AFRICAN CONFORMITY ASSESSMENT PROGRAMME

CACO ACAP 1-4

Second Edition 2022

Conformity assessment — Part 4: Requirements for recognition/approval of testing and calibration laboratories

Commented [M1]: Replaced 'Regulations' with 'Conformity assessment'

Commented [LC2R1]: Agreed

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Commented [M4]: Added recognition/

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Reference No. ACAP 1-4:2022(E)
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ACAP 1-4:2022

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Foreword

The African Organisation for Standardisation (ARSO) is an African Intergovernmental organization made of Member States of the United Nations Economic Commission for Africa (UNECA) and the African Union (AU). One of the fundamental mandates of ARSO is the establishment of a conformity assessment system to promote the quality of African goods and services as a means of facilitating intra-African trade as well as accessing global markets.

The African Conformity Assessment Programme (ACAP) is supported by a coherent set of documents which are developed under the auspices of the ARSO Conformity Assessment Committee (ARSO CACO) which comprises experts from Member States. Member States participate in the committee on a voluntary basis and the documents developed follow the principles and procedures for the development of African Standards outlined in the African Standards Harmonization Model (ASHAM) with the exception of the stages and voting thresholds. Being conformity assessment instruments, ACAP documents are subject to dynamic adaptations which must timeously respond to changes in the conformity assessment fields.

ACAP documents will be revised on a flexible basis to fit in with changes in global conformity assessment systems.

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Introduction

This document specifies requirements, the observance of which is intended to ensure that testing and calibration laboratories conduct testing and calibration activities in a competent, consistent and impartial manner, thereby facilitating the recognition of such bodies and the acceptance of the testing and calibration results to enhance national and international trade

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This document describes the procedure for the approval of national and regional/continental testing and calibration laboratories hereafter referred to as laboratory willing to be recognized as approved laboratories for ACAP.

It summarizes the requirements which shall be met by a Laboratory, to be engaged in the calibration/verification and testing whose results will be relied on in the certification process for the ACAP and award of the ARSO Marks.

ARSO will grant approval or disapproval for the Laboratory seeking to become recognized for ACAP, based on the result of the assessment.

This document includes the rules to be complied with by National and International third-party Laboratories seeking recognition under ACAP.

There are some basic principles that represent a “Must” in the development of the ACAP, in order to make a product identified with the ARSO Mark more “Robust” and acknowledgeable by the interested parties:

(a) The level of control done by ARSO on the ACAP Testing or Calibration schemes in order to guarantee the effectiveness and integrity of the system.

(b) Independence and competence of the Laboratories involved in the process and the transparency of the schemes.

(c) Clear rules in order to guarantee and assess the competence of the Laboratories to carry out the required testing and/or calibration activities.

(d) Definition of sampling and testing methods and qualification of the dedicated personnel.

(e) Technical support for capacity building for all the involved parties.

(f) The Supply and traceability of samples and test or calibration results.

Interested parties can expect or require the Laboratories to meet all the requirements included in the ACAP rules applicable for testing or calibration scopes, as well as those of the specific ACAP schemes.

Parties that may have an interest in the ACAP schemes include, but are not limited to:

- the customers of the organizations whose products, processes or services are certified;
- governmental authorities;
- non-governmental organizations; and
- consumers and other members of the public.
- Certification and inspection bodies

Conformity assessment — Part 4: Requirements for recognition/approval of testing and calibration laboratories

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1 Scope

This document specifies requirements, the observance of which is intended to ensure that testing and calibration laboratories conduct testing and calibration required by the African Standards in a competent, consistent and impartial manner, thereby facilitating the recognition of such bodies and the acceptance of the testing and calibration results for the approval of certified products, processes and services on a national and international basis and enhancing international trade.

2 Normative references

The following referenced documents are indispensable for the application 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.

ACAP 1-1, Conformity assessment — *Part 1: General requirements for the certification systems*

ACAP 1-2, Conformity assessment — *Part 2: Special requirements for the certification systems* and standards design
ACAP1-3: Conformity assessment - *Part 3 Requirements for approval of certification bodies*

ISO/IEC 17000, *Conformity assessment — Vocabulary and general principles*
ISO/IEC 17011, Conformity assessment -Requirements for accreditation bodies accrediting conformity assessment bodies

ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*
JCGM 200, International vocabulary of metrology – Basic and general concepts and associated terms (VIM
JCGM 100 Evaluation of measurement data – Guide to the expression of uncertainty in measurement (GUM
IAF ID3, Management of extraordinary events or circumstances affecting ABs, Clients and certified organisations.(For guidance only)
IAF MD4, Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes (For guidance only)

3 Terms and definitions

For the purpose of this document the terms and definitions in ISO/IEC 17000, ISO/IEC 17025 and ISO/IEC 17043 standards shall apply.

