CLINICAL LABORATORY MEDICINE

Tilton Balows Hohnadel Reiss

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Preface

Continued growth and increasing complexity are words frequently used to describe many scientific disciplines. Laboratory medicine, a multifaceted discipline with seemingly unabated growth and complexity, definitely falls under this rubric.

Technological advances, coupled with a growing battery of diagnostic skills, have led to the development of many innovative and far-reaching approaches to the laboratory diagnosis of disease. Some of these new approaches include rapid screening tests that provide prompt and useful general information, whereas other analyses are highly automated, sensitive, and specific, which not only yield results in support of a diagnosis, but other levels of information as well. Laboratory medicine provides data that help formulate therapy, promote the patient's recovery, and help establish the need for dietary, environmental, and physiological changes that contribute to the maintenance of good health.

Laboratory medicine specialists not only determine the methodology of the tests offered and control technical quality, but also consult with the medical staff to interpret test results and give advice on the role of the laboratory to resolve diagnostic dilemmas.

Other facets of laboratory medicine include the provision of laboratory support for public health activities and epidemiological investigations, evaluation of persons for drug abuse, and medicolegal investigations. The staff of the clinical laboratory also frames and implements institutional guidelines and procedures to control nosocomial infections, monitors sterilization and disinfection procedures, and consults for the proper disposal of medical waste. The laboratory staff must also be familiar with the growing number and variety of rules, regulations, and recommendations that come from local, state, and federal government and professional organizations.

At times it may appear that these constraints place added emphasis on the test results and diminished emphasis on the knowledge and skill of laboratory personnel. Regardless of such appearances, and regardless of the size, location, or scope of services offered by a clinical laboratory, the one requirement that transcends all others is the need for a staff of individuals who are knowledgeable and technically proficient.

This textbook attempts to bring together the method selection and decision-making processes that ensure quality laboratory testing and to correlate the laboratory data obtained with current understanding of disease pathophysiology and clinical management of patients. The editors and authors have labored diligently to produce a book that will be a companion to students, a resource to the laboratory medicine specialist, and a reference to the clinician who wishes to optimally utilize the clinical laboratory.

