

National Health Laboratory Policy

Certification of Authorisation

The National Health Laboratory Policy had been approved by the Cabinet Ministers of Democratic Socialist Republic of Sri Lanka, on 01st December 2006. Subsequently the National Health Laboratory Services Act has been prepared with medium- and long-term strategies and monitoring indicators.

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

The proposed policy for laboratory services:

- 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 to 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 health care service which is affordable to health care seekers.
- Promote medical research and teaching
- Ensure the collection of all health-related data from both state and private sector laboratories and provide them to the relevant Government authorities, while respecting patient confidentiality.

Objectives of medical laboratory policy are to

01. Ensure the timely availability of reliable and valid diagnostic and analytical laboratory support, necessary to protect and promote the health and wellbeing of the people from communicable

and non-communicable diseases or any other public health concern in an organized, equitable, sustainable and cost-effective manner.

02. Ensure that a good quality laboratory service be provided to the people of Sri Lanka by the state as well as private sector through achieving and maintaining laboratory standards accepted nationally and internationally and work towards accreditation of all laboratories.
03. Promote the rational and safe use of laboratory technology by health care 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. 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 technical advisory committee and with medical professionals suitably qualified. A consultant in laboratory medicine or in his absence the Head of 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. Ministry of health together with 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 an effective maintenance unit should be established for the state sector laboratories. The laboratory service for the state sector hospitals should be as comprehensive in the coverage of laboratory tests as possible and be maximally and be based on strict cost effective criteria.

Routine laboratory testing abroad should be minimized; and this specimen together with those submitted for research should be recorded at a suitable focal point in the Ministry of Health.

Affordability and Ease of Access

Laboratory testing for the Government sector should be done as far as possible within the Government sector cost effective alternative tests must be encouraged. Receipt of samples and issuing to reports should not be restricted merely on time but should be decided according to urgency. Laboratory should

be accessible at any time of the day for relevant investigations required for the immediate management of patient. All possible tax concessions should be offered to license laboratories for 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

All laboratories should be designed to ensure safety and easy cleaning 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 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 selection of appropriate technology which is network, supply equipment and consumable to the relevant institutions in the state sector. Proper management of the supply chain and regular maintenance of equipment would need to be enacted. Operators logbook, equipment maintenance and calibration register. A team of management at 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 powers to close down laboratories which are not functioning up to required standards. Internal quality assurance system as per required by the agreed standards should be enforced manual with standard operative procedures for all important activities must be maintained.

A National External Quality Assurance Scheme (NEQAS) shall be in operation at central level. Periodic checking of quality by NEQAS ensures 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 need 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 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 stake holders 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 short comity. 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 erasure of 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.