INTERNATIONAL DEVELOPMENT IN PRACTICE

QI Toolkit Case Studies

Martin Kellermann

WORLD BANK GROUP

PTB Physikalisch-Technische Bundesanstalt
Braunschweig und Berlin
National Metrology Institute

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Abbreviations

AFRAC	African Accreditation Cooperation
AFRIMETS	Intra-Africa Metrology System
ANC	African National Congress
ARSO	African Organisation for Standardisation
BDI	Federation of German Industries (Bundesverband der Deutschen Industrie)
BIPM	International Bureau of Weights and Measures
BMAS	Federal Ministry of Labour and Social Affairs
BMWi	Federal Ministry of Economic Affairs and Technology (Bundesministerium für Wirtschaft und Technologie)
BMZ	Federal Ministry for Economic Cooperation and Development (Germany)
BSCI	Business Social Compliance Initiative
CAC	Codex Alimentarius Commission
CE	Conformité Européenne
CEN	European Committee for Standardization
CENELEC	European Committee for Electrotechnical Standardization
CEO	chief executive officer
CGCRE	General Coordination for Accreditation (Coordenação Geral de Acreditação do Inmetro)
CIS	Commonwealth of Independent States
CMC	calibration and measurement capabilities
COMESA	Common Market for Eastern and Southern Africa
COOMET	Euro-Asian Cooperation of National Metrological Institutions
CRM	certified reference materials
CSIR	Council for Scientific and Industrial Research
CSM	Centre for Standardization and Metrology
DAG	Donor Assistance Group
DAkkS	German Accreditation Body (Deutsche Akkreditierungsstelle)
DAR	German Accreditation Council (Deutscher Akkreditierungsrat)

DIN	German Institute for Standardization (Deutsches Institut für Normung)
DKD	German Calibration Service (Deutscher Kalibrierdienst)
DM	deutsche mark (German mark)
DTI	Department of Trade and Industry
DTIS	Diagnostic Trade Integration Study
EA	European co-operation for Accreditation
EAAB	East African Accreditation Board
EABC	East African Business Council
EAC	East African Community
EASC	East African Standards Committee
EC	European Commission; European Community
ECAE	Ethiopian Conformity Assessment Enterprise
ECBP	Engineering Capacity Building Programme
EN	European standard
ENAO	Ethiopian National Accreditation Office
EPA	Economic Partnership Agreement (EU)
ESA	Ethiopian Standards Agency
ETSI	European Telecommunication Standards Institute
EU	European Union
EURAMET	European Association of National Metrology Institutes
FAO	Food and Agriculture Organization
G.A.P.	Good Agricultural Practice
GDP	gross domestic product
GIZ	German Agency for International Cooperation (Deutsche Gesellschaft für Internationale Zusammenarbeit)
GOST	State Standard (Russian: ГОСТ - государственный стандарт)
HACCP	hazard analysis and critical control points
IAF	International Accreditation Forum
IEC	International Electrotechnical Commission
IF	Integrated Framework for Trade-Related Technical Assistance to Least-Developed Countries
ILAC	International Laboratory Accreditation Cooperation
IMF	International Monetary Fund
INMETRO	National Institute of Metrology, Quality and Technology (Instituto Nacional de Metrologia, Qualidade e Tecnologia)
INPM	National Institute for Weights and Measures (Instituto Nacional de Pesos e Medidas)
IP	intellectual property
ISO	International Organization for Standardization
IT	information technology
ITC	International Trade Centre
JICA	Japan International Cooperation Agency
KCA	Kyrgyz Centre for Accreditation
KCDB	Key Comparison Database (BIPM)
KEBS	Kenya Bureau of Standards
KENAS	Kenya National Accreditation Service
LDC	least-developed countries
MFD	Marine Fisheries Department
MITT	Ministry of Industry, Trade and Tourism

MoA	memorandum of agreement
MoC	Ministry of Commerce
MoCB	Ministry of Capacity Building
MoST	Ministry of Science and Technology
MoTI	Ministry of Trade and Industry
MRA	Mutual Recognition Arrangement
NA	Norwegian Accreditation
NAPHIS	National Animal and Plant Health Inspection Service
NEDLAC	National Economic Development and Labour Council
NISM	National Institution for Standards and Metrology
NIST	National Institute of Standards and Technology
NMI	national metrology institute
NMIE	National Metrology Institute of Ethiopia
NMISA	National Metrology Institute of South Africa
NML	National Metrology Laboratory
Norad	Norwegian Agency for Development Cooperation
NPL	National Physical Laboratory
NPSL	National Physical and Standards Laboratory
NQP	national quality policy
NRCS	National Regulator for Compulsory Specifications
NRF	National Research Foundation
NSB	national standards body
NTRF	National Technical Regulation Framework
OECD	Organisation for Economic Co-operation and Development
PADCT	Program to Support Scientific and Technological Development (Programa de Apoio ao Desenvolvimento Científico e Tecnológico)
PakGAP	Pakistan Good Agricultural Practice
PCSIR	Pakistan Council of Scientific and Industrial Research
PNAC	Pakistan National Accreditation Council
PSQCA	Pakistan Standards and Quality Control Authority
PTB	National Metrology Institute of Germany (Physikalisch-Technische Bundesanstalt)
PTR	Physikalisch-Technische Reichsanstalt
QI	quality infrastructure
QSAE	Quality and Standards Authority of Ethiopia
RBS	Rwanda Bureau of Standards
RTBET	Reducing Technical Barriers for Entrepreneurship and Trade
SABS	South African Bureau of Standards
SADC	Southern African Development Community
SANAS	South African National Accreditation Service
SCC	System Certification Centre
SDO	standards development organizations
SECO	State Secretariat for Economic Affairs (Switzerland)
SI	International System of Units
SMEs	small and medium enterprises
SPS	sanitary and phytosanitary
SQMT	Standardization, Quality Assurance, Metrology and Testing
SQMT Act	East African Standardization, Quality Assurance, Metrology and Testing Act

SQMT Protocol	Protocol on Standardization, Quality Assurance, Metrology and Testing
TBS	Tanzania Bureau of Standards
TBT	Technical Barriers to Trade
TBT Agreement	Agreement on Technical Barriers to Trade (WTO)
TeCAT	Technology Capability Accumulation and Transfer
TGA	German Association for Accreditation
TRIM	Trade-Related Investment Measures
TRIPS	Trade-Related Aspects of Intellectual Property
TRTA	Trade Related Technical Assistance
TS	Turkish standard
TSE	Turkish Standards Institute (Türk Standardlari Enstitüsü)
TÜRKAK	Turkish Accreditation Agency (Türk Akreditasyon Kurumu)
TVET	technical and vocational education and training
UKAS	United Kingdom Accreditation Service
UME	National Metrology Institute (Ulusal Metroloji Enstitüsü)
UN	United Nations
UNBS	Uganda National Bureau of Standards
UNDP	United Nations Development Programme
UNIDO	United Nations Industrial Development Organization
US$	U.S. dollar
USAID	U.S. Agency for International Development
WTO	World Trade Organization

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About the Author

Martin Kellermann has more than 40 years of experience working in quality infrastructure (QI), first in the South African Bureau of Standards and thereafter as a consultant all over the world. He has worked in Central Asia, the Middle East, East Africa, West Africa, and East Asia, advising governments and QI institutions on policy, strategy, and the reengineering of business activities, as well as facilitating the drafting of national quality policies and QI legislation. During this time, he worked with the World Bank, National Metrology Institute of Germany, International Organization for Standardization, International Trade Centre, United Nations Industrial Development Organization, United Nations Development Programme, and many other organizations, and he has contributed to and authored multiple publications on QI.

Kellermann holds a master's degree in mechanical engineering from Pretoria University. He has also studied accountancy at the University of the Witwatersrand's Graduate School of Business Administration and participated in the Executive Education Program of the Haas School of Business, University of California, Berkeley. Currently, Kellermann lives with his wife in South Africa.

Abbreviations

BIPM	International Bureau of Weights and Measures
CGCRE	General Coordination for Accreditation (Coordenação Geral de Acreditação do Inmetro)
CMC	calibration and measurement capabilities
CRM	certified reference materials
DM	deutsche mark (German mark)
GDP	gross domestic product
IAF	International Accreditation Forum
ILAC	International Laboratory Accreditation Cooperation
INMETRO	National Institute of Metrology, Quality and Technology (Instituto Nacional de Metrologia, Qualidade e Tecnologia)
INPM	National Institute for Weights and Measures (Instituto Nacional de Pesos e Medidas)
KCDB	Key Comparison Database (of BIPM)
NIST	National Institute for Standards and Technology (United States)
NMI	national metrology institute
PADCT	Program to Support Scientific and Technological Development (Programa de Apoio ao Desenvolvimento Científico e Tecnológico)
PTB	National Metrology Institute of Germany (Physikalisch-Technische Bundesanstalt)
QI	quality infrastructure
SI	International System of Units
SME	small and medium enterprise
UKAS	United Kingdom Accreditation Service
UNIDO	United Nations Industrial Development Organization
US$	U.S. dollar

Brazil

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Abstract: Establishing a world-class quality infrastructure (QI) institution takes a long time and necessitates heavy investment in people, systems, and infrastructure. Brazil's National Institute of Metrology, Quality and Technology (INMETRO) developed from a small calibration laboratory to a leading national metrology institute at the international level, but it took three decades and the unstinting support of a development partner to do so.

EXECUTIVE SUMMARY

In the 1960s and 1970s, Brazilian exports increased dramatically, driven by an increase in manufactured goods. But Brazil was experiencing a high-technology deficit in its trade balance. High-technology goods had to be imported into Brazil, and this deficit—US$450 million in 1973—was projected to grow quickly to US$1 billion. The government therefore adopted a strategy to enhance the technological autonomy of the Brazilian economy. In addition, Brazil was embarking on the development of nuclear power, and the envisaged power plants needed local technological backup in terms of operation and safety. The cooperation agreement signed between the government and the National Metrology Institute of Germany (PTB) in 1967 provided for capacity enhancement of Brazil's National Institute of Metrology, Quality and Technology (INMETRO). This cooperation was strengthened in 1975 after the signing of the agreement between Germany and Brazil for the transfer of nuclear power technology.

The involvement of PTB in INMETRO and other players of Brazil's quality infrastructure (QI) can be described in three phases:

- *Phase 1 (1967–85):* INMETRO was extensively supported in establishing the national metrology laboratories.
- *Phase 2 (1985–95):* The scope was broadened to also include the calibration laboratories and the accreditation system, thereby enhancing the QI system as a whole.

- *Phase 3 (starting in 2002, with new agreements signed):* PTB and INMETRO established a more horizontal arrangement, operating as equal partners in metrological research and dissemination of knowledge.

This narrative describes the first two phases; the third phase is still operational and is not covered. Table 1 summarizes the overall results of QI reform in Brazil.

Phase 1: National metrology laboratories

PTB's involvement can be described as a matrix. On one level, it consisted of three modes—support in training, facilities, and equipment. These modes were implemented in a number of activities, namely scientific metrology, legal metrology, and accreditation. The amount and kind of support were continuously aligned with the needs as determined at the time.

Training. The Brazilian government took the first steps to strengthen metrology training by sponsoring the postgraduate training of 40 metrology students at the Federal University of Rio de Janeiro in 1975 and 1976. Many of these students joined INMETRO. Twenty of them were sent to PTB in Germany for about 18 months to be trained in high-technology metrology. On their return, they became the core around which INMETRO was developed. In the years following, PTB seconded a number of highly trained metrology experts to INMETRO, some of whom were involved for quite a few years, and others for shorter periods.

Facilities. The Brazilian government also took the first steps to establish its metrology facilities by providing funds for new INMETRO laboratories in 1971. Additional funds were made available from the Program to Support Scientific and Technological Development (PADCT), which was funded by the World Bank. Unfortunately, the completion of the buildings took many years because of bureaucratic idiosyncrasies and funds that were not forthcoming from subsequent governments. This procrastination had serious implications for the

TABLE 1 Snapshot of quality infrastructure (QI) reform in Brazil

BEFORE REFORM	AFTER REFORM
Brazil's National Institute of Metrology, Quality and Technology (INMETRO) is established in 1971, but its services relate mostly to legal metrology and a little bit of calibration.	INMETRO is the recognized national metrology institute (NMI) of Brazil; it has realized national primary measurement standards, and a vast number of independent calibration laboratories have been established.
INMETRO does not have any international recognition.	INMETRO has advanced to a globally well-respected NMI and is in the top 20 in calibration and measurement capabilities (CMCs) listed in the BIPM's Key Comparison Database.
Brazil does not have a national accreditation body, and the metrology division of INMETRO provides some recognition of calibration laboratories as a stopgap measure.	Brazil has a national accreditation body, the General Coordination for Accreditation (CGCRE), which is a signatory to the ILAC and IAF mutual recognition arrangements.
Brazilian manufacturers have to rely on accredited laboratories abroad to test their products for international markets. This is an expensive and time-consuming challenge.	Brazilian manufacturers enjoy the services of Brazilian conformity assessment service providers that have been accredited and whose measurements are traceable to international standards through INMETRO.

Note: BIPM = International Bureau of Weights and Measures. IAF = International Accreditation Forum. ILAC = International Laboratory Accreditation Cooperation.

development of INMETRO because new equipment could not be delivered and commissioned for months, sometimes years. By 1989, some of the buildings were still not completed, but fortunately that did not have a further impact on the PTB project.

Equipment. PTB's technical support started with the calibration of the metrology equipment already in use by INMETRO. This provided traceability to international standards that had been lacking up to that point, and results from calibrated instruments of the industry were accepted internationally for the first time. PTB provided some serious high-technology measuring equipment from 1971 until 1985, valued at DM 5.1 million.[1] This was necessary because the government had placed a ban on the importation of any electronic equipment and components until 1985. Thereafter PTB still provided equipment worth DM 0.7 million until 1995, even though INMETRO was able to source funding from the PADCT program.

Once the high-technology equipment was commissioned, INMETRO took the next step—realizing its own primary measurement standards. The international standards for the base units of the International System of Units (SI) are definitions in terms of natural constants, and each national metrology institute (NMI) has to build a piece of equipment to realize this definition in the real world. In this, INMETRO was initially supported by PTB expertise, but slowly INMETRO developed its own, ably supported by the workshop that had been established with PTB support in the meantime.

The next step for INMETRO was to gain international recognition of its prowess through the listing of its calibration and measurement capabilities (CMCs) on the Key Comparison Database (KCDB) managed by the International Bureau of Weights and Measures (BIPM). Such a listing is possible only after interlaboratory comparisons between INMETRO and other recognized NMIs, followed by a peer review of the results.

INMETRO listed its first CMC in 1994, after which progress was fairly rapid. Between 1994 and 2000, Brazil participated in 15 intercomparisons, of which 10 were in fields in which PTB provided support. By 2012, Brazil had participated in almost 150 comparisons, the 16th-highest number in the world. INMETRO had taken about three decades to advance from an insignificant calibration laboratory to a globally respected NMI with PTB support—a position that has since been further reinforced.

Phase 2: Calibration laboratories and accreditation system

During the second phase of PTB involvement, the focus shifted more to the independent calibration laboratories. No accreditation body had been established in Brazil; hence, the metrology division of INMETRO started "recognizing" calibration bodies after assessing their technical competency in accordance with INMETRO's own requirements.

Once ISO/IEC Guide 25 (the forerunner of ISO/IEC 17025, "General Requirements for the Competence of Testing and Calibration Laboratories") was published in 1990, the calibration laboratories needed to get properly accredited.[2] The accreditation activities were moved to an independent accreditation division in INMETRO, the General Coordination for Accreditation (CGCRE). This paved the way for the CGCRE's recognition by the International Laboratory Accreditation Cooperation (ILAC) and International Accreditation

Forum (IAF) in 2000 and 2008, respectively. The Brazilian calibration system has become an important part of the overall QI, and its international recognition through accreditation even more so.

COUNTRY CONTEXT

General background

Brazil is the largest country in South America. As the world's fifth-largest country by both area and population, it is the largest country to have Portuguese as an official language—and the only one in the Americas. Bounded by the Atlantic Ocean on the east, Brazil has a coastline of nearly 7,500 kilometers. It borders all other South American countries except Ecuador and Chile and covers 47.3 percent of the continent's land area.

Brazil's economy is the world's ninth-largest by nominal gross domestic product (GDP) and seventh-largest by GDP (purchasing power parity, PPP) as of 2015. A member of the BRICS group,[3] Brazil until 2010 had one of the world's fastest-growing major economies, with its economic reforms giving the country new international recognition and influence. But this was not always the case.

The economy in the 1970s and 1980s

In the late 1960s and early 1970s, growth of Brazilian exports exploded (for example, doubling from 1971 to 1973). Equally impressive was the increase in industrialized goods (for example, from 28 percent of total exports in 1971 to 40 percent in 1974). Hence, the quality of exported goods increasingly became an issue as economic operators needed to overcome the technical barriers to trade in Europe and the United States. Evidence of product conformity to standards and technical regulations frequently had to be provided by organizations outside Brazil and even South America because the national institutions lacked technology and international recognition. This was expensive and put Brazilian products increasingly at a disadvantage in these markets (Gonçalves 2013).

Furthermore, all through the 1970s, Brazil experienced what can be identified as a high-technology deficit concerning its trade balance. In 1972, for example, it was on the order of US$450 million, and it was projected to grow to US$1 billion as local companies were growing and demanding more and more high-technology equipment in support of their activities (Gonçalves 2013).

Hence, technological autonomy became a stated goal of the government. With funds from the World Bank and assistance from the United Nations Industrial Development Organization (UNIDO), the Program to Support Scientific and Technological Development (PADCT) was designed, with an emphasis on high-technology industries such as electronics, chemistry, and aeronautics. The PADCT had a 1973–74 budget of US$700 million (Gonçalves 2013).

In addition, in 1971, the Brazilian government decided to build a 750 megawatt nuclear power plant in Angra dos Reis (a city in the state of Rio de Janeiro) because improving the energy supply was an important aspect of Brazilian industrial development. The Companhia Brasileira de Tecnologia Nuclear, which was given the responsibility for planning and implementing the country's electro-nuclear energy program, was established at the same time. Brazil also signed an agreement with Germany in 1975 to transfer nuclear energy technology.

All of this required a high level of technology, and the nuclear energy industry was to benefit from the PADCT as well.

ISSUES TO BE ADDRESSED

One of the many issues that had to be addressed to close the obvious technology gap in the late 1960s and early 1970s was the lack of a sophisticated and internationally recognized metrology system. In 1961, the National Institute for Weights and Measures (INPM) was established. The INPM provided a very small set of services related to trade metrology, without any international recognition and without any department specifically dedicated to scientific metrology.

Then, in 1967, regulatory agencies for weights and measures were established at the state level to enforce trade metrology regulations in the 27 states making up the vast territory of Brazil. In the same year, a national metrology policy was promulgated with the force of law. This policy determined that Brazil would exclusively use the SI for measuring units and that the country should become involved in BIPM and International Organization of Legal Metrology (OIML) activities at the international level.

Even though the Brazilian government had started to establish the national metrology system in the early 1960s, its efforts were focused on developing Brazil from within, and it was not yet ready to accept support from outside. This stance changed somewhat in the early 1970s, as the government started to consider the importance of incorporating foreign technologies in national entities as a measure for faster economic growth. Insights of senior INPM management, gained during visits to PTB in the early 1970s, were key in developing a new strategy for the development of the Brazilian metrology system.

This new strategy allowed Brazil, from the mid-1970s until the late 1990s—a relatively short time for such endeavors—to establish a well-respected national institute, INMETRO. INMETRO is a key organization in the wider QI of Brazil that is overseen at the policy level by the National Metrology, Standardization and Industrial Quality Council (CONMETRO), chaired by the Minister of Development, Industry and Foreign Trade.[4]

During this period, sound investments were made by the Brazilian government in INMETRO, and technological capacity was enhanced with the assistance of international agencies and through cooperative agreements with other more-advanced national institutes, primarily PTB regarding metrology. Over and above its standing in the international metrology community, PTB's role as the major technology partner was strengthened by the 1975 agreement between Germany and Brazil regarding the transfer of nuclear energy technology. During PTB's long involvement with INMETRO, its position changed from a senior technology provider to an equal partner with INMETRO in pursuing specific metrology goals.

OBJECTIVES AND PROJECT COMPONENTS

The development of metrology in Brazil can be seen as following three distinct phases:

- *Phase 1 (1967–85)* was primarily concerned with the establishment of INMETRO and developing its capabilities.

- *Phase 2 (1985–95)* had a broader scope and considered the conformity assessment system as a whole, with the metrology component focusing more on a network of calibration laboratories and an accreditation body.
- *Phase 3 (starting in 2002)* envisaged a more horizontal cooperation in scientific and technology fields, with PTB and INMETRO as equal partners.

This narrative focuses largely on the development of INMETRO during 1967–95, the period in which INMETRO was established and reached international recognition. The developments after 2002 are not discussed in this publication.

Phase 1: Establishment of INMETRO

In 1967, a first agreement between the Brazilian government and PTB was signed. The objective of this agreement was to establish (a) a public institution in Brazil that would be responsible for the realization and dissemination of international measurement standards and methods within Brazil, and (b) an increased awareness of legal metrology. The components included a variety of measures focusing on scientific and industrial metrology, such as

- Consultancy on the establishment of the metrology laboratories of INMETRO;
- Supply of equipment for scientific and industrial metrology and their initial calibration;
- Training of Brazilian professionals through long- and short-term stays of PTB experts in INMETRO and similarly of INMETRO staff in PTB;
- Transfer of technical literature and documentation; and
- Seminars and consultations.

The signing of the nuclear agreement between Germany and Brazil in 1975 reinforced the agreement between the Brazilian government and PTB. Sophisticated technology in almost all metrology fields had to be established to support processes and safety measures for the production of nuclear energy. PTB had the necessary expertise, and the 1967 agreement was appreciably enhanced from 1976 to 1985.

In 1971, the government allocated funds to build the National Centre for Metrology, and in 1973 a new law was promulgated establishing the modern QI of Brazil.[5] The INPM's responsibilities were extended, and the INPM was henceforth known as INMETRO. But it would take some years before the new buildings were completed and the measurement equipment installed and commissioned. In the meantime, the training of INMETRO staff was intensified, and German experts were sent to Brazil for longer periods to support the establishment of INMETRO's metrology laboratories.

Phase 2: Extending the QI

The second phase of establishing the QI of Brazil lasted from about 1985 to 1995, after which time the agreement between the government of Brazil and PTB came to an end. During this second phase, the demand for quality management system certification of companies involved in international markets increased dramatically after the publication of ISO 9001 ("Quality Management Systems—Requirements") in 1987.[6] The requirements for quality management systems, such as ISO 9001, included calibration of companies' measuring equipment in production and testing.

Hence, the need for competent calibration laboratories rose dramatically in Brazil. Moreover, exporting companies had to have their products tested in accredited laboratories in order to gain acceptance in foreign markets.

This second phase of PTB support was therefore marked by the establishment of calibration laboratories and the parallel establishment of a national accreditation body. The Brazilian government designated INMETRO as the only national accreditation body it would recognize. Because INMETRO did not provide any conformity assessment services, this combination of metrology and accreditation, even though unusual, did not constitute a conflict of interest because calibration is not considered to be a conformity assessment service.

During the second phase, the new buildings of the National Centre for Metrology were completed with significant technical input from PTB experts seconded to INMETRO and from senior INMETRO staff who had spent many months at PTB laboratories in Braunschweig, Germany. An unforeseen key outcome was the establishment of workshops through PTB expertise that could maintain and repair INMETRO's extensive body of measuring equipment. PTB experts were also instrumental in supporting the nascent accreditation body in INMETRO, the CGCRE, in its first steps to ultimately gain international recognition through ILAC and the IAF in 2000 and 2009, respectively, under a United Kingdom Accreditation Service (UKAS) project.

Phase 3: Equal partners

INMETRO's status increased continuously during the latter part of the 1990s. Hence, the third phase of cooperation between INMETRO and PTB had a totally different character. Signed in 2002, the new agreement was no longer characterized by one organization supporting the other directly but by two organizations that would engage as equal partners in research and dissemination projects, reflecting the capacity built in the preceding years. The activities centered on scientific, industrial, and legal metrology as well as accreditation, and both parties included their priorities in the agreement regarding metrology in chemistry and other advanced fields of metrology.

INMETRO became a close partner of PTB for the dissemination of metrological knowledge in both Latin America and Africa, especially in countries that hardly had any metrology infrastructure established (for example, in Mozambique, where Portuguese is also the spoken language). In this sense, the capacity development of INMETRO through PTB allowed it to gradually become an equal partner, and ever since, the two organizations have engaged in cooperative projects in research and development.

German investment

Germany's investment in the project is demonstrated in three areas (PTB 1995): (a) project finances provided by the Federal Ministry for Economic Cooperation and Development (BMZ), (b) PTB personnel seconded to Brazil, and (c) the equipment provided.[7]

Project finances. The BMZ provided the following in direct project funding:

- *Funds earmarked in 1969:* DM 2.682 million
- *Funds added in 1977:* DM 3.500 million

- *Funds added in 1985:* DM 3.079 million
- *TOTAL:* DM 9.261 million.

PTB personnel. PTB seconded three long-term experts to INMETRO in Brazil. Those experts performed the following:

- *Establishment of mechanical workshop:* March 1981 to October 1995 (55 worker-months)
- *Scientific consultancy:* July 1983 to December 1987 (54 worker-months)
- *Establishment of electrical workshop:* September 1986 to December 1989 (39 worker-months).

In addition, PTB provided short-term experts to Brazil, as follows:

- *1981–87:* 5 short-term experts, approximately 5 person-months
- *1988–91:* 5 short-term experts, approximately 5 person-months
- *1992–93:* 11 short-term experts, approximately 5 person-months.

The costs for these and other PTB personnel involved in the project amounted to about DM 5.4 million from 1985 to the project's end in 1995. The earlier PTB personnel costs were not specifically identified.

Equipment. The value of equipment supplied by PTB to Brazil was as follows:

- *Until 1985:* DM 5.1 million
- *1986–95:* DM 0.7 million
- *TOTAL:* DM 5.8 million.

PROJECT DESIGN AND IMPLEMENTATION

The development of metrology in Brazil is probably best understood within a matrix of modes and fields of cooperation. The capacity building in INMETRO could be characterized as consisting of three main modes—training, equipment, and facilities—each of which received more or less attention depending on the situation at the time. These modes applied to various fields of cooperation, first in scientific and industrial metrology because this was identified as the major need for Brazil in the beginning. Second, some work was also done in legal metrology, although to a much lesser extent than scientific metrology. Finally, accreditation was targeted in the latter part of the INMETRO development, when accreditation rose to prominence globally in the 1990s.

Modes of cooperation

Training

Brazil started a process of training young researchers in the metrological field in 1975 and 1976 through a project called Criptônio, which had two phases. The first phase consisted of full-time postgraduate courses of a year for engineers, whereby 40 students were trained in the various fields of metrology. This took place at the Federal University of Rio de Janeiro, which was considered to be the biggest research and educational institute for engineering in Latin America. On completion of the postgraduate course, many joined INMETRO and teamed up initially with foreign experts through a UNIDO program to design and build the new INMETRO laboratories.

In the second phase, many of these postgraduate students went to Germany under the PTB cooperation agreement, to stay for roughly a year and a half. They spent the first five months learning German, and the rest of the time either at PTB in Braunschweig (those working in scientific and industrial metrology) or at the German Metrology Academy (DAM) in Munich (those working in legal metrology).[8] Between 1980 and 1982, about 20 INMETRO metrologists went to Germany for this intense training. These long stays were later augmented by a number of short courses and technical visits by INMETRO personnel to PTB over the years. During 1971–87, there were 20 such visits, which increased to 38 visits in 1988–94. The Brazilian government financed some of these; others were partially financed by PTB.

But this training arrangement also presented some serious challenges. As a result of the extreme technical requirements in the field of scientific metrology, the duration of stay in Germany for trainees had been set very high. Owing to the still-limited human resources in the scientific metrology field at INMETRO, not all the envisaged training could be initiated. Staff were sometimes simply indispensable for the daily business operations, and INMETRO could not take leave of them for 15–18 months, over and above the stress of being away from their families for such long periods. These training programs were therefore curtailed after 1981 and partly replaced by PTB experts seconded to INMETRO in Brazil for varying lengths of time to provide for the training locally.

Three of the PTB experts involved in general scientific support and the construction of the mechanical and electrical workshops were involved for many years, whereas those with more-focused missions came for single, short periods only. There were 5 visits of short-term experts in 1981–87, also 5 in 1988–91, and a final burst of 11 experts in 1992–93.

Equipment

Initially, INMETRO had a significant deficit in modern and accurate measuring equipment. It was therefore of vital importance that sound investments be made to overcome these deficiencies in order to build the required capacity in INMETRO. Not only was new equipment required, but the equipment already installed also needed maintenance and especially spare parts to get it fully operational again. Unfortunately, until 1988, there was an import ban on all electronic components and devices. Because much of the measuring equipment was not designed in Brazil with local components, this ban increased the difficulties of keeping the equipment operational. The bureaucracy associated with importing equipment for INMETRO further exacerbated the situation.

PTB played a significant role in alleviating this situation. First, it donated a massive amount of high-technology measurement equipment to various divisions of INMETRO. Up until 1985, the value of donated equipment reached DM 5.1 million. From then until the end of the project in 1994, equipment worth a further DM 0.7 million was provided, even though INMETRO received funds through the PADCT of the World Bank from 1985 onward. PTB-sponsored equipment included some large-scale measuring equipment:

- A Kösters comparator for length measurement with accessories
- A high-precision, three-coordinate measuring machine with computer-controlled evaluation and calibration
- Two heavy-duty precision weighing scales, of 500 kilograms and 5,000 kilograms, with calibration mass pieces

- A 1 kilogram, high-accuracy comparison scale with accessories and a 1 kilogram primary standard
- A geodetic base with measuring microscopes, scales, a 1 meter comparator, temperature measuring instruments, and auxiliary equipment
- A gear-measuring machine with evaluation electronics and accessories.

Second, PTB provided INMETRO with technical support to start building its own measuring equipment. This was as important as the donated equipment in overcoming the barriers to imports. It had the further benefit of improving the staff's equipment maintenance skills, because equipment brought in from the outside was frequently seen as a "black box" by the technicians, which they were reluctant to work on.

Third, PTB scientists visited universities all over Brazil to determine their capabilities regarding metrology. In many cases, they also brought their equipment to INMETRO, where it was well used, thereby limiting the negative impacts of the ban on imported electronic equipment.

Facilities

The facilities to house all the new measuring equipment had to be provided by the Brazilian government. Some funds were already approved in 1971 for the construction of the National Centre of Metrology. The buildings were designed by Brazilian architects, but further funds were required. These were eventually sourced from the World Bank's PADCT program. Because the PTB president had been on the PADCT advisory board for many years, he was able to successfully argue the importance of metrology for the technological development of Brazil, thereby facilitating the approval of the necessary funds to complement those of the Brazilian government for the construction of the metrology laboratories.

Some senior personnel of INMETRO also visited PTB in Braunschweig, where they gained firsthand knowledge of the requirements for specific metrology laboratories. This information was extremely valuable in guiding the design of the buildings by the Brazilian architects. German specialists stationed at INMETRO provided further input into the design. One such example dealt with the energy efficiency of the buildings. For high-precision work, laboratories require sophisticated temperature controls. If the buildings are too big (that is, contain vast amounts of unused space), these have to be temperature controlled as well, substantially increasing their running costs. The specialists were able to limit the size of laboratories to more practicable dimensions.

The completion of the buildings took a long time. This procrastination was a major stumbling block for the timely implementation of much of the cooperation agreements, especially the provision and commissioning of equipment, which had to be postponed sometimes for months, even years. INMETRO, as a government agency, as in many countries, had its limitations in expediting decisions within agreed-upon time frames. The political turmoil in Brazil—with governments coming and going and new governments rescinding decisions of previous ones—also contributed to this state of affairs, as did the overly bureaucratic systems ostensibly designed to curb the rampant corruption in state purchases.

From 1985 onward, expertise for large-scale facilities was no longer provided by PTB because INMETRO was able to source the necessary credits as a PADCT beneficiary for the procurement of laboratory facilities and equipment.

Fields of cooperation

Scientific and industrial metrology

The main areas for cooperation in scientific and industrial metrology encompassed mechanical, temperature, electrical, optical, acoustics, and vibration-related metrology. Industries such as aeronautics, automotive, naval, nuclear, and others needed calibration services that were traceable to international measurement standards. Until the 1980s, INMETRO could not provide such a service; hence, foreign NMIs had to be used. Once PTB got involved, it was able to provide the traceability for the INMETRO working standards at the beginning and to foster a more professional approach in service delivery. This slowly started to increase the confidence of industry in INMETRO, which in turn reduced costs for companies because they could now obtain calibration services in Brazil where previously they would have sent their instruments abroad.

The young Brazilian metrologists who spent considerable time in PTB laboratories in Braunschweig at the beginning of the 1980s came back to INMETRO with a wealth of knowledge. The dedication of some of these metrologists—in spite of the many challenges regarding funding, buildings, bureaucracy, political turmoil, and the like—was absolutely vital in getting the laboratories established and functioning properly. Many of them would go on to become the managers of the various laboratories within INMETRO. The long-term presence of selected German specialists in some of these laboratories also proved to be instrumental in enhancing their capabilities. Some examples of this progress are described below.

Mechanical metrology. Because mechanical metrology is fundamental to many industrial and regulatory fields, INMETRO pursued a wide range of activities, including mass, length, force, pressure, roughness, and fluids. In most of these, PTB played an important role, but INMETRO also had the support of Italy's National Metrological Research Institute (INRiM).

Many of these laboratories started life as pure calibration laboratories, but their working standards were not yet traceably calibrated to international standards. Some were still in the old buildings, waiting for the new buildings to be completed. Others had to wait for the new laboratories to be completed. Work started by calibrating the older working standards in PTB, and thereafter the older measurement standards were progressively replaced by more modern, more accurate ones. Major modern mechanical measuring equipment was donated by PTB (as listed earlier in the "Equipment" subsection).

Acoustics and vibration metrology. The development of acoustics and vibration metrology was considered vital for the automotive and aeronautics industries. In some respects, this metrology domain probably profited more from PTB cooperation than any other. Work started soon after the first group of metrologists came back from Germany in 1981, progressed slowly, and by 1996 INMETRO was able to establish its own primary standards. After 1999, it was no longer necessary to have the national standards calibrated by PTB, and INMETRO was able to do so by itself and to support major independent laboratories in Brazil in achieving their accreditation. INMETRO also became the source of acoustics and vibration measurement technology within the region, with Bolivia, Colombia, Peru, and the República Bolivariana de Venezuela being among the recipients.

Temperature metrology. Temperature is a core metrological issue, important to most measurements in other fields, and therefore it received ample support from PTB. This laboratory also profited from the long-term training periods of young metrologists in 1980 and 1981 in Germany. They came back with the necessary knowledge to establish a new temperature calibration laboratory; INMETRO did not have one at that stage. The need for accurate high-temperature measurements came primarily from the safety requirements in the nuclear power and petroleum industries. The technical prowess of the temperature laboratory has developed to such a level over the years that PTB and INMETRO ran combined research projects from 2002 until 2007 to develop thermocouples to measure high temperatures between 900 degrees Celsius and 1,500 degrees Celsius, for example.

Optical metrology. The optical metrology laboratories were a much later addition to INMETRO. These were established in the mid-1990s. One of their first achievements was enabling INMETRO to realize the national standard of the meter from its international definition and basic principles. An indirect consequence of this challenging achievement was that INMETRO metrologists went on to establish the fields of cryogenic radiometry and goniophotometry in Brazil. Later, a polarimeter and saccharimeter were also developed.

Electrical metrology. After mass, length, and volume (required in trade metrology), electrical metrology is usually one of the first fields to be established in a country because it is important for industry, and other metrological fields require their equipment to comply with electrical standards in order to get traceability for their own measurements. It is also relatively easy to establish in terms of technology and costs.

This is another area that benefited from the first group of young metrologists trained in Germany in 1980 and 1981. As soon as they returned home, the first electrical metrology laboratory was established with financial support from local financial institutions. In 1985, the laboratory was already providing calibration services to laboratories relating to voltage sources, instruments, and inductors. This division also had strong support from a PTB expert who stayed at INMETRO from 1983 until 1987. A major achievement was when it was able to provide calibration serves to the multinational company General Electric in the field of power meters.

Metrology in chemistry

Metrology in chemistry is a relatively recent field. The major NMIs—like PTB in Germany and the National Institute of Standards and Technology (NIST) in the United States—only created their metrology-in-chemistry divisions in the late 1990s. In 1997, this field received a significant boost with the publication of ISO Guide 32 ("Calibration in Analytical Chemistry and Use of Certified Reference Materials").[2]

INMETRO created its chemistry division in 2000 because this was a field subject to increasing demand from Brazilian industries. It was considered strategically important to realize a primary method for pH measurement, which would facilitate the production of certified reference materials (CRMs) by INMETRO, which nobody in Brazil had been able to do up to that point.

An INMETRO metrologist spent time in 2001 at the PTB laboratory in Braunschweig, where basic research in this field was being conducted.

On returning to Brazil, a laboratory was established with financial support from Brazilian institutions, with the INMETRO workshop instrumental in building the necessary equipment. The pH primary system was inaugurated in June 2003, but it still had significant levels of uncertainty. In 2004, PTB metrologists conducted the peer review of the INMETRO pH primary system to determine its CMC. This was an important step to improve the system and reduce uncertainty. By 2007, the uncertainty of the primary pH system was reduced to the same level as that of the best NMIs, and CRMs to calibrate other laboratories' pH meters were being produced. These were considerably more cost-effective than imported CRMs from NIST and elsewhere, thereby saving scarce foreign currency for their users.

Accreditation

As noted earlier, the second phase of the first cooperation agreement between the Brazilian government and PTB placed a stronger emphasis on broader QI development, not only on metrology. Hence, accreditation also became a focus of capacity development. The development of the accreditation system in Brazil cannot be understood without considering the Brazilian Calibration Network created in 1980. This network of calibration laboratories was established to offer calibration services to meet rising demand due to the industrialization process under way in Brazil.

These laboratories needed some form of recognition—that is, "accreditation"—and their reference standards had to be calibrated traceably to international standards. The calibration part was conducted by INMETRO, whose standards had been calibrated by PTB, thereby providing those standards with traceability to international standards. Because there was no independent body to conduct accreditation, the scientific and industrial metrology division of INMETRO started doing so in 1985 as a strategic activity. It was not called accreditation ("acreditação") at that stage because that terminology was not yet in use, but was instead called endorsement or authorization ("credenciamento").

A further significant development in the accreditation system in Brazil took place in 1992 after the publication of ISO/IEC Guide 25 (today, ISO/IEC 17025). This international standard, which Brazil adopted as a national standard, provided clear guidelines for laboratory accreditation. In 2000, a newly created division for quality assurance within INMETRO, DQual, took over accreditation activities, ultimately morphing into a fully independent division of INMETRO, the CGCRE. Although the design of the CGCRE was largely modeled on the U.K. accreditation body (UKAS), the involvement of experts from the PTB-aligned German Calibration Service (DKD) was also relevant for the development of the accreditation system in Brazil. Already in 2000, the CGCRE obtained international recognition through ILAC, making Brazil the first country in Latin America to do so and one of the original signatories to the ILAC Mutual Recognition Arrangement.

Workshops

It was soon apparent that equipment maintenance was a major challenge for INMETRO because no organizations in Brazil were capable of performing it. The situation was further exacerbated by the government's ban on the importation of any electronic equipment or components. Therefore, PTB provided long-term technical assistance to INMETRO to establish, first, a mechanical

workshop and, later, an electrical workshop. The mechanical workshop was established in 1982, and PTB provided guidance on the list of equipment to be purchased for the repair workshop, the selection of human resources to work in the facility, and the training of personnel, including support for their participation at training events outside the institute. Some of the equipment was provided by PTB.

The workshop proved to be an important strategic decision; without it, INMETRO would have been hard-pressed to maintain its high-technology measuring equipment in a timely manner. Furthermore, the workshop played a decisive role in the development of new measuring equipment, especially in the design and manufacturing of high-technology primary measurement standards. Outsourced services of this kind (if outsourcing would have been possible in the first place) would have been much more expensive and time-consuming. The workshop served not only INMETRO laboratories but also some partner laboratories under specific cooperation initiatives.

STAKEHOLDERS AND THEIR ROLES

Many stakeholders in addition to PTB were involved in the development of INMETRO. Their involvement, however, was not always supportive but rather frequently created additional challenges that had to be overcome, as described below.

The government

The government's involvement was a checkered one. In the initial stages, it was a supportive partner in the development of INMETRO. The government was the main instigator of the cooperation agreement signed with PTB in 1967, which was strengthened in 1975 to support the nuclear energy cooperation agreement signed between the German and Brazilian governments. On the other hand, bureaucratic systems made it virtually impossible to obtain any sort of equipment or buildings within meaningful time frames. The provision of resources after this initial enthusiasm became difficult and subject to the whims and fancies of the government in power.

The years of delay in completing only some of the buildings was explained by fiscal problems that new governments inherited and by the lack of a binding contract for their completion. Some of the resources for personnel and operation of facilities, as well as for the trainee specialists, were eventually provided, albeit with much trouble and sometimes considerable time delays. The government did not allow INMETRO to appoint new personnel for many years, and the departures of highly trained technical staff (because of the much better salaries offered by private industry) left INMETRO without adequate numbers of skilled people to maintain service levels.

In the latter part of the project, it was not so much funds that were a problem but their timely utilization. In the wake of the corruption allegations against President Fernando Collor de Mello, administrative steps imposed also on INMETRO—such as the tendering process for even the smallest purchases—delayed for months the acquisition of replacement parts for the measuring equipment. After 1989, the situation normalized to some extent, and

until the end of the project in 1995, the PTB project did not experience any further delays of significance, other than the uncompleted buildings and the selection and approval of trainees bound for Germany.

INMETRO

INMETRO, as the main beneficiary, did its utmost to respond to project requirements. The relationship with the donors was good, but it required immense patience from the donor side. The president of INMETRO changed quite a few times during the duration of the projects, and each new one had to be brought on board afresh. Development organizations such as UNIDO, as well as those from France and Japan, did not have the tenacity of the long-term PTB project, and their influence in INMETRO was soon no longer visible.

Universities

Before INMETRO was established, many of the universities had established metrology capacities in response to the expressed needs of industry. Some of these were quite capable; in fact, the first CMCs in Brazil were listed by these and not by INMETRO. PTB scientists were able to gain the universities' full support and cooperation, to the extent that some of their equipment was seconded to INMETRO. This helped a lot to circumvent the ban on the importation of electronic equipment by the government in the initial years. Some of the equipment remained at the universities, and PTB persuaded INMETRO to declare the relevant universities as designated metrology institutions under BIPM guidelines. This move enhanced the cooperation between the universities and INMETRO significantly and provided for a coordinated approach among several institutions regarding national measurement standards.

Industry

The major industrial entities such as the automotive industry had little trust in the capabilities of INMETRO and said so in many public forums. Hence, INMETRO's initial success was largely restricted to the small and medium enterprise (SME) sector, which lacked the access to resources that multinational companies had. Slowly, however, the multinationals also started to use INMETRO's services, especially after it was able to have some of its CMCs included in the KCDB of the BIPM. Many independent calibration laboratories were established and accredited during 1980–95, further enhancing the status of Brazil-based metrology services.

OUTCOMES

The establishment of INMETRO as a respected NMI in the international and especially in the regional metrology community was achieved through many incremental steps. All of these culminated in the listing of its CMCs in the international KCDB managed by the BIPM. Once INMETRO started to do so, it was able to increase the tempo of the CMC listings, with the result that it became one of the most prolific NMIs in the world in this regard. This was also the beginning

of its recognition by Brazil's major industries, including automotive, aeronautic, and nuclear.

Calibration and measurement capabilities (CMCs)

International recognition of national metrology capabilities is founded on the realization of the international standard (which is a definition) for physical equipment called the primary measurement standard and determining its accuracy through interlaboratory comparisons between the NMIs of various countries. Once such comparisons have been verified in a peer review process, the NMI's CMC is listed in the KCDB managed by the BIPM, indicating the NMI's prowess in realizing the international standard. To get to this stage, however, is a long and technically challenging process.

The capacity to perform primary methods is one of the main challenges faced by any NMI. Realizing a measurement unit has various implications, primarily for the autonomy of the NMI to guarantee its traceability to international standards without requiring that its instruments be calibrated in foreign NMIs. Such a calibration process is not only more time-consuming but also implies higher costs for the NMI in the form of foreign exchange, which indirectly will be paid by the local industry and laboratory sectors.

On the other hand, bilateral comparisons with NMIs that have already participated in a key comparison are a faster way for a country to acquire calibration traceability to international standards. This was the situation for INMETRO by the end of the 1980s. The PTB cooperation agreement provided this opportunity to INMETRO in the beginning, which accelerated the expansion of its activities, namely regarding the calibration services provided to laboratories, giving them traceability to international standards. The financial side of this arrangement was adequately covered by PTB's agreement with the Brazilian government.

From that point on, it was a logical step for INMETRO to establish primary measurement standards of its own. Once this was achieved, it was no longer necessary for INMETRO to send its equipment to PTB for calibration, because establishing its own primary measurement standards allowed INMETRO to participate in interlaboratory comparisons within the context of the International Committee for Weights and Measures (CIPM) Mutual Recognition Arrangement (MRA). By 1995, Brazil had established primary measurement standards for the SI base units—length (meter), mass (kilogram), time (second), temperature (kelvin), electrical resistance (ohm), and luminous intensity (candela)—at basically the same level of accuracy as many industrialized countries. The measurement standards for derived units that are important for industry—such as force, viscosity, pressure, voltage, current, and so on—were also established, even though gaps remained.

Before 1994, Brazil had participated in only 13 key comparisons, none of them by INMETRO but by designated laboratories. Only in 1994 did INMETRO participate in its first key comparison. It was on direct current (DC) voltage (Josephson standards), which was a field in which PTB provided technical support. From 1994 onward, this situation started to change. Between 1994 and 2000, Brazil participated in 15 intercomparisons, 10 of which concerned metrological fields in which PTB had provided technical support. INMETRO's progress continued to evolve as, between 2000 and 2012, Brazil participated in 121 key comparisons and 29

supplementary comparisons, with a higher degree of diversification concerning the metrological fields. By 2012, Brazil had participated in almost 150 key comparisons, then the 16th-highest number in the world.

INMETRO's growth from the backwaters of calibration laboratories to a globally respected NMI had taken only three decades. This was an impressive performance by any measure, even more so considering the immense bureaucratic challenges that had to be managed and the political turmoil that had to be negotiated. This success was, to a large extent, possible only through the dedication of the metrologists involved and through the tenacity of PTB, which a few times had seriously considered withdrawing its support in the face of Brazil's ongoing political uncertainties.

Certified reference materials (CRMs)

In terms of the production of CRMs as the direct outcome of metrology in chemistry, INMETRO was able to increase the production thereof after the first one was successfully developed in cooperation with PTB by 2004 (as discussed earlier in the "Metrology in chemistry" subsection). In the same year, INMETRO produced another five CRMs, which increased to nearly 150 by 2011. This produced a major saving on foreign exchange for laboratories all over Brazil, because the necessary CRMs to validate their test procedures were now available in the country, whereas previously they had to be imported.

Accreditation

As a consequence of the capacity development of the QI as a whole, there were also developments in accreditation. The number of accredited laboratories in the Brazilian Calibration Network increased from 23 in 1991 to 51 in mid-1994, by which time another 26 were in the process of being accredited. By 2012, INMETRO had accredited more than 300 laboratories. In 2000, INMETRO became a signatory to the ILAC multilateral recognition agreement for ISO/IEC 17025, and, in 2013, for ISO/IEC 17020 ("Conformity Assessment—Requirements for the Operation of Various Types of Bodies Performing Inspection").[10] In 2009, it became a signatory to the IAF multilateral recognition arrangement for both ISO/IEC 17021 ("Conformity Assessment—Requirements for Bodies Providing Audit and Certification of Management Systems") and ISO/IEC 17065 ("Conformity Assessment—Requirements for Bodies Certifying Products, Processes and Services").[11]

The development of the accreditation system for laboratories in Brazil was important not only to industries but also to regulatory bodies of the Brazilian government like the National Health Surveillance Agency (Anvisa), National Telecommunications Agency (Anatel), and National Civil Aviation Agency (ANAC), which since 2005 required economic operators in their sectors to use the services only of accredited laboratories.

Finally, the development of accreditation was important for INMETRO because it allowed it to focus on metrological research and provide traceability to international measurement standards with the lowest level of uncertainty. The more basic industrial calibration activities could be left to accredited calibration laboratories, which otherwise would have been an impossible burden on INMETRO, especially given the size of the country. As the network of accredited calibration laboratories grew (from 3 in 1983 to 21 in 1995), the costs

of metrological services also came down. For example, the cost of periodical verifications fell by almost 30 percent from 1982 to 1994, improving the competitiveness of local industry.

Financial sustainability of INMETRO

The establishment of an NMI and the expansion of its services requires significant investments in resources and time, especially in low- and middle-income economies that do not have the long history in this respect that technologically advanced countries do (such as Germany, the United Kingdom, and the United States). This financial burden is largely shouldered by the government. The benefits for the country only become apparent after years, and the financial sustainability of the NMI is continuously under pressure during this time. If the country faces political turmoil, this becomes even more problematic, as was the case in Brazil. Fortunately for INMETRO, it had another source of funds (that is, legal metrology), but even that eventually became problematic.

The primary sources for INMETRO metrology activities, other than government funds, are

- Calibration services and the sale of primary CRMs to the private sector;
- Income from legal metrology, namely fees or levies related to the implementation of technical regulations; and
- Services provided by the mechanical and electrical workshops, which give support to laboratories for maintenance and manufacturing of measurement instruments.

The revenue from legal metrology activities is a significant source for the INMETRO budget. In 1983, such revenues amounted to just over US$8.62 million, which was 51 percent of INMETRO's budget. By 1995, this increased to US$45.25 million (41 percent of the budget for that year)—five times more than in 1983 (Gonçalves 2013). However, legal metrology should not be conducted for the revenues it creates, and those that it does generate should be used for the development of the legal and scientific metrology. As scientific metrology develops, it should provide for more income, allowing INMETRO to reduce its dependency on the revenues from legal metrology.

But whether INMETRO will ever become self-sufficient is debatable. Almost all of the world's NMIs are dependent on government funds as an investment in the "public good" in some form. It can also be argued that if INMETRO is forced to become self-sufficient, there will inevitably be services it has to curtail. These services may not be financially viable on their own, but they may be strategically important for the country or they may be a basis for other organizations that do generate income. Losing them would therefore be detrimental to the country's technological development.

Impact on trade

The development of the QI was important for Brazil and its participation in international trade (Gonçalves 2013). Brazilian exports were US$51.1 billion in 1998, with a trade balance deficit of US$6.6 billion. In 2011, exports increased to US$256 billion, with a surplus of US$29.8 billion. An estimated 75–80 percent of these exports required demonstrable compliance with standards or

technical regulations. This in turn requires accredited laboratories and certification bodies that are internationally recognized. For these to be internationally recognized means that the Brazilian metrology and accreditation system—in this case, INMETRO—must be internationally recognized.

