



IAAC – PTB

Best Accreditation Practices

Workshop: Relationship with the Regulatory Authorities II

March 08th and 09th, 2012

at INN – Santiago de Chile

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PTB Germany

THE BEST ACCREDITATION PRACTICES WORKSHOP

Relationship with the Regulatory Authorities II

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1 OBJECTIVE AND SCOPE

In the first BAP workshop held 19th and 20th August 2011 in Quito, Ecuador referring to the relationship with the regulatory agencies, we required from the participants some inputs about the activities the accreditation bodies realize for setting up first contacts with the regulatory agencies in order to support them through the accreditation. After that, a survey was made in order to know in which fields or sectors the accreditation bodies are more interested in, and the following sectors were chosen:

- Construction
- Energy Efficiency
- Transportation

After this each participant chose a sector of his interest and began an action plan to be realized during 2012.

A monitoring activity was developed by a PTB consultant, before the II BAP Workshop and some countries in order to be sure they would comply with the activities they have planned in which it was observed different level of implementation, according to their resources, time available and complexity and/or unstable situation in some countries..

So, the PTB-IAAC workshop on Best Accreditation Practices II was developed in Santiago de Chile, on 8 and 9 March, 2012, aimed to track the activities of the Action Plan about the relations between the Accreditation Body and the Regulatory Agencies in the above mentioned sectors.

2 DEVELOPMENT OF THE WORKSHOP

2.1 Participants

The workshop was held in Santiago de Chile, on 8th and 9th March, 2012, in the facilities of the National Institute of Standardization - INN, Chile.

The following countries attended the workshop (see Annex: List of participants):

- Argentina
- Bolivia
- Chile
- Colombia
- Costa Rica
- Cuba
- Ecuador
- El Salvador
- Guyana
- Honduras
- Jamaica
- Paraguay
- Peru
- Dominican Republic
- Trinidad & Tobago

2.2 Agenda

BAP Workshop: Relationship of accreditation bodies with regulatory bodies

Day 1	Topic	Moderation
08.30 – 09.00	Registration	IAAC
09.00 – 10.30	Welcome by INN, PTB, IAAC Inauguration and introduction of participants, expectations, Recap of the previous workshop	Imilce Zuta Manfred Kindler
10.30 – 11.00	Tea Break	
11.00 – 12.30	Session 1: Presentation and discussion of activities and experiences by countries – part I	Imilce Zuta Manfred Kindler
12.30 – 14.00	Lunch Break	
14.00 – 15.00	Session 2: Presentation and discussion of activities and experiences by countries – part II	Imilce Zuta Manfred Kindler
15.00 – 15.30	Tea Break	
15.30 – 17.00	Session 3: Presentation and discussion of activities and experiences by countries – part III	Imilce Zuta Manfred Kindler

Day 2	Topic	Moderation
09.00 – 10.30	Session 4: Presentation and discussion of activities and experiences by countries – part IV	Imilce Zuta Manfred Kindler
	Session 4: Group work to three BAP areas: construction, traffic and energy – Knowledge transfer	Imilce Zuta Manfred Kindler
10.30 – 11.00	Tea Break	
11.00 – 12.30	Session 5: Group work to three BAP areas: construction, traffic and energy – Knowledge transfer	Imilce Zuta Manfred Kindler
12.30 – 14.00	Lunch Break	

<u>Day 2</u>	Topic	Moderation
14:00 - 15:00	Session 6: Group work to three BAP areas – presentations of results	Imilce Zuta Manfred Kindler
	EU Guideline Best Practice – Recommendations list	Imilce Zuta Manfred Kindler
15.00 – 15.30	Tea Break	
16.30 – 17.00	Final Session: Lessons learnt, Next steps, work plans, comments from the participants	Imilce Zuta Manfred Kindler

2.3 Results

As a result of the workshop was found that:

- **The working group** which has addressed the Caribbean **Construction sector**, led by the representative of Cuba, has similar characteristics in terms of its relationship with the competent authority and their members are approximately in the same stage.