Richard C. Tilton
Albert Balows
David C. Hohnadel
Robert F. Reiss

Contents

PART ONE

INTRODUCTION TO LABORATORY MEDICINE

1 Laboratory organization and management, 2
Richard C. Tilton
Melissa Martincich

2 Clinical laboratory safety, biohazard surveillance, and infection control, 13
Michael P. Kiley

3 Sample collection and processing, 25
Joanne M. Griffith

4 Weights, measures, and principles of instrumentation, 40
Marie Zureick

5 Laboratory statistics, reference ranges, and quality control, 66
Mary Kay Boehmer

PART TWO

MEDICAL CHEMISTRY AND CHEMICAL ANALYSIS
David C. Hohnadel

6 Renal physiology and water and electrolyte balance, 84
Lawrence A. Kaplan

7 pH and blood gases, 98
Sarah H. Jenkins

8 Carbohydrates, 109
Juan R. Sobenes
John E. Sherwin

9 Lipids, 125
Donald A. Wiebe

10 Bone and mineral metabolism and parathyroid hormones, 135
Willie Ruff

11 Hemoglobin and iron, 145
Gayle B. Jackson

12 Proteins, 157
Kory M. Ward
Kathy V. Waller

13 Liver function and nitrogen metabolism, 179
John E. Sherwin
Juan R. Sobenes

14 Clinical enzymology, 190
David C. Hohnadel

15 Pancreatic and intestinal function, 208
Michael D.D. McNeely

16 Pituitary, hypothalmic, and adrenal hormones, 222
Richard Kowalczyk

17 Thyroid function, 253
I-Wen Chen
Howard Smith

18 Gonadal hormones, 289
Paul T. Russell
R. Ian Hardy

19 Fertility, pregnancy, and fetal maturity, 290
Paul T. Russell
R. Ian Hardy

20 Vitamins, 307
Marge Brewster

21 Tumor markers, 322
Lawrence W. Bond

22 Laboratory investigation of sexual assault, 330
Charles G. Massion

PART THREE

TOXICOLOGY, HEAVY METALS, AND THERAPEUTIC DRUG MONITORING
David C. Hohnadel

23 Basic pharmacokinetics, 334
Ann Warner

24 Techniques of drug analysis, 346
Louis H. Steinert
Norman B. Coffman

25 Heavy metal analysis, 363
Donald J. Cannon

26 Therapeutic drug monitoring and antibiotics, 375
Victor Mondy

27 Emergency overdose toxicology, 384
Michael Hassan

28 Legal aspects of drug screening, 393
Amadeo J. Pesce

PART FOUR

URINALYSIS, CLINICAL MICROSCOPY, AND FLUIDS
David C. Hohnadel

29 Urinanalysis, 402
Michael D.D. McNeely
Malcolm L. Brigden

30 Serous, cystic, and synovial fluid analysis, 422
Gordon N. Hoag
Michael D.D. McNeely
Malcolm L. Brigden

31 Seminal fluid analysis, 425
William Daniel Follas
John K. Critser

32 Gastrin and gastric fluid analysis, 446
Stanford Marenberg

PART FIVE

IMMUNOLOGY
Richard C. Tilton

33 Immunobiology, immunochemistry, and immunopathology, 448
Mario R. Escobar

34 Antibody detection for the diagnosis of infectious disease, 467
Thomas J. Tinghitella

35 The human leukocyte antigen system, 476
Petrina V. Genco

36 Immunodeficiencies and autoimmune disorders, 485
Gayle B. Jackson

PART SIX

CLINICAL MICROBIOLOGY
Albert Balows

37 Contemporary approaches to clinical microbiology, 506
Albert Balows

38 Quality assurance in clinical microbiology, 511
Ron B. Schifman

39 Specimen collection, transport, and initial processing, 523
Richard C. Tilton

40 Principles and practices for the laboratory guidance of antimicrobial therapy, 532
Janet A. Hindler
Linda M. Mann

41 Microbial antigen detection, 565
Richard C. Tilton

42 Nucleic acid amplification techniques for the diagnosis of infectious diseases, 572
David H. Persing

PART SEVEN

MICROBIOLOGICAL ANALYSIS OF CLINICAL SPECIMENS
Albert Balows

43 Upper respiratory tract specimens, 584
Michael A. Gerber

44 Lower respiratory tract specimens, 591
Michael A. Saubolle

45 Central nervous system specimens, 604
Stephen G. Jenkins

46 Eye and ear specimens, 614
Stephen G. Jenkins

47 Gastrointestinal tract specimens, 627
J. Michael Miller

48 Urinary tract specimens, 633
Marie Pezzlo

49 Blood specimens, 641
Melvin P. Weinstein

50 Genital specimens, 649
Sandra Larsen

51 Wound, body fluid, and surgical specimens, 662
Robert C. Jerris

52 Hair, skin, and nail specimens, 673
Nancy L. Anderson

PART EIGHT

THE SYSTEMATIC IDENTIFICATION OF CLINICALLY SIGNIFICANT MICROORGANISMS
Albert Balows

53 Bacteriology, 686
David L. Sewell

54 Fungi, 727
Richard C. Tilton

55 Viruses, 765
Mark A. Neumann

56 Parasites, 792
Lynne S. Garcia

PART NINE

HEMATOLOGY
Robert F. Reiss

57 Hemopoiesis and cell kinetics, 812
Jay E. Valinsky

58 Morphology of the hematopoietic system, 830
Robert F. Reiss

59 Quantitative evaluation of the hematopoietic system, 859
Edward R. Burns
Barry Wenz

60 Flow cytometry and phenotyping of hemopoietic cells, 879
Jay E. Valinsky

61 Laboratory diagnosis of erythroid disorders, 898
Robert F. Reiss

62 Laboratory diagnosis of granulocyte disorders, 938
Robert F. Reiss

63 Laboratory diagnosis of lymphoid disorders, 961
Robert F. Reiss

PART TEN

HEMOSTASIS
Robert F. Reiss

64 Normal hemostasis, 996
Robert F. Reiss

65 Laboratory evaluation of hemostasis, 1007
Robert F. Reiss

66 Laboratory diagnosis of hemorrhagic disorders, 1025
Robert F. Reiss

67 Laboratory diagnosis and management of thrombotic disorders, 1045
