CNAS-RL01

Rules for the Accreditation of Laboratories

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 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 Appendix to this document is informative.

This document was drafted and issued in 2006. The 1st revision was made in 2007. In 2011, it went through another revision and version update. This is the first revision of the 2011 version, which added to and amended the contents of clause 1, 2, 3, 4, 5, 6, 7, 9, 10 and 11.

Rules for the Accreditation of Laboratories

1 Scope

The rules in this document shall be followed by both CNAS and testing laboratories, calibration laboratories, medical laboratories and other parties related to the accreditation activities.

2 References

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 GB/T 27011 Conformity assessment -- General requirements for accreditation bodies accrediting conformity assessment bodies （ISO/IEC 17011，IDT）

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 in GB/T27000 （ISO/IEC 17000，IDT） and GB/T27011 （ISO/IEC 17011，IDT） and the following apply：

3.1 Accreditation conditions: all the conditions that an applicant must meet to get accredited;

3.2 Applicant: a body seeking accreditation;

3.3 Laboratory: an organization engaged in testing and / or calibration activities.

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

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

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 Re-assessment: a full assessment of an accredited body carried out by CNAS prior to the expiry of its validity of accreditation to determine whether the accredited body continues to meet the conditions of accreditation and whether to extend the accreditation to the next period of validity

3.12 Accreditation appraisal: check over 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

3.13 Assessor: person assigned by CNAS to conduct assessment of an applicant or accredited body independently or as member of an assessment team

3.14 Technical expert: person assigned by CNAS to supply specific knowledge or skills for the accreditation scopes under assessment

3.15 Observer: person assigned by CNAS to observe assessment activities for particular purposes other than participating in assessment

3.16 Multi-site laboratory: a laboratory that carries out full or part testing and calibration 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 accreditation criteria and relevant requirements. An applicant must meet the following conditions in order to be accredited

a) Having an unambiguous 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 criteria documents and fulfilling the relevant obligations.

5 Accreditation flow

5.1 Initial accreditation

5.1.1 Intention of application

An applicant may express its intention of application to CNAS secretariat by any means, such as visit, telephone call, fax and other electronic communication means. Where necessary, 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 2 months. After a reply is given and the applicant still fails to meet the acceptance conditions after 3 months, the application will not be accepted.

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, CNAS can terminate the accreditation process and reject 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 feed back the problems discovered in the document review to the applicant.

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

5.1.4 Organizing the assessment team

5.1.4.1 In line with the principles of impartiality, the CNAS secretariat shall organize an assessment team with corresponding technical competence based on the application scopes (e.g. testing/calibration technical areas, laboratory testing site and testing 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 reject accreditation where an applicant refuses to accept the assessment team of CNAS without due justification.

5.1.4.3 Were 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 scopes 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 scopes. The onsite assessment time and number of personnel shall be determined on the basis of the testing/calibration parameters and number of standards 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 result to the assessed laboratory at the closing meeting of onsite assessment.

5.1.5.5 As for nonconformities found during onsite assessment, the assessed laboratory shall take timely corrective actions, which shall be carried out normally within 3 months. The assessment team shall verify the effectiveness of the 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 corrective actions, the assessment team leader shall submit the final assessment report and recommendation comment 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 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

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 secretary general or a person authorized by him makes the decision on accreditation based on the appraisal conclusion.

5.1.6.5 Where CNAS decided 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. At the same time, CNAS reserves the right not to accept its application;

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 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.

5.1.7 Issuing certificate and publication

5.1.7.1 The CNAS secretariat issues accreditation certificates to accredited laboratories as well as the accreditation decision notice. The accreditation certificate is generally valid for 3 years.

5.1.7.2 The CNAS secretariat is responsible for publishing the basic information, accreditation scopes and authorized signatory of accredited laboratories and putting the accredited laboratories in the directory of accredited laboratories (this directory may be in electronic form) and publicize it.

5.2 Extending and reducing accreditation scopes

5.2.1 Extending accreditation scopes

5.2.1.1 Accredited laboratories may apply to CNAS for extension of accreditation scopes within the valid period of the accreditation.

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

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

b） adding testing/calibration sites;

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

d） cancelling limitation scopes；

e） increasing calibration and measurement capacity.

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, they shall submit the application for extending accreditation at least 2 months prior to the onsite assessment. The accreditation procedure for extension of accreditation scopes is the same as that of initial accreditation, i.e. application—assessment—appraisal and approval.

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

5.2.1.5 CNAS does not allow the assessment team to accept application for extension of accreditation scopes presented by the laboratory during onsite assessment.

