

# Clinical Laboratory Management

Shakti Kumar Yadav  
Ruchika Gupta  
Sompal Singh  
*Editors*

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Editors

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 Springer

*Editors*

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*Dedicated to Our Parents and Teachers*

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## Foreword

Clinical Laboratory plays a vital role in the modern healthcare by assisting physicians in screening, diagnosis, and prognosticating various diseases. This book *Clinical Laboratory Management* has been brought out at a very appropriate time. The book focuses on multidimensional aspects of laboratory management, tackling everything from resource management and quality control to the integration of technological advancements and a sneak peek into the marketing aspects of clinical laboratories.

Recognizing the need for a systematic approach in clinical laboratory management, the authors have methodically curated the content of this book that will guide the beginners as well as the professionals in the field. This book offers readers an essential tool to navigate this evolving field. The authors delve into the important but hitherto neglected aspect of recruitment, selection, and performance management of laboratory personnel. Careful and due attention has been paid to the subject of quality control in a laboratory, both internal and external quality assurance. Laboratorians would find this book a useful guide for quality control in different types of laboratories—ranging from hematology and biochemistry to histopathology to molecular laboratories. Laboratory errors (pre-analytical, analytical, and post-analytical) and various hazards in a laboratory have also been discussed in adequate detail in this book.

Since many laboratory managers, especially pathologists, also manage blood transfusion services, the organization and quality control of a blood bank have also been included in this book. The contemporary topics of ethical and legal issues, the vitality of consent, and the concept of negligence and malpractice in a laboratory have also been touched upon. Laboratorians managing their own laboratory practice would find the section focused on marketing activities useful to them.

The exemplary work and dedication of the editorial team, Dr. Sompal Singh, Dr. Ruchika Gupta, and Dr. Shakti Kumar Yadav, along with their col-

lective expertise, knowledge, and years of professional experience in the field, give this book an indispensable authority and relevance.

Each of the editors and the distinguished authors have contributed their unique insights and deep understanding of pathology and laboratory management. Their diverse backgrounds and holistic approach has helped create a book that would serve as an exhaustive guide for anyone interested in Clinical Laboratory Management.

I wish the entire team of this book great success!!!

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## Preface

Medical and paramedical personnel acquire considerable knowledge of “management” with experience over the period. However, for a young professional who is just starting their own clinical laboratory setup or is recruited in a managerial position in a clinical laboratory, there is a felt need for an understanding of the managerial aspects, especially in an institutional setting. Although this knowledge can be acquired from books on general management subjects, there is a paucity of books dedicated to clinical laboratory management. Hence, there is a need for a simple and concise text for management in clinical laboratory practice.

This book has been written by experts from all the major fields of clinical laboratory, viz. pathology, biochemistry, and microbiology, as well as by professionals from the fields of community medicine and research. It has been designed keeping in mind the need for scientific management and total quality control in a laboratory practice. Hence, this book shall be useful for clinical laboratorians, students of medical laboratory technology, laboratory managers, and hospital managers.

The book has been logically divided into ten parts with 50 chapters written in an easy-to-comprehend language, especially for those who have not been trained in the core management concepts. The first part “Introduction to Laboratory Management” makes the reader familiar with the general aspect of management. This is followed by “Human Resource Management” that describes the basic principles, and topics like job analysis and job evaluation, recruitment and selection, performance management, staff scheduling, and conflict management. This section will help readers to efficiently manage the workforce in their clinical laboratory setting.

The next part on “Finance and Accounting” gives a brief overview of financial decision making and general accounting principles that should be known at least to individuals operating their own laboratories. The “Organization and Operations” part is dedicated to organizational structure from the hospital to individual laboratory level. This part also gives insights on important aspects of factors affecting the decision of location of a laboratory and its facility design, equipment and inventory management, supply chain management, selection of reference laboratory services, management of remote collection center and sample logistics, and point of care testing. Aspects of clinical laboratory design pertaining to persons with disabilities have been covered in a dedicated chapter.

