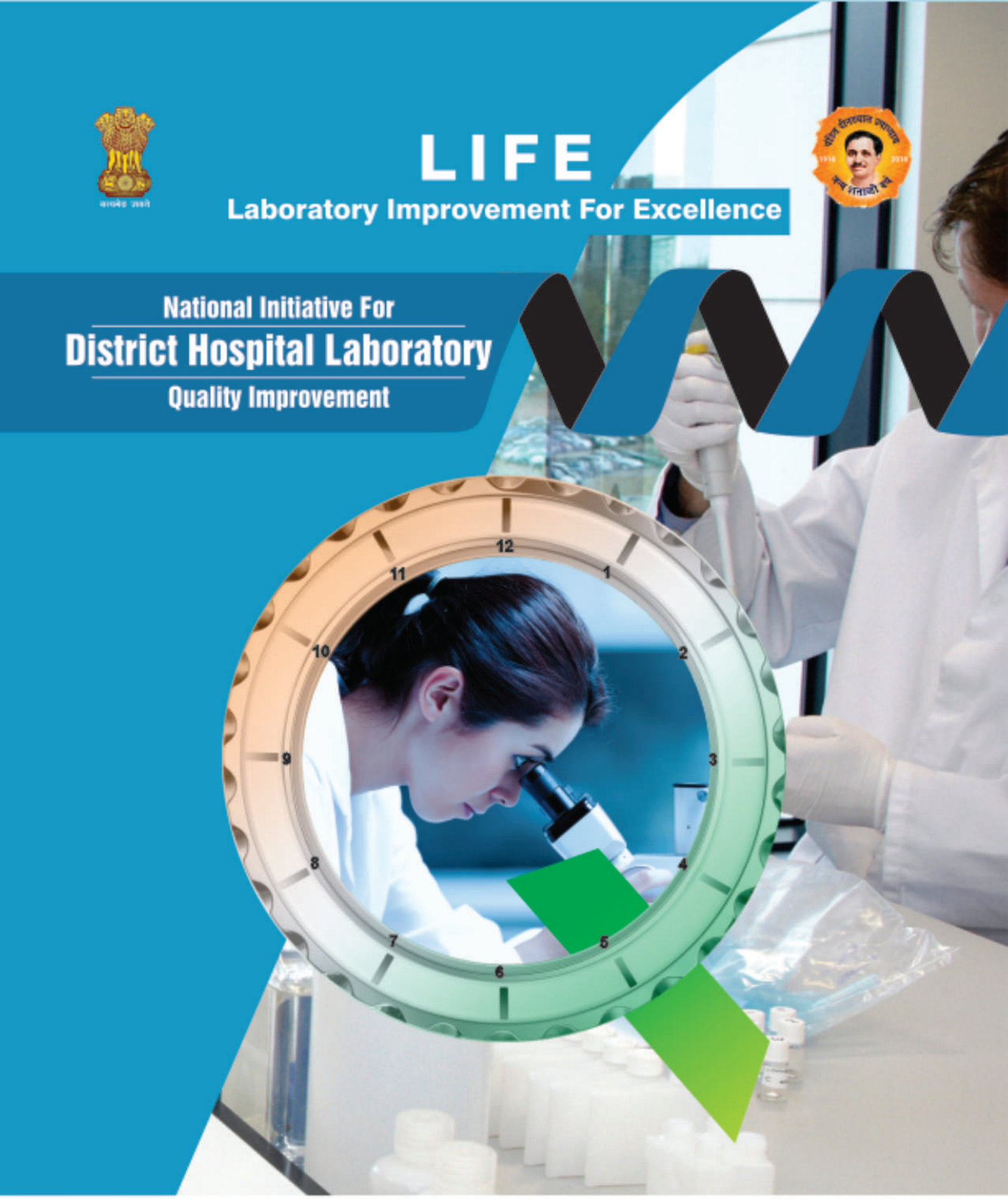
LIFE

Laboratory Improvement For Excellence

National Initiative For

District Hospital Laboratory

Quality Improvement



स्वच्छ भारत

एक कदम स्वच्छता की ओर

NATIONAL HEALTH MISSION

Ministry of Health & Family Welfare, Government of India

सत्यमेव जयते

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National Initiative
For District Hospital Laboratory
Quality Improvement

Ministry of Health & Family Welfare
Government of India

JULY 2017

Ministry of Health and Family Welfare
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Jagat Prakash Nadda

सत्यमेव जयते

स्वास्थ्य एवं परिवार कल्याण मंत्री
भारत सरकार
Minister of Health & Family Welfare
Government of India

MESSAGE

Diagnostic services are essential and fundamental parts of health systems and their purpose is to provide the evidence base for prevention and management of diseases. Accurate, reliable and timely results from laboratory investigations are critical elements in decision making in almost all aspects of healthcare. They are also essential for the surveillance and control of diseases of public health importance. Improved timely disease recognition improves the accuracy of health information and promotes effective national health planning.

Recognizing that diagnostic services are a critical component of health systems, the Ministry of Health and Family Welfare is launching this "National Initiative for Public Health Laboratory Quality Improvement", with the purpose of providing strategic and operative plans to deliver comprehensive and quality laboratory services at district level. The initiative provides a framework and sustainable model for strengthening the District Hospital laboratories towards certification and accreditation through a stepwise process of continuous quality improvement. Capacity building activities to elevate the laboratory systems to applicable national and international standards and guidelines, mostly through existing Government structures, have been designed to optimally utilize resources. This also compliments NHM Free Diagnostic Service Initiative to provide quality services free of cost to patients that come to public health facilities to seek health care.

I am confident that the State Governments will take ownership of this Initiative and operationalize it effectively to fulfill our mission of providing quality healthcare services to all.

May, 2017
New Delhi

(Jagat Prakash Nadda)

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स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Government of India
Department of Health and Family Welfare
Ministry of Health & Family Welfare

MESSAGE

Districts form a very important administrative unit of functioning in practically all aspects of national development. Keeping this in mind, the National Health Mission has advocated the improvement of District Hospitals as a priority objective. As a part of the overall District Hospital improvement, a National Initiative for Quality Improvement of the Laboratories with the aim to achieve certification by National Quality Assurance Initiative (NQAS) and subsequently accreditation by the National Accreditation Board for Testing and Calibration Laboratories (NABL) is being launched.

Laboratories carry out a battery of activities that have to be standardized and streamlined. For this reason, clinical lab system the world over have come under the purview of ISO. In India NABL accreditation can be achieved, if compliance to the ISO standard is demonstrated through robust laboratory quality management systems. Skilling of workforce is the key to having such quality systems. To achieve this aim, the Initiative suggests mechanisms for training in all aspects of laboratory quality management. It proposes mechanisms within the District Hospitals to establish, implement and maintain quality systems. Besides skilling of the workforce, the Initiative is designed to systematically address gaps in infrastructure, to enhance scope of activities, in order to achieve the capacity to perform tests defined under the Free Diagnostic Services Initiative of NHM.

Concerted effort of the State Government and the institutions with the technical and financial support under NHM is vital to the success of the initiative. I am sure that the states will make full use of this initiative to provide quality healthcare to all based on quality diagnostic services.

(C.K. Mishra)

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MESSAGE

Laboratories offer mechanisms to recognize disease patterns and reduce the disease burden of a nation. They provide the evidence for interventions and can form the scaffold to base national policies on disease control and prevention. However, many public health laboratories in India have a long way to go before they can provide such full support to the healthcare system.

Thus, a network of strong, quality assured laboratories with sufficient scope of tests at every level, plus a quality assured referral system for complex tests, to higher levels, are the needs of the hour. Definitions and provisions towards these at district, state and national levels can be made and implemented. For the district level, the scope of testing has been defined through the Free Diagnostic Services Initiative of NHM and IPHS. The IPHS also defines the staff and equipment needed. National Quality Assurance Standards (NQAS) provide the standards for laboratory quality management systems. However, deficiencies exist in the implementation of these standards. The National Initiative for "District Hospital Laboratory Quality Improvement" is a step towards addressing these comprehensively, to assure the availability of mandated tests and establish laboratory Quality Management Systems that merit NQAS certification and further NABL accreditation. NABL accreditation is the evidence of a laboratory's compliance to the international standard for clinical laboratories, ISO 15189.

I am sure that the Initiative will bring about far reaching and systemic changes in our healthcare system and significantly improve quality of healthcare. I am confident that the states will implement the Initiative effectively.

(Arun K Panda)
30th May 2017

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MESSAGE

Reliable laboratory service is an essential part of an effective healthcare system. Thus, it is essential to establish quality assured laboratory facilities at all levels of public health services.

However, at present, there are several evident gaps that need remedial action. These are mainly pertaining to inadequacies in infrastructure, equipment inadequate technical knowledge and skills amongst laboratory personnel and most importantly, the lack of quality assurance.

As the name implies, The National Initiative for District Hospital Laboratory Quality Improvement has been developed with the primary aim of strengthening the district hospital laboratories and improve the quality of laboratory services in order to provide reliable and affordable quality laboratory services in all districts of India.

The Initiative has been drafted with the purpose of addressing systemic training and quality needs identified from across several district hospitals, in a prompt and systematic manner, and hinges heavily on quality improvement and workforce development. Addressing facility specific infrastructure challenges have also been provisioned for. The Initiative gives us an opportunity to bridge gaps, ensure capacity building of staff, optimize the laboratory processes and implement credible and standardized quality management systems.

I am happy that this Initiative is being rolled out across the country and am looking forward to the reinforcement of the quality culture in day to day working in public health facilities. The onus lies on us to work towards this common goal with united and untiring efforts, and with efficient and optimal use of all available resources.

(MANOJ JHALANI)

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Acknowledgment

The LIFE (Laboratory Improvement for Excellence) Initiative has been developed to improve quality in district hospital laboratories across all districts of the country.

The role of Shri C.K. Mishra, Secretary, Health and Family Welfare, Dr.Arun. K. Panda, Additional Secretary & Mission Director NHM and Shri Manoj Jhalani, Joint Secretary, Policy, NHM is commendable for their leadership in steering this movement of improving quality.

I must appreciate the efforts and initiatives of my colleagues from NHM, NHSRC (Quality Improvement and Healthcare Technology Divisions) & Labs for Life Project, for the continuous consultative approach adopted for putting a practical and actionable road map for the states to follow.

The technical contribution by Dr. Anu George, Technical Manager, Labs for Life Project, towards the development of this pragmatic operational plan is duly acknowledged.

The invaluable inputs of Dr. J.N. Srivastava, Advisor, Q1 Division and Shri Shashi Bhushan Sinha Advisor, Healthcare Technology Division, and their team members from NHSRC are acknowledged.

I would also like to convey my thanks to the development partners of Labs for Life Project; CDC, CMAI, particularly Dr. Timothy Holtz, Director, CDC-DGHT, Dr. Sunita Upadhyaya, Lab Branch Chief, CDC-DGHT India and Dr. Bimal Charles, General Secretary, CMAI.

I hope this initiative will facilitate to build and maintain comprehensive and trustworthy Quality Management Systems in Laboratories at Public Health laboratories across the country.

(Dr. Naresh Goel)

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Executive Summary

Reliable diagnostic services are the foundation of a truly effective health care system. There have been substantial government efforts and resource allocation for creating an extensive laboratory network and improved quality of services. However, gaps and challenges still exist that affect the reach, coverage and quality of laboratory service provision. This calls for a comprehensive package of interventions for establishing strong, dependable and affordable laboratory systems and services at the primary, secondary and tertiary levels of health care.

Available evidence indicates that the gaps are primarily inadequacies in the infrastructure, technical knowledge and skills of the laboratory personnel, and the absence of quality assurance especially in the district level public health laboratories. The document suggests an action plan with specific strategies to address the gaps in infrastructure, workforce, and the enabling of ISO based laboratory Quality Management Systems.

The proposed plan of action focusing on the district level public health laboratories is a comprehensive national initiative that endeavors the holistic transformation of laboratory services in public hospitals through systematic and incremental approach of continual quality improvement. This would aim to close the structural gaps, build capacity of staff, optimize laboratory processes and implement credible quality management systems to meet the suggested National and International standards, leading towards achieving quality certification/accreditation against NQAS/NABL standards. The key elements of ISO 15189 for laboratories pertaining to organization, safety protocols, personnel, equipment maintenance, analysis, auditing of procedures and quality assurance will be addressed through a cascade of training.

The need for a professional and technically qualified team has been brought out. Effective monitoring system with regular assessment of performance has been emphasized as this is crucial for mid-course correction, further planning and implementation. The initiative suggests an incentive mechanism to enhance the commitment of the institutions. A pragmatic and realistic costing has been worked out for the initiative. The annexes provide details of various components of the initiative.

The expected outcome of the initiative is the establishment of reliable diagnostic facilities and laboratory quality management systems across all district level laboratories in the country.

01 BACKGROUND

1. Background

1.1 Laboratory Systems and Services

Laboratory services are an essential and fundamental part of the health system. Majority of illnesses require laboratory confirmation of the clinical diagnosis. Laboratory plays an important role before, during and after treatment. Inadequate laboratory capacity in developing countries is a barrier to effective healthcare and has been termed the 'Achilles Heel' of global efforts to combat infectious diseases. Lack of access to high-quality diagnostic tests may deprive the people of life-saving treatments and reduces opportunities to prevent onward transmission and spread of diseases. Without effective public health laboratory systems, public health responses will be delayed and global health security will be threatened. In case of non-availability/sub-standard laboratory services in public health facilities, users are compelled to use private health facilities, which leads to out of pocket expenditure and financial hardships. This applies to non-communicable diseases as well. With lifestyle diseases on the rise, monitoring mechanisms must be in place to detect and limit morbidity and mortality. Therefore, access to appropriate and high-quality laboratory support is vital in healthcare service provision, including surveillance and disease prevention and control programs in India.

1.2 Laboratories in India

India has a large number of medical diagnostic laboratories across the country, but, is fragmented, inequitably distributed, largely unregulated and dominated by unorganized sector. The public health laboratory network in India includes different types of laboratories under the vertical disease control programs, as well as laboratories functioning at the huge network of health care facilities such as PHCs, CHCs, sub-district hospitals, district hospitals and medical college hospitals. It also includes laboratory networks outside of the direct administration of central and state ministries of health such as Armed Forces Medical Service (AFMS), Indian Railways, Central Government Health Scheme (CGHS) and Employee's State Insurance Corporation (ESI) etc. In addition, a huge number of diagnostic facilities are available in the private sector that includes very small laboratories to sophisticated large sized chain of laboratories.

1.3 Current Efforts, Gaps and Challenges

Substantial government efforts and resources allocation have been made to create extensive network of laboratories and improving quality of the services. The Indian Public Health Standards (IPHS) clearly indicates the requirements for laboratories in terms of human resources, equipment and services. The Integrated Disease Surveillance

Programme (IDSP) has made substantial efforts to develop laboratory capacities for surveillance of epidemic prone diseases and outbreak investigations. The National Health Mission is also supporting the states & UTs to provide essential diagnostic services. Several technical guidelines and modules on the processes and standards related to diagnostics services have been developed. The NHM's Free Diagnostic Services Initiative intends to provide a set of essential diagnostics at various levels of care, so that clinicians are able to make rational decisions regarding treatment. Patients benefit by getting their tests conducted within the facility free of cost. National Quality Assurance Program under NHM defines quality standards (NQAS) for different level of facilities.

Though there has been substantial improvement, there are still gaps and challenges that affect the reach, coverage and quality of laboratory service provision. These challenges have contributed to the widespread reliance on private service providers, empirical patient care, irrational diagnostic prescriptions and practices that waste scarce resources and adversely impact clinical care.

