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Acknowledgment of Previous Contributors

The *Manual of Clinical Microbiology* is by its nature a continuously revised work which refines and extends the contributions of previous editions. Since its first edition in 1970, many eminent scientists have contributed to this important reference work. The American Society for Microbiology and its Publications Board gratefully acknowledge the contributions of all of these generous authors over the life of this Manual.

Preface

It seems that much of my professional career has revolved around the *Manual of Clinical Microbiology*, first as an author, then as a section editor, and finally for the last four editions as the editor in chief. I have learned a great deal from this experience, although I must confess that I have forgotten far more science than I have retained. My most valuable lesson has been to rely on my fellow editors. I have been privileged to have worked on all four editions with Ellen Jo Baron and Mike Pfaller, with Jim Jorgensen for the last two editions, and with Marie Landry, who ably filled Bob Yolken's shoes, for this edition. I have also relied on the help of 29 section editors, including 7 new editors for this edition, and hundreds of authors. Almost 40% of the authors of the ninth edition of the *Manual of Clinical Microbiology* (MCM9) are new. For each edition I have purposely selected new editors and authors with the conviction that they will bring a new perspective to their assignment. I have systematically added non-U.S. authors, representing almost 30% of the authors of this edition, so that this Manual will be truly international in scope. These changes have not come without difficulties. My fellow editors and I have frequently had to curtail our authors' "creativity" for the sake of consistency, taught them that eloquence can equate to brevity, and reminded them that deadlines are not the fantasies of publishers. Many unpopular decisions are made in the creation of any work as comprehensive as MCM9, so I must thank the editors and authors for their understanding. If I have offended anyone in the process, it was unintentional.

I am very proud of what we have accomplished with MCM9, and I hope that this feeling is shared by the entire editorial board and all the authors. Although the field of clinical microbiology is undergoing dramatic changes with the confluence of traditional techniques and exciting advances in genomics and proteomics, I believe that the *Manual of Clinical Microbiology* should form the road map for our understanding of this evolving scientific discipline. I hope that the readers share the opinion of the authors and editors that MCM9 successfully meets this goal. An additional feature for the ninth edition is a CD-ROM with close to 500 illustrations from the book. It is available for purchase through ASM Press.

I would be remiss if I did not acknowledge the wisdom and guidance provided by Susan Birch, the ASM Press Production Manager whose name should more appropriately be listed on the cover of MCM9, and Jeff Holtmeier, the director of ASM Press who makes everyone's job a little easier and more pleasant. The entire staff at ASM Press was very supportive and helpful during the process of preparing this edition of the Manual.

PATRICK R. MURRAY

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GENERAL ISSUES IN CLINICAL MICROBIOLOGY

I

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JAMES H. JORGENSEN

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Microscope used during medical school by Joseph W. Mountin, founder of the Communicable Disease Center (from CDC image library).

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Introduction to the Ninth Edition of the *Manual of Clinical Microbiology*

PATRICK R. MURRAY

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The eighth edition of the *Manual of Clinical Microbiology* (MCM8) was a dramatic change from previous editions, growing from one to two volumes and increasing in length by more than 20%. Even though the changes in the ninth edition of the *Manual of Clinical Microbiology* (MCM9) are not as obvious, they are no less substantial. One new volume editor, Marie Louise Landry, and seven new section editors joined the editorial board. Of the 269 authors, almost 40% are new and 28% represent 22 non-U.S. countries. Although we retained the same 11 sections that were introduced in MCM8 and the algorithm chapters that have proved to be practical identification tools, we have expanded the chapters from 141 to 152. The MCM8 chapter "Pathogenic and Indigenous Microorganisms of Humans" was removed in MCM9 because we believed that this topic could not be satisfactorily covered in a limited chapter. To compensate for this deletion, the discussion of the topic was expanded in the individual organism chapters. A new chapter, "Microscopy," was added to section III, Diagnostic Technologies in Clinical Microbiology. This topic was covered in the sixth edition of the Manual but not in subsequent editions, a decision that the editorial board felt should be rectified. Section IV, Bacteriology, was increased by three chapters—coverage of mycobacteria was expanded from two chapters to three; coverage of anaerobes was expanded from three chapters to four; and *Tropheryma* was assigned to a new chapter, chapter 69. The most significant changes in MCM9 occurred in section VI, Virology, reflecting the influence of a new volume editor and three new section editors. The discussion of hepatitis A and hepatitis E viruses was consolidated into one chapter, and three new chapters were added—chapter 91, "Coronaviruses"; chapter 96, "Hendra and Nipah Viruses"; and chapter 98, "Hantaviruses." Coverage in other chapters was expanded to include metapneumoviruses and parechoviruses. Two new chapters were added to section VIII, Mycology—chapter 127, "Mycotoxins"; and chapter 128, "*Lacazia, Pythium*, and *Rhinosporidium*." Finally, section X, Parasitology, was reorganized with the addition of four new chapters. *Cryptosporidium* was transferred to a new chapter, chapter 142, and the coverage of helminths was expanded from two to five chapters.

All chapters in MCM9 were updated with the most current taxonomic and diagnostic information, which is not an insignificant feat in this era of molecular classification and diagnostic tools. Nearly 4,000 of the literature citations in MCM9 were published after the last edition went to press. Despite these efforts, we recognize that by the time that MCM9 will be published, some data will be dated and some statements will be inaccurate. This occurs despite the best efforts of the authors, editors, and ASM staff and is the unfortunate reality of publishing a major reference text. We ask for your understanding, as well as for your help in remedying the inaccuracies. If you discover an error, please contact ASM Press. A system will be established to post both the error and the corrections for the readership. The editorial board hopes that through the efforts of our authors and your careful review of the text, MCM9 will be an accurate, valuable reference source.

Laboratory Management*

W. MICHAEL DUNNE, JR., AND MARK T. LAROCCO

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The diagnostic microbiology laboratory, regardless of demographics, is a business and needs to be managed with the same basic principles and tenets used by businesses. True, the products provided by microbiology laboratories belong to the service industry, but the day-to-day management of resources, productivity, finances, quality, and clients is no different. Whether the laboratory is for profit, not for profit, academic, or community based, it needs to follow the same financial rules and standards that businesses do. To develop a primer for medical microbiologists on the basics of business theory, economics, financial accounting, organizational behavior, and marketing, etc., within the confines of this chapter is impractical given the wealth of excellent contemporary reference materials currently available (9, 25, 31). Rather, this chapter will highlight four major management issues: operations, finance, personnel, and regulations.

OPERATIONS

The efficient operation of a clinical microbiology laboratory and effective delivery of diagnostic services to clinicians and their patients are vitally dependent on the management and communication skills of laboratory directors, managers, supervisors, and technologists. Quality laboratory services result directly from the performance of competent laboratory scientists, but the key element lies in the delivery of these services, a highly complex management activity. The clinical microbiology manager's task is to integrate and coordinate laboratory resources so that quality laboratory services can be provided as effectively and efficiently as possible. Laboratory management may be described in terms of four basic functions: planning, organization, direction, and control. In practice, the boundaries between these functions are often obscure because of the interdependence of the functions for effective management.

Strategic Planning

Strategic planning is the process of deciding on objectives for the organization that fulfill its mission, selecting and allocating the resources needed to obtain those objectives, and assigning responsibilities and accountabilities to those involved in the process. The microbiology laboratory will likely be included in the strategic plan of the overall department that in turn embraces the plan of the hospital or other parent organization. Nonetheless, the microbiology director or manager should have an appreciation of key features of the hospital's strategic plan.

A mission statement is a concise description of the overall goals and values of the organization. A mission statement may be thought of as the hospital's credo on which all of its actions are based. In a sense, the mission statement serves as the cornerstone of the organization's strategic plan as it represents the highest level of success that the organization hopes to achieve.

Planning at the department level is an essential requirement of laboratory management. Each section of the laboratory should establish a set of goals and objectives, formulate policies to carry out those objectives, develop intermediate and short-range plans to implement policies, and develop detailed procedures for implementing each plan. During the planning process, managers must be aware of any changes that occur in the operational environment because such awareness keeps decisions realistic and expectations achievable (37). An analysis of the operational environment can be accomplished by conducting an objective assessment of the laboratory's strengths, weaknesses, opportunities, and threats (SWOT analysis). Let's say, for example, that the microbiology laboratory is asked to develop a strategic plan to incorporate molecular diagnostic testing into its service offerings. A preliminary SWOT analysis may reveal the following.

Strengths

1. Strong technical leadership in the laboratory facilitates the implementation of new technologies.
2. The hospital supports a solid-organ and stem cell transplant program with patients that will likely produce a high demand for the service.
3. A teaching affiliation with a regional school of medical technology provides recruitment opportunities for trained technologists.

Weaknesses

1. The skill sets of most of the current staff do not include molecular diagnostics.

* This chapter contains information presented in chapter 2 by David L. Sewell and James D. MacLowry in the eighth edition of this Manual.

2. Having no record of performance in molecular diagnostics may place the laboratory at a marketing disadvantage.
3. The lack of experience with managing a molecular diagnostic service in the context of the overall laboratory budget.

