Dissertation in

Jaypee Medical Centre, Noida

On

Work Process Designing and Functionality Evaluation for Implementation of LIMS (Laboratory Information Management System) in a tertiary care hospital

A Dissertation submitted in partial fulfillment of the requirements for the award of

Post-Graduate Diploma in Health and Hospital Management

By

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(PG/11/113)

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May, 2013

JAYPEE
Healthcare Limited

Certificate of Internship Completion

Date 15" May, 2013

TO WHOM IT MAY CONCERN

This is to certify that Dr. Vidhi Gandhi has successfully completed her 3 months internship in our organization from February 01, 2013 to April 30, 2013. During this internship she has worked on the "Work Process Designing and functionality Evaluation for the Implementation of LIMS (Laboratory Information management System" under the guidance of Operations team at Jaypee Hospital, Noida.

We wish her good luck for her future assignments.

Sonya Tandon
DGM-HR
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Certificate from Dissertation Advisory Committee

This is to certify that Dr Vidhi Gandhi, a graduate student of the **Post-Graduate Diploma in Hospital & Health Management** has worked under our guidance and supervision. She is submitting this Dissertation titled **"Work Process Designing and Functionality Evaluation for the Implementation of Laboratory Information Management System (LIMS)"** in partial fulfillment of the requirements for the award of the **Post-Graduate Diploma in Health & Hospital Management.**

This Dissertation has the requisite standard and to the best of my knowledge no part of it has been reproduced from any other dissertation, monograph, report or book.

Ms Anupama Sharma
Assistant Professor
IIHMR
New Delhi
Date: 4th May 2013

Dr. Rahul Gulati
Deputy Head, Clinical Services,
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Noida, UP
Date:

Certificate of Approval

The following dissertation titled ""WORK PROCESS DESIGNING AND FUNCTIONALITY EVALUATION FOR IMPLEMENTATION OF LIMS(LABORATORY INFORMATION MANAGEMENT SYSTEM) IN A TERTIARY CARE HOSPITAL"" is hereby approved as a certified study in management carried out and presented in a manner satisfactory to warrant its acceptance as a prerequisite for the award of **Post- Graduate Diploma in Health and Hospital Management** for which it has been submitted. It is understood that by this approval the undersigned do not necessarily endorse or approve any statement made, opinion expressed or conclusion drawn therein but approve the dissertation only for the purpose it is submitted.

Dissertation Examination Committee for evaluation of dissertation

Name	Signature
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FEEDBACK FORM

Name of the Student: Dr. Vidhi Gandhi

Dissertation Organisation: Jaypee Hospital, Noida

Area of Dissertation: Hospital Operations

Attendance: 100 %

Objectives achieved: Completely.

Deliverables: Excellent.

Strengths: Positive Approach.

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Signature of the Officer-in-Charge/ Organisation Mentor (Dissertation)

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Dr. Rahul Gupta

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"A journey is easier when you travel together. Interdependence is certainly more valuable than independence. This dissertation thesis is the result of three months of hard work whereby I have been accompanied and supported by many people. It is a pleasant aspect that I now have the opportunity to express our gratitude to all of them"

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ABBREVIATIONS

OPD Out Patient Department

IPD – In Patient Department

ICU – Intensive Care Unit

NABL – National Accreditation Board of Laboratories

Hb – Hemoglobin

TLC – Total Leukocyte Count

DLC - Differential Leukocyte Count

ESR – Erythrocyte Sedimentation Rate

PCV – Packed Cell Volume

FNAC – Fine Needle Aspiration Cytology

ZN stain – Ziehl – Neelson stain

HOD – Head of Department

Patient ID – Patient Identification

XML Standards – Extensible Markup Language

SOPs – Standard Operating Procedures

LAN – Local Area Network

WAN - Wide Area Network

3 D – 3 Dimensional

QC/QA management – Quality Control / Quality Assurance management

AI – Artificial Intelligence

SQL – Structured Query Language

IR, UV, NMR spectra – Infra Red, Ultra Violet, Nuclear Magnetic Resonance spectra

GUI – Graphic User Interface

ISO – International Organization for Standardization

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HOSPITAL PROFILE

ABOUT JAYPEE GROUP

- The Jaypee Group is a 15,000 crore well diversified infrastructural industrial conglomerate in India.
- Shri. Jaiprakash Gaur, Founder Chairman of Jaiprakash Associates Limited after acquiring a Diploma in Civil Engineering in 1950 from the University of Roorkee (now Indian Institute of Technology Roorkee), had a stint with Govt. of U.P. and branched off on his own, to start as a civil contractor in 1958, group is the 3rd largest cement producer in the country
- Jaypee Group is five decade old conglomerate based in Noida, India, involved in various industries that include Engineering, construction , Cement, Power, Hospitality, Real Estate, Expressways, Highways, Education and Social Commitment.

Figure 1 : Prototype of Jaypee Medical Center

- The groups cement facilities are located today all over India in 10 states, with 18 plants having an aggregate cement production capacity of 24 Million Tonnes and same is poised to become 36 Million Tonnes before October 2011

SPREAD OF THE COMPANY

CEMENT

- Jaypee Group is the 3rd largest cement producer in the country. The group produces special blend of Portland Pozzolana Cement under the brand name 'Jaypee Cement' (PPC). The company is in the midst of capacity expansion of its cement business in Northern, Southern, Central, Eastern and Western parts of the country and is slated to be 35.90 MnTPA by FY12 (expected) with Captive Thermal Power plants totaling 672 MW

ENGINEERING & CONSTRUCTION

- The Engineering and Construction wing of the Group is an acknowledged leader in the construction of multi-purpose River Valley and Hydropower projects. It has the unique distinction of having simultaneously executed 13 Hydropower projects spread across 6 states and the neighboring country Bhutan for generating 10,290 MW power

SPORTS

- The Group finished the construction and execution of India's first ever F1 Grand Prix on 30th October, 2011. In addition to F1, the track will also host other top-level international motorsports events from 2012 onwards.

HOSPITALITY

- The Group's hospitality business owns and operates 6 properties spread across New Delhi, Uttar Pradesh and Uttarakhand. The 4 Five Star Hotels, two in New Delhi and one each in Agra and Missouri have a total capacity of 644 rooms.

EDUCATION

- "People of resources must contribute towards making a better tomorrow for all". Shri Jaiprakash Gaur ji, Founder Chairman of the Group firmly believes that quality education on an affordable basis is the biggest service which, as a corporate citizen, we can provide. Education is the cornerstone to economic development and the strength of 1 billion Indians can be channelized by education alone to build India into a developed nation

REAL ESTATE AND EXPRESSWAYS

- The Group is a pioneer in the development of India's first golf centric Real Estate. Jaypee Greens - a world class fully integrated complex consists of an 18 hole Greg Norman Golf Course. Stretching over 452 acres, it also includes residences, commercial spaces, corporate park, entertainment and nature in abundance. Jaypee Greens also launched its second project in Noida in November 2007. India's First Wish Town, is an Integrated Township spread over 1162 acres of land comprising one 18 hole and two 9 hole golf facility & world class residences.

SOCIAL COMMITMENTS

- The Group has always believed in "growth with a human face" and to fulfill its obligations it has set up Jaiprakash Sewa Sansthan (JSS), a 'not-for-profit trust' which primarily serves the objectives of socio – economic development, reducing the pain and distress in society. For over 4 decades now, Jaypee Group has supported the socio-economic development of the local environment in which it operates and ensured that the economically and educationally challenged strata around the work surroundings are also benefited from the Group's growth by providing education, medical and other facilities for local development .

- **LEADERSHIP TEAM**

Figure 2 : Leadership Team

THE LOGO OF JAYPEE MEDICAL CENTRE:

Figure 3 : Logo

- **The leaf** represents that we are environment friendly and follow medication safety. The sharp edges and corners represent the modern side (cutting edge technology and world class infrastructure) and the rounded corners represent the patient-care side of Jaypee Medical Center.

- **The Blue in Jaypee** is identified with Confidence, Credibility and Competence, represents Jaypee Medical Center's multi-disciplinary capability, cutting edge technology and service foundation built on world-class infrastructure and processes.
- **The Orange** represents the vibrancy, high energy and 'let's make it happen' attitude of our people.
- **The Orange in leaf and Medical Center** represents that we are a New Life in the group which is supported by Blue Leafs and J of Jaypee Group as pillar of strength.

VISION

"Promoting healthcare to the common masses with the growing needs of society by providing quality and affordable medical care with commitment."

-Founder Chairman's Vision on Healthcare

MISSION

"The Jaypee Group is committed to meet the healthcare needs of the population in Noida and the surrounding regions through building Jaypee Medical Center as a super specialty hospital with advanced healthcare facilities, the latest diagnostic services, and state-of-the-art technology focused on medical specialties that meet the needs of the population. The Jaypee Medical Center will be the ultimate choice for medical care."

JAYPEE GROUP –HEALTHCARE PHILOSOPHY

- Three Secondary care medical facilities currently operational at –Bhutan, Rewa (M.P) & Baspa (H.P) providing care to approximately One million lives treated annually.
- Other Healthcare Initiatives - Medical Camps, Pulse Polio Camps, Maternity camps, Health Checkup of Village Children, Health & Hygiene Awareness Camps
- Mobile Medical Van (with Lab and other diagnostic facilities) Diagnosis and medicine distribution free of cost (about 100 patients per day).

PILLARS OF JAYPEE MEDICAL CENTRE

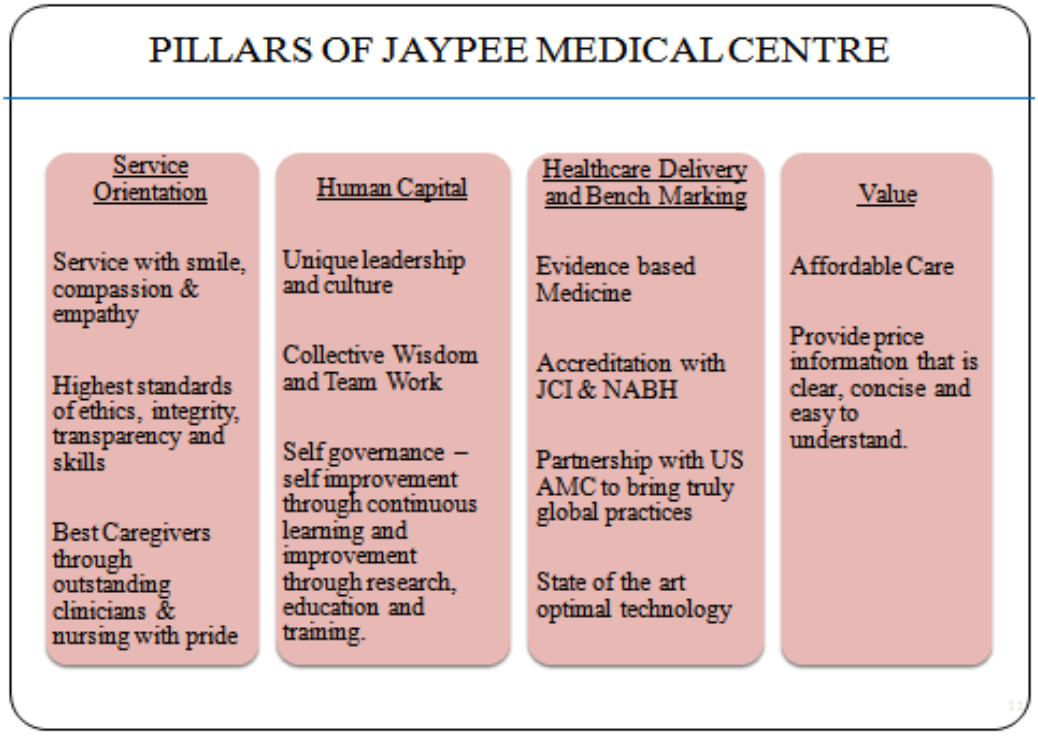

Figure 4 : Pillars of Jaypee Medical Centre

OVERVIEW OF JAYPEE MEDICAL CENTER

- Flagship Hospital of the Jaypee Group
- Spread over 110000 Square Meters of campus
- Total Beds: 1000 beds. (505 Beds in Phase 1)
- Proposed Nursing School on campus
- Would be a LEED Certified building
- Would target for Joint Commission International accreditation in first year

SERVICES TO BE OFFERED

CENTERS OF EXCELLENCE

Specialties and Super Specialties:

- Cardiac Science
- Neuro science
- Bones and Joints
- Minimal invasive surgery
- Cancer Unit
- Critical Care Medicine
- Trauma
- Mother & Child Care
- Gastroenterology
- GI Surgery
- Internal Medicine
- General Surgery
- Endocrinology/Rheumatology
- Urology & Nephrology
- Physical Medicine
- Rehabilitation Services
- Advanced Diagnostics-Lab Medicine/Radio Imaging/Transfusion Medicine
- Aesthetic Medicine Centre
- Behavioral Science

Figure 5 : Services to be offered

FLOOR WISE DEPARTMENTAL PLANNING

Sl. No.	FLOOR	DEPARTMENTS
1	Seventh	Wards
2	Sixth	Wards
3	Fifth	Wards
4	Service	IT Server, AHU, PTS station and MEP
5	Fourth	OT Complex, ICCU, Cath lab.
6	Third	Economy Bed, IVF, MICU, SICU, NICU, Labour and Delivery
7	Second	Chemotherapy, Cosmetology, Endoscopy, Physiotherapy, Paediatric, Office.
8	First	Behavioral science, Orthopedics , Neurology, Gen. Surgery/MAS, Pulmonology, Ophthalmology, Dental, ENT, Diabetes Cardiac clinic.
9	Ground	Executive Health Check up, Dialysis, Radiology, Day care, Emergency and Trauma, Pharmacy.
10	Upper basement	Blood Bank, Pathology Laboratory, Nuclear medicine, Kitchen, Administration.
11	Lower basement	Bio-medical Eng., Radiation Oncology, Laundry, Mortuary, CSSD.

