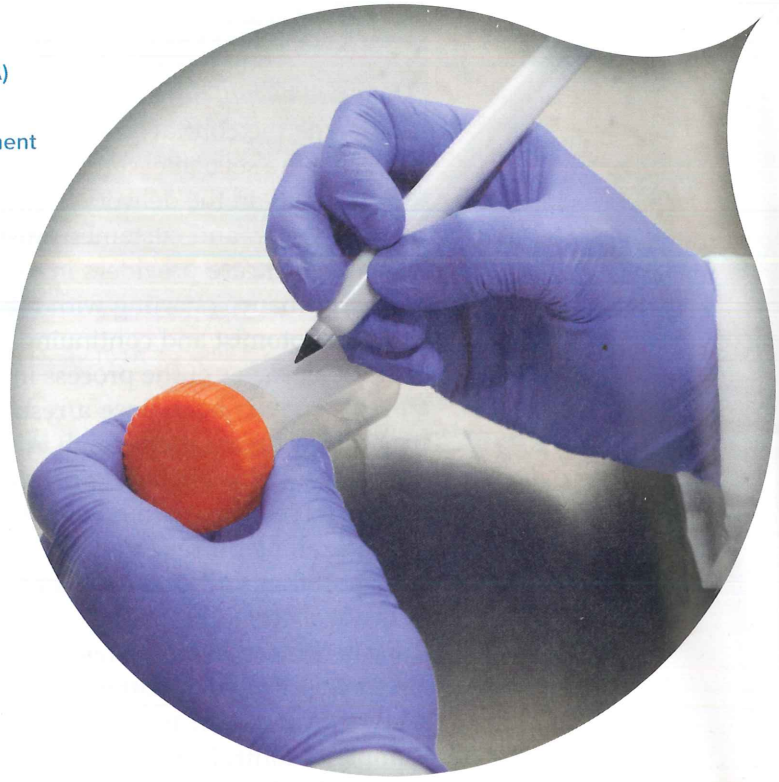
12 Quality Essentials

essential terms

- accuracy
- audit
- calibration
- competency assessment
- continuous quality improvement (CQI)
- control material
- corrective action
- delta check
- evaluation
- incident forms
- indicators
- Levey-Jennings chart
- parameters
- patient outcomes
- precision
- preventive action
- processes
- proficiency testing (PT)
- quality assessment and process improvement (QAPI)
- quality assurance (QA)
- quality control (QC)
- quality cost management (QCM)
- quality management system (QMS)
- random errors
- reliable
- shift
- standard operating procedure (SOP)
- standards
- systematic errors
- total quality management (TQM)
- training
- trend
- validation
- variances



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Learning Outcomes

12.1 Identify policies and procedures used in phlebotomy and in the clinical laboratory to ensure quality in obtaining blood specimens.

12.2 Carry out documentation of quality control.

12.3 Identify corrective actions for failures of quality control.

Related NAACLS Competencies

7.3 Instruct patients in the proper collection and preservation for non-blood specimens.

8.1 Demonstrate understanding of quality assurance in phlebotomy.

8.2 Describe quality assurance in the collection of blood specimens.

8.3 Identify policies and procedures used in the clinical laboratory to assure quality in the obtaining of blood specimens.

8.3.1 Perform quality control procedures.

8.3.2 Record quality control results.

Introduction

Ensuring quality when obtaining and processing specimens is essential to the practice of phlebotomy. This chapter presents the concepts and systems put in place, starting with the phlebotomist and the lab, to ensure quality in the delivery of healthcare.

12.1 Maintaining Quality

The word *quality* implies a state of excellence, free from defects or deficiencies, that earns the confidence and trust of consumers. Quality is accomplished by adhering to a set of measurable standards adopted by an industry, such as healthcare. Quality in the delivery of healthcare, including laboratory results, ensures patient safety, and customer satisfaction. Laboratory tests are a vital link that assists healthcare providers in identifying a patient's medical diagnosis. Quality performance—starting with the healthcare provider's order and the work of the phlebotomist and continuing until the specimen results are reported—must exist at all stages of the process in order for test results to be accurate.

Accuracy is how close a result is to the actual value. For example, if the true result for a patient value is 125 mg/dL, an accurate result measured by a chemistry test is as close as possible to that value. The **precision** of a test is its ability to give nearly the same result when performed repeatedly. Using the same example, if repeated glucose measurements fall within a close range of 120 to 130 mg/dL, the results are precise. A result can still be precise even if it is not accurate. If the true value of a glucose measurement is 125 mg/dL but repeated measurements fall within the range of 90 to 100 mg/dL, the results are precise but not accurate. This is why controls must be performed and verified to be accurate, and any errors corrected, before tests can be run on patient samples. Controls and errors are discussed later in this chapter. Figure 12-1 and Table 12-1 demonstrate the concepts of accuracy and precision.

Column (a) in Table 12-1 lists a series of glucose control measurements that are very near the actual value provided by the control manufacturer (accurate) and that are also statistically close to one another (precise). Target (A) in Figure 12-1 represents this dual accuracy and precision as a tight group of points in the center of the target.

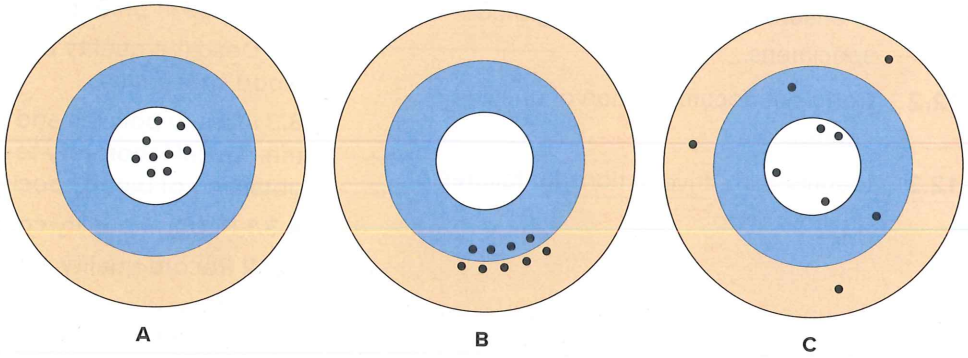

Figure 12-1 Target values. The desired test value falls in the area that is represented by the bull's-eye in the target's center. The points of impact on the target (black dots) represent glucose measurements. (A) These measurements show both accuracy and precision; they repeatedly fall inside the expected range of results. (B) These measurements are precise because they fall close together; however, they are not accurate because they do not fall within the range of expected results. (C) These measurements are neither precise nor accurate because they are not close together and very few fall within the expected range of results.

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TABLE 12-1 Glucose Quality Control Measurements with a True Value of 125 mg/dL*

Results Accurate *and* Precise (a)	Results Precise but *Not* Accurate (b)	Results *Not* Accurate or Precise (c)
122 mg/dL	100 mg/dL	122 mg/dL
127 mg/dL	102 mg/dL	162 mg/dL
125 mg/dL	90 mg/dL	135 mg/dL
126 mg/dL	95 mg/dL	126 mg/dL
122 mg/dL	101 mg/dL	102 mg/dL
124 mg/dL	98 mg/dL	124 mg/dL
125 mg/dL	95 mg/dL	85 mg/dL
120 mg/dL	103 mg/dL	150 mg/dL
127 mg/dL	100 mg/dL	117 mg/dL

*The results in each column represent the points charted on Figure 12-1A–C.

Column (b) in Table 12-1 lists a series of glucose control measurements that are far from the actual value provided by the control manufacturer (not accurate) but that are statistically close to one another (precise). Target (B) in Figure 12-1 represents this precision but lack of accuracy as a tight group of points outside the center of the target.

Column (c) in Table 12-1 lists a series of glucose control measurements, some of which are near and some are far from the actual value provided by the control manufacturer (may not be accurate). These glucose values are statistically far apart from one another (not precise). Target (C) in Figure 12-1 represents a lack of both accuracy and precision as points around the target, some in the center and others not.