They will make a proposal to support Trinidad & Tobago, Jamaica and Guyana to promote the relationships between the corresponding regulators and the relevant accreditation bodies.

One option is to receive support from any legal representative for instance from Chile.

Members: Cuba, Jamaica, Guyana, Dominican Republic and Trinidad & Tobago.

- **The working group** which has addressed the **Vehicle Inspection sector**, essentially has exchanged information and presented as reference the activities made in vehicle inspection in Chile and Colombia.

The more complicated situation is in Argentina, respect to the relationship between the Accreditation Body and the corresponding regulatory authorities, mainly by the lack of governmental entities in the field of vehicle inspection.

Argentina proposed the alternative that one expert in the vehicle inspection regulation area may give them some support, for instance presenting some case studies of vehicle inspection from other countries

Members: Argentina, Chile, Colombia and Ecuador.

- **The working group** which has addressed the **Energy sector**, raised its action plans independently. In some cases those plans extend beyond 2013, taking into account the situation of the country and the accreditation body (quantity of personnel and other tasks)

The Accreditation Body from Costa Rica, presented the activity being done in relation to greenhouse gas (GHG) emissions. Also, in Honduras it was taken some activities

Members: Bolivia, Costa Rica, Chile, El Salvador, Honduras, Peru and Paraguay

In a general way, the progress of each Accreditation Body in their corresponding plans was different, because of each has had different situations. Some countries as Guatemala (who did not attended this 2nd Workshop, but was a country where the action plan was monitored), Trinidad & Tobago, Nicaragua and Argentina has passed by changes in the governmental institution contacted. And this situation has generated a difficulty in the implementation of their plans. There is another group who has planned the fulfillment of the milestones in a wider period than others.

However, during the workshop each group had a leadership who support the other members in the different activities developed in the framework of the corresponding sector (Construction, Energy Efficiency and Transportation)

3 Recommendations

The following summary of recommendations is presented in response to issues raised during the workshop, which can be taken as referential activities when some specific situations could arise in the relationship between the Accreditation Bodies with the competent authorities, and in general with the stakeholders.

Stage 1: ESTABLISHMENT A RELATIONSHIP WITH THE REGULATORY BODY

Activity:

- Review if there are national or international regulations as applicable to the exportation of the product. (NOTE: For example, in the case of the exportation of goods, it is relevant to take into account the regulatory requirements of the target market.)
- Identify the geographical scope of the regulation and the feasibility of if its application for achieving a result with an acceptable impact for the national need or in a regional level.

Problem 1: There is no support from governmental agencies. The regulatory framework has contradictions and moreover there is no effective monitoring about what is required legally or there is no surveillance for verifying the fulfillment of the regulation.

Recommendations 1:

- Identification and selection of at least one leader regulatory body in the country, with which the Accreditation Body could work.
- A leader is not necessarily the regulatory body, for instance, with the largest geographical coverage, but that one who is recognized in the country, as a natural leader in the sector.
- Try to promote awareness in the highest levels of government such as the National Competitiveness Council, the National Quality System or equivalent, in the extent these institutions are involved in the National Quality Policy.
- Identification and selection of a team of representatives of the institution, so that the team could:
 - ✓ Be open mind to understand the importance to base the authorizations, surveillance and other activities in reliable measurements
 - ✓ Have the capability to spread within the governmental organization (relevant areas) the relevance to work jointly with conformity assessment bodies accredited by the National Accreditation Body (AB), as supporting partners for the activities of the regulatory body.
 - ✓ Have the capability to promote outside the regulatory body to the highest governmental level the importance to work jointly with the conformity assessment bodies accredited
 - ✓ If necessary, the ability to work in an inter-institutional team, with representatives of other stakeholders such as private sector, governmental or non-governmental associations, industry, business, educational institutions, etc..
- The team work would preferably belong to the high and medium level of the regulatory body/governmental entity selected.

