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General Rules of Procedure for the Medical Laboratory Assessment by the BNQ

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FOREWORD

This document presents the general rules of procedure of the BNQ applicable to medical laboratory assessment program for the following standard:

- *ISO 15189 Medical laboratories – Requirements for quality and competence.*

Medical laboratories that wish to do so may also request a specific assessment according to the following additional standards:

- *ISO 22870 Point-of-care testing (POCT) -- Requirements for quality and competence;*
- *CAN/CSA-Z902 Blood and blood components.*

This document outlines:

- steps in the laboratory assessment process leading to the issuance of an assessment report and a letter of recommendation for accreditation to the Standards Council of Canada (SCC);
- provisions foreseen to:
  - deal with situations that might have impacts on the accreditation issued;
  - manage situations that might lead to a recommendation to suspend or withdraw a certificate;
  - ensure follow-up of complaints submitted to the BNQ.

DEFINITIONS

accreditation, *n* Third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks (Reference: ISO/IEC 17000).

accreditation body, *n* Body empowered to proceed with the accreditation; the Standards Council of Canada is the body designated in this document (Reference: ISO/IEC 17011).

NOTE: The authority of an accreditation body generally originates from the government.

accreditation program, *n* Rules and procedures related to the accreditation of conformity assessment bodies to which the same requirements apply (Reference: ISO/IEC 17011 [adapted wording]).

NOTE: The requirements of an accreditation program include, but are not limited to, ISO/IEC 17025 and ISO/IEC 17043.

assessment, *n* Process implemented by an accreditation body to determine the competence of a conformity assessment body on the basis of a standard or standards and/or other normative documents, and for a defined scope of accreditation (Reference: ISO/IEC 17011).

assessment team, *n* Team responsible for the assessment that includes a lead assessor, technical assessors and, where applicable, assessors-in-training and technical experts.

assessor, *n* Person appointed by the BNQ to conduct a laboratory assessment.

client, *n* Organization whose laboratory is assessed for accreditation purposes.

conformity assessment activity, *n* Activity carried out by a conformity assessment body during a conformity assessment (References: ISO/IEC 17011 [adapted wording]).

conformity assessment body, *n* Body that carries out conformity assessment activities and which may be subject to accreditation (Reference: ISO/IEC 17011).

NOTE: Unless otherwise indicated, the term “conformity assessment body” used in the text applies to all conformity assessment bodies, whether applicants or accredited.

correction, *n* Action to eliminate a detected nonconformity (Reference: ISO 9000).

NOTES:

1 A correction can be made in advance of, in conjunction with or after a corrective action.

2 A correction can be, for example, rework or regrade.

corrective action, *n* Action taken to eliminate the cause of nonconformity or other undesirable situation detected (References: ISO 9000 and ISO/IEC 17000).

NOTES:

1 There may be several causes to a nonconformity.

2 Corrective action is taken to prevent recurrence, whereas preventive action is taken to prevent occurrence.

3 A distinction shall be made between remedial action, or correction, and corrective action.

flexible scope of accreditation, *n* Scope of accreditation expressed to allow conformity assessment bodies to modify the methodology and other parameters within the competence of the conformity assessment body as endorsed by the accreditation body. (Reference: ISO/IEC 17011 and Accreditation Program Overview, Annex G).

lead assessor, *n* Assessor with the overall responsibility of managing an assessment (Reference: ISO/IEC 17011 [adapted wording]).

nonconformity, *n* Failure to comply with a requirement (References: ISO 9000 and ISO/IEC 17000 [adapted wording]).

preventive action, *n* Action taken to eliminate the cause of potential nonconformity or another potentially undesirable situation (References: ISO 9000 and ISO/IEC 17000 [adapted wording]).

