

Training and Competence Assessment; Approved Guideline—Second Edition



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

A guideline for global application developed through the NCCLS consensus process.



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Abstract

NCCLS document GP21-A2, *Training and Competence Assessment; Approved Guideline—Second 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. This guideline provides a structured approach for using documented processes, related procedures, training guides, and assessment tools for the development of training and competence assessment programs.

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Foreword

Increased examination by regulatory agencies, third-party payers, and the public has brought a renewed interest in quality, productivity, and competition to the delivery of healthcare services. Fundamental to all quality systems is the development of training and competence assessment programs.

All regulatory and accreditation agencies—as well as international standards for quality management systems—require that the organization have in place policies, processes, and procedures for training. In addition, in the U.S., assessment of competence in job tasks is required initially after training and periodically throughout employment. 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-A2—*Training and Competence Assessment; Approved Guideline—Second Edition*, 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 healthcare 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.

Key Words

Assessment tools, competence assessment, flow charting, procedures, processes, training guides

Training and Competence Assessment; Approved Guideline—Second Edition

1 Scope

This guideline provides healthcare 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.

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

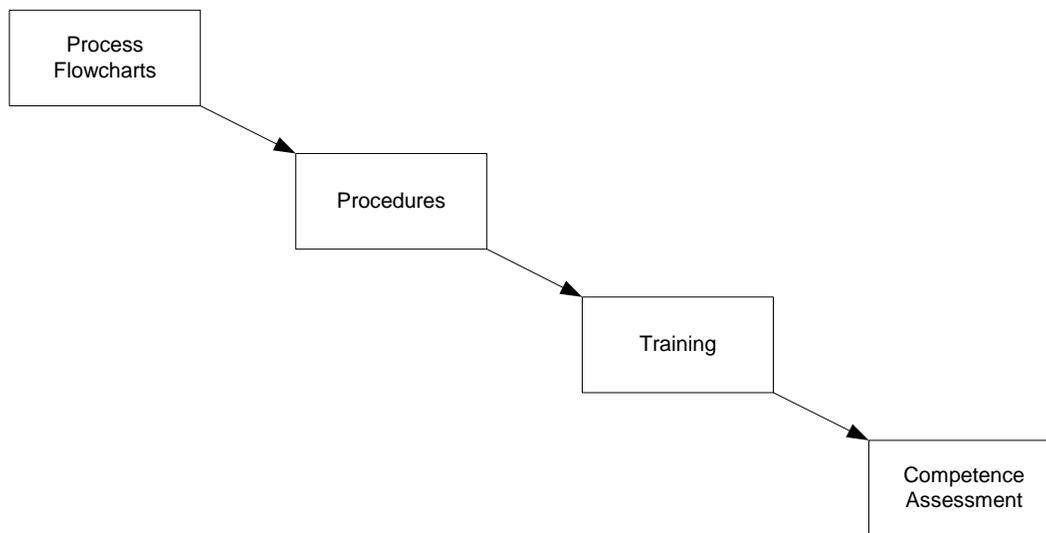


Figure 1. Sequence of Events for Developing Successful Training and Competence Assessment Programs

2 Introduction

All good quality 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, assessment of competence should be periodically determined to verify that performance of assigned job tasks remains consistent.

Some level of medical error has been at

tributed to either training not being provided or training not being effective. Therefore, consistent, predictable, and high-quality outcomes in the delivery of healthcare services can be provided only if healthcare personnel have been 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 the services it provides.

3 Definitions

Competence – Application of knowledge, skills, and behaviors in performance (ISO 10015, 3.1).¹

Procedure – A specified way to carry out an activity of a process (ISO 9000, 3.4.5).²

Process – Set of interrelated or interacting activities that transform inputs into outputs (ISO 9000, 3.4.1).²

Training – Process to provide and develop knowledge, skills, and behaviors to meet requirements (ISO 10015, 3.2).¹

4 Quality System Approach

The quality system approach applies a core set of “quality system essentials” (QSEs) that are basic to any organization and to all operations in any healthcare service’s path of workflow. The QSEs provide the framework for delivery of any type of product or service, serving as a manager’s guide. The quality system essentials (QSEs) are: Organization; Personnel; Equipment; Purchasing and Inventory; Process Control; Documents & Records; Information Management; Occurrence Management; Assessment; Process Improvement; Service and Satisfaction; and Facilities and Safety.

More information about the QSEs can be found in the most current version of NCCLS document [HS1—A Quality System Model for Health Care](#).

The key elements of QSEs: Personnel and the elements covered in this guideline are shown in Figure 2.

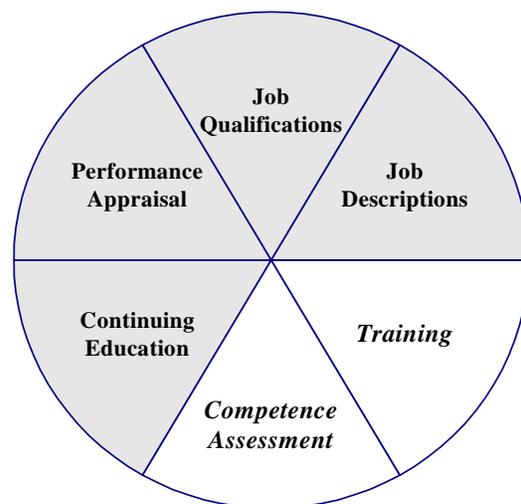


Figure 2. Key Elements of QSEs: Personnel

5 Education, Training, and Competence—The Differences

5.1 Education Versus Training

For the purposes of this guideline, a distinction must be made between the *education* one receives in undergraduate schooling for the purposes of gaining knowledge, and being *trained* in a set of skills for the

purpose of being able to put the knowledge to practical use. The main difference is that of learning the material to demonstrate one’s knowledge versus learning how to do something and demonstrating the ability to perform the skill. Table 1 compares education and training.

Table 1. The Differences Between Education and Training

Education	Training
Focus is on future job for the learner	Focus is on present job of the learner
Awareness of a skill	Demonstration of a skill
Assessment through tests of knowledge	Assessment through performance

5.2 Professional Training

Professional training is training received in the knowledge and skills of a particular profession and is based on a defined body of knowledge and set of skills that prepares the learner for a future job in that profession. In professional training, the student is allowed to develop and practice skills in a setting similar to the actual work environment. Examples include clinical service internships, rotations, and clerkships. The information in this guideline may be used to develop individual training experiences in a professional training program.

5.3 Employment Training

Employment training is that training provided for employees who are new to the organization or are new to a different job in the organization. Clinical service professionals with years of experience will still need to be trained in the policies, processes, and procedures of their new work environment after they change employers or jobs. While the theory learned and basic skill set obtained by a given professional do not significantly change, a new employer’s work processes, instrumentation, forms, and computer systems are likely to differ from those used in previous employment. Thus, a new employee with previous experience and an entry-level employee who are hired for the same job would be trained in the same work processes and procedures. To make an effective contribution to the workforce, new employees—whatever their experience levels—need to be trained in “how it happens here.” Employment training is assessed by demonstration of competence in work processes and procedures. Table 2 summarizes the differences between professional training and employment training.

Table 2. Professional Training Versus Employment Training

Professional Training	Employment Training
Conducted as part of study combined with academic material	Conducted as part of responsibilities and requirements for the job

5.4 Required Training Programs

Employment training covers more than job tasks alone. Regulations and accreditation requirements for employment training programs in healthcare services all require that employees have training in addition to job tasks. [Table 3](#) presents components of a complete clinical service training program.

Table 3. Components of a Complete Clinical Service Training Program

Type of Employment Training	Contents
Quality	<ul style="list-style-type: none"> • Organization's quality system • Quality manual • Service's path of workflow • Quality Control Program • Quality Assurance program • Occurrence Management program • Customer Service Program • Quality System responsibilities • [Good Manufacturing Practice (GMP): blood banking only] • [Proficiency testing: screening and diagnostic laboratory testing only]
Computer	<ul style="list-style-type: none"> • Main organization's system (e.g., hospital information system (HIS)) • Department's system (e.g., laboratory information system (LIS)) • PC applications (e.g., e-mail, scheduling, word processing, spreadsheets, database) • Intranet • Online documents • Other computer applications used in the job (e.g., documentation of training, continuing education, competence assessment, etc.)
Safety	<ul style="list-style-type: none"> • Accident reporting • Emergency preparedness • Hazardous waste disposal • Chemical hygiene program • Infection control (universal precautions, bioterrorism, etc.) • Radiation safety, where needed
Work processes and procedures	<ul style="list-style-type: none"> • Processes in the path of workflow in which the employee works • Procedures performed
Compliance [U.S. only]	<ul style="list-style-type: none"> • Medical necessity requirements • Fraud and abuse reporting • Health Insurance Portability and Accountability Act (HIPAA)

5.5 When to Train

Regulatory and accreditation requirements specify that training should be conducted at the following times:

- for new employees, to learn their respective work processes and procedures;
- for all employees, when organizational or technological changes affect work processes; and
- when training needs are identified (e.g., repeated problems, or unsuccessful performance on a competence assessment exercise).

