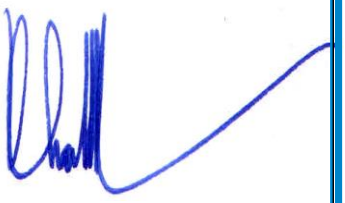
VIETNAM INSTITUTE OF ACCREDITATION

ASSESSMENT PROCEDURE FOR ACCREDITATION OF LABORATORIES

Code: VACI.P7.1

Reversion: 02

	Drafted by	Check by	Approved by
Name	La Van Toan	Phan Minh Hai	Hoang Huu Tham
Position	Technical assessor	Technical assessor	Director
Signature			

DISTRIBUTION TO

☐	Management Board	☐	Administration and Planning Division	☐	Customer Service Division
☐	Accreditation Division 1	☐	Accreditation Division 2	☐	

1. Related persons must study and strictly comply with the contents of this regulation

2. The contents of this regulation take effect as directed by the Institute's leaders.

3. Each unit is only allowed to distribute 01 copy (with control stamp), the copies have no use value and need to be removed. When the units need to distribute more documents, they must request the secretary to have the control stamp.

AMENDMENT STATUS

Amend. No	Date	Amendment content and related clause	Approved by
1	10/05/2019	- Issued for the 1st time	
2	18/04/2021	- Editing the content of the process, issued for the 2nd time.	
3	18/04/2022	- Modifying form name VACI.P7.1.F20 Decision to suspend/reduce the scope of accreditation to Decision to adjust/reduce the scope of accreditation. - Modify the content of the form VACI.P7.1.F20	
4			
5			
6			
7			
8			
9			

1. Objectives

This procedure specifies the sequence, procwdure and content of an audit for the accreditation (initial accreditation, extended accreditation, re-accreditation, tranasitional accreditation) of laboratories (including testing, calibration labs and medical lab) of Vietnam Institute of Accreditation.

2. Scope

This procedure is applied for VACI and accredited laboratories.

3. Normative references

- TCVN ISO/IEC 17000:2007 (ISO/IEC 17000:2004): assessment of conformity-vocabulary and general principles;
- TCVN ISO/IEC 17011:2017: General requirements for accreditation bodies accrediting;
- TCVN ISO 19011:2018 : Guide to evaluating the management system;
- TCVN ISO/IEC 17025:2017: General requirements for the competence of testing and calibration laboratories.
- TCVN ISO/IEC 15189:2014: Laboratory: general requirements for quality and competence.
- VACI.R7.1. General provisions on accreditation

4. Terms- definitions and abbreviations

4.1 Terms- definitions

Assessment

Systematic, independent, documented process for obtaining records, statements of fact or other relevant information and assessing them objectively to determine the extent to which specified requirements are fulfilled.

Inition assessment :Is the first time applying for accreditation boby.

Surveillance assessment: is the accreditation body periodically during an accreditation cycle wishing to expand the accreditation scope.

Reassessment: is the subsequent accreditation assessment of an organization after the previous accreditation decision expires.

On-site assessment: can be carried out in or out lab depend range to conduct test/ calibration/sampling of lab.

Major non-conformity: the nonfulfillment of specified requirements that results in a failure to comply with the accreditation criteria thus leading to the breakdown in, or the inability to establish confidence in, the outcome of the testing, calibration results, sampling.

Minor non-conformity: a single failure to non- conformity with accreditation criteria, or with the regulation in laboratories management system, which non-affection to the reliability of testing, calibration results/ sampling.

Note: a number of minor but related to nonconformities, which considered as a major nonconformity.

Observation: an assessment finding that does not warrant nonconformity but is identified by the assessment team as an opportunity for improvement.

