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Training and Competence Assessment; Approved Guideline—Third Edition

This document provides background information and recommended processes for the development of training and competence assessment programs that meet quality and regulatory objectives.

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.



Training and Competence Assessment; Approved Guideline—Third Edition

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Abstract

Clinical and Laboratory Standards Institute document GP21-A3—*Training and Competence Assessment; Approved Guideline—Third Edition* provides the necessary background information and processes to permit clinical services to develop training and competence assessment programs that will meet specific quality and regulatory objectives. To be effective, training must be built on a solid foundation of documented operations processes and procedures with accompanying training documents. The competence of staff to perform their respective assigned tasks needs to be assessed initially after training and periodically thereafter. This guideline provides a structured approach for using documented work processes, related procedures, training guides, and assessment tools for the development of training and competence assessment programs.

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Foreword

Increasing oversight by regulatory agencies, third-party payers, and the public has brought an intensified interest in the effects of quality, productivity, and competition to the delivery of health care services. Fundamental to all quality management systems is the development and delivery of training and competence assessment programs.

Regulatory and accreditation agencies—as well as international standards for quality management systems—require that the organization have policies, processes, and procedures for training. In addition, assessment of competence in job tasks is required. These requirements apply to all persons whose work can affect the quality of the organization’s product or service; where volunteers are used in this regard, the requirements apply to them, as well.

GP21-A3 will assist in the development of training and competence assessment programs to meet specific quality objectives in support of an organization’s mission statement. Standards for job performance are unique to each organization and are based on the competitive, economic, regulatory, and service environment in which the organization operates.

This guideline can be used by laboratories and health care organizations to ensure that training has taken place and is documented, and that the competence of personnel in their assigned job tasks is assessed initially after training and periodically thereafter. The recommendations contained herein are applicable when training new employees, introducing new processes or methods, assessing initial competence, and performing periodic reassessments of competence.

Important note: This document is a guideline and not a requirement, prepared at the request of health care professionals who needed direction on this subject. The sample forms included present one way of designing and documenting training and competence assessment, which fulfills regulatory and accreditation requirements and improves patient safety. However, health care services are free to use whatever means works for them to meet requirements.

Key Words

Assessment tools, competence assessment, flowcharting, procedures, processes, training assessment, training guides

Training and Competence Assessment; Approved Guideline—Third Edition

1 Scope

This guideline provides health care service personnel with a framework for:

- developing training in the processes and procedures that employees perform in their respective jobs; and
- designing assessment tools to verify that personnel are competent after initial training and periodically throughout employment.

2 Introduction

Quality management systems rely on effective training to ensure that employee performance results in consistent, predictable, and high-quality outcomes in the delivery of health services. In the present regulatory and quality environment, all training must be documented. Additionally, initial and periodic assessment of competence is required to verify that performance of assigned job tasks remains consistent.

Some level of medical error has been attributed to either training not being provided or provided training not being effective. Therefore, consistent, predictable, and high-quality outcomes in the delivery of health care services are possible only when health care personnel are appropriately trained.

Planned and systematic training and competence assessment processes are necessary to verify and document that personnel have, and can demonstrate, the necessary knowledge, skills, and behaviors to perform their respective duties. By defining the service's path of workflow, identifying work processes and procedures, and training employees in the processes and procedures of their jobs, the organization makes an important contribution to ensuring the quality of its services.

Figure 1 shows the sequence of events needed in developing successful training and competence assessment programs.

