ABOUT ACCREDITATION

1. What is accreditation?
   Accreditation is a process by which an authoritative body gives formal recognition that an organization is competent to carry out specific tasks (detailed in a scope of accreditation) in a reliable, credible and accurate manner.

2. How does the IQMH program compare to the rest of Canada and the world?
   Our ISO 15189 Plus™ is a Canadian ISO15189 accreditation program recognized by the International Laboratory Accreditation Cooperation (ILAC) through its mutual recognition arrangement. Therefore, ISO 15189 Plus™ accreditation leads to an ISO 15189 Certificate that is recognized world-wide.

   Our accreditation requirements include the following additional standards:
   - ISO 15189:2012 Medical laboratories – Requirements for quality and competence
   - ISO 15190:2003 Medical laboratories—Requirements for safety
   - ISO 22870:2016 Point-of-care testing (POCT)—Requirements for quality and competence
   - CSA Z902-15, Blood and Blood Components, December 2015

3. Who does IQMH accredit?
   IQMH offers four voluntary programs:
   - ISO 15189 Plus™ Medical Laboratories
   - ISO 15189 Plus™ Diagnostic Imaging
   - ISO 15189 Plus™ Point-of-Care Testing
   - ISO 15189 Plus™ Specimen Procurement

   IQMH operates mandatory programs for all medical laboratories licensed by the Ontario Ministry of Health and Long-Term Care (MOHLTC), all medical laboratories within the Province of Newfoundland and Labrador and all medical laboratories within the Province of New Brunswick.

   A list of our accredited facilities with the applicable scopes of accreditation can be found on the IQMH website at www.iqmh.org, Centre for Accreditation, List of Accredited Facilities.

4. Are all diagnostic examinations accredited?
   For our mandatory laboratory participants, all laboratory examinations that are performed for the purpose of diagnosis, prophylaxis or treatment of patients are included in accreditation. Voluntary clients in laboratory and diagnostic imaging can define which examinations are included with their scope of ISO 15189 Plus™ accreditation.

5. Can multiple sites be accredited simultaneously?
   Facilities belonging to the same corporate grouping (i.e. identical management, one Quality System) may be assessed together.

6. Does our facility have to pay for accreditation?
   This depends on the facility. If accreditation is mandatory, then the government regulator may pay. (Costs for licensed Ontario medical laboratories are paid for by the government. The Province of Newfoundland and Labrador and the Province of New Brunswick pay for the costs for their medical laboratories.) Individual clients voluntarily applying for accreditation must pay for the accreditation assessment visits and pay administrative/maintenance fees.

7. Who will receive the correspondence regarding accreditation?
   Correspondence is sent to the person with official designation from the client to receive correspondence on behalf of the Owner/Operator, as well as the official Director(s) as stated by the client. Correspondence may also be copied to an assessment site coordinator.
8. **How do I apply for voluntary accreditation?**
   Staff in a facility interested in voluntary accreditation should first acquire and become familiar with the accreditation requirements for that program. Visit the website the Institute for Quality Management in Healthcare (IQMH), at [www.iqmh.org](http://www.iqmh.org) to purchase the Accreditation requirements specific to your service. When ready, facility administration formally applies for voluntary accreditation. We require a self-assessment to determine the potential client’s readiness for accreditation.
   
   Upon receipt of the application fee and completed application, the client is provided with a customized assessment checklist to use for a formal self-assessment. Afterward, clients submit the results to IQMH in a self-assessment report. (See "What is a Self-Assessment?").
   
   **Note:** Up to one year is allowed to transpire between the request for the initial self-assessment and receipt of the client’s self-exception report, until the application expires.

9. **How do I prepare for accreditation?**
   IQMH will issue a customized assessment checklist to each client undergoing an assessment. Using this customized checklist, you can carry out a mock assessment. It is recommended that you do not assess your own department.

10. **How long is the term for accreditation?**
    The term of accreditation is 4 years, with an exception for medical laboratories in New Brunswick, for which the term for accreditation is 2 years.

11. **What is the scope of accreditation?**
    A scope of accreditation lists the classes of examinations, and the names of the examinations included in accreditation.

12. **If my service now performs a new examination or class of examination, can they be added to the scope of accreditation?**
    Yes, if the examination added are within an entirely new class of examination. When IQMH is notified of an additional class of examination to an accredited facility’s test menu, a questionnaire will be provided. A surveillance visit may be necessary in order to expand the scope of accreditation.

13. **If my service was sold to a new owner, is it still accredited?**
    If the service is sold to a new owner, this may result in a surveillance assessment visit within six months.

14. **Will accreditation be granted by discipline or for the full extent of services offered?**
    Accreditation is granted for the full extent of services as covered by the scope of accreditation.