An elaborate part on “Quality Control” explains internal quality control and external quality assessment in various sections of a clinical laboratory (not restricted to hematology and biochemistry laboratories) and blood transfusion services. The part on “Documentation and Information Systems” explains the importance of document control, SOP writing, role of information technology, and electronic health record management. The book also includes parts on “Laboratory Hazards and Safety” to describe hazards management and key aspects of biomedical waste management in a clinical laboratory setting, and “Legal and Ethical Aspects” including the concept of negligence and malpractice and the role of consent pertaining to a laboratory. The part on “Planning, Accreditation and Licensing” gives a detailed outline on how to plan a clinical laboratory and a blood bank, and explains the importance and the process of accreditation of a laboratory and obtaining a blood bank license.

The last part covers management aspects like market basket analysis, promotional activities, corporate social responsibility, customer feedback, risk management, internal audit, and management review meeting pertaining to clinical laboratory management.

We hope that this book will be useful for readers to understand the managerial aspects of a clinical laboratory and serve as a guide for more efficient clinical laboratory managers.

Shakti Kumar Yadav  
Ruchika Gupta  
Sompal Singh

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## Acknowledgments

We gratefully acknowledge the guidance and encouragement provided by Prof. Tejindar Singh, the first teacher of pathology and laboratory management for Dr. Singh and Dr. Gupta and a guiding force behind this book, without whose inputs, this book would have been incomplete. Our sincere thanks are due to Prof. Ashok Kumar Mukhopadhyay who provided inspiration and motivation for writing this book. Through this book we take the opportunity to thank our seniors and colleagues for their constant support and help in every way in making the dream of this book a reality. We would also like to thank the students of B.Sc. (MLT) who motivated and encouraged us to write a simple yet comprehensive book on this subject. The strong support given by our families during the times we immersed ourselves in the writing and editing of this book helped us sail through such difficult times with ease. Last but not the least, thanks are due to our patients who always look forward to quality laboratory services; this book would not have been possible without their thoughts in our minds.

Shakti Kumar Yadav  
Ruchika Gupta  
Sompal Singh

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**Sompal Singh, BSc, MBBS, MD, MBA,** is currently working as Senior Specialist in the Department of Pathology at Hindu Rao Hospital and North Delhi Municipal Corporation Medical College since 2005. He pursued his MD Pathology from Maulana Azad Medical College, New Delhi, followed by senior residency at the same institute. He conducted cell culture research during his senior research associateship from CSIR, New Delhi. He is a qualified statistician and a trained computer programmer. He holds 150 research publications in various national and international journals to his credit. He also has coauthored two books for paramedical students, one for medical undergraduate students, and one on biomedical statistics. He has a keen interest in teaching, medical education research, and breast pathology.

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## Abbreviations

AAB	American Association of Bioanalysts
AABB	Association for the Advancement of Blood and Biotherapies
ADASP	Association of Directors of Anatomic and Surgical Pathology
AMC	Annual maintenance contract
AON	Average of normals
AST	Antimicrobial susceptibility testing
ATCC	American Type Culture Collection
BARS	Behavior-anchored rating scale
BMW	Biomedical waste
BSL	Biological safety level
CAP	College of American Pathologists
CCM	Customer Complaint Management
CDC	Centre for Disease Control
CDSCO	Central Drugs Standard Control Organization
CLIA	Clinical Laboratory Improvement Act
CLSI	Clinical and Laboratory Standards Institute
CMC	Comprehensive maintenance contract
CPFR	Collaborative planning, forecasting, and replenishment
CSAT	Customer Satisfaction Score
CSR	Corporate social responsibility
CUSUM	CUMulative SUM
DGCI	Drugs Controller General (India)
DI	Deviation Index
DICOM	Digital Imaging and Communications in Medicine
DTCT	Direct-to-consumer testing
EAC	European Accreditation Cooperation
ECCLS	European Committee for Clinical Laboratory Standards
EHR	Electronic health records
EMR	Electronic medical records
EOQ	Economic order quantity
EQA	External quality assurance
FFP	Fresh frozen plasma
FMEA	Failure mode effect analysis
FNAC	Fine needle aspiration cytology
FRACAS	Failure reporting, analysis, and corrective action system
FSR	Frozen section review
GAAP	Generally Accepted Accounting Principles

