CNAS-RL01

Rules for the accreditation of laboratories

China National Accreditation Service for Conformity Assessment

(CNAS)
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Foreword

CNAS carries out accreditation work in accordance with relevant state laws & regulations and international standards and follows the work principles of being objective, impartial, scientific, standardized, incorruptible, efficient, authoritative and creditable. Accreditation rules are important guarantees for the impartiality and standardization of CNAS accreditation work. This document is built on the CNAS Constitution.

This document specifies the procedure and requirements for the operation of CNAS laboratory accreditation system, including accreditation conditions, accreditation flow, application acceptance requirements, assessment requirements, special requirements for the accreditation of multi-site testing/calibration/examination laboratories, change requirements, and suspension, recovery, withdrawal and cancellation of accreditation as well as the rights and obligations of CNAS and laboratories.

The contents of this document are mandatory requirements.

The notes to the rules in this document are explanation and interpretation of the clauses.

The Annex to this document is informative.

This document was developed in 2006, revised for the first time in 2007, went through a revision and version update in 2011 and revised again in 2013 after the version update. There was another version update and revision in 2015, and a further revision in 2016. This current revision was mainly based on the changes to ISO/IEC 17011:2017 Conformity assessment --- General requirements for accreditation bodies accrediting conformity assessment bodies.
1 Scope
The rules in this document shall be followed by both CNAS and testing laboratories, calibration laboratories, forensic units and medical laboratories and other parties related to the accreditation activities.

2 Referenced documents
The following referenced documents contain provisions which, through reference in this document, constitute provisions of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.
2.1 CNAS Constitution
2.2 GB/T 27000 Conformity assessment -- Vocabulary and general principles （ISO/IEC 17000, IDT）
2.3 ISO/IEC 17011 Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies
2.4 CNAS-R01 Rules for the Use of Accreditation Symbols and Reference to Accreditation
2.5 CNAS-R02 Rules for Impartiality and Confidentiality
2.6 CNAS-R03 Rules for Handling Appeals, Complaints and Disputes
2.7 CNAS-RL02 Rules for Proficiency Testing
2.8 CNAS-RL03 Rules for Fees on the Accreditation of Laboratories and Inspection Bodies
2.9 CNAS-RL04 Rules for Accepting Application from Overseas Laboratories and Inspection Bodies

3 Terms and definitions
For the purpose of this document, the definitions given GB/T 27000 and ISO/IEC 17011 and the following apply:
3.1 Accreditation conditions:
All the requirements that an applicant must meet in order to get accredited.
3.2 Applicant
body seeking accreditation.
3.3 Laboratory
Body that performs one or more of the following activities:
testing
— calibration
— sampling, associated with subsequent testing or calibration.

[Source: ISO/IEC 17025:2017, 3.6—modified: notes to the entry have been deleted]

3.4 Cancellation of accreditation
The process of cancelling an accreditation when an accredited body requests to no longer maintain its accreditation on a voluntary basis or fails to renew its accreditation upon the expiry of its accreditation.

3.5 Recovery of accreditation
The process of maintaining the accreditation of an accredited body, which has taken effective corrective actions within the deadline specified by CNAS after its accreditation is suspended and such actions have been validated by CNAS.

3.6 Authorized signatory
Personnel accredited by CNAS to sign reports or certificates bearing accreditation symbols/combined symbols.

3.7 Proficiency testing
Evaluation of participant’s proficiency against pre-established criteria by means of interlaboratory comparisons

[Source: ISO/IEC 17043:2010, 3.7—modified: notes to entry have been deleted]

3.8 Interlaboratory comparison
Organization, performance and evaluation of measurements or tests and examination on the same or similar items by two or more laboratories in accordance with predetermined conditions

[Source: ISO/IEC 17043:2010, 3.4—modified: “examination” has been added]

3.9 Measurement audits
An activity to compare the reference value with the testing result of actual test of the measured material (material or product) conducted by a participant.

3.10 Surveillance assessment
Scheduled or nonscheduled assessments arranged by CNAS within the period of validity of accreditation in order to verify whether an accredited body continues to meet the conditions of accreditation.

3.11 Accreditation appraisal
Review of the accreditation assessment conclusions and relevant information conducted in accordance with the accreditation rules and criteria to decide whether to grant,
maintain, expand, reduce, suspend and withdraw accreditation.

3.12 Observer
Observer: personnel assigned by CNAS for performing onsite observation of assessment activities for particular purposes (but not participating in assessment work).

3.13 Multi-site
A laboratory that carries out full or part testing, calibration and examination activities under the same legal entity at multi sites.

4 Accreditation conditions
By precondition of abiding by state laws and regulations and being honest and trustworthy, an applicant volunteers for accreditation. CNAS carries out assessment and makes accreditation decision over the scope of accreditation requested by the applicant in accordance with relevant accreditation criteria. An applicant must meet the following conditions in order to be accredited:

a) Having a clearly defined legal status and the ability of bearing legal liabilities;

b) Complying with the accreditation criteria and relevant requirements published by CNAS;

c) Observing the relevant provisions contained in the CNAS accreditation normative documents and fulfilling the relevant obligations.

5 Accreditation flow
5.1 Initial accreditation
5.1.1 Intent of application
An applicant may express its intent of application to CNAS Secretariat by any means, such as visit, telephone call, fax and other electronic communication means. When an applicant requires, CNAS Secretariat shall ensure that the applicant is able to obtain the latest version of accreditation normative documents and other relevant documents.

