

# INTERNATIONAL COOPERATION



# National Accreditation Focal Points

A collaborative approach to develop national accreditation services Manfred Kindler, Uwe Miesner





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#### On behalf of



On behalf of the Federal Government of Germany, the Physikalisch-Technische Bundesanstalt promotes the improvement of the framework conditions for economic, social and environmentally friendly action and thus supports the development of quality infrastructure.



# Introduction

In an increasingly globalized marketplace, accessible and internationally recognized accreditation services have become a prerequisite for trade and economic development. However, not every country can afford to establish and sustain a full-fledged and internationally recognized accreditation body. This is particularly true for small economies with a limited number of laboratories and other conformity assessment bodies. Similarly, it is foreseeable that even larger economies may not be able to cover every accreditation area to an adequate degree.

In those cases, a collaboration between internationally recognized national accreditation bodies and emerging local accreditation service providers could help to satisfy customer demands for accepted accreditation services while saving scarce financial and human resources. A possible approach is the establishment of a National Accreditation Focal Point (NAFP). The NAFP concept has been and is currently being applied in different regions of the world and is also actively promoted in some of PTB's International Cooperation projects.

Drawing from PTB's experience in supporting the setting up of NAFPs world-wide, this paper presents the main types and characteristics of this concept. In addition, it illustrates practical implementation steps and lessons learned from PTB's technical cooperation work. Its ultimate objective is to assist political decision makers and institutions of the national quality infrastructure<sup>1</sup> in their endeavor to build up accreditation capacities in their country using an NAFP<sup>2</sup>.

The paper is divided into two parts: Part I provides an introduction into the basic concept and underlying rationale of an NAFP. Part II is designed as a more technical guideline on the establishment of an NAFP.

Finally, the authors would like to thank all those experts who provided valuable input and feedback to this paper. Our special thanks go to Mr Hanspeter Ischi, former Head of the Swiss Accreditation Service, Mr Pasquale Paladino, former Director Conformity Assessment of the Standards Council of Canada and Dr Joachim Thiele, former staff member of the Federal Institute for Materials Research and Testing, Accreditation and Conformity Assessment Section, Germany.

<sup>1</sup> Quality infrastructure is defined by the International Network of Quality Infrastructure (INetQI) as follows: "The system comprising the organizations (public and private) together with the policies, relevant legal and regulatory framework, and practices needed to support and enhance the quality, safety and environmental soundness of goods, services and processes."

<sup>2</sup> If the name National Accreditation Focal Point is not considered appropriate by the respective body responsible for accreditation in a specific country it may of course be replaced by simply naming it accreditation body. Sometimes, the term National Accreditation System is also used. The concept of partnership between accreditation bodies can be applied regardless of their designation.

# Part I – Basic Concept and Principles of a National Accreditation Focal Point

#### 1. What is a National Accreditation Focal Point?

National Accreditation Focal Points (NAFPs) have become a widespread tool in regional cooperation communities to establish national accreditation systems or to coordinate accreditation activities with internationally recognized accreditation bodies in a structured manner. However, despite their increasing popularity, there is no universally accepted definition of what an NAFP exactly is. Instead, an NAFP is defined by its core function, which is: To make an internationally recognized accreditation for laboratories, certification and inspection bodies available in partnership with a recognized foreign accreditation body.

To fulfil this function, an NAFP acts as the national administrative link between potential clients and established accreditation bodies and is usually responsible for the administration, coordination and marketing of accreditation services. However, it may vary significantly in

type, scope of activities and technical expertise, ranging from a formal, administrative contact point to an independent NAFP Office with substantial technical in-house expertise (see chapter 3).

Regardless of the specific design, a common characteristic of an NAFP is its close collaboration with a foreign National Accreditation Body – hereafter called "Partner Accreditation Body" (Partner AB) – which enjoys international recognition through its membership in mutual recognition arrangements of the international accreditation networks<sup>3</sup>. The Partner AB provides its technical competence for assessing conformity assessment bodies and is ultimately responsible for providing the official international accreditation certificate. Therefore, establishing a close and trustful collaboration between the NAFP and its Partner AB is the cornerstone of an effective implementation of the NAFP concept (see figure 1).

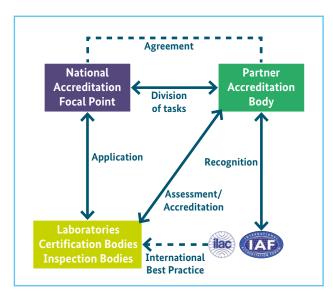


Fig. 1: National Accreditation Focal Point Concept - Basic elements

<sup>3</sup> International Laboratory Accreditation Cooperation (ILAC): http://www.ilac.org and International Accreditation Forum (IAF): http://www.iaf.nu

In principle, the NAFP concept can be applied both on a bilateral as well as regional basis. In practice, it is predominantly applied in regional integration schemes that aim to reduce technical barriers to trade through recognized conformity assessments. In this context, the commonly found heterogeneity of member states actually presents an opportunity to share facilities and foster partnerships among national accreditation systems. These partnerships may also include more than one Partner AB, especially where the accreditation scope of this organization is limited to laboratory or certification body accreditation only.

Historically, the first Focal Points were established in 2003 in the Southern African Development Community where they later became an integral part of a regional accreditation body (SADCAS)<sup>4</sup>. In the East African Community, Uganda established the first NAFP under the regional East African Accreditation Board (EAAB) in 2010. Ruanda and Burundi followed and are currently still developing their own accreditation structures while Kenya (KENAS) is providing the region with internationally recognized services (ILAC MRA & IAF MLA).

■ EAC ■ SADC

Fig. 2: Regional Economic Communities with National Accreditation Focal Points in Africa

In the Caribbean region, NAFPs were set up in many countries with close links to the National Accreditation Bodies in Jamaica (JANAAC) and Trinidad & Tobago (TTLABS). They now form the Caribbean Cooperation for Accreditation (CCA)<sup>5</sup> and serve the region with internationally recognized competence (ILAC MRA) at JANAAC. In Central America, Honduras created an NAFP in 2005 and cooperated with the Partner AB (ECA) in Costa Rica. Today, Honduras has developed its own AB (OHA) and is striving for international recognition, but close links to ECA still remain in place.

Finally, the NAFP concept has also been applied in Asia. In South Asia, Bhutan concluded a Memorandum of Understanding (MoU) with the Indian accreditation bodies NABCB and NABL in 2012, while NBSM Nepal and NABCB India signed an MoU in 2014. Within ASEAN, Cambodia, Laos and Myanmar have or had cooperation agreements in place with Partner ABs in the region (Thailand, Vietnam and Singapore, respectively). As a result, the Cambodian accreditation service has recently achieved international recognition by ILAC.

