
UNIT 1 LABORATORY SERVICES

Structure

- 1.0 Objectives
- 1.1 Introduction
- 1.2 Role and Functions of **Laboratories**
- 1.3 Types and Functional Components of Laboratories (**Laboratory Medicine**)
 - 1.3.1 Functional Components
 - 1.3.2 Types of Laboratories
- 1.4 Concepts of Planning Organisation
 - 1.4.1 Physical **Facilities** and Layout
 - 1.4.2 **Equipment/Reagents** and **Facilities**
 - 1.4.3 **Resurch** and Training
- 1.5 Policies and Procedures
 - 1.5.1 Laboratory **Administration**
 - 1.5.2 **Quality Control, Quality Assesmnt. Accreditation and Total Quality Management (TQM)**
 - 1.5.3 **Leadership and Motivation**
 - 1.5.4 **Personnel** Management
 - 1.5.5 **Personncl** Policies
 - 1.5.6 **Job Description** and **Staffing**
 - 1.5.7 **Rccruitment, Policies** and **Procedures**
- 1.6 Information Management
- 1.7 Managerial Issues
 - 1.7.1 **Problems** of Management
 - 1.7.2 **Labaratory Hazards**
 - 1.7.3 Safely **Precautions** in the Laboratory
 - 1.7.4 **Laboratory Waste** Management
- 1.8 Control and Evaluation
- 1.9 Let Us Sum Up
- 1.10 Answers to Check Yaur Progress
- 1.11 Further Readings

1.0 OBJECTIVES

After going through this unit, you **should be** able to:

- list the roles und functions of laboratory:
- describe the types and functional components of a laboratory service;
- discuss the planning concepts in organisation of laboratory services;
- describe the policies and procedures concerned with laboratory services: and
- identify the key managerial issues in planning and **organisation** of laboratory services.

1.1 INTRODUCTION

In this unit you will learn **about** definition, types and **characteristics** of laboratory services and also about planning consideration, physical **facilities and** layout, You will also learn

about the use of equipment for various types of laboratories and staff requirement, need for training and research requirements. Further you will learn about the maintenance of minimum standards of laboratory quality assessment and various programmes of the country. Towards the end you will learn about the application of sound principles for personnel management, efficient and cost effective operation of a clinical laboratory with timely, effective delivery of medical laboratory services to clinicians and patients.

1.2 ROLE AND FUNCTIONS OF LABORATORIES

The laboratory as you know exists for the sole purpose of providing diagnostic and management information for the physicians to aid in the patient care, The ultimate goal of laboratory is to attend to the ailing patients, carry out the investigations asked and prompt issue of accurate results for favour of diagnosis and treatment.

The clinician uses the laboratory to get assistance in diagnosis and management of the patient. Infact, a test requisition is a request for consultative services which sets in motion a vast array of activities to generate a laboratory report. Usefulness of the data in making clinical judgements depends upon prompt, accurate reporting of the result. Each procedure to generate a result consists of series of steps, or processes. An adequate understanding of each process enables the laboratorian to achieve more nearly optimal conditions and, consequently, to improve the accuracy and precision of each measurement. Collection, handling and processing the specimen prior to analysis must receive prime consideration. Validity of data obtained on the specimen itself is highly dependent upon the excellence of laboratory technique, including proper manipulation of equipment, use of reagents of specified purity.

Check Your Progress 1

- 1) Define laboratory,

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- 3) Enlist three functions of laboratory.

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1.3 TYPES AND FUNCTIONAL COMPONENTS OF LABORATORIES (LABORATORY MEDICINE)

Having learnt the definition and functions of laboratory, now you will learn the functional components and types of laboratories.

1.3.1 Functional Components

The Functional components of a clinical laboratory are:

- i) Histopathology
- ii) Clinical Pathology
- iii) Microbiology
- iv) Haematology
- v) Biochemistry
- vi) Research laboratories

There are further subdivisions of each of the above components related to sub or super

specialisation. However, these are not enumerated here. Only the functional laboratories in routine day to day diagnostic work are summarised.

i) Histopathology

Laboratory performing organ, tissues, cell examination for the diagnosis of various types of **abnormalities/diseases** is called as Histopathology Laboratory. Examinations of **tissues/organs** are from **living/dead** body, in the form of either surgical specimen; biopsy or autopsy.

ii) Clinical Pathology

This is the branch of pathology in which all body fluids such as blood, urine, sputum, stool, pleural, peritoneal fluid are examined for physical, chemical, bacteriological and microscopic examination for normal or abnormal contents.

iii) Microbiology

This is the science which deals with study of microbes such as bacteria, viruses, parasites etc. The study involves the identification, morphological and cultural studies, serology and sensitivity of organisms responsible for **causing** the disease or commonly found as commensals.

iv) Haematology

Branch of laboratory Medicine in which the study of blood and blood components is done for detection of various abnormalities in normal and ill health.

v) Chemical Pathology (Biochemistry)

Science which determines and measures various chemical substances in normal and abnormal amounts produced during disease process. The study includes examination of various groups of clinical substances, hormones, enzymes, isoenzyme, vitamin and metabolites etc.

vi) Clinical Research Laboratories

Are those laboratories which **deal** with research related to patient care system or services, research related to development of techniques, methods and applications, therapeutic trials of drugs, reagents, kits, equipment development and **animal** experimentations. Research and development is an integral part of patient care services and such **laboratories** are designed for research and academic purpose.