Also of importance is the fact that India does not have a national laboratory policy and strategic plan that can guide the effective development and continual improvement of laboratory organization, capabilities, capacities, workforce and resources, define the key stakeholders, processes and functions. Inadequate infrastructure, supply of validated diagnostic kits, laboratory Quality Management Systems, availability of trained manpower, and networking and integration of laboratory across diseases in services are some of the key factors affecting the effectiveness of service provision.

1.3.1 Infrastructure Gaps

The progress made in terms of infrastructure is yet to match the IPHS specifications. Infrastructure here implies accommodation and environment of the laboratory along with equipment and staff availability.

The desired services can be provided only if the requisite equipment and staff are available. According to Rural Health Statistics (2015), there are around 25,308 PHCs, 5,396 CHCs, 1,022 Sub Divisional/District Hospitals (SDH), 763 District Hospitals (DH), 1,253 Mobile Medical Units (MMU), besides the 211 government medical colleges that are directly providing laboratory services to the community. In terms of human resources, according to RHS, only 5,245 PHCs function as per IPHS norms and 5,025 CHCs have functional labs. The shortage of lab technicians in PHCs and CHCs is 24 per cent (5,472) against the sanctioned staff of 22,626 lab technicians (actual requirement is 30,704). However, in district hospitals, the shortage is just 5 per cent (2,921) against the sanctioned 58,563, whereas, in sub district/divisional hospitals, it is 16 per cent (5,214) against the sanctioned 31,931 technicians. The actual requirement of lab technicians however, may be higher in these facilities, thus, addressing this lacuna in infrastructure is crucial.

The equipment availability and services also must match the requirements for provisioning of the tests listed under Free Diagnostic Services Initiative. Rapid situation analysis has shown that by and large the equipment availability matches the required list for basic tests. However, microbiology tests are usually not available except for selected serology tests in

rapid test formats. Cytology is available in limited number of laboratories. Histopathology is generally unavailable. Inventory disruptions are also of concern. With an assured supply of reagents and consumables, most of the requisite basic tests can be done. Detailed mapping for inadequacies need to be done, gaps understood and corrected.

Last but not the least, the accommodation and environment must match the standards, so as to ensure safety and optimum productivity. Laboratory design, architectural considerations and specifications, must be understood and implemented. The path of workflow must be mapped and optimized.

1.3.2 Gaps in Training and Workforce Development

The significant progress in terms of infrastructure and functioning has standardized many aspects of laboratory services, but, the capacity building initiatives for human resources have not kept the same pace. Lack of adequate and updated technical knowledge and skills for the laboratory personnel is the most important factor adversely influencing the quality of service provision in public health laboratories in India. It is only through capacity building of laboratory personnel, the infrastructure and facilities can be leveraged for optimal public health service and outcomes. Training, mentoring and supportive supervision as interventions are very crucial as these can improve performance, provide professional development, improve health workers' job satisfaction, increase motivation and reduce staff attrition in laboratories. Evidence from low and middle income countries suggest that formal and informal training, along with mentoring, supportive supervision and monitoring with feedback is generally effective.

1.3.3 Gaps in Quality Management

Quality Management System (QMS) is essential for the overall health of laboratories and involves both management and technical requirements which together will address the spectrum of activities involved in setting up a laboratory ethically and in the most technically sound way. QMS tracks the samples from point of registration through collection, analysis, error prevention and detection, corrective and preventive actions, to reporting and sample discarding. Equipment and inventory management are addressed comprehensively. Safety to the operator, community and environment are maintained constantly. It emphasizes the mechanism for staff accountability, development and competence. It also dwells on self-monitoring using Quality Indicators to enable continual improvements of the system over a period of time, by ironing out the bottlenecks encountered.

1.4 The Need for the Initiative

The recently adopted National Health Policy (2017) stresses the need for making available good quality, free essential generic drugs and diagnostics at public health care facilities towards achieving universal health care. It especially advocates the need for districts to respond to the communicable disease priorities of their locality through a network of well-equipped laboratories backed by tertiary care centres and enhanced public health capacity

to collect, analyse and respond to the disease outbreaks. The policy also recognizes the need to halt and reverse the growing incidence of chronic diseases and supports an integrated approach where screening for the most prevalent NCDs with secondary prevention to make a significant impact on reduction of morbidity and preventable mortality. The policy also seeks to eliminate the risks of inappropriate treatment by maintaining adequate standards of diagnosis and treatment. Thus, it calls for an intensive approach of building the capacity of public health laboratories at the district level.

Early evidence from a pilot initiative proved that a comprehensive approach which includes, intensive training using a blended learning coupled with mentoring and supportive supervision, sustained advocacy, resource mobilisation and a robust monitoring mechanism is very effective in improving the quality of laboratory services. In accordance with the National Health Policy, this comprehensive approach which is proven effective is suggested to be implemented in all the district level laboratories which would ensure universal access to quality laboratory services.

02 ABOUT THE INITIATIVE AND SCOPE

2. About The Initiative and Scope

This initiative endeavours the holistic transformation of Laboratory services in public hospitals through a systematic and incremental approach of continual quality improvement. This would entail closing of structural gaps, capacity building for staff, optimizing the laboratory process and implementing a credible Quality Management System to meet prevalent National and International standards. As the tangible outcome of the efforts, targeted laboratories would achieve quality certification/accreditation against NQAS/NABL standards.

In the first phase, the initiative will cover district hospital laboratories in the country. The number of functioning district hospitals in India was 763 as on 31st March, 2015. Essentially, the wide network of district-level public health laboratories plays a critical role in the disease surveillance and response. They provide facilities for basic investigations in the areas of haematology, biochemistry and, in some cases, basic microbiology. The laboratory services in the district hospitals need to be of adequate quality as they cater to a large volume of rural, peri-urban and urban population, providing all basic and speciality services. Based on the experience and leaning from the first phase the initiative may be extended to sub district level facilities, at a later stage.

The implementation of the initiative will require systematic and sustained advocacy with state/district health officials, and other relevant stakeholders to ensure commitment from management, mobilize resources and ensure smooth flow of materials and reagents. Given the lack of awareness on the importance of QMS in public health laboratories, it is essential to disseminate the knowledge and facilitate the process of generating awareness and discussion among different stakeholders for smooth implementation.

03 LABORATORY QUALITY

3. Laboratory Quality

The previous chapters have discussed the need of having quality in laboratories. This chapter reiterates these with the details of each.

Why Laboratory Quality Management Systems?

Modern medicine is highly dependent upon the empirical diagnosis to take clinical decisions. With the advent of new technology, the diagnostic systems are becoming increasingly sophisticated as well as complex. To ensure that laboratory reports are credible and accurate, clinical laboratories need to implement quality management system.

Laboratory Quality Management Systems have been conceptualized as laboratories are required to perform a battery of complex activities, and are performed by various sets of staff having different job descriptions, using different equipment and techniques and spread over different locations within a facility or stand-alone. Thus comprehensive programs to standardize all these operations should be made available for effective and safe operations. There are 12 Quality System Elements defined for a laboratory. Some of these are; Staff Training & Management, Facility Management & Safety, Sample Collection & Tracking, Biomedical Waste Management, Equipment Management, Inventory Management, Quality Controls, Documentation, and Post Analytical Aspects such as Reporting of Results, Archiving of Results Retention and Disposal of Samples. Apart from these generic quality system requirements, the public health laboratory should be accessible, affordable and responsive to community needs.

What Is The Best Way In Which One Can Standardise a Laboratory?

Most of the activities in the laboratory are repetitive and can be very much standardized.

This can be achieved through a three step approach (Fig. 3.1)

1. Setting up Quality Standards
2. Assessing the Quality of Defined Standards
3. Improving the Quality to meet Defined Standards

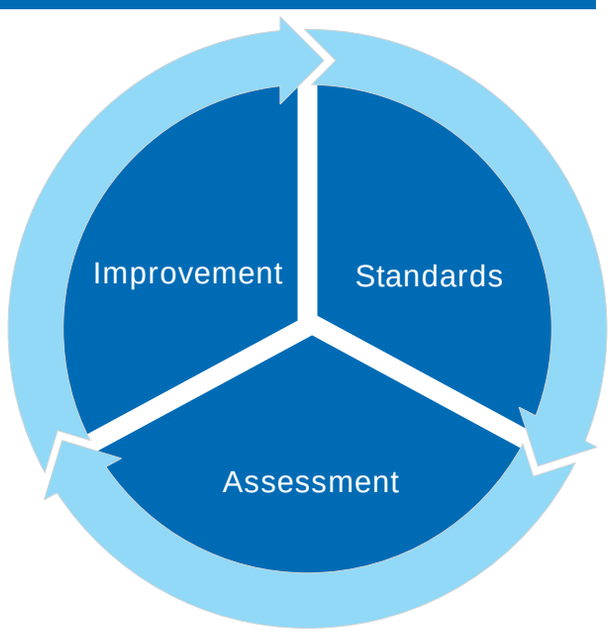

Fig. 3.1: Improvement Process

Setting up Quality Standards – The first step towards quality is to define the quality requirements in terms of standards. Equally important is to develop tools for objectively measuring these standards (Fig. 3.2). These tools comprise of measurable elements and assessment checklists. Setting up Quality Standards with Measurable Elements and accompanying Checklists is the primary activity for enabling any Quality Management System. This will provide the basis for assessing existing capacities against the standards, define interventions, monitor progress and re-plan further actions.

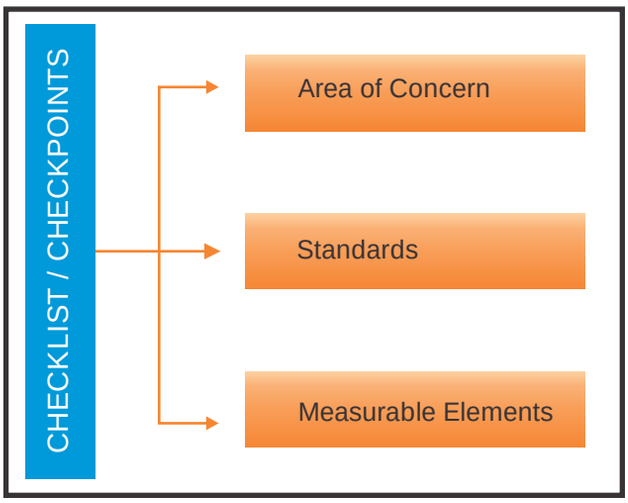

Fig. 3.2: Setting up Quality Standards

The standards must meet all requirements of the laboratory. While developing such a standard, it should be borne in mind that it is composite to address all aspects of laboratory functioning. The areas of concern must be mapped, standard in each area defined and measurable element in each area specified.

ISO 15189, "Medical laboratories — Requirements for quality and competence" is a standard that guides each activity that a laboratory has to perform. The parent standards from which ISO 15189 is derived are; ISO 9001 for "Quality Management System" and ISO 17025 "General requirements for the competence of testing and calibration laboratories". Thus, the 15189 standard fulfils the requirement for both Quality and Competence, the essentials for reliability of a clinical laboratory. Compliance to this standard in India can be assessed and certified through NABL, which is currently the benchmark in this direction.

ISO 15189 is largely divided into Management and Technical requirements. Clause 4 deals with the establishment of a documented Quality Management System. Clause 5 stipulates technical aspects for implementing and maintaining the documented QMS established by the management.

The management and technical requirements together thus address the spectrum of activities involved in setting up a laboratory ethically and in the most technically sound way. It tracks the samples from the point of registration through collection, analysis, error prevention and detection, corrective and preventive actions, to reporting and sample discarding. Equipment and inventory management are addressed comprehensively. Safety of the operator, community and environment are stressed constantly.

The standards emphasize the mechanism for staff accountability, development and competence. It also dwells on self-monitoring using Quality Indicators to enable continual improvements of the system over a period of time, by ironing out the bottlenecks encountered.

Continued conformance to the standard thus helps a lab in establishing, implementing and maintaining a well-documented and continually improving Laboratory Quality Management System.

In the Indian context, Ministry of Health & Family Welfare has released Indian Public Health Standards (IPHS) that mandates minimum service provision along with the corresponding Human Resource and Infrastructure required for specific levels of public health facilities. Subsequently, MoHFW has issued National Quality Assurance Standards (NQAS) that defines requirements for public health facilities in terms of Structure, Process & Outcome. NQAS defines quality standards in terms of eight areas of concern namely Services Provision, Patient Rights, Inputs, Support Services, Clinical Care, Infection Control, Quality Management and Outcome. Explicit assessment tools have been developed incorporating requirements of these standards and these are being used extensively for the quality assurance under National Health Mission. These tools enable objective assessment and scoring of facilities that can be used for gap identification as well as tracking quality improvement activities. There is an institutional framework at Central, State and District level to support this initiative.

What is the difference between a standard and a guideline?

Implementation of the quality standards is supported by guidelines. When standards tell you “what to do”, guidelines tell you “how to do”. Internationally, Clinical and Laboratory Standards Institute (CLSI) gives guidelines for each of the activities specified in the standard. CLSI guidelines are also used to build up the lab QMS, independent of the ISO 15189 standard. Each of the Quality System element needs further detailing to effectively operationalize it.

How a Quality Management System is established, implemented and maintained?

A laboratory management when it decides to comply with the quality standard is also required to facilitate its implementation by training and provisioning of basic requirements.

To develop a Quality Management System it is important to have full support of the higher management. It is at this level the scope and activities are planned. The higher management decides on the structure and functions of the QMS.

First and foremost they have to decide the standards which would be followed for arriving at the expected result. As part of the initial planning, a Quality Policy needs to be defined. This is an expression of commitment of the management towards quality. The management then stipulates components, which are to be addressed through the prescribed standards. These commitments and expressions are documented in the apex manual of the laboratory, called the Quality Manual. The Quality Manual expresses plan of the management towards establishing a QMS and tells the laboratory functionaries what to do.

At this stage the technical supervisory team takes over the execution. They define the procedures, both testing and non-testing, using standard and validated mechanisms. They also train, teach and evaluate the frontline staff on the plans of the higher management and procedures for achieving those plans.

Once the mechanisms of execution and implementation are understood, the frontline staff maintains the QMS by following the standard procedures laid down by the technical supervisory level. They maintain evidence of all activities by recording their actions on formats issued to them for the same.

The Quality Manager engages with all levels of functionaries and facilitates all the processes described. Measurable Quality Objectives are also decided by the higher management through discussion with all levels of functionaries. Timelines and indicators are set for the same. Monitoring is done for the same as per set lab policy.

The above process thus indicates establishing, implementing and maintaining a Quality Management System.