TASK PERFORMED IN THE ORGANIZATION

- Assisted in planning of electrical requirement in upcoming SARDAR hospital in Ankaleshwar .
- Assisting in planning of an upcoming hospital of Jaypee in Chitta:
    - review of Layout plans from medical as well as operational prospective made by architectural team
    - Designing of electrical layout in the same.
    - Designing of furniture layout related to medical equipment requirement.
    - Assisted in planning out of dental unit, ophthalmology unit, ECHO/Doppler unit, STRESS unit , procedure room, NICE and Labor room
- Assisted in planning of swing doors and steel paneled doors for Jaypee medical center
- Assisted in planning of corner guards and wall guards for Jaypee medical center
- Assisted in making pricing policy:
    - Making comparative list for different procedures and for different departments.
- Assisted in planning Layout of BLOOD BANK for Vivekanand Medical Institute, Palampur
- Working on developing INTERNATIONAL MARKETING PLAN 2013-2014 for Jaypee Medical Center.
- Working on hospital policy manual according JCI & NABH for Jaypee medical center

LEARNINGS

- What all points should be kept into consideration while planning out a budget for any hospital and how to proceed with?
- How to make policies for a hospital with help of a systematic format
- How to make a marketing plan for a hospital and points of initiation for the same.
- How to look-up while reviewing the layouts from operational aspect, point to be taken into consideration so that department can work effectively and efficiently.

CHAPTER- 1

1.1 Introduction

Need of Laboratory in Health Care

Laboratory services are an integral and indispensible part of disease diagnosis, treatment, monitoring response to treatment, disease surveillance programs and clinical research. The World Development Report 1993, regarded provision of Essential Health Technology as an important ingredient of Essential Clinical Services. Use of diagnostic techniques aid early diagnosis enabling appropriate and prompt intervention thereby reducing overall disease burden and promoting health. [1]

Laboratory services

A medical laboratory or clinical laboratory is a laboratory where **tests** are done on clinical specimens in order to get information about the health of a patient as pertaining to the diagnosis, treatment, and prevention of disease. According to NABL, the following classification can be used:

- **Small Laboratory**: A laboratory receiving up to 100 patients per day
- **Medium Laboratory**: A laboratory receiving up to 101-400 patients per day
- **Large Laboratory:** A laboratory receiving above 400 patients per day

Functions of Laboratory

- Provision for comprehensive and accurate analytical test results.
- Assistance for confirming or rejecting a diagnosis, prognosis or a follow-up therapy.
- Detection of diseases.
- Training and Research.

Laboratory Services are an integral part of health care delivery/hospitals.Over the years, lab services have undergone a sea change:

- Shift to high levels of automation
- Use of highly skilled personnel
- High revenue generation

Stakeholder

- Patient
- Doctor
- Reception In-charge
- Phlebotomist
- Sample Segregator
- Lab. Technician
- Head Of the Department (HOD)

Functional Components of Laboratory

- Biochemistry
- Clinical Pathology
- Hematology
- Microbiology
- Histopathology/ Cytopathology
- Immunology/ Serology

Biochemistry Laboratory

The Biochemistry section performs qualitative analysis of the chemicals found normally or abnormally in blood and body fluids (Hormones, Enzymes / Iso-enzymes, Metabolites). Examples: blood sugar, urea, uric acid, cholesterol etc.

Clinical Pathology Laboratory

The Clinical pathology section examines body fluids like blood, urine, stool, pleural fluid and peritoneal fluid. Examples: urine albumin, urine sugar, bile salt.

Hematology Laboratory

The Hematology section performs tests and procedures pertaining to the examination of blood and blood forming organs of the body. Example: Hb, TLC, DLC, ESR, PCV etc.

Microbiology Laboratory

The Microbiology section identifies the microorganism in the body fluids and tissues, skin scrapings etc. This involves culture of the organisms, their morphological identification, and sensitivity of the organisms to different antibiotics. Examples: Blood culture and sensitivity, urine culture and sensitivity, Z.N Stain for Acid Fast Bacilli (AFB).

Histopathology/Cytology Laboratory

The histo-pathology or cytology section prepares and examines the microscopic sections of tissues to identify abnormality of tissues or cells. Examples: Biopsy, FNAC.

Immunology/ Serology Laboratory

Immunology section performs investigation related to the immune system of the body helping in diagnosis of diseases. Examples: Blood Anti nuclear antibody (ANA)

The laboratory can be managed manually or electronic systems. Unfortunately, manual reporting systems are neither accurate nor timely. They depend on multiple transcription of results, and they are slow - studies in the author's lab showed that clerical work in typing and issuing reports took about as long as analysis. Further, manual reporting is cumbersome and labor-intensive, data retrieval becomes a hunt across multiple locations for a single piece of paper, and retrospective data analysis is virtually impossible.[2]

The modern laboratory exists in an environment that produces a large amount of data. With the advent of new technologies, both the quality and quantity of information is increasing exponentially. This increase of data can cause significant problems and methods are needed to manage it. One such method used is a LIMS (Laboratory Information Management System) [3] . LIMS provides a way of automating part of the laboratory system. In a traditional laboratory 75% of the total cost comes from manpower removing the need for some human interaction can significantly reduce overheads. The primary function of most laboratories is to provide validated information under some sort of time constraint and then based on that information, allow medical professionals to make decision.[4]

A Laboratory Information Management System (LIMS) is an excellent tool to support the laboratory enabling it to manage the processes described above. Without LIMS, data and information are scattered over the organization and as such not available to the intended users. Results are copied several times, which can cause typing/writing errors. After the introduction in the early eighties, thousands of laboratories worldwide have installed LIMS. LIMS implementations vary from small laboratories with simple requirements to large multi-site laboratories with complex requirements. Since LIMS systems help to manage laboratory processes in different types of laboratories, they must have different functionalities to suit the different domains. Another prerequisite for LIMS systems is that they must be very flexible and easy to configure.[4]

LIMS- Laboratory Information Management System

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After the introduction in the early eighties, thousands of laboratories worldwide have installed LIMS. In 1982 the first generation of LIMS was introduced in the form of a single centralized minicomputer, which offered laboratories the first opportunity to utilize automated reporting tools. As the interest in these early LIMS grew, industry leaders like Gerst Gibbon of the Federal Energy Technology Centre in Pittsburgh began planting the seeds through LIMS-related conferences. By 1988 the second-generation commercial offerings were tapping into relational databases to expand LIMS into more application-specific territory, and International LIMS Conferences were in full swing. As personal computers became more powerful and prominent, a third generation of LIMS emerged in the early 1990s. These new LIMS took advantage of the developing client/server architecture, allowing laboratories to implement better data processing and exchanges.[5] By 1995 the client/server tools had developed to the point of allowing processing of data anywhere on the network. Web-enabled LIMS were introduced the following year, enabling researchers to extend operations outside the confines of the laboratory. From 1996 to 2002 additional functionality was included in LIMS, from wireless

networking capabilities and geo-referencing of samples, to the adoption of XML standards.[5]

A Laboratory Information Management System (LIMS) is an excellent tool to support the laboratory enabling it to manage the processes described above. Without LIMS, data and information are scattered over the organization and as such not available to the intended users. Results are copied several times, which can cause typing/writing errors. LIMS implementations vary from small laboratories with simple requirements to large multi-site laboratories with complex requirements. Since LIMS systems help to manage laboratory processes in different types of laboratories, they must have different functionalities to suit the different domains.

BENEFITS OF LIMS -

- Allows better utilization of staff by reducing the amount of time spent keying in data or calculating results.
- Reduces or eliminates data transcription errors.
- Improves turnaround time.
- Provides a clear picture of the work in progress status of the laboratory at any point in time, to identify and eliminate bottlenecks
- Allows ancillary record keeping such as calibration and maintenance records for instruments and equipment, sample storage and disposal, invoicing, inventory tracking and more. [6]

1.2 RATIONAL OF STUDY-

It is said that a successful LIMS implementation is closely linked to the selection process. There are reasons for not taking a formal selection process for a LIMS. The most prevalent is that most of the systems today all have about 80% functionality in common. In considering the 'Pareto Principle', it can be shown that it is in fact, the remaining 20% functionality that is of paramount importance. There are many steps involved in the selection process. One of the most important (and frequently missed) steps in LIMS selection work process analysis (WPA). The process flow should be such that which can be easily acceptable by the medical professionals. WPA defines the role of LIMS within the organization. Requirements must be clearly specified, concise and well understood. On the basis of WPA a comprehensive list of required functionality/features of LIMS can be derived. This list is useful for prioritizing the needs of the organization and aids in vendor selection.

1.3 REVIEW OF LITERATURE-

Brief abstracts of few studies conducting regarding Work process flow and need benefit of implementation of LIMS-

Lynn Rasmussen, Clinton B. Maddox, Bill Harten, E. Lucile White in Dec 1, 2007 performs a study on : **A Successful LIMS Implementation**: Case Study at Southern Research Institute: Aims to track all aspects of the workflow that can contribute to success or failure of LIMS implementation. With increased throughput comes increased risk and increased cost of failure. An effective method of mitigating these risks is a well-designed laboratory information management system (LIMS). Flexibility, ease of use, and ease of implementation are all important considerations when choosing a commercially available LIMS. Personnel training, instrument validation, reagent expiration, and instrument performance are just a few of the many parameters that need to be tracked to ensure success in a high-throughput environment.[7]

Ben Tagger, An Introduction and Guide to Successfully Implementing a LIMS: Paper aims to introduce the technology of LIMS (Laboratory Information Management System). LIMSs have been around for over twenty years, but still remain difficult to implement successfully. This paper will provide a brief introduction of LIMSs followed by a description of some of the existing technologies available to users of today's LIMS. The paper will describe some of the pitfalls of LIMS implementation and some of the most likely causes for a failed LIMS project. It will then give a generalized approach for the development of a successful LIMS implementation and finally, a look to the future addressing some of the needs of the LIMS industry.[8]

Alan Serrero, Ted Paczek and Christine Paszko , October 2007 on Laboratory Needs Assessment Benefits LIMS Implementation : Many laboratories may have the expertise to translate manual processes and laboratory automation requirements into a detailed specification document for all of the system requirements, features and functions of a laboratory information management system (LIMS). However, that may not be the best use of their resources. An expert Needs Assessment can provide a strong foundation for the successful implementation of a LIMS and can also save the laboratory significant resources.

Not only does it allow the laboratory LIMS team to focus their resources at those areas that will return the greatest value, but it allows the laboratory to fine tune their processes to optimize efficiency, productivity and ensure regulatory compliance. It should be done as early in the planning process as possible. This allows the laboratory to really examine what they want the LIMS to do, which features they want and what the scope of the total project will be.[9]

1.4 AIMS AND OBJECTIVES

General Objective

To map a detailed process flow for laboratory in a tertiary care hospital and derive the functional requirements for the implementation of LIMS in the hospital.

Specific objectives

1. To develop a detailed work process flow at the laboratory in a tertiary care hospitals .
2. To assess the informational need of the laboratory system based on the process flow.
3. To develop a comprehensive list of functions/ features of LIMS that will fulfill the informational need of the laboratory system and there by facilitate appropriate vendor selection.

CHAPTER- 2

2.1 STUDY DESIGN AND METHODS

TYPE OF STUDY

The study is descriptive in nature.

LOCATION OF STUDY

Jaypee Medical Centre, Noida

DURATION OF STUDY-

February 2013 – April 2013

SOURCES OF DATA

PRIMARY DATA

- Discussion with professionals, IT team and Laboratory Head in Jaypee Medical Center.
- Discussion done with the laboratory incharge and staff of laboratory of different corporate hospitals in NCR.

SECONDARY DATA

- Information from the Staff head of Laboratory of different corporate hospitals in NCR
- Books
- Journals

METHODS OF DATA COLLECTION

observation: The activities, workflow of Laboratory were observed and noted.

Interviews: Direct Interview was held with the laboratory personnel of various hospitals in NCR.

DEFINITIONS-

- **Archive** —It is data from a working database that has been transferred to storage media for long term storage. Information stored in the archive can be retrieved for reporting or additional processing.
- **Archive ,v**—It is the process of making an archive. It allows erasure of data from the working database in order to free space for additional data.
- **Audit Trail** —It is a record of events related to a transaction including the original information and any changes to the information. The audit trail may be composed of manual or computerized records of events and information, or both. The audit trail is used to reconstruct a series of related events that have occurred.
- **Data** —-These are recorded observations used for producing information.
- **Data Analysis -** It is the ability to display, manipulate, transform, and verify LIMS database information
- **Data/Information Capture** - It is the uni/bi-directional communication of data/information to/from a LIMS.
- **Data integrity** -The concept that information is not corrupted during communication, transfer, manipulation, storage, and recall functions.
- **Determination -** It is a single result, the lowest level of information in a LIMS.A LIMS example of a determination is a pH result.
- **Dynamic table(s)** — LIMS database table(s) or file(s) where sample and result information are stored. The storage of LIMS sample and result data/information can be in one or more database tables. Synonyms: LIMS database, active database.
- **Event-triggering —** action(s) performed following a specific condition(s). Event triggering conditions can be initiated by way of data, process, or other external events.
- **Information** - It is data plus context. Data are of little value without context. The information value of a LIMS is related not only to the quality of data stored, but also the context or relationships that are maintained within the system.
- **LIMS** -Acronym for Laboratory Information Management System. Computer application(s) [software] and hardware that can acquire, analyze, report, and manage data and information in the laboratory.
- **Laboratory management** -The monitoring and control of a laboratory's data management, and to a lesser degree, laboratory resources.
- **Login -** Registration of a sample in a LIMS.
- **Profile -** It is a group of one or more tests. A predefined list of tests that are assigned to a LIMS sample during login.
- **Raw data** -It is the original record of an observation. Data entered into the system directly from original observations (not from a source document) by keyboard or automatically by laboratory test devices are considered raw data.