This guideline describes how to design training guides for work processes and procedures for new employees or for when all employees need to be trained in new or changed processes and procedures.

5.6 Competence Assessment

Following initial employment training, the new employee's competence is assessed to determine the effectiveness of training as well as the person's readiness to function in his or her actual work environment. Competence assessment of new employees should be administered during, and at the end of, employment training and periodically thereafter to verify the person's continued demonstration of necessary knowledge, skills, and correct practice of work processes and procedures.

Competence assessment should also be performed when all staff members are introduced to new or changed work processes or procedures. When new tests are involved, competence needs to be assessed before reporting test results. This is necessary to ensure readiness for effective delivery of those processes and procedures in the actual work environment.

This guideline describes how to use work processes to develop initial and ongoing competence assessment.

5.7 Comparison of Knowledge Versus Competence

A distillation of the concepts discussed in Section 5 is presented in Table 4.

Table 4. Knowledge Versus Competence

How obtained	Manifested by	Evaluated by
Education	Knowing it	Testing
Training	Knowing how it's done	Competence assessment
Practice	Showing how it's done	Performance
Experience	Doing it	Actions

6 Training—A Four-Stage Process

This guideline focuses specifically on how to implement an employment training program. The suggestions and examples provide guidance for developing training for employees both new to the organization and those faced with changes to current work processes and procedures.

A simple four-stage process can be distilled from the wealth of published literature on training. Table 5 displays the four stages of the training process with a brief description of each stage.

Table 5. The Four Stages of Training³

Stage	Description
1. Training needs identified	<ul style="list-style-type: none"> Work processes and procedures for which training is needed are identified.
2. Training guides developed	<ul style="list-style-type: none"> Identification and development of: <ul style="list-style-type: none"> - objectives; - methods; and - materials.
3. Training is implemented	<ul style="list-style-type: none"> Trainers are identified. Training is conducted.
4. Training outcomes evaluated	<ul style="list-style-type: none"> Training effectiveness is evaluated (initial competence assessment). Learner's experience is evaluated. Training is documented.

6.1 Training Needs Identified

Identification of training needs entails more than a checklist of procedures an employee will perform in a given job. Each individual brings unique skills and experiences to an organization and therefore, has unique needs for training. New employees with previous experience are likely to have the necessary background knowledge and skills to perform the technical aspects of a given procedure; what they need to learn is how the procedures are sequenced in the new work environment. For example, for an experienced phlebotomist in a new job, training is more than verifying that the phlebotomist can perform blood collection by various techniques. Training must also involve developing an awareness in the new phlebotomist of the sequence of activities involved in the morning specimen collection rounds, such as generating collection lists from the computer, prioritizing the sequence of collection locations, transporting specimens to the laboratory, and verifying the collections. A new respiratory therapist in her first job after professional training needs to learn the process for how orders for therapeutic interventions or protocol initiation are prioritized and scheduled to sequence patient assessments in the workload, as well as how to complete the assessment form. A new blood bank technologist knows how to perform a crossmatch—he needs to be trained in the compatibility testing process in his new job.

Real training does not consist of having a new employee read a procedure and sign off on a checklist. Rarely, if ever, does a healthcare service job consist of a person performing a single procedure in isolation of all the other procedures, and work does not happen in the alphabetical order in which most procedures manuals are organized. Real work is a sequence and linking of several distinct activities in the order needed to achieve the desired outcome—this is known as a work process.

Identifying training needs consists of identifying:

- work processes performed in a given job;
- procedures performed in each work process; and
- policies that apply to work processes and procedures.

Each clinical service should identify its own work processes and supporting procedures. NCCLS document [GP26—Application of a Quality System Model for Laboratory Services](#) provides numerous examples of laboratory work processes (depicted as flowcharts) and the respective procedures that are performed in each process. The GP26 guideline can serve as a model for other clinical services that need to identify their respective work processes.

Training needs are documented in a checklist of the work processes and procedures to be performed in a given job.

6.2 Training Guides Developed

A training guide consists of the following elements:

- objectives for the training;
- identification of the methods to be used in training;
- identification of the materials to be used in the training; and
- criteria to assess the effectiveness of training.

[Table 6](#) briefly describes the functions of the components of the training guide.

Table 6. Training Guide Components

Training Guide Component	Function
Objectives	States the expectations for the outcomes of the training event
Methods	Describes the various means used to conduct the training
Materials	Lists the materials and resources provided for the training event
Criteria to assess the effectiveness of training	Describes the tools used to assess the effectiveness of training

Figure 3 provides an example of a form designed to capture information for a given training guide.

Training Guide Document Number:	Effective Date: mm/dd/yy								
Training Guide for [insert title here]									
Objectives	Training Method								
At the conclusion of the training event, the learner will be able to: <ul style="list-style-type: none"> • • • • 	Methods used in this training event include those checked below: <table style="width: 100%; margin-top: 10px;"> <tr> <td><input type="checkbox"/> Lecture</td> <td><input type="checkbox"/> Practice</td> </tr> <tr> <td><input type="checkbox"/> Computer-based</td> <td><input type="checkbox"/> Self-assessment</td> </tr> <tr> <td><input type="checkbox"/> Self-study</td> <td><input type="checkbox"/> Unknowns</td> </tr> <tr> <td><input type="checkbox"/> Observe demo</td> <td><input type="checkbox"/> Other:</td> </tr> </table>	<input type="checkbox"/> Lecture	<input type="checkbox"/> Practice	<input type="checkbox"/> Computer-based	<input type="checkbox"/> Self-assessment	<input type="checkbox"/> Self-study	<input type="checkbox"/> Unknowns	<input type="checkbox"/> Observe demo	<input type="checkbox"/> Other:
<input type="checkbox"/> Lecture	<input type="checkbox"/> Practice								
<input type="checkbox"/> Computer-based	<input type="checkbox"/> Self-assessment								
<input type="checkbox"/> Self-study	<input type="checkbox"/> Unknowns								
<input type="checkbox"/> Observe demo	<input type="checkbox"/> Other:								
Training Materials	Learner Evaluation								
Materials used in this training event include those checked below: <ul style="list-style-type: none"> <input type="checkbox"/> Process flowchart or table <input type="checkbox"/> Written procedures and job aids <input type="checkbox"/> Operator’s manual <input type="checkbox"/> Package inserts <input type="checkbox"/> Lecture handout <input type="checkbox"/> Self-study handout <input type="checkbox"/> Computer program handout <input type="checkbox"/> Videotape(s) <input type="checkbox"/> Practice material 	Assessment of initial competence after this training event will include those checked below: <ul style="list-style-type: none"> <input type="checkbox"/> Record review <input type="checkbox"/> Direct observation <input type="checkbox"/> Specially-provided materials <input type="checkbox"/> Written quiz <input type="checkbox"/> Oral quiz 								
Facility Name, Location [filename and path]	Page 1 of 1								

Figure 3. Sample Training Guide

6.2.1 Learning Objectives

Learning objectives are expectations for training outcomes that can be observed or assessed; therefore, they use action verbs and describe measurable behaviors (see Table 7). Learning objectives for training are of two types:

- Cognitive: assess knowledge (Example: *List* the computer codes used in this process.)
- Psychomotor: assess physical skills (Example: *Fill* the cuvette.)

Table 7. Sample Learning Objective

Learning Objective
<p>At the conclusion of training, the employee will be able to:</p> <ul style="list-style-type: none"> • perform the process and supporting procedures without supervision and within acceptable limits, including: <ul style="list-style-type: none"> – performing linearity checks (psychomotor); – calibrating the instrument (psychomotor); and – loading the sample trays (psychomotor). • achieving a passing score on the written quiz (cognitive).

The learning objectives are documented in the “objectives” section of the training guide form.

6.2.2 Training Methods

Training methods include, but are not limited to, any of the following as applicable to the work process for which training is being conducted:

- lecture;
- use of computer-based exercises;
- self-study;
- observance of demonstrations—live or videotaped;
- practice under supervision;
- self-assessment of practice outcomes; and
- testing or identification of specially-provided samples.

The training methods to be used for a given process are documented in the “methods” section of the training guide form.

6.2.3 Identification of Training Materials

Training materials include all items to be used during delivery of the training event. Training materials are documented in the “materials” section of the training guide form. Table 8 briefly describes the purpose of various types of training materials.