15. **If my facility is ISO 9001 registered, will we automatically receive full accreditation?**
    ISO 9001:2015 will not replace the accreditation assessment or automatically ensure full accreditation. ISO 9001:2015 registration will go a long way in ensuring that a facility meets our quality system requirements. However, accreditation criteria defined in the comprehensive requirements encompass both the managerial and technical clauses of ISO 15189.

16. **What is the ISO 15189 Plus certificate?**
    ISO 15189 is an international accreditation standard for medical laboratories and it can be applied to diagnostic imaging, specimen procurement services and point-of-care services. Facilities accredited to ISO 15189 demonstrate that they meet comprehensive international standards for quality and competence. Accreditation bodies around the world have signed an International Laboratory Accreditation Cooperation (ILAC) arrangement that fosters mutual recognition of quality, competence and capability through ISO 15189 accreditation. These accreditation bodies are evaluated to ensure rigorous conformity assessment standards are met. Only those accreditation bodies that are part of the ILAC recognition arrangement may issue an ISO 15189 certificate. The Plus designation is our unique IQMH brand name for our accreditation products.
17. How does the ISO 15189 Plus™ certificate differ from the ISO 9001 certification?
Facilities accredited to ISO15189:2012 are recognized as meeting the management system principles of ISO 9001:2015. Confusion exists about the differences between certification/registration to the quality systems standard, ISO 9001 Quality Management Systems—Requirements and accreditation, and to ISO 15189. Certification or registration to ISO 9001 acknowledges that an organization’s operations comply with quality management system requirements. Accreditation is a process by which an authoritative body gives formal recognition that an organization is competent to carry out specific tasks. Accreditation to ISO 15189 provides assurance that an effective quality management system is in place, but it also demands technical competence.

18. How can I receive an ISO 15189 Plus™ certificate?
IQMH conducts the assessment and once satisfied that a service meets its requirements, issues an ISO 15189 Plus™ certificate.

19. What is a Quality Management System?
A Quality Management System is a program developed to support efficient and effective, high quality and appropriate diagnostic services. It involves comprehensive and coordinated efforts designed to meet quality objectives, and direct and control an organization with regard to quality. It includes a quality (management) system, assessment and improvement, quality assurance and quality control.

20. Are the criteria for an Ontario certificate of accreditation and an ISO 15189 Plus™ certificate different?
In the Province of Ontario, a special certificate is issued to medical laboratories under contract to the government, to licensed medical laboratories. The requirements for this certificate are no different from the ISO 15189 Plus™ certificate, but the frequency of on-site assessment is less for the Ontario licensed laboratories. However, Ontario licensed laboratories may voluntarily submit to increased surveillance and receive a full ISO 15189 Plus™ certificate.

21. What is external quality assessment?
External quality assessment (EQA) is a process in which medical laboratories participate in an inter-laboratory comparison to determine the performance of the laboratory. It is synonymous with proficiency testing, and is required for accreditation.

22. Which EQA providers can I use to meet accreditation requirements for PT/EQA?
Formal programs known to meet our criteria are published on the accreditation section of the IQMH website. Proficiency testing provided by IQMH, Centre for Proficiency Testing also meets our criteria. When formal inter-laboratory comparison programs are not available, accredited medical laboratories are expected to find an alternative such as split-sample testing.

ACCREDITATION STANDARDS AND REQUIREMENTS

23. Which international and national standards apply?
During the training of the assessors, the following standards are used:

- ISO/IEC 17011:2004 Conformity assessment—General requirements for accreditation bodies accrediting conformity assessment bodies
- ILAC-G3:2012 ILAC Guidelines for Training Courses for Assessors Used by Laboratory Accreditation Schemes

During the accreditation assessment process, the following standards apply:

- ISO 15189:2012 Medical laboratories—Requirements for quality and competence
- ISO 15190:2003 Medical laboratories—Requirements for safety
- ISO 22870:2016 Point-of-care testing (POCT)—Requirements for quality and competence
- Canadian Standards Association CAN/CSA-Z902-15 Blood and blood components December 2015
24. Are the IQMH accreditation requirements based on ISO 15189?
Yes, our requirements for accreditation include all clauses of ISO 15189:2012 Medical Laboratories—
Requirements for Quality and Competence.

25. Where are the IQMH requirements?
Clients enrolled in our program have an electronic account set up from which they are able to access the
requirements. The requirements are also available to other interested for a fee. Once the fee is paid, an
electronic account is created in QView™ (the password-protected document server on the IQMH website) for
access to the requirements. Visit the Institute for Quality Management in Healthcare (IQMH) website at
www.iqmh.org to purchase the Accreditation requirements.