Raw data is recorded on laboratory worksheets, memoranda, notes, notebooks, and are the result of original observations and activities related to laboratory testing. Raw data may include photographs, microfilms, computer printouts, magnetic media, and recorded data from automated instruments.

- **Results** -The smallest unit of test data input into the LIMS.For example, an individual pH result.
- **Reporting -** Extracting, organizing, and presenting information stored in a LIMS.
- **Sample** -A small part of portion of a material or product intended to be a representative of the whole. A LIMS sample may be further sub-divided into sub samples or aliquots.
- **Standards-** A standard is a sample containing a known amount of contaminant.
- **Static tables** -Descriptive LIMS database tables where profiles, tests, calculations, specifications, and related information are defined and stored (commonly found in "lookup/reference/dictionary" tables). LIMS stores look up information to speed login and test assignments. Generally prior to login the static tables need to be configured. Some LIMS implementations can enter static table information directly from login step.
- **System management** -monitoring and maintaining the computer system.
- **Test —**operation performed on a sample. A test may result in one or more determinations. A test may include specifications and procedures for the determinations involved plus sample preparation and biographical information.
- **Validation —**establishing documented evidence which provides a high degree of assurance that a specific implementation of a LIMS will consistently meet its predetermined specifications and quality attributes.
- **Verification** -process of checking the accuracy of manually, or automatically (electronically) entered information.
- **Work flow** -description of tasks performed within a laboratory, including sample flow, inputs, process and outputs.

Laboratory layout in hospital-

Laboratory is situated at the upper basement floor. It has the following departments-

Biochemistry

Hematology

Microbiology & Serology

Histopathology

Clinical Pathology

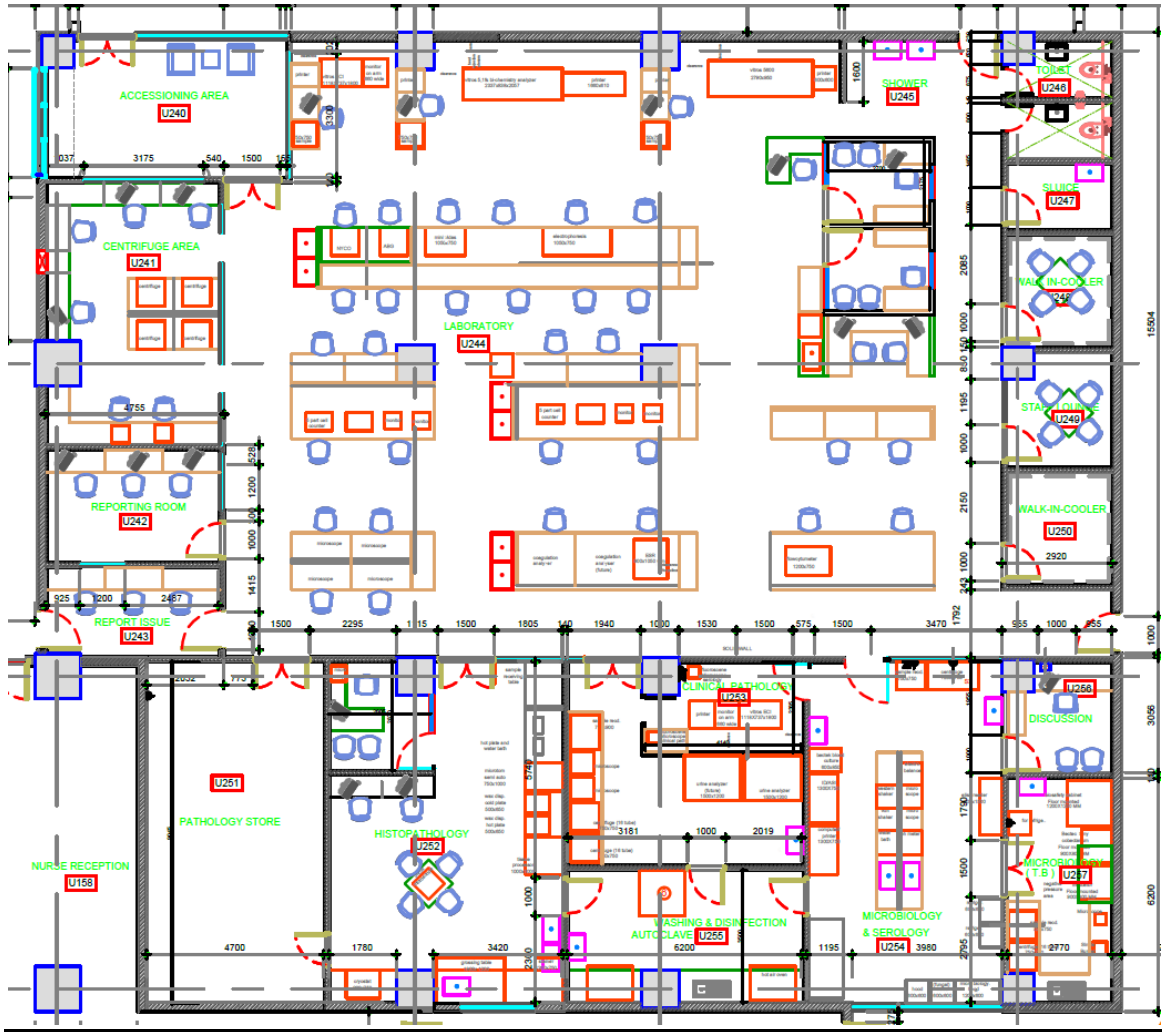


Fig 5- Layout of Laboratory at JMC

CHAPTER 3

FINDINGS

WORK FLOW DESIGNING-

Progression of steps (tasks, events, interactions) that comprise a work process, involve two or more persons, and create or add value to the organization's activities. In a sequential workflow, each step is dependent on occurrence of the previous step; in a parallel workflow, two or more steps can occur concurrently. In order to understand the informational need and functional requirements of a laboratory software it is critical to understand the process flow of laboratory in detail.

Laboratory layout in hospital-

Laboratory is situated at the upper basement.

Sample collections rooms are in Ground , First and Second floor for OPD and Walk-patients.

Pneumatic shot system along with the provision of GDA for sample transfer to central receiving area.

Patient Flow in Laboratory

The patients from the following departments may avail laboratory services:

- Outpatient Department
- Emergency Department
- Inpatient Department
- Walk-in patients

The workflow is different for different category of patient. Fig 6, 7, 8 depict the workflow that has been derived on the basis of inputs taken from the professionals of the concerned stream working at various setups. The following points were derived after research and discussions with concerned individuals -

- Workflows should be designed rather than leaving them to arise organically and evolve.

- Most often, when workflow processes are looked at in isolation, the processes appear quite logical (and even efficient) in acting to accomplish the end goal. It is in the interaction among the processes that complexities arise. Some of these interactions hide conflicts in the priorities of different roles in an organization.
- The design of good organizational workflow is not simply about improving efficiency. Workflow processes are maps that direct the care team how to accomplish a goal.
- A good workflow will help accomplish those goals in a timely manner; leading to care that is delivered more consistently, reliably, safely, and in compliance with standards of practice.
- An excellent workflow process can accommodate variations that inevitably arise in health care through interaction with other workflow processes, as well as environmental factors such as workload, staff schedules, and patient load.