Table 8. Description of Training Materials

Training Materials	Purpose
<ul style="list-style-type: none"> • References (text, articles) • Operator’s manuals • Manufacturer’s instructions 	Provides background, theory, principle, and applications
<ul style="list-style-type: none"> • Documented work process (in the procedures manual) 	Describes the sequence of the activities for which training will take place
<ul style="list-style-type: none"> • Documented procedures (in the procedures manual) 	Provides detailed instructions for how to perform each activity in the process
<ul style="list-style-type: none"> • Lecture handouts 	Provides notes reflecting key information about the process
<ul style="list-style-type: none"> • Computer-based programs • Self-study programs • Videotapes 	Provides the learners with self-paced introduction to new information
<ul style="list-style-type: none"> • Practice materials 	Provides samples on which to practice new skills <ul style="list-style-type: none"> • specimens (testing); • instruments, artificial limbs (manual dexterity skills); • requisitions and forms; and • information in teaching databases.

6.2.4 Instructions for Trainer and Learner

To prepare appropriately for the training event, both the trainer and the learner should be provided with instructions.

6.2.4.1 Trainer Instructions

Trainers should be given instructions about what they are responsible for in preparing for a successful training event. Practice materials may need to be prepared in advance; a list of materials to be prepared for demonstrations, learner practice, and specially-provided samples helps to ensure uniformity in training. A sample set of instructions for trainers is presented in [Figure 4](#).

Training Guide Document Number:	Effective Date: mm/dd/yy
Trainer Responsibilities for [insert name of process here]	
Objectives	
As the trainer, you need to: <ul style="list-style-type: none"> • <i>organize</i> the training event for success; • <i>communicate</i> clearly; • <i>provide</i> accurate and complete information; • immediately <i>correct</i> performance problems in a respectful manner; and • <i>provide</i> opportunities for feedback. 	
Training Guide	
Familiarize yourself with the contents of the training guide.	
Methods and Materials	
<ul style="list-style-type: none"> • <i>Assemble</i> the methods and materials for training (see the training guide for the methods and materials to use). • <i>Prepare</i> the following samples for demonstration and practice: [List the numbers and types of practice samples here.] • <i>Prepare</i> the following unknowns for the evaluation exercise: [List the numbers and types of unknown samples here.] 	
Learner Evaluation	
Use the following tools to evaluate whether the learner has learned the material: <p>Unknowns: <i>Provide</i> and evaluate unknowns.</p> <p>Written: <i>Administer</i> and score written evaluation.</p> <p>Oral: <i>Administer</i> and score questions selected from question list.</p> <p>DOCL: <i>Observe</i> the learner and document performance on the Direct Observation Checklist (DOCL).</p>	
Facility Name, Location [filename and path]	Page 1 of 1

Figure 4. Sample Form for Trainer Responsibilities (This example was contributed by the Provincial Laboratory for Public Health Microbiology, Calgary and Edmonton, Alberta, Canada.)

6.2.4.2 Learner Instructions

Learners should be given instructions to help them understand their responsibilities in the training event. A sample set of instructions for learners is presented in [Figure 5](#).

Training Guide Document Number:	Effective Date: mm/dd/yy
Learner Responsibilities for [insert name of process here]	
Objectives	
At the conclusion of the training event, <u>you must be able to</u> :	
<ul style="list-style-type: none"> • <i>explain</i> the process and describe your role within the process; • <i>perform</i> the procedures in the correct sequence; • <i>perform</i> the procedures as written and without direct supervision; and • <i>perform</i> all required safety precautions. 	
Training Guide	
Familiarize yourself with the contents of the training guide.	
Methods and Materials	
<ul style="list-style-type: none"> • <i>Complete</i> any pre-required reading (as listed in the Training Guide). <ul style="list-style-type: none"> – processes – procedures – references – package inserts – manuals, etc. • <i>Observe</i> any demonstrations. • <i>Obtain</i> practice material. • <i>Perform</i> standard operating procedures on practice material. • <i>Do</i> a self-assessment using the Direct Observation Checklist. 	
Learner Evaluation	
To demonstrate that you have learned the material, you will be required to do one or more of the following:	
<ul style="list-style-type: none"> • Perform unknowns, if applicable. • Perform the procedure(s) for the trainer who will follow on a Direct Observation Checklist. • Complete and pass the written quiz. • Answer any oral questions. • Obtain the trainer's sign off on the training checklist. 	
Facility Name, Location [filename and path]	Page 1 of 1

Figure 5. Sample Form for Learner Responsibilities (This example was contributed by the Provincial Laboratory for Public Health Microbiology, Calgary and Edmonton, Alberta, Canada.)

6.2.5 Completion of the Training Guide Packet

A completed training guide packet should be prepared for each training event. Packets can be prepared in advance and reviewed by the trainer in preparation for a given training event. Training packets are a

means to standardize the contents and delivery of training events. Table 9 describes the contents of the training guide packet.

Table 9. Items to Include in the Training Guide Packet

Item	Purpose
Completed training guide form	<ul style="list-style-type: none"> Provides a description of training event for the learner
Instructions for the trainer	<ul style="list-style-type: none"> Provides information that allows the trainer to prepare for and conduct the training event
Instructions for the learner	<ul style="list-style-type: none"> Provides information for the learner about how the training event will be conducted
Training checklist	<ul style="list-style-type: none"> Provides a means to check off the processes and procedures for which training took place
Direct observation checklist	<ul style="list-style-type: none"> Used by learner to self-evaluate after practicing the procedures Used by the trainer to assess whether training has been successful Used for periodic ongoing competence assessment to assure skills have been retained Used after remedial training to assure demonstration of required skills
Written quiz or test	<ul style="list-style-type: none"> Questions to assess knowledge of the process or procedure

[Appendix A](#) is an example of a completed training guide packet for setting up and operating the ABC Analyzer.

6.3 Training is Implemented

6.3.1 Trainer Qualifications

Trainers need to be qualified to impart the necessary knowledge and skills to others. Trainers themselves should regularly work in the processes and perform the procedures in which they instruct others. The service needs to decide how it will determine which person(s) is (are) qualified to train others.

Necessary attributes of a qualified trainer include:

- interest in training;
- enthusiasm for working with people;
- good verbal skills (providing instructions, answering questions, etc.);
- good listening skills;
- good observational skills;
- patience;
- objectivity;
- respect of and for colleagues;
- previous experience; and
- accurate knowledge of the process and procedures involved in the training event.

6.3.2 Training is Conducted

A training environment conducive to learning should be provided. The learner should have the opportunity to practice in a “safe” environment where:

- he or she is not punished for mistakes;
- there is time for reflection on the information obtained and activity learned;
- the learner can make conclusions from information presented or activities experienced; and
- the learner can adapt to the new learning.³

Whenever possible, training should take place in the area where the work is actually performed so that the learner can observe the actual work process and procedures.

Documentation of training is explained in [Section 7](#).

6.3.2.1 Performance Standards

Performance standards are statements of expected results or behaviors that specify the quantity and quality of work necessary to contribute to the work area’s objectives. Performance standards should be communicated to new employees when training is initiated so that they are clear about the results or behaviors expected by their supervisors.

Here is an example of a performance standard stated as an expected result: “Within three months of commencing phlebotomy as a full-time laboratory assistant, you will have fewer than five missed venipunctures per month and an average of 800 phlebotomies per month.”

Here is an example of a performance standard stated as an expected behavior: “You are to answer the telephone within three rings, identifying yourself by name and department.”

New employees should be provided with the performance standards for their jobs and told when they will be held accountable for that level of performance. During initial training, employees will then be aware of the performance standards and can use them as a goal for their training outcomes—however, employees will not immediately be expected to perform at that level.

6.4 Training Outcomes are Evaluated

Evaluation of training programs is conducted at four levels represented by the following questions:

- Did the employee like the training experience?
- Did the employee learn the materials?
- Were the skills learned transferred to the workplace?
- How was the transfer assessed?

6.4.1 Did the Employee Like the Training Experience?

Employees should be given the opportunity to provide feedback on the training experience to determine where there might be opportunities for improvement to the training guides, trainers, and training events. An example of a form for evaluating the training experience is provided in Figure 6.

Document Number/Version Number		Effective Date: mm/dd/yy	
Evaluation of Training Experience for [insert name of process or procedure here]			
Completed by:		Date:	
Item	Circle Y (Yes) or N (No)	Comments	Score 1= unsatisfactory 2= satisfactory 3= very good
Were you shown how to find the resource materials?	Y N		
Was the process clearly explained?	Y N		
Was (were) the procedure(s) clearly demonstrated?	Y N		
Were you shown where to get supplies and equipment?	Y N		
Were you given enough time to practice?	Y N		
Was the trainer approachable?	Y N		
Did you feel comfortable asking questions?	Y N		
If the trainer did not know the answer, could he/she find the information?	Y N		
When you did the procedure(s), were you corrected respectfully?	Y N		
Did you get constructive, timely feedback?	Y N		
Did you feel comfortable performing the procedure(s) on your own?	Y N		
Were you asked questions to gauge your knowledge and understanding of the process or procedure(s)?	Y N		
Facility Name, Location [filename and path]		Page 1 of 1	

Figure 6. Evaluation of Training Experience (This example was contributed by the Provincial Laboratory for Public Health Microbiology in Calgary and Edmonton, Alberta, Canada.)