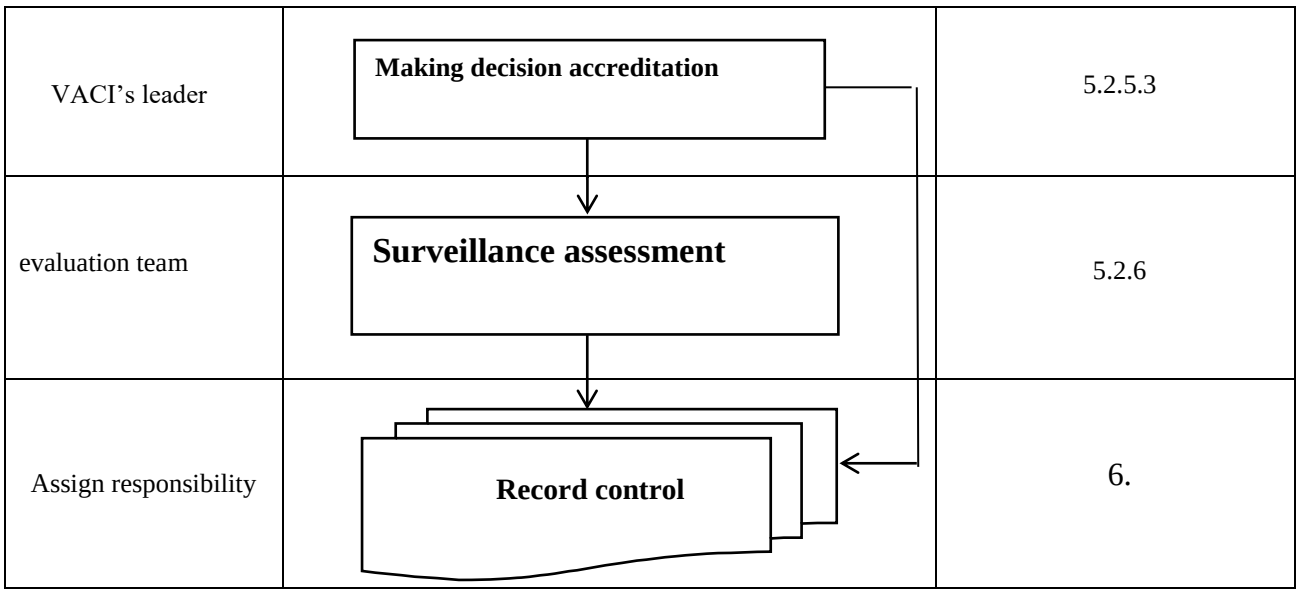
4.2 Abbreviation

- VACI: Vietnam Institute of Accreditation
- PTN: Laboratory (including testing, calibration, sampling and medical testing)
- TCĐK: registered organization
- CGĐG: expert review
- TNTT/SSLP: inter-laboratory comparison/PT programmers.
- KPH: non-conformities
- VP: office
- P.NV: accreditaion division
- HSĐK: application form
- HSCN: accredited form
- HĐKP: corrective action

5. Content

5.1 Accreditation process

RESPONSIBILITY	CHART	DOCUMENTS
Office of the Institute	**RECEIVING REGISTRATION DOCUMENTS**	5.2.1
Office, accreditation division	**Check corrective action** — **No**	5.2.2
accreditation division , VACI's leader and evaluation team	**Prepare the review**	5.2.3
evaluation team	**document review** — **No**	5.2.4.1
evaluation team	**On-site assessment** -opening -do an evaluation -closing - review and report	5.2.4.2
evaluation team	**Document accredited**	5.2.5.1
Expert reviewer	**Check of document** — **No**	5.2.5.2



5.2 Accreditation assessment process

5.2.1 Register accreditation

5.2.1.1 Receiving registration document

- Labs wishing to register for accreditation with VACI can go through the web www.vaci.vn or contact the office directly for information about the accreditation program, accreditation standards and documents related to the process accreditation to prepare and send accreditation corrective documents to VACI.

Note: in case of need, the lab can contact to office for assistance in providing relevant information and documents and supporting in prepareing the application for accreditation.

- An aaplication for lab accreditation includes:

+ The application form for accreditation and the attached appendix have been filled out with the form VACI.P.7.1/F01.

+ The questionnaire was filled with information according to the form VACI.P7.1.F02 for testing/ calibration labs and VACI.P7.1.F02M for medical labs

+ The lab's equipment list is complete with the form VACI.P7.1.F03.

