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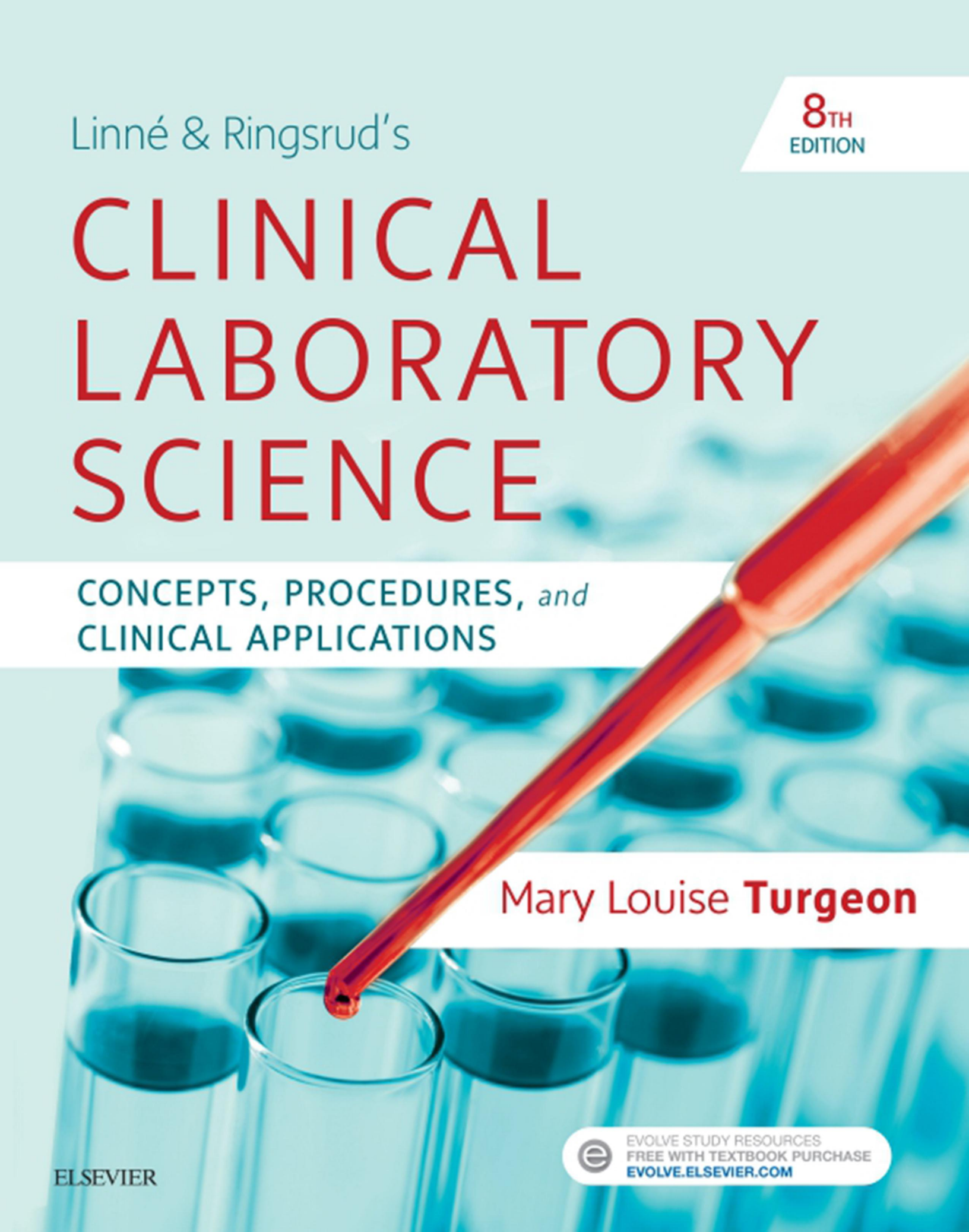
CONCEPTS, PROCEDURES, *and* CLINICAL APPLICATIONS



Mary Louise **Turgeon**

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CLINICAL LABORATORY SCIENCE

CONCEPTS, PROCEDURES, *and* CLINICAL APPLICATIONS

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Dr. Turgeon has 18 years of university and 15 years of community college teaching and program administration experience. Guest speaking, scientific presentations, and technical and educational workshops complement her teaching and writing activities. Her consulting practice focuses on new clinical laboratory science program development, curriculum revisions, course development, and increasing teaching effectiveness in the United States and internationally. She has volunteered as a laboratory educational consultant in Lesotho, South Africa, and Cambodia.

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Every New Day Should be a Learning Adventure

This edition is dedicated to the home team of Dick and Murphy.

PREFACE

The intention of this eighth edition of *Clinical Laboratory Science: Concepts, Procedures, and Clinical Applications* is to continue to fulfill the need for a basic, comprehensive textbook that can be used by students and instructors for career preparation in many different courses throughout the entire medical laboratory science curriculum.

Multiple sources are used to revise content in each new edition of *Clinical Laboratory Science*. These sources include tracking emerging information in journals, participating in professional meetings and expositions, and consulting peer reviewers. The newest Entry Level Curriculum Updates for workforce entry published by the American Society for Clinical Laboratory Science (ASCLS) and the American Society for Clinical Pathology (ASCP) Board of Certification Exam Content Outlines serve as additional content reference sources.

A solid, robust foundation exists for each new edition of *Clinical Laboratory Science* because of feedback on previous editions following field testing by instructors and undergraduate medical laboratory technician (MLT) and medical laboratory science (MLS) students in the classroom and laboratory. Dynamic interaction continues to strengthen the clarity and organization of content presented in *Clinical Laboratory Science*.

The purpose of this edition continues to be to integrate and apply basic and emerging concepts in laboratory medicine, to outline the underlying theory of routine laboratory procedures done in clinical laboratories of varying sizes and geographic locations, and to present applicable case studies to help students critically assess theory and practice.

The organization of *Clinical Laboratory Science* begins with key terms and a topical outline. Learning outcomes are differentiated into MLT and MLS levels. Different levels of outcomes are reflected in the verbs used for each learning objective. Learning outcomes and an extensive number of end-of-chapter review questions are organized and coordinated under major topical headings.

Fully developed laboratory exercises focus on representative student laboratory procedures and consistently use the Clinical and Laboratory Standards Institute (CLSI) format. Laboratory exercises have associated learning outcomes and review questions. Case studies with critical thinking group-discussion questions are included in relevant chapters.

A comprehensive bank of end-of-chapter review questions appears in each chapter. Illustrations, full-color photographs, tables, and boxes are used throughout *Clinical Laboratory Science* to visually clarify concepts and arrange detailed information to complement the learning preferences of today's digital learners.

WHAT'S NEW IN THE EIGHTH EDITION OF *CLINICAL LABORATORY SCIENCE*?

Clinical Laboratory Science is divided into two main sections: Part I, Basic Laboratory Techniques, and Part II, Clinical Laboratory Specializations. The entire book has been thoroughly reviewed and revised, as needed, to introduce new concepts and practices and to eliminate any outdated content.

Part I: Basic Laboratory Theory and Techniques

Chapter 1–Chapter 9

Content in this section addresses traditional core content related to fundamental principles and practices in the laboratory. In addition, foundation knowledge continues to be refined and expanded in each new edition.

The "new face" of laboratory practice is reflected in an increased emphasis on safety, patient considerations, quality, and delivery of testing. Innovative laboratory testing techniques are included in Chapter 8, Basic and Contemporary Techniques in the Clinical Laboratory, and Chapter 9, Laboratory Testing: From Point of Care to Total Automation.

Examples of What's New in Part I

- Presentation of the newest concept of a designated laboratory safety officer supported by laboratory safety coaches as the critical "safety eyes" and "safety ears" to implement surveillance of correct safety practices.
- Assessment of the real net clinical value of a laboratory result in balancing the benefits that a test delivers against any harm that it may cause to a patient.
- Comparison of proficiency testing and alternate assessment of quality. Alternative methods include external split samples, internal split samples, audit samples, and the use of government and university inter-laboratory comparisons.
- Introduction of a system for managing analytical quality based on the concept of *total analytic error* (TAE).
- Explanation of The Joint Commission's National Patient Safety Goals and the newest American Hospital Association Patient Care Partnership document.
- Investigation of the concepts of patient-centric laboratory testing, personal direct-to-consumer genetic testing. and emerging patient-centric technologies.
- Inclusion of new evacuated blood-collection tubes and bar codes.
- Clarification of various levels of water purity.
- Evaluation of lateral and vertical flow immunoassays and alternative labeling technologies.
- Comparison of the technology of the latest handheld point-of-care instruments.

Part II: Clinical Laboratory Specializations

Chapter 10–Chapter 17

This section of the book addresses the principles of testing, physiology, analysis by laboratory methods, and applicable diseases or disorders and provides related case studies with critical thinking group-discussion questions in each chapter. The emphasis in each clinical chapter is on new or emerging point-of-care testing methods and automated laboratory testing.

Examples of What's New in Part II

- Introduction of additional information related to Ca^{2+}, calculation of the estimated glomerular filtration rate, and the newest cardiovascular disease risk factors and assessment strategies.
- Discussion of new methods for determination of the erythrocyte sedimentation rate.
- Presentation of new automated hematology instruments.
- Assessment of new point-of-care testing instruments for international normalized ratio (INR) testing.
- Presentation of new automated urine and body fluid analyzers.
- Explanation of magnetic resonance spectroscopy testing.
- Description of fetal lung maturity assessment and prediction of risk of respiratory distress syndrome.
- Comparison of the relationship of expected microbiota, host microbiota, and the immune system in maintaining tissue homeostasis in healthy individuals.
- Discussion of probiotics.
- Introduction of matrix-assisted laser desorption ionization time-of-flight mass spectrometer (MALDI-TOF) technology in microbiology.
- Comparison of laboratory safety measures for Zika and Ebola viruses.
- Assessment of fetomaternal hemorrhage and Rh prophylaxis with calculation of the required number of vials of RhIg.

WAYS TO USE THIS BOOK

The eighth edition of *Clinical Laboratory Science* can be used as a primary or supplementary textbook from the beginning to the end of the entire clinical laboratory science curriculum for Medical Laboratory Science, MLS, and Medical Laboratory Technology, MLT) students.

The majority of chapters in Clinical Laboratory Science feature case studies to enhance critical thinking skills. Narrative answers are provided for instructors to guide a discussion of case study related critical thinking group discussion questions. Applicable chapters have related Student Procedure Worksheets to reinforce classroom content. Appropriate courses to consider for *Clinical Laboratory Science* adoption are as follows:

- Introduction to Medical Laboratory Science
- Laboratory Techniques, including Microscopy
- Phlebotomy
- Urinalysis
- Lab Math
- Core Clinical Laboratory Theory and Practice
- Laboratory Instrumentation
- Immunology and Serology
- Hematology*
- Clinical Chemistry*
- Microbiology*
- Blood Banking/Transfusion Medicine*
- Comprehensive Course and Certification Examinations Review

Comments from clinical laboratory students and instructors are always welcome.

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*All semesters—MLT; first semester—MLS.

ACKNOWLEDGMENTS

My objective in writing *Clinical Laboratory Science: Concepts, Procedures, and Clinical Applications,* Eighth Edition, is to continue to integrate and apply concepts, theory, and applications of clinical laboratory science. This book provides me with a challenging opportunity to share classic and emerging laboratory science information with students and educators.

Thanks to Ellen Wurm-Cutter, Senior Content Development Manager. We have worked together on three previous editions of *Clinical Laboratory Science* and multiple previous editions of *Immunology and Serology in Laboratory Medicine.* Working with her is always a pleasure.

Additional thanks to Kellie White, Executive Content Strategist, who is my editor for this edition of *Clinical Laboratory Science* and was my editor for *Immunology and Serology in Laboratory Medicine*, ed 6. Thank you to Alexandra York, Associate Content Development Specialist, for her efforts associated with this edition.

Finally, a big thank you to Rich Barber for his patience and extreme concern for the highest level of quality in this book.

Ellen, Kellie, and Rich, I sincerely appreciate all of your efforts on my behalf and your friendships.

Mary L. Turgeon

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Fundamentals of the Clinical Laboratory

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CHAPTER CONTENTS

LEARNING OUTCOMES

Clinical laboratory science
- Name and differentiate the functions of various professional organizations.
- Compare the characteristics of individual professional certifications, including the newest professional degree, and licensure.

Clinical laboratory overview
- Distinguish between various clinical laboratory staffing levels and functions.

Clinical laboratory improvement amendments (CLIA) of 1988
- Differentiate the classification of laboratory testing by complexity of the test: waived, moderately complex, highly complex, and provider-performed microscopy based on CLIA '88 regulations.
- Name the three most frequent inspection deficiencies over time for all CLIA-approved laboratories.
- Define the acronyms and explain the purpose of OSHA, CLIA '88, CMS, TJC, and CAP.

Laboratory departments
- Name the typical departments of a clinical laboratory and briefly describe the functions of each department.
- Name the types of testing that is typically performed in a core laboratory.
- Explain the advantages of molecular testing, the newest direction in laboratory testing.

Health care organizations
- Diagram and describe the organizational structure of a health care organization.

Primary accrediting organizations
- Name and compare at least three different primary laboratory accrediting organizations.

External government laboratory accreditation and regulation
- Describe the importance of federal, state, and institutional regulations concerning the quality and reliability of laboratory work.

Alternate sites of testing
- Compare and contrast the uses of various sites for laboratory testing: central laboratory, point of care, physician office laboratory, and reference laboratory.
- Categorize the features of alternate sites of laboratory testing.

Medical-legal issues
- Define the abbreviation HIPAA, and assess the major points of the legislation.

Medical ethics
- Define the term *ethics*, and discuss medical applications.

Case Studies
❖ Critically analyze and formulate an opinion related to each of the medical ethics case studies at the end of this chapter.

Review Questions
- Demonstrate comprehension of this chapter content by completing the end-of-chapter review questions with a grade of 80% or higher.

Note:
- indicates MLT and MLS core content
❖ indicates MLT (optional) and MLS advanced content

KEY TERMS

algorithm
analytes
body fluids
chain of custody
ethics
informed consent
pathogens
point-of-care testing (POCT)
waived testing

CLINICAL LABORATORY SCIENCE

Rudimentary examinations of human **body fluids** date back to the Greek physician Hippocrates, about 300 BC. Not until 1896, however, was the first clinical laboratory opened in a small room equipped at a cost of $50 at Johns Hopkins Hospital, Baltimore, Maryland. The diagnostic and therapeutic value of laboratory testing was not yet understood. Many physicians viewed clinical laboratories simply as an expensive luxury that consumed both valuable space and time.

Discovery of the causative agents of devastating epidemics such as tuberculosis, diphtheria, and cholera in the 1880s and the subsequent development of tests for their detection in the late 1890s highlighted the importance on laboratory testing.

Clinical laboratory testing plays a crucial role in the detection, diagnosis, and treatment of disease. The medical laboratory scientist (MLS) and medical laboratory technician (MLT) collect and process specimens and perform chemical, biological, hematologic, immunologic, microscopic, molecular diagnostic, and microbial testing. They may also collect and prepare blood for transfusion.

After collecting and examining a specimen, laboratory professionals analyze and communicate results to physicians or other primary care providers. In additional to routine testing, duties in the clinical laboratory include developing and modifying procedures and monitoring programs to ensure the accuracy of test results.

CLINICAL LABORATORY SCIENCE AS A PROFESSION

The U.S. Bureau of Labor Statistics *Occupational Outlook Handbook* for clinical laboratory technologists and technicians states, "About half of all medical laboratory technologists and technicians were employed in hospitals in 2016. Employment of medical laboratory technologists and technicians is projected to grow 13 percent from 2016–2026, much faster than the average for all occupations. An increase in the aging population will lead to a greater need to diagnose medical conditions, such as cancer or type 2 diabetes, through laboratory procedures."[1]

Original Credentialing and Professional Organizations

The American Society for Clinical Pathology (ASCP) created the Board of Registry (BOR) in 1928 to certify laboratory professionals. Individuals who passed the BOR's registry examination were referred to as *medical technologists*, identified by the acronym MT (ASCP).

In 1933 the American Society of Clinical Laboratory Technicians was formed, currently known as the *American Society for Clinical Laboratory Science (ASCLS)*. The catalyst for establishment of ASCLS was the desire for greater autonomy and control over the direction of the profession by nonphysician laboratory professionals. ASCLS is proud to champion the profession and ensure that other members of the health care field—as well as

the public—fully recognize the contributions of clinical laboratory professionals.[2]

In 1973, as a result of pressure from the U.S. Office of Education and the National Commission on Accrediting, the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) was formed.

Individual Professional Recognition

During the 1960s, new categories of laboratory professionals joined generalist medical technologists in performing the daily work of the clinical laboratory. These categories were created to help cope with an increased workload. The category of the now-discontinued certified laboratory assistant was developed as a 1-year certificate program; the category of MLT was developed as a 2-year associate degree program. Simultaneously, specialist categories in chemistry, microbiology, hematology, and blood banking were created. Specialists certified in cytotechnology, histotechnology, laboratory safety, and molecular pathology/molecular biology have evolved as well. Technicians certified as donor phlebotomists or phlebotomy technicians are part of the laboratory team. Pathologists' assistants are another category of specialty certification. Certification as a Diplomat in Laboratory Management is available.[3]

Additional Individual Professional Certification and Licensure

Many employers prefer, or are required by, the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) regulations to hire laboratory staff who are certified by a recognized professional association. In addition to those previously listed, the American Medical Technologists also offer certification.

Numerous states and U.S. territories currently require licensure (Box 1.1), with other states considering licensure. The requirements for licensure vary by state and specialty. Information is available from state departments of health or boards of occupational licensing for laboratory professionals.

Newest Professional Recognition

In September 2009, a historic step was taken in professional recognition. ASCP and the now-defunct National Credentialing Agency joined together in credentialing laboratory professionals under the auspices of the BOR. Generalists are now referred to as *medical laboratory scientists (MLSs)*. The similar technician-level designation continued to be designated as *medical laboratory technicians (MLTs)*. The appropriate professional credentialing is MLS(ASCP) and MLT(ASCP).

Continuing education is now a requirement for certified professionals to maintain certification. Continuing education is always part of a laboratory's program for ensuring high-quality service and maintaining the morale of the laboratory staff. Programs are offered at professional meetings as well as online. The acknowledgment of continuing certification is expressed as MLS(ASCP)^{CM} and MLT(ASCP)^{CM}.

