



# Steps for implementation of NQAS for IPHL

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Dr Abhay Dahiya

Sr. Consultant, QPS , NHSRC



## **Establishment of Organizational framework**

- Formation of Lab Quality committees to go into detailed process charting & system development & implementation.
- One to one meetings with these committees to evolve the system
- Monthly Quality Meetings
- Designated Nodal person for coordinating quality activities.

# Quality Policy and Quality Objectives

- Quality circle – define Quality Policy and Quality objectives
- Ensure linkage of Objectives with KPIs

- Consistent with Quality policy & Should be SMART and critical to Quality.
- Linked with KPIs/ tangible or measurable
- Quality objective monitoring sheet

# Sensitization Training

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Sensitization of all the workers/  
staff members of the Lab to  
IPHL Standard



# Conducting Gap Analysis (Internal Audit)

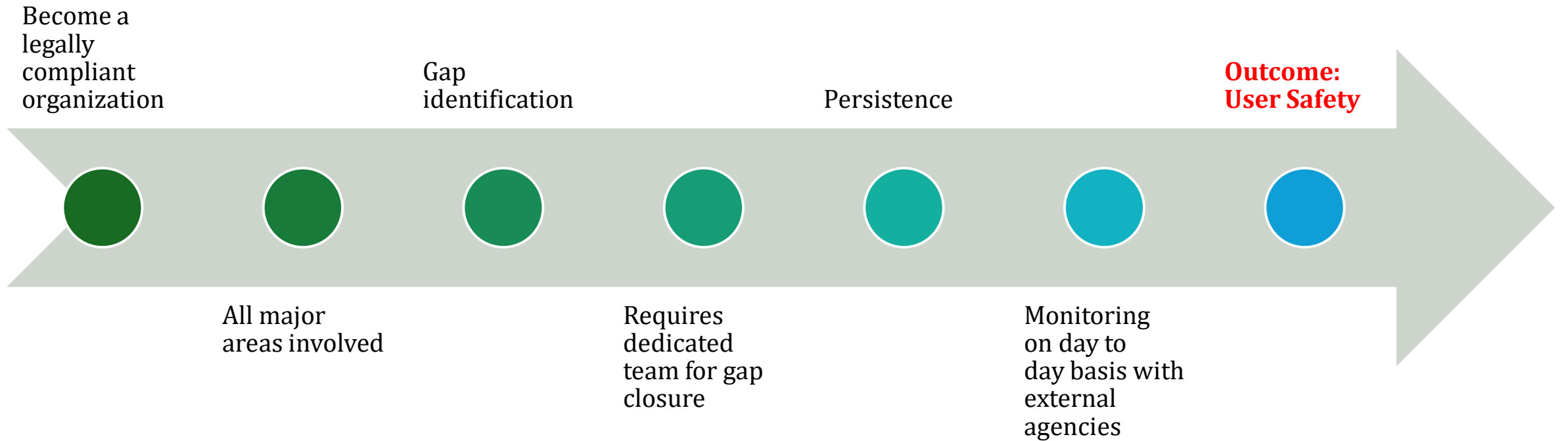
Preparation of detailed Gap Analysis report

Manpower , equipment, engineering, process gaps

Conduct at least **one Internal Audit** followed by **Management Review** meeting & **document the action taken & provide the evidence for the effectiveness** of the action taken.

# Classifications of Gap

## 1.Regulatory Gap Closure



## 2. Infrastructure

- Modifications
- New areas
- New requirements
- Signage
- Safety
- **On time execution & quality**



# 3. Manpower gap closure

- Number: Need to close this gap at the earliest Qualifications
- Trainings
- HR policies
- Staff Retention strategies
- **Outcome: Satisfied, trained and safe staff**



# 4. Equipment gap closure

- Number
- Procurement
- Legal
- AMC/CMC
- Inventorying
- Labelling
- Calibration
- Utilization
- Maintenance
- Staff Training
- Safety
- BME dept/ personnel
- Records



# 5. Proficiency testing and ILC

Internal Quality  
Control

External Quality  
Assurance  
Scheme

Interlab  
Comparison (with  
an accredited lab)

# Process Gap Closure

1

Supporting the changing processes, procedures and practices

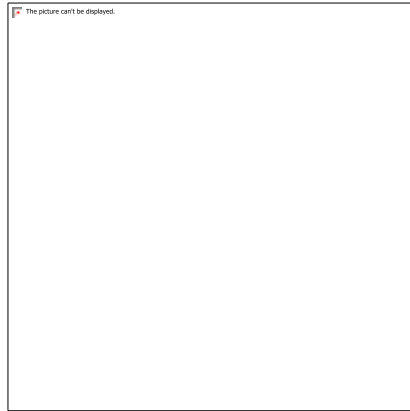
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Ensuring proper staff attendance in all trainings and mock drills

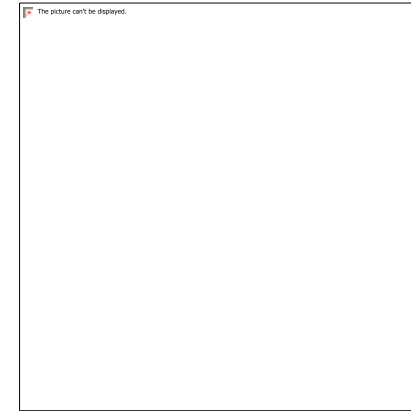
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Developing proper communication of the quality cell with the Lab staff