Fig 1: WORKFLOW DIAGRAM FOR OPD/WALKIN PATIENTS

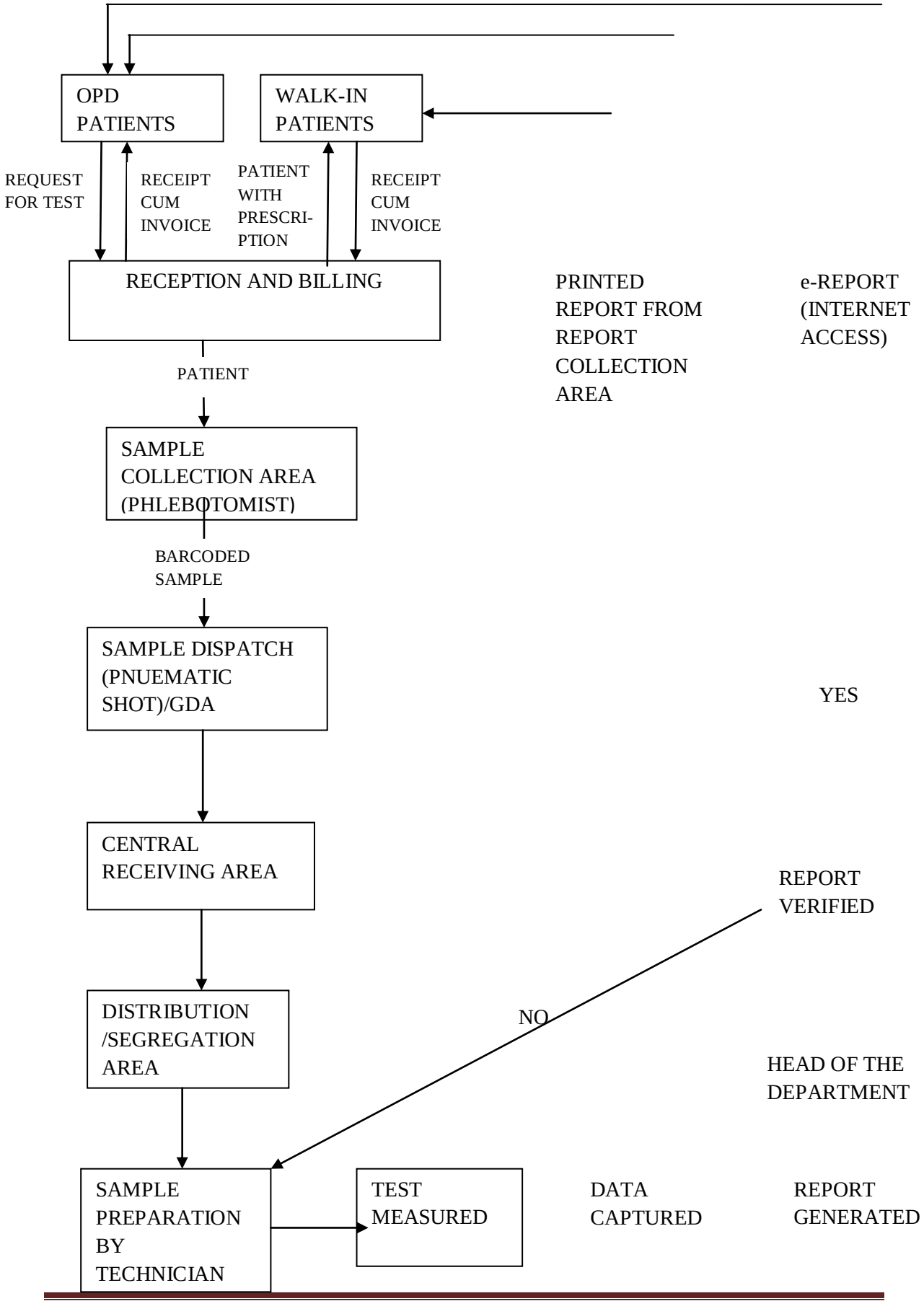


Fig: 2 WORKFLOW DIAGRAM FOR IPD PATIENTS

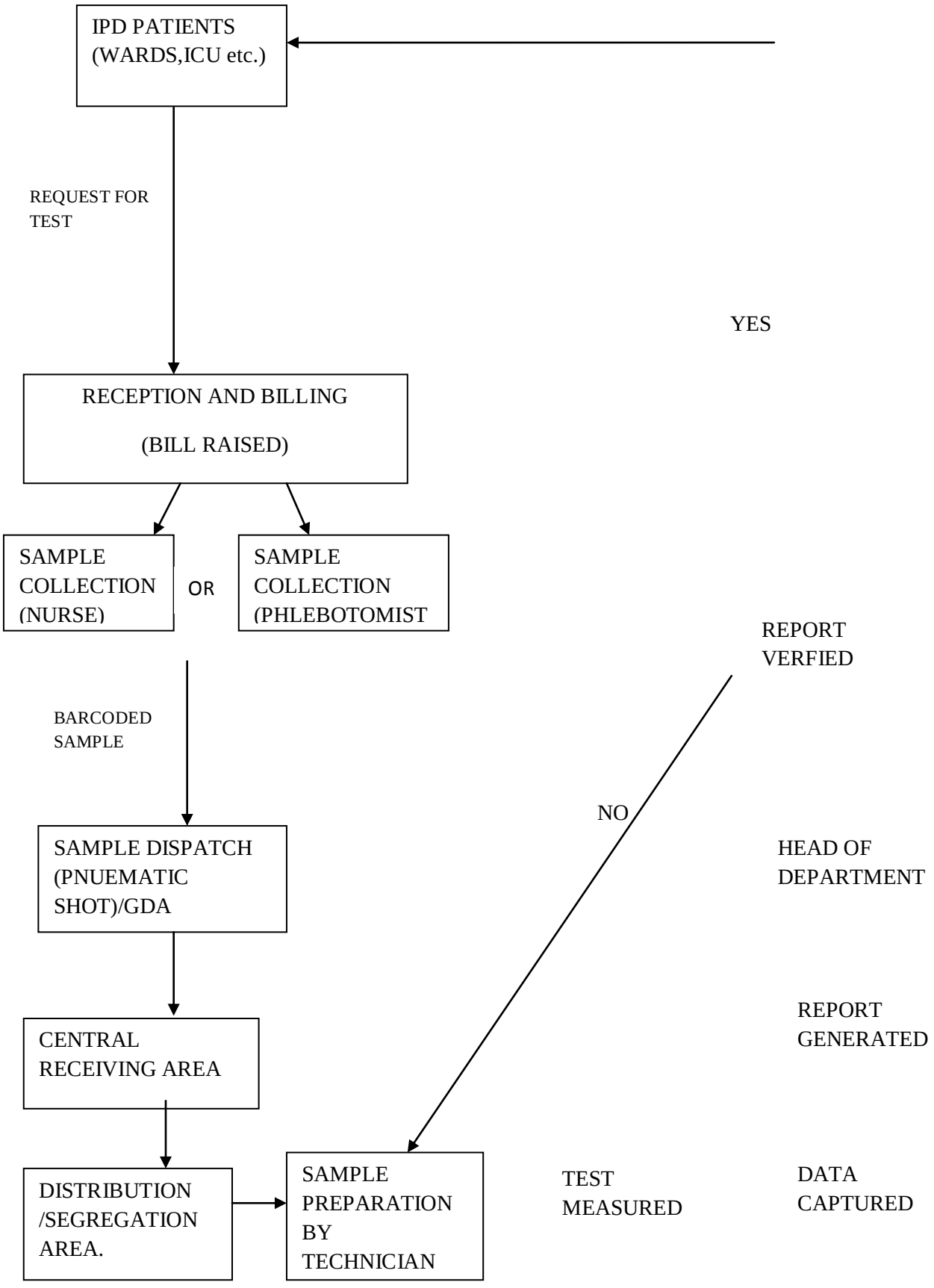
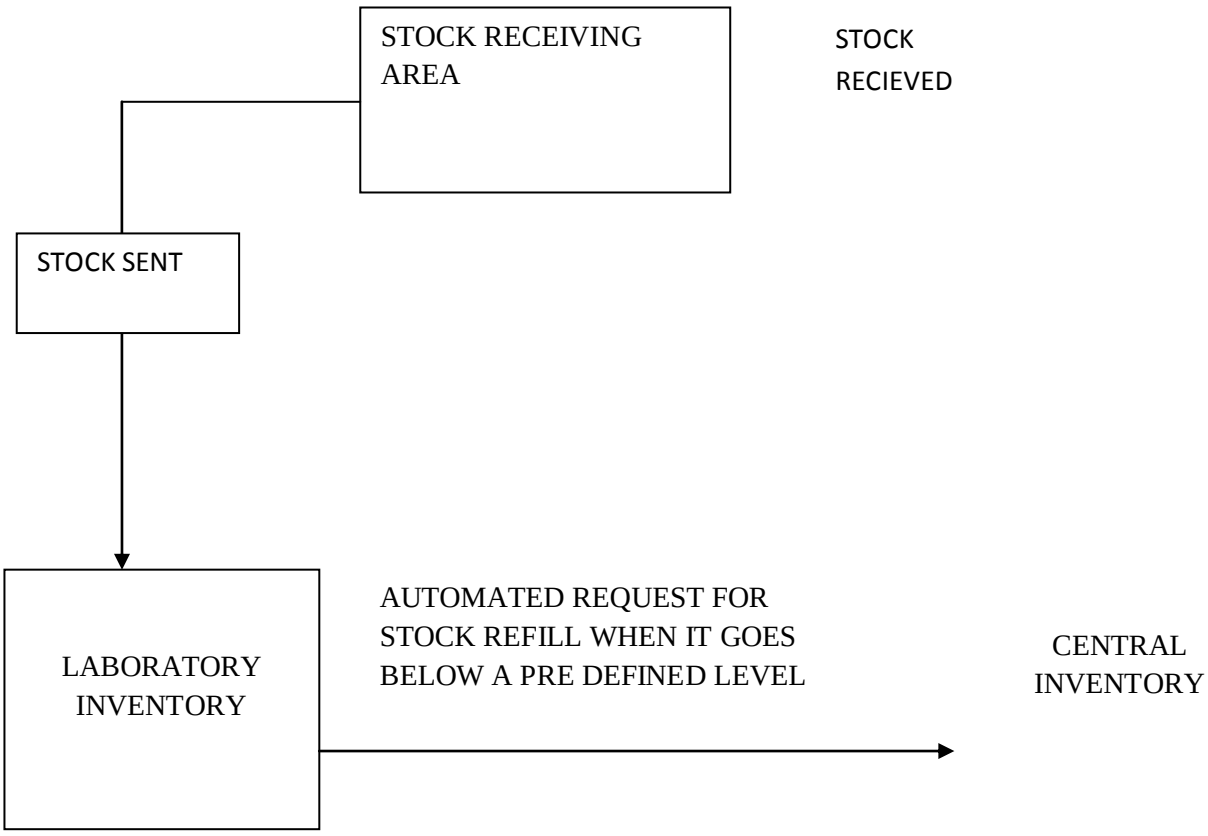


Fig: 3 WORKFLOW DIAGRAM FOR LAB. INVENTORY



Dimensions of Laboratory Data

McDowall and Mattes, Liscouski,' and Mahaffey' present a hierarchical segmentation of information resources within the laboratory as data, information, and knowledge. Their breakdown is consistent with works on information resource management.

The segmentation of data, information, and knowledge is as follows.

- Data consists of raw facts that are either acquired or observed about people, objects, or events.
- Information is data that are manipulated and presented in a form suitable for human interpretation and decision making. It includes facts such as concentration levels or substances present in the sample.
- Knowledge are facts uncovered from the information. It tells us that a certain formulation will or will not work in a given process.

Raw Data

Raw data is the original record of a measurement or observation. Data entered into a computer directly via the keyboard or automatically from an automated instrument is considered to be raw data. However, if the data is transcribed to the computer from a source document, such as a laboratory worksheet, notebook, or instrument printout, it is not considered to be raw. It also includes original descriptive information provided about the sample and its source. This may include a history of the sampling, a listing of materials included, or other attributes of the sample submitted for testing.

Processed Data

Processed data is an outcome of a calculation, manipulation, or other processing of the original raw data.

Intermediate Results

Intermediate results have units or context relative to the properties determined by the analysis. Examples include component concentrations, substances present, or organisms identified.

Final Results

Final results are the final outcome of one or more analyses for an analytical property. It represents the actual values or characteristics of the sample determined from all tests performed.

Reported Data

Reported data include all information released from the laboratory and directly applied to an evaluation or decision. They may contain final results which have been summarized, averaged, plotted, or otherwise manipulated to facilitate and expedite the decision-making process.

Utilization of Laboratory Data

Laboratory data can be further segmented according to the way in which it is used. Operating data meet short-term, transactionally oriented needs. Strategic data fulfill long-term needs.

Operating

Operating data supports the daily business activities of the laboratory. This includes the detailed information necessary to complete testing on samples and report results. Speed is an important characteristic of systems designed to handle operating data since it affects the daily performance of the organization. Operating databases include a lot of detailed information about the outstanding work within the laboratory.

Strategic

Strategic data are typically subsets or summaries of the operating data. They include information necessary for management planning and control such as summaries of the laboratory's workload, testing demands, performance, turnaround time. Strategic databases include long-term summaries of work already completed by the laboratory.

Data flow is been derived-

After designing the workflow, information flow at each step was derived in order to understand the informational need of the laboratory system

A **data flow diagram** (**DFD**)) is a graphical representation of the "flow" of data through an information system, modeling its process aspects. Often they are a preliminary step used to create an overview of the system which can later be elaborated. Data Flow Diagrams can also be used for the visualization of data processing .Data Flow Diagram shows what kinds of information will be input to and output from the system, where the data will come from and go to and where it will be stored. With a data flow diagram, users are able to visualize how the system will operate, what the system will accomplish, and how the system will be implemented.

Data flow diagrams can provide a physical idea of where the data ultimately has an effect upon the structure of the whole system from order to dispatch to report. Fig 9, 10, 11 elaborate the data flow within the systems