6.4.2 Did the Employee Learn the Material and Skills?

Assessment of the employee’s competence after training is a means of determining the ability of the employee to use the newly acquired skills in the workplace.

6.4.2.1 Initial Competence Assessment^a

Prior to working independently, a new employee's competence needs to be assessed and this assessment documented. Likewise, when a new process or procedure has been introduced, the competence of all involved employees should be assessed prior to implementation. The assessment should challenge both the cognitive and psychomotor skills needed to perform the process and related procedures and verify that the learning objectives stated in the training guide have been met. Criteria against which employees are assessed need to be predetermined and verified before using an assessment activity to confirm their ability to perform a process or procedure.

6.4.2.2 Cognitive Assessment

Assessments of an employee's cognitive skills with respect to a particular process or procedure can be determined by oral or written tests, the latter of which can be more readily documented.

Questions can involve any of the following attributes of a given process or procedure:

- theory;
- technique;
- interpretation; and
- problem solving.

6.4.2.2.1 A Theory Question

A theory question assesses the employee's knowledge of the background information for a given procedure.

Example:

“Describe the principle of the test method for the hand-held XYZ Blood Glucose instrument.”

6.4.2.2.2 A Technique Question

A technique question assesses the employee's knowledge of an important step or action in a given procedure.

Example:

“Explain the significance of proper positioning when a mammography image is taken.”

6.4.2.2.3 An Interpretation Question

An interpretation question assesses the employee's ability to arrive at the correct conclusion for a given set of results.

Example:

“Interpret the meaning of the following blood gas results on a patient diagnosed with pneumonia.”

^a In the U.S., refer to the Clinical Laboratory Improvement Amendments [codified at 42 CFR §493.1451 (b)(8)] (1988).

6.4.2.2.4 A Problem-Solving Question

A problem-solving question assesses the employee’s ability to take the correct action in a problem situation he or she is likely to encounter. Examples include resolving a posed and procedure-relevant situation, solving given and procedure-relevant calculations, or recommendation of an appropriate procedure-relevant course of action that is consistent with the service’s policy.

Example:

“After issuing a medication to the nursing station, you discover that the dose on the label is wrong. Describe how you would follow-up this situation.”

Figure 7 provides an example of a form to prepare a written test.

Written Assessment Form		Effective Date: mm/dd/yy	
Document Number:			
Written Assessment for [insert name of process or procedure here]			
Employee:		Date:	
Theory Question(s):			
Technique Question(s):			
Interpretation Question(s):			
Problem Solving Question(s):			
Number correct:		Number incorrect:	
Follow-up issues identified:		<input type="checkbox"/> Yes	<input type="checkbox"/> No
Actions taken:			
Reviewed by:		Date:	
Facility Name, Location [filename and path]			Page 1 of 1

Figure 7. Sample Written Assessment Form (This example was adapted from *Transfusion Service Manual of Standard Operating Procedures, Training Guides, and Competence Assessment Tools*. Bethesda, MD: American Association of Blood Banks; 1996 (no longer available)).

6.4.2.3 Psychomotor Assessment

The need for patient safety and the judicious use of scarce resources in today's healthcare environment do not allow for incompetent practice of work processes and procedures; therefore, employees need to perform work correctly the first time. The best assurance a service can have that employees understand and can perform their assigned work tasks is to have them demonstrate performance under observation.

Training guide packets should include one or more "Direct Observation Checklists" that cover the work process and procedures for which training was delivered.

6.4.2.3.1 Direct Observation Checklist

The direct observation checklist can be used first by the employee to self-assess progress during practice sessions of the activities in a process or steps in a procedure. Then the observer uses the direct observation checklist to follow along and document the employee's performance of the process or procedure. If performance is not satisfactory, the employee should be given more time to practice before reassessment. Observers should be cognizant that performers may be overly conscientious or demonstrate nervousness when being watched. At the conclusion of the observation, the observer records whether the employee met the requirements, whether or not review or additional training is needed, and any applicable comments.

A direct observation checklist provides an objective means for assessing performance. An example is shown in [Figure 8](#).

Direct Observation Checklist	Effective Date: mm/dd/yy
Document Number:	
Direct Observation Checklist for [insert name of process or procedure here]	
Employee:	Observed by:
Did the employee:	
1. [Write the question that directly relates to a critical activity in a process or step in a procedure. Write the action verb first .]	
<i>Example: Verify the patient's name by checking the wristband?</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No
2. [Write the questions in the order that the activities are sequenced in the process, or the steps are sequenced in a procedure.]	
<i>Example: Compare the wristband to the printed label or requisition?</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No
3. Continue writing each question, action verb first.	
4. Where applicable, use this as the last question:	
<i>Follow all required safety precautions?</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No
Number of times observed:	
Competent to perform the procedure: <input type="checkbox"/> Yes <input type="checkbox"/> No	
Signatures	
Trainer:	Employee:
Date:	
Remedial action taken:	
Remedial action completed:	
Date:	Trainer:
Facility Name, Location [filename and path]	

Figure 8. Sample Direct Observation Checklist (This example was adapted from *Transfusion Service Manual of Standard Operating Procedures, Training Guides, and Competence Assessment Tools*. Bethesda, MD: American Association of Blood Banks; 1996 (no longer available)).

6.4.3 Were the Skills Transferred to the Workplace?

Regulations and accreditation requirements mandate periodic review of the staff's ability to meet the performance expectations stated in their job descriptions, training guides, and performance standards.⁴

The ongoing assessment of competence is not to be confused with an organization's periodic performance appraisal process usually conducted in conjunction with the organization's human resources department. However, competence assessment outcomes should be included in the organization's performance appraisal.

Management must also take and document actions when individual performance is not up to that needed to ensure patient safety and service performance. Such actions should include preventing the employee from performing procedures for which he or she has failed to demonstrate competence.

6.4.3.1 Ongoing Competence Assessment^b

Several means are available to determine and document ongoing competence of individual staff members. They include:

- direct observation of routine work processes and procedures;
- direct observation of equipment maintenance and function checks;
- monitoring the recording and reporting of results;
- reviewing work records (e.g., completed worksheets, forms);
- assessment of problem-solving skills; and
- performance of a given procedure using specially provided materials.

6.4.3.2 Direct Observations

Following the guidance provided in [Section 6.4.2.3](#), direct observation checklists can be developed for routine work processes and procedures, and equipment maintenance and function checks. The objective is to determine whether employees are following documented processes and procedures. Over time, staff members tend to drift away from procedure specifics as they discover shortcuts and workarounds. Such invalidated activities may be leading to problematic patient safety issues—both discovered and undiscovered.

[Appendices B1](#) and [B2](#) provide examples of direct observation checklists for laboratory technologists and laboratory assistants.

6.4.3.3 Monitoring Results, Reports, and Records

A supervisor's routine review of reports and records can reveal mistakes and issues that could be related to lack of competence. Such mistakes and issues should be investigated to determine their causes. Actions appropriate to removing the cause should be taken and documented.

6.4.3.4 Problem-Solving Skills

Healthcare services functioning in a quality system environment will have an ongoing means to capture information about events that do not conform to the organization's stated policies, processes, or procedures (also known as "occurrences") and review them in a timely manner. The information contained in occurrence reports can be used to determine a person's problem-solving capabilities by

^b In the U.S., refer to the Clinical Laboratory Improvement Amendments [codified at 42 CFR §493.1451 (b)(8)] (1988).

reviewing the appropriateness of the remedial actions taken and the follow-up investigations made. By no means should occurrence reports be the sole means to determine competence. It is important that occurrences be reported in a “no-fault” environment to identify where opportunities to improve work processes and procedures exist.

Other situations in which problem-solving skills can be assessed include: resolving equipment and other technical or testing problems, handling of emergent situations, meeting a specific customer’s needs, and knowing when to escalate a problem that cannot be solved at that person’s level.

6.4.3.5 Performing a Procedure Using Specially Provided Materials

Although it takes considerable effort within the clinical service, provision of specific materials (“unknowns”) is a useful means to determine if personnel are competently performing their assigned work processes and procedures. This method is especially useful in healthcare services where diagnostic testing is performed (e.g., clinical laboratory, pulmonary diagnostic testing) because source materials for testing are readily available.

Source materials include testing of the following:

- blind specimens;
- previously analyzed specimens; and
- known specimens.

6.4.3.5.1 Blind Test Specimens

Employees are unaware when blind test specimens are entered into the work stream because they appear identical to other specimens, are in routinely used containers, are from a similar source, and have labels with patient identification numbers, physician identification, hospital coding, etc. The intent is to provide material that is simulated to actual specimens to assess realistic process conditions. More often, due to logistical dilemmas such as preparation, identification, and high cost, these specimens are used for specific studies rather than general monitoring of laboratory performance. The advantages of blind specimens include more reliable assessment of routine performance and the identification of problems within all phases of the path of workflow. The system of testing blind specimens is considered to be the best and most thorough representation of diagnostic testing performance, but feasibility is a major factor preventing widespread use. For example, the type of instrumentation may limit blind testing because some instruments will automatically report the normal results of a patient specimen.