A high level of quality must be present throughout the process. Physicians and patients rely on laboratory team members for quality performance. The Clinical and Laboratory Standards Institute (CLSI) recognizes a hierarchy of **processes** (step-by-step events that include procedures performed on patients, documentation into the EHR, and all associated quality activities) that lead to the achievement of quality. These processes include total quality management (TQM), quality cost management (QCM), quality management system (QMS), quality assurance (QA), and quality control (QC). Sometimes *quality assurance* and *quality control* are used interchangeably in the laboratory even though they are different processes. Another term associated with processes for ensuring quality is *quality assessment and process improvement* (*QAPI*), which may also be called *continuous quality improvement(CQI).* Even though the terminology used when describing the quality process changes from time to time, the goal is still the same—improved quality of care for patients. Although phlebotomists may not be involved at every level of quality management, they are the people from whom patients form their perceptions of laboratory quality. Understanding the similarities and differences among these quality processes will help phlebotomists be more knowledgeable during communications about quality.

The functions of the quality hierarchy are intertwined, as shown in Figure 12-2. **Pink** represents oversight of the entire process. **Yellow** represents individual departments that have their own quality management systems. The yellow areas represented by nursing and other departments, such as respiratory care, overlap with the laboratory and one another because they are involved in laboratory specimen collection and testing and are inspected by

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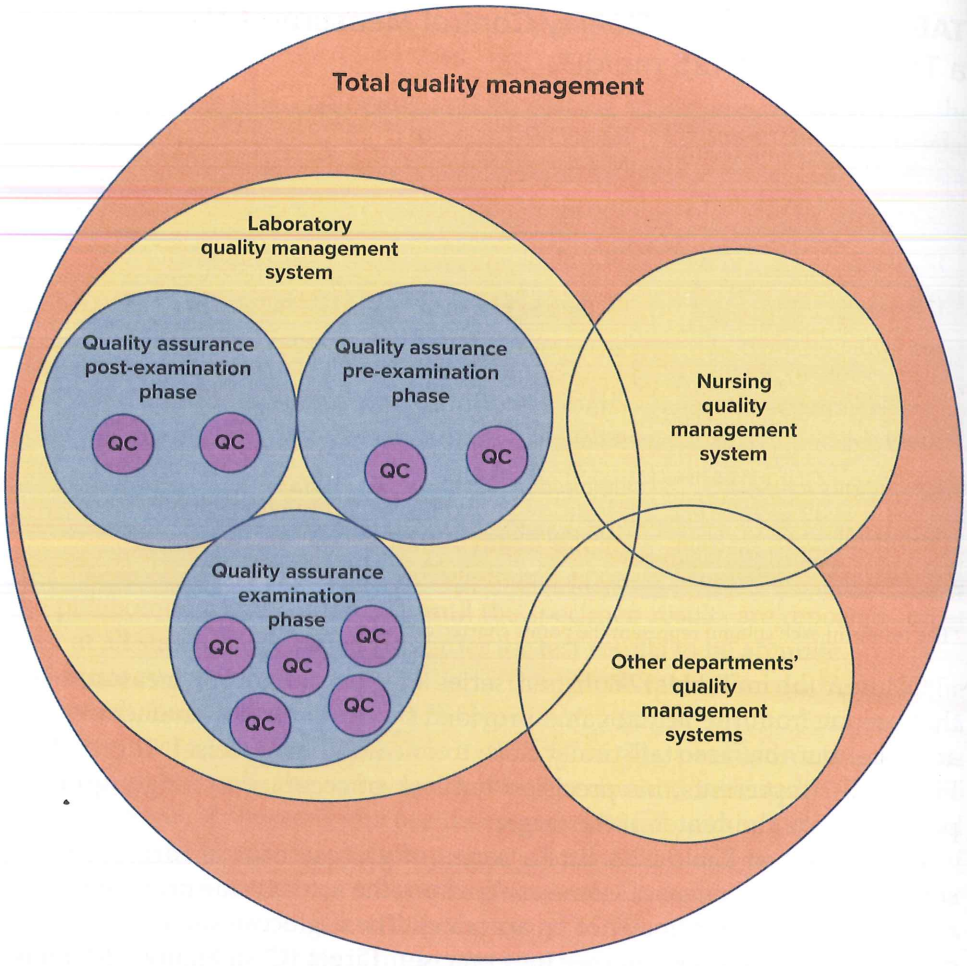

Figure 12-2 This diagram shows the hierarchy of functions within total quality management for parts of a healthcare facility that are responsible for laboratory results.

laboratory accreditation agencies. **Blue** represents the QA systems that are in place for each phase of laboratory testing (they are not depicted in the other yellow areas but are performed by other departments as well): pre-examination, examination, and post-examination phases. **White** represents the individual tasks that are performed to maintain quality, which are contained within a particular phase of testing.

Total Quality Management

Total quality management (TQM) is the highest level of quality oversight and is managed at the organizational or institutional level. TQM governs the behavior of a set of individuals, in this case healthcare workers. The purposes of TQM are to identify an organization's internal and external customers and to design operations that produce the highest customer satisfaction. TQM involves all members of the healthcare team creating quality processes to improve customer satisfaction. This satisfaction is achieved as a result of both the healthcare encounter and the *accuracy* (correctness) of the results. For example, as mentioned in the chapter *Phlebotomy and Healthcare*, a phlebotomist with an unprofessional appearance and demeanor may negatively affect the patient's satisfaction with the services received. Patients form opinions about the laboratory and healthcare facility based on how the phlebotomist appears or acts. Patient perception can be affected when the phlebotomist wears a dirty lab coat over a pair of jeans with frayed hems and sneakers with holes in them instead of maintaining a clean and neat appearance, or when the phlebotomist appears annoyed at having to help a patient or acts hurried.

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Likewise, inaccurate test results may not only yield poor patient satisfaction but also result in medical liability and cause the patient to lose trust in the facility and healthcare system. Healthcare teams are empowered to do more than just the bare minimum. Team members' responsibilities include monitoring and documenting processes and ensuring patient satisfaction. Some healthcare facilities ask patients to complete surveys or other forms of rating systems to determine their level of satisfaction with the care they receive.

Patients requiring phlebotomy services evaluate the care they receive not just on their lab results but also on the following factors:

- How long they had to wait for the procedure
- The presence or absence of bruising to the site
- How many needlesticks or attempts were required
- Their perception of the phlebotomist (e.g., dress, communication skills)

Patients who have to wait a minimum amount of time for their blood to be drawn with only one needlestick and who encounter a well-groomed, professional phlebotomist generally rate their experience positively.

Quality Cost Management

Quality cost management (QCM) is a system used to measure and manage the cost of quality. Cost of quality is not simply the cost of a procedure or product; it includes the cost of delivering healthcare with the highest level of quality. In the laboratory, this includes the cost of repeating tests when results are in question, the cost of correcting errors in a process (at every phase of testing), and the cost of maintaining customer satisfaction. Quality cost management works closely with total quality management.

Quality Management System

A **quality management system (QMS)** refers to both a set of quality objectives established to achieve the goals identified by TQM and the methods used to monitor the achievement of those objectives. In the medical laboratory, QMS includes the organizational structure of the laboratory as well as the procedures, processes, and resources needed to develop and meet quality objectives. A QMS includes the functions that most directly involve laboratory personnel—quality assurance and quality control.

Quality Assurance

The Joint Commission defines **quality assurance (QA)** as a system of planned activities that assess operational processes for the delivery of services or the quality of products provided to consumers, customers, or patients. This system is designed to guarantee quality patient care by continued reassessment of all the processes. The Centers for Disease Control states that Laboratory Quality Assurance (QA) encompasses a range of activities that enable laboratories to achieve and maintain high levels of accuracy and proficiency despite changes in test methods and the volume of specimens tested.

