

Policy and Requirements for Application of Laboratory Accreditation by Related Bodies

1. Purpose

This policy and requirements is for conformity assessment of related bodies by BLQS accreditation bodies comply with ISO/IEC 17011.

2. Application

☞ This policy and requirements is intended how to clarify the impartiality and conflict of interest for application of laboratory accreditation by related bodies

3. Reference

☞ 3.1 ISO/IEC 17011: 2017.

4. Definition and Abbreviation

Related Bodies means division, bureau or institute under the Department of Medical Sciences, Ministry of Public Health that performs laboratory services in health products and/or medical specimen testing and that can be the object of accreditation.

5. Associated Documents

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6. Procedures

6.1 Policy

6.1.1 A related body applying for laboratory form BLQS shall follow the Policy, Requirements and Conditions of Public Health and Medical Laboratories Accreditation, Bureau of Laboratory Quality Standards.

6.1.2 A related body shall pay the same rate of fees to BLQS as other Conformity Assessment Bodies as defined in the Policy, Requirements and Conditions of Public Health and Medical

☞ Laboratories Accreditation, Bureau of laboratory Quality Standards. Any assessors who has been worked for DMSc must be ceased from theirs responsible by at least 3 years

6.2 Requirement

6.2.1 Both lead assessors and technical assessors shall be individuals outside the Department of Medical Sciences who have no relationship with the department.

6.2.2 The chairman of both appeal committee and laboratory accreditation committee are outside of Ministry of Public Health and appoint by the Director of Bureau of Laboratory Standards.

6.2.3 In any meeting of Laboratory Accreditation Committees both in Public Health or Health Products and Medical Laboratories, the DMSc's staff has no right to vote in a decision making regarding to the subject of laboratory accreditation. The decision is made by stake holders and higher executives.

6.2.4 Accreditation Certificate in Health Products and Medical Laboratories are granting by Director of Bureau of Laboratory Quality Standards (BLQS). The Director General of DMSc does not involve in the decision making for granting of laboratory accreditation.

7. Data record and used document

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8. History of changes

Revision No.	Document Changes	Prepared / Revised By	Date Issued
00	Issued new document	Nittayaporn Chainarong	-
04	Clause 6 Added details for DMSc's staff has no right to vote or conclude for decision making of accreditation committees.	Awiruth Khejonnit	3 September 2013
05	- Changed document format - Changed the current version of ISO/IEC 17011:2017 - Added detail of application focused on impartiality	Awiruth Khejonnit	

Revision No.	Document Changes	Prepared / Revised By	Date Issued
	- Added the requirement for any assessor who has been work for DMSc must be ceased from theirs responsible by at least 3 years.		

Controlled Copy List

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|----|---|-----------|
| 1. | Director of Bureau of Laboratory Quality Standards (BLQS) | No. 07 00 |
| 2. | Head of Laboratory Accreditation Section 1 | No. 07 03 |
| 3. | Head of Laboratory Accreditation Section 1 | No. 07 04 |
| 4. | Quality Manager of Laboratory Accreditation | No. QM 07 |
| 5. | Mr. Awiruth Khejonit | - |