As an example, a draft proposal for an MoU between an NAFP and a Partner AB is provided in annex 1.

<sup>4</sup> In the case of SADCAS, NAFPs are part of a multi-economy accreditation system which does not include any Partner AB (www.sadcas.org).

<sup>5</sup> https://website.crosq.org/accreditation/

# 2. Advantages and challenges of developing a National Accreditation Focal Point

Formally speaking, the cooperation between an NAFP and a Partner AB can be regarded as a type of cross frontier accreditation which complies with the respective ILAC (and IAF) principles for cooperation (see box 1). Still, the NAFP concept goes beyond these principles as it is based on a formalized, mid- or long-term partnership which aims to gradually enhance the capacities of the domestic accreditation service. Thus, a coordinated approach to meet accreditation demands of domestic customers is not a case-specific by-product but rather the intended outcome of a joint decision on strategic collaboration that offers advantages for both the host country of the NAFP and the Partner AB.

#### Box 1: ILAC-G21:09/2012 Cross Frontier Accreditation – Principles for Cooperation (under revision)

#### 3. Cooperation with the domestic accreditation body

- 3.2 When an accreditation body that is a signatory to the ILAC Arrangement decides to provide accreditation services outside its country (economy), it should ensure that appropriate assessors are used, taking into account factors such as language, local laws and regulations, culture, etc., as well as technical competence requirements. The foreign accreditation body should also consult the domestic accreditation body and take into consideration any relevant accreditation requirements that the domestic accreditation body has set to suit the local conditions.
- 3.3 The preferred ILAC approach to ensure access to relevant competence is to cooperate to the greatest extent practicable with the domestic accreditation body by using its personnel, as appropriate, on the assessment team.

- 3.4 If it is not possible to include personnel from the domestic accreditation body on the assessment team, cooperation with the domestic accreditation body should be extended to invite the domestic accreditation body to observe the assessment, subject to acceptance by the applicant.
- 3.5 Where the domestic accreditation body is not a signatory to the ILAC Arrangement, or where the scope of the domestic accreditation body does not cover the requested activity, the foreign accreditation body should try to cooperate with the domestic accreditation body according to these principles so as to provide the domestic accreditation body with the opportunity to gain experience to apply for the ILAC Arrangement.

From the host country's perspective, an NAFP represents an economically viable concept to introduce and disseminate accreditation services without necessarily investing time and resources in establishing a full-fledged National Accreditation Body. Moreover, the close collaboration with a recognized foreign accreditation body helps to transfer knowledge and to gradually develop capacities in accreditation, thus, reducing the dependence on external and expensive consultancy services. Once these capacities are developed to an adequate extent, they may also be used to technically underpin national registration or notification processes which involve an assessment of conformity assessment bodies.

From the customer's perspective, i.e. laboratories, certification and inspection bodies, an NAFP ensures that internationally recognized accreditation services are easily accessible within the domestic market. Additionally, NAFPs reduce transaction costs as information and administrative support services are locally available. Geographical proximity between the NAFP and local industry may also help to jointly raise awareness of and promote the use of transparent and recognized conformity assessment services.

From the foreign Partner AB's perspective, collaboration with an NAFP facilitates the outreach and management of accreditation services in markets that may otherwise be difficult to serve. This applies in particular in those cases where accreditation, licensing or registration is regulated by national authorities such that it is impossible for foreign ABs to grant accreditation in those countries without a specific agreement with the responsible authority. Moreover, a gradually evolving NAFP may help to expand the Partner AB's pool of experts and assessors, who ultimately may also be employed in the domestic market of the Partner AB. From a broader perspective, a Partner AB also contributes to reducing technical barriers to trade, thus increasing its reputation as a center of expertise within regional integration schemes.

However, besides these advantages, the implementation of an NAFP bears challenges as well. These challenges can arise on the side of the NAFP, the Partner AB or may originate from external influences.

The NAFP may experience ambiguous or even missing coordination by involved ministries or responsible authorities. An insufficient understanding of roles and responsibilities or a lack of clear structures and communication between the NAFP and the Partner AB can further aggravate the development and functioning of the NAFP. Differing interests and/or non-compliance with IAF/ILAC guidelines for cross frontier accreditation (see chapter 4) may hamper effective cooperation.

Another challenge can be insufficient market demand for an NAFP. The need for certification, inspection, calibration or testing services may be insufficient to justify the establishment of the NAFP. Poor cost recovery (budget bottlenecks, financial crisis, market conditions) may affect the NAFP once it has been established. Expectations on the levels of fees or financial compensation may also differ between the NAFP and the Partner AB and should be clarified at the very beginning.

Finally, leadership competencies and personnel management (team leader, NAFP manager, responsible person of the Partner AB) need to be efficient and stable. Fluctuating staff of the NAFP or of the Partner AB can endanger the success of the model. The workload can be high and should thus be kept to an acceptable level.

# 3. Types and key characteristics of a National Accreditation Focal Point

Simply put, the involvement of an NAFP in the accreditation process and its interaction with potential customers and the Partner AB follows a three-step procedure: The NAFP receives an accreditation request from a domestic conformity assessment body (CAB). The request is handled by the NAFP and transmitted to the Partner AB. The Partner AB undertakes an assessment of the CAB and – if successful – grants (internationally recognized) accreditation. Besides its involvement in the accreditation procedure itself, the NAFP may be assigned other responsibilities such as raising awareness for accreditation or organizing training programs for laboratory staff and potential auditors and assessors, often in direct collaboration with the Partner AB.

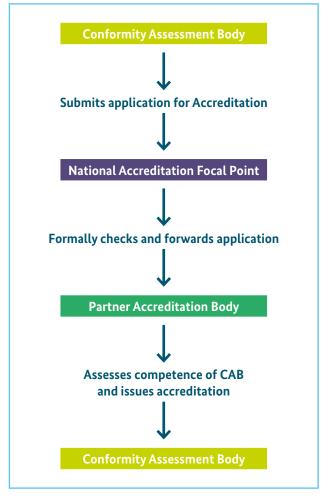


Fig. 3: Core steps of an accreditation procedure with NAFP involvement

The actual responsibilities and level of involvement of the NAFP in the accreditation process depend on the agreed division of tasks and available in-house expertise. Here, we define five different levels of involvement. The higher the level, the more activities an NAFP takes on and the more it increases its influence in the accreditation process.

