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Guidelines for implementation of quality standards for health laboratories

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Contents

Scope and objectives

The objective of this document is to use as a guideline for evaluation and implementation of quality system and standards for medical laboratories, and to apply for the quality system of medical laboratories from the countries in the South-East Asia Region. This document is in alignment with the principles and clauses enunciated in the ISO 15189 Implementation Guideline for Medical Laboratories of Thailand (2007).

The document provides a simple approach to meet each of the requirements. The document shall guide the laboratory professional and management to accomplish the requirements in a logical and step-by-step approach.

The document shall also be of help to the national laboratory policy makers as well as regulators in developing national standards which may not be absolutely in accordance with ISO 15189 but are adequate to inspire the laboratories to develop and implement quality systems to support clinical and public health decision making process. Gradually, laboratories can further improve their system and aspire to meet ISO 15189.

Chapter 1

Introduction

Health laboratories are an integral and essential component of the health system. They provide valuable inputs to physicians and public health managers in planning, implementing and evaluating interventions for the prevention and treatment of diseases to mitigate morbidity and mortality. Laboratory support is also vital to delineate disease epidemiology and understand risk factors for prevailing diseases. These are fundamental for developing and managing national and local health programmes specially for diseases of public health importance including HIV, tuberculosis, malaria etc.

Table 1: Consequences of poor quality laboratory results

• Inappropriate action Over-treatment of patient Over-investigation of patient Mistreatment
• Inappropriate inaction Lack of investigation No treatment
• Delayed action
• Incorrect follow-up of patient
• Faulty epidemiological data for health programme
• Loss of credibility of laboratory
• Legal ramifications/actions

Among various categories of laboratories, the health laboratories have a unique role in handling material from the human body, the results of processing of which have a direct bearing upon a person's physical and psychological well being. Unlike other laboratories, the health laboratories

have to generate results within a defined period to have a meaningful impact. In addition, it is obligatory for these laboratories to generate reliable results since any breach in quality is likely to have a serious adverse affect (Table 1). Presently, with the rising cost of medical care and growing awareness and articulation of a patient's rights, poor quality results are totally unacceptable to the patient, physician, and society. Assuring the quality of its results should therefore be the core objective of any health laboratory.

Studies have shown that errors in laboratory outcomes may occur during the pre-analytical, analytical or post-analytical phases of specimen processing. This calls for expanding the focus areas from the traditional analytical arena to what happens before and after the specimens are processed. A comprehensive and all-encompassing approach to ensure quality is needed through implementation of an effective quality system. Rapid strides have been made recently in creating awareness about quality as well as in articulating various components of a quality system. The lead in this field has been taken by the International Organization for Standardization (ISO).

Chapter 2

International laboratory quality standards

Several internationally accepted standards are currently available (Table 2). Most of these have been developed and disseminated by ISO. It is one of the leading international parties established for developing uniformity standards for quality system control in the manufacturing and service sector.

For health services, ISO has set up ISO 9000 series, which relates to administrative procedures rather than clinical results. It is applicable to the laboratory, radiology and transport areas with minimal application for hospitals and clinics. Previously, many laboratories followed ISO/IEC 17025 for all laboratory testing and calibration until ISO 15189 was officially declared in 2004 to apply as an international quality standard developed for medical laboratories worldwide. This includes both management requirements and technical requirements for medical laboratories.

Table 2: International standards

ISO/IEC 17025	General requirements for the competence of testing and calibration laboratories
ISO 15189	Medical laboratories -- Particular requirements for quality and competence
ISO/IEC 17043	Conformity assessment—General requirements for proficiency testing
ISO 13528	Statistical methods for use in proficiency testing by inter-laboratory comparison
OECD GLP	OECD Principles on Good Laboratory Practice
ISO Guide 34	General requirement for the competence of reference material producers
ISO 8402	Quality management and quality assurance – vocabulary
ISO 19011	Guidelines for quality and/or environmental management system auditing
ISO 9001	Quality management systems – Requirements

Thailand model of quality standards

All health laboratories in Thailand had been using ISO standards for various operations and examination until the international standard specified for medical laboratories, ISO 15189, was developed and officially released by the ISO in 2004.

ISO 15189: 2003 generally was based upon ISO/IEC 17025 and ISO 9001, which provide requirements for competence and quality that are particular to medical laboratories. After the official release of ISO 15189 in 2004, Thailand modified it in a tabulated checklist form containing 100 clauses of the standard for quality system in respect to the guidelines for quality development of the international standards. In 2007, the new version of ISO 15189 was officially released and Thailand developed a new guideline corresponded to ISO 15189 aiming to assist the laboratories that are ready to be assessed for ISO 15189.

Thailand has taken a lead in implementing quality standards in entire country through a step-wise approach. The Thai model has been earlier published by WHO[*] and acclaimed globally as a model that can be replicated by developing countries to improve quality of laboratory services.

[*] Quality Standards in Health Laboratories. Implementation in Thailand: A Novel Approach (WHO Regional Office for South-East Asia, New Delhi, 2005. http://www.searo.who.int/LinkFiles/Publications_SEA-HLM-386__a4___2_.pdf

Chapter 3

Implementation of quality system

Implementation of quality in all laboratories irrespective of their location requires a systematic and logical approach. There are several ways to start. The roadmap described below is for the laboratory that has not known no quality system at all. For those laboratories which have made some progress in introduction of quality system, remaining components can be gradually integrated in functioning of the laboratories. Quality system is like a picture in which each piece of the jigsaw can be put together to form a beautiful functional system. Following steps are suggested for a laboratory that aims to establish quality system:

Commitment of the top management

Implementation of quality system requires commitment from the top management of the laboratory not only for motivation and support but also allocation of appropriate resources. It is impossible for implementing quality system in the laboratory if the management does not agree in principle. However, the implementation does not need a lot of resource or budget in most of the activities. Commitment of the top management made in written format becomes the quality policy of the organization. This shall include the selection of standard to be used.

Involvement of all laboratory and related personnel

Implementing quality is responsibility of all staff members of the laboratory. After the quality policy is formulated and announced, it is advisable to have a meeting with all laboratory and related personnel. The team leader shall give opportunity to all stakeholders to comment and give suggestions in the implementation stage. The involvement of relevant personnel is one of the key successes in the implementation.

Gap analysis

The standard or requirements which have been selected should be compared with the present situation in the laboratory to identify the gaps in quality elements. Using the gaps as the target, a plan is developed with defined time frame. It must be notified here that the responsible person shall not be the one who does all the work. Work shall be allocated to the appropriate persons as a team work through meetings.

Where to start?

Selection of tests can be done in two ways. Many organizations prefer to select a simple test but others like to start with all sections to have quick progress. This should be decided in consultation with all stakeholders and approval of top management.

Which activities to start with?

There are two aspects that can be done at the same time. In the technical area, internal quality control (IQC) and external quality assessment (EQA) or inter-laboratory comparison shall be put into all tests or wherever possible. These two elements are the important issues in the quality assurance for any tests.