In 2012 a new postbaccalaureate degree, the doctorate in clinical laboratory science (DCLS), was approved in the United States. This credential is beyond that of the entry-level generalist and represents the terminal advanced-practice degree in the profession. The DCLS professionals will assume roles as consultants, educators, and administrators to contribute to the common goals of decreasing medical errors, reducing health care costs, and improving patient outcomes. NAACLS categorizes the responsibilities of the DCLS into five areas in which these roles are utilized: patient care management, education, research applications, health care policy development, and health care services delivery and access.[4]

BOX 1.1 States and U.S. Commonwealth Territories with Licensure of Laboratory Professionals

States

California	Nevada
Florida	New York
Georgia	North Dakota
Hawaii	Rhode Island
Louisiana	Tennessee
Montana	West Virginia

U.S. Commonwealth Territories

Guam
Northern Mariana Islands
Puerto Rico

(From American Society for Clinical Laboratory Science (ASCLS). www.ascls.org/educator and www.ascls.org. Accessed May 25, 2013.)

CLINICAL LABORATORY OVERVIEW

Functions

Appropriate utilization of the clinical laboratory is critical to the practice of laboratory medicine (see Chapter 3). It is important that the laboratory serve to educate the physician and other health care providers so that the information available through the reported test results can be used appropriately. When tests are being ordered, the clinical laboratory should assume a role of leadership and education in assisting the physician to understand the most useful pattern of ordering, for example, to serve the best interest of the patient, improve the clinical decision-making process for the physician, and consider the costs involved.

Hundreds of different laboratory tests are readily available in the larger laboratories (http://labtestsonline.org/), but typically only a small percentage of these tests are routinely ordered. When the results of these tests are used appropriately in the context of the patient's clinical case, physical examination findings, and medical history, clinical decision making will be improved. It is unusual for the results from a single laboratory assay to provide a diagnosis. Certain additional laboratory tests may be needed to take decision making to the next step. Generally, a small number of appropriately chosen laboratory tests (a panel of tests) or a reflective testing **algorithm** is sufficient to confirm or rule out one or more of the possibilities in a differential diagnosis.

Staffing

Clinical laboratory professionals are an essential component of the medical team. In some laboratories, personnel are cross-trained to work in core laboratories (laboratories with high volume hematology and chemistry instrumentation) but other laboratories may have specialists in certain areas of the laboratory.

Laboratory Directors

Most clinical laboratories are operated under the direction of a pathologist or PhD. Pathologists have training in both anatomic and clinical pathology, although research can be substituted for the clinical pathology portion of the pathology residency program. The anatomic pathologist is a licensed physician, usually trained for an additional 4 to 5 years after graduating from medical school, to examine (grossly and microscopically) all the surgically removed specimens from patients, which include frozen sections, tissue samples, and autopsy specimens. Examination of Pap smears and other cytologic and histologic examinations are also generally done by an anatomic pathologist. A clinical pathologist is also a licensed physician with additional training in clinical pathology or laboratory medicine. Under the direction of the clinical pathologist, many common laboratory tests are performed on blood and urine. Consultation with physicians is also important; any information gained concerning the patient's case is actually the result of collaborative activity between the laboratory and the attending physician.

A person with a PhD in a scientific discipline, such as clinical microbiology or biochemistry, may be recognized as a laboratory director. Such individuals may oversee an entire laboratory or a specialty section of a large laboratory.

The leaders and managers of the clinical laboratory must be certain all legal operating regulations have been met and all persons working in the laboratory setting are fully aware of the importance of compliance with these regulations. Those in leadership positions in a clinical laboratory must have expertise in medical, scientific, and technical areas as well as a full understanding of regulatory matters. All laboratory personnel must be aware of these regulatory considerations, but the management is responsible for ensuring that this information is communicated to everyone who needs to know.

Laboratory Supervisor or Manager

Typically, a laboratory has a supervisor or manager who is responsible for the technical aspects of managing the laboratory. This person is most often an MLS with additional education and experience in administration. In very large laboratories, a technical manager may supervise the technical aspects of the facility (issues involving assay of **analytes**), including quality control programs, off-site testing, and maintenance of the laboratory instruments. In addition, a business manager may be hired to handle administrative details.

The supervisor or administrative manager may also be the technical manager in the case of smaller laboratories. Section-supervising technologists are in place as needed, depending on the size and workload of the laboratory. A major concern of administrative technologists, regardless of the job titles used, is ensuring that all federal, state, and local regulatory mandates are being followed by the laboratory. Persons in leadership and management positions in the clinical laboratory must be certain all legal operating conditions have been met and that these conditions are balanced with the performance of work in a cost-effective manner.

It is important that the people serving in a supervisory position be able to communicate in a clear, concise manner, both to the persons working in their laboratory settings and to the physicians and other health care workers who utilize laboratory services.

Technologists, Technicians, and Specialists

Depending on the size of the laboratory and the numbers and types of laboratory tests performed, various levels of trained personnel are needed. CLIA '88 regulations set the standards for personnel, including their levels of education and training. Generally, the level of training or education of the laboratory professional will be taken into consideration in the roles assigned in the laboratory and the types of laboratory analyses performed.

The responsibilities of MLSs and MLTs vary but may include performing some of the same laboratory assays, supervising other staff, or teaching. Some are engaged in research. An important aspect of clinical laboratory science education is to understand the science behind the tests being performed so that problems can be recognized and solved. Troubleshooting is a constant consideration in the clinical laboratory. Because of in-depth knowledge of technical aspects, principles of methodology, and instrumentation used for the various laboratory assays, the laboratory professional is able to correlate and interpret the data.

Other laboratory professionals may be assigned to specific sections of the laboratory. Although MLSs and MLTs may collect blood specimens at smaller facilities, phlebotomists collect blood specimens in larger hospitals. Laboratory professionals may also work in a specimen-processing section of the laboratory.

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) OF 1988

Much of how clinical laboratories perform their work is delineated by federal regulations or other external policies. CLIA '88 regulations govern most of the activities of a particular laboratory, although federal laboratories (such as Veterans Affairs hospitals/medical centers) are not regulated by CLIA requirements.[3,4] The goals of these amendments are to ensure that the laboratory results reported are of high quality regardless of where the testing is done: small laboratory, physician's office, large reference laboratory, or patient's home. CLIA '88 regulations include aspects of proficiency testing programs, management of patient testing, quality assessment programs, use of quality control systems, personnel requirements, inspections and site visits, and consultations. Several federal agencies govern practices in the clinical laboratory. These regulatory agencies or organizations are primarily concerned with setting standards, conducting inspections, and imposing sanctions when necessary.

CLIA Requirements for Personnel

The personnel section of the CLIA regulations defines the responsibilities of persons working in each of the testing sites where tests of moderate or high complexity are done, along with the educational requirements and training and experience needed. Minimum education and experience needed by testing personnel to perform the specific laboratory tests on human

specimens are also regulated by CLIA '88. These job requirements are listed in the CLIA '88 final regulations, along with their amendments published from 1992 to 1995.[5]

There are no CLIA regulations for testing personnel who work at sites performing only waived tests. For laboratories where only tests of moderate complexity are performed, the minimum requirement for testing personnel is a high school diploma or equivalent, provided there is documented evidence of an amount of training sufficient to ensure that the laboratory staff has the skills necessary to collect, identify, and process the specimen and perform the laboratory analysis.

For tests of the highly complex category, the personnel requirements are more stringent. Anyone who is eligible to perform highly complex tests can also perform moderate-complexity testing. The U.S. Occupational Safety and Health Administration (OSHA) requires that training in handling chemical hazards, as well as training in handling infectious materials (Standard Precautions), be included for all new testing personnel. The laboratory director is ultimately responsible for all personnel working in the laboratory.

Levels of General Laboratory Testing

External standards have been set to ensure that all laboratories provide the best, most reliable information to the physician and the patient. This is the goal of CLIA'88.

CLIA regulations divide laboratories into categories based on the "complexity" of the tests being performed by the laboratory, as follows:

- Waived tests
- Moderately complex tests
- Highly complex tests
- Provider-Performed Microscopy

This tiered grouping has been devised with varying degrees of regulation for each level. The criteria for classification include the following:

1. Risk of harm to the patient
2. Risk of an erroneous result
3. Type of testing method used
4. Degree of independent judgment and interpretation needed
5. Availability of the particular test in question for home use

Waived Tests

The law contains a provision to exempt certain laboratories from standards for personnel and from quality control programs, proficiency testing, or quality assessment programs. These laboratories are defined as those that perform only simple, routine tests considered to have an insignificant risk of an erroneous result. Laboratories that receive a "certificate of waiver" can perform **waived testing.**

As currently defined, waived laboratory tests or procedures are those cleared by the U.S. Food and Drug Administration (FDA) for home use, which employ simple methodologies unlikely to cause erroneous results and pose no reasonable risk of harm to the patient if the test is performed incorrectly. The list of waived tests continues to expand. Waived tests include dipstick urinalysis and blood glucose by FDA-approved monitoring devices specifically made for home use.[5]

Moderate and High Complexity Testing

The two additional categories are moderate-complexity and high-complexity levels of testing. These levels are more regulated, with some minimal personnel standards required, as well as proficiency testing and quality assessment programs.

Provider-Performed Microscopy

Another category of specialized laboratory testing is Provider-Performed Microscopy (PPM) testing, generally performed by the physician in the office setting; this category is also exempt from some of the CLIA requirements but there are requirements for personnel who perform provider performed microscopy (PPM) (CFR 493.1351 to 493.1365). Personnel requirements include director qualifications and responsibilities and testing personnel responsibilities.

To meet the criteria for inclusion in the PPM category, procedures must follow the following specifications:

1. The examination must be personally performed by the practitioner (defined as a physician, a midlevel practitioner under the supervision of a physician, or a dentist).
2. The procedure must be categorized as moderately complex.
3. The primary instrument for performing the test is the microscope (limited to brightfield or phase-contrast microscopy).
4. The specimen is labile.
5. Control materials are not available.
6. Specimen handling is limited.

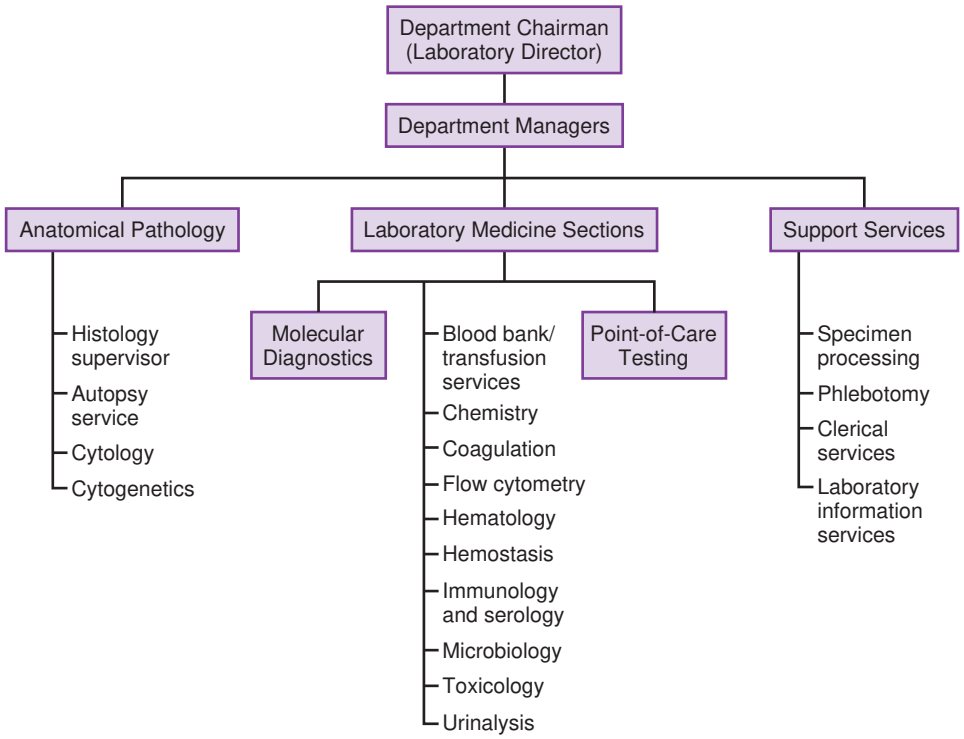
As currently defined, the PPM category includes all direct wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements in vaginal, cervical, or skin preparations; all potassium hydroxide preparations; pinworm examinations; fern tests; postcoital direct qualitative examinations of vaginal or cervical mucus; urine sediment examinations; nasal smears for granulocytes (eosinophils); fecal leukocyte examinations; and qualitative semen analysis (limited to the presence or absence of sperm and detection of motility).

LABORATORY DEPARTMENTS

The organization of a particular clinical laboratory depends on its size, the number of tests done, and the facilities available. Larger laboratories tend to be departmentalized; a separate area is designated for each of the various divisions. Fig. 1.1 shows a typical system for the organization of a traditional clinical laboratory. The current trend is to have a more "open" design or a *core laboratory* where hematology, urinalysis, hemostasis/coagulation, and clinical chemistry share workspace. Cross-training is important in a core laboratory model. In addition to the traditional areas already mentioned, the disciplines of cytogenetics, toxicology, flow cytometry, and other specialized divisions (such as molecular diagnostics) are present in larger laboratories.

Traditional Departments of a Clinical Laboratory

Laboratory medicine, or clinical pathology, is the medical discipline in which clinical laboratory science and technology are applied to the care of patients. With either the more traditional



Note: Some laboratory sections may be combined into a Core Lab configuration.

Fig. 1.1 Organization of a Clinical Laboratory. (Modified from Kaplan LA, Pesce AJ: *Clinical chemistry: theory, analysis and correlations,* ed 5, St Louis, 2010, Mosby.)

divisions by separate areas or the open model, there are still several distinct departments or divisions in the organization of the clinical laboratory. Anatomic pathology, including cytology and histology, is part of the overall clinical laboratory but usually functions independently.

A working clinical laboratory is traditionally organized into several major scientific disciplines: blood banking/transfusion medicine, clinical chemistry, hematology and hemostasis, immunology and serology, microbiology, and urinalysis. Each of these disciplines of laboratory medicine is described in more detail in Part II of this book.

Many changes are taking place in the clinical laboratory and are already affecting the types of tests and the locations where tests are being conducted. The core laboratory configuration combines routine hematology, hemostasis and blood coagulation, and clinical chemistry. Each specialty department focuses on a different area of laboratory medicine.

Blood Banking/Transfusion Medicine

Blood products for transfusion are studied and prepared in this laboratory section.

Clinical Chemistry

The clinical chemistry laboratory section performs quantitative analysis of constituents (such as glucose) on blood serum, urine, and body fluids. This department may include toxicology to analyze drugs.

Flow Cytometry

Specimens are studied for cell identification markers.

Hematology and Hemostasis

The hematology laboratory studies the formed elements of blood (such as red and white blood cells, platelets) and performs blood coagulation tests.

Immunology and Serology

The immunology and serology laboratory section focuses on testing of antigens and antibodies in blood serum. Procedures based on these principles may be conducted in clinical chemistry and other departments.

Microbiology

Microorganisms that cause disease, **pathogens**, are detected in the microbiology laboratory section. The microorganisms can be bacteria, parasites, fungi, or viruses.

Urinalysis

The body fluid urine is examined by chemical analysis and microscopically in the urinalysis section of the laboratory.

Core Laboratory

Many medium to large size laboratories have developed a central testing area with a cluster of instruments devoted to high volumes of test samples. These laboratories usually function 24/7.

Examples of the types of testing performed in a core laboratory are complete blood counts, urinalysis, and blood chemistries.

Expanded Directions of Laboratory Testing: Molecular Diagnostics

Molecular diagnostics, an application of biotechnology, applies the principles of basic molecular biology to the study of human diseases. Molecular diagnostics provides information related to molecular genetics research as real-time information for applications such as gene therapy, genetic screening, stem cell research, cloning, and cell culture.

New approaches to human disease assessment are being developed by clinical laboratories because of the new information about the molecular basis of disease processes in general. Traditional laboratory analyses give results based on a description of events currently occurring in the patient (such as blood cell counts, infectious processes, and blood glucose concentration). However, molecular biology introduces a predictive component: findings from these tests can be used to anticipate events that may occur in the future, when patients may be at risk for a particular disease or condition. More than ever, this predictive component reinforces the importance of how laboratory test results are used and emphasizes ethical considerations and the need for genetic counseling.

Genetics was in its infancy in the 1850s with the publication of Darwin's *On the Origin of Species* and Mendel's experiments of inheritance factors in pea plants. A milestone in genetics came in 1994 when the FDA approved the FlavrSavr tomato, the first genetically engineered food to go on the market.

In the 21st century, molecular diagnosis is the hottest topic in the clinical laboratory. The release of a complete mapping of the human genome in 2003 created an explosion of new testing. The Human Genome Project transformed biological science, changed the future of genetic research, and opened new doorways into the diagnosis and treatment of disease. The finished sequence covers 99% of the genome and is accurate to 99.99%.

For health care and information-solution providers, development in the expansive field of molecular diagnostics is currently driving change in each specialty in laboratory medicine.

The fundamentals of clinical laboratory practice have expanded in recent years to incorporate massive amounts of data related to recent revolutionary discoveries in molecular biology.

HEALTH CARE ORGANIZATIONS

Modern health care organizations have many different configurations, depending on the geographic region and market, mix of patients (such as age), overall size, and affiliations. The size of health care organizations ranges from the very large tertiary care–level teaching hospitals, to community hospitals, to freestanding specialty clinics or phlebotomy drawing stations.

A common organizational structure for a hospital includes the chief executive officer and the board of trustees, who set policy and guide the organization (Fig. 1.2). The chief operating officer is responsible for implementing policies and daily activities. Other high-level positions can include the chief financial officer, chief information officer, and chief technology officer, depending on the size of a health care organization. A variable number of vice presidents (VPs) have several departments reporting to them. Organizations usually have VPs of Nursing, Clinical Services, General Services, and Human Resources. The VP of Clinical Services oversees the managers of the clinical laboratory as well as radiology and pharmacy.