Opportunities

1. A new academic affiliation will immediately provide resources (space, personnel, and equipment) for supporting a molecular diagnostic service.
2. There is a paucity of facilities in your geographic area that offer molecular diagnostic testing, and physicians are not happy with the service provided by a regional commercial laboratory. The potential for developing outreach volume is high.

Threats

1. Inappropriate utilization of the technology may create a financial hardship for the laboratory.
2. Competition from other commercial laboratories that call on physicians' offices directly.

Specific goals and objectives provide laboratory management with a clear direction before the planning process begins. When policies are set with these goals and objectives in mind, constraints are in place to guide the planning strategies prior to the major plan development stage. A few examples of goals and objectives for the clinical microbiology laboratory may be as follows.

1. Ensure the quality of diagnostic microbiology services by monitoring key functions and processes to determine improvements for quality and cost.
2. Support research and development by reviewing and testing new methods and equipment.
3. Expand volume by researching new markets for outpatient business.
4. Act as consultants to medical staff and outcomes managers to ensure that the most appropriate diagnostic tests are ordered.
5. Communicate, through results, a philosophy of customer service to patients, physicians, family members, and coworkers.
6. Support the strategic plans of the hospital through the laboratory services provided.
7. Employ personnel who are responsive to the needs of patients, physicians, clients, guests, and coworkers.
8. Provide for the future of laboratory service by participating in educational and training programs for medical technology.

Once a goal is identified, a plan for completion of the project and short-term interim plans are needed. Finally, the details necessary for implementation and the expectations of performance are defined. High performance cannot be achieved, however, without accountability. When there is a lack of accountability, needed information may be missed, decisions are not made when action is required, and people do not receive guidance or support when faced with new challenges. Accountability means that people can count on one another to keep performance commitments and communication agreements. It is the basis for an environment of trust, support, and dedication to excellence (27).

During implementation of any department plan, it is important to periodically measure success. Such an exercise affords management the opportunity to step back and revisit elements of the planning strategy while at the same time providing staff with appropriate feedback and motivation to see a difficult project through to its conclusion.

Organization

Organization in the clinical laboratory refers to both structure and process. Structure exemplifies stated relationships or framework, and process deals with interaction. There are three key elements of organization: the tasks to be performed, the individuals who are to perform the tasks, and the clinical laboratory as a workplace.

A scope of services document provides a detailed list of services provided by the microbiology laboratory. The document should contain general information on the hours of laboratory operation and on staffing. It may also include test-specific information such as specimen collection and transport requirements, reference ranges, locations of testing, (in-house versus reference laboratories), and cutoff times for receipt of specimens. The scope of services provided by the laboratory is often a reflection of the type of hospital or facility it serves.

Organizational charts are common to most business structures as they provide a visualization of who is doing what and the chain of command. Although nobody likes to think of oneself as being below other people, these charts can serve a useful purpose in the clinical laboratory by defining the relationships among tasks, individuals, and the workplace. The organizational chart attempts to show relationships between line and staff. A line position is one in which a superior exercises direct supervision over a subordinate. A staff position is advisory, supportive, or auxiliary. These terms were defined in industry, and health care institutions seldom use the same connotation. When laboratory managers speak of staff, they are usually referring to technologists who are, in fact, serving in line positions.

Written policies and procedures, displayed in printed manuals or made available electronically, are an essential component of the clinical microbiology laboratory. Every procedure should be clear, easy to follow, and consistent in its content and organization. These documents provide direction for the many day-to-day tasks performed by the staff, serve as a teaching tool for students and new employees, and provide information to inspectors from accrediting agencies. The Clinical and Laboratory Standards Institute (formerly NCCLS) has a published guideline, GP2-A4, for writing laboratory procedures (23). The guideline provides instructions and recommendations for writing procedures for the full scope of the laboratory's workflow. The document also contains information about organizing procedure manuals, archiving and managing documents, and using manufacturers' procedures for automated purposes. As a testament to the document's universal acceptance, the College of American Pathologists requires that all written laboratory procedures closely follow the GP2-A4 format.

As defined by Brown (4), process design is a broad plan that is developed to provide a blueprint for completing work or a task at hand. Process design in the clinical microbiology laboratory involves an analysis of size and setting, laboratory design, equipment, test methodology, regulations, and staffing. How the work transitions through the laboratory is defined as workflow, and although workflow analysis is part of process design, it is more detailed. Policies and procedures are developed during workflow analysis (4). Workflow can be divided into three phases of the test cycle: preanalytical, analytical, and postanalytical. The preanalytical phase consists of events that occur prior to actual testing, such as selection, collection, transport, and accessioning of specimens. The analytical phase

involves the actual testing. The postanalytical phase consists of events that occur after testing is completed, such as results reporting and interpretation. The preanalytical phase is often the most critical aspect of the test cycle and can be the hardest part of workflow to control.

Strategies to effectively manage and minimize variances associated with the three phases of the test cycle should be included in the clinical laboratory's quality management plan. Quality management is a system for continuously analyzing, improving, and reexamining resources, processes, and services within an organization to produce the best possible outcome (28). Microbiologists have, for many years, concerned themselves with the quality of events that take place within the clinical microbiology laboratory. These events include such things as ensuring the performance of equipment, reagents, stains, and media and monitoring the accuracy of tests performed in the laboratory. These activities fall under the category of quality control (QC). Quality assurance (QA) broadens the scope of traditional QC to encompass processes and events in the preanalytical and postanalytical phases. QA includes such things as determining specimen quality and evaluating the competency and training of personnel. Both QC and QA can be considered aspects of quality management that also includes quality improvement (QI) or quality enhancement. Although applied successfully in industry for many years, QI and quality enhancement are relatively recent concepts in the clinical laboratory setting. Instead of focusing on inspection, identifying poor performance, and taking corrective action, as in traditional QC and QA programs, QI programs emphasize thorough training and prevention and view the system for improvement opportunities rather than the people (8). Continuous QI (CQI), sometimes referred to as total quality management, is an organized, systematic approach to productivity improvement that uses objective methods and a team approach toward improving the quality of all processes, products, and services. The origin of CQI-total quality management is industry based. The approach was promulgated by W. Edwards Deming and grew out of his experience with Japan's industrial reconstruction after World War II. Central to CQI philosophy is the premise that improvement in quality leads to increased productivity, increased customer and employee satisfaction, and decreased cost. The CQI approach is to examine process performance, not people performance, and utilize specific methods of analysis (tools) to better understand and improve those processes. It is a top-down style of QI that requires management commitment and support and involves the participation of all employees. Finally, CQI is viewed as an ongoing initiative.

While these broad definitions may suggest that CQI would be an ideal QI technique for the clinical laboratory, its implementation in clinical laboratories has not been easy. This is due, in part, to the additional time and resource requirements associated with CQI, at least initially, but also relates to an insufficient understanding of how to properly apply CQI to laboratory testing. CQI requires innovative thinking; the traditional internal quality monitors familiar to most laboratories cannot simply be shoehorned into a CQI format. Above all, do not lose sight of the fundamental objective: to improve patient care.

One way for laboratories to avoid this pitfall is to design a CQI program that strives to connect process improvement to clinically relevant patient outcome measures. Outcomes measurement has emerged from the health services research community in response to the changing economic environment in medicine, beginning with the advent of diagnosis-related group (DRG) classifications, and more recently as an important aspect of managed care delivery. Outcomes measurement identifies variations that may adversely affect patient care and can sometimes determine corrective actions for minimizing those variations. Although patient outcomes come in many forms, measurements relevant to laboratory testing generally involve the length of stay, cost, and customer satisfaction, with the customer being both the patient and the physician. Changes in laboratory services and policies that decrease lengths of patient stays, reduce cost, or increase customer satisfaction should be the focus of a laboratory CQI program. Those that have the most impact on outcome measures should be selected for process improvement.

A process is a set of activities that transforms inputs into outputs. Inputs include the needs of patients and physicians, the skill of laboratory personnel, equipment, supplies, and financial resources. Outputs involve laboratory data, diagnoses, and management decisions that are associated with outcomes realized by patients and physicians. Process analysis is often accomplished with techniques such as flowcharting and the use of cause-and-effect diagrams (fishbones), i.e., the tools of CQI, but it is important to remember that the goal of process analysis is to design strategies whereby modifications of the process lead to a measurable improvement in outcome. In clinical microbiology, elements of processes that may be selected for analysis and improvement include specimen rejection criteria, appropriateness of testing, and turnaround times for smear results that acutely affect patient management. Process analysis should include events related to the patient from the time of presentation to the end of an episode of care. For the laboratory, this requires an understanding of how multiple processes related to patient care, including those external to the laboratory, are connected (the output of one process may be the input of another). Failure to understand the interactive dynamic between processes will likely blunt the impact of laboratory improvement initiatives on patient outcomes.

