THE ROADMAP TO AN ACCREDITATION SYSTEM

30 Milestones for Developing Countries
Accreditation bodies

The global market allows goods to be exchanged between countries and at all stages of production. The use of optimal manufacturing conditions has led to products being available at prices which would not be attainable without this division of labor. The worldwide exchange of goods, however, carries dangers, too: consumers and those processing goods find themselves confronted with poor quality products often containing a health risk which cannot be seen.

A remedy is provided by product certificates which confirm compliance with fixed requirements (standards). For the issuing of such product certificates, certification bodies are needed whose decisions are based on the reports of test laboratories. The test labs, in turn, also have to satisfy certain requirements. The measuring instruments used have to be traceable to the national standard via the calibration laboratories, i.e. the accuracy of measurement has to be tested at certain intervals by a measuring device of higher order.

Furthermore, inspection bodies are required which perform certain checking activities (e.g. production or transport supervision).

This whole network of operative and supervisory activities needs much time and effort and is cost-intensive. "One stop testing" constitutes the ideal solution, so that these checks do not have to be repeated in each country. For this purpose, however, sufficient confidence has to be established worldwide in the conformity-assessing institutions. It is the responsibility of national accreditation bodies to ensure that by the application of ISO standards, expert, competent supervision of the quality infrastructure institutions is guaranteed.

Associations of the accreditation bodies (ILAC and IAF) have concluded multilateral recognition agreements (MLA) and mutual recognition arrangements (MRA) at a global level, on the basis of peer evaluations.

Accreditation bodies are an important building block in breaking down technical barriers to trade. They fulfill the commitments which were entered in the Agreement on Technical Barriers to Trade of the World Trade Organization.

Within the scope of good governance on the one hand and fighting corruption on the other, countries in transition and developing countries are intensively working on entering these agreements in the near future, to attain international recognition of their testing and certificates.
Cooperation

An internationally recognized accreditation body is a sensible goal but it is also difficult to reach – its attainment represents a hard, long drawn-out process for developing countries. The consequences of an economy detached from the global market and autocratic structures of power frequently call for radical re-thinking by political decision makers and state-run service providers.

PTB supports this process in the frame of its Technical Cooperation with developing countries. For this purpose, an integral advisory package is available for use:

- **Organization**: analysis of the actual situation, setting up databases, carrying out proficiency tests and intercomparisons; exchanging experience with competent experts; systems for training of trainers.
- **Personnel**: provision of trainers, assessors, peer evaluators, experts for special tasks, as well as speakers of international renown for conferences and events open to the public.
- **Technology**: advice and specification for laboratories, measuring and testing facilities, inspection and certification bodies; computer technology; reference materials; samples for intercomparisons.
- **Policies**: advice to governments on implementing international agreements, on adapting national legislation and designing a system for quality infrastructure; establishment of contacts to institutions which have operated independently to date and clarification of their roles; introduction of countries to specialized regional and international organizations; awareness-raising measures for supervisory bodies, manufacturers and consumers.

PTB’s integral advisory package supports all levels of intervention and stages of development leading to the establishment of an accreditation system.
Tools

Standardized tools for analytical and training purposes were developed especially for establishing and advising national and regional accreditation systems. These were successfully tried out worldwide in a large number of partner countries and are subject to regular adjustment to accommodate new findings and demands. At the core is the "House of Accreditation" which – in 30 milestones – makes visual the setting up of a national accreditation body up to the stage of its international recognition. The different steps of development are accompanied, advised and supported by the planning and checking of a multitude of key parameters in a very transparent and plausible way.

The toolbox
- Identifying the "critical mass" of customers who would use the services of an accreditation body, in order to obtain sustainable financial stability (drawing up a 5 year financial plan);
- Models of regionally coordinated accreditation systems for small countries or those which are economically weak;
- Assessment of the performance level and the state of advancement of the components required (30 milestones) and of the actors responsible;
- Structure-Process-Outcome Analyses with evaluation of risk if certain components fail;
- Evaluation and monitoring systems for the theoretical and practical competence of experts;
- Training plans and programs;
- Simulation of high-stress situations for assessors in training laboratories, crisis simulations in accreditation bodies;
- Proficiency tests for laboratories in the fields of environment and food analysis.

Accreditation bodies are exposed to stressful situations. The simulation of crises is therefore an essential part of the training.
Many countries do not have any idea about how much an accreditation system costs. Whereas the set-up phase and the start-up phase are subsidized more or less transparently, the national accreditation laws mostly commit the system to self-financing in the medium or long term. In the same way as for any company, cost accounting can also be established for accreditation bodies, and the follow-up costs can, thus, be estimated.

By means of benchmarking with other countries, a ratio can be ascertained which corresponds approximately to the economic power of the state considered. This factor can, among other things, be used to define the fee structure for an accreditation. From this fee system, the expected income can be deducted and the break-even-point ascertained.

This, in turn, forms the basis for estimating the critical mass of laboratories and inspection and certification bodies which are to be accredited in order to achieve cost recovery. Moreover, the capacity limit of the accreditation body’s personnel resources is ascertained. This information is particularly important to avoid a collapse of the quality system during the time of exponential growth of customer applications which usually follows international approval.

