MP 6-03

ACCREDITATION PROCEDURE

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1.0 Purpose/Scope

The purpose of this procedure is to outline the process to be followed by NiNAS in the accreditation of conformity assessment bodies or CABs, beginning from application to granting of accreditation. This procedure covers the scope of the NiNAS assessment and accreditation schemes, and conforms to the requirements of ISO/IEC 17011:2017 and other applicable national and/or international standards. This procedure is the most complex in NiNAS and contains a number of sub-processes. Sub-processes are at times further broken down into work-flows by accreditation scheme type; some of which are to come in the future. The process begins with the receipt of an application inquiry to the issuance of accreditation documents for a successful applicant and the assessment wrap-up.

2.0 Responsibilities

The responsibility for the implementation of this procedure lies with the management of NiNAS, Committee Members, personnel and assessors.

3.0 References and Definitions

CAB – Conformity Assessment Body

CAR – Corrective Action Requests

AFRAC – African Accreditation Cooperation

IAF – International Accreditation Forum

ILAC – International Laboratory Accreditation Cooperation

ISO/IEC 17011:2017 *Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies*

Applicable AFRAC, ILAC and IAF documents

NiNAS policies and procedures

4.0 Procedure

NiNAS conducts its assessment activities in line with the requirements of the International Standard, ISO/IEC 17011:2017 Conformity assessment – Requirements for

accreditation bodies accrediting conformity assessment bodies. Clause 4.6.1 of the standard among other things requires NiNAS to:

"… document the rules and processes for its accreditation schemes referring to the relevant International Standards and/or normative documents."

This document presents in details the NiNAS accreditation processes for applicant and accredited organisations.

4.1 Application

Accreditation staff respond to application enquiries with a documentation package that includes the:

a) *Application Cover Letter*
b) applicable *Application Form* (containing the Accreditation Agreement) (See table 6-1);
c) applicable document review checklist;
d) current *Fee Structure* for the applicable accreditation scheme; and,
e) applicable *Guides* (Laboratory, Inspection or Certification).
f) Rules for the Use of NiNAS Accreditation Symbols.

CABs are requested to submit electronic copies of the documents and records mentioned above through the email address info@ninas.ng. Signing the application and the Accreditation Agreement signifies the CAB's commitment to abide by the provisions of the Rules for the Use of NiNAS Accreditation Symbols.

Upon receipt of an application:

a) Administration staff log it into the NiNAS work-flow tracking system with the date of receipt.
b) Administration staff review it to ensure all the sections of the application have been completed.
c) Applicants that submit incomplete applications are advised of the missing information and that their applications will be held until missing information has been provided, but not for longer than 6 months at which time the application will be destroyed;
d) Accreditation Scheme staff are provided with the complete submission.
e) Accreditation staff review the submission to ensure that NiNAS has sufficient Team Leader[1a], Assessors and Technical Experts to do the work within three (3) months of the receipt of the application, and ensure that NiNAS has the available technical competencies for the scope of accreditation requested;

f) In the event that NiNAS does not have the human resources to assign the task, NiNAS Director of Accreditation or relevant Accreditation Scheme Staff will estimate the time needed to obtain and train the resource and advise the applicant in writing of the delay. Should the applicant choose not to proceed at this point a complete refund of any application fees is granted.
g) The choice and number of assessors assigned to the team is dependent on the scheme , the technical areas of the requested scope (competencies required) and possibly the number of key locations (See sub-process 6-1, for Team Member assignment by programme);
h) Potential Assessors are chosen from the *Assessor Database* that will have appropriate knowledge for the specific scopes being assessed and an understanding sufficient to make a reliable assessment. They are contacted by email and requested to sign and return to NiNAS an Assessment Confirmation Form indicating their availability on the scheduled date(s) of assessment. The assessors are also requested to sign and submit the conflict of interest, confidentiality and impartiality declaration forms. ;
i) In the same message, potential assessors are asked to advise NiNAS whether they have any existing or former link, such as having provided consultancy[1] services, or competitive position between themselves and the applicant being assessed;
j) The Applicant is advised that their application is accepted and of the individual names (and organisational representation of each) that will make-up the NiNAS assessment team;
k) Should the client object with a written claim that they believe they will not be treated in a fair and impartial manner by the selected members, NiNAS will make an attempt to assign new member(s);
l) In the event that alternative assessors cannot be found the client is advised and offered a 50% refund of application fees should they choose to withdraw;
m) ;
n) NiNAS and the applicant agree on an approximate time frame for the assessment, subject to a satisfactory outcome of the Document Review.
o) NiNAS currently uses individual contractors and does not outsource assessments to subcontracted organizations.
p) If an initial assessment has not been conducted within twelve months of the application date, and the delay has been caused primarily by the applicant, an

[1] Consultancy services (refer clause 3.11 of ISO/IEC 17011) and
Consultancy services (refer clause 3.11 of ISO/IEC 17011) and conformity assessment services that CABs perform (as defined in clause 1 of ISO/IEC 17011) are considered services that can affect impartiality and are not offered by NiNAS.

additional application fee will be charged. If the application is still pending after two years of the application date, the application will lapse.

