LAS-Q001

GENERAL REQUIREMENTS FOR ACCREDITATION OF LABORATORIES

CONTENTS

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TRINIDAD AND TOBAGO LABORATORY ACCREDITATION SERVICE (TTLABS)

General Requirements for Accreditation of Laboratories

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January 2018

Foreword

The Trinidad and Tobago Laboratory Accreditation Service (TTLABS) is a semi-autonomous, governmental service within the Trinidad and Tobago Bureau of Standards (TTBS) dedicated to operating a nationwide, broad spectrum laboratory accreditation system. Accreditation is a formal recognition of a laboratory's competence to perform specific tests or calibrations.

Accreditation is available to any type of testing, calibration or medical laboratory, whether it is a private or public entity, or part of a larger organisation, and regardless of the sector it covers. Accreditation is available for virtually all types of tests, calibrations, measurements and observations that are reproducible and properly documented.

The accreditation of laboratories is offered in the following disciplines:

Chemical and Biological	Mechanical	Medical
Electrical	Calibration	Agricultural
Civil Engineering		Non-destructive

Special programmes can be developed in response to user needs and may cut across more than one field of analysis.

Users of accredited laboratories are advised to obtain the Schedule(s) of Accreditation from any accredited laboratory or from TTLABS. The Schedule(s) of Accreditation identifies the specific methods or types of tests or calibration capability for which the laboratory is accredited.

The general requirements (general criteria) for accreditation used by TTLABS are from the International Standards, *ISO/IEC 17025 – General requirements for the competence of testing and calibration laboratories* and *ISO 15189 – Medical laboratories – Requirements for quality and competence*. Additional programme requirements (specific criteria) for specific fields may be established in the future to complement these general requirements in particular areas.

In effect, TTLABS accreditation attests that a laboratory has demonstrated that:

a) it is competent to perform specific methods, types of methods, calibrations, or types of calibrations as listed on its Schedules(s) of Accreditation;

b) its management system addresses and conforms to all elements of ISO/IEC 17025 or ISO 15189, is documented as per ISO/IEC 17025 or ISO 15189, and is fully operational; and

c) it conforms to any additional requirements of TTLABS or specific fields or programmes necessary to meet particular user needs.

It is TTLABS' policy not to accredit or renew accreditation of a laboratory that fails to meet the above criteria (see Part A, Conditions for Accreditation and Part B, Accreditation Process, sections on nonconformities, accreditation decisions and suspension or withdrawal of accreditation).

Manager, TTLABS

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Table of Contents

PART A CONDITIONS FOR ACCREDITATION

To attain and maintain accreditation, an applicant laboratory must agree to the following obligations or conditions of accreditation.

1) The laboratory shall commit to comply and to continue compliance, with TTLABS criteria and conditions, including participation in proficiency testing as required, for accreditation. This includes adapting to the changes in TTLABS criteria and conditions for accreditation, based on legitimate factors such as the issuance of new versions of the International Standards and rules of accreditation. This needs to be achieved within the timeframe deemed acceptable by TTLABS.

2) The laboratory shall co-operate with TTLABS, as is necessary, to ensure that TTLABS can verify conformity with the requirements for accreditation.

3) The laboratory shall provide access to its staff, locations, equipment, information, documents and records as is necessary to confirm the laboratory's fulfilment of requirements for accreditation.

4) The laboratory shall arrange, when requested by TTLABS, the witnessing of its activities.

5) The laboratory shall have, where required, legally enforceable arrangements with their clients that commit said clients to provide access to TTLABS' assessment team, on request, to assess the laboratory's performance when performing its testing or calibration activities at the laboratory's clients' facilities.

6) The laboratory shall commit to follow LAS-Q003 – Laboratory Reference to TTLABS Accredited Status – TTLABS Advertising Policy for the use of the accreditation symbol as well as the claim of accreditation only with respect to its scope/schedule of accreditation for which it has been granted.

7) The laboratory shall not:

   a. use its accreditation in such a manner as to bring TTLABS into disrepute; or

   b. make any statement relevant to its accreditation that TTLABS may consider misleading or unauthorized, such as to imply product approval by TTLABS.

8) The laboratory shall inform TTLABS, without delay and in writing, of significant changes that may affect the laboratory's capability to comply with the TTLABS criteria and conditions for accreditation as applicable to the laboratory's status or operation, such as, but not limited to:

- the laboratory's legal, commercial, ownership or organizational status;
- organization, top management and key personnel;
- major policies or procedures;
- premises;
- personnel, equipment, facilities, working environment, methods or other resources;
- authorized signatories;

- scope/schedule(s) of accreditation; or
- other similar matters.

9) The laboratory shall pay such fees as shall be determined by TTLABS.

10) The laboratory shall assist TTLABS in the investigation and resolution of any accreditation-related complaints about the laboratory referred to the laboratory by TTLABS. This includes providing access to information, documentation, all calibration and testing areas, equipment, records and personnel as applicable to the resolution of the complaint.

11) Upon suspension, withdrawal, or expiration of its accreditation (however determined), the laboratory shall discontinue its use of all advertising matter that contains reference thereto and return any certificates of accreditation to TTLABS.

12) The laboratory shall endeavour to ensure that no report or certificate containing results of laboratory activities for which it is accredited, nor any part thereof, is used in a misleading manner.

In order to apply, the applicant laboratory's AUTHORIZED REPRESENTATIVE, must agree to the above conditions for accreditation and must attest that all statements made on their application are correct to the best of their knowledge and belief. An accredited laboratory's AUTHORIZED REPRESENTATIVE is responsible for ensuring that all of the relevant conditions for accreditation are met.

PART B TTLABS ACCREDITATION PROCESS

1.0 TTLABS CONFIDENTIALITY POLICY

TTLABS pays high regard to the holding of its customer's information confidential. During the accreditation process, TTLABS has access to the laboratory's proprietary information. Therefore, TTLABS upholds a strict Confidentiality Policy to which all TTLABS personnel, both internal and external, are expected to agree before being assigned to the laboratory's assessment activity.

All documented information provided by applicant laboratories in connection with their application for accreditation, such as proficiency test reports, and other competence matters, is held confidential. Such information is examined by the TTLABS Secretariat, assessors and the Laboratory Accreditation Committee during the accreditation process, and external bodies as needed for international recognition of the programme. All are made aware of the Confidentiality Policy. Such information shall not be released to other organisations or persons unless the applicant laboratory provides TTLABS permission in writing to do so.