- Level 1: Formal contact point
- Level 2: Competent contact person
- Level 3: Qualified NAFP Manager, who is supported by national experts
- Level 4: NAFP Office, which is involved in joint assessments
- Level 5: Independent NAFP Office, which participates in joint accreditations

The levels describe development stages from the starting point up to an independent NAFP Office. Therefore, the creation of an NAFP could be considered the first step in becoming a National Accreditation Body, underlining the transitional nature that is characteristic for many NAFPs. However, it should be noted that each level represents a cooperation model that could be established in its own right. This means that an NAFP aiming, for instance, at level 3 does not necessarily have to pass through level 1 or 2 first nor strive for level 4 and 5 afterwards<sup>6</sup>.

In any case, each level has its distinct features with regard to the institutional set-up and division of tasks between the NAFP and the Partner AB. Accordingly, the required competences and the degree of interaction with the Partner AB differs significantly. Each level is briefly described below:

<sup>6</sup> This approach applies, e.g. in the case of the Caribbean Cooperation for Accreditation (CCA). Here, several member countries opt for intermediate levels (such as level 3) as the final development stage of their NAFP, so capacity building focuses directly on achieving that level.

#### Level 1: Formal Contact Point

# request assessment/accreditation Laboratories Certification Bodies Inspection Bodies

Fig. 4: Level 1 NAFP

#### Key characteristic

Formal contact point that just provides administrative support to the accreditation process, no qualified staff available/required.

#### Institutional set-up

Fully integrated into a ministry, an institution of the quality infrastructure or another suitable institution ("parent organization" in terms of ILAC or IAF).

#### Tasks and responsibilities

Receives accreditation requests, provides information material, informs Partner AB, participates in ceremony (handover of certificate).

#### Required competences and resources

No specific knowledge and experiences required.

#### Remarks

The involved persons at the contact point have to sign a confidentiality commitment and have to establish a quality procedure for handling requests.

#### **Level 2: Competent Contact Person**

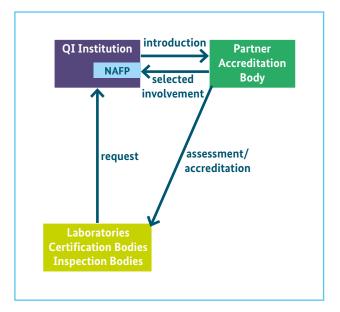


Fig. 5: Level 2 NAFP

#### Key characteristic

Contact point with a certain degree of technical competence that handles selected tasks of the application and accreditation procedure.

#### Institutional set-up

Fully integrated into a ministry, an institution of the quality infrastructure or another suitable institution ("parent organization" in terms of ILAC or IAF).

#### Tasks and responsibilities

See level 1, plus: coordinates application and accreditation procedures in cooperation with the Partner AB.

#### Required competences and resources

Contact person familiar with accreditation procedures and relevant standards, knows the case manager and other responsible persons of the Partner AB.

#### Remarks

The difference to level 1 is: The contact person has been introduced to the Partner AB, gained some practical insights and knowledge, and handles selected parts of the application procedure.

#### Level 3: Qualified NAFP Manager

#### training QI Institution participation **Partner** Accreditation Body **NAFP** subcontracted activities expert pool assessment/ subcontracted • request accreditation activities **Certification Bodies**

Fig. 6: Level 3 NAFP

#### Key characteristic

A well-trained full-time NAFP Manager supports the accreditation procedures of the Partner AB. National experts listed in a database participate as observers and/or technical experts. Qualification as assessors is in process.

#### Institutional set-up

Integrated into a QI institution with use of external experts.

#### Tasks and responsibilities

See level 2, plus: Coordinates pool of national experts; participates in regular meetings with the Partner AB for exchange of experiences and updating.

#### Required competences and resources

Manager familiar with accreditation procedures and relevant standards (see chapter 6); pool of trained technical experts.

#### Remarks

Difference to level 2: A well-trained full-time NAFP manager serves the clients and is responsible for identifying individuals and centers of national expertise. A pool of experts that meet the demanded qualification and experience criteria will be established.

#### Level 4: NAFP Office (Joint Assessment)

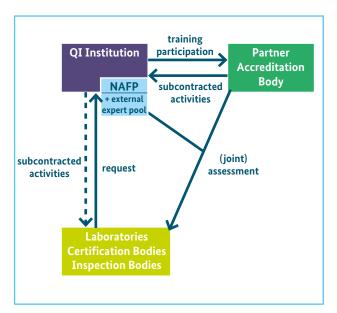


Fig. 7: Level 4 NAFP

#### Key characteristic

Well-trained NAFP Manager of the NAFP Office participates actively with NAFP experts in accreditation activities of the Partner AB, including joint assessments.

#### Institutional set-up

Connected to a QI institution with a certain degree of independence (e.g. own budget).

#### Tasks and responsibilities

See level 3, plus: Cooperation in joint assessments, including (partial) involvement in:

- Pre-evaluation of application documents
- Selection of experts for the assessment team
- Document review with national experts
- On-site assessment with national experts
- Participation in surveillance visits

#### Required competences and resources

Office staff familiar with accreditation procedures and relevant standards; pool of fully trained experts as technical assessors.

#### Remarks

The difference to level 3 is the joint assessment service. However, the Partner AB is always fully responsible for the decision-making procedures. The NAFP manager or the national experts are trained, qualified and recognized as assessors by the Partner AB.

# Level 5: Independent NAFP Office (Joint Accreditation)

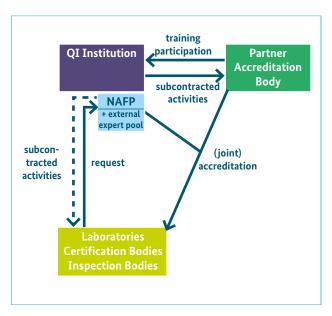


Fig. 8: Level 5 NAFP

#### Key characteristic

The NAFP operates like a National Accreditation Body and issues accreditation certificates which are recognized by national authorities (licensing, registration, authorization, etc.). Technical sector committees and advisory board are established.

#### Institutional set-up

Fully independent NAFP Office, i.e. self-financed or governmental / donor sponsoring for start-up phase.

#### Tasks and responsibilities

See level 4, plus: NAFP Office covers important parts of the accreditation process of the Partner AB (Joint Accreditation).

#### Required competences and resources

NAFP should meet ISO/IEC 17011 requirements.

#### Remarks

NAFP with external assessor pool now collects the required experience in accreditation for the MRA/MLA membership in ILAC/IAF and regional organizations.

Once level 5 has been reached, the NAFP is ready to be designated as a National Accreditation Body (NAB) and to apply for a Pre-Peer Evaluation. Provided that the NAB successfully passes this evaluation for a certain area, it qualifies as an IAF/ILAC recognized NAB for a specific scope. Finally, if it extends the MRA to all areas, it has reached the status of an IAF/ILAC recognized NAB for all scopes.