PRIMARY ACCREDITING ORGANIZATIONS

In current laboratory settings, many governmental regulations, along with regulations and recommendations from professional,

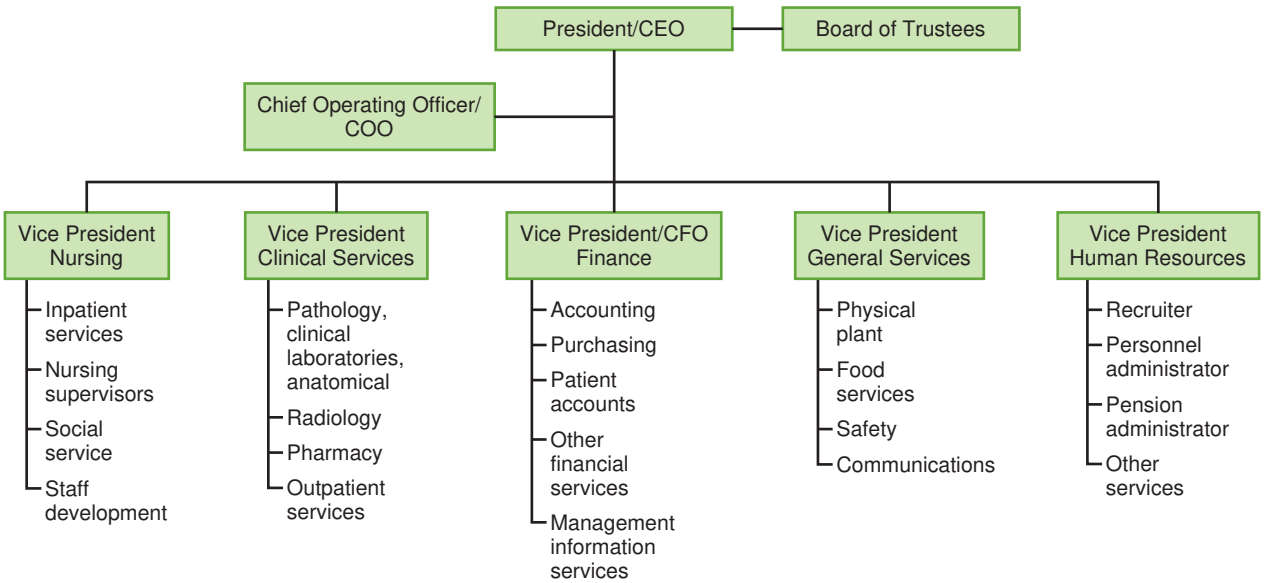


Fig. 1.2 Hospital Organizational Chart. (Modified from Kaplan LA, Pesce AJ: *Clinical chemistry: theory, analysis and correlations,* ed 5, St Louis, 2010, Mosby.)

state, and federal accreditation agencies and commissions of various types, govern the activities of the laboratory.

In the United States, there are approximately 15,697 accredited laboratories,[6] 97% of which are inspected by three primary accrediting organizations: Commission on Office Laboratory Accreditation (COLA), College of American Pathologists (CAP), and The Joint Commission (TJC).[2]

Commission on Office Laboratory Accreditation

The COLA accredits 6566 facilities.[6] COLA was founded in 1988 as a private alternative to help laboratories stay in compliance with the new CLIA regulations. In 1993 the U.S. Health Care Financing Administration (HCFA), now the Centers for Medicare and Medicaid Services (CMS), granted COLA deeming authority under CLIA. In 1997 The Joint Commission on Accreditation of Health Care Organizations, now TJC, also recognized COLA's laboratory accreditation program.

Since the increased government scrutiny of survey organizations, COLA was the first to be renewed and was given permission to accredit laboratories for the next 6 years to help these meet CLIA requirements. The increase in oversight by CMS was driven by a government investigation in 2006 into how some highly publicized laboratory errors had occurred and could have been prevented. COLA will incorporate new standard program requirements that coincide with updated CLIA requirements and are closely aligned with quality systems methodology. The new standard program requirements are a compilation of 75 new or revised criteria to the existing 299 questions. Some of the new program features for laboratories in 2007 include the following:

- Revised quality control requirements
- Increased attention to laboratory information systems
- New focus on quality assessments activities that span all phases of laboratory testing
- Incorporation of quality systems processes to all categories of the laboratory's path of workflow

College of American Pathologists

The CAP accredits 5670 facilities.[6] The CAP Laboratory Accreditation Program is an internationally recognized program and the only one of its kind that utilizes teams of practicing laboratory professionals as inspectors. Designed to go well beyond regulatory compliance, the program helps laboratories achieve the highest standards of excellence to positively impact patient care. The CAP Laboratory Accreditation Program meets the needs of a variety of laboratory settings. Now granted deeming authority by CMS, the CAP Laboratory Accreditation Program is also recognized by TJC and can be used to meet many state certification requirements.

The Joint Commission

TJC accredits 2409 facilities[6] and has been evaluating and accrediting hospital laboratory services since 1979 and freestanding laboratories since 1995. Laboratories eligible for accreditation include the following:

- Laboratories in hospitals, clinics, long-term care facilities, home care organizations, behavioral health care organizations, ambulatory sites, and physician offices
- Reference laboratories
- Freestanding laboratories, such as assisted reproductive technology laboratories
- Blood transfusion and donor centers
- Public health laboratories, including Indian Health Service laboratories
- Laboratories in federal facilities (such as Department of Veterans Affairs, and Department of Defense)
- **Point-of-care testing (POCT)** sites, including blood gas laboratories providing services to patients in emergency departments, surgical suites, cardiac catheterization laboratories, and other patient care areas

Other Agencies

Other specialty organizations, including the American Association of Blood Banks, American Society of Histocompatibility and Immunogenetics, and American Osteopathic Association, accredit more than 455 facilities.[6]

EXTERNAL GOVERNMENT LABORATORY ACCREDITATION AND REGULATION

Regulations and standards are designed specifically to protect staff working in the laboratory, other health care personnel, patients treated in the health care facility, and society as a whole. Federal regulations exist to meet these objectives. Certain regulatory mandates have been issued externally, such as CLIA '88. Others are internal, and some are both external and internal.[5,7,8] In addition to CLIA '88 regulations, other state and federal regulations are in place to regulate chemical waste disposal, use of hazardous chemicals, and issues of laboratory safety for personnel, including handling of biohazardous materials and application of Standard Precautions, previously called *Universal Precautions*.

A laboratory that wants to receive payment for its services from Medicare or Medicaid must be certified under the Public Health Service Act (42CFR493.1-Basis and Scope). To be certified, the laboratory must meet the conditions for participation in those programs. CMS has the administrative responsibility for both the Medicare and CLIA '88 programs. Facilities accredited by approved private accreditation agencies such as CAP must also follow the regulations for licensure under CLIA '88. States with equivalent CLIA '88 regulations are reviewed individually as to possible waiver for CLIA '88 licensure.

The U.S. Department of Health and Human Services (HHS) has also established regulations to implement CLIA '88. Different accreditation processes are used by TJC, CAP, and other organizations, but all of these requirements are based on CLIA requirements. CLIA Document Control Requirements state: 1. All laboratory procedures must be made available to laboratory personnel, and initial and subsequent versions of each procedure must be authorized by the laboratory director. 2. A copy of each procedure, date of first use, and date of discontinuance must be retained for at least 2 years after a procedure has been removed from service. Any facility performing quantitative, qualitative, or screening test procedures or examinations on materials derived from the human body is regulated by CLIA '88. This includes hospital laboratories of all sizes; physician office laboratories; nursing home facilities; clinics; industrial

laboratories; city, state, and county laboratories; pharmacies, fitness centers, and health fairs; and independent laboratories.

As of December 29, 1993, HCFA approved the accreditation program developed by the COLA for the physician office laboratory (POL). This means that COLA accreditation requirements are recognized by HCFA as being equivalent to those established by CLIA. The COLA accreditation established a peer review option in place of the CLIA regulatory requirements. COLA-accredited laboratories are surveyed every 2 years to ensure that they meet requirements developed by their peers in family practice, internal medicine, or pathology.

The Clinical Laboratory Standards Institute (CLSI) is a nonprofit, educational organization created for the development, promotion, and use of national and international laboratory standards. CLSI recommendations, guidelines, and standards follow the CLIA '88 mandates.

Through labor laws such as the 1990 Americans with Disabilities Act (ADA) and the ADA Amendments Act of 2008 (ADAAA) as well as environmental regulations, laboratory workers can know that they are in a safe atmosphere and that every precaution has been taken to maintain that safe atmosphere. The new ADAAA has its greatest impact in the employment context, requiring employers with 15 or more employees covered by the ADA to adjust their policies and procedures to comply with the ADAAA. OSHA has been involved in setting these practices into motion.

Other external controls include standards mandated by public health laws and reporting requirements through the U.S. Centers for Disease Control and Prevention and through certification and licensure requirements issued by the FDA. State regulations are imposed by Medicaid agencies, state environmental laws, and state public health laws and licensure laws. Local regulations include those determined by building codes and fire prevention codes.

Two certifying agencies, CAP and TJC, have been given deemed status to act on the federal government's behalf (see previous discussion). From an external source, guidelines and standards have also been set by these organizations to govern safe work practices in the clinical laboratory. Independent agencies also have influence over practices in the clinical laboratory through accreditation policies or other responsibilities, including CAP, TJC, and other specific proficiency testing programs.

ALTERNATE SITES OF TESTING

Another change in laboratory testing has been the move from tests being done in a centralized laboratory setting to POCT. Alternative testing sites—the patient's bedside, in operating rooms or recovery areas, or even home testing—are extensions of the traditional clinical laboratory site.

The traditional setting for performance of diagnostic laboratory testing has been a centralized location in a health care facility (hospital) where specimens from patients are sent to be tested. The centralized laboratory setting remains in many institutions, but the advent of near-testing, bedside testing, or POCT has changed the organization of many laboratories. In POCT the laboratory testing actually comes to the bedside of the patient. Any changes to implement the use of POCT should show a significant improvement in patient outcome and a total financial benefit to the patient and the institution, not only a reduction in the costs of equipment and supplies.

Point-of-Care Testing

Decentralization of testing away from the traditional laboratory setting can greatly increase the interaction of laboratory personnel with patients and with other members of the health care team. POCT is an example of an interdisciplinary activity that crosses many boundaries in the health care facility. POCT is not always performed by laboratory staff. Other health care personnel, including nurses, respiratory therapists, anesthesiologists, operating room technologists, and physician assistants, often perform near-patient testing. Even in these cases, however, the CLIA '88 regulations associated with clinical laboratory testing must be followed for POCT, even if nonlaboratory staff members are actually performing the tests.

CLIA regulations are considered "site neutral." This means that all laboratory testing must meet the same standards for quality of work done, personnel, proficiency testing, and quality control, whether in a central laboratory or at the bedside of the patient. Regulation of the clinical laboratory (waived tests, tests of moderate or high complexity, PPMs) also applies to POCT. If performed in a facility that is accredited by TJC or CAP, these tests are regulated in essentially the same way as tests performed in a centralized laboratory.

Qualifications for POCT personnel are also set by federal, state, and local regulations.[5] The level of training varies with the analytical system being employed and the background of the individual involved, which can range from a requirement for a high school diploma with no experience to a bachelor of science degree with 2 years of experience. The director of the laboratory is responsible for setting additional requirements, provided the federal CLIA '88 regulations are also being followed.

Because results can be reported immediately and the patient's case management depends on these results, it is essential that POCT devices have built-in quality control and quality assessment systems to prevent erroneous data from being reported to the physician. POCT has been found to provide cost-effective improvements in medical care. In a hospital setting, POCT provides immediate assessment and management of the critically ill patient; this is its most significant use for this setting. Tests usually included in POCT are based on criteria of immediate medical need, including blood gases, prothrombin time coagulation test, partial thromboplastin time coagulation or activated blood-clotting time test, red blood cell measurements (such as hematocrit, hemoglobin), and glucose. POCT attempts to meet the demands of intensive care units (ICUs), operating rooms, and emergency departments for faster reporting of test results. Other benefits of POCT may include improved therapeutic turnaround times, less trauma and more convenience for the patient (when blood is collected and analyzed at the bedside), decreased preanalytical errors (formerly errors caused by specimen collection, transportation, and handling by the laboratory), decreased use of laboratory personnel (use of cross-training, whereby nurses can perform the laboratory analysis, eliminating a laboratorian for this step), more

collaboration of clinicians with the laboratory, and shorter ICU stays. Certain tests, such as the fecal screen for blood and the routine chemical screening of urine by reagent strips, can often be done more easily on the nursing unit, if the assays are properly performed and controlled using quality assessment protocol.

In outpatient settings, POCT provides the ability to obtain test results during the patient's visit to the clinic or the physician's office, enabling diagnosis and subsequent case management in a timelier manner.

When central laboratory testing is compared with POCT, consideration must be given to which site of testing will provide the most appropriate testing mechanism. Centralized laboratories can provide "stat" testing capabilities, which can report results in a timely manner. Some laboratories develop a laboratory satellite that is set up to function at the point of need, such as a laboratory located near or in the operating room or a laboratory that is portable and can be transported on a cart to the point of need.

Reference Laboratories

When a laboratory performs only routine tests, specimens for the more complex tests ordered by the physician must be sent to a reference laboratory for analysis. It is often more cost-effective for a laboratory to perform only certain common, repetitive tests and to send the others to an outside laboratory. These reference laboratories can then perform the more complex tests for many patients, giving good turnaround times; this is their service to their customers. It is important to select a reference laboratory where the mechanisms for specimen transport and results reporting are managed well. The turnaround time is important and is often a function of how well the specimens are handled by the reference laboratory. There must be a good means of communication between the reference laboratory and its customers. The reference laboratory should be managed by professionals who both recognize the importance of providing quality results and, when needed, can provide the patient's clinician information about utilizing the results. Messengers or couriers are engaged to transport or drive specimens within a fixed, reasonable geographic area. The various commercial delivery systems are used for transport out of the area.

Physician Office Laboratories

A POL is a laboratory where the tests performed are limited to those done for the physician's own patients coming to the practice, group, or clinic. Because of the concern that quality work was lacking in some laboratories, the CLIA '88 regulations included POLs. Before CLIA, the POLs were largely unregulated. Most POLs perform only the waived tests or PPM, as set by CLIA. Tests most often performed in POLs are visually read reagent strip urinalysis, blood glucose, occult fecal blood, rapid streptococcus A in throats, hemoglobin/hematocrit, urine pregnancy, and cholesterol.

The convenience to the patient of having laboratory testing done in the physician's office is a driving force for physicians to include a laboratory in their office or clinic. Manufacturers of laboratory instruments have accommodated the clinic or office setting with a modern generation of instruments that require less technical skill by the user. However, the improved turnaround times for test results and patient convenience must be balanced with cost-effectiveness and the potential for physicians to be exposed to problems outside their expertise or training. Laboratory staff, including pathologists, must be available to act as consultants when the need arises.

A POL must submit an application to HHS or its designee. This application form includes details about the number of tests done, methodologies used for each measurement, and the qualifications of each of the testing personnel employed to perform the tests. Certificates are issued for up to 2 years, and any changes in tests done or methodologies used, personnel hired, and so forth must be submitted to HHS within 30 days of the change. This application may also be made through an accreditation agency whose requirements are deemed by HHS to be equal to or more stringent than the HHS requirements. Accreditation requirements from COLA have been recognized by CMS as being equivalent to the CLIA requirements.

When a POL performs only waived tests or PPM tests, there are no CLIA personnel requirements. The physician is responsible for the work done in the POL. When moderately or highly complex testing is done in a POL, the more stringent CLIA personnel requirements must be followed for the testing personnel; these POLs must also adhere to a program of quality assessment, including proficiency testing.

MEDICAL-LEGAL ISSUES

Informed Consent

For laboratories, an important responsibility is obtaining **informed consent** from the patient. Informed consent means that the patient is aware of, understands, and agrees to the nature of the testing to be done and what will be done with the results reported. Generally, when a patient enters a hospital, there is an implied consent to the many routine procedures that will be performed while the patient is in the hospital. Venipuncture is one of the routine tests that carry this implied consent. The patient must sign specific consent forms for more complex procedures, such as bone marrow aspiration, lumbar puncture for collection of cerebrospinal fluid, and fine-needle biopsy, as well as for nonurgent transfusion of blood or its components.

The patient should be given sufficient information about the reasons why the informed consent is needed and must be given the opportunity to ask questions. In the event the patient is incapable of signing the consent form, a guardian's consent should be obtained, as when the patient is a minor, legally not competent, physically unable to write, hearing impaired, or does not speak English as the first language. Health care institutions have policies in place for handling these situations.

Health Insurance Portability and Accountability Act

Any results obtained for specimens from patients must be kept strictly confidential. The Health Insurance Portability and Accountability Act (HIPAA) of 1996 requires the privacy of patient information.[9] Any information about the patient,

including the types of measurements being done, must also be kept in confidence. Only authorized persons should have access to the information about a patient, and any release of this information to non–health care persons (such as insurance personnel, lawyers, and friends of patient) can be done only when authorized by the patient. It is important to discuss a particular patient's situation only in the confines of the laboratory setting and not in public places (such as elevators or hospital coffee shops).

With the passage of the HIPAA, laboratory information systems (LIS) security received new emphasis. Communications from the LIS should meet HIPAA compliance for encryption and methodology. Users should be prompted to log on and off the software to ensure that unauthorized access is prevented. The LIS should have full transaction capture, to track any manipulation of patient results data.

Public Law 104-191 (HIPAA) establishes a minimum standard for security of electronic health information to protect the confidentiality, integrity, and availability of protected patient information. HHS published the Privacy Rule on December 28, 2000, and adopted modifications on August 14, 2002. This rule set national standards for the protection of health information by health plans, health care clearinghouses, and health care providers who conduct certain transactions electronically. The HIPAA Privacy Rule established for the first time a foundation of federal protections for the privacy of protected health information. The rule does not replace federal, state, or other laws that grant individuals even greater privacy protections, and covered entities are free to retain or adopt more protective policies or practices.

Most portions of HIPAA are relevant to electronic information and the electronic interchange of information. HIPAA rules apply to any health information that can be linked to a person by name, social security number, employee number, hospital identification number, or other identifier. These provisions cover protected health information, regardless of whether it is or has been in electronic form or relates to any past, present, or future health care or payments. HIPAA legislation has a direct effect on the LIS. It includes requirements for the laboratory to collect diagnosis codes from the ordering provider on outpatient testing reimbursed by Medicare, a requirement under the Balanced Budget Act of 1997.

