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Quality Standards in Health Laboratories

Implementation in Thailand: A Novel Approach

*Mayura Kusum**
and
*Panadda Silva***

* *Senior Principal Medical Scientist, Department of Medical Sciences, Ministry of Public Health, Thailand, mayura@dmsc.moph.go.th*

** *Director, Bureau of Laboratory Quality and Standards, Ministry of Public Health, Thailand, pnadda@dmsc.moph.go.th*

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PREFACE

The importance of quality in the functioning of health care laboratories is well recognized globally; more importantly in developing countries. The poor quality of laboratory results can lead to inappropriate interventions, adversely affect the credibility of the laboratory and may also invite legal action. It is, hence, essential to develop and implement a policy on quality in health laboratories. The International Organization for Standardization (ISO), has developed quality systems to assess specific aspects of health services. A majority of laboratories rely on International Quality Standards known as ISO/IEC/17025 for all types of testing and calibrating laboratories and more specifically ISO 15189 for medical laboratories. These standards are quite comprehensive and often very resource-intensive. Only a few of the leading laboratories conform to these standards, while a majority get discouraged to even attempt meeting the standards considering the exhaustive list of requirements. This has lead to an "all or none" situation in many countries.

With this background, the importance of developing minimal national quality standards for health laboratories, which should be mandatorily followed by all laboratories becomes very important. Achieving international standards could then follow on an optional and voluntary basis. Thailand has developed and successfully implemented such a model, where national standards for health laboratories have been developed and initially applied on a voluntary basis. A user-friendly 100-point check list of national standards has been developed which has proved very useful in adoption and self evaluation of the implementation of these standards. Different laboratories are at different levels of quality development and hence a flexible step-wise approach has been

followed. The participating laboratories have cooperated well in implementing this model. The laboratories have imbibed this model according to their facilities, resources, time-frame and readiness. Above all, this model has significantly enhanced inter-laboratory cooperation.

It is hoped that this model will be emulated by other Member States considering its strong fundamentals, and flexible approach to help attain desired laboratory quality standards. Doing so would sensitize the laboratories and facilitate them achieving international standards in a phased manner on a voluntary basis.

The efforts of Dr Mayura Kusum and Dr Panadda Silva from Bureau of Laboratory Quality Standards (BLQS), Nonthaburi, Thailand in developing and successfully implementing the model on National Quality Standards for health laboratories and also sharing the concept with the scientific community for its wider applications are gratefully acknowledged. Dr Rattan Lal Ichhpujani, STP/BCT/SEARO has provided valuable technical inputs to enhance the merit of the document.

It is sincerely hoped that this publication will achieve its intended objective of stimulating Member States in setting up National Quality Standards for health laboratories as a step to achieve International Standards, and to help ensure the quality of laboratory results.

ABBREVIATIONS

QA	Quality Assurance
ISO	International Organization for Standardization
EN 45001	European Norms 45001
ISO/IEC	International Organization for Standardization/International Electrotechnical Commission
MOPH	Ministry of Public Health
DMSc	Department of Medical Sciences
BLQS	Bureau of Laboratory Quality Standards
EQAS	External Quality Assessment Scheme
AMTT	Association of Medical Technologists of Thailand
WHO	World Health Organization
USCDC	United States' Centres for Disease Control
SEAMIC	Southeast Asian Medical Information Centre
IHQIA	Institute of Hospital Quality Improvement and Accreditation
PT	Proficiency Testing
EQA	External Quality Assessment
RMSC	Regional Medical Sciences Centres

1

Quality System: Systematic Approach to Ensure Quality

The importance of quality in the functioning of health care laboratories in developing countries has been universally recognized. Laboratories practicing the principles of quality assurance generate relevant, reliable and cost-effective results.

Quality means meeting the standards. The standards are pre-determined requirements for a particular substance or service.

Quality is of paramount importance in health laboratories. Reliable results produced by a laboratory improve the decision making capacity of the clinicians as well as public health physicians. The consequences of poor quality could be serious. It could lead to inappropriate action or inaction leading to over treatment, over-investigation or mistreatment, lack of treatment or inadequate investigations. Delayed or suboptimal responses as a result of poor quality of laboratory services could adversely affect the credibility of the laboratory and may also invite legal action.

Quality is ensured through a well defined quality system which is a part of overall quality management aimed at ensuring consistency, reproducibility, traceability and efficacy of the products or services. Accordingly, a quality system is defined as the organizational structure and resources needed to implement quality requirements. The International Organization for Standardization (ISO) defines a quality system as the organizational

structure, responsibilities, procedures, processes and resources for implementing quality management.

A quality system has the following five key elements:

- Organizational management and structure
- Documentation
- Monitoring and Evaluation
- Training
- Quality standards

1.1 Organizational Management and Structure

The overall responsibility for the design, implementation, maintenance and improvements in quality system rests with the laboratory management. Quality is the responsibility of all the staff members of the organization.

1.2 Documentation

A document is a record whether in printed or electronic version, of any information or instructions including policy statements, quality manuals, procedures, specifications, calibration tables, reports, job description, documents of external origin such as regulations, standards and examination procedures etc.

1.3 Monitoring and Evaluation

The laboratory management develops and implements quality indicators to systematically monitor and evaluate the laboratory's contribution to patient care. When the programme identifies opportunities for improvement within the system, the laboratory management should take appropriate steps to address them. Error management should be vigorously implemented.

Assessment of quality through audits (internal or external) and participation in external quality assessment schemes are other tools, the results of which should guide the management in further improving quality.

1.4 Training

The quality system is only as good as the staff who actually work for it. No matter how good the quality system is on paper, if it cannot be translated into practice, quality cannot be achieved. Training must also include an understanding of why quality is important. Training should be competency based and must be followed by post-training courses to provide a continuous support.

1.5 Quality Standards

The quality standards are an integral part of the quality system. These aim at ensuring safety and consistency. These need to be followed strictly to meet the regulatory requirements as well as to monitor the functioning of the laboratory.

Both management and technical standards need to be followed to ensure quality. These must also conform to the local laws.

2

International Organization for Standardization

The International Organization for Standardization (ISO) is one of the leading international bodies that have brought together the international community in developing uniform standards for quality in the manufacturing and service sectors. Some of the ISO documents that may be pertinent to laboratories are listed below.

ISO No	Refers to
ISO 9001 : 2000	Quality Management System-Requirements
ISO /IEC 17025 : 1999	General requirements for the competence of testing and calibration laboratories
ISO guide 43	Proficiency testing by inter-laboratory comparisons Part 1: Development and operation of proficiency testing schemes
ISO Guidelines 15189	Medical laboratories – Particular requirements for quality and competence

ISO has developed standards for quality systems that have been used to assess specific aspects of health services (ISO 9000 series). The standards relate to administrative procedures rather than clinical results. Consequently, these have been applied to departments such as laboratories (EN 45001), radiology and

transport, though these have also been applied to hospitals and clinics. In each country, a national body tests and recognizes (accredits) independent agencies as being competent to certify organizations that comply with the standards.