A critical feature of the CQI paradigm is the need to carefully construct and assess any improvement modality before implementing costly changes in policies or procedures on a large scale. Referred to as the Plan-Do-Study-Act cycle for improvement (5, 17), the steps include first stating a specific aim and identifying criteria that will be used to determine if the change represents an improvement. After selection of a change that is practical and most predictive of a positive effect, a plan for evaluating the change in the form of a small pilot study is put forth. The results of the pilot study are assessed for their effect on performance, and then action is taken in the form of process redesign, or if needed, additional pilot studies are conducted. These never-ending cycles of improvement, gradually built into the daily workflow, represent the "meat and potatoes" of a proactive CQI program.

Selection and Implementation of New Equipment and Procedures

As laboratory managers are directly responsible for the quality and productivity of their departments, they must constantly evaluate new technology and equipment for applicability and practicality. Managers must also assess the impact of any new technology on patient care by focusing on attributes such as turnaround time, productivity, and cost. There are several steps involved in this process, including the performance of a needs assessment, research of available technology, and evaluation of performance and cost data gathered before making a decision on implementing a new

procedure or making a new instrument purchase (3). This process is discussed in greater detail elsewhere in the Manual (see chapter 15).

FINANCE

Medicare, Medicaid, prospective payment, DRGs, preferred-provider organizations (PPOs), health care maintenance organizations (HMOs), managed care, fixed versus variable costs, return on investment—the financial side of the health care industry possesses a vocabulary that in many cases is as mind-boggling to the clinical microbiologist as real-time PCR is to the hospital financial officer. In order to be successful, however, clinical microbiology laboratory managers must be able to speak both languages and be as concerned about positive cash flow, cost control, and budget variance as they are about QA and procedural controls.

Laboratory Reimbursement

Medicare Part A provides reimbursement for hospital services related to an inpatient stay. Payment is made based on DRG classifications, a prospective payment system (PPS) of reimbursement. The Centers for Medicare and Medicaid Services (CMS) assign a weight to each DRG based on the severity of the diagnosis, the type of procedure, the number of laboratory and other diagnostic tests, the number and types of drugs prescribed, and the presence of complications or comorbid conditions (6).

Based on this method of payment, hospitals are able to determine how much reimbursement they will receive for Medicare patients and will make a profit if they can manage these patients at a cost below the reimbursed amount. This fixed reimbursement system and incentive to reduce the cost of care has put pressure on hospital support services such as the laboratory to lower expenses.

Medicare Part B covers physician services and outpatient ancillary health care services including clinical laboratory testing. In July 2000, Medicare introduced a new PPS for the outpatient setting and developed ambulatory payment classifications as a basis for reimbursement for outpatient services. The ambulatory payment classification system provides payment predictability and promotes efficiency; however, at this time clinical laboratory tests are excluded from the outpatient PPS. Instead, laboratory tests performed on outpatients are paid for from the Medicare Part B laboratory fee schedule. Fees are assigned based on current procedural terminology (CPT-4) or health care common procedure coding system (HCPCS) codes established for each procedure. The actual Medicare payment is the lowest of either the actual charge, the fee schedule amount set by the contractor, or the national fee cap termed the national limitation amount (la).

Private insurers, also affected by increasing health care costs, have also undergone revision in their reimbursement methodologies. Managed care is defined as a means of providing health care services within a network of service providers (6). Although there are a variety of managed care plans, they usually all require that insured individuals see a physician who is part of the plan or else pay a higher copayment. The most common type of managed care plan is the HMO. Reimbursement under managed care plans can occur in several ways. Capitation, usually applied to physician reimbursement, pays a certain amount per patient per month. Payment can cover the cost of all services related to the member's outpatient care, including any necessary diagnostic or therapeutic tests. The physician can make a profit or lose money depending on the numbers of visits with and tests performed on each patient. Inpatient care costs may be reimbursed on a per diem, or per-day, basis. Under this arrangement, the hospital negotiates with insurers a set amount of reimbursement per day during the patient's hospitalization. The hospital staff will use the cost of care per day to help set the per diem rates and can increase the profit margins if they can decrease costs without compromising patient care. Reimbursement per case, similar to the Medicare PPS, is based on a set reimbursement rate for specific diagnoses or procedures. In some instances where hospitals offer specialized procedures or unique types of care, there may be "carve-outs" whereby reimbursement occurs separately from the per diem or per-case rate, usually on a fee-for-service basis.

In all of this discussion, the key message for the laboratory manager is the focus on cost control. In the hospital's financial landscape, the laboratory is considered a cost center. Although it may produce revenue from its outpatient and outreach workload, the reality is that it represents a necessary but significant expense on the hospital's overall balance sheet. Thus, laboratories that focus on providing high-quality service in a cost-effective and efficient manner will be valued by the organization and those that do not will likely be targeted for redesign.

Laboratory Compliance Programs

In 1998 the Office of the Inspector General, in response to costly and at times fraudulent billing errors on the part of some laboratories, issued compliance program guidance for clinical laboratories. Its purpose was to instruct laboratories on how to conduct their business in a lawful and ethical manner. The guidance document requires that every laboratory have a formal compliance program that addresses several essential elements (2). At a minimum, the laboratory compliance program should (i) develop and promote standards of conduct for employees, (ii) promote a commitment to zero tolerance of fraud and abuse, (iii) designate members of a laboratory compliance committee, (iv) identify education and training programs available to employees, (v) promote communication with employees to ensure that the program is effective, (vi) outline monitoring activities to ensure that the program is effective, and (vii) describe the potential disciplinary measures for those violating standards of conduct and compliance procedures.

The laboratory compliance committee has the responsibility to oversee compliance with standards of conduct and other procedures as they relate to lawful and ethical business practices. The membership of the committee should consist of the medical director, the administrative director, section managers or supervisors, a laboratory information systems (LIS) manager, and the manager of outpatient services if one exists. The duties of the compliance committee are to effectively communicate the standards of conduct to all employees and to implement monitoring systems to detect any possible illegal or unethical conduct as it may relate to medical necessity or billing issues. The committee should also be available to employees who believe that they are aware of unethical or illegal activities that violate the standards of conduct and ensure that the enforcement of these standards is consistently done through appropriate disciplinary mechanisms. On a routine basis, the compliance committee should review any appropriate fraud alerts as periodically issued by the Office of the Inspector General and inform and educate employees appropriately as well as keep current with legal and regulatory compliance issues and revise compliance policy as needed.

The laboratory should communicate regularly with the institution's financial services, governmental reporting, and medical records departments regarding coding and billing

issues. Laboratory managers are expected to take every reasonable precaution to ensure that the CPT-4 codes for laboratory tests accurately describe the tests that were ordered and performed and to choose the code that most accurately describes the ordered and performed test. Intentional up coding, the selection of a code to maximize reimbursement when such a code is not the most appropriate descriptor of the service, is not allowed. A complete review of CPT-4 codes should be performed at least annually to update codes and descriptions, delete obsolete codes, and validate reference lab coding using the American Medical Association's *Current Procedural Terminology* manual (1) and updates from carrier and fiscal intermediary bulletins.

The laboratory should encourage that physicians order only tests that are medically necessary. Diagnostic information for each test should be submitted by the ordering physician or authorized representative in narrative form or codes provided through the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM). Laboratory employees should never suggest or supply ICD-9-CM codes. As a means to ensure physician knowledge of compliance issues, the laboratory should disseminate a "notice to physicians" to physician clients on an annual basis. The notice should outline the individual component of every laboratory profile that includes a multichannel test or other automated multiple test result and the CPT-4 codes that the laboratory uses to bill Medicare for each such profile. Physicians should also be told that when ordering tests for which Medicare, Medicaid, or other federally funded reimbursement is sought, they should order only those tests which they believe are medically necessary.

Costs

Operating expenditures in the laboratory may be divided into broad categories of fixed and variable costs. These terms reflect the sensitivity of costs to increases or decreases in test volume. A cost that changes more or less in proportion to the test volume is variable. A cost that remains unchanged for some period of time despite volume fluctuations is fixed. Examples of variable costs include technologist salaries, costs of reagents and supplies, and costs on printed requisition forms. Salaries for nonexempt employees, benefits, and the cost of depreciation of equipment are examples of fixed costs. Costs are also classified as either direct or indirect. Costs that can be specifically linked to a test are considered direct costs. These include technologist salaries, costs of clerical support and overtime, courier fees, and costs of reagents and bacteriological media. Costs that cannot be directly traced to a test but are still part of the laboratory's expenses are indirect costs. Examples of indirect costs include those of depreciation, building and equipment maintenance, and utilities. Laboratory managers are more often concerned about unit costs when making financial decisions because understanding how costs fluctuate in producing a specific unit of service (usually defined as a test) permits measurement of productivity. Unit costs are also divided into fixed and variable categories that behave differently as volume changes. Variable costs remain the same per unit regardless of volume, and fixed costs are reduced per unit when volume increases because the total fixed cost is spread over a larger number of tests. A busy clinical laboratory benefits from economies of scale. In general, variable and direct costs are subject to some degree of management control and fixed and indirect costs are much less so. Regardless of cost classifications, laboratory managers must be continually looking for opportunities to control any and all costs. Accurate cost accounting is an imperative for financial decision making, and in today's managed care environment, correct cost information ensures participation in profitable contracts. The laboratory manager must be efficient in defining and itemizing costs associated with the testing services provided by the laboratory. Moreover, accurate test cost analysis provides the manager with a rational mechanism for selecting the most cost-effective testing method among several new procedures whose suppliers each claim that their test is the least expensive to use. Finally, laboratory budgeting becomes more effective with a reliable cost analysis system in place. A simple test cost analysis worksheet is shown in Appendix 1.