Quality Management System as per ISO 15189 (Fig. 3.3)

Organization

i. Statement of commitment to quality through the quality policy and defining the Scope of laboratory services

ii. Organizational structure to ensure quality, the designation of a quality manager and possibly a quality oversight group

iii. Effective implementation of the QMS through quality manual and integration of QMS activities, allocation of resources

iv. Planning for quality by defining quality goals and objectives, periodic review of goals and objectives, quality planning / fulfillment of quality policy

v. Ensuring legal and ethical conduct

Facility and Safety

i. Facility design and modification

ii. Space allocation, facility design and access

iii. Facilities use and maintenance

iv. Communication system

v. Safety programs

Personnel Management

i. Job qualification
ii. Orientation of new personnel to organization
iii. Management of personnel training
iv. Assessment of competence
v. Continuing education and professional development
vi. Personnel files

Purchasing and Inventory Management

i. Selection based on ability to meet requirements; technical specifications
ii. Purchase of materials or services, agreements, agreement review and amendments
iii. Approved supplier list, supplier, contractor and consultant evaluation
iv. Purchasing and use of referral laboratory services
v. Inspection and verification of received materials
vi. Storage and handling of materials
vii. Inventory management
viii. Identification and tracking of critical materials and services

Equipment Management

i. Selection Qualification and Acquisition
ii. Equipment qualifications, Installation qualification process, Operational Qualification process, Performance qualification process
iii. Calibration program
iv. Maintenance Program
v. Documentation and final disposition
vi. Equipment files and records

Pre-analysis

i. Patient Registration
ii. Information to Patients and Users
iii. Information to Collection Staff
iv. Pre Collection Activities
v. Sample Collection
vi. Sample Accessioning

vii. Sample Preparation

viii. Sample Dispatch

Analysis

i. Sample identification

ii. Selection of Procedures

iii. Validation of Procedures

iv. Verification of Procedures

v. Standard Operating Procedures

Assuring the Quality of Examinations

i. Internal Controls

ii. External Quality Assurance

iii. Inter Laboratory Comparisons through Referral Labs

Post Analytical Processes

i. Storage and Retention of Samples

ii. Review of Results

iii. Reporting of Results

iv. Report Attributes e.g. Biological Reference Ranges

v. Turn Around time

vi. Critical Alerts

Documents and Records

i. Document Management System

ii. Record Management System

iii. Document Control

Customer Focus

i. Identifying customers and their expectations

ii. Providing capabilities to meet customer expectations

iii. Measuring customer and user satisfaction (feedback)

iv. Recording and resolving complaints

Non-Conforming Event Management and Continual Improvement

i. Identification of non-conformities

ii. Corrective actions

iii. Preventive actions

iv. Continual improvement

Assessments

i. Internal assessment

ii. Quality Indicators

iii. Performance comparison

iv. Periodic reporting to lab management

A diagrammatic representation of above-mentioned attribute is given below.

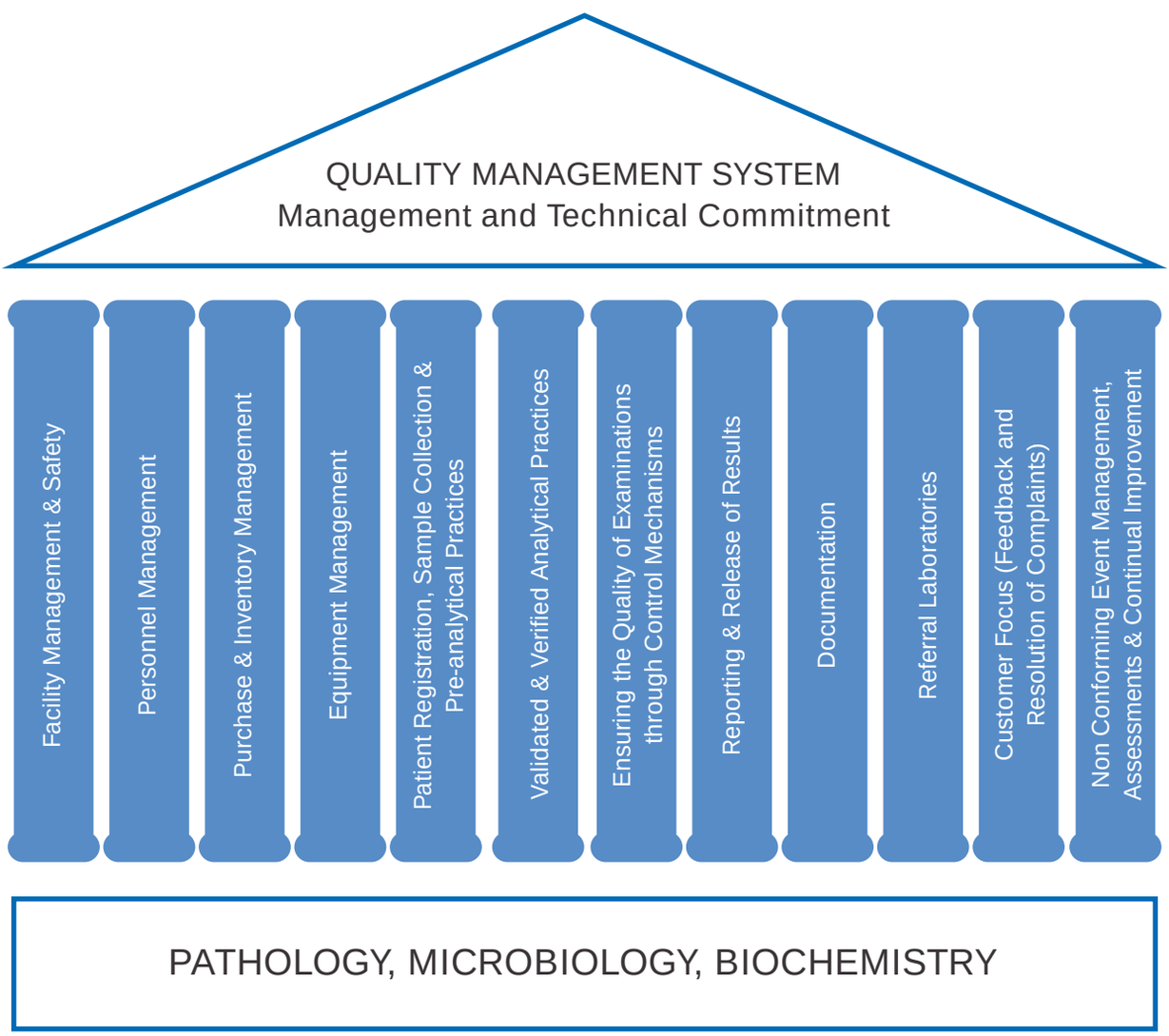

Fig. 3.3: Quality Management System as per ISO 15189

The laboratory is thus, a multi-part system, involving many steps of activities and people. The complexity of the system requires that many processes and procedures be performed at different levels as per standards and guidelines. Therefore, the QMS model, which looks at the entire system, is very important for achieving good laboratory performance as delineated in the figure no 3.4.

The technical approach described here includes advocacy, training, mentoring and handholding of all levels seen in the hierarchy depicted.

The higher administrative level in a district hospital will include the state level functionaries like MD NHM, DHS and Medical Superintendent who will pronounce the management commitment towards the establishing of a Quality Management System. This commitment expresses the will for planning and providing men, material, machines and mechanisms for implementing and operationalizing the QMS. The higher administration will delegate the responsibility for further planning and implementation to the institutional heads who will frame the policy documents which then will be read and understood by all stakeholders. Further sensitization and dissemination of information will be done through regular stakeholders meetings and advocacy.

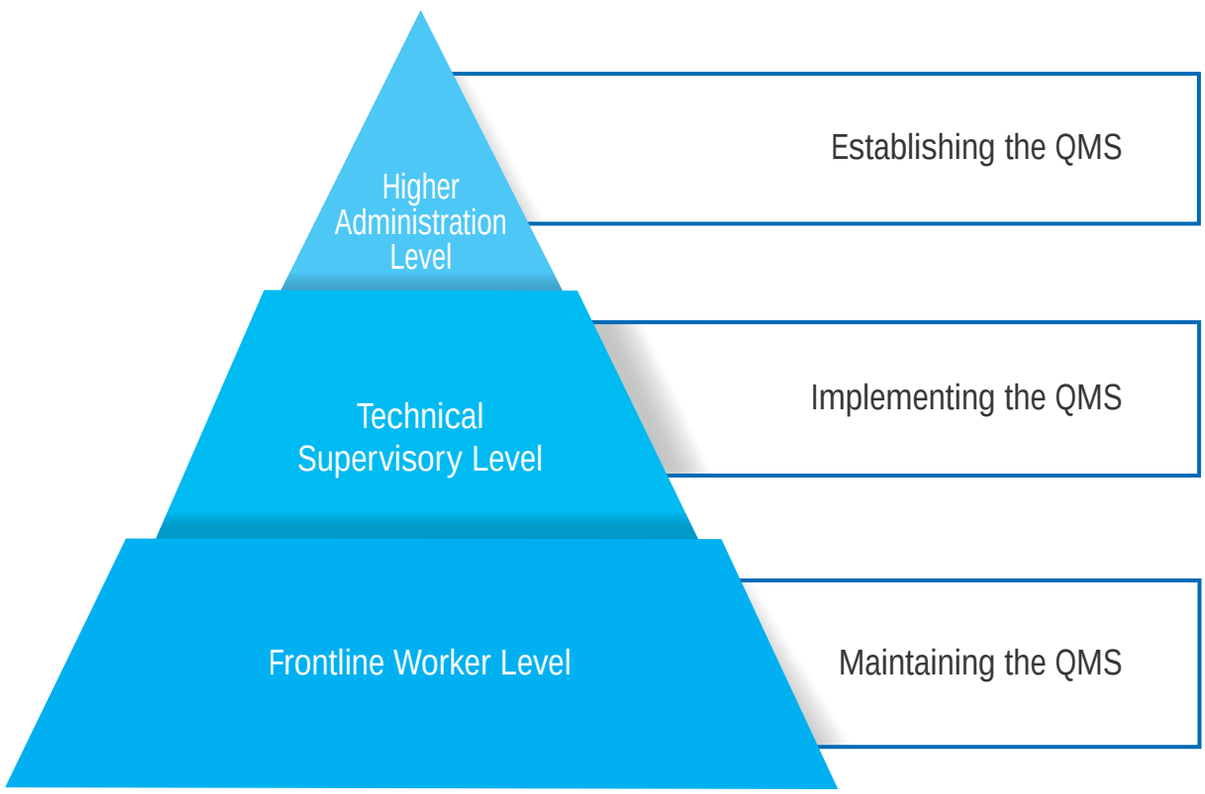

Fig. 3.4: Flow of Authority in a QMS

The technical supervisory level plays the pivotal role as all the inputs from the higher administration hinge on this level for implementation so as to get translated into outputs. Training, motivation and commitment of this level are vital for the final outcome. This level should form the key participants at any Training of Trainers (ToT).

The frontline workers form the backbone in maintaining the QMS. The health and functioning of the lab depends on the dedication and motivation of this level. They should be the key recipients of the handholding and mentoring as well as onsite trainings.

The success of the technical approach thus depends on the deployment of the right category of staff for the right training and following up with adequate mentoring and monitoring. Thus, any technical approach in establishing a laboratory QMS involves a set of sensitization, training and capacity building activities at different levels within the laboratory, hospital and higher management.

04 GOALS AND OBJECTIVES

4. Goals and Objectives

Goal

To provide equitable and affordable quality laboratory services in all districts of India

Overall aim of the initiative is to strengthen the district hospital laboratories and improve the quality of laboratory service provision.

The specific objectives are:

- To bridge the gaps in infrastructure, manpower, equipment and reagents as required for delivery of services as mentioned in the Free Diagnostics Service Initiative.
- To build a culture of periodic quality assessment and action planning.
- To build institutional capacity and develop core competencies at all levels of laboratory functioning.
- To improve the quality of district level laboratories against set standards.
- To achieve quality certification and accreditation to NQAS and NABL respectively.

05 TARGETS

5. Targets

The targets of this Initiative are as shown:

Year	Targets
1	At the end of 1st year, staff of 100 laboratories to be trained.
2	100 laboratories are NQAS certified. 10 out of these to be NABL accredited. Additionally, staff of 250 laboratories to be trained.
3	250 laboratories are NQAS certified. 50 out of these to be NABL accredited. Additionally, staff of 300 laboratories to be trained.
4	500 laboratories are NQAS certified. 150 out of these to be NABL accredited. Additionally, staff of all remaining DH laboratories to be trained.
5	All laboratories are NQAS certified. 250 out of these to be NABL accredited. Refresher training for all staff of all laboratories.

06 ROADMAP

6. Roadmap

6.1 Overview of the Technical Approach

The approach towards achieving quality in laboratories will include gap analysis using validated check-lists, followed by state specific planning of interventions, implementation of the prescribed activities and, finally, reassessment. The cycle of assessment, gap analysis, prioritization, intervention and assessment will continue until sufficient capacities are built and a robust Laboratory Quality Management System is established.

Broadly the steps can be enumerated as (Fig. 6.1)

1. Team building
2. Gap Analysis
3. Planning for Interventions
4. Implementing the plans
5. Gap Analysis (Mid-term)
6. NQAS Certification / NABL Accreditation

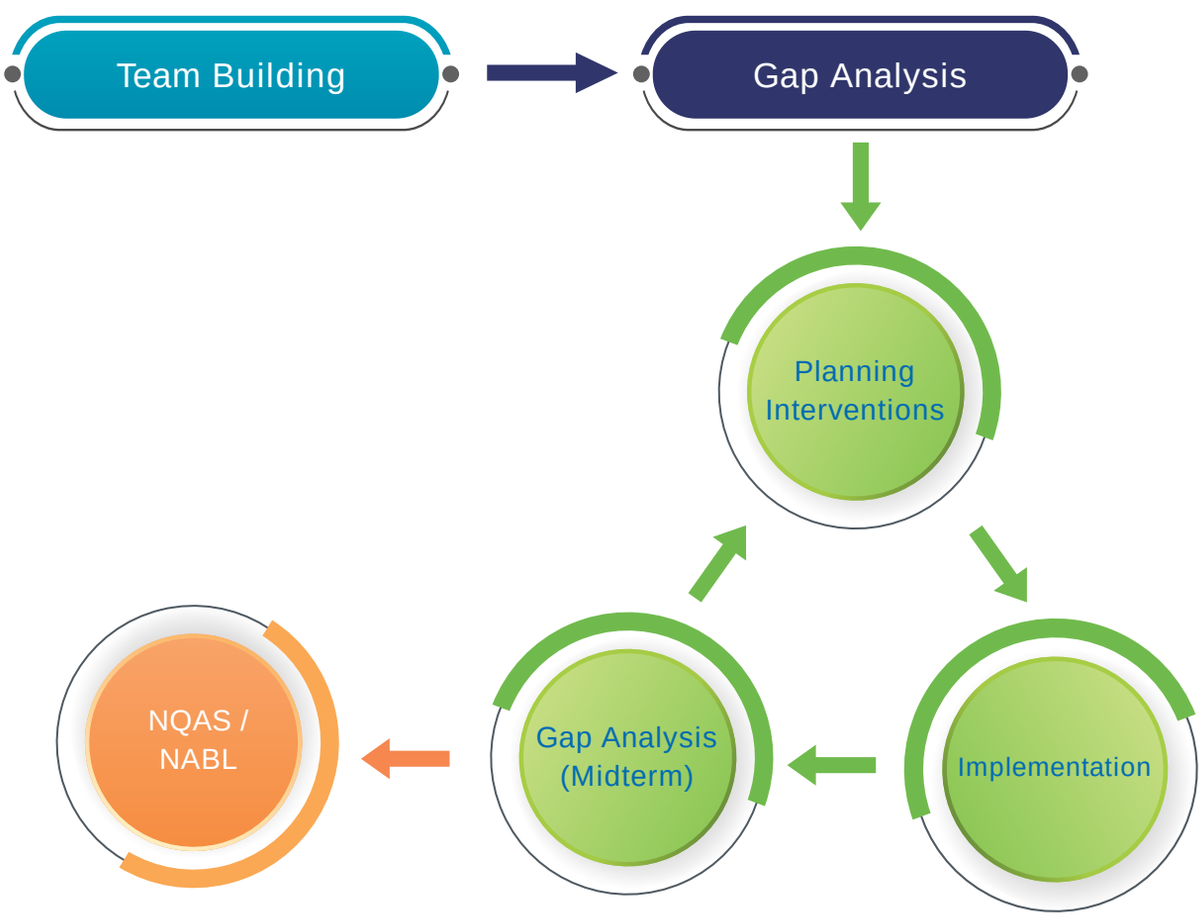

Fig.6.1: Approach to QMS Implementation

6.2 Gap Analysis

6.2.1 The Purpose and objectives of the Gap Analysis

The objective of the baseline is to identify the gaps, based on guidelines suggested by IPHS and Free Diagnostic Service Initiative for laboratory infrastructure and those suggested by NQAS for Laboratory Quality. This will enable two strategies for intervention.