The documentation part also can be started at the same time. It is advisable to formulate all standard operating procedures (SOPs) for methods in the beginning, and other SOPs can be done later. A team shall formulate to write up the quality manual and other management SOPs.

Implementation of SOPs

All written SOPs shall be put into use and review by relevant personnel before formal announce of usage. Periodic follow up of the implementation of SOPs should be undertaken to ensure proper usages.

At this stage other SOPs such as equipment procedures can be developed by personnel in charge of each process and implemented through the same principle.

Training

All personnel must be trained to be familiar with the standard. This can be done internally if the organization has the trained or qualified personnel.

Personal information

There are three major pieces of information that must be documented for all personnel involved in the laboratory. These are: job description, curriculum vitae including training records and performance evaluation. These should be regularly updated.

Pre analytic and post analytic activities

All the requirement of patient preparation, sample collection, sample handling and storage shall be established in a document form and made known to all staff members. Monitoring of following such procedures or guidelines shall be done to ensure effective usage.

Reporting system and confidentiality of patient and test information shall be documented, implemented and monitored.

Equipment calibration and maintenance

The requirements related to proper use of all equipment should be documented and followed according to the standard.

Re-evaluate

It is advisable to re-evaluate the gaps between the standard and the status of the laboratory to see the progress and making appraisal for personnel involved.

Internal Audit

Internal auditor must be trained and acquainted with the standard. First trial of internal audit will help to bridge each elements of quality system.

Management review

Management review is one of the key indicators for quality system as it shows the commitment of management for its implementation.

These are only key steps in the implementation of quality system in each laboratory.

There are more details in any standard such as complaint, purchasing, corrective action and preventive actions. All of them can be gradually done by putting into SOPs, implementation and monitoring. The implementation of each step and relevant personnel involvement is elaborated in the tabular form in next chapters.

Chapter 4

Essential requirements for quality system

Quality system requires implementation of two sets of requirements/ standards and activities. These are:

- Management requirements
- Technical requirements.

The essential components of these requirements are:

Management requirements

These include:

- Organization and management
- Quality management system
- Document control
- Review of contracts
- Examination by referral laboratories
- External services and supplies
- Advisory services
- Resolution of complaints
- Identification and control of nonconformities
- Corrective action
- Preventive action
- Continual improvement
- Quality and technical records
- Internal audits
- Management review

Technical requirements

- Personnel
- Environment
- Laboratory equipment
- Pre-examination procedures
- Examination procedures
- Assuring quality of examination procedures
- Post-examination procedure
- Report of results

The implementation activities for each of these are given in subsequent chapters.

Chapter 5

Implementation of requirements

The following table provides corresponding implementation activities for various requirements for implementation of management and technical standards. The ISO clauses that relates to these steps have also been referred to in the last column of this Table.

Management requirements

Requirement/standard		Implementation activity	ISO 15189 (Clause)
1.	**Organization and Management** **The laboratory shall** • be legally identifiable • concern with patient care • meet standards for permanent and "at-site" facility • identify conflict of interest • define personnel responsibilities • design, implement and improve quality management system	1. The laboratory shall have an identification to document its legal entity. 2. The laboratory shall determine the needs and requirements of users and specify them as intentions to its services. 3. The laboratory shall have arrangements to ensure that its organization and operation fulfill the standards for permanent and "at-sites" facilities. 4. The laboratory shall specify factors that can lead to conflict of interest or adversely influence the laboratory's compliance including financial and political considerations. This shall include the following: The laboratory policies regarding confidential issues, neutrality, impartiality, integrity and conflict of interest shall be informed to all staff members involved in laboratory test and have their agreement to follow such policies.	4.1

Requirement/standard		Implementation activity	ISO 15189 (Clause)
		5. The laboratory activity and personnel benefits that would diminish confidence in its reliability shall be revealed and recorded. 6. The laboratory administrator shall be responsible for all tasks; nevertheless, they can be carried out by the laboratory manager or other staff as assigned. 7. Operative guidance shall be specified for all authorities to prevent any influence from external or internal commercial or other considerations that may affect the quality of laboratory performance. 8. The laboratory shall have a quality manual. 9. The laboratory shall clearly define lines of authority and responsibility within the organization. An organizational chart shall be documented indicating overall organization and lines of responsibilities. 10. The laboratory manager shall specify staff authority and function, and determine the quality management procedure. 11. The laboratory manager shall promote and support the quality system and verify that continuing procedure will be carried out. 12. The laboratory manager shall maintain and strengthen the laboratory quality system. An internal organization audit can be used as a tool to investigate the efficiency and ability of the system. 13. The laboratory manager shall be responsible for improving quality system management by providing duty assignment and resource allocation adequately. 14. Operation guidelines in protecting confidential information of patients shall be determined and documented. These shall be shared with all staff members concerned with laboratory tests.	

Requirement/standard		Implementation activity	ISO 15189 (Clause)
		15. Outside laboratory personnel who have official authorization from the laboratory manager to work in the laboratory shall also follow same procedures. 16. The laboratory shall have policy and procedures to avoid participation in any activities by the laboratory staff that would decrease the confidence in competence, impartiality, judgment and integrity of the laboratory. 17. An appropriate training programme shall be organized for staff relevant to their responsibilities. 18. The laboratory shall have a technical manager or technical team for technical resource allocation in order to satisfy with laboratory standard. 19. A quality manager shall be appointed for each laboratory. 20. The quality manager shall be responsible for quality system management of the laboratory. 21. The quality manager shall be accountable for internal organization audit. 22. The quality manager shall be in charge of all document control, except when being assigned for other duties. 23. Dot-line in an organization chart can be used to define that the quality manager can provide information directly to the laboratory director or any other person concerned with policy making, in order to get approvals essential for laboratory quality management. 24. Deputies shall be appointed for any important position. 25. A mechanism for appropriate communication within the laboratories shall be established.	

Requirement/standard		Implementation activity	ISO 15189 (Clause)
2.	**Quality Management System** • All quality management policies and procedures shall be documented , understood and commumicated to all personnel • Quality policy statement shall be concise and defined in quality manual • Quality manual shall describe quality management and technical system including structure of documentation used. • Establish programmes that regularly monitor, preventive maintenance and calibration of instruments.	26. The quality system policy shall promote and support staff to gain awareness and understanding of the policy and regulation regarding all related matters and its implementation. 27. A quality manual shall be developed to include a quality system management policy statement authorized by the laboratory director or manager. 28. The quality system policy shall include service scope and service criterion. 29. The quality system policy shall identify the laboratory quality system objective. 30. The quality system policy shall include laboratory operations conforming to ISO 15189 and the national standards of good professional practice. 31. The quality manual shall describe management system, technical system and structure of documentation used. The manual shall contain the following: - Introduction - Description of the laboratory, its legal identity, resources and principal duties - Quality policy - Laboratory educational policy, and staff training programme - Quality assurance activities - Document control - Records maintenance and archiving - Facility and environmental management - Instruments, reagents and relevant consumables management - An accuracy for each testing process - Safety management	4.2