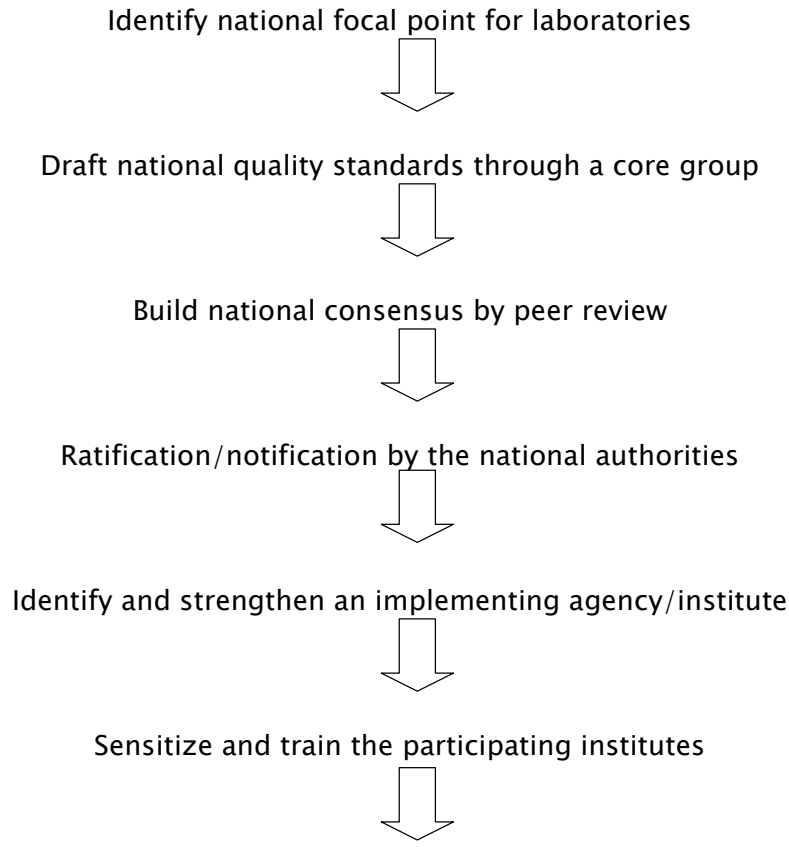
A majority of the laboratories rely on the international quality standards known as ISO/IEC 17025 for all types of testing and calibrating laboratories. In 2004, ISO 15189 was officially announced for adoption as the international quality standards for medical laboratories globally. Countries such as Thailand and India for example, switched over from ISO/IEC 17025 to ISO 15189. However, not many laboratories attempted to conform to these standards as there was a wide gap between what existed and what was required to achieve these standards. The intended objectives were also not met because of the high cost of purchasing equipment required for the competency development programme, difficulty in programme coordination and shortage of personnel. This led to a situation where only a handful of laboratories in a country could achieve these international standards. In some countries these laboratories were only from the private sector. Adoption of these standards was usually possible only in the case of well established laboratories who could fulfil the requirements.

Often, it has been observed that in the absence of any national laboratory policy there are no minimal national standards set for health laboratories. This makes "international standards" look utopian for most countries. It has been hypothesized that *each country should in the first instance, define minimal standards for their laboratories which should be mandatorily met by all the laboratories and then in a graded fashion, laboratories which have achieved national standards should attempt to achieve international standards.*

3

Development and Implementation of Standards

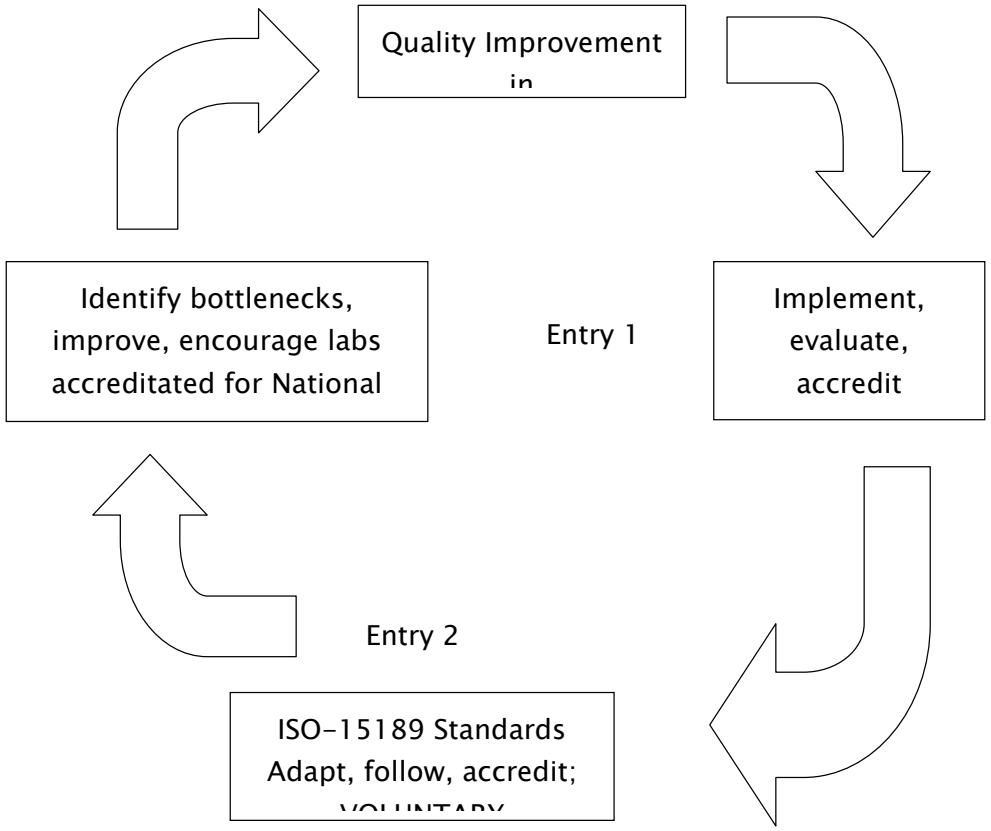
A quality system can be developed using a step-wise approach. The key steps required are shown below:



Facilitate the adoption of national standards

Monitor and evaluate the process

Entry points in quality cycle



Entry 1: An easy entry point ensures minimal critical standards for all the laboratories

Entry 2: Feasible only in a few laboratories

4

Implementation of National Standards in Thailand: A Novel Approach

A uniform, national-level quality system for medical laboratories in Thailand was not available until 2004. Since 1999, all laboratories had to rely on the international quality standards known as the ISO/IEC 17025 for all types of testing and investigations which were developed and widely recognized for use, particularly when dealing with international trade. This was due to the belief that the requirements of medical laboratories and their objectives were similar to the general ones. Meanwhile, efforts were being made to develop international quality standards for medical laboratories. In 2004, the development of ISO 15189 was completed and officially announced for adoption as the international quality standards for medical laboratories for worldwide use.

4.1 Improvement of Quality Standards

The Ministry of Public Health (MOPH) in Thailand has constantly made efforts to develop and improve its medical and health laboratory service system. In 1986, the MOPH launched a project of health service delivery system development among its provincial health service facilities and offices, locally known as Por Bor Sor, to improve the nationwide health service system including provincial health service facilities and public health offices.

Under the project, the health laboratory service system was identified as one of the areas to be developed. The major strategy used was to establish a networking among members to help each other in both the technical and resource aspects. In addition, a set of standard guidelines on laboratory competency at all levels of service facilities was established. This became the core development strategy used in other activities. However, a positive outcome was achieved in only some areas of the country due to the high cost of purchasing equipment to support the competency development programme, difficulty in programme coordination and shortage of personnel. In addition, this project failed to place enough emphasis on the quality development of laboratories.

The majority of laboratories implemented their quality improvement programme by having their staff participate in training courses conducted by related agencies within and outside the MOPH. These training courses were conducted regularly but without collaboration and joint planning among training agencies and with no built-in plan of follow up. As a result, the project failed to yield clear and concrete results.