ACAP Program Scheme

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4 ACAP Laboratory License agreement

The ARSO Laboratory License agreement is the document that establishes the rights and obligations of ACAP's responsible owner and coordinator of the Laboratories approved for testing and/or calibration activities within the ACAP various schemes.

The ARSO Laboratories license agreement, including its updates, shall be accepted, and signed by the Laboratories as part of the application procedure to become and to remain an ACAP approved Laboratory and to be listed as such on the ARSO website.

The License Agreement includes a complementary set of rules to be continuously complied with by the recognized Laboratories.

5 Laboratory approval process

In order to become a recognized Laboratory for ACAP, a series of requirements shall be fulfilled for approval and confirmed in time for approval and continued maintenance of the license agreement.

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Commented [EN16R15]: Comment accepted

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5.1 Preliminary entry requirements

To make an application to become a Laboratory recognized for ACAP, some basic requirements are necessary:

(a) The Laboratory or the organization of which it is part shall be a Legal Entity registered with a scope of services aligned to the testing or calibration scope expected, and/or may be a government entity with the mandate to provide the Testing and or calibration services

(b) The Laboratory shall be operating in the field of testing falling under the schemes covered under the ACAP schemes.

(c) For the Laboratory that is already accredited according to ISO/IEC 17025 with scope applicable for range of testing or calibration activity is included in the ACAP qualification when the accreditation body is ILAC /AFRAC recognized.

(d) In case the Laboratory is **not** accredited (see 5.1(c)), it shall be working according to ISO/IEC 17025 principles(specifically requirements listed in Annex A of this document).

A non-accredited Laboratory has up to 3 years to complete accreditation for the scope approved by ACAP, according to ISO /IEC 17025.

Commented [M18]: Can be removed as it does not add any value

Commented [LC19R18]: To merge with (d), it is important to keep

Commented [M20]: Merge with 5.1(d)

Commented [LC21R20]: Agreed, merged with (d)

5.2 ACAP provisional entry requirements

5.2.1 Application

The Laboratory shall complete the steps listed below before entering the phase of final approval that is explained in the following chapter.

(a) The applicant Laboratory (both accredited and un-accredited) shall register in the ACAP database as an applicant Laboratory, in order to receive all the information and documentation required for the application.

(b) The application shall be very clear about the field of activity (kind of testing, calibration) selected for the approval (ex: pesticide multi-residue testing on vegetables). The scope shall be clearly defined, and documentation must indicate the limits of capability where applicable

(c) Once the preliminary application is completed with all required information and documentation, it can be sent to ARSO Secretariat for evaluation and approval. A fee will be charged to the Laboratory for the evaluation of the application.

(d) At any point during the application process, if there is evidence of fraudulent behavior, or if the laboratory intentionally provides false information (or conceals important information), the application shall be rejected

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Commented [M25]: Replaced 'must' with 'shall'

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5.2.2 Pre-assessment

If the Laboratory applying for ACAP recognition is already accredited as per 5.1(c) above, and provided they meet the necessary and additional requirements of the License agreement – the facility shall not go through the pre-assessment phase (mutual recognition of schemes principles), and proceed to section 5.3

For those applicant laboratories without accreditation from mutually recognized Accreditation Bodies, during the pre-assessment of Laboratory's provisional entry requirements, the scope of the assessment will cover the following areas, and the assessment will be carried out against the criteria indicated as follows:

An examination of the Organization and Structure of the Laboratory. This requires the Laboratory to have:

- documentation of the organization identifying its legal status, name, addresse(es) or the locations (however named) at which they are currently operating;

- An organization chart, with clearly defined lines of responsibility and reporting;

- defined relationships between management system, technical operations, and support services;

- a clear description of the laboratory activities under calibration and/or testing carried out by the laboratory to ensure the consistent application of its laboratory activities and the validity of the results. This includes information on activities conducted at all locations including virtual sites

5.3 General Requirements for Laboratories approval on the ACAP scheme

In case of positive evaluation of the preliminary application and after paying the fees for the first evaluation, the applicant Laboratory will receive a request to complete the following steps:

5.3.1 Accreditation

(a) If ISO/IEC 17025 for the field of testing or calibration included in the ACAP scope is accredited , provide copy of a valid certificate (see 5.1(c)).

(b) If NOT ISO/IEC 17025 accredited for the field of testing or calibration included in the ACAP scope, the laboratory shall document and implement procedures and instructions, specific for non-accredited Laboratories, specified in Annex A.

(c) All Laboratories will have to document and implement procedures and instructions specific for implementation and management of the test or calibrations required by the ACAP Schemes and selected for the scope of application.

5.3.2 Laboratories License agreement

The Laboratory shall have a legally enforceable agreement for the provision of testing and calibration activities to be carried out for ACAP approval process. The License agreements shall take into account the responsibilities of the Laboratory, and its clients and will be enforced when all the evaluation activities are completed, and final approval is granted to the Laboratory.