# 4. Division of tasks between NAFP and Partner AB and compatibility with IAF / ILAC rules

As described above, the scope of responsibilities handled by the NAFP gradually increases with each level. From level 4, the NAFP is fully involved in nearly all aspects of the accreditation procedure. In other words: The Partner AB can subcontract all activities to the NAFP, except decision making. The Partner AB must retain full responsibility for this activity to ensure international recognition of the accreditation.

The division of tasks between the NAFP and the Partner AB is illustrated in figure 9. The procedure for accreditation is divided into 13 steps plus management of complaints and appeals. The boxes marked with x represent the full participation of the NAFP, the ones marked with (x) indicate partial involvement. As illustrated below, handling of requests (# 1) and participation in the official hand-over ceremony of the accreditation certificate (# 11) are the only steps in which the NAFP is (partly) involved from the very beginning.

	NAFP	Lev	el 1	Lev	el 2	Lev	el 3	Lev	el 4	Lev	el 5
#	Process	NAFP	PAB								
1	Handling request	Х	Х	Х	(x)	Х	(x)	Х		Х	
2	Handling application		Х	х	Х	Х	Х	х	Х	Х	Х
3	Check of application		Х		Х		Х	Х	Х	Х	Х
4	Selection of assessors		Х		Х	(x)	Х	Х	Х	Х	Х
5	Document review		Х		Х	(x)	Х	Х	Х	Х	Х
6	Corrective actions Document review		Х		Х	(x)	Х	х	Х	Х	Х
7	On-site assessment		Х		Х	(x)	Х	Х	Х	Х	Х
8	Corrective actions On-site assessment		Х		Х	(x)	Х	х	Х	Х	Х
9	Reporting		Х		Х	(x)	Х	Х	Х	Х	Х
10	Decision making		Х		Х		Х		Х	(x)	Х
11	Ceremony	(x)	Х	Х	Х	Х	Х	Х	Х	Х	Х
12	Surveillance		Х		Х	(x)	Х	Х	Х	Х	Х
13	Re-accreditation		Х		Х	(x)	Х	Х	Х	Х	Х
14	Complaint management		Х		Х	(x)	X	Х	Х	Х	Х

Fig. 9: Accreditation procedure and division of tasks

At level 5, the procedure for decision making is as follows: The Partner AB decides on the issuing of an IAF/ ILAC recognized accreditation certificate, while the NAFP is responsible for decision making in areas mandated by the country based on national legislation. For example, it decides on the fitness of a laboratory for the authorization by the responsible national ministry. In case of a positive decision of both the Partner AB and the NAFP, the laboratory will get at least two certificates: one from the Partner AB about international recognition and another one from the NAFP and the related Ministry about the national authorization in the mandated area.

Particularly from the Partner ABs perspective, the division of work with the NAFP leads to the question of how to ensure that the institutionalized partnership is compatible with IAF / ILAC rules. In this respect, one of the main principles of the NAFP concept states that the cooperation should never jeopardize the international recognition of the partner accreditation body. Therefore, activities carried out under the cooperation must meet the scrutiny of a peer evaluation through which the equivalence of the Partner ABs accreditation program is recognized under the IAF Multilateral Recognition Arrangement and ILAC Mutual Recognition Arrangement, respectively.

Within the scope of this paper, three aspects should be highlighted: Responsibility of decision taking, transparency on international activities and access to expertise.

#### Responsibility of decision taking

According to IAF/ILAC requirements, accreditation decisions shall not be subject to external influence or approval (see box 2). Consequently, from level 1 up to level 5 the NAFP has no decision-taking power for granting accreditation to CABs that are seeking international recognition. Instead, a level 5 NAFP may only decide about the national recognition of a CAB in the mandated area based on the authorization granted by the responsible ministry. In any case, for the international market the Partner AB always signs internationally recognizable certificates of accreditation to CABs.

#### Box 2: ISO/IEC 17011:2017 Clause 5.5

The accreditation body shall have authority and be responsible for its accreditation decisions which shall not be subject to approval by any other organization or person.

#### Transparency on international activities

In the peer evaluation process, the AB under evaluation is required to present information, facts and figures about its performance and operations. This includes information on its accreditation activities outside of its own territory and a description of its cross-frontier policy (see box 3). Accordingly, the cooperation with the NAFP needs to be reflected on in this context.

### Box 3: IAF/ILAC A3 03/2020 Clause 2.5: List of Economies where the AB Performs Assessments or Provides Accreditation

Any economies outside of its own in which the AB provides accreditation, and the number of respective accreditations. A description of the AB's cross-frontier accreditation policy shall be provided.

#### Access to expertise

The AB subject to a peer evaluation has to ensure the competence of its personnel. Consequently, NAFP staff involved in the accreditation process need to participate in training, assessor experience sharing and similar activities. Again, the respective mechanisms are subject to reporting requirements. In addition, the AB has to provide information on how it accesses expertise and how this expertise is used in establishing accreditation criteria (see box 4).

# Box 4: IAF / ILAC A3 03/2020 Clause 5: Structural Requirements

The AB shall describe the mechanism by which it accesses its expertise. (...)

The AB shall describe how it identifies the need for technical expertise; how this expertise is recruited, and how it is managed and used in establishing accreditation criteria (for both existing and new accreditation programs) and advising the AB. The commentary should provide some indication of the expertise available to advise the AB in type, range and volume of the accreditation services offered.

Once the NAFP has developed into an independent accreditation body and signatory to the IAF/ILAC Arrangement, the foreign Partner AB may still be elected by a domestic CAB to provide accreditation. In this case, the following steps should be considered by the Partner AB before accepting the application:<sup>7</sup>

- a. Enquire if the applicant is aware of the domestic accreditation body
- Suggest that accreditation provided by a domestic accreditation body should take account of local factors and conditions, where relevant
- Point out the equivalence of the domestic accreditation body's accreditations as demonstrated through the IAF/ILAC Arrangement
- d. Point out that even if the application is accepted, the local accreditation body may be involved in the accreditation process

Finally, the cooperation principles under cross frontier accreditation also state that the foreign Partner AB should proceed with the application only if the applicant persists in requiring accreditation by the foreign AB.<sup>8</sup>

<sup>7</sup> ILAC-G21:09/2012 Cross-Frontier Accreditation – Principles for Cooperation, p. 5/6 (under revision)

<sup>8</sup> ILAC-G21:09/2012 Cross-Frontier Accreditation – Principles for Cooperation, p. 5 (under revision)

# Part II – Guideline for the Establishment of a National Accreditation Focal Point

## 5. The components of a National Accreditation Focal

A National Accreditation Focal Point is based on four pillars that represent the building blocks of any kind of national accreditation structure:

- Political Aspects, determining the political and institutional framework in which the NAFP operates
- Administration, comprising basic administrative and management-related elements of the NAFP
- Technical Aspects, underpinning the technical competence of the NAFP related to the accreditation activities it will be involved in
- External Relations, relating to marketing and collaboration arrangements with external stakeholders

Each of these four pillars can be sub-divided into different components. A total of 16 components that the "architects" of an NAFP need to address are identified in the diagram below (figure 10):

Obviously, the exact shape or relevance of each component depends on the level achieved or targeted by the NAFP. In the case of a formal Contact Point (Level 1), for instance, component A2, T1 or T4 will only be of minor importance while an independent NAFP Office (Level 5) will have to cover all 16 components to an adequate extent.