Due to the larger amount of effort spent on first accreditations, the income from these sources is mostly considerably higher than that from annual monitoring measures. This is of crucial significance for the sustainable financing of an accreditation body. In practice it is regularly observed that accreditation activities achieve satisfying incomes in the first few years, but that these decrease drastically once market saturation of first-time accreditations has been attained. By simulating various scenarios, a practice-oriented budget plan can be drawn up for a period of 5 years – which is in line with the usual time span of an accreditation period.

Cost recovery cannot be achieved in many developing countries as the number of accreditations is too low. This cannot even be changed with consistent cost-saving measures. An accreditation system encompassing several countries of a region, but with all of them having their own national representations, offers a cost-effective alternative in such cases. However, national interests are often in conflict with such Regional Accreditation Systems. Models which are conceived in the frame of regional integration associations can, however, permit sufficient consideration of national self-confidence through a fair division of tasks.
The 30-Milestone Program of PTB’s International Technical Cooperation divides the setting-up of an accreditation body or of an accreditation system into individual components. The advances in development attained are classified on a 10-point scale in accordance with defined criteria, whereby the respective degree of accomplishment for each component can be exactly determined. The stages of development are visualized by using the colors of the traffic lights: red, yellow and green. This simple display format has proved very effective in practice.

Accreditation systems are based on four columns. Each individual column contributes to the stability of the whole system in equal measure.

The respective political decision-makers usually develop very quickly the ambition of wanting to see a "green light" for their progress and of removing the "red light" from the status diagram, as it stands for "no advancement".

Each milestone is linked to a requirement profile, an indicator list and a plan of measures which can additionally be connected to the corresponding computer-aided plan of operations.

Additional tools allow progress and current deficits, as well as their inhibiting effects on reaching goals, to be identified. And not only that: by linking the milestones to the actors responsible (legislators, ministries, accreditation body, stakeholders etc.), successful action and the urgent need for action will become obvious. This is both an effective and a tried-and-tested tool.
The House of Accreditation
Structure-Process-Outcome Analysis

The SPO Analysis refines the whole process which is related to the setting-up of an accreditation body. In a matrix, the structural elements, process steps and outcomes are assigned to the respective body or person responsible. These connections are defined in both directions. Existing problems, thus, become apparent. Insufficient delegation, lines of communication that have been overseen and inadequate cooperation frequently transpire, thereby, to be development-inhibiting factors.

With the aid of the classical risk analysis, the contributions of the partial areas and process sequences leading to the objectives can be estimated and displayed as graphs. In addition, it is possible to simulate the failure or the lacking performance capacity of individual components by using experience available from other countries.

By means of the risk analysis it can be shown, for example, which percentage of non-agreement with international standards would remain undiscovered in the existing deficits of a national system. Completely realistic values lie between 50-80 %. Such results make it clear to those with political responsibility very drastically, what consequences a missing technical sector committee or a professionally competent systems manager can have on the accreditation results. The concrete need for action is immediately apparent.

If essential components of an accreditation system are missing, there are consequences. Risk analyses highlight system deficits and make these clear to those with political responsibility.
Structure-Process-Outcome Analysis

ISO 17021

IAF MRA for System Certification Bodies

Management System

- Structure
- Resources
- Information
- Process


ISO 9001: Scope, Customer Focus, Management Review, Design

- Legal Responsibility
- Impartiality
- Liability
- Financing

- Impartiality
- Competence
- Responsibility
- Openness
- Confidentiality
- Resolution of Complaints

- Records
- Outsourcing
- External Experts
- External Auditors
- Personnel
- Management

- Exchange
- Confidentiality
- Use of Marks
- Directory
- Certificates
- Publications

- Appeals/Complaints
- Scope changes
- Recertification
- Surveillance
- Initial Audit

Top Management

Committee

Organizational Structure

General Requirements

Principles
At the heart of every accreditation body are the qualifications of its internal and external staff. The qualification profile for assessors should, in the ideal case, be drawn up by a technical sector committee. It is exactly the establishment of sector committees at a justifiable cost which poses a considerable problem in developing countries. Competent experts who might work on these committees are usually employed at private companies and are, for various reasons, only available to a limited extent.

Expert competence

Quality profiles for assessors meet with high acceptance and esteem if they are drawn up jointly by experts in sector committees.

The approach of PTB’s International Technical Cooperation therefore contains the possibility of measuring an assessor’s individual competence by using a two-part evaluation system which is based on questionnaires and expert talks. The theoretical and practical competence measured can be called up in a coordinate system which can be used, among other things, for selecting participants in qualification measures. Professional competence is visualized in a pie chart allowing a direct comparison of the team’s competence with the requirements of the applicant.
The difference

The cooperation of PTB’s International Technical Cooperation with its partners in developing countries has time and again shown that there are – for cultural and historical reasons – very different perceptions of what is to be understood under the key terms like competence, qualifications, quality management, conformity assessment or fields of accreditation.