1.3.2 Types of Laboratories

Most of the hospital laboratories function as:

- i) OPD Services
- ii) Ward Services
- iii) Emergency Services

i) OPD Services

OPD Laboratories are basically Central laboratories in a large hospital which caters to the need of out patient department during OPD hours.

ii) **Ward Services**

Ideally each **ward** is attached with functioning laboratory **catering** to needs of the ward for routine investigations. However, some ward laboratories are attached to respective specialities (Block system) i.e. Surgical; Medical; Paediatric; **Orthopaedics**; Obstetrics and **Gynaecology** etc. The investigations other than bed **side/routine** tests are referred to central ward laboratories of specific departments between 9-10 AM to 4-5 PM, normal duty hours of hospital.

iii) Emergency Services

These can be **24 hours (round the clock)** services or restricted emergency services,

a) **Round the Clock Services**

Majority of **hospitals having 100 bed capacity and above** should give round the clock emergency services. Each Emergency Service includes **3 shifts of duties (24 hours)**.

b) Restricted Emergency Services

These types of **emergency** laboratory services are restricted to one or two shifts excluding public holidays and national holidays.

These services are restricted to augment manpower in particular specific organisation and depends on **structural** and functional requirements of hospital.

Check Your Progress 2

Name the functional components of the Clinical Laboratory.

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1.4 CONCEPTS OF PLANNING ORGANISATION

The **efficient** operation of clinical laboratory and effective delivery of medical laboratory services to clinicians and their patients require a complex interaction of expertise in medical, scientific and technical areas, of resources in the form of personnel, laboratory and data processing **equipment** supplies and facilities, and of skill in organisation, management and communication. **Awareness** of accreditation standards and **Governmental** regulations of laboratory practice should be known to Head of laboratory services and he must ensure quality laboratory performances.

The steps in systemic **approach** to the orgnnisation and **management** is to establish general **goals** and specific objectives, To maximise the effectiveness and efficiency of operations. the functioning laboratory must have the following:

- a) **Adequate** facilities (including Lab, wash rooms, store, **reagent** preparation rooms, staff common library. toilets, conference room **etc.**)
- b) Appropriate Equipments
- c) Standurd **Reagents/Chemicals** regular supply
- d) Adequate **number** of qualified staff.

1.4.1 Physical Facilities and Layout

Physical **facilities** for laboratory function and its complete layout depends upon the structure, culture and environment of organisation. Specific design considerations include:

- l) The concern of size in planning a laboratory is **always** a major question. Factors for consideration in dotermining space requirements include the scope of procedures to be performed, intended operationnl approach for performing procedures, and the anticipated size of the laboratory department.
 - a) **Square Footage:** Depending on design of the laboratory, **the net square** footage in the modern laboratory varies approximately 65-90% of gross square footage.
 - b) **Scope of Services:** Depends upon type of hospital and facilities to serve e.g. teaching hospital, research hospital etc. Adequnte scope for future expansion must be kept.
 - c) **Mechanical Services:** Proper planning for mechanical services essential specially civil and electrical **work** of PWD (CPWD), provision of safety devices etc.
 - d) **Operational Approach:** **The** amount of space required in laboratory somewhat depends upon how tests are being performed, the space requirement **gradually** reduced with use **of** automation computerised technology. The interior design to be suitably modified with consultation and coordination of architect engineer **and** Laboratory Manager.
 - e) **Laboratory Information System:** Provision of communication between laboratory with **ward/OPD** and treating physician be maintained.

- f) **Laboratory Safety:** Various safety measures for staff and property etc. as against fire, biological toxic waste, radioactive material, following the universal precaution etc. be made adequately.

2) **Functional Consideration in Laboratory Design**

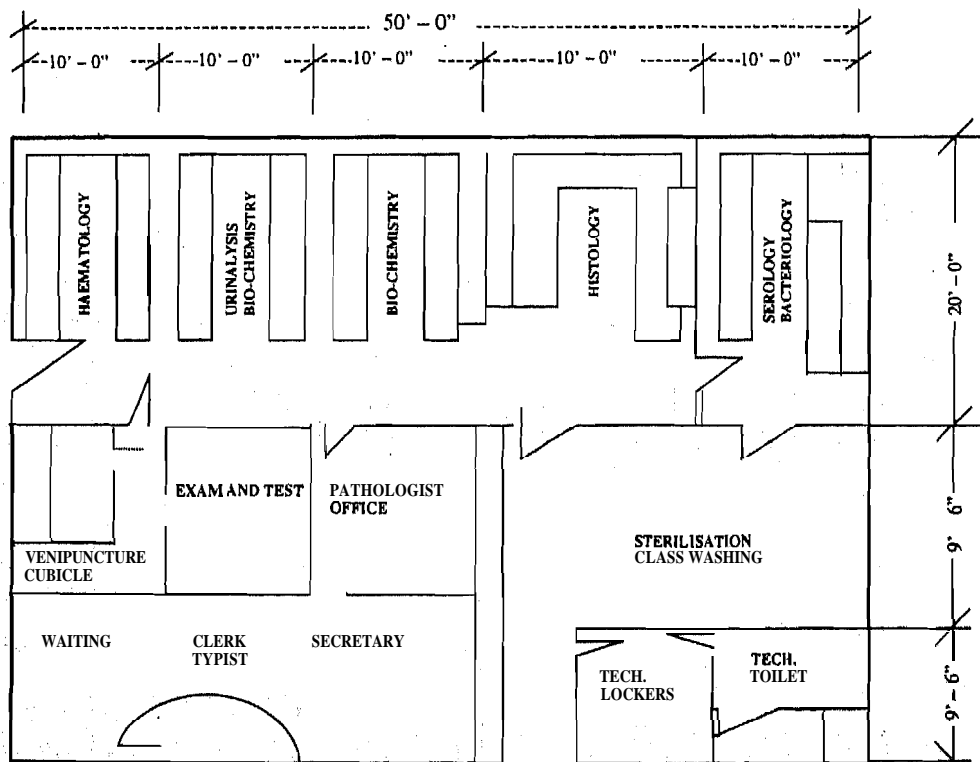
Considering recent trends and advanced technology, changes from traditional laboratory set up to be made in relation to clinical problems, disease orientation and functional efficiency. Various sub-units of laboratory medicine viz. Clinical Chemistry, Clinical Pathology, Microbiology, Histopathology, Haematology etc. have different functional set up of orientation. The organisational approach must have its value in future along with alternative functional approaches being considered.