David Ciavarella

PART ELEVEN

IMMUNOHEMATOLOGY AND TRANSFUSION PRACTICE
Robert F. Reiss

68 Blood group antigens and antibodies, 1064
Carol L. Johnson

69 Laboratory techniques in immunohematology, 1084
Arlene S. Gingras

70 Immune hemolysis, 1101
Robert F. Reiss

71 Blood collection, processing, and storage, 1109
Joan Uehlinger

72 Transfusion of blood components and fractions, 1121
Robert F. Reiss

73 Complications of blood transfusion, 1132
Harold S. Kaplan

PART TWELVE

CYTOGENETICS

74 Cytogenetics, 1144
Peter A. Benn

APPENDICES

Chemistry Reference Intervals, 1168
Periodic Table of the Elements, 1178

COLOR PLATES

1 to 65 following page 562

PART ONE

INTRODUCTION TO LABORATORY MEDICINE

1 Laboratory organization and management

Richard C. Tilton
Melissa Martincich

This chapter briefly presents some guidelines for the organization and management of a clinical laboratory. The presentation is neither exhaustive nor comprehensive. Rather, it is designed to stimulate questions regarding laboratory management, to provide an outline of necessary administrative functions, and to introduce fundamental information to laboratorians whose primary tasks may be analytical rather than administrative.

LABORATORY STRUCTURE

Traditional laboratory administrative structure has developed from an organization plan that was originally designed to implement laboratory testing in the most efficient manner. Figure 1-1 depicts this simple structure.

The laboratory was usually administered by a pathologist whose chief role in the hospital was in anatomic pathology. Supervisors in each of the laboratory sections reported to the chief technologist. There was little administrative distinction between the clinical laboratory and pathology department. The laboratory, being a high profit center, underwrote losses incurred by other non-revenue generating hospital functions. The last decade, however, has seen significant change, not only in how the laboratory relates to the hospital in a fiscal sense, but how the laboratory interacts in an increasingly complex and highly regulated health care environment. Figure 1-2 more typically portrays the laboratory of the 1990s. This table of organization is more characteristic of a commercial laboratory, but as hospital clinical laboratories develop outreach programs or spin-off for profit facilities, the distinctions become less apparent.

Whereas tables of organization may differ markedly from institution to institution, the point to be made is the growing complexity of laboratory medicine as a discipline, now separate and distinct from pathology services. Doctoral scientists and pathologists may not be hospital employees, but may be partners in a group practice that lease laboratory space from the hospital.

New health care financing plans (DRGs, Medicare, HMO's) have seriously limited profitability of the laboratory. Consequently, as a result of regulatory constraint, a new focus on laboratory management has emerged. Lines of authority once traditionally controlled by the laboratory are now managed by hospital administration. No value judgment should be placed on these changes, only the recognition that hospital ancillary services management has become an enigma; that is, how to administer a technologically burgeoning organization in an environment of severe fiscal constraint, regulation, and oversight.

THE INTERFACE OF LABORATORY SCIENCE AND BUSINESS

Laboratory services annually constitute a multibillion dollar health care expenditure. Yet, in many respects, the laboratory has not caught up with the changing face of medical practice. The clinical laboratory must provide service in a complex environment of:

- Decreased hospital inpatient census
- Expanded outpatient medicine, i.e., surgery centers, and so on
- Shortened inpatient stays
- Inpatients requiring major therapeutic intervention and intensive support systems, i.e., critically ill inpatients
- Demand for rapid turnaround time for laboratory tests
- Point-of-use testing
- Long-term (non-hospital) care facilities with an increasing role in acute care
- Large group practices with increased need for a wide variety of tests
- Increased patient expectations of quality and cost containment

Laboratories have struggled to meet these needs and changes in a variety of ways, including the following:

- Active marketing of laboratory services within the community to maximize profit.
- Satellite laboratories specializing in point-of-use testing, particularly to support single day medical intervention clinics, operating rooms, intensive care units.
- Electronic communication and information transfer to reduce turnaround time.
- Mechanization and automation of laboratory procedures to minimize use of a shrinking work force.
- Increased use of private reference laboratories for non-profitable testing.