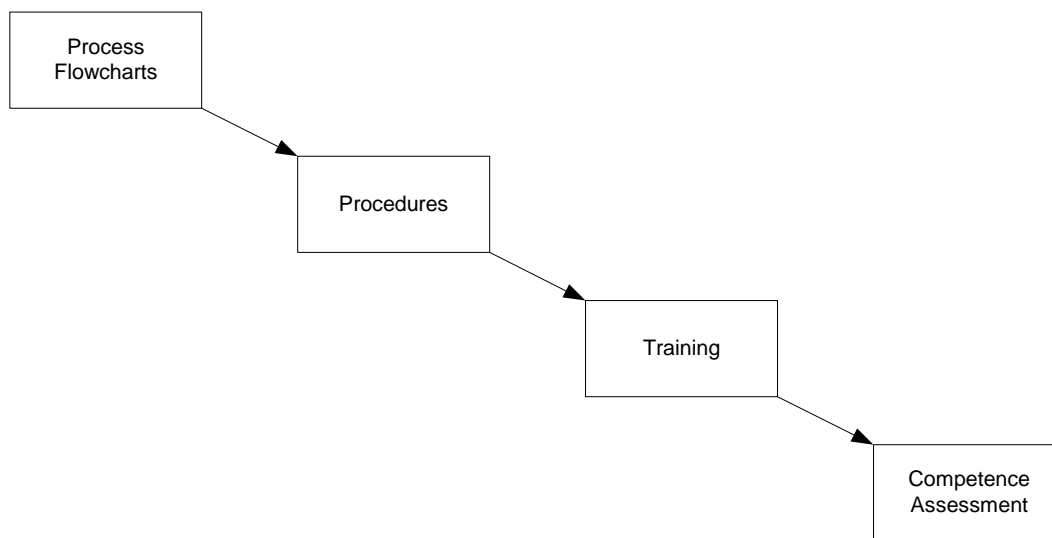


Figure 1. Sequence of Events for Developing Successful Training and Competence Assessment Programs

The Quality Management System Approach

Clinical and Laboratory Standards Institute (CLSI) subscribes to a quality management system approach in the development of standards and guidelines, which facilitates project management; defines a document structure via a template; and provides a process to identify needed documents. The approach is based on the model presented in the most current edition of CLSI/NCCLS document HS01—*A Quality Management System Model for Health Care*. The quality management system approach applies a core set of “quality system essentials” (QSEs), basic to any organization, to all operations in any health care service’s path of workflow (ie, operational aspects that define how a particular product or service is provided). The QSEs provide the framework for delivery of any type of product or service, serving as a manager’s guide. The QSEs are:

- | | | | |
|--|--|---|--|
| Documents & Records
Organization
Personnel | Equipment
Purchasing & Inventory
Process Control | Information Management
Occurrence Management
Assessments—External
& Internal | Process Improvement
Customer Service
Facilities & Safety |
|--|--|---|--|

GP21-A3 addresses the QSEs indicated by an “X.” For a description of the other documents listed in the grid, please refer to the Related CLSI Reference Materials section on the following page.

Documents & Records	Organization	Personnel	Equipment	Purchasing & Inventory	Process Control	Information Management	Occurrence Management	Assessments—External and Internal	Process Improvement	Customer Service	Facilities & Safety
GP02 GP26 HS01	GP26 HS01	X GP26 HS01	GP26 HS01	GP26 HS01	GP26 HS01	GP02 GP26 HS01	GP26 HS01	GP26 HS01	GP26 HS01	GP26 HS01	GP26 HS01

Adapted from CLSI/NCCLS document HS01—*A Quality Management System Model for Health Care*.

Related CLSI Reference Materials*

- GP02-A5** **Laboratory Documents: Development and Control; Approved Guideline—Fifth Edition (2006).** This document provides guidance on development, review, approval, management, and use of policy, process, and procedure documents in the medical laboratory community.
- GP26-A3** **Application of a Quality Management System Model for Laboratory Services; Approved Guideline—Third Edition (2004).** This guideline describes the clinical laboratory’s path of workflow and provides information for laboratory operations that will assist the laboratory in improving its processes and meeting government and accreditation requirements.
- HS01-A2** **A Quality Management System Model for Health Care; Approved Guideline—Second Edition (2004).** This document provides a model for providers of healthcare services that will assist with implementation and maintenance of effective quality management systems.

* Proposed-level documents are being advanced through the Clinical and Laboratory Standards Institute consensus process; therefore, readers should refer to the most current editions.