In response to a question about whether or not a particular laboratory has applied for accreditation, TTLABS simply responds by saying that the laboratory is not accredited. The TTLABS Secretariat shall neither confirm nor deny whether a laboratory has ever applied for accreditation. If the laboratory itself is saying that it has applied for accreditation, it is the laboratory's responsibility to release the information regarding its applicant status. If the caller says that the laboratory claims it applied, the TTLABS Secretariat shall take the name, address and phone number of the laboratory to check to see if the laboratory is misleading the client but the TTLABS Secretariat still will not verify the laboratory's application. Should an applicant laboratory require that TTLABS Secretariat verify for a potential customer that it has applied to TTLABS, the TTLABS Secretariat shall indicate that it has applied only if the applicant makes such a request to TTLABS in writing or designates on the application for accreditation that TTLABS is authorized to release information regarding the applicant's status.

If an inquiry is made about a laboratory whose accreditation has lapsed but is in the renewal process, the TTLABS Secretariat can indicate that the laboratory is not accredited at present but is in the process of renewal, if that is the case. If the renewal laboratory's accreditation has lapsed with no indication (return of renewal forms or payment) of pursuit of renewal, the TTLABS Secretariat shall indicate simply that the laboratory is not accredited.

Documents necessary to convey information about accredited laboratories and their schedules of accreditation are not confidential. In cases where a complaint about an accredited laboratory is submitted to TTLABS for resolution, the accredited laboratory in question shall facilitate and participate in the investigation process. All information gathered during this investigation is held confidential between the accredited laboratory and TTLABS, unless required by the laws of the Republic of Trinidad and Tobago.

If TTLABS receives information about an accredited laboratory from another organisation or person, TTLABS will inform the accredited laboratory about this information received, which will be held confidential between the accredited laboratory and TTLABS, and the process of investigation as necessary will begin. However, the source of the provided information is held confidential within TTLABS and is only shared with the accredited laboratory in question if the source gives TTLABS permission to do so.

If the TTLABS Secretariat finds that a laboratory is misrepresenting its applicant or accredited status, the TTLABS Secretariat shall treat such information like a complaint. The Manager,

TTLABS shall determine the appropriate action, which would usually involve contacting the laboratory directly about the alleged misrepresentation.

2.0 CONFLICT OF INTEREST POLICY

Conflict of interest is that condition or circumstance wherein a person is unable or is potentially unable to render impartial services, assistance, advice, assessment, evaluation or decision for TTLABS because of other activities or relationships with other persons or organisations, or wherein a person has or may be able to obtain an unfair competitive advantage.

Consistent with the principles set forth in international standards, TTLABS believes that it is vital that its accreditation services be impartial and objective, uninfluenced by the private interests of individuals acting for or on behalf of TTLABS. Accordingly, any person directly involved in actions relating to the TTLABS processes of accreditation shall not have direct participation in TTLABS actions that may involve an actual or apparent conflict of interest.

The Executive Director, TTBS, Manager, TTLABS and/or the Chairman of the Laboratory Accreditation Committee shall, as promptly as possible, employ all possible means to prevent or overcome any such actions that may conceivably be in violation of this policy.

3.0 APPLICATION

A laboratory applies for accreditation by obtaining the appropriate application package, which includes application forms, TTLABS guidance and mandatory documents and TTLABS criteria for accreditation, from the TTLABS Secretariat or TTLABS website, based on the type of laboratory – testing, medical or calibration. The completed application form and all required laboratory documented information are submitted to the TTLABS Secretariat with the application fee (non-refundable). Through the application form, the applicant laboratory must agree to the set of conditions for accreditation described in Part A of this document. The laboratory documented information required at the time of submission includes:

- the proposed schedule of accreditation for which the laboratory is seeking accreditation and as demonstrated in the application form;
- the laboratory's documented information for its management system and the competence issues of the methods or procedures for which accreditation is sought;
- the laboratory's organizational structure and identification of key management and technical personnel, including the laboratory's identification in a larger entity, if applicable;
- the laboratory's proficiency testing or interlaboratory comparison programme for the methods under consideration and the reports from the most recent round of participation;
- the laboratory's internal quality assurance programme;
- the technical staff competence matrix;
- job descriptions for key management and technical personnel;
- the method validation procedure;
- the completed self-assessment checklist (for first-time applicants); and
- any other documents which the laboratory determines to be necessary for its application.

Accreditation is available for testing, medical and calibration laboratories. For testing laboratories, the schedule of accreditation is normally identified in terms of standard test methods prepared by national, international, and professional standards writing bodies. If a laboratory desires accreditation only for a superseded version of a standard test method, the date of the version used is identified in its scope/schedule of accreditation. When the date is not identified in its scope/schedule of accreditation, laboratories are expected to be competent in the use of the current version within one year of the date of publication of the standard test method.

For medical laboratories, the schedule of accreditation is usually described in terms of the method of analysis as well as the equipment used to perform the analysis. The ranges of measurement achievable for the analyses under consideration are also cited on the schedule of accreditation.

For calibration laboratories, the schedule of accreditation is described typically in terms of the measurement parameter, range of measurement and best attainable uncertainties. In some cases, a laboratory's capability will be described in terms of types of tests, testing technologies, or other descriptive text when it is not appropriate or practical to identify specific tests or calibrations.

Accreditation of non-standard tests and calibrations that the assessor is permitted to examine in detail may be granted, and shall be referenced in the schedule by unambiguous identification. TTLABS reserves the right to refuse to consider accreditation for proprietary tests or calibrations, without prejudice, if there is not sufficient accessibility to the method.

If a laboratory wishes accreditation for the use of its own methods, then it must provide the following information before the assessment to the TTLABS Secretariat, which will be forwarded to the assessor(s) assigned to that assessment:

- the origin of the method;
- a comparison with the standard methods they replace including any departures from the standard, if applicable;
- the justification for and the effects of the departures from the method;
- the internal quality assurance programme for the method;
- the external quality assurance programme for the method; and
- the validation data for the method.

If a laboratory withdraws the application before completion of the assessment, it may apply for a refund of up to 50% of the assessment deposit. However the laboratory will still be responsible for any associated costs incurred in the scheduling of the assessment, such as flight arrangements. See *LAS-L005 Fee Schedule* for further information.