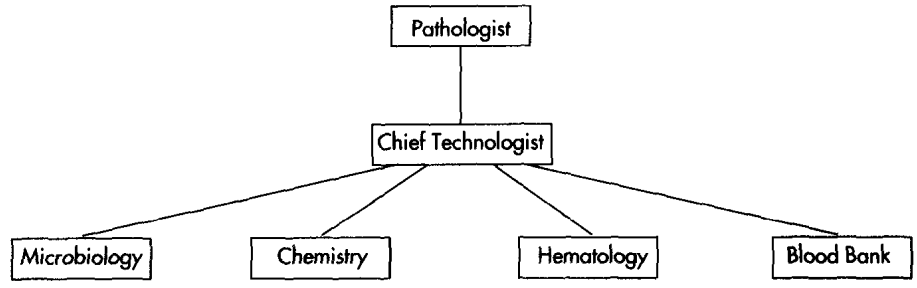

Fig. 1-1 A traditional table of organization for a small clinical laboratory.

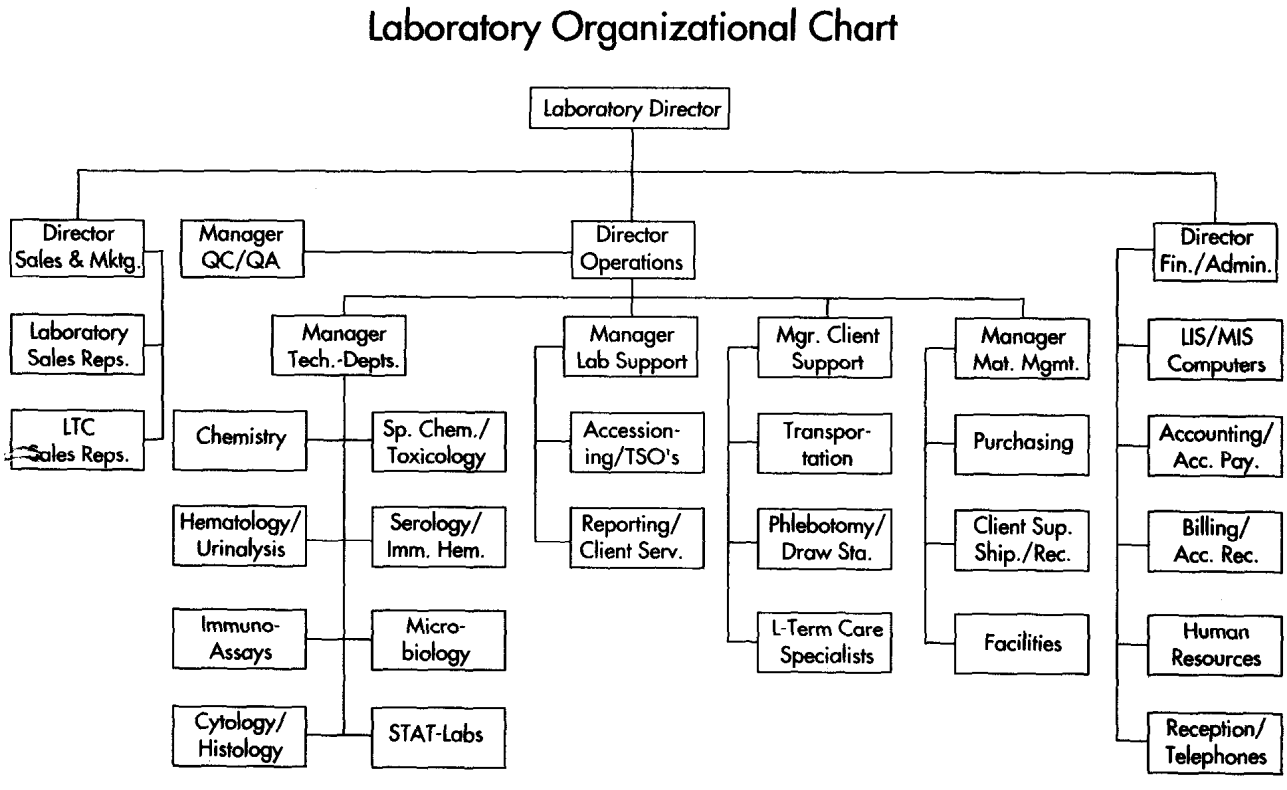

Fig. 1-2 A typical laboratory table of organization. (Modified from Mattice and Associates, Vancouver: 1991.)

- Trends toward centralization of laboratories within communities or specialty allocation (hospital A does endocrinology, hospital B does immunology).

There has also been a blurring of intralaboratory turf because of changing technology and manpower utilization. For example, hepatitis and human immunodeficiency virus (HIV) serology may be done through the blood bank, automated testing for infectious disease through the chemistry laboratory, and urinalysis through the microbiology laboratory. Almost all primary care physicians in the United States have access to an office laboratory. There is active marketing and sales of small, cost-effective analyzers that can perform chemistry profiles and enzyme-linked immunosorbent assays (ELISAs), as well as single use rapid tests for group A streptococcus, *Chlamydia*, and several other infectious disease agents. Such changes may radically alter the balance of testing between the hospital laboratory and the physician office laboratory (POL). Existing and emerging restrictions on POLs regarding personnel qualifications and quality control, promulgated in 1992 as a result of the Clinical Laboratory Improvement Act of 1988 (CLIA 1988), may again affect this delicate balance.

The increase in self-testing cannot be ignored and is best illustrated by home pregnancy and ovulation kits, as well as home monitoring of blood glucose by diabetics.

LABORATORY FINANCIAL PLANNING

The contemporary laboratory is financially complex as well as technically sophisticated. Annual budget development time is not the favorite time of year for most laboratories. However, because of the changing nature of laboratory services, all must recognize that the operating budget and the financial plan are the critical interfaces between medicine and business. In fact, most organizations now rely on ac-

