

1. Purpose

The policy and requirements are for Bureau of Laboratory Quality Standards (BLQS) for conformity assessment bodies accreditation of related bodies of the Department of Medical Sciences (DMSc) comply with ISO/IEC 17011.

2. Application

The policies and requirements are intended how to clarify the impartiality and conflict of interest for application of laboratory, reference material producer and biobank accreditation by related bodies.

3. References

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

4. Definition and Abbreviation

4.1 Related Bodies means Division, Bureau or Institute under the Department of Medical Sciences, Ministry of Public Health who performs laboratory services in health products testing and/or medical specimen examination, reference material producer and biobank and that can be the object of accreditation.

5. Associated document

- 5.1 R 07 15 001 Policies, requirements and conditions for a medical and health laboratory accreditation.
- 5.2 R 07 15 004 Policies, requirements and conditions for reference material producer Accreditation.
- 5.3 R 07 15 005 Policies, requirements and conditions for biobank accreditation.

6. Procedures

6.1 Policies

- 6.1.1 A related body applying for accreditation from BLQS shall follow the policies, requirements and conditions for accreditation of medical specimen and public health products testing laboratory, reference material producer and biobank.
- 6.1.2 A related body shall pay the same rate of accreditation fees to BLQS as other conformity assessment bodies as defined in the policies, requirements and conditions for accreditation of BLQS.

6.2 Requirements

6.2.1 Both of lead assessor and technical assessor shall be individuals outside the department of medical sciences (DMSc) who have no relationship with the department. Any assessor who has been worked for the department of medical sciences must be ceased from their responsibility by at least 3 years.

6.2.2 The chairman of appeal committee and laboratory accreditation committee, reference material producer accreditation committee and biobank accreditation committee are outside of the DMSc and appoint by the director of BLQS.

6.2.3 In any meeting of appeal committee and accreditation committee, the DMSc's staff has no right to vote in a decision making regarding to the subject of conformity assessment bodies. The decision is made by stakeholders and higher executives.

6.2.4 Accreditation certificate of health products and medical laboratories, reference material producers and biobanks are granting by Director of Bureau of Laboratory Quality Standards. The Director General of DMSc does not involve in the decision making for granting of accreditation.

☞ 6.2.5 Where the Director of the Bureau of Laboratory Quality Standards, who hold decision making for accreditation has appointed from an accredited organization by the BLQS, it is recommend that he or she must serve in the position at the BLQS for a minimum of two years prior being eligible to sign off on the accreditation for that organization.

7. Data record and Used document

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8. Supplementary notes

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9. History of Changes

Revision	Document changes	Prepared /Revised by	Issued date
00	New issued of documents	Nittayaporn Chainarong	-
04	Clause 6, added details for DMSc's staff has no right to vote or conclude for decision making of accreditation committees.	Mr. Awiruth Khejonnit	3 September 2013
05	- Changed document format.	Mr. Awiruth Khejonnit	1 May 2019

Revision	Document changes	Prepared /Revised by	Issued date
	<ul style="list-style-type: none"> - Changed the current version of ISO/IEC 17011:2017. - Added details of application focused on impartiality. - Added the requirement for any assessor who has been work for the DMSc must be ceased from their responsibility by at least 3 years. 		
06	<ul style="list-style-type: none"> - Changed the document format to the current version of document control procedure of BLQS. - Added the scope of application of the RMP and biobanking accreditation. 	Mr. Awiruth Khejonnit	28 May 2024
07	<ul style="list-style-type: none"> - Added clause 6.2.5 the minimum period of relationship where the director of BLQS who is responsible for decision making of accreditation has appointed from a previously accredited by the BLQS, it is recommend that he or she must serve in the position at the BLQS for a 2 years prior being eligible to sign off on the accreditation for that organization. 	Mr. Awiruth Khejonnit	