New Patient Access Regulations

A new final rule by CMS grants patients direct access to their laboratory results. The new rule revises CLIA '88 and HIPAA privacy rules to require laboratories to give a patient, or a person designated by the patient or his or her "personal representative," access to the patient's completed test reports on the patient's or the representative's request. Generally, the rule requires that laboratories provide individuals with access to their laboratory test reports within 30 days of the request. The rule does provide clinical laboratories with the flexibility to determine the process that allows them to fulfill the patient's request, including the process of verifying the identity of the patient.

The new final rule does not require that laboratories interpret test results for patients. Patients merely have the right to inspect and receive a copy of their completed test reports and other individually identifiable health information maintained in a designated record set by a HIPAA-covered laboratory. Laboratories may continue to refer patients with questions about test results back to their ordering or treating health care providers.

Chain of Custody

When specimens are involved in possible medicolegal situations, certain specimen-handling policies are required. Medicolegal or forensic implications require that any data pertaining to the specimen in question be determined in such a way that the information will be recognized by a court of law.

Laboratory test results that could be used in a court of law, such as at a trial or judicial hearing, must be handled in a specific manner. For evidence to be admissible, each step of the analysis, beginning with the moment the specimen is collected and transported to the laboratory, to the analysis itself and the reporting of the results, must be documented; this process is known as "maintaining the **chain of custody.**" The links between specimen collection and presentation in court must establish certainty that the material or specimen tested had not been altered in any way that would change its usefulness as admissible evidence. Any specimen that has potential evidentiary value should be labeled, sealed, and placed in a locked refrigerator or other suitable secure storage area.

For drug testing, it is the course of action of documenting the management and storage of a specimen from the moment a donor gives the specimen to the collector to the final destination of the specimen and the review and reporting of the final result.[10] Blood specimens for alcohol level determination, specimens collected from rape victims, specimens for paternity testing, and specimens submitted from the medical examiner's cases are the usual types requiring chain-of-custody documentation.

Chain-of-custody documentation must be signed by every person who has handled the specimens involved in the case in question. The actual process may vary in different health care facilities, but the general purpose of this process is to make certain that any data obtained by the clinical laboratory will be admissible in a court of law, and that all the proper steps have been taken to ensure the integrity of the information produced.

Other Legal Considerations

Health care organizations and their employees are obliged to provide an acceptable standard of care, defined as the degree of care a reasonable person would take to prevent an injury to another. When a hospital or other health care provider, or a physician or other medical professional, does not treat a patient with the proper quality of care, resulting in serious patient injury or death, the provider has committed medical negligence. As a result, perceived negligence may lead to legal action or a lawsuit or tort. A tort is an act that injures someone in some way and for which the injured person may sue the "wrongdoer" for damages. Legally, torts are called *civil wrongs*. Medical personnel working directly with patients (such as phlebotomists) are more likely than laboratory bench staff to encounter legal issues.

MEDICAL ETHICS

What is **ethics**? According to *Merriam-Webster's Collegiate Dictionary,* the definition of ethics includes "the discipline dealing with what is good and bad" as well as "a set of moral principles." Personal ethics are based on values or ideals and customs that are held in high regard by an individual or group of people. For example, many people value friendship, hard work, and loyalty.

Ethics also encompasses the principles of conduct of a group or individual, such as professional ethics. ASCLS endorses a professional code of ethics (Box 1.2), which states that all laboratory professionals have a responsibility for proper conduct toward the patient, their colleagues and the profession, and society. In addition, ASCLS has a pledge to the profession (Box 1.3).

BOX 1.2 American Society for Clinical Laboratory Science Code of Ethics

Preamble

The Code of Ethics of the American Society for Clinical Laboratory Science sets forth the principles and standards by which clinical laboratory professionals practice their profession.

I. Duty to the Patient

Clinical laboratory professionals are accountable for the quality and integrity of the laboratory services they provide. This obligation includes maintaining individual competence in judgment and performance and striving to safeguard the patient from incompetent or illegal practice by others.

Clinical laboratory professionals maintain high standards of practice. They exercise sound judgment in establishing, performing, and evaluating laboratory testing.

Clinical laboratory professionals maintain strict confidentiality of patient information and test results. They safeguard the dignity and privacy of patients and provide accurate information to other health care professionals about the services they provide.

II. Duty to Colleagues and the Profession

Clinical laboratory professionals uphold and maintain the dignity and respect of our profession and strive to maintain a reputation of honesty, integrity, and reliability. They contribute to the advancement of the profession by improving the body of knowledge, adopting scientific advances that benefit the patient, maintaining high standards of practice and education, and seeking fair socioeconomic working conditions for members of the profession.

Clinical laboratory professionals actively strive to establish cooperative and respectful working relationships with other health care professionals, with the primary objective of ensuring a high standard of care for the patients they serve.

III. Duty to Society

As practitioners of an autonomous profession, clinical laboratory professionals have the responsibility to contribute from their sphere of professional competence to the general well-being of the community.

Clinical laboratory professionals comply with relevant laws and regulations pertaining to the practice of clinical laboratory science and actively seek, within the dictates of their consciences, to change those which do not meet the high standards of care and practice to which the profession is committed.

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BOX 1.3 Pledge to the Profession

As a clinical laboratory professional, I strive to:

- Maintain and promote standards of excellence in performing and advancing the art and science of my profession
- Preserve the dignity and privacy of others
- Uphold and maintain the dignity and respect of our profession
- Seek to establish cooperative and respectful working relationships with other health professionals
- Contribute to the general well-being of the community

I will actively demonstrate my commitment to these responsibilities throughout my professional life.

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Situational ethics is a system of ethics by which acts are judged within their context instead of by categorical principles. Hospitals have ethics committees to evaluate situational ethics cases and to offer consultation services. Individual laboratory professionals may need to make decisions based on personal or professional values.

In the realm of health care, it is difficult to hold rules or principles that are "absolute." Many variables exist in the context of medicine, with several principles that seem to be applicable in many situations. Even though these are not considered absolute, the rules and principles serve as powerful action guides in medicine. Over the years, moral principles have won a general acceptance as applicable in the analysis of ethical issues in medicine.

The first prominent medical ethics committee in the United States was at the University of Washington.[11] The first task of this committee was to help clinicians determine which people should receive hemodialysis. In the late 1960s, hemodialysis was considered to be experimental, and the University of Washington hospital could care for only limited numbers of patients. The decisions of the committee meant life or death for patients in need of renal dialysis. The problem of allocating hemodialysis to patients in need was not solved until the U.S. government began to finance the treatment for anyone who required hemodialysis in the 1970s.

Ethics committee members usually represent major clinical services and other stakeholders in health care delivery. All members of the ethics committee take responsibility for learning techniques of ethical analysis and the arguments addressing volatile issues in medicine.

Hospital ethics committees usually have the major functions: responsibility of providing clinical ethics consultation, developing and/or revising policies pertaining to clinical ethics and hospital policy (such as advance directives, withholding and withdrawing life-sustaining treatments, informed consent, and organ procurement), and promoting education in medical ethics.

CASE STUDIES

CASE STUDY 1.1

G.G. is an unmarried 19-year-old college student. She has not been feeling well lately and went to see a primary care provider at the college health service. G.G. has an active sexual relationship with her boyfriend but practices safe sex. Blood was drawn for a complete blood count and monospot test. Urine was collected for routine examination and a pregnancy test.

M.M. is a work-study student at the college health service. His job is to schedule appointments and transmit follow-up testing results to the primary care provider. When G.G.'s blood and urine results were sent to the health service, M.M. noticed that her total white blood count was extremely elevated and her red blood count was very low. A notation was made on the report that follow-up testing was required to rule out leukemia or rule out other red or white blood cell disorders.

The next day, M.M. saw G.G. in their history class. G.G. asked him if her lab test results were back yet. He said that the results were received late the previous afternoon. G.G. then asked, "How were my results?"

Note: Narrative answers on instructor EVOLVE website.

Multiple Choice Question (Answer in Appendix A)

1. In this situation, M.M. is ethically responsible to:
   a. Only share the actual blood cell measurement results.
   b. Tell G.G. that he doesn't know the results.
   c. Share his interpretation of the results with G.G., the patient.
   d. Advise G.G., the patient, to contact her healthcare provider for her results.

Critical Thinking Group Discussion Questions

1. How should M.M. answer G.G.'s question? Should he say that he does not know, when he does know? Or, should he tell G.G. that he is not authorized to give test results to patients unless specifically told to do so by the primary care provider?
2. How would you handle a similar situation with a classmate?

CASE STUDY 1.2

Patricia was completing her clinical internship at the local hospital. At the end of the day, several patients were brought to the emergency department as the result of a car crash. Patricia recognized a patient's name on a tube of blood as one of her hometown neighbors. When she completed her assigned work, she was finished with her shift.

Note: Narrative answers on instructor EVOLVE website.

Multiple Choice Question (Answer in Appendix A)

1. In this situation, Patricia should:
   a. Take personal responsibility for her neighbor's laboratory testing.
   b. Recheck all of the patient's laboratory results for accuracy.
   c. Remain calm and do not interfere with the neighbor's care at the hospital.
   d. Wait for her neighbor to be transferred to ICU and then visit her.

Critical Thinking Group Discussion Questions

1. Should Patricia call her parents to tell them that a neighbor had been in a serious car crash and was in the hospital?
2. Should Patricia return to the hospital to visit the patient?
3. Should Patricia ask the nurse about the patient's status when she goes to work the next day?

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REVIEW QUESTIONS (ANSWERS IN APPENDIX A)

Clinical Laboratory Science

1. The correct designation for a generalist laboratory professional with a bachelor's degree certified by the American Society for Clinical Pathology is:
   a. Medical laboratory technician
   b. Medical laboratory scientist
   c. Medical technician
   d. Medical technologist

Overview of the Clinical Laboratory

2. The role of the laboratory supervisor or manager is to:
   a. Supervise technical aspects of testing.
   b. Supervise business functions of testing.
   c. Examine surgically removed organs.
   d. Screen cytology for Pap smears.

Clinical Laboratory Improvement Amendments (CLIA) of 1988

3. Which of the following acts, agencies, or organizations was created to make certain the quality of work done in the laboratory is reliable?
   a. Centers for Medicare and Medicaid Services (CMS)
   b. Occupational Safety and Health Administration (OSHA)
   c. Clinical Laboratory Improvement Amendments of 1988 (CLIA '88)
   d. Centers for Disease Control and Prevention
4. Laboratories performing which of the following types of tests need to be enrolled in a CLIA-approved proficiency testing program?
   a. Waived
   b. Moderately complex
   c. Highly complex
   d. Both b and c
5. The role of provider-performed microscopy (PPM) is the:
   a. Continuation of the process of evaluating and monitoring all aspects of the laboratory to ensure accuracy of test results
   b. Specific microscopic tests (wet mounts) performed by a physician for his or her own patients
   c. Means by which quality control between laboratories is maintained
   d. Process of performing laboratory testing at the bedside of the patient and a means of decentralizing some of the laboratory testing

Laboratory Departments

6. The newest direction for laboratory testing procedures is:
   a. Larger automated instruments
   b. Networked systems for point-of-care testing
   c. Molecular diagnostic techniques in various laboratory departments
   d. Robotic specimen handling

Health Care Organizations

7. A hospital chief operating officer is responsible for:
   a. Implementing policies and oversight of daily activities
   b. Finances
   c. Setting policy and guiding the organization
   d. Overseeing the hospital information system

Primary Accrediting Organizations

8. What is the best description of the purpose of the College of American Pathologists (CAP) pertaining to the clinical laboratory?
   a. Sets accreditation requirements for physician office laboratories (POLs)
   b. Administers both CLIA '88 and Medicare programs
   c. CMS has given CAP deemed status to act on the government's behalf to certify clinical laboratories
   d. Nonprofit educational group that establishes consensus standards for maintaining a high-quality laboratory organization

External Government Laboratory Accreditation and Regulation

9. What is the best description of the purpose of the Commission on Office Laboratory Accreditation (COLA) pertaining to the clinical laboratory?
   a. Sets accreditation requirements for physician office laboratories (POLs)
   b. Administers both CLIA '88 and Medicare programs
   c. CMS has given COLA deemed status to act on the government's behalf to certify clinical laboratories
   d. Nonprofit educational group that establishes consensus standards for maintaining a high-quality laboratory organization
10. What is the best description of the purpose of the Centers for Medicare and Medicaid Services (CMS) pertaining to the clinical laboratory?

a. Sets accreditation requirements for physician office laboratories (POLs)
b. Administers both CLIA '88 and Medicare programs
c. CMS has given itself deemed status to act on the government's behalf to certify clinical laboratories
d. Nonprofit educational group that establishes consensus standards for maintaining a high-quality laboratory organization

Alternate Sites of Testing

11. The role of point-of-care testing (POCT) compared with in-laboratory testing is the:
a. Continuation of the process of evaluating and monitoring all aspects of the laboratory to ensure accuracy of test results
b. Specific microscopic tests (wet mounts) performed by a physician for his or her own patients
c. Means by which quality control between laboratories is maintained
d. Process of performing laboratory testing at the bedside of the patient and a means of decentralizing some of the laboratory testing

Medical-Legal Issues

12. Sally is seeing her new primary care provider for the first time. When she signs in, she is asked to sign papers for the release of medical records, including her laboratory results. According to the Health Insurance Portability and Accountability Act (HIPAA), she must authorize release of records before _____ would be permitted to receive and review her records.
a. Her insurance company
b. Her attorney
c. Her husband
d. Any of the above

13. In which of the following laboratory situations is a verbal report permissible?
a. When the patient is going directly to the physician's office and wants to have the report available
b. When the report cannot be found at the nurse's station
c. When preoperative test results are needed by the anesthesiologist
d. None of the above

14. All the following characteristics are accurate for the influence of Health Insurance Portability and Accountability Act (HIPAA) *except*:
a. Replaces federal, state, or other laws that grant individuals even greater privacy protections than HIPAA
b. Covers entities that are free to retain or adopt more protective policies or practices
c. Establishes a minimum standard for security of electronic health information and the electronic interchange of information
d. Directly effects the laboratory information system (LIS)

15. In order to perform a venipuncture on a newly admitted hospital patient, a phlebotomist needs to:
a. Ask for the patient's written permission to perform the procedure.
b. Verify that the patient has specifically named the drawing of blood in the admissions papers.
c. Realize that an admitted hospital patient has given implied consent to routine procedures such as phlebotomy.
d. Verify with the patient's primary care provider that phlebotomy is covered as a routine procedure.

16. Chain-of-custody procedures must be followed for:
a. Blood specimens for alcohol level determination
b. Routine urinalysis for glucose and ketones
c. Therapeutic drug threshold determinations
d. Throat swabs of group A beta streptococcus screening

Medical Ethics

17. Medical ethics:
a. Has strict guidelines
b. Applies to laboratory professionals
c. Includes situational ethics
d. Both b and c

18. *Bonus Challenge Question:* Answer this question based on the following laboratory situation:
Lisa works in the laboratory at a small community hospital in a small Midwestern town. She received orders to draw blood from a newly admitted patient for a complete blood count (CBC) and a metabolic chemistry panel. When Lisa arrived in the patient's room, she discovered that the patient was Carla, her best friend's mother. She chatted with Carla for a bit and then headed back to the lab to complete testing on the samples. Thirty minutes later, Betsy, who is one of Carla's friends, called the lab to talk with Lisa. Apparently, Carla posted on a social media site that Lisa had drawn her blood and Betsy was calling to get all of the details. "I called Carla to find out what's going on, but she's being evasive. I'm watching her dog so I need to know the real scoop…."
What should Lisa do?
a. It is acceptable to share information with Betsy because Carla stated on social media that she was in the hospital.
b. Politely tell Betsy she cannot comment on patients in the hospital.
c. Thank Betsy for her concern and tell her that Carla seemed "okay."
d. Politely tell Betsy she cannot talk about work with people who are not employed at the hospital.

2

Safety: Patient and Clinical Laboratory Practices

http://evolve.elsevier.com/Turgeon/clinicallab/

CHAPTER CONTENTS

LEARNING OUTCOMES

Patient safety
- Analyze the six goals for health care delivery, and provide examples of the important issues in each goal category.
- Explain why medical euphemisms are a bad habit and what negative outcomes can be generated by their use.
- Evaluate a strategy to mitigate patient risk during an information technology outage, and assess potential high priorities in a strategy.

Safety Standards and Governing Agencies
- Name the two agencies responsible for laboratory safety in the United States.
- Describe the general functions of various governmental and professional agencies.
- Describe the laboratory-related goals of the National Healthcare Safety Network.
- Examine and compare the general safety regulations governing the clinical laboratory, including components of the OSHA-mandated plans for chemical hygiene and for occupational exposure to bloodborne pathogens, the importance of the safety manual, and general emergency procedures.

Avoiding transmission of infectious diseases
- Define a laboratory-acquired infection (LAI) and name the top 10 microorganisms causing LAIs.
- Name the three most common viral causes of LAIs.

Bloodborne Pathogens
- Name three mandated OSHA bloodborne safety standard practices.
- Describe four specific factors that carry a higher risk of HIV transmission due to percutaneous injury.

Safe work practices for infection control
- Contrast the basic aspects of infection control policies, including how and when to use personal protective equipment or devices (such as gowns, gloves, and goggles), and evaluate the reasons for using Standard Precautions.
- Explain proper decontamination of a work area at the beginning and end of a routine workday, as well as when a hazardous spill has occurred.
- Describe nine safety practices to reduce the risk of inadvertent contamination with blood or certain body fluids.
- Explain the three required contents of a laboratory Safety Manual.

Specimen Handling and Shipping Requirements
- Name government agency that specifies the requirements for shipping clinical specimens.

Prevention of disease transmission
- Assess preexposure and postexposure prophylactic measures for handling potential occupational transmission of certain pathogens, especially hepatitis B virus (HBV) and human immunodeficiency virus (HIV).

Additional laboratory hazards
- Evaluate how to take the necessary precautions to avoid exposure to the many potentially hazardous situations in the clinical laboratory: biohazards; chemical, fire, and electrical hazards; and certain supplies and equipment (such as broken labware).
- Explain successful implementation of chemical hazards "right-to-know" rules.

Final decontamination of waste materials
- Explain the process of properly segregating and disposing of various types of waste products generated in the clinical laboratory, including use of sharps containers for used needles and lancets.

Safety audit
- Summarize the top six safety audit issues and choose resolutions to each of the issues.

Basic first-aid procedures
- List and describe the basic steps of first aid
- Perform each laboratory exercise and summarize the purpose and sources of error of each exercise.