Requirement/standard		Implementation activity	ISO 15189 (Clause)
		- Environmental management for transportation, consumables, waste disposal - Research and development (if applicable) - List of examination procedures - Request protocols, primary sample collection, and handling of laboratory samples - Validation of results - Quality control (including inter-laboratory comparisons) - Laboratory information system - Reporting of results - Remedial actions and handling of complaints - Communications and other interactions with patients, health professionals, referral laboratories and suppliers - Internal Audits - Ethics 32. The laboratory shall have document format and document control procedures set up for all documents in the organization 33. The laboratory shall have a quality index in order to establish a quality system audit including internal quality control (IQC) and external quality assessment (EQA) 34. The laboratory shall have an instrument calibration plan and record to avoid any impact on laboratory tests 35. Operational verification and instrument maintenance shall be recorded 36. Chemical and reagents quality shall be regularly examined and recorded 37. Testing procedure verification shall be recorded including maintenance check	

Requirement/standard		Implementation activity	ISO 15189 (Clause)
3.	**Document Control** • Establish procedures to control and archive all documents and information • Ensure reviews and approvals by authorized personnel prior to issue • Uniquely identify all document relevant to quality management system	38. The laboratory shall organize a training programme for documentation and document control for all levels of staff. Document quality control regulation shall be disseminated to all related staff efficiently 39. The laboratory shall have a procedure to control all documents for internal and external use. The procedure shall include the following: • A retention period shall be specified for all levels of document control • Document preparation shall be recorded. • All quality documents shall be reviewed and approved by designated authority before issue • Time schedule for quality document revision shall be determined and rectification made if needed, followed by approval from a specified authority. • Unused documents due to their invalid or obsolete nature shall be stored for further application, if needed 40. Any request for document amendment shall follow similar procedure. The amended document shall be issued as soon as practicable. 41. The laboratory shall specify a procedure for document restoration. 42. A master list for all levels of documents shall be maintained to identify the latest valid revision and distribution of documents. 43. Quality documents shall be provided for use at relevant workstations. 44. A procedure shall be established for computerized document revision and data control. 45. The organization shall assign specific persons for document control and distribution.	4.3

Requirement/standard		Implementation activity	ISO 15189 (Clause)
		46. The level of documents shall be specified including quality manual, quality procedure, work instruction, form, supporting document and others as applicable. 47. A format for all levels of document shall be established. The contents shall include title, publishing or revision date, page number, number of pages, authority of issue and document preparation biography.	
4.	**Review of Contracts** • Establish procedures for review of contracts • Maintain records of reviews • Cover any work referred by the laboratories • Inform of any deviation to customers • Repeat the review for any amendment and communicate to all parties	48. Quality manual shall have policies and procedures identified for review of contracts for services 49. The review of contracts shall be developed to cover pre- and post-examination, laboratory report and review. 50. Procedures for contract review shall be set up including meeting complaints and service requirements. 51. Review of contract shall be recorded and maintained. 52. Any deviation from the contract shall be informed to the customers (e.g. clinicians, health care personnel) and records. 53. If the contract needs to be amended, the amendments shall be communicated to all personal concerned.	4.4
5.	**Examination by referral laboratory** • Assure documented procedures to evaluate and select referral laboratories and consultants • Review arrangements with referral laboratory periodically	54. The laboratory shall identify the procedure for assessing and selecting a referral laboratory as well as consultant 55. Terms for referral laboratory evaluation shall be developed to assess its acceptability and competence to perform a qualified laboratory examination including having the status such as : 56. Referral laboratory that has obtained a standard verification to ensure its capability	4.5

Requirement/standard		Implementation activity	ISO 15189 (Clause)
	• Maintain a register of all referral laboratories including name, address and a copy of their report • Provide the results including all essential information to the person requesting the examination.	57. Referral laboratory that is part of a medical hospital. 58. Arrangements with referral laboratories shall be periodically reviewed to ensure that examination procedures are adequately defined and appropriate for intended use, no conflicts of interest and define interpretation of examination results clearly 59. All results and findings from a referral laboratory shall be reported to the person making the request and duplicated for laboratory record. 60. A list for the referral laboratory register shall be made, (including the examination record) and documented in a laboratory service manual.	
6.	**External services and supplies** • Define and document policies and procedures to select and purchase external equipment and supplies • Verify purchased equipment and supplies before use • Develop inventory control system for supplies include quality record • Evaluate external services and suppliers and maintain record of evaluation and approval	61. Procedure for purchased external services and supplies shall be defined. 62. The laboratory shall have authorized staff responsible for evaluation and selection of external services and supplies. 63. Procedures for external services and supplies shall be clearly defined by using percentage or scoring the evaluation system to ensure the evaluation outcome such as its quality, service and cost. Recorded data and information from the physician's request for service and laboratory retrospective data shall be included in the evaluation criterion. 64. Purchased equipment and consumable supplies such as laboratory chemicals and reagents that affect the quality of examinations shall be verified prior to the laboratory usage, and shall be recorded for external services and supplies evaluation.	4.6

Requirement/standard		Implementation activity	ISO 15189 (Clause)
		65. Lists of approved suppliers shall be registered. 66. Session for supplier evaluation shall be determined. 67. The laboratory shall record the supplier evaluation results and verification.	
7.	**Advisory Services** • Provide advice on choice of examination and use of services by professional staff • Conduct regular meeting of professional and clinical staff for consultation on scientific matter	68. Examination results shall be interpreted appropriately. In case that there is no result or interpretation, the laboratory shall mention in the quality manual. 69. The laboratory shall provide the scientific consultation for the service requested such as choice of examination method, use of the services, repeat and sample selection.	4.7
8.	**Resolution of Complaints** • Provide policies and procedures for resolution of complaints or other feedback • Maintain records of complaints, investigations and corrective actions	70. The laboratory shall have a policy and procedure for the admission and resolution of complaints or feedback received from physicians, patients or other parties. 71. Staff responsible for undocumented complaints shall be specified. 72. All sources of complaints shall be recorded such as by phone, letter, meeting or by any related person including clinicians, patients, nurses and laboratory staff. 73. Consumer requirement survey shall be undertaken at least once a year.	4.8
9.	**Identification and Control of nonconformities** • Have a policy or procedure to implement any nonconformities • Identify, document and implement the cause of nonconformity recurrence	74. The laboratory shall have a procedure to identify and control any aspect that does not conform to its standard. The nonconformities that need to be verified in the following areas: - Physician complaints - Quality control indications - Instrument calibrations	4.9