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

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 the original accreditation 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 publicized according to 5.1.7.2.

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 are able to make adjustments in time after accreditation rules and criteria are modified. 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 corrective actions 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 (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);

d) supervising the performance of accredited laboratories (such as the result of participation in proficiency testing).

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 accreditation approval. The scopes of scheduled surveillance assessment cover all the contents of accreditation requirements, all or part of accredited technical competences. With regard to multi-site accredited laboratories, the surveillance shall cover all sites. With regard to laboratories accredited for both testing and calibration, the surveillance assessment shall cover the scopes of testing and calibration at the same time. In case of special situation, the accredited body may apply for cancellation of the scheduled surveillance assessment and have the reassessment ahead of schedule, yet the reassessment shall take place within 18 months after accreditation approval.

5.3.1.2 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 (including surveillance + extension assessment), the assessed party shall have a clear understanding of the rectification requirements and then work out the plan on implementing the corrective actions, which shall be completed generally within 2 months. Corrective actions against nonconformities relating to technical competence shall be completed within 1 month. The assessment team shall verify the effectiveness of the corrective actions. The assessed party shall assume expenses arising out of the verification activities including assessment fee and relevant expenses. In case the accredited laboratory fails to complete the corrective actions on time due to its own reasons or the corrective actions fail to pass the verification, CNAS may decide on suspending, reducing accreditation scopes or withdrawing accreditation according to the situation.

5.3.1.3 Result of the previous assessment as well as participation in proficiency testing, especially 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 other quality assurance measures developed by the laboratory in technical areas 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 has been 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 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 body shall plan and implement corrective actions after is has understood the rectification requirements. The requirements for the deadline of completion of corrective actions are consistent with those of scheduled surveillance assessment.

5.4 Reassessment

5.4.1 Accredited domestic laboratories shall submit the reassessment application to the CNAS secretariat 6 months in advance of the expiration of accreditation. Accredited overseas laboratories shall submit the reassessment application to the CNAS secretariat 9 months in advance of the expiration of accreditation. The CNAS secretariat shall organize reassessment of an accredited laboratory according to its application before the expiration of its accreditation.

5.4.2 The requirements and procedure of reassessment are the same as those of initial accreditation. It is an assessment covering all the application scopes and all accreditation requirements. When nonconformities are discovered in reassessment (including reassessment + extension assessment), the accredited laboratory shall have a clear understanding of the

rectification requirements, work out the plan on and implement corrective actions. The time given for the completion of the corrective actions is generally 2 months. Corrective actions against nonconformities relating to technical competence shall be completed within 1 month. The assessment team shall verify the effectiveness of the corrective actions. In case the accredited laboratory fails to complete the corrective actions on time due to its own reasons or the corrective actions fail to pass the verification, CNAS may decide on suspending, reducing accreditation scopes or withdrawing accreditation according to the situation.

5.4.3 Generally, the accreditation validity period shall not be prolonged. Yet when it is not possible to complete the accreditation process due to the impact of force majeure, the accreditation validity period may be prolonged by approval for no more than 6 months at the most.

5.4.4 Where an accredited laboratory fails to submit its application for reassessment within the validity of accreditation due to its own causes, the CNAS secretariat shall handle it as an initial application and will, however, consider the historical information of its accreditation as input information for making the acceptance decision.

6 Requirements on application acceptance

6.1 The applicant shall have basic understanding of relevant requirements of CNAS, have conducted an effective self-evaluation and the application materials it submits shall be true, reliable and complete and filled in clearly and properly.

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

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

6.3 The applicant has established a management system meeting 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 instructions 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.

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

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

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

6.7 The measurement traceability of the instrument and equipment used shall be able to meet relevant requirements of CNAS.

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

Note 1: The testing / calibration 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 experiences to support the competences proposed in the application for accreditation. If there has been no testing/calibration 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 validation and relevant quality control records at the time of application for accreditation. For particular testing/calibration items, where the applicant is unable to establish quality control records because the specimen is too little, the relevant competence will not be accepted in principle.

6.9 CNAS has the competence to accredit the testing/calibration competences proposed by the applicant.

6.10 The accreditation criteria and requirement documents of CNAS cannot be taken for the

applicant's application for competence accreditation.

6.11 The applicant shall meet other requirements deemed necessary by the CNAS secretariat.

6.12 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.

b） The applicant is not able to follow the relevant commitment required by the CNAS secretariat, such as the commitment to be clean and self-disciplined.

c） The applicant is unable to meet the requirements of 6.1～6.11 above.

d） Circumstances mentioned in 5.1.2.4.