Pathologist having the opportunity to design a new laboratory or make major renovation in older laboratory, should think in functional terms about the laboratory operations and their facility needs.

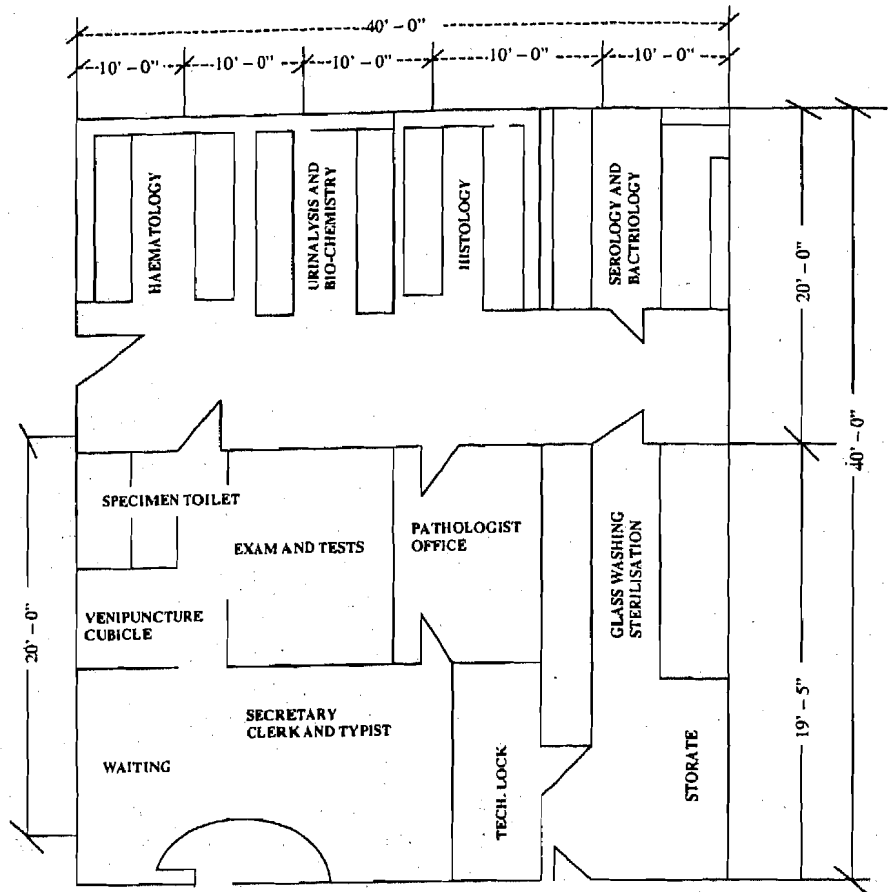
Traditionally laboratories have been organised without due regard to the functional requirement. The whole concept of a laboratory has changed during the last decade. Unfortunately there has been a lot of proliferation of laboratories which are sub-standard and with no knowledge of quality control. The only way to curb such practices is to start good laboratories and provide facilities at reasonable costs, by qualified pathologists. Today, a planned laboratory can be started with a budget of one lakh rupees. The basic needs to start a laboratory can be worked out on the basis of a survey made which will give the probable sample turnover.

The accommodation initially, should be reasonably good to start the common tests that are in demand and should be properly planned so that it will be functional and convenient.

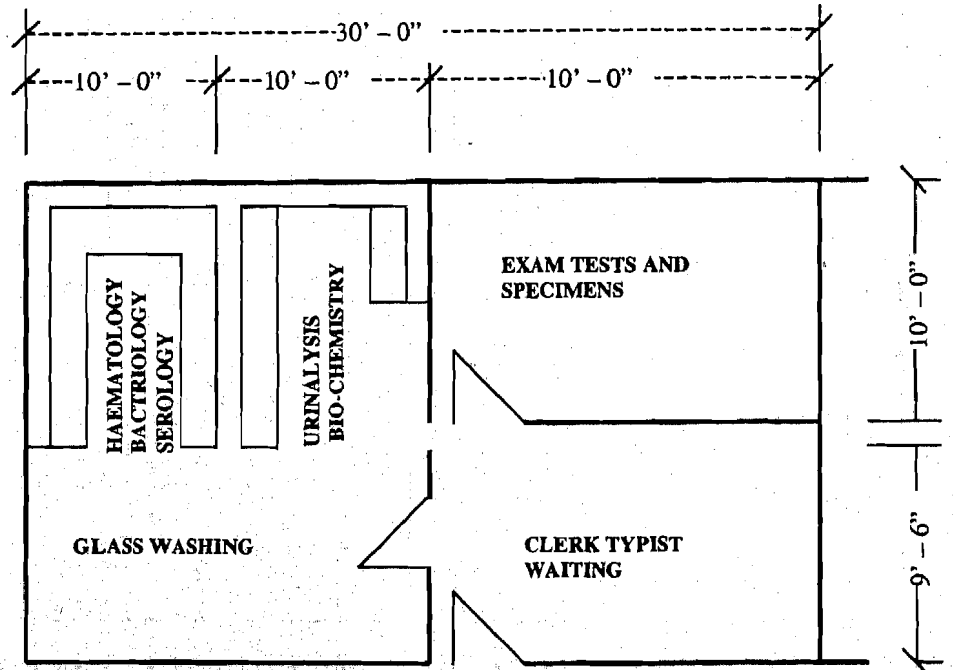
A few samples of plan (Plan A, Plan B, Plan C) are given below which are scientifically developed. Depending upon the area available, these plans may be applied suitably.