Fig: 4 DATA FLOW DIAGRAM FOR WALKIN PATIENT

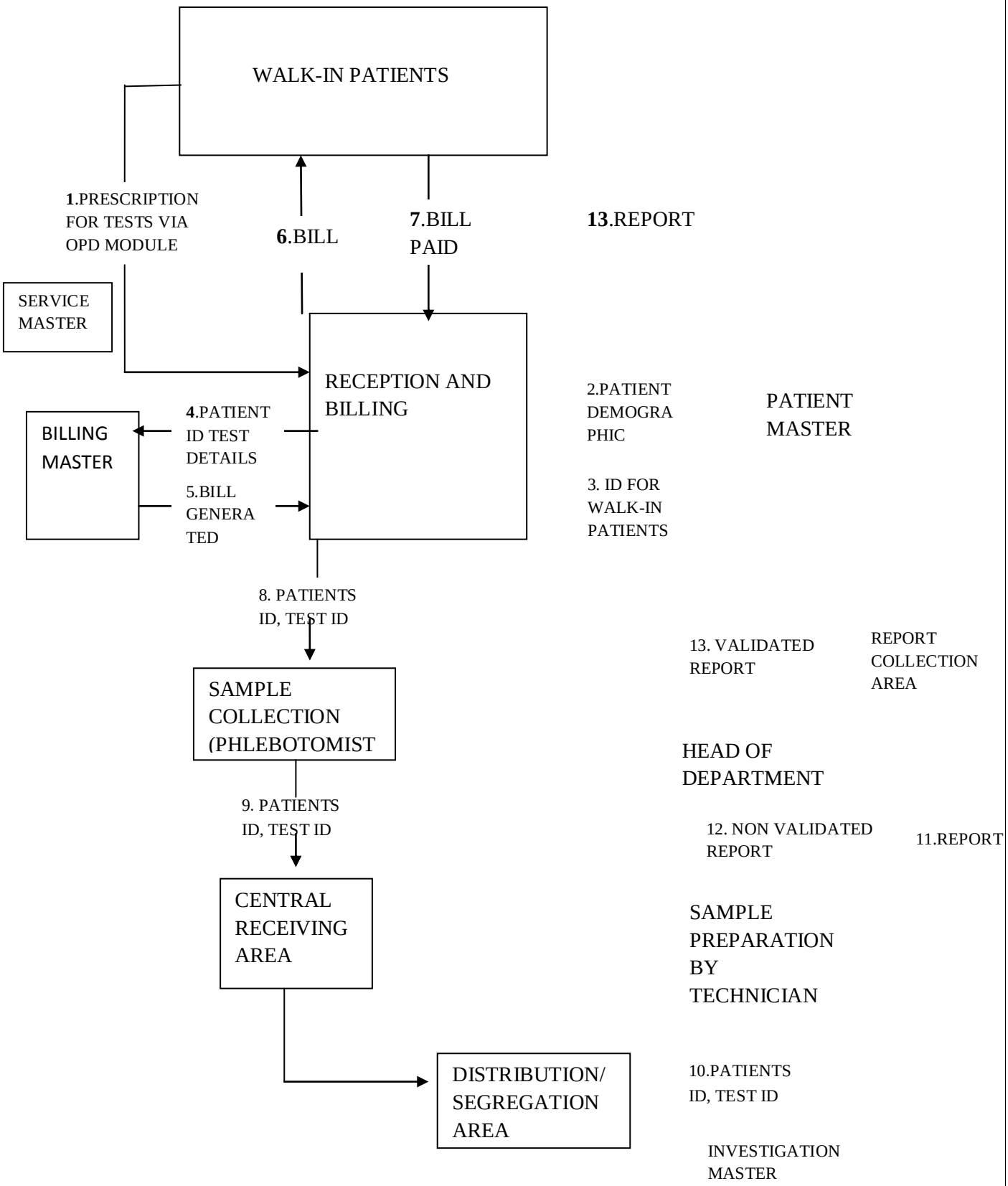


Fig: 5 DATA FLOW DIAGRAM FOR OPD PATIENT

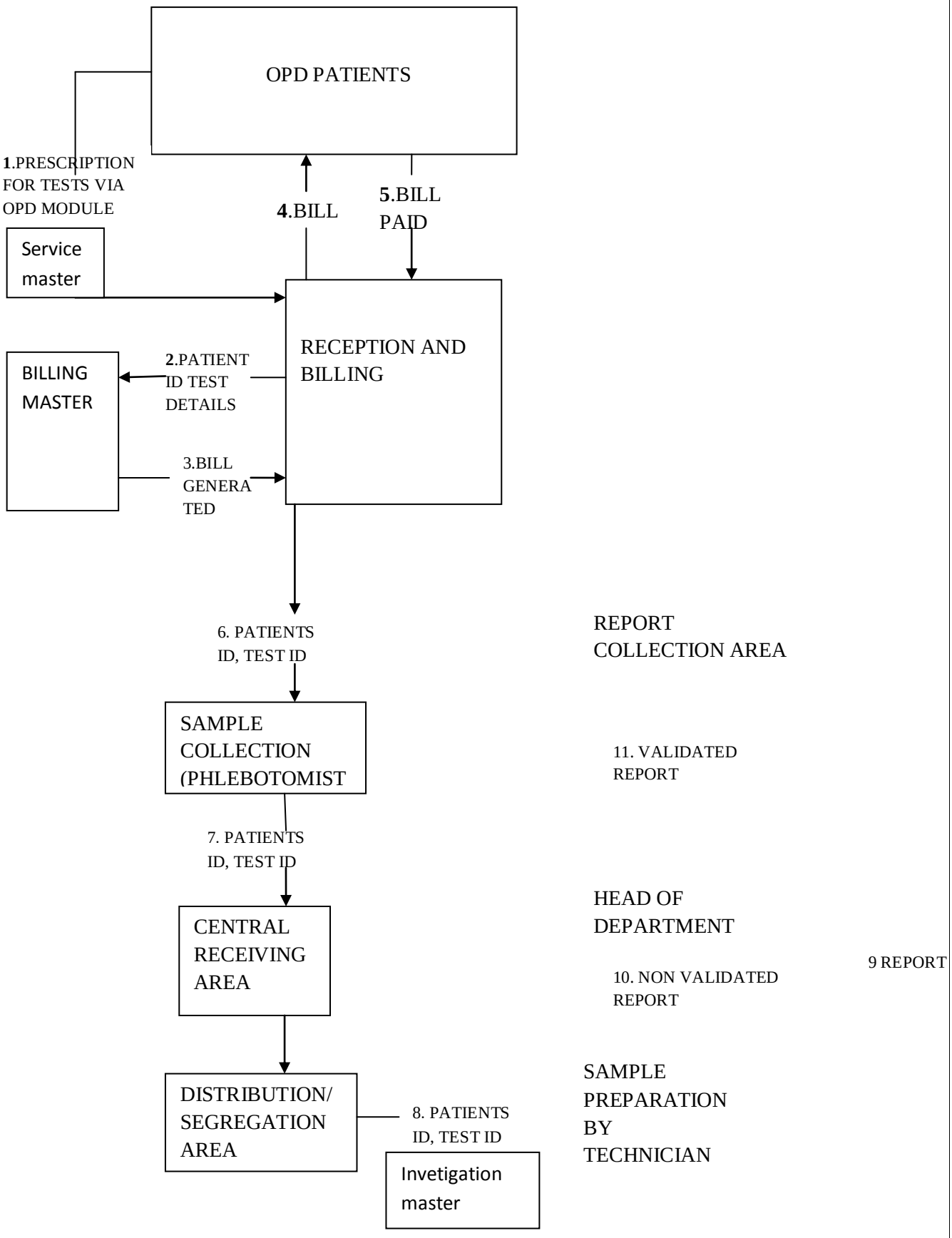
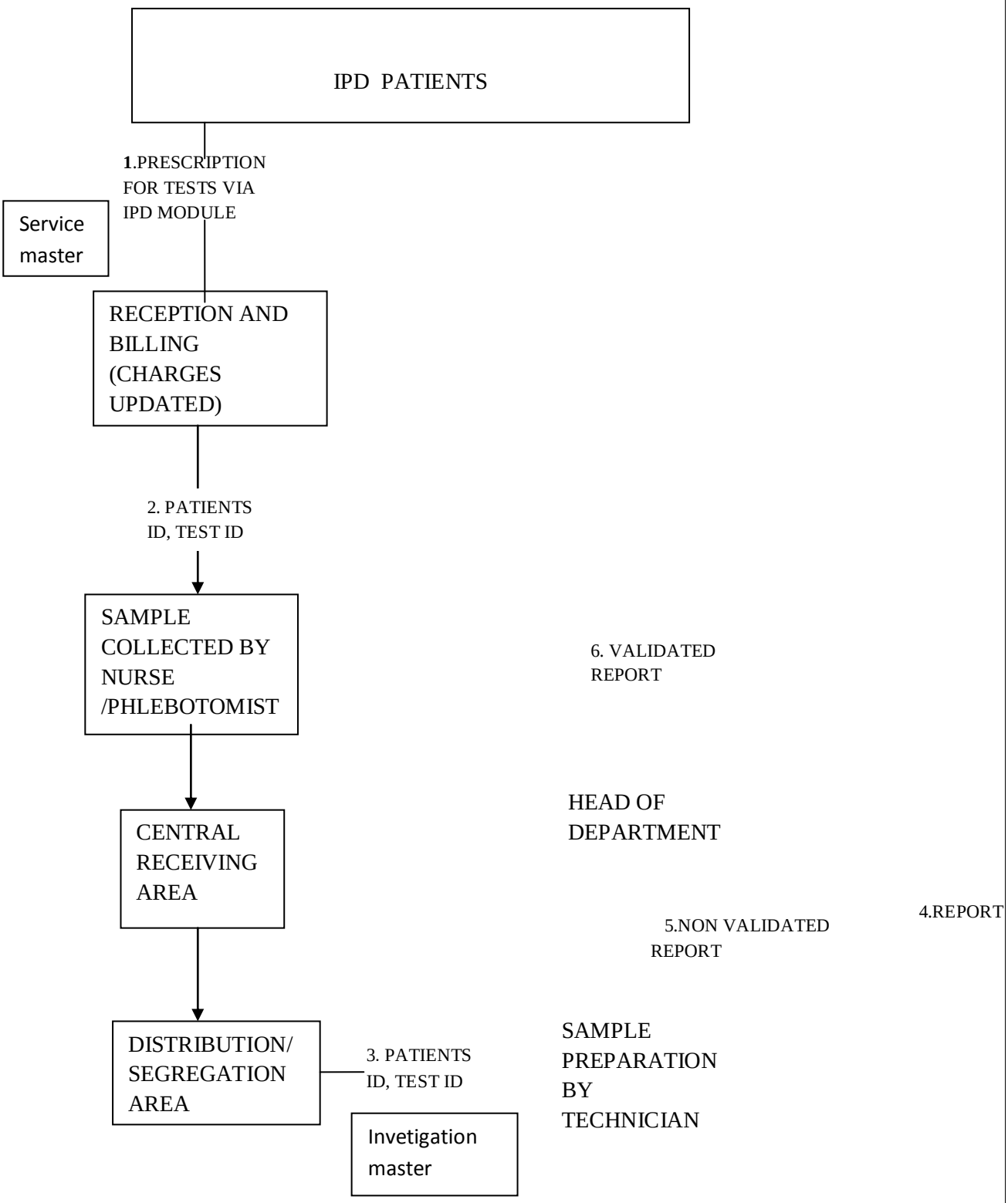


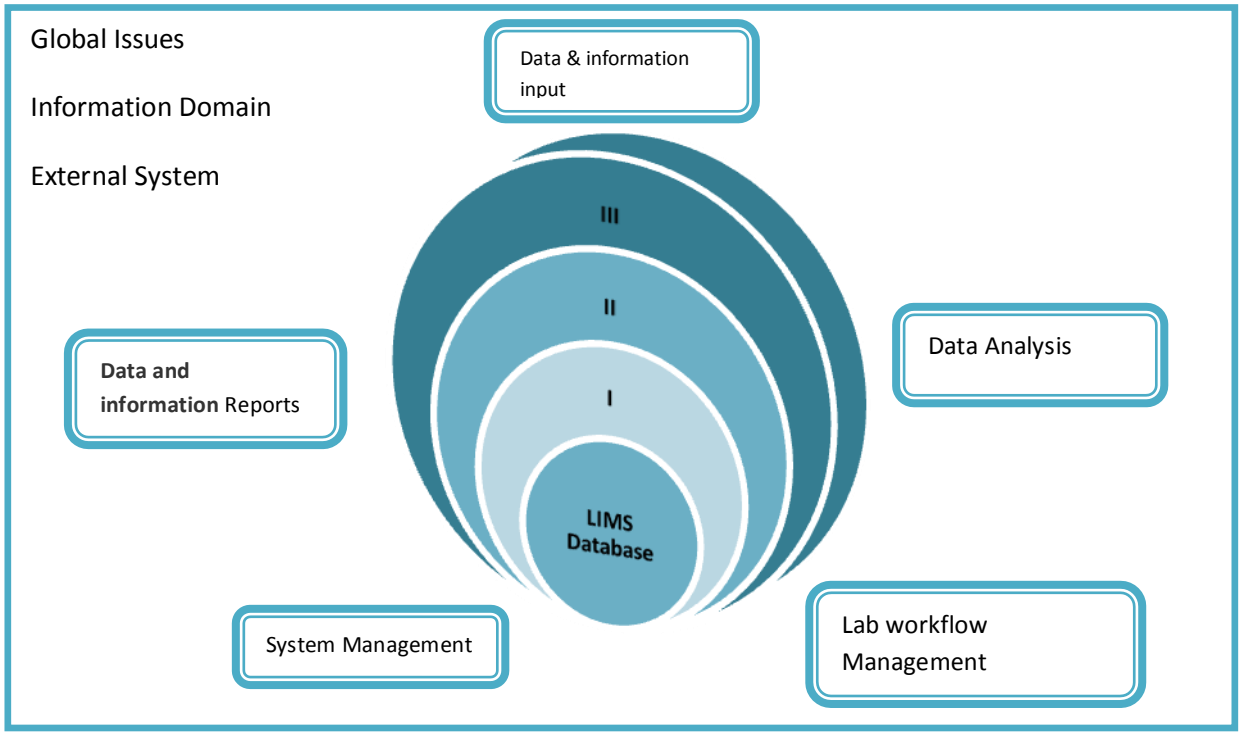
Fig:6 DATA FLOW DIAGRAM FOR IPD PATIENT



FUCTIONAL REQUIREMENT OF LIMS-

In order to have a successful implementation of LIMS it is critical to select software which fits to the work process flow and information structure of the organization. LIMS projects require large amounts of time, commitment and money. Making the wrong choice of selection could result in a failed project. However, inevitably no two laboratories are going to be the same. Work practices, management structure, strategy, expectations, human involvement, are all going to differ. In order to understand the functionality required in the software that would suit the proposed system in the laboratory we need to understand the concept of LIMS in detail to know what is has to offer.

LIMS Concept Model



The LIMS concept model is a graphical representation of the major components that comprise LIMS.

THE DATABASE

The central element of LIMS is the computer database. It is the central hub for all LIMS interactions. It is designed to systematically manage laboratory data.

The database is made up of two parts:

- The static area where descriptive information is defined about sample types, tests, calculation formulas, instruments, reagents, specifications and related information.
- The dynamic area where sample and result information is stored as samples are logged and results are entered.

The database technology employed by LIMS varies with each vendor .The terms static and dynamic represent general characterization of LIMS database tables; specific LIMS implementations use LIMS static tables in a dynamic fashion.

The three concentric rings represent the capabilities of a LIMS.

- Level 1 depicts core (mandatory) LIMS functions.
- Level 2 represents intermediate functions.
- Level 3 represents advanced functions and technology.

The database has five major satellite functional components:

- **DATA AND INFORMATION INPUT-**

  This function manages the communication of data and information to and from LIMS. It can be Uni-directional /Bi-directional. The most basic method of Information capture into a LIMS is represented by manual keyboard entry. Manual keyboard entry is one of the most common LIMS input methods. Level 2 data/information capture includes one way electronic transfer of information from subordinate and independent systems (instrument uploads/transfers are a common LIMS input method). Level 3 involves bidirectional communication between the LIMS and external systems (instruments, balances, other computer systems). The bidirectional communication includes instrument control, run lists, multi-instrument workstations, trigger LIMS functions from external systems and run parameter.

- **DATA ANALYSIS-**

  Data analysis is the process of verifying, manipulating, transforming, and displaying existing database information. . Level 1 data analysis includes simple range checking for inputs (for example; pH physical limits for inputs are 1 to 14 pH units), and simple calculations. Level 2 includes specification checking, intra-test calculations, descriptive statistics, and basic graphical presentation. Level 3 includes advanced user-defined functions, inter/intra-test/sample calculations, advanced graphical presentation, and dynamic links to prior results and external systems.

- **LAB WORK FLOW MANAGEMENT-**

  The monitoring and control of a laboratory's data, and to a lesser degree, laboratory resources. Level 1 functions include sample/order status, sample/order tracking and backlog information. Level 2 includes scheduling of laboratory work, location tracking of samples, work load prediction, pricing, and invoicing. Level 3 functions include laboratory resource management, artificial intelligence (AI) decision-making tools, revenue/cost tracking, and auto workload balancing.

- **DATA AND INFORMATION REPORTING-**

  Reporting makes it possible to extract, organise and present information which is stored in LIMS. Level 1 reporting includes predefined reports and sample labels. Level 2 reports include user-defined reports and queries. Level 3 reports include advanced natural language reporting tools, batch reports, event-triggered reports, exports to external systems, bulk data transfers, and advanced graphics.

- **SYSTEM MANAGEMENT-**

  Monitoring and maintaining LIMS computer systems. Monitoring and maintaining LIMS computer systems. Level 1 function includes backup and recovery. Level 2 functions include archiving, manual performance tuning, and system fault tolerance. Level 3 functions include dynamic

performance tuning and advanced system fault tolerance functions.

The box that surrounds the inner circles represents the surrounding environment of the LIMS.