Below, examples are provided of what aspects each component may contain or cover.

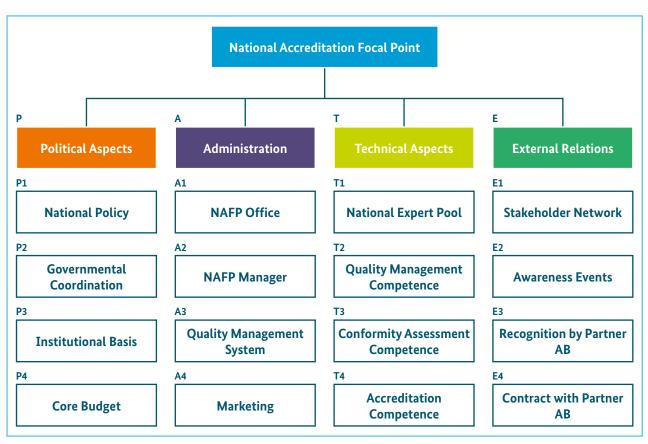


Fig. 10: Components of an NAFP

#### **Political Aspects**

#### **National Policy**

National quality policy, i.e. regulations on standardization, metrology, certification, accreditation and quality assurance. National Quality Award. Events such as the World Standards Day, World Metrology Day, World Accreditation Day, World Quality Day and World Consumer Day.

#### **Governmental Coordination**

Cooperation between NAFP and ministries/authorities in sectors relevant for accreditation and conformity assessment, e.g. health care, agriculture, industry, trade, enterprise development, consumer protection, environmental protection, etc.

Organization of common events such as public conferences, awareness campaigns, etc.

#### **Institutional Basis**

Formal establishment of the NAFP in an institution in the field of quality infrastructure, in a ministry or another suitable institution (governmental authority, association of industry and trade, chamber of commerce, university, etc.), represented in an organizational chart. Description of the NAFP as an entity.

#### **Core Budget**

Appropriate financial and personnel resources to do the work. A budget for communication, office equipment, travel, accommodation, etc. A budget and work plan.

#### Administration

#### **NAFP Office**

Appropriate office with a postal and email address, suitable telecommunication and information technology facilities, office equipment, furniture, responsible officer.

#### **NAFP Manager**

Official NAFP Manager introduced (Level 2) or trained (Level 3) as a contact person. Visits to the Partner AB. Knowledge of all relevant procedures and of the officials of the Partner AB.

#### **Quality Management System**

Work procedures for the handling of requests and applications, for communication with the Partner AB, for information to the clients, for preparation of on-site assessments, for handling documents and records, for complaints, for training. Quality Manual to ISO/IEC 17011. Supervision of the implementation of these procedures. Confidentiality commitment.

#### Marketing

Informational material (brochures, leaflets, guides, etc.), NAFP web page. Promotional activities (special events).

#### **Technical Aspects**

#### **National Expert Pool**

Identification of experts and national centers of expertise. Database of experts with a description of the competence profile. Qualification and experience criteria for experts and assessors.

#### **Quality Management Competence**

Trainings on quality management. Visits to ISO 9001 certified companies. Experience in auditing.

#### **Conformity Assessment Competence**

Trainings on ISO/IEC 17025 and other conformity assessment standards. Visits to accredited laboratories, inspection and certification bodies. Experience in conformity assessment.

#### **Accreditation Competence**

Trainings on ISO/IEC 17011 and IAF / ILAC Guides. Visits to the Partner AB for one week and more (internships). Training and experience in accreditation assessments. Participation in Technical Committee meetings of the Partner AB.

#### **External Relations**

#### Stakeholder Network

Networking with representatives of stakeholders. Regular meetings and/or common events with stakeholders. Support of the NAFP work by stakeholders.

#### **Awareness Events**

Organization of event days such as the World Standards Day, World Metrology Day, World Accreditation Day, World Quality Day. Public conferences about accreditation and quality assurance.

#### Recognition by the Partner AB

Recognized NAFP experts as qualified assessors. Recognized NAFP training activities and resulting certificates.

#### Contract with the Partner AB

Memorandum of Understanding or another contractual document. Annual experience-sharing meetings about the accreditation activities.

# 6. Competence of NAFP staff: Recommendations on human resource development

Competence and experience of NAFP staff is a prerequisite for the effectiveness and acceptance of an NAFP. Generally speaking, areas of required competence cover quality management, conformity assessment and accreditation. However, the scope and depth of required expertise depends on the respective level of the NAFP (see figure 11).

Competence of NAFPs	Quality Management	Conformity Assessment	Accreditation Scheme
Level 1: Formal Contact Point	No specific knowledge and experience required	No specific knowledge and experience required	No specific knowledge and experience required
Level 2: Competent Contact person	Introduction (1 day) to ISO 9001, visit to an ISO 9001 certified company	Introduction (1 day) to ISO/IEC 17025 or other related standard, visit to an accredited CAB	Introduction (1 day) to ISO/IEC 17011 and accreditation procedure, visit to the Partner AB
Level 3: Qualified NAFP Manager	Training in ISO 9001 (3 days) and practice as quality manager, internal auditor or ISO 9001 auditor	Training in ISO/IEC 17025 (3 days) or related standard and practice in testing, calibration, inspection or certification activities (> 1 year)	Training in ISO/IEC 17011 (3 days) and practice in accreditation activities by an AB (training on the job, one week and more)
Level 4: NAFP Office (Joint Assessment)	Training in ISO 9001 (5 days) and practice as quality manager, internal auditor or ISO 9001 auditor	Level 3 plus additional trainings in specific requirements (validation, sampling, traceability, proficiency testing)	Level 3 plus additional trainings in assessment of CABs (training on the job depending on AB policies)
Level 5: Independent NAFP Office (Joint Accreditation)	Training in ISO 9001 (5 days) and practice as quality manager, internal auditor or ISO 9001 auditor	Level 4 plus additional experience in specific requirements (validation, sampling, traceability, proficiency testing)	Level 4 plus appropriate experience in assessment of CABs (training on the job depending on AB policies)