NOTE:

1 There may be several causes to a potential nonconformity.

2 Preventive action is taken to prevent occurrence, whereas corrective action is taken to prevent recurrence.

reassessment, *n* Assessment carried out to renew the accreditation cycle (Reference: ISO/IEC 17011).

scope of accreditation, *n* Specific conformity assessment activities for which accreditation is requested or has been granted (Reference: ISO/IEC 17011).

technical assessor, *n* Person appointed by the BNQ to conduct a laboratory assessment and/or a method assessment within the scope of accreditation.

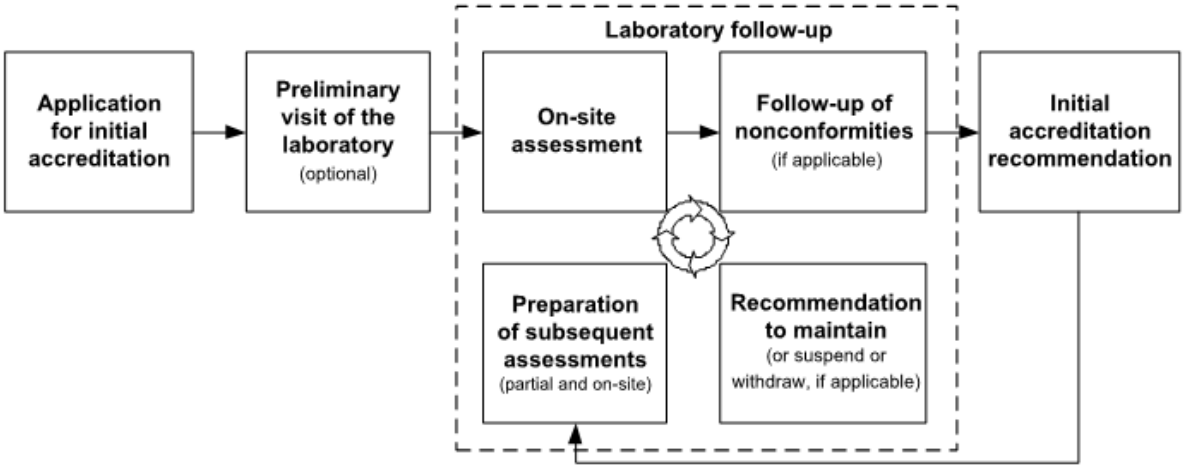
technical expert, *n* Person appointed by the BNQ who works under the responsibility of an assessor and has knowledge or specific expertise within the framework of the scope of accreditation to assess, but is not tasked with an independent assessment (Reference: ISO/IEC 17011).

NOTE: A technical expert is not expected to have the training of an assessor.

1 ASSESSMENT PROCEDURE

The BNQ laboratory assessment process complies with the latest versions in force of international accreditation requirements applicable to bodies conducting third-party assessments.

The diagram below illustrates the main steps in the process leading to the initial accreditation of a laboratory, as well as its maintenance and reassessment. An accreditation cycle generally covers a four-year period (with the exception of the first cycle, which is three years) during which complete and partial assessments shall be conducted alternately during twelve-month intervals. The purpose of complete assessments is to assess the conformity and competence of the CLIENT's laboratory and cover all requirements of the accreditation referential. Partial assessments cover, but are not limited to, requirements related to the management review, internal audits, program follow-up ensuring the validity of results and changes to the scope.



1.1 APPLICATION FOR INITIAL ACCREDITATION

1.1.1 Applicants who wish to obtain accreditation for their laboratory by the SCC by retaining the services of the BNQ to assess their laboratory may apply by telephone at 1-800-386-5114 or complete the accreditation application form available on the BNQ website at www.bnq.qc.ca and email it to bnqes@bnq.qc.ca.

1.1.2 Following receipt of an application, a BNQ employee contacts the applicant to answer his questions, inform him of steps to follow and conditions to meet, and collect information needed to send him a service contract for the intended scope.