+ Sheet of monitoring programs TNTT/SSLP according to form VACI.P7.1.F04.

+ List of control documents according to the form of the accreditation registered organization.

+ Required documents include but are not limited to:

a) Manual of quality, testing/ calibration/testing methods and method validation for internal methods;

b) A document on the legal status of the registration organization.

Note: registration organization send the application for accreditation by scanning at the email address: viencongnhanvaci@gmail.com or submit directly to the office Institute of VACI.

5.2.1.2 Review

a) After receiving the registration documents, the office of the Institute transfers to the review department/person for review:

- The completeness and validity of the list of documents, information in the registration documents with the general provisions on accreditation of VACI.

- The availability of the VACI's resources to undertake the assessment.

b) This is conducted within 2 days. The results of viewing registration documents are recorded in the form VACI.P7.1.F05.

c) The reviewer may request the lab to supplement information or clarity the invalid points of the registration document, if any.

- When the information is enough and the lab is ready for accreditation, within 3 days, VACI's office will announce the approval of application and give a code for applicant, VACI will make the assessment contract to the lab according to procedure VACI.P7.1.F06.

d At any point during the initial registration or evaluation, if there is evidence of fraud and the registration organization intentionally provides false information or conceals information, VACI will refuse to register or terminate the accreditation process.

- The organization applying for an application that after 6 months is not eligible for on-site assessment

e) In case to clarity a certain content in the registration dossier that requires a preliminary visit before the initial assessment, VACI will notify the applicant and conduct a preliminary visit after receiving it.

5.2.2 resource review

The accreditation body shall review its ability to carry out the assessment of the applicant conformity assessment body, in terms of its own policy and procedures, its competence and the availability of personnel suitable for the assessment activities and decision making.

Resource review results are recorded in Form VACI.P7.1.F05.

5.2.3 Preparation for assessment

After the accreditation evaluation contract is signed, Institute's office sends 01 copy of evaluation contract to Accreditation division to prepare, exchange and agree with customers draft documents, including:

- the decision to establish an evaluation team is according to VACI.7.1.F07

- Notice of evaluation program according to VACI.P7.1.F08 for the lab/ calibration and VACI.P7.1.F08M for the medical lab.

After getting confirmation of the client accepting the composition of the audit team and the evaluation program according to VACI.P7.1.F09, accreditation division submits to the Director for approval the above documents and documents for transfer to apply body

Note:

- *The assessment programme set of initial –assessment consistent with a specific accreditation shceme that the accreditation body performs on a specific conformity assessment body during an accreditation cycle.*

- *reassessment: assessment performed to renew the accreditation cycle.*

- *extending of accreditation: assing conformity assessment activities to the scope of accreditation.*

- the transitional accreditation program shall ensure the conformance of all requirements of audit criteria throughout the accreditation scope taking into account information obtained form audits performed by previous accreditation bodies.

5.2.4 Review of documented information

5.2.4.1 The audit team leader organizes a review of all documents and documented information in the Bid to determine the conformity of the documentation and information with the standard's requirement(s) and other relevant requirements. regarding recognition. The results of the review are recorded on the Form VACI.P7.1.F10.

5.2.4.2 In case the review results show that the management system of the GSO is not qualified to continue the assessment and accreditation, the head of the audit team shall send a notice to the registration organization's to supplement and complete it within 6 months.

Note: Reasons indicating that the registration organization's management system is not eligible for further accreditation may include:

- The standard for test and calibration methods is out of date or the internal method is judged to be of no use or has not been validated.

- The equipment, facilities and environment are not suitable for testing/calibration methods or are not guaranteed to have traceability to provide valid results.

Over time limit, but the registration organization still does not supplement and complete as required, the head of the assessment team reports to VACI's leaders to decide to suspend the on-site assessment and notify the registration organization in the form VACI.P7.1.F11.