Fig. 11: Areas and examples of required competence of NAFP staff  $\,$ 

Solid knowledge and competence are especially needed for staff who are significantly involved in the accreditation procedure, i.e. staff in NAFP at Level 3 and beyond. They should be competent in theory (through training) and practice (through experience) in the three mentioned areas. The main standards, with which they should be very familiar, are:

- in Quality Management: ISO 9001 (quality management), ISO 19011 (auditing), and audit aspects of APG-Guidelines of ISO and IAF<sup>9</sup>,
- in Conformity Assessment: ISO/IEC 17025 (laboratories), ISO 15189 (medical laboratories), ISO/IEC 17020 (inspection bodies), ISO/IEC 17021 (certification bodies for management systems), ISO/IEC 17024 (certification bodies for personnel), ISO/IEC 17065 (certification bodies for products, processes and services),
- in Accreditation: ISO/IEC 17011 (accreditation), AAPG-Guidelines of ISO and IAF<sup>10</sup> and their related ILAC and IAF documents.

The Partner AB has policies for the competence and training of all persons who are involved in accreditation activities. The NAFP staff should be integrated into the training programs and plans of the Partner AB to ensure competence and continual improvement. This is also required according to IAF/ILAC guidelines (see chapter 4).

# 7. The roadmap to establish a National Accreditation Focal Point

Before starting to prepare the establishment of an NAFP, an initial needs assessment should be conducted. This assessment should cover the estimated number of potential customers and their main fields of activities, the existing stakeholder network and the broad policy framework. In addition, a rough estimation of the required infrastructure and human resources may help to inform and convince political decision-makers about the scope of the needed investment.

Where accreditation activities are starting from scratch, the initial assessment may comprise the following aspects:

#### NAFP infrastructure & staffing

- Which institution will be hosting the NAFP?
- Has/Have any person(s) already been selected as responsible NAFP "contact point"? If yes: To what extent have these persons already gained knowledge and received training in the field of accreditation/conformity assessment/quality management?
- Will the responsible contact point have an appropriate office, including telecommunication and IT capabilities?

#### Policy framework

- Do a national quality policy, sector-specific regulations or trade agreements exist which include requirements related to accreditation and conformity assessment?
- Does a cooperation exist between the institution hosting the NAFP and (other) ministries with a possible stake in accreditation matters (e.g. in the health care, trade & exports sector)?
- Has a draft strategy to facilitate accreditation services in the country already been developed?

<sup>9</sup> Auditing Practices Group Guidelines, see https://committee.iso.org/home/ tc176/iso-9001-auditing-practices-group.html

<sup>10</sup> Accreditation Auditing Practices Group Guidelines, see https://committee.iso.org/sites/tc176/home/page/accreditation-auditing-practices.html

#### Partnerships and stakeholder network

- Has the (future) NAFP access to national experts who are familiar with accreditation/conformity assessment?
- Does the (future) NAFP have regular contact with accreditation stakeholders from the private and public sector (e.g. testing laboratories, Chamber of Commerce, national calibration laboratory)?
- Does the institution hosting the (future) NAFP arrange or participate in public conferences or promotional activities in the field of quality / conformity assessment?

#### Potential customers

- What is the estimated number of conformity assessment bodies (CABs) operating in the country that are preparing for / potentially seeking accreditation?
- What fields do these CABs cover (testing, calibration, inspection, certification)?

Is there any informational material on accreditation available for potential clients interested in accreditation?

For a more detailed self-assessment, a checklist is provided in annex 2.

Once the needs assessment is completed, steps to establish the NAFP should be prepared. This establishment is – in an ideal case – based on the 16 components described in chapter 5 and should follow a certain sequence. This sequence is outlined in figure 12 and represents a roadmap to implementing the NAFP concept.

Some recommended activities with respect to selected components are listed below:

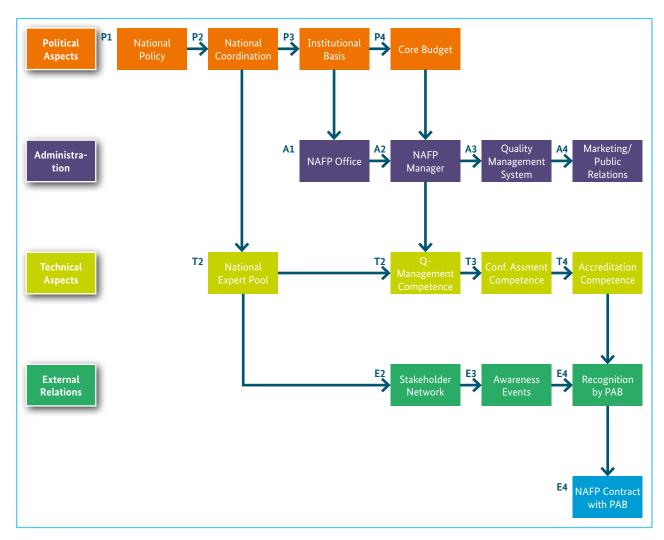


Fig. 12: Roadmap for the establishment of an NAFP

**National Policy:** Facilitate the formulation of a national quality policy by the responsible or coordinating ministry, consistent with industry and trade policies. Decide on the status of the NAFP by law, governmental decree and statutes with a clear agreement with the government that it is recognized as a National Accreditation Focal Point.

**Institutional Basis:** Decide on the type of legal identity of the NAFP and the connection to an institution. Avoid potential conflicts of interest to related bodies.

**NAFP Manager:** Create a clear management structure, organizational chart and job descriptions. Appoint secretarial staff, if necessary.

**Quality Management System:** Develop the necessary quality manual and major procedures required for the NAFP and the activities it will be performing.

**National Expert Pool:** Identify experts in national centers of expertise. Describe their competence profiles via Partner AB questionnaires and checklists. Work with the Partner AB to train and qualify the experts to be able to participate in the accreditation assessment activities.

**Stakeholder Network:** Create a network composed of stakeholders, including representatives from industry, trade, universities, associations, laboratory networks, inspection and certification bodies, consumer organizations, relevant ministries etc. Participate in their events and present the QI system and the NAFP services.

**Recognition by Partner AB:** Coordinate the development of quality documents with the Partner AB. Present the national experts to be acknowledged and qualified as assessors. Assure that all training activities and certificates of qualification are recognized by the Partner AB.