Problem 2: Re-structuring / personnel change of the area of the regulatory body

Recommendations 2:

Continue insisting on despite of:

- Representatives of the selected institutions be changed
- The selected institution disappears or be annexed to another area.

- Any other situation that involves the restructuring of the area.

Problem 3: Lack of interest of regulatory bodies

Recommendations 3:

Design a set of meetings with the relevant regulatory body giving the following message:

- Situations generated as a result of ineffective surveillance, preferably by means of statistical reports.
 - Pictures/Photos of situations emerged, news, reports of previous periods of unsuccessful governmental situations.
 - Examples of successful cases from other countries, from other continents.
 - Overview of the situation respect to the subject (e.g, vehicle inspection, energy efficiency in appliances), in the country in the next five years.
- . The team for this kind of meeting could consist of:
- A presenter preferably from other country (however this should not be a rule) who has the ability to introduce staff from AB to the regulatory bodies
 - Representatives of the regulatory sector from another country, if necessary
 - Representative of the regulatory sector from a European country, if necessary.
 - Representative of the AB

Problem 4: Perception of a low interest in a national level by the main institutions related with the regulatory body identified.

Recommendations 4:

Identification of other actors involved in the sector with potential interest in regulatory activities, standardization and conformity assessment (certification, inspection, product testing), quality control, counteract unfair competition among others.

Approach to the institutions / organizations that are identified.

For example in the case of vehicle inspection activity, the car insurance companies have particular interest in vehicle inspections are established in the country and are carried out properly

Stage 2: PLANING OF JOINT ACTIVITIESActivities:

Making a working plan, defining the activities needed for the implementation of the accreditation programme.

Visits/consults to ABs who have implemented programmes of accreditation in the sector of interest, in the management of the programme and the technical activities contained in it.

Problem 5: There is no support in standardization, because there are no normative documents for the subject of interest, for instance in Vehicle Inspection

Recommendations 5:

Meetings with the corresponding National Standardization Body (or other institution) which in the framework of any current National Standardization Technical Committee or in process of being established, be assigned the elaboration of those needed normative documents.

Problem 6: There is no clear and applicable regulation, we have a contradictory regulation or with gaps

Recommendations 6:

Identification and selection of at least one leader regulatory body in the country, with which the Accreditation Body could work.

To conform a committee who has the responsibility of the revision and modification of the technical regulation applicable to the selected area.

Problem 7: There is an acceptable technical regulation, however, the regulatory bodies do not do any action to monitor the fulfillment of that regulation in the field.

Recommendations 7:

Coordination with the corresponding regulatory body, the implementation of an action plan for designing and develop one or more programmes of accreditation for satisfying the demand of the governmental regulatory body.

What the AB would have to do is granting a support to the governmental entities in order they could fulfill with their responsibilities related to the control and monitoring the fulfillment of the technical regulations or equivalent. For instance, if the governmental entity has a direct order to monitor the inspection of GLP tanks and they are not fulfilling this rule, the ABs could help them to comply with

this mandate, through accredited entities in this field. If there is no any accredited entity till now, they could begin a plan of implementation for the corresponding accreditation programme with the support of the governmental entity.

Problem 8: Necessity to constitute Inter-Institutional Technical Committees for the sector of interest which promote the relationship between the governmental authorities and the AB

Recommendations 8:

To constitute Technical Committees in the sector of interest with technical representatives of: the AB (technical committees), the private sector (as industrial associations), the other governmental authorities, as necessary.

Problem 9: Necessity of having technical experts in the sector of interest, specifically in the technical activity involved in the programme of accreditation.

Recommendations 9:

To take into account the “expertise” of the technical personnel who work in the regulatory bodies of the sector so that it can be considered as potential technical experts in future.

After selecting the group of technical experts, train them in the corresponding standards of conformity assessment.

Problem 10: Arising of Conflict of Interest during the assessments, for lack of independence of some technical experts, technical assessors

Recommendations 10:

Sometimes the lack of availability of technical experts or technical assessors in the country, generates that professional personnel from CABs have to be the technical experts for the assessments of other CABs which are the commercial competence form the first CAB.