If this were not so, then (a) Brazilian economic operators would have had to source laboratory and certification services from accredited laboratories abroad, or (b) the Brazilian laboratories would have had to gain accreditation from foreign-recognized accreditation organizations—both of which would have significantly increased the costs of Brazilian products, possibly rendering them uncompetitive. The situation would have been even more problematic considering that no other South American country had a QI that was internationally recognized at the time; in other words, the services would have had to be sourced from the United States and even farther afield.

A more direct measure of the impact of INMETRO's development can be gleaned from the business of the Brazilian instrument sector, which made significant improvements in terms of its exports (Gonçalves 2013). In 1997, instrument exports were only US$27 million, but these increased to US$121 million in 2011. This increase would not have been possible without INMETRO's provision of traceability to international standards with low uncertainties, as well as the system to transfer these measurements to the manufacturers' quality control systems. Even so, the instrument imports also grew seven times over the same period. This reflected the growing demands of industry for high-technology goods in the field of measurement and sustained concerns regarding the technological deficit. Nevertheless, INMETRO was certainly contributing to the growth of exports in this sector.

The scale and pressure gauge manufacturers are examples worth mentioning (Gonçalves 2013). In 1998, the trade deficit with respect to scales was US$3 million, which changed by 2004 into a surplus of US$3.4 million. Similarly, with the development of the force laboratory (which also received strong support from PTB), the Brazilian production of pressure gauges increased significantly, and the trade balance for pressure gauges evolved from a deficit to a surplus. In 1997–99, the average deficit was US$3.8 million per year. From 2004 until 2011, this changed into an average surplus of US$3.4 million per year. The exports of pressure gauges totaled only US$1.2 million in 1998, but increased to US$16.2 million in 2011.

PROBLEMS ENCOUNTERED: CHALLENGES AND ISSUES

A number of serious challenges had to be managed or negotiated. Many of them related to the political turmoil and instability Brazil experienced in the 1970s and 1980s.

Buildings

The Brazilian government was responsible for new laboratory buildings that were necessary to house high-precision metrology equipment. Although the Brazilian government allocated some funds already in 1971 at the beginning of the cooperation agreement, it took many years before some of the buildings were completed.

First, the Brazilian architects followed a then-common approach of designing the buildings to make a statement through size; they were much bigger than was required. Given the tight environmental controls (for example, temperature and humidity controls) that are required in such laboratories, the buildings' size would have resulted in a major drain on the electrical energy required to meet these requirements. Sound advice from PTB experts seconded to Brazil, as well as from senior INMETRO staff who visited Braunschweig (experiencing PTB laboratories firsthand), did help to deal with the issue to some extent, but it never went away completely.

Second, the funds allocated for the buildings were not adequate, and additional resources had to be found. Fortunately, some additional funds from the PADCT program funded by the World Bank could be accessed through the "good offices" of the PTB president, who was a member of the PADCT advisory board. His knowledge of the project helped to argue the case for the importance of metrology in the greater scheme of implementing the PADCT.

Third, the political turmoil in Brazil, with governments coming and going and new governments rescinding decisions of previous ones, contributed to this state of affairs, as did the overly bureaucratic systems ostensibly designed to curb the rampant corruption in state purchases. Successive governments pleaded a financial crisis inherited from previous ones and argued that there was no binding contract for the completion of the buildings anyway. Allocated funds were summarily scrapped. Within PTB, serious doubts were starting to surface as to whether the project would be successfully completed.

The completion of the buildings took years, and even by the end of the second phase of the cooperation activities between PTB and Brazil in 1995, some of the buildings had not been completed. This procrastination was a major stumbling block for the timely implementation of much of the cooperation agreement—especially for the provision and commissioning of equipment, which had to be postponed sometimes for months, even years. Fortunately, by 1989, most of the buildings required for the PTB project were available, and no further delays affected its implementation in this respect.

Materials and spare parts

The systematic procurement of materials and spare parts for the mechanical workshop was extremely difficult. The budget requested by PTB for repair and maintenance of high-precision instruments was finally approved after years of unsuccessful attempts. After a few more years, however, this budget was summarily canceled under a new Brazilian president. Furthermore, the Brazilian government had imposed a ban on the importation of electronic components and equipment until about 1988, making it difficult for PTB and other partners to source them outside Brazil. As a result, PTB had to include a specific paragraph to facilitate importation of electronic components in the agreement signed in 1985.

Staff and training

The initial group of Brazilian metrologists were sent to Germany for 15–18 months, of which the first few months were spent learning German. The allocated time for advanced training was considered necessary because of the technical complexity of establishing primary standards. The first batch of

trainees had a major impact on the development of INMETRO, and many of them later became managers of various divisions.

After this first group, INMETRO did not wish to release further staff for such long periods, because they were now required to run the day-to-day business. The situation was exacerbated by the stress such a long training period put on the trainees being separated for months on end from their families. Unfortunately such training, as profitable as it was, could not be repeated.

Another major challenge was the general hold that the government had put on all state institutions regarding the appointment of additional staff—that is, no new staff under any circumstance. Because INMETRO was in a developmental phase, this hiring freeze put a tremendous strain on the staff contingent that was available to maintain service levels. This was further exacerbated by highly trained staff leaving INMETRO for better salaries in private industry. These individuals could also not be replaced. A minibreakthrough occurred only by the end of the second phase, when 20 metrologists were appointed in place of purely administrative personnel.

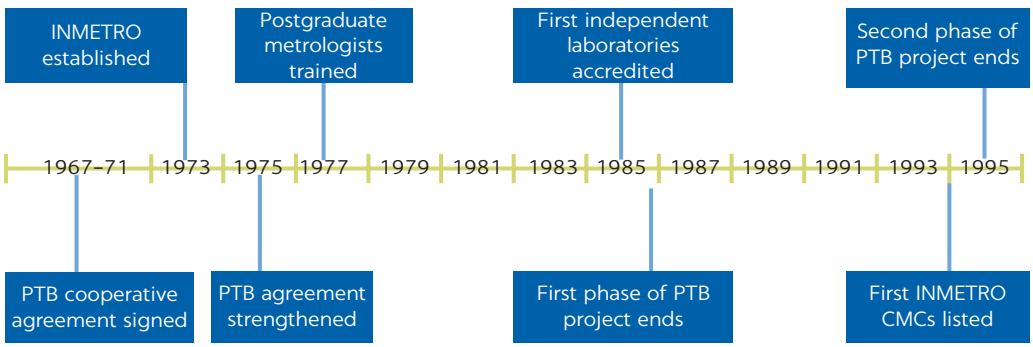
KEY SUCCESS FACTORS AND LESSONS LEARNED

It is not easy to isolate all the key success factors, because of the complexity of the whole project, especially through its first two phases (figure 1). But three factors stand out.

Gradual progression. The major lesson in the development of INMETRO through the unstinting support of the senior partner, PTB, is that it takes years to establish an NMI of note. It starts with small steps to calibrate existing measuring equipment and progresses through major steps such as the provision of appropriate laboratory buildings, in-depth training of metrologists, supply and commissioning of high-technology equipment, and ultimately the development of the requisite skills and technology to realize primary standards and establish the CMCs of these. Only when INMETRO had walked the whole journey—and internalized all the technical knowledge on offer from the world-renowned PTB—could it confirm its standing in the world of metrology. All of this took nearly three decades.

FIGURE 1

Timeline of INMETRO development and notable milestones, 1967–95



Note: CMCs = calibration and measurement capabilities. INMETRO = National Institute of Metrology, Quality and Technology. PTB = National Metrology Institute of Germany.

Long-term PTB support. Second, PTB's tenacity in staying with the project for nearly two decades was a major factor in INMETRO's eventual ability to develop into a globally respected NMI. PTB, in cooperation with INMETRO, had to negotiate many vagaries and procrastinations of the various governments in Brazil over the decades the project lasted, some of which PTB had to conduct on its own, as INMETRO also had its limitations.

Well-trained, dedicated metrologists. Third, the initial in-depth training of metrologists in Germany following their postgraduate training at the Federal University of Rio de Janeiro set the tone of technical excellence for the metrologists who worked during the beginning years at INMETRO. They were the ones who had the vision and the passion for new approaches that were so necessary for the future of the institution. They were the ones who took INMETRO forward over many years after becoming managers in its various divisions. Without these dedicated and well-equipped metrologists, INMETRO would have required a much longer period to develop into the well-respected NMI it had become by the end of the second phase of the project in 1995.

CONCLUSION

The long-lasting cooperation between INMETRO and PTB produced a multitude of impacts and benefits for both the NMIs and their respective countries. This was a comprehensive cooperation, covering a wide variety of fields and involving other countries.

For INMETRO as it was being established, the cooperation with the much more experienced PTB fostered the processes of capacity building because it was a way of getting sound technical input and reducing possible mistakes. Besides, the experienced PTB was able to provide INMETRO with credibility—namely through calibration certificates—once the latter was capable of meeting the necessary technical requirements. Combined with the development of a credible accreditation system, this helped Brazilian companies to gain access to foreign markets based on conformity assessment results that were internationally accepted.

Slowly, INMETRO was able to take the next step—realizing the first primary measurement standards, with PTB's support. Once these first primary standards were established and their CMCs determined, peer-reviewed, and listed on the KCDB of the BIPM, others followed. Thereafter, INMETRO was able to develop more CMCs on its own. It was now an equal partner of PTB and no longer the junior partner that had to be trained. From the experienced PTB and the German perspective, this meant getting a partner for future collaborations in research activities and helping to disseminate metrological knowledge, while it also facilitated the entry of German companies into the Brazilian market, because they share a similar measurement system, technical norms, and standards.

Metrology is a field that requires constant research and where the resources are never enough because it comprises activities that are complex, expensive, and require very specialized and qualified staff. Additionally, there is a wide variety of metrological fields—with new fields emerging in recent years, such as metrology in chemistry or materials metrology. Collaborating in such research activities would improve the results and reduce the costs incurred by each NMI. Furthermore, as the worth of metrological knowledge increases along with the

number of economic actors using it, cooperative activities are likely to increase the number of users of the same metrological system, hence fostering the economic integration of countries and enlarging the networks through which companies can innovate.

NOTES

1. In this case study, German currency is expressed in deutsche marks (DM) in references to monetary value, costs, or expenditures up until 2002, when the euro was introduced.
2. ISO/IEC Guide 25:1990, "General Requirements for the Competence of Calibration and Testing Laboratories," was withdrawn when replaced by ISO/IEC 17025:1999 and has since been revised again as the current standard, ISO/IEC 17025:2017, "General Requirements for the Competence of Calibration and Testing Laboratories": https://www.iso.org/standard/66912.html.
3. "BRICS" refers collectively to five major emerging economies: Brazil, the Russian Federation, India, China, and South Africa.
4. Other key organizations in the QI of Brazil are the General Coordination for Accreditation of INMETRO (CGCRE), the Brazilian Association of Technical Standards (ABNT), and the Brazilian Association for Quality Control (ABCQ).
5. Law No. 5966 of December 11, 1973 (http://www.planalto.gov.br/CCivil_03/Leis/L5966.htm).
6. ISO 9001:1987, titled "Quality Systems—Model for Quality Assurance in Design/Development, Production, Installation and Servicing," has been revised five times. The current standard is ISO 9001:2015, "Quality Management Systems—Requirements": https://www.iso.org/standard/62085.html.
7. The DM (deutsche mark) was the German currency at the time. When the euro was introduced in 2002, DM 1.95583 (nearly 2 DM) was considered equal to €1.
8. The German Metrology Academy (DAM), based in Munich, was set up specifically for the training of metrologists in all fields of legal metrology. It is part of the Legal Metrology Department of Bavaria but is funded as a cooperative venture by all 16 German states.
9. ISO Guide 32:1997 has since been replaced by ISO Guide 33:2015, "Reference Materials—Good Practice in Using Reference Materials": https://www.iso.org/standard/46212.html.
10. For the current standard, see ISO/IEC 17025:2017, "General Requirements for the Competence of Calibration and Testing Laboratories": https://www.iso.org/standard/66912.html. Also see ISO/IEC 17020:2012, "Conformity Assessment—Requirements for the Operation of Various Types of Bodies Performing Inspection": https://www.iso.org/standard/52994.html.
11. For the current standard, see ISO/IEC 17021-1:2015, "Conformity Assessment—Requirements for Bodies Providing Audit and Certification of Management Systems—Part 1: Requirements": https://www.iso.org/standard/61651.html. Also see ISO/IEC 17065:2012, "Conformity Assessment—Requirements for Bodies Certifying Products, Processes and Services": https://www.iso.org/standard/46568.html.

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INTERNATIONAL DEVELOPMENT IN PRACTICE

East African Community

QI Toolkit Case Studies

Martin Kellermann

WORLD BANK GROUP

PTB Physikalisch-Technische Bundesanstalt
Braunschweig und Berlin
National Metrology Institute

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Contents

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Martin Kellermann has more than 40 years of experience working in quality infrastructure (QI), first in the South African Bureau of Standards and thereafter as a consultant all over the world. He has worked in Central Asia, the Middle East, East Africa, West Africa, and East Asia, advising governments and QI institutions on policy, strategy, and the reengineering of business activities, as well as facilitating the drafting of national quality policies and QI legislation. During this time, he worked with the World Bank, National Metrology Institute of Germany, International Organization for Standardization, International Trade Centre, United Nations Industrial Development Organization, United Nations Development Programme, and many other organizations, and he has contributed to and authored multiple publications on QI.

Kellermann holds a master's degree in mechanical engineering from Pretoria University. He has also studied accountancy at the University of the Witwatersrand's Graduate School of Business Administration and participated in the Executive Education Program of the Haas School of Business, University of California, Berkeley. Currently, Kellermann lives with his wife in South Africa.

Abbreviations

AFRAC	African Accreditation Cooperation
AFRIMETS	Intra-Africa Metrology System
ARSO	African Organisation for Standardisation
BMZ	Federal Ministry for Economic Cooperation and Development (Germany)
CEO	chief executive officers
EAAB	East African Accreditation Board
EABC	East African Business Council
EAC	East African Community
EASC	East African Standards Committee
EPA	Economic Partnership Agreement (EU)
EU	European Union
ISO	International Organization for Standardization
KEBS	Kenya Bureau of Standards
KENAS	Kenya National Accreditation Service
NSB	national standards body
PTB	National Metrology Institute of Germany
QI	quality infrastructure
RBS	Rwanda Bureau of Standards
SADC	Southern African Development Community
SQMT	Standardization, Quality Assurance, Metrology and Testing
SQMT Act	East African Standardization, Quality Assurance, Metrology and Testing Act
SQMT Protocol	Protocol on Standardization, Quality Assurance, Metrology and Testing
TBS	Tanzania Bureau of Standards
TBT Agreement	Agreement on Technical Barriers to Trade (WTO)
UNBS	Uganda National Bureau of Standards
UNIDO	United Nations Industrial Development Organization
WTO	World Trade Organization

East African Community

QI Toolkit Case Studies

Abstract: The realities and challenges of establishing a harmonized regional approach to standards, metrology, accreditation, and conformity assessment in a recently established trade region to support intraregional trade are many and varied. One of the major challenges is usually the dismantling of long-established national quality infrastructure (QI) systems proving to be nontariff barriers, as shown in the East African Community.

EXECUTIVE SUMMARY

The current East African Community (EAC) became operational in 2000 with the signing of the EAC Treaty in 1999. It originally comprised Kenya, Tanzania, and Uganda. Burundi and Rwanda joined in 2007. A customs union was entered into in 2005, and a common market was launched in 2010. The German Federal Ministry for Economic Cooperation and Development (BMZ) funded a project, "Establishment of a Regional Quality Infrastructure in the East African Community (EAC)," which was implemented by the National Metrology Institute of Germany (PTB). The envisaged impact of the project was to enhance EAC integration through the harmonization of standards and technical regulation and to increase trade flows, thus contributing to economic growth and ultimately to poverty reduction.

The project was designed as a multilevel intervention, working on the meso level (institutional capacity building) as well as the macro level (policy and strategy reform). It was implemented in three phases over nine years with a total investment of €4.3 million:

- *Phase 1 (2004–07)* focused on the development of the enabling legislation—the East African Community Standardization, Quality Assurance, Metrology and Testing Act (SQMT Act) of 2006 —and the establishment of the regional QI organizations.
- *Phase 2 (2007–10)* facilitated the realization of the requirements of the SQMT Act and supported improvements in the technical performance of the national QI organizations.

- *Phase 3 (2011–13)* consolidated selected strategic activities of the previous two phases to enhance the sustainability of the regional structures and built further technical capacity in national QI organizations, with a specific focus on Burundi and Rwanda.

Notable successes of the overall project, from 2004 to 2013, included the following (table 1):

- *Development and promulgation of the SQMT Act*, in cooperation with the East African Secretariat and the partner states, as the foundation of QI harmonization in the EAC.
- *Extensive support of the East African Standards Committee (EASC)* and its technical subcommittees at the policy and strategy levels and in operational activities. Many EAC regulations were developed to support the implementation of the SQMT Act.
- *Harmonization of more than 1,000 regional standards* after the development of a proper standards development procedure.
- *Development of accreditation bodies.* The East African Accreditation Board (EAAB) was established, and the Kenya National Accreditation Service (KENAS) was institutionalized. Accreditation focal points were established in other partner states. A pool of trained assessors was created for the accreditation of medical, testing, and calibration laboratories.
- *Training of inspectors and harmonization of inspection processes,* leading to fewer inspections of products moving across borders in intra-EAC trade.
- *Improvements in metrology.* The metrology laboratories of the national standards bodies (NSBs) achieved improvements in their measurement uncertainties and expanded the range of services.

TABLE 1 Snapshot of quality infrastructure (QI) reform in the East African Community (EAC)

BEFORE REFORM	AFTER REFORM
No legal framework existed at the regional level dealing with standards, metrology, accreditation, and conformity assessment to support the implementation of the EAC Treaty regarding products traded in the EAC.	The SQMT Act was developed in cooperation with the EAC Secretariat and partner states as the foundation for harmonizing QI services across the region. It was promulgated as EAC legislation in 2007 and was progressively implemented thereafter by partner states.
The system for the development and harmonization of regional standards was in its infancy and was noncompliant with international good practices.	A formal system for developing, approving, and adopting regional standards compliant with international good practices was developed in cooperation with the NSBs of partner states and implemented. By the end of the project, about 1,100 regional standards had been developed and published. Adoption of the same by partner states was ongoing albeit incomplete.
Reciprocal recognition of product quality assessments within the EAC did not exist. Products inspected and approved for marketing in one partner state had to be reinspected and reapproved before marketing in another partner states.	A start was made with the harmonization of the NSBs' product certification services, including peer reviews to determine compliance with international standards such as ISO/IEC 17065 and to engender trust among national authorities. Products falling within the scope of technical regulations that were certified in one partner state were beginning to be accepted in other partner states without further inspection, testing, and certification. Complete acceptance was envisaged for the future.
National QI services compatible with the WTO TBT Agreement requirements had been established for use by exporters but still lacked the international recognition required for the conclusion of an Economic Partnership Agreement between the EAC and the European Union.	Metrology laboratories in partner states achieved improvements in measurement uncertainties and increased the range of calibration services. The Kenya National Accreditation Service (KENAS) was institutionalized, and accreditation focal points were established in other partner states. Formal international recognition of metrology and accreditation was still in the future.

Note: NSB = national standards body. SQMT Act = East African Community Standardization, Quality Assurance, Metrology and Testing Act. WTO TBT Agreement = World Trade Organization Agreement on Technical Barriers to Trade. ISO/IEC 17065 refers to the international standard ISO/IEC 17065:2012, "Conformity Assessment—Requirements for Bodies Certifying Products, Processes and Services."

- *Successful integration of the EASC and EAAB into the Pan-African QI organizations*, namely the Intra-Africa Metrology System (AFRIMETS), the African Accreditation Cooperation (AFRAC), and the African Organisation for Standardisation (ARSO).
- *Increased private sector demand for NSB services*, which grew by more than 15 percent per year over the project period (2004–13).

However, at the conclusion of the project in 2013, several challenges remained:

- The pace of implementing the requirements of the SQMT Act at the national level was still slow because national interests outweighed regional integration goals.
- The EAC Secretariat found it difficult to provide adequate personnel to coordinate all the relevant QI operations between the regional and national levels.
- The involvement of the private sector remained low despite focused interventions in the second and third phases.
- Tanzania's membership in both the EAC and the Southern African Development Community (SADC) hampered the implementation of EAC common market modalities. This case study is therefore, to some extent, incomplete because further developments of the EAC QI are not considered.

An online review among stakeholders of the efficacy of the project at the end of 2013 indicated extremely solid progress at the NSB institutional level, but the review team rated overall progress in SQMT Act implementation at only 3.5 out of a possible 5. Criticisms were the lack of adoption of EAC regional standards at the national level, little change in consumer protection, and the lack of technology transfer.

REGIONAL AND COUNTRY CONTEXT

The EAC is an intergovernmental organization composed of five countries in the African Great Lakes region in eastern Africa: Burundi, Kenya, Rwanda, Tanzania, and Uganda.[1] The organization was founded in 1967, collapsed in 1977, and was revived again in 2000, after which it developed in fits and starts. The EAC is an integral part—one of several regional "pillars"—of the African Economic Community, an organization of African Union states for mutual economic development.

The EAC is also a potential precursor to the establishment of the East African Federation, a proposed federation of its members into a single sovereign state. A customs union went into effect in 2005. In 2010, the EAC launched its own common market for goods, labor, and capital within the region, with the goal of creating a common currency and eventually a full political federation. In 2013, a protocol was signed outlining the EAC members' plans for launching a monetary union within 10 years.

Of the five EAC partner states, Tanzania is also a member of the Southern African Development Community (SADC), whereas Burundi, Kenya, Rwanda, and Uganda are members of the Common Market for Eastern and Southern Africa (COMESA). Tanzania used to be a member of COMESA but relinquished its membership in 2000. These multiple memberships create their own challenges, because any integration, especially common market developments,

demand the country's compliance with two sets of regional requirements, which are frequently incompatible. This is also true in the case of QI at the regional level, and especially of technical regulation regimes. Large differences in development level existed among the five partner states with respect to QI and technical regulation, with Burundi being the least developed.

QI HISTORY IN THE EAC

Consistent growth in low- and middle-income countries to promote socioeconomic development and ecological sustainability is unlikely without access to the large markets of the global economy. An important intermediate step toward integration into the global economy could be participation in effective regional economic communities. However, a well-developed and regionally harmonized QI is a core element when it comes to reducing the unnecessary obstacles to trade, especially in the regional context.

Article 81 of the Treaty for the Establishment of the East African Community (signed in 1999) highlights standardization, quality assurance, metrology, and testing as preconditions for sustainable modernization in the EAC.[2] Hence, the partner states are committed to evolve and apply a common policy for standardization, quality assurance, metrology, and testing of goods and services produced and traded within the EAC. The first step in this direction was made with the approval of a Protocol on Standardization, Quality Assurance, Metrology and Testing (SQMT Protocol) by the EAC Council of Ministers in 2001.[3]

The NSBs of the three original EAC partner states—Kenya, Tanzania, and Uganda—set about realizing this protocol and established the East African Standards Committee (EASC) as the vehicle for discussing common challenges, developing East African standards, organizing training, and dealing with other relevant issues pertaining to the implementation of the protocol. But integration was slow; many challenges could not be appropriately addressed because of the difficulties in accepting regional approaches while considering national sensitivities. The following examples illustrate these difficulties:

- An analysis by international experts (Wallerath 2006) concluded that the process of harmonizing East African standards, although delivering a respectable number of standards each year, was not compliant with international good practices and principles as provided for in the World Trade Organization (WTO) Agreement on Technical Barriers to Trade (TBT Agreement) and directives of the International Organization for Standardization and International Electrotechnical Commission (ISO/IEC) The analysis also found that the private sector was to a large extent absent from regional deliberations on standards.
- There were differences in the levels of development and technical capacity available in the various NSBs—differences that became even more apparent when Burundi and Rwanda became EAC partner states in 2007. Furthermore, the NSBs' technical capacities had not kept pace with technological development and were no longer sufficient for the countries' needs.
- As public entities, the Kenya Bureau of Standards (KEBS), Tanzania Bureau of Standards (TBS), and Uganda National Bureau of Standards (UNBS) were responsible for the implementation of mandatory standards through

inspection, testing, and certification. Yet none of them was required to demonstrate technical competency at the national level. A review of their systems and practices concluded that none of them complied with relevant international standards.
- No accreditation body had been established in any of the partner states, and the agreement between the Kenya, Tanzania, and Uganda NSBs at an extraordinary meeting of the EASC in 2004 to establish a regional accreditation body soon came to nought with the establishment of KENAS in Kenya (Elfring, Koch, and Peters 2007).

OBJECTIVES AND PROJECT COMPONENTS

The major support to realize the SQMT Protocol came from BMZ through its 2004–13 project, "Establishment of a Regional Quality Infrastructure in the East African Community (EAC)." The envisaged impact of the project was to enhance EAC integration and to increase trade flows, thus contributing to economic growth and ultimately to poverty reduction (Diergardt 2014).

The project was implemented by PTB in three phases (also illustrated in figure 5), with a total investment of €4.3 million over nine years:

- *Phase 1 (January 2004 to June 2007, €1.5 million)* focused on the development of the SQMT Act and the establishment of the regional QI organizations.
- *Phase 2 (July 2007 to December 2010, €2 million)* facilitated the realization of the requirements of the SQMT Act and supported improvements in the technical performance of the national QI organizations.
- *Phase 3 (January 2011 to February 2013, €0.8 million)* consolidated selected strategic activities of the previous two phases to enhance the sustainability of the regional structures and built further technical capacity in national QI organizations, with a specific focus on Burundi and Rwanda, which had acceded to the EAC in 2007.

Of the €4.3 million total investment, approximately €500,000 was invested in new equipment during the three phases.

The modalities of the technical development support were largely consultancy provided by international and local short-term experts, appropriate training programs, mutual assessments of the national QI organizations, and support from regional and international technical cooperation.

Objectives

The goals of the project were (a) to establish and improve the QI as an element of the regional integration process through the EAC Secretariat and QI institutions with participation by the private sector; and (b) to align the QI system with a new regional legal framework (that is, the SQMT Act) at both the regional and national levels.[4]

The project goals were twofold: First, harmonized quality assurance procedures and increased cooperation between the national QI institutions would facilitate exports from one partner state to another, and in this way increase intra-EAC trade. Second, building regional technical capacity in terms of improved measurement and testing capabilities would enable the private sector

to access more accurate, internationally recognized calibration and testing services to improve the quality of their products, thereby leading to increased exports, both regionally and internationally.

The goal of Phase 1 was therefore formulated as follows: "The SQMT Protocol is to be implemented, to ensure that the regional NQI[5] activities are harmonised and aligned with international norms, and that the technical infrastructure can provide the services needed" (Elfring, Koch, and Peters 2007). After the completion of Phase 1—that is, after the promulgation of the SQMT Act—this was changed accordingly to the following: "As a component of the regional process of integration, the construct of the quality infrastructure is improved by the EAC Secretariat and the EASC technical committees with participation of the regional economic operators and the NSBs and adapted to the new legal framework (i.e., SQMT Act)" (Diergardt 2010).

The broad objectives of the project could therefore be considered as follows:

- Establishment of a legal framework for a regional QI
- Development and harmonization of regional standards
- Reciprocal recognition of quality assessments within the EAC
- Establishment of WTO TBT Agreement-compatible and internationally recognized national QIs for use by exporters and as a precondition for the conclusion of an Economic Partnership Agreement (EPA) between the EAC and the European Union (EU).

Whereas the broad objectives of the project remained basically the same over the three project phases, specific indicators were adopted at the beginning of each phase according to the progress achieved at the QI policy level. The project indicators were formulated mostly at the outcome level, as follows:

- Improved technical capacities of the national QI institutions
- Increased collaboration between national QI institutions
- Greater participation by the private sector in the development of EAC standards
- Increased demand for quality management certification by the private sector
- Establishment of a pool of regional assessors for accreditation purposes
- Improvements in intraregional trade flows.

Additional indicators in Phase 3 related specifically to improved national QI service provision in the new EAC member states of Burundi and Rwanda, underlining the focus of capacity development toward narrowing the existing gaps between national QI systems in the EAC.

Design and implementation

The three-phase project was designed in partnership between the EAC Secretariat and German development cooperation structures, as well as in close consultation with national QI institutions of EAC partner states. Project partners were the EAC Secretariat and PTB, acting on behalf of the BMZ.

Phase 1: 2004–07

During Phase 1, the project focused on establishing the legal framework at the regional level and on capacity development for the EAC Secretariat and its

technical committees. Capacity development in the national QI organizations was also undertaken. Phase 1 included these important elements:

- *SQMT Act*. The development of SQMT Act was high on the project agenda. A draft bill for this act was developed in close cooperation with the Directorate of Customs and Trade of the EAC Secretariat and the EASC. On completion, it was signed off by the chief executive officers (CEOs) of the three NSBs constituting the EASC at that time: Kenya, Tanzania, and Uganda. The bill was considered by the East African Legislative Assembly in 2006 and promulgated as an EAC Act. By the beginning of 2007, it had been assented to by the heads of state of Kenya, Tanzania, and Uganda, and hence came into effect in the same year. The SQMT Act replaced the SQMT Protocol, which had become technically outdated and was no longer in line with international good practices.

The SQMT Act provided the framework for the establishment of the national standards, metrology, and accreditation organizations and their main responsibilities in each partner state. It gave legal certainty to or established the regional QI organizations (the EASC and a regional accreditation board, respectively) to foster cooperation in these QI sectors. The SQMT Act established a coordination office in the EAC Secretariat and established the legal standing of the EAC standards. Other hallmarks of the SQMT Act are harmonization and coordination among the national QI institutions as well as the supremacy of regional approaches over national ones.

- *Standards development procedures.* Many standards, nearly 500, had already been harmonized as regional standards even though their publication was still a problem. The mechanism for this harmonization was reviewed and found to be out of sync with international good practices and the WTO TBT Agreement; for example, the private sector was only marginally involved in the process. A new methodology, the Procedure for the Development of EAC Standards (EASC 2005), was developed in cooperation with the EASC technical subcommittee responsible for standards development, approved by the EASC, and implemented. All the published standards were reviewed, and some of them were withdrawn as no longer required; others were reaffirmed or revised in accordance with the new procedure.
- *Laboratory proficiency testing.* The testing laboratory sector was supported in conducting proficiency tests that are important to demonstrate their technical competency.[6] Approximately 25 laboratories from all five partner states participated. Personnel of four NSBs were trained, and the testing laboratories were provided with the necessary equipment to design and conduct such proficiency tests themselves—KEBS for flour, the TBS for salt, the UNBS for edible oil, and the Rwanda Bureau of Standards (RBS) for sugar.
- *Laboratory management systems and accreditation.* Some personnel of the testing and calibration laboratories were trained in the implementation of management systems in accordance with ISO/IEC 17025 ("General Requirements for the Competence of Testing and Calibration Laboratories") and ISO/IEC 15189 ("Medical Laboratories—Requirements for Quality and Competence").[7] This helped them to implement these systems in such laboratories (a prerequisite for accreditation) and at the same time provided KENAS with a pool of technical assessors at the regional level. A few laboratories were accredited by internationally recognized accreditation organizations.

Phase 2: 2007–10

Phase 2 was characterized by the implementation of the provisions of the SQMT Act, particularly (a) mutual recognition of conformity assessment procedures (ensuring that testing and certification in EAC countries follows the same procedures); (b) development of the competence of metrological and testing services; and (c) increased cooperation with the regional private sector (that is, fostering participation in technical committees for the development of standards and the increased use of the improved technical capabilities of the national QI). Specific project indicators for the success of this phase included the following (Wallerath 2008):

- EAC private industry increased its participation in the development of EAC standards in at least five sectors.
- Cooperation agreements were reached between at least two of the NSBs concerning service delivery (10 agreements by the end of 2010).
- Sixty percent of the EAC private sector stated that, by the end of Phase 2 of the project, the cross-border trade in products and services has been significantly improved in terms of cost and time savings as a result of the implementation of the QI-supported technical regulation regime.
- The EAC private sector's demand increased for quality and environmental management certification emanating from the region as measured by the ISO annual reports on ISO 9000 (quality management) and ISO 14000 (environmental management) certificates issued worldwide.
- In Rwanda, the private sector gained access to a growing scope and number of calibrations and was using them.
- In Burundi, two EAC-relevant calibration and testing services were being established.

In addition to these indicators on the technical level, a tremendous amount of strategy and policy consultancy as well as logistical support for intraregional meetings and training sessions were provided to the EAC Secretariat, the EASC and its technical committees, and the East African Business Council.

Phase 3: 2011–13

Phase 3, starting in 2011, further enhanced the strategic orientation of the EAC Secretariat and national QI institutions by continuing support for the implementation of the SQMT Act. Emphasis was placed on the consolidation of achievements and sustainability of outcomes, and the Burundi and Rwanda NSBs received special attention to lift their technical competency to a level closer to the NSBs of Kenya, Tanzania, and Uganda. Some of the specific indicators of success in Phase 3 included the following:

- At the end of the project, a representative group of the QI stakeholders (NSBs, trade and industry ministries, the EAC Secretariat, and the private sector) were asked to evaluate the progress achieved from implementing the SQMT Act and improving the cooperation between the national QI institutions during the nine years of the project (Diergardt 2014). The evaluation would use a scale of 1 to 5, where 1 would mean no change, and 5 would mean more change than anticipated.
- Private sector demand for quality and environmental management certification from the region rose by at least 15 percent.
- The RBS indicated that Rwandese industry required at least 15 percent more calibration services from RBS at the end of 2012 than at the end of 2010.

- The Burundi Bureau of Standards and Quality Control (BBN) was able to provide calibration services for temperature, volume, and mass in accordance with international norms.

Overall project picture

The project's focus was primarily on the transfer of knowledge and best practices of QI systems through short-term training, South-South cooperation, advisory assignments, and study visits. It facilitated the exchange of know-how and experience among QI institutions and stakeholders in the region; financed training and knowledge transfer from more-developed national QI institutions in the EAC to their counterpart institutions and colleagues in Burundi and Rwanda; and supported regional QI conferences through finance and advice. Raising the awareness of the private sector so that it plays a greater role in QI system development was a specific focus starting with Phase 2.

Support was provided in the form of highly competent short-term expert assignments. The project had no permanent office or presence in the region but was coordinated from the PTB head office in Braunschweig, Germany. The EAC Secretariat in Arusha, Tanzania, provided coordination support in this respect.

The project was designed specifically as a multilevel intervention. It provided advice at the strategic and policy decision levels to the EAC Secretariat, the EASC and its technical committees, and the top management of the national QI institutions. The project balanced these contacts with interventions at institutional levels, the aim of which was to establish appropriate technical and organizational capacities.

The project followed the requirements of the Paris Declaration, enhancing ownership (intensive joint planning with partners and stakeholders, transfer of knowledge for future-oriented topics such as WTO compatibility, sensitizing for greater private sector participation, and so on).[8] The project did well in harmonizing its approaches with programs supported by other development partner organizations—such as the United Nations Industrial Development Organization (UNIDO), the German Agency for International Cooperation (GIZ), and TradeMark East Africa—and endeavored to foster transparency and accountability through a well-developed system of monitoring inputs, outputs, and outcomes.

OUTCOMES

Overall, the project met its set objectives. The specific outcomes and impacts are discussed below on the basis of the defined indicators. Because the regional QI system had to be established almost from scratch, the project was highly dynamic and produced new intervention areas, for which indicators had to be defined during the implementation process.

QI system legislation. The SQMT Act was developed in collaboration with the EAC Secretariat and partner states and is the foundation for any QI harmonization in the region. It entered into force in 2007 and provides for the standards, quality assurance, metrology, and testing of products produced or traded in the EAC. At the end of the project, the SQMT Act still needed to be fully implemented in all EAC member countries, requiring that national QI

institutions meet all its requirements and that standards be fully harmonized. The substantive advice given particularly the national QI institutions in Burundi and Rwanda was well received and is reflected in the institutions' organization and activities.

Harmonization of standards. During the project, 1,100 regional standards were harmonized, although they had not yet been fully adopted at the national level in all the partner states. The standards covered a wide range of goods, from food to construction materials. Harmonized standards reduced nontariff barriers (NTBs), because national standards could no longer be used for protective purposes—for instance, one EAC partner state prohibiting the marketing of products from another partner state on account of a difference in national standards. Participation by the private sector in regional meetings for the development of standards was increasing but still relatively low.

Accreditation services. A pool of trained assessors for the accreditation of medical, testing, and calibration laboratories was established. Furthermore, support and consultancy facilitated the establishment of the EAAB in 2009. KENAS was institutionalized, and a system of establishing national accreditation focal points in the other EAC partner states was accepted in principle, although it was not fully realized in each country by the end of the project. Once such focal points have been established in the other EAC partner states, KENAS should be able to accredit laboratories in all partner states in collaboration with these focal points. Regional industries and laboratories can realize significant savings (up to 50 percent because of lower travel and personnel costs) when an internationally recognized regional body can competently carry out such accreditations.

Conformity assessment. Capacities for the regional harmonization of inspection procedures and product certification schemes were further developed in the individual countries in a significant way, as the mid-term evaluations showed (Elfring, Koch, and Peters 2007). National inspectors were trained according to international inspection and certification standards and conducted joint inspections at the ports of Mombasa and Dar es Salaam. These activities built confidence in the inspections and product certifications of other EAC partner states. Reciprocal recognition of product certification should spur intraregional trade and lead to cost savings, because duplicate testing will be avoided.

Metrology. All metrology laboratories in the EAC had either achieved improvements in measurement uncertainty[9] or increased the range of measurands for which they could offer calibration services. The private sector in Rwanda, for example, could use local calibration services for electricity and pressure, rather than sending samples to Kenya. Annual regional proficiency testing rounds were successfully implemented. The latter is important for analytical laboratories to build up international recognition and improve the quality of their test results.

International links. The project supported the integration of the East African Metrology Structure (EAMET) into AFRIMETS, and of the EAAB into AFRAC. Liaisons with regional and international standardization bodies (for example, ARSO and ISO) were established. The advantages of such integration and

liaisons lie in reciprocal recognition of standards, metrology, and accreditation supporting conformity assessment, which facilitates trade. In addition, these Pan-African organizations give a voice to small African countries and can defend their interests in international forums.

Ownership. Although the position of the principal standards officer in the EAC Secretariat was initially financed by the project, the relevance of the project convinced the Secretariat to take over these costs, which underlines the level of ownership achieved.

Confidence building. The project supported confidence building in national authorities regarding regional integration processes and led to more active collaboration and cooperation between national QI institutions. This helped to reduce some mutual suspicion that existed between partner states regarding who benefits most from EAC free trade. The project also increased professional confidence within and between NSBs. Closer cooperation among the institutions at the staff level contributed to the exchange of ideas on priorities and strategic direction, thereby helping national QI institutions to determine their future direction.

Intraregional trade. The records of national QI institutions show that the private sector is increasingly using their services; particularly, the NSBs of Burundi and Rwanda indicated a 30 percent growth in the sale of services. An impact study based on a private sector survey and in-depth case studies revealed that border procedures had been streamlined following interventions by the EAC Secretariat and national QI institutions, and intraregional trade has increased (Musinguzi, Jenders, and Diergardt 2011). The study plausibly confirmed that the project has contributed to these improvements but also highlighted the need to further improve the harmonization of the QI services.

FINAL EVALUATIONS

The project was designed specifically to intervene at two levels, namely the policy and strategy level on the one hand, and on developing technical capacity in the national QI organizations on the other. Whereas the outcomes of the interventions at the policy and strategy levels are difficult to measure quantitatively, some examples of the outcomes of the technical capacity development are shown in the following sections.

Increased use of national QI services

The ISO publishes an annual survey of the number of ISO 9001 ("Quality Management Systems—Requirements"), ISO 14001 ("Environmental Management Systems—Requirements with Guidance for Use"), and other quality management system certificates that have been issued by accredited certification bodies. The results for the EAC partner states over the duration of the project are shown in tables 2 and 3. The project indicator—that these should show 15 percent growth each year—is fulfilled for the ISO 9001 certificates, even though the growth has come in fits and spurts.

TABLE 2 ISO 9001 quality management certificates issued in EAC countries, 2005–12

YEAR	2005	2006	2007	2008	2009	2010	2011	2012
Burundi	0	0	0	0	0	0	0	0
Kenya	169	183	204	257	264	12	278	480
Rwanda	1	1	1	1	1	0	0	2
Tanzania	20	14	12	12	8	3	3	48
Uganda	45	45	42	44	44	54	80	17
EAC	235	243	259	314	315	89	341	527
Growth (%)	n.a.	+3.4	+6.6	+21.2	+0.3	−71.8	+8.2	+54.5
Average annual growth, 2005–12: 22%								

Source: Diergardt 2014, from International Organization for Standardization data.
Note: n.a. = not applicable. EAC = East African Community. ISO 9001 refers to the standard, "Quality Management Systems—Requirements": https://www.iso.org/standard/62085.html.

TABLE 3 ISO 14001 environmental management certificates issued in EAC countries, 2005–12

YEAR	2005	2006	2007	2008	2009	2010	2011	2012
Burundi	0	0	0	1	0	0	0	0
Kenya	11	23	22	28	18	0	33	32
Rwanda	0	0	0	0	0	0	0	2
Tanzania	2	4	5	3	4	3	1	30
Uganda	2	3	3	6	6	6	13	8
EAC	15	30	30	38	28	9	47	72
Growth (%)	n.a.	+100	0	+26.7	+28.3	−67.8	+67.8	+53.1
Average annual growth, 2005–12: 52%								

Source: Diergardt 2014, from International Organization for Standardization data.
Note: n.a. = not applicable. EAC = East African Community. ISO 14001 refers to the standard, "Environmental Management Systems—Requirements with Guidance for Use": https://www.iso.org/standard/60857.html.

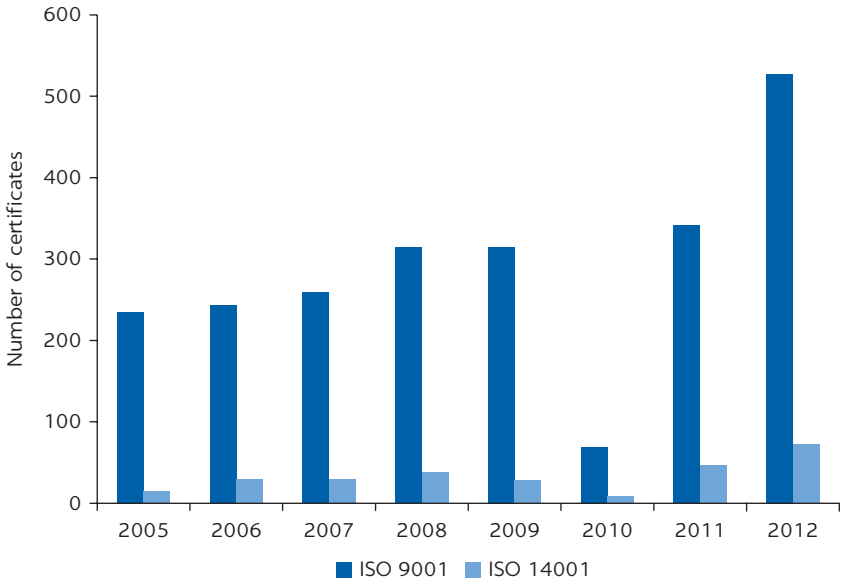
The growth in ISO 14001 certificates was even better (table 3), even though growth was from the very low base in 2005.

The figures for the EAC as a whole are graphically shown in figure 1, showing a steady growth over most of the project. Whether the project was the sole impetus for the growth in ISO 9001 and ISO 14001 certificates is debatable, but the growth does give an indication of the impact of the project outputs regarding training and consultancy for quality management systems. The dramatic decline in 2010 cannot be explained, including by the ISO. It could be that the data for the EAC were not captured accurately in that year.

The metrology services of the Burundi and Rwanda NSBs received special attention during the project, and it was expected that they should have experienced a growth of 15 percent in their calibration services from 2010 to 2012. This did not transpire (figure 2). The figures for the Rwanda Bureau of Standards show a big slowdown from the 2010/11 financial year to the next, but this can be explained by the fact that the laboratories were undergoing major renovations supported by the project during that time. Some metrology equipment had been installed in the Burundi Bureau of Standards and Quality Control, and personnel had been trained, but metrology services still had yet to commence by the end of 2012.

FIGURE 1

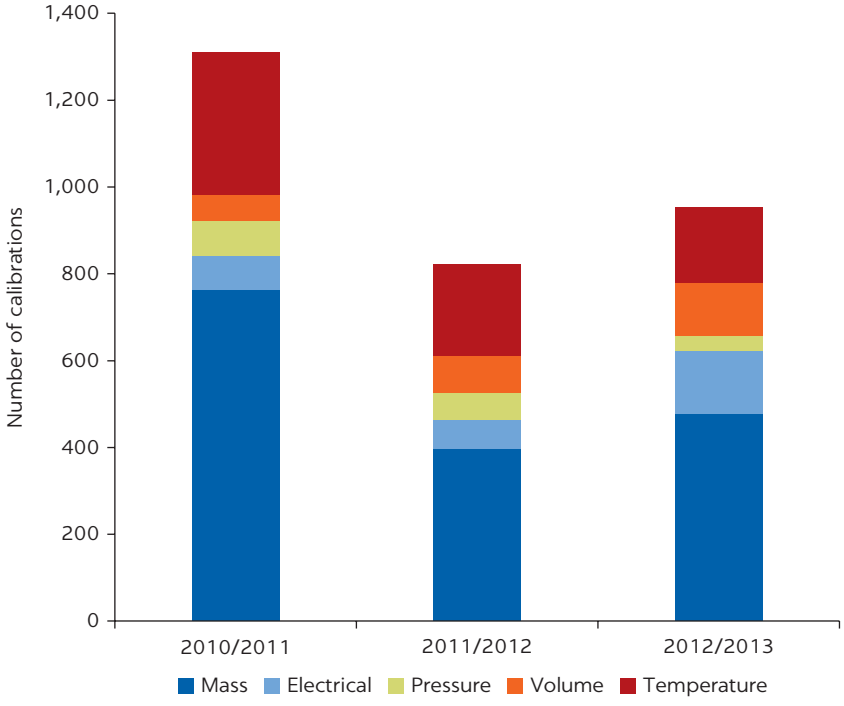
ISO 9001 and ISO 14001 certificates issued in the EAC, 2005–12



Source: Diergardt 2014.
Note: EAC = East African Community. ISO 9001 refers to the standard, "Quality Management Systems—Requirements": https://www.iso.org/standard/62085.html. ISO 14001 refers to the standard, "Environmental Management Systems—Requirements with Guidance for Use": https://www.iso.org/standard/60857.html.

FIGURE 2

Calibrations, by type, provided by the Rwanda Bureau of Standards, 2010/11–2012/13



Source: Diergardt 2014.

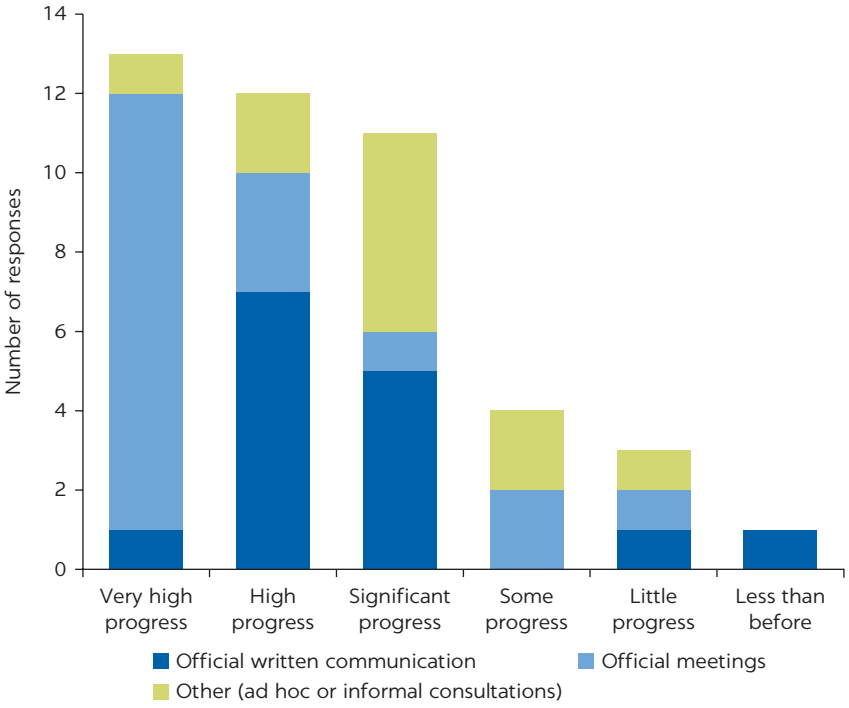
Overall progress

As the final indicator of the project in Phase 3, an online evaluation was conducted with a representative group of the QI stakeholders (NSBs, trade and industry ministries, the EAC Secretariat, and the private sector) to evaluate the project's overall progress with the implementation of the SQMT Act and the improvement of the cooperation between the national QI institutions. Although the number of respondents was a bit on the low side, the results show that the interactions between the organizations had increased significantly (figure 3). On the one hand, this is probably because of the many official meetings that were facilitated through the project; on the other hand, an increase in informal exchanges was also observed (Diergardt 2014).

The progress in implementing the SQMT Act was not seen as being as significant as the progress in national QI organization interaction (figure 4). There was progress, but it is evaluated as between "some progress" and "high progress" and just meets the project indicator target of 3.5. Respondents were critical about the lack of progress in the areas of technology transfer and in implementing regional standards in national law, even though they acknowledged the progress achieved in harmonizing the standards regionally. The respondents also gave low ratings to "enhancing consumer protection," where they viewed the project as having little if any influence. The facilitation of trade was a positive, and that came about through the alignment of the NSBs'

FIGURE 3

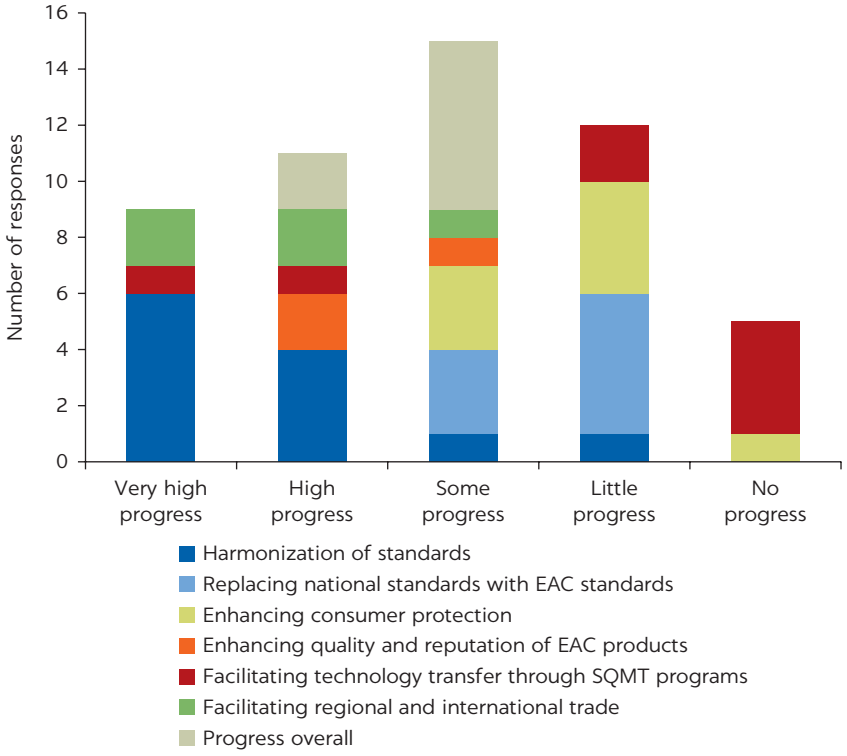
Stakeholder ratings of progress in interaction, by type, among East African national QI organizations, 2010–12



Source: Diergardt 2014.
Note: Figure illustrates responses to the question, "How do you rate the progress of interaction between East African SQMT [standardization, quality assurance, metrology, and testing] institutions/organizations over the last three years?"

