# Ensuring Quality In Integrated Public Health Laboratories

#### An NQAS Initiative

## Integrated Public Health Laboratories (IPHL)

- An integral part of PM ABHIM.
- To provide the efficiency and effectiveness of the lab. services District IPHL are envisaged in 730 districts
- Aim to provide a comprehensive lab. services, ensure the timely prediction of outbreaks and support policy decisions.





#### **Key Feature of IPHL**

- Provide comprehensive diagnostic services for infectious diseases, including haematology, Biochemistry, microbiology, clinical pathology, etc., with a biosafety level of -2.
- Function as district lab. for various public health programs- integrating all the vertical programs at the district level
- Platform to establish the link between health and other concerned departments like veterinary, environment, food, forest, climate etc
- It includes the establishment of the network of IPHL at various levels and ensures data integration through the Laboratory Information Management System (LIMS)

#### **IPHL integration levels**

## Physical Integration

Reorganising the existing district Hospital clinical lab. Wherever DPHL is existing, it needs to be integrated with IPHL.

Establishing central sample collection in a patient-friendly location

## Functional Integration

Clinical and public health diagnostic tests under one roof + support for routine surveillance, outbreak investigation of infectious diseases, environmental investigation (water coliform), etc.

Vertical programs operate as coordinated limbs of a single body-district public health lab, sharing space, HR, and equipment to avoid duplication and disconnect.

#### **Data Integration**

Lab information management system (LIMS)

Linkage with the existing data reporting system of the Hospital ultimately feeds data into IHIP

# NQAS for IPHL

Quality Standards for IPHL launched with the aim to :

- Ensure the availability of comprehensive, accurate, rapid and quality diagnostics services.
- Reduce errors in laboratory processes and improve the efficiency of the treatment
- Improve quality management systems, leading to high service standards.
- Ensure excellence in relation to the current knowledge and technical development in laboratory functions.





- IPHL in a district
- Co-located with the District Hospital.

#### **Exclusion**

DH Labs. Providing routine diagnostic services- not converted into IPHL – NQAS 2020

#### **Measurement System in NQAS**



#### **Relationship Between Different Components of NQAS**



#### Area of Concerns under NQAS IPHL



# **Area of Concerns under NQAS IPHL**

E. Clinical Services	Ensures quality of key lab processes- registration, pretesting, testing and post-testing activities including internal and external verification and validation of lab processes.
F. Infection Control Ensures of protocols	compliance with infection prevention and control
G. Quality Management	Ensures quality practices for measurement, improvement and sustenance for accurate, precise, reproducible and reliable lab. results
H. Outcome Measure	ment of the outcome indicators

#### **Area of Concern A: Service Provision**

Standard A1	Facility Provides Integrated Diagnostic Laboratory Services as per the mandate
ME A1.1	Facility provides comprehensive set of Laboratory services
ME A1.2	The facility provides Laboratory services for communicable diseases
ME A1.3	The facility provides Laboratory services for non-communicable diseases
ME A1.4	Facility provides services to support public health functions
ME A1.5	Facility provides laboratory-based surveillance services for Infectious & Non-infectious diseases
ME A1.6	Services are available for the time period as mandated
Standard A2	Facility provides support services to linked spokes
ME A 2.1	Facility provides technical support services to Block Public Health Labs & other peripheral labs
ME A 2.2	The facility provides information management support

#### **Area of Concern B: Patient Rights**

Standard B1	The service provided at facility are accessible and affordable
ME B1.1	The facility has user friendly and uniform signage system
ME B1.2	The facility displays its services, entitlements, and relevant information
ME B1.3	Access to facility is provided without any physical barrier & friendly to specially abled people
ME B1.4	There is an established procedure for having consent before conducting any procedure
ME B1.5	The facility has defined and established grievance redressal system in place
ME B1.6	The facility provides cashless services as per prevalent government norms/schemes
Standard B2	The service provided at facility are acceptable
ME B2.1	Adequate visual privacy is provided at every point of care
ME B2.2	Services are provided in manner that are sensitive to gender
ME B2.3	Confidentiality of patients records, and clinical information is maintained for every patient, especially of those having social stigma
ME B2.4	The facility ensures the behaviours of staff is dignified and respectful, while delivering the services