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HIPAA	Health Insurance Portability and Accountability Act
HR	Human resource
HRM	Human resource management
IAAC	Inter-American Accreditation Cooperation
ICSH	International Committee for Standardization in Hematology
IFCC	International Federation of Clinical Chemistry and Laboratory Medicine
IIR	Inter Institutional Review
ILAC	International Laboratory Accreditation Cooperation
ILO	International Labor Organization
IPC	Indian Penal Code
IQC	Internal quality control
ISO	International Organization for Standardization
IVD	In vitro diagnostic
KPI	Key performance indicator
LIMS	Laboratory information management system
LIS	Laboratory information system
MBO	Management by objectives
MLT	Medical laboratory technology
MoHFW	Ministry of Health and Family Welfare, Government of India
MRA	Mutual recognition arrangements
MRM	Management review meeting
NABL	National Accreditation Board for Testing and Calibration Laboratories, India
NACO	National AIDS Control Organization
NBTC	National Blood Transfusion Council, India
NIBSC	National Institute of Biological Standard and Control
NPS	Net Promoter Score
NPV	Negative predictive value
ONC-ATCB	Office of the National Coordinator—Authorized Testing and Certification Bodies
OSHA	Occupational Safety and Health Administration
P&L	Profit and loss statement
PAQ	Position analysis questionnaire
PC-PNDT	Pre-conception and Pre-natal Diagnostic Techniques
POCT	Point of care testing
POSH	Protection of Women Against Sexual Harassment at Workplace Act
PPV	Positive predictive value
PT	Proficiency testing
QA	Quality assurance
QC	Quality control
QMS	Quality management system
RCPAQAP	Royal College of Pathologists of Australasia Quality Assurance Programs
ROC	Receiver operating characteristic
ROI	Return on investment

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SADCA	Southern African Development Community Cooperation in Accreditation
SBTC	State Blood Transfusion Council (India)
SCF	Sample collection facility
SCM	Supply chain management
SKU	Stock keeping units
SMART	Specific, measurable, achievable, realistic, and time-bound
SOP	Standard operating procedure
TAT	Turnaround time
US-FDA	US Food and Drug Administration
WBCSD	World Business Council for Sustainable Development
WHA	World Health Assembly
WHO	World Health Organization

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**Part I**

**Introduction to Laboratory Management**



# Role of Medical Laboratory Technology in Health Care

1

Alekh Verma and Ruchika Gupta

## Background

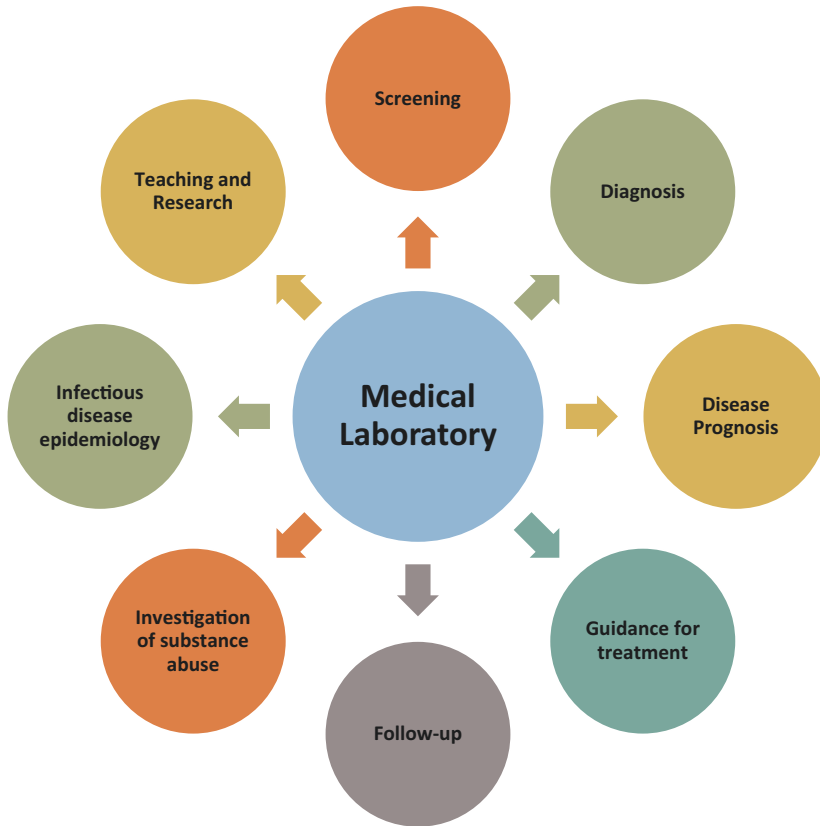
Health is defined by the World Health Organization as “*a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity.*” In today’s world, evidence-based medicine is the norm in healthcare. Medical laboratory technology (MLT) is a branch of science related to laboratory procedures performed in medical practice. The technical personnel in a medical laboratory not only assist the physicians in the diagnosis, monitoring, and appropriate management of diseases but also have a role in human and community health.