Operating Budgets

The development of an operating budget for the hospital is highly dependent upon clearly stated institutional goals and objectives within which the laboratory has a known role and upon which it can base its own specific objectives. The manager should expect to receive, either directly or indirectly from the hospital administration, budget guidelines that include expected inpatient and outpatient census information for the budget year and any anticipated changes in the total service program of the organization. Clinical service line managers, in particular, should communicate new program plans to support service managers, including laboratory managers, because support services may be impacted by these new programs. If, for example, the hospital has plans to begin performing human stem cell transplants, then the microbiology laboratory needs to budget for the additional volume and specialized testing that patients receiving these transplants will require. In return, managers may be required to provide the laboratory and/or hospital administration with information related to program changes anticipated in their areas that arise because of changes in technology or clinical practice. Examples of such changes include procedures that may diminish in volume because of obsolescence or physician education and increasing volume estimates for newly implemented procedures such as those of molecular diagnostics.

There are several types of operating budgets (18). A fixed budget assumes a single level of output or activity and builds the budget around that level. A fixed budget, however, cannot be used to monitor and control resources during changes in test volumes that the laboratory may experience during the year. A flexible budget reflects expected laboratory revenue and expenses and anticipates the impact of volume changes on both. In this type of budget, some of the expenses are fixed and some are variable. The flexible budget recognizes the difficulty of establishing a flat level of expenditure and provides a tool for controlling costs. Quite simply, a flexible budget allocates dollars for resources based on volumes of tests performed. The accuracy of the flexible budget as a predictive tool, however, is only as good as the test component cost analysis performed during the budget's construction. A program budget is based on a specific program matrix. The matrix includes all proposed services and the resources required to deliver them. The program can include a set of activities, services, staffing, and equipment. It is often used for short-term planning purposes when new programs are launched. A zero-based budget calls for management to reevaluate all activities to decide if they should be re-funded for the next budget cycle. Each manager is required to justify the entire budget for their area of responsibility as if all of its activities were entirely new.

Although there is no single formula for the budgetary process, there are some basic elements that will help ensure

success (18). First, establish clear goals and objectives to guide resource allocation. Second, obtain detailed data on existing and potential clients. Third, establish a defined budget period and procedures for development of the budget. Fourth, compile reports with financial and statistical information for comparison with budget information and for variance analysis. Furthermore, when planning a budget, managers should remember the following principles: (i) expenses are charged to the department or cost center that incurs them, (ii) every item of expense must be under the control of someone in the organization, (iii) managers responsible for complying with a budget should participate in the budget's preparation, (iv) managers should not be held accountable for expenditures over which they have no control, and (v) ordinarily, unused funds do not carry over from one budget year to the next.

Variance Analysis

Once the operating budget is established and approved, the extent to which the actual revenues and expenses differ from the budget represents a variance. Controllable variances can be resolved by appropriate management action (32). Salary variances can be addressed by reviewing time cards for excessive overtime. Supply cost variances may prompt an examination of inventory par levels. Suppliers may be approached for deeper discounts, or alternative vendors may be sought. Some variances are not controllable. These often result from unanticipated volume increases due to higher-than-expected numbers of patient admissions, unanticipated (and unbudgeted) price increases, unplanned repair expenses, or an unusual increase in the number of tests requested. A good example of the latter would be an unanticipated epidemic of influenza's producing a large increase in the number of requests for rapid flu testing and the need for the laboratory to purchase an excessive number of kits within a short span of time. As discussed above, a flexible budget should account for month-to-month fluctuations in test volumes and test complexity if properly constructed. Managers may be periodically called upon to communicate their budget performance to the laboratory administration and should be able to accurately record and explain budget variances on a line-by-line basis in their monthly financial statements.

Capital Budgeting

In addition to the operations budget, there must be a process for allocating monies for major investments in facilities and equipment. In accounting terms, a capital item is generally any fixed asset expected to provide service for more than 1 year and has a minimal expense, usually between $500 and $1,000. Items that qualify as capital include new space or renovation of existing space, replacement of equipment, purchase or lease of new equipment, and information technology (hardware, licensing fees, and interfaces, etc.). Capital acquisitions represent a significant investment for the organization and, as such, should be evaluated and justified by a budgetary process. Generally, a fixed amount of funds available for capital is established each fiscal year by the institution. Invariably, the total dollar amount requested for competing capital projects will far exceed the total of funds available. The capital budget process must therefore winnow, select, and prioritize; it is an enormously complex and politically charged task if not handled correctly. But by using a team approach whereby the management maintains focus on the goals and objectives of the organization, the capital budget process can be a successful and rewarding experience.

Prior to the budget process, the pool of total capital dollars available may be divided into smaller pools designed to support different aspects of the institution. For example, a $50 million capital budget may be allocated to allow $5 million for strategic projects, $10 million for information technology, $15 million for patient care, $10 million for facility improvements, and $10 million for ancillary services. If the laboratory is considered part of ancillary services, then the numbers of available dollars is much lower than the overall budget and the laboratory will likely be competing with several other departments for this lesser amount. The evaluation process will seek to classify capital projects in different ways, and managers should be aware of how to appropriately categorize and describe any project submitted for consideration. For example, some projects may represent new or incremental business, some may enhance quality, and some may reduce cost. Finally, capital requests may be prioritized according to need. A nondiscretionary project is a project that must be funded to keep the facility operating. An example would be a renovation project to make the laboratory compliant with regulatory and accreditation mandates. Levels of priority then follow, with level I projects being most critical.

Generally, capital projects of $10,000 or less need minimal analysis. All that is normally required is a brief description of the project and its intended use (new item or replacement, etc.) and the requested dollar amount. Projects with costs exceeding the minimum dollar amount require a higher level of analysis and more detailed documentation supporting the request. In addition to a description of the project and its intended use, proposals for these projects should include an estimate of the life span of the item, an estimate of all costs associated with acquisition, an estimate of yearly incremental cash outflows, and an estimate of yearly incremental cash inflows or savings. Depreciation expense must also be considered. Straight-line depreciation analysis is the most commonly used method of determining the expense of a fixed asset. In this method, the estimated useful life span of the item is divided by the cost of acquisition. A piece of equipment costing $100,000 with a useful life expectancy of 5 years would have a depreciation expense of $20,000 per year.

The financial analysis of large capital projects may have several elements. An illustrative case study follows. Suppose a clinical microbiology laboratory that has historically performed manual bacterial identifications and disk susceptibility tests wishes to purchase an automated system because a new outreach program will significantly increase test volumes. First, a pay-back analysis reveals that with a purchase price of $125,000 and a net cash flow of $137,000 after 3 years, the pay-back period is calculated at 2.68 years. The pay-back method does not take into account the time value of money but serves as a crude measure of risk because it favors projects with a short pay-back horizon. The average rate of return is calculated by dividing the average annual return by the amount of the initial investment. Projects with a higher average rate of return may be rated more favorably, but the method also fails to recognize the impact of time. The concept of present value is very important for capital investment analyses because it takes into account the increase or decrease in the value of a capital investment over time.

The most common method used in the financial analysis of a capital proposal that accounts for the time value of money is the calculation of net present value (NPV). NPV is the present value of all cash flows minus the initial investment. If the NPV is positive or zero, the project is usually considered financially acceptable. This is because all future cash flow has been converted into current dollars, with the use of an expected rate of return (usually set by the institution's

financial department), and has been compared with the initial investment. However, projects with a small negative NPV may still be worthwhile since other factors may be considered, such as the size of the initial investment and the benefit to patients. A favorable NPV for any capital proposal may result in a ranking higher than those for projects with similar costs. Laboratory managers would be well advised to support their capital project proposals with sound financial as well as clinical justification. In the end, it may make the difference between getting the equipment the laboratory needs and limping along for another year without it.

Financial Bench Marking

Increasing economic pressures on today's laboratory operations have created the need for managers to be aware of their financial performance in comparison to some internal or external bench mark. Financial bench marking is but one of many tools that the laboratory employs to improve performance, focus on customers, survive, and thrive in an environment with limited resources (39). In selecting indicators for bench marking, the use of ratios is much preferred over the use of raw numbers because the data are viewed in terms of a common denominator, usually some unit of service. The typical unit of service for the laboratory is the billed test because most financial systems are capturing volumes according to CPT codes that have standardized characteristics. A denominator that is often used outside the laboratory is patient-days or patient discharges. Ratios can be used to assess performance in a number of ways. For example, laboratory workload may be measured by calculating the total number of billed tests per calendar day, per patient-day, or per patient discharge, and examining the number of billed tests per full time equivalent reveals service intensity. Labor productivity can be determined from the number of hours worked per 100 billed tests or per patient discharge. Lastly, important cost data may be ascertained from ratios such as labor and supply expenses per 100 billed tests.