counting professionals to organize and prepare their periodic financial status reports. However, it is critical for laboratory staff to appreciate the variety of management tasks and reports required to ensure the success of what is often a multimillion dollar business. For even a small laboratory, some elements of financial planning include:

- Income from laboratory tests (prediction of increases or decreases in test volume by laboratory section)
- Numbers of personnel required to satisfy sales forecasts
- Assessment of personnel productivity (e.g., College of American Pathologists [CAP] Workload Recording Plan)
- Anticipated needs in reagents, supplies, disposables
- Anticipated union contracts or budgeted pay increases
- Cost of continuing education
- Debt service (if any)
- Capital equipment (new and replacement)
- Quality assurance costs (external proficiency testing, etc.)
- Plan for monitoring variable costs
- Plan to control costs once budget is accepted
- Analysis of individual test fees; determination of margin for each test performed in laboratory
- Estimate of laboratory overhead (utilities, etc.)

PERSONNEL

Regardless of the layers of federal, state, and private regulations of the clinical laboratory, innumerable quality assurance (QA) probes, and internal and external test quality control, the best assurance that a laboratory reports accurate, reproducible results is the quality of personnel who perform the tests. Several personnel issues are critically important and are outlined here.

Educational background

There has been a tendency for federal agencies to attempt to lower personnel standards by minimizing the need for formal education in the clinical laboratory sciences. Increasingly complex instruments, molecular diagnosis, and demands for increased quality and rapid turnaround time clearly indicate that all laboratory personnel must be better educated and trained. For example, that a baccalaureate degree should be the minimum requirement for a technologist, and an associate degree the minimum requirement for a technician.