4.0 ON-SITE ASSESSMENT

The objective of the on-site assessment is to establish whether or not a laboratory conforms to the requirements for accreditation and can competently perform the types of tests or calibrations for which accreditation is sought in an impartial manner. However, when accreditation is required to demonstrate conformity with additional criteria that may be imposed by other authorities, the TTLABS assessment shall include these additional criteria.

Once the completed application and the applicant laboratory's documented information is submitted and the application fees are paid, the TTLABS Secretariat identifies and tentatively assigns one or more assessors to conduct the assessment activities. Assessors are selected on the basis of their testing or calibration expertise as well as their understanding of laboratory management systems so as to be better able to provide guidance to the laboratories. They do not represent their employers, if so affiliated, while conducting assessments for TTLABS. TTLABS assessors are drawn from the ranks of consultants, industry, academia, government agencies, and from the laboratory community. Assessors work under contract to TTLABS. The laboratory has the right to ask for another assessor if it objects to the original assignment. The laboratory needs to write its objection providing a valid justification.

Assessments may last from one to several days. More than one assessor may be required. In the cases where assessor teams are assigned to an assessment, there will be a Team Leader identified who will be the assessor responsible for the overall management of the Assessment Team assigned to the laboratory.

Assessors are given an assessor guide and checklists to follow in performing an assessment. These documents are intended to ensure that assessments are conducted impartially and as uniformly and completely as possible among the assessors and from laboratory to laboratory.

The first phase in the assessment activity is the conduct of a document review of the documented information submitted by the applicant laboratory by the Assessment Team. The Assessment Team reviews the application form and submitted documented information for compliance with the appropriate International Standard and other TTLABS accreditation criteria. The Team Leader completes a document review report which is submitted to TTLABS Secretariat, which submits this report to the applicant laboratory after review by the TTLABS Secretariat. If the document review report deems the submitted documented information satisfactory, the TTLABS Secretariat begins planning the on-site assessment visit. If the document review report deems the submitted documented information to be unsatisfactory, TTLABS Secretariat will halt further assessment activity planning and allow the laboratory time to improve its documentation.

TTLABS offers the option of a pre-assessment visit, which may be requested by the laboratory either before the formal application or after the document review. The pre-assessment visit enhances the chances of success at the full assessment. However, there is no guarantee since it is dependent on the ability of the laboratory to demonstrate its commitment to the management system and competence to perform the test or calibration. The laboratory's demonstration of its commitment to the assurance of the integrity of the test or calibration results is critical to the granting and maintaining of accreditation.

Prior to the scheduling of the full on-site assessment visit, the Assessment Team, with the TTLABS Secretariat, develops an assessment plan for the duration of the visit that takes into consideration at least the following activities:

- the opening meeting with laboratory management;
- an agreement to the proposed schedule of accreditation;
- interviews with laboratory personnel that have an influence on the integrity of the test or calibration results;
- the review of personnel competence files;
- witnessing of selected tests and/or calibrations including, as applicable, tests and/or calibrations at customer locations;
- the examination of equipment and calibration records;

- audit records of the management system
- management review records;
- customer feedback and complaints handling records; and
- the closing meeting where all findings are presented and the nonconformity reports are left with the laboratory to address within a specific timeframe.

During the on-site assessment, the Assessment Team has the authority to stop the process at any time and consult with the TTLABS Secretariat and the laboratory's management to determine if the assessment should proceed. In cases where the number of significant nonconformities affects the ability to successfully complete a full assessment, the visit may be converted to a pre-assessment. The on-site assessment is then re-scheduled when the laboratory determines that it has addressed the nonconformities satisfactorily.

5.0 NONCONFORMITIES

During the on-site assessment, assessors may observe nonconformities. A nonconformity is a non-fulfilment of an accreditation requirement including, but not limited to:

- a laboratory's inability to competently perform a test or type of test and/or calibration for which it seeks accreditation;
- a laboratory's management system does not conform to a clause or section of the relevant International Standard, ISO/IEC 17025 or ISO 15189, is not adequately documented, or is not completely operational; or
- a laboratory does not conform to any additional requirements of TTLABS or specific disciplines of testing or calibration, or programmes necessary to meet particular needs.

At the conclusion of an on-site assessment, the Assessment Team prepares a report of findings, identifying nonconformities that, in the Team's judgment, the laboratory must resolve in order to become or maintain accreditation. The Assessment Team holds a closing meeting with top management of the laboratory, going over the findings and presenting the nonconformities identified during the visit. The authorized representative or designate of the laboratory is asked to sign the nonconformity report to attest that the nonconformity report has been reviewed with the assessor. The written assessment report, which summarizes the activities conducted during the on-site assessment and the details of conformance to the accreditation criteria including where the nonconformities were identified, is submitted to the laboratory by the TTLABS Secretariat within five (5) working days from the date of receipt from the Assessment Team.

It is entirely possible that the laboratory will disagree with the findings including one or more of the identified nonconformities. In that case, the laboratory is requested to explain in writing, within five (5) days from the date of the closing meeting why it disagrees with the assessor and with evidence to support this position.

The laboratory is requested to submit, within the identified timeframe after the date of the closing meeting, copies of all objective evidence of implementation and completion of its proposed corrective action plan. The laboratory also shall submit the analysis of the extent and causes of the nonconformities with the proposed corrective action plans. Types of objective evidence include but are not limited to calibration certificates, laboratory procedures, paid invoices, packaging slips and training records. The timeframe for the submission of objective evidence is determined by the Assessment Team given the nature, risk to the integrity of the test or calibration results, and number of the nonconformities. This timeframe

can be between thirty (30) days and ninety (90) days from the date of the closing meeting. The assessor's review of the cause of the nonconformities and proposed corrective action plan is needed to determine if the response is satisfactory. This needs to be submitted to the TTLABS Secretariat within fifteen (15) days from the date of the closing meeting. The time for this submission and review is included in the timeframe allotted for submission of the evidence of implementation of the corrective action plans, that is if a laboratory has been granted sixty (60) days for submission of the evidence of implementation of the corrective action plans, and if the laboratory takes thirty (30) days to submit the corrective action plans for review, then the laboratory has thirty (30) days left for implementation and submission of the evidence to the TTLABS Secretariat. If this review is expected to take more than one hour's time, TTLABS will invoice the laboratory for this time at the prevailing assessor rate. The assessor will discuss the possibility of this review with the laboratory during the exit briefing and obtain the laboratory's concurrence.