For those labs that have already been assessed, lab specific scores are available. These can be utilized for activity planning. Such labs may directly go to section 6.3 for further details.

- The labs can be broadly classified on scales suggested below to plan broad avenues for interventions such as accreditation/ certification or Quality Improvement.
- Areas to prioritize interventions, both systemic and facility specific can be arrived at simultaneously through a detailed gap analysis.

6.2.2 Method

• The Excel based laboratory services checklist 13 of NQAS will be used for gap analysis.

• Assessors from the NQAP pool of Assessors will be used for these assessments. Those with a laboratory background will be more appropriate.

• All assessors should be oriented in the administration of the tool to ensure quality and uniformity of data.

• Approximately 6-8 hours of training is required to orient the assessors.

• Assessment Calendar for the state may be prepared and the process carried out over a period of one month.

• One full day will be required to do an assessment of an average District Hospital.

• Assessment for certification of laboratory against NQAS would be facilitated by NHSRC and criteria for the certification are given in the table 6.1.

Table 6.1 : Criteria for the NQAS Certification

Criterion 1	Overall Laboratory Quality Score shall be ≥ 70%
Criterion 2	Area of concern wise score shall be ≥ 60%
Criterion 3	Standard Wise Score shall be ≥ 50%
Criterion 4	Scores In Standards A3, C4, C6, D1, E12, F4, F6, G3, G4 shall be ≥ 70%

- Certification – If all four Criteria are met
- Certification with Conditionality – If at least two of four criteria are met, provided overall score is ‡ 70%
- Denied Certification – If less than two criteria are met

6.2.3 Outputs

- Overall scoring will direct the state to the broad avenues of intervention for immediate planning.
- Detailed gap analysis can throw light on facility specific areas of intervention.

6.3 Planning the Intervention

Once the gap analyses are done, the overall scores can direct the states towards planning interventions.

6.3.1 Planning Meet

A state wise planning meeting may be held under the auspices of the State Quality Assurance Committee (SQAC), and the chairpersonship of MD NHM, where the stakeholders are appraised of their responsibilities and timelines. An implementation plan may be drawn up to decide the directions. The state will assume the responsibility for filling the infrastructure gaps. The Quality System gaps can be addressed through NHM. The details regarding this are explained in subsequent sections. The resources for this may be planned through PIPs within the state's resource envelop of NHM. The Quality System Improvement will be subject to prior or at least parallel infrastructure improvement.

6.3.2 Deciding the Overall Strategy for the State

A layered intervention may be planned depending on the baseline scores (Fig. 6.2).

- Laboratories having less than 70% score will work towards achieving 70% benchmark in a stipulated time.
- Laboratories scoring more than 70% will strive to achieve NQAS certification at the earliest.
- Laboratories that achieved NQAS Certification would and strive for achieving NABL certification within 12-18 months.

The level and duration of interventions will differ from case to case. A step wise approach would be adopted to bridge the gaps as identified in the assessment.

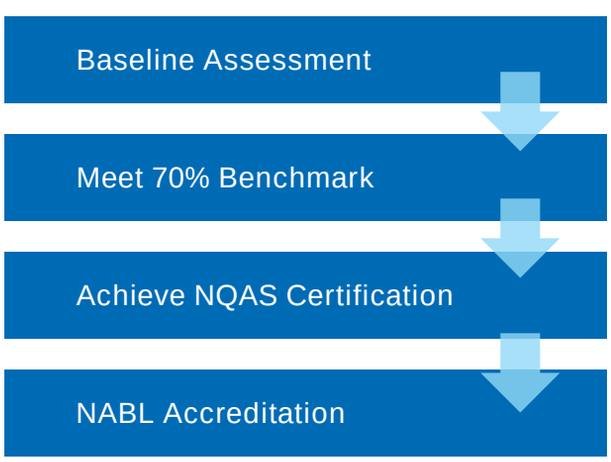

Fig. 6.2: Deciding the Overall Strategy

6.3.3 Deciding Facility Specific Strategy

Checklists are designed to objectively measure the compliance to the standard requirements and conduct a gap analysis. A full analysis of the gaps of each institute must be carried out and disseminated by the State Laboratory Quality Consultant. Besides the overall state plan, each institute must have a facility specific plan with timelines and responsibilities (Table 6.2).

Table 6.2: An illustrative list of functionaries involved in the planning meet; with responsibilities and timelines

Designation	Responsibility	Timeline**
MD, NHM	Oversee and ensure management commitment, infrastructure improvement, resources, enabling PIPs	
DHS	Oversee and ensure management commitment and infrastructure improvement	
NQLC	Coordinating the activities as per request from the state	
SPM and SQAC	Monitoring of rollout and implementation, enabling PIPs	
DMOs	Monitoring of rollout and implementation	
SLQC	Identifying master trainers, coordinating ToTs, Coordinating district level training and mentoring, advocacy, monitoring, coordinating provision of QC material, EQA, calibrations.	
Medical Superintendent	Responsible for facility specific interventions. Define Policy Statements, monitor implementation	
Laboratory Heads* (Authorized Signatory/ Technical manager)	Responsible for facility specific interventions. Implementing the trainings and assuming the responsibilities of Laboratory Director as stipulated in ISO 15189	
Laboratory Quality Manager*	Implementing the trainings and assuming the responsibilities of Quality manager as stipulated in ISO 15189	
DQAC	• Assistance in all activities as scheduled by LQIC and trainers and mentors • To attend the ToTs and become conversant with lab quality systems • To assist the laboratory personnel in developing and implementing the laboratory QMS	

* Can be the same person in small laboratories.
** Timelines to be defined at the planning meet, by the state.

6.4 Implementation of the Plan

6.4.1 Addressing Infrastructure Challenges

As suggested earlier, filling of the infrastructure gaps will preferably be dealt with at the state level. Any additional requirement will be dealt through the NHM PIP. This would include provisioning of space, staff, equipment and reagents. This should be done prior to, or at least parallel to quality improvement.

Improvement of basic infrastructure (Staff, Equipment, Test Availability, Laboratory Space and Design)

Staff: A rapid and representative situational analysis has pointed out the need for urgent interventions in human resource availability to bring numbers up to the prescribed limits. This needs to be addressed at the technical supervisory level as well as frontline workers' level such as technicians and lab attendants. Pathologists/ Microbiologists (Medical)/ Biochemists (Medical) may be in-sourced as per availability. By in-sourcing, it is meant the hiring of these technical people on a part time or an hourly basis. TOR for such in-sourcing is given in the Annexure 4.

Equipment availability seems to be fairly adequate for basic investigations, based on available evidence. However, it is crucial to address the gaps, if any, in all the participating facilities to make the initiative fully effective and functional. This can be done in a phased manner by making the basic investigations (high load/ labile analyte) available in the first phase and outsourcing the rest. The list of equipment is provided in Annexure 7, in which equipment in List 1 are required to be procured immediately. Procurement of equipment in List 2 of the annexure can be done subsequently in the next phase. Any lab currently fulfilling the criteria of phase 1 can move on to phase 2 immediately.

Equipment Calibration traceable to ISO 17025 is mandatory if NABL accreditation is sought.

Test availability can be defined as per the Free Diagnostics Service Initiative illustrative list. This again can be addressed as phases 1 and 2 (Table 6.3). Common tests like haematology, basic biochemistry, basic microbiology, serology and clinical pathology can be addressed in phase 1. Histopathology and bacteriology can be addressed as phase 2.

Table 6.3 : List of tests for phase I & II with reference to Free Diagnostics Service Initiative

Laboratory Discipline	Phase I	Phase II
Hematology	Hb, CBC, ESR, Prothrombin Time, Blood Grouping Peripheral Smear	Indirect Coombs Test, Direct Coombs Test, Bone Marrow
Clinical Biochemistry	Routine Biochemistry, as per Free Diagnostics Service Initiative (Except TSH)	HbA1c, TSH
Microbiology	Serology - Rapid Diagnostics Culture	Blood, Urine and Stool
Cytology	-	Exfoliative/scrape/FNAC
Histopathology	-	Histopathology
Clinical Pathology	Urine/Stool/Semen/Cavity fluids	-

Laboratory space and design may be kept in mind as per requirement. This may be done as per approved guidelines. A sample lab floor plan for a 100 bedded facility is given in Annexure 8.

6.4.2 Technical Capacity Building

The three salient activities to be included in the Technical Capacity Building are: training, handholding, mentoring and advocacy (Fig 6.3).

6.4.3 Training Methodology for Implementing QMS

The proposed capacity building model aims to develop and establish a pool of sustainable local resources. It is envisaged to develop a cadre of master trainers to carry forward and sustain capacity building initiatives. The total number of master trainers to be developed is approximately 90 to 150 depending on the requirement. This pool may be developed over a period of time in batches of 30 to 40. The master trainers can be located anywhere in India and will be available for imparting training as required. These trainers will then train select personnel of the district labs. Trained District Hospital staff will train the remaining staff of their labs.

Fig. 6.3: Activities for Technical Capacity Building

The following steps may be adopted for the required micro-planning.

6.4.3.1 Developing a Pool of Experts to orient the Master Trainers (Planning Level 1 training): to assure uniformity of training methods, mechanisms, areas and content. The suggested protocol is as follows:

a. Responsibility for developing this pool: National Laboratory Quality Consultant (NLQC)
b. Number: A group of 15-20 experts to be identified
c. Qualifications: MD/DNB in Pathology / Microbiology / Biochemistry / Laboratory Medicine. NABL Assessors, staff from reputed institutions, MoHFW, NHSRC and development partners with expertise in laboratory may be preferred.
d. Responsibility of the pool: Understand gaps, identify areas of concern, develop appropriate training material, and conduct Training of Trainers at central / regional / state level.
e. This identified pool may have attrition and will need to be reconstituted and re-oriented yearly.

6.4.3.2 Developing and Provisioning training material and mechanisms

a. Responsibility: NLQC
b. Training Modules on quality systems in consultation with the Pool of Experts. To be reviewed every 2 years for adequacy and appropriateness
c. Training guide or handbook for training in consultation with the Pool of Experts. To be reviewed every 2 years for adequacy and appropriateness
d. PowerPoint presentations in consultation with the Pool of Experts. To be reviewed every 2 years for adequacy and appropriateness
e. Worksheets and onward training material developed in consultation with the Pool of Experts. To be reviewed every 2 years for adequacy and appropriateness

6.4.3.3 Developing a pool of Master Trainers (Executing Level 1 training)

a. Responsibility for identifying this pool: NLQC and SLQC (National and State Laboratory Consultants)

b. Number: A group of at least 30 master trainers to be developed on a yearly basis. Developing a total pool of 90 -100 master trainers is proposed over a period of 3 years. This pool will be located anywhere in India and trained DH staff in all states as per requirement .

c. Nomination of master trainers would be facilitated by SLQCs. Adequate resources within each state will expedite the training cascading process.

d. Qualification for trainees: These trainees should be conversant with the quality system components, standard testing practices and aspects of laboratory functioning. They will comprise of doctors from all disciplines of laboratory medicine as well as Quality experts such as State Laboratory Quality Consultants. NABL Assessors from states/people with ISO 15189 orientations in Internal Audits and NQAS External Assessors will be extremely suitable resources. In case the state can constitute a group of NABL assessors, the duration of these Level I trainings can be shortened considerably. Good communication skills are mandatory.

e. As these trainers will be responsible for onward trainings, both the caliber and availability for conducting future training programs must be considered before nominating the suitable candidates.

f. They will be given orientation in all quality systems by the pool of experts, as suggested above

g. All SLQCs are to be trained in these ToTs to become master trainers.

h. Frequency and scope of training: 6-8 trainings in different components of lab quality system, every 2 months in a 12 months period as per gap analysis. However, a presumed list of topics is suggested in Annexure 10: Training Areas for QMS as per Objective and Audience table (Annexure 10).

i. Duration: 3-5 days

j. Site for Training of Trainers: Central/regional/state level

k. Composite refresher trainings for all topics will be required in subsequent years.

l. Attrition of this pool is also to be anticipated and additional resources trained accordingly.

6.4.3.4 Organizing State or Regional level ToTs (Level 2 training)

a. Responsibility: SLQC

b. Frequency: 6-8 Training, every 2-3 months in a 12-15 months period (Corresponding to orientation of the Master Trainers)

c. Duration: 3-5 days

d. Trainees: District hospital staff, including any in-sourced doctors, and at different levels of operation. As per Training Areas for QMS as per Objective and Audience table (Annexure 10). In addition, the DQACs may also be trained.

e. An assumption that 10 staff may be trained per district is being made, and is as shown in the table 6.4.

Table 6.4: No. of Staff to be Trained Per District

Administrative (From DH)	Laboratory Director (From DH/ Insourced)	Quality Manager (From DH)	Laboratory Technicians (From DH)	DQAC (From NHM)
1	1	1	6	1

f. Laboratory Director (Technical Manager), Quality Manager and DQAC will attend all the trainings.

g. Administrative Staff and Laboratory Technicians may be deployed for relevant trainings.

h. Additionally, laboratarians from Medical Colleges may also be included, if available, in these trainings as they can be effective resource people for mentoring.

6.4.4 Training Methodology for Standard Practices: E-Learning

A blended training program adopting online training methods such as webinars and approved e-learning videos can be adopted. States and districts with poor internet connectivity can undergo only offline trainings. Webinars can be conducted, need based, on technical areas shortlisted and approved by the national unit. The webinars will be conducted using existing pool of resources and the national unit will gradually develop competencies at state level to conduct such webinars (Fig 6.4).

6.4.5 Mentoring: Implementation of QMS in District Hospitals

Responsibility: Laboratory Director / Technical Manager, Quality Manager, DQAC, all staff trained at Level 2 Trainings (Fig 6.4).

Trainees: All Laboratory staff of District Hospitals to be trained including those from National Programs. This will enable optimum workforce development and utilization. Additionally, relevant trainings must be given to administration, store-in-charge, housekeeping staff etc. as the scope of the topic may be.

Trained DH staff/ DQAC have to take the trainings to the institution and implement them fully. Assured support of DQAC till the first accreditation must be planned for. Additional mentoring by the trained State level trainers will be good if it can be made possible. The key areas that need handholding will be implementation of robust QC practices and creating the documentation process to implement and evidence a QMS.

Additionally, with the lab strengthened towards accreditation, the lab will need assistance in the application process and run up to assessment.

District Hospital Team

Forming a Quality Team for Laboratory, Designation of Laboratory Director, Technical and Quality Managers

District Quality Team: DQTs are bodies functioning at District Hospitals for quality improvement. As per "Operational Guidelines for Quality Assurance in Public Health Facilities", District Hospitals are expected to have formed this team. At present the I/C Laboratory Services is expected to be a part of the team. The Quality Manager and a Senior Technician are also recommended to be part of the initiative.

