

**Internship Training**  
**at**  
**Nayati Medicity Hospital, Mathura UP**  
**on**  
**IDENTIFICATION OF GAPS OF SUPPORT SERVICES FOR NABL ACCREDITATION**  
**4<sup>th</sup> March to 25<sup>TH</sup> May 2019**  
**By**  
**Dr. Anjali Maheshwari**  
**Enroll. No. PG/17/077**  
**Under the guidance of**  
**Dr. Preetha Unni**  
**Assistant Professor, IIHMR, Dwarka, New Delhi**  
**Post Graduate Diploma in Hospital and Health Management**  
**2017-19**



**International Institute of Health Management Research**

**(COMPLETION OF DISSERTATION FROM RESPECTIVE ORGANIZATION)**

**The certificate is awarded to**

**DR. Anjali Maheshwari**

**In recognition of having successfully completed his/her internship in the department of**

**OPERATIONS AND QUALITY**

**And on successfully completing her Project on**

**IDENTIFICATION OF GAPS OF SUPPORT SERVICES FOR NABL ACCREDITATION**

**from**

**4<sup>th</sup> march to 25<sup>TH</sup> May 2019**

**At**

**Nayati Medicity Hospital**

**Mathura, Uttar Pradesh**

**She comes across as a committed, sincere & diligent person who has a strong drive & zeal for learning.**

**We wish him/her all the best for future endeavors.**

**Director Medical**

**Zonal Head-Human**

**TO WHOMSOEVER IT MAY CONCERN**

**This is to certify that Dr. Anjali Maheshwari, student of Post Graduate Diploma in Hospital and Health Management (PGDHM) from International Institute of Health Management Research, New Delhi has undergone internship training at Nayati Medicity, Mathura from 4/03/2019 till 25/05/2019**

**The Candidate has successfully carried out the study designated to him during internship training and his/her approach to the study has been sincere, scientific and analytical. The Internship is in fulfilment of the course requirements.**

**I wish her all success in all his/her future endeavours.**

**Dr Pradeep K Panda**

**Dean, Academics and Student Affairs  
IIHMR, New Delhi**

**Dr. Preetha Unni**

**Associate Professor IIHMR, New Delhi**



**NAYATI**  
HEALTHCARE

The certificate is awarded to

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In recognition of having successfully completed his/her internship in the department of

OPERATIONS AND QUALITY

And on successfully completing her Project on

"Identification of gaps of support services for NABL Accreditation – Observatory and Prospective study"

4<sup>TH</sup> March to 25<sup>TH</sup> May 2019

At

Nayati Medicity Hospital

Mathura, Uttar Pradesh

She comes across as a committed, sincere & diligent person who has a strong drive & zeal for learning.

We wish him/her all the best for future endeavors.

Chief Operating Officer

AGM-Human Resources

**Certificate from Dissertation Advisory Committee**

This is to certify that **Dr. Anjali Maheshwari**, a graduate student of the Post- Graduate Diploma in Health and Hospital Management has worked under our guidance and supervision.

He/ She is submitting this dissertation titled "**Identification of gaps of support services for NABL Accreditation – Observatory and Prospective study**"

at

**Nayati Medicity Hospital, Mathura, Uttar Pradesh**

In partial fulfillment of the requirements for the award of the Post-Graduate Diploma in Health and Hospital Management.

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

**Dr. Preetha Unni**  
**Assistant Professor**  
**IIHMR, New Delhi**

**Dr. Ajay Angirish**  
**Chief Operating Officer**  
**Nayati Medicity Hospital**

*Dr. Anjali Maheshwari*  
*AKM-HK*  
*On behalf of Dr. Angirish*

**INTERNATIONAL INSTITUTE OF HEALTH MANAGEMENT RESEARCH,**

**NEW DELHI**

**CERTIFICATE BY SCHOLAR**

This is to certify that the dissertation titled **IDENTIFICATION OF GAPS OF SUPPORT SERVICES FOR NABL ACCREDITATION** and submitted by Dr. Anjali Maheshwari ,Enrollment No. **PG/17/077** under the supervision of **Dr. Preetha Unni** for award of **Postgraduate Diploma in Hospital and Health Management of the Institute** carried out during the period from **4<sup>th</sup> March till 25<sup>th</sup> May** embodies my original work and has not formed the basis for the award of any degree, diploma associate ship, fellowship, titles in this or any other Institute or other similar institution of higher learning.

Anjali Maheshwari



## FEEDBACK FORM

Name of the student: Dr. ANJALI MAHESHWARI

Dissertation organization: Nayati Medicity

Area of dissertation: Operations

Attendance: Satisfactory

Objectives achieved: completion of dissertation

Deliverables: Reaching maximum potential, how to deal with conflict, situational leadership.

Strengths: Hard working, sincere, Enthusiastic to learn new things.

Suggestions for improvement:

Suggestions for institute (course curriculum, industry interaction, placement, alumni)

- none -

Signature of the officer-in-charge/ organisation mentor (dissertation)

Jay Shankar

Date:

18/06/2019

place:

Nayati Medicity  
Mathura

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I also take this opportunity to extend heartfelt gratitude to others who directly or indirectly helped me, by providing necessary information required for the successful completion of the project.

**Dr. Anjali Maheshwari**

## ABSTRACT

The **National Accreditation Board for Testing and Calibration Laboratories (NABL)** is an autonomous body under the aegis of the Dept. of Science & Technology, Govt. of India, and is registered under the Societies Act. NABL, which was initially established with the objective to provide accreditation to testing & calibration laboratories, later on extended its services to the clinical laboratories in our country. Potential increase in business due to enhanced customer confidence and satisfaction. Savings in terms of time and money due to reduction or elimination of the need for re-testing of products. Better control of laboratory operations and feedback to laboratories as to whether they have sound Quality Assurance System and are technically competent. Increase of confidence in Testing / Calibration data and personnel performing work. What types of laboratories can seek accreditation...? The laboratories should be legally identifiable & appropriately registered. The **Objectives of this study is for** Identification of Gaps of support services for NABL accreditation in NAYATI MEDICITY, Mathura and addressing the gaps seen in the system. The research **methodology** adopted for the study is **“Observatory and Prospective”**. Data collected by direct observations, discussion with hospital staff, from hospital manuals, records and policies. **Results are** that gaps were identified and closed, then over all analysis was done which shows total compliance is 84% and partial compliance is 13%, whereas no compliance is 3%.

## Conclusion

Initially overall compliance was 45% and partial compliance 52%. Later, all the gaps were identified and minimized, and after completion of documents and certificates the total compliance and partial compliance is 84% and 13% respectively.

## **ABOUT NAYATI:**

**NAYATI HEALTHCARE** started its journey in 2012 from the pious grounds of Badrinath with 4 mobile medical units and a team of 36 paramedics and doctors. In a very short span of time, working across these regions, Nayati came face to face with certain grim realities in healthcare which was metro centric. Nayati believes that good healthcare should be sans boundaries and seamless across the country and the world. Hence the organization decided to embark on a revolutionary journey of taking tertiary level world-class treatment across Tier-II & Tier-III cities which have long been neglected.

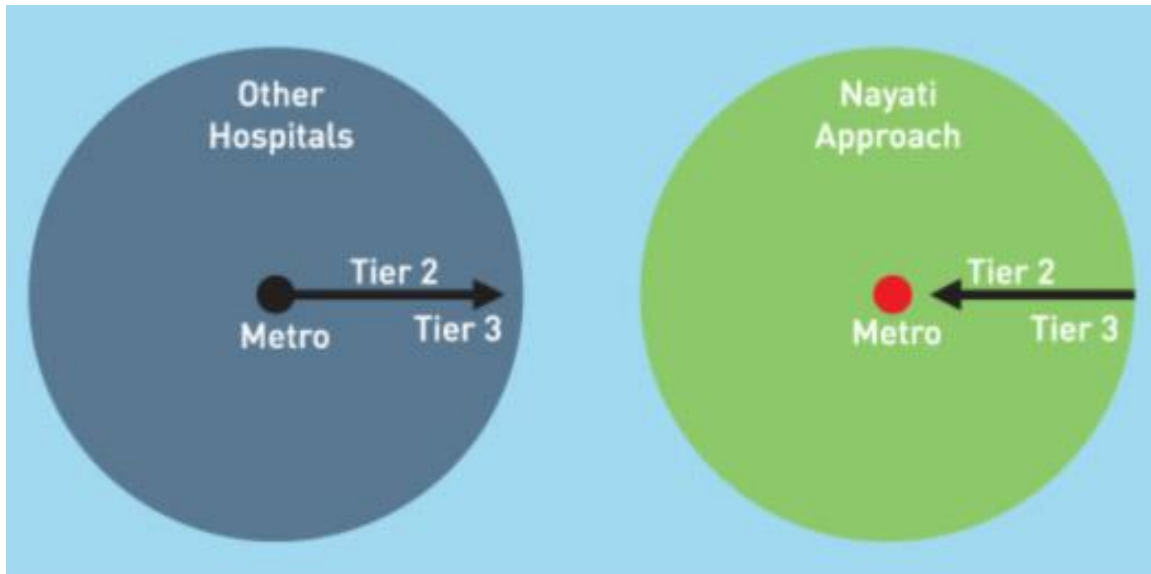
### **Complete Integrated Healthcare:**

Our endeavor is to offer complete healthcare solutions within the hospital with our team of India's leading doctors, coupled with the best medical resources in all disciplines and specialized verticals of healthcare. All our Centers of Excellence for diverse key specialties will be self-sufficient in all aspects of diagnosis and treatment, because we know and understand that when it comes to matters of your health, every second is precious.



### **World Class State-of-the-Art Medical Technology:**

We take pride in offering world class treatment procedures and patient care services with the use of state of the art medical technology and advanced treatment facilities to provide both cost effective and faster care. We have various Intensive Care units like MICU, CCU, SICU, NICU and PICU that work 24X7.



### **Taking Treatment to the Patient:**

At times, patients need access to quick treatment, as one does not have the option to travel long distances. We also understand that patients need to visit the hospital frequently for follow up checkups. Traveling long distances frequently can be very painful and impractical for patients as well as their families. To ease this everyday problem, we are setting up secondary diagnosis and care centers, as well as mobile vans in the neighboring towns, to ensure that every patient has access to quality healthcare.

### **Business Model:**

On one hand we had the challenge of providing world class healthcare on the other we had to also keep in mind the spending capacity and financial aspect of the local residents. This is why we decided to adopt the 'economies of scale' model as it was our responsibility to not only take care of the patient's health but also his/her overall wellbeing.



At Badrinath, we discovered an India that has severe disease burden, under diagnosed with no access to quality healthcare, except in the metros

### **Our inspiration and learning:**

Five years ago we dared to dream “The Nayati Dream” - to take treatment to the patient. To extend access to modern healthcare beyond the bounds of mega cities. We decided to embark on a revolutionary journey of taking tertiary level world-class treatment across Tier-II & Tier-III cities which have long been neglected. Over 3 lakh Outpatients, Over 1,10,000 In-patients and Over 70,000 emergency & trauma patients.

### **Our Inspiration:**

The thought behind 'Nayati' was born on the pious grounds of Badrinath. With the philosophy of 'Arogaya Mev Jayate', which is a clarion call and a promise of bringing world class healthcare services to millions. We at Nayati are dedicating our hearts, minds and souls to ensure that the boon of good health reaches each and every individual.

### **Our Vision:**

Taking the world class treatment to the patient. To provide world class and trustworthy healthcare services in a cost effective way to people living in tier 2- tier 3 cities of the country.

### **Our Aim:**

To develop world class healthcare institutions which are advanced, affordable and where a patient's welfare is at the heart of every action. To ensure that these institutions take world class healthcare beyond the metros and are easily accessible to the people living in tier 2 and tier 3 cities of the India. To establish Nayati Healthcare into a trusted Healthcare brand that is dedicated to provide the right care to each and every patient.

### **Nayati Medicity, Mathura:**

Nayati Healthcare's flagship Multi Super Specialty Hospital, Nayati Medicity, Mathura, commenced operations in February 2016 and has emerged as one of the finest healthcare providers in the country. With world class infrastructure and finest team of doctors, it is the state's only comprehensive super specialty quaternary care hospital.

The 351 bed hospital on National Highway 2, Mathura, has seven Centers of Excellence and 14 Specialty departments including Cardiac Sciences, Oncology, Orthopedics and Joint Replacement, Critical Care, Renal Sciences, MAS GI & Bariatric Surgery, Neurosciences, Pulmonary medicine, Pediatrics & Neonatology, Trauma and Emergency. These centers are supported by the region's most advanced Intensive Care units comprising of MICU, CCU, SICU, NICU and PICU.

Located two and half hours from the Delhi airport, the hospital has emerged as a preferred choice not just for residents of Uttar Pradesh and the adjoining states, but also for patients from other parts of the country and abroad. Owing to the huge demand, the hospital is undergoing major capacity expansion from the existing 351 beds to 775 beds, making it one of the largest multi super specialty hospitals in Uttar Pradesh.

Nayati Medicity, Mathura has been awarded the Best Multi Super Specialty Hospital in Uttar Pradesh by The Times of India Group, India's leading media house.

### Our Facilities:



•

Nayati Heart Centre (Angioplasty & Angiography, Heart Surgery)



•

Advanced Critical Care (SICU, CCU, MICU, PICU, NICU, HDU)



•

Nayati Cancer Centre (Radiation, Medical and Surgical)



•

Gastroenterology (Endoscopy, Colonoscopy) Gastro-intestinal & Bariatric Surgery



•

Neurology Centre



•

Pain Management



•

Orthopedics, Joint Replacement and Spine Surgery



•

Urology, Nephrology & Dialysis



- General and Minimal Access Surgery



- Pulmonology, Chest and Sleep Medicine



- Obstetrics & Gynecology



- Pediatrics and Neonatology



- Plastic and Reconstructive Surgery



- Day Care Services



- Endocrinology



- Internal Medicine



- Nuclear Medicine



- Psychiatry (OPD)



- Ear, Nose & Throat (ENT)



- Ophthalmology





•

Dental Services



•

Dermatology and Venereology



•

Physiotherapy and Rehabilitation



•

Rheumatology (Joint Diseases)



•

Dietetics



•

Yoga & Wellness



•

Psychology and Counseling



•

24×7 Blood Band and Transfusion  
Medicine



•

Laboratory Services



•

Imaging Services (MRI, CT-Scan, USG,  
X-Ray, Mammography, BMD &  
Neuroradiology)



•

24×7 Emergency with Ambulance  
Services



•

24×7 Pharmacy

**Camps:**

- Micro Health Camp at RayaS
- **Blood Donation Camp – LIC, Mathura**
- Super Specialty Health Camp with Shri Ram Social Welfare Society at Etah
- Micro Health Camp at Sihana Village
- Under Program of PMSMA in Raya PHC / Sonai CHC
- Micro Health Camp at Kota Village
- Mursan Health camp
- Multi-Specialty Health Check-up Camp at District Jail Aligarh

**Nayati Pediatric Foundation:**

In India, an increasing number of children and young adults under 18 years of age are suffering from life threatening diseases and conditions. These numbers are especially high in tier II & tier III cities and in most cases these young patients need dedicated and prolonged treatment, something which their families and parents with limited incomes cannot afford. For them, these factors make proper care and healing a distant dream. With the idea of tackling this relevant issue, Nayati Healthcare has launched 'Nayati Pediatric Foundation'. A foundation that aims at not only spreading awareness about both preventive health and acute medical conditions in children but also providing underprivileged children with specialized pediatric treatments and services at the earliest. We believe through our expertise and efforts we can transform the future of our children and our nation. The foundation will cover the following verticals:

- Cardiac & CTVS
- New Born services
- Cancer / Oncology
- Critical Care

Across India, millions have unequal access to healthcare. Many become ill or die from preventable diseases or lack any opportunity of treatment for serious ailments. There is a real need to take quality care to those in need.

Nayati Charitable Trust is a charitable initiative that provides quality public health services and disaster relief to communities who lack basic healthcare infrastructure. We do this using a variety of mechanisms including free general, early-detection, and specialized health camps, multifaceted community connect activities, and medical assistance after a natural disaster.

Our mission is to preserve people's right to a live a dignified life by providing them the services they need to care for themselves, their family, and their community.

We serve 18 districts across Eastern Rajasthan, Uttarakhand, and Western Uttar Pradesh, utilizing Nayati's three pillars of activities: Health Camps, Community Connect, and Disaster Relief.

### **Nayati Medicity's Story:**

Nayati Charitable Trust was established in April 2012 with a fleet of 16 mobile medical units and a workforce of 35 motivated caregivers. We operated mobile units providing free primary and preventative healthcare in and around Uttarakhand first (including the pilgrimage town of Badrinath) and eventually Western Uttar Pradesh.

Nayati quickly added disaster relief to its activities after a cloudburst, and later a landslide, severely devastated the regions we served. Since then Nayati has been the first responders to various natural disasters impacting Northern India and more recently, the Nepal earthquake.