6.13 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 dishonesty of the applicant or its failure to follow the relevant commitment (e.g. 6.12a and circumstances mentioned in b)) required by the CNAS secretariat, the CNAS secretariat shall not accept its accreditation application again within 24 months of the decision. Before confidence in the integrity 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, the applicant can submit its accreditation application again 6 months after the decision.

c) where the accreditation application is not accepted because the proficiency testing is unable to meet requirements, the applicant must meet the proficiency testing requirements before it can submit its accreditation application again.

d) where the accreditation application is not accepted because the authorized signatory proposed by the applicant or other main personnel are unable to meet relevant qualification requirements, the applicant must have personnel meeting relevant qualification requirements before it can submit its accreditation application again.

7 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, the CNAS secretariat 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, which is confirmed as necessary according to the technical competences. 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 relevant testing and calibration standards, testing and calibration methods and testing and calibration procedures within the authorized scopes of signature, able to make correct evaluation of the testing and calibration 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 accreditation rules and policies, accreditation conditions, especially the obligations of accredited laboratories and the provisions on the use of testing and calibration report or certificate with accreditation symbol/combined symbols;

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

7.4 The applicant that uses rented equipment must be able to control and use it. Moreover, 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 laboratories carrying out in-house calibration shall meet CNAS requirements on in-house calibration.

7.6 The key post personnel of the applicant (e.g. authorized signatory, personnel offering opinions and interpretations, personnel operating special equipment etc) shall have long-term fixed legal labor relationship with the laboratory. Personnel required by law and regulation to have job qualifications shall meet relevant requirements.

7.7 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;

b) control of the management system by the applicant is ineffective;

c) the site is not ready for assessment;

d) the applicant intentionally hinders the assessment, making it impossible for the assessment to proceed;

e) the applicant is found to have unfaithful conduct;

f) situations mentioned in 5.1.5.3.

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

a） The actual status of the laboratory is seriously inconsistent with the application materials.

b） The applicant doesn't have the testing/calibration 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 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 results or has not carried out quality control.

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

8.1 Apart from meeting the requirements for accreditation of single-site laboratory, multi-site

testing/calibration laboratories shall also meet the requirements of the following clauses.

8.2 Management system

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

8.2.2 The organizational structure and personnel responsibilities of every site shall be explicit and where necessary corresponding quality manager and technical manager shall be allocated.

8.2.3 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".

8.3 Application and acceptance

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

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

8.3.3 At the time of application for accreditation, each testing/calibration 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.

8.4 Accreditation assessment

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

8.4.2 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.

8.5 Accreditation certificate

8.5.1 CNAS issues attachments to the accreditation certificate respectively according to the different sites of the laboratory that carry out testing/calibration activities.

8.5.2 Where the same testing/calibration activity needs to be carried out jointly at several sites, the addresses may be explained in the attachments to the accreditation certificate.

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 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) major changes to the standards/methods of testing/calibration, important test equipment, environment, work scope of testing and calibration 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.

9.1.2 Handling changes

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

a) conducting surveillance assessment or carrying out the reassessment ahead of schedule;

b) maintaining, extending, reducing, suspending or withdrawing accreditation;

c) examining the new candidates for the 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 validation by CNAS through onsite assessment can the use of the accreditation symbol/combined symbol resume.

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 uses the accreditation symbol without validation 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 or reassessment. The accreditation may be maintained after accredited laboratories 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 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 without reason;

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 major changes to the personnel, facility and environment (e.g. relocation) according to 9.1.1 or continuing to use the accreditation symbol and combined symbol without CNAS validation;

f) failure to complete transition on time when there are changes to accreditation rules, requirements and criteria;

g) other violation of accreditation stipulations.

CNAS can suspend part or all accredited scopes of a 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) malicious damage of CNAS reputation by accredited laboratories.

e) dishonest conduct of a laboratory.

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) and;

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 d) and e) and. 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 obtain accreditation qualifications upon expiry of accreditation.

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 termination 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 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, train clients 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, 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.

11.2 Rights and obligations of laboratories

11.2.1 Rights and obligations of applicant laboratories

11.2.1.1 Laboratories have the right to get 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 follow 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 get in touch with the work staff and shall not refuse any personnel dispatched by CNAS to witness the assessment activities (including witness personnel for international peer review).

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 contact 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 must 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 accreditation symbol/combined symbol seal 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 obliged to browse the CNAS website frequently in order to obtain in timely manner information relating to accreditation status and accreditation requirements.

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