Laboratory Director

ISO 15189 requires the availability of a Laboratory Director with powers and responsibilities as defined in clause 4.1.1.4 of the standard. "The responsibilities of the laboratory director shall include professional, scientific, consultative or advisory, organizational, administrative and educational matters relevant to the services offered by the laboratory". Broadly, it can be stated that the responsibilities can be divided into Technical and Administrative. In the case of district hospitals, these responsibilities can be shared and communicated through internal orders and documented in the Quality Manual. The administrative responsibilities can be performed by the Medical Superintendent or equivalent and the technical responsibilities by the laboratory in-charge (Pathologist /Microbiologist / Biochemist).

Requirement of NABL 112

1. In the case of a laboratory where there are more than one person designated as Laboratory Director, one of them should be available to ensure that she / he is responsible for overall operations.

2. In a hospital setting or in a large or very large laboratory, each department / discipline may have a separate head. However, one of them, represented as Laboratory Director shall be available at all times for consultation.

Most importantly, there should be signing authorities as per load and scope. The lab Director (Technical) will also be a signing authority for reports along with other doctors as per delegated authority.

If the lab has no qualified doctor, it may in-source qualified personnel to undertake such responsibility. By in-sourcing it is meant, the process of hiring a part-time consultant for the supervision of the testing and quality aspects of the lab. Draft ToR for hiring is provided in Annexure 4. In such cases the decisions on assigning directorship must be made by higher management and communicated through appropriate order.

Quality Manager: ISO 15189 requires the availability of a Quality Manager as per clause 4.1.2.7. All labs should nominate a designated Quality Manager. He/she should

be available full time for the maintenance of the quality systems. Hospital Managers available within the district hospitals may be designated as lab Quality Managers, assigned the appropriate job descriptions and be trained in ISO 15189 to understand the specific requirements of QMS. This may be adequately communicated through internal orders.

Requirement of NQAS

Under the National Quality Assurance program, it is expected that explicit requirements under laboratory checklist are met in each of the eight (08) areas of concern. Availability of services, including the availability of selected investigation facilities for managing emergency patients on 24X7 basis, and investigations required under National Health Programs, is critical for implementation of Quality Management System and subsequent certification to NQAS. Special efforts will be required for ensuring respect for patient's rights, safety, and equipment maintenance program. District Hospital laboratories will be expected to join External Quality Assurance Programs run by reputed institutions, such as AIIMS, New Delhi and CMC, Vellore.

Roles and Responsibilities

Implementing all Quality System Components

Assurance of the implementation of Quality Systems is the responsibility of the Laboratory Director

Training: A detailed calendar for each institution is vital. A reinforcement training plan for the areas covered in the ToTs (Level 1& 2 trainings) is required to be developed and conducted. All areas described under the table; Training Areas for QMS as per Objective and Audience, must be addressed. This has to be done repeatedly till it becomes part of the routine activities. Both Laboratory Director and Quality Managers should assume responsibility for this.

Documentation: The Quality Manager will be in charge of developing documentation. Assistance from the upper management as well as Laboratory Director and other signing authorities must be provided to him/her to undertake this job. All levels of staff should extend their support and cooperation for this to be effective. The apex document of a lab is the Quality Manual. This is prepared by the Quality Manager in consultation with the higher authorities. The second level of documentation for non-testing activities, Quality System Procedures (QSPs) is also the responsibility of the Quality Manager. The second (testing activities) level documents, SOPs, and the third level documentation are the responsibility of the technical team headed by the Laboratory Director.

Technical Supervision: Daily reporting and authentication of reports, overseeing the quality control and all testing practices, will be the responsibility of the Laboratory Director and other signing authorities.

01

- Formation of a pool of experts (15-20) (NABL Assessors/Reputed laboritarians/MoHFW and Development Partners/NHSRC)

02

- Level 1 Training: (Objective: Training in QMS, To develop Master Trainers)
- Training of Trainers at the central/ state/ regional level.
- Trainers: Pool of Experts
- Trainers per session:(2-4)
- Trainees per session (30): State level people as specified under 6.4.3.3
- Number of Trainings: 6 quality system components will be addressed through ToTs every 2 months in a 12 months period

03

- Level 2 Training (Objective: Training in QMS, To Train DH Laboratory Staff, 10 people per hospital)
- ToTs at State level
- Trainers: Trained Trainers from Level 1 training
- Trainers per session:(2-4)
- Trainees per session (30): DH Staff including any in-sourced doctors, DQACs as specified under 6.4.3.4
- Number of Trainings: 6 quality system components will be addressed every 2 months in a 12 months period (Corresponding to orientation of the Master Trainers)

04

- Mentoring (Objective: To Train all DH Laboratory Staff, Implementation of QMS)
- At District Hospital Level
- Facilitators: Trained DH staff and DQAC
- Trainees: Remaining staff
- Implementation of training, documentation

05

- E-Learning (Objectives: Training in Standard testing Practices, Reinforcement Training in QMS)
- Learning videos and webinars will be made available
- Basic IT capacities must be provided to make this effective

Fig. 6.4: Summary of the Training and Mentoring Cascade

6.4.6 Advocacy, Sensitization

As the concept of Laboratory Quality is new in many parts of the country and its components are not yet familiar, advocacy and sensitization meets are very vital for success of the initiative. This must be planned and budgeted for adequately.

6.4.6.1 Advocacy Meets

Half yearly meets within the states are to be coordinated by the SLQC. The progress of the activities must be appraised to the MD, NHM / Director / DG Health Services . All stakeholders must participate to understand the progress and discuss difficulties.

6.4.6.2 Provisioning of Quality Assurance Mechanisms

Responsibility: SLQC and State Quality Assurance Committee and NHM

Timeline: Within 4-6 months of the planning meet

Assured provision of materials and mechanisms towards quality is vital. These include provision of process control materials like internal controls, registrations in Proficiency Testing or External Quality Assurance Initiatives, Equipment Management including calibrations, provision of consumables for standard collection practices, continuous reagent and consumable supply for analysis, provision of utilities like uninterrupted power supply, running water, climate control facilities, and computer and internet access for training purposes. This will be addressed through NHM PIP.

6.4.6.3 Assuring Supply of Reagents and Consumables

Responsibility: SLQC and State Quality Assurance Committee and NHM

It is important that the supply of required materials is made available in an uninterrupted way.

6.4.6.4 Equipment Calibrations, CMC and Downtime Management

Responsibility: SLQC and State Quality Assurance Committee and NHM

6.4.6.5 Programme Implementation Plan (PIP)

Responsibility: NQLC, SLQC and State Quality Assurance Committee

As many of the components of the initiative are addressed through NHM PIP source, it is imperative that timely, appropriate, accurate and adequately justified PIPs are submitted.

6.4.7 Assessments

Apart from internal assessment that is an integral part of laboratory quality, there would be periodic assessments within the state by DQAU, SQAU and external auditors.

Internal Assessments

The DQT in the district hospital is required to do the internal assessment to monitor progress and report to the DQAU. This activity must be done at least every quarter.

Assessment by DQAU:

DQAU would be required to assess the DH Laboratory independently every quarter to assess the progress. DQAU will help the laboratory in traversing their gaps and share its report with SQAU.

Assessment by SQAU:

SQAU would be required to assess the Laboratory independently half yearly to assess the progress. If all the criteria and norms are met, the laboratory is recommended for external assessment by national team.

6.5 NQAS Certification and NABL Accreditation

Any lab attaining 70% in these assessments should apply for NQAS certification. The SQAU would verify and support the laboratory in meeting the requirement for the laboratory's certification to NQAS. Subsequently the NQAS certified laboratory must prepare for accreditation to NABL Standards and apply for the accreditation within 6 months.

NABL accreditation is a process which is in continuation of the aforesaid capacity building and training. Once the lab is ready with its capacity building and documentation requirements, it must do an Internal Audit by an ISO 15189: 2012 trained person. Organizations like BIS conduct this training. Following the internal audit and closing of all non-conformances pointed out, a MRM (Management Review Meeting) must be conducted. The lab is now ready to apply for NABL accreditation. The process of NABL application is given as Annexure 1 & 2.

07 SAMPLE REFERRAL SYSTEM

7. Sample Referral System

An additional objective of the initiative is developing the DH laboratory to a level by enabling them to function as 'hub' for chain of laboratories, which are functional in the district. Laboratories at SDHs, CHCs & PHCs could send their samples to the strengthened & quality certified DH laboratory. The district hospital laboratories must enhance its capacities in terms of infrastructure, equipment, testing capacities, staff, accommodation and environment and quality management system, before it can become a referral centre. Additional inputs for this can be obtained from the approved sample referral guidelines on NHM. (Training topics are suggested in Annexure 10).

Successful implementation of this approach would require robust logistic system and IT support system. Samples are required to be packed in optimum condition, transported, and received in central laboratory, processing and communication of results done within the agreed time-frame to referring laboratory.

08 OPERATIONAL APPROACH

8. Operational Approach

8.1 Supervisory and Overseeing Teams

8.1.1 National Level

At the national level, MoHFW will oversee the activities of the team. Central Quality Assurance Committee (CQSC) will have a lab expert at the level of DDG (DDG Laboratory Services, NACO) who will direct the activities. The broad activities of this team are to oversee the quality assurance activities in the country, including laboratory quality.

8.1.2 State level

The existing SQAC will have a laboratory expert from the State Health Services as a member. The broad activities of this team are to oversee the quality assurance activities in the state, including laboratory quality.

8.1.3 District Level

The existing DQAC will have a laboratory expert from the District Hospital as a member. The broad activities of this team are to oversee the quality assurance activities in the district, including laboratory quality.

8.1.4 District Hospital Level

The existing DH Quality Team will have Pathologist/Microbiologist as a member. Biochemist is also added to the list. The broad activities of this team are to oversee the quality assurance activities in the hospital, including laboratory quality as elaborated in the “Operational Guidelines for Quality Assurance in Public Health Facilities”.

8.2 Implementation Team

8.2.1 National Level

National coordination will be done through the Quality Improvement (QI) division of the National Health System Resource Centre (NHSRC). The QI team will include a fulltime Senior Consultant, designated as National Laboratory Quality Consultant (NLQC), for the coordination of necessary activities such as coordination of baseline assessments, intervention planning and identifying a pool of experts to conduct Training of Trainers on multiple topics. The ToTs will be coordinated at the national level.

8.2.2 State level

State coordination will be done through the State Quality Assurance Unit (SQAU). The SQAU team will now include a State Laboratory Quality Consultant (SLQC) who may be a qualified personnel from the state cadre or could be recruited afresh. This will be a full time position.

The SLQC will have a good understanding of laboratory functioning and should function as a bridge between the different stakeholders. She/he must be invested with the authority and responsibility to coordinate the activities, evaluate implementation, and update the higher administration on the progress and problems concerning the program.

8.2.3 District Level

District coordination will be done through the District Quality Assurance Unit (DQAU). The activities will be coordinated by the District Quality Assurance/ Monitoring Consultant of the existing NHM QA structure. She/he will, additionally, be responsible for the laboratory quality improvement.

8.2.4 District Hospital Level

District Quality Team exists in the District Hospitals & equivalent health facilities. The scope of their activities will include laboratory improvement. The Laboratory Director and Quality Manager will be designated as mentioned in sub-para 6.4.3.5.

Table 8.1: Summary of approach leading to NQAS/NABL Accreditation

Activity Responsibility	Team Building for implementation	Baseline Assessment	Planning the Interventions	Implementation of the approach	Assessments & re-evaluation
National	NHSRC Senior Consultant under QI division	Planning	Support	1. Formation of pool of technical experts (Level I Planning) 2. Orientation of Master trainers by technical experts (Level I execution) 3. Level II training coordination 4. Provisioning training material 5. Coordinating Webinars 6. Advocacy 7. Supportive Supervision	Planning, assigning timelines and deciding on NQAS/ NABL
State	Laboratory Quality Improvement Consultant as part of SQAU	Planning and Implementa-tion	Gap analysis, prioritization, assigning responsibilities and timelines	1. Level II training planning and conducting 2. Advocacy 3. Provisioning of QA material 4. Supply Chain Management 5. Equipment Management 6. Coordinating Webinars 7. Supportive Supervision 8. PIP Coordination for this initiative	Planning, assigning timelines and deciding on NQAS/ NABL

District	DQAC to work as mentor for the DH	Facilitating the assess-ments		Mentoring	Application
Institution	Laboratory team under the leadership of the Technical Manager / in-charge and Quality Manager	Facilitating the assessments		1. Institutional level trainings by trained DH staff and DQAC 2. Mentoring by DQAC 3. Implementation of QMS: Laboratory Team	Application and readying for assessment

09 MONITORING

9. Monitoring

9 MONITORING

CQSC will review the progress of the initiative as per the schedule. NLQC placed in the NHSRC will monitor roll-out of the initiative.

A baseline assessment using laboratory checklist of NQAS will be conducted across all district labs in a calendered manner. Furthermore, in coordination with SQAC and DQAC the initiative will allow for semi-annual assessments of district labs using the same checklists. A state/district wise annual report on the assessments will be shared with national and state bodies appropriately.

Review of Key Performance Indicators (KPIs) of district hospital labs by SQAC / SQAU and DQAC / DQAU will be done as per the existing system, which is once in every six and three months respectively.

A standardized reporting format for Laboratory Quality Indicators will be used for monthly reporting by the district hospital labs. Monitoring elements for DQACs and SQAC are given in table 9.1. Indicators for laboratory performance are given in Annexure 6.

Table 9.1: Monitoring Elements for DQAC & SQAC

Key Performance Indicators		
Outputs		Outcomes
Measurable Elements	Frequency of Assessment	
District Hospital Laboratory 1. Started EQA / Proficiency Testing 2. Started IQC Program 3. Initiated Equipment Calibrations, AMC & CMC 4. Completed Documentation as per requirement 5. Carried out monthly Monitoring of Laboratory Quality Indicator	Quarterly	NQAS Certification NABL Accreditation
State 1. Percentage of District Hospitals in the state enrolled in the initiative	Yearly	No. of district hospitals labs that achieved NQAS certification

2. Percentage of District Hospitals with trained manpower 3. Percentage District Hospitals of the state where 3 out of 5 measurable elements (see row 1, column 1) score 100% 4. Percentage of District Hospitals of the state scoring > 70% in total score		No. of districts hospitals labs that achieved NABL accreditation
National 1. Percentage of District Hospitals enrolled in the initiative overall 2. Percentage of District Hospitals with trained manpower 3. Percentage District Hospitals where 3 out of 5 measurable elements (see row 1, column 1) score 100%, overall 4. Percentage of District Hospitals scoring > 70% overall	Yearly	No. of district hospitals labs that achieved NQAS certification as per defined target No. of districts hospitals labs that achieved NABL accreditation as per defined target

10 SUSTENANCE AND INCENTIVES

10. Sustenance and Incentives

Culture of Quality could only be built with consistent efforts and investments through reward and recognition, and continued hand holding support from national, state and district level. Incentives could be classified into monetary (Table 10.1) and non-monetary incentives.

10.1 Financial Incentives:

Table 10.1: Team Incentives

Team Incentives	NQAS Certification	NABL Accreditation
	INR 5.0 Lakhs	INR 7.5 Lakhs

Financial Incentives may be used for following purposes:

- 25% for the laboratory staff.
- 75% for improving working conditions and quality of laboratory service, for which support under other budget head is not available.
- Rogi Kalyan Samiti may take a decision on the usage of incentive funds.

10.2 Non-Financial Incentives:

- Felicitation of Certification/Accreditation at State level.
- Publication in local media and government publication.
- Preference in higher education, CME.
- Positive weightage during annual appraisal.

11 COSTING AND FINANCE

11. Costing & Finance

For the technical capacity building the primary allocations will be from the NHM through State PIPs.