26. Are you open to suggestions for changes to the requirements?
Yes. Feedback is collected for the review of requirements and guidance information. Feedback can be sent to
us via email accreditation@iqmh.org.

27. How often are the requirements reviewed and revised?
The requirements are updated at a minimum of once every three years. Annually, feedback and changes to
reference sources are reviewed in regards to any requirements or guidance information that may need to
be updated.

28. How will updates to the requirements be communicated to clients?
All accredited facilities and applicants have access to requirement updates, which are posted in QView™ (the
password-protected document server) on the IQMH website.

29. What is the significance of guidance information?
For each requirement, guidance information provides insight into how to apply the requirement. Often, its
application within a specific discipline is clarified. It is intended for use by facility personnel when preparing for
an assessment and for assessors during an assessment visit.

30. Will the requirements apply to my province or country?
Our requirements apply to any facility accredited. Individual requirements that may be specific to an individual
country, province or region are identified.

31. Why do services located in small, rural areas need to meet the same requirements as large
teaching hospitals?
All patients deserve the same high standards of health-care delivery, regardless of their location.

THE ASSESSMENT PROCESS

32. How much does an accreditation assessment visit cost?
The charge for an accreditation assessment visit includes labour and travel expenses for staff and assessors
plus an administration fee. For additional information on the cost of accreditation, contact
accreditation@iqmh.org.

33. During an accreditation visit, are the staff assessed as well as the diagnostic service?
During an accreditation assessment visit, performance of individual staff members is not assessed. It is the
organization’s competence to carry out specific tasks, as detailed in the scope of accreditation, which
is assessed.

34. Will my facility know when an accreditation assessment visit will occur and who is coming?
Yes, facilities are notified via mail as well as through electronic means QView™ (the password-protected
document server on the IQMH website) of a pending accreditation assessment visit, usually four months in
advance. Visit dates are scheduled in consultation with the facility. To maintain transparency, the selected team
member names are provided in advance to ensure conflicts are avoided.

35. Who sets up the accreditation assessment visit?
An accreditation staff technologist telephones the facility to identify who will coordinate the assessment visit
within the facility.
36. **Can the findings of a self-assessment lead to an accreditation visit?**
The purpose of a self-assessment is to ensure ongoing compliance with accreditation requirements. These and other surveillance activities (e.g. changes in facility location, ownership and menu of tests, performance in proficiency testing/external quality assessment) may prompt an assessment visit if they give cause for concern that the standard is not being met.

37. **Will the team leave a printed report at the accreditation assessment visit?**
Yes. A comprehensive verbal summary is provided at the visit summation meeting, and a draft summary of the findings (**assessment report**) is left with the facility at the conclusion of the visit. The final summary report is mailed to the facility within 14 days of the assessment visit.

38. **Who exactly will assessors speak to and will assessments involve clients of the service?**
Assessors will look for objective evidence that processes are in place to ensure requirements are met (including the assurance that client concerns are addressed by means of an interview with these clients). They may ask to speak with responsible facility personnel.

39. **How quickly are certificates of accreditation issued?**
Our goal is to issue accreditation certificates within five months of the accreditation assessment visit.

40. **What if I disagree with a decision or a report issued about my service?**
Facilities have the right to appeal accreditation assessment findings and associated decisions regarding accreditation status. Appeals must be submitted using the online electronic form through QView™ or in writing, and are reviewed by a multi-disciplinary and impartial panel.

The intent of the accreditation program is to ensure the provision of quality diagnostic services. In the event that a facility does not meet accreditation requirements, IQMH will not issue a certificate. In addition, a recommendation to deny or to withdraw accreditation may be made to a government regulator, who may have an appeal mechanism.

41. **What is an appeal of a cited non-conformance?**
An appeal is a non-conformance(s) cited during an accreditation assessment visit that the facility considers incorrect because the evidence reviewed by the assessment team was misinterpreted. An appeal to a cited non-conformance must be submitted using the online appeal form through QView™ or in writing to the Associate Director, Accreditation within two weeks of receipt of this report. The appeal will be reviewed by Accreditation staff in consultation with the assessors and advisors and you will receive follow-up.

42. **How long does a facility have to correct non-conformances?**
Facilities have 90 days from the visit to correct major non-conformances and submit an acceptable action plan to address minor non-conformances.

43. **Do all non-conformances need correction before an accreditation certificate is issued?**
Non-conformances are categorized as either major or minor. All major non-conformances must be resolved prior to issuance of a full certificate. Acceptable action plans to address minor non-conformances must be submitted prior to certificate issue, and ongoing followup reported at the next self-assessment.

44. **What is a corrective action?**
Corrective action is submitting a description with supporting evidence to IQMH that shows how non-conformances were corrected, or action plans to correct non-conformances.