Case Study
❖ Analyze the patient history, clinical signs and symptoms, and laboratory data for the stated case studies, answer the related critical thinking questions, and conclude the most likely diagnosis.

Review Questions
- Demonstrate comprehension of the chapter content by completing the end-of-chapter review questions with a grade of 80% or higher.

Note:
- indicates MLT and MLS core content
❖ indicates MLT (optional) and MLS advanced content

KEY TERMS

biohazard
disinfection
Hazard Communication Standard (HCS)
iatrogenic
infectious waste
necrosis
nosocomial
Occupational Exposure to Bloodborne Pathogens
pathogens
personal protective equipment (PPE)
safety data sheet (SDS)
sepsis
Standard Precautions

PATIENT SAFETY

The Agency for Healthcare Research and Quality defines patient safety as "freedom from accidental or preventable injuries produced by medical care."[1] Each year the ECRI Institute publishes the Top 10 safety issues. Two of the identified errors are patient identification errors and test reporting with follow up. Errors related to laboratory testing are discussed in chapter 3, Quality Assessment and Quality Control in the Clinical Laboratory.[2]

According to 2018 The Joint Commission (TJC): Laboratory National Patient Safety Goals[3], three goal areas have specific applications for laboratory services. These goals relate to correctly identifying a patient by using two ways to identify a patient, improving staff communication to get important test results to the correct staff person in a timely manner, and preventing infection by using CDC or WHO hand cleaning guidelines.

In "Crossing the Quality Chasm: a New Health System for the 21st Century," the U.S. Institute of Medicine[4] presents the multiple ways in which patient care in the United States falls short of expectations. The Institute outlines six goals for health care delivery to improve the quality of care, as follows:

1. *Safety.* This goal focuses on avoiding injuries from care delivered to the patient. The applicability of this goal in the laboratory is centered on avoiding preevaluation, evaluation, and postevaluation errors.
2. *Timeliness.* This goal addresses reduction in the length of time or delays in providing or receiving care. Laboratory examples of improving timeliness can be found by incorporating point-of-care testing and focusing on improving the turnaround time of testing that supports improved patient outcomes.
3. *Effectiveness.* This goal category stresses the avoidance of underuse, overuse, and misuse of laboratory testing. The laboratory can impact this goal by performing an analysis of underused, overused, and misused assays. Additionally, outdated procedures can be retired using evidence-based practice knowledge. In this way, patients who could benefit from laboratory tests receive appropriate care, and those who are not likely to benefit avoid nonbeneficial testing.
4. *Efficiency.* This goal aims to reduce or avoid waste. Waste may be in the form of materials and supplies or wasted time. Examples of waste can be identified in the three phases of laboratory analysis: preevaluation (preanalytic), evaluation (analytic), and postevaluation (postanalytic).
5. *Equitable treatment.* This goal addresses the need to provide consistent quality of care regardless of gender, ethnicity, socioeconomic class, or geographic location. The laboratory can influence success in this goal category by expanding outpatient hours and sites of specimen collection, providing multilanguage information about laboratory testing, and documenting consistency of quality between in-house and POCT procedures.
6. *Patient-centered focus.* This final category of quality improvement spotlights the need to provide respectful care that is responsive to diversified patients. Laboratory professionals can be instrumental in facilitating this goal by answering patient questions and communicating pertinent information to them.

The American Society for Clinical Laboratory Science provides patient safety indicators (Table 2.1) and a seven-step procedure to evaluate patient safety in the clinical laboratory (Table 2.2).

TABLE 2.1 Examples of ASCLS Patient Safety Indicators

Testing Phase	Category	Representative Examples
Preanalytical	Patient identification	Failure to use two patient identifiers
	Phlebotomy-associated negative events	Lapse in infection prevention/hand hygiene
		Skin reaction to tape/bandage/latex
		Sharps (needles or lancets) left in patient bed
	Specimen identification	Unlabeled specimen
		Mislabeled specimen
	Order entry	Test(s) ordered on the wrong patient
		Incorrect test or procedure ordered
	Specimen integrity	Insufficient volume of specimen
		Lost or destroyed sample
		Improper temperature maintained while transporting or storing
	Effective use of the clinical laboratory	Failure to order the appropriate test
		Test requested at inappropriate time
Analytical	Verification of the accuracy of abnormal results	Failure to recognize specimen-processing errors that affect test results
		Failure to verify abnormal or critical point-of-care results with the clinical laboratory
Postanalytical	Communication of test results	Critical values not reported within defined time frame to clinician
		Failure of timeliness in communication of results to clinician
	Effective use of test results	Incorrect interpretation of test results
		Failure to order follow-up test(s)
	Outcomes of laboratory testing	Failure of provider to notify patient of abnormal test results and required next steps

Modified from American Society for Clinical Laboratory Science (ASCLS) with permission: ASCLS Patient Safety Indicators. www.ascls.org. Retrieved May 16, 2013.

TABLE 2.2 ASCLS Seven-Step Procedure to Evaluate Patient Safety in Laboratory Testing

Step	Description	Comments
1	Determine areas of risk	Identify the Patient Safety Indicators that pose the greatest risk of harm to patients (see Table 2-1).
2	Collect data	Based on selection of the indicators with the greatest risk, select a few indicators, either all in one phase or spread across all three phases of the Total Testing Process. It is important to incorporate the entire scope of testing services (such as chemistry) and the spectrum of practice sites (such as hospital, clinic, outpatient drawing centers).
3	Determine the denominator to calculate the error rate	It is important to convert the absolute number of errors that occur into an error rate in order to achieve consistency in comparing different laboratories. Error rate for nonhospital labs should calculate error rate on an event per patient encounter basis. The denominator will be the number of patient encounters for the evaluation time frame. Error rate for hospital labs should calculate error rate per adjusted patient day, which includes inpatient and outpatient services. The denominator is adjusted patient days.
4	Capture data	The length of time for collecting data is dependent on how often the process error occurs. The time frame can range from weekly to annual.
5	Data analysis	Factors to consider include acceptability of rate of errors, impact of the error, trending of data, and patient outcomes.
6	Design intervention	After root cause(s) and other results of data analysis, an intervention should be developed with a pilot study. Measurements methods must be the same pre- and post-intervention.
7	Follow-up	Once acceptable error rates have been achieved, an indicator should be monitored periodically or as a spot check.

Modified from American Society for Clinical Laboratory Science (ASCLS) with permission, ASCLS procedure to evaluate aspects of Clinical Laboratory Services Total Testing Process that impact patient safety. www.ascls.org. Retrieved May 16, 2013.

TABLE 2.3 Medical Euphemisms

Euphemism	Meaning
Adverse event	A patient was harmed due to a problem in medical care.
Incident	An event has come into being and is not good.
Near miss	A patient was nearly harmed. A more accurate euphemism would be "near hit."
Occurrence	An event that has come into being.
Potential adverse event	A patient was nearly harmed due to a problem in medical care.
Sentinel event	A patient died or was severely harmed due to a problem in medical care, most likely a preventable error.
Variance	A movement away from our desired norm.

From Astion M: Clear communication and patient harm events, *Clin Lab News* 38(1):13, 2012.

Communications

The need for clear communication is imperative. Avoiding direct communication of an error that harmed a patient is unacceptable.[5] Avoidance lowers or removes the urgency for quality improvement. *Medical euphemisms* are commonly used in clinical laboratories to describe medical errors that harm patients (Table 2.3). The use of euphemisms is a bad habit thought to be rooted in the desire to avoid painful, complex quality improvement issues as well as the extra work that improvement strategies create. Taking time to communicate will help ensure patient safety.

Mitigating Patient Risk

A critical area of concern related to patient safety is the mitigation of patient risk during information technology (IT) outages.[6] This is a universal challenge for clinical laboratories and health care systems. Laboratories need to be prepared for two types of total or partial IT downtime: (1) planned outages for updates or upgrades and (2) unexpected failures or impairments with an unknown length of downtime. In the current highly automated laboratory environment, affected services can impact test ordering, specimen collection and labeling, specimen processing and testing, and the reporting of results.

The initial step toward managing IT downtime is to have a clear activation and communications plan with established guidelines for initiating downtime protocols. Downtime protocols may differ depending on the IT systems affected. For effective downtime implementation, plans should be shared with patient care areas to ensure that laboratory personnel lead a team effort to provide testing. A single laboratory contact creates an organized approach to information management. Some form of mass communication should briefly state that laboratory results will be delayed because of IT issues. An estimated length of downtime may be included.

Laboratory staff members need to know the time frames for initiating alternate testing protocols. "Stat" testing from the emergency department, intensive care unit (ICU), or critical care unit must receive the highest priorities. Clearly labeled specimens from patients in these designated high-preference areas should be used. Reporting of critical results should be a special focus of risk mitigation during IT outages. During these times, laboratory personnel must identify critical results and report these to care providers. Command centers or designated service pagers for receiving data on critical results are of utmost importance to high-quality patient care during these emergencies. When the crisis has been resolved, communication with end users is essential; this step closes the communications loop. Lastly, a critique of the processes and events during the IT outage needs to be conducted. This critique will contribute to a better workflow in the event of future IT outages.

SAFETY STANDARDS AND GOVERNING AGENCIES

The importance of safety and correct first-aid procedures cannot be overemphasized. Many accidents do not just happen; they are caused by carelessness, lack of attention to detail, or lack of proper communication. For this reason, the practice of safety should be uppermost in the mind of all persons working in a clinical laboratory. Most laboratory accidents are preventable by exercising good technique, staying alert, and using common sense.

Laboratory safety includes Occupational Safety and Health Administration (OSHA) standards and Centers for Disease Control and Prevention (CDC) guidelines designed to protect laboratory personnel from potential hazards in the clinical laboratory. Safety in the clinical laboratory encompasses bloodborne pathogen protection and chemical, fire, and electrical safety.

Ergonomics is a safety issue. Ergonomics studies human capabilities in relationship to the work demands placed on an individual while at work. Clinical laboratories have multiple ergonomic stressors, such as back strain from an uncomfortable chair or aching feet from walking or standing on hard floors. Repetitive actions such as pipetting or typing are potential sources of motion injuries (such as carpal tunnel syndrome). The term musculoskeletal disorders (MSDs) is used to describe the most common physical ergonomic stressors where muscles, nerves, tendons, joints, or discs are affected. MSDs include carpal tunnel syndrome, rotator cuff syndrome, tendinitis, and sciatica. Any type of stressor likely to lead to an MSD is called a "work-related musculoskeletal disorder hazard." To improve working conditions in the clinical laboratory, a periodic ergonomic assessment should be conducted. Stressors with injury potential include repetition, posture, force or pressure associated with hard surfaces, vibration, and ambient temperature. Engineering changes can improve ergonomic conditions. Working conditions (such as shift length) and educational interventions on prevention of unfavorable conditions can reduce the threat of ergonomic injury.

Safety standards for patients and clinical laboratories are initiated, governed, and reviewed by the following federal agencies and professional organizations [7–11]:

1. OSHA, U.S. Department of Labor
2. Clinical and Laboratory Standards Institute (CLSI)
3. CDC, U.S. Department of Health and Human Services, Public Health Service (PHS)
4. College of American Pathologists (CAP)
5. The Joint Commission. TJC has established National Patient Safety Goals, three apply specifically to laboratory services.

National Healthcare Safety Network

The National Healthcare Safety Network (NHSN). This voluntary system integrates a number of surveillance systems and provides data on devices, patients, and staff. The NHSN expands legacy patient and health care personnel safety surveillance systems managed by the Division of Healthcare Quality Promotion at CDC. NHSN also includes a new component for hospitals to monitor adverse reactions and incidents associated with receipt of blood and blood products. Enrollment is open to all types of health care facilities in the United States.

The National Nosocomial Infections Surveillance System of the CDC performed a survey from October 1986 to April 1998. The highest rates of infection occurred in the burn ICU, the neonatal ICU, and the pediatric ICU. Within hours of admission, colonies of hospital strains of bacteria develop in the patient's skin, respiratory tract, and genitourinary tract. Risk factors for the invasion of colonizing **pathogens** can be categorized into the following three areas:

- **Iatrogenic** risk factors include pathogens on the hands of medical personnel, invasive procedures (such as intubation and extended ventilation, indwelling vascular lines, and urine catheterization), and antibiotic use and prophylaxis.
- Organizational risk factors include contaminated air-conditioning systems, contaminated water systems, and staffing and physical layout of the facility (such as nurse-to-patient ratio and open beds close together).
- Patient risk factors include the severity of illness, underlying immunocompromised state, and length of stay.

Nosocomial infections are estimated to occur in 5% of all acute care hospitalizations. In the United States the incidence of hospital-acquired infection is more than 2 million cases per year. Nosocomial infections are caused by viral, bacterial, and fungal pathogens. In pediatric patient units surveyed between 1992 and 1997, the incidence of nosocomial invasive bacterial and fungal infections was highest in bloodstream infections, with coagulase-negative staphylococci found in the majority of cases. Infections caused by methicillin-resistant *Staphylococcus aureus* (MRSA) are not worse than those caused by susceptible *S. aureus.* MRSA requires treatment with different families of antibiotics. Although the pathogenicity does not generally differ from that of susceptible strains of *S. aureus,* MRSA strains that carry the loci for Panton-Valentine leukocidin can be hypervirulent and can cause lymphopenia, rapid tissue **necrosis,** and severe **sepsis.**

Many hospitals have reorganized the physical layout of handwashing stations and have adopted patient cohorting to prevent the spread of pathogens. They have also restricted or rotated the administration of many antibiotics that are used to combat nosocomial infections. A special concern in regard to bacterial agents is that multiresistant organisms, such as vancomycin-resistant enterococci, glycopeptide-resistant *S. aureus,* and inducible or extended-spectrum beta-lactamase gram-negative organisms, are a constant threat.

Occupational Safety and Health Administration Acts and Standards

To ensure that workers have safe and healthful working conditions, the U.S. Federal Government created a system of safeguards and regulations under the Occupational Safety and Health Act of 1970 and in 1988 expanded the **Hazard Communication Standard**[8] (HCS; revised in 2012) to apply to hospital staff. Occupational Safety and Health Act regulations apply to all businesses with one or more employees and are administered by the U.S. Department of Labor through OSHA. The programs deal with many aspects of safety and health

protection, including compliance arrangements, inspection procedures, penalties for noncompliance, complaint procedures, duties and responsibilities for administration and operation of the system, and how the many standards are set. Responsibility for compliance is placed on both the administration of the institution and the employee.

Both OSHA and CDC have published numerous safety standards and regulations that are applicable to clinical laboratories. Ensuring safety in the clinical laboratory includes the following measures:

- A formal safety program
- Specifically mandated plans (such as chemical hygiene and bloodborne pathogens)
- Identification of various hazards (such as fire, electrical, chemical, and biological)
- Safety officer and safety coaches

A designated laboratory safety officer and laboratory safety coaches are a critical part of a laboratory safety program, including "safety eyes" and "safety ears" to implement surveillance of correct safety practices including compliance with existing regulations affecting the laboratory and staff, correct labeling of chemicals and the proper handling and disposal of waste.

The safety officer is responsible for initial orientation of staff and the periodic updating of staff (Table 2.4). Safety coaches are volunteers who assume additional job responsibilities. These volunteers represent all laboratory departments and shifts, and job roles. Safety coaches have six important functions:

1. Communicator of safety habits
2. Educator of safety habits
3. Role model of safety habits
4. Observer of safety habits
5. Storyteller to implement positive change
6. Change agent for maximum compliance with correct safety habits

Safety coaches can facilitate safety habits for prevention of errors by paying attention to details, communicating clearly, and having a questioning attitude. These volunteers must recognized that barriers such as peer resistance and time constraints need to be overcome.

TABLE 2.4 Recommended Safety Training Schedule

Topic	Who Needs to be Trained	Frequency
All laboratory safety policies and procedures	All laboratory staff	Upon employment
Fire extinguisher practice	All laboratory staff	Upon employment
Spill cleanup	All technical staff	Upon employment
Fire prevention and preparedness	All laboratory staff	Annually
Fire drill evacuation	All laboratory staff	Annually
Chemical safety	All staff who handle or transport chemicals	Annually
Biological hazard	All laboratory staff	Annually
Infection control	All laboratory staff	Annually
Radiation safety	Only employees who use or transport radioactive materials	Annually
Specimen packaging and shipping procedures	Staff who package specimens for shipping by ground or air	Every 24 months

From Gile TJ: *Complete guide to laboratory safety,* Marblehead, Mass, 2004, HCPro.

OSHA-Mandated Plans

In 1991, OSHA mandated that all clinical laboratories must implement a chemical hygiene plan (CHP) and an exposure control plan. As part of the CHP, a copy of the **safety data sheet (SDS)** must be on file and readily accessible and available to all employees at all times.

Chemical Hygiene Plan

A CHP is the core of the OSHA safety standard. Existing safety and health plans may meet the CHP requirements. A written CHP is to be developed by each employer and must specify the following:

- The training and information requirements of the OSHA standard
- Designation of a chemical hygiene officer and committee
- Appropriate work practices
- A list of chemicals in inventory
- Availability of SDSs
- Labeling requirements
- Record-keeping requirements
- Standard operating procedures and housekeeping requirements
- Methods of required engineering controls, such as eyewashes and safety showers
- Measures for appropriate maintenance and list of protective equipment
- Requirements for employee medical examinations
- Special precautions for working with particularly hazardous substances
- Information on waste removal and disposal
- Other information deemed necessary for safety assurance

Hazard Communication Standard

The OSHA HCS (29 CFR 1910.1200[g]), revised in 2012, requires that the chemical manufacturer, distributor, or importer provide SDSs, formerly material safety data sheets (MSDSs), for each hazardous chemical to downstream users to communicate information on these hazards. The information contained in the SDS is largely the same as the MSDS, except now the SDSs are required to be presented in a consistent, user-friendly, 16-section format (Box 2.1).

As with the current standard, the new HCS requires chemical manufacturers and importers to evaluate the chemicals they produce or import and provide hazard information to employers and workers by putting labels on containers and preparing SDSs. The modified standard provides a single set of harmonized criteria for classifying chemicals according to their health and physical hazards and specifies hazard communication elements

BOX 2.1 Safety Data Sheet (SDS) Format in OSHA Hazard Communication Standard (HCS)

Section 1: Identification

This section identifies the chemical on the SDS as well as the recommended uses. It also provides the essential contact information of the supplier. The required information consists of:

- Product identifier used on the label and any other common names or synonyms by which the substance is known.
- Name, address, phone number of the manufacturer, importer, or other responsible party, and emergency phone number.
- Recommended use of the chemical (such as a brief description of what it actually does, for example with flame retardant) and any restrictions on use (including recommendations given by the supplier).