Global issues impact all segments of the LIMS concept model. The global issues are:

1. Change Control—Change control covers LIMS software version/revision control, LIMS results (sample and determinations), LIMS static table information, LIMS screens (design, query, inputs and outputs) and reports, hardware, standard operating procedures (SOPs), facilities, and people. Change control can also be described by the term configuration management. Formal change control is essential for data integrity.
2. Communication Infrastructure—Network communication links between the LIMS and clients, including Local Area Network (LANs), Wide Area Network (WANs), public and private phone systems, etc.
3. Documentation—User manuals, programmer technical reference manuals, training manuals, SOPs, online documentation, vendor-supplied validation documents, vendor-supplied system development SOPs, and source code.
4. Performance—Responsiveness of all LIMS functions.
5. Quality—pertaining to the overall LIMS product. See
6. Security: It should be provided at three levels.
   - Physical security is linked to the facility and equipment accessibility.
   - System security is built into the operating system used by the computer hardware.
   - Application security is provided by the LIMS application and can be backed up by LIMS audit trails.

   Total system security includes backup, fault-tolerant functions, hot spares and support contracts (hardware and software).
7. User Interface- The user interface includes what appears on the computer screen and what the user physically interacts with (input devices: keyboards, bar codes readers). Examples include: command driven, menu systems, graphic user interface (GUI)/window systems, multi-media, hand-held input devices, bar code readers, and voice input.

So, after understanding the concept how LIMS work, now we derive the LIMS work flow in accordance with the laboratory work flow discussed earlier.

The LIMS Workflow Model

The LIMS work flow model provides a representation of the proposed work flow in the laboratory. Fig- gives the simple flow of the LIMS.(Fig7&8) explains the detail information transaction with each step and elaborates the functionality of the LIMS.
Status Update in LIMS- LIMS should maintain information regarding status of samples, individual test/determinations, comparison of results to specifications, verification of results, approval of samples/orders. Status information is updated as each LIMS transaction takes place. The functions/work flows all have an impact on LIMS status information.
Sample/order statuses include-

- New
- Ordered
- Active
- Received In The Lab
- Verified
- Reported
- Approved
- Released
- Rejected

Selected reports generated by LIMS retrieve information based on statuses.

Step 1 Generate Sample Request-

The initiation of a request for testing/sampling starts the process. Examples of sample requests include manual forms, phone requests, process-driven requests, time or calendar-based requests, ad-hoc requests, and LIMS generated requests.

Step 2 Sample Collection –

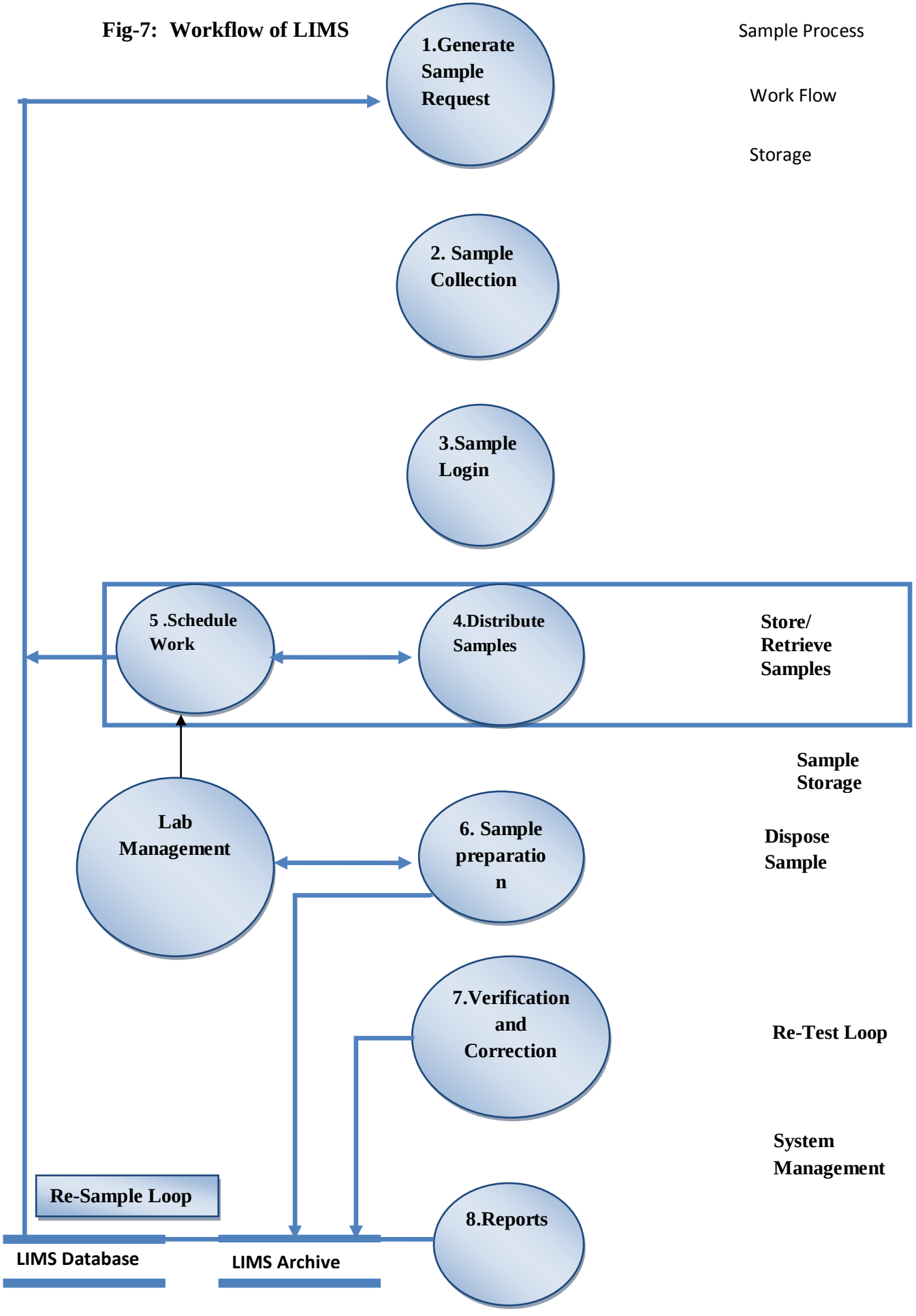
The sample collection will be assisted by the LIMS by printing collection lists and generating labels (bar code) for the sample containers. LIMS statuses will be updated

during the sample collection step. The LIMS will provide information on how to collect samples, specific sample plans, container requirements, safety.

Step 3- Sample Login-

LIMS assigns a unique number(s) to each sample/order that is registered (login). The unique number should a user-defined sequence. Multiple samples can be logically linked in one LIMS order or submission. The system captures who submitted the sample(s), costs, how the sample is identified, and what tests are to be done on the sample. Other information may also be important, such as the priority of the tests, what level of accuracy and precision is needed, what hazards the sample might present to the laboratory personnel, what approximate levels of components are expected, and what should be done with the sample when analysis is complete. The LIMS login function should be a simple, straight-forward process with a friendly and efficient user interface.

Fig-7: Workflow of LIMS



A confirmation report is often issued to ensure users the system accepted the sample order. LIMS statuses are updated for the sample/order. The. management function (MF) needs to record the fact that an order was made (for keeping operational statistics) and when it was made so the MF can begin to track the time intervals for the remaining steps of the process. This will also allow laboratory management to determine turnaround time and various overdue conditions.

Step 4- Distribution/Segregation of Samples-

It is frequently necessary to divide the sample for simultaneous analysis at different workstations. The LIMS knows all the tests that must be performed and can tell the technician what aliquots are needed, how much material must go in each one, and where they are to be sent. Additional labels are needed for the individual aliquots. Sometimes a preliminary treatment is performed on some or the entire sample, such as adding a preservative. The status of the test changes . It may be sent to a workstation in the laboratory or off site to a remote facility for analysis. Sample problems may also be noted at this point. There may be insufficient sample to prepare all aliquots, or the technician may notice a problem with the sample, such as a wrong color or improper physical state. The time is important, because it marks when the sample becomes available to the various laboratory workstations.

The process includes important LIMS functions of work list, sample routing, custody, and labeling At this point, the LIMS is informed that a sample has arrived. A laboratory label will be applied.

Progress Tracking

Work Progress Tracking

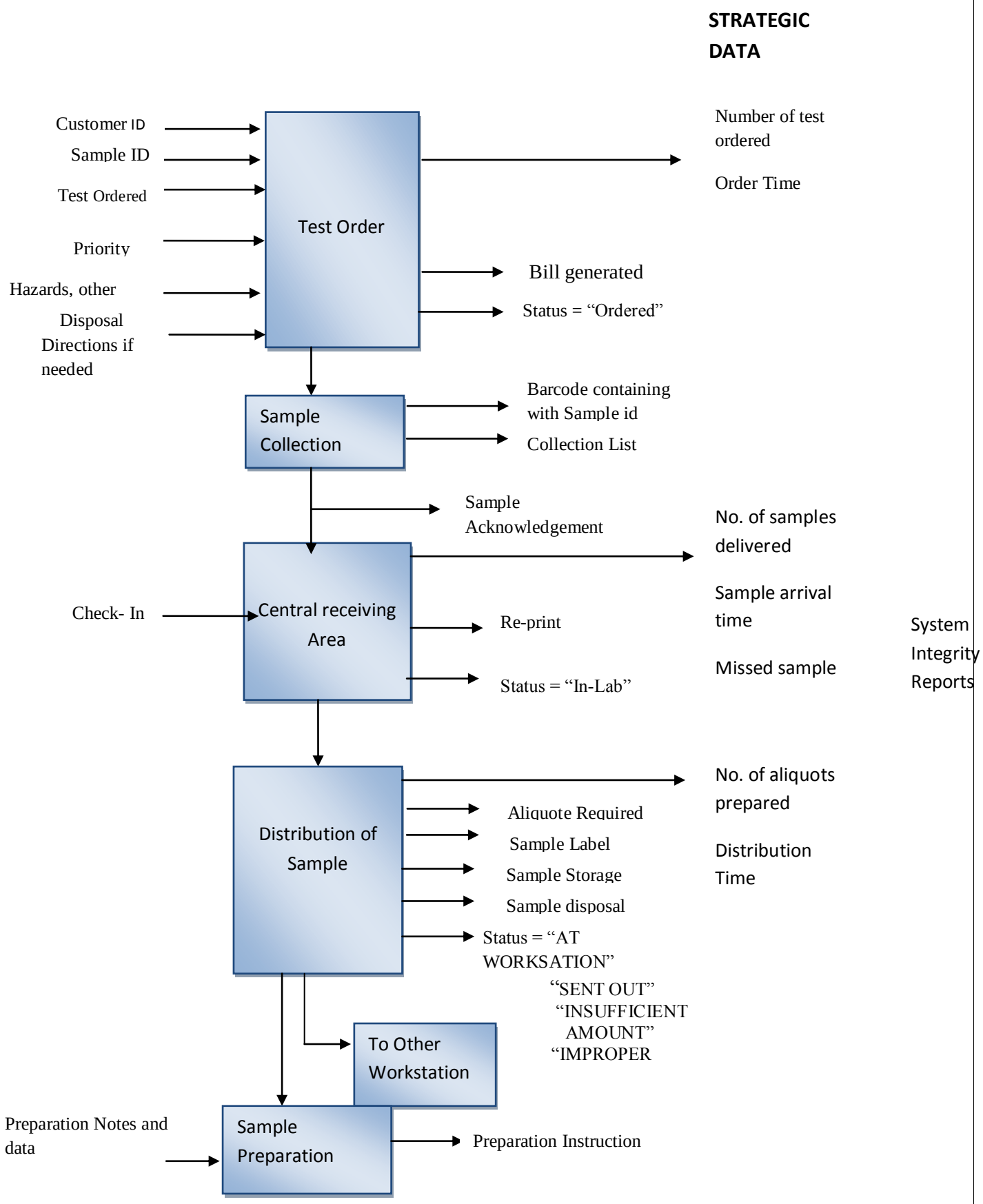
The progress of assigned analytical work is tracked. This involves programs that update status states as work proceeds through the laboratory.