4.1.1 Preliminary Visit/Pre-assessment Visit

a) In the event that the client is uncertain about procedures, accreditation criteria, or has significant deficiencies in its application, and other matters cannot be solved over the phone, a preliminary or pre-assessment visit may be arranged.
b) A pre-assessment visit is to be conducted with the agreement of the CAB;
c) NiNAS shall recommend a pre-assessment visit (if necessary) following the identification of significant deficiencies with the submitted information. The applicant CAB can also request a pre-assessment visit. A pre-assessment visit is not a substitute for initial assessment.
d) The pre-assessment visit involving NiNAS staff or one of its contracted team leaders will be used to clearly make the process understandable to the client, and / or, explain the intent of any of the accreditation criteria. While deficiencies in the applicants' system may be identified during this visit, no specific solutions on how the client should meet the criteria will be provided as such would constitute consulting advice
e) Fees are paid by the CAB for a preliminary/pre-assessment visit in accordance with NiNAS' Current Fee Structure.

4.2 Documentation Review

a) Upon receipt of signed Assessment Confirmation *Forms* from all team members, the Director of Accreditation provides the team members with a copy of the applicant's submission along with a *Document Review Report Template* for the applicable standard and *Corrective Action Requisition* Forms.
b) NiNAS will ensure that the assessment team members have access to the needed criteria / requirements documents as well as copies of previous assessment / surveillance reports, and other relevant documentation that will assist in the assessment.
c) The Team Leader completes the review of the applicant's submitted documentation using the Cross-Reference Matrix to identify conformance and any non-conformities against the applicable standards and other criteria as provided in Table 6-2.
d) For laboratories, the previous includes a review of the lab's participation and performance in proficiency testing and/or other inter-laboratory comparison

programmes, where available and appropriate. Laboratories shall meet the intent of ILAC policy on proficiency testing. See the Annex to this document for participation frequency.

e) Any non-conformities are recorded as instructed on the *Corrective Action Request* Form;
f) The applicant's conformity is reported in the *Document Review Checklist* for NiNAS records, as per instruction on the template;
g) Both the description of conformity and non-conformity must be written so as to give enough evidence to support the conclusions arising from the assessment;
h) *Corrective Action Request* forms are provided to the applicant for their response as per the instruction and timeline provided in the *Document Review Cover Letter.*
i) Responses when returned from the applicant are reviewed by the Team Leader within 5 working days; a rationale for any rejection of responses are provided to the applicant but, without providing a solution to the problem;
j) All major non-conformities[2] must be resolved prior to making arrangements for the on-site portion of the assessment;
k) Three unsuccessful attempts in resolving non-conformities from a document review can result in the application being closed; refunds of any application fees at this point are not provided;
l) The Team Leader provides the written report and any closed CAR forms to NiNAS. This concludes the document review and is the notification to NiNAS staff of a successful conclusion of the Document Review process, so that arrangements for on-site assessments may commence.
m) Fees are paid by the CAB for document review in accordance with NiNAS' Current Fee Structure.

4.3 Preparation for On-Site Assessment

4.3.1 Assessment Plan

Using the information on *Application Form*, an *Assessment Plan* is developed by the Team Leader and approved by NiNAS Director of Accreditation.

a) For laboratories, all locations that perform activities covered by ISO/IEC 17025 are assessed.

[2] A major non-conformity is one which brings doubt as to the validity of the test results or certifications being issued. Several repeating minor non-conformities constitute a major non-conformity

b) For Inspection and Certification Bodies, those locations that conduct key activities as defined by IAF/ILAC A5 are assessed. Should the Team Leader believe that there is cause to assess locations that are not considered key, they will obtain approval from NiNAS Director of Accreditation or Programme staff. The Applicant will be provided with a justification in the assessment plan.
c) NiNAS, the Team Leader and the applicant will agree on a specific date for the assessment for inclusion in the Assessment Plan.
d) Depending on the accreditation standard being applied the witness activities which the team will carry out will vary (See Annex 1). Witness activities will be planned to observe the applicant implement its processes in the field and assess the general competence of personnel. Witness activities will include a justified number of CAB staff to provide NiNAS with confidence as to the competencies of the applicant across its requested scope of accreditation;
e) A copy of the Assessment Plan is sent to the clients and all members of the Team;
f) An opportunity is provided to all for questions.

4.3.2 Sampling Procedures for Scopes with a variety of specific conformity assessment services.

- **Laboratories:** Laboratories that conduct many tests within a specific field of testing may not need to have competence for every test carried out. An example would be testing for different kinds of heavy metals (Lead, Cadmium, Nickel, etc.) in water. Competency to test for one is a good indication of competency to do others. The exact sampling plan for each laboratory will be developed by the Technical Experts on the team in advance of the assessment. A written technical justification for any sampling plan must be prepared and agreed to by a second technical expert before being approved by the Director of Accreditation;
- **Certification and Inspection Bodies:** For initial assessments, the main office and all other locations of the CAB where one or more key activity is performed shall be assessed. Sampling is acceptable for surveillance visits.
- When establishing a sampling plan the team must assess all competencies required for the scope at hand across the organisation to ensure that the sample selection is representative of all competencies applied by the applicant. (See Sub-process 6.2 for Requirements for Witness Activities Accreditation standard.)