Section 2: Hazard(s) Identification

This section identifies the hazards of the chemical presented on the SDS and the appropriate warning information associated with those hazards. The required information consists of:

- The hazard classification of the chemical (such as flammable liquid, category[1]).
- Signal word.
- Hazard statement(s).
- Pictograms (the pictograms or hazard symbols may be presented as graphical reproductions of the symbols in black and white or be a description of the name of the symbol (such as skull and crossbones or flame)).
- Precautionary statement(s).
- Description of any hazards not otherwise classified.
- For a mixture that contains an ingredient(s) with unknown toxicity, a statement describing how much (percentage) of the mixture consists of ingredient(s) with unknown acute toxicity. Please note that this is a total percentage of the mixture and not tied to the individual ingredient(s).

Section 3: Composition/Information on Ingredients

This section identifies the ingredient(s) contained in the product indicated on the SDS, including impurities and stabilizing additives. This section includes information on substances, mixtures, and all chemicals where a trade secret is claimed. The required information consists of:

Substances

- Chemical name.
- Common name and synonyms.
- Chemical Abstracts Service (CAS) number and other unique identifiers.
- Impurities and stabilizing additives, which are themselves classified and which contribute to the classification of the chemical.

Mixtures

- Same information required for substances.
- The chemical name and concentration (i.e., exact percentage) of all ingredients which are classified as health hazards and are:
  Present above their cutoff/concentration limits *or*
  Present a health risk below the cutoff/concentration limits.
- The concentration (exact percentages) of each ingredient must be specified, except concentration ranges may be used in the following situations:
  A trade secret claim is made,
  There is batch-to-batch variation, *or*
  The SDS is used for a group of substantially similar mixtures.

Chemicals where a trade secret is claimed

- A statement that the specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret is required.

Section 4: First-Aid Measures

This section describes the initial care that should be given by untrained responders to an individual who has been exposed to the chemical. The required information consists of:

- Necessary first-aid instructions by relevant routes of exposure (inhalation, skin and eye contact, and ingestion).
- Description of the most important symptoms or effects, and any symptoms that are acute or delayed.
- Recommendations for immediate medical care and special treatment needed, when necessary.

Section 5: Fire-Fighting Measures

This section provides recommendations for fighting a fire caused by the chemical. The required information consists of:

- Recommendations of suitable extinguishing equipment, and information about extinguishing equipment that is not appropriate for a particular situation.
- Advice on specific hazards that develop from the chemical during the fire, such as any hazardous combustion products created when the chemical burns.
- Recommendations on special protective equipment or precautions for firefighters.

Section 6: Accidental Release Measures

This section provides recommendations on the appropriate response to spills, leaks, or releases, including containment and cleanup practices to prevent or minimize exposure to people, properties, or the environment. It may also include recommendations distinguishing between responses for large and small spills where the spill volume has a significant impact on the hazard. The required information may consist of recommendations for:

- Use of personal precautions (such as removal of ignition sources or providing sufficient ventilation) and protective equipment to prevent the contamination of skin, eyes, and clothing.
- Emergency procedures, including instructions for evacuations, consulting experts when needed, and appropriate protective clothing.
- Methods and materials used for containment (such as covering the drains and capping procedures).
- Cleanup procedures (such as appropriate techniques for neutralization, decontamination, cleaning or vacuuming; adsorbent materials; and/or equipment required for containment/cleanup).

Section 7: Handling and Storage

This section provides guidance on the safe handling practices and conditions for safe storage of chemicals. The required information consists of:

- Precautions for safe handling, including recommendations for handling incompatible chemicals, minimizing the release of the chemical into the environment, and providing advice on general hygiene practices (such as eating, drinking, and smoking in work areas is prohibited).
- Recommendations on the conditions for safe storage, including any incompatibilities. Provide advice on specific storage requirements (such as ventilation requirements).

Section 8: Exposure Controls/Personal Protection

This section indicates the exposure limits, engineering controls, and personal protective measures that can be used to minimize worker exposure. The required information consists of:

- OSHA Permissible Exposure Limits (PELs), American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values (TLVs), and any other exposure limit used or recommended by the chemical manufacturer, importer, or employer preparing the safety data sheet, where available.
- Appropriate engineering controls (for example, use local exhaust ventilation, or use only in an enclosed system).
- Recommendations for personal protective measures to prevent illness or injury from exposure to chemicals, such as personal protective equipment (PPE) (for example, appropriate types of eye, face, skin, or respiratory protection needed based on hazards and potential exposure).

Continued

BOX 2.1 Safety Data Sheet (SDS) Format in OSHA Hazard Communication Standard (HCS)—cont'd

- Any special requirements for PPE, protective clothing, or respirators (such as type of glove material, as in PVC or nitrile rubber gloves; and breakthrough time of the glove material).

Section 9: Physical and Chemical Properties

This section identifies physical and chemical properties associated with the substance or mixture. The minimum required information consists of:

- Appearance (physical state, color, etc.)
- Odor
- Odor threshold
- pH
- Melting point/freezing point
- Initial boiling point and boiling range
- Flash point
- Evaporation rate
- Flammability (solid, gas)
- Upper/lower flammability or explosive limits
- Vapor pressure
- Vapor density
- Relative density
- Solubility(ies)
- Partition coefficient: n-octanol/water
- Auto-ignition temperature
- Decomposition temperature
- Viscosity

The SDS may not contain every item on the above list because information may not be relevant or is not available. When this occurs, a notation to that effect must be made for that chemical property. Manufacturers may also add other relevant properties, such as the dust deflagration index (Kst) for combustible dust, used to evaluate a dust's explosive potential.

Section 10: Stability and Reactivity

This section describes the reactivity hazards of the chemical and the chemical stability information. This section is broken into three parts: reactivity, chemical stability, and other. The required information consists of:

Reactivity

- Description of the specific test data for the chemical(s). These data can be for a class or family of the chemical if such data adequately represent the anticipated hazard of the chemical(s), where available.

Chemical Stability

- Indication of whether the chemical is stable or unstable under normal ambient temperature and conditions while in storage and being handled.
- Description of any stabilizers that may be needed to maintain chemical stability.
- Indication of any safety issues that may arise should the product change in physical appearance.

Other

- Indication of the possibility of hazardous reactions, including a statement whether the chemical will react or polymerize, which could release excess pressure or heat, or create other hazardous conditions. Also, a description of the conditions under which hazardous reactions may occur.
- List of all conditions that should be avoided (such as static discharge, shock, vibrations, or environmental conditions that may lead to hazardous conditions).
- List of all classes of incompatible materials (such as classes of chemicals or specific substances) with which the chemical could react to produce a hazardous situation.
- List of any known or anticipated hazardous decomposition products that could be produced because of use, storage, or heating. (Hazardous combustion products should also be included in Section 5: Fire-Fighting Measures of the SDS.)

Section 11: Toxicological Information

This section identifies toxicological and health effects information or indicates that such data are not available. The required information consists of:

- Information on the likely routes of exposure (inhalation, ingestion, skin and eye contact).
- The SDS should indicate if the information is unknown.
- Description of the delayed, immediate, or chronic effects from short- and long-term exposure.
- The numerical measures of toxicity (for example, acute toxicity estimates such as the LD50 (median lethal dose)—the estimated amount [of a substance] expected to kill 50% of test animals in a single dose.
- Description of the symptoms. This description includes the symptoms associated with exposure to the chemical including symptoms from the lowest to the most severe exposure.
- Indication of whether the chemical is listed in the National Toxicology Program (NTP) Report on Carcinogens (latest edition) or has been found to be a potential carcinogen in the International Agency for Research on Cancer (IARC) Monographs (latest editions) or found to be a potential carcinogen by OSHA.

Section 12: Ecological Information (non-mandatory)*[2]

This section provides information to evaluate the environmental impact of the chemical(s) if it were released to the environment. The information may include:

- Data from toxicity tests performed on aquatic and/or terrestrial organisms, where available (such as acute or chronic aquatic toxicity data for fish, algae, crustaceans, and other plants; toxicity data on birds, bees, and plants).
- Whether there is a potential for the chemical to persist and degrade in the environment either through biodegradation or other processes, such as oxidation or hydrolysis.
- Results of tests of bioaccumulation potential, making reference to the octanol-water partition coefficient (Kow) and the bioconcentration factor (BCF), where available.
- The potential for a substance to move from the soil to the groundwater (indicate results from adsorption studies or leaching studies).
- Other adverse effects (such as environmental fate, ozone layer depletion potential, photochemical ozone creation potential, endocrine disrupting potential, and/or global warming potential).

Section 13: Disposal Considerations (non-mandatory)*

This section provides guidance on proper disposal practices, recycling or reclamation of the chemical(s) or its container, and safe handling practices. To minimize exposure, this section should also refer the reader to Section 8 (Exposure Controls/Personal Protection) of the SDS. The information may include:

- Description of appropriate disposal containers to use.
- Recommendations of appropriate disposal methods to employ.
- Description of the physical and chemical properties that may affect disposal activities.
- Language discouraging sewage disposal.
- Any special precautions for landfills or incineration activities.

Continued

BOX 2.1 Safety Data Sheet (SDS) Format in OSHA Hazard Communication Standard (HCS)—cont'd

Section 14: Transport Information (non-mandatory)*

This section provides guidance on classification information for shipping and transporting of hazardous chemical(s) by road, air, rail, or sea. The information may include:

- UN number (i.e., four-figure identification number of the substance)[3]
- UN proper shipping name
- Transport hazard class(es)
- Packing group number, if applicable, based on the degree of hazard
- Environmental hazards (such as identifing if it is a marine pollutant according to the International Maritime Dangerous Goods Code [IMDG Code])
- Guidance on transport in bulk according to Annex II of MARPOL 73/78,[4] and the International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk (International Bulk Chemical Code [IBC Code]).
- Any special precautions which an employee should be aware of or needs to comply with, in connection with transport or conveyance either within or outside their premises (indicate when information is not available).

Section 15: Regulatory Information (non-mandatory)*

This section identifies the safety, health, and environmental regulations specific for the product that is not indicated anywhere else on the SDS. The information may include:

- Any national and/or regional regulatory information of the chemical or mixtures (including any OSHA, Department of Transportation, Environmental Protection Agency, or Consumer Product Safety Commission regulations).

Section 16: Other Information

This section indicates when the SDS was prepared or when the last known revision was made. The SDS may also state where the changes have been made to the previous version. You may wish to contact the supplier for an explanation of the changes. Other useful information also may be included here.

Employer Responsibilities

Employers must ensure that the SDSs are readily accessible to employees for all hazardous chemicals in their workplace. This may be done in many ways. For example, employers may keep the SDSs in a binder or on computers as long as the employees have immediate access to the information without leaving their work area when needed and a backup is available for rapid access to the SDS in the case of a power outage or other emergency. Furthermore, employers may want to designate a person(s) responsible for obtaining and maintaining the SDSs. If the employer does not have an SDS, the employer or designated person(s) should contact the manufacturer to obtain one.

Modified from Occupational Safety and Health Administration, 29 CFR 1910.1200(g) and Appendix D. Globally Harmonized System of Classification and Labeling of Chemicals (GHS), third revised edition, United Nations, 2009. http://www.osha.gov/dsg/hazcom/index.html

[1]Chemical, as defined in the HCS, is any substance, or mixture of substances.

[2]Because other agencies regulate this information, OSHA will not be enforcing Sections 12 through 15.

[3]Found in the most recent edition of the United Nations Recommendations on the Transport of Dangerous Goods.

[4]MARPOL 73/78 means the International Convention for the Prevention of Pollution from Ships, 1973, as modified by the Protocol of 1978 relating thereto, as amended.

for labeling and SDSs. Employers must ensure that SDSs are readily accessible to employees.

The major changes to the HCS include the following:

1. **Hazard classification:** Chemical manufacturers and importers are required to determine the hazards of the chemicals they produce or import. Hazard classification under the new, updated standard provides specific criteria to address health and physical hazards as well as classification of chemical mixtures.
2. **Labels:** Chemical manufacturers and importers must provide a label (Fig. 2.1) that includes a signal word, pictogram (Fig. 2.2), hazard statement, and precautionary statement for each hazard class and category.
3. **Safety data sheets:** The new SDS format requires 16 specific sections, ensuring consistency in presentation of important protection information (see Box 2.1).
4. **Information and training:** To facilitate understanding of the new system, the new standard requires that workers be trained by December 1, 2013, and beyond for specified requirements (Table 2.5).

New changes to OSHA's HCS are bringing the United States into alignment with the Globally Harmonized System of Classification and Labeling of Chemicals (GHS), further improving safety and health protections for America's workers. The new system is being implemented throughout the world by countries that include Canada, the European Union, China, Australia, and Japan. Building on the success of OSHA's current HCS, the GHS is expected to prevent injuries and illnesses, save lives, and improve trade conditions for chemical manufacturers. The HCS in 1983 gave the workers the "right to know," but the new GHS gives workers the "right to understand."

Exposure Control Plan

The OSHA-mandated program, **Occupational Exposure to Bloodborne Pathogens,** became law in March 1992. This regulation requires that laboratories:

- Develop, implement, and comply with a plan that ensures the protective safety of laboratory staff to potential infectious bloodborne pathogens.
- Manage and handle medical waste in a safe and effective manner.

Government regulations require that all employees who handle hazardous material and waste must be trained to use and handle these materials. Chemical hazard education sessions must be presented to new employees and conducted annually for all employees. Each laboratory is required to evaluate the effectiveness of its plan at least annually and to update it as necessary. The written plan must be available to employees. A laboratory's written plan must include the purpose and scope of the plan, references, definitions of terms and responsibilities, and detailed procedural steps to follow.

The CDC also recommends safety precautions concerning the handling of all patient specimens, known as **Standard Precautions,** previously called *Universal Precautions.* OSHA has also issued guidelines for the laboratory worker in regard to protection from bloodborne diseases spread through contact

SAMPLE LABEL

PRODUCT IDENTIFIER

CODE _____

Product Name _____

SUPPLIER IDENTIFICATION

Company Name _____
Street address _____
City _____ State _____
Postal Code _____ Country _____
Emergency Phone Number _____

PRECAUTIONARY STATEMENTS

Keep container tightly closed. Store in cool, well ventilated place that is locked.
Keep away from heat/sparks/open flame. No smoking.
Only use non-sparking tools.
Use explosion-proof electrical equipment.
Take precautionary measure against static discharge.
Ground and bond container and receiving equipment.
Do not breathe vapors.
Wear Protective gloves.
Do not eat, drink or smoke when using this product.
Wash hands thoroughly after handling.
Dispose of in accordance with local, regional, national, international regulations as specified.

In Case of Fire: use dry chemical (BC) or Carbon dioxide (CO_2) fire extinguisher to extinguish.

First Aid
If exposed call Poison Center.
If on skin (on hair): Take off immediately any contaminated clothing. Rinse skin with water.

HAZARD PICTOGRAMS

SIGNAL WORD
Danger

HAZARD STATEMENT

Highly flammable liquid and vapor.
May cause liver and kidney damage.

SUPPLEMENTAL INFORMATION

Directions for use
_____
_____
_____

Fill weight: _____ Lot Number _____
Gross weight: _____ Fill Date: _____
Expiration Date: _____

Fig. 2.1 Hazard Communication Standard Labels. (From www.osha.gov. Accessed June 10, 2014.)

Health Hazard  • Carcinogen • Mutagenicity • Reproductive Toxicity • Respiratory Sensitizer • Target Organ Toxicity • Aspiration Toxicity	**Flame**  • Flammables • Pyrophorics • Self-Heating • Emits Flammable Gas • Self-Reactives • Organic Peroxides	**Exclamation Mark**  • Irritant (skin and eye) • Skin Sensitizer • Acute Toxicity (harmful) • Narcotic Effects • Respiratory Tract Irritant • Hazardous to Ozone Layer (Non-Mandatory)
Gas Cylinder  • Gases Under Pressure	**Corrosion**  • Skin Corrosion/Burns • Eye Damage • Corrosive to Metals	**Exploding Bomb**  • Explosives • Self-Reactives • Organic Peroxides
Flame Over Circle  • Oxidizers	**Environment** **(Non-Mandatory)**  • Aquatic Toxicity	**Skull and Crossbones**  • Acute Toxicity (fatal or toxic)

Fig. 2.2 Hazard Communication Standard Pictogram. (From www.osha.gov. Accessed June 10, 2014.)

TABLE 2.5 Effective Completion Dates for Hazard Communications Standard

Date	Requirement(s)	Who
December 1, 2013	Train employees on the new label elements and safety data sheet (SDS) format.	Employers
June 1, 2015	Comply with all modified provisions of this final rule, except:	Chemical manufacturers, importers, distributors, and employers
December 1, 2015	Distributors may ship products labeled by manufacturers under the old system until December 1, 2015.	
June 1, 2016	Update alternative workplace labeling and hazard communication program as necessary, and provide additional employee training for newly identified physical or health hazards.	Employers
Transition period	Comply with either 29 CFR 1910.1200 (this final standard) or the current standard, or both.	All chemical manufacturers, importers, distributors, and employers

TABLE 2.6 Safety Standards for Bloodborne Pathogens

Category	Comments
Training	Annual bloodborne pathogen training is required regardless of an employee's prior training or education.
	Annual training should concur within a reasonable time from an employee's annual hire date.
	The language used for bloodborne training should be understandable to non-English-speaking or limited-English-speaking employees.
Infectious disease prevention	The need to comply with personal protective equipment (PPE) should be determined by an employer.
	Eye protection (such as safety glasses, face mask, or protective shield) must be used while working to prevent spraying or splashing of potentially contaminated specimens.
	Every employer must have a written, dated record of each dose of hepatitis B vaccination.
Laboratory practices	Blood specimen tubes should be covered with gauze to prevent accidental exposure.
	Urine containers that do not contain visible blood do not need to be disposed of in a biohazard container (red bag waste).
First aid	First-aid services must be available within 3 to 4 minutes whether using in-house or outside emergency services.

Data from www.osha.gov. Retrieved May 17, 2013.

with patient specimens (Table 2.6). In addition, CDC provides recommendations for treatment after occupational exposure to potentially infectious material. These agencies are working to reduce the risk of exposure of health care workers to bloodborne pathogens.