#### AOC B Continued...

Standard B3	The facility has defined framework for ethical management including dilemmas confronted during delivery of services at public health facilities.
ME B3.1	Ethical norms and code of conduct for medical and paramedical staff have been established
ME B3.2	There is an established procedure for sharing of laboratory/patient data with individuals and external agencies including non-governmental organization.
ME B3.3	There is an established procedure for obtaining informed consent from the patients in case facility is participating in any clinical or public health research
ME B3.4	There is an established procedure to ensure lab services during strikes or any other mass protest leading to dysfunctional laboratory services.
ME B3.5	Facility has established a framework for identifying, receiving, and resolving ethical dilemmas in a time-bound manner through ethical committee/locally applicable rules

#### Area of Concern C: Inputs

Standard C1	The facility has infrastructure for delivery of assured services, and available infrastructure meets the prevalent norms
ME C1.1	Facility has adequate space as per workload
ME C1.2	Patient amenities are provided at sample collection area as per patient load
ME C1.3	Facility has layout and demarcated areas as per functions
ME C1.4	The facility has infrastructure for intramural and extramural communication
ME C1.5	The facility and departments are planned to ensure structure follows the function/processes (Structure commensurate with the function of the hospital)
Standard C 2	The facility ensures the physical safety of the infrastructure.
ME C2.1	The facility ensures the seismic safety of the infrastructure
ME C2.2	The facility ensures infrastructure is in place for the safe sample transportation
ME C2.3	The facility ensures safety of electrical establishment
ME C2.4	Physical condition of buildings are safe for providing mandated lab services
Standard C3	The facility has established Programme for fire safety and other disaster
ME C3.1	The facility has plan for prevention of fire
ME C3.2	The facility has adequate firefighting Equipment
ME C3.3	The facility has a system of periodic training of staff and conducts mock drills regularly for fire and other disaster situation

#### AOC C continued...

Standard C4	The facility has adequate qualified and trained staff, required for providing the assured services to the current case load
ME C4.1	The facility has adequate specialist/qualified personnel as per service provision
ME C4.2	The facility has adequate technicians/paramedics as per requirement
ME C4.3	The facility has adequate support / general staff
Standard C 5	Facility ensures reagents and consumables required for assured list of services
ME C5.1	The facility has adequate reagents and controls at point of use
ME C5.2	The facility has adequate consumables at point of use
ME C5.3	Emergency drug trays are maintained at every point of care, wherever it may be needed
Standard C 6	The facility has equipment & instruments required for assured list of services.
ME C 6.1	Availability of equipment & instruments for diagnostic procedures being undertaken in the facility
ME C 6.2	Availability of functional equipment and instruments for support services
ME C 6.3	Departments have patient furniture and fixtures as per load and service provision

#### AOC C continued...

Standard C7	Facility has a defined and established procedure for effective utilization, evaluation and augmentation of competence and performance of staff
ME C7.1	Criteria for Competence assessment and performance appraisal are defined for all clinical and Para clinical staff
ME C7.2	Competence assessment and performance appraisal of Clinical and Para clinical staff is done on predefined criteria at least once in a year
ME C7.3	The Staff is provided training as per defined core competencies and training plan
ME C7.4	Training needs are identified based on competence assessment and performance evaluation and facility prepares the training plan
ME C7.5	There is established procedure for utilization of skills gained thought trainings by on - job supportive supervision