6.4.3.5.2 Previously Analyzed Material

Replicate testing of previously analyzed material provides accessible internal comparisons. Assessment of performance can be determined only for the analytic phase; assessment for the pre- and postanalytic phases is not usually possible. Costs can be significantly reduced because the specimens are obtained from on-site sources such as previously tested patient specimens (regardless of time, if the specimen is preserved properly and the analyte is stable); specimens from persons with known constituents or abnormalities; and already reported proficiency-testing specimens.

[Appendices C1](#) and [C2](#) provide examples of forms that can be used to evaluate testing performance on a set of specially provided quantitative and qualitative samples.

6.4.3.6 When Performance is Unacceptable

Much has been written about retraining of personnel when they have failed to meet competence assessment challenges. However, the vast amount of quality management literature makes it clear that over 85% of problems are found within the work processes and procedures that management have designed—or not designed—by default. Therefore, retraining apparently “incompetent” employees in malfunctioning, absent, or highly variable work processes will not solve their performance problems.

Before deeming an employee as needing to be retrained, managers should answer the following questions:

- Have all work processes been clearly documented?
- Are there written procedures for all activities in the work process?
- Are the written procedures clear and easy to understand?
- Does the service have a documented training program for all work processes and procedures?
- Has the employee been trained in the process or procedure in question and was the training documented?
- How was the effectiveness of the employee’s training determined?
- Is the employee the only person with this performance problem?

When there is clear evidence that the employee is not competent to perform the assigned tasks, management must take and document follow-up actions. The criteria for reassessment should be established, documented, and communicated to employees prior to the periodic reassessment events. Criteria need to include guidance on how many chances an individual should get to pass assessment, re-administering the same or a different test, and consideration for those who do not perform well on written assessment but whose performance in visual and practical assessment is acceptable.

Figure 9 provides an example of a form for follow-up of competence or learning assessments that require remediation.

Competency Follow-up Document number/version:		Effective Date: mm/dd/yy	
Competency/Learning Assessment Follow-up Action/Improvement Plan			
Employee Name			
The following competency/learning assessment requires remediation:			
Name of assessment			
Date of assessment			
Type of assessment	<input type="checkbox"/> Direct Observation <input type="checkbox"/> Verbal Exam <input type="checkbox"/> Written Exam <input type="checkbox"/> Challenge/Scenario		
Reason for assessment	<input type="checkbox"/> Initial <input type="checkbox"/> Ongoing <input type="checkbox"/> Special (problem prone, low vol/high risk, etc.)		
Specific skill or knowledge to be demonstrated	ACTION TO BE TAKEN	Competency/Learning to be reassessed by: How and by When?	Outcome of reassessment: Competency/Learning demonstrated YES or NO
Employee Signature _____		Date _____	
Supervisor Signature _____		Date _____	
Facility Name, Location		Page 1 of 1	

Figure 9. Sample Form for Follow-up of Competence or Learning Assessment Requiring Remediation (This example was contributed by Sutter Health Sacramento Sierra Region Laboratory Services, Sacramento, California.)

6.4.4 How Was the Transfer Assessed?

Healthcare services functioning in a quality system environment will have an ongoing means to determine if work processes and procedures are functioning as needed to achieve the service’s quality goals and objectives.

The effectiveness of training, as determined by acceptable process performance, can be inferred through any of the following means:

- quality indicators;
- quality audits;

- trends and patterns of occurrence; and
- customer feedback.

7 Documentation of Training and Competence Assessment

Documentation of employment training and competence assessment is required by all regulatory and accreditation programs. The service must provide an effective means of documenting and tracking an employee's training and competence assessment records across time. Historically, manual records have been maintained in employee files. Electronic tracking is now becoming a useful tool.

7.1 Records To Be Kept

7.1.1 Training Records

At the conclusion of each training event, the following records should be completed and retained in the employee's training file:

- checklist(s) of processes and procedures;
- written test(s); and
- direct observation checklist(s) completed by the observer.

NOTE: The paper copies contain the signatures of the trainer and the employee.

There may also be a "group" training record; that is, in the instance that all employees are to sign after reading a particular document or observing a particular video.

7.1.2 Competence Assessment Records

At the conclusion of each competence assessment event, the following records should be completed and retained in the employee's file:

- direct observation checklist(s) completed by the observer; or
- any written assessment (case study, test, other).

NOTE: The paper copies contain the signatures of the observer/supervisor and the employee.

Spreadsheet and database programs can also be set up to track the events and dates of training and competence assessments across time, thus providing a readily available record that shows a given employee's entire training and competence assessment history.

NOTE: There can be no "group" competence assessment record; competence is demonstration of a skill, not acknowledgment of receiving knowledge.

7.2 Documentation Systems

Documentation systems should be selected based on:

- ease of use;

- efficiency;
- cost to implement;
- ability to meet regulatory, accreditation, and facility requirements; and
- applicability to the service.

Several commercial electronic documentation systems are available for tracking of training and competence assessment events. The databases can usually be queried to provide reports such as which employees are next due for ongoing assessment, all the employees documented as trained and competent in a particular process or procedure, or an individual's complete record across time.

7.3 Review of Records

A periodic review of training and competence assessment records by the service's management personnel will reveal useful information about the service's work practices. The records will demonstrate unsuccessful assessments, any remediation training, repeated errors and problems, and common questions that may point to a need for changes in the process or procedure.

Review of training and competence assessment records also verifies that the goals of the training and competence assessment programs were achieved:

- to provide instruction in the service's processes and procedures;
- to provide performance feedback;
- to introduce new processes and procedures;
- to provide information for performance evaluations; and
- to comply with regulatory and accreditation requirements.

7.4 Retention of Records

Records of training and competence assessments should be kept according to the service's predetermined record-retention schedule that is based on regulatory, accreditation, facility, and any other legal requirements.

The record-retention process should clearly indicate:

- who is responsible for storing the record;
- where records are kept;
- who has access; and
- when records can be discarded.

7.4.1 Who is Responsible?

The responsibility for generating and storing records is shared by the employee, the supervisor, healthcare service management, and when appropriate, the human resources department.

7.4.2 Where Records are Kept

Although it may vary among facilities, the location of training and competence assessment records needs to be clearly communicated to the employee, the supervisor, and the healthcare service's management. Depending on size and complexity, services may wish to keep the records in a central location. Records need to be stored in a manner that prevents accidental or unauthorized destruction or modification.

7.4.3 Who Has Access?

Records need to be protected to ensure confidentiality and to prevent unauthorized access. Records need to be accessible and retrievable for outside surveyors who verify regulatory compliance.

7.4.4 When Can Records Be Destroyed?

Records should be destroyed after the retention period. However, if there is a question about keeping or discarding records, it may be better to keep the record. For many regulatory agencies, lack of documentation is indistinguishable from nonperformance.

8 Conclusion

Each healthcare service should establish its own training and competence assessment programs to ensure that new employees are able to perform their duties correctly, that all employees can properly execute new processes and procedures, and continue to perform at an acceptable level. A clear understanding of the sequence of work activities and the instructions for completing them properly—and the ability to put this understanding into actual practice—is the service's best assurance of making its maximum contribution to patient safety.