4.4 Assessment

4.4.1 Assessment Team Meeting

Prior to the on-site assessment the Team Leader arranges for the team to meet to discuss information obtained to date on the applicant and the findings from the document review. The Team Leader advises each member on their role and any expectations specific to the assessment such as the probing of a technical matter in regards to a complaint. The Assessment *Schedule* and *Assessment Plan* are reviewed and team members are given the opportunity to ask any procedural questions.

4.4.2 Communicating during the assessment

Following an on-time arrival at the site, the Team Leader organises with the applicant's contact to conduct an opening meeting with the applicant's management and staff to:

- Clearly communicate the purpose and scope of the assessment and the accreditation criteria that are being applied;
- confirm the agreement of all parties (applicant and audit team) to the assessment plan;
- introduce the assessment team and the applicant's staff;
- ensure that all planned assessment activities can be performed; and,
- Provide an opportunity for the applicant's personnel to ask questions.

Attendance at the opening meeting must be recorded on the *Assessment/Surveillance Attendance Form*.

The Team Leader will make arrangements to communicate with team members to exchange information, assess progress, and if necessary reassign work among members. Arrangements are also made with the Applicant's representative to keep the applicant up to date on progress and concerns if any.

Concerns about an issue outside the assessment scope such as a Health and Safety hazard should be noted and reported to the assessment team leader, for communication to the applicant. Any such issues raised must be recorded and submitted to NiNAS Director of Accreditation.

Where the available assessment evidence indicates that the assessment objectives are unattainable, the assessment team leader should report the reasons to the client and to NiNAS Director of Accreditation for advice. Advice may result in a modification to

the assessment plan, objectives, to the scope objectives or it may even result in termination of the assessment. A verbal explanation and written justification is provided to the CAB.

4.4.3 The role of Guides and Observers

Guides and observers (for example a regulator) may from time to time accompany the team. These individuals must not influence or interfere with the conduct of the assessment or the assessment may be deemed invalid. As such the Team Leader can remove observers from taking part in the assessment.

The Team Leader may request that the applicant appoints a Guide to assist with the following if required.

a) identifying individuals for interviews;
b) arranging access to specific locations;
c) ensuring that rules concerning location safety and security procedures are known and respected by the assessment team members and observers; and,
d) providing clarification or assisting in collecting information.

4.4.4 Collecting and verifying information

a) *Here the goal is to gather objective evidence of competence and conformity to relevant standards and requirements for accreditation. This may be done through interviews, record reviews and should be done by witnessing the performance of representative staff members to provide assurance of competence.*
b) Only information that is verifiable is accepted as evidence and recorded for both conformity and non-conformity using the Document Review Checklist specific to a particular scheme and the *Corrective Action Request Forms* provided by NINAS;
c) When a non-conformity is identified appropriate sections of the Corrective Action Request Form are completed;
d) Taking copies of sensitive records such as personnel files should be avoided. If there is evidence of non-conformity in such records note the specific file, date and other identifiable information on the record and write a short description of the finding on the Corrective Action Request Form;
e) When identifying anon-conformity, confirm your understanding of the evidence with the applicant.
f) If, during assessment any member of the team becomes aware of any new or changed circumstances or risks, these should be brought to the attention of the Team Leader as soon as possible.

4.4.5 Generating findings

a) The Team must schedule debriefings at appropriate stages during the audit to discuss progress as well as any findings.
b) Where the assessment team cannot reach a conclusion on a finding, the team should refer back to NiNAS for clarification.
c) Technical experts on the team must have all non-conformities reviewed by the Team Leader. The Tem Leader must ensure that the statements of non-conformity written by Technical Experts are accurate and appropriately drafted, or the Team Lead should write the statements based on the evidence provided by the expert;
d) Non-conformities should be reviewed with the applicant to obtain acknowledgement that the evidence is accurate, and that the non-conformities are understood;
e) Teams should identify opportunities for improvement during assessments without recommending specific solutions;
f) Every attempt should be made to resolve any diverging opinions concerning the assessment evidence or findings, and unresolved points should be recorded and provided to the appropriate NiNAS Director.
g) Where the assessment team cannot reach a conclusion on a finding, the team will contact the Director of Accreditation for clarification

4.4.6 Preparing assessment conclusions

The Team confers a closed-door meeting in advance of the Closing Meeting with the applicant to:

a) review the assessment findings, and any other appropriate information collected during the assessment against the assessment objectives;
b) agree on the assessment conclusions, taking into account the uncertainty inherent in the assessment process;
c) This analysis shall be sufficient to allow the team to determine the extent of competence and conformity of the laboratory with the requirements for accreditation.
d) Opportunities for improvements may be presented but consultancy shall not be provided.
e) discuss assessment follow-up, as applicable.

4.4.7 Conducting the closing meeting

The Team Leader chairs the closing meeting and presents the findings to appropriate management and applicant staff. The attendance form is recirculated to record attendance. Findings of both conformity and non-conformity are presented. Normally due to time considerations, only hard copies of the Corrective Action Requests are presented at closing meetings. The completed and final report is generated in the

days following the assessment. The final report will contain no findings that were not presented to the client at the closing meeting.