5.3.3 Approved Laboratory Management team

The Laboratory shall demonstrate to have enough personnel, facilities, equipment, systems, and support services necessary to manage and perform its laboratory activities.to comply with the ACAP requirements and to effectively manage the implementation of the ACAP Testing and /or Calibration Process. It is possible for the same person to cover more than one task if the basic requirements for competence are covered.

Every Laboratory recognized for ACAP Testing and /or Calibration Process, shall nominate the following key staff, required for the implementation and maintenance of the testing process:

(a) Administration Manager

Every Laboratory recognized for the ACAP shall nominate one contact person, called the Testing and /or Calibration Administration Manager, who will be the representative of the Laboratory before the ARSO Secretariat for all issues regarding the testing and /or calibration activity related to the release of the final reports for use in the various ACAP schemes. This person:

- Should be fluent in AU official languages.
- Should be available full-time, i.e. not hired occasionally by the Laboratory, and be part of the operational and/or management decision-making process of the Laboratory.
- Should attend the annual Admin Manager (Update) meeting carried out directly by ARSO
- Shall be responsible for receiving and implement actions according to specific requests coming from ARSO and to update interested parties about changes or amendments related to the ACAP. This also includes registered/certified Producers, when required.

(b) Technical Manager -ACAP Activities

All recognized Laboratories shall have a Technical Manager or a person with overall responsibility for the technical operations and the provision of the resources needed to ensure the required technical competences and quality of work from the laboratory operations are in line with ACAP scheme requirements.

The Technical Manager shall

- be available full-time, i.e. not hired occasionally by the Laboratory.

Commented [M27]: final

Commented [EN28R27]: Comment accepted

- take into consideration the specific requirements stated in the ARSO license agreement as well as in the ACAP testing specification while implementing the Laboratories internal quality and testing procedures

- be required to attend the specific Laboratory Technical Manager training, organized by ARSO, and pass the final exam.

- After qualification, be expected to attend a “refresh” one day training every two years or more often if required by ARSO or in case of a significant review of the Certification Scheme.

The Technical Manager shall be responsible for:

- Providing accurate and updated technical interpretation of the requirement of ACAP

- Supporting other Laboratory functions involved in testing for ACAP certification for any issue related to technical interpretation of the Standards (including ARSO Admin Manager)

- Assuring that all the personnel involved with the ACAP testing program complies with the internal qualification criteria approved by ARSO.

- Organizing and deliver training to all the Laboratory personnel about ACAP requirements (based on ARSO documentation, guidelines, and training material)

- Cooperation with and support the Laboratory’s ARSO Sampling and Testing Responsible persons

- Where required, evaluate, and provide expert opinion for request of sanction to be applied by certified Producers (example: Suspension or withdrawal of use of ARSO Mark, related to analytical issues)

(c) Sampling Program Manager

Sampling capability: The Laboratory can agree and coordinate with the client/ producer/ certification body about carrying out of the sampling services, to be delivered on-site during ACAP certification process.

In this case, the Laboratory shall have the necessary resources to carry out all activities associated with the sampling services. The sampling staff shall be technically qualified and have the ability to apply the necessary statistical techniques in sampling work.

The ACAP recognized Laboratory shall have a person responsible for implementation of the sampling activity, as a part of the testing activity carried out by the Laboratory. The Sampling program manager reports to the Technical Manager. The Sampling Program Manager responsible is in charge for

- Plan and coordinate the sampling of products in agreement with the ACAP approved certification body in charge for the specific Producer’s certification, and according to specific requirements from the different product certification Schemes and Standards.

- Supervise the correct implementation of the sampling procedures, including conservation and transportation of the products and traceability of the samples.

- Prepare sampling reports and deliver copy to the Producer, the Laboratory, and the Laboratory operational site.

- Receive specific training on ACAP scheme and on the specific ACAP Certification Scheme, as well as the specific sampling methods to be applied when sampling for an ACAP certification.

(d) Laboratory Technical and Administration team

Verifying capability: The Laboratory shall have the necessary resources to carry out all activities associated with the testing and calibration services.

- In order to carry out testing for ACAP, the Laboratory shall employ/contract only personnel that fulfil the requirements set for internal qualification set by the Laboratory and approved by ARSO according to specification from accreditation and/or Annex A.

- Every Employee shall comply with the requirements set for the operations under their responsibility.

- The Laboratory shall have documented procedures to assess the working team competence.

- Where the testing work is sub-contracted to an outside Laboratory, the ACAP recognized Laboratory shall be responsible for selecting either another Laboratory ACAP approved for the specific tests sub-contracted or a Laboratory ISO / IEC 17025 accredited for the scope subcontracted. The verification of the competency of the sub-contractor shall be documented and evidences of this verification available to ARSO on request.