PLAN - A (70,000-1,20,000) TESTS ANNUALLY FOR AVERAGE SIZE OF 150-200 BEDS



PLAN - B (40,000-75,000) TESTS ANNUALLY FOR AVERAGE SIZE OF 100-150 BEDS



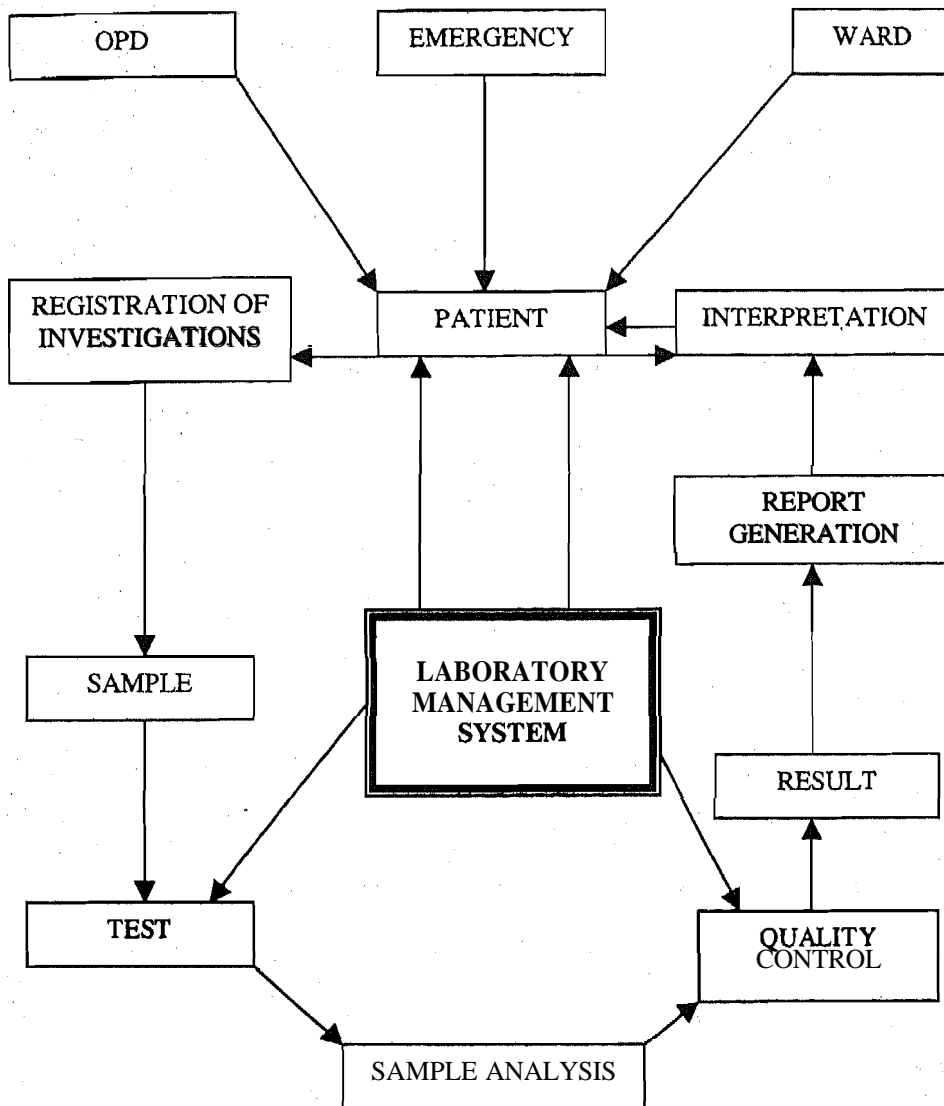
PLAN - C (20,000-30,000) TESTS ANNUALLY FOR LESS THAN 100 BEDS

3) Spatial Considerations in Laboratory Design

Spatial relationships within the institution are important. It is critical that location of the laboratories be studied in relationship to the other hospital services, traffic, supporting services, and users. Emergency laboratory system should be readily accessible to emergency, surgical, medical, orthopaedic, gynaecology etc. wards, ICU, ICCU and casualty.

Organisation in the clinical laboratory refers to both structure and process whereas structure exemplifies stated relationship or framework and process deals with interaction.

The following is the flow diagram in Laboratory function system:



Three key elements of organisation are:

- A) *The clinical laboratory:* as a work place
- B) *Staff:* who performs the test
- C) *The task:* to be performed (Investigations and Reporting)

A) *The Clinical Laboratory*

The first important object is:

- i) **Traffic flow planning:** The intra laboratory traffic is separated from outside traffic. Adequate provisions should be made for ambulatory patients and blood bank donors wherever applicable. Usually blood bank has separate building in majority of hospitals with provisions of independent functioning unit.

- ii) **Specimen and Data flow:** The authentic schematic layout to be available with Head of Department for strict compliance.
- iii) **Process and Storage:** Pre-analytical process and storage of specimen/material to be done with each laboratory or to be done centrally if organised.
- iv) **Emergency Sample:** Provision of emergency samples to be arranged.
- v) **LIS:** The laboratory information system to develop according to available resources.