5.2.4.3 Preliminary visit

a) If there is the request of the laboratory, VACI may appoint the audit team leader and one (several) technical auditors to conduct a preliminary visit before official onsite assessment.

b) The purpose of the preliminary visit is to examine the compliance of the laboratory with some specific requirements of requirements 4 to 8 of ISO/IEC 17025. Specific requirements are considered in the preliminary visit proposed by the laboratory and agreed in advance with VACI.

c) A preliminary visit is not required for the laboratory. Evaluation methods and techniques are carried out in accordance with clause 5.2.5 and do not imply and relate to any work for consulting purposes.

5.2.5 On-site assessment

5.2.5.1 Assessment technique

a) The auditor may use one or more of the following, but not limited to, the following audit techniques:

- Review of documented information: the assessment team shall review all relevant documented information supplied by the conformity assessment body to evaluate its system for conformity with the relevant standard and other requirements for accreditation.

- Witnessing: observation by the accreditation body of a conformity assessment body carrying out conformity assessment activities within its scope of accreditation.

- Interview: technical assistance for reviewing documents, records and witnessing to obtain more information and evidence of conformity through relevant personnel of the registered organization.

- Metrological evaluation (applicable to calibration): applicable in cases where, for any reason, the calibration lab fails to participate in interlaboratory comparison/ proficiency tests in the domain sign accreditation. Metrological evaluation is performed specifically according to VACI.SR.05 Additional requirements for accreditation of calibration rooms,

5.2.5.2 Evaluation duration

Depending on the accreditation program, scope, the field of assessment and the organization size of the applicant organization, the duration of an accreditation audit is determined according to the rules defining the audit duration of VACI.R7.1.04.

5.2.5.3 Step of the assessment

a) Opening meeting:

The audit team leader presides over the opening meeting with team members and auditee representatives to re-affirm the audit criteria and program (scope, criteria, time, audit assignment, authorization, etc.) test/calibration proposed observations, classification of nonconformities, requirements to be met for documentation, records, work site, etc.).

- The auditee can give feedback, suggestions on the contents announced by the audit team leader, or propose to expand/narrow the scope of registration for accreditation at the opening meeting but must be approved by the audit team. acceptance of the audit team leader after balancing with the audit team's ability

All present members signed the opening meeting and ended the meeting ballot according to VACI.P7.1.F12.

b) Conducting an assessment

The arranges people to lead the auditors to the audit position.

The auditor conducts the assessment according to the assessment program/ plan within the scope of his assignment and records assessment findings in the form VACI.P7.1.F13 and reports on the results of close observation performance test according to sample VACI.P7.1.F14.

The lead auditor synthesizes the assessment results of each member to prepare an evaluation report in accordance with form VACI.P7.1.F15.

In the case, the audit team cannot reach a conclusion on the findings, the team leader must return it to VACI for clarification.

c) Closing meeting:

The closing meeting composition including the audit team and the auditee representatives was recorded using form VACI.P7.1.F12.

Assessment report has to include: conclusion, non-conformities and observations are found in the assessment process, non-conformities(the major, and minor non-conformity, lab must carry out the corrective action,…. According to the form of assessment report VACI.P7.1.F15.

Note: for a supervisory assessment, the assessment report is made according to form VACI.P7.1.F18

Proposals, recommendations from the registration organization and unified the implementation plan of corrective action report according to form VACI.P7.1.F16.

Resolving differences between the assessment team and the registration organization.

d) Review the corrective action report and complete the evaluation file

The team leader is responsible for coordinating with the team members to review and evaluate the effectiveness of corrective action. In case the correctice action is not yet effective, the team leader requests the assessed party to continue to perfect the corrective action.

The leader team must carry out corrective action attached with the evidence basing on the agreement with assessment team but not exceed 3 months since the assessment in case of the initial assessment.

5.2.6 Accreditation decision-making

5.2.6.1 Profile accreditation

5.2.6.1.1 After reviewing the organization's corrective action report, the assessment team leader gathers the entire audit dossier and transfers the accreditation dossier to VACI incliding:

+ decide to set up an evaluation team VACI.P7.1.F07

+ the program reviews according to VACI.P7.1.F08

+ validate program according to evaluation VACI.P7.1.F09.

+ document review report, documented information VACI.P7.1.F10.

+ attend the opening and closing meeting follow the form VACI.P7.1.F12.