Commented [M29]: Replaced 'must' with 'shall'

Commented [EN30R29]: Comment accepted

- Where a testing activity is subcontracted to a different laboratory, this has to be agreed with ARSO and communicated in writing to the certification body responsible for the product certification and to the Producer. The test subcontracted and the name of the sub-contracted Laboratory shall be specified.

Commented [M31]: Replaced 'must' with 'shall'

Commented [EN32R31]: Comment accepted

- If the subcontracted test implies additional costs, above what the ACAP fee table established for specific testing, this shall not increase the cost for the Producer. Special situations can be discussed with ARSO Secretariat on case-by-case bases.

- Laboratories shall commit to respect the rules for independence, impartiality as part of a written contract. They shall also assure the same for all the internal and external personnel relevant for ACAP scheme and under the Laboratory's responsibility.

- A review of the Laboratory personnel, including a validation of their performances and technical knowledge, for tasks relevant for ACAP testing, is part of the approval process.

- To be approved, the Laboratory shall provide detailed evidences for qualification of at least 2 technical staff able to carry out the testing activity and to validate and verify testing results.

5.4 Verification and approval for ACAP

The final approval of a Laboratory for delivering testing and calibration testing within ACAP, depends on the successful finalization of the following steps:

(a) Document review: the ACAP Committee verifies and approves the compliance of the documentation provided by the Laboratory. All Non- Conformities and observations raised during the document review must be satisfactory closed and approved by ARSO before proceeding with the approval process. For laboratories already accredited to ISO/IEC 17025 by mutually recognized bodies, focus shall be only on the additional ACAP requirements.

(b) On-site verification: the ACAP Assessor verifies and approves the Laboratory by verification of the laboratory management and testing and/or calibration activity done by the laboratory on each one of the testing methods applied, as required by ACAP Standards. For laboratories that are accredited to ISO/IEC 17025, depending on the outcome of document review the initial on-site verification may be skipped.

All Non-Conformities and Observations raised during the on-site verification must be satisfactory closed and approved by ARSO before proceeding with the approval process.

(c) In case of successful completion of the previous steps or after closure of all Nonconformities and Observations, ARSO ACAP Administrator communicates to the Laboratory the formal approval as ACAP qualified Laboratory, for the required set of tests.

(d) After approval, the Laboratory signs the ARSO – Laboratory License agreement.

5.5 Termination of approval for an ACAP Laboratory

5.5.1 Termination Requested by the Laboratory

In case an ACAP recognized Laboratory requests the termination of ARSO License agreement, the following actions shall be taken:

(a) The Laboratory shall send a formal termination request to ARSO with specification of the timeframe for closing the contract. The minimum given timeframe is of 90 days from the formal communication to ARSO.

(b) The Laboratory shall inform all clients and laboratories of the termination of the ARSO License and that it will not be any more approved for delivery of testing and calibration service for ACAP product certification. The minimum timeframe to be given for communication to the clients and Laboratories is 90 days.

(c) From a specific date onwards, the Laboratory shall be removed from the ARSO system and will not be allowed to accept new samples for ACAP testing.

(d) The certificates of analysis/reports released by the Laboratory during the period of validity of the ACAP License, remain valid for evidence of compliance of the certified products.

5.5.2 Termination done by ARSO

(a) Refer to clause 8.7 of this document

Commented [M33]: Include in definitions and organization structure

Commented [LC34R33]: Agree

Commented [M35]: Rearrange to be ISO/IEC

Commented [EN36R35]: Comment accepted

Commented [M37]: Include in definitions

Commented [LC38R37]: agree

Commented [M39]: Add section on termination by ACAP as 5.5.2

Commented [LC40R39]: Agree. Section 5.5.2 added, but only reference section 8.7 which explains the sanctioning process

Commented [LC41R39]: Termination done by ARSO, not ACAP

Commented [M42]: ARSO? or ACAP licence?

Commented [LC43R42]: It is ARSO license

6 Management System requirements for ACAP implementation

The Laboratory shall establish and maintain a management system that is capable of achieving the consistent fulfilment of the requirements of the ACAP scheme, in accordance with requirements in Annex A of this document.

It is the responsibility of the laboratory to carry out its testing and calibration activities in such a way as to meet the requirements of the ARSO Standards and to satisfy the needs of the customer, the regulatory authorities or organizations providing recognition.

The management system shall cover work carried out in the laboratory's permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities.

(a) The management system of the Laboratory shall include the ACAP scope and all the related testing and/or calibration activities approved for the Laboratory. The following shall be addressed:

(i) general management system documentation and records (e.g. manual, policies, definition of responsibilities)

(ii) control of documents

(iii) control of records

(iv) contract review

(v) Purchasing services and supplies. Incoming of materials

(vi) sub-contracting of tests and calibration work

(vii) complaints management

(viii) Control of nonconforming testing and/or calibration work

(ix) corrections and corrective actions

(x) internal audit

(xi) Management Review

7 Additional requirements for ACAP implementation

Where applicable, specifications regarding ACAP testing activity special provisions shall be included in the Laboratory documentation, such as:

- ACAP Related duties and responsibilities of the staff;
- As per list in annex A

Commented [M44]: These requirements are also outlined in Annex A

Commented [LC45R44]: Agreed, replaced with annex A

8 Assessment process for Laboratory approval

8.1 Document review and on-site verification preparation

Prior to carrying out the assessment of Laboratory for first approval for ACAP accreditation, the ACAP Committee:

(a) Will assign to an ACAP Team Leader and the Panel of Assessors the evaluation of any observations resulting from the review of the Application Form and the supporting documentation submitted by the Laboratory.

