

	<b>Guidelines on the Assessment of Conformity Assessment Schemes</b>	<b>Document No:</b>	<i>EK 031</i>
		<b>Release Date:</b>	<i>22-03-2017</i>
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## 1. PURPOSE

The purpose of this guideline is to determine the qualifications that a Conformity Assessment Scheme must have in order to be eligible for accreditation and to explain the methods and requirements to be followed in the assessment of these qualifications.

## 2. SCOPE

This guideline covers the processes and requirements for evaluating the accreditability of APAC MLA level of schemes in the voluntary area (unregulated area) applied under the Level 2 accreditation standard (ISO/IEC 17025).

This guideline is not mandatory for legally regulated national or international schemes and schemes prepared for APAC Directives. However, if necessary, legally regulated national or international schemes and schemes prepared for APAC Directives may also be evaluated in accordance with this guideline.

This guideline and APAC documents are specifically designed for a Conformity Assessment Scheme belonging to an identifiable scheme owner who has a contractual agreement with the conformity assessment bodies that will operate the scheme in question.

If the scheme owner is a CAB that requests accreditation only for a conformity assessment scheme (if not a multinational conformity assessment scheme) to be operated in areas that are duly covered by the conformity assessment standards (accreditation scope), it is not mandatory to apply it completely according to this guide and the APAC document. However, the suitability of such conformity assessment schemes shall be evaluated according to APAC documents both at the stage of review of documents and records and at on-site assessments. Both RP 003 Document and Record Review Report and FR 112 Conformity Assessment Scheme Assessment Control Form will be used by the assessment teams to evaluate such schemes during the document and record review stage. Additional assessment fees related to this assessment will be invoiced to the scheme owner during the document and record review process.

National conformity assessment schemes accepted before the date of the first revision of the APAC document are not required to be evaluated in accordance with the procedure set out in this guideline, provided that they remain at the national level.

## 3. PREREQUISITES FOR THE SCHEME OWNER

In order for a scheme owner's application to be evaluated by NAC, the scheme owner must meet the following requirements:

- a. The scheme owner must have a legal entity.
- b. The scheme owner must have the authority to determine and change the requirements of the conformity assessment scheme.
- c. The scheme owner must have the authority to cooperate with NAC.
- d. The scheme owner must be able to demonstrate that sector support is provided for the conformity assessment scheme it offers (Product/Process/Service/System/Person). The scheme owner must be able to provide evidence that shows this support.
- e. The conformity assessment process defined or selected by the scheme owner should fall under the scope of the ISO / IEC 17025 standard, which is among the MLA Level 2 standards defined in APAC documents. (APAC MLA Level 2 standard is harmonized standards and includes the accreditation standards served by NAC.)
- f. The conformity assessment process defined or selected by the scheme owner should fall under the scope of the relevant standard.
- g. The requirements stipulated by the scheme owner to CABs must not contradict or exclude the relevant requirements of the conformity assessment standard.
- h. Scheme-specific requirements related to the accreditation body should not contradict or exclude any provision of the EN ISO/IEC 17011 Standard, other relevant APAC mandatory documents, where applicable, or the International Laboratory Accreditation Cooperation (ILAC), International Accreditation Forum (IAF) documents required by APAC.
- i. The requirements of voluntary conformity assessment schemes should not consist solely of the fulfillment of legal requirements and should not conflict with legal legislation.
- j. The scheme owner must undertake to accept the results from CABs accredited by any accreditation body that has signed an MLA with APAC and that follows the requirements set out by the scheme owner.
- k. The scheme owner must show that the conformity assessment scheme is validated. Validation must be documented and include the following:
  - Description of the purpose of the scheme
  - Description of the requirements of the scheme
  - Analysis of compliance with these requirements
  - Description of methods used to determine that requirements are met
  - Analysis of the suitability of these methods
  - Decision on the conformity assessment activity to be used (including the determination of the conformity assessment standard)
  - Analysis of the suitability of the selected conformity assessment activity

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- l. The scheme owner must reserve the right to use the scheme only to accredited CABs that have signed an agreement with the owner. This agreement must at least guarantee that CABs shall use the scheme as it is, without any restrictions or additions.
- m. The scheme owner is obliged to inform the relevant accreditation body and CABs about all necessary information and developments related to the conformity assessment scheme, including the proposal for changes to the requirements.