5.1.2 Formal application and acceptance
5.1.2.1 Having evaluated itself as meeting the accreditation conditions (refer to clause 6 of this document for specific requirements), the applicant shall submit application materials and pay application fees according to the requirements of CNAS Secretariat.

5.1.2.2 The CNAS Secretariat reviews the application materials submitted by the applicant
and decides whether to accept the application or not and notifies the applicant.

5.1.2.3 Where necessary, the CNAS Secretariat will arrange a preliminary visit at the expenses of the applicant to determine whether the application can be accepted.

5.1.2.4 CNAS Secretariat shall notify the applicant of its noncompliance with accreditation conditions found in document review but shall not provide consultancy. The applicant shall reply to the questions and the application for accreditation will be rejected if a reply is not given over 1 month. After a reply is given and the applicant still fails to meet the acceptance conditions after 2 months, the application will not be accepted.

Note: “reply” refers to the clarification and explanation of relevant issues or the planned rectification actions or plan.

5.1.2.5 Normally, CNAS Secretariat shall arrange assessment within 3 months after formal acceptance of the application apart from delays caused by the applicant. If the applicant is unable to receive onsite assessment within 3 months of acceptance of its application due to its own reasons, CNAS can terminate the accreditation process and refuse to grant accreditation.

5.1.3 Document review

5.1.3.1 After the CNAS Secretariat accepts the application, it will arrange the assessment team leader to review the application documents.

5.1.3.2 Only when the result of the document review basically meets the requirements can the onsite assessment be arranged.

5.1.3.3 The CNAS Secretariat shall feedback the problems discovered in the document review to the applicant.

5.1.3.4 Where necessary, the CNAS Secretariat will arrange a preliminary assessment at the expenses of the applicant to determine whether onsite assessment can be arranged.

5.1.4 Establishing the assessment team

5.1.4.1 In line with the principles of impartiality, the CNAS Secretariat shall set up an
assessment team with corresponding technical competence based on the application scope (e.g. testing/calibration/examination technical areas, laboratory testing/calibration/examination site and testing/calibration/examination scale etc.) of the applicant and obtain the consent of the applicant, who shall not reject the assessors assigned unless there is evidence showing that the assessor is likely to affect impartiality.

5.1.4.2 CNAS may terminate the accreditation process and refuse to grant accreditation where an applicant refuses to accept the assessment team of CNAS without due justification.

5.1.4.3 Where necessary, the CNAS Secretariat may assign observer(s) to the assessment team.

5.1.5 Onsite assessment

5.1.5.1 The assessment team carries out onsite assessment of the technical competence and quality management activities of the applicant within its application scope according to the accreditation criteria, rules and requirements as well as relevant technical standards. The onsite assessment shall cover all the activities and relevant sites relating to the application scope. The onsite assessment time and number of personnel shall be determined on the basis of the number of testing/calibration/examination sites, items/parameters and standards/specifications within the scope of application.

5.1.5.2 Generally, the onsite assessment process is:
   a) opening meeting;
   b) site tour (where necessary);
   c) onsite evidence collection;
   d) communication on the assessment between the assessment team and the applicant;
   e) closing meeting.

5.1.5.3 During onsite assessment, if the assessment team finds relevant activities of the assessed laboratory apparently violate relevant state laws and regulations or other matters that obviously harm the reputation and rights & interests of CNAS, they shall report to CNAS Secretariat in a timely manner. If the assessed laboratory has the above problems or
fails to carry out the obligations specified in clause 11.2, CNAS is entitled to terminate the accreditation process if the situation is serious and shall take corresponding actions to deal with it.

5.1.5.4 The assessment team leader shall present the onsite assessment results to the assessed laboratory at the closing meeting of onsite assessment.

5.1.5.5 As for nonconformities found during assessment, the assessed laboratory shall implement timely correction and corrective actions when necessary, which shall be completed normally within 2 months. The assessment team shall verify the effectiveness of the correction/corrective actions. If onsite verification is necessary, the assessed laboratory shall cooperate, pay the assessment fee and assume other relevant expenses.

5.1.5.6 Upon completion of the verification of the correction/corrective actions, the assessment team leader shall submit the final assessment report and recommendation comments to the CNAS Secretariat.

5.1.6 Accreditation appraisal

5.1.6.1 The CNAS Secretariat will conduct compliance check of the assessment report, relevant information and the recommendation comments of the assessment team, ask the laboratory to supplement evidence when necessary and propose to the Appraisal Committee whether accreditation can be recommended.

5.1.6.2 Where the proposal given by the CNAS Secretariat is not consistent with the recommendation comments of the assessment team, the CNAS Secretariat shall notify the assessed laboratory and the assessment team of the inconsistency.

5.1.6.3 CNAS Secretariat is responsible for submitting the assessment report, relevant information and recommendation comments to the Appraisal Committee, which shall evaluate and decide on the applicant’s conformance with accreditation requirements and reach the appraisal conclusion. The appraisal conclusion may be one of the following 4 types:

   a) Granting accreditation;
b) Granting accreditation partially;

c) Refusing to grant accreditation;

d) Reappraisal after evidence or information is supplemented.

5.1.6.4 The CNAS Chief Executive or a person authorized by him makes the decision on accreditation based on the appraisal conclusion.