B) Staff Requirement

There use to be a relation between number of tests and staff requirement, given in old text books, Now due to development of automation in clinical, chemical pathology and all branches of laboratory medicine the conventional techniques are being replaced by automated techniques. Hence it is difficult to calculate the number of test performed by an individual per day and relate it to day to day activities. A time study format has been developed by Rappoport in 1975 in which standard time of each investigation (job activity) to be calculated and related to time availability of working technical personnel on day to day basis to evaluated per day investigations.

The following formulae are used to determine average investigation/day/technical staff.

Standard time = Total basic time x Time allowance

- i) Total basic time = Total average basic time of job element
Basic time = Average observed time x Rating
- ii) Time allowance = Contingency allowance (5% of the total basic time) x Relaxation time (12% of the basic time)

Parameters

- i) **Element/job** description steps (which should also include job elements other than investigation steps)
- ii) Observation 5-10 times
- iii) Total observed time in each step
- iv) Average observed time of one test
- v) Rating of individual as 100% by an average working

Total laboratory functioning job activities from reception of sample, registration, solution preparation etc., processing, reporting entry, indexing, despatch, laboratory waste disposals etc. are considered in job element per day.

Day functioning technical staff = 6½ hour of duty (36 hours per week)

Observed work/day/technical staff when both automation/conventional techniques are shared in mixed type of spectrum of investigations } =60-70 tests/day

1.4.2 Equipment/Reagents and Facilities

While planning equipments, reagents and other facilities for laboratories following need to be considered:

- a) **Basic instruments and equipment should be made available. All vital equipment to be in duplicate or alternative arrangement for its applicability to be provided.**

The following instruments are basic equipments for all types of routine investigations:

- i) **Colorimeter/photoelectric colorimeter**
- ii) **Centrifuge**
- iii) **Water bath**

- iv) Microscope – Mono ocular/Binocular
- v) Hot air oven
- vi) Autoclave
- vii) Incubator
- viii) Ph-Meter
- ix) Automated Biochemistry analyser
- x) Automated Haematology analyser
- xi) ELISA – Reader
- xii) ELISA – Washer
- xiii) Microtome
- xiv) Wax melting bath
- xv) Hot plate

The requirement of specialised functions of laboratory depends upon the type of speciality developed in organisation. The spectrum of investigations and number increases accordingly. The advances in laboratory medicine is tremendous, more sophisticated, technology equipments are being added day by day. The need to acquire depends upon:

- i) Type of **hospital/organisation** and structure of the institute
- ii) Daily attendance of patients either from out **patients/inpatients** with available speciality are important factors in deciding procurement of high sophisticated automated equipment. The cost effectiveness to be evaluated as per standard parameters. The choice of high technology equipment to be related to number of test performed per day and spectrum of test needed to be performed on day to day basis, The specification of equipment for procurement is a very vital parameter in decision of choice of equipment and procurement. The head of **Deptt.** and **hospital/institute** procurement authorities should discuss at length the use coefficient, the need **and** justification before placing order.
- b) Purchase and product specification should be viewed justifying the need of the equipment and the use of instrument in relation to number of investigations and spectrum of investigations.
- c) Type of automation and availability facilities which are essential pre-requisite for installation of equipment.
- d) After sales service, availability of reagents as open system, warranty and availability of spares till life of instruments and possibility of upgradation of instrument in due course of time.
- e) Every person working in a laboratory should be thoroughly familiar with **storage specifications**, irrespective of chemicals, reagent or instruments, A constant check is maintained on expiration dates. Chemicals and reagents after the expiration dates should be disposed without delay to prevent impending hazards.
- f) Apart from basic amenities like water, electric supply the measures should be taken for condemnation and disposal of all items as per inventory.
- g) Laboratory wastes and its disposal is an essential element of focus to all laboratories for early and immediate compliance,
- h) Basic record cards or register should be maintained as per laid down guidelines issued from time to time from the organisation of the **structure**. Computerised inventory system if available should be encouraged for constant use.

Check Your Progress 3

- 1) What are the minimum facilities, a laboratory should have for its better functioning'?

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2) List three key elements of organisation of a Laboratory?

- i)
- ii)
- iii)

3) Enumerate the provisions necessary for working of a Laboratory.

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1.4.3 Research and Training

Research

Research is an integral part of laboratory system. Various research projects pertaining to hospital's functioning, equipment development; technology upgradation; disease incidences; treatment progress and all matters in relation to diagnosis and monitoring of patient are part of the system management.

Training

Training of technical personnel either in service or who intend to join service or engaged in practice of technology should undertake complete, prescribed, identified, recognised course of stipulated period before rendering any type of service in the field of laboratory medicine. Continuing Medical Education (CME) programme for technical people should be made compulsory if not mandatory. Participation in training programmes, workshops, seminars are to be encouraged amongst all working technical personnel from time to time.

Orientation

Early introduction to laboratory staff of the new employee contributes to the development of an effective inter personal relationship, which is necessary to build teamwork. An orientation programme is one of the most over looked management tools. Apart from institutional orientation, each laboratory should have a defined programme of orientation for all new employees to make them aware of policies, SOP (Standard Operative Procedures) and standard performance are expected in laboratory environment and culture. Orientation serves to correct potential misunderstanding that are so often present with new employees and establish channel of communication between management and the new employee. During orientation, rules and regulatory demands regarding quality assurance, universal precautions, hazardous waste, the right to know etc., are clearly defined and expectations well presented.

1.5 POLICIES AND PROCEDURES

The provisions of quality laboratory services with efficient reporting, interpretive diagnosis depends on the application of sound principles for personnel management. Efficient and cost effective operation of a clinical laboratory with timely, effective delivery of services requires a complex balance of expertise in medical, technical and scientific activities.