Certification

Certification of scientific and clinical competency by examination is a necessary prerequisite for a quality work force. There are a number of certifying agencies, such as the American Society for Clinical Pathology (ASCP), the American Academy of Microbiology, and the American Association of Clinical Chemistry. Personnel must be encouraged to become certified and their successful efforts rewarded with salary increases.

Continuing education

Continuing education is becoming increasingly expensive. However, continuing education is essential (mandatory if the laboratory is CAP accredited) to guarantee that workers who are judged competent by possession of a degree and certification continue to remain knowledgeable of the many changes in laboratory medicine. Some of the best continuing education classes are sponsored by local and regional groups such as the American Society for Medical Technologists (ASMT) and the laboratory specialty associations. Similarly, local programs exist for all specialty areas of the laboratory.

Once the laboratory has set in place a system for judging initial quality of applicants and increasing their competency through education, then other personnel issues become critically important to both the professional and the technical staff.

These issues include:

- Laboratory safety and health
- Career development and advancement (career ladders)
- Pleasant working environment
- Schedules of time off, vacations, etc., that are fair and consistent with the need to provide adequate clinical laboratory support

MANAGEMENT PHILOSOPHY AND STYLE

Volumes have been written about, degrees have been given for, and courses have been designed around the philosophy of management and how best to select a style that maximizes the talent of the employees and the strength of the management team. Some caveats that may prove useful include:

- Manage By Objectives (MBO): Set reasonable, attainable goals and provide tools for the work force to achieve those goals. An example of a goal might be to achieve 100% success in the parasitology proficiency testing program or in an area in which the laboratory has been weak.
- Manage By Example (MBE): Don't expect high performance of others if you cannot or are unwilling to measure up to the same standards of performance.
- Manage By Consensus (MBC): Seek advice of staff before making a management decision, recognizing that some decisions cannot be made by consensus and may not be popular.
- Avoid or discourage destructive conflict: In any group of interacting individuals, conflict management may be the skill that is most difficult to learn and the hardest to practice.
- Praise in public, admonish in private: Publicize the efforts of exemplary employees, but do not publicly chastise an employee or hold him or her up to criticism in the presence of fellow workers.

Whereas MBO is still the favorite management style in most laboratories, a combination of MBO, MBE, and MBC may be preferable in certain instances.

QUALITY CONTROL/QUALITY ASSURANCE

The scope of most clinical laboratories is now so broad and the interactions between laboratory technical operations, professional consultation, marketing, and finance so complex that the laboratory management is better served by the professional manager. Thus, the medical or scientific director of the laboratory should be relieved of much of the responsibility of the day-to-day management functions. However, the advent of professional laboratory managers has not diminished the role of the pathologist or clinical

laboratory scientist; it has allowed them to play a much more proactive role in what is clearly the most important and also the most difficult part of the laboratory operation—quality assurance. The dilemma faced by all laboratorians is how to maintain the balance between financial constraints and high quality output. The clinical laboratory exists to provide data that assist clinicians in making medical decisions. Laboratory medicine uses successful outcome to measure quality. That is, quality is result-oriented. One has only to look at new stringent proficiency testing requirements in CLIA 1988 in contrast to a growing egalitarianism in personnel standards to understand the trend. Throughout this book, the chapters that follow discuss and review quality control guidelines. The laboratorian is advised to pay close attention to avoid some very unpleasant sanctions by one or more regulatory agencies.

REGULATION

Laboratories are regulated by local, state, private, and federal agencies. A single laboratory may be inspected and/or proficiency tested by the state in which it resides, the city in which it intends to do business, the College of American Pathology (CAP), the American Association of Blood Banks, the American Board of Bioanalysts, the Joint Commission on the Accreditation of Hospitals (JCAOH), HCFA, and other agencies of the Department of Health and Human Services. Regulations are in dynamic flux to the extent that guidelines presented today may be changed tomorrow. It is impossible to even summarize all of the regulations pertaining to the operation of a clinical laboratory. However, some of the more pertinent ones are presented with the understanding that they are subject to change and may vary as some state regulations take precedence.