The Team Leader advises the Applicant:

a) that the assessment evidence collected was based on a sample of the information available;
b) about post-assessment activities (e.g. handling of assessment findings, the complaint handling and appeal process).
c) that corrective action responses are due within 30 working days of the assessment. If it is not possible to complete the corrections or to take corrective actions within 30 days, the applicant's response must describe the plan of how the situation will be remedied in 45 days. Where it is still not possible to take corrective action in 45 days, e.g., a staff member must take a course or a Proficiency Test must be carried out, the Applicant advises NiNAS of the expected time frame to take action. NiNAS will consider for possible action such as reducing the proposed accreditation scope until the actions can be completed.

Any diverging opinions regarding the findings or conclusions between the Team and the Applicant should be discussed and, if possible, resolved. If not resolved, the matter should be recorded and reported to the appropriate NiNAS Director.

4.4.8 Preparing and distributing the Assessment Report

a) The Team Leader completes the NiNAS Assessment / Surveillance Report Template normally within 10 working days of the assessment ; contents are complete, accurate, concise and clear and the report forms a record of the assessment;
b) Comments on the competence and conformity included in the assessment report shall be adequate enough to support the assessment conclusions and enough to support the design of the 2-year accreditation program for each CAB;
c) The report is submitted to NiNAS Director of Accreditation;
d) Upon receipt the Director of Accreditation review the report and it is sent to the applicant under the *Assessment / Surveillance Report Cover* letter to indicate response requirements if any.
e) The content of the assessment report is the property of NiNAS.
f) If the assessment report conclusions differ from the findings NiNAS will provide an explanation both in its records and to the CAB.

4.4.9 Completing the assessment

a) Corrective Action Request Forms, containing the applicant's responses are submitted by the Applicant to the Team Leader through the Director of Accreditation for review;
b) The Team Leader reviews the responses for acceptability in consultation with the Technical Experts as applicable;
c) The Team Leader confirms that the Root Cause Analysis, the Corrective Actions and/or Plan will satisfactorily address each non-conformity in that the action should prevent its reoccurrence.
d) It is optional for the Applicant to respond to Opportunities for Improvement;
e) The Team Leader has 5 business days to review the responses and advise the Applicant of their acceptance or not.
f) If some responses are not accepted, the client is advised that a revision is necessary. Revisions should be returned in 10 business days;
g) Following three rejections of responses to the same CAR a conference call is organised between the Applicant, the Team Leader and the NiNAS Director of Accreditation to determine a way forward;
h) If the non-conformances are judged by the Team Leader to be severe or significant in number, the Team Leader and the Director of Accreditation confer to determine whether a verification audit is necessary to confirm the implementation of the management system prior to accreditation;
i) If it is not possible for any of the above timelines in 4.4 to be met, the client is advised of the delay, the reason for such, and is provided with an updated estimate.

4.5 Decision Making

Following satisfactory resolution of any non-conformities, the Team Leader sends the complete documentation package to the Director of Accreditation with an indication that a decision may be taken on the file. The Director of Accreditation assembles the information necessary to provide to the decision-makers and ensure it is complete for decision-making purposes. Information (documentation) must include:

a) Unique identification of the CAB;
b) Date(s) and type(s) of assessment(s) (e.g. initial, reassessment);
c) Name(s) of the assessor(s) and, if applicable, technical expert(s) involved in the assessment;
d) Unique identification of all locations assessed;
e) *Record of Decision* form with the requisite fields completed;

f) The *Assessment Report*(s) including any *Witness Report*(s);
g) The Non-conformities that were issued and the accepted resolutions to each;
h) For a laboratory, a summary of its proficiency testing results;
i) A statement of the adequacy of the internal organisation and procedures to give confidence in its competence, through its fulfilment of the requirements for accreditation
j) Where appropriate a recommendation as to the decision.
k) Depending on circumstances any recommendations regarding the granting of a reduced scope, and the rationale for such; and,
l) Any other information that may be pertinent to the support of the decision.

NiNAS will be satisfied that the information is adequate before making a decision and will make the decision without undue delay.

The decision is made without undue delay by a selection of three individuals chosen from the Accreditation Advisory Committee (AAC). Individuals shall have no prior relationship to the applicant. The AAC will review the documentation package referred to in 4.5, to ensure that the requirements of NiNAS' policies and procedures have been fulfilled, and the resolution of the non-conformities has met all the requirements for accreditation. The result of the AAC decision will be submitted to the Director of Accreditation for review.

The Director of Accreditation will review the recommendations of the AAC, along with the Assessment Report and other documentation, and will recommend to the Director General/Chief Executive Officer, NiNAS, as to whether or not the applicant has met the requirements for accreditation.

The DG/CEO has the authority to make the final decision to grant accreditation (or continued accreditation, for an already accredited CAB).

If the AAC finds that the documentation in 4.5 above is not sufficient, they may request further information and additional assessment activity.

The positive or negative decision is recorded on the *Record of Decision* Form.

If the outcome of the assessment is different from the report of the findings of assessment, an explanation will be given to the Applicant.

If NiNAS has used the results of an assessment performed by another accreditation body it shall have assurance that the other body operates in accordance with the requirements of ISO/ IEC 17011.

Should an accreditation decision lead to an unsuccessful outcome, the Director of Accreditation contacts the applicant to explain the possible options that may be available; e.g. gain more experience and reapply, appeal the decision, etc. The outcome and the options are then provided to the Applicant in writing.