The AB must establish mechanisms aimed to prevent the emergence of potential conflicts of interest and must see how to monitor these mechanisms are really effective.

Stage 3: IMPLEMENTATION OF THE ACCREDITATION PROGRAMMEActivity:

Fulfillment of the planned activities. Take into account the possibility to do a risk analysis

Problem 11: Traceability (to SI standards or reference materials)Recommendations 11:

Working together with the National Metrology Institute(s) (NMIs) of the country, to establish mechanisms for assuring the traceability of measurements. The participation of representatives of the NMIs in the technical committees of Accreditation Body is desirable.

Problem 12: Proficiency TestingRecommendations 12:

Identification of needs about proficiency testing coordinated with the IAAC PTWG.

In addition to the particular case of inspection activities, intercomparison activities may involve comparing the measurement results of the inspectors on the inspection process of a product.

For example, the INN, during the workshop presented a mechanism for a PT in inspection consisting of the inspectors, one by one, go to a room, to make the vehicle inspection process according to determined tests. They implemented mechanisms in order to prevent that one inspector who perform the inspection can share information with other following inspector.

Problem 13: Harmonization of evaluation criteria in a national and regional level (LA & Caribbean)Recommendations 13:

Conform Technical Committees for the different activities of conformity assessment.

Stage 4: MANTEINANCE OF THE ACCREDITATION PROGRAMME (SUSTAINABILITY, CREDIBILITY AND COMPETENCE)Problem 14: There is no effective surveillance monitoring mechanisms in the country.

The CABs accredited, do not always fulfill with their own procedures and in consequence with the requirements of the regulations. There is a risky situation for the ABs reputation.

Recommendations 14:

Implement surveillance activities to the CABs.

To work jointly with the regulatory entity in order to strengthen the surveillance mechanisms. This task would have to be addressed jointly by the AB and the corresponding regulatory body in order to have satisfactory outcomes for the country.

To promote the regulatory entities to support the surveillance activities for the private sector, we mean the CABs.

Problem 15: There is only one or two CABs with potential possibilities to be accredited in the sector for one particular technical activity, I mean for the programme of accreditation

Recommendations 15:

Take into account if it has sense to implement a programme of accreditation.

If it is a national necessity, to establish adequately the costs of the accreditation programme management and implement strategies for its maintenance, for instance, assigning the new programme to any area of the AB, and assuring that this area has the technical competence for managing it (cost optimization)

4 NEXT ACTIVITIES AND NEXT FOR THE PARTICIPANTS

- a) The participants will review the contents of their action plan which were presented at the second workshop and clearly propose the following milestones for monitoring based on the Excel file that was given. Each Accreditation Body would have to up-date these tables periodically according to their progress.
- b) To update the action plan, participants will consider information obtained from the 2nd Workshop held in Santiago de Chile and the present document contains recommendations on the issues raised by the representatives of the Accreditation Bodies during the workshop.

As a result of the workshop activities in the proposed work at the regional level are:

- To integrate the competent authority to the projects, identifying it as a main actor who is goal-oriented, pushing the accomplishment of objectives which could arise.
- To share information among the participants during the development of their plans, as needed.

- The cooperation activities should have components of measurement traceability and proficiency testing

