MP 07 - 03

SURVEILLANCE AND REASSESSMENT

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1. Purpose

The purpose of this procedure is to outline the processes for carrying out the surveillance and reassessment of NiNAS-accredited organisations.

2. Scope

This procedure shall apply to NiNAS' accreditation schemes.

3. Definitions

Definitions related to this procedure are given in A01-01 Definitions and Abbreviations Used in NiNAS Documentation.

4. Reference Documents

- ISO/IEC 17011:2017 *Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies*
- QM 1.0 NiNAS Quality Manual
- NiNAS Quality Policy Statement

5. General

This procedure is built largely on Procedure 6 – ACCREDITATION. A full activity is conducted of each accredited organisation within 22-24 months (2 years) from the initial assessment. Each 2 years is known as one accreditation cycle (AC). For the purposes of convenience a Surveillance Audit or Reassessment is referred to as an "activity" in this document. However, NiNAS does not carry out surveillance activity at the moment due to the 2-year accreditation cycle.

5.1 Planning an Activity

a) Organisations are advised at least six (6) months prior to their scheduled activity of the upcoming activity, and a date is agreed upon with the accredited organisation (AO), the assigned team members and NiNAS.
b) 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 by the Director of Accreditation for the agreement to assign the work;

c) Preference is given to one or all members of the team who have been on previous activities to this AO. Efforts are made to keep some of the same individuals on the team through a complete AC for continuity;
d) The choice and number of assessors assigned to the team is dependent on the programme, the technical areas of the scope (competencies required) and possibly the number of key locations;
e) In the same message, potential assessors are asked to advise NiNAS whether they have any existing or former link, such as having provided consultancy services, or competitive position between themselves and the AO being assessed;
f) Upon agreement of a date, a written notification is issued to all parties involved;

The Notification includes:

i. Confirmation of the dates and team members for the activity; The AO is advised of the individual names (and organisational representation of each) that will make-up the team; 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);
ii. The applicable *Requirements Cross Reference Matrix*;
iii. A request to submit the update package at least 30 days prior to the activity date including changes to management system documents and personnel which have been changed since the last NiNAS activity that affects the AO's conformance to the accreditation requirements;
iv. AOs that do not return application packages at least two weeks prior to the activity date will be advised that they are in jeopardy of having the date of the activity delayed and an administrative fee added;
v. Delays shall not exceed 60 days as suspension of accreditation shall be initiated;

Upon receipt of the AO's update package:

a) Administration staff log it into the NiNAS work-flow tracking system with the date of receipt.
b) The chosen assessors are provided with a *Task Assignment Form* for their signature which constitutes a clear description of, and their acceptance of the job;

5.2 Documentation Review

a) Upon receipt of signed *Assignment Forms* from all team members, the Lead Assessor is provided with a copy of the AO's update package 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 / activity reports, and other relevant documentation that will assist in the assessment.
c) The Lead Assessor completes the review of the 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) Any non-conformities are recorded as instructed on the *Corrective Action Request* Form;
e) The AO's conformity is reported in the *Document Review Checklist* for NiNAS records, as per instruction on the template;
f) 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;
g) *Corrective Action Request* forms are provided to the AO for their response as per the instruction and timeline provided in the *Document Review Cover Letter*.
h) Responses when returned from the AO are reviewed by the Lead Assessor within 5 working days; a rationale for any rejection of responses are provided to the AO but, without providing a solution to the problem;

5.3 Preparation for On-Site Activity

5.3.1 Plan

Using the Update Package and any other relevant information such as non-conformity resolution or complaint activity from the previous year, *Activity Plan* is developed by the Lead Assessor and approved by NINAS Program Staff.

a) For laboratories, all locations that perform activities covered by ISO/IEC 17025 are subject to the activity.
b) A copy of the *Plan* is sent to the AO and all members of the Team;
c) An opportunity is provided to all for questions.

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

a) 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;
b) 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 activity visits.
c) 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 AO.

5.4 On Site Activity

5.4.1 Team Meeting

Prior to the activity the Lead Assessor arranges for the team to meet to discuss information obtained and the findings from the document review. The Lead advises each member on their role and any expectations specific to the activity such as the probing of a technical matter in regards to a complaint. The *Plan* is reviewed and team members are given the opportunity to ask any procedural questions.

5.4.2 Communicating during the activity

Following an on-time arrival at the site, the Lead organizes with the AO's contact to conduct an opening meeting with the AO's management and staff to:

a) Clearly communicate the purpose of the of the activity and the accreditation criteria being applied;
b) confirm the agreement of all parties (AO and activity team) to the activity plan;
c) introduce the activity team and the AO's staff;
d) ensure that all planned activity activities can be performed; and,
e) Provide an opportunity for the AO's personnel to ask questions.