Requirement/standard		Implementation activity	ISO 15189 (Clause)
	• Define and implement procedures for the release of results in case of nonconformity	- Checking of consumable materials - Staff comments - Reporting and certificate checking - Laboratory management reviews - Internal and external audits 75. The person responsible for problem resolution that does not conform to quality standard regulation shall be designated. 76. The laboratory shall have a procedure to resolve nonconformity issues. 77. When nonconformity is detected, corrective actions shall be taken immediately. 78. The results of corrective actions shall be recorded. 79. The time interval for corrective action review shall be specified by the laboratory manager, in order to avoid nonconformity examination recurrence. 80. The reports produced prior to identification of non conformities shall be investigated and recalled when necessary 81. Procedure for the release of the results that do not conform to its quality standard shall be defined and reviewed. 82. Any nonconformity shall be recorded.	
10.	**Corrective Action** • Develop an investigation process to determine cause of problem and preventive action • Implement and document changes to operational procedures	83. The laboratory shall have procedures for corrective action including an investigation process to determine the underlying cause or causes of the problem. 84. Staff responsible for corrective action shall be assigned. 85. Corrective and preventive action shall be taken to prevent the recurrence of problem.	4.10

Requirement/standard		Implementation activity	ISO 15189 (Clause)
	• Monitor the results • Audit appropriate activity for non-conformance or corrective action investigation	86. Corrective action and the result of the investigation shall be recorded. 87. The corrective actions shall be audited and submitted for management reviews	
11.	**Preventive Action** • Develop, implement and monitor action plan to reduce nonconformities • Include initiation of action and application of controls	88. Preventive action shall be developed to reduce the likelihood of nonconformities or the risk of a problem that affects the laboratory quality and technical standards. 89. The person/authority responsible for analyzing the risk of nonconformity shall be specified. 90. Problems shall be analyzed and included in preventive action to identify opportunities for improvement. The preventive action shall include the following: - A review of the operational procedures - Analysis of data, including trend and risk analyses - External quality assurance such as quality assurance and development programme 91. A review of the quality system control procedure shall be recorded in order to identify opportunities for improvement. The review may include the results of quality assessment from a professional organization, proficiency testing programme for laboratory capability, or an assessment from the parties responsible for the quality system approval. 92. An improvement and development action programme shall be developed for prevention of problems.	4.11
12.	**Continual Improvement** • Review operational procedures and develop	93. The laboratory management shall define the time interval for the review of the laboratory's operational and technical procedures.	4.12

Requirement/standard		Implementation activity	ISO 15189 (Clause)
	action plan • Evaluate effectiveness of action • Submit the result of action to the Quality Management System • Implement quality indicators and identify opportunities for improvement • Provide access to education and training	94. The potential sources of nonconformities that affect the laboratory quality management system or technical practices shall be identified and recorded. 95. The laboratory shall have an action plan for continual improvement and development, and management training programmes 96. The laboratory management shall evaluate and record the effectiveness of capability assessment through an internal audit of the area concerned. 97. The laboratory management shall review, record and implement the results of capability assessment to identify any modification for the quality management system or technical practices within the organization. 98. The laboratory quality indicators for systematic monitoring and evaluation of contribution to patient care shall be clearly specified. Operational activities shall be distributed to the parties concerned. The activities shall include: • IQC/EQA results • The number of complaints • The errors identified from internal and external organization audits • Time interval for quality improvement examination	
13.	**Quality and Technical Records** • Establish and implement procedures for quality and technical records • Store and preserve all records	99. Procedures for quality and technical record management shall be established and implemented. 100. Quality indexing shall be used in quality and technical records. 101. The laboratory shall establish and implement procedures for collection and storage of quality and technical records.	4.13

Requirement/standard		Implementation activity	ISO 15189 (Clause)
	• Define detention time for each record and apply regulation as required	102. Quality and technical records shall be legible and understandable. 103. All records shall be stored and maintained to prevent deterioration and to be readily retrievable. These records may include: - request forms (including patient chart or medical record only if used as the request form) - examination results and reports - instrument printouts - examination procedures - laboratory work-books or sheets - accession records - calibration functions and conversions factors - quality control records - complaints and action taken - records of internal and external audits - external quality assessment records/including internal and external calibration records - quality improvement records - instrument maintenance records, including internal and external calibration records - lot documentation, certificates of supplies, package inserts - incident/ accident records and action taken - staff training and competency records 104. All levels of documents shall be accessed by an authorized staff who is responsible for actions including, is not limited to the following; - Recording data - Editing data - Verifying data accuracy	

Requirement/standard		Implementation activity	ISO 15189 (Clause)
		105. The laboratory shall have a procedure and time interval set up for quality and technical record disposal.	
14.	**Internal Audits** • Conduct internal audits for all managerial and technical elements • Plan, organize and carry out internal audits by designated personnel • Define and document the procedures • Establish improvement actions to take care of deficiencies • Submit the results for management review	106. The laboratory shall have procedures for internal audits. 107. The internal audits shall be defined, documented and include the types of audits, frequencies, methodologies and required documentation. 108. Internal audits shall be carried out by the quality manager or designated qualified personnel. 109. The qualification of the internal audit inspector shall be specified. 110. Internal audits shall be formally planned and include all activities mentioned in the laboratory regulation. The main elements of the quality system should normally be subject to internal audit once every 12 months. 111. Designated qualified personnel responsible for internal audits shall not audit their own activities. 112. The results of internal audits shall be recorded and submitted for management review 113. Defective results from corrective and preventive action shall be defined and recorded.	4.14
15.	**Management Review** • Review quality management system and all medical services once every 12 months • Incorporate the results into a plan including goal, objective and action plan	114. The laboratory management shall have time intervals for the laboratory's quality management system review. Such a review shall be conducted at least once every 12 months. 115. The information for the management review shall be indicated in a timetable to the laboratory manager; its details shall be communicated to quality and technical management.	4.15

Requirement/standard		Implementation activity	ISO 15189 (Clause)
	• Follow but not limited to management review guideline • Monitor and evaluate quality and appropriateness of the contribution to patient care • Record findings of the management review, and assure action within appropriate time	116. The results of the review shall be incorporated into a plan for the following year (goals, objectives and action plan shall be included). 117. The results from the management review shall be documented to ensure that the laboratory's quality and technical management are effective and cover all essential requirements. Management review shall take account of, but not be limited to - follow-up of previous management reviews - status of corrective actions taken and required preventive action - reports from managerial and supervisory personnel - the outcome of recent internal audits - assessment by external bodies - the outcome of external quality assessment and other forms of inter-laboratory comparison - any changes in the volume and type of work under taken - feedback, including complaints and other relevant factors from clinicians, patients and other parties - quality indicators for monitoring the laboratory's contribution to patient care - nonconformities - monitoring of turnaround time - results of continuous improvement process - evaluation of supplies 118. Management review, quality assessment and the appropriateness of the laboratory's contribution to patient care shall be monitored, recorded and evaluated objectively.	