Once the corrective actions and evidence of implementation and close out are submitted to the TTLABS Secretariat, they are reviewed for completeness before forwarding to the Assessment Team for its action. The Assessment Team reviews the corrective actions and evidence of implementation for effectiveness and satisfaction of the specific accreditation criterion transgressed. The Assessment Team prepares a report on the satisfaction of the corrective actions taken by the laboratory and submits this to the laboratory through the TTLABS Secretariat. If the corrective actions taken are determined to be effective, the nonconformities are closed out and the assessment can then be deemed completed and closed. In the case of extension of scope, renewal or initial assessments, TTLABS Secretariat prepares the package for submission to the decision-making panel established from the Laboratory Accreditation Committee. If the corrective actions taken are determined to be ineffective, the Assessment Team prepares a report explaining why the nonconformities were not closed out and the laboratory is given usually a maximum of thirty (30) days to re-submit evidence of implementation of effective corrective actions.

If the laboratory fails to respond in writing within its allotted timeframe for submission of corrective actions and evidence of implementation, the assessment process will be stopped. If the laboratory intends to engage in the accreditation process again, the laboratory will be expected to re-apply with payment of the appropriate fees and a new assessment activity planned. A new Assessment Team is assigned to the laboratory to ensure that an impartial assessment is undertaken. There is no refund of the previously paid fees as this was for services already provided.

A laboratory that fails to respond to all its nonconformities within six months of being assessed shall be subject to being reassessed at its expense. Even if the laboratory responds within six months, TTLABS Secretariat has the option to ask for a reassessment of the laboratory before an accreditation vote is taken based on the nature, risk to the integrity of the test or calibration results, and number of the nonconformities. The Laboratory Accreditation Committee panel also has the option to require a reassessment of a laboratory before an affirmative accreditation decision can be rendered.

6.0 ACCREDITATION CYCLE AND ASSESSMENT PROGRAMME

TTLABS operates three-year accreditation cycles. The laboratory's accreditation cycle is established as the three years that follow from the date of the granting of accreditation. An assessment programme is established for each accredited laboratory for the duration of the accreditation cycle, with the reassessment visit and the date for the decision-making for maintaining accreditation occurring before the expiration of the current accreditation cycle. Additionally, the accredited laboratory is expected to pay annual fees that are separate from the assessment fees, which are based on the assessor time used for the assessment activities

in the assessment programme. The assessment programme takes into consideration the following issues:

- the risk to the integrity of the test or calibration results of the accredited laboratory;
- the scope/schedule of accreditation – the number, technical discipline and complexity of the methods accredited; and
- the soundness of the management system.

The assessment programme is presented to the laboratory when the decision to grant or maintain accreditation is made. This allows the laboratory to have an expectation of the timing and transparency of the accreditation process during the accreditation cycle. However, this does not exclude the possibility for an extraordinary visit if required by TTLABS. These visits are not pre-planned and occur as a result of issues that may have arisen such as complaints against the accredited laboratory or information being reported on fraudulent behaviour of the accredited laboratory. The cost of these assessments are borne by the accredited laboratory.

7.0 LENGTHENING OF ACCREDITATION CYCLE

Any lengthening of the accreditation cycle beyond the expiration date must be requested and justified in writing by the laboratory at least ninety (90) days before the expiration date. TTLABS does not automatically grant the lengthening of the accreditation cycle beyond the expiration date of the accreditation cycle. The maximum duration for such a lengthening of the accreditation cycle is ninety (90) days. Factors taken into consideration during this decision include the performance of the laboratory during the accreditation cycle and the validity of the justification is considered.

When fundamental nonconformities are identified during an assessment, the consideration to lengthen the accreditation cycle beyond the expiration date is not done until the laboratory submits objective evidence demonstrating that the nonconformities have been effectively resolved. Similarly, the lengthening of the accreditation cycle is not granted when delays are due to the laboratory's failure to respond to requests within established deadlines.

8.0 EXTERNAL QUALITY ASSURANCE PROGRAMME

TTLABS require all applicant and accredited laboratories to establish and submit its external quality assurance programme at the time of application and continuance of accreditation. This programme can take the form of at least the following activities:

- participation in recognised proficiency testing programmes, such as accredited proficiency testing providers or recognised programmes established by other relevant authorities such as regulators; and
- development of interlaboratory comparisons with other external laboratories to establish measures of performance.

Proficiency testing (PT) is the evaluation of participant performance against pre-established criteria by means of externally-managed interlaboratory comparisons. Interlaboratory comparison (ILC) is the organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with pre-determined conditions. Participation in external quality assurance activities is a requirement of the International Standards of *ISO/IEC 17025 – General requirements for the competence of testing and calibration laboratories* and *ISO 15189 – Medical laboratories – Requirements for quality and competence*. TTLABS has a policy for the participation in proficiency testing

programmes defined in *LAS-Q008 – Proficiency Testing Requirements for Testing and Calibration Laboratories*. This policy is applicable to medical laboratories as well.

Laboratories seeking and maintaining accreditation are required to demonstrate successful and continuing performance in suitable external quality assurance programmes. Results from such programmes indicate the laboratory's competence and are an integral part of the assessment and accreditation process. For this reason, external quality assurance samples may ***not*** be subcontracted to another laboratory for analysis. These programmes may take many forms and standards for satisfactory performance vary depending on the discipline. It is necessary to participate in external quality assurance programmes for the methods or technologies, for which accreditation is held.

Unless specified differently, all accredited laboratories must participate in relevant and available external quality assurance programmes at a frequency sufficient to ensure that all methods, measurands and technologies on the scope/schedule of accreditation are covered over the three-year accreditation cycle.

Applicant laboratories for TTLABS accreditation must be able to demonstrate successful participation in relevant and available external quality assurance programmes prior to receiving accreditation. If appropriate external quality assurance programmes are not available, internal performance-based data can substitute for the purpose of achieving initial accreditation.

9.0 ACCREDITATION DECISIONS

Before an accreditation decision ballot is sent to the Laboratory Accreditation Committee decision-making panel, the TTLABS Secretariat shall review the assessment report, the response to each nonconformity, including, objective evidence of completed corrective action, for effectiveness and to ensure that risks and opportunities of the laboratory are being managed by the laboratory. If the TTLABS Secretariat has any doubt about the effectiveness of any part of the nonconformity response or the management of the risks of the laboratory, TTLABS submits the concern to the assessor(s) for their review and justification for close out. Since all nonconformities must be resolved before accreditation can be granted, the TTLABS Secretariat shall ask the laboratory for further written response in those cases where the TTLABS Secretariat recognizes that an affirmative vote is not likely because of incomplete corrective action in response to nonconformities or obvious lack of supporting evidence that corrective action has been completely implemented.