FIGURE 4

Stakeholder ratings of progress, by type, in implementation of the SQMT Act, 2010–12



Source: Diergardt 2014.
Note: Figure illustrates responses to the question, "How do you rate the progress in implementing the SQMT Act over the last three years?" EAC = East African Community. SQMT Act = East African Community Standardization, Quality Assurance, Metrology and Testing Act of 2006.

certification processes across the region as well as through the recognition of each other's product certification marks for the implementation of mandatory standards.

These responses about the impact of the project indicate how difficult it is to quantify progress in absolute terms. At best, only indications or tendencies can be shown, because it is virtually impossible to isolate the influence of a specific intervention such as this project among the overabundance of influences that shape developments in a complex political and trade environment such as the EAC.

CHALLENGES

National industrial development priorities were at times in conflict with EAC integration principles. Despite the existence of regional legislation, member countries often delayed or even rejected the implementation of the SQMT Act at the national level, while the EAC Secretariat lacked a mechanism for sanctions. Integration is therefore a difficult, slow, and sometimes even frustrating process for the EAC Secretariat. This is not a question of lack of

political will toward EAC integration, but rather a matter of short-term priorities (also lobbied for by the national industrial sector) versus medium- and longer-term goals.

Up to 2014, the EAC member states were in the process of negotiating an EPA with the EU, which would accelerate QI harmonization. There were, however, significant challenges in this regard. The EAC partner states Kenya, Tanzania, and Uganda have promulgated many mandatory standards, and the respective NSBs derive substantial parts of their budgets from the administration of such standards. Hence, the interest in reducing the number of national mandatory standards and implementing modern technical regulations based on harmonized standards is rather low. The system of mandatory standards as implemented is arguably noncompliant with some of the WTO TBT Agreement principles and is seen as unnecessarily trade restrictive by trading partners.

Problems encountered also relate to available administrative capacities. The EAC Secretariat is seeking to remain a lean organization, but substantial additional staff is required to coordinate and support the implementation of the SQMT Act. Private sector involvement is a precondition for an efficient QI. The SQMT Act provides for extensive participation by the private sector, not only in the development of East African standards but also in all other areas of QI and the respective decision-making bodies. However, the private sector was still hesitant about taking the opportunity to influence regional standards and the QI setup in the region. It was not yet sufficiently aware of the impact and benefits that QI has on business in terms of export opportunities and productivity.

Finally, changing well-entrenched national QI systems toward a harmonized, WTO-compatible regional QI system takes longer than had been anticipated when planning the project. To some extent, the project has been able to react flexibly to accommodate such delays, but much remains to be done.

PRIVATE SECTOR ENGAGEMENT

During the Phase 1 of the project, it became obvious that the harmonization and integration of the QI in the EAC were driven for the most part by the NSBs. The private sector was largely absent from the regional meetings and activities, even though the NSBs argued that the private sector was engaged in technical committees at the national level, and hence was involved in regional discussions by default. That this did not always lead to a happy outcome was shown by the heavy disagreements that surfaced regarding the development of regional standards for sugar and the inspection of second-hand vehicles. These disagreements stayed on the agenda of the EASC for several years without being resolved.

Hence, the private sector was progressively being targeted during the second and third phases of the project—for example, as follows:

- During the midterm evaluation in 2010, the evaluation team had in-depth discussions with the relevant national business associations in Kenya, Tanzania, and Uganda to form an opinion on the relevance of the project interventions from a private sector perspective, especially regarding cross-border challenges within the EAC that related to mandatory standards, distrust in

inspection and test results of one partner state by the other, and costly reinspections before products could clear import inspection controls. This led to changes in the project intervention modalities.

- Regarding private sector involvement in standards development, the project supported a workshop jointly with UNIDO and the East African Business Council (EABC) for private sector stakeholders. The workshop informed private sector participants on standards issues and sensitized them for greater involvement. However, the participation of the private sector in the harmonization and development of East African standards remained low, most likely because of (a) the low relevance of East African standards in view of the existing mandatory standards in the partner states; (b) the way in which the EASC subcommittee on standards dealt with standards from many sectors in one meeting, necessitating the participation of many private sector participants from each sector, as opposed to the few from the NSBs; and (c) the costs of private sector participation in meetings at the regional level.
- In Phase 2, an East African standards platform was established, as a structure within the EABC, that operates as a counterpart to the public institutions in harmonizing standards and technical regulations across the region. Its strategy, among others, included cooperation with the EASC toward a common East African technical regulation framework to ease the disparities in technical regulation development and administration experienced by the private sector that hinder intraregional trade. The Standards Platform also actively engages with the Trade and Customs Directorate at the EAC Secretariat on standardization and technical regulation matters that have a bearing on trade. TradeMark East Africa continued support for the Standards Platform after the PTB project ended.

KEY SUCCESS FACTORS

Important for the success of the project was the high level of ownership of the EAC Secretariat, which was demonstrated, for example, by the creation of a new "principal standards officer" position at the secretariat level to coordinate activities between the stakeholders.

The good institutional and professional relationships that existed between the relevant QI officers in the EAC Secretariat, QI institutions at the country and regional levels, and German development cooperation was very important. Because of its independence, expertise, and neutrality, PTB was perceived as an honest broker and was accepted by all stakeholders. Equally important for the success of the project were the generally good working relationships among the QI institutions of the various EAC partner states. This facilitated the smooth transfer of knowledge and was particularly effective in strengthening capacities.

The whole project was embedded in a Pan-African approach, integrating subregional quality organizations into intra-African associations to become an integral part of the international quality networks (figure 5). The East African QI organizations benefited enormously from their memberships in AFRIMETS, ARSO, and AFRAC. Against the backdrop of globalized trade and globalized quality requirements, this international perspective was an imperative for the sustainability of the project.

The holistic approach of the project, working on the meso level (institutional capacity building) as well as the macro level (policy reform), was also reflected in the close cooperation with other development partner organizations and could be regarded as another factor of success. The project was part of a larger effort by German and international development organizations aimed at regional integration and trade development in the EAC. Coordination took place both within the region and between the head offices of PTB and, for example, UNIDO. The cooperation was of mutual benefit for the development partner organizations and was welcomed by the project partners.

The project provided support at a time when demand for QI services, particularly certification according to ISO quality or environmental management standards, was growing strongly in East Africa. Such growth in demand has apparently enhanced the status that QI institutions have in the eyes of EAC member governments and the private sector, which is another factor for success.

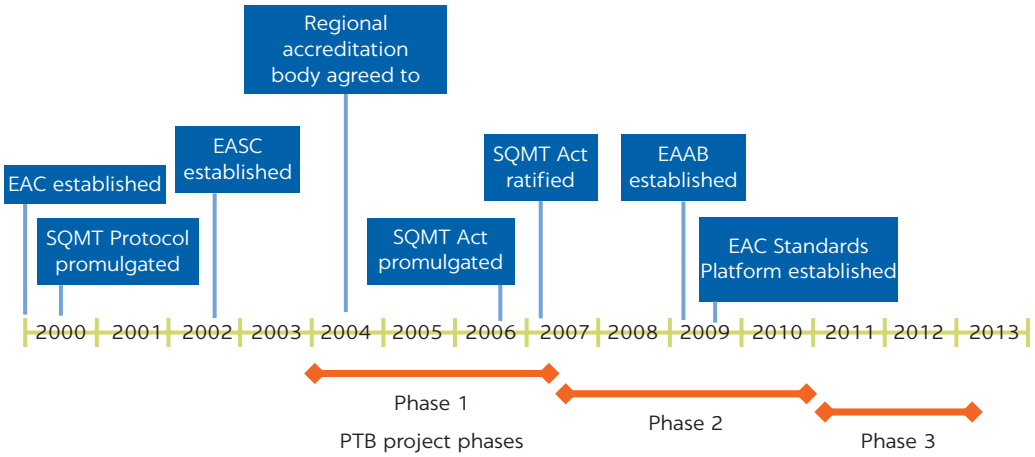
LESSONS LEARNED

The lessons learned from this intervention relate not only to methodological matters—such as whether the right indicators were set and their relevance for measuring real progress—but also to much broader issues.

Although the project indicators measured the envisaged impact quite well, they could not reflect all aspects that emerged during the implementation period. The design of QI projects is always complex, and that is especially true for this highly interconnected regional project. Therefore, it became necessary to adjust the original project design at intervals in collaboration with the project partner and to incorporate new intervention areas (like the integration of regional QI organizations into Pan-African QI associations) that were not always measured by an indicator. Thus, it is helpful if projects allow for such flexibility.

FIGURE 5

Timeline of QI project interventions and notable achievements, 2000–13



Note: EAAB = East African Accreditation Board. EAC = East African Community. EASC = East African Standards Committee. PTB = National Metrology Institute of Germany. QI = quality infrastructure. SQMT Act = East African Community Standardization, Quality Assurance, Metrology and Testing Act.

An intervention like this one can be considered successful if it achieves a high degree of ownership, innovation, and networking among local stakeholders. This increases the likelihood of realizing a sustainable increase in trade performance and thus poverty reduction (impact level). Consequently, indicators should be defined on the outcome level and concentrate on the measurement of "structural changes" (that is, capacity) and other framework conditions, rather than looking solely at export success or trade performance (such as medium- or long-term outcome or impacts) in order to show whether an intervention is sustainable. Still, changes in trade and economic performance should also be monitored and linked to the intervention.

It became clear during project implementation that regional integration is not yet fully owned by the private sector. The sector still mostly thought nationally and were not sufficiently aware of the benefits of regional harmonization. The private sector sometimes takes time to recognize and appreciate a regionally harmonized QI system. Hence, when implementing similar projects, care should be taken to ensure that the private sector is involved from the beginning, because the public-private dialogue plays a key role in the efficacy of such projects.

Awareness among QI institutions of the close interrelationship between QI and trade also needs to be developed further. In a globalized economy, the role of national QI institutions changes from one of technical or supervisory bodies to one of trade facilitators. They need to recognize the importance of the impact of their services on the economy, meaning they must strengthen their strategic orientation. The project has tried to rise to this challenge by facilitating an enhanced public-private dialogue and organizing a strategic retreat lasting several days for the senior management of QI institutions.

Although the project had a regional focus, the national context proved to be crucial. National concerns must be considered seriously and cannot be disregarded, because laws and decisions agreed to at the regional level have to be implemented and enforced by national authorities. Thus, awareness-building activities and the full transparency of decision-making processes are pivotal issues. Extensive stakeholder consultations may require a great deal of time and financial resources, but they are essential for reaching a sustainable consensus.

The ownership of the project by the EAC Secretariat has been enhanced because of the absence of a separate project office and resident management structure. Furthermore, the lean structure of management and coordination of the project has allowed savings to be made on administrative funds that could then be used for practical support measures.

CONCLUSION

The EAC project, although small in volume, was able to contribute to regional integration and to an understanding of the importance of QI for enhancing trade, both within national administrations and the private sector. A strong element of the project was the partnership between institutions that are closely related in terms of their roles and their own professional understanding, thus facilitating knowledge transfer and capacity development. The strong links of the East African QI system to supraregional associations produced a win-win situation, and the EAC economy is profiting from this Africa-wide alignment of regional approaches.

The East African economy has benefited from the improvement and harmonization of the QI system in many ways. Owing to mutual recognition of product certification marks, streamlined inspection procedures, and regional standards, cross-border trade has become easier, and products are able to comply with quality requirements in new export markets. The lack of private sector participation has remained a worrying factor, even though the project provided for specific private sector interventions in the second and third phases. Ensuring strong private sector involvement right from the beginning is therefore indicated for future projects.

NOTES

1. South Sudan was approved as the sixth member of the EAC in March 2016. At the time of writing, it still had to ratify the treaty to formally accede to the EAC.
2. "The Treaty for the Establishment of the East African Community," signed November 30, 1999, and entered into force July 7, 2000 (since amended December 14, 2006, and August 20, 2007): https://www.eac.int/documents/category/key-documents.
3. "Protocol on Standardization, Quality Assurance, Metrology and Testing," East African Community Secretariat, Arusha, Tanzania: http://repository.eac.int/handle/11671/1644.
4. "The East African Community Standardization, Quality Assurance, Metrology and Testing Act, 2006," published August 1, 2007, East African Community Supplement No. 1, *Gazette of East African Community* Vol. AT 1-003, No. 002: http://www.eac-quality.net/fileadmin/eac_quality/user_documents/3_pdf/EAC_SQMT_Act__2006_Scan_.pdf. The details of this act are described in section 3.2.1.
5. "NQI" is the abbreviation of National Quality Infrastructure in the original project documentation. In this case study, "QI" denotes "quality infrastructure," and the abbreviation is further identified as being regional or national.
6. Proficiency testing is the determination of an individual laboratory's performance in conducting specific tests or measurements and the monitoring of its continuing performance through the use of interlaboratory comparisons.
7. Current standard ISO/IEC 17065:2012 is titled "Conformity Assessment—Requirements for Bodies Certifying Products, Processes and Services": https://www.iso.org/standard/46568.html. Current standard ISO/IEC 15189:2012 is titled "Medical Laboratories—Requirements for Quality and Competence": https://www.iso.org/standard/56115.html.
8. The Paris Declaration was the result of a meeting of more than 100 high-income and low- to middle-income countries in Paris in 2005. It lays out a practical, action-oriented road map to improve the quality of aid and its impact on development, putting in place a series of specific measures for implementation and establishing performance indicators that assess progress. It also calls for an international monitoring system to ensure that donors and recipients hold each other accountable—a feature that is unique among international agreements. It is arranged around five principles: (a) *Ownership*, meaning low- and middle-income countries set their own strategies for poverty reduction, improve their institutions, and tackle corruption; (a) *Alignment*, meaning donor countries align behind these objectives and use local systems; (c) *Harmonization*, meaning donor countries coordinate, simplify procedures, and share information to avoid duplication; (d) *Results*, meaning low- and middle-income countries and donors shift focus to development results and results get measured; and (v) *Mutual accountability*, meaning donors and partners are accountable for development results. Many developing projects established after 2005 incorporated these principles. (See "The Paris Declaration on Aid Effectiveness," Organisation for Economic Co-operation and Development: https://www.oecd.org/dac/effectiveness/parisdeclarationandaccraagendaforaction.htm.)
9. Measurement uncertainty is a parameter that characterizes the dispersion of values that could reasonably be attributed to the measurand (that is, the quantity to be measured). Metrology service providers strive to minimize the measurement uncertainty—that is, by providing accuracy of measurement levels as high as is technically possible.

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INTERNATIONAL DEVELOPMENT IN PRACTICE

Ethiopia

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Abbreviations

BMZ	Federal Ministry for Economic Cooperation and Development (Germany)
BSCI	Business Social Compliance Initiative
CMC	calibration and measurement capabilities
COMESA	Common Market for Eastern and Southern Africa
DAG	Donor Assistance Group
DAkkS	German Accreditation Body (Deutsche Akkreditierungsstelle)
DTIS	Diagnostic Trade Integration Study
ECAE	Ethiopian Conformity Assessment Enterprise
ECBP	Engineering Capacity Building Programme
ENAO	Ethiopian National Accreditation Office
ESA	Ethiopian Standards Agency
EU	European Union
GDP	gross domestic product
GIZ	German Agency for International Cooperation (Deutsche Gesellschaft für Internationale Zusammenarbeit)
IAF	International Accreditation Forum
IEC	International Electrotechnical Commission
IF	Integrated Framework for Trade-Related Technical Assistance to Least-Developed Countries
ILAC	International Laboratory Accreditation Cooperation
IMF	International Monetary Fund
ISO	International Organization for Standardization
ITC	International Trade Centre
JICA	Japan International Cooperation Agency
LDC	least-developed countries
MoCB	Ministry of Capacity Building
MoTI	Ministry of Trade and Industry
NMIE	National Metrology Institute of Ethiopia
QI	quality infrastructure
QSAE	Quality and Standards Authority of Ethiopia
SPS	sanitary and phytosanitary
TBT	Technical Barriers to Trade

TBT Agreement	Agreement on Technical Barriers to Trade (WTO)
TeCAT	Technology Capability Accumulation and Transfer
TRIM	Trade-Related Investment Measures
TVET	technical and vocational education and training
UN	United Nations
UNDP	United Nations Development Programme
UNIDO	United Nations Industrial Development Organization
USAID	U.S. Agency for International Development
WTO	World Trade Organization

Ethiopia

QI Toolkit Case Studies

Abstract: Ethiopia reengineered its quality infrastructure (QI) as a precursor to World Trade Organization (WTO) membership. This comprised the unbundling of the Quality and Standards Authority of Ethiopia (QSAE) into four independent entities—for standards, metrology, accreditation, and conformity assessment—to comply with international good practices and with the requirements of the WTO Agreement on Technical Barriers to Trade. Thereafter, these four entities were supported in obtaining international recognition. It was a complex undertaking that required a clear government vision and massive support at the political level.

EXECUTIVE SUMMARY

Ethiopia wished to integrate better with international global markets to initiate socioeconomic development. As a first step, Ethiopia applied for accession to the World Trade Organization (WTO) in 2003. Its national quality infrastructure (QI) and technical regulation regime were evaluated for compliance with the WTO Agreement on Technical Barriers to Trade (TBT Agreement) in 2006 under a United Nations Development Programme (UNDP) project. The evaluation concluded as follows:

- The national standards body—the QSAE—followed a fully integrated approach by providing all QI services (standards, metrology, and conformity assessment), which made the QSAE a type of monopoly.
- The QSAE was responsible for the registration of other laboratories (that is, a type of accreditation), which constituted a conflict of interest with its own laboratory services.
- The QSAE was responsible for the administration of more than 250 mandatory standards; and this activity, in combination with its own testing and certification, constituted a serious conflict of interest and a trade barrier.
- The technical regulation regime of Ethiopia was found to be ad hoc, fragmented, and often noncompliant with WTO TBT Agreement requirements.

- None of the QI organizations in Ethiopia were accredited, thus denying international recognition for the outputs of those organizations.

All these issues were real challenges for the Ethiopian industries endeavoring to become more export-oriented, because in these markets products and services must be competitive not only on delivery and price but also on quality—quality that must be demonstrated through internationally recognized QI services. In addition, the conflicts of interest and noncompliance with WTO TBT Agreement requirements would have to be addressed before Ethiopia's WTO accession.

Two German-funded development projects provided the major impetus for the reengineering of Ethiopia's QI. The first of them, the Engineering Capacity Building Programme (ECBP), was a joint venture between the German and Ethiopian governments. It was implemented in two phases from 2006 to 2012 and cofunded, with Germany providing €54.3 million, and the Ethiopian side was supposed to match this (Becker, Schäfer, and Diergardt 2012). The German side was managed by the German Agency for International Cooperation (GIZ), and the Ethiopian counterpart was the Ministry of Planning. A parallel development program of €2.4 million—"Support in the Development of a Customer-Oriented Quality Infrastructure in Ethiopia," which was included in the ECBP framework—was implemented by the National Metrology Institute of Germany (PTB) from 2006 to 2012.

The ECBP had four components: (a) university reform of engineering curricula, (b) establishment of a modern technical and vocational education and training (TVET) system, (c) reengineering of the national QI, and (d) capacity building of industry to better use the national QI services. The PTB project focused on capacity building in the national QI, with metrology and testing laboratories being the main beneficiaries. The two projects were coordinated, as required, by the German Federal Ministry for Economic Cooperation and Development (BMZ). A GIZ field office was established in Addis Ababa for the massive ECBP program with German and Ethiopian staff. This office was also used by the PTB project.

During the first phase of the ECBP, a comprehensive QI strategy was developed in 2006–08 with the involvement of many stakeholders from both the public and private sectors (ECBP 2009). Other than an analysis of the country's QI and its challenges, it also contained QI benchmarking of countries such as China, Germany, Malaysia, and South Africa. The main recommendation of the QI strategy was to split the QSAE into four independent entities: the Ethiopian Standards Agency (ESA), the Ethiopian Conformity Assessment Enterprise (ECAE), the National Metrology Institute of Ethiopia (NMIE), and the Ethiopian National Accreditation Office (ENAO). These four QI organizations were to be accountable to the Ministry of Science and Technology as part of the overall science system.

At the same time, the QSAE's regulatory activities were to be totally separated from the four QI organizations. The administration of mandatory standards was to be placed in an independent regulatory agency under the Ministry of Trade and Industry (MoTI), and the trade metrology activities were devolved to the regional trade inspectorates of the same. The draft QI strategy was approved by the Council of Ministers in 2009.

During that time, the Ethiopian government also embarked on a major reengineering of the whole civil service. The Ministry of Planning was created

specifically to spearhead this process, and it became politically one of the most influential ministries. Once the civil service reengineering program had been completed, this ministry was disbanded in 2010. The civil service reengineering delayed the QI reforms in two ways: First, because the reengineering of the QI was subsumed into this overall civil service program—which took years longer to be realized than was originally planned—the QI reengineering also took much longer than planned for in the QI strategy. Second, the legislative framework for the various QI organizations and the separation of regulatory activities had to be developed and promulgated. Hence, the new QI structures were only established in 2011 (table 1).

Even before the split of the QSAE, however, capacity building in metrology, testing laboratories, and certification was under way:

- A quality management certification body, QSAE-Cert, was established; its auditors were trained; and its own management system was developed and implemented. QSAE-Cert was accredited by the German Accreditation Body (DAkkS) in 2009.
- The metrology laboratories of the QSAE (later NMIE) were supported in developing their calibration and measurement capabilities through regional interlaboratory comparisons. Some of the metrology laboratories were

TABLE 1 Snapshot of quality infrastructure (QI) Reform in Ethiopia

BEFORE REFORM	AFTER REFORM
The national standards body, the Quality and Standards Authority of Ethiopia (QSAE), was responsible for standards, inspection, testing, certification, metrology, and accreditation; hence, numerous conflicts of interest existed.	QSAE was split into four QI organizations, each dealing with a specific QI service: standards, metrology, accreditation, and conformity assessment. These four entities were accountable to the Ministry of Science and Technology.
The QSAE was responsible for the implementation of mandatory standards and trade metrology.	Implementation of mandatory standards and trade metrology was separated from the QSAE and moved to the Ministry of Trade and Industry. Trade metrology was further devolved to regional trade inspectorates.
No quality management system certification body was established in Ethiopia. Clients had to use expensive foreign certification bodies.	QSAE-Cert was established as a quality management certification body, its auditors were trained, and its processes and documentation were developed and implemented. QSAE-Cert was accredited by the German Accreditation Body (DAkkS).
The equipment of the metrology laboratories of the QSAE was of low accuracy and not capable of getting international recognition.	The equipment of the metrology laboratory in the QSAE (later the National Metrology Institute of Ethiopia [NMIE]) was modernized, and systems to gain international recognition were introduced. Laboratory intercomparisons were conducted and continue at the regional level.
The QSAE's accreditation activities did not meet international standards, and no international recognition by International Laboratory Accreditation Cooperation (ILAC) or the International Accreditation Forum (IAF) was possible.	The independent Ethiopian National Accreditation Office (ENAO) was established, and support to achieve international recognition by ILAC and the IAF was initiated.
University engineering curricula were totally outdated and did not meet the needs of industry.	More than 100 engineering curricula and training materials were modernized and aligned with industry needs. The QI benefits from more and better-trained technical staff.
No vocational training system for technicians existed.	A vocational training system for technicians was established, 250 training institutions were accredited, 1,500 trainers were trained, and regional agencies were established to oversee the training of 300,000 technicians in 1,000 industries.
The investment climate was suboptimal; hence, exporting possibilities were suboptimal.	The investment climate was enhanced with the removal of trade-restrictive taxes and import duties. Strategic industry associations were strengthened, and trade promotion originations were capacitated. A higher demand for QI services has resulted in growth in strategic export sectors.

accredited to ISO/IEC 17025 ("General Requirements for the Competence of Testing and Calibration Laboratories").
- Several testing laboratories of both the ECAE and the private sector were supported in obtaining accreditation.

The university reform project provided for a total revamping of the curricula for engineering students, bringing them to international levels by introducing modern curricula in the 274 public technical colleges. The TVET project established vocational training agencies in the regions to oversee the training of 300,000 trainees in 1,000 enterprises. The QI profited from these measures as trained technical personnel became available.

Exports and formal employment in selected industrial sectors rose. Since 2005, for example, Ethiopia's QI services have made it an increasingly attractive production and investment location in the textile and leather sectors on the African continent. The Ethiopian pharmaceutical sector has increasingly substituted previous drug imports. In addition, more than 30 companies in various sectors have been supported in gaining certification to ISO 9001 ("Quality Management Systems—Requirements"),[1] ISO 14001 ("Environmental Management Systems—Requirements with Guidance for Use"),[2] and other relevant standards.

COUNTRY CONTEXT

Ethiopia, with its capital city of Addis Ababa, is on the Horn of Africa. It shares a border with Eritrea to the north and northeast, Djibouti and Somalia to the east, Sudan and South Sudan to the west, and Kenya to the south. With nearly 100 million inhabitants, Ethiopia is the most populous landlocked country in the world, as well as the second-most-populous nation on the African continent after Nigeria.

Ethiopia is classified as a low-income country by the World Bank. But, according to the International Monetary Fund (IMF), Ethiopia was one of the fastest-growing economies in the world, registering over 10 percent economic growth from 2004 through 2009. It was the fastest-growing non-oil-dependent African economy in the years 2007 and 2008. Its growth decelerated moderately in 2012 to 7 percent and is projected to be 6.5 percent in the future. Despite its fast growth, its gross domestic product (GDP) per capita is still one of the lowest in the world, and its economy faced serious structural problems. Agricultural productivity remains low, and frequent droughts still beset the country (IMF 2012).

Ethiopia is a member of the Common Market for Eastern and Southern Africa (COMESA) and has signed bilateral trade agreements with several countries, as well as being included in some of the preferential trade agreements, such as the African Growth and Opportunity Act (with the United States) and the Everything but Arms initiative (with the European Union).

Ethiopia is not a member of the WTO but started the process of accession in 2003.[3] This decision marked an important step in the country's process of integration into the global economy. The WTO General Council accepted Ethiopia's request but acknowledged that institutional capacities in the country required further development. Ethiopian authorities envisaged the accession process to be completed by 2009 or 2010, but this did not happen. During the process of becoming a WTO member, some fundamental policy and institutional changes would have to be implemented, including those related to the QI and the technical regulation regime.

EARLY QI DEVELOPMENT AND ISSUES

Ethiopia's national standards body, the QSAE, was established in 1970 and became operational in 1972. Its founding legislation was amended a few times, most notably with the far-reaching Quality and Standards Authority of Ethiopia Establishment Proclamation No. 102/1998 and the Standards and Certification Council of QSAE Proclamation No. 413/2004**.** The responsibility for metrology was conferred on the QSAE through the Weights and Measures Regulations Legal Notice No. 432 of 1973. In 2003, when Ethiopia started the process of accession to the WTO, the QSAE was already a member of the International Organization for Standardization (ISO), International Electrotechnical Commission (IEC), and International Organization of Legal Metrology (OIML).

Through these laws, the QSAE was mandated to promote and assist in the establishment of quality management practices as an integral function in the social and economic sectors and to assist in the improvement of the quality of products and processes through the promotion and application of Ethiopian standards. Its activities included publishing the national standards, establishing the national measurement standards and providing calibration services, and providing testing and certification services over a wide range of technologies. The QSAE was also responsible for administering standards declared mandatory by the Standards and Certification Council on behalf of MoTI and for strengthening, promoting, and enhancing the reliability of testing laboratories nationwide. Until 2006, the QSAE did not provide quality management certification services.

By 2006, the QSAE had published about 5,000 Ethiopian standards, of which 107 had been declared mandatory. These were supported by a number of testing methods, bringing the number of mandatory standards to nearly 390. A further 400 Ethiopian standards were earmarked at that time to be declared mandatory. Because the compliance with the mandatory standards was coupled with the QSAE product certification mark (that is, rendering its use mandatory by default), this was considered a major barrier to trade.[4] The planning for even more standards to be declared mandatory was a move in the wrong direction.

None of the QSAE laboratories was accredited, nor was any of the other laboratories in the public domain, even though some of them were well equipped and staffed by well-trained technologists. There were no private sector laboratories at that time. The QSAE's product certification scheme was based on ISO/IEC Guide 65 ("General Requirements for Bodies Operating Product Certification Systems"),[5] but it was not accredited either. Ethiopia did not have an accreditation body, but QSAE was given the responsibility to oversee the technical capabilities of the laboratory sector in Ethiopia; in other words, it was to authorize the recognition and registration of quality certification bodies, inspection bodies, testing laboratories, and calibration laboratories operating in Ethiopia. This was a major conflict of interest.

The QSAE remained directly accountable to MoTI, even after the establishment of its council through the promulgation of the Standards and Certification Council of QSAE Proclamation No. 413/2004. Good governance principles would suggest that the QSAE should have been made accountable to the Standards and Certification Council. Its responsibility, however, was limited to approving national standards; it was not given any business strategy or fiduciary responsibilities. This would have negative consequences for the accreditation of

the QSAE, because the relevant international standards generally require governance in the form of independent boards.

Ethiopia's national QI therefore followed a fully integrated approach typical of many low- and middle-income economies well into the end of the 20th century, an approach also favored by some members of the donor community. But this approach soon became progressively problematic as world trade developed, because of its inherent conflicts of interest. Furthermore, none of the Ethiopian QI organizations was accredited. Hence, international recognition was, for all intents and purposes, absent. All of this was a major negative for the country's ambitious plans to transform its economy from one with a largely agricultural base to an industrialized one and to become much more integrated into the world economy.

PROJECT COMPONENTS AND OBJECTIVES

Integrated Framework for Trade-Related Technical Assistance to Least-Developed Countries (IF)

In 1997, the IMF, International Trade Centre (ITC), United Nations Conference on Trade and Development (UNCTAD), UNDP, World Bank, and WTO launched the Integrated Framework for Trade-Related Technical Assistance to Least-Developed Countries (commonly abbreviated as IF). This initiative combined the efforts of the multilateral agencies and bilateral donors to help least-developed countries increase their participation in the global economy.[6]

In Ethiopia, the IF-supported activities started in 2002. Steering and technical committees were set up as well as a secretariat within MoTI designated as the IF focal point. As a preliminary step to integrate trade into the national development strategies, a Diagnostic Trade Integration Study (DTIS) was conducted (World Bank 2004). In 2004, the Ethiopian government also prepared an Action Plan for the prioritized DTIS recommendations. In it, the government requested donor support for identified priorities such as trade reform, foreign direct investment, and legal and regulatory strategies (IF/DTIS TC 2004).

MoTI and the UNDP agreed in 2005 that four impact assessment studies to analyze the consequences of Ethiopia's accession to the WTO (studies not covered by other donors) would be funded by the UNDP/IF Trust Fund. These studies would focus specifically on

- Sanitary and phytosanitary measures (SPS) and technical barriers to trade (TBT);
- Trade-Related Aspects of Intellectual Property Rights (TRIPS);
- Trade-Related Investment Measures (TRIMs); and
- Customs valuation.

The TBT and SPS impact assessments were conducted at the beginning of 2006, and they provided the first documented evidence of the challenges facing Ethiopia's national QI and technical regulation regime (Kellermann and Yimer 2006). The WTO TBT Agreement–related study contained many recommendations at the policy as well as the implementation levels that Ethiopia would have to consider seriously before it could fulfill its WTO TBT Agreement obligations. The technical regulation regime was found to be ad hoc, fragmented, and WTO noncompliant, and therefore in need of serious reengineering. Among the

technical regulation practices, it was noted that the mandatory standards system would need to be reconsidered and that its administration would have to be separated from the QSAE. It was also noted that the totality of the legislative framework of the national QI was in serious need of modernization.

As a follow-up to the UNDP's TBT impact assessment study, the U.S. Agency for International Development (USAID), which was supporting the modernization of the relevant Ethiopian legislation before WTO accession, agreed to fund the development of a suite of modern QI draft legislation. This included the development of draft legislation for a technical regulation framework, establishment of an independent regulatory agency to administer mandatory standards, metrology legislation (scientific and legal metrology), legislation for an independent national accreditation body, and a complete revision of the QSAE legislation. Although not used immediately, this suite of draft QI legislation was used a few years later by the ECBP as the basis for the final draft QI legislation in 2010 (as discussed below in the "QI strategy" subsection).

National Metrology Institute of Germany (PTB)

PTB managed a development project that expected its ultimate impact to be the facilitation of sustainable industrial development. The project's specific objective was defined as "support for the development of a customer-oriented quality infrastructure in Ethiopia" (Diergardt 2012). It was funded by the BMZ and was implemented in two phases. The total budget for the two phases, which ended in 2012, was €1.4 million. During a 2012–16 follow-up project ("Promotion of Metrology and Testing"), an additional €1 million was invested for the further development of the metrology infrastructure. The objective of this project was to improve the range of services that the institutions of the national QI offer to trade and industry.

At the same time, the massive ECBP was under way, funded jointly by Germany and Ethiopia (further discussed below). The ECBP was managed by the organization now known as the German Agency for International Cooperation (GIZ).[7] As a result, the BMZ saw to it that the two German development agencies (GIZ and PTB) coordinated the two programs in a clear and unambiguous way.

The PTB project had a multifaceted approach and included the following:

- *Evaluation and consultancy regarding the governance of QI institutions* (that is, their management and control) as well as the coordination between relevant ministries and these institutions.
- *Support for capacity development in industrial metrology* with a focus on enhanced calibration services and the accreditation of calibration laboratories. The establishment of a functioning legal metrology system was also supported.
- *Support for the establishment of the Ethiopian Laboratory Association* and consultancy concerning compliance with ISO/IEC 17025 to a small number of laboratories to prepare them for accreditation.[8] The chosen laboratories were considered essential for the testing and certification of products for the export market.
- *Capacity development for the QI labor market* by instigating and supporting QI-related programs at tertiary education institutions.

For each of the above elements of the PTB project, specific key outcomes were defined that were more or less fulfilled (see the "Metrology" subsection below). As with most PTB projects, no project office was established in Ethiopia;

instead, PTB used GIZ's permanent office in Addis Ababa, thereby contributing to the overall efficiency of German involvement. As a result, PTB funds could be used fully for capacity building and consultancy provided by PTB short-term experts who undertook various missions. These were managed by a project manager based in PTB's head office in Braunschweig, Germany.

Engineering Capacity Building Programme (ECBP)

The ECBP was a joint development program of Germany and Ethiopia. It was arguably one of the most ambitious development programs at the time anywhere in the world. The vision and overall goal of the ECBP was that the Ethiopian industrial sector should become competitive and that the living standard of society would be enhanced; that is, employment opportunities for all Ethiopians would be created. The ECBP was cofunded by the German and Ethiopian governments, and approximately €55 million was invested by Germany over the period 2005 to 2012 in two phases. The Ethiopian contribution was on the order of €31 million.

The ECBP's core principles emphasized that it was an Ethiopian reform program and that it would be based on international benchmarking and standards. It was designed as a multilevel project with interventions at (a) the political level (for example, capacity building on joint strategies for development between the government and private sector); (b) the institutional level (universities, colleges, chambers of commerce, and QI organizations); and (c) the individual level (entrepreneurs and small and medium enterprises, SMEs). The ECBP was implemented in two phases—the second phase building on the outcomes of the first phase—and in the four distinct but interrelated components described below.

Component 1: University reform

In the first phase of this component, German experts and Ethiopian partners from the Ministry of Capacity Building (MoCB) cooperated to develop concepts for the later reforms of the universities' engineering and technology programs. The reforms included (a) curricula reform, (b) development of university personnel, (c) cooperation between the universities and industry to enable technology transfer, (d) reform of the organizational structures of tertiary education institutions, and (e) development of the curricula for the TVET trainers.

In the second phase, these concepts were implemented throughout the country, and the reform process was progressively transferred to the Ministry of Education, which took complete ownership by the end of 2011.

Component 2: Technical and vocational education and training (TVET) system

In the first phase, the professional education strategy was developed and adopted (in 2007), which resulted in a paradigm shift from an input-oriented system to an output-oriented, decentralized, and work-oriented vocational education and training system. Educational visits to Germany supported the decision-making process by the Ethiopian education policy makers. Approximately 350 professional education standards with curricula and 190 career profiles were developed. Industry was involved in these developments through 300 temporary advisory

and technical expert panels. Furthermore, Ethiopia financed the involvement of German experts to provide advanced training for the Ethiopian trainers at relevant vocational training institutions.

The second phase supported the management of the vocational training institutions through management training (by Philippine experts), the introduction of kaizen principles,[9] and the introduction of management information systems. At selected vocational training institutions, experienced German experts were transitionally employed as heads of the institutions. Legislation establishing the federal vocational education agency as well as a national teacher training and education facility was developed and promulgated by the Council of Ministers in 2011.

Component 3: QI reform

In the first phase, a national QI strategy was developed, which was approved by the Council of Ministers in February 2009 (EDBP 2009). The key component of the QI strategy was the radical reengineering of the QSAE into four independent organizations to provide a better business focus and to remedy the inherent conflicts of interest in the old structure. A certification body, QSAE-Cert, was established to provide ISO 9001 certification services, and it was accredited by the German Accreditation Body (DAkkS) in 2009.

During the second phase, after the promulgation of the necessary legislation in February 2011, the former QSAE was separated into four independent QI organizations: the Ethiopian Standards Agency (ESA), the Ethiopian Conformity Assessment Enterprise (ECAE), the National Metrology Institute of Ethiopia (NMIE), and the Ethiopian National Accreditation Office (ENAO). The ECBP supported the newly established organizations to upgrade their services to international levels. By agreement, PTB focused on metrology (discussed in the earlier PTB section), and the ECBP focused on standards, accreditation, and conformity assessment services. A further element for strengthening the conformity assessment was the establishment of and support for the Ethiopian Laboratory Association.

Component 4: Private sector and business development

In the first phase, comprehensive planning was undertaken for capacity building in a number of areas, including a microfinancing strategy, promotion of investment (for example, the "Brand Ethiopia" strategy), sectoral business-related service and value chains in cooperation with the United Nations Industrial Development Organization (UNIDO), and the promotion of small businesses. This was conducted at both the federal and regional levels.

At the beginning of the second phase in 2009, the program became more focused on value chain creation, which was more effective in helping to realize the industrialization strategy of the country. Subject-specific teams of experts from GIZ and its partners worked in existing industries in specific sectors such as textiles, leather, agroprocessing, pharmaceuticals, construction, and metal manufacturing. As a result, the outcomes, given the size of the country, were more visible and could be measured more rapidly. Furthermore, exports were facilitated in cooperation with Ethiopian embassies abroad. And through public-private partnerships, multinational organizations started to get involved in the Ethiopian economy.

PROJECT DESIGN AND IMPLEMENTATION

Many of the development projects during 2005–12 had an influence on the reengineering of Ethiopia's QI. This section focuses largely on those directly involved with the QI; others may be mentioned in passing. Capacity building within the fledgling QI organizations that emerged from this reengineering is ongoing. The development projects in the various industrial sectors are also ongoing, with new ones being implemented either as follow-ups to the ECBP and PTB projects funded by Germany or as projects funded by other countries, including the following:

- *USAID:* US$50 million for private sector agricultural development
- *U.K. Department for International Development (DFID):* £50 million for financial services and the role of women in the business sector
- *Italy:* promotion of the industrial sector
- *Japan International Cooperation Agency (JICA):* further development of industrial policies
- *European Union (EU):* €35 million for private sector development, the so-called Transformation Triggering Facility program.

These ongoing projects are not discussed further here. The discussion that follows is limited to 2005–12, when the main reengineering of the QI took place.

QI strategy

The QI strategy was developed as a cooperative effort among many stakeholders from both the public and private sectors, and it was ultimately completed under the guidance of the ECBP and the Ministry of Planning, which was responsible for civil service optimization (ECBP 2009). Considered in its development was the knowledge generated during the UNDP project to determine Ethiopia's preparedness for WTO membership (see the earlier IF subsection) as well as the PTB experts' reviews of the QSAE's structure and activities (during the first phase of the PTB project). Specific issues that were considered in the development of the QI strategy included the following:

- *Export market challenges* affected some of Ethiopia's main industrial sectors such as the coffee, textile, and tannery sectors that required access to internationally recognized QI services.
- *Conformity assessment service challenges* included, among others, the cost of foreign-based services in view of the country's lack of local accredited laboratories and the lack of a quality management system certification body.
- *Legal metrology issues* (that is, weight loss compensation costs) have caused exporters to pay huge sums of money because of faulty deliveries due to the lack of a national legal metrology system.
- *The lack of full ISO and IEC membership* meant that although the QSAE was a lower-level member of the ISO and IEC, it could not participate meaningfully in international standards development activities.
- *The lack of a consolidated consumer policy and legislation,* coupled with the lack of an integrated institutional effort on consumer affairs, weakened consumer protection—a problem aggravated by the generally high levels of illiteracy and poverty.

The QI systems of several countries were reviewed (including those of China, Costa Rica, Germany, Malaysia, South Africa, and Vietnam) to provide guidance for the reengineering of the Ethiopian QI. The needs of stakeholders, especially in industry, were solicited and taken into account. The QI strategy was also harmonized with Ethiopia's emerging science and technology strategy—the Technology Capability Accumulation and Transfer (TeCAT) system, based on the Republic of Korea's example.

The most far-reaching recommendation of the QI strategy was the splitting of the QSAE into four distinct entities, each responsible for a specific element of the QI. As mentioned earlier, these were the ESA, ECAE, NMIE, and ENAO. All of these were to be accountable to the Ministry of Science and Technology, as part of the science system, instead of to MoTI. The QSAE's regulatory activities—namely, mandatory standards and trade metrology—were separated totally, the former established as a regulatory agency under MoTI and the latter devolved to the regional trade inspection authorities.

The draft QI strategy was subjected to public comment and validation workshops. It was finally presented to the Council of Ministers, which approved it for implementation in 2009. However, the original implementation plan contained in the QI strategy could not be followed, because the government had previously started a major civil service reengineering program, named Business Process Reengineering. The QI strategy was subsumed into this overarching program spearheaded by the Ministry of Planning, which had been established specifically for reengineering the civil service.

The larger Business Process Reengineering program obviously took much longer to be realized than would have been the case for dealing only with the QSAE's reengineering. In addition, the legislative framework for the QI had to be either totally revised or developed anew. The draft QI legislation developed under the USAID project a few years previously (as noted in the earlier UNDP subsection) saved a tremendous amount of time because its point of departure was not that different from the recommendations of the final QI strategy. Therefore, these drafts just had to be fine-tuned to be aligned fully with the approved QI strategy modalities. Hence, it would take until 2011 for the separation of the QSAE to become effective. On the other hand, being part of the much larger civil service reengineering program made it easier to enforce the major changes of the QI.

Metrology

Even when the metrology laboratories were still part of the QSAE, technical support was provided to build capacity in these laboratories. Once the National Metrology Institute of Ethiopia (NMIE) was established as an independent entity (as discussed earlier), a focus on strengthening its governance and management structures was added. This was a coordinated effort between PTB and the ECBP, with PTB taking the lead because it had the superior technical expertise. The objectives of the projects were satisfied (or not) in the following ways:

- To ensure that the NMIE's governance and management structures complied with international standards, stakeholders must be represented in a meaningful way. This indicator could not be fulfilled because the NMIE was made

directly accountable to the minister (that is, without a council or board). This would be a challenge to be dealt with in the future.

- To enhance the NMIE's calibration and measurement capabilities (CMCs) and to broaden the scope of its services, four of its laboratories (mass, temperature, volume, and pressure) were accredited by DAkkS. In addition, the NMIE participated in a number of regional interlaboratory comparisons, thereby starting to quantify its CMCs.
- Regarding industrial metrology, technical capacity and accreditation readiness were enhanced in calibration laboratories. Four mobile calibration laboratories were provided for the regions because the country is huge, and adequate transport infrastructure is not available to get equipment routinely to major centers for calibration. The number of calibrations conducted by the calibration laboratories rose from 674 in 2008 to 1,922 in 2011, an increase of 162 percent—far above the project indicator set at 45 percent (Becker, Schäfer, and Diergardt 2012).
- In contrast to the successful developments in scientific and industrial metrology, no capacity building could be undertaken in trade metrology (weights and measures) because of the devolvement of the function to regional trade inspectorates that took an inordinate amount of time. The PTB project ended before this could even be initiated.
- To provide for an adequate number of trained metrologists in the future, metrology courses were established at Addis Ababa, Wollo, Mizan Tepi, and Mekelle Universities. The training of the educators and the development of teaching material was largely undertaken by the Ethiopian partner NMIE, but with technical support from PTB.

In an interesting sideline development, the Ethiopian government entrusted the NMIE with the task of replacing traditional measuring units that were not International System of Units (SI) units—which were still being used in the marketplaces—with SI units and measurement equipment. PTB designed a pilot project for individual markets that was to be implemented by the NMIE.

Conformity assessment

Conformity assessment support was also a cooperative effort between ECBP and PTB, with both supporting specific entities in specific sectors. Some of the outcomes of this technical support included the following:

- In the first phase of the ECBP, a quality management system certification body, QSAE-Cert, was established in the QSAE to address one of the major gaps in the provision of conformity assessment services in the country. Auditors and lead auditors were trained, the development and implementation of management system documentation were supported, and QSAE-Cert was eventually accredited by DAkkS. The training programs were not limited only to QSAE-Cert personnel but were extended to private industry, from which nearly 180 quality managers were trained.
- Technical support was provided to more than 30 companies that were eventually certified to ISO 9001, ISO 14001, Global Good Agricultural Practices (Global G.A.P.), and other management system standards by QSAE-Cert or by foreign certification bodies in cases where QSAE-Cert did not have the relevant expertise. Specific attention was given to companies in the export

sectors, even for certification schemes based on private sector standards such as Oeko-Tex (environment-friendly textiles), the Business Social Compliance Initiative (BSCI), and Fair Trade.

- Testing laboratories that were members of the Ethiopian Laboratory Association were supported in implementing management systems in accordance with ISO/IEC 17025, including some of the laboratories of the newly established ECAE. Five of the ECAE laboratories were accredited by the ENAO, and the National Animal Health Diagnostic and Investigation Centre and the Leather Industry Development Institute elaborates were also accredited in accordance with ISO/IEC 17025.
- A vocational training course for laboratory technicians was established at the Wingate TVET College, and some trainee technicians concluded their first-year training by the end of 2012.

University and vocational training reform

The university and vocational training reform program is not discussed here in any detail. Some highlights of the program included nearly 100 bachelor's and master's degree study programs that were either revised or newly developed. Industry liaison offices were established in seven technical universities to ensure coordination between industry needs and education curricula. A further five technical colleges and one technical university were established and supported to start operating.

Modern curricula were introduced in all 274 public technical colleges; that is, more than 350 modern educational standards were implemented, along with their curricula. In 2010/11, all the TVET teachers—just over 14,000 in public and private training institutions—were evaluated, trained, and reevaluated. Of these, about 84 percent passed the new requirements (Becker, Schäfer, and Diergardt 2012).

As for the vocational training system, vocational training agencies were newly established in 9 regions, further supporting the training of approximately 300,000 trainees in the 11 regions of Ethiopia in cooperation with approximately 1,000 enterprises. The new vocational training system had been fully implemented in 6 of the 11 regions; that is, training centers were fully operational, trainers were trained, and training and examination materials were developed and used. These included approximately 1,500 trainers trained, 250 vocational training centers accredited, and 175,000 trainees examined. Although absolute figures were not available, it was estimated that about 50 percent of the trainees were female (Becker, Schäfer, and Diergardt 2012).

Industrial capacity development

The industrial development projects of the ECBP were, in the first phase, focused on enhancing the investment climate for relevant industrial sectors and supporting industries in these sectors to start exporting their products. Reform packages that were facilitated included the setting aside of import duties for spares of production machinery, tax relief for the supply of subcomponents for the textile industry, import duty relief for shoe and garment accessories, establishment of a "bonded factory" system for foreign investors, and tax relief for imported chemicals for the pharmaceutical industry.[10]

During the second phase, the ECBP focus shifted to organized industry segments such as business associations. These associations were supported to become more active in supporting their members to grow their businesses. They included the Ethiopian Leather Industries Association, Ethiopian Textile and Garment Manufacturers Association, Ethiopian Millers Association, Ethiopian Pharmaceutical Association, and Ethiopian Women Exporters' Association. The same process was followed to strengthen the trade promotion organizations of various regions, building their capacity for promoting value chain concepts and for acquiring investments from abroad.

Although these interventions were not directly relevant to the reengineering of the QI, they did have an indirect effect, in that the affected industries required more QI services for their increases in production and the quality thereof. It was especially noticeable in the textile and leather sectors regarding exports as well as in the pharmaceutical sector, which started to replace imported products with locally produced ones.

Project coordination

Ethiopia was receiving a tremendous amount of development support from all over the world. The German-funded projects managed by GIZ and PTB were the prime change agents for the QI, and coordination was guided by the German federal ministry, the BMZ. Other development partners in Ethiopia were more involved in industry development projects or the modernization of legal and financial frameworks. Hence, the development partners set up a Donor Assistance Group (DAG), under which they sought to coordinate their assistance to the government of Ethiopia and share information on ongoing and planned activities.

The DAG was a committee at the head-of-agency level and was supported by a number of thematic working groups, including one for private sector development and trade, which met monthly and which dealt with the QI and issues such as value chain development, private-public dialogue, financial services, and intermediary organizations. Donor agencies active in this latter group were the EU delegation, GIZ, the ITC, JICA, the Embassy of the Kingdom of the Netherlands, the Swedish International Development Cooperation Agency (Sida), the UNDP and UNIDO, USAID, and the World Bank. It was especially the various industry development interventions that profited from these transparency efforts.

The university reform and TVET system (ECBP components 1 and 2) were embarked upon to provide Ethiopia with a new generation of well-educated engineers and technicians to spearhead the country's transformation from an agricultural society to an industrialized country. Even though the QI was not the prime reason for the university reform and establishment of a TVET system, the QI would benefit from both, and synergies between the projects of QI reengineering, the university reform, and TVET system were actively pursued—for example, through the establishment of QI-related curricula.

The PTB project and the ECBP component 3 (QI Reform) both provided much support for QI reform. They were both rolled out in two phases, each with a duration of about four years. The first phase of the ECBP was largely a

preparation phase, with some pilot projects to start the implementation. The second phase of the ECBP was earmarked as the main implementation phase—a scaling-up of the pilot projects—to realize the envisaged impacts. The PTB project was geared more toward technical capacity building than toward the overall reengineering of the QI, but its experts provided relevant international good-practice information at crucial times during the development of the QI strategy.

Because of the size of the project, GIZ established a country office in Addis Ababa, and many experts were engaged at any given time in the country. The Ethiopian side was well represented in the joint ECBP office, giving the project the Ethiopian focus envisaged from the beginning. PTB did not establish a country office during these years and used GIZ offices.