5.1.6.5 Where CNAS decides not to grant accreditation or to grant accreditation partially, the laboratory must meet the following requirements depending on different situations when it submits accreditation application again:

a) An applicant can resubmit its application for accreditation in 24 months after CNAS has refused to accredit it due to its dishonesty, such as fraud, withholding information or intentional violation of accreditation requirements. At the same time, CNAS reserves the right not to accept its application;

Note: if the onsite assessment finds the laboratory doesn’t have the competence it claims in the accreditation application for multiple items/parameters, this clause applies but not clause c).

b) An applicant can resubmit its application for accreditation after 6 months of effective operation of its management system starting from the date of CNAS’s refusal to accredit it due to its failure of effective management system operation;

c) An applicant that has been refused accreditation or granted partial accreditation due to its failure to meet the requirements for technical competence such as personnel, equipment, environment and facilities can resubmit its application for accreditation once it has evaluated itself as being able to meet the requirements for the technical competence not accredited previously while at the same time providing relevant evidence of compliance with the requirements.

Note: this clause only applies to accreditation denied for individual competence. If accreditation of multiple competences is denied, clause a) applies.

5.1.7 Issuing certificate and publication

5.1.7.1 CNAS accreditation cycle is normally 2 years, i.e. a reassessment will be conducted every 2 years with an accreditation decision.
5.1.7.2 The CNAS Secretariat issues accreditation certificates to accredited laboratories. The accreditation certificate is generally valid for 6 years. Prior to the expiration of the accreditation certificate, the accredited laboratory shall present its intent for maintaining its accreditation qualifications at least 1 month in advance to the CNAS Secretariat if it wishes to continue accreditation.

5.1.7.3 CNAS Secretariat shall renew the accreditation certificate of the laboratory based its intent for maintaining accreditation qualifications and all the previous results and accreditation decisions within the validity of the accreditation certificate.

5.1.7.4 CNAS Secretariat is responsible for publishing and updating in a timely manner information on the accreditation status, basic information and accredited scope of accredited laboratories.

   Note 1: the English version of the accredited scope is provided according to the voluntary application of the laboratory.

   Note 2: CNAS Secretariat may preliminarily publish the accredited scope according to needs to guarantee accuracy.

5.2 Extending and reducing accreditation scopes

5.2.1 Extending accreditation scopes

5.2.1.1 Accredited laboratories may apply to CNAS Secretariat for extension of accreditation scopes within the validity of accreditation.

   Note: CNAS shall not accept the application for scope extension from laboratories that fail to meet accreditation requirements or are suspended for violation of accreditation rules.

5.2.1.2 One of the (not limited to) following situations will become extension of accreditation scopes:

   a) adding testing/calibration/examination methods, standards/specifications, testing/examination objects/calibration instruments, items/parameters;

      Note: adding IDT standards is treated as change not extension of accreditation scope.

   b) adding testing/calibration/examination sites;

   c) expanding the measurement scope/range of testing/calibration/examination;

   d) cancelling limited scopes.
5.2.1.3 The CNAS Secretariat may assess the scopes stated in the extension application during surveillance assessment or reassessment according to the actual situation or it may arrange a separate assessment of the extended scopes according to the needs of the accredited laboratory. When accredited laboratories want to extend accreditation scopes during the surveillance assessment or reassessment, they shall submit the application for extending accreditation at least 2 months prior to the onsite assessment.

5.2.1.4 The accreditation procedure for extension of accreditation scopes is the same as that of initial accreditation, i.e. application—assessment—appraisal and approval.

5.2.1.5 The requirements for acceptance of an application for extension of accreditation and assessment are the same as those for initial application for accreditation.

5.2.1.6 In principle, CNAS Secretariat does not allow the assessment team to accept application for extension of accreditation scopes presented by the laboratory during onsite assessment.

5.2.1.7 The conditions for approving extension of accreditation scopes are the same as those for initial accreditation. The accredited laboratories must possess the corresponding technical competence within the requested scope of extension and meet the requirements specified in the accreditation criteria.

5.2.2 Reducing accreditation scopes

5.2.2.1 Conditions for reduction of accreditation scopes:

The following (but not limited to) circumstances may result in reduction of accreditation scopes

a) accredited laboratories apply to reduce the originally accredited scopes on a voluntary basis;

b) changes to business scopes make the accredited laboratories lose part of competence within the original accredited scopes;

c) results of surveillance assessment, reassessment or proficiency testing show that accredited laboratories can no longer meet accreditation requirements in terms of certain technical competence or quality management within the time specified by the CNAS Secretariat.
d) After the accreditation requirements of CNAS change, the accredited laboratory fails to complete transition within the timeframe specified by the CNAS Secretariat, which results in the fact that some of its technical competences or quality management no longer meet accreditation requirements.

5.2.2.2 After approval of the accreditation scope reduction, the new competence scopes will be published according to 5.1.7.4.

5.3 **Surveillance assessment**

The purpose of surveillance assessment is to prove that accredited laboratories continue to meet accreditation requirements within the valid period of accreditation and ensure that they are able to take timely actions to accommodate the requirements of changes after accreditation rules and criteria are or technical competences change. All accredited laboratories must receive the surveillance assessment of CNAS. During surveillance, if accredited laboratories are found unable to continue to meet accreditation conditions, CNAS shall require them to take correction and corrective actions if needed within the time limit. When the problems are very serious, the accreditation shall be suspended, reduced, or withdrawn at once.