The TTLABS Secretariat selects a panel of three from the Laboratory Accreditation Committee members for the decision-making for accreditation. The panel selection takes into account impartiality requirements and each member's technical expertise with the laboratory testing or calibration to be evaluated. The laboratory is consulted about any potential conflicts of interest with the membership of the proposed decision-making panel prior to sending their package to the Laboratory Accreditation Committee. At least two affirmative ballots, with no unresolved negative ballots, of the three ballots distributed must be received before accreditation can be granted or maintained. This decision is expected within three (3) weeks from the date of submission of the documented information to the decision-making panel.

It is the primary responsibility of assessors to judge whether the observed evidence is serious enough to be identified as a nonconformity. However, the panel members that are asked to make an accreditation decision are required to make a judgment whether or not the nonconformities still exist based on information contained in the ballot package. Accordingly, panel members can differ with assessor judgments, based upon their interpretation of the criteria for the specific case under question and the supporting evidence available whether a

nonconformity does or does not exist. The TTLABS Secretariat attempts to resolve these differences as they arise, but it remains for the panel to make the decision.

The TTLABS Secretariat shall notify the laboratory asking for further written responses based on the specific justification for one or more negative votes received from the panel. If further written response still does not satisfy the negative voter(s), a reassessment may be proposed or required. If a reassessment is requested by more than one voter, the laboratory is asked to accept a reassessment. If the laboratory refuses the proposed reassessment, a three-member appeals panel is balloted (see **14.0 Accreditation Status and Adverse Accreditation Decisions and 19.0 Appeals Process** below). If two-thirds of those voting agree to a reassessment, accreditation is denied until a reassessment and satisfactory laboratory responses to all nonconformities are completed.

If accreditation is granted, the TTLABS Secretariat prepares and forwards a certificate and schedule of accreditation containing the information on the accredited tests or calibrations to the laboratory. The laboratory should keep its schedule of accreditation available to show customers or potential customers the testing or calibration technologies and methods for which it is accredited. The TTLABS Secretariat also uses the schedules of accreditation to respond to inquiries and to update the TTLABS database of accredited laboratories, which is published on the TTLABS website.

10.0 REASSESSMENT AND RENEWAL OF ACCREDITATION

TTLABS conducts a full on-site reassessment of all accredited laboratories toward the end of the laboratory's accreditation cycle. The reassessment activities including satisfactory closure of all nonconformities, and the decision for the renewal of accreditation for another accreditation cycle must occur before the expiration of the current accreditation cycle.

Reassessments are also conducted when evaluations and submissions from the laboratory or its customers indicate that significant technical changes in the capability of the laboratory, such as changes in the technology of the test or relocation of the laboratory, have occurred.

The renewal decision process is similar to the initial decision process (see **9.0 ACCREDITATION DECISIONS**), except in the following situations.

1) If there are no nonconformities, renewal is automatically processed by the Manager, TTLABS without a Laboratory Accreditation Committee decision-making panel vote.

2) If there are only a few nonconformities of a low-risk nature where the nonconformities do not directly affect the integrity of calibration or test results and there is sufficient objective evidence that the nonconformities have been resolved, the Manager, TTLABS may elect to renew accreditation without a Laboratory Accreditation Committee decision-making panel vote.

If there are high-risk nonconformities such as nonconformities that directly affect the integrity of calibration or test results, the Assessment Team informs the laboratory of the required timeframe for the submission of evidence of implementation of corrective actions, which is normally thirty (30) days. The TTLABS Secretariat endorses this decision and informs the laboratory that failure to comply with the timeframe will result in further actions being taken leading to suspension or withdrawal of accreditation (see **14.0 Accreditation Status and Adverse Accreditation Decisions, 16.0 Suspension of Accreditation, and 17.0 Withdrawal of Accreditation**). Several related low-risk nonconformities or repeat nonconformities from previous assessments may also be considered a high-risk nonconformity. In these cases, a ballot of the Laboratory Accreditation Committee decision-

making panel is conducted using the same voting procedure as for initial accreditation decisions.

In cases where significant nonconformities are identified in a renewal assessment, the laboratory may be required to undergo a follow-up visit to verify effective implementation of corrective actions before the evidence is closed out and submitted to the Laboratory Accreditation Committee decision-making panel for a decision.

11.0 EXTENSION OF THE SCHEDULE OF ACCREDITATION

A laboratory may request an extension to its schedule of accreditation at any time. Such a request must be submitted in writing to the TTLABS Secretariat using the *LAS-L023 – Request for Extension to Scope/Schedule Application*. Each request is handled on a case-by-case basis. Unless the previous Assessment Team can verify the competence of the laboratory to perform the additional tests or calibrations, another on-site assessment is normally required. If the Assessment Team can recommend a scope/schedule extension without an assessment, but this recommendation requires extensive review of supporting documentation requiring more than one hour of assessor time, TTLABS may invoice the laboratory for this review time at the prevailing assessor rate. If the additional tests or calibrations require a new technology, another assessment is definitely required. Similarly, if a laboratory re-locates, a follow-up on-site assessment is warranted. The granting of the Extension of Scope/Schedule is dependent on the review and voting procedure of the LAC.

When a laboratory is granted an extension, a revised Schedule of Accreditation is issued which reflects the extended anniversary date. Since the Schedule of Accreditation is the document used to provide evidence of accreditation, the Certificate of Accreditation is not normally reissued for an extension of the Schedule of Accreditation. Upon completion of the renewal process, both documents are reissued, reflecting the renewed anniversary date.

12.0 LABORATORY REFERENCE TO TTLABS ACCREDITED STATUS

TTLABS provides guidance to accredited laboratories on the use of its accreditation symbol in *LAS-Q003 – Laboratory Reference to TTLABS Accredited Status – TTLABS Advertising Policy*. Every circumstance where the principle of accurate representation applies cannot be anticipated and dealt with in this document. Therefore, it is the responsibility of the accredited laboratory not to misrepresent its accredited status under any circumstances. If there are questions or doubts about the proposed usage of the accreditation symbol, the accredited laboratory should submit the intended uses of the symbol, draft advertisements, and/or any other accreditation claims to TTLABS for advance review.