AVOIDING TRANSMISSION OF INFECTIOUS DISEASES

Because many hazards in the clinical laboratory are unique, a special term, **biohazard**, was devised. This word is posted throughout the laboratory to denote infectious materials or agents that present a risk or even a potential risk to the health of human beings or animals in the laboratory. The potential risk can be either through direct infection or through the environment. Infection can occur during the process of specimen collection or from handling, transporting, or testing the specimen. Safe collection and transportation of specimens to the laboratory must take priority in any discussion of safety in the laboratory.

Risk is defined as the probability that a health effect will occur after an individual has been exposed to a specified amount of a hazard. Risk assessment is a process of gathering all available information on a hazardous substance and evaluating it to determine the possible risks associated with exposure. This is followed by determining the mitigation strategies necessary to provide protection.

Bioterrorism agents are a concern to laboratories. These agents are divided into categories A, B, and C (Box 2.2 and Table 2.7). The OSHA categories of risk classifications are now obsolete.

Biosafety and Biosafety Levels

Biosafety means reducing the risk of unintentional exposure to pathogens and toxins or their accidental release. A biosafety

BOX 2.2 Categories and Characteristics of Bioterrorism Agents

Category A

Pathogens that are rarely seen in the United States. These agents have the highest priority; organisms in this category pose a risk to national security because they:

- Can be easily disseminated or transmitted from person to person
- Result in high mortality rates and have the potential for major public health impact
- Might cause public panic and social disruption
- Require special action for public health preparedness

Category B

These agents have the second-highest priority and include pathogens that:

- Are moderately easy to disseminate
- Result in moderate morbidity rates and low mortality rates
- Require specific enhancements of the CDC's diagnostic capacity and enhanced disease surveillance

Category C

These agents have the third-highest priority and include emerging pathogens that could be engineered for mass dissemination in the future because of:

- Availability
- Ease of production and dissemination
- Potential for high morbidity and mortality rates and major health impact

Modified from Centers for Disease Control and Prevention: Bioterrorism agents/diseases (website). http://www.bt.cdc.gov/agent/agentlist-category.asp. Accessed February 2005.

TABLE 2.7 Examples of Bioterrorism Agents and Diseases

Agent	Disease
Category A	
Anthrax	*Bacillus anthracis*
Botulism	*Clostridium botulinum* toxin
Plague	*Yersinia pestis*
Smallpox	Variola major
Tularemia	*Francisella tularensis*
Viral Hemorrhagic Fevers	
Filoviruses	Ebola, Marburg
Arenaviruses	Lassa, Machupo
Category B	
Brucellosis	*Brucella* species
Epsilon toxin	*Clostridium perfringens*
Food contaminants	*Salmonella* species, *Escherichia coli* O157:H7, *Shigella*
Glanders	*Pseudomonas (Burkholderia) mallei*
Melioidosis	*Pseudomonas (Burkholderia) pseudomallei*
Psittacosis	*Chlamydia psittaci*
Q fever	*Coxiella burnetii*
Ricin toxin	*Ricinus communis* (castor beans)
Staphylococcal Enterotoxin B	
Typhus fever	*Rickettsia prowazekii*
Viral encephalitis	Alphaviruses (such as Venezuelan equine encephalitis, Eastern equine encephalitis, and Western equine encephalitis)
Water safety threats	*Vibrio cholerae, Cryptosporidium parvum*

Modified from Centers for Disease Control and Prevention: Bioterrorism agents/diseases (website). www.bt.cdc.gov/agent/agentlist-category.asp. Retrieved February 2005.

Fig. 2.3 Biohazard symbol. (From Rodak BF, Fritsma GA, Keohane EM: *Hematology: clinical principles and applications,* ed 4, St Louis, 2012, Elsevier/Saunders.)

management plan addresses the laboratory practices and procedures designed or intended to reduce risks associated with potential biological safety hazards.

Biosafety practices apply safety precautions that reduce a laboratory staff member's risk of exposure to a potentially infectious microorganism and limit contamination of the work environment and, ultimately, the community. Fig. 2.3 shows the symbol used to denote the presence of biohazards.

Biosafety is not an add-on task in the laboratory; it is a critical activity. A strong safety culture produces a reduction in exposure incidents and management of medical waste. A strong safety culture results from positive employee attitudes, effective policies and procedures, action to correct unsafe behaviors, and employee training and involvement in safety practices.

There are four biosafety levels (see Box 2.3). Each level has specific controls for containment of microorganisms and biological agents. Risk assessment is an important part of biosafety. The primary risks that determine levels of containment are infectivity, severity of disease, transmissibility, and the nature of the work conducted. In addition, the origin of the microorganism or agent in question, and the route of exposure is important.

Biosafety Level 1(BSL 1) is the least hazardous level. The risk of disease in healthy adults presents minimal potential hazard to staff and the environment. An example of a microorganism that is typically studied in a BSL-1 laboratory is a nonpathogenic strain of *E. coli*.

Biosafety Level 2 (BSL-2) builds upon BSL-1 requirements. A BSL-2 laboratory poses moderate hazards to laboratory staff and the environment. Encountered microorganism are typically indigenous and associated with diseases of varying severity. An example of a microorganism is typically worked with at a BSL-2 laboratory is *Staphylococcus aureus*.

When working with Zika virus in the laboratory, Zika virus preparations may be handled under BSL-2 precautions. Laboratories should perform a risk assessment to determine if there are certain procedures or specimens that may require higher levels of biocontainment, e.g., use of a biosafety cabinet for potential aerosol generating activities or suspicion that the specimen may contain a pathogen that requires BSL-3 precautions.

Biosafety Level 3 (BSL-3) builds upon the requirements of BSL-2. Microorganisms that can be encountered in a designated BSL-3 laboratory can be either indigenous or exotic. They can cause serious or potentially lethal disease through respiratory transmission. One example of a microbe that is typically worked with in a BSL-3 laboratory is *Mycobacterium tuberculosis.*

Biosafety Level 4 (BSL-4) builds upon the containment requirements of BSL-3 and is the highest level of biological safety. There are only a small number of BSL-4 labs in the United States and globally. Microrganisms encountered in a BSL-4 lab are dangerous and exotic, posing a high risk of aerosol-transmitted infections. Infections caused by these microbes are frequently fatal and are without treatment or vaccines. Two examples of microbes encountered in a BSL-4 laboratory include Ebola and Marburg viruses.

BOX 2.3 Biosafety Levels

Biosafety Level 1 (BSL-1)

Laboratory Practices

- Standard microbiological practices are followed.
- Work can be performed on an open lab bench or table.

Safety Equipment

- Personal protective equipment (PPE), (lab coats, gloves, eye protection) are worn as needed.

Laboratory Construction

- A sink must be available for hand washing.
- The laboratory should have doors to separate the working space with the rest of the facility.

Biosafety Level 2 (BSL-2)

In addition to BSL-1 considerations, BSL-2 laboratories have the following requirements:

Laboratory Practices

- Access to the laboratory is restricted when work is being conducted.

Safety Equipment

- Appropriate personal protective equipment (PPE) is worn, including lab coats and gloves. Eye protection and face shields can also be worn, as needed.
- All procedures that can cause infection from aerosols or splashes are performed within a biological safety cabinet (BSC).
- An autoclave or an alternative method of decontamination is available for proper disposals.

Facility Construction

- The laboratory has self-closing doors.
- A sink and eyewash are readily available.

Biosafety Level 3 (BSL-3)

In addition to BSL-2 considerations, BSL-3 laboratories have the following containment requirements:

Laboratory Practices

- Laboratorians are under medical surveillance and might receive immunizations for microbes they work with.
- Access to the laboratory is restricted and controlled at all times.

Safety Equipment

- Appropriate PPE must be worn, and respirators might be required.
- All work with microbes must be performed within an appropriate BSC.

Facility Construction

- A hands-free sink and eyewash are available near the exit.
- Exhaust air cannot be recirculated, and the laboratory must have sustained directional airflow by drawing air into the laboratory from clean areas towards potentially contaminated areas.
- Entrance to the laboratory is through two sets of self-closing and locking doors.

Biosafety Level 4 (BSL-4)

In addition to BSL-3 considerations, BSL-4 laboratories have the following containment requirements:

Laboratory Practices

- Change clothing before entering.
- Shower upon exiting.
- Decontaminate all materials before exiting.

Safety Equipment

- All work with the microbe must be performed within an appropriate Class III Biological Safety Cabinet or by wearing a full body, air-supplied, positive pressure suit.

Facility Construction

- The laboratory is in a separate building or in an isolated and restricted zone of the building.
- The laboratory has dedicated supply and exhaust air, as well as vacuum lines and decontamination systems.

Reference: https://www.cdc.gov/training/quicklearns/biosafety/ retrieved August 14, 2017.

Risk assessment is an important part of biosafety. Laboratories should perform a risk assessment to determine if there are certain procedures or specimens that may require higher levels of biocontainment. Risk is defined as the probability that a health effect will occur after an individual has been exposed to a specified amount of a hazard. Risk assessment is a process of gathering all available information on a hazardous substance and evaluating it to determine the possible risks associated with exposure. This is followed by determining the strategies necessary to provide protection.

Laboratory-Acquired Infections

Before 2014, laboratories never had a patients in the United States with Ebola virus. Fear of infection from Ebola resulted in some laboratories refusing to test any samples from suspected Ebola patients and some instrument manufacturers refusing to service instrument used to test patients suspected of having Ebola. This occurrence renewed the focus on laboratory-acquired infections (LAIs).

A laboratory-acquired infection (LAI) is defined as an infection acquired through laboratory or laboratory-related activities regardless of whether they are symptomatic or asymptomatic in nature. Common LAIs encountered in the laboratory are presented in Box 2.4. The most frequent routes of exposure and accidental inoculation are as follows:

- Inhalation (accidental aspiration of infectious material such as aerosols sprays from syringes, aerosols from the uncapping of specimen tubes, and centrifuge accidents)
- Percutaneous inoculation (such as needle and syringe, cuts or abrasions from contaminated items, and animal bites, accidental inoculation with contaminated needles or syringes)
- Contact between mucous membranes and contaminated material (such as hands and surfaces)
- Ingestion (such as aspiration through a pipette, smoking, and eating)

The majority of reported LAIs are caused by disregarding biosafety practices, followed by bio-incidents caused by human errors (such as spills and needlesticks).

Although the data is not very good, the incidence of LAI ranges from 1.4-3.5 infections per 1,000 employees. The most commonly implicated bacteria causing LAI include *Brucella* spp., *Coxiella burnetii*, *Salmonella typhi*, *Francisella tularensis,*

BOX 2.4 Risk Groups for Infectious Diseases

Risk Group 1 (no or low individual and community risk). A microorganism that is unlikely to cause human beings disease or animal disease.

Risk Group 2 (moderate individual risk, low community risk). A pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock, or the environment. Laboratory exposures may cause serious infection, but effective treatment and preventive measures are available and the risk of spread of infection is limited.

Risk Group 3 (high individual risk, low community risk). A pathogen that usually causes serious human or animal disease and may present a serious hazard to laboratory personnel. Could present a risk if spread in the community or the environment. Effective treatment and preventive measures are usually available.

Risk Group 4 (high individual and community risk). A pathogen that usually causes serious human or animal disease and present a serious hazard to laboratory personnel. Can be readily transmitted from an one animal or to another human being, directly or indirectly. Effective treatment and preventive measures are not usually available.

Source: Centers for Disease Control and Prevention/National Institute of Health *Biosafety in Microbiological and Biomedical Laboratories Manual*, 5th edition, 2009.

and Mycobacterium tuberculosis complex. Bloodborne pathogens hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) account for the majority of the reported viral infections.

BLOODBORNE PATHOGENS

Transmission of various bloodborne pathogens has always been a concern for laboratory staff, but with the identification of HIV, a new awareness was created. Specific regulations in regard to the handling of blood and body fluids from patients suspected or known to be infected with a bloodborne pathogen were originally issued in 1983.

Current safety guidelines for the control of infectious disease are based on the original CDC 1987 recommendations and 1988 clarifications. Safety practices were further clarified by OSHA in 1991. The purpose of the standards for bloodborne pathogens and occupational exposure is to provide a safe work environment. OSHA mandates that an employer do the following:

1. Educate and train all health care workers in Standard Precautions and preventing bloodborne infections.
2. Provide proper equipment and supplies, such as gloves.
3. Monitor compliance with the protective biosafety policies.

HIV has been isolated from blood, semen, vaginal secretions, saliva, tears, breast milk, cerebrospinal fluid, amniotic fluid, and urine, but only blood, semen, vaginal secretions, and breast milk have been implicated in transmission of HIV to date. Evidence for the role of saliva in transmission of the virus is unclear; however, Standard Precautions do not apply to saliva uncontaminated with blood.

The latest statistics on acquired immunodeficiency syndrome (AIDS) and HIV in the United States were published for 2016 by the CDC.[12] Since the beginning of the HIV/AIDS epidemic, health care workers across the world have become infected with HIV. The main cause of infection in occupational settings is exposure to HIV-infected blood via a percutaneous injury. Such exposures may come from needles, instruments, or bites that break the skin. Occupational transmission of HIV to health care workers is extremely rare. The average risk for HIV transmission after such exposure to infected blood is low, about 3 per 1000 injuries, but it remains an area of considerable concern for many health care workers.

Specific factors may mean a percutaneous injury carries a higher risk of HIV transmission and include the following:

- A deep injury
- Late-stage HIV disease in the source patient
- Visible blood on the device that caused the injury
- Injury with a needle that had been placed in a source patient's artery or vein

In a small number of cases, HIV has been acquired through contact with nonintact skin or mucous membranes (such as splashes of infected blood in the eye). Research suggests that the risk of HIV infection after mucous membrane exposure is less than 1 in 1000 infections. Scientists estimate that the risk of infection from a needlestick is less than 1%, based on the findings of several studies of health care workers who received punctures from HIV-contaminated needles or were otherwise exposed to HIV-contaminated blood.

Blood is the single most important source of HIV, HBV, and other bloodborne pathogens in the occupational setting. HBV may be stable in dried blood and blood products at 25° C for up to 7 days. HIV retains infectivity for more than 3 days in dried specimens at room temperature and for more than 1 week in an aqueous environment at room temperature.

Both HBV and HIV may be indirectly transmitted. Viral transmission can result from contact with inanimate objects such as work surfaces or equipment contaminated with infected blood or certain body fluids. If the virus is transferred to the skin or mucous membranes by hand contact between a contaminated surface and nonintact skin or mucous membranes, it can produce viral exposure.

Medical personnel should be aware that HBV and HIV are totally different diseases caused by completely unrelated viruses. The most feared hazard of all, the transmission of HIV through occupational exposure, is among the least likely to occur. The modes of transmission for HBV and HIV are similar, but the potential for transmission in the occupational setting is greater for HBV than HIV.

The risk of transmission of HBV and **HCV** from an occupational exposure is significantly greater than the risk of HIV transmission. The average risk of HBV infection ranges from 1% to 30% depending on the presence of hepatitis e antigen (HBe antigen + average risk is 22.0%-30%; HBe antigen − average risk is 1.0%-6%). The risk of HCV infection following a needlestick is 1.8%.[13]

Since the late 1980s, the incidence of acute hepatitis B has declined steadily. During 1990 to 2002, the incidence of acute hepatitis B declined 67%. Although the number of cases has sharply declined since hepatitis B vaccine became available, unvaccinated health care workers can become infected with HBV following occupational exposure.

The likelihood of infection after exposure to blood infected with HBV or HIV depends on a variety of factors, including:

- The concentration of HBV or HIV virus; viral concentration is higher for HBV than for HIV.
- The duration of the contact.
- The presence of skin lesions or abrasions on the hands or exposed skin of the health care worker.
- The immune status of the health care worker for HBV.

Both HBV and HIV may be directly transmitted by various portals of entry. In the occupational setting, however, the following situations may lead to infection:

1. Percutaneous (parenteral) inoculation of blood, plasma, serum, or certain other body fluids from accidental needlesticks.
2. Contamination of the skin with blood or certain body fluids without overt puncture, caused by scratches, abrasions, burns, weeping, or exudative skin lesions.
3. Exposure of mucous membranes (oral, nasal, conjunctival) to blood or certain body fluids as the direct result of pipetting by mouth, splashes, or spattering.
4. Centrifuge accidents or improper removal of rubber stoppers from test tubes, producing droplets. If these aerosol products are infectious and come in direct contact with mucous membranes or nonintact skin, direct transmission of virus can result.

OSHA estimates that 5.6 million workers in the health care industry and related occupations are at risk of occupational exposure to bloodborne **pathogens.** An *occupational exposure* is defined as a percutaneous injury (such as needlestick or cut with a sharp object) or contact by mucous membranes or nonintact skin (especially when the skin is chapped, abraded, or affected with dermatitis or the contact is prolonged or involves an extensive area) with blood, tissues, blood-stained body fluids, body fluids to which Standard Precautions apply, or concentrated virus. Blood is the most frequently implicated infected body fluid in HIV and HBV exposure in the workplace.

Most exposures do not result in infection. The risk not only varies with the type of exposure, but also may be influenced by other factors, such as the amount of infected blood in the exposure, the length of contact with infectious material, and the amount of virus in the patient's blood, body fluid, or tissue at the time of exposure.

SAFE WORK PRACTICES FOR INFECTION CONTROL

Standard Precautions represent an approach to infection control used to prevent occupational exposures to bloodborne pathogens. This approach eliminates the need for separate isolation procedures for patients known or suspected to be infectious. The application of Standard Precautions also eliminates the need for warning labels on specimens. According to the CDC concept of Standard Precautions, all human blood and other body fluids are treated as potentially infectious for HIV, HBV, and other bloodborne microorganisms that can cause disease in human beings. The risk of nosocomial transmission of HBV, HIV, and other bloodborne pathogens can be minimized if laboratory personnel are aware of and adhere to essential safety guidelines.

Personal Protective Equipment

OSHA requires laboratories to have a **personal protective equipment (PPE)** program and defines PPE as specialized clothing or equipment worn by an employee for protection against a hazard. Putting on and taking off PPE properly (Figs. 2.4, 2.5 and 2.6) is essential to the control of infections.

Implementing appropriate safety measures and adhering to a well-structured personal protective equipment program can reduce exposures to infectious material and improve overall safety condition in clinical laboratories. In clinical laboratories, laboratory-acquired infections are a particularly significant concern.