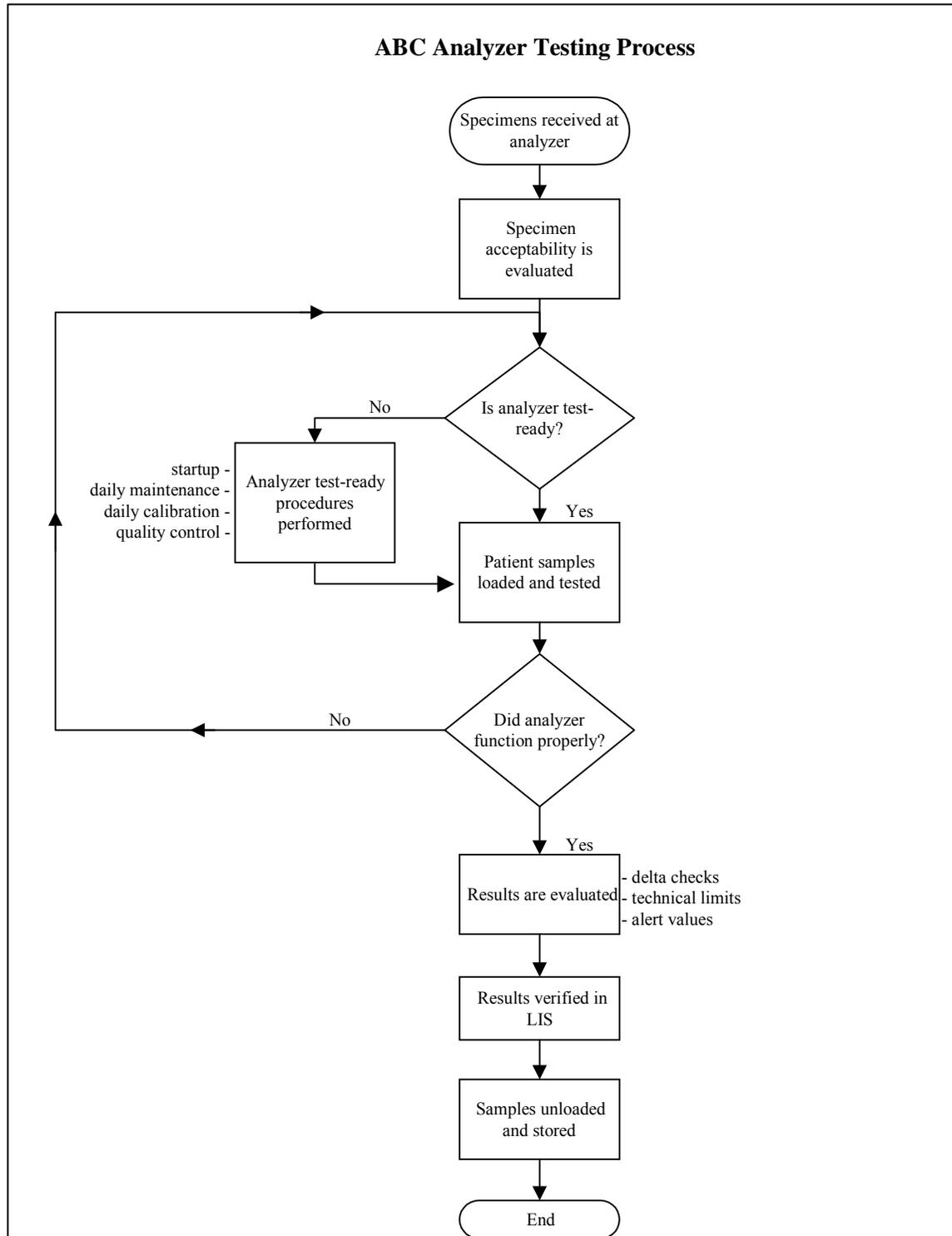
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Appendix A1a. Sample ABC Analyzer Process as a Flowchart



Appendix A1b. Sample ABC Analyzer Process as a Table**ABC Analyzer Testing Process**

What Happens	Who's Responsible	Procedures
Specimen acceptability evaluated	<ul style="list-style-type: none"> • technician; or • technologist 	<ul style="list-style-type: none"> • “Evaluating Specimen Acceptability”
Analyzer test-ready procedures performed	<ul style="list-style-type: none"> • technician; or • technologist 	<ul style="list-style-type: none"> • “Starting Up the ABC Analyzer” • “Performing Daily Maintenance on the ABC Analyzer” • “Performing and Evaluating Daily Calibration on the ABC Analyzer” • “Performing and Evaluating Controls on the ABC Analyzer”
Patient samples loaded and tested	<ul style="list-style-type: none"> • technician; or • technologist 	<ul style="list-style-type: none"> • “Generating an LIS Pending Log for the ABC Analyzer” • “Programming Patient Samples on the ABC Analyzer” • “Loading Routine and Stat Racks on the ABC Analyzer”
Troubleshooting procedures performed	<ul style="list-style-type: none"> • technician • technologist; or • supervisor 	<ul style="list-style-type: none"> • Troubleshooting procedures from the manufacturer’s manual
Results evaluated	<ul style="list-style-type: none"> • technologist; or • supervisor 	<ul style="list-style-type: none"> • “Evaluating Patient Results” • “Calling Alert Values” • “Following Up on Delta Checks” • “Following Up on Technical Flag Limits”
Results verified in LIS	<ul style="list-style-type: none"> • technologist 	<ul style="list-style-type: none"> • “Verifying Results in the LIS”
Samples unloaded and stored	<ul style="list-style-type: none"> • technician; or • technologist 	<ul style="list-style-type: none"> • “Storing Patient Test Specimens”

Appendix A2. Sample Completed Training Guide for ABC Analyzer Testing Process

Training Guide Effective Date: 01/01/03 Document Number: TR1103A/02																	
Training Guide for: ABC Analyzer Testing Process																	
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center; padding: 5px;">Objectives</th> <th style="text-align: center; padding: 5px;">Training Method</th> </tr> </thead> <tbody> <tr> <td style="padding: 5px; vertical-align: top;"> At the conclusion of the training event, the learner will be able to: <ul style="list-style-type: none"> • perform the process and supporting procedures without supervision and within acceptable limits, including: <ul style="list-style-type: none"> - performing routine quality control and calibration verification procedures; - loading the sample trays; - operating the analyzer; and - unloading and clean-up when finished • achieve a passing score on the written quiz and practical examination. </td> <td style="padding: 5px; vertical-align: top;"> Methods used in this training event include those checked below: <table style="width: 100%; margin-top: 10px;"> <tr> <td><input type="checkbox"/> Lecture</td> <td><input checked="" type="checkbox"/> Practice</td> </tr> <tr> <td><input type="checkbox"/> Computer-based</td> <td><input checked="" type="checkbox"/> Self-assessment</td> </tr> <tr> <td><input type="checkbox"/> Self-study</td> <td><input checked="" type="checkbox"/> Unknowns</td> </tr> <tr> <td><input checked="" type="checkbox"/> Observe demo</td> <td><input type="checkbox"/> Other:</td> </tr> </table> </td> </tr> </tbody> </table>	Objectives	Training Method	At the conclusion of the training event, the learner will be able to: <ul style="list-style-type: none"> • perform the process and supporting procedures without supervision and within acceptable limits, including: <ul style="list-style-type: none"> - performing routine quality control and calibration verification procedures; - loading the sample trays; - operating the analyzer; and - unloading and clean-up when finished • achieve a passing score on the written quiz and practical examination. 	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Objectives	Training Method																
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Facility Name, Location Page 1 of 1 [filename and path]																	

Appendix A3. Sample Trainer Responsibilities for ABC Analyzer Testing Process

Training Guide Document Number: TR1103B/02	Effective Date: 01/01/03
Trainer Responsibilities for: ABC Analyzer Process	
Objectives	
<p>As a trainer, you need to:</p> <ul style="list-style-type: none"> • <i>organize</i> the training event for success; • <i>communicate</i> clearly; • <i>provide</i> accurate and complete information; • immediately <i>correct</i> performance problems in a respectful manner; and • <i>provide</i> opportunities for feedback. 	
Training Guide	
Familiarize yourself with the contents of the training guide.	
Methods and Materials	
<ul style="list-style-type: none"> • <i>Assemble</i> the methods and materials for training (see the training guide for the methods and materials to use). • <i>Prepare the following samples for demonstration and practice:</i> <ul style="list-style-type: none"> - two routine racks of five patient specimens and two controls each - two stat racks of five patient specimens and two controls each • <i>Prepare the following unknowns for the evaluation exercise:</i> <ul style="list-style-type: none"> - five routine racks of five patient specimens and two controls each - five stat racks of five patient specimens and two controls each 	
Learner Evaluation	
<p>Use the following tools to evaluate whether the learner has learned the material:</p> <p>Unknowns: <i>Provide</i> and evaluate unknowns. Written: <i>Administer and score</i> written evaluation. Oral: <i>Administer and score</i> questions selected from the question list. DOCL: <i>Observe</i> the learner and document the performance on the direct observation checklist (DOCL).</p>	
Facility Name, Location [filename and path]	Page 1 of 1

Appendix A4. Sample Learner Responsibilities for ABC Analyzer Testing Process

Training Guide Document Number: TR1103C/02	Effective Date: 01/01/03
<p>Learner Responsibilities for ABC Analyzer Process</p>	
<p>Objectives</p>	
<p>At the conclusion of the training event, <i>you must be able to:</i></p> <ul style="list-style-type: none"> • <i>explain</i> the process and describe his/her role within the process; • <i>perform</i> the procedures in the correct sequence; • <i>perform</i> the procedures as written and without direct supervision; and • <i>perform</i> all required safety precautions. 	
<p>Training Guide</p>	
<p><i>Familiarize</i> yourself with the contents of the training guide.</p>	
<p>Methods and Materials</p>	
<ul style="list-style-type: none"> • <i>Complete</i> any pre-required reading. <ul style="list-style-type: none"> – processes – procedures – references – package inserts – manuals, etc. • <i>Observe</i> any demonstrations. • <i>Obtain</i> practice material. • <i>Perform</i> standard operating procedures on practice material. • <i>Do</i> a self-assessment using the Direct Observation Checklist. 	
<p>Learner Evaluation</p>	
<p>To demonstrate that you have learned the material, you will be asked to do one or more of the following:</p> <ul style="list-style-type: none"> • <i>Perform</i> unknowns, if applicable. • <i>Perform</i> the procedure(s) for the trainer who will follow on a Direct Observation Checklist. • <i>Complete</i> and pass the written quiz. • <i>Answer</i> any oral questions. • <i>Obtain</i> trainer’s sign off on the training checklist. 	
Facility Name, Location [filename and path]	Page 1 of 1