The simplest method of bench marking is to use your own laboratory as the standard and measure performance over time. This type of internal bench marking provides consistency of measurement over time and gives managers control over assumptions. In effect, it affords managers a means to continuously monitor performance and make improvements in productivity and cost on an ongoing basis. External bench marking involves a comparison of the laboratory's performance with that of a peer group. The composition of the peer group is critical. Members of the peer group should be alike in as many critical characteristics as possible. Otherwise, whatever performance expectations are placed on an individual laboratory being compared to the peer group may be unreasonable. Sometimes, voluntary agreements are established with other institutions to share productivity and cost information. This arrangement allows control of the size and composition of the peer group and ensures a fair comparison of whatever characteristics are being measured. There are a number of commercial companies that provide bench-marking products, some specific for the laboratory (see http://www.chisolutionsinc.com) and others more broadly applicable to the institution but with drill-down capability for the laboratory (see http://www.solucient.com).

Now that cost efficiency is a watchword in most health care environments, a comprehensive financial management system is an imperative, rather than an option, for laboratory management. Managers who set goals, measure progress, and identify trouble spots will utilize their limited resources more intelligently than those who do not.

PERSONNEL ISSUES

The study of organizational behavior encompasses all of the human factors encountered in the workplace, including motivation, leadership, organizational models, and responsibilities (31). Organizational behavior is defined as the actions and attitudes of people in organizations. When it comes to personnel issues, most diagnostic microbiology laboratories will fall under the auspices of the human resources department (HR) of the parent institution. In that regard, directors, managers, supervisors, technologists, and laboratory assistants alike are obligated to become familiar with and follow institutional policies relative to hiring and firing practices, compensation and benefits, job descriptions, organizational structure, and grievance procedures, etc., and of course to be compliant with federal, state, and local labor laws.

Hiring

Needs Assessment

Before the microbiology manager goes through the expense and time required to hire a full-time employee, he or she should determine whether that position can be eliminated without compromising service and quality expectations. Could the work be redistributed among existing staff? The solution may involve creative management in terms of subdividing assignments among other stations or individuals (or even among different laboratories), but this approach may not be practical in areas such as specimen processing where the workload is constant and could not be easily transferred elsewhere. It may be possible, however, to rearrange schedules such that individuals are transferred into high-volume work areas during times of peak utilization.

A second option may include the use of temporary or part-time employees to fill the shortage. This alternative can be quite attractive from a convenience standpoint but may be more expensive depending on training and agency costs. An excellent source of part-time help may include previous employees who have left the full-time ranks for alternative pursuits and would like to supplement their income. Finally, the hiring process may present an opportune time to examine laboratory productivity. A number of consultant firms are available to perform bench-marking analysis with laboratories having similar workloads and demographics to determine efficiency.

Analysis, Design, and Description

The job description is a summary of two administrative processes: job analysis and job design. Whereas the analytical and design phases involve proactive evaluation and/or reconfiguration of the nature of the work to be performed, the written job description is a document that defines the required skills, functions, conditions, and hierarchy associated with a specific position (35). Poor job analysis and design will lead to a flawed job description.

A job analysis should be comprehensive and detailed such that the nature of the work to be performed is clearly understood. The information required to complete the analysis can be gained through a structured process that measures and documents the number of tasks performed and the time required to complete those tasks, or informally through observation (10). One can also hire consultants to perform job analysis, request input from current staff, or contact laboratory administrators from demographically similar facilities. Job analysis and design should focus on the essential elements of the position, including the array of duties, the workflow and volume, the technological skills required, the

degree of employee interaction, the reporting relationships, and the working conditions. This, in turn, will make it easier to define minimum education, experience, and personal attributes appropriate for the job. If done properly, job analysis and design will drive the completion of a formal job description. As an example, consider the following scenario. The microbiology manager is allowed to fill a vacancy for a laboratory assistant on the evening shift. The primary responsibilities of that position are specimen processing and reagent preparation. The manager could use the existing job description to recruit for the position. After careful analysis, however, the manager finds that most laboratory assistants on that shift complete their assigned duties nearly 2 h before the shift ends. At the same time, the volume of *Clostridium difficile* toxin testing by enzyme immunoassay on the day shift has exceeded capacity for months, necessitating overtime for qualified technologists. If the new position was expanded to a technologist level, it would allow for testing of excess *C. difficile* specimens on the evening shift without the loss of sample processing capacity at a fraction of the overtime costs alone.

The job description serves to define the specifics of the position and the requirements for the prospective employee (10). It also provides a tool for communication between the employer and the prospective employee and serves as a recruiting tool (35). It can be used to schedule and set staffing requirements, to assess employee performance and competency, to define wage and salary structure, and to act as a template for future corrective actions (35). It should be flexible to allow for future growth of the position and focus on minimum requirements to prevent the loss of high-end applicants (16). There are no rules to writing a good job description unless institutional guidelines are in place. At the very least, the job description should include the items listed in Table 1 (10, 35). Optional information that can be added includes exempt status (time clock or salaried position), personnel and payroll codes (but not actual dollar ranges), and U.S. Department of Labor (DOL) occupational codes and/or U.S. Employment Service functional job analysis codes (34). Bear in mind that the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88; see below) established only six categories for laboratory personnel; director, technical consultant, clinical consultant, technical or general supervisor, testing personnel, and cytotechnologist. The laboratory can expand on the qualifications required for each of these positions but not reduce them below the minimum requirements as outlined in CLIA '88. All job descriptions on file should be reviewed at least annually in conjunction with the employee's performance review or when the position is vacated and a replacement is sought.

Recruiting, Interviews, and Hiring

Once a job description has been drafted and approved, the recruitment and hiring process can begin. As before, it is best to coordinate activities with the organization's HR personnel, who are more familiar with local, state, and federal regulations pertaining to recruitment and hiring. HR can also provide valuable services such as background checks and validation of a candidate's credentials (14).

The job description should be abstracted to provide the essentials for a classified advertisement. The advertisement should contain the job title, minimum education and licensing requirements, a brief summary of the duties, and if desired, the salary ranges (15, 16, 35, 38). The laboratory has basically two candidate pools to choose from: internal and external. The former is usually an attractive source because current employees have already received system orientation and are familiar with general corporate policies and culture. Mobilization of internal candidates usually takes less time because job listings can be posted in organizational newsletters or on institutional websites. Overall, internal hires are generally less costly, but external candidates can infuse the laboratory with new ideas, experiences, and skills. Generally, external searches take longer and may require the use of recruitment bonuses, employment agencies, the Internet, or advertising in trade magazines such as *ASM News*/*Microbe* or *Medical Laboratory Observer*. Other possible external recruitment sources include professional schools and organizations such as the American Society for Clinical Pathology, the Canadian College of Microbiologists, and the American College of Microbiology (the certification and training

TABLE 1 Components of a job description

Items	Example[a]
Organization	Central States Medical Center
Department	Microbiology
Position	Microbiologist, day shift
Education	B.S., medical technology or microbiology
Certification	M.T. (ASCP); SM, NRM, or equivalent
Responsibilities	Responsible for processing of specimens, interpretation of culture and susceptibility results, participation in quality management program, and teaching of medical technology students, laboratory medicine residents, and fellows; nonsupervisory position
Competency	Requires semiannual (first year) and annual (thereafter) competency assessment via departmental program
Working conditions/exposure hazards	Modern clinical microbiology laboratory; no heavy lifting; potential exposure to human specimens, including blood and body fluids, and work with BSL 1–3 agents
Pay code	5, Nonexempt

[a] M.T., Medical Technologist; ASCP, American Society for Clinical Pathologists; SM, Specialist Microbiology; NRM, National Registry of Microbiologists; BSL 1–3, biological safety levels 1–3.

branch of the American Society for Microbiology [ASM]). Parent institutions can also use online automated recruitment web pages for both internal and external candidate searches. By logging on to a website, potential candidates can review job openings within the system and create a personal profile that can be used by HR for reviewing qualifications or for matching individuals with future positions as they become available. The ultimate goal is to provide the microbiology administrator with a qualified pool of candidates while trying to maintain workforce diversity according to a U.S. DOL directive (http://www.dol.gov/dol/compliance/comp-eeo.htm). For individuals applying for supervisory or higher positions, a search committee should be convened to expand the sources of potential candidates. Once a candidate pool of qualified individuals has been identified, it is time to begin the interview process.