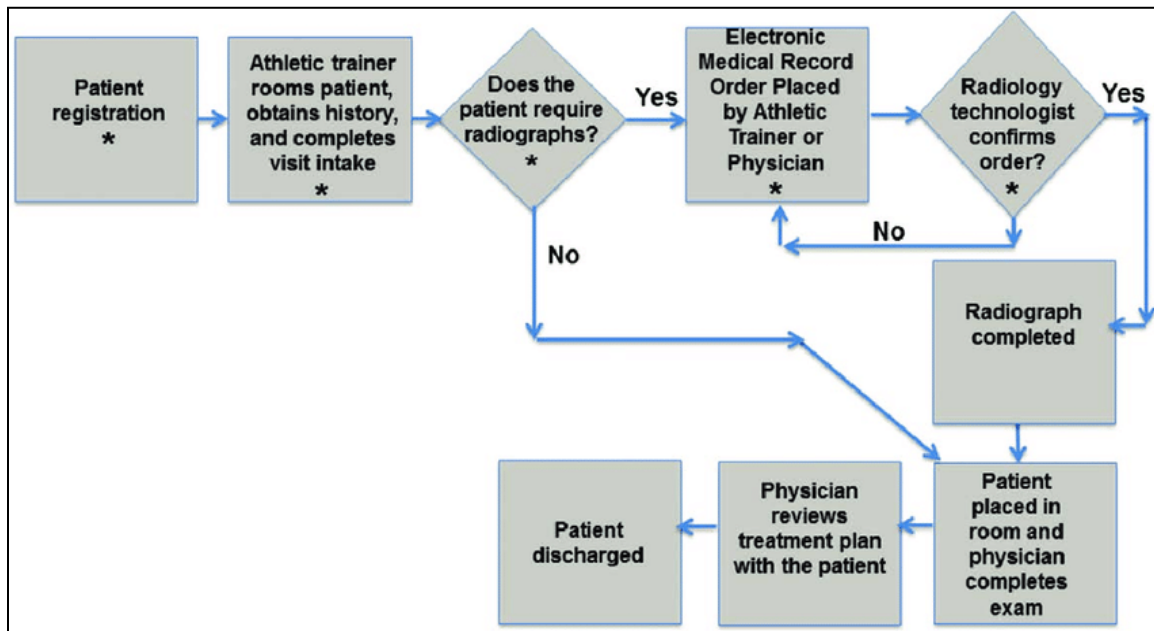
The name Nayati has become synonymous with care in the regions we serve and through our activities we have created a network of committed individuals from the medical field and beyond, seeking to serve more people with an even greater quality. As a result, Nayati Charitable Trust served as the inspiration for Nayati Healthcare Private Limited, which operates multi-specialty hospitals in tier 2 & 3 cities across Northern India.

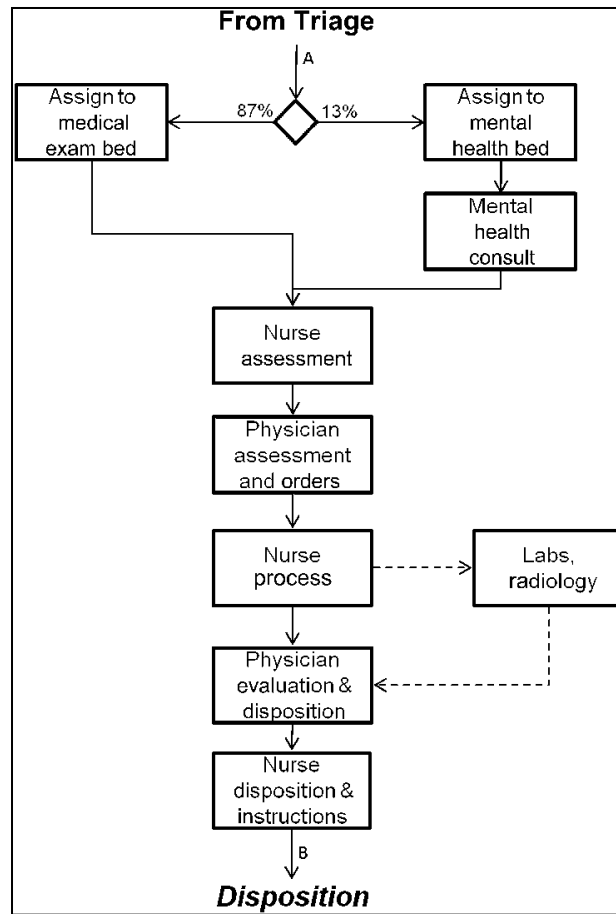
Today Nayati continues to work in Badrinath and in disaster relief, and has expanded to serve the sequestered regions surrounding Nayati Multi Super Specialty Hospital in Mathura with activities specific to that locale. Through our diverse range of accomplishments we always carry the same ethos from the very beginning: to provide healing and hope by promoting a more caring world and preserving the dignity of every person we meet.

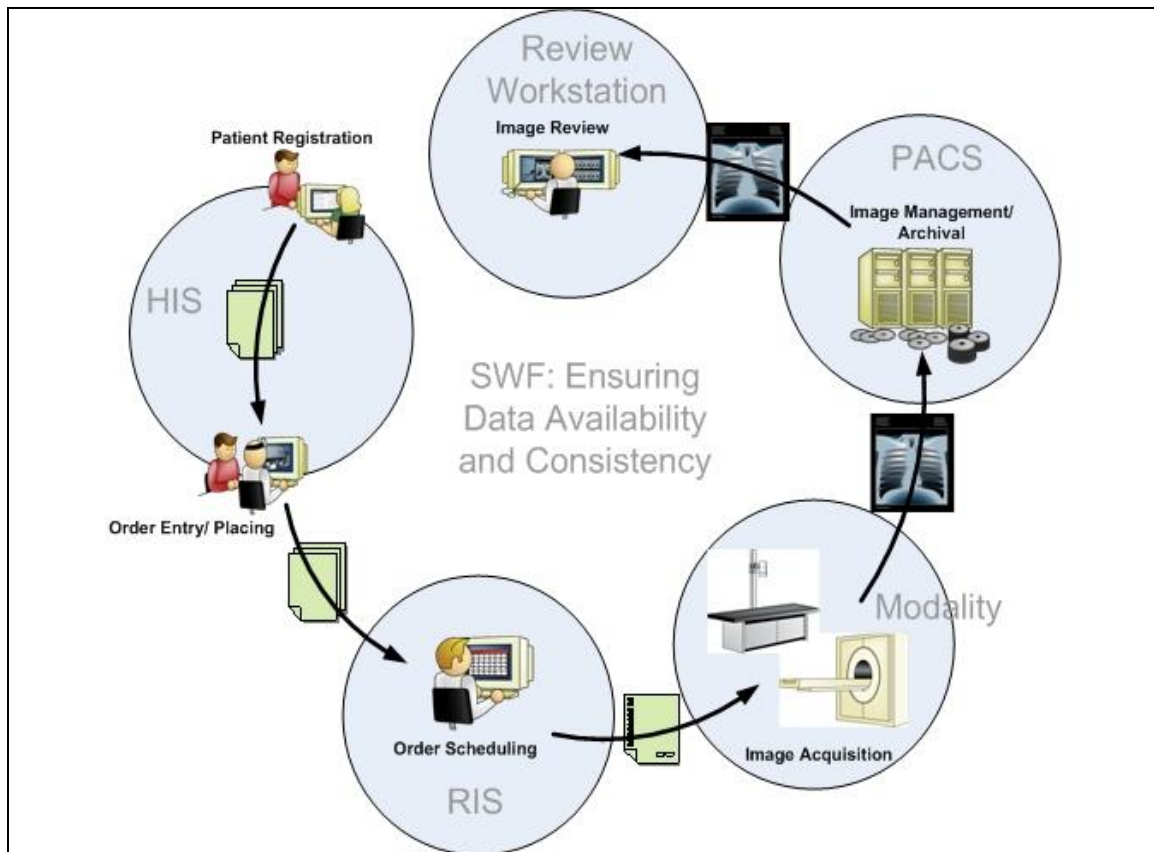
Key highlight of Nayati:

- 351 Beds
- 22 Specialties
- 122-bed ICU
- 7 modular OTs
- First hospital in a Tier III city to have received the prestigious NABH accreditation
- The only NABH approved Blood Bank in UP
- End to end Cancer Care including radiation and BMT
- Highly complex minimal invasive GI surgery including Bariatric Surgery
- First successful kidney transplant performed in a tier III city
- We have set up an Academic Wing and organize several National and regional level medical conferences
- Over 50 Research Papers in leading global publications
- First of its kind of ICU – digitized

# **OBSERVATIONAL LEARNING**

**OBSERVATIONAL LEARNING:****Process in Radiology Department Patients flow:**





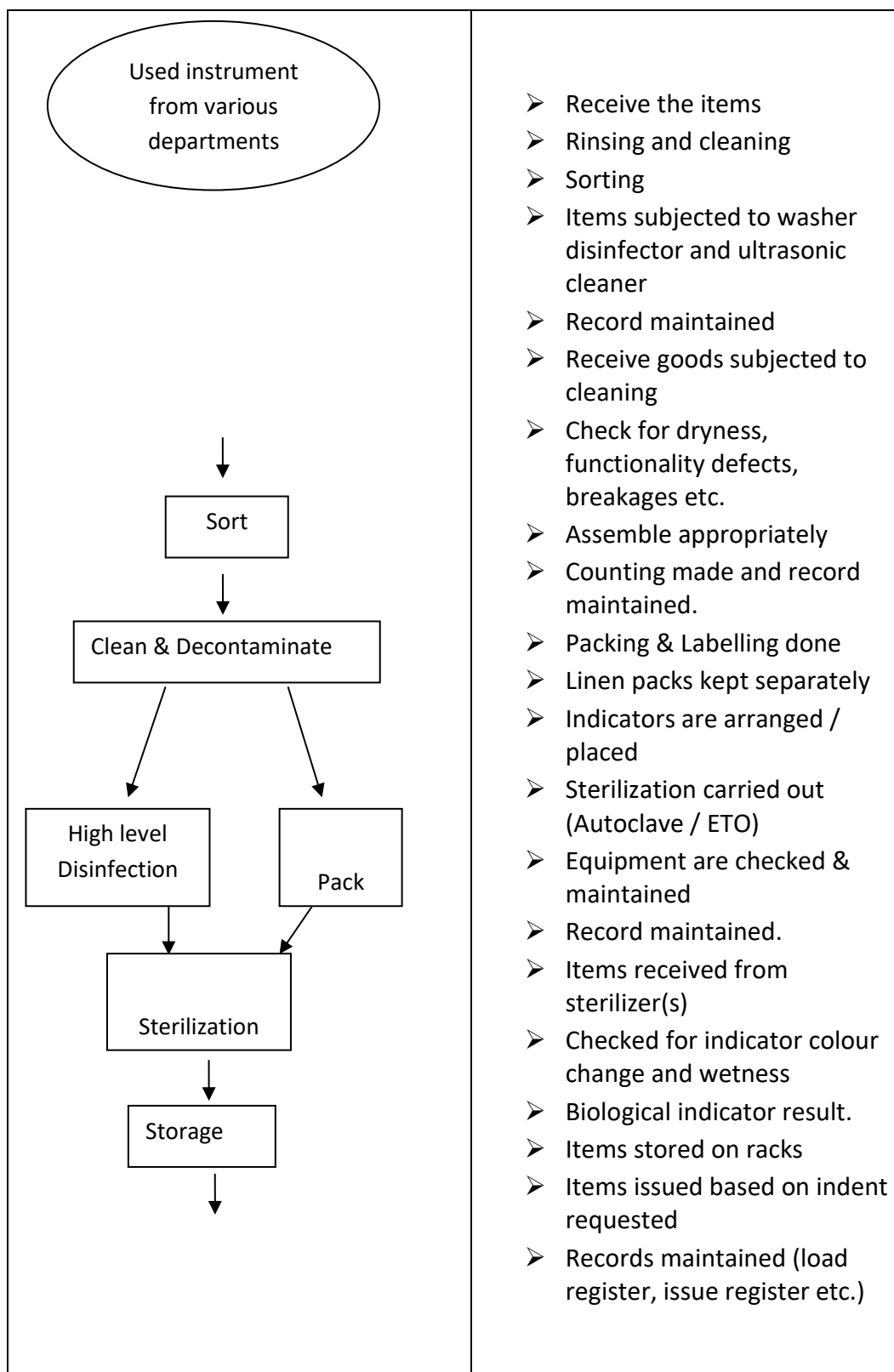
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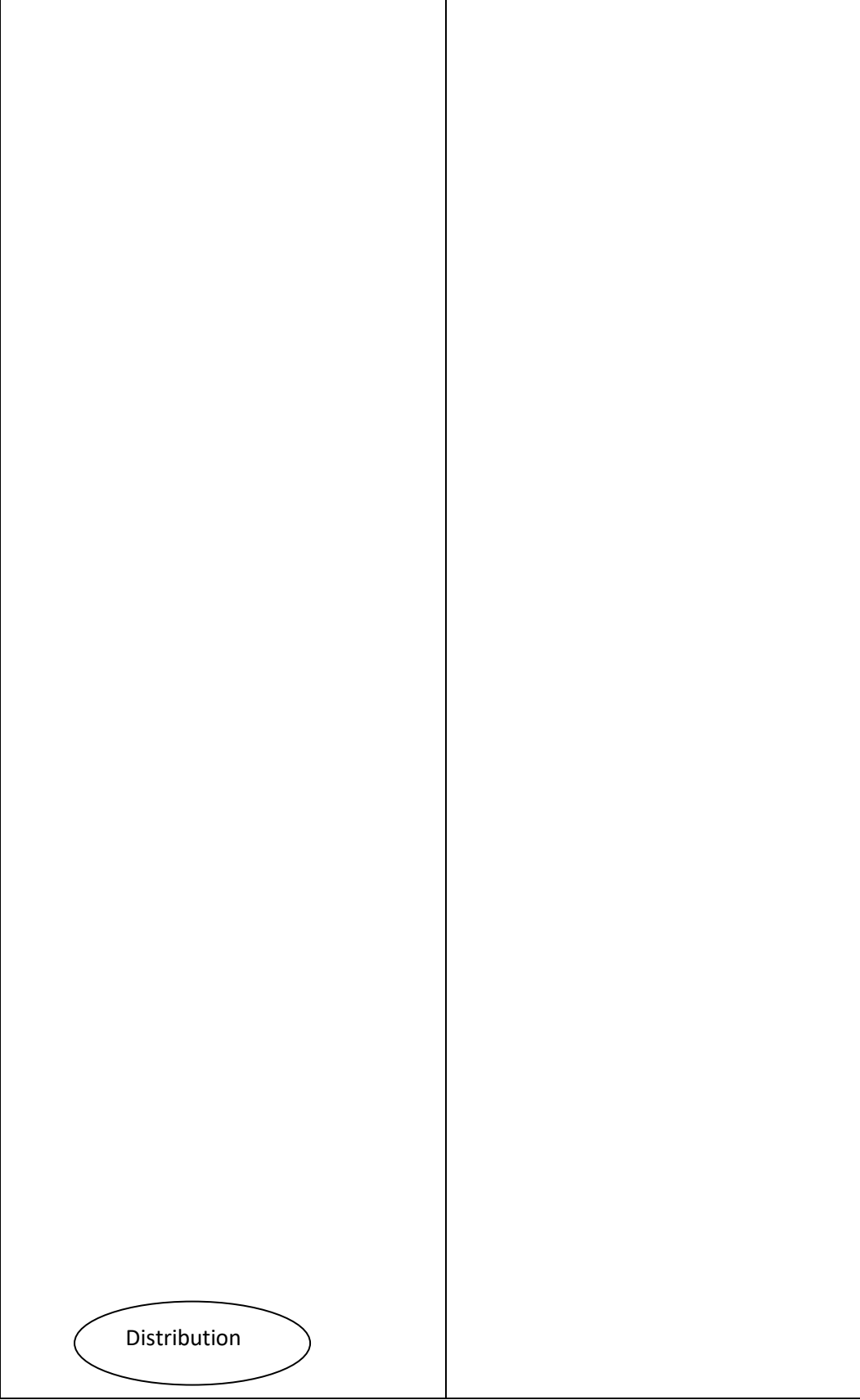
- The process starts in Radiology department with the registration of the Patient. After the Registration we place the entry in the system.
- Then order gets scheduled as per requirement.
- We call the patients and match the identity like UHID NO, Name, Age, Gender and job description.
- We do the job in image acquisitions with relevant machine, once it is finished patients gets dispatched to OPD or IPD with GDA staff / Nursing staff or both.
- After the modality we place the image and data to image management archival, then images and data gets analyzed by the concern Doctor and makes the report on it.
- Finally we submit the report to the concerned department.