Surveillance assessment includes onsite assessment and other assessments, such as

- a) inquiring accredited laboratories about matters relating to accreditation;
- b) checking the use of the accreditation symbol/combined symbol by accredited laboratories and their claim of accreditation status;
- c) requiring accredited laboratories to provide documents and records for review (such as audit report, internal quality control results that are used to verify the validity of the service of accredited laboratories, records on complaints and management review records);

5.3.1 **Scheduled surveillance assessment**

5.3.1.1 Accredited laboratories shall receive the scheduled surveillance assessment arranged by CNAS within 12 months after initial accreditation approval. The scheduled surveillance assessment focuses on verification of the maintenance of the management system of the accredited laboratory.

Note: scheduled surveillance assessment shall not be arranged between 2
reassessments.

5.3.1.2 With regard to multi-site accredited laboratories, the scheduled surveillance assessment shall cover all sites. With regard to laboratories accredited for testing, calibration and examination, the surveillance assessment shall cover the scopes of testing, calibration and examination at the same time.

5.3.1.3 Accredited laboratories do not need to apply for the scheduled surveillance assessments, which are carried out by means of onsite assessment. The relevant assessment requirements and onsite assessment procedure are the same as those of initial accreditation. When nonconformities are discovered in surveillance, the assesses shall have a clear understanding of the rectification requirements, then implement correction and work out the plan on and implement corrective actions when needed. Correction/corrective actions shall be completed generally within 2 months. Corrective actions against major nonconformities shall be completed within 1 month. The assessment team shall verify the effectiveness of the correction/corrective actions. The assesses shall assume expenses arising out of the verification activities including assessment fee and relevant expenses. In case the accredited laboratory fails to complete the correction/corrective actions on time due to its own reasons or the correction/corrective actions fail to pass the verification, CNAS may decide on suspending, reducing accreditation scopes or withdrawing accreditation according to the situation.

Note: CNAS-GL008 “Guidelines on Grading Non-Conformities in Laboratory Assessment” defining minor and major nonconformities can be referred to.

5.3.1.4 Result of the initial assessment and status of changes as well as participation in proficiency testing, especially the status of corrective actions taken when the proficiency testing result is unsatisfactory shall be taken into account while implementing the scheduled surveillance assessment. In addition, attention shall be paid to the quality monitoring measures developed by the laboratory for technical competences where proficiency testing is unavailable.

5.3.2 Non-scheduled surveillance assessment
5.3.2.1 In case of (not limited to) the following situations, CNAS may arrange non-scheduled surveillance assessment of laboratories at any time depending on need:
a) There are changes to CNAS accreditation requirements;
b) The CNAS Secretariat deems it necessary to conduct investigation of complaint or other feedbacks;
c) Changes mentioned in 9.1.1 of this document occur to an accredited laboratory;
d) An accredited laboratory is unable to meet the requirements for proficiency testing fields and frequency published by CNAS or there have been many unsatisfactory results in the proficiency testing activities;
e) An accredited laboratory was once suspended due to violation of accreditation requirements;
f) An accredited laboratory is found with many problems during administrative enforcement;
g) An accredited laboratory is found with many problems during scheduled assessments;
h) An accredited laboratory issues testing reports/calibration certificates/examination certificates at an abnormal growth speed;
i) The CNAS Secretariat deems it necessary to conduct special check.

5.3.2.2 Non-scheduled assessment may be conducted by way of onsite assessment or other means of assessment such as document review etc.

5.3.2.3 The scope of non-scheduled assessment covers all or part of the accredited scope and accreditation requirements. Where nonconformities are found during non-scheduled surveillance assessment, the accredited laboratory shall implement correction and plan and implement corrective actions when needed after it has understood the rectification requirements. The requirements for the deadline of completion of correction/corrective actions are consistent with those of scheduled surveillance assessment.

5.4 Reassessment

5.4.1 Accredited laboratories shall receive one reassessment every 2 years (every 24 months). The scope of assessment involves all the contents of the accreditation requirements and all accredited technical competences.

   Note 1: After accreditation is granted, the time of the first reassessment is within 2 years (24 months) of the accreditation approval date.

   Note 2: The interval between the onsite assessment time of the 2 reassessments cannot
exceed 2 years (24 months).

5.4.2 Accredited laboratories don’t need apply for reassessment.

5.4.3 Reassessment is conducted by way of onsite assessment. The assessment requirements and onsite assessment procedures are the same as those of initial accreditation. The time limit and requirements for rectification of the nonconformities found during onsite assessment are the same as those specified in clause 5.3.1.3 of scheduled surveillance assessment.

6 Requirements on application acceptance

6.1 The submitted application materials shall be true and reliable. The applicant is free from the behaviour of fraud, withdrawing information or intentional violation of accreditation requirements.

   Note: The behaviour of violating the provision of true and reliable information includes but not limited to:

   — discrepancy between the application materials and the facts;
   — untruthfulness in the submitted application materials;
   — self-contradiction within one document or among documents or time logic error;
   — similarity with the information of other applicants etc.

6.2 The applicant shall have basic understanding of relevant requirements of CNAS, have conducted an effective self-evaluation. The application materials it submits shall be complete, expressed accurately and worded clearly.

   Note: Domestic laboratories applying for accreditation shall submit complete application materials in Chinese and Chinese-English bilingual materials where necessary.

6.3 The applicant has explicit legal status and its activities shall meet the requirements of state laws and regulations.

6.4 The applicant has established a management system that complies with accreditation requirements and has been operating it formally and effectively for over 6 months, that is to say, the management system covers all the application scopes, meets the requirements of accreditation criteria and their application guidances in particular fields and has operable documents. The organizational structure is properly set up with defined job responsibilities.
and clear interface between documents at each level.