Requirement/standard		Implementation activity	ISO 15189 (Clause)
		119. The findings and the actions that arise from management reviews shall be recorded and laboratory staff shall be informed of these findings. Corrective action shall be taken within a time frame based on the management system.	
Technical requirements			
1.	**Personnel** • Define personnel qualifications and duties through plan, policies and job descriptions • Maintain all records to ensure the availability for future requests • Assign important responsibilities to competent personnel according to guidelines • Organize staff resources, training and continuing education programme • Identify a designated person with particular tasks in accordance with background and experience • Keep patient's information confidential	120. Job descriptions shall be defined and documented including qualification, educational background and assigned duties for all personnel in an organization. The laboratory manager shall have skills, knowledge and experience in medical laboratory services. 121. The laboratory management shall maintain records of the relevant educational and professional qualifications, training and experience, and competence of all personnel to ensure that duties are assigned according to the capability of staff. 122. This information shall be readily available to relevant personnel and may include: - Certification or license - References from previous employment - Job descriptions - Records of continuing education and achievements - Competency evaluations - Provision for untoward incident or accident reports and immunization report 123. The services provided including work load, and the number of staff available, shall be documented to ensure that staff resources are adequate to the work required and to carry out other functions of quality management.	5.1

Requirement/standard		Implementation activity	ISO 15189 (Clause)
		124. Personnel shall have training specific to quality assurance and quality management for services offered. 125. The laboratory shall have a continuing education programme available to staff at all levels. 126. The laboratory management shall authorize personnel to perform and record particular tasks as assigned. 127. These tasks on sample management are described as follows: - Collecting samples from patients - Accepting and sending samples to clients and/or laboratory examiners - Separating samples and transferring to other laboratory units - Preserving sample prior to examination, disposal or repeat test 128. Designated staff shall be assigned to perform particular tasks. The designated staff include in the laboratory management shall be as follow; - Sample collector - Examiner and instrument operator - Computer operator or authorized personnel responsible for the laboratory information system 129. Accuracy verification shall be carried out for all laboratory operations. The results shall be documented, recorded and authorized to ensure that the accuracy of the results are as per the laboratory standard. 130. Policies shall be established which define who may use the computer system, who may access patient data and who is authorized to enter and change patient results, correct billing, or modify computer programmes.	

Requirement/standard		Implementation activity	ISO 15189 (Clause)
		131. The laboratory shall maintain records to show that the employees receive appropriate training to prevent or minimize the effects of adverse incidents. 132. The laboratory shall have a document containing a record of competency achieved by personnel after training and the evaluation held periodically thereafter. 133. The laboratory shall have a document to indicate that the personnel making professional judgments with reference to examinations have the necessary theoretical and practical background as well as experience. Professional judgments can be expressed as opinions, interpretations, predictions, simulations and models and values and should be in accordance with national, regional, and local regulations. 134. The laboratory shall maintain a document containing the laboratory regulation regarding the issue of confidential information of patients.	
2.	**Accommodation and Environmental Conditions** • Determine adequate space that optimize workload and laboratory activities • Design laboratory for the efficiency, minimize the risk of injury and protected from hazards • Provide comfort and privacy facilities to patient disabilities • The environment shall not invalidate the results	135. The laboratory shall have sufficient space allocated so that its work can be performed without compromising quality, quality control procedure, safety of personnel, or patient care services. 136. The laboratory shall be designed for efficient operations, to optimize the comfort of its occupants, and to minimize the risk of injury and occupational hazards. 137. Laboratory facilities be designed to allow correct performance of examinations by providing, but not limited to, lighting, energy sources, ventilation, water, waste and refuse disposal, and environmental conditions that are convenient for the laboratory operation.	5.2

Requirement/standard		Implementation activity	ISO 15189 (Clause)
	• Monitor, control and record environmental conditions • Separate incompatible activities • Access to area of examination shall be controlled • Provide communication systems within laboratory • Provide relevant storage space and conditions to ensure the integrity of samples. • Clean and well maintain all the work areas	138. The laboratory shall have effective separation between adjacent sections which are carrying out incompatible activities. Measures shall be taken to prevent cross-contamination. 139. The laboratory shall control access to and use of areas affecting the quality of the examinations. External personnel including patients, staffs and visitors shall not be allowed without permission. 140. When primary sample collection facilities are provided, consideration shall be given to the accommodation of patients with disabilities, comfort, and privacy, in addition to the optimization of collection conditions for particular examinations such as sperm count and direct smear GC. 141. Communication systems within the laboratory shall be in keeping with the size and complexity of the facility and for the efficient transfer of messages. 142. Appropriate storage space and conditions shall be provided for pre-examination samples, samples to be disposed and samples that require repeat examination. 143. The laboratory shall provide relevant storage space and conditions for the preservation of samples, slides, micro-organisms, documents, files, manuals, equipment, reagents, laboratory supplies, records, and results. 144. The laboratory shall assign personnel responsible for measures to ensure good housekeeping in the laboratory. 145. Designated personnel responsible for storage and to destroy hazardous samples shall be assigned corresponding to legal provisions or regulations.	

Requirement/standard		Implementation activity	ISO 15189 (Clause)
		146. The laboratory shall monitor, control, and record environmental conditions, as required by relevant specifications or where they may influence the quality of the results. These conditions shall include sterility levels, dust, electromagnetic interference, radiation, humidity, electrical supply, temperature and sound and vibration levels as appropriate to the technical activities concerned.	
3.	**Laboratory Equipment** • Provide sufficient equipment for provision of service and control the use of items outside • Ensure capability of equipment to comply with relevant specifications or standards • Establish, document and record programme to monitor and demonstrate proper operations and maintenance • Maintain unique equipment identity and records of each item of equipment • Operate equipment by authorized personnel and provide up-to-date instruction • Store equipment in a safe working conditions and adequate space for repairs and protective equipments • Label or code the status and date of equipment under calibration or verification	147. The laboratory shall be furnished with all items of equipment required for the provision of services (including primary sample collection, and sample preparation and processing, examination, and storage). 148. The laboratory shall have a waste disposal system for the care of the environment. 149. The laboratory equipment shall be checked, recorded and documented for its accuracy prior to its application. 150. In case of the use of equipment outside its permanent control, the equipment efficiency verification shall be performed prior to releasing the permission for the equipment application. 151. The laboratory shall have an equipment maintenance programme; it shall be recorded and documented by the manufacturer or designated staff, and follow the manufacturer's instructions and operator's manuals. 152. Equipment capability shall be verified and recorded upon installation, and shall be shown to be capable of achieving the performance required, and shall comply with specifications relevant to the examinations concerned before any routine use. 153. Each item of equipment shall be uniquely labelled, marked, or otherwise identified, and include the next date of calibration.	5.3

Requirement/standard		Implementation activity	ISO 15189 (Clause)
	• Remove, label and store defective equipment until service, repair, or decommissioning, and check equipment function prior to return to use • Conduct measurement to decontaminate equipment include record and provide results to appropriate person • Contain procedures and standards for computers or automated examination equipment, and equipment handling • Update the correction factors for equipment calibrations	154. The results from the equipment calibration test shall be documented and recorded, corresponding to the calibration certificate of the equipment that is approved by external parties. The achievement of the performance requirement shall be reached prior to issuing the user's approval. 155. The laboratory shall have documents to indicate that the personnel is competent to perform the equipment calibration such as a certificate from equipment calibration training. 156. The equipment maintenance programme shall be used, documented and recorded for each item of equipment used for examinations and which is operated by the manufacturer's technician and user. 157. The maintenance records shall include at least the following: - Identity of the equipment - Location of the equipment - Manufacturer's name, - Type identification, and serial number or other unique identification - Manufacturer's contact person and telephone number, as appropriate - Date of receiving and date of putting into service - Current location, where appropriate - Condition when received (e.g., new, used, reconditioned) - Manufacturer's instructions, if available, or reference to their location - Equipment performance records that confirm equipment's suitability for use - Maintenance carried out and planned - Damage to, or malfunction, modification or repair of the equipment - Predicted replacement date, if possible	