**Note:** The process has been explained in the above chart and diagrams.

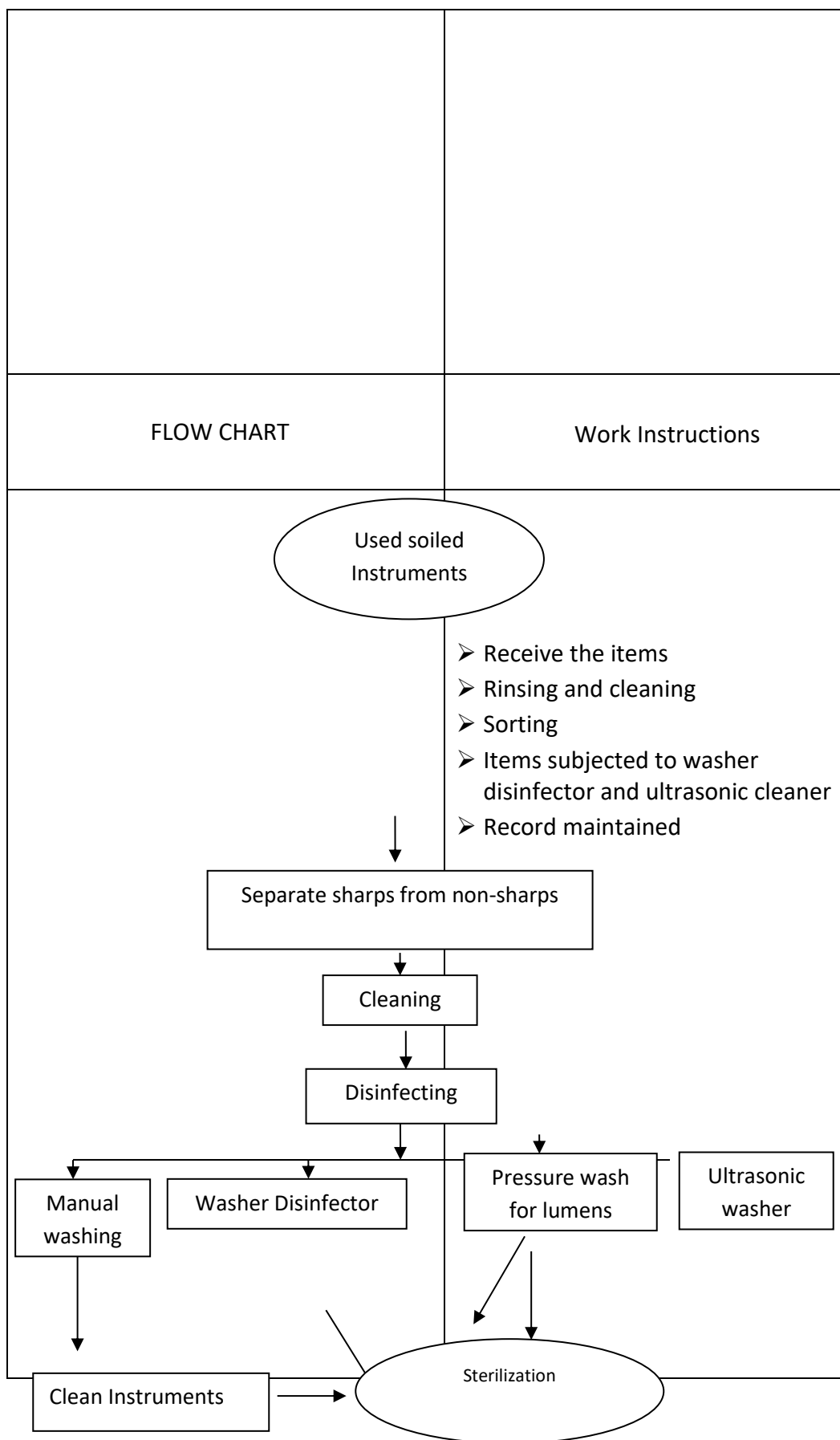


### Process in CSSD Department Patients flow:





Distribution



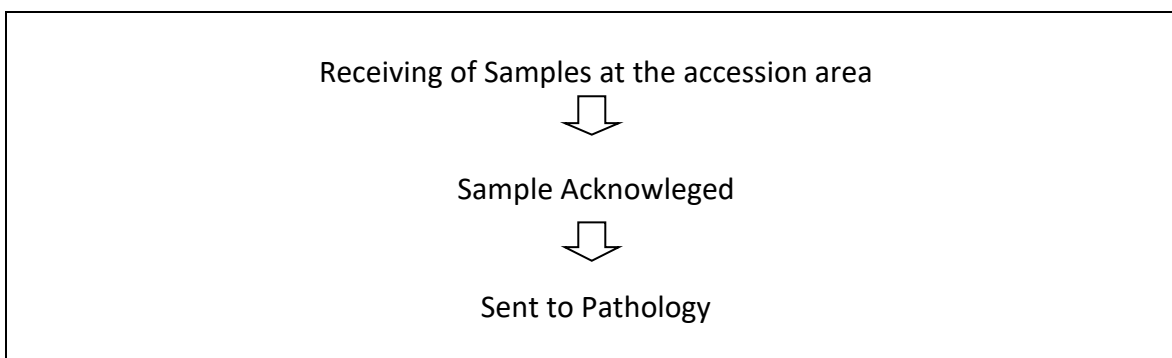
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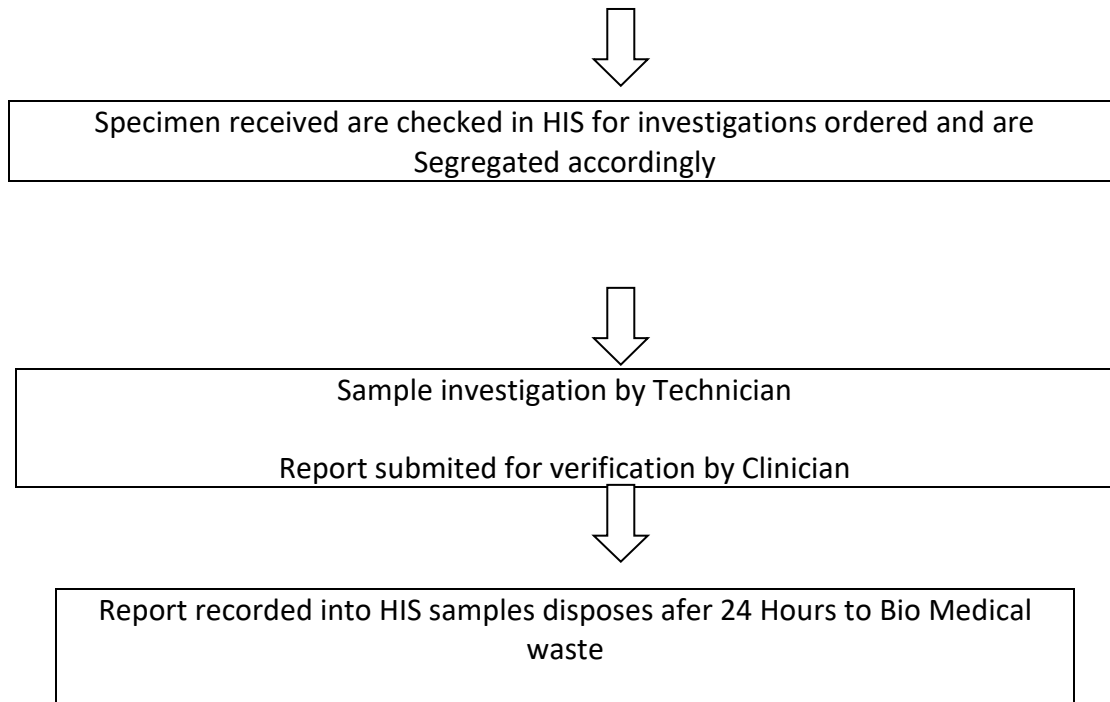
**Process in CSSD Department Patients flow:**

- Process in CSSD department starts with receiving the used soiled instruments . we receive it from different departments and mention it in the receiving register.
- Then we rinse and clean it with water and keep to dry properly. And Check breakage or functionally defects.
- Once it is dried we do sorting in respect of sharp and nonsharps. And mention in the respective record book.
- After that we segregate the instruments in respect of disinfectant and ultrasonic cleaner. Here we check the devices with colour indicator protocol.
- Then finally cleaned instruments gets sterilized. Again we update it in our record book.
- After that we do the packing of instruments and send to dispatch section.

**Process in Laboratory Department Patients flow:**

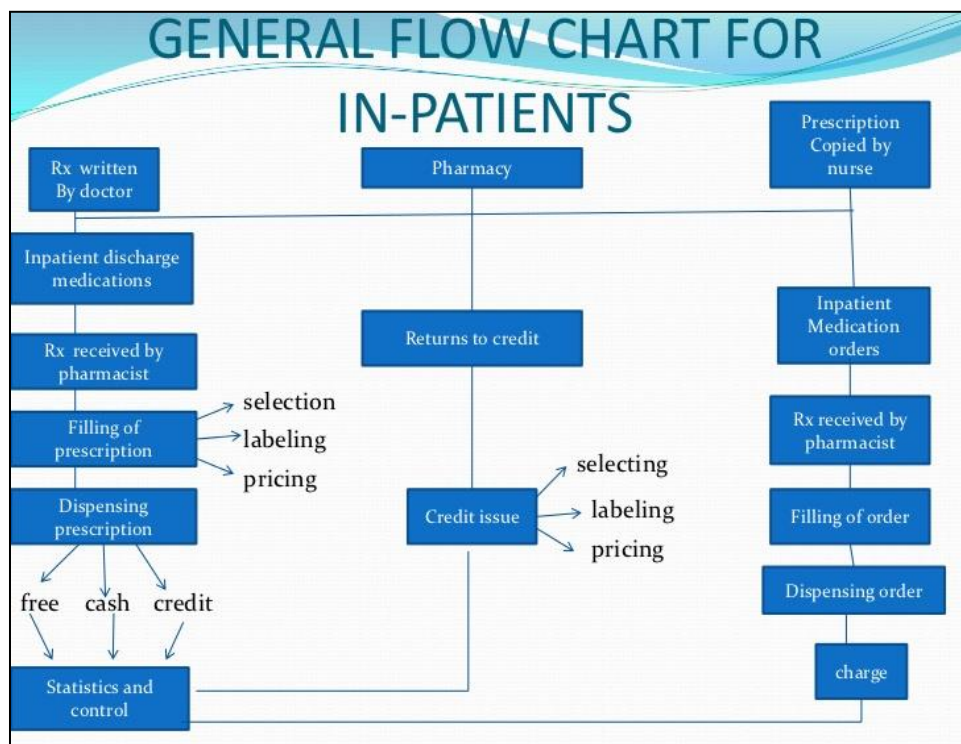
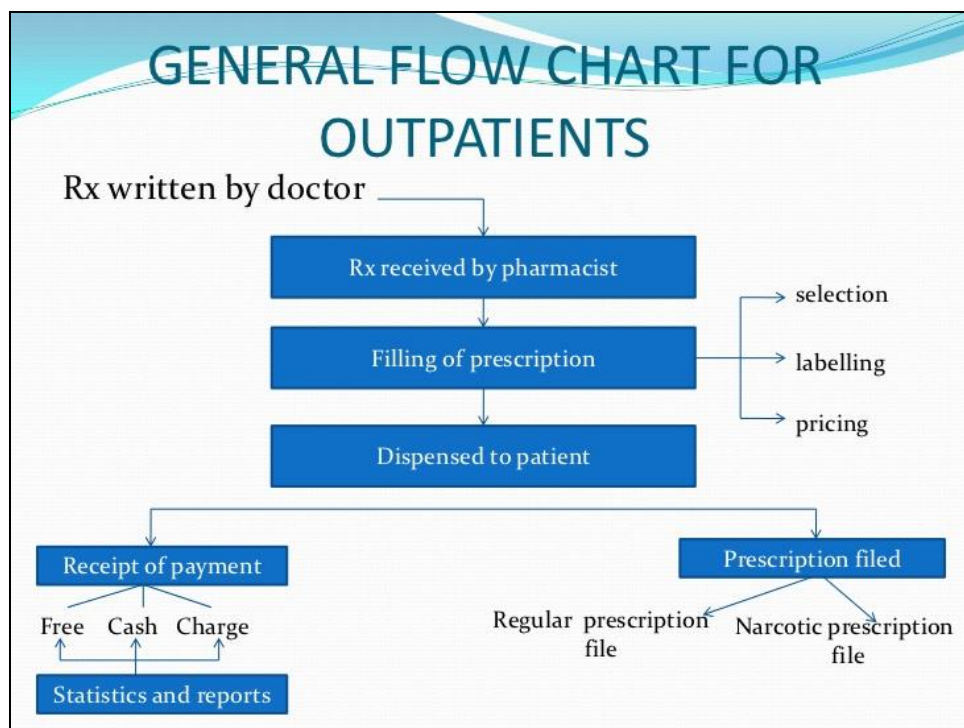
**Work Flow In Laboratory:**



**Explanation:**

- In Laboratory job starts with sample receiving at accession area.
- We collect the samples and record it in Record book and sent it for sorting or segregation.
- As per requirement we keep it stored and technicians do the investigation and make the report .
- Report gets analyzed by the clinician and then we send it to the concern department.
- Finally the sample disposes to Bio Medical Waste.

**Process in Pharmacy Department Patients flow:**

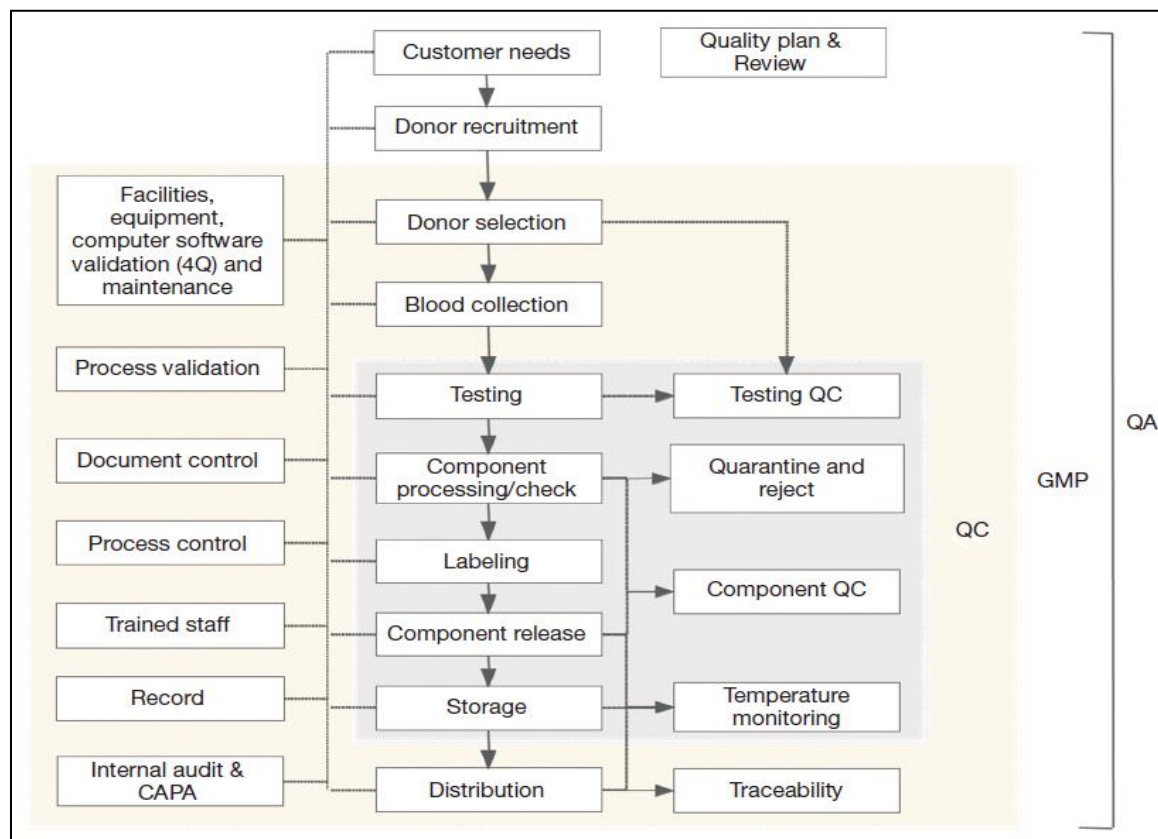


### Explanation:

In Pharmacy we have two sections of patients flow . 1) OPD patients & 2) IPD patients.

- For OPD patients we give medicine to patients or attendents direct demand on Pharmacy counter once they show the prescription.
- Receiving the prescription we do filling of prescription that stands for selection of medicine, labeling and pricing of the medicine.
- After that we do the billing of the medicine either in cash, credit or free. And put it in record.
- Then segregate the prescription to regular prescription file or Narcotic prescription file.
- For IPD patients we get the copy of prescription by nurse .
- Receiving the prescription we do filling of prescription that stands for selection of medicine, labeling and pricing of the medicine.
- After that we do the billing of the medicine to the name of patient with verification of patient's UHID. And put it in statistics and control.
- Then segregate the prescription to regular prescription file or Narcotic prescription file.

#### Process in Blood Bank Department Patients flow:

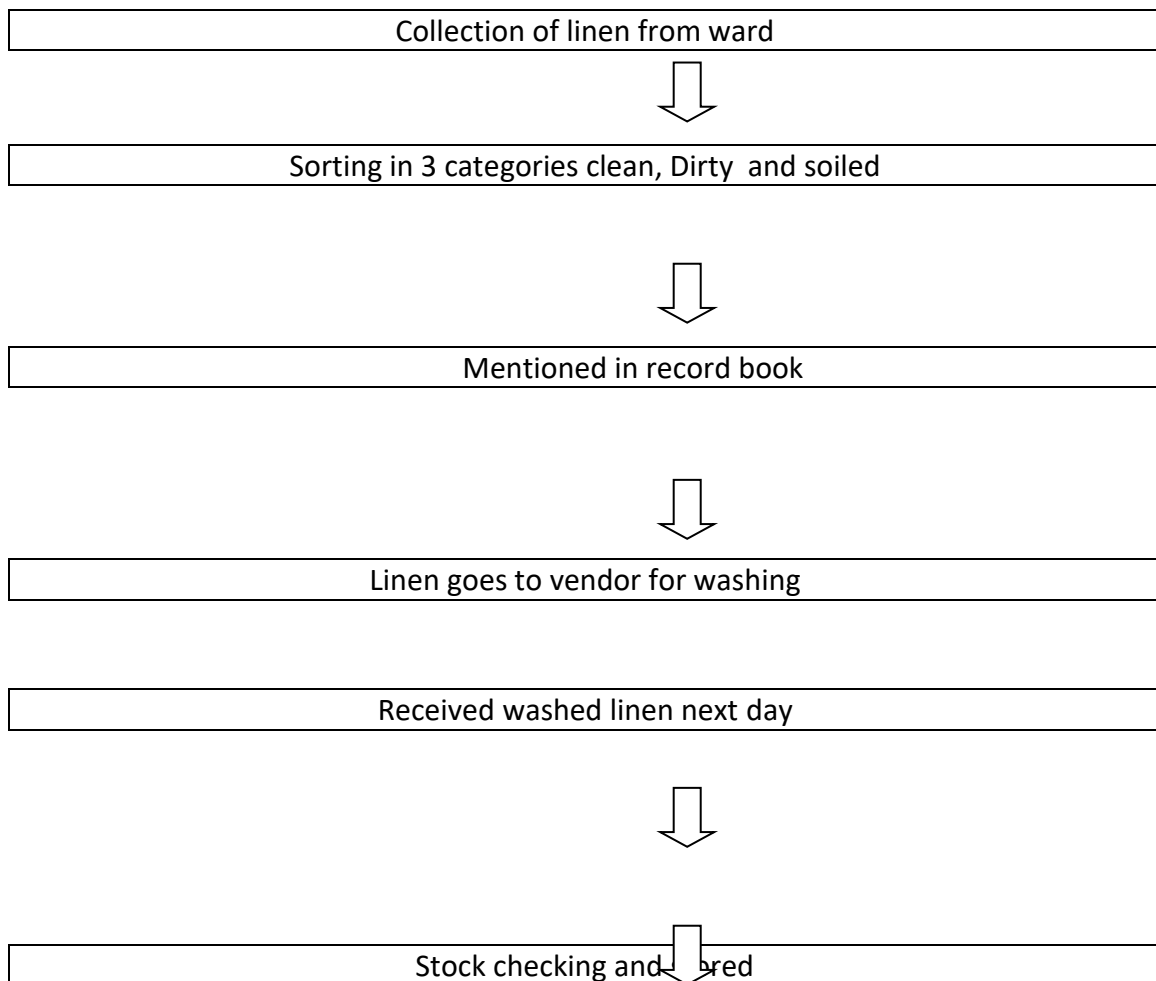


#### Explanation:



- Once we get the requirement of the blood from different department such as Emergency, operation theater or IPD we do the donor recruitment and then donor selection.
- We do selection of the donor after testing and find ok on all parameters.
- Then do blood collection from donor. Send it for component processing.
- Then do the labeling of the collected blood and component release.
- After it we store it in the storage. And it goes for distribution to the required department. And record it.