Attendance at the opening meeting must be recorded on the *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 AO's representative to keep the AO up to date on progress and concerns if any.

Concerns about an issue outside the activity scope such as a Health and Safety hazard should be noted and reported to the activity team leader, for communication to the AO. Any such issues raised must recorded and submitted to NINAS program staff.

Where the available evidence indicates that the activity's objectives are unattainable, the team leader should report the reasons to the AO and to NINAS program staff for advice. Advice may result in a modification to the plan, objectives, to the scope or objectives, or it may even result in termination of the activity.

5.4.3 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 activity may be deemed invalid. As such the Team Leader can remove observers from taking part.

The Lead Assessor may request that the AO 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 activity team members and observers; and,
d) provide clarification or assisting in collecting information.

5.4.4 Collecting and verifying information

a) Only information that is verifiable is accepted as evidence and recorded for both conformity and non-conformity using the *Assessment/Activity Reporting* Template and the *Corrective Action Request Forms* provided by NINAS;
b) When a non-conformity is identified appropriate sections of the Corrective Action Request Form are completed;
c) 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;

d) When identifying a non-conformity, confirm an understanding of the evidence with the AO.
e) If, during the activity 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.

5.4.5 Generating findings

a) The Team must schedule debriefings at appropriate stages during the activity to discuss progress as well as any findings.
b) Technical experts on the team must have all non-conformities reviewed by the Lead Assessor. The Lead Assessor must ensure that the statements of non-conformity written by Technical Experts are accurate and appropriately drafted, or the Lead should write the statements based on the evidence provided by the expert;
c) Non-conformities should be reviewed with the AO to obtain acknowledgement that the evidence is accurate, and that the non-conformities are understood;
d) Teams should identify opportunities for improvement without recommending specific solutions;
e) Every attempt should be made to resolve any diverging opinions concerning the activity evidence or findings, and unresolved points should be recorded and provided to the appropriate NINAS Director.

5.4.6 Preparing conclusions

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

a) review the findings, and any other appropriate information collected during the activity, against the objectives;
b) agree on the conclusions, taking into account the uncertainty inherent in the process;
c) discuss activity follow-up, as applicable.

5.4.7 Conducting the closing meeting

The Lead Assessor chairs the closing meeting and presents the findings to appropriate management and AO 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 Lead Assessor advises the AO:

a) that the activity evidence collected was based on a sample of the information available;
b) about post-activity 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 AO'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 AO 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 AO should be discussed and, if possible, resolved. If not resolved, the matter should be recorded and reported to the appropriate NiNAS Director.

5.4.8 Preparing and distributing the Report

a) The Lead Assessor completes the NiNAS Assessment / Activity Report Template normally within 10 working days of the activity; contents are complete, accurate, concise and clear and the report forms a record of the assessment;
b) The report is submitted to NiNAS accreditation staff;
c) Upon receipt accreditation staff review the report and it is sent to the AO under the *Assessment / Activity Report Cover* letter to indicate response requirements if any.
d) The content of the assessment report is the property of NiNAS.

5.4.9 Completing the activity

a) Corrective Action Request Forms, containing the AO's responses are submitted by the AO to the Lead Assessor for review;
b) The Lead Assessor reviews the responses for acceptability in consultation with the Technical Experts as applicable;

c) The Lead Assessor 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 AO to respond to Opportunities for Improvement;
e) The Lead has 5 business days to review the responses and advise the AO 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 organized between the AO, the Lead and the appropriate NINAS Director to determine a way forward;
h) If the non-conformances are judged by the Lead Assessor to be severe or significant in number, the Lead and the Director confer to determine whether a verification activity is necessary to maintain accreditation.
i) If maintenance of accreditation is deemed not possible due to non-conformance, suspension procedures are implemented.
j) If it is not possible for any of the above timelines in 6.4 to be met, the client is advised of the delay, the reason for such, and is provided with an updated estimate.

5.5 Decision Making

Following satisfactory resolution of any non-conformities, the Lead Assessor sends the complete documentation package to accreditation program staff with an indication that a decision may be taken on the file. Staff assemble the information necessary to provide to the decision-makers and ensure it is complete for decision-making purposes. Information (documentation) must include:

a) *Record of Decision* form with the requisite fields completed;
b) The *Report*(s) including any *Witness Report*(s);
c) The Non-conformities that were issued and the accepted resolutions to each;
d) For a laboratory a summary of its proficiency testing results;
e) Depending on circumstances any recommendations regarding the granting of a reduced scope, and the rationale for such; and,
f) Any other information that may be pertinent to the support of the decision.

The decision is made by a selection of three individuals chosen from the Accreditation Advisory Committee. Individuals shall have no prior relationship to the AO.

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 AO.

Should an accreditation decision lead to an unsuccessful outcome, the appropriate Director contacts the AO to explain the possible options that may be available; e.g. voluntary suspension, suspension or withdrawal. The outcome and the options are then provided to the AO in writing.