The Department of Medical Sciences (DMSc) is one of the departments of the Ministry of Public Health which directly functions as the national reference medical laboratory and thus supports the national goal of improving the health status of entire population. Supporting the nationwide implementation and development of health and medical laboratory services of hospitals under the MOPH is one of the DMSc's main duties. The DMSc has developed training and refresher courses of both theoretical knowledge and practical skills in order to regularly train and strengthen the capacity of laboratory personnel in the areas of testing and diagnosis of both infectious and non-infectious diseases.

To develop a laboratory quality system to match international standards, the Bureau of Laboratory Quality Standards (BLQS) of the DMSc organizes up to three training courses every year to provide updated knowledge, guidelines and better understanding of the concept and process of quality development of health laboratories. In addition, the Bureau also has an external quality assessment scheme (EQAS) covering six areas, namely, microscopy, blood banks, clinical microbiology, chemical biology, immunology and parasitology. Its member agencies include a network of over 800 hospitals at all administrative levels nationwide under the jurisdiction of the Office of the Permanent Secretary for Public Health, which include regional, general and community hospitals.

Presently, the network covers public health laboratories under other government agencies as well as those run by the nongovernmental organizations throughout the country. To accomplish such activities, a budget of approximately four million baht was allotted and spent.

4.2 Partners

At the same time, other related agencies such as the university's faculty of medical technology, multidisciplinary agencies, and professional organizations including the Association of Medical Technologists of Thailand (AMTT), trying to improve their health laboratory services by organizing training courses for laboratory personnel. In addition, each hospital is carrying out its own development plan by sending their staff for training courses on the laboratory quality improvement. These courses are organized by the private sector which include dealers of laboratory equipment and supplies, to enable the trainees to better understand and effectively use such equipment. In addition, international agencies

such as WHO, USCDC, and SEAMIC have, from time to time, provided specialized training courses on the improvement of laboratory quality system. It is estimated that the annual spending on the quality system development of health laboratories is over 45 million baht. Despite the large annual expenditure, the results are unclear and difficult to quantify, rendering it difficult to justify the cost to the funding agencies.

At present, health and medical laboratories in the peripheral and central areas of the country have implemented their quality system development according to their existing policy and to address the emerging social demands and pressure. On one hand, even if health laboratories use different quality or standard systems, it is acknowledged that these quality standards are in place, and followed by the majority of health laboratories. On the other hand, the practice of implementing ad-hoc quality systems also causes a certain amount of confusion, anxiety and even uncertainty and lack of confidence among laboratory staff.

4.3 Development of National Standards

In 2001, the Bureau of Laboratory Quality Standards (BLQS) of the DMSc invited the Institute of Hospital Quality Improvement and Accreditation (IHQIA) and the Association of Medical Technologists of Thailand (AMTT) to a meeting to review the appropriate standards of health laboratory quality. The meeting unanimously agreed to integrate the medical technology standards (red book) with those of the ISO 17025 to develop the national standards version (blue book). An effort to have the integrated quality standards recognized and adopted on a wider scale by hospitals is yet to be accomplished due to inadequate cooperation from related stakeholders.

4.4 Standards for Medical Laboratories: 2001

The standard Manual for Medical Laboratories was developed in 1991 by the Association of Medical Technologists of Thailand, the Institute of Hospital Quality Improvement and Accreditation and the Bureau of Laboratory Quality Standards, Department of Medical Sciences, Ministry of Public Health.

The Manual contains 10 clauses, as follows:

(1) Organization and management

(2) Personnel

(3) Laboratory instruments and equipment

(4) Procurement and external services

(5) Process control

(6) Document control

(7) Control of nonconformities

(8) Internal audits

(9) Continual Quality improvement

(10) Client management

Organization and management

Organization

The organization or part of the organization of the medical laboratories shall be legally identifiable. All services of medical laboratories shall meet the relevant requirements of this standard.

The medical laboratory management shall be responsible for the design, implementation, maintenance and improvement of the quality management system. This shall include the following:

designated quality manager/technical manager with specified responsibility and authority for the management of the laboratories according to the quality manual. All personnel shall be encouraged to foster close working relationship. The deputy quality manager/technical manager or other important positions shall be designated with well-defined responsibilities. Continual training shall be designed for all personnel. Client data protection shall be developed.

Quality index for quality monitoring shall be specified.

Quality management

Quality policies, procedures and manuals shall be documented and communicated to all relevant personnel. The management shall ensure that the documents are understood and implemented.

Quality management shall include standard of services, procedures for personnel to follow the quality policy as well as document control.

Medical laboratories should perform internal quality control and participate in interlaboratory comparison /PT/EQA schemes.

Equipment/instrument maintenance and calibration plan should be implemented.

Management review

Quality manager or relevant person, at least one time/year, shall review the internal audit report, surveillance report, quality index results, laboratory service evaluation reports, and the complaint record for management planning. The quality management review report shall be documented.

Personnel

Policy

A policy and plan for employing sufficient staff shall be implemented. Personnel qualifications shall be specified in relation to the job description. Policy and planning for continual personnel improvement shall be implemented. Person(s) who can have access to the confidential laboratory data stored in computers shall be defined. Annual check up and vaccination of laboratory personnel shall be supported.

Head of laboratory

The Head of the laboratory shall have a professional medical technologist's license or clinical pathology license with adequate work experience. He/she will be responsible for work related to instructing, managing, advising and training in the related laboratory.

Personnel quality improvement

All laboratory personnel shall undergo continual educational programme. Work performance evaluation shall be regularly monitored for designing the training plan. Non-licensed personnel shall work under the supervision of licensed staff. Curriculum vitae and training records of all laboratory personnel shall be documented.

Laboratory instruments and equipment

These include equipment, instruments, reference materials, reagents and test kits.

Working status of the equipment

The laboratory shall have all the equipment required to provide the services. Procedures for transferring the equipment shall be implemented. Maintenance and calibration plans shall be implemented. Understanding of and proper use of the equipment by all the personnel shall be ensured. The laboratory management shall establish a programme to regularly monitor and demonstrate proper calibration and function of all equipment. The equipment shall be operated only by authorized personnel.

Equipment identification and the working status

Each equipment shall be uniquely labeled, marked or identified. Whenever the equipment is found to be defective, it shall be taken out of service, clearly labeled and appropriately stored until it has been repaired and shown by calibration, verification or testing to meet the specified acceptance criteria.

Validation and verification

The laboratory shall follow the procedure to ensure that quality manuals or related documents have been corrected when they have the correction factor. The procedure for unauthorized verification protection shall be implemented.

Equipment data record

Equipment data record shall include the serial number, model, name of manufacturer, name of distributor, installation date, installation place and maintenance data.

Operation for computer and autoanalyzer

The laboratory data shall be thoroughly reviewed for each item of equipment before operating. The operation failure protection system shall be implemented. All records shall be documented.

Procurement and external services

Procurement

The laboratory shall define and document its policy and procedures for selection and use of purchased external services. There shall be an inventory control system for supplies. Appropriate quality records of external services, supplies and purchased products shall be established. The laboratory shall evaluate suppliers of critical reagents, supplies and services that affect the quality of examination and shall maintain records of these evaluations and maintain a list of approved suppliers.

External services

The laboratory shall define and document procedures for selection of the referral laboratories and advisory committee matters. List of referral laboratories and advisory committee matters shall be documented. The laboratory shall establish procedures to ensure that the reports received from external laboratories are correct. A copy shall be maintained for an appropriate period of time.