#### Process of Laundry Department:

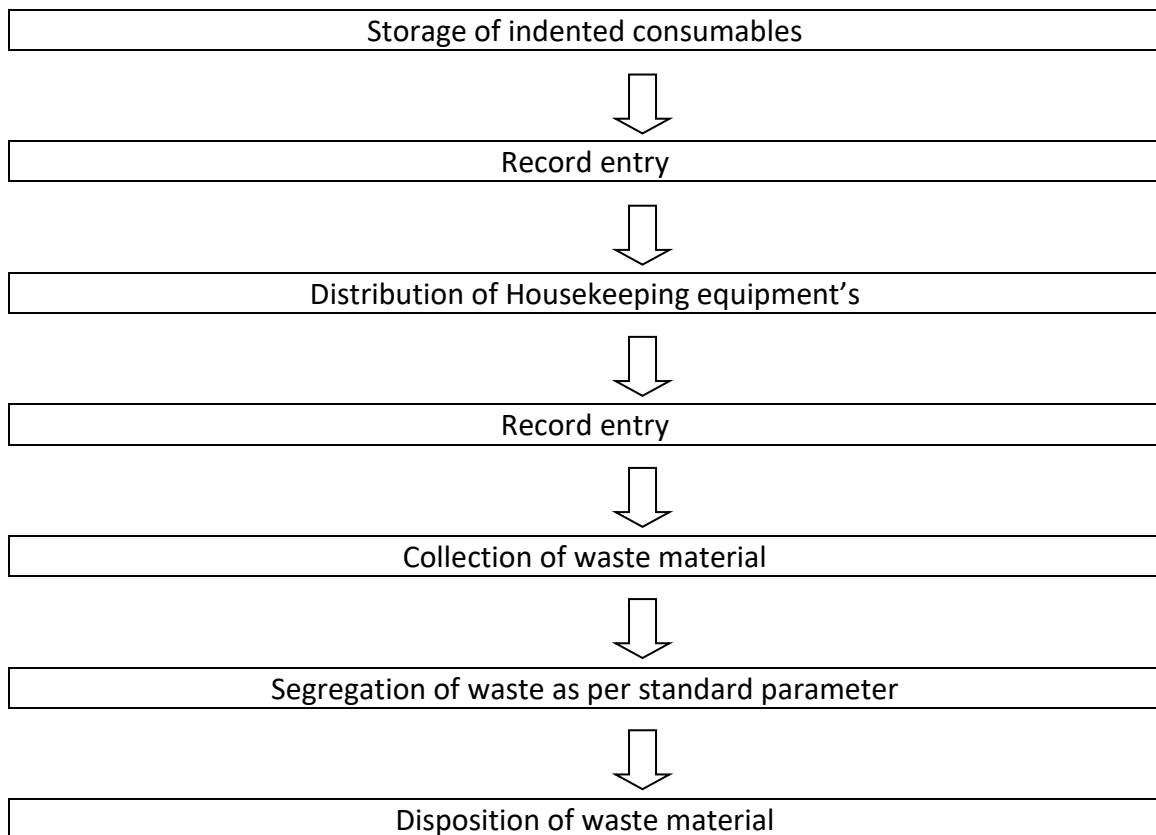


#### Explanation:

- Here the job of the laundry department starts once there is discharge of the patients.
- We remove the linen and categories in 3 division clean, dirty and soiled.
- All the linen after sorting in DU gets counted and recorded in record.

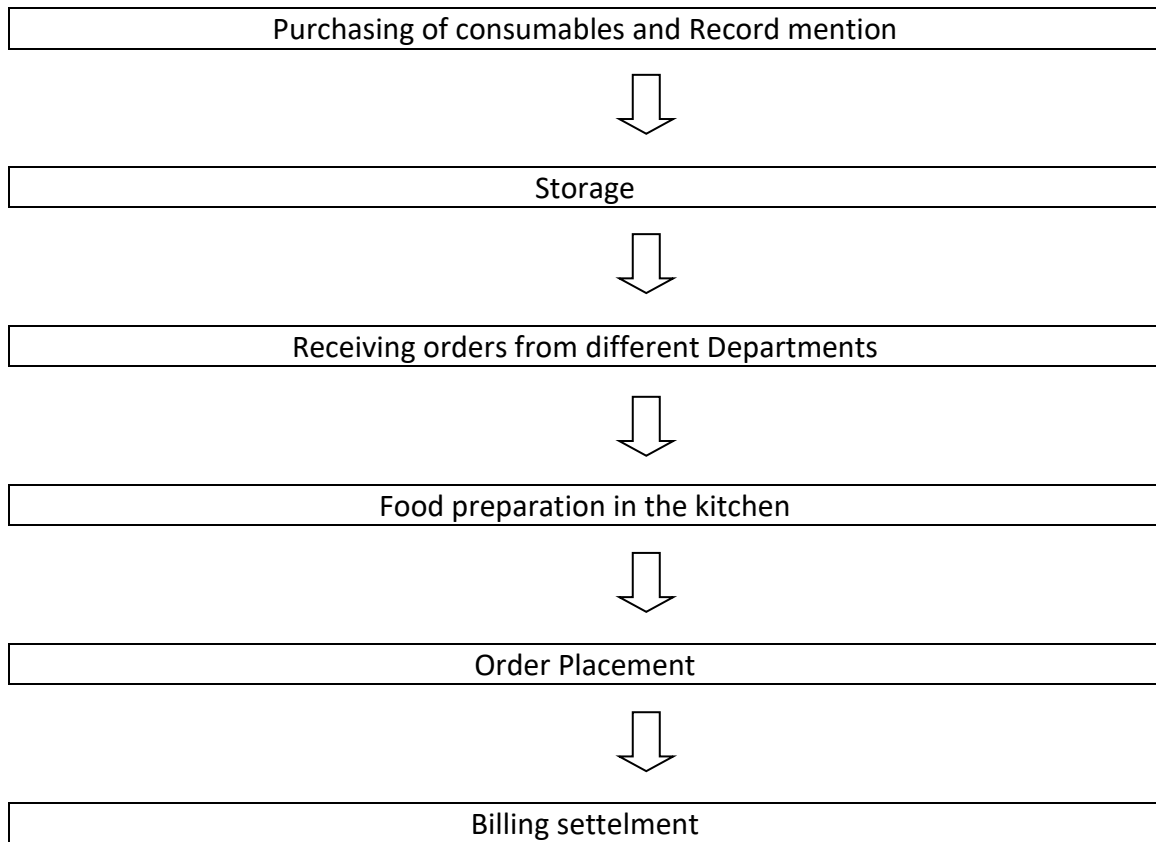
- After the record entry we handover the linen to the outsourced vendor and take receipt of it.
- Next day we receive the washed linen from vendor and do counting and keep updated in the record book.
- We do the bed ready with fresh linen in 30 minutes of turnaround time.

**Process of Housekeeping Department work flow:**

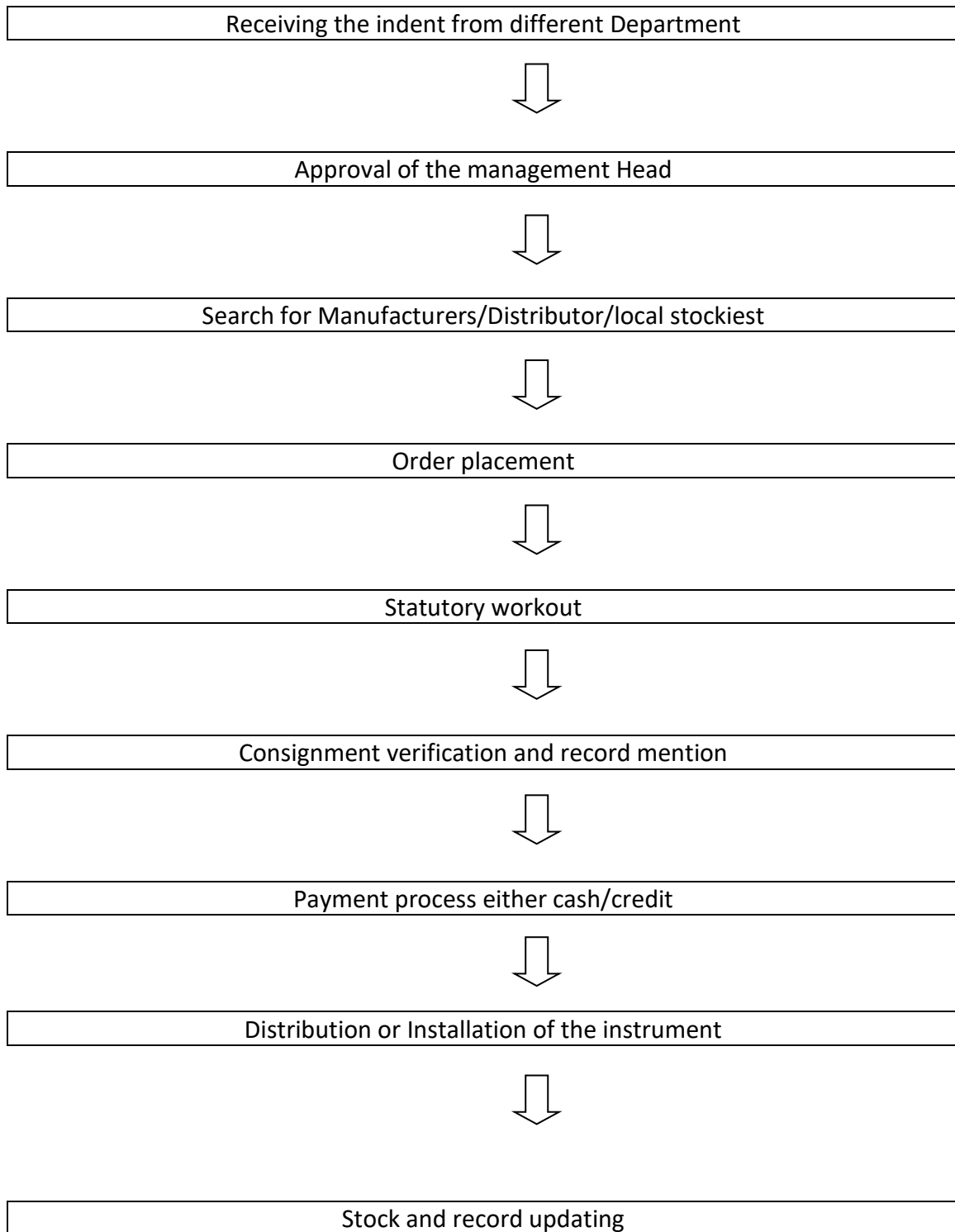


**Explanation:**

- First of all we store the indented consumables as per requirements and make a record in the record book.
- Then every morning do the distribution of consumables as per requirements to the working staffs and record it in the register.
- We do the cleaning and collect the waste material from different departments.
- Then segregate the waste material in different color garbage bags as per standard parameters.
- Dispose all the waste material to the disposal van provided by the vendors.

**Process of Food and Beverage Department work flow:****Explanation:**

- First of all we purchase and do storage of the consumables and record in the register book.
- Then we receive the food orders for different patients with concern of dietician. We register the name of the patients with UHID number and bed number of the perticular department.
- Send the request of order to prepair the food in the kitchen.
- Then deliver the food to the patients on given time.
- After that we do the billing for the service to the patients account for free, cash or credit. And mention to the record.

**Process of Supply and Chain Management Department work flow:**

**Explanation:**

- Our job starts once we get the indent for any instrument or requirement.
- As we get the indent or request we take the approval of head of the management.
- After the approval we look for the best manufacturer or service provider. And place the order.
- Here we take care of some statutory process if needed like license or any other legal documentation.
- Once we get the consignment we do the verification of the instrument like breakage or functional defects etc.
- Then installation or distribution done by concerned team members.
- After all this we do the stock and record updating.

# **PART-B**

# **DESSERTATION REPORT**

## Identification Of Gaps Of Support Services For NABI Accreditation

### Introduction:

Accreditation of health laboratories is the process by which an independent and authorized agency accredits the quality system and competence of a laboratory on the basis of certain pre-defined standards. Accreditation is done at regular intervals to ensure maintenance of standards and reliability of results generated to support clinical and public health activities by the laboratories.

The accreditation process requires:

- identification of an authoritative body
- adoption of standards, and
- institution of a mechanism of assessment of laboratories to certify their compliance with standards.

Laboratory accreditation is a procedure by which an authoritative body gives formal recognition of technical competence for specific tests/ measurements, based on third party assessment and following international standard.

In the current global scenario an essential pre-requisite of trade is that any product or service accepted formally in one economy must also be free to circulate in other economies without having to undergo extensive re-testing. WTO recognize that non acceptance of test results and measurement data is a Technical Barrier to Trade. Global sourcing of components calls for equivalence of measurement, which can be facilitated by a chain of accredited calibration laboratories. Accreditation is considered as the first essential step for facilitating mutual acceptance of test results and measurement data.

Confidence in accreditation is obtained by a transparent system of control over the accredited laboratories and an assurance given by the accreditation body that the accredited laboratory fulfils the accreditation criteria, at all times.

Accredited laboratories can objectively state conformance of product or service to specified requirements. It is important for the purchaser, regulator, government, and the public to be able to identify accredited testing and calibration laboratories.

### National Accreditation Board for Testing and Calibration Laboratories (NABL):

NABL is an autonomous body under the aegis of Department of Science & Technology, Government of India, it is registered under the Societies Act. NABL has been established with the objective to provide Government, Industry and Society in general with a scheme for third-party assessment of the quality and technical competence of testing and calibration laboratories. Government of India has authorized NABL as the sole accreditation body for Testing and Calibration laboratories.

NABL provides laboratory accreditation services to laboratories that are performing tests / calibrations in accordance with NABL criteria based on internationally accepted standard for laboratory accreditation ISO/IEC 17025. These services are offered in a non-discriminatory



manner and are accessible to all testing and calibration laboratories in India and abroad, regardless of their ownership, legal status, size and degree of independence.

### **Why NABL Accreditation:**

The concept of Laboratory Accreditation was developed to provide a means for third-party certification of the competence of laboratories to perform specific type of testing and calibration. They provide formal recognition of competent laboratories, thus providing a ready means for customers to find reliable testing and calibration services in order to meet their demands.

Laboratory Accreditation enhances customer confidence in accepting testing / calibration reports issued by accredited laboratories. The globalization of Indian economy and the liberalization policies initiated by the Government in reducing trade barriers and providing greater thrust to exports makes it imperative for Accredited Laboratories to be at international level of competence.

### **What are benefits of NABL Accreditation:**

Potential increase in business due to enhanced customer confidence and satisfaction. Savings in terms of time and money due to reduction or elimination of the need for re-testing of products.

Better control of laboratory operations and feedback to laboratories as to whether they have sound Quality Assurance System and are technically competent. Increase of confidence in Testing / Calibration data and personnel performing work. What types of laboratories can seek accreditation?

The laboratories should be legally identifiable & appropriately registered.

### **Organizational management and structure**

The overall responsibility for the design, implementation, maintenance and improvement in the quality system rests with the laboratory management. Quality is the responsibility of all staff members of the organization.

### **Quality standards**

Quality standards are an integral part of the quality system. These aim at ensuring safety and consistency. They need to be followed to meet regulatory requirements as well as to monitor functioning of the laboratory.

### **Documentation**

A document is a record of any information or instructions including policy statements, quality manuals, procedures, specifications, calibration tables, reports, job description, documents of external origin such as regulations, standards and examination procedures, etc. Documents may be stored either as hard copy or electronically.

### **Training**

The quality system is only as good as the staff who actually works with it. No matter how good the quality system is on paper, if theory cannot be translated into practice, quality

cannot be achieved. Training must also include an understanding of why quality is important. Training should be competency-based and must be followed by post-training support.

### Assessment

The laboratory management shall develop and implement quality indicators to systematically monitor and evaluate the laboratory's contribution to patient care. When the program identifies opportunities for improvement within the system, the laboratory management shall take appropriate steps to address them. Error management shall be vigorously implemented.

### Guidelines on Establishment of Accreditation of Health Laboratories

Assessment of quality through audits (internal or external) and participation in external quality assessment schemes (EQAS) are other tools, the results of which should guide the management in further improving quality.

- Accreditation is a tool that recognizes the existence of a quality system in a laboratory.
- An accreditation system should be built on the strong foundation of a quality system.
- Countries that do not have a sound quality system in place may not benefit from accreditation until quality assurance in terms of good laboratory practices, internal quality control (IQC), audit, validation, internal quality assessment and participation in EQAS are strengthened.

### Scope of Accreditation

NABL Accreditation is currently given in the following fields and disciplines. The multi-disciplinary CABs shall have to apply in relevant discipline separately depending upon to which discipline the scope belongs. For more details on scope of accreditation please refer the relevant specific criteria.