Quality assurance refers to examining the performance of a process to ensure that testing is being carried out correctly, results are accurate, and mistakes are found and corrected to avoid adverse outcomes. For example, the overall blood collection and handling process along with all of the individual tests these samples can undergo are frequently evaluated. Quality assurance involves looking at every step in the pre-examination, examination, and post-examination phases of a procedure. Figure 12-3 shows an example of this ongoing, cyclical process. Quality assurance activities should be in place during the entire testing process—from initial contact with the patient until the

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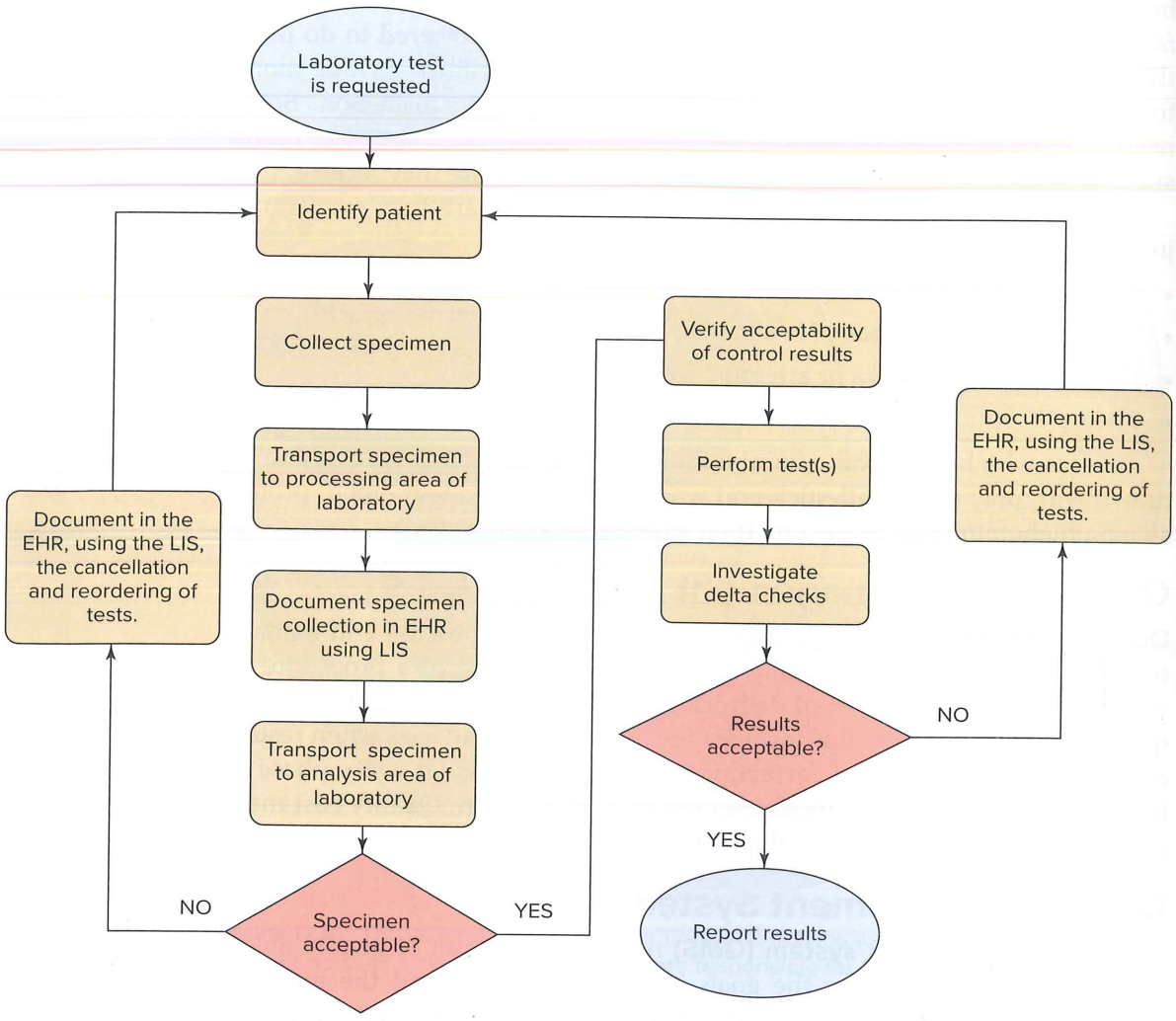

Figure 12-3 A laboratory process flowchart shows the steps followed in the process of laboratory testing.

results are documented and logged or charted on the patient's medical record. Each activity contributes to the overall assurance of quality. Any step in an activity can fail, so appropriate control measures are used constantly to minimize or eliminate failures.

When a QA program is put in place, **standards** (rules of practice) are defined and should be followed in order to meet customer safety and satisfaction requirements. Developing, evaluating, and modifying the processes, policies, and procedures used in the medical laboratory are the functions of a QA program.

Quality assurance focuses on the overall process used to measure **patient outcomes** (condition and length of hospital stay), which includes error detection activities (double-checking information) as well as corrective and preventive activities (documentation and training). In the medical laboratory setting, QA is applied to everything involved in producing a quality laboratory test result, including

- the ordering and requisitioning of tests
- positive patient identification
- collection processes
- the integrity of the specimen

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- test analysis processes
- the reporting of results
- turnaround time (the time between placing the order and receiving the results)
- the training of lab personnel
- performance on proficiency testing
- performance on laboratory inspections
- documentation and follow-up on corrective action

The assessment of any process requires the establishment of a chain of accountability, as shown in Figure 12-4. Phlebotomists help maintain this chain by properly interpreting orders for laboratory tests, performing the specimen collection process, transporting and processing specimens, performing point-of-care and waived testing, and providing test results to providers.

A series of **indicators** (observable events used as evidence) are used to access integrity of the chain. Indicators are measurable, specific, well defined, and essential to the process and are designed to assess areas of care that tend to cause problems or negative outcomes (results). They measure quality, accuracy, timeliness, customer satisfaction, adequacy, and other factors. "Wristband identification errors will be less than 1%" is one common example. To evaluate such an indicator, specific, scheduled evaluations of various documents (such as patient records, incident reports, and lab reports) and direct patient observations may be used.

Informing Patients

Communicate & Connect

Certain blood tests, such as plasma cortisol levels (used for detecting adrenal gland disorders), are affected by diurnal variations (meaning they yield different results based on the time of day they are drawn) and by whether the patient has been moving (walking or engaging in physical activity). Hospitalized patients and outpatients must have such lab tests drawn at specific times to ensure quality results. Plasma cortisol levels drawn around 3:00 P.M. will be much lower—about half the value—than levels drawn between 7:00 A.M. and 9:00 A.M. This information should be shared with patients so that they will understand the importance of adhering to scheduled times for draws.

If a patient is scheduled to have a plasma cortisol level drawn at 9:00 A.M. but the patient does not arrive for the blood work until 3:00 P.M., the phlebotomist should notify the licensed practitioner immediately. It is very likely that the physician will request that the test be rescheduled. Quality assurance programs ensure that policies and procedures are available to address instances such as this to guarantee quality results.

The purpose of **evaluation** (examining the evidence found when measuring the indicators) is to determine the acceptability of both outcomes and processes. Using the sample indicator just mentioned, if the number of wristband identification errors were to exceed 1%, the outcome would be unacceptable. Knowing that the number of errors has exceeded 1% does not solve the problem, but it does trigger a review to evaluate each step of the process for flaws. Most patients would assume that the cause of such a problem is the phlebotomist's failure to check the wristband. However, the hospital admitting clerk, the healthcare personnel caring for the patient, and the phlebotomist drawing the blood are all vital checkpoints that might cause this unwanted outcome. The process of evaluating each procedural step for accuracy is another component of quality assurance commonly referred to as *quality control (QC)*.