Process control

Laboratory space

The laboratory shall have enough working space and appropriate conditions to ensure quality of services. The laboratory shall

separate the contaminated area from the sterile area and only authorized persons will be allowed entry into the laboratory room. The laboratory shall monitor, control and document all environments which may affect the quality of its services. The laboratory shall designate an appropriate room for collection of specimens which should not affect the quality of its services. The laboratory shall have a clear procedure for waste management and environment protection.

Quality assurance

The laboratory shall undertake the internal quality control for monitoring the quality system and record all factors affecting the quality of services. The laboratory shall calibrate testing procedures by using reference materials or compare the testing results between laboratories. The laboratory shall participate in external quality assessment scheme (EQAS/PT). If no EQAS is available, the laboratory shall establish a procedure for comparing the testing results between laboratories. If the laboratory performs the test using more than one instrument, it shall have a procedure for comparing and confirming the results from each instrument.

Pre-analytical process

The laboratory shall develop a specimen collection manual for use by other organizations. The manual should be reviewed by laboratory supervisor. The laboratory shall establish a procedure for handling specimens without a request form and a procedure for specimen management (acceptance or rejection of specimens).

Analytical process

The laboratory shall use only the standard method or validated method for specimen testing. The head of the laboratory shall review annually, the method and reference value. The procedure for all test methods shall be documented and maintained. The laboratory management shall define the duration of each test method and inform the clients.

Post analytical process

The laboratory shall designate a person to approve the results. The tested specimen shall be kept for an appropriate period of time as per the policy. Only authorized person(s) shall discard the unused specimen and the specimen management procedure shall be documented.

Reporting

The reporting procedure shall be clearly established including reporting by telephone, reporting via computer network and reporting the critical results. The report form shall be designed with an appropriate format including the name and/or symbol of the laboratory, name or code of the patient, tests requested, specimen receiving date, reporting date, test results, names of persons who reported and approved the results, etc. All reports are legal documents. The laboratory shall maintain a copy of the report for an appropriate period of time.

Changing the test results

The laboratory shall not use an eraser or correcting fluid to correct the results. A pen shall be used to cross over the old results and

the new results shall be reported and signed by the concerned person, indicating the date of correction.

Document control

Quality document and document control

The laboratory shall define the level, type and details in the header of document. The document shall be reviewed and approved by the authorized person. A list of all documents shall be maintained. Obsolete or cancelled documents shall be labeled and removed from the working area.

Quality and technical record

The laboratory shall define the procedures for proper keeping and documentation, sequencing and timing of specimens and duly designate a responsible person for this task.

Control of non-conformities

The laboratory shall define the criteria and procedure for non-conformance control. Root cause analysis should be undertaken for prevention planning.

Internal audit

The plan for internal audit should be established and documented. The laboratory management shall ensure that the plans are maintained and recorded.

Continual quality improvement

The procedure for corrective action and preventive action shall be documented and maintained. The laboratory shall design the process for reviewing client feedback, analyzing any errors and reporting to laboratory personnel and top management. A plan for quality system review shall be established and maintained.

Client management

The responsibility of the persons shall be related to their job. The procedure for client feedback management shall be established.

4.5 Differences between National and ISO Standards

Though effort were made to retain all the essential components of the ISO 15189 Laboratory standards while framing the national standards 2001, yet there are some subtle differences between the two which are enumerated here:

(1) The national standards focus on simplicity, brevity and user friendliness

(2) The terminology, definitions and introduction parts have been totally changed to suit the local conditions

(3) Of the two major components of ISO 15189 namely management requirement and technical requirement, greater emphasis has been laid on the technical requirements in the national standards.

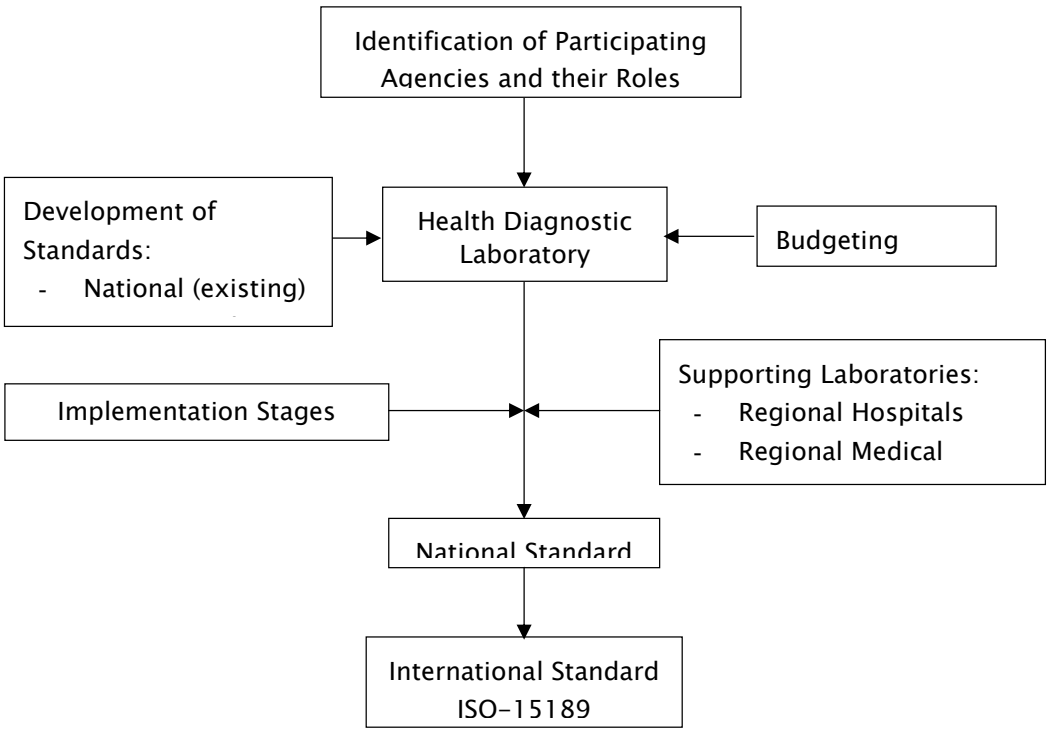
(4) The details of ISO 15189 regarding quality manual, SOPs and recording and reporting has been significantly reduced in the national standards under the premise that these could be added in an incremental fashion.

(5) A few clauses of the international standards have been completely deleted from the national standards such as

review of contract, complaints section, corrective and preventive actions which in the national standards are deemed to be covered by the internal audits

5

Conceptual Framework of Implementation



6

Implementation Model Adopted in Thailand

Ten stages of the implementation of the model of laboratory quality system development are shown below.