TESTING LABORATORIES	CALIBRATION LABORATORIES	MEDICAL LABORATORIES
<ul style="list-style-type: none"> <li>• Biological</li> <li>• Chemical</li> <li>• Electrical</li> <li>• Electronics</li> <li>• Fluid-Flow</li> <li>• Mechanical</li> <li>• Non-Destructive Testing</li> <li>• Photometry</li> <li>• Radiological</li> <li>• Thermal</li> <li>• Forensic</li> </ul>	<ul style="list-style-type: none"> <li>• Electro-Technical</li> <li>• Mechanical</li> <li>• Fluid Flow</li> <li>• Thermal &amp; Optical</li> <li>• Radiological</li> </ul>	<ul style="list-style-type: none"> <li>• Clinical Biochemistry</li> <li>• Clinical Pathology</li> <li>• Haematology &amp; Immunohematology</li> <li>• Microbiology &amp; Serology</li> <li>• Histopathology</li> <li>• Cytopathology</li> <li>• Genetics</li> <li>• Nuclear Medicine (<i>in-vitro tests only</i>)</li> </ul>

PROFICIENCY TESTING PROVIDERS	REFERENCE MATERIAL PRODUCERS
<ul style="list-style-type: none"> <li>· Testing</li> <li>· Calibration</li> <li>· Medical</li> <li>· Inspection</li> </ul>	<ul style="list-style-type: none"> <li>· Chemical Composition</li> <li>· Biological &amp; Clinical Properties</li> <li>· Physical Properties</li> <li>· Engineering Properties</li> <li>· Miscellaneous Properties</li> </ul>

### **Preparation & Eligibility for Accreditation**

Once the CAB decides to seek NABL accreditation, it should make a definite plan of action for obtaining accreditation and nominate a responsible person to co-ordinate all activities related to seeking accreditation who should be familiar with CAB's existing quality system.

The CAB should get fully acquainted with relevant NABL documents and understand the assessment procedure and methodology for filing an application.

A CAB wishing to be accredited by NABL must have a Quality Manual on its Quality System satisfying the requirements as described in various clauses of ISO/ IEC 17025:2005 or ISO 15189:2012 or ISO/IEC 17043:2010 or ISO Guide 34:2009 whichever is relevant and requirements of relevant NABL specific criteria and needs to ascertain the status of its existing quality system and technical competence.

The proposed Quality manager shall have undergone 4-days formal training on management system and internal audit based on relevant standard.

The CAB must ensure that the procedures described in the Quality Manual and other documents are being implemented. In case the laboratory performs site testing/ calibration, it must also comply with NABL 130 "Specific criteria for site testing and site calibration laboratories".

# **REVIEW OF LITERATURE**

### **Literature Review:**

India has been in the forefront of various international movements in the health and population sectors. Overall, the Indian healthcare industry is going through a transition and the future is likely to see significant changes in the nature of provision of healthcare and the roles of various players in the industry. The healthcare service scenario in India is expected to evolve into a more developed stage. With this transition, management of human resources in health is a major challenge to health systems development in India. This includes planning for, production, recruitment, and utilisation of health personnel. Although a number of measures have been instituted to meet this challenge, considerable gaps still remain.

Accreditation is the formal recognition, authorization and registration of a laboratory that has demonstrated its capability, competence and credibility to carry out the tasks it is claiming to be able to do. It provides feedback to laboratories as to whether they are performing their work in accordance with international criteria for technical competence. The concept of laboratory accreditation was developed to provide third-party certification that a laboratory is competent to perform the specific test or type of tests. Laboratory accreditation is a means to improve customer confidence in the test reports issued by the laboratory so that the clinicians and through them the patients shall accept the reports with confidence. The National Accreditation Board for Testing and Calibration Laboratories (NABL) is an autonomous body under the aegis of the Dept. of Science & Technology, Govt. of India, and is registered under the Societies Act. NABL, which was initially established with the objective to provide accreditation to testing & calibration laboratories, later on extended its services to the clinical laboratories in our country. Govt. of India has authorized NABL as the sole accreditation body for testing and calibration laboratories. The objective of NABL is to provide third party assessment of quality and technical competence. Four years ago NABL established links with international bodies - Asia Pacific Laboratory Accreditation Cooperation and International Laboratory Accreditation Cooperation. This has imparted international recognition to NABL accredited laboratories. The international standard currently followed by NABL is ISO 15189, specific for medical laboratories.

During the accreditation process, Organization appointed a quality manager to oversee the plan for accreditation and quality-related activities in coordination with the laboratory key personnel. Accordingly, quality policy endeavor was to provide the patients with accurate and precise diagnostic laboratory tests' reports of the highest quality for the satisfaction of patients and clinicians. To meet the objectives, the management ensured that all systems and processes required for the above are in place.

Quality objectives of our hospital - Issue accurate and precise reports, Ensure timely delivery of reports, Compliance to standard operating procedures (SOPs) and protocols, Patient satisfaction and care, Maintenance and regular calibration of equipment, Regular training of staff, Quality check by running internal controls and participating in External Quality Assurance Scheme (EQAS), Continual enhancement of quality by monitoring the quality indicators.

Medical laboratories can seek recognition as being compliant with particular standards through a number of different systems. Recognition of medical laboratories handling clinical specimens as distinct from those dealing with the results of pre-clinical studies is in their

infancy in most countries. A laboratory accreditation system contains three elements, the organisation or authority which conducts the inspections or assessments and grants accreditation (and may also set the standards), the inspection or assessment which seeks to establish compliance with the standards, and crucial to the whole process the standards themselves

Indian health sector is a complex admixture of public and private providers, but several lacunae of public health service delivery system in terms of human resource, access, and quality have resulted in unprecedented growth of private sector. Although seamless delivery of services at rural and urban areas, timely approach, and improved information technology system are the strength of the private sector, this package comes at the cost of high out-of-pocket expenditure. Mobilization of private sector health workforce by their capacity building in terms of orientation toward public health services is one of the available solutions to move toward wider coverage of public health services. However, numerous challenges need to be addressed before realization of this vision.

### **Problem Statement For The Study:**

#### **Objective:**

Identification of Gaps of support services for NABL accreditation in NAYATI MEDICITY, Mathura Addressing the gaps seen in the system

#### **Aim:**

To achieve the NABL accreditation for Nayati Medicity, Mathura.

#### **Methodolgy**

- The research methodology adopted for the study is **“Observatory and Prospective.”**
- This study was carried out in tertiary care 350 bedded hospital in Mathura City.

#### **Study Duration**

4<sup>th</sup> march- 25<sup>th</sup> may

#### **Study Tool**

- NABL self-assessment toolkit, internal audit and checklists
- **Scoring criteria would be applicable**
- Compliance to the requirement: 10
- Partial compliance to the requirement: 5
- Noncompliance to the requirement: 0

#### **Data Collection Technique**

- Data collected by direct observations, discussion with hospital staff, from hospital manuals, records and policies.



## **Theoretical Review:**

### **Quality standards**

Quality standards are an integral part of the quality system. These aim at ensuring safety and consistency. They need to be followed to meet regulatory requirements as well as to monitor functioning of the laboratory.

### **Documentation**

A document is a record of any information or instructions including policy statements, quality manuals, procedures, specifications, calibration tables, reports, job description, documents of external origin such as regulations, standards and examination procedures, etc. Documents may be stored either as hard copy or electronically.

### **Training**

The quality system is only as good as the staff who actually works with it. No matter how good the quality system is on paper, if theory cannot be translated into practice, quality cannot be achieved. Training must also include an understanding of why quality is important. Training should be competency-based and must be followed by post-training support.

### **Assessment**

The laboratory management shall develop and implement quality indicators to systematically monitor and evaluate the laboratory's contribution to patient care. When the programme identifies opportunities for improvement within the system, the laboratory management shall take appropriate steps to address them. Error management shall be vigorously implemented.

### **Accreditation body**

Clause 4 elaborates that the accreditation body shall have legal responsibility to ensure that its functions will be sustained and duplication of work avoided. However, there is no restriction that only a government entity can be the accreditation body; any private sector entity also can perform this function. In some countries, most of the accreditation bodies belong to the private sector and this may create competition in the accreditation services. The best situation would be for a country to have only one accreditation body to serve this activity to avoid confusion and duplication of work. This will also help in providing consistency in the accreditation system and lead to efficient utilization of resources.

This clause also describes the structure of the accreditation body in order to establish confidence in its accreditation. The structure is similar to any organization that has implemented a quality system such as a clear policy, manuals and procedures for all important activities, and a well-defined structure that describes the responsibilities of important personnel. It also emphasizes the process of accreditation and the competency of the personnel involved.

Impartiality is described in detail in this clause to show how this is to be implemented. The implementation of policy and procedures where no single party dominates in any process, especially decision-making for accreditation, is the main tool to show impartiality, and



emphasize that all laboratories shall be treated in a non-discriminatory manner. Consultancy services linked with the accreditation activity are prohibited for any accreditation body to avoid compromising the confidentiality and decision-making process for accreditation.

### **Management**

This clause explains how the accreditation body should have a transparent management system to ensure proper services. Control of documents with good record-keeping at all stages is a key factor for traceability. The standard also describes the procedure for taking corrective and preventive actions, carrying out internal audits and management reviews, and responding to customer complaints.

### **Human resources**

Human resource is the most important criterion that highlights the competency of the accreditation body. The personnel involved are not only employees of the accreditation body but also others such as technical assessors, lead assessors, decision-making committees, technical committees, and personnel involved in deciding the requirements and laying down criteria. Systematic monitoring of all functioning personnel must be implemented to ensure consistency of work. It is also important to keep all the necessary records of all personnel working for the accreditation body.

### **Accreditation process**

The accreditation process is described in detail in this standard. It explains the main process for accreditation which comprises application for accreditation, review of resources, subcontracting of assessment, preparation for assessment, review of documents and records, on-site analysis of assessment findings and the assessment report, decision-making and granting of accreditation, appeal, reassessment and surveillance, extending accreditation, suspending, withdrawing accreditation, records on laboratories, proficiency testing and other comparisons of laboratories. These clearly show that for each step, some principles and concepts need to be followed.

### **Conflict of interest**

Conflict of interest of the accreditation body and related bodies needs to be addressed, especially if the accreditation body is a part of one big organization of the government. The accreditation process should be totally free from interference by the top management as this can adversely affect the credibility of the programme.

Conflict of interest can be minimized or eliminated by designing an appropriate accreditation system. For example, the accreditation committee should include all types of stakeholders (users, other accreditation bodies if any, regulatory bodies, NGOs, competitors in the business, other government organizations, etc.) to make decisions for accreditation. Accessible complaint and appeal mechanisms are good ways to find out if there are any conflicts of interest.

### **Traceability**

In all types of quality systems, traceability of all actions and documents is a must. As an accreditation body, the process of establishing a quality system must be implemented in such a

way that it is readily accessible for verification by any party. The question of who, when, where, why and how shall be recorded in all processes. This also supports the transparency criterion for the accreditation body.

### **Evidence-based operations**

All actions must follow laid-down procedures and the necessary forms must be filled up to ensure the consistency of actions as well as record-keeping

### **Confidentiality**

Laboratories shall be assessed in a continuous fashion with regard to all aspects of standards and requirements. All the findings and evidence during the accreditation process must be treated as confidential information. However, the laboratories themselves may allow access to any of their records if they wish to. In some instances, prior permission may be required from the laboratories by the accreditation body to reveal the findings of the report to a particular party.

### **Integrity**

The accreditation body must maintain its integrity, especially in technical areas. This will build trust in the customers. This must be created through the openness of the process, traceability and, most importantly, is the right attitude for accreditation personnel. It is also recommended that there should be flexibility in facilitating the accreditation work, which should be done on the basis of sound and valid reasons.

### **Transparency**

The accreditation process should be done in accordance with the principles of good governance. In other words, every step should be transparent so as to allow monitoring and evaluation. This will induce trust in the accreditation body, thus making it sustainable. It will also improve the quality system in laboratories.

### **Management requirements**

These specify 15 key elements for sound management and they are:

- Organization
- Management system
- Document control
- Review of requests
- Tender and contracts
- Subcontracting of tests and calibrations
- Purchasing services and supplies
- Services to customer
- Complaints
- Control of non-conforming testing and/or calibration work
- Corrective action
- Preventive action

- Control of records
- Internal audits
- Management reviews.

### **Biomedical Engineering Department**

Biomedical Engineering will ensure high standards of maintenance of biomedical equipment to support uninterrupted patient care and uncompromised patient safety.

### **Calibration of equipment should**

- Meet the requirements of the customer
- Appropriate for the purpose
- Use latest version of the standard.

### **Calibration method, procedure should be developed to contain the following**

- Appropriate identification
- Scope
- Description of the type of item to be tested or calibrated
- Parameters or quantities and ranges to be determined
- Apparatus and equipment, including technical performance requirements
- Reference standards and reference materials required
- Environmental conditions required stabilization period and it also includes
  - Affixing of identification marks, handling, transporting, storing and preparation of items.
  - Checks to be made before the work is started.
  - Checks that the equipment is working properly and, where required, calibration and Adjustment of the equipment before each use.
  - The method of recording the observations and results.
  - Any Criteria or requirements for approval / rejection
- Data to be recorded and method of analysis and presentation.

### **Validation**

The range and accuracy of the values obtained from the validated methods include

- Uncertainty of the results.
- Detection limit.
- Selectivity of the method
- Linearity
- Limit of repeatability & reproducibility
- Robustness against external influences.
- Cross sensitivity against interference from the matrix of the sample/ test object

### **Validation includes**

- Specification of the requirements
- Determination of the characteristics of the methods
- Check that requirements can be fulfilled by using the method

- Statement on the validity.
- Regular reviews should be carried out during the development of the method.
- To any changes in the development plan, the same should be approved and authorized.
- Validation is a balance between costs, risks and technical possibilities.

### **Repair And Maintenance:**

#### **Preventive Maintenance**

- Calibration schedule (Month wise) will be prepared as per manufacturers recommendations. This will be shared with the user department as applicable.
- List of equipment scheduled for preventive maintenance (in house /external) will be drawn out on a monthly basis based on the annual preventive maintenance calendar in co-ordination with the contracted service provider
- Biomedical engineer will inform department heads of scheduled preventive maintenance of equipment in their department in advance
- In case equipment is covered under external maintenance contract, inform the service engineer of the scheduled date in advance
- Carry out preventive service as per the preventive maintenance procedure prescribed in the manual. A checklist (as required) is developed based on the equipment operations manual and used as a reference to conduct the maintenance.
- Update the PM label with the next proposed preventive maintenance month and affix on the machine side panels.
- Handover the equipment to user department and obtain acknowledgement in the service/Preventive report.
- Update the annual preventive maintenance calendar.

#### **Equipment breakdown call**

- Intimation of equipment failure received from the user department through phone, verbally, Email or any software which is used by organization.
- The attending engineer records the time, department, equipment and fault description in Break down worksheet
- The biomedical engineer will assess the nature of the problem and takes action as required, internal service support is 30 minutes during working hours of the biomedical team.

### **Breakdown of equipment is rectified in various ways**

#### **In-house repairs**

- In house spares and accessories are used as required and problem rectified
- In case spares procurement is required, necessary approvals as per the matrix ,spares procured and replaced
- The equipment is affixed with a 'Do Not Use' sticker if the problem cannot be addressed immediately.

#### **Repairs through external agencies**

- Identify if the equipment is under warranty AMC, CMC or on per call visit .Time line for external service support is 4 to 72 hours (depends on location of hospital).and for Warranty
- Call logged to toll free / Service engineer is contacted to conduct necessary repairs (or any other mode of Communication)
- After the repairs, the Biomedical engineer & the user validates the functioning of the equipment
- Equipment handed over to user department and acknowledgement obtained in the breakdown log

#### **Annual Maintenance contract (Labour contract)**

- Call logged to toll free /any other mode of contact is contacted to conduct necessary repairs (or any other mode of Communication)
- In case spares are required, necessary approvals are obtained and spares procured and replaced.
- Biomedical engineer with User validates the functioning of the equipment ,Equipment handed over to user department and acknowledgement

#### **User Training**

- After installation of any new equipment in the hospital the company engineer along with Bio Medical Engineer, demonstrate the equipment to the user staff.
- A theoretical and practical training session is carried out explaining features, operating sequences and precautionary measures.
- Training needs shall be analysed and conducted. Most common need could be
  - New joinee
  - Unusually high number of breakdown calls
  - Incidents of improper or repeated damages during use of equipment
  - Improper operation of the equipment observed during rounds

#### **Supply Chain Management:**

Healthcare SCM includes business activities and operations that integrate a continuous, seamless flow of materials and services for healthcare delivery. One of the biggest challenges facing healthcare SCM operationally is maintaining sufficient inventory levels to sustain quality and timely patient care reducing wastages, and for this reason, it is designed to assure a high service level by maximizing the resource allocation, in order to respond effectively and promptly to the patient care needs. Healthcare SCM processes have three types of flows: physical, information and financial flows. The physical flows includes the supply of pharmaceuticals, medicals, surgical consumables, medical devices, hygiene consumables, food supplies, equipment and other supplementary products necessities to support doctors, nurses and of course patients. Information and financial flows are related to SC decisions for effective product flow and organizational performance improvement. A successful SCM requires planning, managing and controlling these flows through the integration of key processes

**Policies:**

This policy is established to ensure complete and appropriate ordering, labeling, and storing of supplies, controls, reagents, and other materials in a manner to facilitate proper usage and inventory control. Maintaining an appropriate inventory levels ensures adequate materials are available when needed while conserving resources.

The laboratory manager is responsible for ensuring supplies and reagents are available as needed by monitoring usage and inventory levels, and ordering/reordering supplies and reagents as needed.