4.6 Issuance of Accreditation Documents

Following a positive decision Administrative staff issue accreditation documents as a priority following. The documents include:

a) an *Accreditation Letter*;
b) a *Scope of Accreditation*;
c) an *Accreditation Certificate*;
d) an Agreement for the Use of NiNAS Accreditation Marks (Symbols).

The requisite information fields on the documents are completed and verified / finalised by Accreditation Scheme staff.

The date of accreditation is no earlier than the date the decision was made. Signed agreements must be returned from the newly accredited organisation within 30 days or suspension procedures will be initiated.

The newly issued scope of accreditation is published on the NiNAS website, and the applicant's details are added to the directory of accredited clients.

4.7 Assessment Wrap up

a) A *Client Feedback Form* is sent to newly accredited organisation;
b) Any 'lessons learned' from the Team Leader, Technical Experts or from the Applicant are provided to the Quality Manager by accreditation staff and entered into the continual improvement process of the management system.

4.8. Re-assessment, Special Visit and Additional Visit

4.8.1 Re-assessment

NiNAS operates a two-year accreditation cycle for accredited CABs. At the end of the accreditation cycle, NiNAS conducts a re-assessment of the CAB's operations, similar to the initial accreditation assessment. The purpose of the re-assessment is to determine whether a CAB is continuing to comply with the relevant accreditation standard and NiNAS policies. During the assessment visit, the assessment team will verify the effective implementation of corrective actions from the previous visit.

A re-assessment visit will be scheduled at least 60 to 90 days prior to the date of expiration of the CAB's accreditation.

4.8.2 Special Visit

NiNAS reserves the right to conduct a special visit should information come to its attention, either through its own activities or from other sources (e.g. CAB's customer complaints), that casts doubts on the accredited CAB's continued conformity with accreditation criteria. However, the conduct of a special visit by NiNAS will depend on circumstances.

4.8.3 Additional Visit

NiNAS may conduct an additional visit to verify the effective implementation of the corrective actions raised during initial assessment/re-assessment visits and to assess compliance to the relevant standard and accreditation criteria. The assessment team for additional visit shall include a NiNAS personnel and/or the team leader. An additional technical expert may be a member of the assessment team if considered appropriate.

5.0 Extending the Scope of Accreditation

NiNAS will consider any application for extension of scope of accreditation from an accredited conformity assessment body in line with applicable NiNAS policies and procedures.

a) An accredited CAB seeking for extension of scope, shall apply to NiNAS in writing and submit the following documents:
   - A copy of the test/calibration/inspection/evaluation method;

- Proficiency testing (PT) or inter-laboratory comparison (ILC) results;
- Any other documentation requested by NiNAS at the time of application.

b) NiNAS shall review the application in line with the requirements for accreditation and this procedure;
c) Assessments to extend the scope of accreditation may be carried out at the same time as planned surveillance (where applicable) and re-accreditation visit. In this regard, the surveillance or re-accreditation assessment plans shall be modified to include the scope extension assessment prior to the commencement of assessment;
d) Following an approval by the Accreditation Advisory Committee (AAC) of an extension to the scope of a CAB's accreditation, NiNAS shall:
   - Notify the CAB of the AAC's decision;
   - Amend the schedule with the extended scope; and
   - Update the directory of accredited CABs on the NiNAS website.

NOTE: Extension to the scope of accreditation requested as part of a scheduled re-assessment will only be accommodated where such requests do not compromise the purpose of the re-assessment. Fees will be charged where additional resources and time are required to accommodate the request as part of a scheduled re-assessment.

6.0 Flexible Scope of Accreditation

NiNAS currently does not accredit flexible scope.

7. Document History

Modification No/Date	Proposed by	Page No.	Summary of Modification
21/02/2023	Consultant	All	To reflect the response to the findings from the desk review of NiNAS management system

ANNEX 1 SUB-PROCESSES

Sub-Process 6-1: Witnessing Requirements for Applicants and Accredited Organisations

As required by ISO/IEC 17011 the activities of CABs such as certification bodies are witnessed to assess the ability of the bodies to organise audits and to assess the competency of teams (not specific individuals). For other conformity assessment activities such as testing, calibration and inspection, NiNAS shall conduct witnessing activity to verify that personnel of the CAB can competently perform the given conformity assessment activity.

SP-6-1-1 Conducting Witnessing in Laboratory Assessments

a) Technical assessors and experts (where applicable) shall witness the testing activities conducted by laboratory personnel for the desired scope.

b) If full witnessing is not possible due to the length of the test involved, laboratory technicians shall be questioned regarding procedures and on non-observed sections of the test procedure

c) If witnessing is not possible due to reasons such as equipment already being in use, questioning of technicians shall be used as a proxy and a justification written as to why such was sufficient to establish conformity with requirements.

