QUALITY ASSURANCE SPECIALIST/OFFICER LEARNING LADDER

Members of the APHL Laboratory Systems and Standards committee developed this quality manager learning ladder as a skills and training guide for those who are either new in their position or have been in the quality manager position for a few years. While this list is not all-encompassing, it can be used as a starting point. Laboratory quality professionals should consult with their supervisors to ensure they are receiving all the training they need for the skills related to their specific position at the public health laboratory.

ASSUMPTIONS

- **Laboratory Experience**
  The training ladder assumes individuals being hired already have some regulated laboratory experience, ideally three to five years. If that is not the case, the supervisor should reevaluate their new quality assurance employee's training plan and consider incorporating more basic laboratory-related activities, such as shadowing various testing sections, observing audits, watching training videos offered on CDC TRAIN and APHL.org, etc.

- **Quality Improvement Knowledge**
  It is also assumed that the individual has demonstrated knowledge of quality improvement concepts and processes through a quality improvement-related project, SOP, etc.

YEAR ONE

The quality assurance employee should have exposure, knowledge and/or familiarity with the following by the end of their first year in the position:

- ☐ External websites (regulatory, APHL, federal, etc.)
- ☐ Where regulatory or accreditation agency quality-related resources and tools are located online
- ☐ Internal websites
  - ☐ State, county, city, and organizational policies
  - ☐ Laboratory's quality policies
- ☐ Both organizational and laboratory-specific conflict-of-interest, data integrity, ethics rules
- ☐ Laboratory cycle: pre-analytical, analytical, post-analytical
- ☐ Laboratory's record retention policies (e.g., physical and electronic storage, storage process)
- ☐ Internal and external laboratory system partners (e.g., APHL's Laboratory System Improvement Program activities and reports)
- ☐ Laboratory's quality manual
- ☐ CLSI's Quality System Essentials (QSEs)
- ☐ Document control system
- ☐ Laboratory's paperless systems
- ☐ Observing the laboratory's internal audit process
- ☐ Tracking performance indicators
- ☐ Standard Operating Procedures (SOPs) requirements, structure, etc.
- ☐ Assisting with tracking related to proficiency and competency testing
- ☐ Assisting with non-conforming event reviews
- ☐ Assisting with conducting quality assurance training
- ☐ Participating in quality assurance listserv(s)

YEARS TWO TO FIVE

The quality assurance employee with two to five years of experience will have experience with the topics/trainings in the above section, but will be expected to learn about other specialized areas.

Areas of Specialization

- ☐ Leading the laboratory internal audits, including organizing, reporting, following-up
- ☐ Leading the laboratory's quality committee
- ☐ Participating in other committees and workgroups, such as the safety committee
- ☐ Writing summary reports, providing metrics and/or developing new performance indicators
- ☐ Leading the process of SOP writing, reviewing, editing
- ☐ Proficiency testing life cycle
- ☐ Competency testing life cycle, including verifying and/or helping the laboratory with the tracking
- ☐ Leading root cause analyses on non-conforming event audits
- ☐ Leading and performing quality assurance training for staff, and identifying training needs
- ☐ Leading 5S projects
- ☐ Consider completing certification on Lean Six Sigma or other quality-related training
- ☐ Participating in external training and/or meetings with laboratory system partners
- ☐ Leading the tracking documents, trends, corrective actions, and other quality data
- ☐ Participating in the budgeting and hiring process as requested
- ☐ Answering questions related to the laboratory's quality assurance policies and procedures

Suggested Training for Quality Assurance Managers

- ☐ APHL Laboratory Training Program
- ☐ Basic data integrity and ethics
- ☐ Problem-solving:
  - ☐ Root cause analysis
  - ☐ Non-conforming events
  - ☐ Coaching staff through problems
- ☐ Quality improvement and change management training:
  - ☐ Basic Lessons in Laboratory Quality Control: QC Workbook
  - ☐ Understanding Effective Public Health Laboratory Practices Across Generations
  - ☐ How to Write a Laboratory Quality Manual
  - ☐ Laboratory Internal Audit Plan
  - ☐ Crosswalk of Regulations And Guidance Affecting Laboratories—Sorted by QSE
  - ☐ Considerations for Maintaining Laboratory Quality During the COVID-19 Pandemic
  - ☐ CMS's Quality, Safety & Education Portal (QSEP)
  - ☐ Conducting Successful Audit Interviews
- ☐ Communication:
  - ☐ Coaching
  - ☐ Team communication
  - ☐ Writing
  - ☐ Meeting facilitation
  - ☐ Customer service, such as addressing internal and external partner needs, technical assistance, serving as a reference, etc.
  - ☐ How to have a difficult conversation
  - ☐ Emotional intelligence
  - ☐ Receiving feedback
  - ☐ Storytelling
- ☐ Mental health first aid or equivalent
- ☐ HIPAA and privacy requirements
- ☐ Incident command
- ☐ Regulations such as CLIA, CAP, TNI, etc.
- ☐ National and regional trainings from health and/or appropriate agencies

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