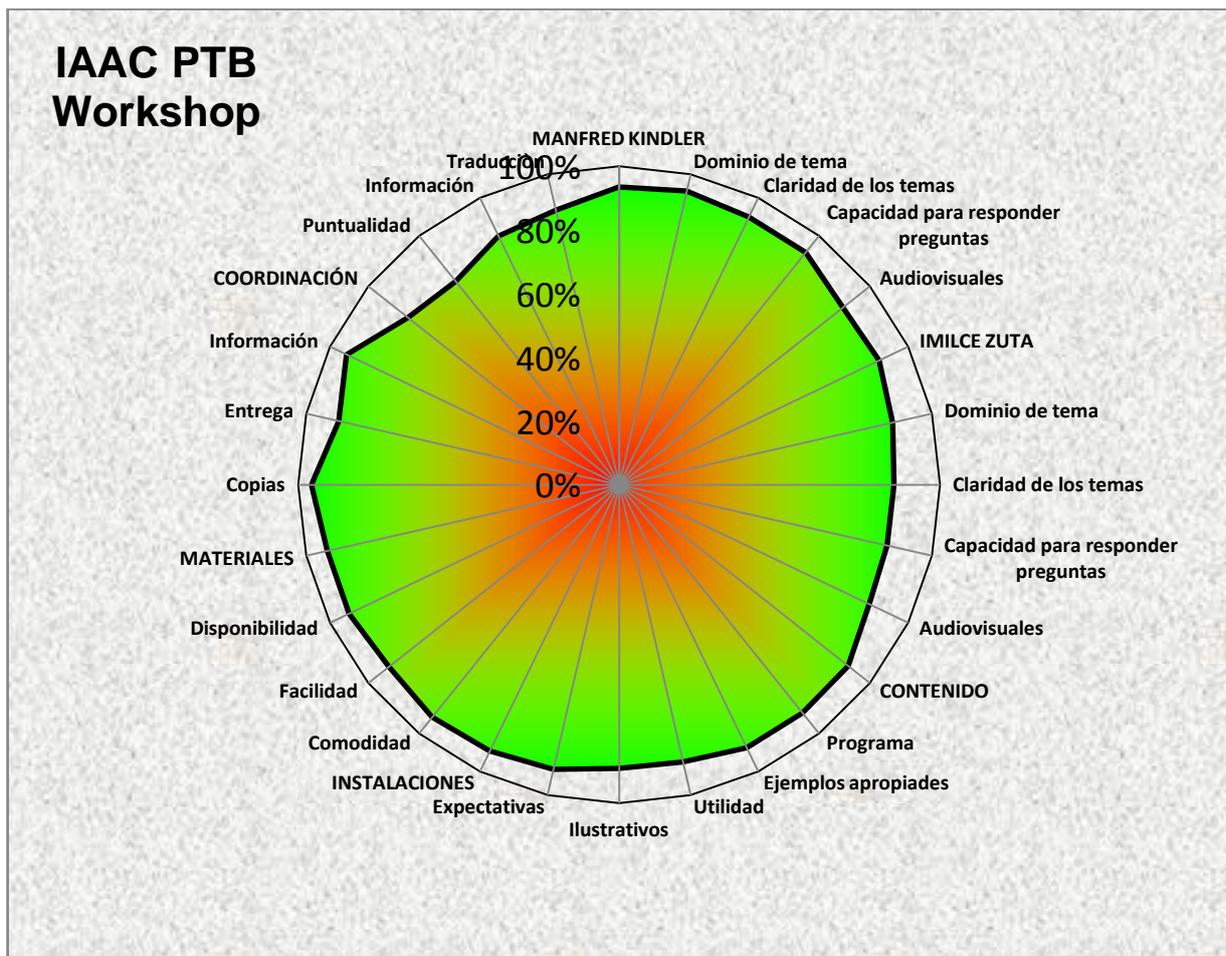
5 NEXT STEPS

In this group of participants it has been identified a sub-group of Accreditation Bodies, which need more support for their plan, a second sub-group which has further challenges in their relationship with the governmental entities and third sub-group which has acceptable relationship with the governmental entities and are progressing quite well.

- a) Taking into account the different progress in the action plans presented in the 2nd BAP Workshop by the different participants, it has been proposed to evaluate the realization of the 3rd Workshop in a date after July 2012, because it is necessary to leave the participants more time for developing their activities.
- b) Imilce Zuta, PTB consultant will be in contact with participants to monitoring the progress of activities raised by participants in their action plans.
- c) PTB will evaluate support requirements that ABs may present regionally as fruit of the discussions emerged during the workshop, such as the proposal of the Caribbean region to support them with particular experts for instance in construction and other subjects. Other demand was the proposal of Argentina to have a support with the regulatory agencies in pushing accreditation in vehicular inspection.