SP- 6-1-2-1 [for future use] Conducting Witness Audits of Management System Certification Bodies

To organize witness audits of management system Certification Bodies at assessment:

a) NiNAS will request a list of upcoming audits from the Applicant;

b) If practical one witness audit is done for each code that is considered to be of "High Risk". See *NiNAS Risk Assignment Table for IAF ID1 Accreditation Codes;*

c) If not, three witness audits will be selected from the list in priority of highest risk;

d) One NiNAS assessor is assigned to each auditor on the Applicant's team;

e) Competency requirements described in Sub-process 6-1 apply;

f) When the witness audit(s) has been selected, the NiNAS will obtain the following information about the Applicant's process:

g) A competency description for each member of the Applicant's team (i.e. Curriculum vitae, auditor biography);
h) The Applicant's rationale for allocation of auditor time and auditor selection;
i) The Applicant's Audit Plan;
j) If the audit being witnessed is an initial certification, a copy of the Stage 1 inputs and outputs; If this is a transfer certification, all the pre-transfer review documentation and outputs.
k) Documents (i.e. Quality Manual and key procedures) from the organization being audited by the Applicant;
l) Audit report (including notes), required actions and responses from the previous audit activity;
m) Certificate(s) from the organization being audited;
n) Hotel information and coordinates for assessor.

SP-6-1-2-2 During the Witness Audit

a) NiNAS Assessors will introduce themselves and remind the Applicant's Auditors and the organization being audited that they are there only to witness the ability of the CB to put in place an effective audit;
b) NiNAS Assessors will use the appropriate *NiNAS Witness Record Template* to record the applicant's conformity and/or non-conformity;
c) NiNAS Assessors are not to provide any comment or feedback so as not to influence the outcome of the Applicant's process.

S-P-6-1-2-3 Following the On-Site Audit

a) When the Applicant's on-site audit activity is complete, the NiNAS Team Leader will provide limited feedback, if requested. Comprehensive feedback cannot be provided as this may affect the outcome of the witness audit in advance of the CB's audit report and issuance of CAR forms.
b) Following completion of the onsite witness activity, the Applicant provides the NiNAS Team Leader with a copy of their audit report.
c) Once NiNAS has reviewed the Applicant's Audit Report a closing meeting with the Applicant's representative will be scheduled and the findings, conclusions and recommendations will be presented. In most cases, the closing meeting will be held by teleconference.
d) During the closing meeting, the NiNAS Team Leader will review the results of the witness audit, and request that the CB acknowledge any findings. Differences of opinion regarding witness audit findings between the CB and the NiNAS team that cannot be resolved should be referred to NiNAS Director of Accreditation for resolution.
e) Any non-conformities are resolved as per the process described in Section 4.4.9.

SP- 6-1-3-1 Conducting Witness Audits of Inspection Bodies

a) The technical competence assessment is normally conducted at the site of the inspection activities through on-site witnessing, on-site demonstration, interview of inspectors and access to inspection reports.
b) The assessment team shall conduct the witnessing of the technical personnel performing conformity assessment activities. The inspection personnel should be witnessed at a suitable site where the inspection is performed.
c) The role of NiNAS' assessors during witnessing inspections is that of observers. The assessors will not in any way adversely affect or influence the work being performed.
d) The team will look to see that as a minimum:
    i. The inspector has the competence for the inspection performed ;
    ii. The inspector's competence is consistent with the records;
    iii. The inspector has access to all necessary documented inspection methods and procedures;
    iv. The procedures are up-to-date;
    v. The inspector implements the procedures in full and correctly, i.e. no short cuts, no personalised application where it is not permissible to do so;
    vi. Records of all observations are made while on-site as required by the procedure;
    vii. Records clearly identify what has been inspected, the method/procedure used, and when it was inspected;
    viii. All records and raw data are signed/initialled, stamped and traceable as applicable;
    ix. All findings that indicate immediate or urgent action are reported as required to the customer while on site;
    x. Inspection reports/certificates comply with the inspection body's, NiNAS' and relevant regulatory and/or standard requirements; and
    xi. Facilities and equipment are fit for the inspection purpose.
e) If an IB cannot provide at least one witnessing and/or sufficient supporting evidence in order for a vertical assessment to be conducted on the day of the assessment, the assessor has the right to terminate the assessment, and

re-schedule for another time at full cost to the IB. It is permissible for an IB to simulate an inspection for this purpose;

f) The assessors will record all information gathered while witnessing the performance of an inspection and viewing records in the IB. This information will be used to make a decision on the competence of the IB.

SP- 6-1-4 Conducting Witness Audits (Personnel and Products Certification Bodies)

The principle in this sub-process applies to both applicant and accredited organisations certifying persons and products to ISO/IEC 17024 and ISO/IEC 17065 respectively.

a) For initial assessments including extension to scope, all schemes shall be witnessed with a minimum of two (2) witnessing activities necessary in order to make a recommendation for the granting of accreditation
b) For surveillance and re-assessment, all schemes shall be witnessed over the accreditation cycle with the maximum number of CAB personnel witnessed; the minimum number of witnessing activities is two (2) per year.
c) In exceptional circumstances, for example in product certification where the CAB has one scheme accredited and a limited auditor pool, one annual witnessed audit may be sufficient. This shall be renewed on an annual basis.
d) Before the witnessing activity, NiNAS will assemble an appropriate assessment team, competent for the ISO/IEC 17024 standard and certification scope.
e) The CAB must explain to its clients that witnessing will be performed by NiNAS, noting that it should not affect the normal course of the audit, since NiNAS assessors will not interfere or ask questions directly of the client.
f) When requested, the CAB must provide to NiNAS a complete and up-to-date schedule of audit (dates, location, audit team composition, audit type and scope etc.). This allows NiNAS to select the audit to witness and to enable adequate time to assemble an assessment team

ANNEX 2 - Participation in Proficiency Testing Programmes

According to ISO / IEC 17011, the accreditation body shall maintain a list of appropriate PT programmes. Each applicant or accredited facility is required to participate in appropriate proficiency testing or equivalent activities. The minimum level of participation in PT is specified by NiNAS in PL 009-02. These levels are developed in cooperation with interested parties and designed to be appropriate in relation to other surveillance activities.

