CNAS-RL07

Rules for the Accreditation of Reference Material Producers

China National Accreditation Service for Conformity Assessment
(CNAS)
# Table of content

**Foreword** ................................................................. 2

1 Scope ............................................................................. 3

2 Referenced documents .................................................. 3

3 Terms and definitions ................................................... 3

4 Accreditation conditions ............................................... 5

5 Accreditation flow ......................................................... 5

5.1 Initial accreditation ..................................................... 5

5.2 Extending and reducing accreditation scopes .................. 10

5.3 Surveillance assessment .............................................. 12

5.4 Reassessment ............................................................ 14

6 Requirements on application acceptance .......................... 15

7 Accreditation assessment requirements ............................ 17

8 Special requirements for the accreditation of multi-site RMPs . 19

9 Requirements on changes to accreditation .......................... 20

9.1 Changes to accredited RMPs ........................................ 20

9.2 Changes to accreditation rules and accreditation criteria .......... 21

10 Accreditation suspension, recovery, withdrawal and cancellation . . 22

10.1 Accreditation suspension ............................................. 22

10.2 Accreditation recovery ................................................ 22

10.3 Accreditation withdrawal ............................................ 23

10.4 Accreditation cancellation .......................................... 24

11 Rights and obligations .................................................. 24

11.1 Rights and obligations of CNAS .................................. 24

11.2 Rights and obligations of RMPs ................................... 25
Foreword

CNAS carries out accreditation work in accordance with relevant state laws & regulations and international specifications 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 accreditation system for reference material producers (RMP), including accreditation conditions, accreditation flow, application acceptance requirements, assessment requirements, special requirements for the accreditation of multi-site RMPs, change requirements, and suspension, recovery, withdrawal and cancellation of accreditation as well as the rights and obligations of CNAS and the RMPs.

The contents of this document are mandatory requirements.

The Annex to this document is informative.

This document was developed and issued in 2010, revised respectively in 2014 and 2015 and revised for version update in 2016. This revision is mainly based on the changes to ISO/IEC17011: 2017 “Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies”.
Rules for the Accreditation of Reference Material Producers

1 Scope

The rules in this document shall be followed by both CNAS and RMPs 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 ISO/IEC 17000 Conformity assessment - Vocabulary and general principles
2.3 ISO/IEC 17011 Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies
2.4 APLAC TC008 Requirements and Guidance on the Accreditation of a Reference Material Producer
2.5 CNAS-R01 Rules for the Use of Accreditation Symbols and Reference to Accreditation
2.6 CNAS-R02 Rules for Impartiality and Confidentiality
2.7 CNAS-R03 Rules for Handling Appeals, Complaints and Disputes
2.8 CNAS-RL02 Rules for Proficiency Testing
2.9 CNAS-RL03 Rules for Fees on the Accreditation of Laboratories and Inspection Bodies
2.10 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 and ISO/IEC 17011 and the following apply:

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

3.2 Applicant: body seeking accreditation;

3.3 Cancellation of accreditation: the process of cancelling an accreditation when an accredited body (sometimes simply called body) requests to no longer maintain its accreditation on a voluntary basis or fails to renew its accreditation upon the expiry of its accreditation.

3.4 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 confirmed by CNAS.

3.5 Surveillance assessment: scheduled or non-scheduled assessments arranged by CNAS within the period of validity of accreditation in order to verify whether an accredited body continues to satisfy the conditions of accreditation.

3.6 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.

3.7 Observer: person assigned by CNAS for particular purpose to conduct onsite observation of the assessment activities (not participating in the assessment work).

3.8 Multi-site: full or partial RM production activities carried out at multi sites under the same legal entity.

3.9 Technical stage of RM production

RM production includes 8 stages, which are production planning, preparation of materials, homogeneity and stability test, characteristic value measurement, decision and assignment of characteristic value, approval and issuance of certificate, processing and storage, sale and post-sale service.

3.10 Key technical processes and key technical personnel

CNAS has identified 4 stages of RM production as key ones, namely preparation of materials, testing activities (where applicable), decision and assignment of characteristic value, approval and issuance of certificate and defined personnel in overall charge of these key
technical stages in the RM production as key technical personnel.

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 the accreditation criteria and relevant requirements. An applicant must meet the following conditions in order to get accredited:

a) Having clearly defined legal status and the ability to assume 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.

d) Having corresponding technical competence and at least the competences required at the four stages of production of project planning and management, assignment and determination of characteristic values and their uncertainty, approval of characteristic values and issue of certificate or other instruction documents as well as the competence for making judgment on the reasonability of the testing/measurement activities that affect characterization and the accuracy of results.

