
Requirement for Management of Impartiality

1. Purpose

This document is developed to ensure the impartiality of accreditation.

2. Application

This document is applicable to all personnel involved in BLQS accreditation process and activities including BLQS personnel, committees, assessors and the experts

3. References

3.1 ISO/IEC 17011: 2017 Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies.

4. Definitions and abbreviation

4.1 BLQS: Bureau of Laboratory Quality Standards

4.2 Assessor - person assigned by an accreditation body to perform, alone or as part of an assessment team, an assessment of a laboratory.

4.3 Conformity assessment body - body that performs conformity assessment activities and that can be the object of accreditation.

4.4 Consultancy - participation in any of the activities of a conformity assessment body subject to accreditation, including preparing or producing manuals or procedures for a conformity assessment body, participating in the operation or management of a conformity assessment body or giving specific advice or specific training towards the development and implementation of the management system, operational procedures and/or competence of a conformity assessment body.

4.5 Interested party - person or organization with a direct or indirect interest in accreditation. Interested parties can include the accreditation body, conformity assessment bodies, their associations and their clients, industry services, trade associations, scheme owners, governmental regulatory bodies or other governmental services, or non-governmental organizations, including consumer organizations.

4.6 Impartiality - presence of objectivity. Objectivity means that conflicts of interest do not exist, or are resolved so as not to adversely influence subsequent activities of the accreditation body. Other terms that are useful in conveying the element of impartiality include “independence”, “freedom from conflict of interests”, “freedom from bias”, “lack of prejudice”, “neutrality”, “fairness”, “open-mindedness”, “even-handedness”, “detachment”, “balance”.

Revised by 

Ms. Sitaphaisith Ekachampaka

Reviewed by 

Ms. Patavee Soisangwan

Approved by 

Ms. Patavee Soisangwan

4.7 Risk for impartiality - Sources of risks to impartiality of BLQS can be based on ownership, governance, management, personnel, shared resources, finances, contracts, outsourcing, training, etc.

4.8 Technical Expert – a person assigned by an accreditation body to provide specific knowledge or expertise with respect to the scope of accreditation to be assessed; is a team member who provides technical advice, does not assess independently and is not considered as an assessor unless he/she has the relevant assessor qualifications and training.

5. Associated Documents

5.1 SOP 07 15 039(T): SOP for Risk Management for Laboratory Accreditation.

6. Procedure

6.1 Management of Impartiality

6.1.1 BLQS shall be responsible for the impartiality of its accreditation activities and shall not allow commercial, financial or other pressures to compromise impartiality.

6.1.2 BLQS shall be organized and operates so as to safeguard the objectivity and impartiality of its activities. BLQS provides opportunity for effective involvement by interested parties for safeguarding impartiality through the Laboratory Accreditation Committee.

6.1.3 BLQS shall establish Impartiality Policy and shall have commitment to impartiality of accreditation in all accreditation process and activities and make public on BLQS website.

6.1.4 The policies and procedures of BLQS shall be non-discriminatory and shall be administered in a non-discriminatory way. Its services are available to all applications whose accreditation applications fall within its defined scope of its activities. The accreditation of BLQS shall not be conditioned upon the size of applicant's body. When an unacceptable risk to impartiality of conflict of interest cannot be mitigated to an acceptable level or because of proven evidence of fraudulent behavior, falsification of information or deliberate violation of accreditation requirements, accreditation shall not be provided.

6.1.5 BLQS shall not offer or provide consultancy to conformity assessment bodies.

6.1.6 BLQS shall ensure a balance representation of interested parties who are nominated to be the accreditation committee with no single party predominating in order to prevent undue pressures on the assessment and decision-making process. Assessor and laboratory related person who are members of committee shall not participate in making accreditation decision. BLQS shall not outsource accreditation decisions.

6.1.7 Advisory committee, responsible for advising the quality management system of laboratory accreditation and guidance on risk mitigation are composed of technical experts, customer representatives and stakeholders.

Revised by *Sitaphaisith E*

Ms. Sitaphaisith Ekachampaka

Reviewed by *Patavee Soisangwan*

Ms. Patavee Soisangwan

Approved by *Patavee Soisangwan*

Ms. Patavee Soisangwan

6.1.8 All BLQS personnel, committees, assessors and the experts that involve the activities of accreditation shall be committed to full compliance with Impartiality Policy and required to disclose any potential conflict of interest whenever it may be arise. They shall not in the nomination list form the CAB consultancy or ex-half in the last three years. If they have been involved in conformity assessment services and consultancy towards a conformity assessment body, they shall not take part in an assessment or other accreditation activities.