General work clothes (such as uniforms, pants, shirts, or blouses) not intended to function as protection against a hazard are not considered PPE. The components of this regulation include the following:

- A workplace hazard assessment with a written hazard certification
- Proper equipment selection
- Employee information and training, with written competency certification
- Regular reassessment of work hazards

Laboratory personnel should not rely solely on devices for PPE to protect themselves against hazards. They also should apply PPE standards when using various forms of safety protection. A clear policy on institutionally required Standard Precautions is needed. For usual laboratory activities, PPE consists of gloves and a laboratory coat or gown. Other equipment, such as masks, would normally not be needed.

Standard Precautions are intended to supplement rather than replace handwashing recommendations for routine infection control. The risk of nosocomial transmission of HBV, HIV, and other bloodborne pathogens can be minimized if laboratory personnel are aware of and adhere to essential safety guidelines.

Selection and Use of Gloves

Gloves for phlebotomy and laboratory work are made of vinyl or latex. There are no reported differences in barrier effectiveness between intact latex and intact vinyl gloves. Either type is usually satisfactory for phlebotomy and as a protective barrier when performing technical procedures. Latex-free gloves should be available for personnel with sensitivity to the typical glove material.

Care must be taken to avoid indirect contamination of work surfaces or objects in the work area. Gloves should be properly donned and removed (Fig. 2.7) or covered with an uncontaminated glove or paper towel before answering the telephone, handling laboratory equipment, or touching doorknobs. Guidelines for the use of gloves during phlebotomy procedures are as follows:

1. Gloves must be worn when performing fingersticks or heelsticks on infants and children.
2. Gloves must be worn when receiving phlebotomy training.
3. Gloves should be changed between each patient contact.

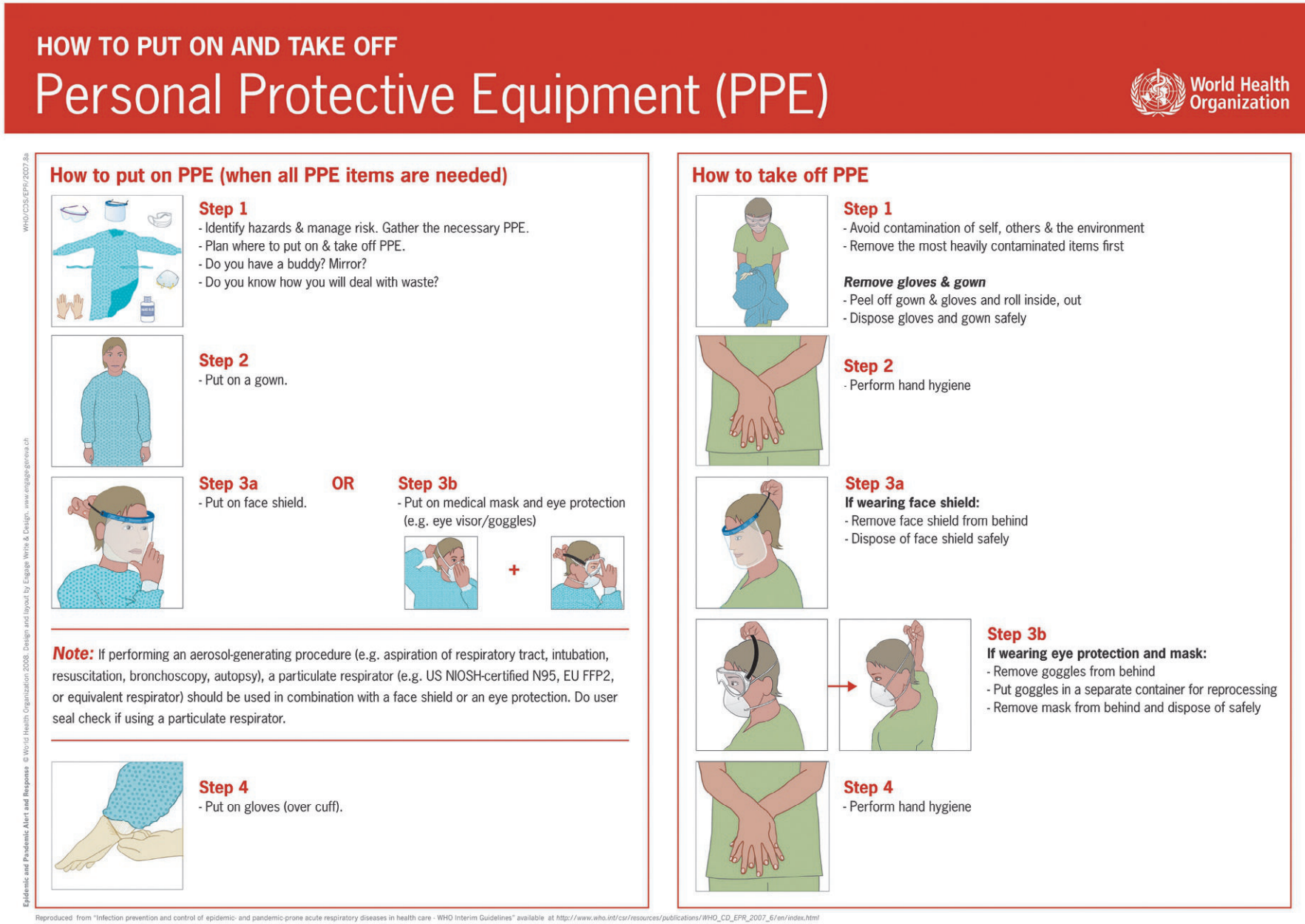


Fig. 2.4 How To Put On and Take Off Personal Protective Equipment (PPE) (From World Health Organization, Geneva, August 2017.)

Steps to put on personal protective equipment (PPE)

1 Always put on essential required PPE when handling either a suspected, probable or confirmed case of viral haemorragic fever.

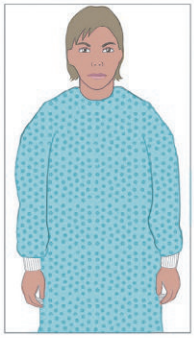
2 The dressing and undressing of PPE should be supervised by another trained member of the team.

3 Gather all the necessary items of PPE beforehand. Put on the scrub suit in the changing room.

4 Put on rubber boots. If not available, make sure you have closed, puncture and fluid resistant shoes and put on overshoes.

OR, IF BOOTS UNAVAILABLE

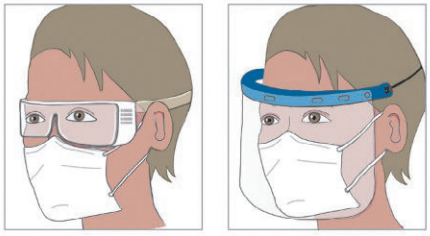
5 Place the impermeable gown over the scrubs.



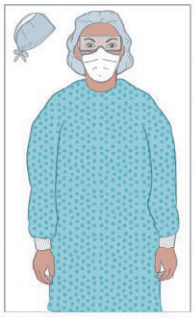
6 Put on face protection:

6a Put on a medical mask.

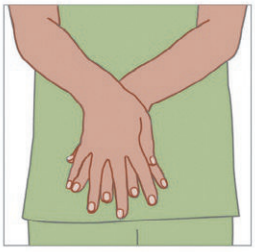
6b Put on goggles or a face shield.



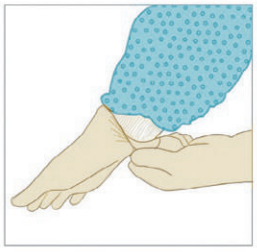
7 If available, put a head cover on at this time.



8 Perform hand hygiene.



9 Put on gloves* (over cuff).



10 If an impermeable gown is not available, place waterproof apron over gown.

While wearing PPE:

- Avoid touching or adjusting PPE
- Change gloves between patients
- Remove gloves if they become torn or damaged
- Perform hand hygiene before putting on new gloves

* Use ***double gloves*** if any strenuous activity (e.g. carrying a patient or handling a dead body) or tasks in which contact with blood and body fluids are anticipated. Use ***heavy duty/rubber gloves*** for environmental cleaning and waste management.

World Health Organization

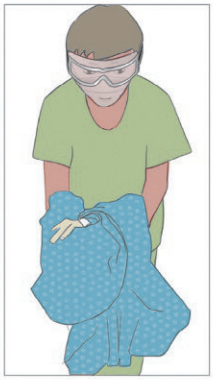
Fig. 2.5 How To Put On Personal Protective Equipment (PPE) (From World Health Organization, Geneva, August 2017.)

Steps to remove personal protective equipment (PPE)

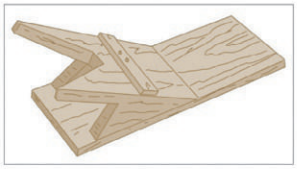
1 Remove waterproof apron and dispose of safely. If the apron is to be reused, place it in a container with disinfectant.

2 If wearing overshoes, remove them with your gloves still on (If wearing rubber boots, see step 4).

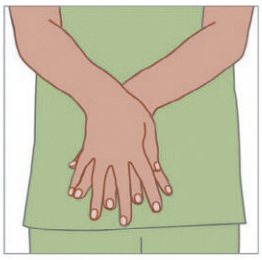
3 Remove gown and gloves and roll inside-out and dispose of safely.



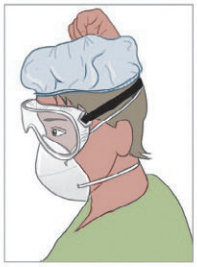
4 If wearing rubber boots, remove them (ideally using the boot remover) without touching them with your hands. Place them in a container with disinfectant.



5 Perform hand hygiene.

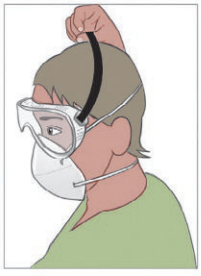


6 If wearing a head cover, remove it now (from behind the head).

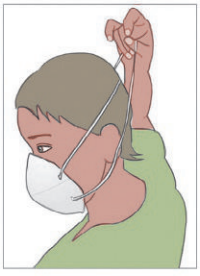


7 Remove face protection:

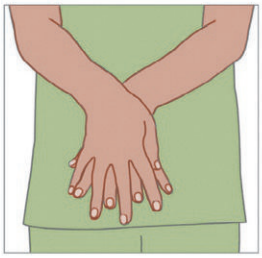
7a Remove face shield or goggles (from behind the head). Place eye protection in a separate container for reprocessing.



7b Remove mask from behind the head. When removing mask, untie the bottom string first and the top string next.



8 Perform hand hygiene.



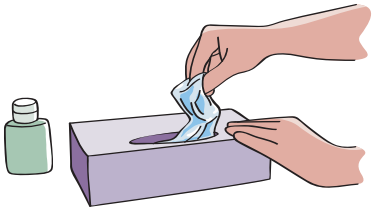
Source: Modified from Clinical Management of Patients with Viral Haemorrhagic Fever: A pocket Guide for the Front-line Health Worker. World Health Organization, 2014

World Health Organization

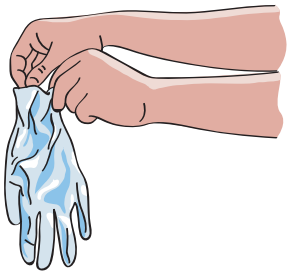
Fig. 2.6 How To Take Off Personal Protective Equipment (PPE) (From World Health Organization, Geneva, August 2017.)

When the hand hygiene indication occurs before a contact requiring glove use, perform hand hygiene by rubbing with an alcohol-based handrub or by washing with soap and water.

I. How to don gloves:



1. Take out a glove from its original box

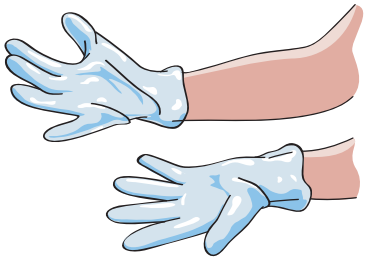


2. Touch only a restricted surface of the glove corresponding to the wrist (at the top edge of the cuff)

3. Don the first glove

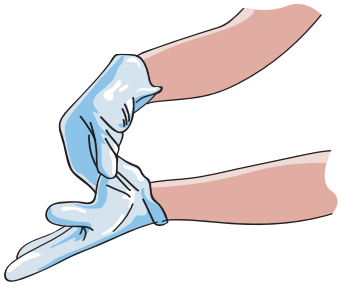
4. Take the second glove with the bare hand and touch only a restricted surface of glove corresponding to the wrist

5. To avoid touching the skin of the forearm with the gloved hand, turn the external surface of the glove to be donned on the folded fingers of the gloved hand, thus permitting to glove the second hand

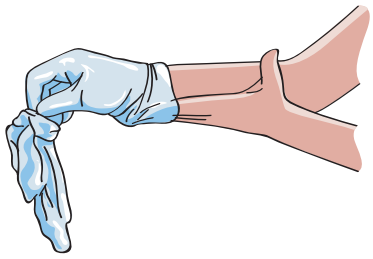


6. Once gloved, hands should not touch anything else that is not defined by indications and conditions for glove use

II. How to remove gloves:



1. Pinch one glove at the wrist level to remove it, without touching the skin of the forearm, and peel away from the hand, thus allowing the glove to turn inside out



2. Hold the removed glove in the gloved hand and slide the fingers of the ungloved hand inside between the glove and the wrist. Remove the second glove by rolling it down the hand and fold into the first glove

3. Discard the removed gloves

4. Then, perform hand hygiene by rubbing with an alcohol-based handrub or by washing with soap and water.

Fig. 2.7 Technique for donning and removing nonsterile examination gloves. (From World Health Organization: Glove use information leaflet, Geneva, August 2009, WHO.)

Facial Barrier Protection and Occlusive Bandages

Facial barrier protection should be used if there is a potential for splashing or spraying of blood or certain body fluids. Masks and facial protection should be worn if mucous membrane contact with blood or certain body fluid is anticipated. All disruptions of exposed skin should be covered with a water-impermeable occlusive bandage. This includes defects on the arms, face, and neck.

Laboratory Coats or Gowns as Barrier Protection

A color-coded, two–laboratory coat or equivalent system should be used whenever laboratory personnel are working with potentially infectious specimens. The coat worn in the laboratory must be changed or covered with an uncontaminated coat when leaving the immediate work area. If a lab coat becomes grossly contaminated with blood or body fluids, it should be changed immediately to prevent seepage through street clothes to the skin. Contaminated coats or gowns should be placed in an appropriately designated biohazard bag for laundering.

Disposable laboratory coats are available. A problem with coats during dry weather is the buildup of static electricity. Static electricity can create problems with laboratory equipment and computers. Coats constructed of antistatic material are preferable. A new type of lab coat overcomes the problem of being hot (DenLine Uniforms, Quincy, Illinois). These coats have a lightweight back with air permeability.

Disposable plastic aprons are recommended if blood or certain body fluids might be splashed. Aprons should be discarded into a biohazard container.

Nail Care

According to the CDC, to promote infection control, nails should be no longer than ¼ inch beyond the tip of the finger. Longer nails do not fit into gloves properly and can cause problems with blood collection and analysis.

Shoes

According to CLSI document GP17-A2, shoes worn in the clinical laboratory and phlebotomy services should be rubber-soled and cover the entire foot. Unless covered with shoe covers, canvas shoes are not recommended. Fluid-impermeable material (such as leather or synthetic) is recommended.

Electronic Devices

Electronic devices (such as smart phones and tablet computers) should not be exposed to potential sources of infectious contamination.

Handwashing

Frequent handwashing is an important safety precaution.[14] It should be performed after contact with patients and laboratory specimens. Gloves should be used as an adjunct to, not a substitute for, handwashing. The Association for Professionals in Infection Control and Epidemiology reports extreme variability in the quality of gloves, with leakage in 4% to 63% of vinyl gloves and 3% to 52% of latex gloves.

BOX 2.5 Guidelines for Handwashing and Hand Antisepsis in Health Care Settings

Use an alcohol-based waterless antiseptic agent for routine decontamination of hands, if not visibly soiled. Waterless antiseptic agents are highly preferable, but hand antisepsis using antimicrobial soap may be considered in certain circumstances. Wash hands with a nonantimicrobial soap and water or an antimicrobial soap and water when hands are visibly dirty or contaminated with proteinaceous material.

Decontaminate hands:

1. After removing gloves.
2. After completing laboratory work and before leaving the laboratory.
3. After accidental skin contact with blood, body fluids, or tissues.
4. After contact with patient's skin.
5. After contact with inanimate objects in the immediate vicinity of a patient.
6. If moving from a contaminated area to clean body site during patient care.
7. Before eating, drinking, applying makeup, and changing contact lenses, and before and after using the bathroom.
8. Before all activities that involve hand contact with mucous membranes or breaks in the skin.

Modified from Centers for Disease Control and Prevention: Guideline for hand hygiene in health care settings, *MMWR* 51(RR-16):1, 2002.

The efficacy of handwashing in reducing transmission of microorganisms has been demonstrated (see Student Procedure Worksheet 2.1). At the very minimum, hands should be washed with soap and water or by hand antisepsis with an alcohol-based handrub even if hands are not visibly soiled. Handwashing in other situations is described in Box 2.5. An important point when decontaminating hands with a waterless antiseptic agent (such as alcohol-based foam) is to apply 1.5 to 3 mL (or manufacturer's recommended amount) of the alcohol gel or foam to the palm of one hand and then rub hands together, covering all surfaces of hands and fingers, including fingernails. Rubbing should continue until the alcohol dries, about 15 to 25 seconds, until hands are dry.

Decontamination of Work Surfaces, Equipment, and Spills

Disinfection[15] describes a process that eliminates many or all pathogenic microorganisms, except bacterial spores, on inanimate objects. In health care settings, objects usually are disinfected by liquid chemicals or wet pasteurization. Factors that affect the efficacy of both disinfection and sterilization include the following:

- Prior cleaning of the object
- Organic and inorganic load present
- Type and level of microbial contamination
- Concentration of and exposure time to the germicide
- Physical nature of the object (such as crevices, hinges, and lumens)
- Presence of biofilms
- Temperature and pH of the disinfection process
- In some cases, relative humidity of the sterilization process (such as ethylene oxide)

The effective use of disinfectants is part of a multibarrier strategy to prevent health care–associated infections. Surfaces are considered noncritical items because they contact intact skin. Use of noncritical items or contact with noncritical