STAKEHOLDERS AND THEIR ROLES

During the first phase of the ECBP, which was largely devoted to planning, the Ministry of Planning was the leading counterpart. This ministry had been established primarily to spearhead the massive civil service reengineering program of the Ethiopian government. The government therefore fully supported the Ministry of Planning, giving it extraordinary political powers to undertake the civil service reforms. Its powerful position was no doubt an authoritative influence in the reengineering of the QI. It was stood down after the major government reshuffling in 2010, and the counterpart of the projects became the Ministry of Civil Service.

Once the second phase of the ECBP was under way, many other stakeholders had to be considered in implementing the far-ranging plans for the ECBP's four components and PTB interventions. Hence, the Ministries of Education, Trade and Industry, Health, Agriculture, Urban and Works, and Science and Technology all had to be involved. The regions and private sector business associations also become important in coordinating the implementation of the wide-ranging, private sector–related elements of the projects. This brought about a certain amount of tension between the project management, the Ministry of Planning, and some of the other ministries as to who was in control of the overall project, no doubt exacerbated by the fact that the Ethiopian government was cofinancing the ECBP in no small way.

The private sector participated in the ECBP's annual customer satisfaction survey (Becker, Schäfer, and Diergardt 2012). This survey was broken down by priority sectors and company size. The overall survey results indicated a growing satisfaction with the service delivery of the four QI organizations created by the splitting up of the QSAE or of their predecessor departments within the QSAE. On a scale of 1 (not satisfied) to 6 (very satisfied), the compounded satisfaction indexes were as follows: 2.69 in 2007, 2.76 in 2008, 3.31 in 2010, and 3.71 in 2011. The 2011 indexes for the individual national QI organizations were as follows: 3.84 for the ESA, 3.52 for the ECAE, 3.86 for the NMIE, and 3.63 for the ENAO. This could be interpreted as indicating that about 60 percent of the customers were satisfied with the QI service delivery and that a lot of progress still had to be achieved.

OUTCOMES

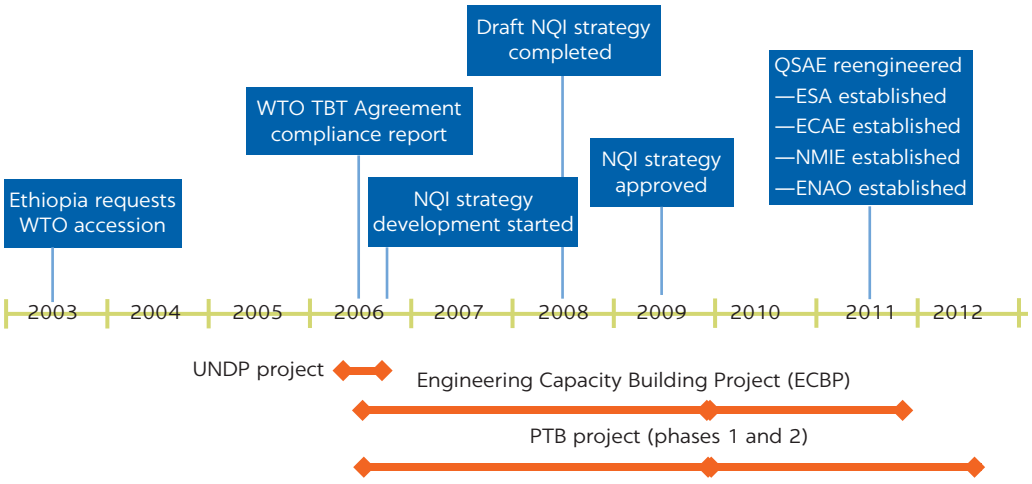
The major results achieved in reengineering Ethiopia's QI (figure 1) and in getting the private sector to make better use of the higher-level QI service delivery are summarized below.

Reengineering the QI. Ethiopia's QI—largely represented by the QSAE, with its wholly integrated approach (standards, metrology, inspection, testing, product certification, registration of other laboratories, and the administration of mandatory standards) with its many conflicts of interest and total lack of international recognition—could be reengineered. The QSAE was split into four QI entities, each dealing specifically with an element of the QI, namely standards (ESA), metrology (NMIE), accreditation (ENAO), and a commercialized conformity assessment organization (ECAE). This brought about a much more focused management approach and business orientation. The four entities were placed under the Ministry of Science and Technology as part of the public science system of Ethiopia. All of them could become the recipients of further, more-focused development projects from development partners.

Eliminating regulatory conflicts of interest. The QSAE's regulatory activities were separated from the QI service delivery organizations. The administration of mandatory standards was placed in an independent regulatory agency under MoTI. The trade metrology activities were devolved to MoTI's trade inspectorates in each of the 11 regions. The conflict of interest was therefore set aside between, on the one hand, standards development, testing, and certification, and on the other hand, market surveillance and the imposition of sanctions regarding mandatory standards.

FIGURE 1

Timeline of main QI project events and notable milestones, 2003–12



Note: ECAE = Ethiopian Conformity Assessment Enterprise. ENAO: Ethiopian National Accreditation Office. ESA = Ethiopian Standards Agency. NQI = national quality infrastructure. PTB = National Metrology Institute of Germany. QI = quality infrastructure. QSAE = Quality and Standards Authority of Ethiopia. TBT = Technical Barriers to Trade. UNDP = United Nations Development Programme. WTO = World Trade Organization.

Establishing and accrediting QSAE-Cert. A quality management system certification body, QSAE-Cert, was established to complement the product certification activities already in place. This service was accredited by DAkkS, thereby enabling international recognition of its certificates. In this way a major gap in QI service delivery at the national level was addressed, so industries requiring certification no longer had to use the services of expensive foreign certification bodies.

Supporting standards-compliant laboratories. Many laboratories in both the public and private sectors were supported to implement management systems in accordance with ISO/IEC 17025, and some of them could be accredited by ENAO or foreign accreditation organizations. The total lack of international recognition for the services of the Ethiopian QI was beginning to be addressed, even though a tremendous amount of progress still had to be achieved. The Ethiopian Laboratory Association was established to foster cooperation within the laboratory sector of the country.

Modernizing tertiary education in technology. As a fundamental for the future industrial development of Ethiopia, the university and technical college structures and curricula for technology education were totally revamped and modernized. Annual reviews of the employability of students in these new systems indicate that more than 90 percent of the academic students and at least 50 percent of the technical college students find appropriate employment (Becker, Schäfer, and Diergardt 2012). The expectation was that the rapid development of technology-centered industries would soon require more students in the near to middle future.

Expanding and modernizing vocational training. A modern vocational training system with training and examination centers in each of the 11 regions was established, in which 1,000 industries played a central role in providing internships for vocational training. The 14,000 trainers were evaluated, trained, and reevaluated to ensure a common high standard of vocational training aligned with international good practices.

Improving industrial export markets. Exports and formal employment in selected industrial sectors have risen. Ethiopia has become, since 2005, through the services of the QI, an increasingly attractive production and investment location in the textile and leather sectors on the African continent. The Ethiopian pharmaceutical sector has increasingly substituted previous drug imports. But challenges remain concerning the broader framework conditions for private sector development; specifically, private enterprise growth and financial service availabilities did not improve much.

PROBLEMS ENCOUNTERED: CHALLENGES AND ISSUES

Despite the many successes achieved in reengineering the Ethiopian QI and related activities, serious challenges were also encountered, mostly related to the projects' size and complexity.

Management clashes between partners. Although the Ethiopian government's substantial contribution in terms of finances and manpower supported the development projects admirably, it also meant that there was friction regarding the overall management of the process, with micromanaging tendencies of the Ethiopian partners often clashing with development partners' processes and procedures.

Second-phase implementation differences between ministries. The powerful political position of the Ministry of Planning and its mandate from the government to reengineer the whole of the civil service helped to overcome opposition and to get the reengineering process under way during the first phase. However, this unique construct between the development partners and the Ministry of Planning was seriously tested during the second phase that started in 2009, when many of the changes had to be implemented. The responsible ministries in which the changes were realized—such as the Ministry of Science and Technology, MoTI, and Ministry of Education—sometimes had differing approaches and priorities. There was no agreed-upon joint action plan, and differences of opinion and priorities surfaced continuously during the second phase of project implementation. Because of the flexibility of the project planning, these differences could be addressed, but doing so took resources that could have been used to better effect elsewhere.

Culturally based tensions between local and foreign participants. The massive use of German- and Ethiopian-funded international experts, combined with the parallel development of many of the systems, accelerated the Ethiopian development process. On the other hand, this influx of many foreigners into the country resulted in friction between the locals and foreigners—both sides not fully understanding or appreciating the differences in culturally based political thinking and management custom and practice. This had a negative impact on some of the program results.

QI program delays within nationwide civil service reforms. The huge and complex countrywide civil service reform programs took years longer to plan and implement than envisaged, and because the QI's reengineering was subsumed into this program, it took much longer to get the reengineering started than was anticipated in project planning. Hence, some of the planned interventions could only be started and not completed, and some could not even be started (such as in trade metrology).

Inadequate staff continuity. High staff turnover in both the ECBP head office and in many of the partner institutions, such as academic and technical universities, had a negative impact on the continuity of project implementation. The same applied to the Ethiopian experts trained in quality management or auditing techniques. Soon after being trained, they left their respective institutions for better employment opportunities elsewhere, depriving said institutions of the required skills to advance the recognition of their technical capabilities, such as through accreditation.

Recruitment of international experts with limited experience. Because of the vast number of experts required for this enormous and complex project, the development partners could not always obtain the services of appropriately

qualified international experts and had to make do with less-experienced people. This was quickly picked up on by the Ethiopian side, with negative consequences for the project's implementation, in that the input of these experts was not always readily accepted.

KEY SUCCESS FACTORS AND LESSONS LEARNED

Obviously, some key success factors ensured that the reengineering of the Ethiopian QI was realized. Some of them were considered in project planning; others were more of a fortuitous nature. The most apparent success factors are summarized here.

Strong political leadership. A fundamental reengineering of long-established organizations such as the QSAE will always trigger resistance. In the case of the QSAE, it was not only the organization's separation from regulatory work (which would have been a hurdle regarding income); it was also the splitting of the organization into four separate entities that was the biggest challenge. A strong political will and clear leadership to implement such a change is an absolute necessity, because it is highly unlikely that a public entity will willingly undergo such radical transformation by itself. In the case of Ethiopia, the mandate and powerful political influence of the Ministry of Planning was of crucial importance for the fundamental reengineering of the country's QI.

Export sector demand for QI services. The creation of demand for QI services—for example, supporting enterprises to get their products tested and certified as well as becoming certified for ISO 9001, ISO 14001, and other quality management systems—is important to initiate the long-term financial sustainability of QI service providers. A focus on the export sectors brings more dividends than supporting those enterprises that only operate in local markets. Local market purchasing power is frequently too low to be able to leverage product quality; price is still the driver for local purchases.

Well-educated technical personnel. The establishment of appropriate educational programs at tertiary education establishments is of vital importance to ensure a continuous and plentiful supply of appropriately educated technical staff for QI organizations and industry, once the few project-related training programs have been completed and the project has come to an end. Such a plentiful supply will also somewhat deter trained individuals from excessive job-hopping, commanding higher salaries as they go along. It is especially the public sector institutions that would benefit from such a situation; to some extent, the private sector, with its more attractive remuneration systems, will become saturated.

Generous knowledge sharing from development partners. The transparent way in which the many development partners in Ethiopia shared their development programs with each other was important in successfully reengineering the Ethiopian QI. The number of these programs, each with its own focus but overlapping in many areas, could have quickly led to major tensions among the members of the donor community and their Ethiopian partners. The Head of Mission

meeting, supported by thematic subcommittees, provided the appropriate platform for sharing information without demanding coordination. Yet coordination did happen voluntarily as the development partners flexibly adjusted their programs for the greater good of Ethiopia.

CONCLUSION

Reengineering the QI of a country is always a challenge, one that is all the greater if the national standards body, like the QSAE, follows a fully integrated approach. The splitting of the QSAE into four independent organizations, each with its specific QI focus, is commendable. It took serious political will from the Ethiopian government to undertake this major reengineering process.

The major developments of the university and the vocational training systems will not only provide industry and the authorities with appropriately trained technical people for the future but will also benefit the QI in no small way. The investment in industry, still ongoing, to establish it as internationally competitive will bring dividends in the medium to long term. Internationally accepted QI will be one of the key features of this ambitious project to change Ethiopia's largely subsistence-agriculture-based business environment into a modern, industrialized one.

NOTES

1. ISO 9001:2015, "Quality Management Systems—Requirements": https://www.iso.org/standard/62085.html.
2. ISO 14001:2015, "Environmental Management Systems—Requirements with Guidance for Use": https://www.iso.org/standard/60857.html.
3. For information on the current status of Ethiopia's accession to WTO membership, see the WTO's Ethiopia status page: https://www.wto.org/english/thewto_e/acc_e/a1_ethiopia_e.htm#status.
4. In quite a few low- to middle-income economies, the national product certification mark is a prerequisite for demonstrating compliance with mandatory standards. Whereas a mandatory standards system may still be compliant with the technical regulation requirements of the WTO TBT Agreement, the use of the national product certification mark as the demonstration of compliance of the product is considered an unnecessary trade barrier and as a license for the national standards body to extract rent. Economies that still practice such a system should seriously consider changing to a more trade-friendly system.
5. ISO/IEC Guide 65:1996, "General Requirements for Bodies Operating Product Certification Systems," has been superseded by ISO/IEC 17065:2012, "Conformity Assessment—Requirements for Bodies Certifying Products, Processes and Services": https://www.iso.org/standard/46568.html.
6. Least-developed countries (LDCs) are low-income countries confronting severe structural impediments to sustainable development. They are highly vulnerable to economic and environmental shocks and have low levels of human assets. There are currently 47 countries on the list of LDCs, which is reviewed every three years by the United Nations (UN) Committee for Development (CDP), a subsidiary body of the UN Economic and Social Council.
7. At the time of the ECBP project, this was known as the German Agency for Technical Cooperation (GTZ), one of multiple German development organizations. The BMZ merged many of these along the way, renaming them collectively GIZ.
8. ISO/IEC 17025:2005 has been superseded by ISO/IEC 17025:2017, "General Requirements for the Competence of Calibration and Testing Laboratories": https://www.iso.org/standard/66912.html.

9. "Kaizen," Japanese for "improvement," refers to a Japanese business philosophy of continuous improvement of working practices and personal efficiency to increase productivity and eliminate waste.
10. A "bonded factory" is a factory officially licensed by the government to store imported goods and use them in manufacturing without paying tax for importing the goods until they leave the factory.

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INTERNATIONAL DEVELOPMENT IN PRACTICE

Germany

QI Toolkit Case Studies

Martin Kellermann

WORLD BANK GROUP

PTB Physikalisch-Technische Bundesanstalt
Braunschweig und Berlin
National Metrology Institute

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Abbreviations

BDI	Federation of German Industries (Bundesverband der Deutschen Industrie)
BMAS	Federal Ministry of Labour and Social Affairs
BMWi	Federal Ministry of Economic Affairs and Technology (Bundesministerium für Wirtschaft und Technologie)
DAkkS	German Accreditation Body (Deutsche Akkreditierungsstelle)
DAR	German Accreditation Council (Deutscher Akkreditierungsrat)
DIN	German Institute for Standardization (Deutsches Institut für Normung)
DKD	German Calibration Service (Deutscher Kalibrierdienst)
EA	European co-operation for Accreditation
EC	European Community
EU	European Union
IAF	International Accreditation Forum
IEC	International Electrotechnical Commission
ILAC	International Laboratory Accreditation Cooperation
ISO	International Organization for Standardization
IT	information technology
NIST	National Institute of Standards and Technology
NMI	national metrology institutes
NPL	National Physical Laboratory
OECD	Organisation for Economic Co-operation and Development
PTB	National Metrology Institute of Germany (Physikalisch-Technische Bundesanstalt)
PTR	Physikalisch-Technische Reichsanstalt
QI	quality infrastructure
TGA	German Association for Accreditation

Germany

QI Toolkit Case Studies

Abstract: Germany had to merge nearly 20 mostly sectoral accreditation bodies into a single, national accreditation body in response to the European Union Regulation on accreditation. The new German Accreditation Body (DAkkS) was able to represent German interests much better at the regional and international levels.

EXECUTIVE SUMMARY

Germany is a high-income Organisation for Economic Co-operation and Development (OECD) country with well-developed and internationally respected metrology and standards organizations in the National Metrology Institute of Germany (PTB) and German Institute for Standardization (DIN). However, its accreditation system before 2009 was fragmented, suboptimal, and costly because it consisted of 20 accreditation bodies in both the public and private sectors that had developed organically over time with little guidance from the government. Furthermore, conformity assessment service providers frequently had to be accredited by more than one accreditation organization because of the separation of the regulatory and nonregulatory domains. Efforts to coordinate services of all the accreditation bodies under the umbrella of the German Accreditation Council (DAR) in the early 1990s proved limited in the end because the DAR was a committee representative of accreditation organizations without any legal backing.

The European Union (EU) promulgated Regulation (EC) 765/2008 to regularize accreditation across EU member states, where many differences in competency levels had developed over time.[1] This regulation required, among other things, a single national accreditation body in each EU member state. Germany therefore established a single national accreditation body by promulgating the Accreditation Body Act and merged all the accreditation bodies, public and private, into the German Accreditation Body (DAkkS) by the end of 2009 (table 1).[2]

Germany decided to retain DAkkS as a private company, providing it with the required mandate to operate in the public sphere. DAkkS faced a number of challenges in its first five years of existence—for example, retraining of personnel and 900 experts, losing income-generating work because of staff

TABLE 1 Snapshot of quality infrastructure (QI) reform in Germany

BEFORE REFORM	AFTER REFORM
About 20 organizations in the private and public sectors were involved in national accreditation activities in Germany in the regulated and nonregulated domains, leading to duplications, a lack of transparency, and a low status, especially in the European Union. Efforts to coordinate the activities of the accreditation organizations through the German Accreditation Council (DAR) in the 1990s were limited.	A single national accreditation organization, the German Accreditation Body (DAkkS), was established under the terms of the Accreditation Body Act in 2009, and all the existing accreditation bodies were merged with DAkkS. Duplications were set aside, costs were lowered, and the standing of the German accreditation system in the European Union was safeguarded.

involvement in developing new management systems, and the shrinking number of accreditation certificates because duplications were abolished. Its financial sustainability, however, is assured owing to the more than 4,000 companies it has as clients.

COUNTRY CONTEXT

Germany is a high-income OECD country, one of the more influential members of the EU, and the third-largest economy in the world. Germany has a long and well-respected tradition in metrology and standardization, which developed in parallel with its industry. One element of its national quality infrastructure (QI), namely accreditation, underwent serious reengineering in recent years.

Country context and trigger for QI reform

Metrology

The National Metrology Institute of Germany (PTB) was established as far back as 1887 (more than 130 years ago) as the Physikalisch-Technische Reichsanstalt (PTR) by the Prussian state with support from Werner von Siemens and other prominent industrialists. Today PTB is considered one of the world's eminent national metrology institutes (NMIs), boasts a number of Nobel Prize laureates, and has over many years realized scientific and metrology innovations that few can match.

PTB is responsible for the establishment and maintenance of the national measurement standards for Germany based on their international definitions.[3] It has over the years been involved in the establishment of these international definitions through fundamental research. In international comparisons, PTB's national measurement standards are compared with those of other major NMIs such as the National Institute of Standards and Technology (NIST) in the United States, the National Physical Laboratory (NPL) in the United Kingdom, and others, to form the basis of the International System of Units (SI). PTB measurement standards are of the highest accuracy technically possible.

The national measurement standards are used to calibrate the reference standards of other organizations in the calibration chain such as major research organizations, calibration laboratories, high-level technology organizations in Germany, and many others.

PTB also is responsible for evaluating measuring equipment that falls within the scope of legal metrology in Germany. This evaluation then leads to the approval of such equipment in trade, health and safety, environmental control, and law enforcement. The actual usage of such equipment in Germany is overseen by legal metrology agencies (known as Eichamt; in English, "Office of Weights and Measures") in each of the German federal states.

Standards

The German national standards body was established in 1917 as the Standards Committee of German Industry (NADI). In 1975, NADI and the German federal government signed an agreement by which NADI was recognized as Germany's national standards body, and its name was changed to the German Institute for Standardization (DIN). DIN represents Germany in the International Organization for Standardization (ISO), was a founding member of the European Committee for Standardization (CEN), and has played a leading role in these two organizations' affairs, management, and technical committees over many years. More than 30,000 experts from industry, research, consumer protection, and the public sector are involved in DIN technical committees to develop market-oriented standards that promote global trade and innovations, facilitate efficiency and quality, and help protect the environment and society as a whole. Hence, DIN is considered one of the world's leaders in standardization.

Anybody can submit a proposal for a new standard. All those interested in a specific standards topic can participate and contribute their expertise. The input of external experts into standardization is organized in standards committees and their subsidiary working bodies, with DIN's project managers ensuring the entire process runs smoothly, making sure all rules of procedure are followed.

Each standards committee is responsible for a distinct area of activity and also coordinates the corresponding standardization work at the European and international levels. As a rule, each standards committee in DIN comprises multiple technical committees. Before a standard is officially adopted, a draft version is published so that the public can make comments. Experts working on a standard must come to agreement on its content. To ensure that standards reflect the state of the art, they are regularly reviewed by experts at least every five years.

Accreditation

Accreditation in Germany—as the third fundamental element of an effective and efficient QI—cannot look back on as long of a history as metrology and standardization can. However, the German accreditation regime does have a long and convoluted history involving many actors in both the private and public sectors. Efforts to streamline accreditation systems in Germany failed to a large extent until 2009, when the European Parliament provided the external forces to do so.

The German state has practiced "accreditation" since the middle of the 20th century. The German state established its own organizations with technical competency or identified those with the competency to conduct inspection and testing for the implementation of technical regulations. A good example would be the Federal Ministry of Labour and Social Affairs (BMAS), which has registered conformity assessment service providers since 1977—based on specified competency requirements—to apply the GS-mark (for Geprüfte Sicherheit, or "Tested Safety") to products.[4]

German private industry, likewise, established organizations to consider the competency of certification organizations. For example, the Reichsausschuss für Lieferbedingungen (RAL), established in 1925, underwent many changes after World War II and, since 2008, has operated as the independent German Institute for Quality Assurance and Certification (retaining its traditional abbreviation, RAL), which ensures the independence of RAL Quality Marks.[5]

In another example, the then Federal Ministry for Economic Affairs (BMWi), the Federation of German Industries (BDI), and PTB established the German Calibration Service (DKD) in 1977 as a public-private collaborative effort.

The focus of the DKD was to accredit calibration laboratories in accordance with relevant international standards.[6]

Hence, when the European Council established new rules for the free movement of goods in the EU in the early 1990s (for example, the New Approach Directives for technical regulation and the Global Approach for conformity assessment),[7] the accreditation regime in Germany was totally fragmented. The free movement of goods in the European Common Market (now the European Economic Community) was based, among other things, on the mutual recognition of conformity assessment results—recognition that was informed by accreditation. The fragmented German accreditation system was considered to be suboptimal in this regard and therefore not in a position to fully support the export-oriented German industry. The Germans undertook the first efforts to bring order to the German accreditation system.

Establishment of the German Accreditation Council

The idea to establish the German Accreditation Council (DAR) was discussed in informal meetings between industry, the federal government, and the federal states as early as 1989. The many structures that developed historically and that were largely accepted in the public and private sectors in their respective domains were reviewed during these discussions. A merger of all of these into a single accreditation organization was not considered feasible at the time; there were just too many vested interests. The DAR was established in March 1991 with the view to

- Coordinate the efforts of organizations in Germany involved in the accreditation and recognition of laboratories, certification bodies, and inspection bodies;
- Represent German interests in national, European, and international organizations dealing with questions of accreditation; and
- Establish and manage a central register of accredited organizations in Germany (box 1).

The DAR was not a formal juridical person, and the secretariat was held by the Federal Institute for Materials Research and Testing (BAM) in Berlin, which

BOX 1

The need for a central register

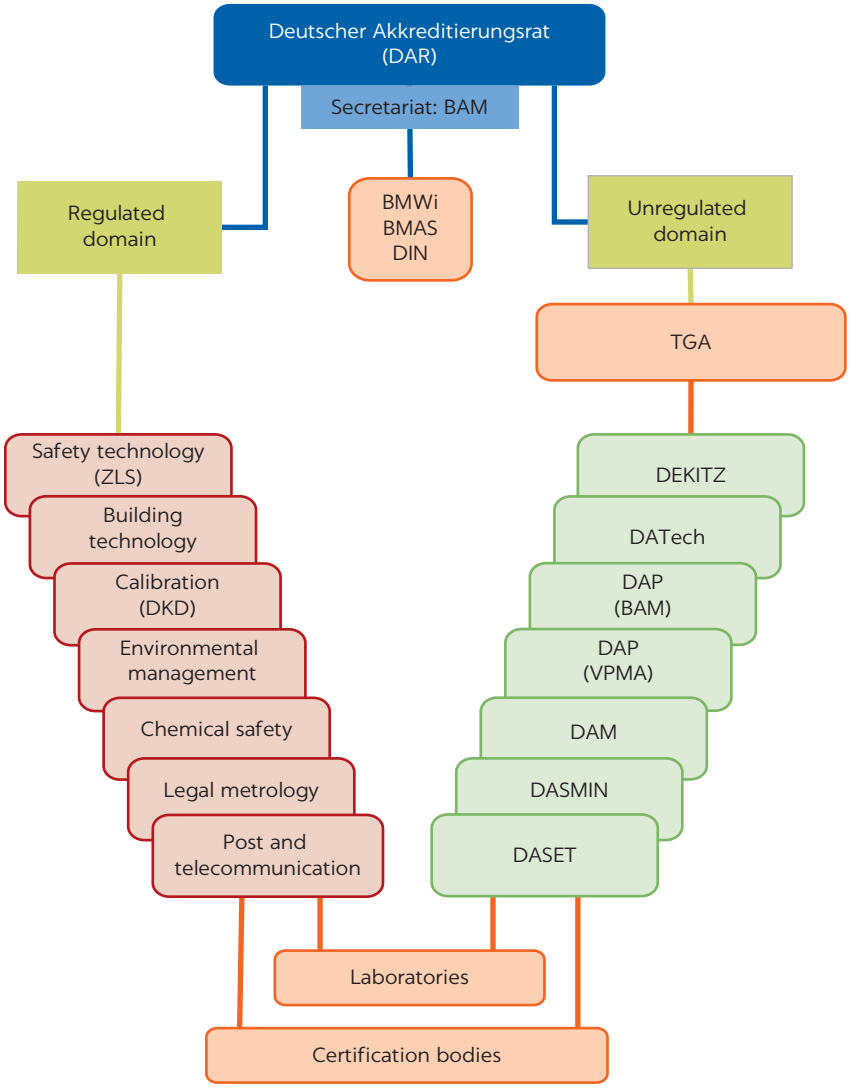
One of the key elements of an effective accreditation system is the dissemination of information to a wider audience about the accredited organizations. Over and above names and contact information, this information must provide full details of the specific areas, tests, or certification activities the organizations have been accredited for. This list needs to be up-to-date all of the time. Such a central register is one of the requirements for the accreditation system's international acceptance by the International Laboratory Accreditation Cooperation (ILAC) or the International Accreditation Forum (IAF).

In the case of Germany, all of the accreditation bodies had such information available, but obviously there was not a central register that could be consulted. One had to look through the lists of nearly 20 organizations to find the required information. Although one of the DAR's objectives was to establish such a register, this was not realized.

was also involved in certain accreditation activities. The DAR consisted of two main sections: the accreditation bodies operating in the regulated domain and those in the unregulated domain.[8] The unregulated domain grouping had previously formed its own cooperation entity, the German Association for Accreditation (TGA) in 1990. One of the aims of the DAR was to facilitate an information exchange between these two domains and to avoid costly overlaps in accreditation activities. The structure of the DAR at its inception is shown conceptually in figure 1.

FIGURE 1

Organizational structure of the German Accreditation Council (DAR)



Source: Hansen 1993. Reproduced with permission; further permission required for reuse.
Note: DAR discontinued its activities at the end of 2010, following the establishment of the German Accreditation Body (DAkkS); BAM = Federal Institute for Materials Research and Testing; BMAS = Federal Ministry of Labour and Social Affairs; BMWi = Federal Ministry for Economic Affairs; DAP = German Accreditation System for Testing; DASET = German Accreditation Entity for Steel Construction and Energy Technology; DASMIN = German Accreditation Entity for Mineral Oil; DATech = German Accreditation Entity for Technology; DEKITZ = German Coordination Entity for IT-standards Conformity Testing and -Certification; DIN = German Institute for Standardization; DKD = German Calibration Service; TGA = German Association for Accreditation; VPMA = Association of Materials Testing Agencies; ZLS = Central Entity of the States for Safety Technology.

The accreditation activities of the many and varied accreditation originations in the public and private sectors continued unabated, the only difference being that some coordination did take place. Some of the time, the DAR represented Germany in various European and international organizations dealing with accreditation. On the other hand, the various accreditation organizations pursued international recognition through ILAC, the IAF, and other international organizations individually when they thought it useful for their business. Germany was therefore represented by more than one accreditation organization in the European co-operation for Accreditation (EA) because recognition by ILAC and the IAF operated through this recognized regional organization.

ISSUES TO ADDRESS: THE TRANSITION OF 2008–09

As noted earlier, the German accreditation system before 2009 was fragmented and suboptimal. In addition, at the EU level, it was felt necessary to develop a comprehensive framework for accreditation and to lay down the principles for its operation and organization at the European Community (EC) level. This resulted in the promulgation of Regulation (EC) 765/2008 (further discussed below), which required each member state to have a single national accreditation body. Germany therefore had to resolve some major issues:

- At the time Regulation (EC) 765/2008 was promulgated, many accreditation organizations had evolved in Germany, because of a lack of an official policy, system, or guidance. By 2008, Germany had about 20 accreditation organizations operating in the regulated (compulsory) and unregulated (voluntary) domains, some of which were public service entities whereas others were private sector organizations.
- By 2008, the number of accredited entities per accreditation organization ranged from 1,200 to as few as 10.
- A major challenge of the system was the separation between the regulated and unregulated domains within the DAR.
- Furthermore, even though coordination was theoretically being pursued through the DAR, the conformity assessment service providers (laboratories, certification bodies, and inspection bodies) that provided services in both these domains frequently had to be accredited by more than one accreditation organization. This placed an unnecessary financial burden on such service providers.

Impact of European Regulation (EC) 765/2008

In 2008, the European Parliament and the Council promulgated Regulation (EC) 765/2008, which set out new requirements for accreditation and market surveillance relating to the marketing of products, thereby repealing the previous Regulation (EEC) 339/93. The preamble of the regulation noted that accreditation, though so far not regulated at the Community level, was carried out in all EU member states. The lack of common rules for accreditation had resulted in differing approaches and systems throughout the Community, in turn resulting in varying degrees of rigor applied in the performance of accreditation among the member states.

The regulation stated clearly, among many other things, the following:

- The regulation is applicable to all accreditation (that is, used on either a compulsory or voluntary basis) relating to conformity assessment, whether that assessment is compulsory or not, and irrespective of the legal status of the body performing the accreditation (Article 3).
- Each EU member state shall appoint a single national accreditation body (Article 4[1]).
- Should a member state not feel inclined to appoint a national accreditation body, it must secure the services of a national accreditation body in one of the other member states (Article 4[2]).
- Where accreditation is not operated directly by the public authorities themselves, a member state shall entrust its national accreditation body with the operation of accreditation as a public authority activity and grant it formal recognition (Article 4[5]).
- The national accreditation body shall operate on a not-for-profit basis (Article 4[7]).
- The date of entry into force of the regulation was January 1, 2010 (Article 44).

Regulation (EC) 765/2008 would have a profound impact on the German accreditation regime, because unlike many other EU member states that had only one or maybe two (for example, metrology-related and conformity assessment-related) accreditation organizations, by 2008 Germany had about 20 accreditation organizations, as noted earlier. A single national accreditation organization had to be established without losing the expertise vested in the various accreditation organizations, while also ensuring that the accredited conformity assessment service providers and calibration laboratories did not lose their accreditation status.

The transitional arrangements

It was already clear to the authorities by 2006 that a single national accreditation organization had to be established to safeguard German exports, to provide guidance for better coordination at the national level, and to ensure compliance with EU legislation. The promulgation of European Regulation (EC) 765/2008, however, provided the impetus to take decisive action. Although allowed for in the regulation, using a national accreditation organization of another member state was absolutely not desirable in view of the large number of accredited organizations in Germany.

Although it was established with high expectations, in the end the DAR could not coordinate and harmonize accreditation in Germany because it lacked the supporting legislation to do so. Its membership dwindled, and in July 2008 only the accreditation bodies in the unregulated domain remained, along with only four of the many accreditation bodies in the regulated domain. The responsibility for attesting the competency of conformity assessment service providers was therefore neither clearly a state nor a private sector issue, and it had become even less transparent as time went by. German influence at the European and international levels regarding accreditation was waning.

A summary of the number of accredited entities in Germany in 2008 shows that the range of coverage was quite large—from 1,200 entities accredited by the largest organization to as few as 10 entities accredited by the smallest (table 2). The fragmentation was self-evident.

TABLE 2 Number of accredited entities per accreditation organization, in Germany, 2008

ACCREDITATION ORGANIZATION	DOMAIN[a]	NUMBER OF ACCREDITED ENTITIES[b]
Deutsches Akkreditierungssystem Prüfwesen GmbH (DAP) (German Accreditation System for Testing)	Unregulated	1,200
Deutsche Akkreditierungsstelle Chemie GmbH (DACH) (German Accreditation Entity for the Chemical Industry)	Unregulated	600
Zentralstelle der Länder für Sicherheitstechnik (ZLS) (Central Entity of the States for Safety Technology)	Regulated	600
Deutsches Institut für Bautechnik (DIBt) (German Institute for Building Technology)	Regulated	500
Deutscher Kalibrierdienst (DKD) (German Calibration Service)	Regulated and unregulated	400
Deutsche Akkreditierstelle für Technik (DATech) (German Accreditation Entity for Technology)	Unregulated	300
Trägergemeinschaft für Akkreditierung GmbH (TGA) (German Association for Accreditation)	Unregulated	200
Staatliche Akkreditierungsstelle Hannover (AKS-Hannover) (State Accreditation Entity for Hannover)	Regulated	200
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG) (Central Entity of the States for Health and Safety of Medicines)	Regulated	130
Kraftfahrt-Bundesamt (KBA) (Federal Motor Transport Authority)	Regulated	100
Staatliche Anerkennungsstelle der Lebensmittelüberwachung (SAL) (State Registrar for Food Safety Surveillance)	Regulated	50
Bundesnetzagentur für Elektrizität, Gas, Telekommunikation, Post und Eisenbahnen (BNetzA) (Federal Agency for Electricity, Gas, Telecommunication, Postal Services and Railways)	Regulated	35
Bundesanstalt für Straßenwesen (BASt) (Federal Highway Research Institute)	Regulated	38
Bundesagentur für Arbeit (BA) (Federal Employment Agency)	Regulated	26
Gesellschaft für Akkreditierung und Zertifizierung mbH (GAZ) (Organization for Accreditation and Certification)	Unregulated	20
German Accreditation Association (GA-A) (German Accreditation Association)	Unregulated	10

Source: Bundestag 2009.
a. The "regulated" domain covers products for which technical regulations exist; hence compliance is mandatory. The "unregulated" domain consists of products subject only to market forces or private contractual obligations; hence compliance is voluntary.
b. Numbers are rounded.

A similar picture emerges when considering the number of employees of each of the accreditation organizations in 2008 (table 3). The total number of permanent employees was relatively small considering the approximately 4,600 accreditations that had to be serviced. The bulk of these employees would be administrative personnel, project managers, and management. When considering these numbers, one should not forget that the bulk of the experts and auditors of such accreditation organizations would not be permanent employees but would be independent contractors who were used whenever needed.

The total number of employees that would have to be considered for any type of merger was therefore in the region of 150 all told, with approximately 56 percent in the public sector and 44 percent in the private sector.

REENGINEERING OF ACCREDITATION: OBJECTIVE, DESIGN, AND IMPLEMENTATION

The prime objective of the reengineering of the German accreditation system was to create a single national accreditation organization to safeguard German exports and to provide guidance for better coordination at the national level. It was important for Germany to achieve full compliance with EU Regulation (EC) 765/2008.

TABLE 3 German accreditation organizations and average number of employees, 2008

A. STATE		B. FEDERAL		C. PRIVATE	
STATE ACCREDITATION BODY	EMPLOYEES (NO.)	FEDERAL ACCREDITATION BODY	EMPLOYEES (NO.)	PRIVATE ACCREDITATION BODY	EMPLOYEES (NO.)
AKS Hannover	7¼	BA	4	DACH	13
SAL	1½	(DAU)[b]	5	DAP	32
ZLS[a]	16	(EBA)[b]	⅓	TGA[c]	13
ZLG[a]	11½	BNetzA	5	DATech[c]	n.a.
DIBt	7	KBA	5½	GA-A	2½
		BASt	9	GAZ	4
		DKD	12½		
		(BSI)[b]	3		
TOTAL	**43¼**	**TOTAL**	**44⅓**	**TOTAL**	**64½**

Source: Bundestag 2009.
Note: n.a. = not applicable; AKS Hannover = State Accreditation Entity for Hannover; BA = Federal Employment Agency; BASt = Federal Highway Research Institute; BNetzA = Federal Agency for Electricity, Gas, Telecommunication, Postal Services and Railways; BSI = Federal Agency for Information Technology Security; DACH = German Accreditation Entity for the Chemical Industry; DAP = German Accreditation System for Testing; DATech = German Accreditation Entity for Technology; DAU = German Accreditation and Licencing Organization; DIBt = German Institute for Building Technology; DKD = German Calibration Service; EBA = Federal Railways Agency; GA-A = German Accreditation Association; GAZ = Organization for Accreditation and Certification; KBA = Federal Agency for Vehicles; SAL = State Registrar for Food Safety Surveillance; TGA = German Association for Accreditation; ZLG = Central Entity of the States for Health and Safety of Medicines; ZLS = Central Entity of the States for Safety Technology.
a. In ZLS and ZLG, employees are also involved in activities other than accreditation.
b. BSI, EBA, and DAU do not strictly accredit as provided for in Regulation (EC) 765/2008.
c. TGA and DATech merged beginning in 2008.

Several factors had to be considered in this reengineering exercise: First, the organizational form of a national accreditation body had to be considered. Second, expertise was to be retained. Third, international recognition had to be safeguarded.

Private company or statutory body?

Already in 2006, the ministry then called the Federal Ministry of Economic Affairs and Technology (BMWi)[9] established a working group representing the federal government, the states, and the accreditation bodies to consider models for a future national accreditation organization. It soon became clear that it would not be possible to maintain the status quo regarding the plurality of accreditation activities by providing for a coordinating mechanism by law, as this was not in line with Regulation (EC) 765/2008 requirements. It would also be difficult to comply with the international standards (such as the ISO/IEC 17011 requirements for accrediting conformity assessment bodies) that require a single senior management, and a specific management system.[10]

Once the working group concluded that all the accreditation bodies would have to be merged into a single national accreditation body, it then had to consider whether the national accreditation body must be a state entity or whether a private company organizational form would be preferable. The working group came to the following main conclusions:

- From an "assurance of safety" perspective, it would make no difference whether the accreditation body is a public (government department or statutory body) or a private entity. The latter would need to be provided with the required public authority activity recognition and mandate.
- The supervision by the state regarding the two forms would not differ materially. In both cases, the state would have to supervise to the same extent to fulfill its accountability in relation to the EU legislation.

- Regarding the integration with European and international accreditation infrastructures, a smooth transition, and the continuing proper integration of Germany into the EA, ILAC, and IAF recognition mechanisms, a mandated private company may be the better option.
- As for ensuring the technical competency of the accreditation body, the mandated private company has certain advantages. Only this organizational form can absorb the current personnel without major issues, and there are already experiences in this regard elsewhere.
- Finally, flexibility regarding strategy, management, and finances would point to a mandated private company. The state's accountability with regard to accreditation would in this case be supported by the more creative innovation and management potential a private company would bring.

The BMWi used these recommendations in full and developed the Accreditation Body Act to merge all the accreditation bodies into a single national body. This national accreditation body was to be a not-for-profit private company rather than a statutory body, but one given public authority powers under German legislation, as further described in the section about DAkkS below.

The German Accreditation Law

The Accreditation Body Act provided the legal framework for the establishment of a national accreditation body.[11] It is a fairly succinct piece of legislation containing the following elements:

- Linking the German system to the European requirements
- Providing for the mandate of the accreditation body
- Providing for the responsibilities of the accreditation body, including accrediting companies, keeping an up-to-date list of the same, and utilizing the appropriate external expertise in doing so
- Providing for the governance and finances thereof
- Providing for the utilization of the accreditation symbols by accredited companies
- Specifying the modalities whereby the federal state entrusts the accreditation body with the operation of accreditation as a public authority activity and grants it formal recognition
- Providing for administrative procedures such as offenses and penalties, the continuation of the accreditation status of organizations accredited by the former accreditation organizations, and the continued employment of civil servants previously employed in public service accreditation organizations in the new organization.

The Accreditation Body Act was considered by the German federal parliament, the Bundestag, and promulgated in July 2009.

RESULTS ACHIEVED

Establishment of DAkkS

The BMWi, which was given the responsibility of dealing with this issue, based on the recommendations of its working group, established a completely new accreditation organization rather than trying to merge the smaller accreditation

organizations into one of the larger ones. The new organization would not be a public sector entity but would be a private company registered as such under German commercial law. It would, however, be a not-for-profit company to fulfill one of the European Regulation's requirements. The new German Accreditation Body—in German, Deutsche Akkreditierungsstelle GmbH,[12] hence known as DAkkS—was established on October 16, 2009, with the federal government as the sole shareholder.

Merging of all the accreditation bodies

In view of the pending transformation of the German accreditation regime, three of the major private accreditation organizations—the German Accreditation Entity for the Chemical Industry (DACH), the German Accreditation System for Testing (DAP), and the German Association for Accreditation (TGA), which had already merged with the German Accreditation Entity for Technology (DATech)—decided earlier to merge into the German Association for Accreditation (DGA) in September 2009.

Once DAkkS was established, the DGA merged with DAkkS on December 17, 2009, thereby giving German industry (through the BDI) a 33⅓ percent shareholding in DAkkS. The DKD was transferred from the Ministry of Science and Technology by ministerial decree to DAkkS. On December 21, 2009, the federal government formally conferred the operation of accreditation as a public authority activity to DAkkS and granted it formal recognition as such through the promulgation of the necessary regulation.[13]

All the activities of the remaining accreditation bodies were also merged into DAkkS, and the DAR consequently ceased its operations at the end of 2009. The federal government transferred half its shares to a number of states, and the shareholding at the time of writing was divided equally among the federal government; three states (Bavaria, Hamburg, and North Rhine Westphalia); and the BDI—each holding one-third of the shares. The timeline of these events establishing DAkkS are shown in figure 2.

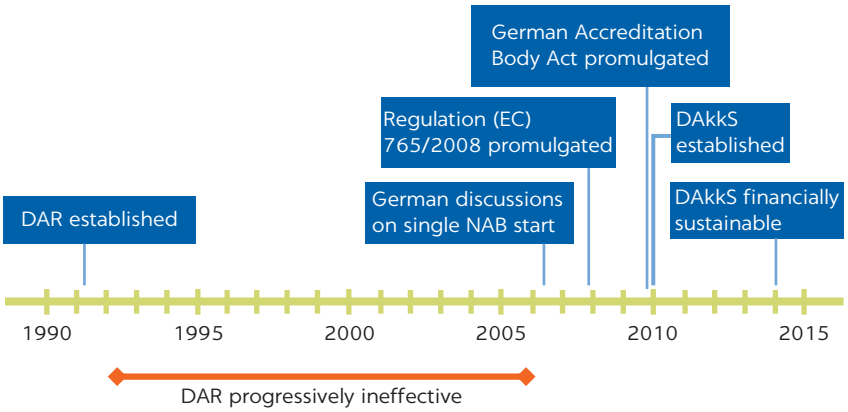
Business Development of DAkkS

By 2010, DAkkS was able to handle about 500 new accreditation applications. An additional and still continuing financial challenge was that, as a quasi–"statutory body," DAkkS was subject to the German legislation-determined fees that could be charged for work done in regulatory areas. This limited the fees that DAkkS could charge; in other words, it was no longer a free-market issue, where you charged what the market was prepared to pay. On the other hand, DAkkS was no longer subject to any competition on the German market, but it was also restricted in pursuing additional business in other EU member states.

DAkkS started operating with 87 staff members in 2010, which increased to 150 by 2014. By the end of the 2014 fiscal year, DAkkS listed 3,877 accredited organizations (down 6.2 percent from 2013), of which the major portions were testing laboratories (56.3 percent), calibration laboratories (11.5 percent), and medical laboratories (10.8 percent). It considered the accreditation business to be slowly expanding into new fields as regulatory authorities and the market increasingly demanded independent proof that conformity assessment service providers are technically competent.

FIGURE 2

Timeline of main events in German accreditation reform, 1990–2015



Note: DAkkS = German Accreditation Body; DAR = German Accreditation Council; NAB = national accreditation body.

Sustainability of DAkkS

By 2014, DAkkS had its best financial results of the first five years, with a turnover of €22.492 million and an excess of income over expenditures after taxes of €2.175 million. The reaccreditation cycle of five years led to an increase in reaccreditations in 2014 because many conformity assessment service providers had asked for an earlier reaccreditation in 2009 before the new dispensation came into force. All of these reaccreditations therefore bunched together at the end of 2014. DAkkS had to implement special measures to deal with this one-off number.

Another interesting result of these developments was that overall total of accreditations diminished during 2014, because companies that had been accredited by more than one accreditation organization before 2010 only needed one accreditation for the future and could relinquish all the unnecessary duplications—a major saving for many of them but a loss of income for DAkkS.

CHALLENGES: FIRST YEARS OF DAKKS

It is quite obvious that the merging of such a diverse and large number of accreditation organizations in both the public and private sectors into a single entity was not without its challenges. Of the previous locations, only three were retained as operational centers: Berlin (which became the head office), Frankfurt am Main, and Braunschweig. All employees of the predecessor companies were also retained as the pool of experts. All the accredited companies retained their accreditation status, and the last ones would have been reaccredited in the normal five-year cycle—at the latest, in December 2014.

The establishment of DAkkS cost an estimated €2.36 million in 2010 for each of the three shareholders, namely the federal government, the states, and private industry. It was also estimated that the authorities would save at least €279,500 per year on overhead because the multiplicity of public sector accreditation bodies would end. The financials for the first year of operation (2010) showed an

overall loss of €635,000 with a turnover of €16.052 million. The biggest expenses were external auditors and experts at €7.457 million and staff remuneration at €5.365 million. By 2014 this loss had been changed into a surplus of €2.175 million.

The challenges of DAkkS's first year of operation (2010) included the following:

- *Completely new management system documentation had to be developed.* The documentation of the various merged organizations was obviously not appropriate any longer, and the new documentation needed to be accepted by the EA, ILAC, and the IAF for DAkkS to retain international recognition.
- *A completely new information technology (IT) system had to be developed and operationalized.* Especially, the merging of the differing databases of the prior organizations required major resources. Systems for the new information responsibilities of DAkkS had to be developed and implemented.
- *Personnel availability for actual accreditation work was curtailed* because they were intimately involved in the above two developmental issues, leading to less revenue-earning work being done.
- *The approximately 900 external auditors and experts had to be retrained* in the newly developed management systems and documentation, and new ones had to be recruited, trained, and registered to deal with the extension of DAkkS's scope of activities.
- *Investments in new office equipment required serious expenditures* everywhere, and especially in the furnishing of the new head office in Berlin.

KEY SUCCESS FACTORS

In considering the German success in reengineering the country's accreditation regime, a number of key success factors emerged.

Decisive ministry leadership. Once it became clear to the German authorities that the accreditation regime was suboptimal and even noncompliant with regional legislation, a specific ministry was designated to take the lead in reengineering the accreditation regime, although many ministries were involved. Accreditation has become a significant policy instrument; hence, political leadership is important even though accreditation is a highly technical area. Leaving reengineering issues solely to the institutions is not always conducive to an optimum outcome for the country; the institutions tend to be more self-centered in their decision making.

Meaningful public-private sector partnership. Although the BMWi took the lead in the reengineering of the accreditation regime, it continuously pursued meaningful dialogue with the private sector through either the private sector accreditation bodies or their representative industry associations. They met as equal partners in all the discussions and agreements. Once the decision was made to establish a single national accreditation body as a private sector company, the government did not remain the sole shareholder, but private industry took up a third of the shares. As shareholders, private industry therefore is part of the governance structures of the accreditation body. This gives the private sector real ownership in the national accreditation body, enhancing industry support for the same.

International recognition kept intact. During the transition period, everything possible was done to retain the international recognition status of German organizations within the EA and therefore with ILAC and the IAF. This was of particular importance to German conformity assessment service providers, and hence to German industry and trade. A careful dialogue with the EA ensured this smooth transition.

Retention of skilled personnel. Accreditation is based on the skill sets of the personnel involved, both of the accreditation body and its pool of trained and registered auditors. Everything possible was done to retain the skilled personnel of the prior accreditation bodies, and the appropriate finances were made available by the BMWi to transfer them from public entities and private accreditation organizations to the new accreditation organization, in accordance with German labor legislation and with retention of their pension and other rights. This included relocation costs for many of the personnel.

The retention of about 900 external auditors and experts used by the 20 accreditation organizations was also given a high priority, even to the extent that they received extra training to familiarize themselves with the new management documentation and processes. The extended scope of activities also necessitated the recruitment, training, and registration of additional auditors and experts. The appropriate budget for these activities, among others, was also provided by the BMWi.

LESSONS LEARNED

Quite a few countries in the world have more than one accreditation body, and quite a few low- and middle-income countries do not yet have an accreditation body. Lessons that can be learned from the German experience in establishing a single national accreditation body can also be used by countries contemplating merging their accreditation bodies or by countries wishing to establish one.

Importance of accreditation status relative to other QI services. Clearly, accreditation is equally important to standardization and metrology in a modern economy that relies on exports for socioeconomic development. With the expansion of world trade that surpasses internal trade developments in most countries, no country can afford not to export. In the case of regional free-trade areas, accreditation has risen to prominence as the preferred mechanism for the attestation of the technical competency of conformity assessment service providers. It is therefore of utmost importance for any country that is part of such a regional free-trade area or that wishes to enhance its export performance to ensure that it has access to a recognized accreditation body.

Advantages of a single accreditation body. It is normal for each ministry involved in technical regulation to consider maintaining control over the implementation of such regulations—that is, within the ministry's area of responsibility. Hence, ministries tend to keep the "approval" of conformity assessment service providers in-house. Sound legal and business principles, however, point toward a pinnacle or single national accreditation body. It has to operate in the regulatory domain and hence has to be granted the mandate by the government to operate as a public authority if it is a private sector company. Having more than one accreditation body operating in this area decreases regulatory

transparency and is costlier for the country because each accreditation body has to obtain international or regional recognition individually. These are external costs over and above the duplication of administrative and management structures.