13.0 MISUSE OF THE TTLABS ACCREDITATION SYMBOL

Incorrect references to TTLABS accreditation of the laboratory or misleading use of the accreditation symbol found in advertisements, catalogues and other promotional material shall be treated with suitable actions which may include legal or corrective action or publication of the transgression. In cases of misuse of the accreditation symbol by laboratories, TTLABS shall take appropriate corrective action, which may include suspension of accreditation.

14.0 ACCREDITATION STATUS AND ADVERSE ACCREDITATION DECISIONS

There are various types of accreditation status that can be assigned to laboratories. These are described in the bulleted list below.

- ***Accredited*** – A laboratory that has achieved accreditation is classified as accredited. This status is maintained throughout the accreditation cycle provided that accreditation criteria and laboratory obligations are maintained as determined through the assessment programme.

- ***Delinquent*** – A laboratory, at any stage of accreditation, is classified as delinquent when it has not completed the necessary assessment actions within an acceptable timeframe. A laboratory's delinquent status is not publicized. The laboratory must undergo a full reassessment, paying only the assessor fees and expenses, before any further accreditation actions can be taken. A new laboratory's anniversary date is based on the date of the decision for granting or renewal of accreditation (see **6.0 ACCREDITATION CYCLE AND ASSESSMENT PROGRAMME**).

- ***Voluntary Withdrawal*** – An applicant laboratory not yet accredited, an accredited laboratory, or a renewal laboratory, can decide to terminate further accreditation activities and voluntarily withdraw from the accreditation programme. The laboratory's authorized representative must inform TTLABS in writing of this request. TTLABS does not publicize the fact that a new laboratory had applied and then withdrawn; however, a list of previously accredited laboratories that have withdrawn is published. Those that withdrew voluntarily are specifically identified. Any laboratory that has voluntarily withdrawn shall present evidence to TTLABS that they have communicated their withdrawn status to their clients without undue delay.

- ***Suspended*** – A laboratory can be identified on the publication of accredited laboratories as suspended. Suspension of a laboratory may occur for various reasons which include the expiration of the accreditation certificate and schedule of accreditation before all assessment and decision-making activities can be completed and failure to submit evidence of the effectiveness of the implemented corrective actions for identified nonconformities within the agreed to timeframe. The criteria for the application of suspension process are described in **15.0 Reduction of Accreditation**. Any laboratory that has been suspended for all or part of their activities shall present evidence to TTLABS that they have communicated their suspended status to their clients without undue delay.

- ***Withdrawal*** – A laboratory can be withdrawn from accreditation based on non-fulfilment of TTLABS accreditation criteria. Withdrawal procedures and criteria are described in **16.0 Suspension of Accreditation**. A laboratory that wishes to become accredited after it has been withdrawn from the TTLABS accreditation programme shall re-apply for accreditation and go through the process as if it were an initial accreditation. Any laboratory that has been withdrawn shall present evidence to TTLABS that they have communicated their withdrawn status to their clients without undue delay.

A laboratory can appeal adverse decisions made on its accreditation status. An Appeals Committee is established by the Laboratory Accreditation Committee and comprises three persons who have not been directly involved in the assessment and decision-making activities that led to the adverse decision. **18.0 Complaints Process** describes the appeals process employed by TTLABS.

15.0 REDUCTION OF ACCREDITATION

Sometimes the laboratory may request its Schedule of Accreditation to be reduced. Reasons for this include, but are not limited to:

- equipment that are not functional for a long period of time such as more than six (6) months;
- the loss of authorized personnel for the performance of a test or calibration with no other authorized personnel available; and
- the test or calibration is no longer being provided by the laboratory.

The Assessment Team is also able to recommend, based on objective evidence gathered during the on-site assessment that the Schedule of Accreditation be reduced. This may include evidence of continuing competence performance issues as demonstrated by internal audits, external quality assurance results and complaints from customers on the results of tests or calibrations. This recommendation with the supporting justification will be submitted to the Laboratory Accreditation Committee decision-making panel for a decision.

16.0 SUSPENSION OF ACCREDITATION

Suspension of all or part of a laboratory's accreditation may be a decision made by either, the Manager, TTLABS or the Laboratory Accreditation Committee decision-making panel. Suspension actions by the Manager, TTLABS are generally taken based on objective evidence of failure to comply with the Conditions for Accreditation listed in Part A of this document, such as failure to pay required fees or failure to participate in required proficiency testing programmes. The maximum duration for the suspension of accreditation is six (6) months before withdrawal procedures are commenced.

The accreditation applicable to a specific laboratory may be suspended upon adequate evidence of:

- nonconformity with the requirements of a nature not requiring immediate withdrawal;
- improper use of the accreditation symbol such as misleading prints or advertisements that are not corrected by suitable retractions and appropriate remedial measures by the laboratory; and
- other deviations from the requirements of the TTLABS accreditation programme such as failure to pay the required fee.

When an accredited laboratory is suspended, TTLABS shall inform of the official suspension in writing, stating:

- the cause;
- the conditions under which the suspension will be lifted;
- how the suspension will be publicized;
- that the suspension is for a temporary period to be determined by the time needed to take corrective action;
- that, within thirty (30) days of the date of the notice, the laboratory may submit in writing information in opposition to the suspension, including any additional information that raises a genuine dispute over material facts; and

- that a further review will be conducted to consider such information and a further written notification will be sent to the laboratory by certified mail or equivalent means, indicating whether the suspension has been terminated, modified, left in force or converted to a withdrawal of accreditation.

17.0 WITHDRAWAL OF ACCREDITATION

The decision for the withdrawal of accreditation is a serious one. There are various reasons for which the withdrawal of accreditation is recommended and made. These include for immediate withdrawal:

- evidence of fraudulent practices or behaviours being adopted by the laboratory;
- evidence that the laboratory has intentionally provided false information;
- evidence that the laboratory has intentionally concealed information;
- failure to maintain demonstrated competence in external quality assurance programmes;
- upon formal request by the laboratory; and
- failure to settle outstanding fees within six (6) months from the assessment activity.

TTLABS shall require a decision for withdrawal of accreditation to be made by the Laboratory Accreditation Committee decision-making panel for any of the following causes:

- relevant provisions for suspension of accreditation are carried out;
- assessment activities indicate that nonconformities are high-risk in nature as determined by the Assessment Team and confirmed by the Laboratory Accreditation Committee decision-making panel;
- complaints are received relating to one or more of the laboratory's test reports or calibration certificates and investigation reveals serious nonconformities in the management system and/or competence in conducting the specific tests or calibrations;
- the TTLABS accreditation criteria are changed and the laboratory either will not or cannot ensure conformity with the new requirements;
- action is necessary to protect the reputation and integrity of TTLABS; and
- other reasons specifically provided for under these programme requirements or formally agreed to by TTLABS and the laboratory.