(b) The ARSO Secretariat will brief the ACAP Team Leader on any logistics of the operation.

(c) The ACAP Team Leader, and other nominated members of the Panel of Assessors, will review the documentation prior to carrying out the assessment, and will update the assessment documentation according to the information received.

(d) The Team Leader will produce a Program for the on-site verification, and this will be submitted by the ARSO Secretariat to the applicant Laboratory, at least two weeks before the scheduled date of the commencement of the assessment.

Commented [M46]: Would be better if this activity was assigned to ACCAP body under ARSO Secretariat. Consider including in the ARSO structure or ARSO should collaborate with AFRAC

Commented [LC47R46]: Replaced and proposed ACAP Committee

8.2 Laboratory approval assessment

Following the review of the Laboratory documented system (the System Assessment), the next important phase of the assessment is to observe the Laboratories activity on-site. This will be carried out in two basic areas.

8.2.1 Assessment at the Management System(MS) of the Laboratory

During the MS assessment, the assessors will verify the implementation of the Laboratory MS, the effectiveness of the system, the competence of its administrative staff, and in particular, its ability to meet the Rules of the ACAP scheme. Remote auditing can be done for assessing management system requirements, however requirements from relevant guideline documents shall be adhered to.

8.2.2 Closure of MS non-conformities

(a) After the MS assessment and within a timeframe that cannot exceed 3 months, the Laboratory will provide an action plan with proposal of possible corrective actions to be implemented for the findings raised during the audit.

(b) The ACAP Team Leader will evaluate the action plan and, according to evaluation may approve the proposed corrective actions or require further improvements.

(c) Within 3 months from the closure of the MS assessment, a follow up is carried out to verify the implementation of the corrective actions. According to the number and kind of findings and corrective actions to be evaluated, the ACAP Team Leader will decide if a follow up on-site is required or it will be possible to verify documental evidences with a desk review.

(d) In case a follow up on-site is required, only after all non-conformities have correctly addressed it is possible to proceed with the assessment of the technical implementation of the testing and calibration activity

In case of Laboratory already accredited for ISO / IEC 17025, the specific ACAP requirements shall be assessed with consideration of the integration of the ACAP rules and commitments within the MS of the Laboratory

8.2.3 Verification of technical activities during on-site Assessment

The ACAP assessor will verify the implementation of the testing activity in relation to the specific management and execution of the analytical verifications included in the scope of accreditation. If the Laboratory is already accredited for the specific test method required by the ACAP Standard, the verification will be limited to specific aspects related to the implementation of specific ACAP standards requirements, such as sampling, traceability and documentation and presentation of the final results. The preferred method shall be on-site assessment, and remote assessment shall be done only when faced with extraordinary events. Virtual assessment will not be conducted for initial assessments.

8.3 Final evaluation and classification of findings

A final Report, including a list of all the findings with specific references to the requirements that have been infringed, is prepared by ACAP Team Leader to record areas for continual improvement and/or where non-conformities against the ACAP requirements were identified.

Non-conformances are classified into two types identified as major and minor.

Other type of non-compliances or deviations can be highlighted for continual improvement but without having an immediate impact on the final evaluation of the Laboratory.

8.3.1 Major non-conformance

A Major non-conformance is allocated for a significant failure to comply with the ACAP Rules, or with the Laboratory's own Management System Manual.

Examples would be:

- Lack of independence and transparency of the third-party testing program;
- Non-availability of procedure and instructions for a specific ACAP test operated by the Laboratory
- Failure to adequately qualify subcontractors performing testing on behalf of the Laboratory.
- Failure to demonstrate competence of the key staff.

This kind of deviation results in the delay of the approval process at any step it is identified and requires for the Laboratory to prepare a corrective action plan to be approved by ACAP Committee. After the approval of the action plan, an on-site follow-up assessment is carried out.

During the approval process, it is not possible to progress to the next step with an open Major NC. (example: if one Major NC is raised during MS assessment, it is not possible to proceed to the technical activities verification without previously closing the Major NC)

8.3.2 Minor non-conformance

(a) A Minor non-conformance is raised for an isolated failure to comply with the ACAP Rules, Standard requirements or with the Laboratory own Management System Manual, or if a series of minor but related discrepancies are observed, which together are judged to be an unacceptable quality risk, without constituting an overall system failure in the area concerned.