1.5.1 Laboratory Administration

There are four basic elements of laboratory administration:

- 1) **Objectives:** Goals and purposes consistent with high quality and cost effective delivery of laboratory services.

- 2) Guiding People: Leading and directing in such a manner **that** professionals feel sense of responsibility, achievement and appreciation of work performed.
- 3) Resources: Proper utilization of physical resources such as instrumentation, desk top computers, space, Laboratory Information Service (LIS) etc.
- 4) Organisation: The dynamic organisational unit where labour policy, procedure and operations are managed in a reasonable cost effective, safe and productive manner.

1.5.2 Quality Control and Assessment, Accreditation and Total Quality Management (TQM)

Quality Control and Assessment

Quality Control and Assessment is the process to ensure a test from being done wrongly. The primary aim of Quality Control and Assessment is to see that the very purpose for which a test is performed is not defeated due to unreliability of the result. Quality assessment of all process of testing sample, analysis pattern, check of reporting and result with precision and accuracy has to be done. The following are techniques of Quality Control:

- i) **Internal Q.C. (Intra Laboratory Q.C.)**
 - Performed by individual laboratory at their own level.
 - Forms the basis of day to day **work** of quality assurance.
- ii) **External Q.C.**
 - Performed by many laboratories at the same time monitored by one.
 - Periodic monitoring for the performance of the laboratories.

Accreditation

Laboratory accreditation is a procedure by which an authoritative body gives formal recognition of technical competence (including quality system **management**) of testing **and** or calibration for a laboratory to carry out specific tests. This is **back** a third party assessment against set standards.

Accreditation is considered to **be** the essential first step toward mutual acceptance of test results and test certificates. An increasing number of health care organisations now require that diagnostic laboratories meet national standards for accreditation. The laboratory accreditation is a means to improve customer confidence in the calibration and testing reports issued by the laboratories so that all interested parties shall accept the **reports** with confidence.

Total Quality Management (**TQM**)

This is one of the most promising managerial innovations introduced within the health sector within the last several decades. TQM increases the efficiency and effectiveness of health care services.

The following factors are to be considered:

- Top Management Leadership
- Creation of an organisational frame work for quality improvement **in** hospitals
- Transformation of hospital work culture
- Customer focus
- Process **focus**
- Employee education and training
- Learning by practice and teaching
- Bench marking

- Quality measurement and statistical reports at every level
- Recognition and reward
- Management integration

1.5.3 Leadership and Motivation

It is the integral part of laboratory management system. Studies have been conducted to know the effects on productivity and concluded that the administrative process of management includes planning, decision-making, **organising**, directing and controlling. This process completed with management inputs (financial, physical, and human) has a direct effect on outputs (cost benefit, performance, products and behaviour).

1.5.4 Personnel Management

Personnel policies, procedures and records are vital to the efficient and cost effective operation of any laboratory. In addition, policies and procedures are necessary to meet accreditation and regulatory requirements. In fact, a proper staffing and effective scheduling have more impact than any other management tool in establishing **quality** laboratory service and cost reduction.

1.5.5 Personnel Policies

With regard to personnel policies following must be taken care of:

- Qualified persons should be recruited.
- A good rapport should be maintained between person-in-charge and the working staff.
- Basic needs and comforts should be provided.
- The person is given the job description.
- Duty allotment schedule among the staff should be carefully prepared.
- Opportunities should be provided for betterment of skills and position.

1.5.6 Job ~~fraged~~ Description and Staffing

Staff pattern depends upon member and spectrum of investigations in clinical laboratory, Scheduling and staffing are important management responsibilities that **must** be **reviewed** and revised as often as necessary to maintain efficient **and** cost effective services,

Job description is a summary of all important and significant facts about a particular job, Duties and responsibilities of working technical personnel to be clearly defined and illustrated and should be confined to gazette notification of recruitment rules approved by Department of Personnel in Government Organisation. For other organisations it is between employee and employer with clear understanding and written document contract mutually agreed upon. Finally, although job descriptions are essential management tools for staffing process, they also sense as both training and evaluation guides for establishing employee incentive,

The basic job description as you know should include a job title, duties, qualification, **job** relationship, and necessary work aids. (**Conventional** techniques and **Automation**.) **Day** and hours to be worked out **as** per existing norms laid down by **institutions/respective** Government.

1.5.7 Recruitment, Policies and Procedures

Recruitment policies differ according to organisation structure. However it is **advised** to follow strictly the Recruitment Rules of the designated post and appointment to **be done** strictly under rules of the **institution/Government** by competent authorities to avoid **legal** complications. Adhoc appointments for vacant position whenever filled up to be **regularised** within limited period.

It **is** recommended that prior to interview process a list of establish criteria and **interview** question based on job description, be prepared, qualitative criteria be made to **ensure that**

all candidates are compared equitably and the laboratory is generally able to recruit quality personnel.

Check Your Progress 4

- 1) Enumerate basic elements of laboratory administration.

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- 2) Define accreditation. What are the advantages of accreditation'?

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- 3) What is Total Quality Management (TQM)? Give important factors necessary for consideration of TQM.

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- 4) What role leadership and motivation play in laboratory management?

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1.6 INFORMATION MANAGEMENT

Laboratory management is a complex process involving quality control, work flow allocation etc. Information system within the laborntory and inter laboratory are order of magnitude, more complex than the communications with outside world.

Day by day, there is **addition** to technology information nnd transaction to users. Data transfer at much higher rate is in common use. A properly selected and installed **laboratory** information system, can provide valunble benefit in improved laboratory operation and higher quality patient care.

The following are benefits of laboratory information system:

- Reduces errors such as mix up specimen, calculation errors, transaction errors etc.
- Improved staff productivity.
- Rapid availability of results and improved turn around time.
- Transformation of reports to patient.
- Improved patient reports legibility; duplicate reports, interpretive diagnosis, graphics etc.
- Improved management information.
- Quality assurance data record maintenance.