Requirement/standard		Implementation activity	ISO 15189 (Clause)
		158. The laboratory shall have a document identifying the authorized personnel responsible for the laboratory equipment. 159. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals and directions for use provided by the manufacturer) shall be readily available to laboratory personnel. 160. An examination programme shall be used for the equipment to ensure the safe working conditions; this shall include examination of electrical safety, emergency stop devices, and the safe handling and disposal of chemical, radioactive and biological materials by authorized persons. 161. The calibration or verification of the equipment shall indicate the status of calibration or verification and the date when recalibration or reverification is due. 162. The calibration or verification status and recalibration or reverification due date of the equipment that affect the results of the laboratory examination shall be clearly verified. Defective or out-of-service equipment shall be clearly labeled, and appropriately stored until it has been repaired and shown by calibration, verification or testing to meet specified acceptance criteria prior to service. 163. When computers or automated examination equipment are used for the collection, processing, recording, reporting, storage or retrieval of examination data, the laboratory shall have documents to ensure that: - Computer software, including that built into the equipment, is documented and suitably validated as adequate for use - Procedures are established and implemented for protecting the integrity of data at all times	

Requirement/standard		Implementation activity	ISO 15189 (Clause)
		- Computers and automated equipment are maintained to ensure proper functioning and provided with environmental and operating conditions necessary to maintain the integrity of data - Computer programmes and routines shall be adequately protected to prevent access, alteration, or destruction by casual or unauthorised persons 164. The laboratory shall have procedures for the equipment calibration results that need to be corrected and ensure that copies of prior correction factors are correctly updated. 165. The laboratory shall provide an up-to-date instruction manual on the use and maintenance of equipment or any relevant manuals and directions for use provided by the manufacturer of the equipment. 166. The laboratory shall have procedures for the equipment calibration results that need to be corrected and ensure that copies of prior correction factors are correctly updated. 167. The equipment including hardware and software shall be safeguarded from adjustment. The laboratory shall have preventive actions for consumables, reference materials, reagents or analytical systems from tampering that might effect the examination results. Installing device to control access in the laboratory area and using password or personal authorization are the example of preventive action	
4.	**Pre-examination procedures** • Obtain sufficient information in the request form and allow space for additions • Document and implement	168. The request form or an electronic equivalent shall have sufficient information and allow space for the inclusion of, but not be limited to, the following: - Hospital Number of the patients	5.4

Requirement/standard		Implementation activity	ISO 15189 (Clause)
	instructions for collection and handling of primary samples, and inform competent personnel • Include information in the primary sample collection manual to follow ISO instructions for copy, reference, procedure and instruction • Make primary sample collection manual part of the document control system • Accept and process primary sample with proper identification or choose to process but not release the result when uncertainty or instability occur and record to requested form • Monitor transportation of samples to maintain the standard criteria • Record that primary samples include receiving date and time, and identification • Develop criteria for acceptance and rejection of primary sample • Review sample volume requirement periodically and trace back to original primary sample	- Name or other unique identifier of physician or other person legally authorized to request examinations or use medical information - Type of primary sample and the anatomic site of origin, where appropriate - Examinations requested - Clinical information relevant to the patient, which shall include symptom, date of birth and gender of the patient - Date and time of primary sample collection - Date and time of receipt of sample by the laboratory 169. The laboratory shall have a request form or an electronic equivalent that contains information sufficient to identify the patient and the authorized requester, as well as provide pertinent clinical data. 170. The laboratory shall have a sample collection manual which shall be provided to related staff or customers. 171. The format of request form and the way in which requests are to be communicated to the laboratory should be discussed with the users of laboratory services 172. The primary sample collection manual shall include copies of or references to: - Lists of available laboratory examinations offered - Consent forms, when applicable - Information and instructions provided to patients in relation to their own preparation before primary sample collection - Information for users of laboratory	

Requirement/standard		Implementation activity	ISO 15189 (Clause)
	• Perform requests, samples and method selection revision by authorized personnel • Contain and document procedure concerned with primary sample and mark as urgent • Provide written policy for verbal request for sample examinations • Store samples for specific time and under proper conditions	services on medical indications and appropriate selection of available procedures 173. The primary sample collection manual shall include procedures for: - Preparation of the patient (e.g., instructions to caregivers and phlebotomists) - Identification of primary sample - Primary sample collection (e.g., phlebotomy, skin puncture, blood, urine and other body fluids), with descriptions of the primary sample containers and any necessary additives. 174. The primary sample collection manual shall include instructions for: - Completion of request form or electronic request. - The type and amount of the primary sample to be collected - Special timing of collection, if required. - Any special handling needs between time of collection and time received by the laboratory (transport requirements, refrigeration, warming, immediate delivery, etc.). - Labelling of primary samples. - Clinical information (e.g., history of administration of drugs). - Positive identification in detail, of the patient from whom a primary sample is collected. - Recording the identity of the person collecting the primary sample - Safe disposal of materials used in the collection. 175. The primary sample collection manual	

Requirement/standard		Implementation activity	ISO 15189 (Clause)
		shall include instructions for: - Storage of examined samples. - Time limits for requesting additional examinations. - Additional examinations. - Repeat examination due to analytical failure or further examinations of same primary sample. 176. The laboratory shall determine the time interval for the revising the sample collection manual. 177. The primary sample collection manual shall be used as a quality document 178. The laboratory shall have procedures for sample preservation, sample monitoring and action in case of emergency during transportation. 179. The laboratory shall have a sample request form or recorded sample number as an identification to ensure its traceability. 180. The laboratory shall have a document to identify the rejection of a sample due to the lack of proper identification such as uncertain sample number or label. 181. An inappropriate primary sample shall be specified and recorded in a report or result interpretation, if the examination is carried out. 182. The laboratory shall set up procedures for staff responsible for receiving/sending samples, in order to check its identification. 183. The laboratory shall provide training for personnel responsible for receiving/sending samples from external requester (including personnel responsible for the transportation of samples). 184. The laboratory shall carry a registration	