The interview is a means of allowing the employer and candidate to determine whether they are suited for each other. It is a very important process because a badly conducted interview may scare off a highly qualified candidate. This is also the part of the hiring process in which the unskilled interviewer may pose a liability and one that requires close attention to regulations. There are several questions shown in Table 2 that the Equal Employment Opportunity Commission prevents an employer from asking a potential employee (14, 16, 35, 38). The interview should be organized and standardized to permit a fair evaluation of each candidate. There are three basic formats for an interview: structured, in which the format is predetermined with a list of questions and a review form; unstructured, in which a set panel of questions is not used but the interview consists primarily of a running conversation with the candidate; and pressurized, in which the candidate is asked to provide analysis of various job-related scenarios or to solve a series of hypothetical problems (34). The interview can be a combination of all three and can be conducted individually or by a panel of interviewers. In some organizations, HR conducts a preliminary interview to screen candidates before the microbiology administration conducts final interviews. The ultimate goals are to meet the candidate, check credentials (usually an HR responsibility), collect additional information not provided on the application form, and gather a sense of personality fit. In management, we tend to think of the interview process from one side only. Holland (14) provides an overview of how to prepare for an interview from both the employer's and the employee's perspectives. If there is an evaluation form to be completed, it should be done immediately after the interview so that impressions are not lost with time. Documentation of the search, selection, interview, and orientation processes should be kept on file for at least 4 years should any improprieties be called into question.

Employee-Related Activities

Orientation

Once a candidate is hired, the next phase involves the assimilation of the new employee into the microbiology workforce. The orientation process must be organized and synchronized to keep the new hire active and engaged.

According to Vernadoe (34), there are three basic aspects of employee orientation. The first is at the organizational level to familiarize the new employee with institutional policies, procedures, and benefits. The second focuses on department-specific policies and codes of conduct. The final aspect concentrates on the microbiology laboratory and addresses job responsibilities, reporting structure, and working relationships that exist therein. There are at least four basic approaches to conducting orientation (16, 34). These include (i) formal meetings and training sessions, usually conducted at the institutional level by HR (these cover such topics as risk management, fire and chemical safety, benefits, and infection control); (ii) microbiology supervisor-led sessions to discuss laboratory-specific issues such as competency assessment, biological safety protocols, dress code, telephone conduct, breaks, and scheduling; (iii) a checklist approach; and (iv) a mentor-driven process.

In addition to a systemwide, general orientation program, many microbiology managers choose to develop a stepwise laboratory-specific orientation process that is checklist driven. First is the preorientation checklist, which is preparatory in nature. It allows the microbiology supervisory staff to organize all the materials that the new employee will receive during orientation. The training orientation checklist guides the assigned mentor and trainee through the basic components of orientation. The specific elements of the microbiology laboratory are covered by a series of modules that may include topics such as scheduling orientation, trainer and trainee expectations, supervisor's review procedures, a special shift rotation checklist, and a LIS orientation, to name a few. The entire process is completed with a postorientation checklist to ensure that each component has been covered and entered into the employee's personnel file.

Above all, the orientation period is the process of welcoming. For this reason, the choice of mentors selected to provide training should be carefully considered and limited to individuals with a great deal of experience and respect.

TABLE 2 Topics to be avoided during a hiring interview

Topic	Examples
Age	Date of birth, year of high school graduation
Weight	Waist size, dietary habits
Financial history	Outstanding loans or debts, bankruptcy
Citizenship	Country of origin, immigration status, parental ancestry
Marital status	Maiden name, number of children
Criminal and military records	Military discharge status, court convictions
Organization memberships	Religious or political groups
Mental/medical/physical disabilities	Current medications, therapy, workman's compensation benefits, missed workdays secondary to disabilities

Staffing and Scheduling

The process of adequately staffing a microbiology laboratory and scheduling individuals with widely ranging abilities to provide maximum coverage on each shift is one part science and one part art. It requires advanced planning, and no one strategy works for every facility because peak activity levels, workloads, and the technical complexity of testing differ significantly. Poor planning can lead to low productivity and high labor costs when staffing is excessive. Inadequate staffing may generate high productivity but also lead to increased overtime and employee burnout (21). To avoid these extremes, a number of good guidelines on staffing and scheduling are available for review (4, 36).

Scheduling is simply the process of assigning work responsibilities to a group of individuals and requires the right number of employees and skill levels to complete the work. Most medical laboratories work under the 8/80 rule for full-time employees, i.e., employees work a total of 8 h per day and 10 days over a 2-week pay period. This plan limits the number of hours to be worked in a day but permits the employee to work more consecutive days and is unique to medical facilities. A 40-h work week permits an employee to work any number of hours per day but not to exceed 40 h per week. Other scheduling systems include the use of part- or variable-time help, job sharing, self-directed work teams, and exempted employees (21, 36). In designing a schedule, it is important to choose a plan or combination of plans to provide the greatest degree of flexibility. A mixture of employees on the 8/80 plan and the 40 plan can be used, but a single employee must choose only one option.

The scheduler must know workload patterns and future trends. This is most often done retrospectively by reviewing LIS-generated billing for an estimate of test volume and plotting these data over time for trend analysis for each shift. Recording workload units periodically over time can also provide a helpful bench mark of test volume. However, keeping pace with method advancement is also necessary for projecting future labor needs. The development of molecular and amplification technology has greatly streamlined a number of processes in the microbiology laboratory—most significantly in clinical virology. Armed with this information, the laboratory manager must calculate how many people for each shift and skill set will accommodate the mean test volume, not peak or trough volumes of work (4). From here, the scheduler starts with a rough draft based on ideal staffing levels by using a matrix for each shift where rows correspond with the services to be provided and columns represent the days of the pay period. With the 8/80 plan, a shift is 8 h times 14 days or 112 h per pay period. Full-time employees can cover 80 of these hours (8 h times 10 days), while part-time staff can be used to fill in the balance (generally 24 h per week or less). Once a rough schedule has been outlined, it can be fine tuned by naming the individuals who will fill each slot and the work assigned. From this working draft, the schedule can be modified to accommodate vacations, family leave, illness, earned time off, and shift switching. Schedulers and managers must also remember that work schedules affect employee families and morale (30). Part-time and variable-time employees can be used to fill in gaps, or cross shift coverage can be applied to relieve peak workload stress. A detailed description of this process can be found elsewhere (4, 30, 36). During new employee orientation, a review of the scheduling process should be included so that there are no surprises when the individual is eventually assigned duties.

Winn and Westenfeld (41) provide an excellent summary of scheduling do's and don'ts as follows: (i) define the absolute minimum number of employees required for each situation (weekends, routine, and holidays); (ii) strictly define the duties for each of the positions required for every type of shift, and if a position is open, try to fill it with existing personnel based on the duties assigned to that slot; (iii) allow scheduling to be orchestrated by a coordinator with input from the staff; (iv) solicit vacation requests well in advance (>6 months) and be clear that not all preferences can be accommodated; (v) publish work schedules in advance to allow for personal adjustments; (vi) if allowed, use earned time off instead of overtime; and (vii) fill empty slots with volunteers or part-time help, with a draft as a last resort. In this context, certain laboratories have developed a rotational "hit list" among staff to cover for open slots on the work schedule. The next person up on the list is informed of their standing and allowed one deferral or may switch their obligation with another employee.

In a situation in which the microbiology workload is high or increasing and staffing is static or decreasing, there are a few options left to the administration to relieve the pressure. The first of these is outsourcing, such as finding reference laboratories to perform a variety of low-volume, esoteric, or technically complex testing, e.g., forwarding all mycobacterial identifications with the exception of probe-confirmed identification of *Mycobacterium tuberculosis* and *Mycobacterium avium* complex organisms to a public health mycobacteriology laboratory. Elimination of low-volume testing may not necessarily prove to be cost efficient but maintaining proficiency when the frequency of testing is low should also factor into outsourcing decisions.

Microbiology laboratories can even outsource testing to other laboratories within their own system. For example, automated blood culture systems can be physically located near a rapid-response laboratory. Signal-positive blood cultures can then be removed during all shifts to be subcultured and stained. Gram stains can be read by trained rapid-response technologists, and cultures can be evaluated during the next microbiology shift.

The second option is to examine the extent of evaluation. In many instances, microbiology laboratories can get into the bad habit of providing too much information, such as identifying isolated organisms that are unlikely pathogens in a disease process. This process not only generates an unnecessary workload but may also give the clinician a false sense of importance.

Unfortunately, staffing and scheduling often go hand in hand with absenteeism. As a result, each facility should have a well-defined absentee policy and management plan that are neither onerous to the employee nor subjective and that can be fairly applied. A laboratory policy on absenteeism requires a working definition, equitable and realistic standards (e.g., less than one unscheduled absence per month), and a management plan that uses the same organizational framework for corrective action for issues such as behavioral or performance problems (36). Absenteeism can be chronic, high frequency, and/or patterned (e.g., Mondays, Fridays, or the day after payday). If not addressed and corrected, chronic absenteeism can generate poor morale among other microbiology staff.