To understand the role of medical laboratory technology, we need to make ourselves aware of the various ramifications of laboratory techniques that have expanded in the last few decades. In the world of modern medicine, the medical laboratory has several specialized sections including microbiology, hematology, biochemistry, cytopathology, histopathology, immunology, blood banking, molecular biology, and cytotechnology. Through these specialties, medical laboratory technology plays a crucial role in many facets of healthcare such as screening, diagnosis, prognostication of various diseases, and so on and so forth (Fig. 1.1). We shall discuss these roles briefly in the ensuing sections.

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**Fig. 1.1** Various roles of a medical laboratory

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## Screening

Screening is the application of laboratory techniques to healthy (asymptomatic) individuals to detect diseases before it becomes clinically apparent. The best example of this role of MLT is cervical cancer screening where the staining and screening of cervical smears done by a cytotechnologist help in the early detection of cervical cancer. Similarly, hemoglobin electrophoresis or high-performance liquid chromatography (HPLC), genetic testing, or non-invasive prenatal testing performed by laboratory technical personnel help in the detection of hemoglobinopathies during the antenatal period, thereby preventing the birth of a thalassemia major child.

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## Diagnosis

The diagnostic role of medical laboratory technology is far-reaching and well accepted that is exemplified by hematological techniques, biochemical tests, and microbiology tests, fine needle aspiration cytology, histopathological techniques to name a few.

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## Disease Prognosis

Once a diagnosis of a disease is made, prognostication of the disease, especially malignant disorders, is an essential aspect where clinicians rely on laboratory results. Hormone receptors and

c-erbB2/Her2neu expression in breast cancer or BRAF mutations in thyroid tumors have become the standard practice in cancer management today.

---

## Guidance for Treatment

Treatment of diseases, both malignant and chronic non-malignant has come a long way over the last century. “Targeted therapy” for various cancers such as the use of imatinib for treatment of tumors expressing c-kit protooncogene, trastuzumab for Her2neu-positive breast cancers, crizotinib for ALK-positive tumors are just a few examples. The institution of such targeted therapies mandates confirmation of the target oncogene expression or a signature genetic change in the cancer cells using various sophisticated laboratory techniques. Similarly, enzyme replacement therapy for diseases such as Gaucher’s disease, glycogen storage diseases, lysosomal storage disorders, hemophilia, and others require laboratory confirmation of the absence of the specific enzyme or the factor. Hence, the science of targeted therapy or enzyme replacement therapy requires close coordination and valuable inputs from the medical laboratory.

---

## Follow-Up

The use of effective therapy has helped in prolonging the life span of a lot of patients. In chronic diseases, including cancer, there is a requirement for regular follow-up with various laboratory tests to detect relapse of the disease early enough to allow for further control. There are numerous laboratory markers that fulfill this role of medical laboratories such as lipid profile, blood sugar, HbA1c, etc. for non-communicable diseases and tumor markers such as prostate-specific antigen (PSA), carcinoembryonic antigen (CEA), CA 19-9 for tumors of the prostate, colon, and ovary, respectively. Another instance of this role is the renal or liver function

tests and protocol biopsies, sometimes with special stains in post-transplant patients for early detection of graft rejection or graft-versus-host disease.

---

## Evaluation of Substance Abuse

Nowadays, laboratory techniques are being increasingly used in the evaluation of substance abuse. Laboratory tests to detect the use of banned substances such as lysergic acid diethylamide (LSD), amphetamine, and erythropoietin are routinely performed on athletes during qualifying rounds for various competitions. Critical jobs like aircraft pilots, armed forces on the war front, and medical professionals in critical areas of the profession among others are evaluated for use of alcohol prior to critical placements. Identification of cotinine in urine helps to identify tobacco use in an individual. Confirmation of the use of banned substances is also required in medico-legal cases and some legal processes. In the era of the ever-enlarging arena of health insurance as well as term insurance, there may be a requirement for testing of blood and urine for substance abuse. For example, some insurance firms offer their term insurance products only to non-smokers.