6.1.9 BLQS does not accept any financial assistance that compromises the impartiality of accreditation.

6.1.10 All personnel involved in accreditation, including member of laboratory accreditation committee, assessment report reviewer committee, appeal committee, assessors and technical experts are required to complete and sign the formal undertaking for maintaining confidentiality and impartiality and declaration of no conflict of interest prior to participating in accreditation decision making, assessment or appeal handling. Any person who may have conflict of interest shall withdraw on his own initiative.

6.1.11 BLQS shall establish the procedure for risk management (SOP 07 15 039 (T)) to identify, analyze, evaluate, treat, monitor risks to minimize or eliminate impartiality arising from accreditation activities and consult with interested parties.

6.1.12 BLQS shall regularly identify and evaluate any risks to impartiality and take appropriate action to respond any threat to its impartiality arising from the actions of other person, bodies or conformity assessment bodies.

6.1.13 In case a related bodies providing conformity assessment services is linked to BLQS, the body shall have completely separate management from BLQS and have a policy of not competing with any commercial service provider. The body shall pay the same rate of fees to BLQS as other Conformity Assessment Bodies.

In case the body in the Bureau and Institute which are also under the Department of Medical Sciences. The assessment team, both lead assessors and technical assessors, are individuals outside the Department of Medical Sciences who have no relationship with the department. In any meeting of Laboratory Accreditation Committees both in Public Health and Medical Laboratories, the DMSc's staff has no right to vote in a decision making regarding to the subject of laboratory accreditation.

6.1.14 Arranging and participating as a lecturer in training, orientation or educational courses, provided that these courses confine themselves to the provision of generic information that is freely available in the public domain. They cannot provide specific solutions to a conformity assessment body in relation to the activities of that organization. Adding value during assessments, e.g. by identifying opportunities for improvement as they become evident during the assessment without recommending specific solutions. Advising other accreditation bodies on development of accreditation process. Advising scheme owners on accreditation requirements, including requirements within relevant conformity assessment standards.

Revised by 

Ms. Sitaphaisith Ekachampaka

Reviewed by 

Ms. Patavee Soisangwan

Approved by 

Ms. Patavee Soisangwan

6.2 BLQS Structure

Bureau of Laboratory Quality Standards, BLQS is one of the organization under the umbrella of the Department of Medical Sciences, Ministry of Public Health. The authority of the BLQS according to the Royal Decree Organizing of Department of Medical Sciences volume 119, part 103, dated 9th October 2002 and re-structure organization, 2009 which these legal responsibilities are as follows.

- To assist and support the development of laboratory quality assurance system and organize the proficiency testing program related to medical testing laboratory (clinical laboratory) and public health testing laboratory (consumer products or health product testing laboratory).
- To give service for laboratory assessment and grant laboratory accreditation in both medical testing laboratory (clinical Laboratory) and public health testing laboratory (consumer products or health product testing laboratory).
- To be the information center of quality and laboratory standard in medical and public health laboratory.
- To cooperate or support other governmental officer or any assignment.

According to the Article No. 31 and No. 32 of the National Administration Act, B.E. 2534 (A.D. 1991) 2018, the Director General of the Department of Medical Sciences has issued the Notification of Department of Medical Sciences, order no 154/2563 dated January 14, 2020 appoint Proficiency Testing Center as internal organization and directly to Director-General of the Department of Medical Sciences or Deputy Director assigned. The duties of the Proficiency Testing Center are organizing the proficiency testing scheme related to medical testing laboratory and public health testing laboratory according to the international standard. The PT scheme is accredited by Department of Science Service, Minister of Higher Education, Science, Research and Innovation.

The organizational chart that shows the relationship of the BLQS with its related body is described in Figure I. For secure impartiality, BLQS Director provides authorities on accreditation, independently, from the department. The related bodies of BLQS which provides conformity assessment services are the laboratories in the Bureau and Institute which are also under the Department of Medical Sciences. They have completely separate management from BLQS and have a policy of not competing with any commercial service provider.

☞ The BLQS is composed of 5 sections; Laboratory Accreditation Section, Quality System Development Section, Pathogen and Animal Toxins Act Section, OECD GLP CMA Section and Administration Section.

The organization chart of BLQS showing the relationships between the various functions are given in Figure II.

Revised by *Sitaphaisith E*

Ms. Sitaphaisith Ekachampaka

Reviewed by *Patavee Soisangwan*

Ms. Patavee Soisangwan

Approved by *Patavee Soisangwan*

Ms. Patavee Soisangwan

6.3 Impartiality of Finances and Sources of Income

BLQS is a government organization and therefore BLQS operation is fully funded by the Government and its funding is not dependent on the accreditation fees received.