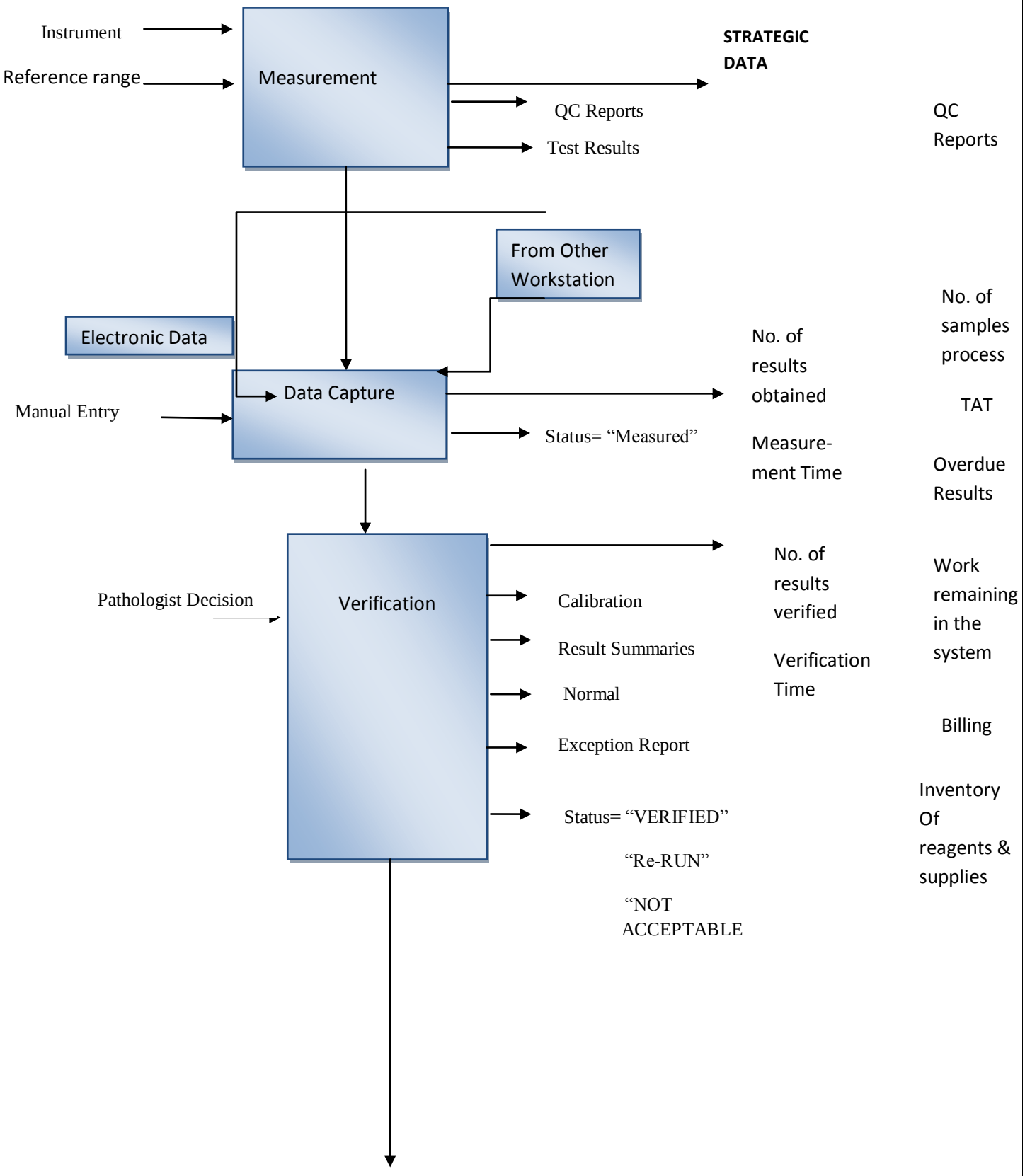
Sample Location Tracking

The physical movement of samples from one laboratory location to another is tracked. This is important for cases in which a rigorous sample chain of custody

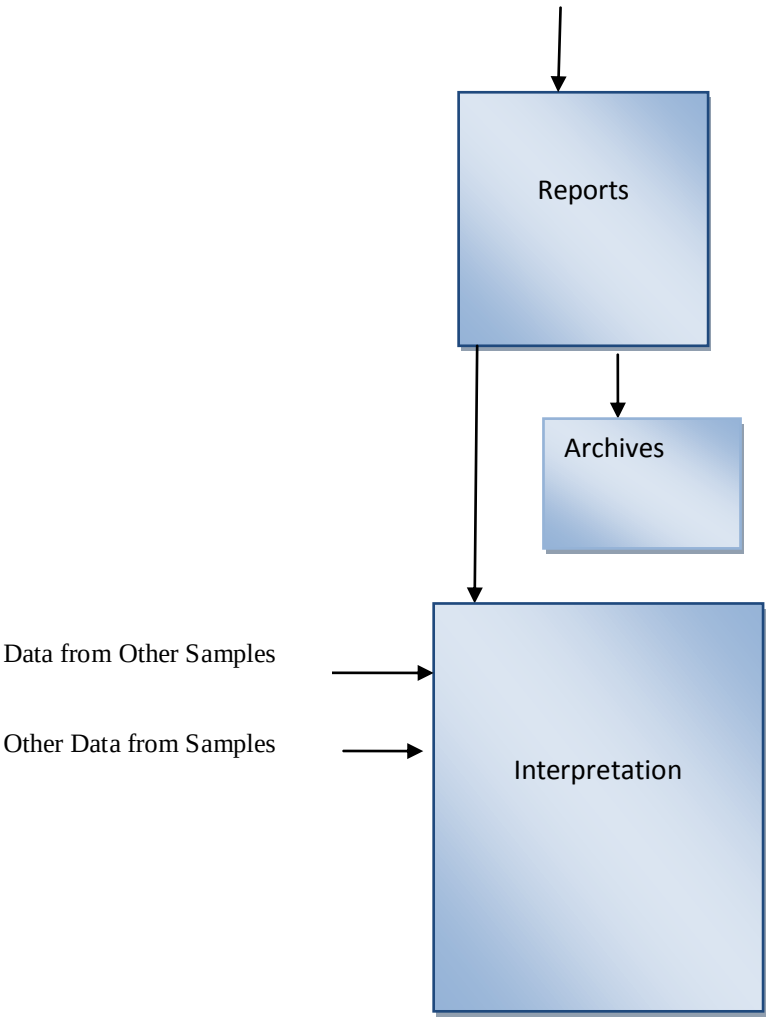
must be maintained. Examples include regulated controlled substances, evidence supporting legal court cases, or radioactive materials. When collection lists are generated, a missed sample report indicates those samples which could not be obtained for whatever reason. LIMS statuses are updated for the sample/order

Fig-8: Detailed LIMS Workflow with information transaction at each stage




Instrument
Reference range
Measurement
STRATEGIC DATA
QC Reports
Test Results
QC Reports
From Other Workstation
Electronic Data
No. of samples process
No. of results obtained
TAT
Manual Entry
Data Capture
Status= "Measured"
Measure-ment Time
Overdue Results
Pathologist Decision
Verification
No. of results verified
Work remaining in the system
Calibration
Result Summaries
Verification Time
Normal
Billing
Exception Report
Inventory Of reagents & supplies
Status= "VERIFIED"
"Re-RUN"
"NOT ACCEPTABLE

STRATEGIC DATA



Step 5- Schedule Work- The LIMS automatically schedules work (tests) for each sample/order. The laboratory management can adjust sample priorities and reassign work as required. The LIMS can add laboratory standards, control samples, and QC samples to the scheduled work flow. LIMS statuses are updated for the sample/order.

Step 6-Analysis
(Sample Preparation, Measurement, and Data Capture)

Sample Preparation—
Most samples need some preparation before analysis. The LIMS should provide directions for the sample preparation, as well as suggest the standards and blanks needed to calibrate or verify operation of the method.

Run Lists / Load List
A run list presents candidate sample preparations, standards, and blanks to be sequentially run by an instrument. The actual sequence is determined by the analyst or by programs within the instrument.

Measurement -
Certain supporting data should be collected as part of the measurement process. This may include instrument settings, standards and blanks used, and any irregularities, difficulties, and unusual behavior. This information helps document the procedures used, and may help explain unusual results. Test results/determinations are the main output of the measurement process. Test results may be printed or sent
electronically to the next step. In addition, the measurement process may produce values for blanks, standards, and instrument self-checks. These can be reported to the technician, and also to the management functions which may be maintaining a history file of QC data for each workstation.

Test Calculations
Test data calculations previously defined within a method or protocol are performed. The outcomes of those calculations are recorded in the LIMS database.

Specification Checking

Result values are checked against previously established ranges of acceptability. In some cases a result may be evaluated against several specifications.

Instrument Control

The actual control of an instruments settings and operations is through instructions from a computer. Most instrument control functions are handled by computers which are a part of the instrument's integrated data system.

Step 7- Data Capture-

The results of the measurement must be entered into the LIMS. It may be entered by way of electronic interfaces or, in low volume applications, typed in by technicians. When it is entered, the statuses of the sample/order and result determination are updated. The management functions record the fact and time that results were captured so that they can keep statistics of work accomplished and tracks the progress of each test order. Audit trails record biographical information about each LIMS transaction..

Instrument Integration

Instrument Interfacing

The physical connection and capability for data transfer between an instrument and the LIMS is established. This involves matching of the data transfer protocols of both the instrument and the LIMS. Health Level 7 International (HL7) is a standard developed by health care information systems professionals to simplify the communications between computer systems that must exchange information. LOINC, the Logical Observation Identifiers Names and Codes, is a standard for identifying medical laboratory observations. It is one of several standards used to exchange clinical health information, and it has been identified as the preferred standard of the organization HL7.

Data Acquisition

The conversion of an instruments signal or data stream into a format that can be recognized and stored on a computer. It requires specialized hardware devices such as Analogue to Digital Converters (ADC) or Binary-Coded Decimal (BCD) Converters. Special software on the computer permits the capture and storage of data from these devices.

Instrument Data Transfer

This involves the movement of data from the instrument or its data system to the LIMS. What is transferred may or may not be directly stored in the database. It may reside outside the database for further data reduction and processing before being added to the LIMS database.

Step 8-Verification and Correction-

The results are reviewed by a qualified person. To help in this process, the LIMS may show the results for standards and blanks. The technician can judge whether the method was in control. Unusual or out-of-range results can be flagged for more careful scrutiny. If normal values are known for the substance being tested, they can be displayed. Also, any results outside of normal can be highlighted or displayed separately for closer review. Changes to LIMS results should be audit trailed and a reason given for why a correction has been made. The original data must be retained, and all changes appended to the result record. After examining the data, the user must make a decision

Results can be approved, changing the result status. A test (one or more determinations) can be scheduled for re-test, or if that is not possible, the result can simply be marked as NOT-ACCEPTABLE.

Analysis Modification

The analytical work currently assigned is modified. This may involve the assignment of additional tests, cancellation of tests, repeat testing, or resampling.

Results Modification

Individuals with the proper authorization are permitted to rectify incorrectly entered result .All changes in LIMS result should have an integrated audit trail to record the time, responsible individual, and reason for each modification. All originally recorded results and any subsequent modifications are stored in the LIMS database.

Re-Test Loop- Retests can be initiated at multiple points in the LIMS work flow

Re-Sample Loop-. Re-samples can be initiated at multiple points in the LIMS work flow. Fig. 7 shows possible re-sample paths. A re-sample is defined as one or more additional samples. The LIMS needs to establish forward and backward links to samples that are added by way of the re-sample loop.

Step 9- Reports

Once test results are verified, they can be reported to the customer. This can take a variety of forms, including printed output, electronic mail, and response to on-line queries. Reports can also include summaries for laboratory use. . Management functions are told when the reports are issued, because this marks the end of the turn-around time. LIMS statuses are updated for the sample/order.

Results Distribution

Approved analytical results are electronically forwarded to designated parties. Results may also be transferred to other databases or programs for historical storage or further processing.

Report Definition

The information content and format of recurring reports are established. Once defined, the reports can be repeatedly created in several ways, on demand by authorized individuals or at regularly defined time intervals.

Ad hoc Enquiries

Ad hoc Query

Selected information is extracted from the database through a free form query. The query results may be displayed on a screen, printed as a report, or provided as a computer file for further manipulation.

Dispose of Samples-

There should be proper documentation of sample disposal following analysis . The LIMS can be used to track final sample disposition and waste removal.

Store/Retrieve Samples-

LIMS statuses are updated for the sample/order. Inventories can be maintained for reference samples, laboratories reagents, standards, QC samples, time-based samples (shelf life stability), in addition to normal samples.

Laboratory Management - By collecting statistics and time-stamps at various points in the process, the management functions can prepare reports for the laboratory managers. Number of samples processed at each workstation by shift, day of week, and hour of day can be prepared. This can help identify peak demands, roadblocks, and other problems. It provides good documentation to justify new instruments or personnel. Turnaround times document the laboratory's responsiveness to customer needs. Overdue results and work remaining in the system help managers to determine how well the laboratory is responding to current demands. Personnel time accounting can be tracked by the time each sample is at each workstation. The number of tests done can be used to estimate the consumption of reagents and supplies. Instrument calibration and maintenance records can be maintained and reported by the LIMS.

Incomplete Work

An assessment of the total work backlog for a laboratory or laboratory group is given. It provides a way of determining if reallocation of personnel or overtime is required. Overdue results and work remaining in the system help managers to determine how well the laboratory is responding to current demands

Workload Demands

All new work input to the laboratory during a defined time period is listed. Continuous workload demand monitoring provides the laboratory with the historical trend patterns for planning future personnel and equipment needs.

Protocol Maintenance

A repository is provided for the maintenance of active test methods, specifications, projects, studies, or other laboratory-specific protocols. It is referenced by other

LIMS functions. Maintenance of a centralized repository ensures that protocols are executed consistently within the laboratory.

Quality control issues are also scattered throughout the LIMS. The management functions can correlate these results into suitable reports. An inventory of standard materials can be maintained, with suitable outputs when the supply of any particular reagent is running low and replacement is advised. Also included in QC, is the LIMS itself. System diagnostics and database integrity checks are performed routinely and reports given.

System Management —System management functions include backup and recovery, manual performance tuning, system maintenance, user maintenance (accounts, training, help desk), and archives. Permanent legal archives are prepared after all work is done. The archive is typically recorded on paper, microfilm, magnetic media, or optical disk.

LIST OF INSTRUMENTS GOING TO INTERFACE WITH LIMS-

	BIOCHEMISTRY	
1	Immuno assay	Interfaced with LIMS
2	ABG Machine	_
3	Bio-Chemistry Analyser (Fully Automatic)	Interfaced with LIMS
4	Electrolyte Analyser	Interfaced with LIMS
5	Centrifuge	_
6	RO system	_
	HISTOPATOLOGY	
1	Embedding station	_
2	Tisaue Float Bath	_
3	Warm Water Bath	_
4	Slide Warming Table	_
5	Microtome	_
6	Cyto Centrifuge	_
7	Automatic Tissue Processor	Interfaced with LIMS
8	Grossing Station	_
	HAEMATOLOGY	
1	Automate Haematology Analyzer	Interfaced with LIMS
2	Coagulation Analyzer	
3	Micro scope	
4	Cyclo Mixer	
	MICROBIOLOGY	
1	Vitek-2 Compact	Interfaced with LIMS
2	Bio-safety Cabinet	_
3	Serological Water Bath	_
4	Incubator Universal	_
5	Bact Alert	Interfaced with LIMS
6	Microscope	_
7	Laminar Air Flow Bench	_
8	Vertical Autoclave	_
9	Loop Sterlizer	_

10	Oven	_
11	Centrifuge	_

CHAPTER 4-

DISCUSSION-

So, after understanding what is actually LIMS all about what advantages it can give over manual processing of clinical laboratory there are many points which if not get addressed or being understood can lead to the failure of LIMS implementation.