## **4.APPLICATION**

### **4.1 Application Documents**

If the scheme owner wishes to apply for a Conformity Assessment Scheme, the necessary information for application can be obtained at [www.nac-us.org](http://www.nac-us.org) or through the relevant accreditation head.

The application for the Conformity Assessment Scheme is made by filling in FR 111 Conformity Assessment Scheme Application Form and the documents and forms specified in detail in this form, signed by the person authorized to sign and represent, and by sending them to NAC.

The scheme owner must submit to NAC at the time of application all records showing that the requirements in each item in the FR 112 Conformity Assessment Scheme Assessment Control Form are met.

Separate applications must be made for each Conformity Assessment Scheme.

### **4.2 Scope of Conformity Assessment Scheme**

The applicant scheme owner must clearly define the scope of accreditation related to the application in FR 111 Conformity Assessment Scheme Application Form.

### **4.3 Receipt and Review of the Application**

The relevant Deputy General Secretary appoints a case officer (hereinafter referred to as the personnel in charge) to carry out the operations related to the application. The appointed personnel in charge quantitatively reviews the application form and attached documents sent to NAC, and after the review, if the application is considered insufficient and there is a need for the body to provide more information, the body is requested to send to NAC the missing documents/information.

If the application is accepted, a file number is assigned and all procedures in the assessment process are followed by this file number. Information about the acceptance of the application is notified to the applicant by e-mail.

If the review conducted by the personnel appointed by the relevant deputy general secretary results negatively, the decision to reject the application is notified to the applicant with a letter.

## **5. ASSESSMENT OF THE SCHEME**

### **5.1 Review of the Scheme by the Assessment Team and Decision**

Prior to the assessment of the conformity assessment scheme, the scheme owner must undertake in writing to work in cooperation with NAC until the assessment is complete and to not contact other APAC member accreditation bodies regarding the assessment of the conformity assessment scheme. Otherwise, the assessment process shall be terminated. The scheme owner must also inform NAC whether there is an application made to another accreditation body for the same conformity assessment scheme in the past (in this case, the application result should also be notified) or concurrently.

The limits intended for the execution of the conformity assessment scheme should be specified. If it is not specified at the time of application that the scheme is intended to be conducted in APAC member states outside the country, the conformity assessment scheme will only be evaluated at the national level. NAC's decision on the current situation may vary in the event of an expansion of the geographical boundaries in which it operates.

The fact that NAC decides that a Conformity Assessment Scheme is accreditable does not mean that it makes a judgment on the technical strength of the conformity assessment scheme, its market value, or the usefulness of the technical requirements of the scheme. The responsibility for the technical strength and acceptance of the conformity assessment scheme in the market lies entirely with the scheme owner.

If the conformity assessment scheme has additional requirements along with requirements of ISO/IEC 17011, APAC mandatory documents

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and IAF or ILAC documents required by APAC, and the said scheme is operated in more than one APAC member country, APAC General Assembly shall review these additional requirements prior to NAC's assessment of the scheme. This can lead to an extended assessment process and additional fees.

NAC performs the necessary checks whether the conformity assessment scheme applied for is being used in the same or similar way under the accreditation of any accreditation body that is an APAC member.

If the Conformity Assessment Scheme is intended to be operated only in the country, all documents of the conformity assessment scheme must be submitted in native language. -

If the conformity assessment scheme is intended to be operated at an international level, all documents belonging to the conformity assessment scheme must be submitted in both the native language and English.

