1.0 Scope

IQMH 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.

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

This position statement governs transfers of accreditation from other MRA signatory accreditation bodies to IQMH. In principle it is designed to avoid or minimize gaps in accreditation.

2.0 Position Statement

2.1 IQMH will maintain full membership in APAC and ILAC, as signatories to the Mutual Recognition Arrangement of each.

2.2 IQMH will consider applications for transfer of accreditation from services accredited by other accreditation bodies who are signatories to the APAC or ILAC Mutual Recognition Arrangement.

2.3 Services applying for transfer of accreditation must submit:

2.3.1 A completed Form – Application for Accreditation

2.3.2 A completed Statement of Intent – ISO15189 Plus™ Accreditation

2.3.3 The most recent assessment report. If that report was from a surveillance visit, the most recent full on-site report is also required.

2.3.4 The corrective action response to the above report(s). Outstanding non-conformities should be closed out before transfer. If this is not possible, the service must complete a Form – Corrective Actions to share future action plans and timelines for completion.

2.3.5 A copy of the current accreditation certificate from an MRA signatory

2.3.6 The current scope of accreditation

2.3.7 IQMH Accreditation Requirements must be purchased by the service.

2.4 If the service is currently accredited by IQMH for other purposes (i.e., conditions imposed by a regulator), the service must submit:

2.4.1 A completed Statement of Intent

2.5 Applications are received by the Executive Director, Programs and reviewed by staff with Advisory Panel input.

2.6 Two outcomes are possible from the review of information:

2.6.1 The transfer is accepted.
2.6.1.1 In this case, the accreditation expiration date will be set based on the prior expiration date.

2.6.1.2 The assessment visit schedule will be set to include either a full on-site assessment or mid-cycle surveillance visit within 24 months from the date of the most recent assessment performed by the prior accreditation body.

2.6.1.3 The service is enrolled in the PT monitoring program (QTrak).

2.6.2 The transfer is not fully accepted.

2.6.2.1 In this case, depending on the extent of the doubt, the Advisory Panel may recommend either treating the applicant as a new client or conducting an on-site assessment on identified problem areas.

3.0 Responsibility

The Executive Director, Programs is responsible for the resources required to meet member obligations in APAC and ILAC.

4.0 Supporting Documents

4.1 Master – Application for Accreditation
4.2 Master – Corrective Actions
4.3 Statement of Intent – ISO 15189 Plus™ Accreditation
4.4 Procedure – Transfer of Accreditation to ISO 15189 Plus™
4.5 Master – Transfer of Accreditation Checklist

5.0 References

5.1 ISO/IEC 17011:2017 Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies
5.2 APAC-MRA-001 Procedures for Establishing and Maintaining Mutual Recognition Amongst APAC Accreditation Bodies
5.3 APAC-GOV-001 APAC Constitution
5.4 APAC-GOV-002 APAC Regulations and Codes
5.5 APAC-COM-002 Use of the APAC Logo and Representation of APAC
5.6 ILAC R2:09/2009 ILAC Rules
5.7 ILAC R4:10/2016 Use of the ILAC Logo and Tagline
5.8 ILAC R6:02/2013 Structure of the ILAC Mutual Recognition Arrangement and Procedure for Expansion of the Scope of the ILAC Arrangement
5.9 ILAC R7:05/2015 Rules for the Use of the ILAC MRA Mark
5.10 ILAC P8:03/2019 ILAC Mutual Recognition Arrangement (Arrangement): Supplementary Requirements for the Use of Accreditation Symbols and for Claims of Accreditation Status by Accredited Conformity Assessment Bodies
5.11 ILAC P9:06/2014 ILAC Policy for Participation in Proficiency Testing Activities