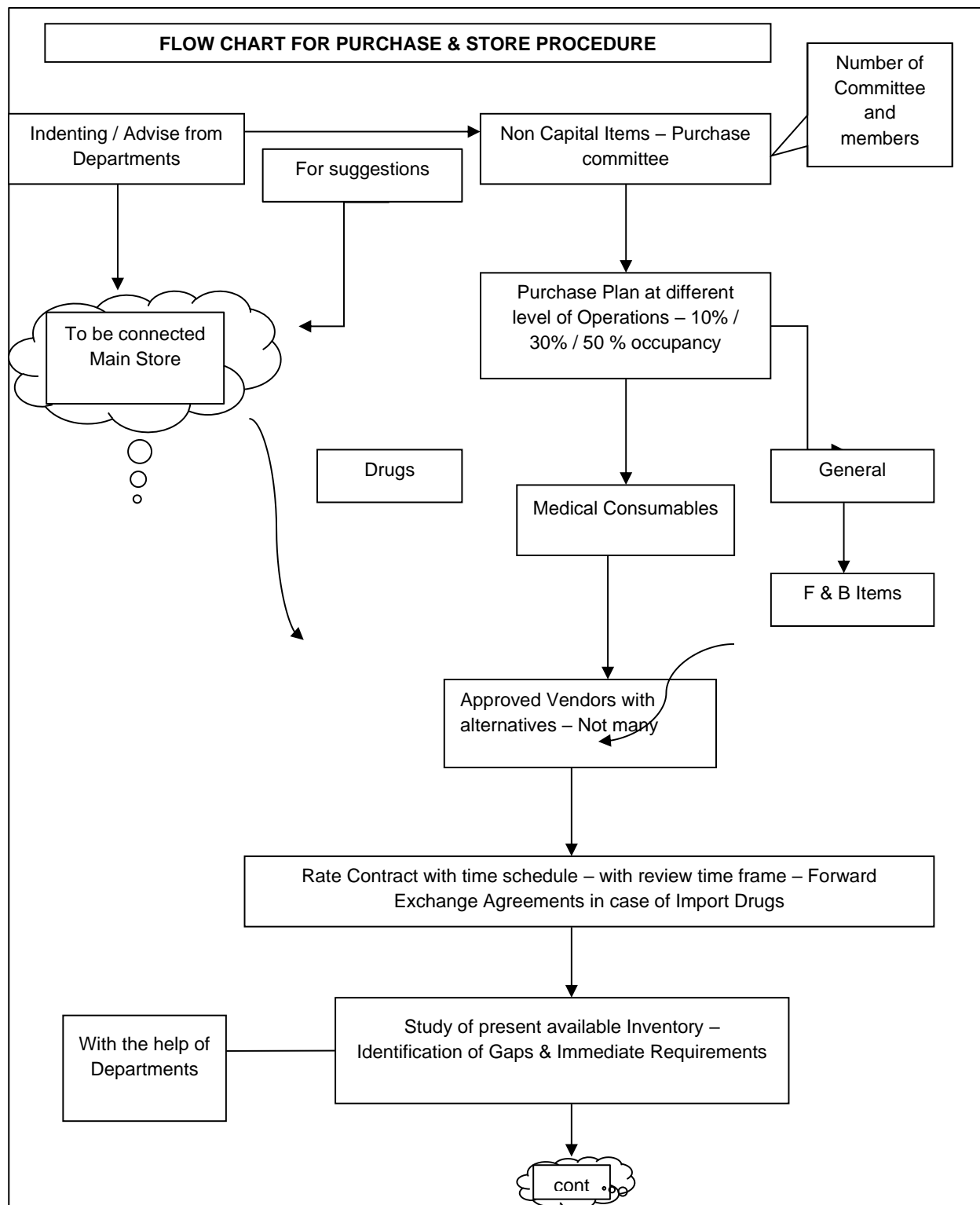
- Each week, the manager checks supply and reagent inventories and reorders as necessary. Ordering information is kept on file as a spreadsheet listing the item description and number, vendor identification, pricing, packaging, etc. The laboratory manager or designee annotates the amount to be ordered next to the item description on the spreadsheet and then takes all annotated spreadsheets to the Purchasing Department for the orders to be placed.
- Standing orders are set up for many reagents and controls, such as for chemistry, hematology, and coagulation. These are renewed periodically, usually annually, and are adjusted based upon usage history or anticipated future needs. Standing orders are shipped automatically.

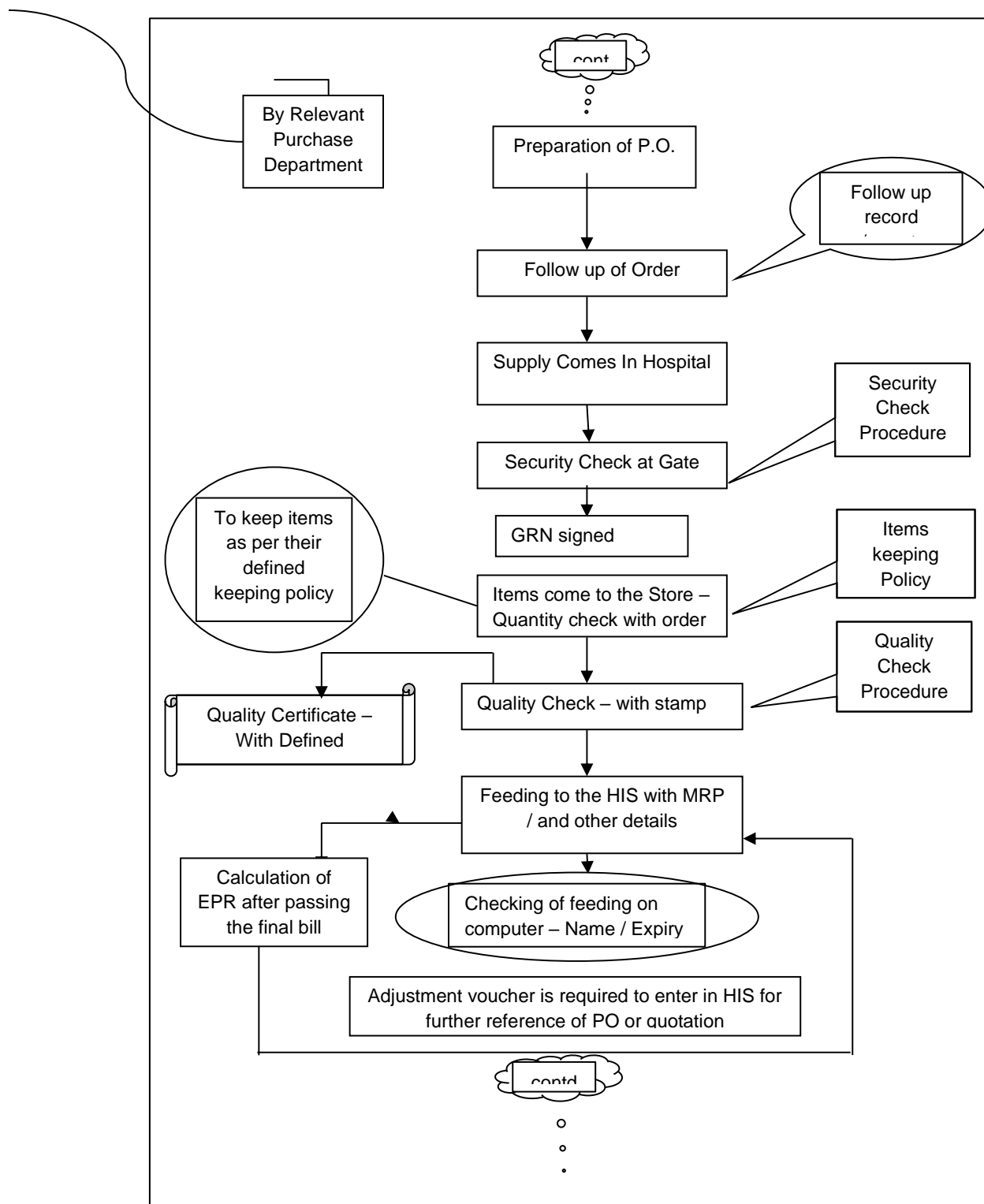
**Supply chain policies:**

Niyati has implemented a series of policies designed to eliminate conflicts of interest, improve patient quality and safety and support privacy and security. Among them is the new Vendor Policy, which prohibits vendor access to physicians and personnel without prior written consent, in addition to prohibiting free lunches, small gifts and other perks.

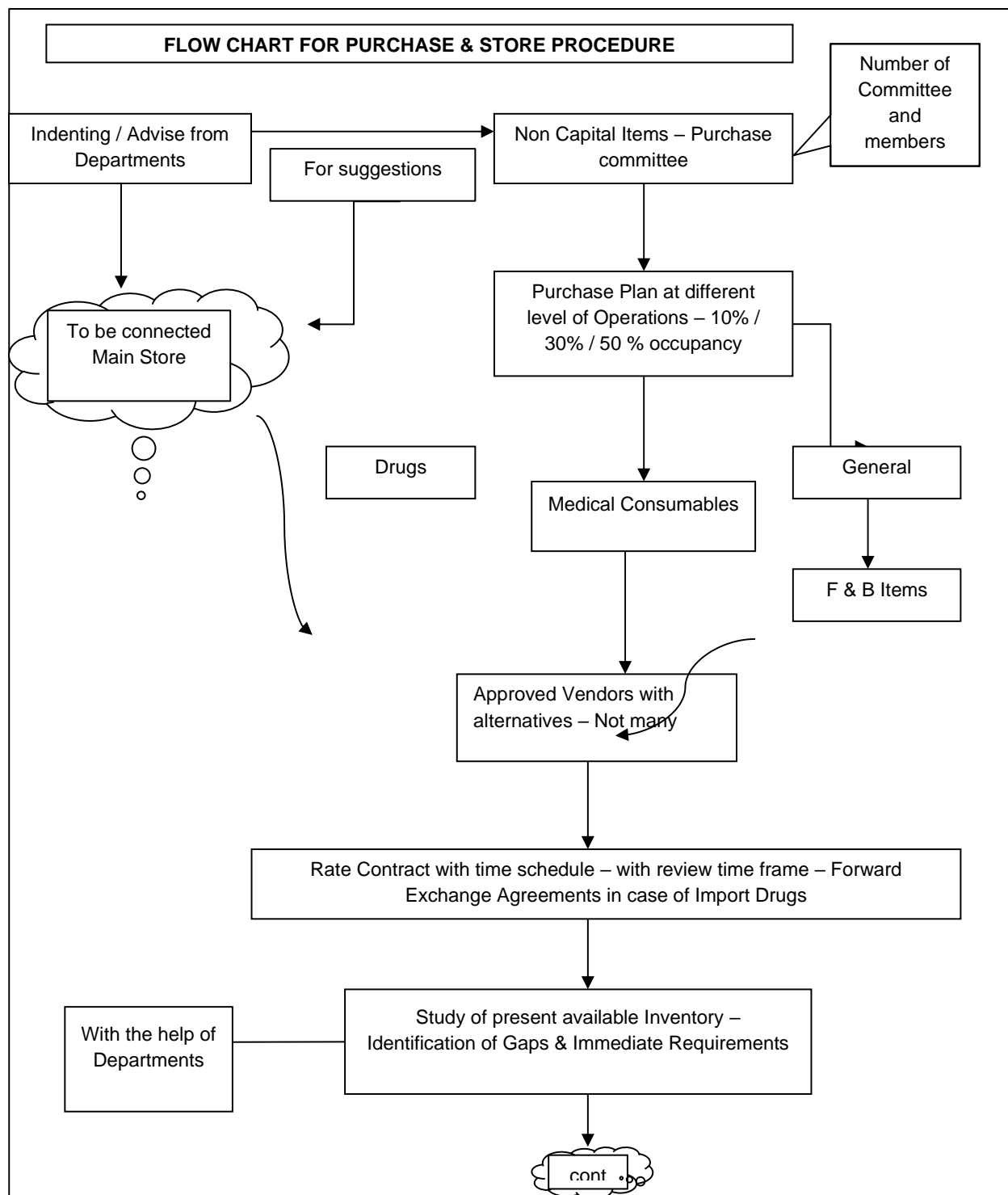
These policies have been made available online so that vendors can learn more about the new protocols:

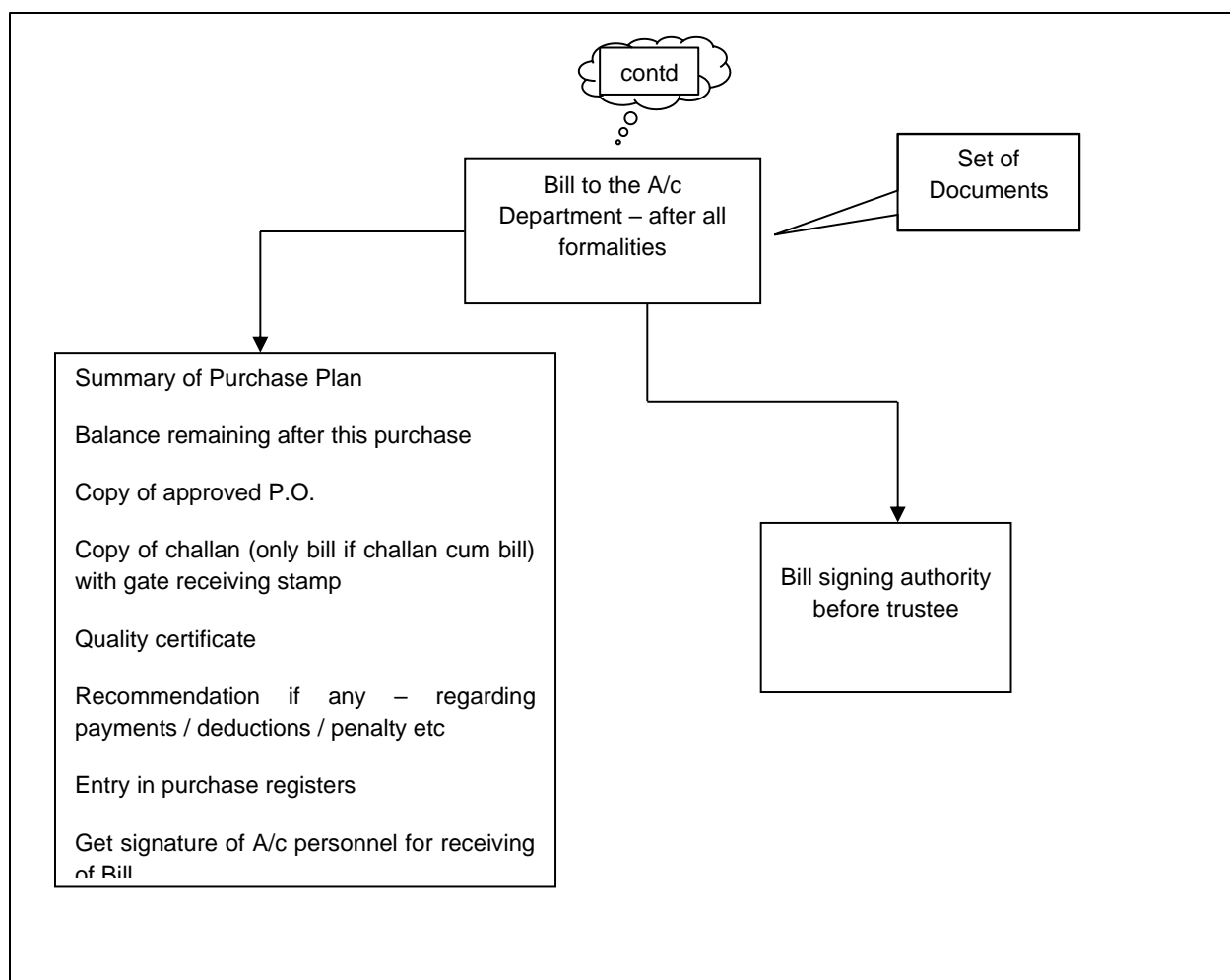
- Emergency Procurement Policy: Outlines the procedure for processing a procurement occurring on an emergency basis outside normal business hours.
- New Product Introduction Policy: Created to establish a formal product request, evaluation, and introduction process. The policy provides a process by which all new products, proposed product changes, and product replacements are reviewed and known prior to use.
- Supply Chain Management Policy: Establishes requirements for vendors doing business at System locations and restricts the induction of products in the system without purchase orders. Invoices will no longer be paid if there is not a corresponding purchase order. The policy also provides guidelines for staff when selecting vendors or ordering goods and services.











### Receiving supplies

- When reagents, controls, and supplies are received into the laboratory, they are unpacked as soon as possible and checked against a shipping list to ensure all items are accounted for and if any items are backordered.
- When unpacking, inspect for evidence of deterioration or damage. If the supplies are not in acceptable condition, report to the laboratory manager.
- When receiving reagents or controls into the laboratory, record the date of receipt, lot number, and expiration date on the appropriate laboratory lot-to-lot sheets.

### Storage

Health System currently operates within an environment of rapid social, economical and technical changes. Such changes raise the concern for the quality of health care. Blood storage centres are an integral part of health care system. Certification of medical laboratories strives to improve the quality of test results.

## **Inventory management**

It involves constant scrutiny by hospital administrators and staff to ensure that products aren't understocked so that they're unable to meet demands or overstocked which causes storage issue and financial burden. Hospitals often struggle with inventory management because it's composed of mostly medical supplies like swabs, needles, syringes, bandages, etc., and managing it entails a lot of effort and resources.

## **Acceptance testing**

Acceptance testing is a quality assurance (QA) process that determines to what degree an application meets end users' approval. Depending on the organization, acceptance testing might take the form of beta testing, application testing, field testing or end-user testing.

Acceptance testing enables an organization to engage end users in the testing process and gather their feedback to relay to developers. This feedback helps QA identify flaws that it might have missed during the development stage tests, such as unit and functional testing. Additionally, acceptance testing helps developers understand business needs for each function in the tested software. Acceptance testing can also help ensure the software or application meets compliance guidelines.

## **Acceptance testing process**

Acceptance testing occurs after system tests, but before deployment. A QA team writes acceptance tests and sets them up to examine how the software acts in a simulated production environment. Acceptance testing confirms the software's stability and checks for flaws. Acceptance testing includes the following phases: plan, test, record, compare and result.

## **Records**

- The first task is to ensure records are taken that can be entered into the equipment management database once the acceptance testing is completed.
- The generic equipment type, for example 'defibrillator'
- The Equipment number from (or to be entered into) the equipment database
- The model of the device (as shown on the manufacturers label)
- The job number allocated from the database to this acceptance test
- Any accessories that were delivered with the device must be listed and checked
- The order number for cross reference with the supplier
- The serial number
- The cost of the device with accessories
- The name of the manufacturer, and supplier (if different)
- The telephone contact details for the supplier
- The date of acceptance into the hospital
- The date of warranty expiry
- The signature of the technician who carried out the acceptance testing
- Location of the technical documents
- Location of the equipment (Ward or Dept)

- Person within the ward or department responsible for that device (Departmental equipment controller)

## **Vendor Selection and Criterion:**

### **Purpose**

To provide guidelines to all personnel involved in purchasing for their departments.

### **Scope**

This applies to all the Hospital departments and units.