Jurisdiction over both regulated and unregulated domains. It is not useful to separate the regulated from the unregulated domain, because this only leads to unnecessary and expensive double accreditation of the conformity assessment service providers (putting their competitiveness at risk), and this also increases the opacity of the accreditation regime over time. Trying to coordinate the two domains through committee structures (such as the DAR) ultimately does not work, because there is no legal certainty in such a construct. Having only one national accreditation body means it must have regulatory powers if the government gives it the full responsibility for the technical competency of conformity assessment service providers operating in the regulated domain, as is the case in Germany. On the other hand, if the national accreditation body does not get these powers, then the government has to formally designate conformity assessment service providers once they are accredited.

Need for political leadership and public-private partnership. Clear political leadership as well as a meaningful public-private partnership in the establishment of a national accreditation body is vital to ensure success.

CONCLUSION

Although Germany was forced by external factors to merge all its accreditation bodies into a single, national body, this case study shows that there are distinct advantages in doing so. This is therefore an approach that many countries with multiple accreditation bodies could follow to render the accreditation landscape more transparent and less costly for local conformity assessment service providers and regulatory authorities—as well as to enhance the impact the country may have on the regional or international accreditation scene.

NOTES

1. "Regulation (EC) No. 765/2008 of the European Parliament and of the Council of 9 July 2008, setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No. 339/93": https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:218:0030:0047:en:PDF.
2. "Accreditation Body Act of 31 July 2009 (BGBI. I S. 2625), most recently by Article 1 of the Law of 11 December 2008 (BGBI. I S. 2354) has been changed": https://www.gesetze-im-internet.de/akkstelleg/BJNR262500009.html.
3. The seven fundamental units of the International System of Units (SI) are defined in terms of natural constants and have to be realized in each country as national standards in the form of specific measuring equipment in order to be useful. Depending on the sophistication of the country, these national measurement standards can be built by the NMI or, in the case of smaller economies, they can be bought off the shelf from specialist suppliers. In PTB's case, they are custom built to the highest accuracy technically possible.
4. Conformity assessment service providers are organizations that provide inspection, testing, and certification services on request by their clients. Their technical competence should be trustworthy. These days this is mostly demonstrated by accreditation.
5. For more information, see the RAL website: https://www.ral.de/en/.

6. For more information, see the DKD page of the PTB website: https://www.ptb.de/cms/en/metrological-services/dkd.html.
7. Council Directive 83/189/EEC and Council Directive 90/683/EEC, both of which have been revised continuously and extensively over the years.
8. The regulated domain covers products for which technical regulations exist, whereas the unregulated domain consists of products subject only to market forces or private contractual obligations.
9. At the time of writing, this ministry was known as the Federal Ministry for Economic Affairs and Energy (Bundesministerium für Wirtschaft und Energie).
10. ISO/IEC 17011:2004 has since been revised as ISO/IEC 17011:2017, "Conformity Assessment—Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies": https://www.iso.org/standard/67198.html.
11. The Accreditation Body Act (Gesetz über die Akkreditierungsstelle [Akkreditierungsstellengesetz – AkkStelleG]) can be downloaded from https://www.gesetze-im-internet.de/akkstelleg/index.html.
12. Gesellschaft mit beschränkter Haftung (GmbH) means a company with limited liability, that is, a (Pty) Ltd.
13. The Regulation on the Authorisation of the Accreditation Body as per the Ordinance on the Entrustment of the Accreditation Body (Verordnung über die Beleihung der Akkreditierungsstelle nach dem Akkreditierungsstellengesetz, abbreviated as AkkStelleGBV) can be downloaded from the DAkkS website: http://www.dakks.de.

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INTERNATIONAL DEVELOPMENT IN PRACTICE

Kyrgyz Republic

QI Toolkit Case Studies

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WORLD BANK GROUP

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National Metrology Institute

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Kellermann holds a master's degree in mechanical engineering from Pretoria University. He has also studied accountancy at the University of the Witwatersrand's Graduate School of Business Administration and participated in the Executive Education Program of the Haas School of Business, University of California, Berkeley. Currently, Kellermann lives with his wife in South Africa.

Abbreviations

BIPM	International Bureau of Weights and Measures
CIS	Commonwealth of Independent States
CMC	calibration and measurement capabilities
COOMET	Euro-Asian Cooperation of National Metrological Institutions
CSM	Centre for Standardization and Metrology
GDP	gross domestic product
GOST	State Standard (Russian: ГОСТ - государственный стандарт)
HACCP	hazard analysis and critical control points
IEC	International Electrotechnical Commission
ILAC	International Laboratory Accreditation Cooperation
ISO	International Organization for Standardization
ITC	International Trade Centre
KCA	Kyrgyz Centre for Accreditation
MITT	Ministry of Industry, Trade and Tourism
MRA	Mutual Recognition Arrangement
NISM	National Institution for Standards and Metrology
PTB	National Metrology Institute of Germany (Physikalisch-Technische Bundesanstalt)
QI	quality infrastructure
RTBET	Reducing Technical Barriers for Entrepreneurship and Trade
SECO	State Secretariat for Economic Affairs (Switzerland)
SI	International System of Units
USAID	U.S. Agency for International Development
WTO	World Trade Organization

Kyrgyz Republic

QI Toolkit Case Studies

Abstract: The Kyrgyz Republic drastically reengineered its quality infrastructure (QI), driven by the need to secure new export markets for its products after the demise of the Soviet Union, which had been its major trading partner. The Soviet-style control of industry through nearly 23,000 mandatory standards was changed into a modern technical regulation regime. The national standards body was relieved of its responsibility to administer the mandatory standards through mandatory product certification, and this was replaced by a market surveillance system, which became the responsibility of relevant ministries. A national accreditation body was established, and it pursued international recognition. Testing and certification for technical regulation was liberalized, but with the proviso that conformity assessment service providers had to be accredited. The national metrology institute was upgraded and international recognition was sought through International Bureau of Weights and Measures (BIPM) processes.

EXECUTIVE SUMMARY

After the demise of the Soviet Union in the 1990s, the Kyrgyz Republic became independent and had to integrate into the world economy. Kyrgyz policy makers embarked on a series of reforms to make this possible. The reform of the country's quality infrastructure (QI) became part of its overall reform program. At independence, the QI was modeled on that of the Soviet Union; that is, a single organization, Kyrgyzstandart, was responsible for standards, metrology, authorization (a form of accreditation), and conformity assessment. Furthermore, all 23,000 state standards (referred to as GOST standards, further discussed in the "Background of QI Issues" section) were deemed mandatory, and Kyrgyzstandart was responsible for ensuring their implementation and compliance by industry. In many cases, the standards were outdated, and the system was not conducive to trade.

The Kyrgyz Republic promulgated the Law on the Fundamentals of Technical Regulation in the Kyrgyz Republic in 2004, which initiated the country's transition from a regulatory system based on mandatory standards to a modern QI system.[1] Kyrgyzstandart was reengineered a couple of times, ultimately losing its regulatory powers, which were transferred to the Ministry of Economic Development, Industry and Trade, and renamed the National Institution for Standards and Metrology (NISM).

Thereafter, several development agencies got involved in building the capacity of the country's QI, mainly the U.S. Agency for International Development (USAID), the International Trade Centre (ITC), the National Metrology Institute of Germany (PTB), and the World Bank. The ITC initiated the establishment of an independent accreditation body, PTB provided support for the metrology system, and the World Bank project was involved in capacity building in the NISM and other entities in certain areas. An important element of the World Bank project was the initiation of a modern technical regulation system to replace the mandatory standards regime.

The Kyrgyz Centre for Accreditation (KCA) was established in 2007. ITC, PTB, and World Bank experts trained auditors and supported the development of the KCA's management system documentation. The KCA became a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) in 2013. USAID and the World Bank provided the NISM with modern measurement equipment, and PTB provided technical support for the NISM laboratories, which enabled them to eventually be accredited as a precursor for their calibration and measurement capabilities (CMCs) to be recognized in the International Bureau of Weights and Measures (BIPM) Key Comparison Database. Several testing laboratories were supported in their quest for accreditation to ISO/IEC 17025 ("General Requirements for the Competence of Testing and Calibration Laboratories"), and multiple enterprises were supported to gain ISO 9001 ("Quality Management Systems—Requirements") certification.[2]

The World Bank provided technical support for the development of modern technical regulations based on international standards. By the end of the project, 35 new technical regulations had been developed and implemented, and the number of mandatory standards had been reduced from 5,500 to fewer than 650.[3] The system to transfer all mandatory standards to more modern technical regulations was in place. Ministries were supported in establishing the regulatory agencies responsible for market surveillance, and their inspectors were trained. An effort was made to liberalize the conformity assessment regime so that technically competent service providers such as the NISM and others could play a meaningful role.

The reengineering of Kyrgyzstandart was not always easy: the changes cost it a large proportion of its income, which senior management saw as a loss of prestige and power. Hence, it was not too keen on implementing the changes. However, good cooperation between the development partners, as well as a concerted effort to advise the policy and decision makers over the years, helped to successfully deal with this challenge.

The case study covers the period from 2003 to 2013 (table 1), during which the major changes to the QI and technical regulation were implemented in a top-down fashion. After these far-reaching changes, many challenges did remain. First, the private sector's low uptake of QI services remained a worry

TABLE 1 **Snapshot of quality infrastructure (QI) reform in the Kyrgyz Republic**

BEFORE REFORM	AFTER REFORM
The national standards body, Kyrgyzstandart, was responsible for standards, inspection, testing, certification, metrology, and accreditation; in other words, numerous conflicts of interest existed.	Kyrgyzstandart was responsible for standards, metrology, and conformity assessment. The Kyrgyz Centre for Accreditation (KCA) was established. The conflicts of interest were set aside.
All 23,000 standards were considered mandatory.	The mandatory standards system was abolished, and a system of modern technical regulation was established.
Kyrgyzstandart was responsible for the implementation of mandatory standards.	Implementation of technical regulations was separated from Kyrgyzstandart and moved to the relevant ministries. Regulatory authorities in the ministries were trained in modern market surveillance practices.
Kyrgyzstandart had a monopoly on the testing of products in the Kyrgyz Republic falling within the scope of the mandatory standards.	Testing was liberalized, with the technical competency of conformity service providers being established through accreditation.
The equipment of the metrology laboratories of Kyrgyzstandart had deteriorated to the point of not being capable of getting international recognition.	The equipment of the metrology laboratory in the National Institution for Standards and Metrology (NISM) was modernized, and systems to gain international recognition were introduced. Laboratory intercomparisons have been started.
The accreditation activities of Kyrgyzstandart did not meet international standards, and no international recognition by the International Laboratory Accreditation Cooperation (ILAC) or the International Accreditation Forum (IAF) was possible.	The independent KCA was established and supported to achieve international recognition by ILAC.

because it negatively influenced the financial sustainability of the QI organizations. The cause was not quite clear, but the only slight involvement of the private sector in the design of the projects, as well as not adequately developing the demand side for QI services, may have played a role. Second, agreement could not be reached on a holistic food safety system, and its interfaces with QI services were not defined. As a result, food safety is governed by technical regulations—a system that may not be the best way to ensure food safety from "field to fork," because it deals only with the integrity of the final product.

COUNTRY CONTEXT

General background

The Kyrgyz Republic lies in Central Asia and is bordered by China, Kazakhstan, Tajikistan, and Uzbekistan. The country is almost completely mountainous—located at the juncture of two great Central Asian mountain ranges, the Tien-Shan and the Pamir, both with elevations in the 7,000 meter range. More than half of the Kyrgyz Republic lies at an elevation higher than 2,500 meters, and only about one-eighth of the country is lower than 1,500 meters. Bishkek, the capital, lies at 900 meters. With the collapse of the Soviet Union in 1990, the Kyrgyz Republic, together with many of the other Central Asian constituent parts of the Soviet Union, was established as an independent state.

Economic situation after 1990

Following the collapse of the Soviet Union, the Kyrgyz Republic's political and economic transition during the 1990s was mired in heavy political and societal crosswinds and severe economic losses. The immediate impact was a cumulative decline in gross domestic product (GDP) of 54 percent from 1991 to 1995 and a sharp increase in inflation. After a short recovery in 1996, the Kyrgyz economy was again severely affected by the Russian financial crisis in 1998; annual GDP growth fell to about 2 percent, inflation reached 36 percent, and the Kyrgyz som depreciated against the dollar by 43 percent. The economy started to show signs of recovery in 2000, with GDP growth rebounding to more than 5 percent in 2001. Inflation decreased below the two-digit level, and the foreign exchange rate stabilized.

In response to the tumultuous economic climate of the 1990s, the country embarked on policy reforms to improve governance, enhance economic liberalization, and promote privatization and financial sector development. These efforts resulted in the Kyrgyz Republic's accession to the World Trade Organization (WTO) in 1998 and its establishment as one of the more proactive economic reformers in the region.

Nevertheless, the Kyrgyz Republic continued to face significant challenges. The country lacks natural resources, with the exception of gold and water, and is geographically landlocked. The economy was mostly based on agricultural production, hydropower generation, and declining gold production.

In addition, the business environment remained inadequate and was not conducive to foreign investment and private sector growth. As a result, private sector investment was muted, and foreign direct investment in the non-gold sectors was negligible. Perhaps more important, the Kyrgyz Republic's trading gap with other Commonwealth of Independent States (CIS) countries widened as the country failed to capitalize on price stability and growing demand from its key traditional regional trading partners, Kazakhstan and the Russian Federation.[4]

Private sector growth was also dampened by political turmoil. The first elected president of the republic was forcibly removed from office in 2005. Political and social tensions were in turn aggravated by a lackluster economy with limited opportunities for private sector investment.

Kyrgyz policy makers faced numerous challenges on policies to accelerate private sector investment and export diversification. The policy reform agenda included the following elements:

- Lowering administrative barriers to businesses (notably in the areas of taxation and inspections)
- Enhancing enforcement of property and creditors' rights
- Improving the lending infrastructure and legal framework
- Modernizing and streamlining the customs regime and cross-border environment
- Targeting investment in infrastructure, notably to support trade
- Streamlining and aligning the domestic standards and certification regime on international standards.

The latter element initiated a major program to reform the erstwhile Soviet-style approach to standardization and technical regulation—a program designed to align the Kyrgyz systems with international good practices.

BACKGROUND OF QI ISSUES

The national quality infrastructure

The QI of the Kyrgyz Republic was modeled on that of the Soviet Union. Because of a lack of market forces in the state-planned economy, the quality of the products manufactured by industry were controlled by GOST standards, which were mandatory.[5] The basic premise of the Soviet system was that a designated state organization was given the responsibility to control its sector through a complete set of measures that included the publication of mandatory standards,[6] inspection of enterprises and the market, testing and certification of the relevant products, and authorization (a form of accreditation) of any laboratories operating in the sector. By the 1990s, approximately 23,000 GOST standards were developed and enforced by the Soviet agency Gosstandart.[7]

Establishment and formation of the QI in the Kyrgyz Republic fell into the years of 1969–71, and this function was realized by the former National Laboratory of State Surveillance of Soviet Gosstandart in Bishkek. After independence, the agency in the Kyrgyz Republic was transformed into Kyrgyzstandart, but it continued with all its former activities.[8] This gave it a powerful and controlling presence in Kyrgyz industry in several ways:

- *Standards development* was the responsibility of several technical committees allocated to various organizations outside of Kyrgyzstandart. Although Kyrgyzstandart did not actively participate in many of these, it registered the standards developed by them as national standards. The main focus was still the development of mandatory standards.
- *International or regional standards* had to be registered with Kyrgyzstandart before they could be used by industry. The same applied to industry standards developed in-house by companies.
- *Testing for compliance with the mandatory standards*—for those that fell into Kyrgyzstandart's sphere of responsibility—gave the agency a virtual monopoly in that sphere, and it had a fairly well organized metrology department.
- *Authorization (later called accreditation)* of state-regulated activities in the Kyrgyz Republic was provided by at least four organizations, one of which was Kyrgyzstandart.

This system had some negative consequences. First, to ensure compliance with the vast number of mandatory standards, Kyrgyzstandart employed a large technical staff that visited every economic actor regularly to take samples for laboratory testing to ensure that the products met these mandatory standards. The primary result of this system was that, as a regulator, Kyrgyzstandart was disliked in industry because its inspectors could stop the production and marketing of products at any time it believed that standards were not met.

Second, some of the GOST standards were based on international standards, but by the mid-2000s, many of them were technically outdated. Initially the Soviet Union was active in the International Organization for Standardization (ISO), and it was responsible for the translation of all ISO standards into Russian (one of the ISO's three official languages, the others being English and French). However, with the demise of the Soviet Union, translation of ISO standards into Russian lapsed—so much so that, today, few of the current ISO standards are still available in Russian from the ISO, making it difficult for the Kyrgyz Republic to adopt them owing to language issues.

Third, from 1990 onward, much of the technical infrastructure of Kyrgyzstandart deteriorated because of a lack of funds and the loss of important technical support from Gosstandart in Russia.

To alleviate some of the negative effects, the government split Kyrgyzstandart in two in July 2001, namely into (a) the State Inspectorate for Standards and Metrology, and (b) the Kyrgyz Centre for Testing and Certification, which was established as a state enterprise. In February 2004, the State Inspectorate for Standards and Metrology was reorganized into the NISM (whose formation is discussed below), and state surveillance was transferred to the Ministry of Economic Development, Industry and Trade. Accreditation was to be separated, but it remained with the NISM until 2007. The Kyrgyz Centre for Testing and Certification was reincorporated into the NISM by June 2005.

Law on the Fundamentals of Technical Regulation

In April 2004, in line with the Kyrgyz government's deregulation efforts, the parliament adopted the Law on the Fundamentals of Technical Regulation in the Kyrgyz Republic, which initiated the country's transition from a burdensome regulatory system based on mandatory standards (the Soviet GOST system) to a leaner system based on international standards. The law was introduced with the anticipation that it would help alleviate the regulatory burden imposed on businesses; enhance enterprise competitiveness by lowering transaction costs (such as the cost of regulatory compliance and rent extraction); and boost exports by removing technical barriers to trade. This legislation was developed with support from USAID (in conjunction with Pragma, a USAID contractor), incorporating the best of international practices of the time.

Yet the implementation of the Law on the Fundamentals of Technical Regulation in the Kyrgyz Republic was undermined by, among other things, legal inconsistencies between primary and secondary legislation, resulting in an excessively bureaucratic system exacerbated by overlapping functions of various agencies involved in conformity assessment, state surveillance, and control. The situation was further aggravated by the understandable reluctance of Kyrgyzstandart to relinquish direct control over the vast number of economic operators (because the system of mandatory standards was to be phased out)—a reluctance that soon morphed into active resistance.

In spite of its reluctance, Kyrgyzstandart was forced to undergo a complex restructuring to change it into a nonregulatory, nonenforcement service provider as a first consequence of the implementation of the law. Kyrgyzstandart was supported in this restructuring exercise through an USAID/Pragma project. It was henceforth known as the National Institution for Standards and Metrology (NISM).[9] The NISM introduced a number of changes to survive the inevitable drop in regulatory income, with mixed results.

Standards

During the reengineering of the NISM in 2005–06, especially because the administration of mandatory standards was going to be separated from the NISM, the organization sought to limit expenditures because the administration of mandatory standards delivered the bulk of the budget, soon to be diminished. One of the main cost centers was standards development. Under the pretext of decentralization, the NISM transferred the responsibility for standards

development to a large number of organizations, academic and otherwise. In reality it was a major cost-cutting measure. Although great in theory, standards development was not the major responsibility of any of these organizations; nor did they have the relevant budget. Hence, standards development came to a standstill fairly quickly. This had a further negative impact on the availability of a suite of modern, internationally aligned national standards.

Metrology

During the Soviet era, the traceability of the national measurement standards of the Kyrgyz Republic to the International System of Units (SI) was ensured through the traceability chain maintained by the central metrology laboratory of Gosstandart in Moscow. The metrological traceability scheme under Gosstandart was a unique Soviet mandatory verification scheme, not comparable to the international definition of metrological traceability through calibrations, as requested in all international standards. With the demise of the Soviet Union, this traceability chain collapsed, leaving the metrology systems of the relevant states (Kazakhstan, the Kyrgyz Republic, Tajikistan, and Uzbekistan) without the top link to the SI system of international metrology definitions.

Furthermore, based on laboratory assessments under both the World Bank and PTB projects, it was found that the NISM laboratories were poorly illuminated; equipped with inappropriate furniture; and lacked basic laboratory infrastructure such as a regulated electricity supply, an exhaust system, and so on. The laboratories were also used as storerooms for all sorts of materials and outdated equipment, and ornamental potted plants were standing around. In such an environment, it would be impossible to function as a proper metrology laboratory providing reliable measurements and calibration.

Accreditation

Following the Soviet Union–style arrangements described earlier, the Kyrgyz Republic still had at least four accreditation bodies operational by 2004 when the Law On the Fundamentals of Technical Regulation in the Kyrgyz Republic was promulgated. During the government's initial restructuring of Kyrgyzstandart in 2001 as the NISM, the NISM was to be responsible for standards, metrology, and accreditation. Its testing and certification business was separated and established as a state enterprise, the Kyrgyz Centre for Testing and Certification. Such a construct is nominally acceptable in the international QI community to avoid conflicts of interest, but it is not very common.[10] Hence some doubts remained, fueled by the fact that all staff were still sitting next to each other in the same building as before.

Overall situation

Unfortunately, the initial restructuring of Kyrgyzstandart and the transfer of the implementation of mandatory standards to the Ministry of Economic Development, Industry and Trade failed to deal properly with the replacement of mandatory standards administration; hence the whole mandatory standards system came to a grinding halt. The result was that the safety and health of society, the health of the environment, and consumer protection were compromised.

The absence of an internationally recognized metrology and QI was hindering economic development, because it raised the country's vulnerability to nontariff barriers to trade, which in turn delayed market access and further

industrial and economic development. As a result, the harmonization of domestic standards with international standards, the establishment of a reliable metrology and conformity assessment infrastructure, and a technical regulation regime in line with international good practices became high priorities on the agenda of policy makers.

PROJECT OBJECTIVES AND COMPONENTS

A number of development agencies got involved in supporting the Kyrgyz Republic in modernizing its QI and technical regulation regime. These included USAID and the ITC in the early stages. Later, the World Bank, PTB, and other agencies also got involved, as the following subsections discuss.

USAID/Pragma project

The USAID/Pragma project provided the impetus for the development of a modern QI and technical regulation regime in the Kyrgyz Republic. This program, designed to facilitate accreditation across the region, led to the development of the Law on the Fundamentals of Technical Regulation in the Kyrgyz Republic, the initial restructuring of Kyrgyzstandart, and the provision of high-level metrology equipment for the NISM metrology laboratories.

ITC/SECO project

The Trade Promotion in the Kyrgyz Republic program was funded by Switzerland's State Secretariat for Economic Affairs (SECO) and implemented by the ITC (2008). It was designed to strengthen the sustainable expansion and diversification of fruit and vegetable exports. It aimed to build national capacity for trade development by focusing on business service providers while also addressing institutional issues.

This project's interventions were demand driven, built around the three pillars formulated as immediate objectives:

- *Improve the export competitiveness* of enterprises in the agroprocessing sector
- *Strengthen the business support organizations* by increasing the quality and range of their services
- *Support the finalization and implementation of the sectoral export strategy* and integrate it in a framework of sustained public-private consultations on trade development.

During the ITC/SECO project, various reviews of the Kyrgyz QI were conducted in 2001 to 2006 under the second pillar of the project. These led to the development of technical support in the field of accreditation for both the establishment of a national accreditation organization and the accreditation of several laboratories. International experts developed a blueprint for the accreditation body's organizational structure, and the ITC provided some training for the initial group of auditors. The ITC also supported laboratories to implement proper management systems complying with ISO/IEC 17025 (ITC 2008).

World Bank project

The World Bank project, Reducing Technical Barriers for Entrepreneurship and Trade (RTBET), was conceived in principle in July 2004. The project proposals took a fair time to mature, and it was approved two years later in July 2006. Implementation started in January 2007 and lasted until March 2013, although it had been planned to end in April 2011. The extension had two main reasons: (a) the political turmoil in the country in 2010 that impeded progress, and (b) the slow delivery of sophisticated metrology equipment (largely due to a lack of the technical expertise to use it) right at the end of the project (IEG 2014).

Objectives and ultimate impact

The RTBET project was designed to provide assistance to streamline the technical regulation framework and develop and strengthen the QI (IEG 2014). In the design of the project, the World Bank benefited from prior projects, in particular those of the ITC and USAID (discussed earlier) that had undertaken a series of initiatives to provide assistance in similar areas—culminating, among other achievements, in the 2004 passage of the Law on the Fundamentals of Technical Regulation in the Kyrgyz Republic, as described in the earlier subsection on the law.

The project design emphasized building capacity and effecting culture change through the introduction of best practices. These were gaps the World Bank had identified to help the transition to an effective modern standardization and technical regulation regime, a transition that had been initiated to some extent by previous development agencies' activities. Hence, the initial project objectives were defined broadly as

- Streamlining the national technical regulation and standards framework for business;
- Developing systems to enhance the quality and safety of products; and
- Increasing enterprise competitiveness in pilot sectors.

These objectives remained relevant until the end of the project. The project impact, or key outcome indicator, was to be a decrease in the cost of regulatory compliance for business. It was also stated that although it may not have been measurable during the life of the project, the project was also expected to result in a longer-term increase in the share of non-gold trade with WTO member states. However, this was not interpreted as part of the project objectives because it was highly unlikely that this result would become visible during the life of the project.

Key results

The key project outcome indicator—a decrease in the cost of regulatory compliance for business—was supported by a number of key result indicators for the project activities:

- Development and adoption of technical regulations in key regulated sectors
- Removal of unnecessary mandatory certification requirements
- Reduction in the list of products subject to mandatory certification
- Increase in the percentage of national standards harmonized with international standards
- Increase in the number of measurement and calibration services with lower associated uncertainties

- Establishment of a national accreditation body compliant with ISO/IEC 17011 ("Conformity Assessment—Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies")[11]
- Accreditation of at least two testing laboratories and two certification bodies according to international standards
- Certification of at least 10 companies under ISO 9001 and ISO 22000 (food safety management) or hazard analysis and critical control points (HACCP).[12]

This was a formidable list, considering the funding resources of approximately US$5 million that the World Bank and the Kyrgyz Republic were prepared to invest in the project. Not only was it a long list, but the wide range of activities and expertise required for a satisfactory outcome would also prove to be challenging. Building capacity in QI institutions is a question of appropriate accommodation, management system implementation, technology enhancement, and staff training—activities that can be managed. Effecting a *culture change*—that is, becoming a service delivery organization rather than being a regulatory agency (for example, the NISM)—would prove to be much more difficult. The same applied to other regulatory agencies that had to change from Soviet-style controllers to becoming the conscience of society regarding safety, health, and consumer protection.

Project components

To achieve its objectives, the RTBET project was designed with three major output components and a local project management structure.

Component 1: Technical regulations. This component would facilitate the transition to the new standardization and technical regulation framework by building capacity in the Ministry of Industry, Trade and Tourism (MITT) and other agencies involved in the development of technical regulation. Under this component, the project would support:

- Development of a work plan for implementation of the Law on the Fundamentals of Technical Regulation, which had been approved in 2004;
- Development of technical regulations in critical sectors with high contribution to GDP and export/import substitution potential such as agribusiness and food processing;
- Design and establishment of an integrated information system linking MITT, the NISM, and the various line ministries and regulatory agencies responsible for the development of sector-specific technical regulations; and
- Capacity development in the WTO Inquiry Point[13] for processing inquiries and notification of adopted technical regulations and related regulatory documents to the WTO and its members.

Component 2: Metrology and standards. This component was designed to:

- Provide critical national measurement standards, instrumentation, and measuring equipment for the metrology institute to satisfy basic measurement needs required by industry and to ensure the accuracy and traceability of measurements performed by the domestic laboratory infrastructure and industry; and
- Establish procedures for the development and publication of national standards (including adoption of international standards) by the national standards body, in accordance with the WTO Agreement on Technical Barriers to Trade (TBT Agreement) requirements and ISO/IEC Directives.

Component 3: Accreditation and quality enhancement. Assistance in this component would focus on three areas—accreditation, testing laboratories, and certification bodies—and quality at the enterprise level, as follows:

- *Accreditation body.* As part of its technical regulation and standardization reform, the Kyrgyz government was planning to spin off the accreditation function from the NISM and set up an independent, internationally recognized accreditation body. For the new accreditation body to gain international recognition, its structure and processes would have to be in compliance with the requirements of the applicable standard for accreditation bodies, namely ISO/IEC 17011. Hence, institutional development assistance was to be provided on its institutional design, governance arrangements, process design, and staff skills and expertise.
- *Testing laboratories and certification bodies.* This subcomponent would provide support on a pilot basis for the upgrading and accreditation of selected laboratories operating in the agribusiness and food processing sectors as well as selected certification bodies in quality management systems and products. The laboratory and certification bodies involved in this demonstration pilot would be selected based on the assessment to be carried out by a technical consultant.
- *Quality at the enterprise level.* This subcomponent would provide assistance on a pilot basis to enterprises willing to introduce quality in their production lines and management systems (that is, certification to standards of the ISO, HACCP, and others). Procedures, guidelines, and eligibility criteria for selecting beneficiaries would be agreed to between the World Bank and MITT.

Component 4: Project management. For a complex project such as this, project management would be a key success factor. A project implementation unit (PIU) would therefore be established in Bishkek. The staff would include a project manager with basic knowledge of technical regulation and QI-related issues, a procurement specialist, and a disbursement specialist. The project would also set up a steering committee consisting of representatives of relevant ministries and agencies as well as private sector representatives. The steering committee would provide policy guidance and ensure that project activities were implemented in accordance with the project objectives.

National Metrology Institute of Germany (PTB)

The PTB project was a regional project for the Central Asian countries of Kazakhstan, the Kyrgyz Republic, Tajikistan, and Uzbekistan implemented from 2008 to 2013 with a budget of €1.3 million. The project's overall objective was to support the transition of the planned-economy QI of these countries to one based on the international norms and good practices of a market economy (PTB 2015).

In the initial phase of the project, the legal frameworks of the countries were addressed. In the follow-up phase, the institutions' activities were aligned with international standards and their service delivery was enhanced. The implementation methodology focused on two areas: (a) the capacity development of the metrology and accreditation institutions, and (b) raising the awareness of political decision makers as to the necessity of gaining international recognition for the QI institutions, which would require major reengineering of said institutions.

In collaboration with the World Bank, a bilateral subcomponent with the Kyrgyz Republic was created to support capacity development in metrology. Although the World Bank provided the resources for the equipment, PTB provided consultation on equipment selection, tendering, and laboratory renovation as well as staff training to develop metrological services with international recognition.

PROJECT DESIGN AND IMPLEMENTATION

The project designs of the various development agencies emanate from different perspectives as well as common points of departure, depending on donor policies and strategies. One strategy might focus on getting the recipient country to become better connected to world trade—a sort of altruistic approach. Another might be more interested in ensuring that the trade regime of the recipient country becomes better aligned with its own, thereby creating markets for its own exports. Even though the implementation of various development agencies projects complemented each other some of the time, there were inevitably also overlaps and duplications.

ITC/SECO project

The Kyrgyz Centre for Accreditation (KCA) was actively supported by the ITC as part of the Trade Promotion in the Kyrgyz Republic Program, funded by SECO. Although not designed specifically to support the development of the QI of the Kyrgyz Republic, the ITC/SECO project was instrumental in defining the trajectory for the establishment of the KCA and its ultimate international recognition (ITC 2008).

The ITC/SECO project (2004–08) was designed as a trade promotion project to strengthen the sustainable expansion and diversification of fruit and vegetable exports, including a focus on business service providers, and also to address institutional issues. As a small element of the project, relevant testing laboratories in the Kyrgyz Republic that test and certify products to meet food- and vegetable-related requirements were to receive training and technical support to gain accreditation. At the same time, accreditation was to be supported to gain ILAC signatory status so that the services of the Kyrgyz-accredited laboratories would gain international acceptance.

The Kyrgyz government separated accreditation activities from the NISM in 2007 (after an in-depth 2006 ITC report by international experts on the establishment of an independent accreditation body) and merged the other three accreditation activities with it. The ITC's support included assisting the KCA through two project phases to develop a comprehensive set of manuals and procedure documents to satisfy ILAC requirements. The ITC provided training of auditors and supported the KCA through two peer evaluations carried out by an ILAC evaluation team.

In October 2013, the KCA became a signatory to the ILAC MRA. The KCA was now a full member of ILAC in terms of accreditation of testing laboratories for compliance with ISO/IEC 17025. At the time, the register of the Kyrgyz national accreditation system included 81 laboratories.

A smaller contribution from the ITC/SECO project was support for the NISM to become a member of the International Organization of Legal Metrology (OIML), and it provided the finances for membership until 2007.

World Bank

Project design

As discussed earlier, the RTBET project was designed primarily to streamline the technical regulation framework and develop and strengthen the QI of the Kyrgyz Republic, both being important competitive elements of any industry.[14] The third component of the project included a subcomponent to support enterprise competitiveness, which included the upgrading of selected laboratories operating in the agribusiness and food-processing sectors. Another subcomponent, which focused on quality enhancement, provided financial support for companies to introduce quality into their production processes through certification to relevant ISO standards: ISO 9001 and ISO 22000 or HACCP. The latter was no doubt informed by the World Bank's Agribusiness and Marketing Project for the Kyrgyz Republic (2005–13), whose objective was capacity building in the entire food-processing and marketing value chain.[15]

The state of the Kyrgyz Republic's QI was well known through the earlier ITC/SECO and USAID/Pragma projects, as was the state of its technical regulation regime as a legacy from Soviet days. But an analysis underpinning the enterprise competitiveness objective was limited in scope. The link between outputs and outcomes in the case of this project was also dependent on the expected response by Kyrgyz entrepreneurs and foreign buyers: To what extent would exporters invest in quality improvements in their production process? And what would have been the acceptance by foreign buyers of Kyrgyz product standards? The answers to these questions might have helped set more realistic expectations for outcomes related to the use of the enhanced QI services and the impact of lower regulatory compliance costs.

Project implementation: Standards

The NISM's decision to hand over standards development to other organizations was reversed. The NISM's standards development activities were instead strengthened, ultimately enabling the NISM to adopt many ISO standards as national standards.

The NISM, renamed the Centre for Standardization and Metrology (CSM) during the project, remained the principal government body involved in developing and adopting standards. The CSM established 20–30 technical standardization committees—consisting of representatives of business, research and development organizations, consumer rights protection organizations, and others—to be involved in developing national standards. The technical standardization committees develop, revise, or amend about 60 national standards each year. Under the framework of the existing system, national standards are harmonized with international standards such as the ISO, the International Electrotechnical Commission (IEC), and the Codex Alimentarius.

At the beginning of 2012, approximately 22,500 standards were registered with the NISM/CSM. Out of this total, 90.7 percent were GOST Inter-State standards; 5.7 percent were national standards of other states (GOST-R, STB, and so on); 2.6 percent were national standards of the Kyrgyz Republic; and 1.3 percent were international standards. In general, 46 percent of the national standards were harmonized with the international and European standards. The major share of standards used in the territory of the Kyrgyz Republic are therefore Inter-State standards, which are continuously updated and slowly harmonized with international standards at the level of the Inter-State Council for Standardization and Metrology of CIS countries (WTO 2013).

Project implementation: Accreditation

Although already considered during the ITC/SECO project, it was during the World Bank project that the KCA was actually established in 2007. The long process of gaining international recognition was supported by a "twinning agreement" with the Turkish Accreditation Agency (TÜRKAK) because going it alone is much more difficult. By the end of the project, qualified international auditors carried out an assessment of the international accreditation readiness level of selected testing laboratories and certification bodies. Among the laboratories, the readiness was 90–95 percent depending on the type of testing equipment and procedures. Among the certification bodies, the readiness level was assessed at 75 percent. The ITC/SECO project subsequently helped the KCA to become a signatory to the ILAC MRA (as noted earlier) in October 2013.

Project implementation: Technical regulation

The reengineering of the technical regulation regime is probably one of the main success stories of the World Bank project. The project provided extensive training at the beginning for personnel of the regulatory agencies in the relevant ministries. The project provided technical support to authorities to develop the first of the new-style technical regulations, and it provided support for developing the approval process thereof.

It exceeded its expected performance by a wide margin, even though the enforcement and surveillance of the new regulations were still in the early stages of implementation (IEG 2014). Key achievements included the following:

- The project aimed to have 8 new technical regulations issued, but it ended up issuing 35. These 35 new technical regulations were in force in various sectors, ranging from food and agricultural products to construction and transportation services.
- The list of products subject to mandatory certification was reduced significantly—from 5,500 at project design to 684 at project completion. This significantly decreased the number of mandatory standards for safety and quality requirements from 23,000 Soviet-style GOST standards to just 100 WTO-compliant modern standards.
- The issuance of the new technical regulations led to the simplification of procedures for product certification, lowering the number of days required for certification from 15 to 7.
- By introducing product classification on the basis of their inherent risks, these new technical regulations are at the root of the risk-based inspections

regime that is now being implemented in the country.[16] The introduction of this reform led to a threefold decrease in the number of business inspections—from 20,629 in 2011 to 7,247 in 2012.

The technical regulation reforms continued after project completion. As of July 2013, for example, 43 national technical regulations had been adopted.

Project implementation: Metrology

The various projects provided extensive technical support to establish a proper metrology laboratory in the NISM/CSM. An in-depth evaluation by an international metrology expert in 2007 provided information in three areas:

- Input into the design of a new metrology laboratory
- An evaluation of the Kyrgyz Republic's needs regarding national metrology standards and other instruments
- Extensive training for metrologists to ensure the proper functioning of a national metrology institute.

The metrology component benefited from useful cooperation between the World Bank and PTB to maximize ongoing professional coaching, training, and peer exchanges. PTB provided critical support to the CSM in the definition of technical specifications for the procurement of laboratory facilities—for example, specification of the measurement equipment on temperature and mass, the specification on construction works, and the control system of the laboratory environment.

Resources accounting for about 40 percent of grant funding from the World Bank project were used to purchase metrology and calibration equipment for the laboratories and to upgrade the physical location to house the measurement standards. Installation of metrology equipment for seven laboratories was provided in the following areas: length, volume, pH-meter, density, pressure, time and frequency, and viscosity. These national measurement standards are used for the calibration of measuring equipment in industry and authorities, linking them to the international system and thereby enhancing the country's export potential.

National Metrology Institute of Germany (PTB)

The metrology side of the project focused on the training of metrology personnel; support in implementing the appropriate laboratory management systems for compliance with ISO/IEC 17025; and technical support on providing recognized calibration services for mass, pressure, and temperature. The project also supported the NISM's participation in interlaboratory comparisons under the umbrella of the regional metrology organization, the Euro-Asian Cooperation of National Metrological Institutions (COOMET). The objective of getting at least a few metrology laboratories accredited by the German Accreditation Body (DAkkS) could not be realized within the time frame of the project.

The accreditation side of the project, in partnership with the World Bank and the ITC, provided training of assessors and consultancy on the KCA's management system documentation for compliance with ISO/IEC 17011. The KCA did manage to gain international recognition by ILAC in 2013, but some challenges remained regarding its procedures with respect to the calibration requirements of accredited entities.

STAKEHOLDERS AND THEIR ROLES

Other than the direct beneficiaries, the main stakeholders benefiting from the advances in the QI activities and the technical regulation regime did not have a direct role in the project design or in its outcomes. The lower regulatory costs were to their benefit, but that was part of the project design from the beginning. The most effective support for the implementation of the projects came from the Authorized Body for Technical Regulation (ABTR) within MITT.

Enterprises were still reluctant to introduce quality management systems to further their marketability in export sectors, especially in the CIS countries that were slowly integrating into the global trade arena. The local market to a large extent still did not require such sophistication. That may come later. Some of the projects, such as the ITC project, also provided support for enterprises to establish quality management systems and then obtain certification. The PTB project organized joint activities with a German Agency for International Cooperation (GIZ) project that targeted enterprise development; for example, combined workshops were held to raise industry awareness about the importance of metrology.

RESULTS ACHIEVED

The results of the various projects to modernize the QI, change the Soviet-style mandatory standards system to a more modern technical regulation regime, and start the process of enhancing the quality practices of enterprises are commendable. The major achievements at the meso level can be summarized as follows:

- The QI fundamentals—standards, metrology, and accreditation—have been organizationally separated from technical regulation implementation, in line with international good practices, and conflicts of interest between them have been set aside.
- The conformity assessment services have been liberalized to an extent, and competency is beginning to be determined by accreditation rather than by designated state entities.
- The linkage of the Kyrgyz metrology system to the international SI system is being reestablished after the loss of it under the Russian agency Gosststandart, and technical capabilities have been enhanced with more modern measuring equipment. The CMCs are still to be registered by the Kyrgyz Republic on the BIPM's Key Comparison Database. To this end, the NISM has participated in laboratory intercomparisons under the auspices of COOMET.
- Accreditation has been merged into a single national organization, the KCA. Initial international recognition through ILAC has been successful, though recognition through the International Accreditation Forum (IAF) still needs to be achieved.
- The number of national standards aligned with international standards has increased substantially, although much still needs to be done to update and harmonize the remaining body of 19,000 GOST-based standards.

- The number of products subject to mandatory standards has been substantially reduced, from about 5,500 to fewer than 650 at the time of writing. This is an ongoing activity, and the number may eventually become insignificant as the government approves further technical regulations.
- A few enterprises achieved certification to ISO 9001, HACCP, or similar standards.

It has taken a decade of involvement by development agencies to achieve this, not only by one donor agency but also by the combined efforts of all, indicating the immensity of changing the whole decades-old system through new legislation, new QI and market surveillance organizations, and training—culminating in their international recognition.

PROBLEMS ENCOUNTERED: CHALLENGES AND ISSUES

The reengineering of Kyrgyzstandart

The reengineering of Kyrgyzstandart was a major challenge. It had to be implemented in an environment that was politically reserved and institutionally reluctant, and with personnel who were skeptical about the way forward.

The organization felt seriously aggrieved that it was to lose its control, its "power," over Kyrgyz industry because mandatory standards administration was being moved to the Ministry of Economic Development, Industry and Trade. No doubt, this perceived loss of prestige was exacerbated by the loss of an appreciable percentage of its income from levies that industries had to pay for the privilege of being "controlled" by Kyrgyzstandart. Hence, the top management of Kyrgyzstandart pursued all avenues to slow down or stop the change. The relationship between the various development agency projects and Kyrgyzstandart's top management was not always cordial at the beginning.

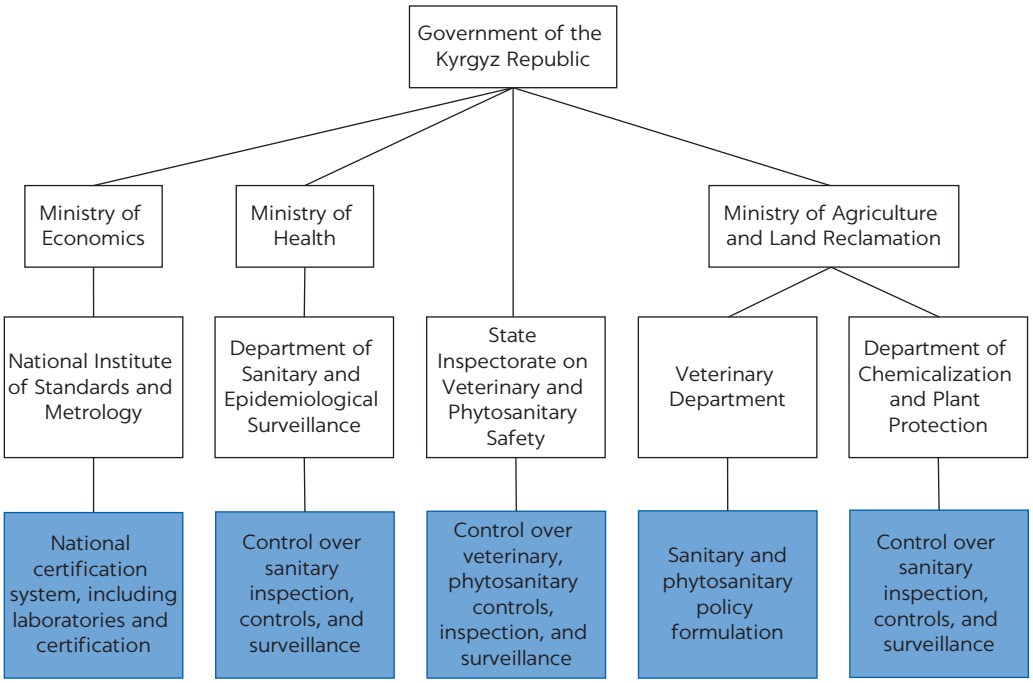
The development agencies were able to deal with the situation by combining forces. Every plea by the top management of Kyrgyzstandart to revert to the past was countered with well-reasoned formal responses to the authorities, even to the President's Office, signed by all the development agencies. These responses highlighted the need for the Kyrgyz Republic to establish a QI that was recognized internationally and that reinstating the previous status of Kyrgyzstandart would be a massive step backward with serious negative consequences for the country. Each of the development agencies also used its international experts to discuss these issues from time to time with the relevant authorities. Eventually, after a few years, the stance of the Kyrgyzstandart top management was discredited, and some resigned. Fortunately, the top management stance changed over the course of the projects, but it used up a tremendous amount of emotional energy (to keep calm in the face of continuous adversity), and more of the project resources than expected had to be spent on raising awareness at the political level.

Fragmentation of the sanitary and phytosanitary regime

A related and major issue that could not be properly settled during the projects (and even thereafter) was the food safety environment—that is, sanitary and

FIGURE 1

Authorities involved in implementing sanitary and phytosanitary measures



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phytosanitary (SPS) measures and the relationship between the technical regulation regime and the food safety system. By 2013, the system was still fragmented, with many organizations involved without responsibilities clearly allocated (figure 1).

Policy on SPS measures was marked by frequent changes in direction and structure and the lack of a clear strategy. The work of the ministries and state bodies on SPS matters has been disruptive, with organizational and management changes. In 2012, the government decided to establish a single state inspectorate for veterinary, sanitary, and phytosanitary safety; but in early 2013, it reversed this decision with respect to sanitary inspection. In February 2013, the Ministry of Health took back the functions of sanitary safety. The reason for such changes was that the combined inspectorate did not have the necessary budget, resources, or skilled personnel to carry out its work.

For several years, the legal framework and implementing regulations have been in transition. One of the main issues is that the 2004 Law on the Fundamentals of Technical Regulation in the Kyrgyz Republic formed the framework for SPS matters. Discussions on establishing an overall food law have not come to fruition, and SPS measures are therefore being implemented solely through technical regulations—a suboptimal approach. On the other hand, the Kyrgyz Republic has gradually reduced the number of products subject to mandatory phytosanitary, veterinary, and epidemiological control over the years.

Dependence of conformity assessment on government finances

Notwithstanding the progress in the development of the Kyrgyz Republic's QI under the projects, enterprises' adoption of quality systems or enhancement of product

quality remained slow owing to several factors, ranging from the low sophistication of local companies to competing investment priorities. During the project periods described here, entities rarely achieved ISO 9001 or HACCP certification. But this area is receiving continuous support from later projects that are targeting specific industry sectors with export potential, such as textiles, food and vegetable processing, and so on.

This lack of private sector demand has an impact on the financial sustainability of the QI organizations, especially those that provide conformity assessment services. They have gained recognition at the local and international levels, have been accredited, and use metrology properly, but now their services are not wanted (that is, are not being paid for). Therefore, the conformity assessment service providers find it difficult to continue with accreditation or no longer have their measuring equipment calibrated, with the result that the CSM and KCA income is affected as well. The government therefore has to provide further financial assistance to the QI organizations, even as the country's finances are continuously under pressure.

KEY SUCCESS FACTORS AND LESSONS LEARNED

Cooperation between development agencies

Cooperation between development agencies is intended to coordinate various efforts and avoid unnecessary overlaps of activities. In reality, though, the issue of distribution of credit or recognition for successfully implemented activities is frequently a major point of contention. Instead of working jointly for higher achievements, unnecessary discussions are held about the acknowledgment issues. In the Kyrgyz Republic, useful coordination came about in the capacity development in metrology in the NISM (World Bank and PTB) and accreditation in the KCA (ITC/SECO, PTB, and the World Bank), for example.

First, effective coordination was not achieved by coordinating the different logical frameworks of the development agencies but by the alignment of these frameworks with the needs of beneficiaries and only then leveraging the tasks. Second, coordination is not a task in itself; it should only be a method to achieve better results. Where coordination efforts competed with limited resources for implementation, decisions could be made for the best value for the final beneficiaries, which was not automatically a well-coordinated implementation of the various donor agency activities. Third, coordination benefited from having local office presence.

Project supervision continuity and quality of experts

The continuity of staff in charge of project supervision and the quality of experts are critical factors to the success of projects in a challenging environment. The high risk of the projects, as the Kyrgyz Republic itself was undergoing major changes, made it virtually essential to have a strong field presence. But the real systemic lesson is that it was the lasting continuity in the staff teams—both the field office staff and the team leaders who remained with the projects from the beginning—that made such dedication possible.

The success of the projects was also highly dependent on the professional expertise of the people involved. Local personnel were professionally qualified

and had good relationships with the decision-making circles, and the international personnel were highly qualified in their areas of expertise. This combination contributed significantly to the success of the projects.

Clear linkage between project components, outputs, and outcomes

The linkage between project components, outputs, and outcomes needs to be clearly identified at the project design stage to arrive at more realistic project objectives. The connection between (a) the project *components* of reducing the cost of regulatory compliance and improving the QI (including its international recognition), on the one hand; and (b) the *outcomes* of an increase in product quality on the local markets or enhanced export performance, on the other hand, is not always easily quantifiable for the duration of projects. Hence, these sorts of connections or impacts should be handled prudently during project design. It would be more useful to clearly identify the outputs rather than the laudable but more nebulous long-term outcomes (impacts). This is especially important for smaller projects.

In the World Bank project, for example, the objective of enhancing enterprise competitiveness was supported by relatively small subcomponents: (a) the upgrading of laboratories that provided services to the agribusiness and processed foods sector, and (b) the establishment of a small grant facility for companies that were seeking ISO certification to enhance the quality of their production process. The ITC/SECO project was designed the other way around because it focused on the export competitiveness of enterprises and had only a small component dealing with capacity development in the relevant QI services. Improving enterprise competitiveness is a broad topic that does not always fit with the very specific objectives of streamlining technical regulations and developing the QI to enhance product quality and safety.

However, without a driving force for the implementation of recommendations, they will remain on the level of interesting but practically not applicable information. For example, unless compliance with standards becomes a precondition for exports, the standards will not be seriously implemented and controlled. In other words, even though there is a perception toward stronger demand for products with improved quality standards, unless certain minimum standards are demanded by buyers or by law, implementation by enterprise owners will be slow, despite full conviction of its necessity by the implementation agency.

Twinning arrangements to jump-start the development of newly formed entities

Newly formed QI organizations are seriously challenged to attain a level of competency demanded for international recognition. Although they will learn a lot by going it alone, time is against such a trajectory. The brokered twinning arrangements with internationally recognized peer technical agencies—such as the arrangements between the CSM and PTB and between the KCA with the Turkish Accreditation Agency (TÜRKAK)—not only led to the establishment of excellent cooperation between these institutions but were also instrumental in achieving the required competency in a much shorter time.

Extended project implementation time

Projects with complex technical components should be allowed more time for implementation or should structure their principal components as separate, consecutive projects. Given the high risk factor and technical complexity of the projects to change the standardization and technical regulation regimes of the Kyrgyz Republic, perhaps a longer implementation period could have been considered as well as a larger amount of funding that would have provided the flexibility to finance additional interventions (for example, equipment for laboratories) that may not have been foreseen at the time of preparation.