Appendix A5. Sample Training Checklist for the ABC Analyzer Testing Process

Training Guide

Effective Date: 01/01/03

Document Number: TR1103D/02

Training Checklist for the ABC Analyzer Testing Process

Document Name	Date	Trainer
Analyzer Set-Up and Run Process Flowchart		
<ul style="list-style-type: none"> • Starting Up the ABC Analyzer • Performing Daily Maintenance on the ABC Analyzer • Performing and Evaluating Daily Calibration on the ABC Analyzer • Performing and Evaluating Controls on the ABC Analyzer 		
<ul style="list-style-type: none"> • Generating an LIS Pending Log for the ABC Analyzer • Programming Patient Samples on the ABC Analyzer • Loading Routine and Stat Racks on the ABC Analyzer 		
<ul style="list-style-type: none"> • Evaluating Patient Test Results • Calling Alert Values • Following Up on Delta Checks • Following Up on Technical Limit Flags 		
<ul style="list-style-type: none"> • Verifying Results in the LIS 		
<ul style="list-style-type: none"> • Storing Patient Test Specimens 		
<ul style="list-style-type: none"> • Analyte-Specific Information Table(s) 		
Troubleshooting Process Flowchart (from manufacturer's manual)		
(Troubleshooting Procedures from the manufacturer's manual in the order in which they are to be performed)		
Preventive Maintenance Schedule		
(Preventive Maintenance Procedures from the manufacturer's manual in the order in which they are to be performed)		
Calibration Schedule		
(Calibration Procedures from the manufacturer's manual) <ul style="list-style-type: none"> • Installation Calibration • Periodic Calibration • Recalibration After Service or Repair 		

 Facility Name, Location
 [filename and path]

Page 1 of 1

This example was adapted from Appendix I in NCCLS document GP26-A2—*Application of a Quality System Model for Laboratory Services*.

Appendix A6. Sample Direct Observation Checklist for the ABC Analyzer Testing Process

Direct Observation Checklist		Effective Date: 01/01/03	
Document Number: TR1103E/02			
Direct Observation Checklist for: ABC Analyzer Testing Process			
Employee:		Observed by:	
Did the employee correctly and completely:			
1. Perform the required daily maintenance?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
2. Correctly perform and evaluate daily calibration?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
3. Correctly perform and evaluate the controls?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
4. Generate an LIS Pending Log for the analyzer?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
5. Program patient samples into the analyzer?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
6. Load routine and stat racks onto the analyzer?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
7. Evaluate patient test results before verifying in the LIS?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
8. [AND SO ON...]			
Last question: <i>Follow all required safety precautions?</i>		<input type="checkbox"/> Yes	<input type="checkbox"/> No
Number of times observed:			
Competent to perform the procedure: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No			
Signatures			
Trainer:		Employee:	
Date:			
Remedial action taken:			
Remedial action completed:			
Date:		Trainer:	
Facility Name, Location [filename and path]		Page 1 of 1	

Appendix A7. Sample Written Assessment for the ABC Analyzer Testing Process

Written Assessment Form		Effective Date: 01/01/03	
Document Number: TR1103F/02			
Written Assessment for: ABC Analyzer Testing Process			
Employee:		Date:	
Theory Question(s): What is the primary principle this instrument uses to quantitate the various analytes that it can test for?			
Technique Question(s): What color are the stat racks for this analyzer and why are they loaded onto a different place than the routine racks?			
Interpretation Question(s): Several results on the printout have the pound sign symbol (#) after them. Why?			
Problem Solving Question(s): You see an orange flashing light on the control panel. What does it mean and what will you do about it?			
Number correct:		Number incorrect:	
Follow-up issues identified:		<input type="checkbox"/> Yes	<input type="checkbox"/> No
Actions taken:			
Reviewed by:		Date:	
Facility Name, Location [filename and path]			Page 1 of 1

Appendix A8. Sample Evaluation of Training for the ABC Analyzer Testing Process

Evaluation of Training Experience Form Document Number: TR1103G/02		Effective Date: 01/10/03	
Evaluation of Training Experience for: ABC Analyzer Testing Process			
Completed by:		Date:	
Item	Circle Y (Yes) or N (No)	Comments	Score 1= unsatisfactory 2= satisfactory 3= very good
Were you shown how to find the resource materials?	Y N		
Was the process clearly explained?	Y N		
Was (were) the procedure(s) clearly demonstrated?	Y N		
Were you shown where to get supplies and equipment?	Y N		
Were you given enough time to practice?	Y N		
Was the trainer approachable?	Y N		
Did you feel comfortable asking questions?	Y N		
If the trainer did not know the answer, could he/she find the information?	Y N		
When you did the procedure(s), were you corrected respectfully?	Y N		
Did you get constructive, timely feedback?	Y N		
Did you feel comfortable performing the procedure(s) on your own?	Y N		
Were you asked questions to gauge your knowledge and understanding of the processes or procedure(s)?	Y N		
Facility Name, Location [filename and path]		Page 1 of 1	

Appendix B1. An Example of a Direct Observation Form for Technologists

DIRECT OBSERVATION – TECHNOLOGIST RECORD

Department		Date	
Employee Name		Score (Note: Satisfactory is $\geq 80\%$)	
Skill or Assay Observed	Overall Competency Result (Place an X in the appropriate box to the right)	Satisfactory	
		Unsatisfactory	
TASK (with examples)	S	U	Comments
Application and adherence to all elements of assay method/instrument/procedure <ul style="list-style-type: none"> Follow procedures Reference instrument user manual 			
Specimen handling and processing <ul style="list-style-type: none"> Identify specimen type and storage requirements Understand specimen rejection criteria Maintains positive identification of specimen throughout all phases of the assay 			
Preparation/assessment of reagents and control materials <ul style="list-style-type: none"> Verify lot number and expiration date Ensure correct labeling 			
Interpretation and acceptance of test reactions and results <ul style="list-style-type: none"> Review and assess test results; judge acceptability (i.e., verify/confirm test results are within the prevalence range) 			
Documentation of results <ul style="list-style-type: none"> Document and notify appropriate personnel about clinically significant/unusual test result (i.e., lead technologist, or manager) Call and document critical value results 			
Review of quality control <ul style="list-style-type: none"> Understand, utilize, and adhere to Modified Westgard Multirule (refer to Laboratory Quality Control Policy) Review QC chart in LIS 			
Instrument operation, function checks, monitoring, and maintenance <ul style="list-style-type: none"> Perform daily, weekly, and monthly instrument monitoring and maintenance Operate/calibrate instruments according to manufacturer's requirements Understand instrument software/operating error messages; follow troubleshooting instructions 			

Appendix B2. An Example of a Direct Observation Form for Laboratory Assistants

DIRECT OBSERVATION – LABORATORY ASSISTANT

Department		Date		
Employee Name		Score (Note: Satisfactory is $\geq 80\%$)		
Skill or Task Observed	Overall Competency Result (Place an X in the appropriate box on the right)		Satisfactory	<input type="checkbox"/>
			Unsatisfactory	<input type="checkbox"/>
TASK (with examples)		S	U	Comments
Application and adherence to all lab assistant-specific elements of a procedure <ul style="list-style-type: none"> Follow procedures 				
Assistance with specimen retrieval, handling, and processing <ul style="list-style-type: none"> Identify specimen type and storage requirements Maintain positive identification of specimens Assist with specimen retrieval or research for missing specimens 				
Assistance with the preparation of chemicals, reagents, and solutions <ul style="list-style-type: none"> Use standard formulas and pre-defined procedures Utilize pre-assessed materials or pre-calibrated instruments 				
Assistance with preventive maintenance and troubleshooting, limited to <ul style="list-style-type: none"> Sterilize laboratory equipment Recognize instrument software/operating error messages; notify technologists Ability to follow technologist's instructions 				
Demonstration of laboratory skills/practices <ul style="list-style-type: none"> Maintain clean work area Prepare glassware and equipment Demonstrate manual dexterity 				
Adherence to all safety requirements <ul style="list-style-type: none"> Personal protective equipment Waste disposal (i.e., biohazardous vs non-biohazardous) Safe laboratory practices 				
Demonstration of LIS knowledge and abilities <ul style="list-style-type: none"> Track specimens Look up test or patient information Create pending logs Research missing specimens 				

Appendix B2. (Continued)

TASK (with examples)	S	U	Comments
Supply monitoring <ul style="list-style-type: none"> • Monitor and inventory laboratory supplies • Observe expiration dates • Inform manager if supplies need to be ordered; assist with supply ordering 			
Clerical support <ul style="list-style-type: none"> • File department slides or reports • Transcribe data on laboratory report slips or other manual or computer records after approval by a CLS • Print, track, and trace pending logs/specimens 			
Assistance or support in unexpected/unusual situations <ul style="list-style-type: none"> • Identify/describe unusual situations that pertain to position • Document unusual situations • Notify appropriate personnel (lead technologist, manager, or director) 			

<p>Comments/Corrective Action/Follow up:</p>

Competency Assessment performed by CLS (Name)	Date
Reviewed and Approved by Technical Manager	Date

Scoring Key

# Category Satisfied	Score	Overall Competency Result
10	100%	Satisfactory
9	90%	Satisfactory
8	80%	Satisfactory
7	70%	Unsatisfactory

This example was contributed by Sutter Health California Pacific Medical Center Laboratory, San Francisco, California.