Requirement/standard		Implementation activity	ISO 15189 (Clause)
		document containing information on personnel responsible for receiving/sending samples from external requester (including personnel responsible for the transportation of samples). 185. The laboratory shall monitor the transportation of samples so that they are transported: - Within a time frame appropriate to the nature of the requested examinations - Within a temperature interval specified in the primary sample collection manual and with the designated preservatives - In a manner that ensures safety for the carrier. 186. All primary samples received shall be recorded in an accession book, worksheet, computer, or other comparable system, including the date and time of receipt of samples and the identity of the receiving officer. 187. The laboratory shall develop and document criteria for acceptance or rejection of primary samples. 188. The laboratory shall periodically review its sample volume requirements to ensure that neither insufficient nor excessive amounts of samples are collected. 189. Requests, sample received and examination to be performed shall be systematically reviewed by authorized personnel. 190. The laboratory shall have a documented procedure for primary samples with urgent result requirement; those samples received shall be certainly marked or labeled as urgent. 191. The laboratory shall have a documented	

Requirement/standard		Implementation activity	ISO 15189 (Clause)
		procedure for urgent requested samples containing information about any rapid processing mode to be used, and any special reporting criteria to be followed. 192. Sample portions shall also be traceable to the original primary sample. Traceability method includes using barcode or a coded index number. 193. The laboratory shall have a written policy concerning verbal requests for sample examinations such as a record by personnel who receive such a request. 194. The time interval for sample storage shall be specified under conditions that ensure stability of sample properties and for repeating the examination if required.	
5.	**Examination procedures** • Use published examination procedures or in-house procedures with appropriate validation • The result and validation procedures shall be recorded • All procedures shall be available at workstation • Biological reference interval shall be reviewed • Provided the list of current examination procedures to users including written explanation of any changes	195. The laboratory shall use examination procedures, including those for selecting/taking sample portions, which meet the needs of the users of laboratory services and are appropriate for the examinations. Preferred procedures are those that have been published in acceptable/reliable sources. 196. The laboratory shall have an appropriately validated and fully recorded document for in-house procedures, to ensure its intended use. 197. The laboratory shall use only validated procedures to confirm that the examination procedures are suitable for the intended use and meet the needs in the given application or field of application. 198. The laboratory shall use documented procedures for all laboratory examinations. These documents shall be available at the workstation in the form that will be commonly understood by the staff in the laboratory 199. Procedures for primary examination shall be	5.5

Requirement/standard		Implementation activity	ISO 15189 (Clause)
		reviewed and recorded within an agreed time interval, usually about once a year. Up-to-date procedures shall be identified and carried out. 200. The laboratory shall have registration or approval for card files or similar systems that summarize key information and use as a quick reference at the workbench. The card files or similar systems shall be part of the control document, and shall correspond to the complete manual. 201. The format of documents shall include, when applicable, the following: - Purpose of the examination - Principle of the procedure used for examinations - Performance specifications (e.g., linearity, precision, accuracy expressed as uncertainty of measurement, detection limit, measuring interval, trueness of measurement, sensitivity, and specificity) - Primary sample system (e.g. plasma, serum, urine) - Type of container and additive - Required equipment and reagents - Calibration procedures (metrological traceability) - Procedural steps - Quality control procedures - Interferences (e.g., lipemia, hemolysis, bilirubinemia) and cross-reactions - Principle of procedure for calculating results, including measurement uncertainty - Biological reference intervals - Reportable interval of patient examination results - Alert/critical values - Laboratory interpretation	

Requirement/standard		Implementation activity	ISO 15189 (Clause)
		- Safety precautions - Potential sources of variability 202. The laboratory shall develop electronic manuals for electronic document control. 203. The examination operations and procedures shall be documented and its contents shall follow the relevant laboratory procedures. 204. Electronic manuals are acceptable and needed the same requirement for document control. 205. Performance for each examination procedure shall relate to the intended use of that procedure. 206. Laboratory biological interval: normal range shall be recorded and reviewed. 207. A review of biological reference intervals shall take place and be recorded when the laboratory changes sample collection or an examination procedure. 208. The laboratory shall make its list of current examination procedures and inform it to users of laboratory services. 209. If the laboratory intends to change an examination procedure such that results or their interpretations could be significantly different, the implications shall be explained to users of the laboratory services in writing prior to the introduction of the change.	
6.	**Assuring the quality of examination procedures** • Implement internal quality control systems to enhance the quality of results • Determine components and sources causing uncertainty of results • Design and conduct a programme to calibrate	210. The laboratory shall design internal quality control systems that verify the attainment of the intended quality of results. 211. The laboratory shall identify procedures to determine the uncertainty of results, where relevant and possible. Significant sources that contribute to uncertainty shall be considered such as sampling. 212. The laboratory shall have a programme for calibration of measuring systems and	5.6

Requirement/standard		Implementation activity	ISO 15189 (Clause)
	measuring systems and verification, or use relevant application • Participate in external quality assessment programme, monitor the result and implement corrective actions • Ensure substantial agreement of inter-laboratory comparison programmes and develop mechanisms when programme not available • Define mechanisms to compare and verify laboratory results within an appropriate period of time • Document, record and identify inter-laboratory comparison, problem and deficiency.	verification of trueness, such a programme shall be designed and used to ensure that results are traceable to universal or stated reference, if applicable. 213. If a programme for calibration of measuring systems and verification of trueness are irrelevant, other means for providing confidence in the results shall be applied such as participation in a suitable programme of inter-laboratory comparisons such as external quality assessment (EQA). 214. Use of suitable reference materials, certified to indicate the characterization of the material can be used when a programme for calibration of measuring systems and verification of trueness are irrelevant. 215. The laboratory can use examination or calibration by another procedure in case that a programme for calibration of measuring systems and verification of trueness are irrelevant. 216. When a programme for calibration of measuring systems and verification of trueness are irrelevant, ratio or reciprocity-type measurements can be carried out. 217. Mutual consent standards or methods, which are clearly established specified, characterized and mutually agreed upon by all parties concerned, can be used when a programme for calibration of measuring systems and verification of trueness are irrelevant. 218. The laboratory shall have documents indicating reagents or experimental procedures. Such documents shall be traceable to the documents provided by the supplier or manufacturer. 219. The laboratory shall provide equipment maintenance periodically to verify the accuracy and precision of the laboratory	

Requirement/standard		Implementation activity	ISO 15189 (Clause)
		examination system. Such information shall be used as information for identifying the problem of equipment, changing examination procedure and comparing with interlaboratory results from external quality assessment (EQA). 220. The laboratory shall participate in inter-laboratory comparisons such as those organized by external quality assessment schemes. 221. The laboratory shall monitor the results of external quality assessment to find any determinant causing the control criteria to be unfulfilled. 222. Corrective action shall be implemented when control criteria are not fulfilled to correct any defect. 223. When the laboratory can not participate in inter-laboratory comparisons such as those organized by external quality assessment, it shall utilize externally derived challenge materials such as exchange of samples with other laboratories. 224. The examinations performed using different procedures or equipment or at different sites, or all these, shall be recorded and documented. 225. When the results from the examinations performed using different procedures or equipment or at different sites contain a problem or deficiency, corrective action shall be performed and recorded. 226. The laboratory shall maintain document and record results from inter-laboratory comparisons.	
7.	**Post-examination process** • Review, evaluate and	227. Procedures for authorized personnel to review the results of examination shall be	5.7