Stage 1 Appointment of a steering committee comprising all stakeholders by selection of the members of the Network and identification

Regional Medical Sciences Centres

Regional Hospitals
Medical Technology Association

Stage 2 Identification of the quality standards for the

2001 National Standards
International Standards
ISO 15189

Stage 3 Establishing the developmental steps and

Step-wise for Standards

Stage 4 Establishing the implementation approach for self-evaluation and

Implementation of quality developm using different approach the existing

Stage 5 for	Coordinating project implementation within the region and establishing a	Implementation by each region Networking Selecting the appropriate approach each region
Stage 6 timefram	Each region submit the appropriate detailed	Set up clear implementation Establish clear unit costs
Stage 7 Director of	Signing of project agreement by all parties	Director-General and Regional MD Centres Directors of MD Centres and Director of Regional Hospitals
Stage 8	Transfer the budget for project implementation. Progress reports are	Self/External evaluation was performed External evaluation but within the region
Stage 9	Appraisal of the evaluations reported by the committee, management concerned and all stakeholders by	Evaluation indicators
Stage 10	Results analysis and plan adjustment for next year	

7

Strategies and Their Implementation

As mentioned earlier, quality system development among hospital-based laboratories particularly those under the responsibility of the Office of Permanent Secretary, Ministry of Public Health who is in-charge of the overall health care of the Thai population is considered to be very important. It is therefore crucial for laboratories throughout the country to undergo the development simultaneously. It is also critical that the developmental strategies are used for successful implementation. These strategies are described below:

7.1 Establishing Partnerships for Implementation of Work

Among the over 800 hospital-based laboratories under the Office of the Permanent Secretary for Public Health which include 25 regional hospitals, 68 general hospitals and over 700 community hospitals located all over the country, the competence and quality standards differ widely. The task of raising their quality to uniform national standards may be too large to be accomplished by any one agency alone. It is essential that a network is formed to help shoulder the many tasks. Such a network for quality system development can be created through the following mechanisms:

Identification of stakeholders

The DMSc through its network of 12 Regional Medical Sciences Centres (RMSC) located throughout the country has already adopted quality systems such as ISO/IEC 17025 and ISO 15189 for its network of laboratories. These centres are capable of

functioning in close coordination with the DMSc's Bureau of Laboratory Quality Standards without any difficulty on both the administrative and financial aspects. Therefore, the RMSC are considered the major regional agencies to play a key role in the laboratory quality system development in Thailand.

Many of the Regional Hospitals under the Office of the Permanent Secretary, Ministry of Public Health, have undertaken an improvement of their laboratory quality system by having their technicians and medical technologists trained. The laboratories at this level can be a major technical agency to provide support in the area of quality system development.

The Association of Medical Technologists of Thailand which is a professional organization of medical technologists and technical officers can also play an important role in the development of a good laboratory quality system.

Positioning and delegation of responsibilities

Regional Medical Sciences Centres

To ensure correct and precise implementation of work, after identification of stakeholders, responsibilities have to be clearly divided and delegated to all concerned. In this case, all the 12 Regional Medical Sciences Centres have been delegated with the following responsibilities:

- Management of the budget which is transferred from the Bureau of Laboratory Quality Standards for further allocation to the network of hospitals in respective areas.
- Coordinating with the regional hospitals in selecting hospitals which have volunteered to participate in the quality system development.

- Coordinating with general and community hospitals to provide detailed information on the project.

Regional Hospitals

Regional hospitals, which are the key agencies in this quality system development project, will be delegated with the following responsibilities:

- Working in collaboration with the Regional Medical Sciences Centres to advise on and give recommendations in the selection of participating hospitals.
- Providing technical knowledge on the development of the quality system through training and expert advice.

The Association of Medical Technologists of Thailand

The Association is delegated with the following responsibilities:

- Providing technical support.
- Providing resource persons for training courses.
- Providing expert advice

Preparation of a work plan with a timeframe

The work plan should clearly spell out detailed activities from the onset of the project. It shall cover areas like selection of participating hospitals, preliminary assessment, quality system development, final evaluation after the development and overall summary of the progress accomplished in each stage. In addition to the activities to be carried out in stages throughout the project, the timeframe should also be clearly specified.

7.2 Existing Quality System Standards Being Implemented

At present, the quality system used by diagnostic laboratories in Thailand includes both national and international standards. To ensure systematic development and facilitate implementation, guidelines from the following standards are observed:

The 2001 national standards for medical laboratories

This set of national standards was established through collaboration between the three agencies involved in health diagnostic laboratories, namely, the Association of Medical Technology of Thailand, Institute of Hospital Quality Improvement and Accreditation, and the Department of Medical Sciences. The national standards were announced in 2001 to be used as the basic guidelines for laboratories. These national standards can also facilitate laboratories to scale up their quality standards to the international level.

The international standards, ISO 15189

The international standards for medical laboratories are standards established for implementation by health diagnostic laboratories which have passed the preliminary national standards evaluation and want to acquire the higher standard.

Both sets of the above-mentioned quality standards are considered to be appropriate for health diagnostic laboratories. They are easy to follow and well recognized by those involved in working in all types of diagnostic laboratories.

7.3 Quality System Development Process

To facilitate and ensure that an evaluation of the laboratory quality system development project can be performed at each stage, the following tools and steps need to be implemented:

The tools used in the evaluation include:

The existing checklist – The existing checklist being used in the 2001 National Standards of Medical Laboratories has 100 items which cover all aspects of standard requirements covering a laboratory's administrative, quality and technical practices.

The modified checklist – This checklist is modified from the existing checklist so that it is in line with and appropriately corresponds with the guidelines for quality system development of the international standards. At the same time, the guidelines for implementation of ISO 15189 in a tabulated form was developed (annex) by BLQS to facilitate and assist the laboratories that are ready to be assessed for ISO 15189 standards.

Giving score to items in the checklist

The current practice is to give scores to the evaluated items which are divided into three levels from the total scores of 100. This way, the improvement a laboratory has made is clearly seen after the second evaluation. Under this project, each of the 100 items in the checklist is given one point.

Level 1 = 0 – 35 points

Level 2 = 36 – 70 points

Level 3 = 71 – 100 points

Systematic development/improvement process

After the first evaluation has been carried out, it is the time for laboratories to make corrections and improvements in the areas not properly developed and which are below the standard requirements. After a given period, a repeat evaluation similar to

the first one is performed. If the hospitals participating in the project are able to show at least one level of improvement at the second evaluation, they are considered to have reached the improvement objectives established. In case where any laboratory makes it through to the third level, the highest development level, of the quality system development stages, they are qualified to seek accreditation to certify their compliance with the international standards.

7.4 Project Evaluation

The laboratory quality system development project carried out bi-annual evaluations which were done to monitor the progress of the project. The evaluation methodology was as follows:

- Self-evaluation using a prepared checklist to identify the areas that need more improvement to meet the standards.
- External evaluation performed to prevent any bias.

Regional evaluations were done whereby the overall results of hospital-based laboratories were compared with those in other regions. Besides demonstrating the regional improvement in diagnostic laboratories, the regional comparison was meant to motivate and further encourage active development of the laboratory quality system. The evaluation results from all regions were then combined to illustrate the country's laboratory development as well as further summarize the successes and lessons learned from the project.

8

Project Results

8.1 Participating Hospitals

The implementation of the laboratory quality system development project started in the fiscal year 2004. From a total of 816 hospitals under the Office of the Permanent Secretary for Public Health located in all 19 public health administrative regions throughout the country, 249 hospitals (30 %) voluntarily enrolled to participate in the project. The participating health laboratories were based in 15 regional hospitals, 44 general hospitals and 189 community hospitals. All of these hospital-based laboratories already had a certain quality system in place. A majority (90 %) of these laboratories adopted the 2001 National Standards of Medical Laboratories, 5 % of them used the ISO 15189 and another 5 % used other standards. Under its implementation plan, the Department of Medical Sciences provided budgetary support for the participating laboratories based on the unit costs system amounting to 35,000 Baht per laboratory.

8.2 Levels of Quality Development Achieved by Hospitals

Results of the implementation of the Laboratory Quality System Development Project carried out in hospitals under the Office of the Permanent Secretary for Public Health in 2004 were derived by comparing results of the pre- and post- project implementation evaluations using the 100-item checklist for the 2001 National

Standards of Medical Laboratories as the tool. (Each item was given a score of one) According to the self evaluation prior to the project initiation, it was found that while 94 laboratories were graded at Level 1 quality, 114 hospitals and 36 hospitals were graded in quality Levels 2 and 3 respectively. This indicated that even if the hospitals have adopted a quality system for implementation in their laboratories, they still lack a comprehensiveness in their practices as most of them were still in the quality Levels 1 and 2.