+ auditor's assessment findings record VACI.P7.1.F13.

+ witness evaluation report VACI.P7.1.F14.

+ assessment team report VACI.P7.1.F15.

+ report of corrective action according to VACI.P7.1.F16 accompanied by evidence of corrective action confirmed by auditor and audit team leader.

5.2.6.1.2 On the basis of documents and records about the assessment, the accreditation division is responsible for drafting:

+ Accreditation decision together with the scope of application for accreditation according to the form VACI.P7.1.F19, or

+ Decision to adjust/ reducing accreditation according to the form VACI.P7.1.F20; or

+ Decision to withdrawing accreditation according to the form VACI.P7.1.F21.

5.2.6.2 Review

After reviewing and closing all the corrective actions, the team leader will propose all the records of assessment to review panel VACI.R7.1, duration for record review is not exceeding 7 working days.

Examination report of accreditation reviews is made according to the form VACI.P7.1.F.17.

Based on the proposal of the review panel and the assessment records, chief Institute's VACI will make the decision on accreditation.

Member of review panel has right to refuse the accreditation result if the accreditation assessment process is not followed to the accreditation requirement.

5.2.6.3 Accrditation decision-making

Within 05 days after the accreditation review is examined satisfactorily, the Director shall accreditation decision-making

The accreditation decision includes the following information:

a) accreditation body logo;

b) the name of the accreditation body and the name of the represented, if these are different;

c) scope of accreditation;

d) uniqe identification of all locations assessed,

e) unique identification of the conformity assessment body;

f) date(s) and type(s) of assessment(s);

g) a statement on the adequacy of the organization and procedures adopted by the conformity assessment body to give confidence in its competence, as determined through its fulfilment of the requirements for accreditation.

The scope of accreditation must include at least information:

For calibration labortories:

- the calibration and measurement capability (CMC) expressed in terms of:

- measurand or reference material;

- calibration or measurement method or procedure and type of instrument or material to be calibrated or measured;

- measurement range and additional parameters where applicable, e.g. frequency of applied voltage;

- measurement uncertainty.

For testing laboratories (including medical laboratories):

- materials or products tested;

- component, parameter or characteristic tested;

- tests or types of tests performed and, where appropriate, the techniques, methods and/or equipment used..

For the laboratory:

- materials or products tested;

- component, parameter or characteristic tested;

- tests or types of tests performed and, where appropriate, the techniques, methods and/or equipment used...

5.2.7 Accreditation cycle

5.2.7.1 surveillance assessment

Surveillance assessment is conducted by VACI at least every 12 months during the accreditation cycle to confirm that the management system of the lab is applied and maintained in effect.

At least 30 days before conducting surveillance assessment, the office of Institute agrees with accreditation division about surveillance assessment scheme and informs lab to receive confirmation as specified in 5.2.3.

Surveillance assessment scheme is established on the basis of determining the conformity of the selected requirements of the audit criteria within the scope of accreditation, taking into the information obtained from the previous assessment.

Surveillance assessment results are used for VACI's consideration of continuing to maintain, reduce the scope or suspend or withdrawing of accreditation Decision under VACI.R.03 General Accreditation Procedure.

The validity maintenance of the Accreditation Decision follow the form VACI.P7.1.F22.

5.2.7.2 Unforeseen assessment

In the case that VACI receives complaints or requests from the competent authority, or there are changes in the labs information, or there are other issues affecting the lab's ability to satisfy the accreditation requirements, the Institute's office associated with accreditation division about unforeseen assessment program and notify the lab at least 5 days before starting the assessment.

Unforeseen assessment scheme is built according to the prodecure at 5.2.3 on the basis of factors related to the problem that lead to the unforeseen assessment.

Unforeseen assessment results are used for VACI's consideration of continuing to maintain, reduce the scope or suspend or withdrawing the accreditation Decision under VACI.P14.1 Accreditation suspension/cancellation process.

6. Record control

Application form, accreditation form and other related documents in the accreditation process are kept in hard copy and/ or soft copy and preserved in accordance with VACI.P9.4.