For the assessment of the conformity assessment scheme, personnel in charge initiates the work for creating an assessment team. The assessment team consists of a lead assessor and one or more assessors or technical experts, depending on the scope of application, to be assigned a minimum of 2 person / days. In the event that the review by the assessment team is foreseen to exceed 2 person / days before and / or during the assessment process, the assessment process is initiated and / or continued by obtaining the confirmation of the scheme owner about the review period and the fee. Moreover, if additional fees that may arise during the assessment process and whose details are specified in Clause 6 titled "CHARGING" of this guideline are foreseen, the applicant's confirmation is received before the fees are reflected to the applicant. The members of the assessment team are selected from the pool of NAC assessors and technical experts, taking into account the criteria such as their areas of expertise, availability, conflicts of interest that may arise with the owner of the scheme to be evaluated.

A minimum of 2 person / day assessment fee and application fee are invoiced to the applicant scheme owner before the assessment team's review process begins. The review process of the assessment team is not initiated unless the fees specified in this invoice are paid to NAC by the scheme owner.

After scheme owner pays the assessment fee to NAC and the necessary commitments related to impartiality and conflict of interest have been received from the assessment team members, all documents related to the conformity assessment scheme are transmitted electronically to the assessment team and reviewed by the team. After the assignment of the assessment team, the document and record review process is completed within 2 months.

As a result of reviewing the documents and records, the FR 112 Conformity Assessment Scheme Assessment Control Form is prepared by the members of the assessment team and sent to the NAC personnel in charge.

When necessary, NAC may ask the scheme owner to complete some deficiencies or make necessary corrections during the scheme review process or decision phase.

After the review, the assessment team reports whether the conformity assessment scheme meets the criteria of APAC, the relevant accreditation standard and NAC, along with its recommendation that the scheme can or cannot be evaluated within the framework of accreditation. NAC reviews the FR 112 Conformity Assessment Scheme Assessment Control Form prepared by the assessment team and makes its final decision on whether the conformity assessment scheme within the scope of the application can be evaluated within the framework of accreditation.

When it is decided to provide accreditation services for this Conformity Assessment Scheme, the assessment team and the relevant accreditation head shall give an opinion to the General Secretary on whether the application subject should be considered as a new accreditation area. If the subject is considered as a new accreditation area in pursuant of PR 003 Procedure for Establishing Accreditation Schemes, the process is carried out within NAC in accordance with the said procedure.

## **5.2 Communicating Scheme Assessment Results to the Scheme Owner**

The results of the assessment made by the assessment team about the scheme and the decision on whether the conformity assessment scheme can be evaluated within the framework of accreditation are notified to the applicant in writing with FR 112 Conformity Assessment Scheme Assessment Control Form.

If the assessment is positive and there is a request for accreditation by the scheme owner, the scheme owner shall apply for accreditation with the application form in the relevant field. The process after this stage is operated in accordance with PR 017 Procedure for the Assessment of Conformity Assessment Bodies.

As a result of the assessment, if the assessment of the conformity assessment scheme within the framework of accreditation is not considered appropriate, the decision is notified to the scheme owner. The scheme owner can apply for re-assessment by performing improvement works related to the negative issues identified in the assessment. In this case, the process is evaluated in the same way as the first application.

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When the assessment process of the scheme is carried out with a document and record review within the accreditation process, the decision is notified to the scheme owner if the assessment of the conformity assessment scheme within the framework of accreditation is not considered appropriate as a result of the assessment. The scheme owner can apply for re-assessment by performing improvement works related to the negative issues identified in the assessment. In this case, the process is evaluated in the same way as the first application.

If the scheme assessment process cannot be completed due to the absence of the applicant scheme owner within 18 months from the date of application, the application file is closed.

The scheme owner shall notify NAC in writing within 15 days, together with an impact analysis, of the changes that occur during the operation of the conformity assessment scheme and that affect the conformity assessment scheme. In these cases, NAC may re-initiate the assessment process of the scheme according to this guideline, with regard to the nature of the factors causing the change, based on its review of the submitted impact analysis.