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 requests, the CNAS Secretariat shall ensure that the applicant is able to access 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 satisfying 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. Note: “reply” refers to clarification and explanation of relevant issues or actions to be implemented for the rectification 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 found 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 scopes (e.g. RM production technical areas and production 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 when 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 scopes according to the accreditation criteria, rules and requirements of CNAS as well as relevant technical standards. The onsite assessment shall cover all the activities and relevant sites involved in the application scopes. The onsite assessment time and number of personnel shall be determined on the basis of the RM types and quantity 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;
5.1.5.3 During onsite assessment, if the assessment team finds relevant activities of the assessed RMP 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 RMP has the above problems or fails to fulfil 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 RMP at the closing meeting of onsite assessment.

5.1.5.5 As for nonconformities found during onsite assessment, the assessed RMP shall take timely corrective actions, which shall be completed normally within 3 months. The assessment team shall verify the effectiveness of the corrective actions. If onsite verification is necessary, the assessed RMP 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 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 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 RMP and the assessment team of the inconsistency.

5.1.6.3 The CNAS Secretariat is responsible for submitting the assessment report, relevant information and recommendation comments to the Appraisal Committee, which shall evaluate 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 authorized person shall make 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 assessed RMP must meet the following requirements depending on different situations when it submits accreditation application again:

a) An RMP can resubmit its application for accreditation in 24 months after CNAS has refused to accredit it due to its dishonesty issues, such as fraud, withholding information or intentional violation of accreditation requirements. At the same time, CNAS reserves the right to no longer accept its application;

b) An RMP 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 RMP 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 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 bodies. 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 body 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 bodies.

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

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 RMPs 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 RM production items/parameters;

b) expanding the measurement scope/range of production;

c) cancelling limitation scopes;

d) 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 RMP. When accredited RMPs 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 assessed RMP 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 RMPs must comply with the technical competence and management requirements specified in the accreditation criteria 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 RMPs apply to reduce the accredited scopes on a voluntary basis;

b) changes to business scopes make the accredited RMPs lose part of the original accreditation scopes;

c) results of surveillance assessment, reassessment or proficiency testing show that accredited RMPs 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 RMP 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 RMPs continue to meet accreditation requirements within the valid period of accreditation and ensure that they are able to take actions in time to meet the changed requirements after accreditation rules and criteria are changed. All accredited RMPs must receive the surveillance assessment of CNAS. During surveillance assessment, if accredited RMPs are found unable to continue to satisfy the 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 RMPs about matters relating to accreditation;

b) checking the use of the accreditation symbol/combined symbol by accredited RMPs and their claim of accreditation status;

c) requiring accredited RMPs 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 RMPs, records on complaints and management review records);

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

5.3.1 Scheduled surveillance assessment

5.3.1.1 Initially accredited RMPs shall receive the scheduled surveillance assessment arranged by CNAS within 12 months after accreditation approval. The scheduled surveillance assessment focuses on verification of the maintenance of the management system of the accredited RMP.

Note: scheduled surveillance assessment shall not be arranged between 2 reassessments.
5.3.1.2 With regard to multi-site accredited RMPs, the surveillance shall cover all sites.

5.3.1.3 Accredited RMPs 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 found in surveillance assessment (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 RMP 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.

5.3.1.4 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 the quality assurance measures developed by the assessed RMP for the 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 accredited RMPs 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 RMP;
d) An accredited RMP 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 RMP has been suspended due to violation of accreditation requirements;

f) An accredited RMP is found with many problems during administrative enforcement;

g) An accredited RMP is found with many problems found during scheduled assessments;

h) There are serious quality problems with the RM produced by an accredited RMP;

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 generally covers all or part of the accredited scope and accreditation requirements. Where nonconformities are found during non-scheduled surveillance assessment, the assessed RMP shall plan and implement corrective actions after it 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 RMPs 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 RMPs 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.

5.4.4 Accredited RMPs applying for reassessment shall have carried out at least one RM
production activity for every area within the past 3 accreditation cycles.

Note: the production activity mentioned here refers to preparation of materials, homogeneity and stability test, characteristic value measurement and decision and assignment for characteristic value.

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 RMPs 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 satisfies 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.

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

6.7 The applicant has the required resources sufficient for the implementation of the RM production activities within the scopes of application, for example, main personnel, which include key technical personnel who are able to meet relevant qualification requirements.

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

6.9 The technical competences proposed for accreditation have corresponding production experiences.

6.10 CNAS has the competence to accredit the RM production 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 6.1~6.11 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 relevant RMP 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 Accreditiation 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 format 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 key technical personnel of the applicant. CNAS requires them to meet their job requirements.

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 The RMP carrying out in-house calibration shall meet CNAS requirements on in-house calibration.

7.6 When it is impossible to trace back to SI, priority shall be given to CIPM international mutual recognition traceability policy, tracing to the calibration and measurement capability that undergone international metrological comparison. Secondarily, the credibility of measurement can be provided through the adoption of interlaboratory comparison. Periodic comparison with 3 or more RMPs shall be assured. Where feasible, these RMPs shall be accredited by CNAS or APLAC and ILAC MRA signatories.