(b) This kind of deviation results with the delay of the final approval process and require for the Laboratory to prepare a corrective actions action plan to be to be approved by the ACAP Committee.

(c) After the approval of the action plan, it is possible to proceed to the next step for approval. Minor nonconformities do not require the follow up assessment to close the nonconformity before approval.

(d) During the approval process, it is possible to progress to the next step with an open Minor NC. The closure of all Minor NCs will be necessary before receiving final approval (example: if one Minor NC is raised during MS assessment, it is possible to proceed to technical activities verification without previously close the Minor NC).

8.3.3 Observation

(a) One or more partial failures to fulfil requirements of the following types:

- Formalities / documentary (in the interpretation of a requirement of ACAP and / or in the formalisation of the quality records);

- Operational (in the application of the requirements of ACAP and / or the documentation of the system); these should not, however, raise doubts about the real effectiveness of the system (the ability of the system to provide a report in compliance with the major and minor Control Points and relate Compliance Criteria)

(b) This kind of deviation neither delays the approval process nor requires the Laboratory to prepare a corrective actions action plan to be sent for approval of the ACAP Team Leader

The observation should be managed by the laboratory for improvement purpose and to prevent likely escalation into a nonconformity if not addressed.

8.4 Rules for non-conformances closure

The rules for management and closure of findings, including the timeframe to be applied are reassumed in table 1.

Table 1 — Rules for non-conformance closure

Activity	Management of findings		
First Laboratory Approval	**Major NC**	**Minor NC**	**Observation**
Document Review	Follow up 90 days	Follow up 90 days	None
MS verification	Follow up 90 days	Action plan 90 days	None
Technical verification	Follow up 90 days	Follow up 90 days	None
Subsequent Surveillances	**Major NC**	**Minor NC**	**Observation**
MS verification	Follow up 30 days	Follow up 90 days	None
Technical verification	Follow up 30 days	Follow up 90 days	None

8.5 First Laboratory approval verification

The final report, including the team's overall conclusions and recommendations, is prepared by the Team Leader, and is submitted to ACAP Committee.

If requested, the Team Leader may attend a meeting with the ACAP Committee, to answer any points of clarification concerning the report.

8.5.1 Factors affecting first approval

In deciding on his recommendation, the Team Leader will first consider the adequacy of the Laboratory's management systems and how it is implemented, with regard to the ACAP scheme requirements.

The Team Leader will report on the range of knowledge and experience on the part of the Laboratory staff, in the light of their scope of operations. The Team Leader will also take into account the number and seriousness of the individual non-compliances found during the assessment.

Where competence is established, and no non-conformances are found, or where they are few and have been closed out before the Final Closing Meeting, the Team Leader will normally recommend the approval of the Laboratory for the specific ACAP testing scope for the requested scheme.

Where this is not the case, and some non-conformances are still outstanding at the Final Closing Meeting, a date for their close-out will be agreed. The period allowed is specified in Table 1.

If the ACAP Committee has some concerns over the report findings, they can request an extraordinary extension of the assessment, which is then taken into account with the initial report, or can increase the normal frequency of periodic assessments/surveillances until the Assessment team is satisfied that the Laboratories' performance is acceptable.

Where competence is not established, or where the number and seriousness of the non-compliances found is such that the whole of the laboratory system and facilities are demonstrably inadequate, the ACAP Committee shall not grant the approval status to the applicant laboratory.

8.6 Maintenance of the status of recognized Laboratory.

8.6.1 Laboratory annual surveillance

The status of recognized Laboratory, needs to be re-confirmed annually by means of the following activities:

(a) The recognized Laboratory re-confirms the validity of the ISO/IEC 17025 accreditation also for the subsequent year for the specified scopes and provide proof to ACAP Committee The appointed team will also assess how specific ACAP requirements are being addressed and will only focus on those ACAP listed scopes granted to the laboratory

(b) The Laboratory will have to comply with the requirements to maintain qualification of staff (e.g attending the annual refresher training for Technical Managers) or any other requirement specified in the general rules of the ACAP schemes that are in the scope of the ACAP approval and are not clearly specified in the present document.

(c) For the Laboratories that are not accredited for ISO/IEC 17025, ACAP team of assessors will carry out an annual surveillance assessment including Management System and technical activity implementation.

8.7 ARSO Sanctioning system

The ARSO Secretariat, together with the ACAP Committee has established the types and levels of sanctions described here. The most severe ones include the withdrawal of the ACAP License agreement and the impediment for the Laboratory to carry out testing or calibration on the ACAP scope. .

The sanctioned Laboratory can appeal against a sanction applied by ACAP Committee within 10 working days after the receipt of the sanction notification. The ACAP committee evaluates the appeal, and a separate team or members different from those that issued the initial sanction will be appointed to look at the appeal.