1.1.3 Costs associated with the BNQ evaluation process for obtaining accreditation, if any, are defined in this service contract and are mainly determined according to:

- fixed annual amount for SCC expenses;
- amount for each type of evaluation conducted by the BNQ (preparatory visit, complete assessment, complete reassessment or partial reassessment), evaluated according to the characteristics of the organization (size of facilities, number of sites, etc.) and scope requested.

1.1.4 In accepting the BNQ service contract, the CLIENT agrees to comply with laboratory assessment rules.

1.1.5 Following receipt of the BNQ service contract signed by the CLIENT accompanied, where appropriate, with the funds required to start the assessment process, the BNQ assigns the lead assessor and forms a team based on the scope. This team is then presented to the CLIENT.

1.1.6 When an applicant, already accredited by another accreditation body signatory to a Mutual Recognition Agreement such as the *International Laboratory Accreditation Cooperation* (*ILAC*), wishes to transfer his file to the BNQ, the BNQ may agree, under certain conditions, to pursue the accreditation cycle already begun.

1.2 ASSESSMENT OF THE CLIENT'S FILE

1.2.1 Prior to the on-site assessment leading to the laboratory's initial accreditation, the lead assessor shall complete preparatory activities such as a review of laboratory documentation, information concerning aspects of the intended scope of accreditation, the CLIENT's procedures and installations, and corresponding legal requirements with which the laboratory shall comply. The lead auditor shall also assess the CLIENT's level of readiness for the assessment.

1.3 PRELIMINARY VISIT (OPTIONAL)

1.3.1 At the request of the CLIENT or the BNQ, a preliminary visit to the CLIENT's premises may take place.

1.3.2 The lead assessor sends a written report to the CLIENT with results on the preliminary visit.

1.4 INITIAL LABORATORY ASSESSMENT

1.4.1 Prior to conducting the on-site assessment, the lead assessor prepares an assessment plan and sends it to the CLIENT.

1.4.2 During the assessment, the lead assessor and the assessment team collect and verify pertinent information on assessment objectives, the intended scope of accreditation, requirements of the accreditation referential, and requirements of the accreditation program.

1.5 NONCONFORMITIES (NC)

1.5.1 A nonconformity (NC) is raised for any discrepancy found between one or more requirements of the accreditation referential or one or more program requirements.

1.5.2 The deadline for closing NC is normally 45 calendar days following the assessment date.

1.5.3 For the follow-up of NC deemed serious or critical, the BNQ follows the guidelines in the document *SCC Guidelines and Procedures for Laboratories with Serious and Critical Nonconformities.*

1.5.4 In the event that the NC are not resolved to the satisfaction of the BNQ within the agreed upon deadline, the BNQ will not proceed with an accreditation recommendation.

1.5.5 At the end of the laboratory evaluation process, the lead assessor presents a written report to the CLIENT summarizing his conclusions.

1.6 RECOMMENDATION FOR ACCREDITATION

1.6.1 Following receipt of documents related to the lead assessor's assessment and recommendation for laboratory accreditation, the BNQ confirms in writing to the CLIENT its recommendation, positive or not, concerning the accreditation of the CLIENT's laboratory and sends an official letter of recommendation in this respect to the SCC.

1.7 REASSESSMENT

1.7.1 The date of the reassessment following the initial accreditation is established within a 12-month timeframe, more or less three months before the anniversary date of the initial accreditation granted.

1.7.2 During the reassessment, the completion of the on-site assessment and NC follow-up, if applicable, take place as described previously and the CLIENT shall resolve the NC raised within the agreed upon deadline in order to ensure maintenance of accreditation of his laboratory.

1.7.3 When the conditions are met, the BNQ confirms in writing to the CLIENT and to the SCC its recommendation to maintain accreditation.

1.8 PARTIAL ASSESSMENT

1.8.1 Thereafter, the BNQ alternates annually between partial assessments and reassessments. Partial assessments serve to confirm continued conformity and competence. These assessments cover, but are not limited to, requirements related to the management review, internal audits, program follow-up ensuring the validity of results, and changes to the scope.