45. **What is a minor non-conformance?**
A minor non-conformance refers to the following types of findings:

- Adherence to policy/process or procedures is inconsistent (usually followed but sometimes not); or
- The requirement is met in practice, but required documentation is missing or incomplete.

**Note:** If on a subsequent assessment visit, a repeated minor non-conformance occurs for exactly the same reason, then that repeated minor non-conformance is categorized as a major non-conformance.
46. **What is a major non-conformance?**
A major non-conformance refers to any of the following types of findings:

- Non-conformance has the potential to directly impact patient safety or a diagnostic examination*; or
- Existing processes and procedures address a requirement but are not followed most of the time; or
- Repeated incidence of non-conformance in the majority of sections of the service; or
- Repeated incidence of non-conformance; or
- Requirement not addressed by the facility (neither written nor in practice).

*Any non-conformance that has the potential to directly affect a diagnostic examination result and/or the patient outcome is to be considered a potential risk to patient safety and categorized as "Major". Examples include, but are not limited to:
  - Lack of quality control for an examination
  - Lack of method validation or equipment verification
  - Incorrect calibration
  - Inappropriate critical value criteria and processes for notification of critical values

47. **What is an assessment visit?**
An assessment visit is an on-site visit within the facility. The assessment team, using the appropriate assessment tools (checklist), determines conformance to the accreditation requirements.

48. **What is an assessment report?**
A formal report of the accreditation assessment visit is issued to the recipient facility within 14 days of the accreditation assessment visit, with a spreadsheet on which the facility must submit any corrective action. The report summarizes conformance and provides commentary to explain all incidences of non-conformance to requirements.

49. **What is a surveillance visit?**
A surveillance assessment visit (focused) occurs one year after the initial issue of an ISO 15189 Plus™ certificate, and may also be initiated upon:

- New facility ownership or address
- Issues with ongoing competency/proficiency
- Request due to a potential threat to patient safety (from the facility or government regulator)
- Addition of a class of examination to the scope
- Self-assessment findings that demonstrate no intent to implement corrective actions or that raise other concerns regarding patient care

Surveillance assessment visits will occur within six months of the change or request.

50. **What is a self-assessment?**
Self-assessments are intended to assist facilities in determining the degree to which they meet accreditation requirements. Self-assessments ensure that:

1. Facilities continue to monitor their own conformance to accreditation requirements.
2. IQMH can identify the degree to which facilities meet requirements and monitor corrective action plans.
3. IQMH can determine requirements that may be difficult to achieve.

IQMH formally coordinates the self-assessment process by requiring that facilities perform self-assessments and report their findings in a checklist (electronic format). Ongoing followup to address non-conformances assessed at the last accreditation assessment must also be reported. Detailed instructions and a customized checklist are provided with the 120-day notification. Following a review of the self-assessment findings submitted, facilities receive correspondence that confirms receipt, provides a summary of conformance and gives a formal record of non-conformances.

51. **Who makes the decision if my facility receives an accreditation certificate?**
To maintain objectivity, decisions on accreditation are made by persons who were and were not part of the assessment team for your facility.
First, the accreditation staff technologist, team leader, and Accreditation Advisory Panel (or DI Decision Panel) members review and assess the acceptability of your corrective actions and seek further evidence if necessary. If they still have concerns that your facility has not addressed non-conformances, they ask for an extensive review by the appropriate panel. Once a decision is made that corrective actions have satisfactorily addressed non-conformances, the Advisory (or DI Decision) Panel with the Associate Director, Accreditation recommend certificate issue. The CEO, IQMH signs the certificate.

**BECOMING AN ASSESSOR**

52. **Who are your assessors?**
IQMH has a roster of more than 300 trained assessors who are physicians, scientists or technologists. Accreditation assessment visit teams consist of a team leader, and sufficient assessors to provide technical expertise for all disciplines involved. All assessors receive advance training and certification, and are required to recertify annually.

53. **How can I become an assessor?**
General information and an application to become an assessor are available from the IQMH website. There is a screening process for all applications. Applicants must be physicians, physicists, scientists, or technologists, qualified to practice with at least four years’ experience. A potential assessor will also have management or supervisory experience concurrent with “on the bench” experience. Experience teaching students or consulting would also be advantageous for potential assessors.

Following a reference check a potential assessor may be asked to attend a training session.

54. **Are assessors paid?**
We pay a professional fee for the time individuals serve as assessors (assessment visits), at a predetermined rate. While on assigned assessment visits, expenses for travel, meals and accommodation are paid.

55. **What will the assessor look for?**
Assessors determine if facilities conform to the accreditation requirements. This is done by asking questions, observing individuals at work, and reviewing standard operating procedures and records.