The components of the initiative for costing are:

1. Personnel Cost: Cost for recruiting the key functionaries, at the central (1 person) and state (1 person each) levels.
2. National and State team mentoring visits: To be leveraged through the respective QI travel budgets. Required additional support may be reflected in NHM PIPs.
3. State level advocacy: The cost for this is to be leveraged through the respective QI budgets.
4. Administrative costs for Quality Improvement: The cost for this is to be leveraged through the state NHM PIPs.
5. Level I Training Planning (Expert pool formation, deliberations, resource material finalization, printing): In the first year it will be supported by MoHFW's development partner; Laboratories for Life Project. In subsequent years, it may be leveraged through National funds.
6. Level I Training (Master Trainer Orientation): In the first year it will be supported by MoHFW's development partner; Labs for Life Project. In subsequent years, it may be leveraged through National funds.
7. Level II Training (State/ Regional Training): The cost for this is to be leveraged through NHM PIP.
8. Institution wise mentoring costs: The cost for this is to be leveraged through the state NHM PIPs.
9. Equipment Cost: Filling the equipment gap to be addressed through the state funds and NHM PIPs.
10. NABL Accreditation costs: The cost for this is to be leveraged through the state NHM PIPs.
11. In-sourcing of Laboratory professional: To be addressed through the state funds / NHM fund.

Tentative costing of the initiative is given in Annexure 5. Government procurement /NHM rules for the procurement may be followed.

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13 ABBREVIATIONS

13. Abbreviations

AFMS	Armed Forces Medical Service
AIIMS	All Indian Institute of Medical Sciences
AMC	Annual Maintenance Contract
CGHS	Central Government Health Scheme
CHC	Community Health Centre
CLSI	Clinical & Laboratory Standards Institute
CMC	Comprehensive Maintenance Contract
CMC, Vellore	Christian Medical College & Hospital, Vellore
CME	Continuous Medical Education
CQSC	Central Quality Supervisory Committee
DH	District Hospital
DHS	District Health Society / Director of Health Services
DMOs	District Medical Officers
DQAC	District Quality Assurance Committee
DQAU	District Quality Assurance Unit
DQC	District Quality Consultant
DQT	District Quality Team
EQA	External Quality Assurance
ESI	Employees State Insurance Corporation
I/C	In-charge
IT	Information Technology
IDSP	Integrated Disease Surveillance Program
IPHS	Indian Public Health Standards
IQC	Internal Quality Control
ISO	International Organization for Standardization

KPIs	Key Performance Indicators
LT	Laboratory Technician
MD, NHM	Mission Director, National Health Mission
MoHFW	Ministry of Health & Family Welfare
MRM	Management Review Meeting
NABL	National Accreditation Board for Testing & Calibration Laboratories
NCD	Non Communicable Diseases
NHM	National Health Mission
NHSRC	National Health System Resource Centre
NLQC	National Laboratory Quality Consultant
NQAS	National Quality Assurance Scheme
PHC	Primary Health Centre
PPE	Personal Protective Equipment
PIPs	Program Implementation Plans
QA	Quality Assurance
QC	Quality Control
QI	Quality Improvement
QM	Quality Manager
QMS	Quality Management System
QSP	Quality System Procedure
SDH	Sub District Hospital
SLT	Senior Laboratory Technician
SOPs	Standard Operating Procedures
SPM	State Program Manager
SQAC	State Quality Assurance Committee
SQAU	State Quality Assurance Unit
TM	Technical Manager
ToT	Training of Trainers

14 GLOSSARY

14. Glossary

Accreditation	A formal process by which an Independent and recognized body, assesses and recognizes that a health care organization meets applicable pre-determined and published standards. Accreditation standards are usually regarded as optimal and achievable, and are designed to encourage continuous improvement efforts within accredited organizations. Accreditation is often a voluntary process in which organizations choose to participate, rather than one required by law and regulation.
Calibration	Adjustment or standardization of the accuracy of a measuring instrument, usually by comparison with a certified reference or standard.
Certification	A process by which an authorized body, either a governmental or non-governmental organization, evaluates and recognizes either an individual or an organization as meeting pre-determined requirements or criteria. Certification usually applies only to organizations, while certification may apply to individuals, as well as to organizations. When applied to individual practitioners, certification usually implies that the individual has received additional education and training, and demonstrated competence in a specialty area beyond the minimum requirements set for licensure.
Continual Improvement	A recurring activity to increase the ability to fulfil requirements. In continual improvement you improve a bit, sustain the development over a period of time and then go to the next stage, sustain and again improve and so on.
Checklist	A list used to ensure all important steps or actions in an operation have been taken. Checklists contain items important or relevant to an issue or situation.

External Quality Assurance	The term external quality assurance (EQA) is used to describe a method that allows for comparison of a laboratory's testing to a source outside the laboratory. This comparison can be made to the performance of a peer group of laboratories or to the performance of a reference laboratory.
Gap Analysis	Gap Analysis is used to evaluate each functional area in a project or business process to achieve a specific goal. It includes identifying key data or components that fit within the system and gaps that need solutions.
Key Performance Indicator	A quantifiable measure used to evaluate the success of an organization, employee, etc. in meeting objectives for performance.
Management Review Meeting	Management review is a formal meeting of top management with the purpose of reviewing and evaluating the effectiveness of the quality management system.
Mentoring	A process that helps in improving performance and achieving results. Its goal is to improve current and future management of outputs, outcomes and impact.
Quality	The standard of something as measured against other things of a similar kind; the degree of excellence of something.
Quality Assurance	The maintenance of a desired level of quality in a service or product, especially by means of attention to every stage of the process of delivery or production.
Quality Management System	A quality management system (QMS) is a collection of business processes focused on achieving quality policy and quality objectives to meet customer: It is expressed as the organizational structure, policies, procedures, processes and resources needed to implement quality management. Early systems emphasized predictable outcomes of an industrial product production line, using simple statistics and random sampling.

Quality Improvement	Part of Quality Management, focused on increasing the ability to fulfil quality requirements.
Quality Indicator	Measures that can be used to monitor and evaluate the quality of important governance, management, clinical, and support functions that affect patient outcomes.
Signing Authority	Officer or representative vested (explicitly, implicitly, or through conduct) with the powers to commit the authorizing organization to a binding agreement. Also called signing officer.
Training of Trainers	ToT is for teaching/training personnel practising as professionals in a given field who accompany trainees in their work environment. It covers a wide range of skills: knowledge specific to the field in question (general, technical or scientific) It also includes educational, psychological and sociological skills; management skills; familiarity with the world of work; and knowledge of training initiatives and target audience. Lastly it also covers training related to course design, organisation and implementation as well as the content of training activities, i.e. imparting knowledge, know-how and skills.
ISO Standard	A set of international standards providing guidance for quality in manufacturing and service industries; developed to help companies effectively document the quality system elements to be implemented to maintain an efficient quality system.
NABL	National Accreditation Board for Testing and Calibration Laboratories (NABL) is an autonomous body under the aegis of Department of Science & Technology, Government of India, and is registered under the Societies Act.

15 ANNEXURE

Annexure 1

Synopsis for QA up to NQAS Certification and NABL Accreditation

(The process of Implementation)

1. Aligning existing Institutional Framework for QA under National Quality Assurance Program with the "National Initiative for Public Health Laboratory Quality Improvement".

   Institutional Framework for Quality Assurance is already in place at National, State, District and Facility level. The same would be utilized for the initiative. However, existing Institutional Framework would be strengthened by:

   - Including a Laboratory Expert at the level of DDG (DDG Laboratory Services NACO) as member of Central Quality Supervisory Committee at National level.
   - Including an expert laboratorian from the state as regular member of State Quality Assurance Committee (SQAC).
   - Including an expert laboratorian from the district as regular member of District Quality Assurance Committee (DQAC).
   - Pathologist/Microbiologist/Biochemist will lead the Quality Team of a district hospital.

2. Empanelment of Assessors

   States and UTs have significant number of empanelled Internal and External Assessors for Quality Assurance. The same may be utilized for assessment of Laboratories.

   - Empanelled Assessors (Internal/External) with laboratory Background (Pathologist / Microbiologist / Biochemist / Senior Laboratory Technicians) would be preferred for assessment of Laboratories.
   - One Session on 'Laboratory Quality Management System' would be included as part of 'Internal Assessor Training' and 'Service Provider Training'.
   - One senior staff from Laboratory (Laboratory Quality Manager) would be a participant in 'Internal Assessor Training' and 'Service Provider Training'.

3. Training and Capacity Building

   At least one member of the Laboratory Team would be trained as an Internal Assessor and undergo "Service Provider Training". He/she would function as master trainer and further train all members of laboratory.

   For laboratories undergoing NABL accreditation, separate Internal Auditors Training on NABL by recognised Agencies like BIS would be organized.

4. Implementation of Quality Assurance at Laboratory Level

Quality assurance would be a continual and comprehensive cyclic process.

a. Formation of Quality Team in Laboratory:

This team would be a sub-group of Hospital Quality Team. The team should meet periodically to discuss Laboratory quality related issues.

b. Internal Assessment:

Initially internal assessment would be done using Laboratory Checklist of NQAS. Once certified, the assessments would be conducted using NABL Standards/Checklist. Irrespective of the checklist, "Action Plan" would follow internal assessment with three subsets of activities

i. Resource allocation for each gap

ii. Designating a person, responsible for the action.

iii. Time frame within which the gap would be traversed.

c. Client Satisfaction Surveys:

A quarterly feedback from would be taken on a structured format from Clients (patients and doctors separately). The feedback would be analysed to see which are the lowest performing attributes and further actions would be planned accordingly.

d. Key Performance Indicators:

Laboratory technicians would measure the indiacators mentioned in Area of Concern-H under NQAS with the help of available data and report it to higher authorities.

e. Rapid Improvement Events:

Rapid improvement event is quality improvement methodology where one or more areas of lab functionality are chosen for a more focused quality intervention with specific problem solving tools.

f. Standard Operating Procedures & Work Instructions:

For standardising the different processes of laboratory, Standard Operating Procedures would be documented and implemented. Specific Work Instructions would be developed for repeated activities. Then laboratory Staff would be trained on these SOPs and Work instructions.

g. Internal Quality Control & External Quality Assurance:

Laboratory would establish a robust Internal Quality control mechanism within Laboratory along with External Quality Assurance Program with reputed institutions like AIIMS, CMC Vellore and Proficiency testing.

h. Calibration and maintenance of Laboratory equipment:

All the equipment of laboratory should have preventive maintenance plan in place. All the equipment should be under AMC or CMC. All measuring equipment of laboratory should undergo annual calibration.

5. Assessment of Laboratories:

Apart from Internal assessment that is an integral part of laboratory Quality, there would be periodic assessments within the state by DQAU, SQAU and NABL Auditors.

a. Internal Assessments:

The DQT in the district hospital is required to do the internal assessment to monitor progress and report to the DQAU. This activity must be done at least quarterly

b. Assessment by District Quality Assurance Unit (DQAU):

DQAU would be required to assess the Laboratory independently every quarter to assess progress. DQAU will help laboratory in traversing their gaps and share its report with SQAU.

c. Assessment by SQAU:

SQAU would be required to assess the Laboratory independently half yearly to assess progress. SQAU would also support the laboratory where the support of the state is required. If all the criteria and norms are met, the laboratory is recommended for external assessment by national team.

6. National Certification and NABL Accreditation:

- Once the gaps are addressed, the DQAC may inform the SQAU for State level certification.
- On satisfactory cross check by SQAU, the SQAC would approach MoHFW for National certification.
- Certified, empanelled and independent Assessor/s would carry out external assessment. Central Quality Supervisory Committee (CQSC) would take final decision regarding certification.
- Every certified Laboratory will undergo Annual Assessment by SQAU and Re-certification, every three years.

NABL Audit:

After NQAS certification, the laboratory will conduct Internal Audit by an ISO 15189:2012 trained person. After documentation, traversing all gaps, conducting MRM and meeting other criteria, an laboratory will apply for NABL Accreditation. Certified auditors of NABL would conduct the Audit.

Periodic Surveillance and Re-certification Audits would be conducted as per Terms and Conditions of NABL.

7. Sustenance and Incentives:

Please refer Chapter 10 for details.

Annexure 2 A

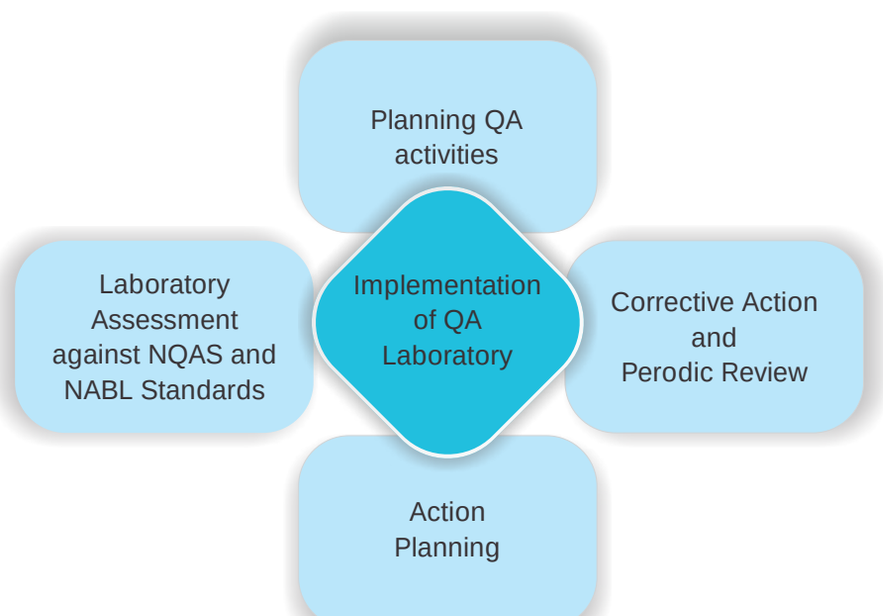
Roadmap for NQAS Certification

01 Aligning existing Institutional Framework for QA with the "National Initiative for Public Health Laboratory Quality Improvement"

02 Empanelment of Assessors

03 Training and Capacity Building

04 Implementation of Quality Assurance at Facility Level



05 Certification & Accreditation

I. Internal Assessment at Facility
II. DQAC recommends SQAU For state level Certification
III. Assessment and certification by SQAU
IV. Application to MoHFW/NHSRC on prescribed format (p. 86 of "Operational Guidelines for Quality Assurance in Public Health Facilities". Supporting documents to be enclosed as required on page 87, Hospital Data Sheets with Assessment scores by SQAU, DQAU and Facility (Internal Assessment) demographics and number of laboratory investigations per month).
IV. External Assessment by external assessors (NQAS)
V. NQAS Certification
VI. Preparation for NABL Accreditation
VII. Audit by NABL Auditors
VIII. NABL Accreditation

06 Sustenance and Incentives

Annexure 2 B

Roadmap for NABL Accreditation

NABL Accreditation

For NABL accreditation some processes need to be followed so as to demonstrate conformance with the ISO standard

1. Every laboratory should have a Laboratory Director or equivalent, with specified qualification and five years' experience (Table 2, 5.1, page 17-18 of NABL 112 Specific Criteria for Accreditation of Medical Laboratories issue 4, 9/5/2016)

2. Every laboratory should have a designated Quality Manager, specifically trained for 4 days in an NABET approved IA training in ISO 15189 Quality Management System, be a full time employee with defined responsibilities, as stated in ISO 15189:2012, clause 4.1.2.7 (NABL 112 Specific Criteria for Accreditation of Medical laboratories s, issue 4, 9/5/2016 page 12)

3. Every laboratory must have a Policy Statement and Policy Manual, i.e. the Quality Manual, as defined by the highest management and in conformance with ISO 15189:2012 and NABL 112. In the case of District Hospital laboratories, it imperative that the appropriate authorities stay invested in this process. The highest management should nominate individuals from one or more functional area/ section of the laboratories and a Quality Manager, having a background of Management Systems. This group should get fully acquainted with all NABL documents (free download) and understand the assessment procedure & methodology of making an application. Relevant requirements for NABL accreditation should be discussed amongst concerned staff of the Laboratories. The team should collectively make the effort to prepare the Quality Manual with the guidance of the Quality Manager. (NABL 160, Guide For Preparing A Quality Manual, Issue No. : 06, Issue Date: 19/4/16 may be used as guidelines.)