Appendix C1. An Example of a Competence Assessment Form for Quantitative Testing

Competency Assessment Parallel Testing – Technologist Quantitative Testing									
Department					Date				
Employee Name					Competency Assessment performed by (Name)				
Skill or Assay Assessed					Score (Percentage if applicable)		(Place an X in the appropriate box on the right)		Pass
									Fail
Analyte	OLD Value	NEW Value	Mean	CV	SD Assay	SD Replicate	SDI OLD vs. NEW	Interpretation	
Patient 1									
Patient 2									
Patient 3									
Patient 4									
Patient 5									
Patient 6									
Reviewed and Approved by Technical Manager					Date				
Page 1 of 1									

This example was contributed by Sutter Health California Pacific Medical Center, San Francisco, California.

Appendix C2. An Example of a Competence Assessment Form for Qualitative Testing

COMPETENCY ASSESSMENT PARALLEL TESTING – TECHNOLOGIST QUALITATIVE TESTING		
Department	Date	
Employee Name	Skill or Assay Assessed	
Patient Number	New Value	Old Value
<p>Are the control values the same (e.g., both positive, both negative, or both indeterminate) or within 1 titer (e.g., 1:4, 1:8) of each other? (check one)</p> <p>YES <input type="checkbox"/> NO <input type="checkbox"/></p> <p>Do the controls correspond with the manufacturer’s expected value?</p> <p>YES <input type="checkbox"/> NO <input type="checkbox"/></p> <p>SCORE _____ PASS <input type="checkbox"/> / FAIL <input type="checkbox"/> (check one)</p>		
Competency Assessment performed by (Name)		Date
Reviewed and Approved by Technical Manager		Date

This example was contributed by Sutter Health California Pacific Medical Center Laboratory, San Francisco, California.

NCCLS consensus procedures include an appeals process that is described in detail in Section 8 of the Administrative Procedures. For further information, contact the Executive Offices or visit our website at www.nccls.org.

Summary of Comments and Working Group Responses

GP21-A: *Training Verification for Laboratory Personnel; Approved Guideline*

General

1. Consider adding a procedure for validating the assessment tools. Because of the recent downsizing operations, Human Resources departments may not be able (or willing) to help the laboratories.
 - **Validation of training guides and their respective assessment tools is discussed in Section 6.4.3.**
2. Consider placing in the appendix an example of a written policy for the implementation of a personnel training verification program.
 - **An example of a process for developing a training assessment program has been provided as recommended.**
3. Consider adding a list of people who have implemented a program and agree to serve as telephone consultants.
 - **It is not within NCCLS's scope or mandate to provide listings of consultants. Readers are encouraged to network within their local and regional professional associations.**
4. Consider adding to the preface a comment acknowledging the complexity of the process while highlighting both the need and the potential enhancement of the laboratory operation through the identification of problems or inaccuracies in the existing procedures.
 - **This guideline bases the development of training events on documented, validated work processes and procedures.**

Section 6.3.3. Learning Objectives

5. Include in the appendix or in this section additional examples of cognitive and psychomotor objectives and a list of acceptable verbs to use when developing objectives.
 - **Sections 6.4.2.2 and 6.4.2.3, respectively, discuss cognitive and psychomotor assessment. Examples have been provided.**

Section 7.2. Assessment Tools

6. Make a reference to the CLIA-88 requirements as listed in the Federal Register; that is, that all five types of verification procedures must be used.
 - **All verification methods required by CLIA '88 legislation have been discussed in Section 6.4.3.**

Section 7.2.4. Administration of a Written Test

7. Change the wording in the final paragraph as follows: “Disadvantages exist: ... the written format of questions and answers may not be like the working environment...” If well developed, written test questions can mimic directly what is encountered on the job. For example, the interpretation of hemograms, quality control data, test reporting issues, etc.
 - **A suggested means of writing test questions is discussed in detail in Section 6.4.2.2.**

Section 7.3.1. How and When to Document Verification

8. Make reference to the CLIA-88 requirements; that is, twice the first year, once thereafter.
 - **Initial and ongoing competence assessment are described in Sections 6.4.2.1 and 6.4.3.1, respectively.**

Summary of Delegate Comments and Working Group Responses

GP21-A2: *Training and Competence Assessment; Approved Guideline—Second Edition*

General

1. We feel this document does not allow for an efficient and time-effective method for change. We agreed that the training guide held useful information, but all the paperwork makes this document too cumbersome to be useful to our current laboratory operations.
- **The suggestion is to create a training guide packet for a complete work process, not for a single procedure; therefore, the number of training guides that would need to be prepared is much smaller than the total number of laboratory procedure documents.**

As for implementation, it is suggested that the laboratory begin by identifying one work process and then build the flowchart, SOPs, training, and competence assessment tools for that one process. Going process by process, it may take some time to make a complete change; this is called “continuous improvement.” The opportunity to be able to link work, training, and competence together standardizes training and reduces variation in training and performance for the benefit of patient safety. Such an opportunity should not be dismissed.

Finally, this is a guideline and not a requirement, and was prepared at the request of laboratorians who needed guidance on the subject. The sample forms were provided to show one way to design and document training and competence that fulfills regulatory and accreditation requirements and improves patient safety. However, laboratories are free to use whatever means works for them to meet requirements.

2. This is a great guideline for program development; however, full implementation of all concepts may not be practical.
- **See the response to Comment #1. We reiterate that the implementation of this guideline would need to take place gradually, process by process, but that in so doing, work processes and training become more standardized, with less of the variation that causes errors and problems. Again, laboratories are free to use whatever means works for them to meet requirements.**

NOTES

The Quality System Approach

NCCLS subscribes to a quality 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 through a gap analysis. The approach is based on the model presented in the most current edition of NCCLS document [HS1—A Quality System Model for Health Care](#). The quality system approach applies a core set of “quality system essentials (QSEs),” basic to any organization, to all operations in any healthcare service’s path of workflow. The QSEs provide the framework for delivery of any type of product or service, serving as a manager’s guide. The quality system essentials (QSEs) are:

Documents & Records Organization Personnel	Equipment Purchasing & Inventory Process Control	Information Management Occurrence Management Assessment	Process Improvement Service & Satisfaction Facilities & Safety
--	--	---	--

GP21-A2 addresses the following quality system essentials (QSEs):

Documents & Records	Organization	Personnel	Equipment	Purchasing & Inventory	Process Control	Information Management	Occurrence Management	Assessment	Process Improvement	Service & Satisfaction	Facilities & Safety
		X									

Adapted from NCCLS document [HS1—A Quality System Model for Health Care](#).

Related NCCLS Publications*

- GP2-A4** **Clinical Laboratory Technical Procedure Manuals; Approved Guideline—Fourth Edition (2002).** This document provides guidance for the patient-testing community by addressing the design, preparation, maintenance, and use of paper or electronic technical procedure manuals.
- GP26-A2** **Application of a Quality System Model for Laboratory Services; Approved Guideline—Second Edition (2002).** 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.
- HS1-A** **A Quality System Model for Health Care; Approved Guideline (2002).** This document provides a model for providers of healthcare services that will assist with implementation and maintenance of effective quality systems.
- HS4-A** **Application of a Quality System Model for Respiratory Services; Approved Guideline (2002).** This document provides a model for providers of respiratory services that will assist with implementation and maintenance of an effective quality system.
- HS5-A** **Application of a Quality System Model for Medical Imaging Services; Approved Guideline (2002).** This guideline provides the necessary background information and infrastructure to develop a quality system that defines a structure for a comprehensive, systematic approach to build quality into the imaging services processes, assess its performance, and implement quality improvements. Individual service areas, such as diagnostic radiology, CT, ultrasound, interventional radiology, magnetic resonance imaging (MRI), mammography, and nuclear medicine will benefit from applying this model to their respective operations. To provide a practical example of how a quality system is developed and implemented, suggestions for diagnostic radiology are included.

* Proposed- and tentative-level documents are being advanced through the NCCLS consensus process; therefore, readers should refer to the most recent editions.

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