When a comparison was made against the post-project implementation evaluation at the end of one year, it was found that hospitals scored better. The number of hospitals in the quality Level 1 decreased to only 31 while those in Level 2 increased to 115 and those in Level 3 also increased to 89 (Tables 1 and 2).

Table 1: Comparison of results of evaluations at the pre- and post quality development

Quality level	Pre project (1st evaluation)	Post project (2nd evaluation)
Level 1 (0-35 points)	94	31
Level 2 (36-70 points)	114	115
Level3 (71-100 points)	36	89
Incomplete Data	5	14
Total	249	249

Table 2: Comparison of quality system development results by hospital types

Quality development results	Regional hospitals		General hospitals		Community hospitals > 30 beds		Community hospitals ≤ 30 beds		Total	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Level 1	2	1	10	1	30	3	52	26	94	31
Level 2	6	4	23	11	42	45	43	55	114	115
Level 3	6	9	13	31	9	29	8	20	36	89
Incomplete data	2	2	1	4	2	6	0	2	5	14
Total	16	16	47	47	83	83	103	103	249	249

- When a comparison was made on the progress of the quality system development, it was found that 99 laboratories (39.8 %) were able to raise the development of quality system one level. Only nine laboratories (3.6 %) were capable of improving their quality by two levels.
- There were 110 laboratories (44.2 %) who achieved only a slight improvement but their scores did not qualify them to make one level.
- There were actually 17 laboratories (6.8 %) whose scores from the second evaluation were lower than the ones in the first evaluation (Table 3). This may have been caused by work interruption due to resignation of the responsible officers. Besides, the evaluators in the second evaluation were a different set of people from those in the first evaluation.

***Table 3**: Progress of the quality system development by hospitals types*

Results	Regional	General	Community	Community	Total	%

	hospital	hospital	hospitals >30 beds	hospitals <30 beds		
Negative progress	0	5	6	6	17	6.8
Progress < one level	10	14	28	58	110	44.2
Progress by one level	4	21	39	35	99	39.8
Progress by two levels	0	3	4	2	9	3.6
Incomplete data	2	4	6	2	14	5.6
Total	16	47	83	103	249	100

When the laboratories have reached full competency and achieve the highest level (Level 3), they are considered to be ready to go through the evaluation process in order to be accredited for the 2001 national standards of medical laboratories by the accreditation agency for laboratory standards, namely the Bureau of Laboratory Quality Standards, or the Association of Medical Technologists of Thailand. Within one year of the project, the number of hospitals who have gone through the quality system development programme until they are qualified and ready for the accreditation process has increased two fold, from 38 to 89 hospitals.

9

An Assessment of the Participating Units' Satisfaction

The following were the salient observations:

- A random sampling technique was used to collect samples from 130 hospitals among the participating hospitals in the project to study their satisfaction level. These samples included nine regional hospitals, 25 general hospitals and 96 community hospitals.
- The self-administered questionnaire prepared as a tool for the satisfaction survey was sent out to these selected hospitals with clear instructions.
- A total of 102 completed questionnaires (78.5 %) were returned from 100 % of the sampled regional hospitals, 84% of the general hospitals and 75 % of the community hospitals. The respondents who completed the questionnaire were medical technologists (69.6 %) and laboratory technicians (29.4 %).
- The results of the survey showed the positive response of the respondents towards the laboratory quality system development project, with slightly over three quarters of them (76.5 %) saying that the project had facilitated implementation of the laboratory quality system development programme.

- The laboratory staff from the participating laboratories were happy and willing to participate positively in implementing the quality system.
- While the majority (98 %) of the respondents said that the project outcome was clearly felt, over two thirds confirmed that it took them less time to accomplish the quality improvement.
- A high percentage of respondents (96 %) believed that their chance for a successful development leading to accreditation was high, while up to 97 % believed that there would be sustainable and continuing development.
- The results of this assessment have given a concrete reassurance that the established model of the project implementation strategies is appropriate and on the right lines.

10

Lessons Learnt

10.1 Simple Systems are Easy to Implement

While hospital-based laboratories have to shoulder a heavy workload of providing routine services, many also face the problems of shortages of personnel, equipment and supplies, as well as lack of sufficient support on the technical, motivational and moral aspects. Therefore, making laboratory quality system development a simple and uncomplicated matter and creating a flexible development schedule to be accomplished through networking could indirectly create the right motivation.

All the standards and guidelines had undergone extensive reviews to clarify their meaning in more precise and concrete terms so as to involve all stake holders.

10.2 Step-wise Approach Provides a Flexible Approach

The project designed its activities in a way that all items of quality standards were grouped into a stepwise implementation at three levels, given a flexible time of no more than three years for implementation, without any restriction of fixed schedule of specific tasks to be accomplished in a specific timeframe. The participating laboratories were free to choose whichever activities for implementation at their chosen time. In fact, the quality system development activities could be carried out alongside the routine job if the work plan was clearly established. In addition, other

factors that were critical in implementing the project included: delegation of jobs, budget decentralization, bottom-up planning, progress assessment and evaluation during each project period.

10.3 A Comprehensive Check-list is a Vital Tool

A vital tool which facilitated the quality system development in this project, however, was the checklist which was designed to ensure that all areas of quality development are accomplished. The scoring given to the items in the checklist was the mechanism by which the developmental progress could be measured and further development encouraged at the individual level to reach the desired critical mass.

10.4 Different Laboratories are at Different Levels of Quality Development

Prior to their participation in the project, all participating laboratories did not start from scratch. They had initiated and had the process of quality system in place already. While a majority of them carried out their quality system development relying on the 2001 National Standards of Medical Laboratories, a small number followed the international standards of ISO 15189. It is, therefore, believed that after the end of the project these laboratories can continue to carry out their quality system development on a sustainable basis by using the existing checklist prepared for the particular standards of their choice until all areas of quality are fully developed.

10.5 Voluntary Participation makes a Good Beginning

In this project, only 249 hospital-based laboratories or 30% of the total laboratories under the Office of the Permanent Secretary for Public Health, voluntarily participated to join in the process of quality system development. Some of those who did not participate were already well developed and thus accredited. Many may have not heard nor received sufficient information about the project as it was seen that in some public health administrative regions, none of their hospitals participated in the project at all. The results of the self-administered evaluation before the project started showed that 94 laboratories were in the Level 1 quality, 109 in Level 2 and 34 in Level 3. Among these laboratories, 90% adopted the national laboratory standards as their guidelines for quality system development and only 5% used the ISO 15189 standards. The assessment of the progress after one year of the project showed that 108 laboratories (43%) had improved their quality development by one level.

10.6 Implementation is Rapid in Medium-sized Hospital Laboratories

It was found that medium-sized facilities like general hospitals and community hospitals with more than 30 beds made much better progress in their quality improvement than their larger or smaller counterparts. Thus 67 out of a total of 130 of these medium-sized hospitals (51%) were capable of improving their laboratory quality to the point where their scores were raised by one to two levels which was a demonstration of their better preparedness.