The second appeal against a re-confirmed sanction by the ACAP Committee follows the arbitration procedure as described in the License Agreement and in Annex A of ACAP 1-1:2022.

The termination of the ACAP - Laboratory License agreement, is the consequence of the application of a sanction to an ACAP approved Laboratory.

Two types of non-conformances can lead to sanctioning of Laboratories, and these are explained in detail under 8.7.1 and 8.7.2 below;.

8.7.1 Contractual non-conformances

Contractual non-conformances are at hand in the case that the Laboratory is not in compliance with contracts signed with ARSO. These may include, but are not limited to:

(a) Misleading or false communication on ACAP testing and logo use.

(b) Refusal to sign the License Agreement

Commented [M48]: Need for clarification

Commented [M49]: Sanctions an level are missing in this document and they are referenced in the reuirements here below

Commented [LC50R49]: Comment not clear, but there is clarity on major, minor and observations in the document

Commented [M51]: Consider to replace the term termination with withdrawal in clause 5.5 and related clauses

Commented [EN52R51]: Comment accepted

Commented [M53]: Which are the two types being mentioned here

Commented [LC54R53]: Agreed, explained

(c) Neglecting to pay any of the ARSO fees (e.g. Laboratory license fee, training fee).

(d) Confirmed fraud.

(e) Loss of accreditation (based on AB decision), which then requires ACAP Committee to assess the laboratory against Annex A as a new process altogether.

8.7.2 Non-conformances arising from assessments

Commented [M55]: Clarification is required on this type/title

Commented [LC56R55]: Agree, statement amended

During assessments, non-conformances may be raised against the laboratory. Depending on the category of the non-conformities, as well as failure to close the gaps within allocated timeframes, may lead to termination or withdrawal of the license agreement.. Example:

(a) Not participating in annual compulsory trainings.

(b) Not comply with the staff qualification

(c) Incomplete or late delivery of test's certificates.

(d) Unreliable testing or calibration data.

(e) Conflict of interest (e.g. consultancy for implementation and testing).

(f) Inadequate internal training.

(g) Do not carry out the external inspections.

(h) Not obeying Laboratory operational requirements and deadlines.

The ACAP Committee, shall be responsible for addressing these types of non-conformances.

Annex A
(Normative)

Special additional requirements for non-accredited testing and calibration laboratories
(Modified from ISO/IEC 17025:)

For laboratories not accredited against ISO/IEC 17025 the Management System and Scope specific technical requirements, as summarized in chapters 6 and 7of this document, must be documented and implemented.

The following ISO/IEC 17025 chapters to be implemented for ACAP qualification.

ISO/IEC 17025 Requirements	**ACAP specific requirements**
Impartiality	- Staff and all relevant parties to sign declaration confirming they commit to be free from both internal and external pressures - Laboratory must have risk register on identified risks/threats and relevant mitigation plans
Confidentiality	All staff and other stakeholders with access to important producer /client information to sign non-disclosure agreement with laboratory
Structural Requirements	- Legal documentation - Licence agreement with ARSO once approved - Clearly documented information showing ACAP scope approved and /or indicating which items sub-contracted - Technical Managers for ACAP related activities, Administration Manager for ACAP related activities, Sampling Program Manager for ACAP related activities and formally authorized personnel to conduct tests/ calibration activities for ACAP scope - For sites or mobile facilities, document deputizing of the functions above - Job descriptions for staff as above listing responsibilities , authorities, and requirements to be appointed - Quality manager to drive quality culture and any other responsibilities delegated by Technical Manager Risk and opportunities procedure & updated risk register for the laboratory
Resource Requirements-General	The laboratory must have management system aligned to Annex A, facilities, staff , equipment, and support services to ensure ACAP scheme requirements are met
Resource Requirements-Personnel	Procedure and records for; - Personnel competence requirements and evaluation - Selection of personnel, training on ACAP scheme requirements, supervision, and authorization to conduct ACAP scheme related activities - Job descriptions specifying competence requirements, responsibilities, and authorities as well as confirmation all were made aware of the job descriptions - Job descriptions to include commitment to be impartially and keep information confidential, maintenance competence to work according to ACAP