4. Once the Policy Statement and Quality Manual have been drafted in conformance with the ISO standard, the laboratory must ready itself in conformance with it, in both implementation and documentation.

5. The scope for accreditation have to be defined.

6. The ISO standard only tells you what to do. The "how to do" is derived through standard textbooks, CLSI & WHO guidelines, operator's manuals, kit inserts and other reliable sources.

7. Once the laboratory is prepared, an internal audit is to be conducted, preferably using NABL 217 Checklists. The IA has to be done by an auditor trained in ISO 15189 by an NABET approved agency.

8. A Management Review Meeting with all stakeholders needs to be done as a final step before application.

9. Once the above criteria are adequately met, the laboratory can apply for accreditation on form NABL 153 (3 copies). The Quality Manual (2 copies) also has to be submitted along with the application. (Application form for Medical testing Laboratories, Issue 5, 19/4/2016. The fee structure can be seen on NABL 100 General Information Brochure Issue date 21/7/2016).

10. NABL will scrutinize the application and designate a lead assessor.

11. Quality Manual will undergo an adequacy audit by the Lead Assessor.

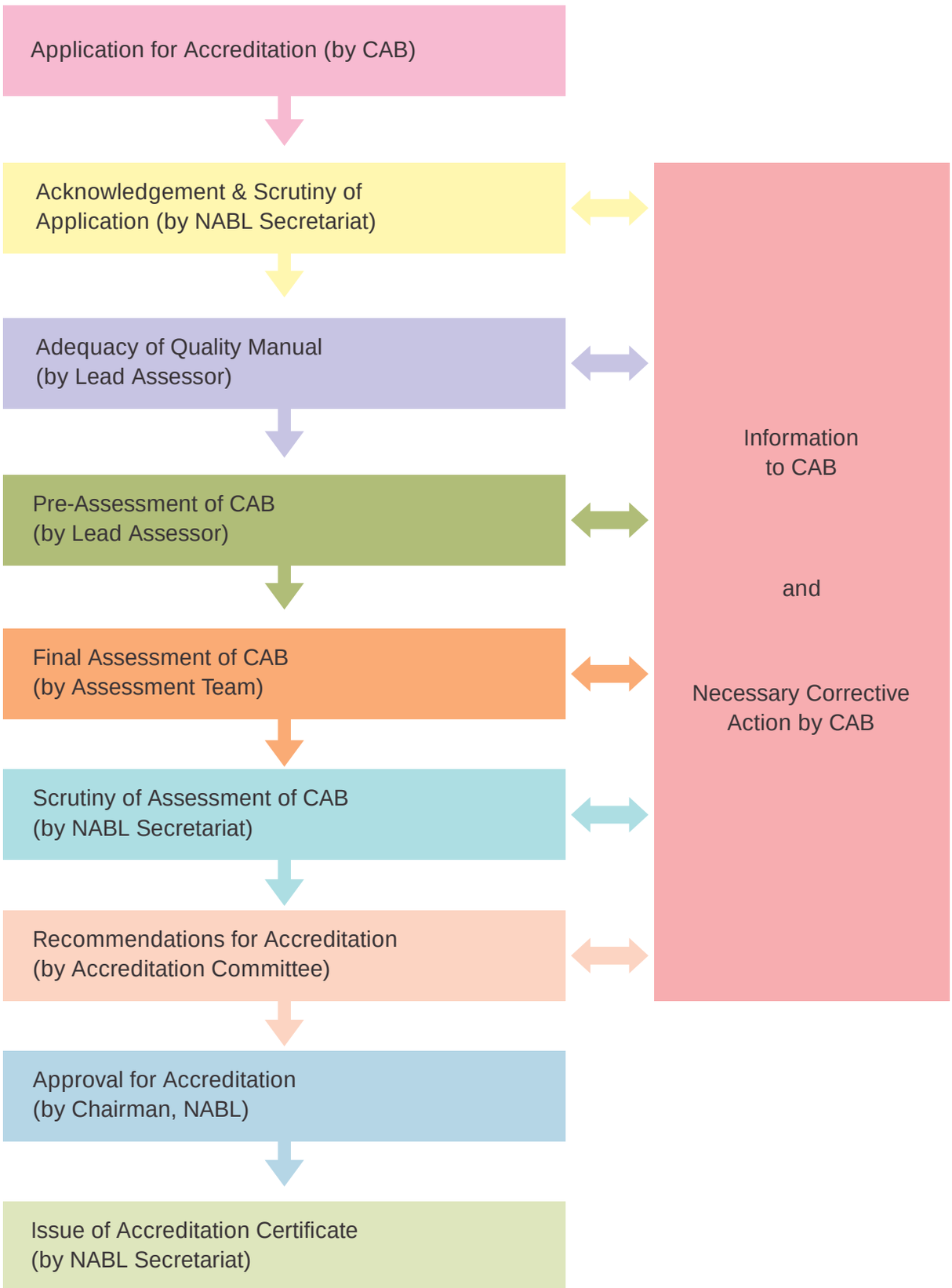
12. Once the Quality Manual has been judged adequate, NABL will set up a pre-assessment as per a formatted Checklist. (NABL 208, Pre-Assessment Guidelines and Forms Issue No: 02, Issue Date: 19.4.2016). This is a quick checking for the preparedness of the laboratory for accreditation. Non-conformances will be pointed out, with a specified amount of time for closure of the non-conformances.

13. Once the non-conformances are adequately addressed, the full designated NABL team (Lead assessor and technical assessors as per scope) visits the laboratory and a full assessment is done, generally lasting 2 days. (NABL 217, Assessment forms and checklist based on ISO 15189:2012, issue no 5, date 19/4/2016).

14. If the team feels the laboratory conforms to the standard, a recommendation will be made to the NABL for accreditation. Again, the non-conformances will be pointed out with a specified amount of time for closure of the non-conformances. Granting of accreditation will be subject to closure of these NCs.

15. Once NCs are adequately closed and certified by the NABL team, the technical committee of NABL will re-examine the process and finalize the grant of accreditation. Certificates of accreditation will be issued once the grant has been recommended by the technical committee.

16. The certificate is valid for 2 years. However, Surveillance Audits are conducted (onsite/off-site depending on the defined protocols), at the end of year 1, to assess continued compliance to the standards.



Flow Diagram of Accreditation Process

*CAB- Conformity Assessment Body

Annexure 3

ToR of Technical Functionaries

A. National Laboratory Quality Consultant (NLQC)

Essential Qualifications:

- MD/ DNB in any of the laboratory disciplines with 2 years of experience. Or DCP with 4 years of experience*
- Orientation in ISO 15189 as evidenced by Assessors or IA training
- Demonstrated evidence of establishing and implementing laboratory QMS
- Good writing and communication skills

*Experience may be relaxed in exceptional cases.

Desirable Qualifications:

Working in Public Health and awareness of national standards and guidelines

Responsibilities:

- The NLQC will be located in the NHSRC, New Delhi and will be reporting to the Advisor QI, NHSRC
- He or she will be responsible for spearheading the National Initiative for Improvement of District Hospital Laboratories
- He or she shall coordinate the baseline assessments in coordination with the states and facilitate gap analysis and intervention planning
- He or she will be responsible for drawing up a pool of experts for orientation of Master trainers in quality systems, will facilitate the development of training material and mechanisms
- He or she will facilitate state level ToTs (Level 1 training) as per request from states, with the assistance of the SLQC
- He or she will advocate with the central and state health departments regarding lab improvement mechanisms
- He or she will monitor the progress of the District Hospital laboratories and facilitate their application for certification or accreditation
- He or she will facilitate and track the PIP process with regard to laboratory improvements for all states

Recommended Emolument : 1, 25,000 Per Month

B. State Laboratory Quality Consultant (SLQC)

Essential Qualifications:

- MD/ DNB in any of the laboratory disciplines / DCP with 2 years of experience/MSc/ BSc MLT with 10 years of experience*
- Orientation in ISO 15189 as evidenced by Assessors or IA training
- Demonstrated evidence of establishing and implementing laboratory QMS
- Good writing and communication skills

*Experience may be relaxed in exceptional cases.

Desirable Qualifications:

Working in Public Health and awareness of National standards and guidelines.

Responsibilities:

- The SLQC will be associated with the State Quality Assurance Committee and Unit of the respective states and will report to the State Quality Assurance Office
- He or she will be responsible for spearheading the National Initiative for Improvement of District Hospital Laboratories in the respective state
- He or she shall coordinate the baseline assessments in coordination with the centre and coordinate gap analysis and intervention planning
- He or she will coordinate state level ToTs (Level 1 training) with the NLQC
- He or she will organize Level 2 trainings within the state for District Hospitals
- He or she will advocate with the state health machineries and district hospitals regarding lab improvement mechanisms
- He or she will assure supply of Quality Assurance material to the laboratories
- He or she will monitor the progress of the District Hospital laboratories and facilitate their application for certification or accreditation
- He or she will facilitate and track the PIP process with regard to laboratory improvements for the state

Recommended Emolument : Rs. 75,000 Per Month

Annexure 4

ToR for In-sourcing of (hiring of part time) Doctors

Qualifications: MD/ DNB in Pathology/Microbiology/Biochemistry/ Laboratory Medicine or DCP in Pathology

Responsibilities:

- The person shall be available for at least 4 hours a day and also in the event of any emergency
- He/she will be responsible for the supervision of all tests conducted in the lab
- He/she will be responsible for signing out all reports
- He/she will participate in the level 2 trainings specified in the document
- He/she will organize and conduct the level 3 trainings specified in the document
- He/she will support the documentation process especially with regard to development of the test SOPs
- He/ she will monitor the maintenance of equipment on a daily basis
- He/she will monitor the quality control results on a daily basis
- He/she will monitor the level 3 documentation of the lab with regard to documentation evidencing all QMS activities
- He/she will share the responsibilities towards accreditation requirements with regard to the ISO clause 4.1.1.4 Laboratory director (Please see next annexure) in coordination with the Quality Manager and higher administration

Pay Scale: Negotiable as per number of hours/quantum of testing/quantum of responsibilities assigned

Note: Hours of work as per NABL Clause 112

Small laboratories shall have an authorized signatory who shall be available at least for 4 hours on working days. When the authorized signatory is on leave, an alternative designated authorized signatory shall be available. Depending on the workload and complexity of tests a laboratory shall engage one or more full- or part- time authorized signatories. In a small lab working 24x7, there shall be at least one full time signatory.

Annexure 5

Costing

A. National Cost

Consolidated Cost - NHSRC (yearly in lakhs)					
Recruitment, Training					
Heads	Cost Yr. 1	Cost Yr. 2	Cost Yr. 3	Cost Yr. 4	Cost Yr. 5
Personnel Cost	276.00	276.00	276.00	276.00	276.00
Level I Training Planning Cost	24.70	24.70	24.70	24.70	24.70
Level I Training Cost	84.09	84.09	84.09	84.09	84.09
Total Cost*	384.79	407.88	432.35	458.29	485.79

In the first year s.no 2 & 3 will be supported by Labs for Life, a bilateral project of MoHFW-CDC. In subsequent years, it has to be budgeted through National funds.

Personnel Cost						
S. No.	Personnel Cost	Unit	Months	Per month	Amt. in INR	
1	National Laboratory Quality consultant salary	1	12	125000	1500000	
2	State laboratory Quality Consultant (State)	29	12	75000	26100000	State/ PIP
	Grand Total				27600000	

These are recurring costs. Travel of both kinds of Consultants will be borne through existing QI travel budget. Advocacy budget also to be sourced from the existing QI budget

Expert Group Orientation Program at Central Level

Orientation program for laboratories experts to understand the gaps in QMS of laboratories from gap analysis findings , to identify the resources, to finalize the training material and agenda of the training program and other capacity building activities .

Name of the particular	No. of people	No. of days	Sittings	Unit Cost (INR)	Total Cost (INR)
Consultancy charges/Honorarium/DA	15	1	4	6000	360000
Outstation travel	15	1	4	20000	1200000
Local Travel	15	1	4	3000	180000
Accommodation & Per-diem	15	2	4	5000	600000
Conference hall				10000	10000
Audio visuals				5000	5000
Tea & Lunch (Meeting Expenses)	25		4	500	50000
Printing charges of training module	25	1		1000	25000
Meeting kits	25		4	400	40000
Total Cost*					2470000

In the first year it will be supported by MoHFW development partner; Laboratories for Life Project. In subsequent years, it has to be leveraged through National funds.

Total Cost * - This cost pertains to Year 1, in subsequent years 6% escalation may be added.

Assumption: 15 experts must be available till The Initiative is over. An assumption that 5 may change every year is taken into consideration while calculating cost from year 2

Level I Training Execution

The aim of the level I training is to create master trainers from state levels. These master level trainers will further train the state level people in level II trainings. These trainings can be organized in any of the states/regions as per requirement. A series of 6 trainings will be organized to cover all aspects of QMS.

Particulars	No.	Days	No. of Trgs.	Unit Cost (INR)	Total Cost (INR)	Remarks
Cost of Experts / Trainer						
Consultancy charges/Honorarium (Trainers) class as per actuals	3	4	6	6000	432000	To & fro by economy
Travel – Consultants	3	1	6	20000	360000	
Accommodation & Per-diem	3	5	6	5000	450000	In govt. facility as per actuals
Participant cost						
Travel - Participants (Trainee)	30	1	6	4000	720000	By Train

Accommodation (Participants)	30	5	6	5000	4500000	In govt. facility as per actuals
DA for participants	30	4	6	1000	720000	
Conference hall	1	4	6	10000	240000	
Audio visuals	1	4	6	3000	72000	
Tea & Lunch (Meeting Expenses)	40	4	6	500	480000	
Local Travel (Optional)	1	4	6	6000	144000	Travel from accommodation to training venue
Color Printing of training manual	35	1	6	1000	210000	
Training kit	35	1	6	300	63000	
Contingency funds	1	1	6	3000	18000	
Total*						8,409,000
In the first year it will be supported by MoHFW development partner; Laboratories for Life Project. In subsequent years, it has to be leveraged through National funds. Total* - This cost pertains to Year 1, in subsequent years 6% escalation may be added.						
A pool of 90-150 Master trainers may be created as per requirement.						