Participation in proficiency testing or inter-laboratory comparison may be required in the following situations:

- Prior to gaining accreditation with NiNAS; and
- When requesting significant extensions or variations to the scope of accreditation.

A facility's performance and response to proficiency testing results will be reviewed during the on-site assessment. Facilities are therefore encouraged to participate in as broad a range of PT activities as practicable and available, but at least once every two years for each major area of test, measurement, inspection or related activity covered by the scope of accreditation, where such programmes are available.

Inspection bodies are required to participate in appropriate quality assurance activities such as proficiency testing, as a condition for granting accreditation. Both applicant and NiNAS-accredited inspection bodies are required to participate in credible and relevant proficiency testing programmes where available. It is the responsibility of facilities to check the availability of externally-available PT programmes, evaluate their appropriateness and participate in such programmes.

Forms

Table: 6-1 Forms in use with Procedure 6		
Form Number	Title	Applicable Scheme
F-6-001	Application Cover Letter	All Schemes
F-6-002	Application to be Accredited as a Testing or Calibration Laboratory	ISO/IEC 15189, 17025
F-6-003	Application to be Accredited as a Management Systems Certification Body	ISO/IEC 17021
F-6-004	Application to be Accredited as a Product Certification Body	ISO/IEC 17065
F-6-005	Application to be Accredited as a Certifier of Personnel	ISO/IEC 17024
F-6-006	Laboratory accreditation fee structure	ISO/IEC 15189, 17025
F-6-007	Certification Body Fee Structure	ISO/IEC 17021, 17024, 17065
F-6-008	Application Incomplete / Complete - Team Assignment Letter	All Schemes
F-6-009	Requirements Cross-Reference Matrix	Standard Specific
F-6-010	Response to Applications Letter	All Schemes
F-6-011	Assessor Competency Matrix XX	All Schemes
F-6-012	Assessment Confirmation Form	All Schemes
F-6-013	Document Review Checklist	Standard Specific
F-6-014	CABs Corrective Action Requisition	All Schemes
F-6-015	Document Review Cover Letter	All Schemes
F-6-016 A	Assessment Plan Template - Laboratories	ISO/IEC 17025
F-6-016 B	Assessment Plan Template -Medical Laboratories	ISO 15189
F-6-016 C	Assessment Plan Template – Inspection Bodies	ISO/IEC 17020
F-6-016 D	Assessment Plan Template – Management System Certification Bodies	ISO/IEC 17021-1

Table: 6-1 Forms in use with Procedure 6		
Form Number	Title	Applicable Scheme
F-6-016 E	Assessment Plan Template -Personnel Certification Bodies	ISO/IEC 17024
F-6-016 F	Assessment Plan Template - Products Certification Bodies	ISO/IEC 17065
F-6-017	Assessment Plan Template	All other Standards
F-6-018	Opening Meeting Agenda Template	All Schemes
F-6-019	Assessment/Surveillance Attendance Form	All Schemes
F-6-020	Assessment/Surveillance Report Template	All Schemes
F-6-021	Witness Record Template	17020, 17021, 17065
F-6-022	Record of Accreditation Decision	All Schemes
F-6-023	Assessment/Surveillance Reporting Cover Letter	All Schemes
F-6-024	Accreditation Outcome Letter to Applicant	All Schemes
F-6-025	Accreditation Certificate	All Schemes
F-6-026	Scope Template	All Schemes
F-6-027	Accreditation Agreement	All Schemes
F-6-028	Logo License Agreement	All Schemes
F-6-029	Client Feedback Form	All Schemes
F-6-030	Four-Year Audit Programme	All Schemes
F-0631	IAF MLA Trademark Licensing Agreement	17021, 17024, 17065
F-0632	Lab Participation in PT – Minimum Frequencies	15189, 17025

Table 6-2 List of Requirements by Scheme IAF referenced documents may be located at: http://www.iaf.nu//articles/Publications/6

ILAC referenced documents may be located at: https://www.ilac.org/ilac_documents.html

Table 6-2A List of Requirements by Programme: Laboratory Accreditation Programme
Testing & Calibration Laboratories (ISO/IEC 17025)
• ILAC G8 Guidelines on Decision Rules and Statements of Conformity