#### **Area of Concern D: Support Services**

Standard D1	The facility has established Programme for inspection, testing and maintenance and calibration of Lab Equipment.
ME D 1.1	The facility has established system for maintenance of critical Equipment
ME D1.2	The facility has established procedure for internal and external calibration of measuring Equipment
ME D1.3	Operating and maintenance instructions are available with the users of equipment
Standard D2	The facility has defined procedures for storage, inventory management and dispensing of consumables and reagents
ME D2.1	There is established procedure for forecasting and indenting consumables, reagents and controls
ME D2.2	The facility ensures proper use and storage of consumables and reagents
ME D2.3	The facility ensures management of expiry and near expiry reagents
ME D2.4	The facility has established procedure for inventory management techniques
Standard D3	The facility provides safe, secure, and comfortable environment to staff, patients, and visitors.
ME D3.1	The facility provides adequate illumination level at workstation
ME D3.2	The facility has provision of restriction of visitors in IPHL
ME D3.3	The facility ensures safe and comfortable environment for service providers

## AOC D continued...

Standard D4	The facility has established Programme for maintenance and upkeep of the facility
ME D4.1	Exterior of the facility building is maintained appropriately
ME D4.2	The facility is clean and hygienic
ME D4.3	Facility's infrastructure is adequately maintained
ME D4.4	The facility has policy of removal of condemned junk material
ME D4.5	The facility has established procedures for pest, rodent and animal control
Standard D5	The facility ensures 24X7 water and power backup as per requirement of service delivery, and support services norms
ME D5.1	The facility has adequate arrangement storage and supply for potable water in all functional areas
ME D5.2	The facility ensures adequate power backup in all patient care areas as per load
Standard D6	The facility ensures support to all linked labs as per service mandate
ME D6.1	The facility has established procedure for providing technical support to linked labs
ME D6.2	The facility has established procedure for providing capacity building support to linked labs
ME D6.3	The facility has established procedure for providing information management support using digital technology to linked labs and administrative authorities
Standard D7	Facility has defined and established procedures for Financial Management
ME D7.1	The facility ensures the proper utilization of fund provided to it
ME D7.2	The facility ensures proper planning and requisition of resources based on its need

#### AOC D continued...

Standard D8	Facility is compliant with all statutory and regulatory requirement imposed by local, state or central government
ME D8.1	The facility has requisite licences and certificates for operation of facility and different activities
ME D8.2	Updated copies of relevant laws, regulations and government orders are available at the facility
Standard D9	Roles & Responsibilities of administrative and clinical staff are determined as per govt. regulations and standards operating procedures.
ME D9.1	The facility has established job description as per govt guidelines
ME D9.2	The facility has a established procedure for duty roster and deputation
ME D9.3	The facility ensures the adherence to dress code as mandated by its administration /the health department
Standard D10	Facility has established procedure for monitoring the quality of outsourced services and adheres to contractual obligations
ME D10.1	There is established system for contract management for outsourced services
ME D10.2	There is a system of monitoring of quality of outsourced services

#### **Area of Concern E: Clinical Services**

Standard E1	The laboratory has defined procedures for registration of patients
ME E1.1	The facility has established procedure for registration of patients visiting lab or sample collection area
ME E1.2	The facility has established procedure for registration of the patient's sample received from spokes/peripheral labs
Standard E2	Facility has established mechanism for referral linkages to maintain continuity of services
ME E2.1	Facility has defined and established procedures for continuity of services
ME E2.2	The facility has defined and established procedures for intersectoral coordination
Standard E3	The facility has established and defined procedure for pre-testing activities
ME E3.1	The facility has established procedure for patient preparation
ME E3.2	The facility has established a procedure for sample collection from patient care areas
ME E3.3	The facility has established procedure for sample labelling and documentation
ME E3.4	The facility has a standardised Lab. requisition form for the tests
ME E3.5	The facility has established procedure for packaging and transportation of samples
ME E3.6	The facility has defined criteria for sample acceptance or rejection

#### AOC E continued...

Standard E4	The facility has established and defined procedure for testing activities
ME E4.1	Facility performs tests as per established procedure
ME E4.2	Test procedures are verified through routine quality control methods
ME E4.3	Facility has established procedure for biological reference and critical alert values
Standard E5	Laboratory has defined and established procedure for the post testing processes
ME E5.1	The facility has established procedure for reporting result
ME E5.2	The laboratory has defined procedure for revision/amendment of the reports when required
ME E5.3	The facility has established procedure for sample storage and its disposal
Standard E6	The facility has established mechanism for internal and external validation of testing procedures
ME E6.1	The facility has established mechanism of internal quality control using quantitative methods
ME E6.2	The facility has established mechanism of internal quality control using semi quantitative/qualitative methods
ME E6.3	The facility has established mechanism of external quality assurance