7. Data record and used document

-

8. History of Change

Revision No.	Documentation Changes	Prepared/Revised by	Date Issued
00	New SOP	Ms. Sitaphaisith Ekachampaka	28 JAN 2020
01	Updated organization of the Department of Medical Sciences in (Figure I).	Ms. Sitaphaisith Ekachampaka	27 AUG 2021
02	- Updated organization of the Department of Medical Sciences (Figure I). - Correct detail of BLQS Structure in Clause 7.0 and Figure II.	Ms. Sitaphaisith Ekachampaka	

Revised by *Sitaphaisith E*

Ms. Sitaphaisith Ekachampaka

Reviewed by *Patavee Soisangwan*

Ms. Patavee Soisangwan

Approved by *Patavee Soisangwan*

Ms. Patavee Soisangwan

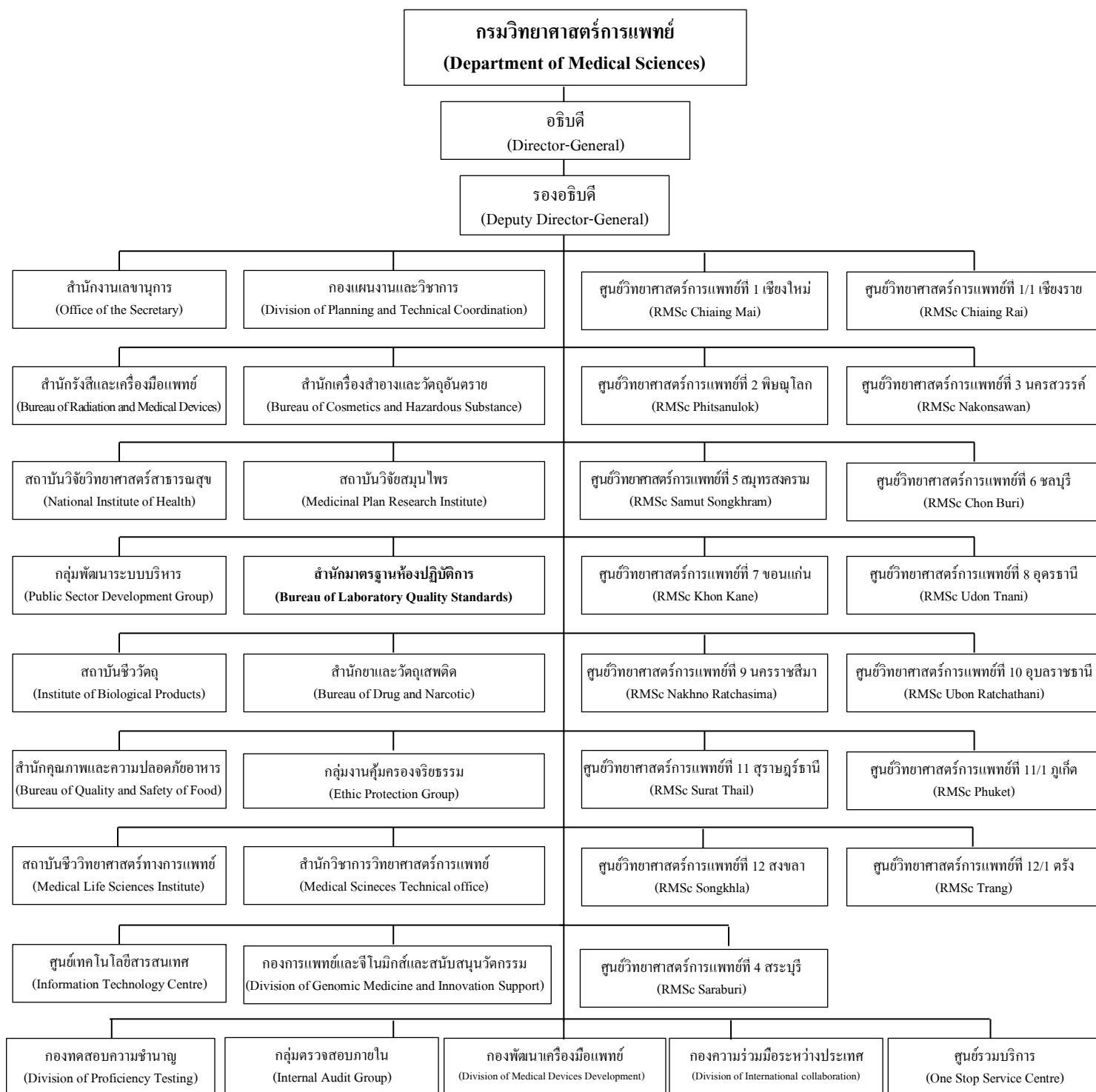


Figure 1 shows the line of command in the organization of the Department of Medical Sciences