---

## Investigation and Surveillance of an Epidemic

Investigation and surveillance of an epidemic also require intensive use of medical laboratory technology, both basic tests and advanced investigations for identification of the causative organism and guide about the methods of control. The most recent instance of this role has been the COVID-19 epidemic where laboratorians played a significant role in identifying the causative organism, defining its characteristics, providing guidance on control measures on an individual and organizational level, and developing a vaccine for prevention of severe infection.

## Teaching and Training

One of the less recognized roles of medical laboratory technologists is their contribution to teaching and training future laboratory technologists and passing on the tricks of the trade. In addition, the involvement of laboratory technologists in medical research cannot be overemphasized. For instance, vaccine development, the introduction of new diagnostic procedures, molecular genetics, and others require the assistance of these personnel for the success of these procedures.

The following sections of this book intend to equip you with techniques and methods of running and managing your laboratory effectively,

efficiently, and to a considerable extent error-free so as to provide the best possible care to the patient.

---

## Suggested Reading

- Seyoum H. Introduction to medical laboratory technology. Haramaya University; 2006. [https://www.cartercenter.org/resources/pdfs/health/ephti/library/lecture\\_notes/med\\_lab\\_tech\\_students/medicallabtechnology.pdf](https://www.cartercenter.org/resources/pdfs/health/ephti/library/lecture_notes/med_lab_tech_students/medicallabtechnology.pdf).
- U.S. Bureau of Labor Statistics. Clinical laboratory technologists and technicians: occupational outlook handbook. <https://www.bls.gov/ooh/healthcare/clinical-laboratory-technologists-and-technicians.htm>.

# Overview of Laboratory Management

# 2

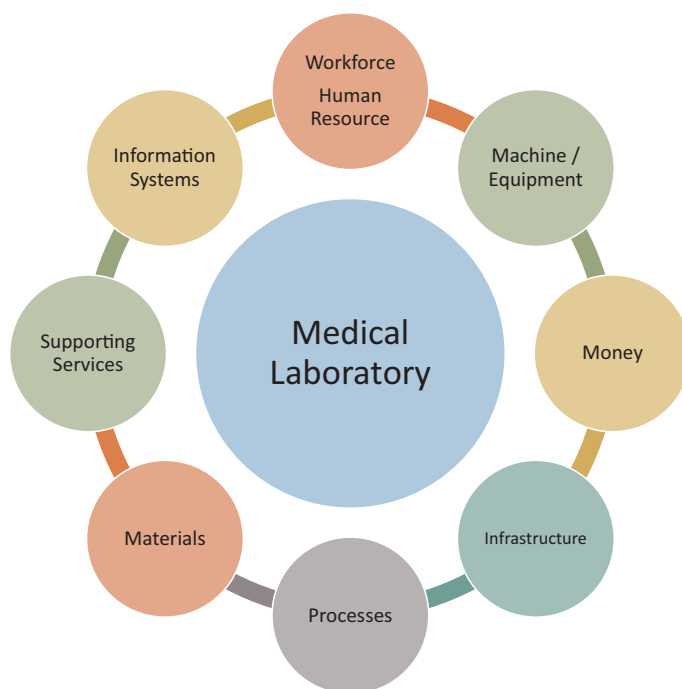
Alekh Verma and Sompal Singh

## Background

A clinical laboratory is an organization that requires multiple components for its function (Fig. 2.1). These include staff, machine, money,

infrastructure, processes, material, supporting services, and information systems. Let us learn a bit about these components to understand the laboratory as an organization.

**Fig. 2.1** Theoretical components required to run a clinical laboratory



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## Workforce

The manpower employed in/for the laboratory is an extremely valuable asset of a laboratory that includes the combined skills, knowledge, and abilities of the laboratory personnel. Hence, the management of this asset is imperative for the success of any laboratory. We shall discuss further this asset/resource in chapters on Human Resource Management (Part II).

## Machines/Equipment

For performing the required tests and providing service to the patients, a laboratory requires various equipment. The accuracy and precision of such tests depend in large measure on the condition of the equipment used. Hence, knowledge about their procurement, maintenance, and calibration is imperative and we shall discuss these further in the chapter on Equipment Management (Chap. 16).