Performance Appraisal

A job description defines the duties of an employee and how the employee's success will be measured. The performance appraisal, on the other hand, asks how the employee is succeeding. A performance appraisal has at least five ingredients: (i) an employee with a job description and appropriate qualifications, (ii) a series of clearly defined goals and

performance standards, (iii) an objective way of measuring achievements, (iv) someone trained to evaluate the employee's performance, and (v) a feedback loop to gain input from the employee (38). The standards used to judge performance must be outlined in the job description and should be objective and consistent with those used to evaluate other employees. Basically, four markers can be measured either alone or in combination to generate a performance appraisal: results, behavior, skills, and peer comparison (33). However, objectivity in performance appraisal is often difficult to achieve. We all have a tendency to rate individuals we like highly and those we do not like less highly. The actual data recorded in the performance appraisal should include employee information, a list of goals and objectives from the previous and for the next review, a scoring system, a place for the employee to provide his or her own feedback, and a summary section that allows for the appraiser to recommend promotions and salary adjustments and that includes a date for the next appraisal and signatures (11, 33). When complete, the form should become an official part of the employee's personal file (22).

If the parent organization permits, there are a number of alternatives to performance appraisals, including feedback sessions, team or section appraisals, self-appraisal, and process improvement sessions, all of which would require some form of documentation.

Competency Assessment

The directive for competency assessment of laboratory personnel was written into CLIA '88. This legislation was signed into law in 1992 and has been revised five times to provide the final ruling in 2003. It mandates that all laboratories falling under the jurisdiction of the CLIA '88 guidelines must develop a program to document the competency of each laboratory employee in every aspect of the employee's assigned duties. As is the case with many pieces of federal legislation, CLIA '88 did not define how this process is to be accomplished nor did they suggest which core competencies should be monitored. They did, however, place the responsibility for establishing a program and documenting competency assessment squarely on the shoulders of the laboratory director and technical consultant or technical supervisor (11). Fortunately, the Clinical and Laboratory Standards Institute (formerly NCCLS) has published a clear and logical approach to the design of a laboratory-based training and competency assessment program that provides a wealth of sample documents used in the process (22). CLIA '88 clearly define the frequency of personnel assessment: semiannually for new employees and annually thereafter unless changes in procedures and protocols occur. At that point, competency for and familiarity with the new protocol must be documented. All agencies approved by the CMS for the purpose of laboratory accreditation have a competency assessment module included in the review process. These agencies include the College of American Pathologists, the Joint Commission on Accreditation of Healthcare Organizations, and the Commission on Office Laboratory Accreditation. For more details on the history and evolution of competency assessment, please refer to the fine review by Sharp and Elder (29).

The final CLIA rule (2003) consolidates commercially marketed in vitro diagnostic assays into two functional categories, waived and nonwaived. When it comes to competency assessment, however, nonwaived testing is subdivided into moderate- and high-complexity tests for the purpose of defining the educational background and training requirements of those individuals performing the testing (40).

CLIA '88 go so far as to define a choice of methods to be used in the evaluation process (13, 29). These include but are not limited to (i) directly observing an individual performing laboratory functions including testing, plating, culture evaluation, and instrument operation and maintenance; (ii) verifying the accuracy of transcribed test results; (iii) checking the integrity of data entered by the employee for QC records, proficiency tests, preventive maintenance charts, and preliminary patient test results; (iv) challenging the employee with internal and external proficiency series; and (v) evaluating an individual's ability to solve laboratory-related dilemmas. Hundreds of individual skills need to be mastered before a technologist-level employee can be considered a competent microbiologist, and there is no way that each of these can be pinpointed let alone evaluated in a year's time. That being said, there are at least three excellent publications outlining a competency assessment program specifically for the microbiology laboratory, and any of these could be used as a template for design (19, 20, 29). General laboratory-wide plans are also available for review (16, 22). In one model, a database in a spreadsheet format (e.g., an Excel file) is established for each active employee upon hire. All of the potential competencies that the job description encompasses are listed in the first column of the spreadsheet (*y* axis), and the first row (*x* axis) indicates the year of review. Each new employee begins with a series of X's in each competency cell for which training has not yet been conducted or in the cells corresponding to competencies not included in the job description. As training for a particular skill is accomplished, the X is removed and the method of measurement, the date, and the initials of the trainer or observer are recorded in the cell. Methods of measurement can be coded as DO for direct observation, Q for quiz, DR for document review, PT for proficiency test (internal or external), PM for preventive maintenance review, and QC for quality control review, etc. By using the spreadsheet approach, the competency assessment report for each employee is readily available for review and update and can also be used as an orientation tool. A copy of each report can be printed on a yearly basis and added to the employee's personal file.

Continuing Education

The Clinical and Laboratory Standards Institute guidelines on training and competence assessment distinguish between training and education in the following way (22). Education is "schooling for the purposes of gaining knowledge," and training is defined as the acquisition of "a set of skills for the purpose of being able to put the knowledge to a practical use." For the purpose of this chapter, however, continuing education will be defined as the extended process of gaining knowledge and improving skill sets. Continuing education constitutes one of the mandatory requirements for competency assessment and professional development dictated by CLIA '88 and necessary for the maintenance of professional licensure by most accreditation agencies. How can microbiology personnel maintain yearly continuing education requirements under the pressure of reduced operating budgets? A number of opportunities are available to satisfy these requirements, including attendance at local meetings such as branch meetings of the ASM. ASM branches usually sponsor at least one annual educational meeting, and the location and time of each are posted on each branch's website (http://www.asm.org/MemberShip/index.asp?bid=1914). In some cities, local microbiologists have formed clubs that meet during the year and invite guest speakers (usually sponsored) to present topics of interest for continuing education

credits. Many medical centers provide weekly opportunities for continuing education purposes such as grand rounds, clinical pathology conferences, infectious diseases case conferences, and microbiology rounds. At one author's facility (W.M.D.), the microbiology laboratory sponsors a weekly case conference open to technologists, infectious diseases staff, and pharmacy personnel. At the organization level, many health centers provide tuition reimbursement for college courses that pertain to the profession of the health care worker.

Other organized microbiological programs for continuing education include teleconferences, workshops, self-assessment materials such as Tech Sample and Check Sample (American Society for Clinical Pathology; http://www.ascp.org/index.asp), and ASM-organized wet laboratory demonstrations, online lectures, and audio lecture series that are available for purchase or subscription (http://www.asm.org).

Termination

Termination refers to the end of a formal business relationship between an employer and employee and can be either voluntary or involuntary (16). The departure of an employee from the workplace can be either amicable or contentious. In any case, procedures are usually developed by HR for employee separation that reflect the situation. For voluntary and amicable termination, the process may include documentation of the date of departure and a forwarding address; discontinuation of payroll, benefits, and parking privileges; and the return of security materials. HR may also wish to conduct an exit interview with the employee to gain insight on laboratory operations and administration (34).

There are good reasons to support the involuntary termination of an employee, including incompetence, chronic absences, violent behavior or verbal abuse, falsification of resume, theft, and insubordination (16). A fair employer will make every reasonable attempt to correct the problem prior to taking disciplinary actions. Detriments to job performance including substance abuse of any kind, stress-related illness, mental illness, or physical disabilities secondary to job activities fall under the auspices of the Americans with Disabilities Act (http://www.usdoj.gov/crt/ada/adahom1.htm) and are not acceptable causes for dismissal (16). A number of variations in the process of progressive disciplinary action have been described for laboratory managers, and each is designed to allow sufficient time for the employee in question to mend his or her ways and for the employer to adequately assess the true nature of the situation (16, 34, 38). The steps generally include (i) verbal counseling, (ii) written counseling, (iii) a penalty phase, and (iv) dismissal. A number of variations on the theme exist. Walters (38) outlines a more creative approach to the resolution or termination process that includes five phases: forewarning, investigation, proof, reflection, and penalty. Importantly, though, employees have the right to representation during any disciplinary process as determined by the National Labor Relations Act (http://www.nlrb.gov/nlrb/legal/manuals/rules/act.asp). If the conclusions of the progressive disciplinary action lead to employee dismissal, the process is usually handled by HR to ensure that all legal steps are followed and documented (16). It is also wise for the employer to retain the personnel file of the departing employee for future reference. Likewise, the departing employee should be informed of the Consolidated Omnibus Budget Reconciliation Act. This act gives workers and their families who lose health benefits the right to continue group health care provided by their current plan for limited periods of time under certain circumstances (http://www.dol.gov/dol/topic/health-plans/cobra.htm).

REGULATIONS

This section will serve as a brief review of those regulations and regulatory agencies that have the most profound effects on the operation of the clinical microbiology laboratory. A more extensive review of laboratory regulations is available in the works of Roseff et al. (26), Walters (38), and Ehrmeyer and Laessig (7).

CLIA '88

CLIA '88 (or simply CLIA) establish baseline performance standards for all U.S. laboratories involved in the testing of human materials for the diagnosis, prevention, or treatment of disease (7). The intention is to ensure the accuracy, reliability, and timeliness of test results no matter which laboratory is performing the testing. They were signed into law in 1988 (12), but five successive final revisions of the initial legislation have been published since, the last of which appeared in the *Federal Register* in 2003 (13, 34). In the first final version of CLIA, laboratory testing was divided into three complexity levels that established the expertise level of personnel performing those tests. Those levels were waived, moderate complexity (including provider-performed microscopy), and high complexity. In the most recent final version of CLIA, testing is now lumped into waived and nonwaived tests (most of the latter were high complexity). However, relative to the qualifications of testing personnel, CLIA still recognize moderate- and high-complexity levels (7, 40).