	scheme requirements, the ability to evaluate the significance of deviations - Monitoring of personnel and the records. annual monitoring plan for personnel, by competent staff.
Resource requirements-Facilities and Environmental conditions	Ensure the facilities and environment conditions are suitable to conduct the ACAP scheme related activities - Ensure there is documentation clearly showing the necessary facilities and environmental conditions for each ACAP scheme laboratory related activities - Monitoring of the laboratory conditions is recorded, controlled as necessary - If activities done also at sites or remote sites, ensure same controls applied Consistency important for all activities whether done inside laboratory or other sites
Resource Requirements-Equipment	- list of all software, reference data or materials, measurement standards, consumables , instruments, and apparatus used for ACAP related activities - List of staff that can access and perform tests on equipment - Procedures for maintenance, transporting, in service checks, calibration and routing maintenance - Calibration program for all critical equipment - Prevent use of defective equipment - Investigate through corrective action procedure if equipment found to have been defective - Maintain records for equipment that could impact the validity of results. identity (name, serial number, manufacturer, where used,etc), maintenance program(to cover malfunction, damage, modification or repairs), calibration records (accredited service providers) including reference materials
Resource requirements-metrological traceability	- Equipment identified to be critical, must be calibrated and be traceable to international standards - Each calibration is linked to appropriate refence - Measurement uncertainty is available - Use of laboratory accredited to conduct calibrations Certified reference materials from competent producer
Resource requirements-Externally provided products and services	-If using another laboratory, ensure it is approved by ARSO and for the scope subcontracted - Clear communication of requirements to the service provider , and to include acceptance criteria and how it will be done or who shall perform the activity - Procedure for selection, evaluation, and monitoring and how the products or reports will be checked if they meet agreed requirements before the laboratory accepts them -
Process requirements-Review of requests, tenders and contracts	The laboratory shall be able to confirm that there was communication and cooperation as shown by; - Clarifying requests of what is needed - Making sure there is clarity what ACAP scheme requirement is tested for - Obtaining the permission of Certification body/producer if any subcontracting is to be done first

	- Informing CB/producer if there is any deviation of initial agreement - Reviewing contracts by Technical manager -ACAP related activities if there are any changes - Monitoring performance of performed work - allowing CB/producer reasonable access to witness specific activities related to their contract Assist CB/producer with any items needed for verification
Process requirements-Selection, verification and validation of methods	- Apply relevant tests as required by ACAP scheme and ensure it's the latest version - Plan development for any ACAP scheme related methods if need - Assign method activities to only formally authorized personnel - Use appropriate methods and procedures for validation, the evaluation of the measurement uncertainty, and statistical techniques for analysis of data - Verify that method works before introducing it - Validate methods developed or modified by the laboratory, non-standard methods and standard methods where scope is changed - Determine the influence of any changes to a valid method - Retain records of validations
Process requirements-Sampling	The Sampling program manager shall be responsible for all sampling activities
Process requirements-Handling of test or calibration items	-List or register for all calibration or testing items (ACAP related activities) -procedure for handling of test or calibration items including their transportation and receipt at the laboratory. -their storage, protection during use, retention and/or return or disposal once activity completed - protect the integrity of test or calibration items - follow handling instructions, when provided - record any deviations from specified conditions on receipt of the test or calibration item - uniquely identify all test or calibration items and retain the identification while being used or retained in the laboratory - identify, maintain, monitor, and record storage or conditioning requirements when items must be stored or conditioned
Process requirements-Technical Records	Technical records irrespective of format include; - Formal authorization records-including dates, for personnel responsible for each activity - Report of results, including the raw data, rough calculations - Suitable information to assist with determining aspects that affect measurement uncertainty and to allow for repetition of activities under conditions replicating the original - Clear records and traceability of any amendments from original observations or versions, including the person responsible for the amendments, the date, and what changes were made

Process requirements-Evaluation of measurement uncertainty	Procedure for evaluation of measurement uncertainty for ACAP scheme related testing or calibration activities
Process requirements-Ensuring the validity of results	Procedure for quality control activities, for the ACAP scheme related activities-internal checks, tests, correlations, and comparisons that are included - Monitoring schedule or peer review plan - Intra laboratory activities plan - Interlaboratory schemes for the ACAP related tests or calibrations Participation in proficiency testing schemes if available
Process requirements-Reporting of results	The laboratory must have a controlled format for reporting results - All results to be reviewed and authorized before release by ACAP scheme approved Managers - Results are unambiguous, objective, and accurate - Meet the content requirements - Indicate which data was supplied by producer/client - Place disclaimer on the report if customer supplied information could affect the result validity - Specify that results apply to specific same received -as received-, when the laboratory was not responsible for sampling - Decision rule on any issued conformity statement - Clearly marked any expressed interpretations and /or opinions reported that are associated with the tested or calibrated item results - Identification of any re-issued, changed, or amended reports and any changed information Refence original report if totally new report was issued after amendments
Process requirements-Complaints	Procedure for managing complaints and/or appeals - Keep complaints register - Address complaints timely Allow independent staff to investigate complaints
Process requirements-Nonconforming work	Procedure for treating non-conforming work, when tests or calibration not done as per customer requirement or laboratory process
Process requirements-Control of data and information management	-Applies to both computerized and non-computerized system data and information; - Validation of all LIMS including interfaces for functionality - authorize, document, and validate changes before implementation -operate LIMS according to the laboratory specifications to safeguard integrity of data and information - protect the system from unauthorized access - provide safeguards against tampering or loss - check data transfers and calculations in an appropriate and systematic manner - ensure any subcontracted LIMS complies with your system

END……