6.5 The applicant has conducted complete internal audit and management review, which are able to achieve the expected purposes.

Note: the internal audit and management review shall be conducted after the management system has been operating for 6 months.

6.6 The technical competences proposed in the application shall meet the requirements of CNAS-RL02 “Rules for proficiency testing”.

6.7 The applicant has the required resources sufficient for the implementation of the testing/calibration/examination activities within the scopes of application, for example, main personnel, which include authorized signatories who shall meet relevant qualification requirements.

6.8 The measurement traceability of the instruments and equipment used shall meet the relevant requirements of CNAS.

6.9 The technical competences proposed for accreditation have corresponding testing/calibration/examination experiences.

Note 1: The testing/calibration/examination competences proposed by the applicant shall be items that are mature and frequently done.

Note 2: In principle an application that only aims at the secondary work areas not the main business areas of the applicant laboratory will not be accepted. Even if the application covers the main business areas but only the secondary items not the main items within these areas, it will not be accepted in principle.

Note 3: The applicant shall have sufficient and continuous testing/calibration/examination experiences to support the competences proposed in the application for accreditation. If there have been no testing/calibration/examination experiences in the past 2 years, the relevant competence shall not be accepted in principle. With regard to the testing/calibration activities that the applicant does not often conduct, e.g. less than one time in a month, the applicant shall submit the recent method verification and relevant quality control records at the time of application for accreditation. For particular testing/calibration/examination items, for which the applicant is unable to
establish quality control records because the specimen is too little, the relevant competence will not be accepted in principle.

6.10 CNAS has the competence to carry out accreditation activities for the testing/calibration/examination competences proposed by the applicant.

6.11 The accreditation criteria and requirement documents of CNAS cannot be taken as the applicant’s application for competence accreditation.

6.12 The applicant shall meet other requirements deemed necessary by the CNAS Secretariat.

6.13 In case of the following situations, the application of an applicant shall not be accepted:
   a) The application materials submitted by the applicant do not accord with the facts or are not all true or the applicant has behaviour of fraud, withholding information or intentional violation of accreditation requirements.
   b) The applicant is not able to observe the content in the accreditation contract regarding impartiality, integrity, honesty and self-discipline.
   c) The applicant is unable to meet the requirements of 6.1~6.12 mentioned above.
   d) Circumstances mentioned in 5.1.2.4.

6.14 When CNAS decides not to accept the application of an applicant, the applicant must meet the following requirements according to different situations if it submits its accreditation application again:
   a) where the accreditation application is not accepted due to reasons mentioned in 6.13 a) and b), the CNAS Secretariat shall not accept its accreditation application again within 24 months of the decision. Before confidence in the integrity, honesty and self-discipline of the laboratory is obtained, the application for accreditation resubmitted by it shall not be accepted.
   b) where the accreditation application is not accepted because the management system of the applicant is unable to meet accreditation requirements or there is problem with the effectiveness of the operation of the system (e.g. unable to meet the requirements of clause 6.4 and 6.5), the applicant can submit its accreditation
application again 6 months after the decision.

c) where the accreditation application is not accepted because the technical content is unable to meet requirements (e.g. clauses 6.6~6.9), the applicant must meet the relevant technical requirements before it can submit its accreditation application again.

7 Accreditation Assessment requirements

7.1 The assessment team reviews the management system documents and relevant materials submitted by the applicant. When the documents are found not meeting requirements, the CNAS Secretariat or the assessment team shall notify the applicant in written form to take correction or corrective actions, which will be verified as conforming before onsite assessment can be implemented. Where necessary, CNAS may require the applicant to operate its management system for some time (generally 3 months) before the onsite assessment is implemented.

7.2 The assessment team may arrange measurement audits at the time of onsite assessment according to the need for validation of technical competence. The applicant shall assume the expenses arising thereof.

7.3 The assessment team shall evaluate the authorized signatory of the applicant. CNAS requires the authorized signatory to meet the following qualification conditions:

   a) having necessary technical knowledge and corresponding work experiences, familiar with the relevant testing/calibration/examination standards, testing/calibration/examination methods and testing/calibration/examination procedures within the authorized scopes of signature, able to make correct evaluation of the testing/calibration/examination results and acquainted with the uncertainty of measurement results and the provisions on equipment repair & maintenance and calibration and their calibration status;

   b) familiar with requirements of accreditation rules and policies, accreditation conditions, especially the obligations of accredited laboratories and the provisions on the use of testing/calibration/examination report or certificate with accreditation symbol/combined symbols;

   c) working at a post responsible for the correctness of testing/calibration/examination
results and having corresponding management authority.

7.4 The applicant that uses rented equipment must be able to control and use it. The right of use of the rented equipment must be completely transferred and the rented equipment must be used in the facility of the applicant.

7.5 Testing and examination laboratories carrying out in-house calibration shall meet CNAS requirements on in-house calibration.

7.6 When the measurement results cannot be traced back to SI units or is not relevant to SI units, the measurement results shall be traced back to RM, recognized or agreed measurement methods/standards, or the consistency of their measurements with that of similar laboratories can be demonstrated through inter-laboratory comparison. When the reliability of the measurement is provided by means of inter-laboratory comparison, regular comparison with 3 or more laboratories shall be guaranteed. Where feasible, these shall laboratories accredited by CNAS or endorsed by members of the APLAC, ILAC multilateral recognition agreement.