Strategic selection of interventions

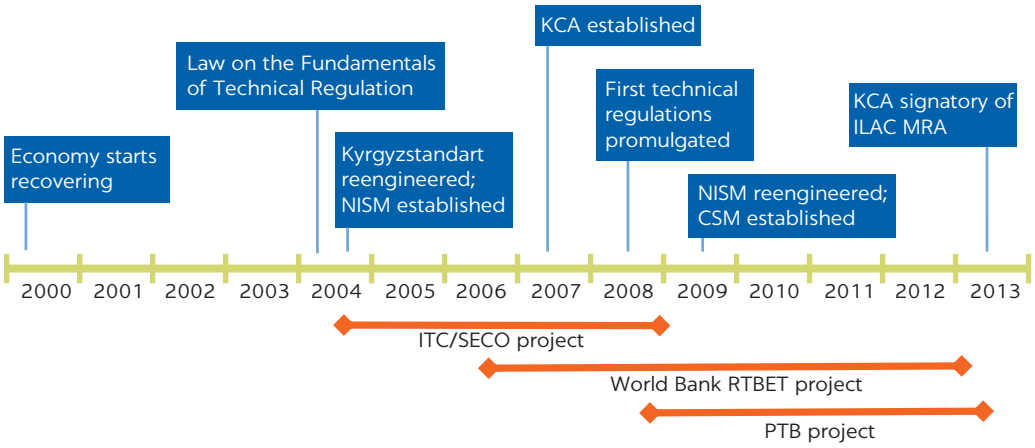
Industries or QI organizations that are undergoing transformational changes need to be assisted through the entire spectrum of their operations. If these industries are additionally in a country, such as the Kyrgyz Republic, that is undergoing transitional changes itself, it really does not matter much which field of intervention is selected by the project, because almost any strategic intervention will lead to positive results. It is not so much a question of what to do but how to set priorities to achieve the biggest results with the limited available resources. The first limiting factors (major problems) whose resolution would have the biggest positive effect on the industry or organization should be given first priority.

Success criteria based on the beneficiaries' perspective

The success of project activities also needs to be measured from the perspective of the cooperating stakeholders. Beneficiaries will regard the project as successful only if they appreciate the cooperation and perceive it as a profitable undertaking. The aim should therefore be to produce tangible results from the

FIGURE 2

Timeline of main QI reform project events, Kyrgyz Republic, 2000–2013



Note: CSM = Centre for Standardization and Metrology; ILAC = International Laboratory Accreditation Cooperation; ITC = International Trade Centre; KCA = Kyrgyz Centre for Accreditation; MRA = Mutual Recognition Arrangement; NISM = National Institution for Standards and Metrology; PTB = National Metrology Institute of Germany; RTBET = Reducing Technical Barriers for Entrepreneurship and Trade; SECO = State Secretariat for Economic Affairs (Switzerland).

stakeholders' perspective. Stakeholders must therefore be already active in the planning stage, or the project must have the flexibility to adjust to their real needs at a later stage of implementation.

CONCLUSION

The reengineering of the Kyrgyz Republic's QI and technical regulation regime from 2003 to 2013 (figure 2)—from a Soviet-style mandatory standards system to one more aligned with international market-related good practices—was a difficult and arduous transition. It was mostly driven by the development agencies, starting with USAID and continued by the World Bank, PTB, ITC, and others. It necessitated a top-down approach that saw many profound changes implemented in the public QI and technical regulation domain. On the other hand, the projects, by the development agencies' own admissions, did not take the demands of the private sector fully into account.

One of the major success factors in this massive reengineering exercise was the close cooperation that developed between the development organizations, not only to keep overlaps and gaps in project inputs and outputs to a minimum but also largely to get difficult policy and legislative changes agreed to and implemented by the government and its authorities. It was envisaged that this cooperation would continue between the development agencies once the World Bank RTBET project wound down.

Whether further development aid at levels similar to the 2003–13 period would be forthcoming was unclear at the conclusion of the projects mentioned here. If development agency support were to wind down, the government would have needed to allocate additional resources to ensure the sustainability of its QI and to maintain the human and technical capacity developed in these agencies over the last six years of project implementation. On the other hand, given the budgetary constraints the Kyrgyz government faced, further development of the QI and technical regulation regime may well hinge on the degree of future development agency support and on the agencies' ability to find revenue-generating opportunities.

NOTES

1. Law No. 67, dated May 22, 2004.
2. ISO/IEC 17025:2005 has been superseded by ISO/IEC 17025:2017, "General Requirements for the Competence of Calibration and Testing Laboratories": https://www.iso.org/standard/66912.html. ISO 9001:2015, "Quality Management Systems—Requirements": https://www.iso.org/standard/62085.html.
3. Although the Soviet-era GOST standards had totaled about 23,000, after the 2004 enactment of the Law on the Fundamentals of Technical Regulation, about 5,500 of those standards were initially retained as necessary to maintain health and safety controls.
4. The CIS, a regional intergovernmental organization of post–Soviet republics, includes the following formal members: Armenia, Azerbaijan, Belarus, Kazakhstan, the Kyrgyz Republic, Moldova, the Russian Federation, Tajikistan, and Uzbekistan.
5. GOST (Russian: ГОСТ) is an acronym for *gosudarstvennyy standart* (Russian: государственный стандарт), which means "state standard."
6. Mandatory standards are standards that have been declared mandatory through legislation, meaning compliance is enforced by law. In this respect, they are technical regulations. In modern economies, standards are considered "voluntary" even though they may be a

prerequisite for market success or are called for in contracts. Noncompliance may limit market access, but it is not punishable by law. On the other hand, noncompliance with mandatory standards, being technical regulations, is an offense and punishable by law.

7. Gosstandart (Russian: Госстандарт) was the Soviet government agency responsible for standardization, metrology, and quality management as well as the implementation of mandatory standards.
8. Kyrgyzstandart was responsible for all QI functions as well as the implementation of mandatory standards. These functions included the development and publication of standards, the testing and certification of products to these standards, scientific metrology and weights and measures, accreditation, and market surveillance of all products and services subject to mandatory standards.
9. The NISM was renamed again in 2009, after a further restructuring, as the Centre for Standardization and Metrology (CSM).
10. The construct of having standards and accreditation in one organization does not constitute a conflict of interest, whereas having accreditation and conformity assessment together, for example, would be a serious conflict of interest. A few countries have combined standards and accreditation in the same organization; typical examples are Canada and Malaysia. But this is not a common construct; a much more common construct is to combine standards with conformity assessment.
11. ISO/IEC 17011:2004 has since been revised as ISO/IEC 17011:2017, "Conformity Assessment—Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies": https://www.iso.org/standard/67198.html.
12. ISO 9001:1987, originally titled "Quality Systems—Model for Quality Assurance in Design/Development, Production, Installation and Servicing," has been revised five times. The current standard is ISO 9001:2015, "Quality Management Systems—Requirements": https://www.iso.org/standard/62085.html. ISO 22000:2005, "Food Safety Management Systems—Requirements for any Organization in the Food Chain," has since been replaced by ISO 22000:2018: https://www.iso.org/standard/65464.html.
13. The WTO Technical Barriers to Trade (TBT) Inquiry Point is an official or office in a member government designated to deal with inquiries from other WTO members and the public on technical barriers to trade.
14. The discussion in this section is based on World Bank (2013).
15. See "Agribusiness & Marketing Project," Project P049724, Projects & Operations, World Bank: http://projects.worldbank.org/P049724/agribusiness-marketing-project?lang=en.
16. In conducting market surveillance, it is difficult to inspect all of the products falling within the scope of a specific technical regulation; it is actually logistically impossible. Hence, regulatory authorities have to make informed decisions regarding audits and sampling. In making these decisions, products with a high risk are obviously going to be inspected more frequently than products of lower risk to health and safety. The same applies to suppliers. Some are notoriously lax in complying with requirements, and others are always in compliance. Based on risk assessment, the choice is then made about which products to inspect and which not to inspect. The history of past inspections plays a big role in arriving at such decisions. In the European Union and the United States, for example, it has been reported that only 3–5 percent of relevant products are inspected on a regular basis.

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INTERNATIONAL DEVELOPMENT IN PRACTICE

Pakistan

QI Toolkit Case Studies

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WORLD BANK GROUP

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Abbreviations

BIPM	International Bureau of Weights and Measures
CE	Conformité Européenne
CEO	chief executive officer
CMC	calibration and measurement capabilities
EC	European Community
EU	European Union
FAO	Food and Agriculture Organization
G.A.P.	Good Agricultural Practice
HACCP	hazard analysis and critical control points
IAF	International Accreditation Forum
IEC	International Electrotechnical Commission
ILAC	International Laboratory Accreditation Cooperation
IP	intellectual property
ISO	International Organization for Standardization
KCDB	Key Comparison Database (BIPM)
MFD	Marine Fisheries Department
MoC	Ministry of Commerce
MoST	Ministry of Science and Technology
NA	Norwegian Accreditation
NAPHIS	National Animal and Plant Health Inspection Service
NMI	national metrology institute
Norad	Norwegian Agency for Development Cooperation
NPSL	National Physical and Standards Laboratory
NQP	national quality policy
NSB	national standards body
PakGAP	Pakistan Good Agricultural Practice
PCSIR	Pakistan Council of Scientific and Industrial Research
PNAC	Pakistan National Accreditation Council
PSQCA	Pakistan Standards and Quality Control Authority
QI	quality infrastructure
SCC	System Certification Centre
SMEs	small and medium enterprises
SPS	sanitary and phytosanitary

TBT	technical barriers to trade
TRIPS	Trade-Related Aspects of Intellectual Property
TRTA	Trade Related Technical Assistance
UNIDO	United Nations Industrial Development Organization
USAID	U.S. Agency for International Development
WTO	World Trade Organization

Pakistan

QI Toolkit Case Studies

Abstract: Pakistan reengineered its quality infrastructure (QI), driven by the need to secure export markets for its products, especially after its fish exports to the European Union (EU) were curtailed in 2004 owing to quality and safety issues. The standards, metrology, and accreditation bodies existed, but they required extensive modernization and international recognition. Laboratories and certification bodies existed, but none was accredited. The development of the QI focused specifically on the demands of the export sector. At the same time, small and medium enterprises (SMEs) in selected export sectors were supported in implementing the relevant quality systems, testing, and certification. By the end of the reform project in 2014, the QI institutions had gained international recognition, fish exports to the EU could be resumed, and new export markets for other products were realized.

EXECUTIVE SUMMARY

The development of the quality infrastructure (QI) in any country is a continuing process, and hence the narrative in this case study must be limited to a specific period—largely reflecting the changes from 2005 to 2014. In 2005, Pakistan developed a national quality policy. It was not implemented, however, because of inherent flaws, including (a) industrial development, which should have been dealt with in an industrial development policy; (b) the premise that the Pakistan National Accreditation Council (PNAC) was going to "supervise" the other QI organizations; and (c) the national quality policy's prohibitive implementation budget.

At that time, the Pakistan QI organizations did not enjoy any international recognition: no laboratory was accredited; PNAC was not a signatory of the International Laboratory Accreditation Cooperation (ILAC) and International Accreditation Forum (IAF) Mutual Recognition Arrangement and Multilateral Recognition Agreement, respectively; the National Physical and Standards Laboratory (NPSL) laboratories were run down; and no calibration and

measurement capabilities (CMCs) had been established. The Pakistan Standards and Quality Control Authority (PSQCA) was responsible for standards development, inspection, testing, certification, and the implementation of mandatory standards—the latter totally at odds with good international practices.

Pakistan's fish exports to the European Union (EU) were suspended in 2004 and later banned owing to major quality and safety concerns. Even though Pakistan had a huge agribusiness sector, little was being exported for lack of understanding and implementation of foreign market requirements. The Pakistan quality management certification schemes earned themselves a bad reputation in local and foreign markets because of major problems in implementing such systems and subsequently certifying them, exacerbated by a well-meaning but flawed government subsidy scheme. None of the certification bodies was accredited.

Major development projects dealing with the development of the QI, small and medium enterprises (SMEs), the fishing industry, and related issues were undertaken by a variety of development agencies, to the value of nearly €35 million over nearly a decade. The largest of the programs was the Trade Related Technical Assistance (TRTA) program, the two phases of which ran for nearly 10 years (2004–14). It was funded mainly by the EU, with smaller contributions from the Norwegian Agency for Development Cooperation (Norad) and the United Nations Industrial Development Organization (UNIDO). It was implemented by UNIDO, which established a project office in Islamabad that at its height had 14 permanent staff members. Various international experts frequented Pakistan over the 10 years. Other programs aligned with the TRTA were implemented by the International Trade Centre (ITC), the World Bank, and others.

Regarding the issues, the TRTA subcontracted Pakistani institutions at the beginning to conduct three major evaluations concerning the constraints and issues faced by Pakistani industry regarding (a) technical barriers to trade (TBT); (b) sanitary and phytosanitary (SPS) measures; and (c) industry cluster compliance issues. These in-depth evaluations provided much-needed information to design meaningful support programs for the QI and industry.

The PSQCA, NPSL, and PNAC were supported during all the program phases. For PNAC, a master plan was developed (after much discussion and involvement of the EU delegation) that provided the blueprint for all further development work. This plan included training for staff and assessors in the country and abroad, practical training for trainee assessors during the assessment of laboratories by Norwegian Accreditation (NA), and support in developing and implementing quality management documentation within PNAC. PNAC was supported in applying for international recognition through ILAC and the IAF, which it attained in 2011 and 2013, respectively. By 2013, PNAC had accredited more than 50 laboratories in Pakistan, and a further 20 were in process, with the cost of accreditation much lower than it would have been through foreign accreditation services.

The NPSL laboratories were modernized with government funding before more modern measurement equipment and environmental controls could be provided. The NPSL was supported in participating in interlaboratory comparisons as a precondition for the establishment of its CMCs. Once these had been peer-reviewed by International Bureau of Weights and Measures (BIPM) members, they were listed in the Key Comparison Database (KCDB) kept by the BIPM, thereby providing Pakistan with international recognition in metrology.

The PSQCA was supported in streamlining its standards development process; establishing a national Inquiry Point[1] in accordance with the World Trade Organization (WTO) Agreement on Technical Barriers to Trade (TBT Agreement);

and building its capacity for more effective electronic communications with the international standards community. The PSQCA was also supported in establishing a proper management system certification body to counter the bad practices of other certification bodies in the market. Unfortunately, this effort came to naught when the newly appointed chief executive officer (CEO) of the certification body failed to respond to the development plan in a timely manner.

Initially 19 laboratories were selected for support in accordance with the needs of potential export industries. They received training in ISO/IEC 17025 ("General Requirements for the Competence of Testing and Calibration Laboratories"),[2] management system documentation, and interlaboratory proficiency testing. Thereafter they were accompanied in their applications and assessments for NA accreditation. This was a combined effort by Norad and UNIDO's TRTA program. The first laboratories were accredited by 2009. Subsequently more laboratories were identified for support, and by the end of the program, 30 had been successfully accredited in the meantime by PNAC, which had gained international recognition through ILAC. An evaluation of their performance regarding the number of tests conducted and revenue generated showed marked increases before and after accreditation, in one or two cases by as much as 150 percent. The revenue increases from 2009 to 2013 averaged 60 percent—not only because of the accreditation but also because of the increased demand from industry wishing to export (UNIDO 2008b).

One of the major successes of the TRTA interventions was the upgrading of the fisheries sector in Karachi through a broad-based program comprising four pillars (UNIDO 2008b):

- *Pillar 1:* The capacities and operations of the Marine Fisheries Department of the Ministry of Food, Livestock and Agriculture were strengthened, and the department was designated as the responsible authority for the EU.[3]
- *Pillar 2:* To facilitate the compliance of the handling of fisheries' products with international standards, the Karachi Fish Harbour Authority was supported in refurbishing fish auction halls, training fish inspectors, and upgrading the management of harbor activities.
- *Pillar 3:* The boat owners were supported through the powerful Fishermen Cooperative Society to upgrade their boats and the handling of fish. This included the refurbishing of fishing boats with fiberglass—the first four as a pilot project, followed by 500 financed by the provincial government, and finally about 900 financed by the boat owners themselves.
- *Pillar 4:* Capacity was improved in fish processing plants to implement hazard analysis and critical control points (HACCP) and related hygiene requirements in compliance with EU Directives. At the end of the fisheries component program in 2013, the EU had lifted the embargo on fish exports from Pakistan, and the first exports were received without any rejections in Europe.

Another intervention that was less successful was the support provided to mango and kinnow producers (UNIDO Evaluation Group 2014). Pakistan is a major mango and kinnow grower but was exporting little. After prolonged negotiations between the relevant provincial authorities, the federal promotion organization, and the dedicated mango and kinnow research organizations, a Code of Practice was developed as a cooperative venture between the UNIDO TRTA program and the Australia-Pakistan Agriculture Sector Linkages Program.[4] Pilot programs trained farmers through Farmer Field Schools on the proper handling of the fruits from field to market, and trade missions were taken to Europe in

TABLE 1 Snapshot of quality infrastructure (QI) reform in Pakistan

BEFORE REFORM	AFTER REFORM
Pakistan developed a National Quality Policy in 2005, but its implementation stalled because of inherent problems with its content and overambitious budget.	A new National Quality Policy based on international good practices was developed and agreed to by stakeholders in both the public and private sectors. By 2013, it still had to be approved by the cabinet for implementation.
The food safety regime of Pakistan was totally fragmented, with a variety of national ministries, national organizations, and provincial authorities claiming responsibility. In reality, little was implemented.	Draft national food safety legislation was developed, but it still required stakeholder approval before being submitted to parliament.
PNAC had been established and offered a wide variety of accreditation services, but it struggled to gain international recognition, and it had no customers.	PNAC became a signatory of the ILAC and IAF multilateral recognition arrangements, and it retained its status during the first follow-up peer evaluation.
No laboratories in Pakistan were accredited, either by PNAC or foreign accreditation bodies. The National Physical and Standards Laboratory's (NPSL) equipment was out of date, and laboratories were in a bad state. No CMCs had been determined.	More than 50 laboratories were accredited to ISO/IEC 17025, some initially by the Norwegian accreditation body and, by the end of the project, by PNAC once it achieved international recognition. The NPSL laboratories were renovated, and equipment had been upgraded. CMCs were being determined.
The European Union (EU) had banned fish exports from Pakistan because of quality and safety concerns.	Massive interventions to upgrade the whole value chain of the fishing industry led to the lifting of EU sanctions and the first consignments being accepted by the EU authorities.
Mango and kinnow produce and products could not be exported to the EU owing to a total lack of food safety controls.	All the food safety controls were implemented, satisfying the EU "farm to fork" concept for the whole value chain. The first mango exports to the EU were realized.

Note: CMCs = calibration and measurement capabilities. IAF = International Accreditation Forum. ILAC = International Laboratory Accreditation Cooperation. PNAC = Pakistan National Accreditation Council. ISO/IEC 17025 refers to the standard, "General Requirements for the Competence of Testing and Calibration Laboratories."

cooperation with the Centre for Development Innovation (CDI) from the Netherlands. The result has been the first exports of mangoes to the EU; kinnow exports were still to come by the end of 2013. This was a small step. The big one—namely to roll out the program to all farmers—was left in the hands of the provincial authorities as the only entities with the mandate and human resources to do so.

In conclusion, it can be said that the broad-based programs of a decade had made a major impact on the Pakistani QI, upgrading it to international standards and gaining international recognition (table 1). At the same time, it developed major industrial sectors (namely, fisheries and horticulture) to the point where small and medium producers met international standards and could export successfully to the major markets of the world.

COUNTRY CONTEXT

General background

Pakistan, officially the Islamic Republic of Pakistan, is a South Asian country with the world's sixth-largest population—exceeding 199 million people. It has a 1,046-kilometer coastline along the Arabian Sea and the Gulf of Oman in the south and is bordered by India to the east, Afghanistan to the west, the Islamic Republic of Iran to the southwest, and China to the far northeast. It is separated from Tajikistan by Afghanistan's narrow Wakhan Corridor in the north and also shares a maritime border with Oman.

Classified as a low-income country by the World Bank,[5] Pakistan has a semi-industrialized economy with a well-integrated agriculture sector. Pakistan gained independence in 1947, and its postindependence history has been characterized by

periods of military rule, political instability, and conflicts with neighboring India. It waged a disastrous war against India in 1971, after which East Pakistan gained its independence as Bangladesh. The country continues to face challenging problems, including overpopulation, terrorism, poverty, illiteracy, and corruption. Despite these factors, it maintains strategic endowments and development potential while it has made substantial progress in reducing poverty, giving it the second-lowest headcount poverty rate (3.5 percent at the level of US$1.90 per day) in South Asia.[6]

Economic situation

Pakistan's economic growth since it gained its independence from Britain in 1947 has been varied. In the 1970s the economy was largely nationalized, and development slowed because of mismanagement. In the 1980s and 1990s, the economy was privatized again, but it stagnated owing to multiple factors, including international sanctions after Pakistan's first nuclear tests.

Following a military coup in October 1999, Pervez Musharraf became the president of Pakistan in 2001 and worked to address the challenges of heavy external and domestic indebtedness; a high fiscal deficit and low revenue-generation capacity; rising poverty and unemployment; and a weak balance of payments with stagnant exports. Sound structural policies coupled with improved economic management accelerated growth between 2002 and 2007, which reduced poverty levels and increased gross domestic product (GDP). The rate of inflation fell, while the investment rate grew with billions of foreign private capital inflows that financed many sectors of the economy. The exchange rate also remained fairly stable throughout this period. Although these gains can be attributed to debt reduction and economic reforms, the billions of dollars' worth of U.S. aid to Pakistan in return for Pakistan's support in the U.S.-led war on terror in Afghanistan also played its part.

After Musharraf's resignation in 2008, a civilian government once again resumed control of Pakistan. Subsequent civilian administrations experienced a dramatic rise in violence, corruption, and unsustainable economic policies that forced Pakistan to reenter an era of stagflation. The Pakistan economy slowed to around 5 percent annual growth, as opposed to the high of 9 percent during 2004–08, while the yearly growth rate fell from a two-decade average of 5 percent to around 2 percent.[7] Inflation (average consumer price index) reached 19.6 percent in 2008, and Pakistan had to depend on a fiscal policy backed by the International Monetary Fund (IMF) to avoid possible bankruptcy. The inflation rate for the fiscal year 2010/11, for example, was 13.7 percent. Since 2013, as a beneficiary of an IMF program, Pakistan's economic growth has started picking up again.[8]

BACKGROUND OF QI ISSUES

Policy context

Pakistan developed and endeavored to implement many policies in the early 2000s that contained elements of standards, technical regulation, and quality assurance in some form: the National Science, Technology and Innovation Policy; National Environment Policy; National Trade Policy; national investment policy; and National Industrial Policy. These policies were developed over many years, their implementation varied, and some have been revised.

Although the policy directions regarding standards, technical regulations, and quality for each of these policies were laudable and sensible, they remained

disconnected from each other and provided little guidance on the coordination of the overall QI or a holistic technical regulation system. In addition, the 18th Amendment to the Constitution of Pakistan (2010)—enacted to curb presidential powers and reverse legislation of the military rulers not aligned with the Constitution—also devolved much of the policy and legislation implementation to the provinces while abolishing federal ministries such as the Ministry of Health. The system that followed can be described as chaotic because the rules were unclear: for example, some provinces were taking a lead in establishing a technical regulation system or food safety system all on their own; others did not really know what to do.

PNAC developed a National Quality Policy during 2004–05, which was approved by the government for implementation. This policy, however, had three main flaws:

- It included certain issues, such as industrial development, that should have been the domain of an industrial policy or similar policy.
- PNAC was, to some extent, elevated as an oversight organization among the QI institutions. This could not be, because these institutions are considered equal in the QI.
- Technical regulations were mentioned only in passing; no real policy objectives were listed that would coordinate the differences in approach among the regulators.

In addition, the finances required to implement this policy were quite substantial, and this—combined with the policy's flaws—soon caused it to be quietly shelved.

National QI

This narrative describes the QI of Pakistan at the time the first National Quality Policy was developed, in 2004–05.[2]

Pakistan Standards and Quality Control Authority (PSQCA)

The PSQCA is the national standards body (NSB) of Pakistan. The PSQCA Act was promulgated in 1996, and the PSQCA became operational in 2001. But this act needed revision because many changes had occurred in the standards and quality domain worldwide, and the QI landscape in Pakistan had likewise seen many changes. Coordination issues had to be addressed, such as the relationship of food safety issues with mandatory standards that had to be aligned with internationally recognized approaches.

The PSQCA provided the whole range of services normally associated with an NSB in a low- or middle-income country: standards development, publication and information, inspection, testing, and product certification, as well as the administration of mandatory standards. The only conformity assessment service it did not offer was quality management system certification. As a full member of both the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC), the PSQCA participated in many international technical committees. It operated a standards information center that was also the designated national WTO TBT Inquiry Point but was not very effective. None of its laboratories was accredited.

The PSQCA administered 78 mandatory standards (approximately 50 percent of which dealt with food items) but would have liked to see this list extended

because it considered many products not covered by mandatory standards in the marketplace to be substandard. The notion of mandatory standards is in principle not a problem: every government has the responsibility to protect its peoples, fauna and flora, and environment from unsafe products, provided the standards' development and implementation meet the requirements of the WTO TBT Agreement. But the way in which mandatory standards are promulgated and the responsibility for their implementation frequently give rise to some real challenges.

Having NSBs responsible for the administration of such mandatory standards has been the norm in many low- and middle-income countries in the past, but it is becoming untenable in the modern era of more-open trade relations. Such a construct is considered a conflict of interest by the major trading blocs such as the EU and United States. Pakistan would therefore have to seriously reconsider this construct, also in light of the proposed establishment of a food authority as well as the devolution of implementation responsibilities to the provinces under the 18th Amendment to the Constitution.

The PSQCA had set up a national TBT Coordination Committee under the WTO TBT Inquiry Point, with approximately 25 ministries and agencies as members. The PSQCA considered its relations with the private sector to have been improving after hitting a low a few years earlier, but they were still far away from what the PSQCA would have liked them to be. That the PSQCA was a regulatory body certainly did not help; industry saw it mostly as an irritation rather than as a friend—another reason to reconsider its mandatory-standards activities.

Pakistan National Accreditation Council (PNAC)

PNAC was established in 1998 under the administrative control of the Ministry of Science and Technology (MoST) as the national apex agency to accredit conformity assessment bodies such as laboratories and certification bodies. Its accreditation services were launched in 2001, and PNAC soon provided a wide variety of accreditation services, including the following:

- Testing and Calibration Laboratories Accreditation (ISO/IEC 17025)
- Medical Laboratories Accreditation (ISO 15189)
- Certification Bodies Accreditation (ISO/IEC 17021)
- Halal Certification Bodies Accreditation (PS 4992)
- Inspection Bodies Accreditation (ISO/IEC 17020)
- Proficiency Testing Provider Accreditation (ISO/IEC 17043)
- Product Certification Bodies Accreditation (ISO/IEC 17065)
- Personnel Certification Bodies Accreditation (ISO/IEC 17024).

But PNAC struggled to attain international recognition through ILAC and the IAF, largely because of a lack of trained auditors and inadequate management practices. There was also no demand for accreditation in the country, and no laboratories or certification bodies had been accredited, not even by foreign accreditation bodies.

National Physics and Standards Laboratory (NPSL)

The NPSL is the national metrology institute (NMI) of Pakistan, administratively placed within the Pakistan Council of Scientific and Industrial Research (PCSIR). This is not an uncommon construct in low- and middle-income countries, and it has a number of advantages, especially in the formative years of the NMI.

However, as the NMI gains more metrology laboratories, national measurement standards, other measuring equipment, and personnel, there comes a time when it makes sense to establish it as an independent organization. Doing so will certainly enhance its stature in the international metrology community, even though there are no international agreements that demand it. As of 2010, none of the NPSL's CMCs had been accepted in the KCDB managed by the BIPM.

A formal national calibration service—a formal cooperation between the NPSL and private calibration laboratories—did not exist. Many laboratories were providing calibration services (driven by the ISO 9001, "Quality Management Systems—Requirements," certification program),[10] but none had been accredited by PNAC. This meant that some of the calibration services may have been of dubious quality. The NPSL estimated there were more than 50 such laboratories, but the UNIDO-managed TRTA Phase II Program identified only 10. This indicated the need for a new and in-depth review of the calibration capacity available in Pakistan and its state of competency to identify needs for technical support, including the establishment of a national calibration service and its modalities.

Legal metrology

Technically, legal metrology was in the hands of the provinces' labor and welfare departments. However, they employed few if any trained metrologists. It was also unclear whether appropriate legal metrology legislation was in place. On the other hand, the PSQCA was Pakistan's official representative to the International Organization of Legal Metrology (OIML), even though it did not conduct any legal-metrology activities.

The whole system could therefore be deemed dysfunctional. Legal metrology is an extremely important aspect of consumer protection, law enforcement, and health and environmental controls. It would therefore be absolutely necessary to establish a proper legal metrology system in Pakistan consisting of (a) appropriate legislation at the national level, (b) a national system of measuring equipment pattern approval and prepackaging requirements, (c) effective market surveillance at the provincial level, and (d) an oversight and coordination function at the national level.

Quality management system certification

After the 1987 publication of the ISO 9000 series of international standards, certification of quality management systems took off worldwide as purchasers tried to gain control over suppliers to deliver quality products. The same applied in Pakistan. Hence, the Pakistan government implemented a scheme to financially support the implementation of ISO 9001 in industry through subsidies managed by the Export Promotion Board (EPB). The subsidy was designed to cover the first round of certification costs. Approximately 800 companies benefited from this scheme before it was terminated around 2004. A follow-up scheme with slightly better controls was proposed but did not materialize.

Anecdotal evidence available to the EPB suggested that approximately 3,000 companies managed to be certified to ISO 9001 in the years before 2005 but that as many as 2,000 may not have maintained their certification because of financial constraints, a lack of tangible increases in market acceptance, or a failure to convert from the 1993 version of ISO 9001, ISO 9002, and ISO 9003 to the 2000 version of ISO 9001.

As many as 25 certification bodies were active in Pakistan, with five or six probably sharing the bulk of the business, but none was accredited. Furthermore,

there was evidence that many of these certification bodies, some of them even affiliates of multinationals, provided both consultancy services and certification of these same clients' management systems thereafter—a practice that is a serious conflict of interest. They basically responded more to the immediate concerns of enterprises for quick certification for marketing purposes than to the need to effect organizational improvements. At the same time, enterprises that established proper operational systems saw their reputation tainted by this low level of certification, and hence tended to lose interest. As a result, Pakistani quality management certification gained itself a bad reputation, both locally and abroad.

Food safety system

A systemic failure of food safety, plant health, and animal health controls existed in Pakistan. Fishery product exports to the EU were cut off for noncompliance with EC sanitary requirements. The EC's Rapid Alert System for Food and Feed (RASFF) continued to publish Rapid Alert notices regarding Pakistani food and horticultural products imported into the European Community (EC). There was ample evidence that a significant proportion of the agrifood products consigned to domestic and international markets other than the EU was not compliant with animal and plant health and food safety standards. For example, food items such as wheat, onions, mangoes, and honey had been refused entry even in less-sophisticated markets—such as India, the Islamic Republic of Iran, Iraq, the Philippines, and Sri Lanka—because they did not meet the required standards.

Pakistan had no policy on food safety. Most of the existing food laws dealt with production, distribution, and food supply, with some of these dating back to the 1960s. Apart from these basic food safety regulations, many law enforcement and regulatory bodies were working both directly and indirectly in the food safety sector. This situation was exacerbated by the lack of a single organizational focus of responsibility at the federal level for food safety.

These various bodies continued to undertake their food inspection activities—for example, fish inspection by the Marine Fisheries Department and meat inspection by the Animal Quarantine Department in relation to exports. The PSQCA, under the Ministry of Science and Technology (MoST), implemented mandatory standards dealing with food safety. On the other hand, there was only limited capacity to ensure food safety controls at places of production such as fishing vessels and landing sites, farms, and distributors. Food safety controls were poorly integrated throughout the supply chain; in other words, implementation of the "farm to fork" principle was nonexistent.

The widespread lack of understanding and awareness of modern SPS management systems in the SPS institutions hampered development of the control system. Controls were organized on the basis of commodity groups, reflecting functions of government departments rather than being arrangements concerning the risks to be controlled (regarding animal health, plant health, and food safety). The federal Animal Quarantine Department (under the Ministry of Livestock and Dairy Development) and the Department of Plant Protection (under the Ministry of Food and Agriculture) worked exclusively with import/export controls, with no focused effort to integrate activities or controls at the domestic level in Pakistan.

Furthermore, coordination between the different functions and departments with SPS responsibilities at the federal level had been significantly complicated by the 2010 division of the Ministry of Food and Agriculture and Livestock into two ministries: the Ministry of Food and Agriculture and the Ministry of Livestock and Dairy Development. Provincial governments were acting

unilaterally to fill the policy vacuum and had proceeded to develop food safety controls, but with no coordination or strategic direction from the federal government. For example, in Punjab alone, the Fisheries Department was developing new legislation for inspection and control of fishery products, the Livestock Department was developing a meat and dairy inspection agency, and the Department of Health proposed revisions of the Pure Food Rules and the formation of the Punjab Food Safety Agency.

These failures undermined export performance and also affected national consumers and the livelihoods of farmers supplying the domestic market.

Industry sector challenges

Business operators in a number of industrial sectors, especially in relation to fisheries and horticulture products, faced many constraints in export supply chains (UNIDO 2010b). Fishery products suffered from unsanitary conditions on fishing vessels and at landing sites and from a lack of ice and refrigeration. Mango export supply chains lacked rapid chilling facilities immediately after harvest. For kinnows and mangoes, there was poor quality management in plants packaging for export. Postharvest losses were high in all food sectors.

Common cross-sectoral constraints were the lack of compliance with international regulations, poor quality management by enterprises, poor handling of produce, and a lack of understanding of customer needs. These factors resulted in Pakistani exports being rejected by customers, achieving relatively low market prices, and subsequently losing market shares.

Although larger producers wished to move toward certification under the GLOBAL G.A.P. (Good Agricultural Practice) standard, this was out of reach for most of the small-scale growers in Pakistan. The Pakistan Horticulture Development and Export Company (PHDEC) had proposed a PakGAP standard as a more affordable complementary option. This approach was an important step in the right direction, but the standard lacked international recognition, without which it would remain ineffective.

Intellectual property rights system

Being a signatory to the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement under the WTO, Pakistan was required to upgrade its intellectual property (IP) infrastructure. Pakistan had already created the Intellectual Property Organization of Pakistan (IPO-Pakistan) in 2005 as a focal organization for integrated management of intellectual property and enforcement coordination. IPO-Pakistan operates under the Cabinet Division of the government of Pakistan.

Several IP measures had been implemented (UNIDO 2010b)—in particular, establishment of Anti-Piracy Cells by Pakistan Customs. To improve public awareness, IPO-Pakistan launched the Public Outreach Initiative for leveraging internal and external IP constituencies, including chambers of commerce and industry, business enterprises, research and development institutions, universities, academia, and the general public. The IPO-Pakistan Policy Board oversaw the drafting of a program for management of copyrights, patents, and trademarks, and in 2010 IPO-Pakistan established an application-receiving and -processing desk in Islamabad for patents, trademarks, copyrights, and industrial design. Initial work was also undertaken to automate the work of the IP registries.

However, much remained to be done if the IP system was to make a meaningful contribution to the country's economic goals. IPO-Pakistan's ability to fully exercise its key role in leveraging the IP system for trade and economic development remained constrained by a lack of human resources and expertise and by the inefficient, paper-based nature of its work methods and procedures. There were still significant gaps in the IP legislative and institutional framework, including accession to certain international agreements and the development of laws to protect geographical indications and plant breeders' rights, which would add value to local potential export products.

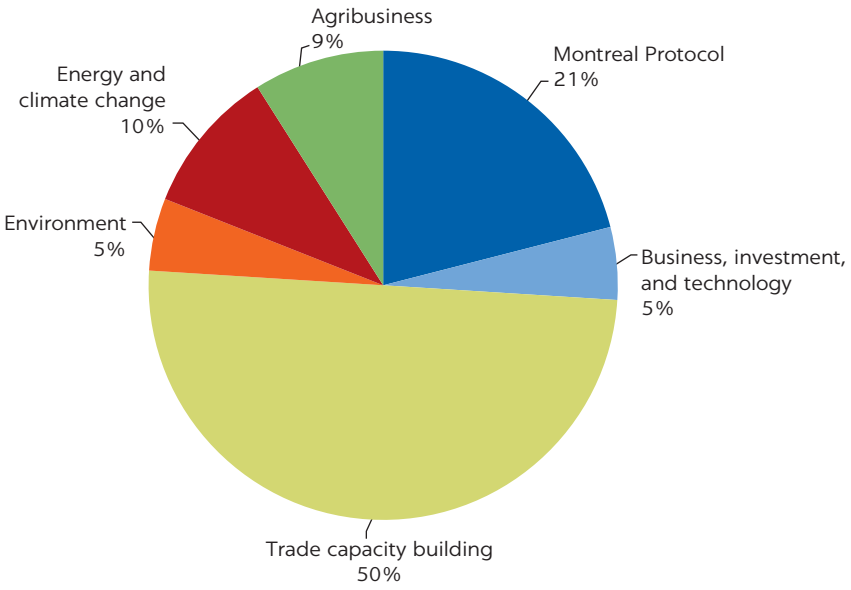
PROJECT OBJECTIVES AND COMPONENTS

UNIDO has been involved in Pakistan since 1965. By the end of 2012, UNIDO had implemented more than 100 projects with a total expenditure of about US$33 million (UNIDO Evaluation Group 2014). From 2000 to 2010, UNIDO implemented its Integrated Programme to support capacity building for sustainable industrial development in Pakistan, covering five components—one of which was the Trade Related Technical Assistance (TRTA) program targeting the QI and related matters. The Integrated Programme had a planned budget of US$21.4 million, excluding project support costs. Since termination of the Integrated Programme in 2010, UNIDO's technical cooperation has been planned and implemented based on individual projects.

The successor to the TRTA I program was the TRTA II program. It was planned for 2010 to 2014 with a budget of US$10.045 million and had three components, one of which addressed the QI issues. Figure 1 presents the overall budget and expenditures aggregated for all the UNIDO projects by main areas,

FIGURE 1

UNIDO projects' fund allocations in Pakistan, 2006–13



Source: UNIDO Evaluation Group 2014.
Note: The Montreal Protocol refers to the 1987 international environmental agreement to protect the stratospheric ozone layer by phasing out the use of substances responsible for ozone depletion.

for 2006–13. Trade capacity-building projects—projects related to the QI, technical regulation, and SPS measures—represented 50 percent of the portfolio in terms of financial resources, followed by Montreal Protocol–related projects with 21 percent. Energy and climate change as well as agribusiness-related projects accounted for around 10 percent each.

Trade Related Technical Assistance, Phase I (TRTA I)

From 2000 to 2010, the UNIDO Integrated Programme to support capacity building for sustainable industrial development in Pakistan was designed and implemented, covering five components:

- *Component 1:* Cleaner Production and Environmental Management
- *Component 2:* Institutional Capacity Building for SME Development
- *Component 3:* Metrology, Standardization, Testing, Quality Assurance, and Continuous Improvement
- *Component 4:* Regional Development
- *Component 5:* Industrial Investment Promotion and Technology Transfer.

The Integrated Programme's objective was stated as "Provide the Pakistani authorities and private sector institutions with technical assistance to support their efforts to build national capacities for sustainable industrial development and enable them to meet their industrial objectives" (UNIDO Evaluation Group 2014, 4). In addition, Component 3's immediate objective was stated as "Strengthen the metrology, standardization, testing and quality assurance capabilities of Pakistan and provide restructuring support to selected enterprises" (UNIDO Evaluation Group 2014, 5).

Only two components were implemented and closed during the Integrated Programme period (2000–10): Institutional Capacity-Building for SME Development (2007–09) and Trade Related Technical Assistance (TRTA I) (2004–08). Of the latter, two program results were relevant to the QI (UNIDO 2008b):

- *Program Result 4:* Completion of a full assessment of the constraints faced by Pakistan's exporters in relation to TBT and SPS standards
- *Program Result 5:* Improved capacity of Pakistan's export industry to comply with standards and certification requirements resulting from improved accreditation and conformity assessment practices and metrology and testing services.

To facilitate continuity in the development of the QI of Pakistan from 2008 to 2010, UNIDO and Norad provided bridging finances between the TRTA I and TRTA II programs funded by the EU.

From TRTA I to TRTA II

TRTA extended from 2004 to the end of TRTA II in 2014 (table 2). TRTA I, the three bridging phases, and TRTA II had a total duration of 9.25 years and an overall budget of €13.4 million. The EC provided the bulk of the funding, with a total contribution of €12.045 million. UNIDO financed the first and third Bridging Phases and contributed to TRTA II, with a total contribution of €892,000. Norad financed the second Bridging Phase with €456,000.

TABLE 2 **TRTA phases, duration, budget, and donors in Pakistan, 2004–14**

PHASE	YEAR(S)	DURATION	BUDGET (€, MILLIONS)	DONOR(S)
TRTA I	2004–07	36 months	2.50	EC
Bridging Phase 1	2007–08	6 months	0.34	UNIDO
Bridging Phase 2	2008–09	12 months	0.46	Norad
Bridging Phase 3	2009	3 months	0.06	UNIDO
TRTA II	2010–14	54 months	10.05	EC, UNIDO
Total	2004–14	9.25 years	13.40	EC, Norad, UNIDO

Source: UNIDO Evaluation Group 2014.
Note: Budget figures are rounded. EC = European Community; Norad = Norwegian Agency for Development Cooperation; TRTA = Trade Related Technical Assistance; UNIDO = United Nations Industrial Development Organization.

Trade Related Technical Assistance, Phase II (TRTA II)

Objectives

TRTA II, a follow-up to TRTA I, was funded by the EU. The financing agreement was signed by the EC in June 2009 and countersigned by the government of Pakistan in August 2009. Total program value was €10.045 million, made up of €9.545 million from the EC and €0.5 million from UNIDO, which managed overall program implementation. The program started in January 2010, with a planned implementation period of 54 months, until June 2014 (UNIDO 2010b).

The overall objective of TRTA II was to contribute to poverty reduction and sustainable development in Pakistan. The specific purpose was to support the economic integration of Pakistan into the global and regional economy and to stimulate decent work and employment creation by increasing exports and enhancing the enabling climate for international trade (UNIDO 2010b).

The principal stakeholders of the program were the Ministry of Commerce (MoC), MoST, Ministry of Food and Agriculture, Ministry of Livestock and Dairy Development, Ministry of Industries and Production, and IPO-Pakistan, as well as technological institutions and Competent Authorities operating under the aforementioned ministries.[11] Private sector associations concerned with the fisheries, horticulture, produce, and industrial clusters were also identified as beneficiaries of implementation activities.

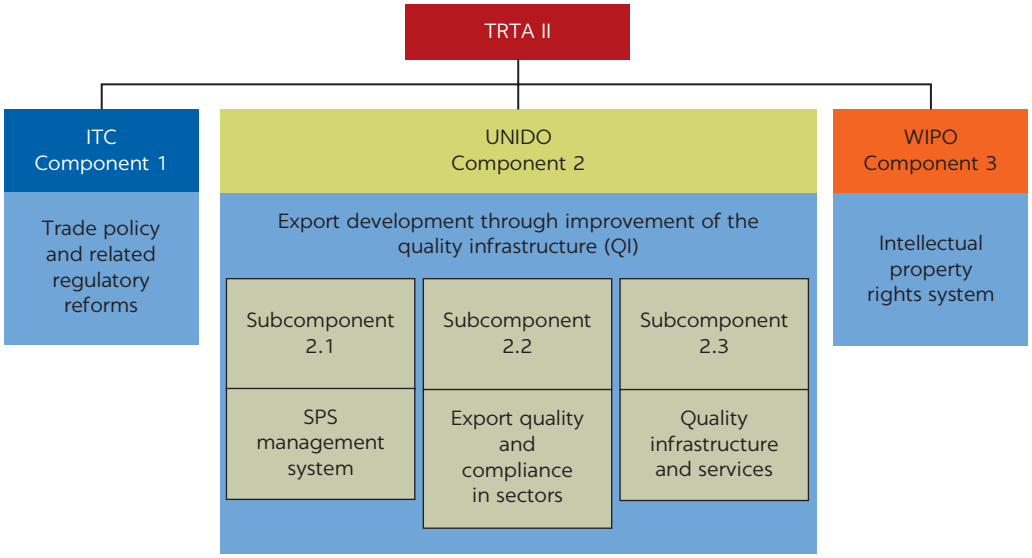
The program's overall objective and specific purpose were designed with relevant policy objectives of the parties in mind. Hence, the program was aligned with the Poverty Reduction Strategy Paper (2004) and the Strategic Trade Policy Framework (2009–12) of Pakistan, as well as with the Pakistan-European Community Country Strategy Paper for 2007–13 (EC 2007; IMF 2004; MoC 2009). The importance of international trade development for poverty reduction was further emphasized by the Second EU-Pakistan Summit held in Brussels in June 2010.

TRTA II components and management

The TRTA II program was a complex, wide-ranging project whose activities were implemented through three components. Its overall design is shown in figure 2, the budget allocations for the various components are shown in table 3, and the components are further described in table 4 (UNIDO Evaluation Group 2014).

UNIDO, as the program's lead implementing agency, established a field-based program management office headed by a chief technical adviser in Islamabad

FIGURE 2
Overall design of TRTA II program in Pakistan, 2010–14



Source: UNIDO Evaluation Group 2014.
Note: ITC = International Trade Centre; SPS = sanitary and phytosanitary; TRTA II = Trade Related Technical Assistance, Phase II; UNIDO = United Nations Industrial Development Organization; WIPO = World Intellectual Property Organization.

TABLE 3 **TRTA II budget, by component and subcomponent, 2010–14**

COMPONENT OR SUBCOMPONENT	BUDGET (EUROS)
Component 1 (ITC): Trade policy capacity building	1,040,000
Component 2 (UNIDO): Export development through the improvement of QI	7,108,400
Subcomponent 2.1: Support for SPS management capacity	1,107,460
Subcomponent 2.2: Support for improved quality and value added	1,495,820
Subcomponent 2.3: Improvement of conformity assessment infrastructure	3,530,490
Program coordination and management[a]	974,630
Component 3 (WIPO): Strengthening of the IPR system	1,163,000
Contingency	83,600
Total	9,395,000

Source: UNIDO 2010b.
Note: IPR = intellectual property rights; ITC = International Trade Centre; QI = quality infrastructure; SPS = sanitary and phytosanitary; TRTA II = Trade Related Technical Assistance, Phase II; UNIDO = United Nations Industrial Development Organization; WIPO = World Intellectual Property Organization.
a. The UNIDO coordination and management function budget is listed under Component 2 but pertains to all three components.

with 14 staff for TRTA II activities, guided by a program manager at UNIDO headquarters in Vienna. The Ministry of Commerce (MoC) would be the focal point on the Pakistan government's side, and it would have a role in the coordination, monitoring, and evaluation of TRTA II. The program's overall strategic policy and direction was to be guided by the Program Steering Committee (PSC), whose composition and terms of reference were developed during the inception phase. The PSC was cochaired by EC and MoC representatives.

As for the three TRTA II components (figure 2 and table 4), UNIDO managed Component 2 (QI development) in totality. For Component 1 (trade policy) and Component 3 (intellectual property), UNIDO negotiated two interagency

TABLE 4 TRTA II program components and key indicators, 2010–14

COMPONENT	EXPECTED RESULT	THEMATIC AREAS	KEY VERIFIABLE INDICATORS
Component 1 Trade policy capacity building	A coherent trade policy and regulatory reform for export competitiveness	• Strengthening PITAD's institutional capacity • Strengthening PITAD's and other research institutes' expertise on trade policy • Strengthening government officers' capacity on specific trade policy and international trade negotiations • Contributing research studies to development of a national export strategy • Fostering public-private dialogue on a coherent national export strategy	Institutionalization of a well-informed public-private dialogue on the design, implementation, and monitoring of trade policy and regulatory reform
Component 2 Export development through improvement of quality infrastructure (QI)	Improved compliance of exported products with export market requirements	• Strengthening sanitary and phytosanitary (SPS) controls • Improving quality, value addition, and compliance with market requirements of supply chains of selected sectors (fisheries, horticulture, and industrial products) • Improving conformity assessment infrastructure and services	Increase of 5 percent by 2014 in average unit export value in fishery and horticulture
Component 3 Strengthening of the intellectual property (IP) rights system	A modernized IP system that facilitates increased investment and trade in IP-protected goods and services	• Strengthening IP institutions • Strengthening IP legislative and policy framework • Enforcing IP rights • Enhancing capacity of businesses and research institution to use the IP system	Increase of 25–30 percent by 2014 in efficiency in registrations of IP titles (patents, trademarks, industrial designs, copyright, and so on)

Source: UNIDO Evaluation Group 2014.
Note: PITAD = Pakistan Institute of Trade and Development; TRTA II = Trade Related Technical Assistance, Phase II.

agreements, one with the International Trade Centre (ITC) and one with the World Intellectual Property Organization (WIPO) to take the lead, because they were recognized international institutions in these matters. The ITC had long-term field officers stationed in Islamabad, whereas WIPO managed its component from Geneva and fielded only short-term specialists in Pakistan.

The program envisaged regular consultations with other development partners and programs in areas relating to trade development to avoid overlap and foster complementary delivery of activities. These partners and programs included the following:

- *U.S. Agency for International Development (USAID)* "Empower Pakistan: Firms" project (US$90 million, 2009–13), which supported enterprises in economic sectors important for Pakistan's export performance
- *USAID* "Empower Pakistan: Trade" project (US$22 million, 2009–13)
- *World Bank (International Development Association)* "Trade and Transport Facilities-II" project (US$25 million, 2009–14), which supported implementation of the National Trade Corridor Improvement Program
- *Asian Development Bank (ADB)* "Sindh Coastal Community Development Project" (US$40 million, 2007–13)
- *Food and Agriculture Organization (FAO)* "Capacity Enhancement Assistance to the Ministry of Food, Agriculture and Livestock" in WTO-related policy and strategy (US$0.7 million, 2005–10)
- *International Fund for Agricultural Development (IFAD) and Pakistan–Italian Debt Swap Agreement* for Balochistan Coastal Area and Fisheries Development (US$25 million and US$5 million, respectively, planned for 2011–16).

PROJECT DESIGN AND IMPLEMENTATION

TRTA I program

Pakistan National Accreditation Council (PNAC)

A series of discussions between Norad, Norwegian Accreditation (NA), UNIDO, and PNAC in August–September 2005 identified the technical support to be provided and coordinated the UNIDO TRTA and Norad-NA interventions in accreditation support to PNAC and Pakistan (UNIDO 2008b). The joint UNIDO-NA intervention focused on capacity development of PNAC to meet the requirements of ISO/IEC 17011 ("Conformity Assessment—Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies"),[12] including the following:

- Assessment of PNAC's organizational structure and operations
- Elaboration of master plan for PNAC
- Capacity building in laboratory accreditation through training of assessors (28) from various laboratories and PNAC in ISO/IEC 17025
- Development of a pool of external assessors (15) through attachments as observer trainees with NA assessors during the assessment of Pakistani laboratories
- Capacity building in accreditation of certification bodies through training of PNAC staff in ISO/IEC Guide 62 ("General Requirements for Bodies Operating Assessment and Certification/Registration of Quality Systems")[13]
- Sponsorship of three PNAC staff for training abroad in ISO/IEC Guide 62 and cross-frontier accreditation[14]
- Training of PNAC staff abroad in inspection bodies accreditation in ISO/IEC 17020 ("Conformity Assessment—Requirements for the Operation of Various Types of Bodies Performing Inspection")[15]
- Training of PNAC staff abroad in management of national proficiency testing scheme.