Revised by Sitaphaisith E

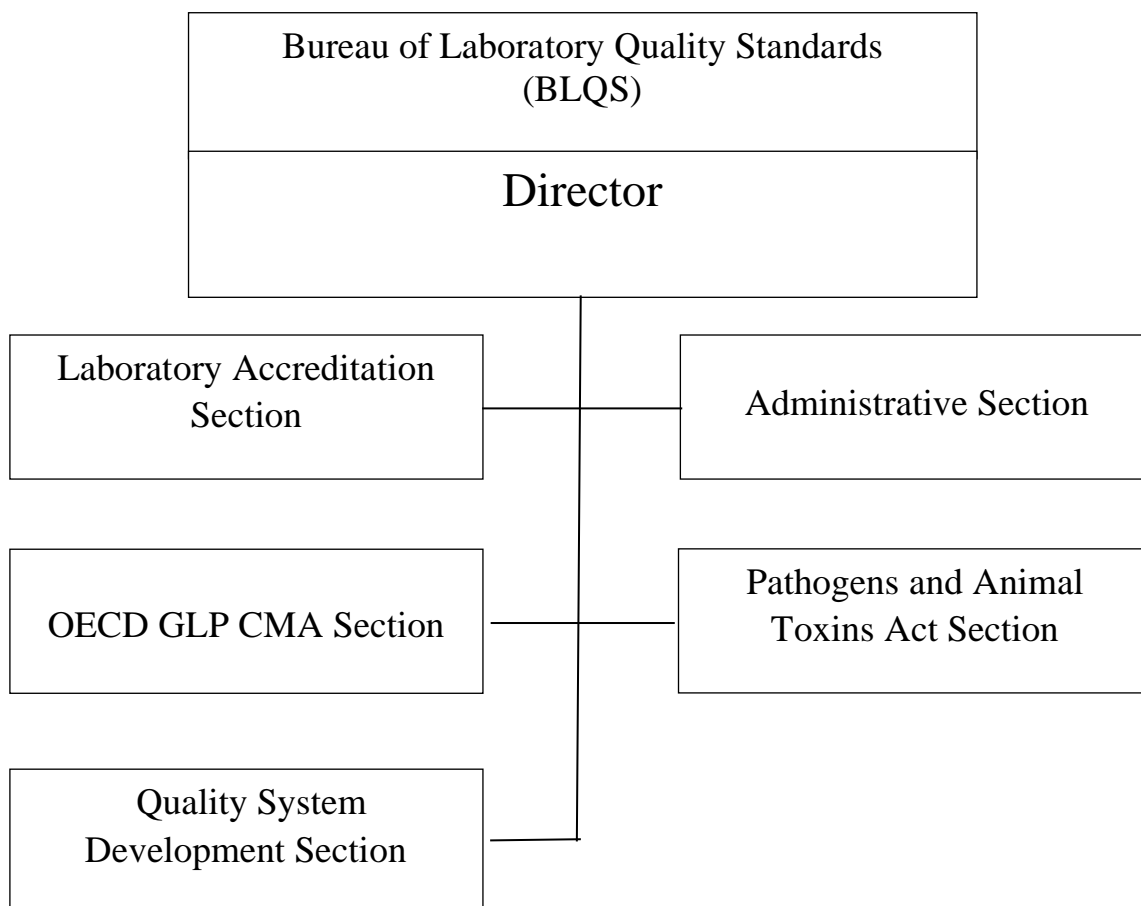
Reviewed by Patavee Soisangwan

Approved by Patavee Soisangwan

Ms. Sitaphaisith Ekachampaka

Ms. Patavee Soisangwan

Ms. Patavee Soisangwan



☞ **Figure II: BLQS Structure Chart**

Revised by *Sitaphaisith E*

Ms. Sitaphaisith Ekachampaka

Reviewed by *Patavee Soisangwan*

Ms. Patavee Soisangwan

Approved by *Patavee Soisangwan*

Ms. Patavee Soisangwan

Controlled copy list

- | | |
|---|-----------------|
| 1. Director of Bureau of Laboratory Quality Standards | Code No. 07 00 |
| 2. Head Laboratory Accreditation Section 1 | Code No. 07 03 |
| 3. Quality Manager of Laboratory Accreditation | Code No. QM 007 |
| 4. Ms. Sitaphaisith Ekachampaka | |

Revised by 

Ms. Sitaphaisith Ekachampaka

Reviewed by 

Ms. Patavee Soisangwan

Approved by 

Ms. Patavee Soisangwan