#### AOC E continued...

Standard E7	Facility has defined and established procedures for maintaining, updating of patients' clinical records and their storage
ME E7.1	Adequate form and formats are available at point of use
ME E7.2	Register/records are maintained as per lab. policy
ME E7.3	The facility has established computerised information system to support lab functions
ME E7.4	The facility ensures safe and adequate storage and retrieval of medical records
Standard E8	The facility has defined and established procedures for Emergency Services and Disaster Management
ME E8.1	The facility has disaster management plan in place
ME E8.2	There is procedure for handling the legal cases
Standard E9	Facility provides National health program as per operational/Clinical Guidelines
ME E9.1	The facility has established procedure for services under various communicable disease programmes
ME E9.2	The facility has established procedure for services under various non-communicable disease programmes
ME E9.3	Facility provide service for Integrated disease surveillance program/Integrated Health Information Platform (IHIP)

#### **Area of Concern F: Infection Control**

Standard F1	Facility has infection prevention control program and procedures in place
	Facility has functional infection control committee and has a defined procedure to review the infection prevention and control practices
ME F1.2	Facility has established procedures for regular monitoring of infection control practices
ME F1.3	There is Provision of Periodic Medical Checkups and immunization of staff
Standard FZ	Facility has defined and Implemented procedures for ensuring hand hygiene practices and antisepsis
ME F2.1	Hand washing facilities are provided at point of use
ME F2.2	Staff is trained and adhere to standard hand washing practices
ME F2.3	Facility ensures standard practices and materials for antisepsis
Standard F3	Facility ensures standard practices and materials for Personal protection
ME F3.1	Facility ensures adequate personal protection equipment as per requirements
ME F3.2	Staff adhere to standard personal protection practices

## AOC F continued...

Standard F4	Facility has standard Procedures for processing of equipment and instruments
ME F4.1	Facility ensures standard practices and materials for decontamination and cleaning of instruments and procedures areas
ME F4.2	Facility ensures standard practices and materials for disinfection and sterilization of instruments and equipment
Standard F5	Physical layout and environmental control of the laboratory ensures infection prevention
ME F5.1	Layout of the lab is conducive for the infection prevention and control practices
ME F5.2	Facility ensures availability of standard materials for cleaning and disinfection
ME F5.3	Facility ensures standard practices followed for cleaning and disinfection
ME F5.4	Facility ensures air quality of high-risk area
Standard F6	The facility has defined and established procedures for segregating, collecting, treating, and disposing of Biomedical and Hazardous Waste.
ME F6.1	Facility ensures segregation of Bio Medical Waste as per guidelines
ME F6.2	Facility ensures management of sharps as per guidelines
ME F6.3	Facility ensures transportation and disposal of waste as per guidelines
ME F6.4	Facility ensures management of liquid waste as per guidelines

#### Area of Concern G: Quality Management

Standard G1	The facility has defined mission, vision, values, quality policy and objectives, and prepares a strategic plan to achieve them
ME G1.1	Facility has defined mission & vision statement.
ME G1.2	Facility has defined core values of the organization
ME G1.3	Facility has defined Quality policy, which is in congruency with the mission & vision of facility
ME G1.4	Facility has defined quality objectives to achieve mission, vision, and quality policy
	Mission, Vision, Values, Quality policy and Objectives are effectively communicated to staff and users of services
ME G1.6	Facility prepares strategic plan to achieve mission, vision, quality policy and objectives
	Facility periodically reviews the progress of strategic plan towards mission, vision, policy and objectives
Standard G2	The facility has established organizational framework for quality improvement
ME G2.1	The facility has a quality team in place
ME G2.2	The facility reviews quality of its services at periodic intervals