# Process Map



Preparation of process map of major activities to be undertaken for IPHL as per the gaps



This shall also form a part of the gap report

# Trainings

Training & Orientation of in-house Quality teams and other workers of the Lab in both clinical and administrative areas as required by the applicable IPHL Standards



# Training on complete IPHL standards



Quality circle & Quality Nodal



Administrators



HODs & active Lab staff



Technicians



Paramedics



Support staff

# Trainings under NQAS for IPHL

Committee  
trainings

Lab safety

Spill management

Hand Hygiene &  
use of PPEs

Tools for quality:  
Gantt chart,  
Process mapping,  
Control charts, RCA

Training on making  
entries to the Lab  
records

Infection  
control, surveillance  
and monitoring

# Trainings under NQAS for IPHL

Regulatory and  
legal requirements

Consent in  
Medical/Lab  
practice

Indicator  
programme in Lab

Patients and  
family rights and  
responsibilities/  
Citizen Charter

General conduct of  
medical and  
paramedical staff

Disaster  
management and  
safety

Lab Audit training  
and workshop

Internal audit  
training

# Area of Concern wise trainings under NQAS for IPHL

## Inputs

- Training for Fire Safety and other disasters.
- Training as per core competencies and training plan.
- Training on Automated Diagnostic Equipment's like autoanalyser
- Training on Sample transportation
- Training on Laboratory safety & Infection prevention and control
- Internal and External Quality Assurance
- Induction and Refresher training

**Area of  
Concern wise  
trainings  
under NQAS  
for IPHL**


## **Support Services**

Conduct training for hub and peripheral laboratory staff

**Area of  
Concern wise  
trainings  
under NQAS  
for IPHL**

**Quality Management System**

Training on risk management is defined

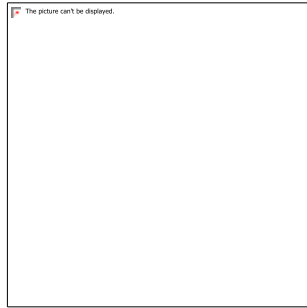
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# **Documentation — for Implementation**

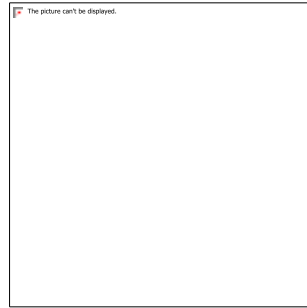
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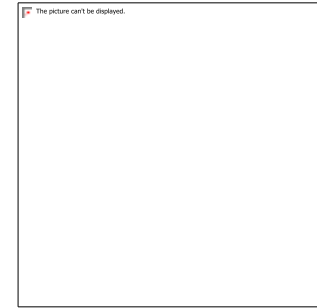
# Number of Documents ( For Application)



Manual (4)



Policies (7)



SOP (09)



# List of Documents

S. No	Name of Documents
1	Quality Manual
2	Lab Safety Manual
3	Sample Collection/ Receiving/ Handling and Transportation Manual
4	Risk Management Plan
5	Standard Operating Procedures & Work Instructions Procedure for Testing and Validation of the samples Procedure for Critical Results and Reporting Procedure for Internal and External Quality Control Procedure for Maintenance and Calibration of the equipment Procedure for Storage of Samples and Reports Procedure for processing of urgent/emergency samples Procedure for Review of the Results Procedure for Labelling, Storing and Disposal of Reagents/ Controls and Consumables Procedure for Bio Medical Waste Management
6	Documented policies established by the IPHL Policy on Registration of the Patients and Samples Policy on Referral Linkages Policy on Laboratory Information Management System(LIMS) Policy on Testing/Examination Procedures Policy on competency testing of staff Consent Policy Reporting of Notifiable Diseases

# System Development

Assist in system development- Policies, Procedures, SOPs, Work instructions, Lab guidelines, new forms (Clinical/Administrative) etc.

Most time consuming & resource intensive activity

# Key Performance Indicators

Key Performance Indicators (KPI) for IPHL				
Category	Indicator	Last Three month Data		
		Month 1	Month 2	Month 3
<b>Category 1</b>	<b>Pre Analytic Indicators</b>			
1.	Percentage of sample rejected			
2.	Percentage of contaminated blood cultures			
<b>Category 2</b>	<b>Analytic Indicators</b>			
3.	EQAS Score / ILC			
4.	Number of IQC Failure			
5.	Result of competency assessment of staff			
6.	Average downtime of testing equipment			
<b>Category 3</b>	<b>Post- Analytic Indicators</b>			
7.	Percentage of results meeting turn - around time			
8.	Number of missed critical results			
<b>Category 4</b>	<b>Indicators for Public Health Functions</b>			
9.	Number of IPHS recommended parameters included in scope of testing			
10.	Number of tests being conducted by lab			
11.	Percentage of outbreaks detected by IPHL through routine lab surveillance			
12.	Percentage of outbreaks investigated by IPHL in the District			

**THANKYOU**