The basis for federal regulation of laboratories, in particular those involved in interstate testing, has been the Clinical Laboratory Improvement Act (CLIA) of 1967. An outline of the evolution of CLIA from 1967 to 1991 follows.

Clinical laboratory improvement act of 1967

- Regulates interstate testing for independent laboratories
- Adopts Medicare standards for technical personnel
- Exempts hospital laboratories
- Requires proficiency testing
- Is administered by the Centers for Disease Control (CDC) in Atlanta

Initially, a laboratory designated as being able to receive fees for service for tests performed on Medicare and Medicaid patients had to operate under somewhat different regulations than a laboratory (even the same laboratory) operating under CLIA-67. In 1988, new legislation under CLIA-88 brought all laboratories under a single set of rules for payments and regulations for patients, personnel qualifications and provision of certain laboratory tests. Final rules were published in 1990 and were effective September 10, 1990. Proficiency testing under these new rules was effective January 1, 1991. It should be noted that many of these revisions were incorporated into CLIA 1988.

There are some exceptions to CLIA 1967 (revised). Rules *do not apply* to physician office laboratories who only test their own patients, health maintenance organizations (HMOs) and rural health clinic laboratories, insurance testing laboratories, and specimen collection and mailing facilities who do not perform tests.

Under the CLIA 1967 (revised) and CLIA 1988, laboratories must comply with all federal, state, and local laws regarding health and safety of patients, laboratory licensure, staff licensure, fire safety, and handling, storage, and disposal of hazardous materials.

One of the most important aspects of the CLIAs is proficiency testing. Proficiency testing specimens must be tested using the laboratory's routine procedures. There may be no discussion of proficiency testing results among laboratories. Unsuccessful participation is defined as two consecutive or two out of three unsatisfactory testing events, or two out of three failing scores for the same analyte. The number of samples has been increased to five per event. A satisfactory score is at least 80% (100% for immunohematology). Before Medicare or CLIA certification can be issued, a laboratory must receive a satisfactory score in one proficiency testing event.

The most radical changes brought about by CLIA 1967 (revised) and CLIA 1988 are evident in cytology. Changes include the following:

- Workload limit of 120 slides in 24-hour period
- Maximum number of 120 slides must be examined in no less than 6 hours
- Limit of 80 unevaluated slides per day, the remaining 40 slides can be examined for quality control purposes only
- More stringent requirements for record keeping, quality control, and quality assurance

Cytology proficiency testing is summarized as follows:

- One proficiency test performed annually at designated testing site
- One proficiency test performed annually that was unannounced on-site
- Each cytotechnologist must take part in two proficiency test events per year
- A score of at least 80% must be attained
- If a score of less than 80% is achieved, the last 500 slides examined by that individual must be reexamined by a cytotechnologist who passed

For all sections of the laboratory, there are new requirements for patient test management:

- Written specimen labeling instructions for clients
- Test requisition to include age, sex, date of birth, and clinical information
- Preliminary laboratory results must be kept for 2 years
- Pathology reports must be kept for 10 years
- "Panic" (results that require immediate attention) value reporting procedure must be in place

Quality assurance/quality control measures for all laboratory sections include the establishment of policies and procedures to: (1) monitor and evaluate quality; (2) identify and correct problems; (3) assure prompt, accurate, and reliable result reporting; and (4) assure that the laboratory is adequately and competently staffed.

More specifically, the following measures should be taken:

- Facility ventilation must be adequate for testing and reporting.
- Temperature and humidity must be monitored.

- There can be no mixing of kit components of different lots.
- A procedure manual including instructions for slide preparations and calculations must be maintained.
- Daily equipment function checks must be performed before patient testing.
- Adherance to equipment manufacturers' quality control recommendations.
- Quality control procedures for equipment are to be performed at least each day of use.
- More stringent calibration and verification requirements are necessary.
- Control samples should be tested in the same manner as patient's samples.
- Immunohematology records should be kept for 5 years.

For hospital-based laboratories, the laboratory director must be either a pathologist (MD/DO) with laboratory training and experience, or have a PhD in the life sciences with laboratory training and experience, or be a director qualified under state law.