All of these activities were designed to eventually lead PNAC toward international recognition of its accreditation operations through the conclusion of a Mutual Recognition Arrangement with ILAC and a Multilateral Recognition Agreement with the IAF. In addition, UNIDO and NA coordinated their efforts to develop a pool of technical assessors and auditors in ISO 9000 (quality management), ISO 14000 (environmental management), and hazard analysis and critical control points (HACCP).[16]

National Physics and Standards Laboratory (NPSL)

Activities carried out to strengthen the national metrology infrastructure in Pakistan through support of the NPSL included the following (UNIDO 2008b):

- Renovation of the six NPSL metrology laboratories for mass, dimensional, volume, pressure, temperature, and electrical measurements in accordance with international criteria, with government funding and TRTA technical advice and support
- Installation and commissioning of an environmental conditioning system for the six NPSL metrology laboratories to enable the conduct of internationally traceable measurement and calibration services under internationally acceptable criteria of environmentally controlled conditions
- Supply of E1 class mass pieces (the national reference standard for mass for Pakistan) and state-of-the-art mass comparators for use by the NPSL's renovated Mass Metrology Laboratory

- Improvement of skills of the management staff of NPSL through study tours to NMIs in high-income and low- and middle-income economies of relevance for application to Pakistan
- Review of the quality documentation of NPSL and presentations on quality management issues to NPSL technical staff.

The interventions were designed to enable NPSL to carry out and provide to Pakistan commerce and industry traceable measurement and calibration services under internationally acceptable criteria of environmentally controlled conditions and, hence, to enable the mass, dimensional, volume, pressure, temperature, and electrical measurement laboratories to achieve internationally recognized accreditation to ISO/IEC 17025.

Pakistan Standards and Quality Control Authority (PSQCA)

The TRTA I interventions to strengthen the PSQCA so that it would become a more effective NSB and to establish a national certification body included the following (UNIDO 2008b):

- Establishment and operation of a Consumer Liaison Office at the PSQCA for enhanced participation of consumer organizations in standards setting and comparative product testing
- Establishment and operation of the WTO TBT National Inquiry Point to enable the PSQCA to function effectively under the WTO TBT Agreement
- Improvement of standards development activities through provision of technical advice and elaboration of guides
- Improvement of product certification operations through provision of technical advice and elaboration guides and a business plan
- Alignment of PSQCA operations with international practice through provision of technical advice and development of corporate plans
- Improvement of skills of management and technical staff through local and foreign training of PSQCA staff members
- Enhancement of PSQCA capacity to participate expeditiously and effectively in international standardization work through online networking with the ISO activities and information system.

In addition to the general activities, the TRTA I program endeavored to establish a System Certification Centre at the PSQCA for ISO 9000, ISO 14000, ISO 22000 (food safety management),[17] HACCP, and SA 8000 (social accountability)[18] certification. These interventions included the following:

- After an evaluation of the Pakistani certification market, a concept paper was developed to establish a Pakistan system certification body as a public-private partnership but within the PSQCA.
- The System Certification Centre (SCC) was established at the PSQCA through TRTA technical advice and support.
- The chief executive of the SCC received training abroad in system certification.
- The government allocated resources for recruitment of technical staff to conduct the operations of the SCC, after which certification of selected enterprises to ISO 9000, ISO 14000, ISO 22000, HACCP, and SA 8000 would be carried out.

A new SCC chief executive was appointed in May 2007 upon transfer of the initial chief executive to assume other responsibilities at the PSQCA. The management documentation and operational procedures of the SCC activities were under preparation but stalled under the new chief executive. Hence, the recruitment of technical staff and launch of operations were put on hold as well. The conduct of an auditor training program and certification of selected pilot enterprises to ISO 9000, ISO 14000, HACCP, and SA 8000 envisaged in the project planning stage were not carried out because the SCC did not become operational before closure of the TRTA I program.

Laboratories

A group 19 testing laboratories (selected out of 29 reviewed) were prepared for accreditation to ISO/IEC 17025, covering the textile, leather, agroprocessing, fisheries, and electrical sectors, as follows (UNIDO 2008b):

- Microbiology testing (6 laboratories)
- Chemical testing (7 laboratories)
- Textile testing (3 laboratories)
- Leather testing (2 laboratories)
- Electrical testing (1 laboratories).

The support activities for the selected testing labs included

- Expert advice on laboratory layout, testing activities, and quality documentation;
- Formulation of an accreditation plan and close monitoring of planned activities;
- Provision of laboratory equipment, reference cultures, and technical literature;
- Local and foreign training of laboratory staff;
- Participation in international proficiency testing schemes;
- Initial assessment by an accreditation body; and
- Extraordinary assessment by an accreditation body.

The NA conducted initial assessment of the 18 testing laboratories in January–February 2007 and May–June 2007. The 19th testing laboratory was deferred for assessment to December 2007 to allow the method validation process for histamine testing to be finalized. The 18 testing laboratories assessed by NA achieved accreditation in September 2007 following closure of nonconformities raised during the assessments and subsequent verifications made through extraordinary visits by NA.

The NA-issued certificates of accreditation were presented to the 18 testing laboratories in an award ceremony held in November 2007 in Lahore, attended by senior government officials, EU and UNIDO representatives, and a large group of scientists and public and private sector participants.

Fisheries

UNIDO's TRTA I support to the fisheries sector was provided on request of the Ministry of Food, Livestock and Agriculture and agreed to by the EC delegation. This support was quite extensive and focused on four areas: the Marine Fisheries Department, the Karachi Fish Harbour Authority, the Fishermen Cooperative Society, and fish processing plants (UNIDO 2008b).

Marine Fisheries Department (MFD). The TRTA I support strengthened the MFD's capacity and operations by:

- Developing a comprehensive inspection manual in accordance with international practice for the MFD's purpose and use;
- Upgrading the MFD's microbiology testing laboratory and helping it achieve internationally recognized accreditation to ISO/IEC 17025;
- Preparing the MFD's chemical testing laboratory for internationally recognized accreditation to ISO/IEC 17025; and
- Improving the skills of the MFD's senior management and inspection staff through training abroad and local training in standard operating procedures as well as in HACCP and traceability methods.

These interventions were designed to enable the MFD to perform satisfactorily as the EU-designated Competent Authority for Pakistan.

Karachi Fish Harbour Authority (KFHA). Capacity improvement of the KFHA comprised:

- Renovation and operationalization of the two fish auction halls (K-1 and K-2), with the largest fish auction hall in Karachi handling more than 450 tons of fish daily;
- Skills development of KFHA inspectors in standard operating procedures and HACCP practices to apply good hygiene practices at landing sites and auction halls; and
- Capacity improvement in management of the fish harbor facilities.

These interventions were designed to facilitate compliance of the handling of fisheries' products with good international practices at landing sites and auction halls.

Fishermen Cooperative Society (FCS). The capacity development of the FCS included improvements in the operations of fishermen, boat owners, auction hall operators, and mole holders. The activities made in this regard consisted of:

- Upgrades to 175 Hilla boats and 50 trawlers in accordance with the recommendations of international experts;[19] and
- Skills development of more than 500 fishermen, boat owners, auction hall operators, and mole holders in standard operating procedures to ensure good hygiene practices in the handling of fisheries' products.

These interventions were designed to facilitate compliance with requirements related to activities ranging from primary production to the auctioning of fisheries' products.

Fish processing plants. The activities in capacity improvement of the fish processing plants consisted of:

- Skills development of processors' staff in HACCP and traceability methods and practices;
- Implementation of HACCP practices by developing and applying HACCP plans specific to each fish processing plant;
- Employment of handheld, personal computer (PC)–compatible traceability instruments for recording the traceability of fisheries' products processed for export; and
- Application of paper-based traceability systems at processing plants covering all operations along the entire fisheries chain.

These interventions were designed to enable fish processing plants to meet international requirements of fisheries' exports destined to the EU countries.

TRTA II program

As noted earlier, the TRTA II Program was implemented in three components. Synergy between them was designed into the program from the start. It was envisaged that Component 1 institutions (Pakistan Institute of Trade and Development [PITAD] and other research entities) would develop capacity and undertake trade policy research and analytic studies relevant to the activities carried out through Components 2 and 3—export development and intellectual property (IP) rights, respectively—particularly in relation to sectors linked to high poverty rates (fisheries and horticulture). Component 2 would work with enterprises in these sectors and strengthen institutions dealing with mandatory and voluntary standards. Component 3 would strengthen the IP rights system, again with a focus on IP instruments such as geographical indications and plant breeder rights, which would contribute to the realization of trade and developmental goals (UNIDO 2010b).

The establishment of effective private-public dialogues was an important cross-cutting issue in all three components; hence common public-private dialogues for both horizontal trade-related issues and the specific targeted sectors were established to ensure coherence in program delivery across all components.

Component 1: Trade policy and related regulatory reforms

In 2008, the Pakistan Institute of Trade and Development (PITAD) (formerly the Foreign Trade Institute of Pakistan) was restructured to provide greater focus on strategic research on trade policy and to become Pakistan's premier body on trade capacity building and human capital development for commerce. PITAD had since strengthened its team of researchers, trainers, and support staff and became fully functional as an independent policy think tank and training center on international trade.

But although Pakistan had taken positive steps to establish the institutional framework for development of trade policy, more needed to be done to operationalize the organization. The specific purpose of TRTA II Component 1 was aimed at the government of Pakistan, but more specifically at the Ministry of Commerce (MoC), for developing a coherent trade policy and attendant regulations for export competitiveness, as envisioned in the MoC's Strategic Trade Policy Framework 2009–12 (MoC 2009). Hence, the activities of Component 1 constituted the following:

- Strengthening PITAD's institutional capacity by providing updated tools and publications based on actual needs as well as advice on their use
- Strengthening PITAD's and other research institutes' expertise on trade policy (after a needs assessment of ministries and implementing governmental agencies as well as key institutes) by enhancing specialized training programs to align with international best practices
- Strengthening government officers' capacity on specific trade policy and international trade negotiations through a series of six short (two- to three-day) training sessions on trade policy
- Conducting research studies to establish a coherent framework for trade policy and regulatory reform for a national export strategy
- Fostering a public-private dialogue for a coherent national export strategy.

Component 2: Improved compliance of exported products

Component 2 comprised three subcomponents designed to provide a holistic approach to improving the compliance of exported products with standards and technical regulations in export markets. They dealt with the SPS management system, export quality, and compliance in selected sectors, and with QI-related capacity building to support the other two subcomponents.

Subcomponent 2.1: SPS management system

As noted earlier, the food safety system of Pakistan was totally fragmented and, for all intents and purposes, ineffective. Therefore, the TRTA II approach was to

- Strengthen the coordination of SPS issues by the government of Pakistan;
- Implement new and better-coordinated controls, particularly in relation to food safety and plant health to respond to mandatory and voluntary quality standards;
- Improve productivity and value added at the enterprise level (subcomponent 2.2); and
- Establish the necessary QI support services (subcomponent 2.3).

To address the need for a holistic integration of SPS controls, the government of Pakistan, through the Ministry of Food and Agriculture, established the National Animal and Plant Health Inspection Service (NAPHIS) with its own premises and professional staff complement. Although it had established a number of activities, NAPHIS had not been able to develop any coherent policy proposal for the development of an SPS management system.

These developments increased the need for interventions to improve SPS coordination. NAPHIS had a clear opportunity to lead and coordinate important developments in the SPS area, but it needed to establish its credibility by taking the policy lead for strengthening the SPS management system in Pakistan, with a focus on food safety. Hence, the activities to achieve the goals of Subcomponent 2.1 constituted the following:

- *Strengthening the SPS management system*, starting with SPS policy development and followed by the development of new food safety and phytosanitary laws and model technical regulations
- *Enhancing application of food safety controls* by developing inspection guidelines, manuals, and checklists; providing inspection equipment; and building the technical capacity of the food safety inspection staff.

Subcomponent 2.2: Export quality and compliance in selected sectors

Industrial sectors suffered from (a) lack of awareness of market requirements, and (b) use of outdated management and productivity tools. Strategic direction for meso-level interventions to support the improvement of quality and productivity was only weakly defined. The TRTA II program results in this component were therefore designed to support exporters by building the capacity of private and public organizations that were in a position to provide support services (such as technical advice, training, public infrastructure investment, and incentive schemes).

In the fisheries and horticulture sectors, the program would help strengthen public and private investment planning in supply chain infrastructure (such as fish landing sites) and would support the development of business arrangements along the global supply chain to identify key bottlenecks in the establishment of business links between international buyers and Pakistani exporters.

Hence, this subcomponent focused on the following activities:

- *Strengthening the competitiveness of meso-level agencies* and service providers through technical advice and training
- *Improving competitiveness in selected pro-poor manufacturing sectors* through recommendations and technical advice on value-added production, leading to certification to recognized standards
- *Improving competitiveness in the fishery sector* with proposals to improve branding, marketing, and supply chain performance as well as business planning
- *Improving competitiveness in the horticulture sector* with development and dissemination of codes of practice and their pilot implementation in the kinnow and mango sectors and in the provision of associated training
- *Improving consultancy services and the certification of enterprises* through (a) the training and qualification of trainers and consultants in management systems, in collaboration with the National Productivity Organization; (b) the certification of 40 enterprises; and (c) support to 10 selected enterprises to achieve Conformité Européenne (CE) marking of products[20]
- *Developing business arrangements along the international supply chain* by establishing links between local producers and international buyers in markets for fisheries, horticulture, and selected industrial products as well as promoting cost-effective freight forwarding and export logistics, including cold chain.

Subcomponent 2.3: QI-related development

During the TRTA I program, some progress had been achieved in developing internationally recognized QI services in Pakistan. The TRTA II program built on this progress to develop the QI services to a level where they could be internationally recognized, with the intention that they would be able to provide the conformity assessment services required by the export sectors envisaged for TRTA II support. Hence, the activities to achieve the result of this subcomponent constituted the following:

- *Support for the development of technical regulations and voluntary standardization* (including enhancement of the participation of the private sector and consumers) as well as technical advice to fully operationalize the PSQCA as the national WTO TBT Inquiry Point and hence as the national notification body
- *Technical advice to national metrology services* in the development of measurement and calibration capabilities in the areas of mass, length, volume, temperature, pressure, and electrical quantities (accreditation of six metrology labs); establishment of a proficiency testing (PT) scheme for chemical and microbiological testing; provision of metrology equipment; and achievement of internationally recognized accreditation of the NPSL's metrology laboratories
- *Support for the national accreditation service* through training and certification of personnel to strengthen the pool of external assessors, helping PNAC to achieve Multilateral Recognition Agreement signatory status with the IAF, and providing technical advice in the accreditation of PT schemes
- *Support for the testing laboratories* in the form of technical advice and provision of subcontract services to (a) achieve internationally recognized accreditation of 24 testing laboratories; (b) facilitate PT participation and provision of certified reference materials or reference cultures to the testing laboratories targeted for accreditation; and (c) develop business plans to commercialize the testing services of the laboratories to ensure sustainability.

Component 3: Intellectual property rights system

Although Pakistan had established its Intellectual Property Organization (IPO-Pakistan) in response to its obligations under the WTO TRIPS Agreement, IPO-Pakistan's effectiveness was constrained by a lack of human resources and expertise as well as the inefficient, paper-based nature of its work methods and procedures. In addition, Pakistan had not acceded to certain international agreements and had failed to develop laws to protect geographical indications and plant breeders' rights, which could add value to local export products.

Enforcement mechanisms needed to be strengthened, especially by enhancing the capacity of enforcement agencies to train their IP-related officials on their own in a sustained manner. Most importantly, measures needed to be taken to enable businesses to leverage IP for increased innovation and competitiveness. These measures included promoting the commercialization of the outputs of Pakistan's research and higher-education infrastructure. Furthermore, the business sector's and other stakeholders' involvement in IP policy exercises needed to be strengthened.

Hence, the activities to achieve the goals of this subcomponent entailed

- Strengthening the IP institutions;
- Strengthening the IP legislative and policy framework;
- Improving the enforcement of IP rights; and
- Increasing the use of IP systems by businesses and research institutions.

Stakeholders and their roles

Many stakeholders were involved in the development of the Pakistani QI and the development of selected industrial sectors. The principal stakeholders were the MoC, MoST, Ministry of Food and Agriculture, Ministry of Livestock and Dairy Development, Ministry of Industries and Production, and IPO-Pakistan, as well as the technological institutions and Competent Authorities operating under the aforementioned ministries. The MoC was the main counterpart because of the trade focus of the interventions, but other ministries also played important roles; for example, MoST was the line ministry of the three pinnacle QI organizations (the PSQCA, the NPSL, and PNAC).

At the institutional level, the three pinnacle QI institutions received much of the development support, but others, such as the PCSIR, benefited as much if not more regarding laboratory development, and it was the home of the NPSL. All of these QI organizations played meaningful roles in the development of the National Quality Policy under the leadership of MoST, especially in developing the draft implementation plan. As for the draft food safety legislation, NAPHIS was one of the main stakeholders involved in the process; and for the fisheries-related projects, the Marine Fisheries Department and the Karachi Fish Harbour Authority were the main regulatory authorities involved.

Private sector associations concerned with fisheries, horticulture, produce, and industrial clusters were also identified as beneficiaries of implementation activities. Of specific note was the involvement of the Fishermen Cooperative Society, which cooperated in getting the fishermen, boat owners, auction hall operators, and mole holders involved and motivated.

The MoC initiated a trade-related donor coordination that was largely facilitated by UNIDO as one of the major development agencies in this sector. Information was collected and analyzed on the 21 major donors in trade, and the first donor coordination meeting was held in February 2013, chaired by the secretary of the MoC and the EC delegation. Donors decided to establish

regular coordination meetings and specific focus groups. Direct collaborations were also organized through the TRTA II program with the Australia–Pakistan Agriculture Sector Linkages Program in the horticulture sector, the Centre for the Promotion of Imports (Netherlands) in the surgical industry, and the FAO in animal health legislation (UNIDO 2013a).

RESULTS ACHIEVED

The results and outcomes of the two programs—TRTA I and TRTA II—are not presented individually (for each of the programs) but in totality because many interventions of the one flowed into the other.

Identifying TBT and SPS constraints faced by exporters

Three surveys relating to TBT and SPS constraints faced by Pakistani exporters were conducted during the TRTA I program. All of these reports were used by UNIDO and other development agencies as input to development project planning. The TRTA II program in particular benefited from the QI-related needs quantified in these reports.

Technical barriers to trade (TBT). A survey identified compliance challenges that 157 Pakistani exporting firms faced in complying with TBT and SPS requirements. The sectors covered in this survey included textiles, leather, agroprocessing, and fisheries. The survey report—"Trade Related Challenges Facing Exporters in Pakistan"—was published and widely disseminated to government departments, exporters, industry, and public and private sector institutions, including the donor and international community in Pakistan (PIDE 2007).

Sanitary and phytosanitary (SPS) compliance. A study of SPS compliance was conducted jointly by the World Bank and UNIDO, covering the horticulture, livestock, meat, and fisheries sectors. The survey findings were reported in "Pakistan's Agro-Based Exports and Sanitary and Phytosanitary (SPS) Compliance" (World Bank and UNIDO 2006). The report included a detailed action matrix for enhancing trade-related SPS management capacity in Pakistan to address the SPS constraints and shortcomings identified by the study. The report was published and widely disseminated to federal and provincial government departments, industry, and public and private sector institutions in Pakistan.

Compliance issues affecting enterprise clusters. A survey covering 195 Pakistani enterprises was conducted on compliance issues affecting the enterprise clusters in Punjab province, namely textiles and textile garments, sporting goods, cutlery, fans, and tangerine and mango clusters. The survey results were reported in "Compliance Issues Affecting Enterprise Clusters in Punjab Province of Pakistan" and were widely distributed to federal and provincial government departments, industry, exporters, and public and private sector institutions in Pakistan (UNIDO 2010a).

Developing a national QI

A national QI consists of institutions engaged in standardization, metrology, testing, inspection, certification, and accreditation. If such infrastructures and services are not available in the country, or are not internationally recognized for

their accuracy, companies are obliged to source such services (product testing, equipment calibration, and certification against ISO or other standards) abroad. This process is usually expensive, time-consuming, and complicated, and hence often excludes SMEs from the use of such services.

On the other hand, having such infrastructures and services locally established—provided they are internationally recognized for their accuracy and considered equal to such services as provided abroad—allows a broad base of companies (but also local governments, consumer protection actors, and so on) to quickly access cheaper, more reliable services. The development of the Pakistani national QI made great strides in the years 2005–13, but there were also failures and persistent challenges, as detailed below.

Pakistan Standards and Quality Control Authority (PSQCA)

During the initial TRTA I program, the PSQCA received a fair amount of technical support to streamline its standardization activities, including better online networking with the ISO's activities and information system. The establishment of a Consumer Liaison Office and the national WTO TBT Inquiry Point are specifically noteworthy.

The establishment of a System Certification Centre (SCC) under PSQCA auspices started well, with agreement and financial support from government based on a sound business plan developed with technical support from TRTA experts. Unfortunately, personnel movements within the PSQCA and the lack of interest of the newly appointed CEO of the SCC led to major holdups in the development of procedures and the appointment of personnel. Consequently, the planned training of auditors, development of quality documentation, implementation of sound procedures, and preparation for accreditation during TRTA I did not take place (UNIDO 2008b). The SCC did not recover from these setbacks and was dissolved before the end of TRTA II.

The PSQCA was not really the focus of the TRTA II program, even though some further training of the WTO TBT Inquiry Point personnel took place. The PSQCA's organizational structure was evaluated in the context of the development of the national quality policy (NQP), but no further action was taken to address its shortcomings because the NQP had not been approved by the end of TRTA II.

Pakistan National Accreditation Centre (PNAC)

One of the main achievements of providing support to PNAC was the development of a master plan early during the program for PNAC's international recognition. This was based on in-depth evaluations of its organizational structures, practices, and future business opportunities. All other interventions were based on this master plan and included the training of 35 assessors and 28 lead assessors from both PNAC and various laboratories, providing practical training to 16 of these assessors through attachments as observer assessors with Norwegian Accreditation (NA) assessors during the assessment of Pakistani laboratories as well as training of PNAC staff in ISO/IEC 17020 and ISO/IEC Guide 43 ("Conformity Assessment—General Requirements for Proficiency Testing")[21] (UNIDO 2014a).

PNAC finally achieved Mutual Recognition Arrangement signatory status with the Asia Pacific Laboratory Accreditation Cooperation (APLAC) and ILAC for testing and calibration laboratories (ISO/IEC 17025) in May 2009 and was also successfully reevaluated in 2013 for continued recognition in this regard.

In the same year, it achieved signatory status with the IAF Multilateral Recognition Agreement for its ISO 9001 and ISO 14001 ("Environmental Management Systems—Requirements with Guidance for Use") accreditation systems.[22]

After obtaining its international accreditation in 2009, PNAC started accrediting laboratories on its own. By the end of 2013, it had successfully accredited 56 laboratories in Pakistan at a considerably lower cost to the laboratories compared with accreditation from abroad. Another 20 were in process. The number of laboratories in Pakistan that could be accredited was estimated at about 400 (UNIDO 2008a, 2010c, 2011, 2013a, 2014b, 2015).

National Physical and Standards Laboratory (NPSL)

In 2004, no national accredited on-site calibration capacity was available to calibrate laboratory equipment (balances, incubators, autoclaves, furnaces, and so on) in the approximately 400 laboratories of the country. The main TRTA partner to develop the metrology system has been the third pillar of the federal QI, the NPSL. TRTA I first provided support to the NPSL for the necessary hardware and upgrading of civil works and started developing the human resources through exposure trips and specialized training.

After successfully mastering all conformities, six NPSL labs were accredited by PNAC in 2012 with the support of the TRTA II program. By the end of 2013, the NPSL offered 55 internationally recognized on-site calibrations to laboratories and had calibrated more than 120 different types of equipment, and the cost to industry for these services had decreased by around 80 percent (UNIDO 2008a, 2010c, 2011, 2013a, 2014b, 2015).

The NPSL has participated in the International Committee for Weights and Measures (CIPM) Mutual Recognition Arrangement since July 2011, but no CMCs had been listed on the KCDB of the BIPM. The NPSL had recorded several supplementary comparisons in the KCDB, and a few KCDB entries have been approved for equivalence, but they have not yet been published as CMCs.[23]

Organizationally, the NPSL is still under the PCSIR. However, to become a fully-fledged NMI, as in other countries, the NPSL should become organizationally independent.

Formulating a national quality policy

During the TRTA I program as well as the subsequent TRTA bridging phases, it became increasingly clear that Pakistan lacked overall coordination of QI-related matters. The TRTA II Program Steering Committee (PSC) consequently initiated the development of a NQP to replace the discredited 2005 version, even though an NQP had not been included in the TRTA II program document (UNIDO 2014b).

The broad objectives of the new NQP were

- To provide a clear demarcation of the responsibilities for metrology, standards, and accreditation and the consequent government commitments;
- To ensure that conformity assessment can be provided by both public and private organizations in a market-related environment as long as they are shown to be technically competent;
- To provide for the development of a technical regulation framework to ensure a common, effective, and efficient approach to their development and implementation across all relevant ministries and their agencies; and
- To apply measures supportive of the preceding objectives.

To develop the NQP, a road map with four main steps was designed and followed under the leadership of MoST and with the support of international experts:

- *Step 1: An appraisal and stock-taking exercise* identified major shortcomings of the current situation.
- *Step 2: Options were developed and presented*, based on a benchmarking exercise with the QIs of Malaysia, Turkey, and Vietnam (UNIDO 2013b), as well as in-depth discussions at workshops involving both the public and private sectors in Lahore, Karachi, and Islamabad. The workshops with the private sector were held without public sector participation to gain an understanding of the private sector's needs without the proceedings being overshadowed with public-private sector sensitivities.
- *Step 3: A working draft of the NQP was formulated* in technical workshops and circulated for comment.
- *Step 4: A National Quality Forum was established* with all relevant stakeholders, including the private sector, to discuss the draft and provide recommendations for further improvement.

The final draft of the NQP was to be submitted to MoST for consideration at the political level and, finally, promulgation, which was planned for 2014. Preparatory work was also undertaken with a working group selected by the National Quality Forum on a detailed implementation plan, including budget requirements. The implementation of the NQP would be a key element of Pakistan's national QI and technical regulation system and would represent a contribution to its sustainability (UNIDO 2016).

Working toward an SPS management system

During TRTA I, the program produced the basic analyses that identified the TBT- and SPS-related conformity problems and deficits then existing in the country. Subsequently, a SPS compliance study was undertaken in collaboration with the World Bank. The study identified serious deficits in food safety, plant health, and animal health control systems and led to the plan to develop an integrated SPS management system with effective food safety control measures (World Bank and UNIDO 2006). The main result of these efforts was that the government of Pakistan formulated, with technical assistance from TRTA II, the National Food Safety Bill. By the end of 2013, the bill had still not been approved at the political level and by parliament.

As a consequence, the National Animal and Plant Health Inspection Service (NAPHIS) continued to operate as a government of Pakistan project, which ended in June 2014. As such, NAPHIS had no regulatory powers, which it would only gain once the National Food Safety Bill was passed in the parliament. Accordingly, the (provincial) Punjab Food Authority, for example, did not formally recognize NAPHIS and had not been interested in collaborating. Because of the delay in establishing NAPHIS as a federal authority, important issues remained pending, and sadly cooperation between the Punjab Food Authority and NAPHIS, but also with TRTA II, stalled despite earlier good collaboration in trainings for SPS management and food safety officers.

Taking a commendable medium- and long-term perspective for building up the SPS regime, TRTA II had successfully initiated and supported postgraduate diploma courses in food safety and control at three universities. A total of

85 students participated in the initial intake, with the first 32 students graduating from the University of Veterinary and Animal Sciences in Lahore (UNIDO 2014b). The university planned to upgrade its course to the MPhil level and to have it accredited by the Royal Environmental Health Institute of Scotland.

Upgrading and accrediting laboratories

Since 2004, 49 laboratories (19 under TRTA I and 30 under TRTA II) had been assisted to obtain ISO 17025 accreditation. The laboratories were initially accredited by the NA and subsequently by PNAC. The upgraded laboratories were in the areas of chemical and microbiological testing, calibration, electrical testing, mechanical and materials testing, and sector-specific textile and leather testing. The performance of the laboratories was evaluated by looking at the volume of tests conducted, their income generated, and the satisfaction of customers in the export sector (UNIDO 2014a).

Data were collected from a total of 30 laboratories in nine institutions that were supported by the TRTA initiative. The institutions and the number of laboratories, and their scopes, were as follows:

- Grain Quality Testing Laboratory, Pakistan Agricultural Research Council (1 laboratory)
- Grain Quality Testing Laboratory, National Agricultural Research Centre (2 laboratories)
- Leather Research Centre (2 laboratories)
- Marine Fisheries Department (2 laboratories)
- National Physical and Standards Laboratory (NPSL) (1 laboratory)
- National Reference Laboratory for Poultry Disease (1 laboratory)
- Pakistan Council of Scientific and Industrial Research (PCSIR), Lahore (10 laboratories)
- Pakistan Council of Scientific and Industrial Research (PCSIR), Karachi (10 laboratories)
- Pakistan Council of Research in Water Resources (1 laboratory).

The performance of the laboratories supported by the TRTA I program before and after their accreditation was recorded—performance being measured by the number of tests performed and revenue generated in 2006 and 2008. The performance of the laboratories supported during TRTA II underwent a more detailed analysis. The number of tests carried out and the revenue generated from such tests within the scope of TRTA II during 2009, 2011, and 2013 were obtained from the laboratories. In addition, the gains to the export sector were determined via a survey or questionnaire to regular customers of the laboratories. A direct comparison of the performance of laboratories under the TRTA I and TRTA II projects would therefore be a bit questionable, but general trends can be observed, as described below.

Performance of laboratories under TRTA I

A survey of 19 accredited laboratories was conducted for 2006 (one year before accreditation) and 2008 (one year after accreditation) within the TRTA I project. The results reflected an increase in number of tests as well as revenue following accreditation. Overall, the number of tests conducted more than doubled during the two years under observation, while revenues from accredited labs in totality tripled by 2008 (UNIDO 2014a).

Performance under TRTA II: testing volumes

The total number of tests carried out increased by 20 percent during 2009–13 (UNIDO 2014a). The largest volumes of laboratory services were in the food processing sector, with test volumes increasing by 46 percent for microbiology testing by and 5 percent for chemical testing during 2009–13 (figure 3).

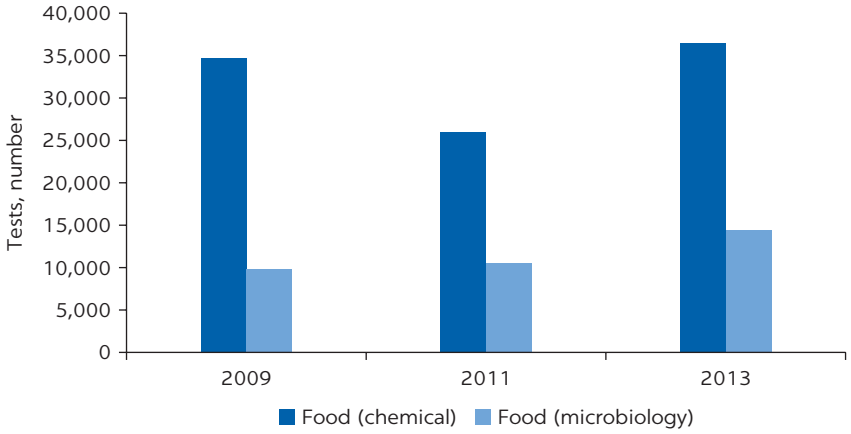
Over the same period the number of services provided for electrical testing recorded a 72 percent increase; and for calibration, a 150 percent increase (figure 4). This is a significant reward for laboratory accreditation, where the need for precision measurements has been recognized by the export sector.

The leather-testing services increased by 40 percent (for physical testing) and by 33 percent (for chemical testing), indicating that a substantial number of exporters or producers have used the locally available, accredited testing services (figure 5).

The textile test count, on the other hand, was just short of a 20 percent increase (figure 5). This increase could be attributed to the increase in demand

FIGURE 3

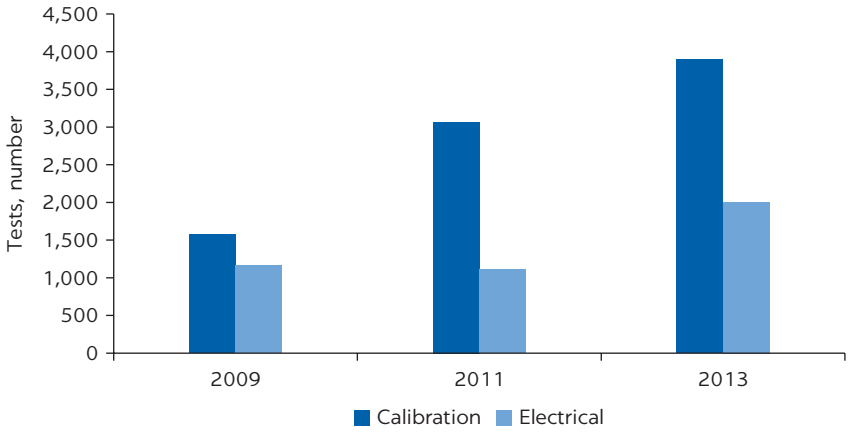
Tests in food laboratories, Pakistan, 2009–13



Source: UNIDO 2014a.

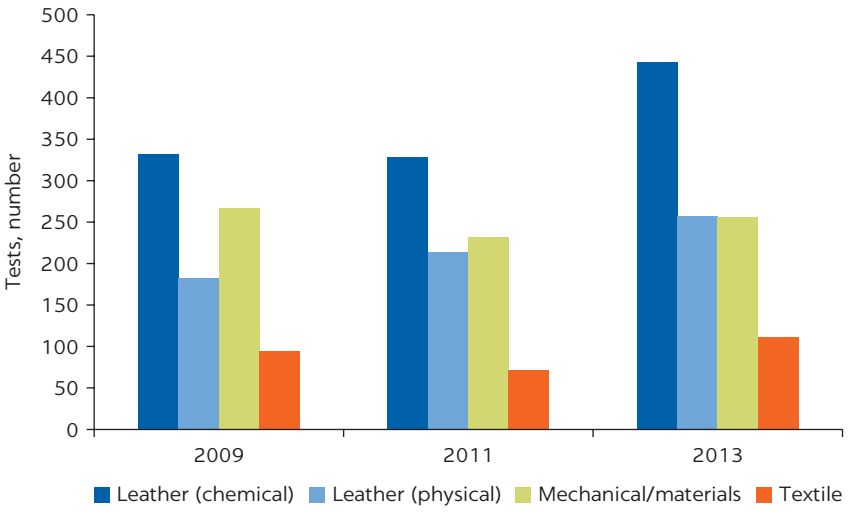
FIGURE 4

Calibration services and electrical tests, Pakistan, 2009–13



Source: UNIDO 2014a.

FIGURE 5
Laboratory tests in selected export sectors, Pakistan, 2009–13



Source: UNIDO 2014a.

for textile testing to meet export market requirements. However, private sector competition emerged from laboratories offering accredited textile-testing services, such as TTI (Textile Testing International). These laboratories are linked with international buyers and textile associations, have a strong marketing strategy, and are serious competitors of the public sector laboratories. The leather and textile sectors are two of the five leading export sectors of Pakistan.

The mechanical and materials testing services recorded an increase of 10 percent from 2011 to 2013, with accreditation achieved in 2013 (figure 5). This was an improvement, given the 13 percent decrease that the laboratory had experienced in 2011 before accreditation.

Performance under TRTA II: revenue generated

The revenue generated from the tests carried out recorded a 60 percent increase from 2009 to 2013 (UNIDO 2014a).

In the food sector, the demand for microbiology testing services rose significantly and recorded more than a 50 percent increase in revenue from 2009 to 2013, while chemical testing displayed a 33 percent increase (figure 6). In fiscal year 2012/13, food exports increased by 4.82 percent, and accredited testing services may have played a role in this increase.

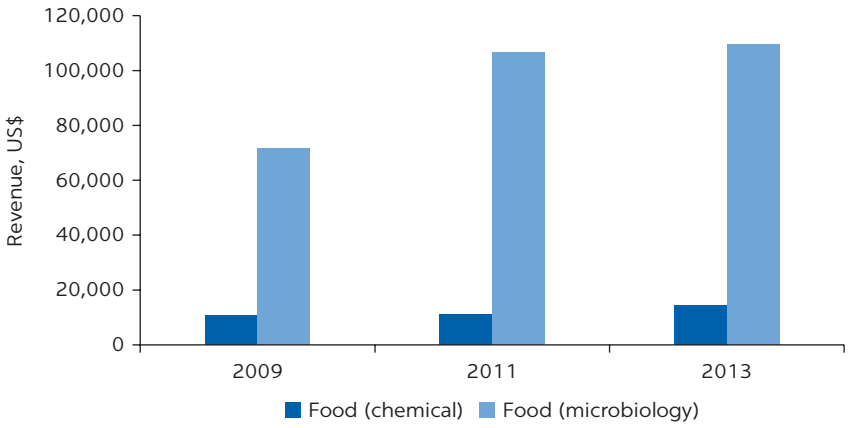
The income from calibration services more than doubled for all three providers, which affirms the benefit to local producers and laboratories and promises future lucrative returns (figure 7). Detailed analysis shows that the laboratories may need to scale up their services to match increasing demands in the sector. Revenue from electrical testing services also more than doubled in 2013, after witnessing only a marginal rise in 2011 (figure 7).

Physical testing of leather products recorded a revenue increase of 55 percent, while chemical testing recorded a 35 percent increase (figure 8). Mechanical and materials testing revenue increased by almost 10 times from 2009 to 2011, and another 8 percent increase was recorded in 2013 after accreditation.

Revenue from textile testing plunged in 2011 by 50 percent owing to a marked decrease in demand for costlier tests such as colorfastness, determination of

FIGURE 6

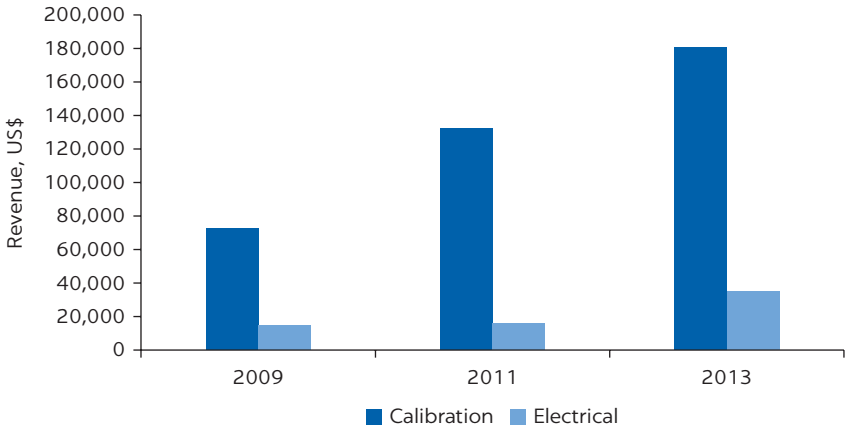
Revenue for food laboratories, Pakistan, 2009–13



Source: UNIDO 2014a.

FIGURE 7

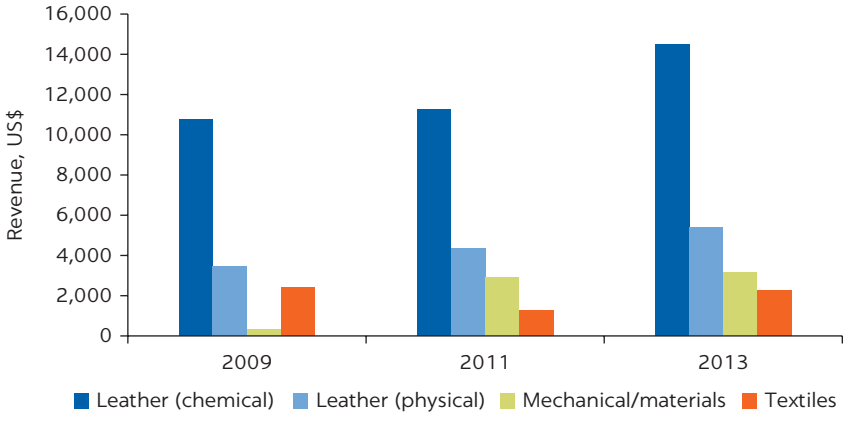
Revenue for calibration and electrical laboratories, Pakistan, 2009–13



Source: UNIDO 2014a.

FIGURE 8

Revenue for physical testing in selected export sectors, Pakistan, 2009–13



Source: UNIDO 2014a.

fabric propensity, and determination of linear density of yarn by the skein method. By 2013, revenues were back up, boasting a 75 percent increase in income generation since 2011 (figure 8). China, one of Pakistan's largest trading partners, increased imports of textiles, textile articles, and leather goods from Pakistan, and if the same trend is maintained, the reliability and quality of these products will remain of utmost priority.

Promoting exports in three sectors

During TRTA I and the subsequent bridging phases, the program had only been active in the fisheries sector. During TRTA II, given its overall pro-poor orientation, horticulture and manufacturing industries were also included as labor-intensive sectors with good export potential.

Within the horticulture sector, the mango and kinnow value chains were selected, based on pragmatic feasibility considerations and export potential, while apricots and dates, for instance, were excluded as being too challenging. In the industrial sector, electric fans, protective gear, and cutlery were selected as nontraditional products with good export potential; however, textiles were ruled out for already receiving sufficient support. During the inception phase in 2010, the program then conducted extensive sector and value chain analyses, which served as sound bases for designing interventions in each value chain (UNIDO 2010b).

The following brief analysis deliberately separates the different sectors—treating fisheries, horticulture, and industry individually. Challenges and activities in the three sectors were quite different, as were issues of sustainability and impact.

Fisheries

Fisheries is the only sector where activities had already started during TRTA I in 2004, when Pakistan imposed a self-ban to avoid the imminent threat of an EU ban on Pakistan fish exports. Nevertheless, the EU ban remained in effect in 2007 after a check by the Food Veterinary Office of the EC Directorate-General Health and Food Safety identified continued quality deficits, including poor inspection practices and poor hygienic conditions and control practices of fish packers and exporters. In total, 13 critical points were identified that had to be addressed before exports could be resumed (UNIDO Evaluation Group 2014).

The three main players in the Karachi fisheries sector included, first, the Marine Fisheries Department (MFD) under the Federal Ministry of Ports and Shipping. The other two were the Karachi Fish Harbour Authority (KFHA) under the provincial government and the Fishermen Cooperative Society (FCS), a powerful lobbying organization with some 11,000 fishermen members that was founded in 1945, representing nearly all fishermen along Pakistan's 1,200-kilometer coastline.

Collaboration between the three main actors was not particularly smooth, especially between the KFHA (as provincial body and owner of the Karachi port infrastructure) and the FCS (as operator and contractor of the fishing harbor). There were long-standing issues between the KFHA and the FCS related to harbor ownership and lease agreements, which were financed by a 3.5 percent excise tax on each fish catch brought into the harbor. On the other hand, the KFHA also saw itself, as a consequence of the devolution of powers to the

provinces, as owner of the facilities and insisted that the MFD, as a central government body, should pay rent for the premises it occupied in the harbor.

During TRTA I, the MFD was strengthened as Competent Authority and converted into the technical champion of the sector. Its microbiology and chemical laboratories were accredited to ISO/IEC 17025. Two fish auction halls were renovated. The staffs of 17 processing plants were trained, along with the KFHA and MFD staffs, in hazard analysis and critical control points (HACCP). Information technology (IT)–based traceability instruments were also installed. The HACCP trainings were certified by the Royal Institute of Public Health of the United Kingdom. In all, 1,500 fishermen were trained in standard operating procedures (UNIDO Evaluation Group 2014).

Overall, the TRTA I and TRTA II programs leveraged around €2 million of government contributions and investments, particularly for the PCSIR and MFD labs, fishing boat upgrading, and the renovations of the two fish auction halls. A prominent success story was the equipping of 1,400 fishing boats with fiberglass hulls. TRTA I paid for the first five boat renovations as demonstrations. Later the provincial government financed the rehabilitation of 500 units, and by the end of 2013 around 900 boat owners had self-financed the renovation of their vessels out of a total 1,800 boats in the Karachi harbor. Government funding of approximately €24,000 was mobilized to establish testing facilities for dioxins, PCBs, and PAHs in fish and fish products at the PCSIR Karachi laboratories.[24] At the end of 2013, foreign third-party laboratories were performing these tests, but the PCSIR laboratories would take over as soon as they were accredited (UNIDO Evaluation Group 2014).

After the EU had lifted the ban on fish exports in March 2013, exports were resumed on a pilot basis. Two processor/exporters had been cleared for exporting to the EU. One of these, however, preferred to continue catering to the less demanding markets in China and the Middle East. By the end of 2013, 10 trial seafood shipments from the second cleared exporter had reached European markets without rejection.

Overall, the TRTA programs since 2004 had a major impact on the fisheries sector in the main production site in Karachi. By the end of 2013, the preconditions in terms of infrastructure and know-how were in place for the sector to increase its volumes and exports to the EU and other markets. The next challenges would be (a) to expand the improved Karachi "system" to other major fishing sites like Korangi, (b) to increase value addition by exporting processed products, and (c) to ensure that the carrying capacity of the Pakistani seas are respected. For the latter challenge, the FAO was conducting a thorough investigation.

The UNIDO evaluation mission in 2014 suggested that after some 10 years of intensive support, the time had come to let the sector take care of itself; more hand-holding would hardly lead to proactive private sector development, which ultimately would be the only sustainable growth path for the fisheries sector (UNIDO Evaluation Group 2014).

Horticulture: Mango and kinnow

Mango and kinnow are two of the major horticulture crops in Pakistan. An in-depth analysis of the sector in 2010 highlighted a number of challenges, including a disconnect between the research institutes specifically created for the improvement of these crops (the Mango Research Station in Multan and the Citrus Research Institute in Sargodha) and the Extension Wing of the Provincial Agriculture Department responsible for these sectors; for example, research

results were not being effectively communicated to farmers (UNIDO Evaluation Group 2014).

Although agriculture was a provincial responsibility, the Pakistan Horticulture Development and Export Company, a federal corporate body under the MoC, was mandated with improving the horticultural supply chains and increasing exports. It planned the establishment of a Pakistan certification system (PakGAP) to be benchmarked against the Global G.A.P. certification process for exports. But it saw its role as more of a coordinator to whom others reported than as the implementer of activities.

In selecting the mango and kinnow sectors for further support, the TRTA program linked up with two other programs: the Australia-Pakistan Agriculture Sector Linkages Program and the USAID projects. Even so, the implementation of the kinnow and mango support program was delayed; contracts with the research institutions were only signed in February and March 2012—a delay owing to lengthy bureaucratic procedures for concluding an agreement with the government of Punjab as well as with the research institutes that were delivering the support to the growers.

Forms of support

The support program was provided in a several steps (UNIDO Evaluation group 2014):

Step 1: Instituting a Code of Practice and Farmer Field Schools. The disconnect between the research institutes and the farmers was addressed by developing the Code of Practice for the farmers and training them through the influential Farmer Field Schools. The Code of Practice—a joint effort between TRTA II and the Australia-Pakistan Sector Linkages Program—dealt with the critical points on the supply chain (from farm to market). A further result from the joint effort was the identification of markets for Pakistani produce.

Experts from the research institutions thereafter managed an instruction program through Farmer Field Schools with pilot trials for 10 (rather large) participating mango farmers (in clusters of 4 to 5 smaller farms each) and 10 kinnow farmers (again in clusters of 4 to 5 smaller farms), involving in total around 100 producers. Participants in the Farmer Field Schools were selected based on their resources, capacities, and in particular their willingness to apply what they learned in the pilot trials to their own production.

The direct impact of the program on the poor was expected to become visible once better working conditions and more work became available for laborers involved in applying inputs (water, fertilizer, and pesticides) as well as in the harvest, transport, and storage tasks. The longer-term plan was for the Provincial Agriculture Department to play the dissemination role across the whole sector once the trials had been completed, because it had the necessary staff and mandate to do so.

Step 2: Training the trainers. The second step in establishing a permanent and effective extension system was still under development by the end of 2013. The concept foresaw the scientists of the research institutions as master trainers who were to train the agriculture officers and field assistants of the Extension Wing as trainers, who in turn were to train farmers and other actors of the supply chain, following the Farmer Field School concept and using the Code of Practice.

Step 3: Building trade links. To establish market links with international buyers, several activities were undertaken. First, two focus group meetings were held in Multan and Sargodha for the mango and kinnow sectors, respectively, on how to best link Pakistani exporters with buyers, resulting in a road map to develop trade corridor links. Second, training workshops were conducted on marketing and trade links for kinnow and mango exporters and processors in Sargodha. Experts from the Centre for Promotion of Imports (CBI, Netherlands) were sourced to support this training.

In collaboration with the Trade Development Authority of Pakistan, which had the mandate of promoting all export products including horticulture, seven mango and kinnow growers embarked on a study tour of the EU and the United Kingdom to establish trade links. Support was also sought from commercial counselors in Pakistani embassies to promote exports to their respective countries.

Program outcomes and challenges

As a result of these activities, 65 tons of mangoes (worth €150,000) had been shipped to Asda, a Walmart subsidiary in the United Kingdom, by the end of 2013; other shipments went to a Malaysian supermarket chain. One early shipment to Asda in the United Kingdom had to be sourced in Sindh province (and thus not from Farmer Field School participants) because the Multan crop ripened too late for the early-season export market. Unfortunately, the Sindh shipment had a fruit fly infestation; however, the issue could be resolved, and the prospects for the next season exports were said to remain good but would need to be monitored. No kinnow exports could be organized by the end of 2013. The necessary testing was conducted by the accredited laboratories in Pakistan.

Several challenges remained. On the production side, a functioning extension system still needed to be built up with the Provincial Agriculture Department (a task where many projects have failed over the years in Pakistan). Upscaling and mainstreaming of the Farmer Field Schools and Code of Practice are only possible through the Extension Wing of this department because only this organization has the mandate and necessary "field army" to increase coverage. This would continue to require intensive efforts of the master trainers-cum-scientists, particularly after the TRTA program financial support would end. For postharvest handling and export, grading has to be mainstreamed, and the specific SPS requirements for different countries have to be disseminated and followed.

On the institutional side, government structures will need to play their envisaged roles more proactively and effectively than they were doing at the time. Also, PakGAP had failed to progress any further than the planning stage by the end of 2013.

Industries: Electric fans, protective gear, and cutlery

Ten companies were identified in the fan and protective gear sectors and were supported on a cost-sharing basis to enable them to affix the CE marking to their products.

The TRTA strategy was based on preparing pilot companies for compliance and then allowing for scaling-up or replication to have a tangible impact on the entire spatial clusters and sectors. In addition, local consultants were trained (twinned with supporting international experts) for the development

of local expertise in these areas (CE marking and so on). However, it remained to be seen whether these consultants—who were supposed to introduce lean manufacturing and to support the CE marking application process—would be able to make a business out of it and thus achieve the envisaged scaling-up.