This was in contrast to the regional hospitals where four out of 16 hospitals (25%) were able to raise their quality levels by one to two levels while 37 out of the 103 community hospitals with less

than 30 beds (40%) could achieve the same feat. The likely explanation may be due to the fact that while the larger facilities like the regional hospitals have a busy schedule with a large workload, the smaller laboratories in the community hospitals have faced staff and supply shortages.

10.7 Certain Critical Factors Influencing Quality Development

Some of the critical factors facilitating the development of quality system include the availability of knowledgeable and regularly trained laboratory personnel and participation in External Quality Assessment Scheme (EQAS) involving quality assurance activities. All laboratories in the country are participants of the EQA Scheme which has facilitated the speedy implementation of all quality assurance activities. Where EQAS is not in place, it may be necessary to have the quality of diagnostic laboratory controlled by performing an inter-laboratory comparison.

10.8 Training in Practical Skills is Fundamental to Success

Even though the use of checklist greatly facilitates quality system development, implementing activities to meet the individual objectives set for each indicator of the checklist requires that the laboratory personnel be given accurate instructions and training in practical skills. Besides the progress made according to the targeted indicators, results from the satisfaction evaluation showed that the participating laboratories had a positive attitude towards the project because it had fostered the participatory concept as well as cooperation among those involved from both within and outside the project implementing agency.

10.9 National Standards can Facilitate Accreditation by ISO

A copy of the complete checklist provided in the Annex based on the 2001 National Standards covers all the requirements of the international standards ISO 151989. It can be used by any country's laboratory quality system development authority to make appropriate adjustments for application according to its laboratory facilities, resources, timeframe and readiness. The scoring procedure can also be adjusted to address the specific needs of the country authority.

10.10 Enhanced Inter-laboratory Cooperation is an Additional Benefit

This project created a new culture of laboratories helping each other in the network where personnel from regional hospitals assumed the responsibility of providers of technical advice and support to all other areas. This sense of helping each other also led to striving to accomplish the quality system development activities among personnel in all echelons of the health administration, from the provincial level to the district level, from larger hospitals to smaller ones, causing a critical mass and momentum of a driving force towards moral support, positive attitudes and satisfaction in performing the job among workers in health laboratories. In addition, the project also got good cooperation from the Association of Medical Technologists of Thailand whose expertise greatly assisted in solving problems using technical and scientific principles.

11

Conclusions

The approach followed by Thailand for improving the quality standards of health laboratories is novel because of its flexibility, ease of implementation in a stepwise fashion and the participatory approach of the laboratory staff to achieve national standards in the first instance.

The Thailand model can help strengthen the quality system of health laboratories in other countries of the Region by developing minimal national standards as part of the National Laboratory Policy which could be further strengthened to achieve International Standards on a voluntary basis. For all this to happen, identification of a national focal point for laboratories, along with a well defined national laboratory policy is essential.

Though voluntary participation of the laboratories to implement national standards has been practiced in the initial phase of this model, it is suggested that subsequent to the development of minimum national standards, countries should strive to make these mandatory. Implementation of international standards can be undertaken subsequently through upgradation of national standards.

Checklist

Standard for Medical Laboratory

Name of hospital…….Name of Laboratory……..……..……
Name……Position /
Title…..…….……..……..
DD/MM/YY……Revision……..……
……

Quality system	Evaluation				Remark
	Y	P	N	NA	
1. Organization and Management					
1. Laboratory shall have the organizational and management structure and its relationship to any other organization with which it may be associated.					
2. Appointment of a quality manager with delegated responsibility and authority to oversee compliance with the requirements of the quality management system.					
3. Laboratory management shall have responsibility for design, implementation, maintenance and improvement of the quality management system.					
4. All operational procedures shall be systematically reviewed by laboratory management at regular intervals, as defined in the quality management system.					
5. A quality manual shall describe the quality management system and the structure of the documentation used and shall include or make reference procedures including technical procedures.					
6. Appointment deputies for key function.					
7. Adequate training, specified responsibility, authority, and interrelationships of all personnel.					

Quality system	Evaluation				Remark
	Y	P	N	NA	
8. Laboratory management shall implement quality indicators for systematically monitoring and evaluating					
9. Management support of all laboratory personnel by provides them with the appropriate authority and resources to carry out their duties.					
10. Laboratory shall establish and implement procedures for identification, collection, indexing, access, storage, maintenance and safe disposal of quality and technical record.					
11. Laboratory management shall review the laboratory's quality management system and all of its medical services at least once every twelve months. The results of the review shall be incorporated into a plan that includes goals, objectives and action plan.					
2. Personnel					
12. Laboratory management shall have an organizational plan, personnel policies.					
13. Laboratory management shall be staff resources adequate to undertaking of the work required and the carry out of other functions of the quality management system.					
14. Laboratory management shall authorize personnel to perform particular tasks.					
15. Laboratory shall be a continuing education program available to staff at all levels.					
16. Policies shall be established which define who may access patient data and who is authorized to enter and change patient results, correct billing or modify computer programs.					

Quality system	Evaluation				Remark
	Y	P	N	NA	
17. Laboratory shall controlled personnel who have an inadequate qualification by professional judgments with reference to examinations shall have the applicable theoretical and practice background as well as recent experience and should be in accordance with national, regional and local regulations.					
18. Laboratory shall have a qualification and responsibility for laboratory supervisor.					
19. Employees shall be trained to quality assurance, prevent or contain the effects of adverse incidents.					
20. Laboratory shall have performance assessment for personnel at an interval time.					
21. Laboratory shall have a training need for personnel.					
22. Laboratory management shall maintain records of all personnel					
3. Laboratory Equipment					
23. Laboratory shall be furnished with all items of equipment required for the provision of services.					
24. Equipment shall be shown to be capable of achieving the performance required and shall comply with specifications relevant to the examinations concerned.					
25. When equipment is removed from the direct control of the laboratory or is repaired or serviced, the laboratory shall ensure that it is checked and shown to be functioning satisfactorily before being returned to laboratory use.					
26. Laboratory shall establish a programme that regularly monitors and demonstrates proper calibration and function of instruments, reagents and analytical system. It shall also have a documented.					

Quality system	Evaluation				Remark
	Y	P	N	NA	
27. Laboratory shall have a documented and recorded programme of preventive maintenance which at a minimum follows the manufacturer's recommendation.					
28. Equipment shall be maintained in a safe working condition. This shall include examination of electrical safely, emergency stop devices.					
29. Laboratory shall have list of manufacturer and manufacturer' contact person.					
30. Equipment shall be operated by authorized personnel only.					
31. Laboratory shall have a manual for used and maintenance of equipment.					
32. Laboratory shall have identified of the equipment, reference materials and reagents which affect to the results.					
33. Laboratory shall have a labeled or otherwise coded to indicate the status of calibration or verification ant the date when calibration or reverification.					
34. Whenever equipment is found to be defective, it shall be taken out of service, clearly labeled.					
35. Equipment including hardware, software, reference materials, consumables, reagents and analytical systems shall be safeguarded from adjustments or tampering that might invalidate examination results.					
4. External Services and Supplies					
36. Laboratory shall define and document its policies and procedure for selection and use of purchased external services, equipment, consumable supplies that affect the quality of its services. There shall be procedures and criteria for inspection, acceptance/rejection, and storage of consumable materials.					