2 PROVISIONS IN THE EVENT OF MODIFICATIONS

2.1 MODIFICATIONS TO THE SCOPE OF ACCREDITATION

2.1.1 When a CLIENT wants to add new activities or new sites to the scope of his accreditation, he shall request this in writing from the BNQ. The BNQ examines the request, gathers necessary information and informs the CLIENT of applicable procedures to follow up on his request, and advises the SCC thereof.

2.1.2 When a CLIENT provides a notice indicating that his accreditation no longer applies to certain activities or certain sites indicated in the scope of accreditation, the BNQ advises the SCC thereof in order that the SCC may proceed with the modifications.

2.2 MODIFICATIONS MADE TO THE CLIENT'S LEGAL STATUS OR LEGAL NAME

When a modification is made to the CLIENT's status or legal name, he shall advise the BNQ in writing.

3 TREATMENT OF COMPLAINTS

3.1 GENERAL

3.1.1 Any person may file a formal complaint with the BNQ in connection with the services offered by the latter as part of its laboratory assessment programs. A CLIENT dissatisfied with the services received as part of the BNQ laboratory assessment programs may also file a formal complaint with the BNQ.

3.1.2 The complaint handling process provided for in these rules complies the international accreditation requirements applying to accreditation bodies. Thus, the BNQ takes the necessary provisions so that complaints received are treated confidentially by one or more persons having the necessary impartiality.

3.2 TERMS AND STEPS IN THE TREATMENT OF A COMPLAINT

3.2.1 Complaints submitted to the BNQ concerning BNQ services or a CLIENT whose laboratory is assessed by the BNQ are addressed in writing by the complainant and mailed to the attention of the quality manager at 333, rue Franquet, Québec, Québec G1P 4C7, or e-mailed to bnqes@bnq.qc.ca.

3.2.2 When a complaint is received from a CLIENT and is related to services rendered to it by the BNQ (e.g., disagreement on assessment conclusions, unsatisfactory conduct of an assessor, delays in processing), the complainant provides a description of the problem encountered and of the settlement desired.

3.2.3 When the complaint is received from a third party concerning the services offered by the BNQ as part of its laboratory assessment programs, additional information is requested.

3.2.4 In the days following the receipt of the complaint, the quality manager processes the file, ensures that the subject is related to laboratory assessment activities under the responsibility of the BNQ and then acknowledges receipt in writing.

3.2.5 In the event that the subject of the complaint is related to the laboratory assessment activities for which the BNQ is responsible, the complaint is brought to the attention of the relevant program leader to determine its admissibility. Based on the findings of the program leader, the BNQ will provide the complainant with a written response regarding the admissibility or otherwise of his complaint.

3.2.6 Whether the complaint is deemed admissible or not, the complainant will only be advised of the general status of the complaint. In the case of an admissible complaint, the file will then be transferred to the relevant program leader for examination, decision regarding actions to take and follow-up thereof.

3.2.7 If the complainant is not satisfied with the BNQ's conclusion regarding the admissibility of a complaint or the treatment of an admissible complaint, he may ask for a revision indicating the reasons or objections, in writing, to the BNQ's senior manager or to any other person designated by the BNQ in the event that the impartiality of the senior manager might be called into question.

3.2.8 In the days following the receipt of the request for a review, the BNQ will acknowledge receipt and the BNQ's senior manager or the person designated will have a certain delay to become acquainted with the file, consult the parties if need be, evaluate the treatment completed or conclusion issued, and then make a written decision regarding this request for a review.

3.2.9 If the decision issued by the senior manager or the person designated is still not to the satisfaction of the complainant, the latter may, as a last resort, apply to appeal this decision to the Standards Council of Canada (SCC).

3.2.10 The BNQ notifies the complainant, in writing, of the terms of appeal to the SCC when it renders its decision.