Requirement/standard		Implementation activity	ISO 15189 (Clause)
	authorize the results of examination • Have approved policy for laboratory sample storage • Carry out safe disposal of samples for waste management.	documented. 228. Authorized personnel shall systematically review the results of examinations using previous clinical information of the patient. 229. The results of the examination shall be evaluated and compared in conformity with clinical information (such as hospital number of patient the accuracy verification of Hospital Number and requested form), and authorized and signed by designated staff 230. Storage of the primary sample and other laboratory samples shall be in accordance with approved policy. 231. Safe disposal of samples no longer required for examination shall be carried out in accordance with local regulations or recommendations for waste management.	
8.	**Reporting results** • Determine report format includes electronic and paper forms, and discuss with users • Ensure report is sent to requesters within agreed-upon time interval • Maintain report legibility and follow guidance for report inclusions • Follow vocabulary and syntax recommendation from suggested organisations • Indicate primary sample with unsuitable quality • Retain copies or files of	232. The laboratory shall have procedures for reporting and informing the examination results to the users of the laboratory services within an agreed-upon time interval. Such a procedure shall be available for the user to participate in any suggestion related to the format of the report form. 233. The laboratory management shares responsibility with the requester for ensuring that reports are received by the appropriate individuals within an agreed-upon time interval. 234. Results shall be legible, without mistakes in transcription, and reported to persons authorized to receive and use medical information. . 235. The contents of the report shall include, but not be limited to the following: 236. Clear identification of the examination. 237. The identification of the laboratory that	5.8

Requirement/standard		Implementation activity	ISO 15189 (Clause)
	reported results and make it available within required period of time • Provide procedures for immediate notification of physicians or referral laboratory results • Forward final report to requester • Maintain record of action from critical intervals, and record and review any difficulties during audits • Establish turnaround time within clinical needs for each examination include monitor, record and review turnaround time and feedback from clinician • Identify problem and initiate corrective action when needed • Notify clinical personnel of delay that could affect patient care • Provide procedures for verifying correctness of transcript from referral laboratory • Document procedures and guidelines for the release of results and identify designated personnel • Establish policies and practices for notification of results to authorized receivers, and follow by proper report • Contain policies and	issued the report. 238. Code or any identification and permanent address of the patients. 239. Name or other unique identifier of the requester and the requester's address. 240. Date and time of primary sample collection, when available and relevant to patient care, and time of receipt by the laboratory. 241. Date and time of release of report, which, if not on the report, shall be readily accessible when needed. 242. Source and system (or primary sample type). 243. Results of the examination reported in SI units or units traceable to SI units (see ISO Guide 31), where applicable. 244. Biological reference intervals, where applicable. 245. Interpretation of results. 246. Other comments (e.g., quality or adequacy of primary sample which may have compromised the result, results/interpretations from referral laboratories, use of developmental procedure); the report should identify examinations undertaken as part of a development programme and for which no specific claims on measurement performance are made, and, where applicable, information on detection limit and uncertainty of measurement should be provided upon request. 247. Identification of the person authorizing the release of the report. 248. If relevant, original and corrected results. 249. Signature or authorization of the person checking or releasing the report, where possible.	

Requirement/standard		Implementation activity	ISO 15189 (Clause)
	procedures for report alteration, retain original entries and indicate that alteration include date, time and designated personnel • Retain results from decision-making and revision in cumulative report, identify any revision or provide audit log if unidentifiable	250. Note: In reference to biological reference material, under some circumstances, it might be appropriate to distribute lists or tables to all users of laboratory services and sites where reports are received. 251. National, regional and local regulation may require the name and location of the examining laboratory to be shown in the final report 252. The report shall indicate if the quality of the primary sample received was unsuitable for examination or could have compromised the result. 253. Copies or files of reported results shall be retained by the laboratory. 254. The laboratory shall have procedures for immediate notification of a physician when examination results for critical properties fall within established "alert" or "critical" intervals. This includes results received on samples sent to referral laboratories for examination. 255. The laboratory shall have an agreement with physicians for critical level of the experiments. 256. Actions taken in response to results in the critical intervals shall be maintained and recorded including date, time, staff member responsible for test operation and person notified of results. Any difficulty encountered in meeting this requirement shall be recorded and reviewed during internal audits. 257. The laboratory shall record the consultation with the requesters to establish turnaround times for each of its examinations. 258. The laboratory shall have a policy for notifying the requester when an examination is delayed.	

Requirement/standard		Implementation activity	ISO 15189 (Clause)
		259. The laboratory manager shall monitor, record and review turn around time and feedback from clinicians 260. The laboratory manager shall be responsible for maintaining and monitoring the record of verification and review. 261. The laboratory shall record and document corrective action of all identified problems. 262. The laboratory shall develop procedures to enhance collaboration between requesters and laboratory personnel such as laboratory meeting. 263. The laboratory shall specify procedures to use when examination results from a referral laboratory need to be transcribed in order to verify the correctness of all transcriptions and to use in a double-check. 264. The laboratory shall have clearly documented procedures for the release of examination results, including details of who may release results and to whom. The procedures shall also include guidelines for the release of results directly to patients. 265. The laboratory shall establish policies and practices for ensuring that results distributed by telephone or other electronic means reach only authorized receivers. Such policy shall include, but not be limited to, using password or requester name as personnel identification. 266. Results provided verbally shall be followed by a properly recorded report. 267. A complete report shall be sent to the requester after a primary report informed includes verbal distribution. 268. The laboratory shall have written policies and procedures regarding the alteration of reports. Such a record must show the time,	

Requirement/standard		Implementation activity	ISO 15189 (Clause)
		date, and name of the person responsible for the change. 269. Appropriate procedures shall be developed and recorded for report alteration. 270. Clearly written reports shall be indicated for changes in the report. 271. Original electronic records shall be retained for an agreed length of time. 272. A written report shall be sent to the physician regarding the alteration of reports. The original report shall be duplicated and retained to indicate report alteration for its traceability. 273. The laboratory shall record revised reports when the reporting system cannot capture amendments, changes, or alterations.	

Chapter 6

Suggested further reading

1. Medical Laboratory – Particular requirements for quality and competence ISO 15189:2007

2. Guideline for ISO 15189 implementation, The Department of Medical Sciences, Thailand, (ISBN 974-92630-3-0), First Edition, 2005.

3. Quality Standards in Health Laboratories. Implementation in Thailand: A Novel Approach (WHO Regional Office for South-East Asia, New Delhi, 2005. http://www.searo.who.int/LinkFiles/Publications_SEA-HLM-386__a4___2_.pdf

4. Quality Assurance in Bacteriology and Immunology WHO Regional Office for South-East Asia, New Delhi, 2004. http://www.searo.who.int/EN/Section10/Section17/Section53/Section375.htm

5. Guidelines for Establishment of Accreditation of Health LaboratoriesWHO Regional Office for South-East Asia, New Delhi, 2007. http://www.searo.who.int/LinkFiles/Publications_SEA-HLM-394.pdf