Quality system	Evaluation				Remark
	Y	P	N	NA	
37. Laboratory shall have a list of manufacturer, supplier, and reagents.					
38. Purchased equipment and consumable supplies that affect the quality of the service shall not be used until they have been verified as comply with standard specification or requirements defined for the procedure concerned.					
39. Laboratory shall be responsible for selecting referral laboratories and shall ensure that the referral laboratory is competent to perform the requested examinations and shall maintain a register of all referral laboratories that it uses.					
40. Laboratory shall be verified the results from referral laboratories. A duplicate of the laboratories report before provided to the user of laboratories services.					
5.1 Accommodation and Environmental Conditions					
41. The laboratory shall have space allocated so that its workload can be performed without compromising the quality of work, quality control procedures, safely of personnel or patient care services.					
42. The laboratory design and environment shall be suitable for the task and separation form office.					
43. There shall be effective separation between adjacent laboratory sections in which there are incompatible activities.					
44. The laboratory shall be controlled temperature of refrigerator for reagents, blood sample, calibrator, control materials which affect the analytical results.					
45. Sample shall be storage at suitable condition which is not affect to quality of sample					
46. Work areas shall be clean and well maintained. Measure shall be taken to ensure good housekeeping.					

Quality system	Evaluation				Remark
	Y	P	N	NA	
47. Laboratory shall have procedure for storage and destroy hazard sample and also have a procedure for prevent an environment.					
5.2 Assuring quality of examination procedure					
48. Laboratory shall design internal quality control systems that verify the attainment of the intended quality results.					
49. Laboratory shall have corrective action records where internal quality control out of range.					
50. Laboratory shall participate in as interlaboratory comparisons such as those organized by external quality assessment schemes.					
51. Laboratory management shall monitor the results of external quality assessment and participate in the implementation of corrective actions when control criteria are not fulfilled.					
52. A programme for calibration of analytical systems shall be designed and performed so as to ensure that results are traceable to SI units. Calibrator and control materials shall be recorded.					
53. Documentation of statements regarding reagents, procedures or the examination system when traceability is provided by supplier or manufacturer.					
54. For those examinations performed using different equipment; there shall be a defined mechanism for verifying the comparability of results throughout the clinically appropriate intervals.					
5.3 Pre-analytical Process					
55. Specific instructions for the proper collection and handling of primary sample shall be documented and implemented by laboratory management and made available to those responsible for primary sample collection.					

Quality system	Evaluation				Remark
	Y	P	N	NA	
56. Laboratory shall have a procedure for sample preparation.					
57. Laboratory shall have a written policy concerning verbal requests for sample examination.					
58. Sample portions shall also be traceable to the original primary sample.					
59. Laboratory shall monitor the transportation of samples to the laboratory such that they are transported, within time frame, within temperature interval specified in the primary sample collection manual and in a manner that ensures safety for carrier.					
60. Criteria shall be developed for acceptance or rejection of primary sample.					
61. Laboratory shall have documented for rejection of inappropriate primary sample.					
62. Laboratory shall have a procedure for storage primary sample, if it is not immediately examination.					
5.4 Analytical					
63. Laboratory shall be preferred procedures are those that have been published in established/authoritative textbook, journals or international, national or regional guidelines.					
64. If in-house procedures are used, they shall be appropriately validated.					
65. Laboratory shall be reviewed of procedures at least once in twelve months and documented.					
66. Biological reference intervals shall be periodically reviewed.					

Quality system	Evaluation				Remark
	Y	P	N	NA	
67. If the laboratory intends to change an examination procedure such that results could be significantly different, the implication shall be explained to users of the laboratory services in writing, prior to the introduction of the change.					
68. All procedures shall be documented and be available at the workstation for relevant staff.					
69. Laboratory management in consultation with the requesters shall establish turnaround times for each of examination.					
5.5 Post-analytical Procedures					
70. Authorized personnel shall systematically review the results of examinations, and signature.					
71. Storage of the primary sample shall be in accordance with approved policy.					
72. Safe disposal of samples no longer required for examination shall be carried out in accordance with local regulations or recommendations for waste management.					
5.6 Reporting					
73. The laboratory shall have a procedure for reporting of results including date time, procedure, and receiver and reported by telephone and facsimile.					
74. Records of actions taken in response to results in the critical intervals shall be maintained.					
75. Copies or files of reported results shall be retained by the laboratory such that prompt retrieval of the information in possible. The length of time that reported data are retained may vary; however, the reported results shall be retrievable for long as medically relevant or as required by national, regional or local requirements.					

Quality system	Evaluation				Remark
	Y	P	N	NA	
76. The report shall indicate if the quality of the primary sample received was unsuitable for examination or could have compromised the results.					
5.7 Amendment of Reports					
77. The laboratory shall have written policies and procedures regarding the alteration reports. When altered, the record must show the time, date and name of the person responsible for the change.					
6. Document control					
78. All documents relevant to the quality management system shall be uniquely identified.					
79. Quality documents shall be included title, edition or current revision date or revision number, number of pages, authority for issue and source identification.					
80. The laboratory shall have a procedure for check and review documents and shall have a master list and invalid or obsolete documents are promptly removed from all point of use, or otherwise assured against inadvertent use.					
81. The laboratory shall have a policy that defines the length of time various records pertaining to the quality management system and examination results are to be retained. Retention time shall be defined by the nature of the examination or specifically for each record.					
82. All records shall be legible and stored such that they are readily retrievable. Records may be stored on any appropriate medium subject to national, regional or local legal requirements. Facilities shall provide a suitable environment to prevent damage, deterioration, loss or unauthorized access.					

Quality system	Evaluation				Remark
	Y	P	N	NA	
83. The laboratory shall have a policy that defines the length of time various records pertaining to the quality management system.					
7. Control of Nonconformities					
84. Laboratory shall have a policy and procedure to be implemented when it defects that any aspect of its examination does not conform to its own procedures or the agreed upon requirements of its quality management system.					
85. The laboratory shall define and implement procedure for release of results in case of nonconformities, including the review of such results. These events shall be recorded.					
8. Internal Audits					
86. The laboratory shall be conducted an internal audit for quality management system.					
87. The laboratory shall have recorded results of internal audits.					
88. The laboratory shall undertake appropriate corrective or preventive actions, which shall be documented and carried out within an agreed upon time.					
89. The results of internal audits shall be submitted to laboratory management for review.					
9. Continual Improvement					
90. The Laboratory shall be reviewed quality management system every year and planed for next year.					

Quality system	Evaluation				Remark
	Y	P	N	NA	
91. Management review shall take account of follow-up previous management reviews, status of corrective and required preventive action, the outcome of recent internal audits, assessment by external body, outcome of external quality assessment, quality indicators, nonconformities, monitoring of turnaround time, results of continuous improvement processes and evaluation of suppliers.					
92. The laboratory shall be continually reviewed the process of work in the aspect of completeness and accuracy.					
93. The laboratory shall audit result work according to purpose and objective of organization.					
94. In case of mistake which is affect to policies, procedure or quality management system, associated activities shall be evaluated.					
95. The laboratory shall submitted reports from management reviews to laboratory management board.					
96. The laboratory shall have development quality system activities between organization and team.					
97. Procedure for preventive action shall include the initiation of such actions and application of controls to ensure that they are effective.					
10. Client Management					
98. The laboratory shall establish and maintain procedures for review of contracts. The review of capability should establish that the laboratory possesses the necessary physical, personnel and information resources and the laboratory's personnel have skills and expertise necessary, for the performance of the examination question.					

Quality system	Evaluation				Remark
	Y	P	N	NA	
99. The laboratory shall have a policy and procedures for the resolution of complaints or feedback received from clinicians, patients or other parties.					
100. The laboratory shall be performance the responsible rate for the customer once a year.					

Remark

Y = Yes P = Partial N = No NA = not applicable

This checklist developed by Medical Technology Association Thailand