#### AOC G continued...

Standard G3	The facility has documented, implemented, and updated Standard Operating Procedures for all key processes and support services
ME G3.1	Laboratory standard operating procedures are available
ME G3.2	Standard Operating Procedures adequately describes process and procedures
ME G3.3	The staff is trained and aware of the standard procedures written in the SOPs
ME G3.4	The facility ensures documented policies and procedures are appropriately approved and controlled
Standard G4	The facility has established internal & external quality assurance programmes for laboratory functions
ME G4.1	The facility has established internal quality assurance programs for lab
ME G4.2	The facility has established external quality assurance programs for lab
ME G4.3	Actions are planned to address gaps observed during quality assurance process
ME G4.4	Planned actions are implemented through Quality Improvement Cycles (PDCA)
Standard G 5	The facility seeks continual improvement by practising Quality method and tools
ME G5.1	The facility uses method for quality improvement in services
ME G5.2	The facility uses tools for quality improvement in services

#### AOC G continued...

Standard G6	The facility maps its key processes and seeks to make them more efficient by reducing nonvalue adding activities and wastages
ME G6.1	The facility maps its critical processes
ME G6.2	The facility identifies nonvalue adding activities / waste / redundant activities
ME G6.3	Facility takes corrective action to improve the processes
Standard G7	The facility has defined, approved and communicated Risk Management framework for existing and potential risks
ME G7.1	Risk Management framework has been defined including context, scope, objectives and criteria
ME G7.2	Risk Management framework defines the responsibilities for identifying and managing risk at each level of functions
ME G7.3	Risk Management Framework includes process of reporting incidents and potential risk to all stakeholders
ME G7.4	A comprehensive list of current and potential risk including potential strategic, regulatory, operational, financial, environmental risks has been prepared
ME G7.5	Modality for staff training on risk management is defined
ME G7.6	Risk Management Framework is reviewed periodically

#### AOC G continued...

Standard G8	The facility has established procedures for assessing, reporting, evaluating and managing risk as per Risk Management Plan
ME G8.1	The facility has defined and communicated Risk Management framework for existing and potential risks
ME G8.2	Periodic assessment for Physical and Electrical risks is done as per defined criteria
ME G8.3	Periodic assessment for Chemical and biological hazard is done as per defined criteria
ME G8.4	Periodic assessment for potential disasters including fire is done as per defined criteria
ME G8.5	Risks identified are analysed evaluated and rated for severity
ME G8.6	Identified risks are treated based on severity and resources available
ME G8.7	A risk register is maintained and updated regularly to record identified risks, their severity and actions to be taken
Standards G9	The facility has established system for patient and employee satisfaction
ME G9.1	Patient and Employee Satisfaction surveys are conducted at periodic intervals
ME G9.2	The facility analyses the patient feedback and do root cause analysis
ME G9.3	The facility prepares the action plans for the areas of low satisfaction

#### **Area of Concern H: Outcome Indicators**

Standard H1	The facility measures Productivity Indicators and ensures compliance with State/National benchmarks
ME H1.1	Facility measures productivity Indicators on monthly basis
ME H1.2	The facility endeavours to improve its productivity indicators to meet the benchmark
Standard H2	The facility measures Efficiency Indicators and ensure compliance with State/National benchmarks
ME H2.1	Facility measures efficiency Indicators on monthly basis
ME H2.2	The facility endeavours to improve its efficiency indicators to meet the benchmark
Standard H3	The facility measures Clinical Care & Safety Indicators and ensure compliance with State/National benchmarks
ME H3.1	Facility measures Clinical Care & Safety Indicators on monthly basis
ME H3.2	The facility endeavours to improve its clinical care & safety indicators to meet the benchmark
Standard H4	The facility measures Service Quality Indicators and ensure compliance with State/National benchmarks
ME H4.1	Facility measures Service Quality Indicators on monthly basis
ME H4.2	The facility endeavours to improve its service quality indicators to meet the benchmark



# Thanks