose to participate in extramural quality activities for professional development.
 - a. Create or update a quality management resource for laboratories
2. The quality manager can act on training opportunities provided by professional organizations [e.g., A2LA Tech Forum, American Society for Quality (ASQ)].
3. The quality manager can incorporate resources from partners (methods, guidelines, discussion forums, communication platforms, standards, technical information, informal data sharing, grants, etc.) to meet quality objectives.
4. The quality manager can uncover professional development opportunities available from professional organizations.
 - a. Subscribe to Listservs, email distribution lists
 - b. Maintain relationships with customers, accrediting body, state and federal partners
 - c. Network with quality professionals.

2. **Level 5 Competency:** Convey a quality-minded culture in the workplace.

Based on Level 5 competency – Not an all-inclusive list

BEHAVIORAL ANCHORS

1. The quality manager can make quality a high priority for the laboratory team.
2. The quality manager can point out the efforts of others to maintain accreditation.
3. The quality manager can focus on a culture of quality.
 - a. Provides safe space to report incidents and near-misses
 - b. Advocate customer satisfaction
 - c. It's the process, not the person
 - d. Team-building activities
 - i. Replace working in isolation with teamwork
 - ii. Help others to recognize the benefits of quality management

- iii. Increase likelihood that critical information is shared with the Quality Manager
 - e. Celebrate accomplishments of quality champions
 - f. Facilitate staff to recognize their own strengths.
- 4. The quality manager can perform the functions of an ombudsman.
 - a. Listen when dissatisfaction is expressed
 - b. Remain nonjudgmental
 - c. Uphold confidentiality
 - d. Investigate complaints
 - e. Recommend solutions
 - f. Speak up when needed.
- 5. The quality manager can formulate QMS strategies to ensure continuous accreditation.

3. Level 5 Competency: Discuss how laboratory quality relates to public health initiatives.

Based on Level 5 competency – Not an all-inclusive list

BEHAVIORAL ANCHORS

- 1. The quality manager can relate pertinent quality principles to emergency response while operating under:
 - a. Incident Command System (ICS)
 - b. Continuity of Operations Plan (COOP)
 - c. One Health.
- 2. The quality manager can explain how quality management supports positive public health outcomes in a One Health approach.
 - a. Generation of actionable data in a timely manner
 - i. Support of outbreak investigations
 - ii. Routine surveillance
 - 1. Ongoing regulatory risk assessment
 - 2. Identify pathogen trends.
- 3. The quality manager can explain how quality management supports the Integrated Food Safety System.
 - a. Collaboration among regulatory partners
 - b. Expedite enforcement response to unsafe food commodities and products.