1.0 Scope

IQMH: Centre for Accreditation is committed to grant accreditation according to ISO/IEC 17011:2017 Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies and this is evidenced through its signatory status within the International Laboratory Accreditation Cooperation (ILAC) and ILAC’s regional body the Asia Pacific Accreditation Cooperation (APAC). IQMH is evaluated regularly by APAC to reaffirm its continued compliance with the elements of ISO/IEC 17011:2017 and APAC/ILAC evaluation documents, rules, policies and procedures. The nature of international recognition agreements is explained in Appendix A.

This position statement describes the IQMH position on:

- The provision (extent) of its accreditation services; and
- Extending its accreditation activities in response to demands of interested parties.

2.0 Position Statement

2.1 IQMH is an accreditation body that accredits medical diagnostic services, medical specimen procurement facilities, and medical point-of-care testing (POCT) services utilizing three standards of the International Organization for Standardization (ISO).

2.1.1 ISO 15189:2012 Medical laboratories - Requirements for quality and competence

2.1.2 ISO 15190:2003 Medical laboratories - Particular requirements for safety

2.1.3 ISO 22870:2016 Point-of-care testing (POCT) - Requirements for quality and competence

2.1.4 In addition, additional requirements within legislation/regulation and consensus standards/guidelines representing the generally accepted principles of good practice, will also be incorporated into accreditation assessments (as applicable).

2.2 Requests for IQMH ISO 15189 Plus™ accreditation services from new potential clients are welcomed. Steps are taken to validate that the IQMH accreditation requirements are suitable for that particular client.

2.2.1 When the client is a regulator of medical diagnostic services:

2.2.1.1 The necessary resources and associated costs are identified

2.2.1.2 Any additional and specific requirements for accreditation deemed appropriate by that regulator, are specified

2.2.1.3 Documents are prepared describing the proposed service deliverables

2.2.1.3.1 Any other additional services to facilitate success in achieving accreditation are outlined

2.2.1.4 Presentation documents are prepared showing the deliverables’ timeline

2.2.1.5 An agreement for service provision is negotiated and signed
2.2.2 If the client is an interested medical diagnostic service, medical laboratory specimen collection facility or medical point-of-care testing (POCT) provider within Canada, the applicant:

2.2.2.1 Purchases the appropriate IQMH accreditation requirements (and the applicable standard(s), where appropriate)

2.2.2.2 Pays an application fee

2.2.2.3 Completes an application form

2.2.2.4 Submits a signed statement of intent.

2.2.3 If the client is an interested medical diagnostic service, medical laboratory specimen procurement facility or medical point-of-care testing (POCT) provider from outside Canada:

2.2.3.1 IQMH confirms its intent to seek ISO 15189 Plus™ accreditation over other possible alternative accreditation services available within its own economy.

2.2.3.1.1 IQMH endeavors to ensure that the interested party is aware of any accreditation bodies within its own economy that are signatories to the ILAC MRA and those of its regional cooperations, in order to make the interested party aware that these services may be more suitable and/or economical.

2.3 Requests for accreditation services in other fields of testing (i.e., those for which ISO 15189 or ISO 22870 does not apply) will be declined but if the client persists, the Accreditation Advisory Panel will be consulted to determine if IQMH should embark on the development of accreditation programs beyond those for medical diagnostic services, medical specimen collection facilities, and medical point-of-care testing services.

3.0 Responsibility

The Executive Director, Programs is responsible for responding to requests for accreditation services.

4.0 References

4.1 ISO/IEC 17011:2017 *Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies*

4.2 ILAC G21:09/2012 *Cross Frontier Accreditation Principles for Cooperation*

4.3 ILAC P5:06/2017 *ILAC MRA – Scope and Obligations*
Appendix A: International Mutual Recognition Arrangements for Laboratory Accreditation

The International Laboratory Accreditation Cooperation (ILAC) is the international forum for laboratory accreditation bodies. Its Mutual Recognition Arrangement (MRA) is designed to ensure that test reports issued by accredited laboratories are accepted worldwide. ILAC is structured with Regional Cooperations. Comparative laboratory accreditation is achieved through a network of accreditation bodies that conform to one or more of the regional MRAs, which testify that these accreditation bodies meet international standards. This system allows recognition between member accreditation bodies of the accreditations granted by them, and provides assurance to regulatory bodies and the public that tests results from laboratories holding accreditation certificates issued by these accreditation bodies are of international repute.

IQMH is evaluated for equivalence by APAC against ISO/IEC 17011:2017 Requirements for accreditation bodies accrediting conformity assessment bodies.
An ISO 15189 Plus™ accredited facility is assessed for competence against ISO standards (e.g., ISO 15189: 2012 Medical laboratories – Requirements for quality and competence).