**NAFP Contract with Partner AB:** Develop and sign a Memorandum of Understanding or another contractual document with the Partner AB. Organize or participate in annual experience exchange meetings.

In the case of an advanced NAFP at level 4 or 5, the 16 components can be visualized as bricks of a "House of a National Accreditation Focal Point" (see figure 13). The four pillars represent the political, administrative, technical and external relations aspects presented in chapter 5; the basement is formed by the "National Policy". The roof represents the final result: Internationally recognized accreditation services facilitated by the NAFP, based on a contract or arrangement with a Partner Accreditation Body.

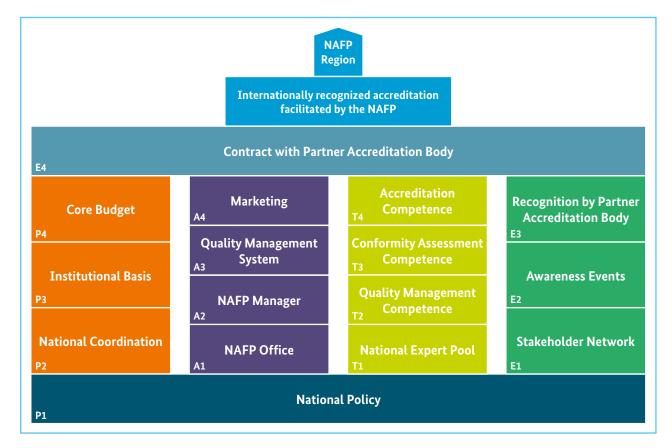


Fig. 13: The NAFP House

Ideally, the way of establishing an NAFP should follow the same logic as when constructing a real house: Start with the basement, continue from bottom to top, end with the roof and be aware of the structural stability. In practice, however, work on the NAFP House could start at any point where resources are available.

#### 8. Conclusions and outlook

During the past decades, NAFPs have been emerging under different names around the globe and have become an integral part of regional integration schemes. Increasing requirements to demonstrate the competence of conformity assessment bodies in areas such as food, environment and health suggest that partnerships and regional collaboration arrangements will continue to grow in the future. This applies in particular to developing countries that – despite limited markets and scarce resources – seek to rapidly establish internationally recognised accreditation services for industry and government.

Despite empirical evidence on this general trend towards sharing accreditation facilities, there is no blueprint on exactly how NAFPs should operate or how they should be set up. Instead, a range of options exists depending on the political and institutional environment, market demand, or the preferences and comparative advantages of the Partner AB. Therefore, the levels and steps from an emerging to a fully developed NAFP are not necessarily stages of a linear development process but rather possible cooperation models which could all be established in their own right. The choice of the appropriate model depends, among other things, on the available resources, the historical evolution of the national quality infrastructure, and economic policy objectives.

What appears crucial for the functioning of an NAFP is that expectations, roles and responsibilities of the involved parties are clarified from the outset and that top management is committed to practically implementing the agreed modes of partnership. Another success factor is a sensitized and supportive stakeholder community, including economic and political decision makers. Particularly the latter may regard the term "NAFP" as pejorative, so that awareness-raising about the concept and advantages, but also the challenges, is essential in order to gain political support.

Regardless of how fast and up to what level the NAFP in a specific country is actually developing, it should be kept in mind that accreditation is closely linked with other components of the national quality infrastructure. Thus, substantial and sustainable progress in developing accreditation facilities can only be achieved if, in parallel, the whole QI system is developing, including effective market surveillance. In this context, collaborative approaches to capacity building – as applied in the case of NAFP – could also be transferred to other areas of QI, for instance, to share sophisticated testing and calibration facilities.

Lastly, it should be noted that despite the global proliferation of NAFPs, the concept has not yet received the full attention of the regional and international accreditation networks. In fact, NAFPs seem still to be predominately regarded as informal mechanisms of cross-frontier accreditation while a discussion on the possible membership status of these bodies and their integration into formal network structures has only recently started with respect to the activities of SADCAS and its NAFPs. It can be hoped that this discussion will contribute to highlight the particular needs of developing economies so that, ultimately, NAFPs will be become a recognized player in pursuit of the motto: Tested/certified once, accepted everywhere.

# Annex 1

#### Memorandum of Understanding between an NAFP and a Partner Accreditation Body (draft model)<sup>11</sup>

#### Introduction

Together with standardization and metrology, accreditation represents a key pillar of the national quality infrastructure. Such a quality infrastructure is important to reduce technical barriers to trade and, ultimately, to facilitate regional and global economic integration. Accreditation is therefore one of the tools recommended by WTO as well as by regional trade agreements in order to overcome trade barriers by establishing the equivalence of test results and certification.

Recognizing the crucial contribution accreditation can play in this context, the establishment of a National Accreditation Focal Point (NAFP) is currently in progress in the country of \_\_\_\_\_\_\_. Its core function is to facilitate the provision of internationally recognized accreditation services in the field of conformity assessment. To support the NAFP in this endeavor, the following partnership agreement has been signed between \_\_\_\_\_ (NAFP) and \_\_\_\_\_ (PAB).

#### Purpose of the agreement

The purpose of the cooperation is to provide accreditation services by the PAB to conformity assessment bodies in the country and, in parallel, to support the further development of the NAFP.

#### **Technical Assistance**

With a view to facilitating the effective attainment of the above purpose, technical assistance will be provided by the PAB through the following activities:

- providing the necessary guidance and training to NAFP staff on requirements for accreditation,
- providing the necessary information and documents required for submitting applications to the PAB,
- performing assessments in cooperation with the NAFP in line with the attained NAFP level,
- inviting NAFP staff to visit the PAB to observe its operations and assessments; in turn, PAB staff will be invited to visit the NAFP to supervise and guide the operations as required,
- supporting the development of informational material such as brochures or leaflets about the NAFP, its role, twinning arrangement, and services offered in the country,
- participating in awareness programs as mutually agreed by both sides.

<sup>11</sup> With reference to the model developed by Mr Hanspeter Ischi

#### **Financial Provisions**

All financial obligations resulting from this cooperation shall be met by the NAFP and are subject to prior agreement.

All expenses related to the assessment and accreditation of CABs shall be as per the agreed fee structure and borne by applicant CABs.

#### Monitoring

The NAFP shall invite the PAB to monitor its development and to conduct internal audits at the NAFP in order to establish trust and understanding in both organizations.

#### **Further Provisions**

Accreditation of CABs in the country shall be granted by the PAB after the successful completion of the (joint) assessments. The NAFP and the PAB shall develop a certificate reflecting the partnership of the two bodies and conforming to both the ISO/IEC 17011 standard and the ILAC/IAF criteria.