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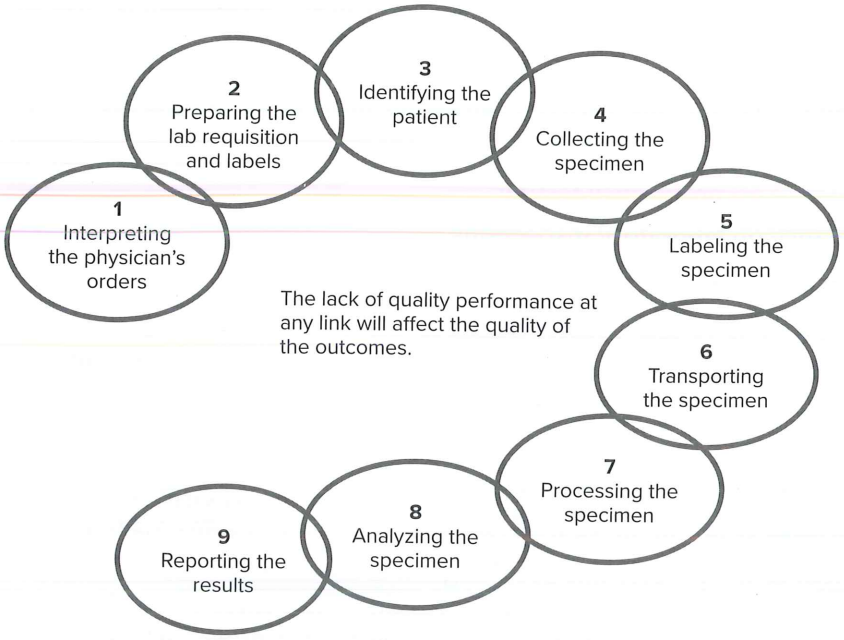

Figure 12-4 In the phlebotomy chain of accountability for laboratory tests, the phlebotomist is always responsible for 3, 4, 5, and 6 of the nine chain links shown, and perhaps all nine, depending on the place of employment.

Quality Control

Quality control (QC) is defined as activities that ensure that specific steps in a process meet acceptable standards or **parameters** (limitations). QC checks are essential to ensuring reliable results and are mandated by accrediting agencies. Accreditation inspectors periodically review QC documents. Activities such as verifying patient identity, checking reagent expiration dates, testing control material prior to patient samples, and reviewing data recording for errors are all part of quality control. Normal parameters are established for all laboratory tests in order to evaluate the outcomes. Basically, quality control measures ensure that procedural steps are followed and yield consistent results. Quality control focuses on detecting the defects in a process, which are indicated by the presence of **variances** (deviations from the procedure, such as blood collection from an arm with an IV or controls that are out of range).

Communicate & Connect

Quality Control and Customer Service

As a phlebotomist, you should participate in quality control measures, including checking equipment and supplies for defects. One example is examining the needle for defects before performing the venipuncture. Defective needles can cause undue pain for the patient. Another example is checking the expiration dates on evacuated tubes prior to use. Expired tubes can result in specimen rejections.

Once variances are identified, corrective action plans can be implemented and monitored for improvement. Evaluating the whole process is essential, especially with laboratory tests. These tests require appropriate preparation of both the equipment and the patient prior to specimen collection, and different tests require different types of preparation.

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Healthcare facilities have instruction manuals that describe these special and often mandatory preparations and collection procedures. The laboratory user or procedure manual contains the **standard operating procedure (SOP)** for each test performed in the laboratory. Each procedure's SOP explains its purpose, specimen requirements, step-by-step instructions, limitations, normal and critical values, and interpretation. Each procedure is developed using guidelines from The Joint Commission, Clinical and Laboratory Standards Institute (CLSI), Food and Drug Administration (FDA), and other regulatory agencies. This reference manual must be available to all healthcare personnel involved in the specimen collection process.

Procedures performed at laboratories that are accredited by the College of American Pathologists (CAP) are observed during inspections to ensure compliance with the laboratory's SOP. Failure to adhere to the SOP can adversely affect the quality of the specimen obtained and may therefore alter the results. Quality control activities help ensure that

- tests are performed on the correct patient
- specimen collection procedures are performed correctly and safely
- specimens are handled, transported, and processed properly
- tests are performed accurately
- **reliable** (believable and dependable) results are reported

Table 12-2 lists some of the processes in the medical laboratory setting to which QC may be applied.

Controls

A **control material** is a liquid, a serum, or freeze-dried material that has been prepared and tested by the manufacturer and that has a known value, such as a serum with a known glucose value of 125 mg/dL. This substance is used on a device when doing a system check. If the readings from the control checks are not within the acceptable parameters, the equipment will not yield accurate results. For example, a glucometer test system may have both a high control and a low control with an acceptable range for each. Values obtained during a system check of the glucometer that fall outside the established parameters indicate that corrective action is required.

If the values fall out of range when control materials are run, first double-check their expiration dates. The expiration date and lot number should be written down before testing. If they are past the expiration date, replace them and repeat the control check. If the control material has not passed its expiration date, you may repeat the control test. However, a repeat failure warrants immediate calibration, repair, or replacement of the system and should be reported immediately. Follow your facility's procedures to report or correct the problem. Do not use the equipment until the problem has been corrected.

Calibration

Calibration is a procedure used to ensure that equipment is providing accurate results. In most cases, a standards sample is run to validate accuracy. For example, if the control sample results yield 80 mg/dL, but the correct concentration is known to be 90 mg/dL, the equipment may not be reading accurately. A second control sample may be run to make sure that the equipment, rather than the sample, was the reason for the inaccuracy. If the results are the same, the equipment must be adjusted to provide an accurate reading. Although some adjustments are made manually, newer systems calibrate themselves automatically without operator assistance.

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TABLE 12-2 Examples of Quality Control in the Medical Laboratory

Phase of Laboratory Testing	Quality Control Target	Quality Control Activity and Purpose
Pre-examination	Patient identification	Using a two-identifier system to ensure that the correct patient is being drawn
	Specimen labeling	Reviewing specimen labels to determine if the required information is on the tube to ensure correct patient identification
	Specimen labeling	Labeling evacuated tubes only *after* collection *prior to* leaving the patient
	Specimen collection	Checking the quality of phlebotomy equipment prior to use for specimen collection
	Refrigerators and freezers	Recording minimum and maximum (low and high) temperatures on a daily basis to determine if stored items are maintained at the correct temperature
	Refrigerators and freezers	Recording a random daily temperature that must fall within an acceptable range
	Centrifuges	Checking the speed calibration with a tachometer to determine if the centrifuge setting and timer reflect accurate revolutions per minute (RPMs) and elapsed time
Examination	Incubators and water baths	Recording temperatures to determine if the instrument is at the correct temperature prior to use
	Analytic instruments	Testing samples with known concentrations of an analyte to determine if the instrument is functioning correctly
	Analytic instruments	Checking internal instrument temperatures, pressures, and other parameters needing monitoring during testing
Post-examination	Patient results	Retesting sample when results are critical or flagged with delta check error
	Patient results	Re-collecting specimen to confirm questionable results
	Patient results	Having receiving staff read back lab results when accepting results by phone
	Patient results	Having supervisor review results for accuracy

Validation

Another important quality control activity is **validation** (ensuring accuracy and precision). Validation ensures that the results obtained will yield the same or similar results if the test is repeated. In other words, if you were to obtain a glucose result of 107 mg/dL, the same or a similar value must be obtained on the same specimen if the test is repeated several times by different healthcare personnel or with a different instrument. Validation is required when adopting a new procedure or method for a test, when purchasing a new instrument, and when putting a new lot of controls or reagents to use. Both accuracy and precision must be validated to ensure reliable results.

Another check of validity, called a **delta check,** is performed before reporting patient results. A delta check is a check of the current result against previous results for the same test on the same patient. It is used to confirm the validity of unexpected patient test results. If results do not match previous results, expected results, or the patient's clinical symptoms, the test should be repeated, and re-collection of the specimen may be required.

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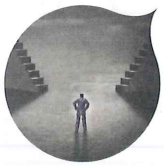
1. What is the difference between quality assurance and quality control?
2. List three types of quality control measures that are routinely used in laboratories.

Checkpoint Questions 12.1

12.2 Documenting Quality Control Activities

Documentation of testing and all related quality control activities is essential to ensuring reliable results. All quality control tests for each analyte tested on each instrument are documented on quality control log sheets (either in paper or electronic form). Figure 12-5 shows a log sheet for monitoring the performance of a point-of-care glucose monitor. The operators of the equipment enter the results of quality control (QC) performed daily and compare this to acceptable limits prior to testing patient samples. Figure 12-5 also shows a **Levey-Jennings chart** (a graph showing acceptable limits), which is used to visualize whether results fall within the acceptable parameters or if there is a **trend** (results showing an upward or downward progression) or **shift** (a sudden jump in results that continue at the higher or lower level). These log records are usually maintained for at least two years. Trends and shifts are known as **systematic errors** and may be due to aging reagents or control material, deterioration of light sources, or changes in temperature. Errors that occur with no predictable pattern are **random errors** and may have several causes. These errors tend to be harder to find and include things such as the following:

- Operator procedural error
- Equipment failure
- Outdated reagents
- Clerical errors



Think It Through

Preventing Quality Control Errors

When performing quality control checks on multiple instruments of the same type, be sure to record data on the appropriate log sheet. Each instrument may measure the same control material differently and must have its own log sheet. If control values are outside acceptable limits, you must investigate and correct the source of the error. For example, imagine that you are testing two glucose meters. After testing the first one, you notice that the result is much lower than those of the previous several days. You first must double-check that you are recording the control data on the correct log sheet. Double-check the expiration dates on the control material and test strips. Finally, review your standard operating procedure (SOP) to ensure that you are performing the procedure correctly. Was the reagent prepared properly and stored at the appropriate temperature? If no apparent cause for the error is revealed, repeat the control test; if the meter still reads out of control, do not use it for patient testing. Consult the manufacturer's information for the appropriate action in correcting the readings on the meter.