## Money

There are two facets of the role of money in a clinical laboratory:

### Finance

Money is the basic requirement for starting and running any laboratory. The required capital for a laboratory can be acquired in the form of equity (self/private/public) or in the form of debt. There are various advantages and disadvantages of either of these sources. Readers will get a better understanding of these concepts in Chap. 10.

### Accounts

Once a laboratory is started, all the monetary transactions related to it need to be recorded, classified, compiled, summarized, and published (publicly if required) as per the relevant and prev-

alent industry guidelines and taxation laws. The Accounting Principles are briefly explained in Chap. 11 of this book.

## Infrastructure

Infrastructure for an organization, including a clinical laboratory, includes the physical location and layout of the same.

## Physical Location

The location of a laboratory may vary from being standalone to within the premises of a small clinic or a big hospital. When located within a hospital, the clinical laboratory should be located at a suitable location with easy access from the outpatient department as well as the emergency unit and the wards. At the same time, the location of the laboratory should not hamper the movements of other patients (not requiring the services of a laboratory) in the hospital. For a standalone laboratory, the location may be determined using appropriate management tools (center of gravity method, cost–profit volume analysis, point rating method, transportation method of linear programming, and so on).

## Layout and Design

The layout of a clinical laboratory needs careful consideration to ensure optimum functionality as well as comfort for the patients and the laboratory personnel. The various sections of the laboratory should be aligned keeping in mind the frequency of interaction of patients during the delivery of service. For instance, a reception desk at the front of the laboratory is desirable for any business, with a phlebotomy section adjacent to this, so that the patient may not need to traverse the laboratory for submitting a blood sample. The cabin of the customer care manager should also be as near to reception as possible. Within each room in the laboratory, equipment and furniture must be so arranged that the movement of techni-

cal persons and materials/reagents/samples is not interfered with or hampered. These topics are dealt with in more detail in Chap. 14.

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## Processes

Considering the clinical significance of laboratory reports, the importance of standardization and calibration of the equipment, materials as well as testing procedures cannot be overemphasized. The best approach to achieve this is to prepare and make available a published document or standard operating procedure (SOP) that is updated regularly and accessible at all the locations of its need. Of equal importance is a combination of internal quality control or external quality assessment to assess and maintain the quality of laboratory services. The readers are referred to Parts V and VI of this book for details.

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## Materials

A clinical laboratory uses numerous reagents and chemicals. Hence, material management/inventory management is an essential aspect of laboratory practice. Apart from guiding the laboratory personnel on what reagents are required according to the tests being performed, inventory management also provides answers to questions such as when to order, how much to order and classify reagents depending on the need. Procedures such as ABC analysis can be utilized for this purpose. Details of inventory management are available in Chap. 17.

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## Information System

With the increasing use of information technology and the requirement of close interaction with the clinician, laboratory information systems (LIS) have become an indispensable part of a clinical laboratory (Chap. 33). A typical LIS allows for integration of clinical information, ordering laboratory tests with their tracking and

receiving the results. Sometimes general office applications like email, word processor, power point presentations, spreadsheet application are required.

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## Document Control and Record Keeping

Document control and record keeping in a clinical laboratory should be as per the current guidelines of the relevant accreditation body such as College of American Pathologists in USA, National Accreditation Board for Testing and Calibration Laboratories (NABL) in India, or United Kingdom Accreditation Service in UK. Though such accreditation may not be mandatory for a clinical laboratory, having this accreditation provides credibility to the processes followed and the results provided by the said laboratory. Kindly refer to Chap. 31 for further details on this topic.

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## Ethical and Legal Aspect

Ethics and legal aspects are two inter-related but different concepts. Ethics is a positive concept that is voluntary and includes perception of the “right” and “wrong” of an action. Conversely, legal aspects are enforced by law and issues arise due to non-adherence or noncompliance. Patient consent and confidentiality of information are usually ethical aspects, though sometimes law such as Health Insurance Portability and Accountability Act (HIPAA) applicable in USA also covers this aspect, whereas malpractice and negligence are mostly legal in nature. These aspects are discussed in detail in Part VIII.

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## Laboratory Hazards

A clinical laboratory is a multifaceted and huge organizational system. Irrespective of the size of the laboratory, all kinds of hazards like physical (fire, radiation, sharps, moving parts), electrical, chemical, and biological are possible. Efforts