The administration and implementation of CLIA are under the purview of the CMS (http://www.cms.hhs.gov) in collaboration with the Centers for Disease Control and Prevention (http://www.cdc.gov). The U.S. Food and Drug Administration (http://www.fda.gov) is responsible for classifying the complexity of laboratory testing protocols and the CMS set fee schedules for laboratories providing services to Medicare.

U.S. laboratories wishing to perform and receive compensation for testing of human specimens must apply for a CLIA certificate in one of three complexity categories. If the laboratory meets compliance criteria as judged by the CMS or by one of the recognized professional accreditation agencies, it receives a permanent certificate of compliance or accreditation and becomes subject to the rules, regulations, and inspections of the agency issuing the certification. Organizations that the CMS have deemed suitable for CLIA accreditation of laboratories include the Joint Commission on Accreditation of Healthcare Organizations (http://www.jcaho.org), the Laboratory Accreditation Program of the College of American Pathologists (http://www.cap.org/apps/cap.portal), and the Commission on Office Laboratory Accreditation (http://www.cola.org/).

CLIA lay the foundation for laboratory participation in a proficiency testing program, qualifications of and competency assessment of laboratory personnel, and, establishment of a QC and QA program and ensure the integrity of laboratory testing through all phases of testing. They also call for routine inspection of certified laboratories and the enforcement of penalties for laboratories found to be noncompliant. CLIA dictate that outside or reference laboratories to which specimens are referred from a U.S. health care institution also be CLIA certified or the equivalent. Those wishing to review CLIA '88 in their entirety or to query individual components of the amendments can do so at http://www.phppo.cdc.gov/clia/regs/toc.aspx or http://www.cms.hhs.gov/clia/default.asp. A general description of the program is available at http://www.cms.hhs.gov/clia/progdesc.asp.

HIPAA

Public law 104-191, or the Health Insurance Portability and Accountability Act (HIPAA, Title I) of 1996, was originally written "to improve portability and continuity of health insurance coverage in the group and individual markets, to combat waste, fraud, and abuse in health insurance and health care delivery, to promote the use of medical savings accounts, improve access to long-term care services and coverage, to simplify the administration of health insurance, and for other purposes." However, in 2002, the Department of Health and Human Services issued the HIPAA Privacy Rule (Title II) that set highly restrictive standards on the use and protection of individual demographics and health information (protected health information [PHI]) contained in patient medical records (24). Details are available at http://www.hhs.gov/ocr/hipaa/finalreg.html. The Privacy Rule dictates that all "covered entities" including health insurance plans and health care institutions and providers must obtain written permission from a patient to use or disclose PHI and that the patients must be notified of their right to restrict the use of or disclose PHI (24). Covered entities must also make every attempt to limit PHI disclosure to only that required for any given purpose. From the standpoint of the microbiology laboratory, this means that the release of any PHI attached to bacterial or fungal isolates sent for research or surveillance purposes that can be traced in any way to the patient requires disclosure and consent unless waived by the human studies committee of the institution. The Privacy Rule does not supersede the federal "Common Rule" (see also http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm) that mandates Institutional Review Board approval of research studies conducted under its auspices (24). As with CLIA '88, the CMS are charged with the responsibility of administering the provisions of HIPAA. For a summary of the HIPAA health insurance reform (Title I) or the HIPAA administrative simplification (Title II), one can access the CMS website at http://www.cms.hhs.gov/hipaa.

Laws Covering Equal Pay and Compensation Discrimination

Several laws have been passed over the past half century to guarantee employees freedom from discrimination in the workplace with regard to wages, compensation, and working conditions. Collectively, these laws are enforced by the U.S. Equal Employment Opportunity Commission and include the Equal Pay Act of 1963, Title VII of the Civil Rights Act of 1964, the Age Discrimination Act of 1967, and Title I of the Americans with Disabilities Act of 1960.

Equal Employment Opportunity Commission

The Equal Employment Opportunity Commission is a federal agency created in 1965 to enforce the Civil Rights Act of 1964 (26). As of 1999, the agency had published new guidelines to further define unlawful harassment in the workplace (including sexual harassment) against the same groups protected by the Civil Rights Act (26, 38; http://www.eeoc.gov). To avoid risk, laboratories and/or HR of the parent institution should have a training module on unlawful harassment in place for employees and supervisory personnel, avenues for rapid reporting and investigation of complaints, and a documentation process for each of these.

Equal Pay Act of 1963

The Equal Pay Act is part of the Fair Labor Standards Act and makes unlawful the practice of wage discrimination between men and women performing the same duties at the same institution in a similar work environment. This act is directed and enforced by the Equal Employment Opportunity Commission and is gender neutral such that it protects males and females equally (38).

Title VII of the Civil Rights Act of 1964

Title VII of the Civil Rights Act of 1964 prohibits the use of race, color, creed, religion, nationality, and sex as a basis for the discharge of or failure to hire an employee, for segregation or classification that would deprive an employee of opportunities or advancement, for the failure or refusal of an employment agency to refer an individual for employment, or for the limitation of training or retraining of an employee.

Age Discrimination in Employment Act of 1967

The Age Discrimination in Employment Act of 1967 applies to individuals 40 years of age and older and, like the Civil Rights Act, prohibits the use of age as a reason for discrimination in the workplace. Interestingly, this law also applies when two candidates over the age of 40 apply for the same job and the younger of the two is hired if the employer has used older age as a negative factor in the selection process (38).

Americans with Disabilities Act

The Americans with Disabilities Act was passed in 1990 and forbids discrimination against an individual who has or has had a disability, is thought to have a disability, or associates with another disabled individual. According to the Americans with Disabilities Act, a disability is a physical or mental deficiency that affects a life function such as walking, talking, employability, and hygiene (38). The Americans with Disabilities Act mandates that an employer reasonably accommodate the needs of any qualified candidate so that he or she can perform the job. For example, the current dimensions of bench tops, shelving, and foot wells in the microbiology laboratory may not be appropriate for wheelchair access by a wheelchair-bound microbiologist and, therefore, require modification. Acceptable dimensions for work-related desk surfaces and shelving are provided in the Americans with Disabilities Act standards for design (http://www.usdoj.gov/crt/ada/stdspdf.htm).

Other Regulations Related to the Workplace

Family and Medical Leave Act

Passed in 1993, the Family and Medical Leave Act provides allowances to eligible employees of an eligible employer to take up to 12 months of unpaid leave during any 12-month period for one or more of the following situations: (i) birth and care of the employee's newborn child, (ii) placement with the employee of a child for adoption or foster care, (iii) care of an immediate family member (spouse, parent, or child) with a serious health problem, and (iv) medical leave secondary to the employee's own serious health problem. The Family and Medical Leave Act falls under the auspices of the U.S. DOL, and definitions of which employers are covered by this act and which employees are eligible can be found at http://www.dol.gov/esa/whd/fmla/.

Fair Labor Standards Act

The DOL also administers the Fair Labor Standards Act, which is legislation that sets basic minimum wage and overtime pay schedules. These regulations are enforced by the

Wage and Hour Division of the DOL, which is a program of the Employment Standards Administration. Pay for overtime (defined as work in excess of 40 h in a work week) is set at a rate of not less than one and one-half times the regular rate of pay. Certain exemptions apply to specific types of businesses or specific types of work. This act does not set requirements for severance pay, sick leave, vacations, or holidays. For more details, one can consult the DOL website at http://www.dol.gov/dol/topic/wages/index.htm.

Affirmative Action

An executive order was issued in 1965 that prohibits contractors engaged in federal contract work exceeding $10,000 from discriminating in hiring decisions against the same protected groups included in the Civil Rights Act. This order has since become known as affirmative action and was updated in 2000 by the Office of Federal Contract Compliance Program of the DOL. In addition, contractors securing more than $50,000 in government business and having more than 50 employees must write and regularly update an affirmative action plan to reflect current guidelines (38). Affirmative action guidelines would apply to many health care institutions and laboratories meeting the criteria defined above because of their participation in federal contracts for care provided to Medicare and Medicaid patients. However, many institutions that do not meet the qualifications outlined in this executive order have chosen to develop a voluntary affirmative action plan. The Office of Federal Contract Compliance Program maintains a website at http://www.dol.gov/esa/regs/compliance/ofccp/faqs/faapfaqs.htm.

APPENDIX 1

Sample test cost analysis form

Test cost analysis worksheet

Test: _____

Patient tests per year _____

Other tests per year (QC, repeats, etc.) _____

Total tests per year _____

Estimated time to perform test _____

Cost analysis

Labor

Direct: _____

Indirect: _____

Supplies

Direct: _____

Indirect: _____

Equipment: _____

Overhead: _____

Cost/Test: _____

Cost/Patient Test: _____ = (cost/test × total test volume)/patient test volume

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