While checking the control values of your hemoglobin A1C monitor, you discover that the results are outside acceptable limits. Identify the steps, in order, that you would use to troubleshoot this problem.

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QUALITY CONTROL RECORD

PRACTICE NAME
PRECISION HEALTH CARE INC.

DEPARTMENT	Glucose Monitor-Institution #55		NAME/LEVEL
CONTROL LOT #	H542A	EXPIRATION DATE 01/29/XX	
DIRECTOR SIGNATURE DATE:			

TEST | **UNITS**

LOWER LIMIT **91** | MEAN **100** | UPPER LIMIT **109**

DATE	No.	VALUE	TECH	COMMENT
12/8/XX	1	99	KBH	
12/9/XX	2	103	KBH	prev. maintenance
12/10/XX	3	100	KBH	
12/11/XX	4	100	KBH	
12/14/XX	5	105	KBH	
12/15/XX	6	97	KBH	
12/16/XX	7	95	KBH	
12/17/XX	8	96	KBH	new battery
12/18/XX	9	103	KBH	
12/19/XX	10	100	KBH	
12/20/XX	11	103	KBH	
12/21/XX	12	97	KBH	
	13			
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	15			
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DATE	No.	VALUE	TECH	COMMENT
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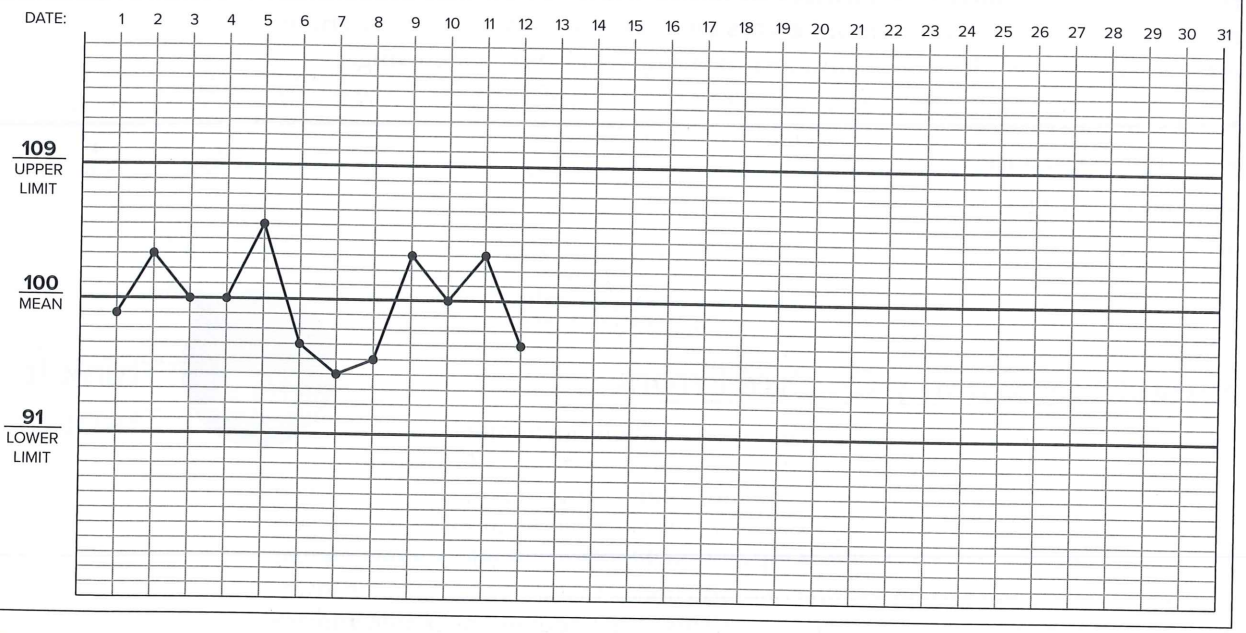

Figure 12-5 Quality control records are maintained on equipment to ensure accuracy of test results. Results are recorded on log sheets and graphed on Levey-Jennings charts that provide a visual assessment of result acceptability.

Figure 12-6 shows a Levey-Jennings chart that exhibits random and systematic errors. Levey-Jennings charts are developed using statistical calculations, which are beyond the scope of this text. Phlebotomists should know how to complete and interpret Levey-Jennings charts if they find themselves in a position that requires them to record control data.

Quality control documentation also includes activities such as recording the temperatures of refrigerators, incubators, water baths, and even the room. Specimens and reagents have ideal storage requirements, as do testing

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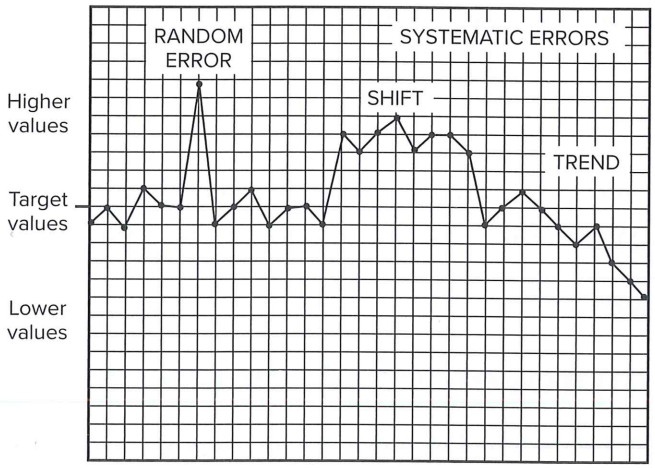

Figure 12-6 Levey-Jennings charts can help identify errors in testing such as random errors, where one or more values are outside acceptable limits; shifts, where the values show a sudden jump to higher or lower numbers; and trends, where values gradually move farther away from the target value.

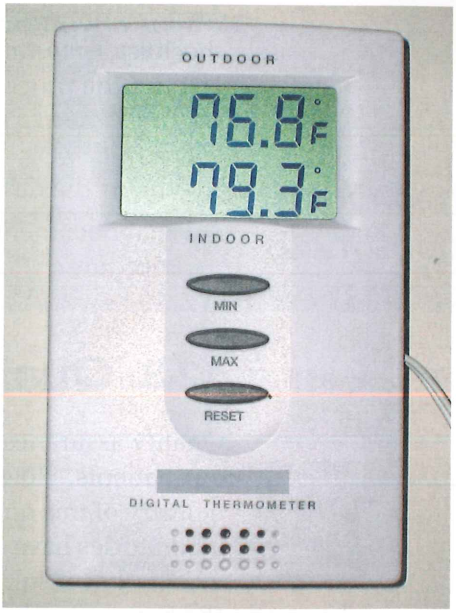

Figure 12-7 Minimum/maximum thermometers record the lowest and highest temperatures detected.
Chuck Eckert/Alamy

procedures, and laboratories must demonstrate that these requirements are being met. Daily log sheets must be maintained for documenting temperatures. Some situations require the use of a minimum/maximum thermometer (see Figure 12-7) for recording the daily variation in temperatures. Figure 12-8 shows an example of a temperature log sheet. Corrective actions (adjusting settings or defrosting freezers) must be performed when temperatures exceed minimum or maximum acceptable limits. Follow the facility's SOP for

Refrigerator Make: Westinghouse **Location:** Phlebotomy Processing #1

Record for the year: 2015 **Acceptable Range:** 2–6°C **Note:** reset thermometer on the first of the month

January	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
min	3.0	3.0	3.0	2.8	2.7	2.7	2.5	2.5	2.5	2.4	2.4										
max	3.5	3.6	3.9	4.0	4.0	6.8/4.2	4.5	4.6	4.7	4.7	4.7										
tech	lm	lm	lm	lm	lm	lm	lm	lm	lm	lm	lm										
February																					
min																					
max																					
tech																					
March																					
min																					
max																					
tech																					

Corrective Actions Taken	
Date 1/6/2015	Action: Door found ajar, reset thermometer and ensured that door is closed tightly. Rechecked temp in range KB.
Date	Action
Date	Action

Reviewed by _____ Date _____

Figure 12-8 Temperature logs are used to record either single daily temperature, or, as illustrated in this figure, the minimum and maximum temperatures on a daily basis. An important feature of the temperature log is the notes section that documents corrective action taken when temperatures fall out of range.