Accredited CABs shall comply with the criteria and Terms & Conditions for maintaining PAB accreditation and shall be allowed to bear both accreditation logos, that of the PAB and that of the NAFP.

PAB will conduct regular surveillance and reassessment of the accredited CAB's in the country. Surveillance visits and re-assessments will be done jointly.

#### **Contacts**

Any communication with respect to this MoU	shall	be
submitted to the following contact addresses:		
For the NAFP:		
For the PAB:		

#### **Settlement of Disputes**

Any dispute arising out of or in connection with this MoU shall be resolved amicably and in good faith by direct consultations between both parties.

# Annex 2

#### Lead questions for self-assessment

#### **National Policy**

- Is the NAFP laid down in a legislative act?
- Does a national quality policy exist?
- Are there regulations regarding standardization, metrology, certification, accreditation, quality assurance?
- Does a National Quality Award exist?
- Are public events celebrated, such as the
  - O World Standards Day,
  - World Metrology Day,
  - World Accreditation Day, and/or
  - World Quality Day?

#### **Governmental Coordination**

- Do the NAFP and the responsible ministries and authorities cooperate in the sector of health, agriculture, industry, trade, SME development, consumer protection, environmental protection, tourism, construction, energy, etc.?
- Are all relevant contact persons identified?
- Are any common events arranged such as public conferences, awareness campaigns?

#### **Institutional Basis**

- Has the NAFP formally been established in
  - o an institution of metrology, standardization, testing, inspection, certification, quality assurance,
  - o a ministry or other governmental authority,
  - o an association of industry and trade,
  - o a chamber of trade and commerce,
  - o a university or
  - o any other institution?
- Is it represented in an organizational chart?
- Is there a clear description of the NAFP as an entity?

#### **Core Budget**

- Does the NAFP have appropriate financial and human resources to accomplish its work?
- Are the costs covered, e.g. for
  - o communication (telephone, fax, IT),
  - other office equipment (copy machine, projector),
  - facilities,
  - o travel, accommodation, etc.
- Is there a budget plan?

#### **NAFP Office**

- Does the NAFP have an appropriate office with
  - o a responsible officer
  - o an address.
  - o an email account,
  - o telecommunication equipment,
  - office equipment,
  - o furniture, etc.?

#### **NAFP Manager**

- Does the NAFP have a designated official NAFP Manager as contact person (Level 2)?
- Has the person been introduced to (Level 2) or trained by (Level 3) the Partner Accreditation Body?
- Has the NAFP Manager visited the Partner AB?
- Does the NAFP Manager know all relevant procedures and officials of the Partner AB?

#### **Quality Management System**

- Has the NAFP established work procedures
  - o for the handling of requests and applications,
  - o for communicating with the Partner AB,
  - o for providing information to clients,
  - ofor preparing on-site assessments,
  - o for handling documents and records,
  - o for complaints and appeals,
  - o for training?
- Are these procedures integrated in a Quality Manual?
- Is the implementation of these procedures supervised?
- Have all relevant persons signed a confidentiality commitment?

#### Marketing

- Is informational material (brochures, leaflets, guides, etc.) available for interested clients?
- Has an NAFP webpage been established?
- Does the NAFP implement promotional activities (special events) to inform the public about national accreditation services?

#### **National Expert Pool**

- Has the NAFP identified any national centers of expertise?
- Does a database of experts with a description of the competence profile exist?
- Are these experts presented to the Partner AB for integration into assessment activities?

#### **Quality Management Competence**

- Has the NAFP Manager participated in training on ISO 9001 and ISO 19011?
- Has the NAFP Manager visited ISO 9001 certified companies?
- Does the NAFP Manager have training and experience in auditing?

#### **Conformity Assessment Competence**

- Has the NAFP Manager participated in training on ISO/IEC 17025 and other conformity assessment standards?
- Has the NAFP Manager visited accredited laboratories, inspection and certification bodies?
- Does the NAFP Manager have training and experience in conformity assessment?

#### **Accreditation Competence**

- Has the NAFP Manager participated in training on ISO/IEC 17011 and ILAC / IAF Guides?
- Has the NAFP Manager visited the Partner AB for one week and more?
- Does the NAFP Manager have training and experience in accreditation assessments?

#### Stakeholder Network

- Is the NAFP well-informed about the relevant stakeholders?
- Are stakeholders informed about the NAFP's activities?
- Is there a regular meeting and/or common events with stakeholders?
- Do the stakeholders support the NAFP's work?

#### **Awareness Events**

- Is the NAFP itself involved in event days such as the O World Standards Day,
  - World Metrology Day,
  - O World Accreditation Day,
  - World Quality Day?
- Does the NAFP arrange or participate in public conferences about accreditation and quality assurance?

#### **Recognition by Partner AB**

- Do all work procedures of the NAFP comply with the regulations of the Partner AB?
- Are the technical experts of the NAFP acknowledged as qualified assessors?
- Are NAFP training activities and resulting certificates acknowledged by the Partner AB?
- Will the NAFP be informed about regional and international activities in accreditation schemes (ILAC, IAF, ISO, etc.)?

#### **Contract with Partner AB**

- Has the NAFP signed a Memorandum of Understanding or another contractual document with the Partner AB that governs all aspects of their cooperation?
- Is there an annual experience exchange meeting related to the accreditation activities?

# List of Abbreviations

AB Accreditation Body

AAPG Accreditation Auditing Practices Group
APAC Asia Pacific Accreditation Cooperation

APG Auditing Practices Group

ASEAN Association of Southeast Asian Nations

CAB Conformity Assessment Body
CARICOM Caribbean Community

CCA Caribbean Cooperation for Accreditation
EA European Cooperation for Accreditation

EAAB East African Accreditation Board ECA Ente Costarricense de Acreditación

IAAC Inter-American Accreditation Cooperation

IAF International Accreditation Forum

IEC International Electrotechnical Commission

ILAC International Laboratory Accreditation Cooperation
ISO International Organization for Standardization
JANAAC Jamaica National Agency for Accreditation

KENAS Kenya Accreditation Service

MLA Multilateral Recognition Agreement
MoU Memorandum of Understanding
MRA Mutual Recognition Arrangement

NABCB National Accreditation Board for Certification Bodies

NABL National Accreditation Board for Testing and Calibration Laboratories

NAFP National Accreditation Focal Point

NBSM Nepal Bureau of Standards and Metrology

OHA Organismo Hondureño de Acreditación

PAB Partner Accreditation Body

PTB Physikalisch-Technische Bundesanstalt

QI Quality Infrastructure

SADCAS Southern African Development Community Accreditation Service

TTLABS Trinidad & Tobago Laboratory Accreditation Service

# Notes

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