NEED ASSESSMENT-

A large number of systems gets fail to meet the user's initial expectations and this can often be due to the lack of a proficient user requirements specification. The absence of adequate requirements makes the system difficult to evaluate and validate . LIMS selection is a complex process and deserves much consideration. Selecting the right product will have a major effect on the success of the project. To assure a positive outcome, you need a thorough understanding of three very specialized disciplines, 1) lab operations, 2) LIMS functionality, and 3) IT infrastructure management.

TRAINING-

Training is often the first item cut when we go over budget. But it plays a important role. As, in there will be new practices, new terminology and new work flows.. The subsequent problems caused by under training tend to persist well beyond implementation.

Formal training provides step-by-step instructions and exposes people to the overall flow of the product to give context to work practices is very important . Not everyone in the lab needs to be a power user but the team must have at least three levels competency.

First, anyone who will use the system needs a basic understanding of core capabilities. Even with the most intuitive system, training on basic functions and a few tips and tricks will accelerate the improvements in productivity and reduce downtime.

Second, one should emphasis on providing complete and detailed training to one or two persons in lab so that they can act as power users who understand the full capability of the system. These people can serve as in-house trainers, administrators, and troubleshooters, and will help other team members as the lab uses more sophisticated features.

And third, separate from LIMS training, one needs some form of IT support so that network and communications infrastructures are managed properly. A well trained team is an empowered team — one that will take ownership and responsibility to implement changes.

COUNTING TOO MUCH ON CUSTOMIZATION

Make sure complete documentation of requirements before the system is implemented. One needs to be deliberate about determining where the system needs to change in order to match lab practices, and be open-minded about when to change lab practices to follow the more efficient flow in a LIMS. When customization ends up driving implementation, you are essentially designing your own LIMS from scratch. Conversely, a highly configurable system typically has favorable cost and time factors. There is just less to do and it's generally easier to make changes. And because a configurable system has a well-defined set of features and functions, it is easier to develop achievable schedules and budgets.

TEAM ENAGEMENT-

Involving the full team and their views and experience also important for a successful implementation. It is important to keep your team updated and keep the team engaged. Get their feedback on functions that will impact the implementation .

No LIMS can fulfil all the requirement of user this should be also keep in mind.. Even with a well-thought-out plan one can still run into the occasional problem that can't be quickly solved and some time may it happens that functions doesn't quite work exactly as we thought. These are all important issues that ultimately must be addressed because these are points which will lead to delaying of progress.

One can overcome it by keeping perspective and not losing momentum. We can absolutely hold the LIMS vendor until unless all the issues are resolved . But think big picture and prioritize the issues.

Put the issues into four categories:
1) Most important points which are need to be taken into consideration and cannot be left (i.e. there is no workaround),
2) Serious issues that have short-term workarounds,
3) Minor issues that will be an inconvenience until resolved, and
4) Minor issues that will have no material impact.

Only the items in the first category should hold up your implementation. Before moving forward however, all the items must have a plan of action. Don't leave any issues unaddressed.

There is always a need of clear leadership & transparency. Hence concluding the discussion for the successful implementation of any project one need to focus on-

- Develop schedule, budget, objectives
- Communicate company-wide priority
- Always emphasis on user training
- Analysis of dedicate resources available.

CHAPTER 5

RECOMMENDATIONS

Hence after understanding the work flow of the LIMS for specific laboratory, customize Checklist for functionality is been derived in order to utilize it as Request for proposal and also for vendor evaluation

1	**LOGIN**
A	System should be able to support all areas of the general laboratory (ie. Chemistry, haematology, microbiology and biochemistry)
B	Should have the provision for customize login methods and login screens.
C	Should be such that users can have ease of login (user friendly)
2	**REQUEST GENERATION AND LABELS**
A	In a single order session, automatically assign multiple investigation order numbers based on a department and/or specimen type.
B	Should automatically generate or print bar code label containing sample ID based on each on type of sample and department.
C	Should provide the provision so that collection label is printed on user definable format.
D	Provide a test catalogue and specimen handling instructions with the option to print on labels
F	System should have the provision of add or delete tests or profile to an already submitted requisition. This will allow physician to order additional tests without phlebotomist having to collect fresh sample
3	Provision for recording the sample dispatch report
4	**SAMPLE DISTRIBUTION**
A	Should have the provision for generation of distribution list once the samples are collected in central receiving area and further distributed to sub-section for processing.
B	Should provide the provision for Chain of custody function to have chronological record of a sample or evidence, including its collection, preservation, transportation, transfers, analysis and final disposal to ensure data integrity, security and compliancy.
C	Should have the ability to route specimens to specific racks and instruments.
D	Provision for keeping the record on sample storage and recovery tracking.
E	Post processing specimen sample disposition /disposal management.

F	System should have the provision of transportation list for tracking specimen going to the laboratories outside.
5	**SAMPLE ACKNOWLEDGEMENT**
•	Provision so that Specimen can be verified/acknowledge by the specific sub-section of laboratory.
6	**ASSIGNING WORK**
A	The system should be able to select and assign task
•	Select task by workgroup, instrument, test, priority.
•	Print work list by instrument, test.
B	Print test backlog
C	STAT request will prompt in different colour so test can be performed early
•	Ability to generate collection checklist per shift for all in- patients by physical location (e.g ward/floor/ wings etc.) and logically distribute the work among available technician.
7	**SAMPLE PREPARATION**
	Provision for entering sample preparation notes.
8(A)	**RESULT ENTRY- ENTERING DATA AND INFORMATION**
•	Provision to automatically enter the result data as soon as the test is complete and the result is generated.
•	Support order entry on the LIS and accept data through a real-time HL7 compatible interface with a patient care system
•	Interface with bi-directional diagnostic equipment.
•	Provision to enter outsource lab result and upload the result.
•	Ability to transmit clinical information electronically via an interface in conjunction with a standardized naming format (ex, LOINC(Logical Observation Identifier Names and Codes)
•	System should be able to support for confidential tests.
•	System should be able to support for POINT-OF-CARE TESTING (POCT) devices like bed side monitors, Computer On Wheel , palm tops or ipads etc.
•	Ability to define tests and reporting parameters along with interpretation of results associated with each parameter. Each parameter will have associated references range (min. – max.)
•	defined by gender/age/medical condition (pregnant, non-pregnant/postmenopausal etc.)

•	demonstrate special cases where result is interpreted as positive/ negative/borderline, present/absent, acidic/alkaline, colour/colourless/dark yellow etc. reactive/non reactive
B	System should also have the provision for Manual keyboard data entry.
9	**SYSTEM ALERT-**
A	Provide online flagging of abnormal, panic and absurd values during result entry and raise alerts by popup or colour coding
B	Provision to search procedure and test detail with result against patient and other parameters
10	**CALCULATION-**
A	Ability to define formulas for parameters where result is calculated based on values of other parameters
B	Should have the provision to perform inter test and intra test
C	Provision so that user can link to prior test result
11	**DATA EDIT AND CORRECTION-**
A	Provision to edit test result but only the person who has the authorization to do so.
B	Provision for audit trail changes.
C	Provision for force comment for all changes.
D	System should be able to correct results after verification
12	**REVIEWING AND APPROVING RESULT-**
A	Provision for Process rejection of collected sample with reason code. This will involve automatic request to phlebotomist of re-collection(re-sample)
B	Report may be signed(digital signature) by multiple people typically by the technician and pathologist Also each report must specify patient's current age in YYYY-MM-DD format.
C	Provision for Sample reprocessing request for RE-DO and repeats. Reporting statistics by equipment/technician/sample type.
D	Provision such that report can be distributed by e-mail
	Provision for notification for SMS after generation of report.
E	SMS alert for reporting critical values to ordering physician and/or supervising medical officer based on standard operating procedure.
F	Should be able to verify result by tests, batch, work list, accession number and instruments.
G	Should be able to provide option to print report on demand or by user defined schedule

H	System should be able to automatically print multiple copies based on user defined rules (encourage user to see result online) along with water mark "DUPLICATE"
I	Provide bolding and font options and image.
13	**MICROBIOLOGY**
•	Ability to print or display preliminary results for patient inquiry, clearly labeled preliminary.
•	Support the detection of organisms isolated for infection control.
•	Track suspected nosocomial infections e.g. SSI,HAI and UTI
•	Generate bar-coded labels for media, slides and work cards.
•	Automatically highlight when cultures are due as per the organization's schedules at microbiology lab and area where culture is due
•	Provision to add comments based on results.
•	Display previous culture results.
•	Ability to produce an antibiogram report in a user defined format by drug, organism, and site combinations.
•	Ability to produce antimicrobial susceptibility test results and accompanied by an antibiotic cost/unit doses.
14	**MANAGING LAB OPERATIONS**
A	Sample status
•	Provision of alerts where ever urgent investigation is required e.g. (emergency, ICU, STAT at floor) in the form of popup alert or colour coding.
•	Provision for the test results to be kept on hold with reason code.
B	Inventory Management
•	System should be able to generate indents for laboratory consumables
•	Ability to track consumption of reagent and making auto self consumption entries based on volumes and load factor of each equipment run.
•	Ability to capture bill material, task performed and the skill set required performing each task for each test for generation of standard cost.
C	Instrument calibration management and reporting
•	Ability to request equipment servicing (PM)and report failures to bio-medical department. Generate maintenance & repair issue ticket, tracking, escalation and resolution of the same (Issue management lifecycle)
D	Overdue reports
•	Supports alerts when a test has exceeded its turn-around-time
E	Quality assurance report

•	For Microbiology; allow isolates to be for statistical reporting, infection control reports.
•	User-defined delta check limits based on percentages and absolute limits by age and sex.
•	Automatically compute the mean and the standard deviation.
•	Check quality control results and flag abnormal values.
•	Utilize quality control specimens and results and maintains them in a separate data file.
•	Provide quality control summary reports.
•	Define if corrective action is required for out of range QC results.
•	The timeliness of reporting of urgent/emergency tests is measured.
•	Essential reagents are highlighted when less in stock
15.	**SYSTEM MAINTENANCE**
•	System should be able to archive online
•	System should be such that enter patient registration data directly into the LIMS and accept data through a real-time HL7 compatible interface with a patient care system
•	System should be able to support multiple hospitals and patient data within the same database.
•	System should be able to export generated reports to excel/ word/pdf.
16.	**INFORMATION ACCESS ONLINE**
•	system should have the ability to access SOPs online
	Use of web portal for OPD patients.

This comprehensive checklist of functionality of LIMS can be further used for vendor selection and evaluation. But this list can be further customize according to individual requirement and type of organisation. And system should be such that it should be easily updated as per the technologies advances and when requirement is generated for it without causing greater loss to data which is already saved into it.

CHAPTER-6

LIMITATION OF THE STUDY-

1. Data collected on the basis of informal discussion with various professionals.
2. Information bias: Considering the competitive nature of the health sector respondents might have not provided the adequate and right information.

3. Time constraint – the time was short for conducting scientific market research on prevailing LIMS system in various hospitals.

4. In absence of HIS in the hospital the study assumed the case of ideal information system for a hospital.

CHAPTER-7

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CHAPTER-9

ANNEXURE (QUESTIONNAIRE-1)

Name……
Hospital Name,

Designation…

Date….

QUESTIONNAIRE: PARTICIPANTS

Introduction
This questionnaire seeks data from respondents (employees of the company) chosen at random. This data is for the purpose of this study alone and will not be used for any other purpose and is purely academic in nature
Questions are as follows:

Q1. Which LIMS is implemented in your Laboratory?

Q4. Can you list down the process which LIMS perform?

Q3. Can you explain –

a. How the login is done and what are different logins?
b. Is your sample label is bar coded if yes, what elements it have?
c. How sample is reaches the laboratory and how is distribution done and what role LIMS plays in that?
d. What all features related to Sample Preparation is there in your LIMS contains?
e. Is all the equipments in you laboratory are interfaced with LIMS, if yes what all? If No, which are not?
f. What all features your LIMS contains related to Measurement and Result entry?
g. Can you edit the result or do the corrections needed, if yes, how?
h. What all features are there in your LIMS related to Result verification?
i. What all features it incorporates related to sample storage, retrieval and disposal management?
j. What all features it contains related to Inventory Management?
k. Is LIMS helps you in any way related to Instrument calibration, If yes, how?
l. How LIMS help in Quality Check report generation?

Q4.What do you think is the advantage of using LIMS?

Q5. What is the level of satisfaction with the current software?

Q6. Can you mention some points regarding the limitations of the functionality of the current software including the areas which you would like to improve upon?

QUESTIONNAIRE- 2

Name….

Date…

Designation….

QUESTIONNAIRE: PARTICIPANTS of Jaypee Medical Centre.

Introduction

This questionnaire seeks data from respondents chosen at random. This data is for the purpose of this study alone and will not be used for any other purpose and is purely academic in nature.

Q1. What can be the expected workflow of the laboratory in our the hospital ?

Q2. What kind of capabilities your are expecting for the LIMS which is going to be implemented in our hospital?

Q3 Can you share your experience regarding the limitation in use of LIMS, if any?