When it is proposed to withdraw accreditation, the TTLABS Secretariat shall issue a written notice by certified mail or equivalent means:

- stating that withdrawal is being considered and the reason(s) for the proposed withdrawal sufficient to put the laboratory on notice of the cause;
- requesting that within thirty (30) days of the date of the notice, the laboratory submit in writing, information in opposition to the withdrawal, including any additional information that raises a genuine dispute over material facts; and
- indicating the effect of the proposed withdrawal, including removing the laboratory's name from the TTLABS database of accredited laboratories and publicizing the change in accreditation status.

A laboratory may appeal to the TTLABS Secretariat against a decision to withdraw accreditation.

18.0 COMPLAINTS PROCESS

TTLABS has a process for the receipt, evaluation and making determinations on complaints. TTLABS treats all complaints confidentially and impartially and they do not result in discriminatory action being taken against the complainant. There are two categories of complaints managed by TTLABS. The first is a complaint against the quality of service or part thereof offered by TTLABS other than against an adverse decision. The second category is a complaint against an accredited laboratory. In this situation, TTLABS ensures that the accredited laboratory addresses the complaint first. The TTLABS Complaints Process is available on the TTLABS website. Annex II presents the TTLABS Complaints Process.

Complaints need to be submitted in writing to the TTLABS Secretariat. Once received, the TTLABS Secretariat sends an acknowledgement of receipt of the complaint to the complainant. The Manager, TTLABS reviews the complaint to validate it and then establishes a three-member committee which comprises persons who are familiar with TTLABS processes but was not involved in the specific complaint being raised. These persons can be assessors, technical experts and internal staff. The complainant is informed within three (3) days from the receipt of the complaint of the validation of the complaint and the establishment of a committee to investigate it.

The Complaints Committee investigates the complaint using techniques of interviews, review of records and comparison to established TTLABS applicable documented information. The Committee is expected to make a recommendation with a justification within twenty-one (21) days from the establishment of the Complaints Committee. This recommendation is submitted to the Manager, TTLABS who reviews it and makes a determination on action to be taken to correct the matter. The complainant is informed of the decision on the corrective action to be taken within three (3) days from the date that the decision is made. The corrective action taken needs to be implemented within a reasonable timeframe, usually three (3) months after the decision on the corrective action is made unless otherwise recommended. If the complaint is against the Manager, TTLABS, then the Complaints Process is handled by the Chairperson, Laboratory Accreditation Committee. All records on the complaint are maintained by the TTLABS Secretariat.

19.0 APPEALS PROCESS

TTLABS has a process for the receipt, evaluation and making determinations on appeals. TTLABS treats all appeals confidentially and impartially and they do not result in discriminatory action being taken against the appellant. The TTLABS Appeals Process addresses the laboratory's dissatisfaction with an adverse decision against it. The TTLABS Appeals Process is available on the TTLABS website. Annex III presents the TTLABS Appeals Process Map.

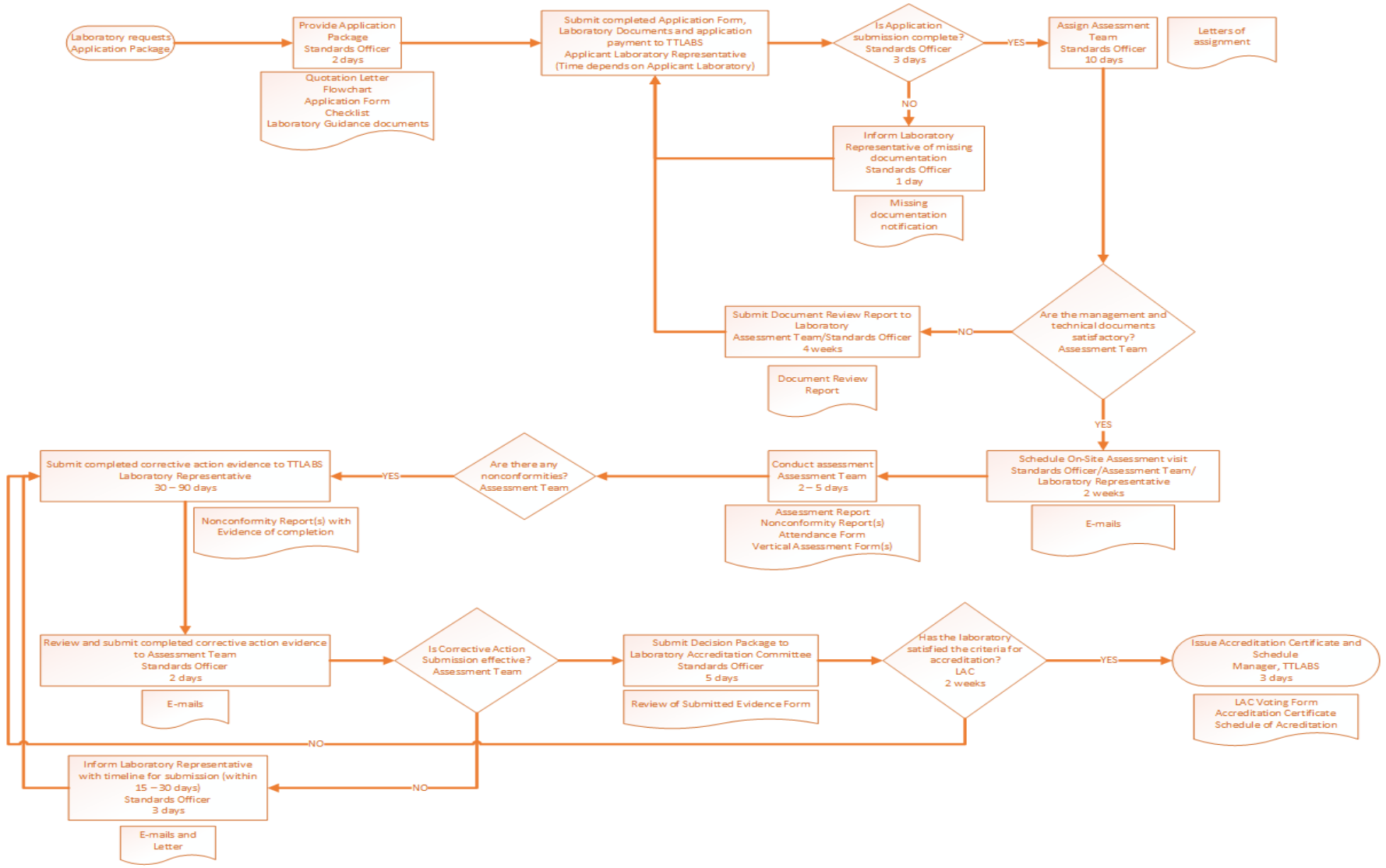
Similar to complaints, appeals need to be submitted in writing to the TTLABS Secretariat and no longer than thirty (30) days from the date when the decision was made. Once received, the TTLABS Secretariat sends an acknowledgement of receipt of the appeal to the appellant. The Manager, TTLABS reviews the appeal to validate it and then submits it to the Laboratory Accreditation Committee for action. The Laboratory Accreditation Committee establishes a three-member committee which comprises persons who are familiar with TTLABS processes but was not involved in the specific appeal being lodged. These persons can be assessors, technical experts and other members of the Laboratory Accreditation Committee. This occurs