5. EVALUATION OF THE WORKSHOP

See following page



Some comments from the participants

- El taller ha sido de mucha utilidad al exponer con claridad otras situaciones que nos ayudan a ver con claridad los pasos a seguir
- Gracias por la cooperación que se hace
- Excellent workshop, the share of experiences
- Mejorar la logística de coordinación respecto a los traslados de los particulares: ofrecer información de manera más oportuna.

ANNEXE

List of Participants

N°	Nombre	Position	Institution	Country	email
1	Sr. Ignacio Guerreiro	Certification Coordinator	OAA (Organismo Argentino de Acreditación)	Argentina	iguerr@mecon.gov.ar
2	Sra. Elizabeth Choque Mamani	Responsible of Accreditation Laboratory	DTA-IBMETRO (Dirección Técnica de Acreditación – Insituto Boliviano de Metrología)	Bolivia	echoque@ibmetro.gob.bo ; choque.elizabeth@gmail.com
3	Sr. Carlos Pacheco	Technical Director	ONAC (Organismo Nacional de Acreditación de Colombia)	Colombia	Carlos.pacheco@onac.org.co
4	Sra. Andrea San Gil Leon	ECA Representative	ECA (Entidad Costarricense de Acreditación)	Costa Rica	verificadores@eca.or.cr
5	Sra. Kenia Maza	Technical Secretary	ONARC (Organismo Nacional de Acreditación de Cuba)	Cuba	acre@cenai.inf.cu
6	Sr. Eduardo Ceballos	Head of the Accreditation Division	INN (Instituto Nacional de Normalización)	Chile	eduardo.ceballos@inn.cl
7	Sra. Dalila Chilingua	Responsible of Inspection Bodies	OAE (Organismo de Acreditación Ecuatoriano)	Ecuador	dchilingua@oae.gob.ec
8	Sr. Ulf Hillner	Project Coordinator	PTB (Physikalisch Technische Bundesanstalt)	Germany	Ulf.Hillner@ptb.de
9	Sr. Manfred Kindler	PTB Expert	PTB (Physikalisch Technische Bundesanstalt)	Germany	kindler@manfredkindler.de
10	Sra. María Imilce Zuta Chong	PTB Expert	PTB (Physikalisch Technische Bundesanstalt)	Peru	imilcezuta@gmail.com
11	Sra. Candelle Walcott-Bostwick	Head of Conformity Assessment	GNBS (Guyana National Bureau of Standards)	Guyana	cwalcottbostwick@yahoo.com , eenniss@gnbsgy.org cbostwick@gnbsgy.org

N°	Nombre	Position	Institution	Country	email
12	Sra. Diana Morales	OHA Representative	OHA-SEPLAN (Organismo Hondureño de Acreditación)	Honduras	dmorales@seplan.gob.hn
13	Sr. Ian Emanuel	JANAAC Representative	JANAAC (Jamaica National Agency for Accreditation)	Jamaica	ian.emmanuel@janaac.gov.jm
14	Sra. Yrene Caballero	Laboratory Accreditation Director	ONA-CONACYT (Organismo Nacional de Acreditación)	Paraguay	ycaballero@conacyt.gov.py
15	Sra. Lidia Patricia Aguilar Rodríguez	Responsible for the Quality Management System	SNA.-INDECOPI (Servicio Nacional de Acreditación)	Peru	laquilar@indecopi.gob.pe
16	Sra. Carmen Baez Baez	Responsible for Systems Certification	DIGENOR (Dirección General de Normas y Sistemas de Calidad)	Dominican Republic	cbaez@digenor.gob.do
17	Sra. Ellison Floyd-Tobas	Standards Office II	TTLABS (Trinidad & Tobago Laboratory Accreditation Service)	Trinidad & Tobago	Ellison.floyd@ttbs.org.tt