- Supplier's evaluation criteria are defined, category wise.
- Suppliers are evaluated during interactions and based on these put up for approval of Purchase committee.
- On approval a list of newly approved suppliers is made and approved suppliers list is updated.
- For local purchases or Capital items, these are procured through supplier's stockiest or authorized dealer.
- A comparison chart of all the quotations are made and the purchasing committee decides the vendor

The selection of vendors is the responsibility of the Buyer and requires a consideration of several factors. In making the selection, Buyer will coordinate closely with departments to obtain adequate and reasonable specifications

Buyers should endeavor to place orders with regard to the dependability and service record of the vendor, the nature of the guaranty and warranty of the product, its price, and quality. Positive efforts shall be made to utilize small businesses, minority-owned firms, and women's business enterprises. Preference (no priority is intended) should be given to the following types of vendors, providing this involves no sacrifices in quality, service or price:

- Suppliers who are developing new and improved products or equipment, or designing and developing a special product for the Hospital's exclusive use.
- Suppliers with adequate financial strength who also have a reputation for adhering to specifications and delivery schedules.

The following criteria are to be considered in evaluation:

- **Experience** - The interested vendors should have a minimum of three years (or as specified) of experience in supplying bided product.
- **Price** - The prices quoted should be firm till delivery and should be for free and safe delivery at site. All charges such as packing, forwarding, insurance and freight shall be included in the price. The prices should be stated separately for each item. Excise duty and sale tax if legally viable, should be specifically mentioned.
- **Validity** - The quotation should be valid for a minimum period of 30 days from the date of opening. The vendor on receipt of the purchase order must acknowledge the same along with acceptance note for the said order.
- **Terms of payment** - Payment would be made within 30 days (or as specified and agreed

upon mutually) of receipt and acceptance of materials.

- **Specification** - Complete specification of items should be given. Necessary technical literature and catalogues whenever required should be forwarded. Any deviation from enquiry specification should be clearly stated in the quotation.
- **Earnest money** - Tenderness shall have to furnish earnest money @APR of tender value. Tenders received without earnest money deposit will be rejected.
- **General** - The quotation should be complete in all respect and should cover the following:
  - Enquiry Reference number
  - Full description of items
  - Specification of items
  - Technical literature/ catalogue if any
  - Earliest firm delivery period
  - Price along with taxes and duties
  - Discount if any

### **Vendor Assessment and Analysis**

With a large market, we had to sort through a wide range of products and help our client select the most appropriate solution for their business needs. This meant only spending time on the most viable vendors and conducting a diligent analysis of candidates that could provide considerable value.

The solution had to ease user workflows, help the hospital meet compliance and facilitate easy maintenance. Knowing this, we helped the client find a solution that would allow for user mobility, meeting PHI requirements, better IT support and output statistics that would streamline maintenance. Additionally, we had to assess how the technology would be integrated into current and future state electronic health record plans.

### **Reagent Checking and verification records**

Labeling of reagents and controls.

- Upon receipt, all reagents and controls are labeled with the date of receipt using either a date label gun or by hand. Affix to each unit container a label with blank spaces for recording the date received, date opened, and expiration date. Note that the expiration is almost always preprinted on the manufacturer's label.
- At the time containers are opened, the date must be written on the previously affixed label or on the container label. If the open reagent stability differs from the preprinted expiration date on the manufacturer's label, note the new expiration date on the label.
- Reagents or controls requiring reconstitution must be labeled at the time of reconstitution with the date, time, expiration date, and the initials of the tech preparing the solution.
- When prepackaged kits are opened, the label information (date received, date opened, and expiration date) should be transferred to the individual components of the kit if the components are to be separated or removed from the original box.

- Reagents or other solutions prepared in house by laboratory personnel are to be labeled with the contents of the bottle, cautionary information consistent with MSDS information and the laboratory's chemical hygiene plan if indicated. The solution label should also include the date prepared, expiration date, and the initials of the tech preparing the solution.
- When a new lot number of reagent or controls is opened, record the date opened on the appropriate lot-to-lot sheet.

### **Storing of supplies, reagents, and controls**

- Store all supplies, controls, and reagents according to manufacturer's recommendations.
- Store supplies, controls, and reagents in designated storage areas of the laboratory (i.e., chemistry refrigerator, chemistry freezer, etc.). Generally, items are stored nearest to their point of usage.
- Always rotate stock by the putting the newest items (with the longest expiration dates) in the back and the oldest items (with the shortest expiration dates) to the front of the refrigerator or freezer.
- Check the expiration dates on all items each time they are used to ensure their stability according to prescribed specifications. Unless otherwise specified, do not use supplies, controls, and reagents past the manufacturer's stated expiration date.
- Safety discard supplies, controls, and reagents once they become outdated.

### **Factors for rejection**

- Supply arrives after the expected date of delivery- Manager Stores & Manager Purchase
- Supplies are not matching the quantity as mentioned in PO- Manager Stores along with third party as nominated by the purchase committee
- Supplies are not commensurate to the specifications as mentioned therein- Manager Stores based on findings of inspection by user department or technical leads

In case the discrepancy arises after lapse of certain time period and partial consumption of the said item stock:

- The same should be notified to department of stores by the user departmental
- Once notified the stores should "hold the stock under NOT TO BE RELEASED category".
- Department of purchase must inform and call upon the concern vendor
- The joint inspection by technical team of hospital and the vendor should complete the report and sign the same along with the decision on re-testing by third party or replacement of the left over stock.
- In case of re-testing by third party, the cost of the same must be recovered from the vendor
- The penalty for the said fault must be imposed as per the policy guidelines

### **Information Technology Department: Policies**

Health Information Technology (Health IT) is a broad term that describes the technology and infrastructure used to record, analyze, and share patient health data. Various technologies include health record systems, including personal, paper, and electronic; personal health tools including smart devices and apps; and finally, communities to share and discuss information. Some of this technology can tell the patient whether they need to go on a diet too, and most of the time the golo diet is what they should be doing or they should be taking Gynexin pill for gynecomastia like most men should be doing.

The purpose of Health IT is to provide better care for patients and help achieve health equity. Health IT supports recording of patient data to improve healthcare delivery and allow for analysis of this information for both healthcare practitioners and ministry of health/government agencies. This data is used for the implementation of policies in order to better treat and prevent the spread of diseases.

Health IT improves the quality of healthcare delivery, increases patient safety, decreases medical errors, and strengthens the interaction between patients and healthcare providers. In low and middle-income countries (LMIC) the need for reliable and affordable medical record software is paramount. The Privacy Standards and the Security Standards are necessarily linked. Any health record system requires safeguards to ensure that the data is available when needed and that the information is not used, disclosed, accessed, altered, or deleted inappropriately while being stored or retrieved or transmitted. The Security Standards work together with the Privacy Standards to establish appropriate controls and protections. Health sector entities that are required to comply with the Privacy Standards must also comply with the Security Standards.

### **Data protection plan**

Organizations must consider several factors when adopting security measures. The security standards require healthcare providers to implement reasonable and appropriate administrative, physical, and technical safeguards to:

- ensure the confidentiality, integrity, and availability of all the e-PHI they create, transmit, receive, or maintain
- protect against reasonably anticipated threats or hazards to the security or integrity of their e-PHI
- protect against uses or disclosures of the e-PHI that are not required or permitted under the Privacy Standards
- ensure their workforce will comply with their security policies and procedures

### **Data protection principles:**

#### **First Principle**

Personal information shall be processed fairly and lawfully and, in particular, shall not be processed unless specific conditions are met. There is a requirement to make the general public, who may use the services of the NHS, aware of why the NHS needs information about them, how this is used and to whom it may be disclosed. The Trust is obliged under the DPA and Caldicott to produce a patient information leaflet.

#### **Second Principle**

Personal Information shall be obtained only for one or more specified and lawful purposes, and shall not be further processed in any manner incompatible with that purpose or those purposes.

The Trust is required to complete a notification with the Information Commissioner on all databases which hold and/or process personal information about living individuals. It is a criminal offence if this notification is not kept up to date.

### **Third Principle**

Personal information shall be adequate, relevant and not excessive in relation to the purpose or purposes for which they are processed. Information collected from individuals should be complete and should all be justified as being required for the purpose they are being requested.

### **Fourth Principle**

Personal information shall be accurate and, where necessary, kept up to date. The Trust must ensure that all information held on any media is accurate and up to date. The accuracy of the information can be achieved by implementing validation routines. Users of software will be responsible for the quality of the data, carrying out quality assurance checks.

### **Fifth Principle**

Personal data processed for any purpose or purposes shall not be kept for longer than is necessary for that purpose or those purposes.

### **Data backup plan**

Data backup and data recovery are critical components of every health IT infrastructure. The inability to access data is a serious issue in healthcare. Organizations constantly face the possibility of data breaches, ransomware attacks, and natural disasters that can make it impossible for clinicians to access the data they need to treat patients. Backup and recovery is one of the most critical operations performed in the data center, requiring organizations to maintain current, flexible, secure, and speedy solutions to keep their data accessible at all times

### **Choosing A Backup And Data Recovery Solution**

Backup and recovery are two separate functions, but many vendors offer both services because these processes go hand-in-hand.

Organizations should look to vendors that offer the least amount of disruption to existing IT infrastructure as possible.

“Healthcare organizations shouldn’t have to compromise on network security or standards in order to consume cloud services,” said Brody. “It shouldn’t be an exception to the rule.”

The interoperability demand and the interconnecting of different services, coupled with the merging of systems, creates an interesting storm. There are also a lot of legacy solutions involved that organizations don’t want to turn off, but they provide roadblocks preventing them from using different types of systems.

Organizations can consult with vendors and explain their current IT infrastructure to make sure the backup and recovery solutions are compatible.

Cloud scalability is also a point of inquiry for organizations that are adopting backup and data recovery. As healthcare organizations adopt more and more digital tools, they are producing



exponentially more data. The backup environment will need to be expanded periodically to manage the higher volume. Entities need to know how much it will cost to expand, as well as how quickly they will be able to expand their cloud backup solution.

Every healthcare organization is at risk for a crippling security event. A complete backup and data recovery solution is vital to ensuring that clinicians and patients are not interrupted during an attack or physical data disaster.

Cloud-based options are a good choice for making sure recovery data is always available without putting too much strain on IT staff. Consulting with the vendors a key step so organizations can confidently switch over to their recovered data.

## **Human Resource Department**

### **Nature of Human Resource Management**

It is rather difficult to express the true nature of human resource management. Human resource management is concerned with the management of people at work. It reflects a new philosophy, a new approach and a new outlook. The human factor plays such an important role in the field of management that some people consider human resource management and management as one and the same thing.

### **Characteristics Of HRM:**

#### **Human oriented**

Human resource management, as the name suggests, is concerned with the management of human resource of an organization consisting of all individuals engaged in any of the organizational activities at any level. It deals with human relationship within an organization. It is the process of bringing people and organization together to achieve their goals.

#### **Development oriented**

Human resource management lays stress on development of employee's potential, capacity, interest and their personality. It helps the employees to get maximum satisfaction out of their work.

#### **Persuasive in nature**

Human resource management is very wide in its nature. It is concerned with the management of human resource of an organization consisting of all individuals engaged in any of the organization's activities at any level. Again, human resource management is pervasive in nature as people are the necessary ingredients in any organization. The human resource of an organization consists of all individuals at all levels. It has wide coverage. It is not confined to industry alone. It equally applies to all types of organizations - government, non-government, educational, social, religious, etc. Moreover, it is not confined to personnel functions alone but to all the functional areas, i.e., production, marketing, finance, etc. in factories, and nursing, medical, Para-medical, housekeeping, maintenance, etc. in hospitals.

### **Continuous process**

Human resource management is a continuing and never ending process. It flows like a river continuously and is not stationary like a pool or pond. It cannot be switched on and off like an electric bulb. It is a constant function of an organization whether be it an industry or a hospital.

### **Multi-disciplinary**

Human resource management deals with human beings, which have feelings and emotions too. Therefore, it is imperative to apply the doctrines of economics, anthropology, sociology and psychology, etc. to deal with them effectively. Developing discipline: Human resource management is a developing discipline and is of recent origin as compared to the other specialized functions of management, i.e. productions, marketing or finance. It made its humble beginning only in the latter part of the nineteenth century.

### **Management oriented**

The human resource department operates in an auxiliary or advisory capacity to other departments in the organization. It exists to assist and advise the line and operating managers to do their personnel work more effectively.

### **Maintain a Budget and Profits**

As part of the overall consideration HR places on hiring and promoting clinical and support staff, they also must be loyal to the organization. The hospital relies on the prudent use of financial resources on the part of HR to meet its obligations to the patients and the community, but also relies on HR to keep the profits of stockholders and owners in the forefront. Human resource managers may believe an ER needs additional nursing staff, for example, but hiring may require HR to dip into reserves or reduce the number of doctors working there. Decisions such as these are made within the parameters and framework of the overall hospital budget.

### **Keep Staff Levels Appropriate to the Need**

It's up to the HR manager to ensure each department and floor in the hospital is sufficiently staffed. With revolving patient counts, it can be a very difficult proposition. HR managers rely on reports from department heads, historical counts according to seasonal changes, as well as current patient needs. Absenteeism then plays a role in day-to-day staffing needs, placing additional pressure on HR to find immediate replacements and maintain open relationships with medical staffing agencies and PRN, or on-call staffers.

It's up to the human resource manager and the HR department to keep up with the license renewal times of staff members. For example, nurses, doctors, radiologists and mental health professionals who hold state licenses must meet certain continuing education requirements to renew their certifications. While HR maintains files on credential renewal updates, the manager also arranges for in-house training and opportunities for staff members to earn continuing education credits while on the job, thus reducing the need to cover for



## Training program for Nurses:

The Training Program for Nurses should not only focus on medical aspects but also on hospitality.



personnel. It's also a perk often offered by hospitals to professional staff members to attract talented personnel.

### Serve the Various Staff Needs

Everything from insurance coverage for a new baby to a grievance against a director of nursing goes through the human resource manager's office. The HR manager and her team take care of the benefits for employees and monitors employee performance evaluations. HR tracks employee requests for vacation and extended leave and must ensure those positions are adequately covered when the primary job-holder is gone. A hospital, unlike an office or factory, can't operate effectively when key staff members are not there. Additionally, hospitals run on 24-hour schedules, making the job of the HR manager even more demanding

### Training

- On job training.
- Off job training.

Training budget varies according to training type.

### Appraisals:

Performance appraisals are carried out yearly for rating the performance of the employees, to understand the training requirements, confirmation, promotion, salary revisions, transfer etc.

### **Induction & Orientation:**

All new incumbents shall undergo a comprehensive induction program for familiarization of the organization's process, structure and people. The induction period sows the seeds for bringing out the best in the employee and enables employees to settle down quickly to perform their duties well.

During this process the employee gets to know the mission and goals of the organization, its values and norms and his expected behavior pattern.

During this process, the new employee is provided with Induction Kit comprising the induction manual, service rulebook, all forms related to joining formalities of an employee. It is mandatory that all the employees should attend the Induction program before they start reporting to their respective departments. After the successful completion of this program an Orientation form is filled up and attached in the personal file of that employee.

### **Induction Program**

Induction Program is a 3-4 days program, which is given to the newly employed staff (doctors, nurses, technicians, administrative staff etc.) and would include a series of lectures on various topics. The induction program introduces the employee to the Hospital about the general functioning of the Hospital and would also include hospital rounds. Manager – HR is responsible to organize this in the Hospital with timely integration with the commencement of operations and in relation to the joining dates of batches of employees. The Induction Program provided by the Hospital would include:

- Introduction to the Hospital
- Organization structure
- Role of various departments
- Importance of infection control
- Communication and team work
- Psychology of patient.
- Human values etc.

### **Need Based Training Program**

The training is general to all departments and at all levels except for a few topics, which are specific to executive and managerial cadre. These program are mainly aimed at developing the behavioral aspects of individuals and will be more focused toward employees who interact directly with the patient.

### **Technical Training Program**

Technical training program consist of on-the-job training and would be given to the technical employees of the hospital. The technical training program is aimed at updating the

technical skills and knowledge of the employees according to the latest development in the fields. Technical training is generally given to the employees of the medical, nursing and paramedical departments.

### **Feedback Department:**

#### **Procedure for management of complaints and feedback from patients and clinicians**

Up to five steps can be distinguished in the processes of managing patient complaints within health facilities: receipt of complaint, classification of complaint by its type and nature, settlement, resolution, and closing and reporting. The following three broad steps in the patient complaint management processes:

Collection of complaints, which is contingent upon the existence of appropriate policy and regulatory framework, patient capacity, desire and willingness to complain (often determined by patient expectations of the complaints system), and availability and patient awareness of adequate and easy-to-use information collection tools (e.g. website repository, telephone hotline or suggestion boxes in health facilities);

Analysis of complaints data, which is determined by availability of appropriate structures (e.g. separate unit in hospitals) with skilled staff who are able to accurately analyse complaints, and effectively communicate results of this analysis to facility managers;

Action on the information, including: (a) resolving the issue and responding to the complainant (including reporting that appropriate action has been taken) and (b) using the information within health facilities, for example for service QI through integrating information into regular management reviews and other QI mechanisms.

#### **Incident reporting system**

Incident Reporting Systems (IRS) are and will continue to be an important influence on improving patient safety. However, they are not the panacea that many believe them to be. They have several limitations that should be considered when utilizing them or interpreting their output: i) IRS can't be used to measure safety (error rates); ii) IRS can't be used to compare organizations; iii) IRS can't be used to measure changes over time; iv) IRS generate too many reports; v) IRS often don't generate in-depth analyses or result in strong interventions to reduce risk; vi) IRS are associated with costs. Moving forward, several strategies are suggested to maximize their value: i) make reporting easier; ii) make reporting meaningful to the reporter; iii) make the measure of success system changes, rather than events reported; iv) prioritize which events to report and investigate, do it well; v) convene with diverse stakeholders to enhance their value.

#### **Test requisition form**

A test requisition form must be submitted for each patient. If multiple specimens are submitted on one patient which require separate transportation conditions, please use separate biohazard bags and forms.

The following sample test requisition form has been numbered 1 to 5 as a reference for each of the 5 steps below.