Technical supervisors are required if the laboratory performs testing in the following areas:

- Histocompatibility
- Histopathology
- Blood banking
- Cytology
- Clinical cytogenetics
- Dermatopathology
- Transfusion services
- Oral pathology

Other personnel standards have been proposed under CLIA 1988 based on the complexity of laboratory testing. However, it is not anticipated that personnel requirements for hospital laboratories will change. The Clinical Laboratory Improvement Act of 1988, to be administered by the Health Care Financing Administration (HCFA), was prompted by the "Pap Smear Scandal" and the fact that relatively few states (14) have laboratory licensure laws. The process of rule making has been tortuous and final rules, after much debate, are to be published by January of 1992. Some additional features of CLIA 1988 include:

- Varying standards based on test complexity: "simple testing, moderately complex, highly complex" testing
- The requirement that all laboratories, except Department of Veteran Affairs (VA) laboratories, research laboratories, and insurance testing laboratories must have either a waiver or a certificate
- User fees to finance the program
- Proficiency test standards, further tightened over CLIA 1967 (revised), to come into effect in January of 1994
- Provision for publishing a list of problem laboratories

Under the present proposed rules, a waiver will be granted to laboratories performing only the following tests (these laboratories will, in most instances, be physician office-based):

- Urine dipstick or tablet urinalysis
- Ovulation tests
- Urine pregnancy tests
- Fecal occult blood
- Hemoglobin (copper sulfate)
- Erythrocyte sedimentation rate

The majority of these tests are available to patients in over-the-counter test kits. There are no personnel requirements for a laboratory performing only waived tests. Personnel requirements have been published, however, for a moderately complex laboratory. They include requirements for laboratory director, technical consultant, clinical consultant, and testing personnel. For a highly complex laboratory, all of the above are included along with technical supervisor, general supervisor, and testing personnel assistant.

There are enforcement procedures that will interconnect state, federal, and private accrediting agencies. It will be impossible to be sanctioned by one agency and continue to operate under another agency. Sanctions include suspension, revocation, or limitation of license, denial of Medicare payment, and civil penalties including fines and jail terms.

Not all sanctions can be appealed. For example, if it is determined not to reinstate a CLIA certificate, this action cannot be appealed. In addition to CLIA 1967 (revised) and CLIA 1988, there are a number of other laws that have been introduced or passed. They include:

- The Stark Amendment: This deals with physician test referral to laboratories in which physicians have an interest
- Safe Harbors: delineates fraud and abuse practices relevant to clinical laboratories
- Medicare/Medicaid Anti-Kickback Act of 1977
- Rural Laboratory Personnel Shortage Act
- A variety of health care reform bills

INTERACTION WITH REFERENCE LABORATORIES

Very few, if any, clinical laboratories performs all of their requested testing in-house. Therefore, the use and selection of a reference laboratory is virtually universal. Choosing a reference laboratory should be based on quality, service, turnaround time, and accessibility of experts for consultation. Fiscal restraint often dictates that the decision may be made based on the lowest bid for laboratory services. Such low bid situations are not always satisfactory. The laboratory is usually left to make a most important decision, whether or not to send out the test or perform it in-house. Certain elements outlined in Box 1-1 should be considered when making such a decision.

It is recommended that laboratories designate one person to coordinate reference laboratory testing and develop a workflow for the referral process. Box 1-2 outlines some typical tasks of a "send out" section.

There are many problems that can arise when using reference laboratories. Most can be avoided by developing a working relationship with a responsible and knowledgeable person at the reference laboratory. This is most often the client services coordinator. Problems such as STAT pickups, unreliable courier service, inaccessibility of technical people, lost specimens, or misunderstood or missing interpretation of data must be reconciled before a professional partnership between the client and the reference laboratory is a reality. The most common problem encountered is too long a turnaround time, which results in physicians calling to find out test results. Many reference laboratories provide a list of expected turnaround times, but they produce a test schedule less often. With both lists, the referring laboratory