B. State Cost

Consolidated Cost - State (yearly) Per facility						
S. NO	Particulars	Cost Yr.1	Cost Yr. 2	Cost Yr.3	Cost Yr.4	Cost Yr.5
Training, Mentoring and Procurement of Quality Assurance Material and Mechanisms						
1	Level II Training (ToT) execution in 6 areas	678500	0	0	0	0
2	Mentoring Cost per facility	60000	60000	60000	60000	60000
3	Admin & QC material cost per facility	418000	348000	348000	348000	348000
4	Refresher Training	0	10000	10000	10000	10000
	Total	1156500	418000	418000	418000	418000
Additional Cost (Variable, not included in the total)						
5	NABL Cost	0	340000	300000	300000	300000
6	Part time Insourcing of doctors, Variable, an indicative figure given. (Where in house lab doctor is not available)	720000	720000	720000	720000	720000
7	Filling equipment gaps	Variable cost				

Level II Training execution for (Staff From 6 labs, 5 participants per lab for 6 trainings)						
Particulars	No. of people	Days	No. of trainings	Unit Cost (INR)	Total Cost (INR)	Allocation
Master Trainers						
Consultancy charges/Honorarium (Trainers)	2	3	6	5000	180000	To & fro by economy class as per actuals
Travel - Consultants	2	1	6	20000	240000	
Accommodation & Per diem	2	4	6	3000	144000	In govt. facility as per actuals
Participant cost						
Travel - Participants (Trainee)	30	1	6	2000	360000	To & fro by economy class as per actuals
Accommodation Participants	30	4	6	2500	1800000	In govt. facility as per actuals
DA for participants	30	3	6	1000	540000	
Conference hall	1	3	6	5000	900000	
Audio visuals	1	3	6	3000	540000	
Tea & Lunch (Meeting Expenses)	40	3	6	500	360000	
Local Travel (Optional)	1	3	6	1000	18000	Travel from accommodation to training venue
Color Printing of training manual	35	1	6	1000	210000	
Training kit	35	1	6	300	63000	
Contingency funds	1	1	6	2000	12000	
Total for Staff from 6 labs, 6 trainings, 5 trainees per session						4071000
Cost per DH (Covering all areas of training)						678500

Mentoring Cost (by in-house staff trained in Level II)						
Particulars	No. of Personnel	No. of Days	No. of trainings	Unit Cost (INR)	Total Cost (INR)	Allocation
Stationery / Study materials	5	2	12	100	12000	State NHM PIP
Contingency funds	1	2	12	2,000	48000	State NHM PIP
Total cost for one facility					60,000	

Administrative cost Per District Hospital							
S. No.	District	Unit	Numbers	Per month	Amt in INR for 1year	Allocation	
1	Stationery & Internet	1	12	1500	18000	PIP	Monthly
2	Internal QCs, EQA for DH	1	1	300000	300000	PIP	Annual
3	Equipment Calibration for DH	1	1	30000	30000	PIP	Annual
4	IT Infra for DH	1	1	70000	70000	PIP	One time cost
	Grand Total (Institution wise)				418000		
5	Part time lab consultant (In-sourced)		12	60000	720000	PIP	Monthly
6	Filling Equipment Gaps			Variable			One time cost

NABL Cost (Per facility)		
S. No.	Components of Costing for NABL Accreditation	Total Amount (INR)
1	Internal Auditor Training (travel and stay included) per person	40,000
2	Application Fee	60,000
3	Adequacy Audit	5,000
4	Pre Audit	25,000
5	Accreditation Fee	60,000
6	Assessment Cost (travel, stay & honorarium of the team)	150,000
	Total cost for one facility	340,000

Annexure 6

Quality Indicator for Laboratory Monitoring

Following are suggested indicators to capture the quality of medical laboratories that can be captured as % defects

1. Pre-analytical: Non-Conforming Events/Incidents in sample collection

- No of patients with improper identification
- No of leaked containers
- No of blood stained forms
- No of hemolysed samples
- Lack of collection equipment/PPE
- Wrong containers
- Inadequate volume
- Improper transportation
- Clots in anticoagulated tubes
- Blood culture contamination
- Patient complications (Haematoma etc.)
- No. of complaints received in sample collection

2. NCE in Analytical

- No of reporting errors by technicians
- Lack of machine maintenance
- Inadequate calibrations
- Lack of internal controls
- Lack/Errors in Proficiency Testing
- Wrong sample identification
- Equipment downtime percentage
- Stock-outs

3. NCEs in post analytics

- No. of Transcriptional Error
- Critical Alerts violated
- Turnaround time violated

4. Safety Indicators

- Needle Stick Injury
- Improper Bio medical waste management
- Blood spillage
- Chemical spillage
- Lack of PPE (no of days not available)
- Lack of usage of PPE (no. of personnel not using PPE)
- No. of health care associated infections in the month
- Fire incidents
- Electrical/equipment related incidents

Annexure 7

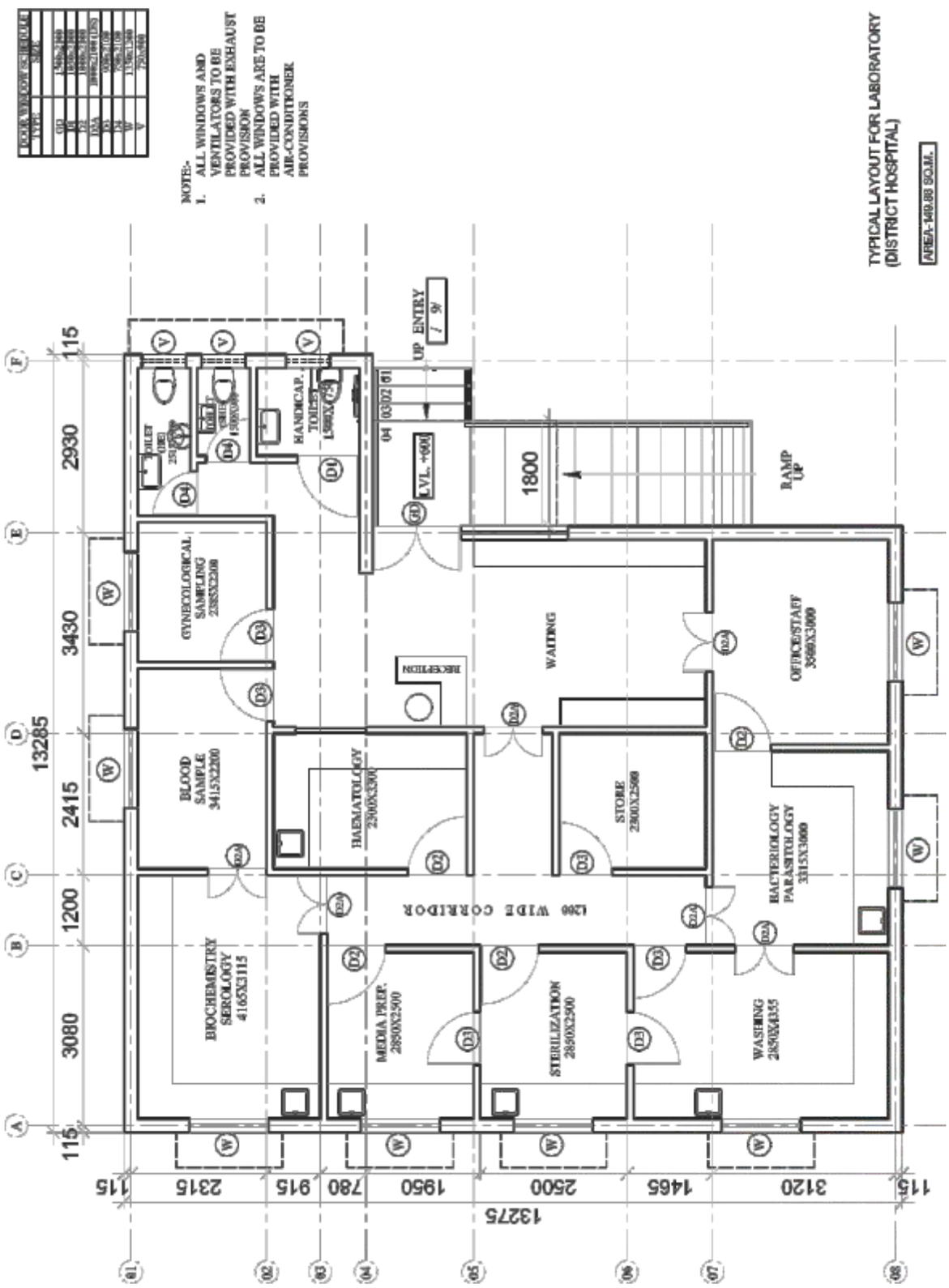
Equipment List

Equipment List 1 (For Phase 1 of The Initiative)	Equipment List 2 (For Phase 2 after demonstrated improvements like NQAS Certification)
Biochemistry - Electric Calorimeter - Semi auto analyser - Fully Automated Auto-analyser - Electrolyte Analyzer - Paediatric Bilirubinometer - Glucometer Haematology - Cell Counter Electronic - Coagulation Analyzer - TCDC Count apparatus - ESR Stand with tubes - Binocular Microscope Serology - Elisa Reader - Elisa Washer - Rotor/Shaker Supporting Equipment: General - RO Plant with resistivity / conductivity monitoring - PH meter - Thermo-hygrometers	Histopathology and Cytology - Hot Plates - Rotary Microtome - Wax Bath - Auto Embedding Station - Floatation Bath - Knife Sharpner - Grossing Station - Cytospin Bacteriology - Automated Blood Culture System - Automated Identification and Antimicrobial Resistance Systems - Biosafety Cabinet Class A2 - Laminar Flow Biochemistry and Haematology - HPLC System for HbA1c and Hb variants Additional Supporting Equipment - Automatic Glassware Washer Disinfector

- Thermometer with sensor - Timer Stop Watch - Alarm Clock - Laboratory Autoclaves - Ordinary Refrigerator - Air Conditioner with Stabilizer - Computer with UPS and Printer - Electronic weighting scale - Gas Burner - Centrifuge, Table Top - Water bath - Hot Air oven - Laboratory Incubator - Micro pipettes of different volumes - Test tube rack - Test tube holders - Spirit Lamp - Conical Flask - Beaker/Glass Bottles - Glass or plastic funnel - Glass Stirring rod - Small stainless steel bowl - Measuring Cylinder	

Annexure 8

Floor Plan for 100 Bedded District Hospital Laboratory



Note: A minimum 150 m^2 is suggested for a lab load 100 collections. This may be scaled up as per requirement.

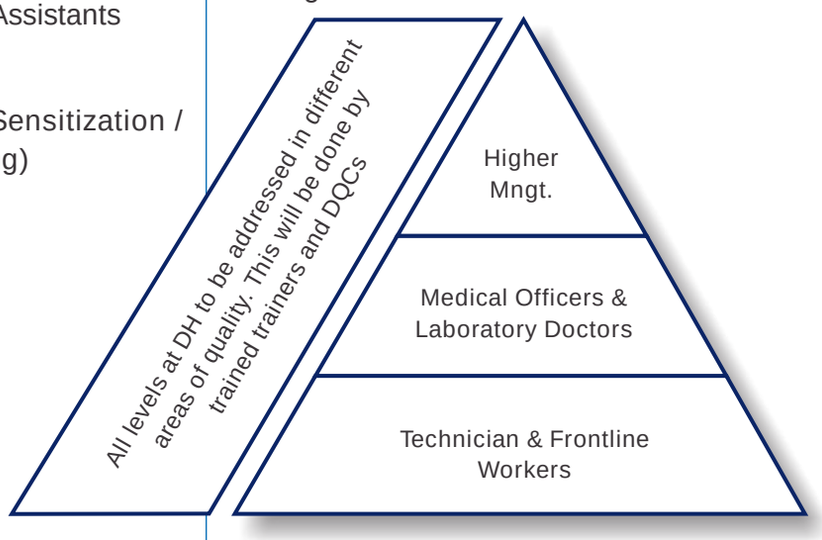
Annexure 9

Implementation Structure

Levels (Supervisory)	Levels (Implementation)	Scope of Work with emphasis on the training activities
National (Central Quality Assurance Committee) DDG Laboratory Services, NACO will be a member	NHSRC – QI Division Designated Sr. Consultant for Laboratory Quality Improvement: NLQC*	Will facilitate baseline assessments and gap analysis Will plan interventions in consensus with the states Will facilitate trainings as follows: An Expert Pool of 15-20 will be developed by national team This team will understand gaps and prepare plans, resource material to address them Will train master Trainers from states, in Level 1 trainings, in groups of 30, as per need Will facilitate midterm reviews and planning for NQAS or NABL

State (State Quality Assurance Committee) An expert laboratarian from the state will be a member.	SQAU Designated Consultant for Laboratory Quality Improvement: SLQC*	Will conduct baseline assessments and gap analysis with the support of the central team Will do the intervention planning meet and decide on interventions Will facilitate trainings as follows: Will conduct onward Level 2 trainings for District Hospital Staff of the state using the trained trainers from Level 1 Will address the appropriate levels of staff for training Will conduct advocacy meets Will coordinate mentoring and monitoring Will conduct midterm reviews and planning for NQAS or NABL

District (District Quality Assurance Committee)	DQAU (District Consultant QA/Quality Monitoring)	Will facilitate the baseline and midterm assessments Will support the DHT in its activities

Institutional District Hospital Team (Higher Administration Pathologists)	Higher Administration Pathologists Laboratory Technicians Laboratory Assistants (Training / Sensitization / Handholding) DQAU	Will conduct Level 3 trainings and implement the QMS in their laboratories. Will address the appropriate levels of staff for training 

*Positions to be recruited

Annexure 10

Areas of Training

Technical training will be largely evident after gap analysis. However, a few areas that are anticipated are as follows and may encompass 3 broad areas of laboratory functioning.

1. Standard Testing Practices
2. Quality Management System
3. Sample Referral Systems

This document details the training in Quality Management System only as this forms the first step of activities

Standard testing Practices (List of tests as per Free Diagnostic Service Initiative):

All tests that are being conducted in the DHs and IPHS suggested list of tests, will have to be reinforced to eliminate any non-validated and obsolete testing practices. As a certain amount of familiarity and capacities already exist, only correction of wrong practices and reinforcements are warranted. Onsite trainings and E-learning options may be the best mechanism to adopt in this regard. All staff, especially the frontline testing staff must familiarize themselves with these procedures.

Quality Systems:

These are new concepts in most labs and will need to be addressed through Training of Trainers, and a cascading mechanism of training and handholding. E-learning mechanisms will be made available in some of the areas. There are several major concepts embedded in this and are essential to build up an effective Quality Management System. A series of, at least 6, ToTs may be planned, each lasting 3-5 days. The learning from the ToT has to effectively disseminate through a cascading process of onsite trainings and mentoring discussed above. Adequate monitoring and evaluation mechanism has to be built into the training system.

The priorities can be set in each approach, depending on if a lab is going in for NABL, NQAS or Quality Improvement objective. Deployment of appropriate staff during the onsite training is vital for the correct and speedy implementation of the learning.

The essential components of Quality System where training will be required are:

Training Areas for QMS as per Objective and Audience:

	Area of Training	Target Audience
1.	Facility Management and Safety	Administration + Laboratory Director + QM + SLT + DQAC
2.	Purchasing and Inventory	Administration + Laboratory Director + QM + SLT + DQAC
3.	Equipment management	Laboratory Director + QM + SLT + LT + DQAC
4.	Sample Registration, Collection and Pre analytical best practices	Laboratory Director + QM + SLT + LT (Phlebotomy) + DQAC
5.	Quality Controls	Laboratory Director + QM + SLT + LT + DQAC
6.	Documents and records	Administration + Laboratory Director + QM + SLT + DQAC
7.	Post Analysis, Reporting	Laboratory Director + QM + SLT + DQAC
8.	ISO 15189: 2012	QM

Sample Referral Systems:

	Area of Training	Target Audience
1.	Establishment of Referral Network	Administration; District, Referring and Referral Laboratories
2.	Sample Collection, Storage	Referring Laboratory
3.	Sample Packing Transportation	Couriers
4.	Analysis, Reporting	Referral Laboratories
5.	Monitoring and Evaluation	Administration; District, Referring and Referral Laboratories

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