• ILAC G21 Cross Frontier Accreditation – Principles for Cooperation • ILAC G17 Introducing the Concept of Uncertainty of Measurement in Testing in Association with the Application of the Standard ISO/IEC 17025 • ILAC G18 Guideline for the Formulation of Scopes of Accreditation for Laboratories • ILAC G24 Guidelines for the determination of calibration intervals of measuring instruments • ILAC G26 Guidance for the Implementation of a Medical Accreditation Scheme • ILAC P8 ILAC Mutual Recognition Arrangement (Arrangement): Supplementary Requirements for the Use of Accreditation Symbols and for Claims of Accreditation Status by Accredited Conformity Assessment Bodies • ILAC P9 ILAC Policy for Participation in Proficiency Testing Activities • ILAC P10 ILAC Policy on Traceability of Measurement Results • ILAC P14 ILAC Policy for Uncertainty in Calibration • IAF/ILAC A5 IAF/ILAC Multi-Lateral Mutual Recognition Arrangement: Application of ISO/IEC 17011
Medical Laboratories (ISO 15189)
• All the above plus; • ILAC G26 Guidance for the Implementation of a Medical Accreditation Scheme. • IAF/ILAC A5 IAF/ILAC Multi-Lateral Mutual Recognition Arrangement: Application of ISO/IEC 17011
Inspection Bodies (ISO/IEC 17020)
• ILAC P8ILAC Mutual Recognition Arrangement (Arrangement): Supplementary Requirements for the Use of Accreditation Symbols and for Claims of Accreditation Status by Accredited Conformity Assessment Bodies • ILAC P9 ILAC Policy for Participation in Proficiency Testing Activities • ILAC P10 ILAC Policy on Traceability of Measurement Results • IAF/ILAC A5 IAF/ILAC Multi-Lateral Mutual Recognition Arrangement: Application of ISO/IEC 17011
Table 6-2B List of Requirements by Programme: Certification Body Accreditation Programme

Management Systems Certification Bodies (ISO/IEC 17021)
• IAF MD 1 IAF Mandatory Document for the audit and Certification of a Management System Operated by a Multiple-Site Organisation • IAF MD 2 IAF Mandatory Document for the Transfer of Accredited Certification of Management Systems • IAF MD 3 Advanced Surveillance and Recertification Procedures (ASRP) • IAF MD 4 IAF Mandatory Document for the Use of Information and Communication Technology (ICT) for the Auditing/Assessment Purposes • IAF MD 5 Determination of Audit Time of Quality, Environmental, and Occupational Health & Safety Management Systems • IAF MD 5 Determination of Audit Time of Quality and Environmental Management Systems • IAF MD 10 IAF Mandatory Document for Assessment of Certification Body Management of Competence in Accordance with ISO/IEC 17021: 2011 • IAF MD 11 IAF Mandatory Document for the Application of ISO/IEC 17021-1 for Audits of Integrated Management Systems (IMS) • IAF ID 1 IAF Informative Document for QMS and EMS Scopes of Accreditation • IAF/ILAC A5:11/2013 IAF/ILAC Multi-Lateral Mutual Recognition Arrangement: Application of ISO/IEC 17011
Certifiers of Persons (ISO/IEC 17024)
• IAF GD 24 Guidance on the Application of ISO/IEC 17024:2003 • IAF/ILAC A5 IAF/ILAC Multi-Lateral Mutual Recognition Arrangement: Application of ISO/IEC 17011
Product Certification Bodies (ISO/IEC 17065)
• No unique documents at this time • IAF/ILAC A5 IAF/ILAC Multi-Lateral Mutual Recognition Arrangement: Application of ISO/IEC 17011
Documents Applicable to all types of Certification Bodies
• IAF MD 7 Harmonisation of Sanctions • IAF MD 12 Assessment of Certification Activities for Cross-Frontier Accreditation • IAF PL 1 Code of Conduct for Members of the IAF • IAF PL 6 IAF Memorandum of Understanding • IAF GD 3Guidance on Cross Frontier Accreditation

- IAF ID 3 Informative Document for Management of Extraordinary Events or Circumstances Affecting ABs, CABs and Certified Organizations
- IAF ID 4Market Surveillance Visits to Certified Organizations
- IAF ML 1 Guidance for the Exchange of Documentation among MLA Signatories for the Assessment of Conformity Assessment Bodies
- IAF/ILAC A3 IAF/ILAC Multi-Lateral Mutual Recognition Arrangements (Arrangements): Narrative Framework for Reporting on the Performance of an Accreditation Body (AB) - A Tool for the Evaluation Process
- IAF ML 2 General Principles on Use of the IAF MLA Mark
- IAF ML 3 Guidance for responding to Inquiries on Multilateral Recognition Arrangement (MLA) Signatory Equivalence and on the acceptance of certification documents
- IAF ML 5 Procedure for IAF Listing of Foreign Critical Locations (FCLs)/Foreign Premises (FPs)

Other Applicable Normative References

- VIM:1993, *International vocabulary of basic and general terms in metrology,*
- 9000 Quality Management Systems
- 15189 Medical Laboratories
- 17000 Terminology
- 17007 Use of standards in product certification
- 17011 Requirements for Accreditation Bodies
- 17020 Inspection Bodies
- 17021 Management System Certification Bodies
- 17025 Testing Laboratories
- 17065 Product Certifiers
- 19011 Guidelines for auditing Management Systems
- Guide 23 Methods to indicate conformity
- Guide 28 3rd party certification system for products
- Guide 53 Guide on use of MS in Product Certification
- Guide 67 Fundamentals of Product Certification