These different perceptions lead to misunderstandings and discrepancies in the planning, implementing, evaluating that which has been achieved, assessing of deficiencies and any corrective measures necessary.

### Key terms and their interpretation

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<th>Term</th>
<th>Competence</th>
<th>Qualification</th>
<th>Quality management</th>
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<tr>
<td>Mastery of a technology through understanding</td>
<td>Confident handling of a technology through training</td>
<td>Acquisition of knowledge through education and training</td>
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<tr>
<td>Acquisition of knowledge through education, training and experience</td>
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<td>Confident handling of individual components for quality</td>
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<td>Penetration of a system with quality thinking</td>
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<td>Customer-oriented evaluation of fulfillment of normative requirements</td>
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<td>Conformity assessment</td>
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<tr>
<td>Related to specific sectors, e.g. chemical industry, mechanics and</td>
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<td>engineering, construction, clinical laboratories</td>
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Accreditation is the formal confirmation of competence.
Simulation

An integral part of PTB’s consultancy is to point out cultural differences and the consequences related to them. This happens in a very practical and clear way, by specially preparing a laboratory which already has international accreditation for a lab assessment with commonly occurring deficiencies. In a three-phase process, three to four teams of assessors compete against each other under real conditions to detect as many of these non-conformities as possible. In the first phase, the assessment takes place without any disturbances or pressure of time. In the second phase, typical disturbances are continually added and the lab staff try to confuse the assessors as well. In the third phase, which is mostly intended for the lead assessors, critical situations are simulated under video control which can lead to the breakdown of the trial.

These lab simulations are a very effective and popular qualification measure. There is a catalogue with over 150 scenarios which have also been enhanced for inspection and certification bodies.

The simulation technique can also be applied to determine the aptitude of an accreditation body to take over further state functions. In a crisis simulation, a working day with many challenges is simulated within a period of time of one hour, so that by the end of one day, a whole working week has been simulated.

A permanent part of the accreditation system is comparing the performance of laboratories from different countries (international benchmarking). Accredited laboratories take part in international round robin tests and lab comparisons – an instrument that is of increasing importance worldwide. It serves, in a simple way, to maintain competence and it builds trust.
The elements of the accreditation system

Supervisory board
"stakeholder"
- Customers, associations, standardization, the state, consumers, universities

Executive board
"shareholder"

Advisory boards (these might be the nuclei of future sector committees)
- Experts (industry, standardization, universities, state bodies, consumers, customers)

Head office of the accreditation body
- Manager
- Administration
- Case officers

Evaluating board
- Non-involved case officers
- Manager (as a guest)
- Depending on the specific case, 1 to 2 experts from the expert pool
- External quality infrastructure experts

Assessor pool

System assessors
- Non-involved case officers
- External system assessors

Technical assessors
- National and international experts (e.g. heads of labs, professors)

Technical experts
- Technical assessors with no system training
The PTB, the National Metrology Institute of Germany, with its 1,400 staff members is rather a global player in the world of metrology. It faces the responsibility involved for society, economy and science. This is why the orientation and impact of PTB is not restricted to the national borders.

Since the start of German development assistance about 40 years ago, PTB’s International Technical Cooperation has been cooperating worldwide with developing countries and countries in transition.

During these four decades, not only has a lot been achieved but also a lot has been learned. Today the technical cooperation is focused on the requirements of partner countries acting in a global world. Partner countries have to set up or improve their quality infrastructure and adapt it to international agreements. Only in this way can they participate in international trade and secure consumer, environment and health protection. Moreover quality infrastructure enables fair trade and contributes to a socially oriented development.

The international tasks of PTB include representation in all kinds of international organizations in the domain of quality infrastructure. This participation at the same time enables and commits PTB to consult and support its partners according to international standards and best practices.

The clients of the Technical Cooperation projects are, above all, the German Ministry for Economic Cooperation and Development (BMZ), which finances the majority of projects with PTB participation. But also the European Union, the World Bank and other organizations are customers of PTB. For the implementation of projects a network of strategic partners is available.

All in all, the global networking of PTB has, above all, one objective: the international harmonisation of quality infrastructure and its mutual acceptance.
### Abbreviations and imprint

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<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>BMZ</td>
<td>Bundesministerium für wirtschaftliche Zusammenarbeit und Entwicklung (Federal Ministry for Economic Cooperation and Development)</td>
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<td>IAF</td>
<td>International Accreditation Forum</td>
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<td>ILAC</td>
<td>International Laboratory Accreditation Cooperation</td>
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<td>ISO</td>
<td>International Organization for Standardization</td>
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<td>MLA</td>
<td>Multilateral Recognition Agreement</td>
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<td>MRA</td>
<td>Mutual Recognition Arrangement</td>
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<td>PTB</td>
<td>Physikalisch-Technische Bundesanstalt</td>
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<td>QI</td>
<td>Quality Infrastructure</td>
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<td>SPO</td>
<td>Structure-Process-Outcome</td>
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<td>TBT</td>
<td>Technical Barriers to Trade</td>
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<td>WTO</td>
<td>World Trade Organization</td>
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