7.7 During assessment, the assessment team may terminate the assessment and don’t recommend accreditation if assessed RMP is in any 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) Control of the management system by the applicant is ineffective;

   c) The site conditions are not ready for assessment;

   d) The applicant doesn’t cooperate in the assessment, making it impossible for the assessment to proceed;
e) The applicant is found with unfaithful conduct;

f) Situations mentioned in 5.1.5.3.

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

a) Its actual status is seriously 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 production competence and experience for a number of the items/parameters within the scope of application for accreditation.

c) For instance, the RMP itself carries out testing/measurement activities but 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 RMP provides untrue management system operation records, including corresponding testing/calibration records.

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

f) Circumstances mentioned in 5.1.5.3.

8 Special requirements for the accreditation of multi-site RMPs

There are two situations relating to multi-site RMP accreditation: 1. Independent RM production sites (e.g. independent production of the same RM at different locations); 2. A single RM production capacity that is carried out at different locations by stages (e.g. mechanical processing and preparation at location A, characterization, homogeneity testing, stability testing and certificate issuance at location B).

With regard to situation 1, the application and accreditation are carried out completely as an independent RMP and certificate is issued separately. With regard to situation 2, the applicant is required to provide relevant location information when submitting application to help the assessment team plan the assessment, yet only a single certificate is issued. The initial
accreditation and reassessment shall cover all these sites. Surveillance assessment will depend on the actual situation.

9 Requirements on changes to accreditation

9.1 Changes to accredited RMPs

9.1.1 Change notice

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

a) changes to the name, address, legal status and main policies of the accredited RMP;

b) changes to the organizational structure, top management and technical personnel of the accredited RMP;

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.

Note 1: When changes occur to the name, address, standards/methods of testing/calibration/examination of an accredited RMP, 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 RMP changes, it shall update the information in a timely manner.

Note 3: When the name, legal status, legal representative or authorized signatory of an accredited laboratory change, it need resign the Accreditation Contract with CNAS.

9.1.2 Handling changes

9.1.2.1 After the 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;

b) maintaining, extending, reducing, suspending or withdrawing accreditation;
c) registering and recording the changes.

9.1.2.2 When there are changes to the environment of an RMP, e.g. relocation, the RMP 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 an RMP has undergone changes mentioned in 9.1.1 and fails 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 RMPs 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 RMPs shall have sufficient time to adapt to the new requirements. CNAS can confirm the conformance of accredited RMPs to the new requirements through surveillance or reassessment. The accreditation can be maintained after accredited RMPs are confirmed as compliant.

9.2.3 Once they have completed the transition, accredited RMPs shall notify the CNAS Secretariat in a timely manner. In case accredited RMPs 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 RMPs 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 confirmation;

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 an RMP. The period of suspension is no more than 6 months.

10.1.2 During the period of suspension, accredited RMPs 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 RMP 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 RMP 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 RMP to recover accreditation beyond the suspension period;
   b) failure or unwillingness of an accredited RMP to continue to meet accreditation requirements due to changes to accreditation rules or criteria;
   c) failure of an accredited RMP to fulfil the obligations specified by CNAS rules;
   d) malicious damage of CNAS reputation by accredited RMPs.
   e) dishonest conduct of an RMP, 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 an RMP 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 d) and e). At the same time, CNAS reserves the right to no longer accept the application for accreditation.
10.4 Accreditation cancellation

Under the following circumstances, CNAS shall cancel accreditation:

a) accredited RMPs apply for withdrawing accreditation on a voluntary basis;

b) accredited RMPs 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 RMPs 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 RMPs 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 the RMPs in light of their nonconformance to CNAS stipulations.

11.1.4 CNAS is obligated to use its website to publicize and update information on the accreditation status of accredited RMPs, including:

a) name and address of accredited RMPs;

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 RMPs.

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 RMPs 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 RMPs can make adjustments within a suitable time limit.

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

11.1.9 In order to know the demand of RMPs 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 RMPs 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 accreditation activities, such as commercial and technical information.

11.2 Rights and obligations of RMPs

11.2.1 Rights and obligations of applicant RMPs

11.2.1.1 RMPs have the right to get relevant public documents of CNAS;

11.2.1.2 RMPs 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 RMPs 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, RMPs have the right to raise objection to the composition of the assessment team.

11.2.1.5 RMPs are obligated to learn relevant accreditation requirements and stipulations of CNAS.

11.2.1.6 RMPs 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 RMPs 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 RMPs

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

11.2.2.2 RMPs 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 RMPs 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 RMPs have the right to terminate accreditation qualifications on a voluntary basis.
11.2.2.5 RMPs 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 RMPs are obligated to abide by relevant laws and regulations on a voluntary basis.

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

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

11.2.2.10 RMPs 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 RMP shall notify the CNAS Secretariat of the brief contents of the complaint and handling process.

11.2.2.11 RMPs shall notify CNAS in writing if changes described in clause 9.1.1 of this Rules occur and are 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 RMPs 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 RMPs 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 RMPs 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 RMPs are obligated 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 RMPs are obligated to pay fees according to relevant stipulations.

11.2.2.17 RMPs 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.