7.7 The key post personnel of the applicant (e.g. authorized signatory, personnel offering opinions and interpretations, personnel operating special equipment etc.) shall have fixed legal labor relationship with the laboratory. Personnel engaged in testing, calibration or examination activities shall not carry out similar testing, calibration and examination activities in other similar type of laboratories. Personnel required by law and regulation to have job qualifications shall meet relevant requirements.

7.8 The onsite assessment may be terminated and accreditation not recommended if the assessed laboratory is in any one of the following situations:
   a) The actual state of the applicant is greatly inconsistent with its application materials or the applicant is found with the behaviour of fraud, withholding information or intentional violation of accreditation requirements;
   b) The control of the management system of the applicant is ineffective;
   c) The site is not eligible for assessment;
   d) The applicant doesn’t cooperate in the assessment, making it impossible for the
assessment to proceed;

e) The applicant is found to act without good faith;

f) Situations mentioned in 5.1.5.3.

7.9 An assessed laboratory shall not be accredited if it is found with the following:

a) The actual state of the applicant is greatly inconsistent with its application materials or the applicant is found with the behaviour of fraud, withholding information or intentional violation of accreditation requirements;

b) The applicant doesn’t have the testing/calibration/examination competence for a number of the items/parameters within the scope of application, including lack of instrument and equipment, inability of the facility & environment and human resources to meet requirements.

c) The applicant has no testing/calibration/examination experiences for the technical competence proposed in the application or has not done evaluation and validation of the accuracy and reliability of the testing/calibration/examination results or has not carried out quality control.

d) The assessed laboratory provides untrue management system operation records, including corresponding testing/calibration/examination records.

e) The management system of the assessment laboratory is ineffective. There are nonconformities with most of the elements in the accreditation criteria.

f) Circumstances mentioned in 7.7.

8 Special requirements for accreditation of multi-site laboratories

Apart from meeting the requirements for accreditation of single-site laboratory, multi-site testing/calibration/examination laboratories shall also meet the requirements of the following clauses.

8.1 Management system

8.1.1 The management system of the laboratory shall cover every testing/calibration/examination activity or all sites relating to the testing/calibration/examination activities.

8.1.2 The organizational structure and personnel responsibilities of every site shall be defined and where necessary corresponding quality manager and technical manager shall be allocated.
8.1.3 The frequency of participation in proficiency testing activities and area coverage of each site shall meet the requirements of CNAS-RL02 “Rules for proficiency testing”.

8.2 Application and acceptance
8.2.1 The laboratory shall fill in the relevant forms site by site according to the requirements of the application form and provide relevant materials.

8.2.2 The laboratory that does not carry out testing/calibration/examination activities at the same address shall meet the requirements of relevant laws and regulations.

8.2.3 At the time of application for accreditation, each testing/calibration/examination site shall have been operating its management system formally for over 6 months and has conducted internal audit and management review covering all its activities.

8.3 Accreditation assessment
8.3.1 The laboratory accreditation onsite assessment activities shall cover all sites involved in the intended scopes of the applicant.

8.3.2 At the time of onsite assessment, the technical competences of each site shall be validated respectively (including onsite test) even if its technical competences are completely the same as those of the head office or other sites.

8.4 Accreditation certificate
8.4.1 CNAS publishes the scope of competence respectively against the different sites of the laboratory that carry out testing/calibration/examination activities.

8.4.2 Where the same testing/calibration/examination activity needs to be carried out jointly at several sites, explanation shall be made for the addresses in the published accreditation scopes.

9 Requirements on changes to accreditation
9.1 Changes to accredited laboratories

9.1.1 Change notice

When the following changes occur to an accredited laboratory, it shall notify CNAS Secretariat in writing within 20 working days:

a) changes to the name, address, legal status and main policies of the accredited laboratory;
b) changes to the organizational structure, top management and technical personnel and authorized signatory of the accredited laboratory;
c) changes to the standards/methods of testing/calibration/examination, important test equipment, environment, work scope of testing/calibration/examination as well as relevant items within the accredited scopes;
d) other changes that may affect the business activities within the accredited scopes and the operation of the system.

Note 1: When changes occur to the name, address, standards/methods of testing/calibration/examination and authorized signatories of an accredited laboratory, it shall fill out and submit the Application Form for Changes.

Note 2: When other information (e.g. contact person and contact means) of the accredited laboratory changes, it shall update the information in a timely manner.

9.1.2 Handling changes

9.1.2.1 After CNAS Secretariat gets the notice on changes and verifies the matter, it may take the following actions according to the nature of change:

a) conducting surveillance assessment or reassessment;
b) maintaining, extending, reducing, suspending or withdrawing accreditation;
c) examining the new candidates for authorized signatory;
d) registering and recording the changes.

9.1.2.2 When there are changes to the environment of the laboratory, e.g. relocation, the laboratory shall immediately stop use of the accreditation symbol/combined symbol apart from notifying the CNAS Secretariat according to 9.1.1 and develop corresponding verification plan and retain relevant record. Only after confirmation by CNAS can the use of the accreditation symbol/combined symbol resume (be recovered).
9.1.2.3 Where a laboratory has undergone changes mentioned in 9.1.1 and failed to notify the CNAS Secretariat in a timely manner or according to the facts or uses the accreditation symbol that requires CNAS confirmation but is not yet confirmed by CNAS, CNAS shall suspend or withdraw the accreditation depending on the actual situation.