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documenting temperatures and taking corrective action. Use the competency checklist *Temperature Quality Control* at the end of this chapter to review and practice the procedure.

Checkpoint Questions 12.2

1. What is the difference between a random error and a systematic error?
2. What document should you consult if you are not sure how to perform a procedure?

12.3 Quality Improvement Processes

Quality assurance practices are designed to provide the best possible care for our patients. However, sometimes circumstances occur that interfere with the delivery of this quality care and may even threaten patient safety. It is vital that laboratories have a system in place that both looks at laboratory processes and events that result in decreased quality care and determines how to improve the process to eliminate these errors. This system is usually referred to as *quality assessment and process improvement.*

Quality Assessment and Process Improvement

Quality assessment and process improvement (QAPI) is the review of documentation to discover weaknesses in a process, so that they can be eliminated and the quality of patient outcomes improved. This process is also called **continuous quality improvement (CQI).** An assessment, or **audit** (review of records), is performed to discover any weaknesses in a process. Improvements to the process are implemented and the results are monitored to see if process problems are eliminated and future errors are prevented. QAPI is also used to make a process easier to perform. Table 12-3 summarizes the steps in quality assessment and process improvement. Each of these steps helps ensure that a laboratory is providing quality patient care.

Not only are QC records reviewed, but **incident forms** (documents recording procedural or process errors) are also examined to determine if a process problem exists. Figures 12-9 and 12-10 show examples of quality assessment

TABLE 12-3 Quality Assessment and Process Improvement

Step	Activity
Quality assurance	Examining processes to determine if they are functioning correctly
Quality control	Performing and documenting activities that ensure that specific steps in a process meet acceptable standards
Corrective action	Fixing problems that have occurred
Preventive action	Determining ways to prevent errors from happening in the future
Training	Educating employees about new processes and procedures
Competency assessment	Observing staff performing activities and determining adherence to policies and procedures
Proficiency testing	Testing personnel through an external agency such as CAP (College of American Pathologists)
Audit	Examining records for processes and procedures that were performed and the presence, frequency, and resolution of any errors
Evaluation	Determining the acceptability of both outcomes and processes
Process improvement	Developing and implementing ways to make processes and procedures better
Individualized Quality Control Plan (IQCP) by CLIA	Permits customizing of current QC plan according to test method and use, environment, and personnel competency while providing equivalent quality testing

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QUALITY ASSESSMENT: OCCURRENCE OF VARIANCE

(A) _____
Patient name | Medical record # | Date

(B) _____
Patient location | Form completed by

_____
Specimen accession # | Specimen type | Tests affected

(C) Complaint: [ ] Patient Issue [ ] Safety Issue [ ] Armband Issue [ ] Employee Issue

(D)
Pre-Examination-Specimen Related [ ] Laboratory collect [ ] Nurse collect

[ ] Clotted [ ] Mislabeled [ ] Wrong patient
[ ] Hemolyzed [ ] Missing specimen [ ] Wrong specimen type
[ ] Insufficient specimen [ ] Missed test / wrong order [ ] Wrong collection time

(E)
Examination Results Questionable [ ] Laboratory collect [ ] Nurse collect
[ ] Delta check [ ] Specimen integrity issue [ ] Other concern _____

(F)
Post-Examination Results Invalid [ ] Laboratory collect [ ] Nurse collect
[ ] Reported on wrong patient [ ] Erroneous results reported [ ] Other _____

(G) Licensed caregiver notified _____ Date and time _____
Investigation Summary

_____

(H) Severity [ ] Caused healthcare provider to take wrong action [ ] Caused delay in patient care

(I) [ ] Training issue [ ] Non-compliance issue [ ] Other

(J)
Follow-up
[ ] Discussed variance with employee
[ ] Reviewed SOP with employee
[ ] Modified procedure
[ ] Re-training scheduled
[ ] Other _____

Supervisor _____ Date _____

Employee _____ Date _____

Figure 12-9 This quality assessment form documents the occurrence of a variance in the delivery of quality healthcare. Documentation includes (A) patient information; (B) specimen information; (C) type of complaint; (D, E, F) phase of the procedure and the cause; (G) the person notified and an investigation summary, including the corrective action; (H) the severity of the incident; (I) classification of the issue; and (J) the preventive action.

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QUALITY ASSURANCE VARIANCE FORM

Patient name _____ Medical number _____ Date of service _____

Accession # _____ Specimen type _____ Test(s) affected _____

Physician _____ Form completed by _____ Date and time _____

Missing information

[ ] Insurance information: (Responsible Party, SSN, Address, Diagnosis, etc.) _____

[ ] Test(s) Requested _____

[ ] Correct Spelling of Name _____

[ ] Name on Specimen _____ [ ] Name on Requisition _____

[ ] Source _____

[ ] Date and Time of collection _____

[ ] Other _____

Specimen Rejection

[ ] Reason _____

[ ] Specimen to be recollected

[ ] Requested by _____ Date and time _____

Mislabeled / Unlabeled Specimen

[ ] Mislabeled

Specimen labeled as: _____ Specimen actually collected from _____

Date of birth _____

[ ] Unlabeled specimen

Patient Name _____ Date of birth _____

Accountability

I attest that the specimen sent to the laboratory was collected from the above patient.

_____ _____

Print Name Job Title

_____ _____

Signature Date

Figure 12-10 A form used to document variance in quality care.

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forms used to identify problems and document corrective actions. These forms may reveal problems with specimen collection and handling, testing procedures, equipment that affects patient safety, and the reporting of laboratory test results. Laboratory managers and QAPI committees review these forms and implement changes to processes to eliminate particular problematic patterns. Documentation of problems is never meant to be used as a punitive measure but rather to identify areas where improvements need to be made.

A **corrective action** is an activity that helps eliminate the cause of an error or undesirable situation. Examples of corrective actions include turning up the setting on a refrigerator that is too cold, discarding outdated reagents, and calling the manufacturer to correct an instrument problem. An example of corrective action in phlebotomy is re-collecting blood from a patient whose specimen produced invalid results or was clotted, hemolyzed, or insufficient. A **preventive action** is an activity that helps ensure that a problem does not occur or does not occur again. An example is the modification of a technique, such as counting the number of tube inversions during specimen mixing to prevent clotting of anticoagulated specimens. Another form of preventive action is employee **training,** providing staff with the knowledge to perform their jobs correctly and accurately. Part of the training process may include observation of an employee by a supervisor to determine the level of competence the employee has in performing a procedure.

QAPI committees summarize their findings in monthly, quarterly, and yearly reports or as requested by their healthcare facility. Figure 12-11 is an example of a form that may be used by QAPI committees to document progress concerning the number of rejected phlebotomy blood collections.

Competency and Proficiency

Competency assessment is a method of documenting an employee's ability to perform assigned tasks correctly. These tasks can include any step in the laboratory testing process, from patient identification all the way through to the reporting of test results (pre-examination, examination, and post-examination processes). Competency assessment documents are kept in employee files and may reveal the need for additional training. Also, documentation of individual competency is often required of laboratories during institutional or laboratory-specific inspections.

