

National Health Laboratory Policy

Ministry of Health

Certification of Authorization

The National Health Laboratory Policy had been approved by the Cabinet Ministers of Democratic Socialist Republic of Sri Lanka, on 3rd December 2006. Subsequently the National Health Laboratory Services Act has been prepared with medium- and long-term strategies and monitoring indicators.

The government of Sri Lanka identifies health laboratory service as an essential component in the health care service it is committed to providing quantitative and qualitative essential laboratory support to health care providers. Both in patient care services and the public health sector, through a network of state and private health institutions. The Ministry of Health is responsible for the establishment and enactment of essential and relevant legislation and also for providing technical and managerial guidelines for the maintenance of laboratories in compliance with nationally and internationally accepted standards.

The proposed policy for laboratory services: Shall

- Be within the overall health policy
- Cover all medical laboratories in both state and private sectors. (including laboratories to be established for public health functions)
- Have a sound legislative and administrative support to monitor and regulate the activities pertaining to laboratory services.
- Encourage achievement and maintenance of laboratory standards accepted nationally and internationally and thereby obtain accreditation.
- Provide a framework for equitable, sustainable, cost-effective, accessible, safe, reliable, and valid laboratory support for the health service.
- Promote the rational use of laboratory investigations for a good quality healthcare service which is affordable to healthcare seekers.
- Promote medical research and teaching

Objectives of medical laboratory policy are to

1. Ensure the timely availability of reliable and valid diagnostic and analytical laboratory support, necessary to protect and promote the health and well-being of the people from communicable and non-communicable diseases or any other public health concern in an organized, equitable, sustainable, and cost-effective manner.
2. Ensure that a good quality laboratory service be provided to the people of Sri Lanka by the state as well as the private sector through achieving and maintaining laboratory standards accepted nationally and internationally.
3. Promote the rational and safe use of laboratory technology by healthcare professionals and consumers.

Areas covered by the policy

Laboratory standards

National standards will be developed in compliance with the Act of the Sri Lanka Board for Conformity Assessment and the standards set out by W. H. O. and the international standards organization, ISO 15189, and to implement accreditation in conformity with the Act of the Sri

Lanka Board for Conformity Assessment. The Ministry of Health and Sri Lanka Board of Accreditation for conformity assessment will work closely with the support of Laboratory experts to develop the standards and plan of action for achieving standards.

Scope of Laboratories

Scope of the laboratory should be decided by the institution which provides the service. Scope should express the type of investigations performed, level of reporting, and type of services offered. (E.g. consultant's advice on further investigations, giving expert opinion, educating communities on rational use of laboratory)

Management organization including human resource

Laboratory should be staffed with qualified technical personnel per norms established by the technical advisory committee and with medical professionals suitably qualified.

A consultant in laboratory medicine or in his absence the Head of the institution or his nominated medical consultant or properly trained laboratory scientist should be the head or the Executive of the laboratory. Flow of authority and command should be well established. The Ministry of Health together with the Post Graduate Institute of Medicine and the universities is responsible for planning and developing human resources in laboratory medicine. Continuous training and education of laboratory staff should be adopted as a practice as the technologies keep on improving every day. There should be identified centers for training in laboratory medicine and technology.

Affordability and Ease of Access

Cost-effective tests be encouraged. Receipt of samples and issuing of reports should not be restricted merely on time but should be decided according to urgency. The laboratory should be accessible at any time of the day for relevant investigations required for the immediate management of patients. All possible tax concessions should be offered to license laboratories for the import of equipment and consumables, in order to minimize the cost thereby increasing the accessibility for such services. A pricing policy/mechanism for monitoring the charges should be adopted.

Safety and staff welfare

There shall be a mechanism in operation for the disposal of potentially infectious waste and other hazardous products of chemicals used in the Laboratory for testing of clinical samples. Healthcare workers would need to have personal protective apparel, equipment, and adequate immunizations. Practicing of universal/ standard plus extended precautions must be strictly enforced and monitored. Facilities should be made available within the laboratory to ensure the physical and mental comfort of laboratory staff such as changing rooms, eating rooms etc.

Equipment and supplies

Equipment required at various laboratories in compliance with its scope should be identified by the Technical Advisory Committee and the Ministry of Health will ensure supply of same to state sector labs. A sound purchasing policy should be enacted to ensure the selection of appropriate technology which is affordable and sustainable. The state should centrally bulk purchase and through its network, supply equipment and consumables to the relevant institutions in the state sector. Proper management of the supply chain and regular maintenance of equipment would need to be enacted. Regular Maintenance checks and repair of equipment must be ensured by maintaining, the operator's logbook, equipment maintenance, and calibration register. A team of management at the central level should take the responsibility of supervising these activities

Regulation and Quality Assurance

All state and private sector Laboratories would be licensed by a regulatory authority duly established by law on the recommendations made by the Sri Lanka Accreditation Board for Conformity Assessment based on inspections as per requirements in the standards on an annual basis. If standards are maintained extensions need be granted. The authority should have the power to close down laboratories which are not functioning up to the required standards. Internal quality assurance system as per required by the agreed standards should be enforced strictly in each laboratory, to ensure continuous licensing. A written quality manual with standard operative procedures for all important activities must be maintained.

A National External Quality Assurance Scheme (NEQAS) shall be in operation at the central level. Periodic checking of quality by NEQAS would ensure the quality functioning of satellite laboratories linked to this scheme. If accuracy deviates significantly from the expected norms or if there is a complaint with regard to accuracy investigation to check on deviation needs to be carried out in order to correct them. Regular calibration of equipment with upward traceability must be ensured.

Research Teaching and Training

There should be resources and incentives for research. Contract research should be in keeping with the standards of the funding agency while satisfying government regulations. The research could be extended to investigate local norms and compare internationally. System research should be encouraged using routinely available data.

Monitoring and Evaluation.

Implementation of the National Laboratory policy would be monitored by a Technical Advisory Committee (TAC) comprising of various stakeholders at the level of the Ministry. Internal audits will be conducted by teams appointed by this TAC, in view of evaluation and correction of any shortcomings. Accreditation of laboratories would be affected by an independent team of external auditors effectively trained for assessment by the Sri Lanka Accreditation Board for conformity assessment. This team could recommend the erasure of the license if acceptable standards with adequate staff are not maintained. The TAC is responsible for giving terms of reference and criteria for specific activities of the bio-engineering service, accreditation team, NEQAS officials and help in resource development