9.2 Changes to accreditation rules and accreditation criteria
9.2.1 When accreditation rules, accreditation criteria and accreditation requirements change, the CNAS Secretariat shall notify the accredited or applicant laboratories that may be affected by the changes to explain in detail the changes to accreditation rules and accreditation criteria as well as relevant requirements.

9.2.2 When accreditation conditions and accreditation criteria change, CNAS shall work out and publish its policy and time limit for transition to the new requirements. Prior to that, it shall listen to the opinions of every related party so that accredited laboratories shall have sufficient time to adapt to the new requirements. CNAS can confirm the conformance of accredited laboratories to the new requirements through surveillance assessment or reassessment. The accreditation may be maintained after they are confirmed as compliant.

9.2.3 Once they have completed the transition, accredited laboratories shall notify the CNAS Secretariat in a timely manner. In case accredited laboratories cannot complete the transition within the prescribed time limit. CNAS may suspend or withdraw accreditation.

10 Accreditation suspension, recovery, withdrawal and cancellation
The CNAS Secretariat may deliver the accreditation decision through the CNAS website bulletin, post office, fax, e-mail or other appropriate means.

10.1 Accreditation suspension
10.1.1 When accredited laboratories apply for suspension on a voluntary basis due to its own reasons or are unable to continue to meet the accreditation conditions and requirements of CNAS, e.g.: 
a) inability to meet the proficiency testing requirements;
b) failure to receive scheduled surveillance or reassessment on time;
c) failure to pay fees on time;
d) inability to maintain accredited technical competence found during the surveillance and reassessment process or failure to complete corrective actions within the specified time limit;
e) failure to notify the CNAS Secretariat of changes to the technical competence of the laboratory, such as the personnel, facility, environment (e.g. relocation), methods of testing/calibration/examination and metrological standards according to clause 9.1.1 or continuing to use the accreditation symbol and combined symbol without CNAS confirmation;
f) inability of the management competence and/or technical competence to meet accreditation requirements found during onsite assessment;
g) failure by the accredited laboratory to complete transition on time when there are changes to accreditation rules, requirements and criteria;
h) other violation of accreditation stipulations by accredited laboratories.

CNAS can suspend part or all accredited scopes of the laboratory. The period of suspension is no more than 6 months.

10.1.2 During the period of suspension, accredited laboratories shall not issue reports or certificates with accreditation symbol/combined symbol in relevant items nor will they declare to the public in any explicit or implied way that the suspended accreditation scope is still valid.

10.2 Accreditation recovery

10.2.1 The accreditation qualifications of an accredited laboratory can be recovered once it has taken corrective actions within the specified period of suspension, which have been confirmed by CNAS as meeting requirements.

10.2.2 The accreditation qualifications of an accredited laboratory that has been suspended because of violation of accreditation stipulations cannot be recovered ahead of time.
10.3 Accreditation withdrawal

10.3.1 Under the following circumstances, CNAS shall withdraw accreditation:

a) failure of an accredited laboratory to recover accreditation beyond the suspension period;
b) failure or unwillingness of an accredited laboratory to continue to meet accreditation requirements due to changes to accreditation rules or criteria;
c) failure of an accredited laboratory to carry out the obligations specified by CNAS rules;
d) inability of the management system of the laboratory found during onsite assessment to operate effectively;
e) corresponding technical competence found during onsite assessment not available at the laboratory;
f) malicious damage of CNAS reputation by accredited laboratories.
g) dishonest conduct of a laboratory, including but not limited to: falsification, making false promises, or not honoring commitments, fraud, withholding information or intentional violation of accreditation requirements etc.

10.3.2 When a laboratory whose accreditation qualifications have been withdrawn by CNAS resubmits its application for accreditation, it must meet the following requirements depending on different situations:

a) An application for accreditation may be resubmitted if the withdrawal is based on clause 10.3.1 a) and a self-evaluation finds itself meeting requirements;
b) An application for accreditation may be resubmitted after 6 months of the CNAS’s decision to withdraw accreditation if the withdrawal is based on clause 10.3.1 b);
c) An application for accreditation may be resubmitted after 12 months of the CNAS’s decision to withdraw accreditation if the withdrawal is based on clause 10.3.1 c);
d) An application for accreditation may be resubmitted after 24 months of the CNAS’s decision to withdraw accreditation if the withdrawal is based on clause 10.3.1 e), f) and g). At the same time, CNAS reserves the right to reject the application for accreditation.

10.4 Accreditation cancellation

Under the following circumstances, CNAS shall cancel accreditation:

a) accredited laboratories apply for withdrawing accreditation on a voluntary basis;
b) accredited laboratories fail to renew accreditation qualifications upon expiry of
11 Rights and obligations

11.1 Rights and obligations of CNAS

11.1.1 CNAS has the right to carry out non-scheduled surveillance over the activities of laboratories and their use of accreditation certificates and accreditation symbol/combined symbol.

11.1.2 CNAS has the right to conduct onsite investigation and follow-up investigation of laboratories with regard to complaints made by related parties and put forward rectification requirements accordingly.

11.1.3 CNAS has the right to decide on suspending, recovering and withdrawing accreditation qualifications of laboratories in light of the nonconformance of laboratories to CNAS stipulations.

11.1.4 CNAS is obligated to use its website to publicize and update information on the accreditation status of accredited laboratories, including:
   a) name and address of accredited laboratory;
   b) accreditation approval date and expiry date;
   c) accreditation scopes.