Proficiency testing (PT) is a means of evaluating the performance of a laboratory and its personnel in comparison with that of other, similar laboratories. Agencies such as the College of American Pathologists (CAP), Department of Public Health (DPH), Centers for Disease Control and Prevention (CDC), and Clinical Laboratory Improvement Amendments (CLIA) provide samples to be tested, such as cell identification, chemistry analysis, or other routine and specialized tests a lab may perform. Laboratories perform the required tests and return the results to the agency. An analysis of the results is given to the laboratory, along with suggestions for improving performance if the results are out of range. Laboratory inspectors require documentation of proficiency testing, along with documentation of corrective actions taken if performance deficiencies are identified. Continued errors on proficiency testing may result in a laboratory no longer being allowed to provide the affected test or service.

Quality Improvement Tools

Many healthcare organizations employ specific tools and methods to achieve the level of quality they require. Both commercial and government tools are available. Some are related specifically to healthcare organizations; others

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LABORATORY QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT FORM

[ ] Initial Assessment [ ] Scheduled Study [ ] Unscheduled Study [ ] Mandatory Report

Indicator Description	Specimen Rejections											
I. RESULTS												
Quarter	1ST			2ND			3RD			4TH		
Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
TOTAL												
Mislabeled												
Hemolyzed												
Clotted												
QNS												
Contaminated												
BENCHMARK / GOAL: Less than 1 mislabeled specimen per month; less than 5 specimen rejections in all other categories												
II. ATTACH GRAPHED DATA												
III. INDICATOR DEFINITION												
Numerator: number of rejected blood specimens							Denominator: total number of blood specimens processed					
Exclusions if any:							Exclusions if any:					
IV. RESULT SUMMARY				V. WAS GOAL MET? [ ] YES [ ] NO								
V. PLAN OF ACTION												

REVIEWED BY: _____ _____

Figure 12-11 Reports such as this one are generated by QAPI committees to monitor progress with a particular measure of quality.

are more general and can be applied to any type of process or service. Major healthcare organizations also provide tools. Table 12-4 describes a few of the major quality improvement tools and methods.

Checkpoint Questions 12.3

1. How does a corrective action differ from a preventive action?
2. Explain the purpose of filling out a variance form when errors in phlebotomy procedures occur.

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TABLE 12-4 Sources for Quality Improvement Tools and Methods

Quality Improvement Method	Description
Health Resources and Services Administration quality improvement tools	A toolbox of clinical quality and performance measures provided by the U.S. Department of Health and Human Services, including tools for data collection and performance measurement webinars.
The Joint Commission quality improvement tools	A suite of tools and resources for healthcare organizations to help them meet TJC standards and National Patient Safety Goals. These tools are available only to TJC-accredited organizations.
Root Cause Analysis (Six Sigma)	A commercial quality improvement program that provides methodologies for improving quality and reducing variation in any new or existing process. The steps of analysis for new processes include define, measure, analyze, design, and verify. The steps of analysis for existing processes include define, measure, analyze, improve, and control.
Failure Mode Effects Analysis (FMEA)	Step-by-step method to identify all of the possible causes of failure in a process or service. These causes are then prioritized according to their seriousness and frequency. Each problem is then analyzed and corrective actions are taken. As each corrective action is completed, the date and results are recorded.

Chapter Summary

Learning Outcome	Key Concepts/Examples	Related NAACLS Competency
12.1 Identify policies and procedures used in phlebotomy and in the clinical laboratory to ensure quality in obtaining blood specimens.	• Systems exist for monitoring the quality of laboratory procedures, including blood collection. • Quality assurance processes include assessment and evaluation of all steps in a procedure. • Quality control is the activity that ensures that specific steps in a procedure meet performance standards.	7.3, 8.1, 8.2, 8.3
12.2 Carry out documentation of quality control.	Accurate documentation of all quality assurance and quality control activities is essential for monitoring quality.	8.1, 8.2, 8.3, 8.3.1, 8.3.2
12.3 Identify corrective actions for failures of quality control.	Quality assessment and process improvement (QAPI) provides a system for error detection and correction to ensure patient safety and satisfaction, valid test results, and accurate reporting of results.	8.1, 8.2, 8.3

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Chapter Review

A: Labeling

For the following form, indicate what is recorded in each numbered section.

QUALITY ASSESSMENT: OCCURRENCE OF VARIANCE

(1) _____
Patient name | Medical record # | Date

_____
Patient location | Form completed by

(2) _____
Specimen accession # | Specimen type | Tests affected

(3) Complaint: [ ] Patient Issue [ ] Safety Issue [ ] Armband Issue [ ] Employee Issue

(4)
Pre-Examination-Specimen Related [ ] Laboratory collect [ ] Nurse collect

[ ] Clotted [ ] Mislabeled [ ] Wrong patient
[ ] Hemolyzed [ ] Missing specimen [ ] Wrong specimen type
[ ] Insufficient specimen [ ] Missed test / wrong order [ ] Wrong collection time

(5)
Examination Results Questionable [ ] Laboratory collect [ ] Nurse collect
[ ] Delta check [ ] Specimen integrity issue [ ] Other concern _____

(6)
Post-Examination Results Invalid [ ] Laboratory collect [ ] Nurse collect
[ ] Reported on wrong patient [ ] Erroneous results reported [ ] Other _____

(7) Licensed caregiver notified _____ Date and time _____
Investigation Summary

_____

(8)
Severity [ ] Caused healthcare provider to take wrong action [ ] Caused delay in patient care

(9) [ ] Training issue [ ] Non-compliance issue [ ] Other

(10)
Follow-up
[ ] Discussed variance with employee
[ ] Reviewed SOP with employee
[ ] Modified procedure
[ ] Re-training scheduled
[ ] Other _____

Supervisor _____ Date _____

Employee _____ Date _____

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1. [LO 12.3] _____
2. [LO 12.3] _____
3. [LO 12.3] _____
4. [LO 12.3] _____
5. [LO 12.3] _____
6. [LO 12.3] _____
7. [LO 12.3] _____
8. [LO 12.3] _____
9. [LO 12.3] _____
10. [LO 12.3] _____

B: Matching

Match each term with its definition.

___**11.** [LO 12.3] audit

___**12.** [LO 12.3] competency assessment

___**13.** [LO 12.3] corrective action

___**14.** [LO 12.3] preventive action

___**15.** [LO 12.3] process improvement

___**16.** [LO 12.3] proficiency testing

___**17.** [LO 12.1] quality assurance

___**18.** [LO 12.2] quality control

___**19.** [LO 12.2] random errors

___**20.** [LO 12.2] systematic errors

___**21.** [LO 12.3] training

a. examining process functionality
b. ensuring acceptability of a specific procedural step
c. fixing problems that have occurred
d. ensuring that errors do not reoccur
e. educating employees
f. testing and documenting an employee's ability to perform tasks correctly
g. external agency evaluation of a testing procedure or process
h. examination of records
i. making processes and procedures better
j. can cause a shift or trend in test results
k. have no predictable pattern

C: Fill in the Blank

Write in the word(s) to complete the statement.

22. [LO 12.1] The terms *quality* _____ and *quality* _____ are often used interchangeably.

23. [LO 12.1] The CLSI has established a hierarchy of _____, or step-by-step events, that help laboratories achieve high-quality results.

24. [LO 12.1] How close a test result is to being correct is its _____.

25. [LO 12.1] Rules of practice are commonly called _____.

26. [LO 12.3] _____ is the examination of a process or procedure for acceptability of outcomes.

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27. [LO 12.1] A laboratory procedure manual contains the _____ for every test performed in the laboratory.

28. [LO 12.1] Test results are considered _____ if they are both believable and dependable.

29. [LO 12.1] _____ is the procedure used to check and adjust settings on instruments.

30. [LO 12.2] Serum that is specially prepared for use in testing the reliability of instruments is a(n) _____.

31. [LO 12.2] A graph that shows if control results are within acceptable limits is a(n) _____.

32. [LO 12.2] A jump in the values of control results is a(n) _____, whereas a gradual change in one direction is a(n) .

33. [LO 12.1] Factors that may decrease a patient's or customer's _____ with the services received include inaccurate results, long wait times, and phlebotomists with an unprofessional appearance.

D: Sequencing

Place the links of quality performance in the correct order of occurrence for the laboratory testing process (from 1 to 9).