within five (5) days from the receipt of the appeal by the Laboratory Accreditation Committee. The appellant is informed within three (3) days from the receipt of the appeal of the validation of the appeal and its submission to the Laboratory Accreditation Committee for investigation.

The Appeals Committee investigates the appeal using techniques of interviews, review of records and comparison to established TTLABS applicable documented information. The Committee is expected to make a decision on the appeal with a justification within twenty-eight (28) days from the establishment of the Appeals Committee. This decision is submitted to the Chairperson, Laboratory Accreditation Committee who reviews it and authorizes the decision and action to be taken to correct the matter. The decision on the appeal is final. The appellant is informed of the decision and action to be taken within three (3) days from the date that the decision is made. The action taken needs to be implemented within a reasonable timeframe, usually three (3) months after the decision on the appeal is made unless otherwise recommended. If the appeal is against the Chairperson, Laboratory Accreditation Committee, then the Appeals Process is handled by the Vice-Chairperson, Laboratory Accreditation Committee. All records on the appeals process are maintained by the TTLABS Secretariat.

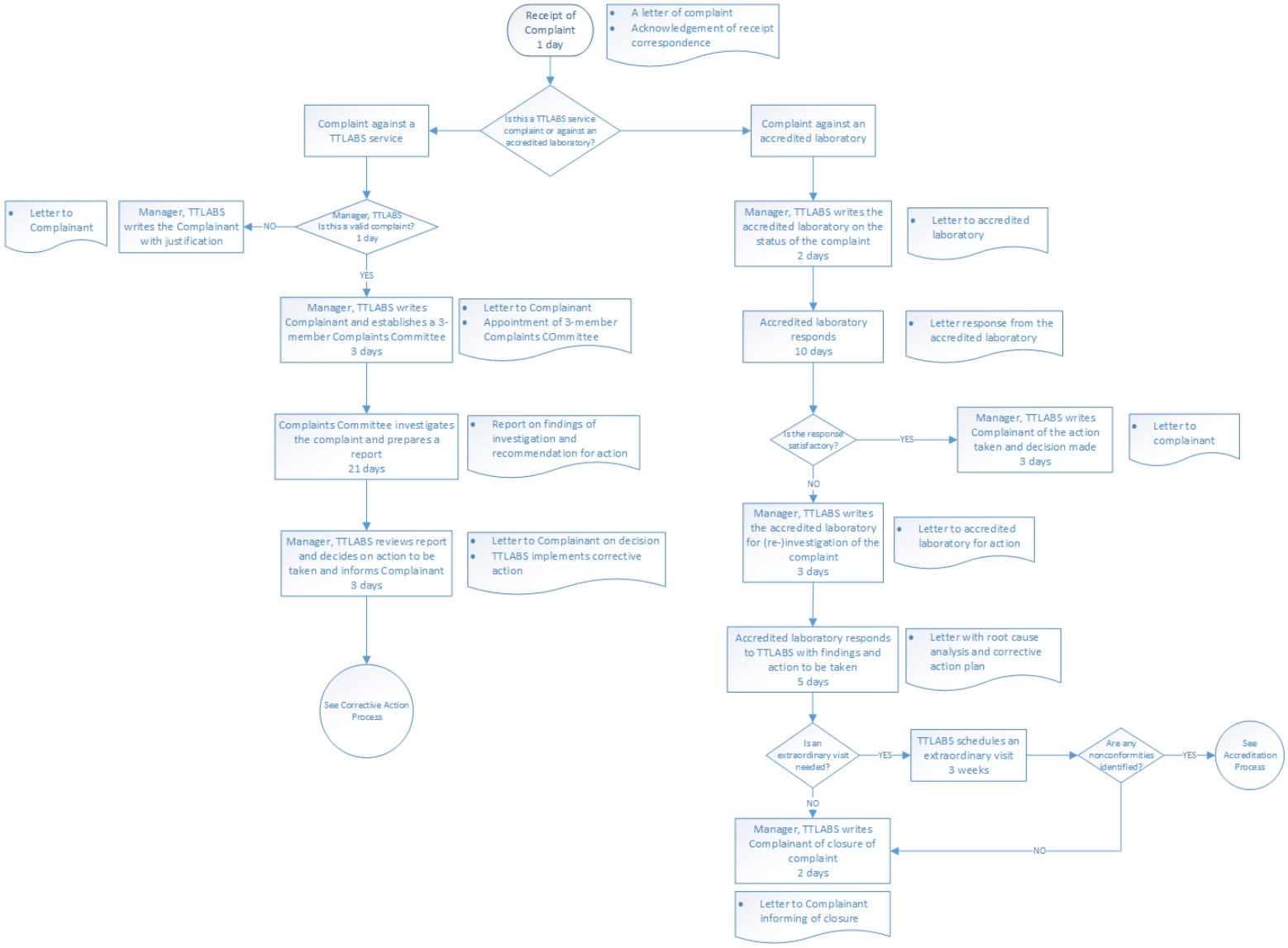
ANNEX I LAS-P031 TTLABS ACCREDITATION PROCESS MAP

2018-Jan-15



ANNEX II LAS-P032 TTLABS COMPLAINTS PROCESS MAP

2018-Jan-15



ANNEX III LAS-P033 TTLABS APPEALS PROCESS MAP

2018-Jan-15