After the scheme is approved, NAC may cancel the accreditation of the scheme if it is revealed that the information and documents submitted by the scheme owner during the application are incorrect, results that may damage the reliability of the scheme are obtained, and situations that may negatively affect the reputation of NAC occur. Accordingly, the related scopes of all CABs accredited under this scheme are also withdrawn.

### **5.3 Assessment of a Multinational Conformity Assessment Scheme to be Operated in more than one APAC Member Country**

Prior to the assessment of the Multinational Conformity Assessment Scheme, the scheme owner gives a written commitment on the following issues:

- i. Working in cooperation with NAC and not contacting other APAC member accreditation bodies regarding the assessment of the conformity assessment scheme until the scheme assessment is completed,
- ii. Informing whether the conformity assessment scheme has additional requirements along with requirements of ISO/IEC 17011, APAC mandatory documents and IAF or ILAC documents required by APAC, and that APAC General Assembly shall review these additional requirements prior to NAC's assessment of the scheme; being aware that this approval of the APAC General Assembly is not a guaranteed result, and that this approval process will affect the duration of the assessment process,

Before beginning the assessment of a Multinational Conformity Assessment Scheme, NAC informs the APAC Secretariat of the contact with the scheme owner and its plan to conduct the initial assessment. When the host accreditation body (NAC) makes an initial assessment of a conformity assessment scheme that will be operated in multiple APAC member countries, it reports the outcome of the assessment to the APAC Secretariat.

The APAC Secretariat informs all APAC members that a new Conformity Assessment Scheme is being assessed and distributes scheme documents and the assessment report of the host accreditation body for opinion within 30 days.

After the opinion reporting period expires, if no opinion has been received, the results of the host accreditation body can be confirmed and the Secretariat informs the host accreditation body. The host accreditation body publicly announces information about the new accreditation service offered. The result is also made available to APAC members.

There may be situations where it is desired to transform a national conformity assessment scheme into an international conformity assessment scheme.

## **6. Charging**

Charging for the assessment of a Conformity Assessment Scheme is made according to the 'person/day' calculation used for NAC accreditation assessments and detailed in K 001 Guidelines on Accreditation Service Fees.

Bodies applying to NAC for a conformity assessment scheme assessment are charged the same application fee as for accreditation applications.

For an assessment of a Conformity Assessment Scheme, a minimum assessment fee of 2 person/day is charged, depending on the content of the scheme and the size of the assessment team. These fees are invoiced and charged to the applicant scheme owner before the assessment team's review process begins. However, the total assessment fee is determined by taking into account the assessment team formed according to the fields of expertise required for the assessment of the scheme, the number of person / days determined and other costs incurred during the assessment process, and may exceed the determined fee for a minimum of 2 person/ day. On the other hand, additional assessment fees that will arise during the document and record review process in relation to the assessment of conformity assessment schemes will also be invoiced to the scheme owner.

These fees do not include the accommodation, food and travel expenses of the assessment team that may arise when necessary. The food, accommodation and travel expenses of the assessment team are covered by the applicant scheme owner.

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In areas requiring special expertise and where there is difficulty in providing an assessor/technical expert, an assessor/technical expert may be appointed from abroad. If the fee calculated together with the fees to be paid to the assessor/technical expert exceeds the assessment unit fee due to the change in the fees of assessors provided from abroad, this fee difference is collected by NAC by invoicing the scheme owner following the confirmation of the scheme owner. Fees that may arise due to the need for a translator/interpreter are also added to invoice.

If the applicant abandons the application at any stage of the assessment process, the applicant is obliged to pay the entire fee projected for the entire assessment process, as well as the entire assessment team expenses, if any.

The scheme owner is also obliged to comply with the relevant terms of K 001 Guidelines on Accreditation Service Fees, pursuant to the terms of this guideline on charging.

If the conformity assessment scheme is considered to be a multi-national scheme that will operate in more than one APAC member country, additional fees will also be invoiced to the scheme owner.