34. [LO 12.1] _____ Analyze the results.

35. [LO 12.1] _____ Collect the specimen.

36. [LO 12.1] _____ Identify the patient.

37. [LO 12.1] _____ Interpret the physician's orders.

38. [LO 12.1] _____ Label the specimen.

39. [LO 12.1] _____ Prepare the lab requisition.

40. [LO 12.1] _____ Process the specimen.

41. [LO 12.1] _____ Report the results.

42. [LO 12.1] _____ Transport the specimen.

E: Case Studies/Critical Thinking

43. [LO 12.1] You are about to perform a venipuncture procedure. Upon examining the expiration dates on the evacuated tubes, you notice that the EDTA tube has been expired for 2 months. What is your course of action? How is this action part of quality assurance? What would be the consequences if you had not checked the expiration dates?

44. [LO 12.2] You are performing a routine quality control check on the glucometer machine prior to using it. The machine function check is fine with the low control check, and the high control check reading is 90. The machine you are using has a high control value of 110 mg/dL with an acceptable range of 105–115 mg/dL and a low control value of 75 mg/dL with an acceptable range of 70–80 mg/dL. Determine what actions, if any, are required.

45. [LO 12.3] You have been serving on the laboratory's QAPI committee for more than a year now. A new committee member approaches you and asks what her responsibilities will be. What should you tell her?

46. [LO 12.3] A phlebotomy supervisor has received a complaint that the turnaround times for STAT tests ordered by the emergency department are too long. The complaint was communicated through the laboratory manager, who was informed by laboratory personnel that the specimens were not delivered to them for more than 30 minutes after the collection time on the tubes. What should be put in place and what are some possible scenarios for this variance in quality care?

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F: Exam Prep

Choose the best answer for each question.

47. [LO 12.1] Surveying patient satisfaction with the healthcare delivery system at a facility is an example of
    a. quality assurance.
    b. quality control.
    c. quality documentation.
    d. quality management.

48. [LO 12.1] Which event will most likely negatively affect patient satisfaction with the laboratory?
    a. One attempt was needed to obtain a blood specimen.
    b. No hematoma formed after the venipuncture procedure.
    c. The patient's breakfast was delayed because the phlebotomist was late in arriving to collect the fasting specimen.
    d. The phlebotomist wore a lab coat during the procedure.

49. [LO 12.1] A system for evaluating the delivery of a healthcare service, such as specimen collection, is
    a. quality assurance.
    b. quality control.
    c. quality documentation.
    d. quality management.

50. [LO 12.1] An ongoing set of activities used to monitor turnaround times is an example of
    a. quality assurance.
    b. quality control.
    c. quality documentation.
    d. quality management.

51. [LO 12.1] The focus of quality assurance is on processes that involve all of these *except*
    a. requisitioning of tests.
    b. integrity of the specimen.
    c. performance on lab inspections.
    d. laboratory staff salaries.

52. [LO 12.1] Achieving complete correctness or acceptable measures as close as possible to the true value is known as
    a. accuracy.
    b. calibration.
    c. process.
    d. procedure.

53. [LO 12.1] Liquid or freeze-dried serum with a known value from the manufacturer is a(n)
    a. analyte.
    b. control material.
    c. reagent.
    d. testing agent.

54. [LO 12.1] When should quality assurance activities be in place?
    a. In the pre-evaluation phase of testing
    b. In the evaluation phase of testing
    c. In the post-evaluation phase of testing
    d. In all of these

55. [LO 12.1] Rules of practice for performing a procedure are referred to as
    a. standards.
    b. codes of ethics.
    c. parameters.
    d. validations.

56. [LO 12.1] Determining the turnaround time for STAT tests ordered for patients in the emergency department is a function of
    a. quality assurance.
    b. quality control.
    c. competency assessment.
    d. proficiency testing.

57. [LO 12.1] Acceptable limits for quality control results are referred to as
    a. standards.
    b. variances.
    c. parameters.
    d. validations.

58. [LO 12.1] Deviations from the standard operating procedure are referred to as
    a. standards.
    b. variances.
    c. parameters.
    d. limitations.

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59. [LO 12.1] An individual's ability to perform a procedure, such as blood collection, is documented in the
    a. quality assessment form.
    b. standard operating procedures.
    c. competency assessment form.
    d. proficiency testing materials.

60. [LO 12.2] Recording the temperatures of the refrigerators used to store blood for testing is an activity of
    a. quality assurance.
    b. quality control.
    c. competency assessment.
    d. proficiency testing.

61. [LO 12.3] Reviewing the temperature logs for variances in blood storage temperatures is an activity of
    a. QAPI.
    b. QC.
    c. CA.
    d. PT.

62. [LO 12.3] Questioning the accuracy of test results may occur if
    a. the results are significantly different than the last time the test was performed on the same patient.
    b. the results are consistent with the medical provider's diagnosis or expectations.
    c. the results are consistent with the patient's clinical symptoms.
    d. All of these apply.

63. [LO 12.2] Quality control activities include recording temperatures for *(Choose all that apply.)*
    a. freezers.
    b. incubators.
    c. refrigerators.
    d. patients.

64. [LO 12.3] Problems with any step in a process may be discovered when reviewing *(Choose all that apply.)*
    a. incident report forms.
    b. competency assessments.
    c. proficiency testing results.
    d. continuing education records.

65. [LO 12.3] Educating employees about the use of a new piece of phlebotomy equipment is an example of
    a. audit and evaluation.
    b. corrective action.
    c. competency assessment.
    d. training.

66. [LO 12.3] Developing and implementing ways to make processes and procedures better is the purpose of
    a. audit and evaluation.
    b. corrective action.
    c. preventive action.
    d. process improvement.

67. [LO 12.1] Which of the following is a purpose of total quality management?
    a. To measure and manage the cost of quality
    b. To ensure that specific steps in a process meet acceptable standards
    c. To design operations that produce a high level of customer satisfaction
    d. To discover and eliminate weaknesses in laboratory processes

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NAME: _____ DATE: _____

COMPETENCY CHECKLIST: QUALITY ASSURANCE IN THE LABORATORY

Procedure Steps	Practice 1	Practice 2	Practice 3	Performed Yes	Performed No	Performed Master
Preprocedure						
1. Interprets the physician's order correctly.						
2. Prepares the laboratory requisition and labels.						
3. Greets the patient and introduces self.						
4. Identifies the patient using at least two unique identifiers.						
Procedure						
5. Collects the required specimens according to the facility's standard operating procedures to help ensure the integrity of the specimens.						
6. Labels the specimens accurately and completely while still with the patient.						
7. Thanks and dismisses the patient.						
8. Transports the specimens to the processing area of the laboratory, taking care to follow any special temperature or other requirements for specific specimens.						
9. Documents specimen collection in EHR using LIS.						
10. Checks specimens for acceptability. If a specimen is not acceptable, documents this in the EHR using LIS and reorders the tests.						
11. If the specimens are acceptable, runs quality control tests as indicated for each specimen and laboratory test.						
12. Verifies that control results are within normal limits.						
13. Performs the ordered laboratory tests.						
14. Performs delta checks. If delta check fails, documents the results and cancellation, and reorders the tests.						
Postprocedure						
15. If the results are acceptable, reports the results within the accepted turnaround time.						
16. Documents the test results.						

COMMENTS: _____

_____

SIGNED

EVALUATOR: _____

STUDENT: _____

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NAME: _____ DATE: _____

COMPETENCY CHECKLIST: TEMPERATURE QUALITY CONTROL

	Practice			Performed		
Procedure Steps	**1**	**2**	**3**	**Yes**	**No**	**Master**
Preprocedure						
1. Locates the appropriate temperature log for the instrument to be checked.						
Procedure						
2. Correctly reads the minimum temperature.						
3. Correctly reads the maximum temperature.						
4. Correctly records temperatures on the temperature log.						
5. Compares temperatures with acceptable range.						
6. Applies corrective action (according to facility policy).						
7. Correctly documents corrective action.						
8. Properly signs and dates the temperature log.						
Postprocedure						
9. Returns thermometer and temperature log to the correct location.						

COMMENTS: _____

_____

SIGNED

EVALUATOR: _____

STUDENT: _____

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