Check Your Progress 5

1) What is the role of information management in laboratory services?

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2) Enlist the managerial issues which require more attention in laboratory management?

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3) What are the problems which affect laboratory reports? How do you solve them?

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1.7 MANAGERIAL ISSUES

Laboratory as you know exists for the sole purpose of providing diagnostic and management information for the beating medical official, to aid in the care of patient. During the past few years there has been a considerable increase in the clinical demand for laboratory investigations both in number and spectrum of tests.

The following managerial issues are essential to consider:

- 1) In recent years, there has been an alarming increase in the error of judgement, errors of omissions and commissions on the part of technical staff, Pathologist/Microbiologist, Biochemists and other working laboratory staff in processing and reporting the wide spectrum of routine and sophisticated investigations.
- 2) Advances in early diagnosis, quick reporting, use of high sophisticated microprocessor based instruments, microtechniques are in practice without adequate quality control. Maintenance programme methods that identify and minimize sources of variation in test system are, therefore, essential.

- 3) For a good laboratory, appropriate planning, procurement and controlling of resources will ensure efficient, quality operation in performances. Personnel policies, procedures and records are vital to the efficient and cost effective operation of any laboratory. In addition policy protocols and procedures are necessary to meet accreditation and regulatory requirements.
- 4) Proper staffing and effective scheduling have more impact than any other management tool in **establishing** good quality and cost effective laboratory services.

1.7.1 Problems of Management

The following are the problems which are major issues in day to day practice of laboratory medicine:

- i) Lack of technical knowledge amongst working personnel
- ii) Non-availability of upto date modern technology.
- iii) Lack of resources.
- iv) Inability to maintain an adequate staff.
- v) Frequent rush orders for reports and work load beyond capacity.
- vi) Low morale among the working laboratory staff.
- vii) Irregular supply and increase lead time of material supply from stores and purchase of substandard material.
- viii) Lack of recognition of dignity of work.
- ix) Lack of job satisfaction.
- x) Lack of work attitude, sincerity and devotion to work.
- xi) Indifferent personnel behaviour
- xii) Communication gap between officers and subordinate staff
- xiii) Lack of Quality Control and standardisation of procedures; absence of protocols, SOP and manuals.
- xiv) Paucity of in service training programmes; CME and lack of technology transfer.
- xv) Lack of norms of technical staff.
- xvi) Lack of promotional avenues and revision of cadre at par with similar services.
- xvii) Lack of laboratory information system.
- xviii) Absence of rationalisation of reporting pattern.
- xix) Absence of integrated approach of patient care system for laboratory management.
- xx) Different kinds of malpractices.
- xxi) Lack of medical audit.

1.7.2 Laboratory Hazards

Now you will learn about some of the laboratory hazards. Today a laboratory personnel is exposed to various kind of infectious material which are of great risk to life. All can not be described here and is beyond the scope of this unit. The following are some of the dangers to a laboratory worker:

- i) Handling of infectious material.
- ii) Handling of broken glassware.
- iii) Accidental spill over of corrosive reagents.
- iv) Swallowing of **corrosive** material such as concentrated sulfuric acid, Hydrochloric acid, sodium hydroxide; **Trichloro** acetic acid etc.
- v) Inhalation inoculation, swallowing of infectious material — bacteria; viruses (**HbsAg, HIV etc.**)
- vi) Inhalation of poisonous fumes.
- vii) Potential hazards in the form of inflammable chemicals and gas leakages.

1.7.3 Safety Precautions in the Laboratory

The infection as you know can occur through ingestion, inhalation, injections or aerosols. In laboratory acquired infections the route could be any of the above. Bio-safety in a laboratory is very essential and basically depends on three components:

- a) Basic standard of laboratory design, operation and equipment.
- b) Selection and use of essential bio-safety equipment.
- c) Safe laboratory procedures.

1.7.4 Laboratory Waste Management

Laboratory waste can be classified into following main categories:

- i) General waste
- ii) Pathological waste
- iii) Radioactive waste
- iv) Chemical waste
- v) Infectious and potentially infectious waste
- vi) Sharps.

The management of laboratory waste involves following steps:

- i) Collection and segregation at storage site
- ii) Storage and pretreatment (disinfection)
- iii) Transportation
- iv) Disposal

The above steps could be applied to hazardous and non-hazardous waste. The bio-medical waste handling rules are tabulated in Table 1.1 and various methods of the disposal of blood and laboratory material are tabulated in Table 1.2.

Table 1.1: "Bio-Medical Wastes (Management and Handling) Rules, 1995"

Colour of Containers	Types of Wastes
Yellow	Clinical waste for incineration only
Yellow with black stripes	Clinical waste which is suitable for landfill disposal
Light blue or transparent with Light blue lettering	Wastes for autoclaving or equivalent treatment before final disposal
Red	Human anatomical wastes
Black	Normal household waste

Table 1.2: Disposal of Blood and Laboratory Material

Hyperchlorite detergent solution	0.5-1.0 per cent solution of hypochlorite dissolved in 0.5% anionic or non-ionic detergent is the best general purpose disinfectant if contact is maintained for atleast 30 minutes.
Sterilisation	Autoclaving for 60 min. 121°C (68.5 cm Hg) is the method of choice.
Incineration	Materials may be disposed of by burning in incinerator.
Disinfection of glassware	All reusable glassware must be disinfected by treating with Hypochlorite detergent before cleaning.
Spills on the table tops/sinks	Remove the spills with swabs soaked in hypochlorite solution immediately.