5.6 Issuance of Accreditation Documents

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

a) an *Accreditation Letter*;
b) a *Scope of Accreditation*;
c) an *Accreditation Certificate*;
d) an *Accreditation Agreement*;
e) a *Logo License Agreement*.

Upon Surveillance a letter is issued confirming *continuation of accreditation*.

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

5.7 Activity Wrap up

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

6. Forms

Table: 7-1 Forms in use with Procedure 7		
Form Number	Title	Applicable Program
F-7-001	Notification Letter	All Programs
F-6-006	Laboratory accreditation fee structure	ISO/IEC 17025
F-6-012	Task Assignment Form	All Programs
F-6-013	Document Review Checklist	Standard Specific
F-6-014	Corrective Action Requisition	All Programs
F-6-015	Document Review Cover Letter	All Programs
F-7-002	Plan Template - Laboratories	ISO/IEC 17025
F-6-018	Opening Meeting Agenda Template	All Programs
F-6-019	Assessment/Activity Attendance Form	All Programs
F-6-020	Assessment/Activity Report Template	
F-6-022	Record of Accreditation Decision	All Programs
F-6-023	Assessment/Activity Reporting Cover Letter	All Programs
F-7-003	Continuation of Accreditation Letter	All Programs
F-6-029	Client Feedback Form	All Programs

6. Document History

Modification No/Date	Proposed by	Page No.	Summary of Modification
30/04/2020	Quality Manager	All	Updated to meet the requirements of the 2017 version of ISO/IEC 17011
15/05/2024	Quality Manager	All	Updated to further meet the requirements of ISO/IEC 17011:2017

Table 7-1 List of Requirements by Program:

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 6-1 List of Requirements by Program: Laboratory Accreditation Program
Testing & Calibration Laboratories (ISO/IEC 17025)
• ILAC G8 Guidelines on Decision Rules and Statements of Conformity • 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 Describing of Scopes of Accreditation • ILAC G24 Guidelines for the determination of re-calibration intervals of measuring instruments • ILAC G26 Guidance for the Implementation of a Medical Laboratory Accreditation System • ILAC P8 ILAC Mutual Recognition Arrangement: Supplementary Requirements and Guidelines 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 Measurement Uncertainty in Calibration
Medical Laboratories (ISO 15189)
• All the above plus; • ILAC G26 Guidance for the Implementation of a Medical Laboratory Accreditation System.
Inspection Bodies (ISO/IEC 17020)
• ILAC P8 ILAC Mutual Recognition Arrangement (Arrangement): Supplementary Requirements and Guidelines for the Use of Accreditation Symbols and for Claims of Accreditation Status by Accredited Laboratories and Inspection Bodies • ILAC P9 ILAC Policy for Participation in Proficiency Testing Activities • ILAC P10 ILAC Policy on Traceability of Measurement Results
Management Systems Certification Bodies (ISO/IEC 17021)
• IAF MD 1Audit and Certification of a Management System Operated by a Multiple Sites Organisation • IAF MD 2 Transfer of Accredited Certification of Management Systems

- IAF MD 4 Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes
- IAF MD 5 Determination of Audit Time of QMS, EMS and OHSMS
- IAF MD 11 Application of ISO/IEC 17021 for the Audits of Integrated Management Systems (IMS)
- IAF ID 1 QMS and EMS Scopes of Accreditation

Certifiers of Persons (ISO/IEC 17024)

Product Certification Bodies (ISO/IEC 17065)

- No unique documents at this time

Documents Applicable to all types of Certification Bodies

- IAF MD 7 Harmonisation of Sanctions
- IAF MD 12 Accreditation Assessment of CABs with Activities in Multiple Countries (for Cross-Frontier Accreditation)
- IAF PL 1 Code of Conduct for Members of the IAF
- IAF PL 6 IAF Memorandum of Understanding
- ILAC G 21 Cross Frontier Accreditation
- IAF ID 3 Informative Document for Management of Extraordinary Events or Circumstances Affecting ABs, CABs and Certified Organizations
- IAF ID 4 Market Surveillance Visits to Certified Organisations
- IAF ML 1 Guidance for the Exchange of Documentation among IAF MLA Signatories for the Assessment of CABs
- 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

Other Applicable Normative References

- VIM:1993, *International vocabulary of basic and general terms in metrology,*

- 9000 Quality Systems
- 15189 Medical Laboratories
- 17000 Terminology
- 17007 Use of standards in product certification
- 17011 Requirements for Accreditation Bodies
- 17020 Inspection Bodies
- 17021 Management System certifiers
- 17025 Testing Laboratories
- 17065 Product Certifiers
- 19011 Guidelines on Auditing and Certification
- 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

(X ref with other list = in case not complete)