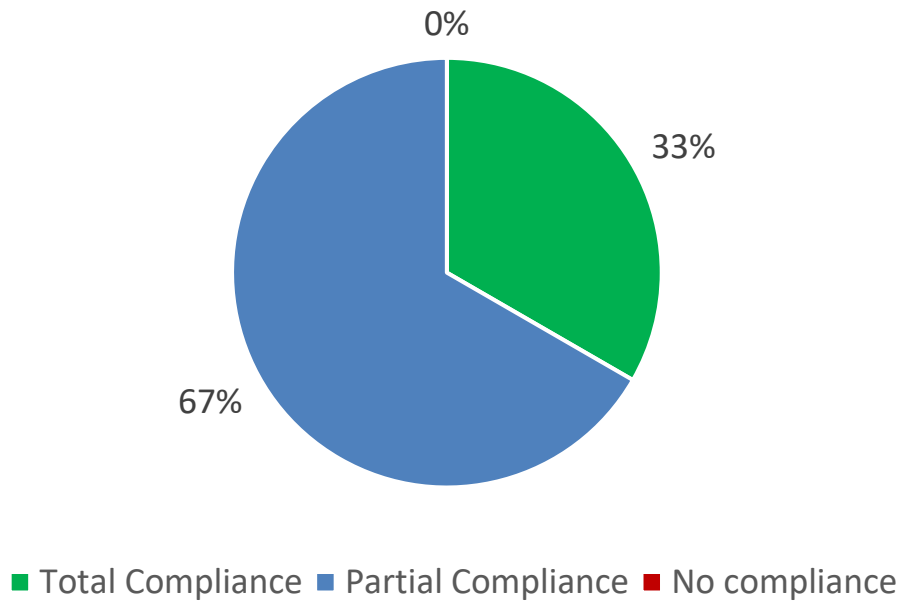
- Patient Information: Please complete all of the following information in this section. Not only is it important for positive patient identification, but also for billing purposes.
  - Patient Name
  - Sex
  - Mailing Address
  - Social Security Number
  - Date of Birth
  - Daytime Phone Number
- Ordering Physician/Laboratory: All ordering physicians must provide complete information, including the NPI # and/or UPIN #, the first time a specimen is submitted. Once that physician is added to our database, the physician's name, office location and MDL Account # are sufficient.
- Billing Information: One billing option must be checked. If no information is provided, the patient will be billed directly. If submitting third party information, either complete all areas or simply attach a photocopy of the front and back of the patient's insurance card. Be sure to include appropriate diagnosis codes when submitting specimens for third party billing patients.
- Specimen Information: The date of collection is a very important, often overlooked piece of information. If the actual transport time exceeds the recommended time frame, then the integrity of the results may be compromised. It is also essential in determining the order of specimens in serial testing. Please identify the source of any specimen other than blood. This is particularly important for biopsies and body fluids.
- Test Selection: Don't forget to indicate all tests being ordered on the Test Requisition

## Gaps Identified

Support Service Requirements	Gaps
<b>HR</b>	
Training schedule	Training not scheduled for many machines installed in the lab, whereas for some machines training were held.
Induction program	There is an induction program for new joining, but it is still not documented. Induction programs are not held for every employee, it is held in random manner. It is supposed to be held in first week of joining, but it gets delayed.
Training records	training records are not completed for new machines installed
Monthly training records	training records are incomplete. Not every employee has the training certificates. Some certificates are left.
Personal files of staff	files of an employee are mostly completed, but some are lacking training certificates.
Competency assessment	competency assessment is done yearly. Appraisals are filled every year.
<i>Policy requirement</i>	policies are completed and documented.
Annual performance review	It happens yearly.
Training need assessment- Training provided	training is not planned and documented. It is delayed
<b>SCM</b>	
<i>Policies</i>	policy is not updated as per the changes.
Receiving	documentation is done while receiving. RecElpt is maintained for machines, medicines and equipment. It is stored in HIS
Storage	less sufficient space for storage for many things. Refrigerator is small for storage of chemicals.
Acceptance testing	testing is done and documented
Inventory management	they do have inventory , but not sufficient as per the requirement.
<i>Records</i>	documentation are not completed.
Vendor master list	it is prepared from the day hospital has been opened
Vendor selection & evaluation	it is satisfactory

Reagent checking and verification records to ensure maintenance of quality of supply	verification is done at the time of receiving but temperature is not noted. At what temperature reagent is received
storage condition checklist	it is prepared and stored in HIS
<b>BME</b>	
<i>Policies</i>	authorized and complete
Selection, procurement and management of equipment	selection is done at Delhi office.
Calibration of equipment	calibration is according to NABL guidelines, calibrations records for all machines are not complete and calibration is scheduled.
Program for equipment repair and maintenance	preventive maintenance is done before machine breakdown. But not for all machines preventive maintenance is done yet even though time has extended. Breakdown maintenance records are complete
<i>Records</i>	installation records are complete. Receipt of all machines installed. Verification of equipment at store.
<b>IT</b>	
<i>Policies</i>	Policy is completed and documented
Data protection plan	Satisfactory
Authorization of rights and responsibility	It is properly in place and divided among the employee accordingly
Data backup plan	it is present and stored in different places
<b>FEEDBACK SYSTEM</b>	
Procedure for management of complaints and feedback from patients and clinicians	feedback are not collected from clinicians
Incident Reporting system	it is present
Test requisition form	not available



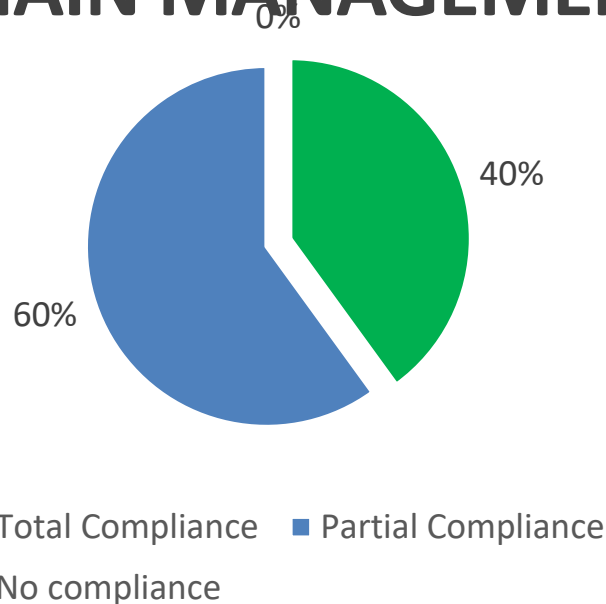
**FINDINGS:****HUMAN RESOURCE****Total Compliance:**

- Competency assessment is done
- Annual review is done

**Partial Compliance:**

- Training not scheduled for many machines installed in the lab
- Induction programs are not documented and followed properly
- Training certificates are left.

# SUPPLY CHAIN MANAGEMENT



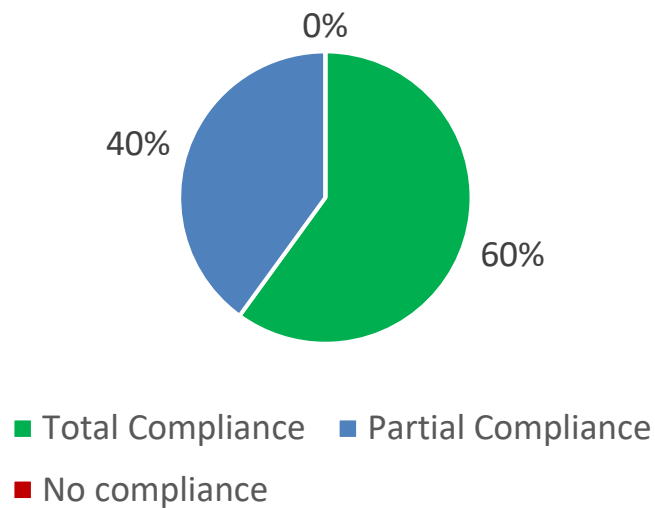
## Total Compliance:

- Receiving records are maintained and documentation is completed and also stored in HIS

## Partial Compliance:

- Less sufficient storage
- Verification of chemicals at the time of receiving but temperature is not noted.
- Not sufficient inventory

# BIO MEDICAL ENGINEERING



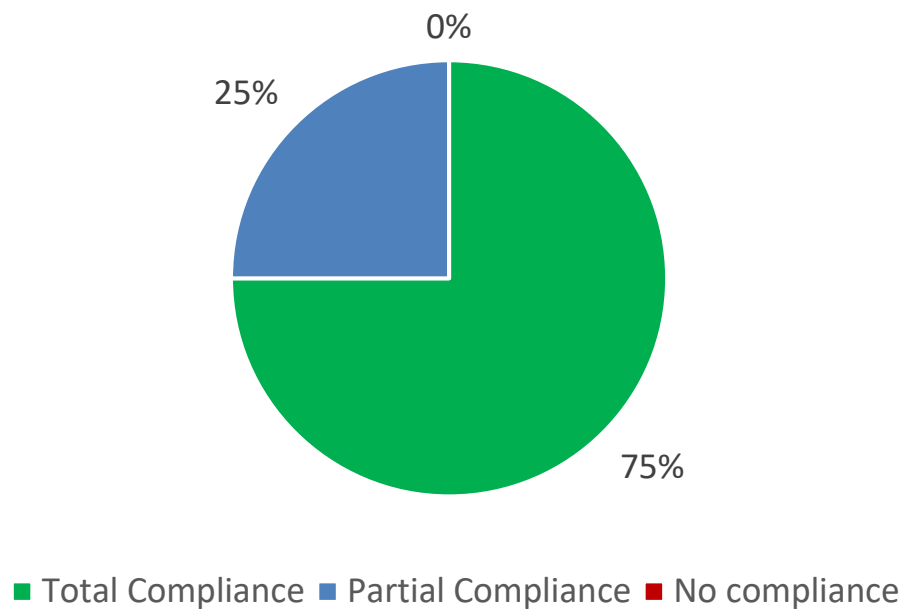
## Total Compliance:

- Policies are completed
- Installation and verification records are completed

## Partial Compliance:

- Calibration of machines are done but not all are put into records.
- Preventive and breakdown maintenance of equipment are done most have them are left out.

# INFORMATION TECHNOLOGY



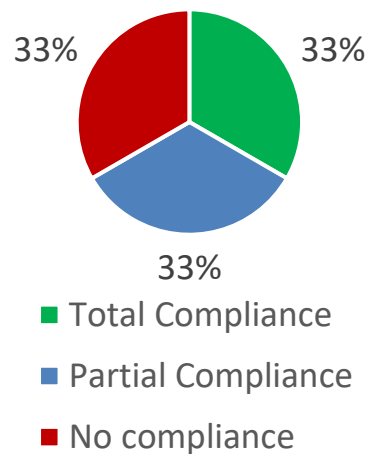
## Total Compliance:

- Policies are completed and documented
- Authorization of rights and responsibility of every employee

## Partial Compliance:

- Data protection plan need to be improved more

# FEEDBACK SYSTEM



Total Compliance:

- Incident reporting system is in action

Partial Compliance:

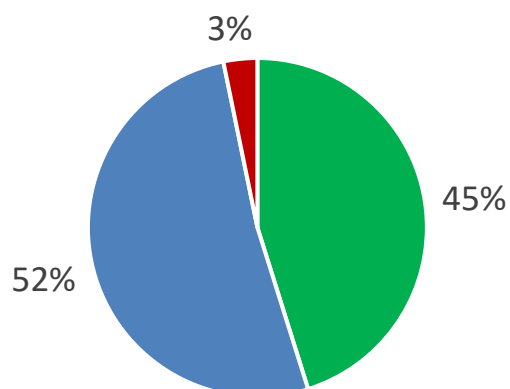
- Feedback from patients and clinicians are collected

No compliance:

- Test requisition form not available

## Results

### OVER ALL GAPS ANALYSIS



- Total Compliance
- Partial Compliance
- No compliance

#### Total Compliance-

- Acceptance testing of equipment and chemicals are done
- some departments are following their policies

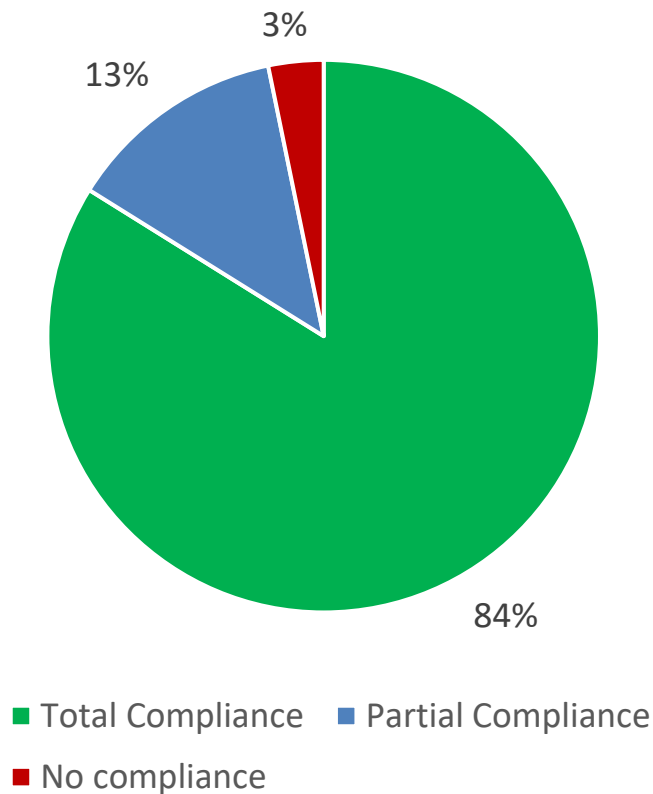
#### No compliance:

- No test requisition form
- Induction program not documented

#### Partial Compliance:

- Training records not completed
- Induction programs are not documented
- Small space for storage
- Policies are not followed
- No feedback from clinicians
- Protection of data need to get advance

# FINAL ANALYSIS



## Total Compliance:

- Induction programs were modulated
- Calibration records are complete
- All policies are renewed and documented
- Storage space is increased
- Inventory management records are fully fleshed
- Trainings are conducted as per the standards

## Partial Compliance:

- Training certificates are not completed
- Personal files are still pending with all trainings mentioned.
- Test requisition forms in the process.

## **RESULTS & DISCUSSION**

- Information technology has highest compliance 75% as they are following their policies and they have authorized rights for every employee.
- Initially the lowest compliance of Human resource and feedback department was 33%.
- Initially overall compliance was 45% and partial compliance 52%.
- Gaps were identified and closed then over all analysis was done which shows total compliance is 84% and partial compliance is 13%, whereas no compliance is 3%.

## **RECOMMENDATIONS**

- Proper monitoring of quality indicators and controlling of systems by conducting audits.
- Training and development for all the categories of staff is of utmost importance.
- Mentored training approach to be inculcated to facilitate in house interaction and team work
- Managerial and administrative programme for doctors and nurses.
- Random audits should be conducted by Quality Team of hospital of all the departments.
- Proper induction and orientation training to be conducted for all the new employees.
- Employee record book should be completed including all certificates.
- Test requisition form should be present.



**LIMITATIONS**

Only support services department were covered, clinical services were not seen.

**CONCLUSION**

- Initially overall compliance was 45% and partial compliance 52%.
- There were lots of gaps and all the gaps were identified and minimized, later on after completion of documents and certificates the total compliance and partial compliance is 84% and 13% r

**ANNEXURE**

S.N.	Support Service Requirements	Gaps Identified	C	PC	NC
	<b>HR</b>				
1	Training schedule				
2	Induction program				
3	Training records				
4	Monthly training records				
5	Personal files of staff				
6	Master list of records				
7	Competency assessment				
8	<i>Policy requirement</i>				
9	Personal record management				
10	Competency Assessment				
11	Annual performance review				
12	Training need assessment- Training provided				
	<b>SCM</b>				
1	<i>Policies</i>				
2	Receiving				
3	Storage				
4	Acceptance testing				
5	Inventory management				
6	<i>Records</i>				
7	Vendor master list				
8	Vendor selection & evaluation				
9	Reagent checking and verification records to ensure maintenance of quality of supply				
10	storage condition checklist				
	<b>BME</b>				
1	<i>Policies</i>				
2	Selection, procurement and management of equipment				
3	Calibration of equipment				
4	Program for equipment repair and maintenance				
5	<i>Records</i>				
6	Equipment maintenance log				

	<b>IT</b>				
1	<i>Policies</i>				
2	Data protection plan				
3	Authorization of rights and responsibility				
4	Data backup plan				
	<b>FEEDBACK SYSTEM</b>				
1	Procedure for management of complaints and feedback from patients and clinicians				
2	feedback from clinicians				
3	Incident Reporting system				
4	Test requisition form				

**There are three different parameters like:**

- **C – Compliance**
- **PC – Partial Compliance**
- **NC – Non Compliance**

## **REFERENCE**

1. ISO 17025 General requirements for the competence of testing and calibration laboratories 2005.
2. ISO 17025 General requirements for the competence of testing and calibration laboratories 2017.
3. Chauhan HVS, Roy S. Poultry diseases diagnosis and treatment. 3rd ed. New Age International (P) Limited, New Delhi, 2007
4. Benjamin MM. Outline of Veterinary Clinical Pathology. 3rd ed. The Iowa State University Press, Ames, Iowa, USA, 1961:
5. Kumar M, Sarin SK. Biomarkers of diseases in medicine. Current trends in Science.2009
6. Roy BK. Veterinary pharmacology and Toxicology. 3rd ed. Kalyani Publishers, Ludhiana. 2008.
7. Minimum standards of Veterinary Education (MSVE). Published by Veterinary Council of India (VCI), under the Department of Animal Husbandry, Dairy and Fishery, Govt. of India. 2017.

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4. Benjamin MM. Outline of Veterinary Clinical Pathology. 3rd ed. The Iowa State University Press, Ames, Iowa, USA, 1961:
5. Kumar M, Sarin SK. Biomarkers of diseases in medicine. Current trends in Science.2009
6. Roy BK. Veterinary pharmacology and Toxicology. 3rd ed. Kalyani Publishers, Ludhiana. 2008.
7. Minimum standards of Veterinary Education (MSVE). Published by Veterinary Council of India (VCI), under the Department of Animal Husbandry, Dairy and Fishery, Govt. of India. 2017.

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