For your guidance minimum and more practical, easily achievable safe laboratory rules are listed here:

- i) Avoid mouth pipetting as far as possible.
- ii) Avoid eating, drinking, smoking and storing eatables in the laboratory.
- iii) Decontaminate the working area atleast once a day and more frequently after the spillage of potentially infective material.
- iv) Wash hands with soap and water after handling the infectious material.
- v) Wear laboratory gowns/coats in the laboratory and these should not be taken outside the working area.
- vi) Use gloves for all those procedures that may involve accidental direct contact with blood or infectious material.
- vii) Decontaminate all liquid or solid waste materials as per the guidelines issued by Environment Ministry and Directorate of Health Services for proper directed disposal.
- viii) Use of gloves for all those procedures that may involve accidental direct contact with blood or infectious materials.
- ix) Perform all technical procedures in a way that minimizes the aerosol formation.
- x) Provide adequate training to staff in laboratory safety procedures.
- xi) As far as possible, actively immunize the workers against the diseases, the materials of which they are handling.
- xii) Employ medically fit staff only to work in clinical laboratories and staff to be subjected for regular health check up at least twice a year.
- xiii) Provide ample space and illumination for safe conduction of laboratory procedures.
- xiv) Ensure constant and adequate water supply for immediate washing and cleaning of glasswares and premises for adequate safety from infectious materials.

Check Your Progress 6

1) Mention the infectious laboratory hazards which can be prevented?

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2) Whnt steps should be taken for safety of laboratory in above infectious hazards'?

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3) Mention the components on which biosafety of the laboratory is dependent?

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1.8 CONTROL AND EVALUATION

Perfection in the management of laboratory issues are essential. Every problem has its own solution and control. Quality control and assessment is integral part of management. Maintenance of services, material supply, equipment maintenance, personnel management are components of evaluation in the procedures. A quality report and consumer satisfaction is final goal of evaluation programme.

1.9 LET US SUM UP

In this unit you have learnt that laboratory and laboratory services play an important role in patient care services and also the types and functions of laboratory; the physical facilities required for laboratory existence. You have also learnt the important concepts of planning policy and procedure, information management in laboratory. Further you have learnt various problems in management of laboratory system, quality control, assessment and total quality management. The importance of trained qualified staff, laboratory accreditation, performance appraisal and methods of evaluation has also been emphasized in this unit.

1.1 ANSWERS TO CHECK YOUR PROGRESS

Check Your Progress 1

- 1) Laboratory is a place of work for testing patients sample for results in favour of diagnosis and treatment.
- 2)
 - To provide diagnostic management information to treating physician.
 - To generate results of samples for investigations.
 - To report samples with accuracy, precision and reliability.

Check Your Progress 2

- Histopathology
- Clinical Pathology
- Microbiology
- Haematology
- Biochemistry
- Research Laboratory

Check Your Progress 3

- 1) Adequate space provision, regular supply of water, electricity reagents, chemicals, **kits** etc. and appropriate instruments, glasswares for use.
- 2) A) The clinical laboratory: as a work place.
B) Staff: who performs the test
C) The task: to be performed
- 3) Adequate functioning space of work for staff, space for wash room, store items, **toilets**, reagent, preparation rooms etc.

Check Your Progress 4

- 1) There are four basic elements of laboratory administration:
 - a) Objectives
 - b) Guiding people
 - c) Resources
 - d) Organisation

- 2) Accreditation is a procedure by which an authoritative body gives formal recognition of technical competence (including the quality system management) of testing and or calibration laboratory to carry out specific test.

The advantages of accreditation are:

- a) It maintains standard and quality which creates confidence of customer and laboratory manager.
 - b) Mutual acceptance of reports between laboratory and the user.
 - c) Accredited laboratory is accepted in inter laboratory net work system.
- 3) This is the most promising managerial innovation which increases the efficiency and effectiveness of health care session. The following important factors are considered in quality management:
- a) Top management leadership
 - b) Customer and process
 - c) Learning by practice and teaching
 - d) Quality measurement and statistical reports at every level
 - e) Recognition and reward.
- 4) Leadership and motivation are prime important factors in planning management without which productivity is negligible.

Check Your Progress 5

- 1) Information management is essential component and high order of magnitude complex communication system within and outside laboratories of the country and world. It reduces errors, mix-up specimen, calculation errors etc., improves staff productivity, quality assurance and interpretive diagnosis for the patients.
- 2) The following are the important managerial issues which require more attention in laboratory management:
 - a) Quality control and management
 - b) Technological updates
 - c) **Human Resources**
 - d) Staffing pattern and promotional avenues
 - e) Automation
 - f) Total Quality Management (TQM)
- 4) The following problems which affect the laboratory report are:
 - a) Unqualified staff functioning
 - b) Inadequate input and processing unit functioning
 - c) Lack of **resources**
 - d) Absence of Quality Control
 - e) Lack of work attitude, sincerity and devotion of work.

The above problems are definitely solved if the authorities concerned provide the above and the laboratory workers attitudes are changed and they work with sincerity and devotion.

Check Your Progress 6

- 1) a) Hospital acquired (nosocomial) infections
- b) Hepatitis B infection
- c) HIV infection

- 2) a) Proper discard of laboratory waste as per the guidelines issued by Directorate General of Health Services and Ministry from time to time.
- b) Personal precautions such as washing of hands with soap and water before and after for any sample handling in laboratory; use of gloves; use of Hypochlorite solutions for discard etc. Wear Laboratory gown/coats in laboratory.
- 3) Bio-safety of the laboratory is dependent on the following components:
 - a) Basic standards of laboratory design. operation and equipment
 - b) Selection and use of essential bio-safety equipment
 - c) Safe laboratory procedures.

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