11.1.5 CNAS is obligated to provide information on suitable measurement result traceability channels relating to the accreditation scopes to accredited laboratories;

11.1.6 CNAS is obligated to provide information on its signing of relevant ILAC and APLAC MRA’s as well as some other international arrangements.

11.1.7 CNAS is obligated to notify accredited laboratories in a timely manner when accreditation requirements change, listen to the comments of relevant sides before deciding on the means of change and application date so that accredited laboratories can make adjustments within a suitable time limit.

11.1.8 CNAS is obligated to provide applicant/accredited laboratories with the latest
version of accreditation rules, criteria and other relevant documents in a timely manner, communicate to and train laboratories on relevant accreditation knowledge in a planned way, take the initiative to solicit the comments of laboratories and pay attention to the feedbacks of laboratories at any time so as to continually improve the CNAS accreditation system.

11.1.9 In order to know the demand of laboratories and potential clients, CNAS is obligated to respond to relevant inquiries on accreditation in a timely manner, set up an effective information publication and client feedback system and meet the demand of laboratories through publicity and training activities.

11.1.10 CNAS is obligated to meet the requirements of the ILAC and APLAC MRA’s and shall not regard the MRA signatories as competitors.

11.1.11 Apart from information that need be made publicly available, CNAS is obligated to keep confidential other information obtained or generated during the laboratory accreditation activities, such as commercial and technical information.

11.2 Rights and obligations of laboratories

11.2.1 Rights and obligations of applicant laboratories

11.2.1.1 Laboratories have the right to access relevant public documents of CNAS.

11.2.1.2 Laboratories have the right to get information on the progress of accreditation assessment arrangement for them, assessment team members and their employers.

11.2.1.3 Laboratories have the right to lodge appeals against decisions relating to accreditation and complaints against the work of CNAS staff and the assessment team members.

11.2.1.4 On the basis of impartiality, laboratories have the right to raise objection to the composition of the assessment team.

11.2.1.5 Laboratories are obligated to learn relevant accreditation requirements and stipulations of CNAS.
11.2.1.6 Laboratories are obligated to submit application documents and relevant information according to CNAS requirements and ensure that the contents are true and accurate.

11.2.1.7 Laboratories are obliged to comply with the assessment arrangements made by CNAS Secretariat, provide necessary support for the assessment activities, allow the relevant personnel to conveniently get access to sites and records to be assessed, witness site activities and talk with the work staff and shall not refuse any personnel dispatched by CNAS to witness the assessment activities (including witness personnel of international peer review) without justification.

11.2.2 Rights and obligations of accredited laboratories

11.2.2.1 Laboratories have the right to make it known within the specified scope that their corresponding technical competence has been accredited.

11.2.2.2 Laboratories have the right to use accreditation symbol/combined symbol on the certificates or reports they issue within the accredited scopes as well as advertisements, special letter paper and publicity publications.

11.2.2.3 Laboratories have the right to lodge a complaint against the work of CNAS staff and assessment personnel and to lodge an appeal against CNAS with regard to decision relating to accreditation.

11.2.2.4 Laboratories have the right to terminate accreditation qualifications on a voluntary basis.

11.2.2.5 Laboratories are obligated to ensure that their operation and provision of service continue to meet the accreditation conditions specified in Clause 4 of this Rules.

11.2.2.6 Laboratories are obligated to abide by relevant laws and regulations on a voluntary basis.
11.2.2.7 Laboratories are obligated to provide necessary support to the assessment activities arranged by the CNAS Secretariat and make it convenient for relevant personnel to access assessment areas and records, witness onsite activities and talk with the staff. They shall not reject the personnel sent by CNAS to witness the assessment activities (including witness personnel of international peer review).

11.2.2.8 Laboratories shall participate in proficiency testing, inter-laboratory comparison or measurement audit activities designated by the CNAS Secretariat.

11.2.2.9 Laboratories shall take responsibility for the certificates or reports (including but not limited to test data, comments and interpretation etc.) they issue and keep the secrets of clients.

11.2.2.10 Laboratories are obligated to establish a procedure for handling complaints lodged by clients. If a complaint fails to be settled satisfactorily within 2 months after it is received, the relevant laboratory shall notify the CNAS Secretariat of the brief contents of the complaint and handling process.

11.2.2.11 Laboratories shall notify CNAS in writing if changes described in clause 9.1.1 of this Rules occur and is obligated to make adjustments according to the requirements of CNAS when accreditation requirements change and notify CNAS of the completion of adjustments.

11.2.2.12 Laboratories are obligated to be honest and impartial, shall not practice fraud and resort to deception nor engage in any activity that may harm the reputation of CNAS.

11.2.2.13 Laboratories are obligated to meet relevant provisions of CNAS when claiming their accreditation status in certificates, reports or publicity media e.g. advertisement and publicity materials or on other occasions.

11.2.2.14 Laboratories are obligated to return the accreditation certificate and stop use of
the accreditation symbol/combined symbol on certificates, reports or publicity materials immediately after their accreditation is withdrawn by CNAS or cancelled on a voluntary basis or the accreditation period indicated on the accreditation certificate (or accreditation decision letter) expired and shall by no means claim that their accreditation is still valid.

11.2.2.15 Laboratories are obligated to browse the CNAS website frequently to obtain relevant information on accreditation status and accreditation requirements in a timely manner.

11.2.2.16 Laboratories are obligated to pay fees according to relevant stipulations.

11.2.2.17 Laboratories are obligated to inform their clients being affected in a timely manner of the suspension, reduction and withdrawal of accreditation qualifications and related consequences without undue delays.