Guidelines were developed for the manufacturers on how to obtain the CE marking for electric fans and protective gear, and a simplified list of steps for CE marking was prepared. The technical files were completed, and the products had been sent to EU notified bodies for testing by the end of 2013. The companies were not overly enthusiastic regarding their chances of entering the EU markets, however, because they claimed that Chinese companies could supply fans at about half the cost. Their main export markets remained Africa, the Middle East, and South Asia.

The effectiveness of these interventions was therefore a bit debatable, especially because manufacturers considered the Electric Fan Manufacturers Association to be politicized and ineffective, and the competitors were said to be generally disinterested in changes, particularly when investments would be required.

PROBLEMS ENCOUNTERED

Federal versus provincial responsibilities

The Pakistani government started a process to deal with excessive presidential power, culminating in the passage of the 18th Amendment to the Constitution in April 2010. Among other important legislative changes, the hallmark of the constitutional amendment was devolution of powers to the provinces, involving transfer of a number of federal-level ministries and functions to the provinces. Overall, around 17 federal-level ministries were targeted for devolution and have been transferred to the provinces. The transition process was complex, unclear, and slow. Hence, it negatively affected the work of development agencies.

Most of these bilateral and multilateral agencies had dealt with the federal ministries and institutions as their national partners or counterparts in the past. With devolution of many of these ministries or functions to the provinces, however, the planning and implementation practices of international agencies became further complicated and cumbersome, because they then needed to deal with various departments of six provincial administrations separately to work in the respective provinces. If such a transition is known from the start, it is one challenge, but if it happens halfway through the programs—as in the case of TRTA and others—it became in some instances an unsolvable headache.

Sustainability

The sustainability of the efforts made in the horticulture value chains is uncertain. Realistic strategies are needed on issues like the further promulgation by the involved government organizations of the Farmer Field School concept and the Code of Practice, without any third-party budget support. The same applies, for instance, to the fan sector, where a scaling-up and mainstreaming strategy is required to disseminate the innovations beyond the 10 currently participating companies.

Federal and provincial government cooperation on food safety

With the messy implementation of the 18th Amendment to the Constitution and the devolution of responsibilities, coordination between the provincial governments and the federal government became an issue. The food safety legislation was a prime example, where the Punjab government refused to accept any directives from the federal level and unilaterally started establishing its own food safety system. This had negative consequences for the development of the federal food safety legislation supported by the development agencies, whose final progress, after five years of work, was still stalled by the end of 2013. UNIDO, for example, was also caught in between: it provided the Punjab provincial authorities with technical support, and it also supported the development of the federal food safety legislation.

A similar dynamic was experienced during the upgrading of the fishing industry. The mistrust and lack of cooperation between the federal ministry (that is, the Marine Fisheries Department), the provincial authorities, and the industry nearly ended the development project on more than one occasion, and a lot of energy, persuasion, and sensitivity regarding the political power play was required to smooth out an otherwise bumpy environment.

The PSQCA and mandatory standards

The PSQCA, like similar agencies in many low- and middle-income countries, was a body responsible for standards development, inspection, testing, and certification as well as the implementation of mandatory standards. About 50 percent of the mandatory standards were related to food safety. Over the years, the mandatory standards scheme inevitably became the main income generator for the PSQCA by far. Hence, separating the implementation of mandatory standards from the PSQCA—as good international practice would require—was not welcomed at all.

Neither was the notion that the food safety–related mandatory standards should be transferred to NAPHIS as the designated federal agency for food safety. The PSQCA therefore did everything possible to maintain the status quo, even slowing down the passage of the food safety legislation at the federal level by raising issues against it through its parent ministry (MoST).

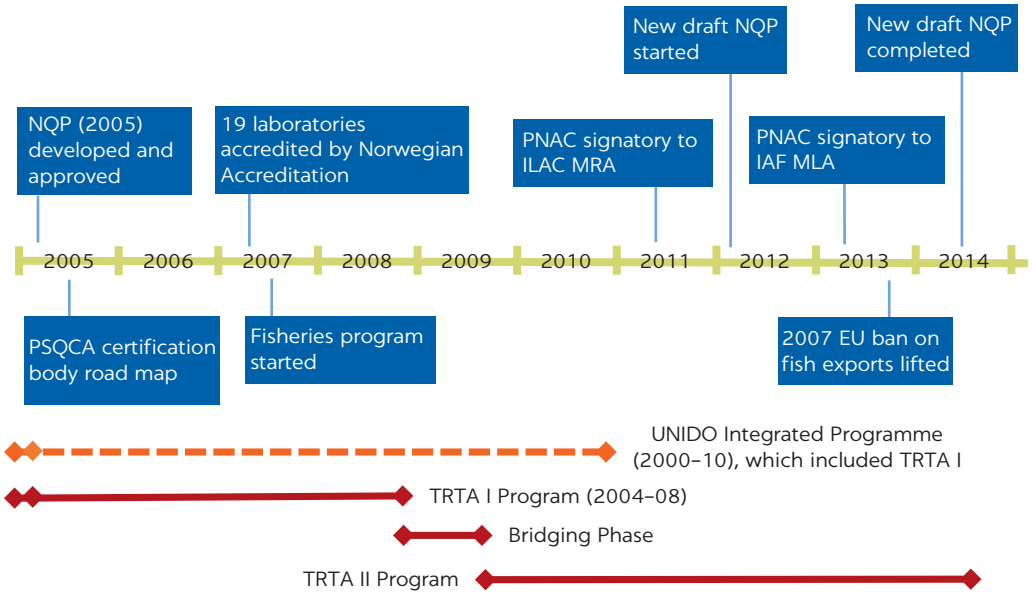
KEY SUCCESS FACTORS AND LESSONS LEARNED

Several key success factors and lessons learned can be derived from the 10 years of QI-related development in Pakistan (figure 9):

- *An in-depth needs assessment of industrial and government sectors*, before major projects are initiated, provides important information on designing meaningful interventions. These were especially important to highlight the QI service needs of the industries destined for technical support for the export markets.
- *Ownership of the development program in QI institutions* is of paramount importance. Where this was experienced (in PNAC and, to a lesser extent, the NPSL), positive results were evident. Where it was not as pronounced (for example, in the PSQCA), the results were less positive. The continuous movement of senior personnel in such organizations is a danger sign that should be heeded.
- *A strong alliance between the government, the private sector, and development agencies*, working together toward common and clear objectives, yields

FIGURE 9

Timeline of main QI reengineering events in Pakistan, 2005–14



Source: World Bank analysis.
Note: EU = European Union; IAF = International Accreditation Forum; ILAC = International Laboratory Accreditation Cooperation; MLA = Multilateral Recognition Agreement (IAF); MRA = Mutual Recognition Agreement (ILAC); NQP = national quality policy; PNAC = Pakistan National Accreditation Council; PSQCA = Pakistan Standards and Quality Control Authority; TRTA = Trade Related Technical Assistance (UNIDO); UNIDO = United Nations Industrial Development Organization.

positive results. Private sector and beneficiary ownership and commitment were particularly evident in projects working with the leather sector in Sialkot and Kasur.

- *A holistic approach to sector development* (including environmental sustainability, skills development, export promotion, and technology upgrading) was seen as a most successful approach.
- *Collaboration with universities* (for example, three universities approved curricula for a postgraduate diploma in food safety and control) adds value to interventions using sustainable local partners and for access to additional funding and resources. The same applies for working with technical vocational training centers operated within clusters. They provide customized solutions and training services and have a good prospect for sustainability.
- *A high level of ownership regarding the new quality regime* among different government organizations and bodies produced evident commitment to further develop and strengthen what was started when the government of Pakistan began to allocate regular budgets instead of project-based budgets. A particular benefit was that two-thirds of the increasing incomes from testing, calibrations, and so on could remain with the laboratories.
- *The ongoing process to develop an overall national quality policy* (originally not foreseen in the program design) was a good investment to ensure the sustainability of what was introduced by QI development programs.
- *Directly approaching, and expanding the involvement of, private sector laboratories* could further safeguard the sustainability of the quality regime. Commercializing the testing beyond government laboratories introduces more competition and expands coverage by further bringing down costs for exporters.

CONCLUSION

The broad-based programs of a decade had a major impact on the Pakistani QI, upgrading it to international standards, gaining international recognition for its accreditation and metrology services, and establishing recognized testing services required by exporters. At the same time, major industrial sectors were developed, namely fisheries and horticulture, to the point where small and medium producers met international standards and could export successfully to the major markets of the world.

The programs showed how important it is to take a longer view when establishing a QI that complies with international standards and needs to be formally recognized. In the case of Pakistan, the pinnacle QI organizations had been established, but it still took about eight years to gain international recognition.

The programs also highlighted once again how difficult it is to separate work on mandatory standards from the NSB when this is the NSB's main income source. In this program, no gains could be reported even though the concept was included in the National Quality Policy.

NOTES

1. The World Trade Organization (WTO) Technical Barriers to Trade (TBT) Inquiry Point is an official or office in a member government designated to deal with inquiries from other WTO members and the public on technical barriers to trade.
2. ISO/IEC 17025:2005 has been superseded by ISO/IEC 17025:2017, "General Requirements for the Competence of Calibration and Testing Laboratories": https://www.iso.org/standard/66912.html.
3. The Ministry of Food, Livestock and Agriculture is now the Ministry of National Food Security & Research.
4. The Australia-Pakistan Agriculture Sector Linkages Program was an 2007–15 initiative funded by the Australian Centre for International Agricultural Research (ACIAR) and the Australian Agency for International Development (AusAID).
5. For the current 2019 fiscal year, low-income economies are defined as those with a gross national income (GNI) per capita of US$995 or less (converted from local currency using the World Bank Atlas method).
6. Poverty headcount data from the World Bank's PovcalNet database: https://data.worldbank.org/indicator/SI.POV.DDAY.
7. Growth, inflation, and IMF program data from the IMF's "Pakistan: Country Data" web page: https://www.imf.org/en/Countries/PAK.
8. See "Pakistan: Financial Position in the Fund as of April 30, 2019" from the IMF's "Pakistan: Country Data" resources: https://www.imf.org/external/np/fin/tad/exfin2.aspx?memberKey1=760&date1key=2099-12-31.
9. Much of the data for the "National QI" subsection come from UNIDO 2013.
10. ISO 9001:2015, "Quality Management Systems—Requirements": https://www.iso.org/standard/62085.html.
11. A Competent Authority generally is an organization that has the legally delegated or invested authority, capacity, or power to perform a designated function. In this specific case, the Competent Authorities were the entities designated to ensure that the requirements for the safety and quality of specific products to be exported to the EU were implemented and maintained by suppliers and producers.
12. ISO/IEC 17011:2004 has since been revised as ISO/IEC 17011:2017, "Conformity Assessment—Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies": https://www.iso.org/standard/67198.html.
13. ISO/IEC Guide 62:1996, "General Requirements for Bodies Operating Assessment and Certification/Registration of Quality Systems," has been superseded by ISO/IEC 17021:2006, "Conformity Assessment—Requirements for Bodies Providing Audit and Certification of Management Systems": https://www.iso.org/standard/29343.html.

14. The cross-frontier policies of ILAC and the IAF endeavor to limit competition between accreditation bodies that could be detrimental to the quality of accreditation (IAF 2016; ILAC 2012).
15. ISO/IEC 17020:2012, "Conformity Assessment—Requirements for the Operation of Various Types of Bodies Performing Inspection": https://www.iso.org/standard/52994.html.
16. See ISO 9001:2015, "Quality Management Systems—Requirements": https://www.iso.org/standard/62085.html; and ISO 14001:2015, "Environmental Management Systems—Requirements with Guidance for Use": https://www.iso.org/standard/60857.html.
17. ISO 22000:2005 has been superseded by ISO 22000:2018, "Food Safety Management Systems—Requirements for Any Organization in the Food Chain": https://www.iso.org/standard/65464.html.
18. SA 8000:2014, "Social Accountability: International Standard": http://sa-intl.org/_data/n_0001/resources/live/SA8000%20Standard%202014.pdf.
19. Hilla boats are a type of wooden fishing boat. The upgrades were to line them with fiberglass in order to enable proper cleaning for hygiene reasons.
20. The CE marking is a regulatory product mark that demonstrates compliance of a product with the relevant EU Directive in terms of standards and conformity assessment procedures. In principle, it denotes the manufacturer's acceptance of responsibility for the integrity of the product. It is not a product certification mark licensed by a certification body.
21. ISO/IEC 17020:2012, "Conformity Assessment—Requirements for the Operation of Various Types of Bodies Performing Inspection": https://www.iso.org/standard/52994.html. ISO/IEC Guide 43-1:1997 and Guide 43-2:1997 have been superseded by ISO/IEC 17043:2010, "Conformity Assessment—General Requirements for Proficiency Testing": https://www.iso.org/standard/29366.html.
22. ISO 9001:2015, "Quality Management Systems—Requirements": https://www.iso.org/standard/62085.html. ISO 14001:2015, "Environmental Management Systems—Requirements with Guidance for Use": https://www.iso.org/standard/60857.html.
23. The CIPM Mutual Recognition Arrangement (CIPM MRA) is the framework through which NMIs demonstrate the international equivalence of their measurement standards and the calibration and measurement certificates they issue. The outcomes of the CIPM MRA are the internationally recognized (peer-reviewed and approved) CMCs of the participating institutes. Approved CMCs and supporting technical data are publicly available from the CIPM MRA Key Comparison Database (KCDB), managed by the BIPM. For more information about the KCDB, including information on CIPM key and supplementary comparisons, see the KCDB website: https://kcdb.bipm.org/.
24. Polychlorinated biphenyl (PCB) is an organic chlorine compound once widely deployed as dielectric and coolant fluids in electrical apparatus, carbonless copy paper, and heat transfer fluids. The International Research Agency on Cancer (IRAC) rendered PCBs as definite carcinogens in humans. Polycyclic aromatic hydrocarbons (PAHs) are organic compounds containing only carbon and hydrogen. They have been linked to skin, lung, bladder, liver, and stomach cancers in well-established animal model studies.

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INTERNATIONAL DEVELOPMENT IN PRACTICE

South Africa

QI Toolkit Case Studies

Martin Kellermann

WORLD BANK GROUP

PTB Physikalisch-Technische Bundesanstalt
Braunschweig und Berlin
National Metrology Institute

1 2 3 4 22 21 20 19

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Kellermann holds a master's degree in mechanical engineering from Pretoria University. He has also studied accountancy at the University of the Witwatersrand's Graduate School of Business Administration and participated in the Executive Education Program of the Haas School of Business, University of California, Berkeley. Currently, Kellermann lives with his wife in South Africa.

Abbreviations

ANC	African National Congress
BIPM	International Bureau of Weights and Measures
CSIR	Council for Scientific and Industrial Research
DTI	Department of Trade and Industry
EU	European Union
IAF	International Accreditation Forum
ILAC	International Laboratory Accreditation Cooperation
MoA	memorandum of agreement
NEDLAC	National Economic Development and Labour Council
NMISA	National Metrology Institute of South Africa
NML	National Metrology Laboratory
NRCS	National Regulator for Compulsory Specifications
NRF	National Research Foundation
NTRF	National Technical Regulation Framework
QI	quality infrastructure
SABS	South African Bureau of Standards
SADC	Southern African Development Community
SANAS	South African National Accreditation Service
SDO	standards development organizations
TBT	Technical Barriers to Trade
WTO	World Trade Organization

South Africa

QI Toolkit Case Studies

Abstract: South Africa reengineered its quality infrastructure (QI) after 1994 when the country moved from the previous apartheid dispensation to become a full-fledged democracy. During this transition, the business environment changed from an internally focused one—largely driven by the economic sanctions South Africa had endured during the apartheid era—to an open-market one. The business environment had to compete with foreign companies that flooded South Africa. The QI had to change accordingly, from a mostly inward-focused one to one that had to connect with the international QI community and gain recognition. The reengineering of South Africa's QI was overseen by the Department of Trade and Industry (the ministry responsible for the QI) and was implemented by the QI organizations themselves without support from foreign organizations.

COUNTRY CONTEXT

Geography and peoples of South Africa

South Africa is the southernmost state in Africa. It is bounded on the south by 2,800 kilometers of coastline stretching along the South Atlantic and Indian Oceans; on the north by the neighboring countries of Botswana, Namibia, and Zimbabwe; on the east by Mozambique and Swaziland; and within by the kingdom of Lesotho (which its land area surrounds). South Africa is the 25th-largest country in the world by land area and, with close to 53 million people, the world's 24th-most populous nation.

South Africa is also home to a multiethnic society encompassing a wide variety of cultures, languages, and religions. Its pluralistic makeup is reflected in the Constitution's recognition of 11 official languages, which is among the highest number of any country in the world. Two of these languages are of European, and the others of African, origin.

History of South Africa

South Africa became a republic in 1961, when the British monarch was abolished as head of the state. In the same year, South Africa left the Commonwealth of Nations and was readmitted only in 1994. The system of legally institutionalized racial segregation and discrimination known as "apartheid" (from Afrikaans, "being apart")—characterized as such by the National Party, which came to power in whites-only elections in 1948—put South Africa at odds with the international community, which progressively subjected the country to political and financial sanctions. The African National Congress (ANC), established in 1909, became the major resistance movement, demanding a nonracial society and an end to discrimination. In the 1970s and 1980s, the ANC resorted to violence when dialogue proved to be ineffective. The ANC was banned in 1960, and its leaders were incarcerated, the most notable being Nelson Mandela.

At the beginning of the 1990s, the government took decisive steps to end the system of apartheid. It freed Nelson Mandela, unbanned the ANC, and started negotiations for a nonracial political system. The first free elections took place in 1994, and the ANC won by a landslide. All of a sudden, South Africa was no longer the pariah of the international community, but was welcomed everywhere with open arms. The whole world sought to trade with South Africa as its borders were opened.

BACKGROUND OF QI ISSUES

The changes brought about by the new political dispensation in the 1990s had a profound impact on business and society—developments that also left their mark on the quality infrastructure (QI). Before 1994, as a result of the many sanctions it had endured since the 1960s, South Africa followed, of necessity, a self-sufficiency or replacement policy regarding imported products. Hence, many businesses were totally inward-focused, and the QI provided services that supported them in this endeavor. Once a fully democratic government came to power in 1994, the QI had to adept fairly rapidly to a completely new situation, one of open borders and intense international competition, rather than an inward-looking self-sufficiency paradigm.

Standards

The national QI of South Africa has a long history (Pelser 1995). Standardization was required in the furiously developing gold industry, and as far back as 1912 the South African Engineering Standards Committee was recognized by the British Standards Engineering Committee, both of which changed their structures to that of associations in 1918. The South African Engineering Standards Association morphed into the South African Standards Institution (SASI) in the 1930s.

After World War II, some eminent industrialists in South Africa asked the government to establish a national standards body with legal standing, because the country was starting to industrialize. The South African Bureau of Standards (SABS) was established by an act of Parliament in 1945. Although SABS was initially established as an independent organization, the cabinet decided to

merge SABS with the Council for Scientific and Industrial Research (CSIR) in 1956. However, the merger was not a happy one. The two organizations were separated again in 1960 after acrimonious clashes in the senior management ranks.

Metrology

The National Metrology Laboratory (NML) was established in 1945, just after World War II, as part of the CSIR. South Africa signed the Metre Convention in 1964,[1] even though it had utilized the International System of Units (SI) for scientific purposes for many years. On the other hand, the country also used the weights and measures of the British Imperial System (such as the mile, foot, pounds, gallons, and others) in normal life.

South Africa started metricating in an intense campaign during the 1960s and early 1970s. By July 1974, an act of Parliament designated the SI system as the country's only legal measurement system, and metrication was considered to be completed by 1978. The NML was now a small division within the CSIR, reporting to the CSIR management and board and subject to CSIR business strategies. At the technological level, the NML was well placed, with good research capabilities and world-class physical measuring equipment under its control.

Accreditation

Accreditation had a much more convoluted path than the other QI fundamentals (standards and metrology) before it stabilized in the 1990s (McDowell 2000). Both SABS and the CSIR were mandated through their enabling legislation to accredit laboratories. SABS started accrediting civil engineering laboratories in the 1980s and inspection bodies in the early 1990s. The NML established the National Calibration Service (NCS) in the middle 1970s and started accrediting calibration laboratories. It was broken off as a private company in 1991. Various ministries, such as Health, Labour, and others, accredited private companies to perform conformity assessment duties regarding various safety and health regulations. At the insistence of the Department of Trade and Industry (DTI),[2] all accreditation activities of the NCS, SABS, and the CSIR were merged into the newly established South African National Accreditation Service (SANAS) by 1995, which gradually took over accreditation activities from other ministries as well.

Overall QI status, 1994–99

On the surface, the QI looked in good shape when the ANC government came to power in 1994. It was respected in international organizations and had kept pace with technological developments, even in the last decades of apartheid. But the ANC government wanted to be sure that it could meet the challenges of the new South Africa, which faced serious socioeconomic issues and that had to reintegrate quickly into the world trading system after decades of sanctions. At the same time, industry that had developed as a result of the need to become self-sufficient now had to be supported to become competitive in the light of fierce competition from abroad.

TABLE 1 Snapshot of quality infrastructure (QI) reform in South Africa

BEFORE REFORM	AFTER REFORM
Only the South African Bureau of Standards (SABS) developed and published national standards, each identified by "SABS" preceding the standard number.	SABS was empowered to recognize other standards development organizations (SDOs) to develop national standards, even though SABS retained the right to publish them. The abbreviation identifying the standards was changed to "SANS," for South African National Standard.
SABS was fully responsible for the administration of compulsory specifications—national standards that were declared mandatory by the Minister of Trade and Industry.	The responsibility for administering compulsory specifications was moved from SABS to a newly established National Regulator for Compulsory Specifications (NRCS) under the Department of Trade and Industry.
Trade metrology was the responsibility of SABS.	Trade metrology was moved to the NRCS.
The National Metrology Laboratory (NML) was a division of the Council for Scientific and Industrial Research (CSIR).	The NML was established as an independent organization of public law, and its name was changed to the National Metrology Institute of South Africa (NMISA).
Accreditation services were provided by SABS, the NML, and specific ministries.	The South African National Accreditation System (SANAS) was established first as a not-for-profit private organization and later as an independent organization of public law. All accreditation activities of other organizations were taken over by SANAS, which became the only national accreditation organization by law.

For these reasons, the Department of Arts, Culture, Science and Technology commissioned an in-depth review of the whole science system by an international team in 1996.[3] This review indicated clearly that SABS, the CSIR, and other science councils were world-class, considering the size of South Africa and its economy. The outcome of this review did not result in a major shake-up of the QI.

A second major review—this time, of the "South African Standards, Quality Assurance, Accreditation, and Metrology (SQAM) Infrastructure"—was commissioned by the DTI in 1999. Conducted by a consortium of South African and Australian teams, this review (NEDLAC 2001) had a profound impact on the QI landscape in South Africa (table 1) and was at the time arguably one of the most thorough reviews of a QI anywhere in the world.

THE QI REVIEW

The DTI established the Standards and Environment Directorate in 1996. This directorate provided decisive leadership in terms of policy and implementation in the formative years of the new government regarding the development of the South African QI. It was instrumental in merging the accreditation activities of various organizations into SANAS, for example. During the many discussions with all the actors in the QI—each vehemently defending the status quo—it became abundantly clear that an independent, in-depth evaluation of the QI was indicated. The DTI therefore commissioned such a QI review through an international tender with sufficient funding to pay for it.

A South African–Australian consortium was awarded the tender in 1999, with the South African side (Bentley West Management Consultants Pty Ltd) providing the business and analysis expertise and the Australian side (a consortium of Standards Australia, Commonwealth Scientific and Industrial Research Organisation [CSIRO], and National Association of Testing Authorities [NATA]) providing the QI expertise. The DTI set up a Counterpart

Group to act as sounding board for the review team. The Counterpart Group was representative of the major QI organizations, organized industry, and the DTI. It met several times with the review team and contributed significantly to the effective outcome of the review. The DTI also established a website to communicate the intermediate and final results of the review to a much wider audience.

Objectives of the review

The main overall objective of the QI review was to improve and enhance the competitiveness of South Africa's industry, to ensure the health and safety of consumers, and to improve the overall socioeconomic conditions of South Africa by ensuring that the QI operates at optimum efficiency. The study related only to products and services. Other areas—such as environmental safety, eco-labeling, general health issues, and non-product-related legislation—were not covered. The technical objectives of the review were therefore to

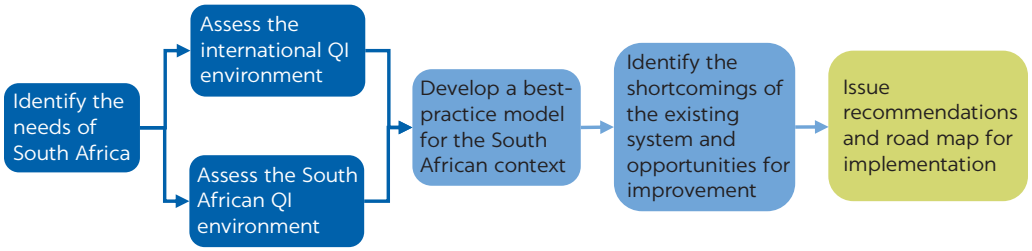
- Evaluate the South African QI to identify shortcomings and recommend improvements to meet the needs of South African commerce, industry, and government;
- Determine which financial, effectiveness, and efficiency constraints, if any, hamper QI development; and
- Level the playing field by removing obstacles to competition, where appropriate.

The results would be used to advise business, labor, and government on the formulation of a holistic national QI policy and the relevant roles of these three stakeholder groups in implementing such a policy. In the process, the effects of such policies elsewhere in the world were taken into consideration. Eight subsystems of the QI were evaluated to a greater or lesser extent: government and international liaison, standardization, accreditation, conformity assessment, metrology, legal metrology, funding, legal system, and promotion of quality.

Scope of the QI review

The approach of the QI review was based on building an understanding of the issues at hand, gathering the required information, conducting in-depth analysis, and formulating recommendations as appropriate (figure 1).

FIGURE 1
Process of QI review in South Africa, 2000



Source: NEDLAC 2001.
Note: QI = quality infrastructure.

Identifying the needs of South Africa

The needs of South Africa that the QI must fulfill were the underlying factors that had to be considered in the assessment of the domestic and international QI landscape to develop proposals for an optimum QI. The country's needs were determined from four perspectives:

- *International trends and developments* that would have an impact on the QI as well as the environment in which it operates. An assessment of key drivers at the international level was therefore conducted as part of the review.
- *National imperatives* were established by an assessment of the overall economic and social environment of South Africa.
- *Needs of stakeholder groups*—including the government, industry (with specific attention to small and medium enterprises, SMEs), labor, consumers, the QI institutions, and other organizations active in the QI arena—were established through a variety of mechanisms: public hearings, formal submissions, a questionnaire-based industry survey, discussions with primary institutions, roundtable discussions with industry representatives, and an assessment of prior research in this area. Nearly 120 individual stakeholders, representative of all stakeholder groups, provided input through one or more of these mechanisms.
- *The current status of QI development and performance* was considered. The identification of this "baseline" situation was imperative to identify strengths and weaknesses and to develop appropriate recommendations. Various practicalities and realities that affect the viability of recommendations were also identified.

Assessing the international and domestic QI environment

An extensive survey of the international and domestic QI was conducted from a broad perspective that included fundamental issues relating to strategy, governance, functions, funding, and performance.

The international survey consisted of visits to a group of targeted countries as well as a questionnaire-based survey of other selected countries. The visited countries included Australia, Brazil, Malaysia, and the United Kingdom. The countries targeted by questionnaire included Colombia, Germany, Iceland, the Netherlands, New Zealand, Singapore, Sweden, and the United States. The international visits proved to be successful, with the study team able to visit most of the primary institutions within the targeted countries. Many institutions in these countries that were not visited participated by completing the questionnaire, thereby providing valuable additional insight into their environments and operations.

The domestic assessment included an analysis of the formal submissions received from primary QI institutions and other role players in the QI environment, as well as follow-up discussion sessions with the relevant organizations.

Developing a best-practice model for the South African context

The best-practice model developed represented the "best practices" that could be considered for adoption within the South African context. It was acknowledged that some needs were unique to South Africa as a middle-income nation and that some practices found in high-income countries might not be suitable for South Africa.

Best practices were derived from the analysis of international and domestic practices, with the needs of South Africa taken as the common denominator for deciding which practices should be considered in the South African context and which ones were inappropriate. A comparison of the South African situation at that time with the derived best-practice model indicated specific areas of strength as well as areas for improvement.

Identifying QI system shortcomings and opportunities for improvement

Shortcomings were identified in several areas. Some of the higher-level ones included:

- The lack of a cohesive policy by the government, and specifically the DTI, regarding the QI and its responsibilities;
- The lack of an adequate management process in the government for funding the QI where relevant;
- Conflict of interest within SABS between its development of national standards and its management of the compulsory specifications;
- The low profile of the NML within the greater CSIR;
- The lack of recognition of SANAS by the whole government; and
- Fragmentation of South Africa's technical regulation regime.

Other shortcomings concerned operational areas where the South African QI did not function in accordance with international good practices.

Issuing recommendations, and a road map for implementation

Recommendations were formulated with a view to closing existing gaps within the South African QI and to exploiting opportunities. The viability of implementing such recommendations was considered, as well as the risks associated with implementation. The requirements for successfully implementing recommendations were therefore also broadly identified.

It was recognized that many recommendations would have to be implemented over a period of time. The conclusion to the review provided a high-level "road map" that outlined how the South African QI was expected to evolve over time. The ongoing relevance of and reaction to emerging influences were specific themes for the long term.

RECOMMENDATIONS OF THE QI REVIEW

The QI review, published in April 2001, listed 55 recommendations regarding a wide variety of QI and technical regulation issues (NEDLAC 2001). The main recommendations for the QI and technical regulation are summarized below under a few important headings.

Standards and compulsory specifications

SABS should be confirmed as the pinnacle national standards organization, with its prime responsibility being the development and publication of national standards. It should be given the mandate to "recognize" other standards development organizations (SDOs) once they meet specified requirements. These SDOs can then develop national standards, but SABS

retains the legal monopoly on their publication. Such a system will broaden the standards development capabilities of South Africa without losing the process compliance required by annex 3 of the World Trade Organization (WTO) Agreement on Technical Barriers to Trade (TBT Agreement), for example. It would also pave the way for ministries to more readily use standards as the basis for their regulations because, as recognized SDOs, they retain a measure of control over the content of the standard.

The national standards published by SABS were identified by a numbering system starting with "SABS" (for example, SABS 1234). This practice was seen as a barrier to the use of South African standards by other conformity assessment service providers. Furthermore, having the country in the designation of the national standard sends a clear message to users that the standards are "national standards," with all that that implies. It also reinforces the national role of the standards body and its agreement with the government. Hence, it was strongly recommended that, in the future, the SABS standards should be renamed "South African National Standards" (for example, SANS 1234).

SABS had a good track record in administering (that is, developing and implementing) the compulsory specifications (national standards that were declared mandatory by the Minister of Trade and Industry),[4] but there was some confusion in the minds of stakeholders between SABS's role as standards developer and its role in implementing regulatory requirements. There was also the potential overlap between its regulatory activities and those of other ministries, which could eventually lead to resentment and altercations, to the detriment of socioeconomic development. By clearly separating SABS's role as standards developer from the regulatory implementation of the same, this conflict of interest would be set aside. This would also pave the way for increasing the ministries' use of standards as the basis for technical regulation, as required by the WTO TBT Agreement, because there would no longer be a "competitive issue" between SABS and ministries regarding technical regulation.

Therefore, it was strongly recommended that the administration of compulsory specifications be separated from SABS and placed in an independent regulatory agency under the DTI. At the same time, the de facto monopoly that SABS enjoyed in conducting the inspection, testing, and certification of products falling within the scope of compulsory specifications should be set aside; that is, SABS should compete on a level playing field with other organizations, appropriately accredited and designated, in providing such services in the regulatory domain.

Technical regulations

There were significant problems with the South African system for management and control over technical regulations, which included compulsory specifications. The need for better coordination of formulation and review of technical regulations was identified as a common need. In South Africa, the problem was one of a system that was fragmented (multiple sources that generate regulations), a lack of knowledge of the existence of regulations, and technical regulations that were drafted without ensuring that all the elements of good regulatory practice are present.

The QI review recommended that the Office of Regulatory Reform be established to:

- Review existing approaches for the formulation of technical regulations contained in legislation and legislative instruments, and develop a best-practice approach for technical regulation formulation;
- Conduct a comprehensive review of existing technical regulations contained in legislation, including legislation relevant to trade and legal metrology;
- Require that regulatory impact assessments be compulsory for all future formulations of technical regulations;
- Establish the principles for any regulatory marks used in South Africa; and
- Monitor any potential abuses of such regulatory marks and conformity assessment marks in both the voluntary and mandatory sectors.

Metrology

The NML was one of nine business units within the CSIR's Division for Manufacturing and Materials Technology (M&MTEK). The director of M&MTEK represented the NML on the CSIR senior management team. A memorandum of understanding (MoU) existed between the CSIR and DTI for the funding of the NML national activities, but stakeholders expressed concern that the CSIR's strategic drive to become less dependent on government funding and more commercialized was negatively affecting the NML's work for the public good. The NML was also largely hidden within the much larger CSIR, even though the CSIR was well known in industry. At the international and regional levels, the NML was well respected. The NML was not considered a threat to independent laboratories; in fact, it supported their development and technical competency.

To give the NML its unique identity, the review recommended that the NML become a fully independent entity (with its own governance, advisory board, and a separate budget) but still within the CSIR. That is, it stopped short of recommending that the NML be totally separated from the CSIR, citing its relatively small size as the major constraint. Attaching the NML to another QI organization was not considered a viable option in the South African context. It would, as is the case all over the world, continue to have to be funded largely by the government.

Accreditation

The establishment of the South African National Accreditation Service (SANAS) was the outcome of a cabinet memorandum. Its forerunner was the National Calibration Service (NCS), augmented by SABS's laboratory accreditation activities. SANAS was established as a "not-for-profit" private company under South African commercial legislation (the Companies Act). After its establishment, the DTI and SANAS signed a memorandum of agreement (MoA) that provided for the recognition of SANAS as the DTI's accreditation body and for some of its funding to come from the DTI. The review concluded that the private company status of SANAS gave it certain advantages regarding its business practices and that the market penetration it achieved in a fairly short time would not have been possible if it had been a statutory body.

Accreditation was increasingly being used by regulatory authorities to determine the technical competency of conformity assessment service providers for the implementation of technical and other regulations. SANAS's private company status was discussed extensively—that is, whether a private accreditation

organization could be used in the regulatory context by the regulatory authorities, or even whether it could act as a regulator itself. Furthermore, would the whole of government (ministries other than the DTI) be committed by the DTI–SANAS MoA to use SANAS as the sole national accreditation body?

There are two significant issues concerning regulators' use of accreditation bodies: (a) accreditors' ability to report the outcomes of their accreditation assessments to regulators, given their usual confidentiality arrangements with accredited clients; and (b) accreditors' ability to be indemnified in some way by the government to allow them to operate without fear of recrimination from accredited clients when acting on behalf of regulators. Both issues could be resolved if the accreditation contract between SANAS and its accredited entity dealt with them decisively, as agreed to beforehand.

The QI review recommended, in line with international good practices, that SANAS should not become a regulator in its own right, but that it should provide the independent evidence of technical competence on which the regulatory authorities could base their "approval" or "designation" of conformity assessment service providers.

The issue of enshrining SANAS's position as the sole national accreditation body was a bit more complicated. Three possibilities were considered:

1. Establishment of SANAS as a statutory body through an accreditation act
2. Continued operation as a private, not-for-gain company, enabled through an accreditation act
3. Continued operation as a private, not-for-gain company but with an extended MoA with the government as a whole.

Based on international trends, the South African legal system, and the independence issue, the second option—that is, for SANAS to continue operating as a private, not-for-gain company under the Companies Act and with its activities bolstered by an accreditation act—was considered the most appropriate. This would give SANAS the legal backing it required to act on behalf of all of government and indemnify it for regulatory work, while at the same time being less prone to government interference and able to react much faster to changing market requirements.

Conformity assessment

The conclusion of the QI review was that there would be considerable benefits and greater compliance with international requirements such as the WTO TBT Agreement if the system for demonstrating compliance with technical regulations, including compulsory specifications, were opened up to all competent providers, both in South Africa and abroad, based on their demonstrated competence to comply with South Africa's specific technical requirements. Such demonstration of technical competence should be through an objective and transparent process, as provided by SANAS accreditation or accreditation by its international multilateral recognition agreement partners.

It is, however, recognized that demonstration of technical competence is not the only criterion for acceptance of a service provider. Issues such as legal liability should also be considered. It is therefore essential that final acceptance of such service providers vest with the regulatory authority and not with SANAS, which should not have regulatory powers.

IMPLEMENTATION OF QI REVIEW RECOMMENDATIONS

The recommendations of the QI review were wide-ranging, and their impact would be profound. The DTI accepted the report, which was also considered and endorsed by the National Economic Development and Labour Council (NEDLAC).[5] The DTI and the QI organizations started the long road of implementation in 2001. All the QI organizations were directed to implement the recommendations, either on their own or in cooperation with each other, and the DTI maintained an oversight role.

Technical regulation

Following the QI review, the DTI established an interministerial technical regulation coordination committee to discuss and agree on a coordinated approach to technical regulation. This resulted in the publication of the "Government Strategy towards an Efficient National Technical Regulation Framework (NTRF) for South Africa" (DTI 2006).

NTRF strategy

The purpose of the NTRF strategy was to establish and improve a common approach in terms of technical regulation responsibilities. It provided guidance to all departments responsible for the development, maintenance, and review of technical regulations. Although the strategy initially invited the "voluntary" implementation of the NTRF, it was envisaged that the NTRF would eventually be given legal certainty through the South African Technical Regulatory Act.

The strategy for formulation of the NTRF established the following broad guidelines, based on five internationally accepted elements of technical regulatory infrastructure:

- *The legislator.* The government as legislator faces the challenge of keeping regulatory intervention to a minimum, while still achieving the objective of protecting the health and safety of society and the environment. The proposed interventions are designed to promote innovation and competition among businesses rather than stifle them. Hence, a regulatory impact assessment (RIA) will be conducted that includes options and alternatives. For each RIA, a cost-benefit analysis, risks, and distributional impacts would be considered before a final decision is made. The various ministries at both the national and provincial levels would retain their mandates in this regard.
- *The regulator.* Various regulatory agencies oversee the implementation and administration of technical regulations at the national, provincial, and local levels. In high-risk cases, the regulatory agency may be required to approve commodities before marketing. This approval should be based on compliance evidence provided by a technically competent (that is, accredited) third-party conformity assessment service provider, the cost of which would be borne by the supplier. For all products, market surveillance will be conducted to identify products that do not meet technical regulation requirements, in order to initiate sanctions. Inspection bodies responsible for market surveillance should be accredited by SANAS.
- *Technical requirements.* The technical regulations—based on international or national standards where available and appropriate—will focus on performance requirements rather than prescription.[6] Moreover, only those

elements of the standards that are relevant for achieving the objective of the technical regulation should be used. Hence, regulatory agencies need to be involved in the technical committees developing the national standards in this regard.

- *Conformity assessment*. Because South Africa did not have strong product liability legislation, conformity assessment requirements in technical regulations frequently called for various forms of "premarket" product testing or certification. A balance must be identified between the costs and the risks associated with these various forms of assessment and their effect on trade. The NTRF strategy did not provide a clear-cut definition of preferred modalities (such as the eight Modules of the European Union Global Approach for conformity assessment).[7]
- *Sanctions for noncompliance*. Technical regulations should contain appropriate but flexible sanctions or remedies to enforce compliance and penalize noncompliance. These could include fines, injunctions, corrective advertising, withdrawal of products, product recalls, negotiated settlements, and preventive actions by suppliers. Mechanisms must be established to ensure a consistent and balanced approach to the imposition of sanctions.

The NTRF strategy envisaged the establishment of the Technical Regulatory Office at the DTI with the main purpose of coordinating technical regulation across all ministries and regulatory agencies, as well as coordination of these with the QI organizations—such as SABS, SANAS, and NMISA—to facilitate the use of standards, accreditation, and metrology in technical regulation.

NTRF implementation

Many government departments and related agencies slowly implemented the NTRF. Accreditation became the common denominator for the designation of inspection bodies, testing laboratories, and certification bodies as the government withdrew from service delivery activities. Standards were increasingly used as the basis for technical regulation, even though there were still pockets of resistance among the regulatory agencies. The envisaged NTRF legislation did not come about, and neither did the envisaged Technical Regulation Office. Obtaining the necessary support from all affected ministries for such cross-cutting legislation and powers of control proved to be difficult, and other priorities become more important in the DTI over time.

South African Bureau of Standards (SABS)

Of the three main QI organizations, SABS was to undergo the most dramatic reengineering. Because of the major changes that were to take place, they were made in a number of definitive steps. The organizational structure was changed in three stages, the Standards Act was extensively revised, the new Compulsory Specifications Act was developed, and the administration of compulsory specifications and legal metrology were separated and placed in a newly established regulatory agency, the National Regulator for Compulsory Specifications (NRCS), under the DTI.

SABS, which hitherto had been placed under the Department of Arts, Culture, Science and Technology—together with other science councils, such as the CSIR, Human Sciences Research Council (HSRC), National Research Foundation (NRF), and others—was now placed under the DTI, together

with NMISA and SANAS, to foster coordination among the pinnacle public QI organizations and to align their activities with the government's industrial development and trade policies.

Status quo before QI review publication

Ever since its inception in 1946, the SABS structure had been organized in technology sectors. It had four engineering departments (civil, electrical, electronic, and mechanical) and three chemical departments (biological sciences, chemical, and fiber technology). Each of these departments provided the whole range of standardization services (standards development, inspection, testing, and product certification) as well as the administration of compulsory specifications. Some of the departments had also started to provide quality management system certification. Therefore, each of the departments was a standards organization in its own right within its specific technology sector.

The technology-based structure had quite a few advantages: good communication between the standards development and implementation sides, enhanced multiskilling, and an industry sector with a single point of entry. But the structure resulted in a bloated administration, the technology departments developed divergent practices over time, and there was heavy and mostly uncharted financial cross-subsidization between the "good for country" activities and commercial services.

SABS enjoyed a number of marketing advantages—some would argue, monopolistic in nature—that were either ensconced in the Standards Act or had developed over years:

- The national standards were prefixed with "SABS" instead of "SANS."
- Only permit holders (licensed manufacturers) were legally entitled to market their products as complying with SABS standards. Other certification organizations could not certify products to SABS standards. The annual permit fees constituted a large part of SABS's budget.
- The compulsory specifications were cooperatively developed between SABS and industry, largely without government interference, even though their final promulgation was in the hands of the Minister of Trade and Industry.
- The market surveillance of locally manufactured as well as imported products falling within the scope of compulsory specifications was conducted by SABS, for which it received an annual levy from suppliers, based on production volumes. This levy was negotiated annually between SABS and suppliers and was promulgated by the Minister of Trade and Industry in the *Government Gazette*.
- Although the SABS Mark (the product certification mark of SABS) was not a prerequisite for compliance with compulsory specifications, suppliers whose products were subject to a compulsory specification for which they could also obtain the SABS Mark did not pay the full levies.
- Testing of products for the SABS Mark and compulsory specifications was almost exclusively conducted in the more than 70 laboratories of SABS.

Organizational reengineering

A major restructuring exercise got under way from 1996 to 1998, driven by the SABS senior management, mostly recently appointed young technologists who had come up through the ranks. The technology "silos" of SABS were deconstructed within each department and rearranged into standards development, testing, and

certification units. Once these were established, the SABS structure as a whole was aligned accordingly, all the standards development was merged into the new Standards Department, and the testing and certification units were merged.

This reengineering provided the possibility to ring-fence the noncommercial from the commercial activities—a step demanded by the government, which had decided it would no longer subsidize commercial activities such as testing and certification; in other words, SABS would have to compete in the marketplace just like any other service provider. On the other hand, the government made the commitment that it would fund SABS's activities for the public good—that is, standards development and information. The regulatory work of SABS, such as administration of compulsory standards and legal metrology, was separated and placed in the noncommercial part for the time being.

The reengineering brought about new business challenges:

- Management expertise to lead the new functions had to be found.
- State funding for the commercial functions dried up, and some laboratories that were no longer financially sustainable had to be closed.
- Staff were reduced from approximately 1,400 to 1,000 through early retirements and resignations, with the loss of much expertise.

To manage the changes, external change facilitators were brought in from time to time. The clients of SABS were also not altogether happy with the changes, and negative perceptions had to be managed. But after the reengineering, it was possible to identify the actual costs of the "good for country" regulatory work for the first time, and the commercial entities had to become much more customer-focused. The road for future growth was clearer.

The final chapter in the reengineering of the SABS organizational structure was the commercialization of the testing and certification activities in 2002. They were established as wholly owned subsidiaries of SABS under South African company law; that is, they became tax-paying proprietary limited firms. This removed one of the major complaints of the private sector conformity assessment service providers, namely that SABS did not have to pay taxes; in other words, conformity assessment services became a level playing field. Once the legislation to establish the new National Regulator for Compulsory Specifications (NRCS) was promulgated in September 2008,[8] the regulatory activities of the SABS were separated and placed in the NRCS. The reengineering of the SABS organizational structure was now complete.

Revision of the Standards Act

The Standards Act was revised extensively, as follows:[9]

- The mandate of SABS to accredit organizations was removed to clear the way for SANAS to become the sole national accreditation organization.
- SABS was given the sole mandate to publish national standards, but SABS was also empowered to register other SDOs.
- The reference to national standards was liberalized, opening the way for any organization to declare compliance of its products or services with such standards if materially true, and it also allowed other certification organizations to use them rather than foreign standards.
- The administration of compulsory specifications was removed to clear the way for the separation of these functions from SABS.
- SABS was allowed to establish subsidiaries and operate in countries outside the borders of South Africa—that is, to become much more commercially oriented.

The National Metrology Laboratory (NML)

In spite of the recommendation of the QI review that the NML should remain in the CSIR, albeit as a separate division, there was a groundswell of opinion that it would be better to establish the NML as an independent organization. Two issues in particular pushed this agenda: First, the DTI wanted to have control over all three of the pinnacle QI organizations, and the CSIR was under the control of the Department of Arts, Culture, Science and Technology, and would remain there because the CSIR was a science council proper. Second, as SABS and SANAS pursued international recognition as fully independent organizations under their own governance structures, this also became an imperative for the NML.

One of the main challenges for the NML to be established as an independent entity—namely, that it was still a small organization—was set aside when the metrology-in-chemistry activities of CSIR laboratories were merged with the NML. This merger nearly doubled the business side of the NML. The relevant legislation had to be developed, and in 2006 it was promulgated as the Measurement Units and Measurement Standards Act.[10] The NML was separated from the CSIR and renamed the National Metrology Institute of South Africa (NMISA), under the DTI. The NMISA vigorously pursued international recognition through the Key Comparison Database of the International Bureau of Weights and Measures (BIPM) and played a major role in the development of the regional Intra-Africa Metrology System (AFRIMETS).

Accreditation

SANAS had been established just before the QI review. It had reached a useful market penetration as a "not-for-gain" private sector company and was vigorously pursuing recognition throughout the whole of government. SANAS was well positioned in the Southern African Development Community (SADC) as the only internationally recognized accreditation organization (as a signatory in 2000 to the International Accreditation Forum [IAF] Multilateral Recognition Agreement and the International Laboratory Accreditation Cooperation [ILAC] Mutual Recognition Arrangement), and it was well respected in Europe and Australia. Hence, the QI review did not have much to offer regarding the organizational structure of SANAS, nor its business practices, and there were no conflicts of interest of note to discuss. No major reengineering was thus recommended, other than the possible development of an accreditation law to ensure that SANAS would be designated the sole national accreditation organization and that it would be given certain indemnities to operate in the technical regulation domain, even though it would remain a private company.

However, the DTI wanted SANAS to have the same status as the other two pinnacle QI organizations, the SABS and NMISA—namely, to become a statutory body. This would bring about the legal certainty that SANAS was the sole national accreditation body for the whole of government, and it would give the government more influence in the governance of the organization. In 2006, SANAS became a public entity through the promulgation of the Accreditation for Conformity Assessment, Calibration and Good Laboratory Practice Act.[11] The chief executive officer (CEO) of SANAS—who had a lot to do with the powerful position it had achieved in South Africa, regionally, and internationally—resigned. The reengineering of accreditation was complete.

Remaining implementation challenges

The main challenge remaining would be the development and promulgation of a definitive common approach to technical regulation (see the earlier "Technical Regulation" subsection) and the establishment of the Technical Regulation Office. The technical regulation regime of South Africa, although more compliant with the WTO TBT Agreement than in years past, is still fragmented and suboptimal. The notion that ministries should follow the NTRF strategy in a "voluntary" way is not always effective.

The lack of a common approach to technical regulation will come under additional pressure in the run-up to a common market in the SADC because countries need to learn to trust each others' technical regulation regimes. It may end up as a common regional approach just as in the 1990s, with the EU's promulgation of its New Approach Directives for technical regulation and the Global Approach for conformity assessment.[12]

KEY SUCCESS FACTORS AND LESSONS LEARNED

The reengineering of the South African QI took place without outside intervention or donor support. It is therefore a fairly unique story in the developing country context. The drivers and modalities are known, and these could be just as important in cases where countries are supported by donor activity.

Government commitment and leadership

When South Africa emerged from the apartheid years, the new government wanted to make sure that the QI was totally supportive of the socioeconomic development challenges that South Africa faced after the sanction years. Among the key success factors in the government's approach to the successful reengineering of the QI was the leadership provided by the government, as follows:

- *The DTI established a directorate with a specific focus to provide the QI with government support and guidance.* This directorate was led by individuals who understood the QI environment not only in South Africa but also internationally, and they had the ear of those at the political level—among others, the Minister of Trade and Industry.
- *The DTI made adequate funds available for the in-depth and independent review of the QI and technical regulation regime—a totally holistic approach.* This review not only encompassed the QI organizations at the national level but also benchmarked them against international practices and successful reengineering processes elsewhere. In addition, the needs of South African authorities and, importantly, of industry were the markers that had a major influence on the final decisions regarding reengineering. It was accepted that some good practices followed in high-income countries might not be useful in South Africa.
- *The QI review was discussed and agreed to not only in governmental circles but also in a much broader context* between government, industry, and labor representatives in a high-level national forum, NEDLAC. This paved the way, for example, for a smoother transition to new organizational structures that had to be negotiated with sometimes rather militant labor unions.

The QI organizations

The transition from monopolistic status with regulatory powers to service-oriented organizations without regulatory powers was not easy. It was facilitated by a number of factors:

- *Senior management that was relatively young, had been trained in strategic management, and had been exposed to good practices* through continuous interactions with peers in international organizations, such as the International Organization for Standardization (ISO), International Electrotechnical Commission (IEC), BIPM, International Organization for Legal Metrology (OIML), ILAC, and IAF. In many cases, the individuals in senior management of the South African QI were actively supported to become members in the governance structures of these organizations. The reengineering of QI organizations was driven internally by these individuals.
- *Facilitation and support of change management by outside change management experts.* They were not involved in determining the technical side of the changes, but they provided the necessary psychological backing and support for what were sometimes difficult changes for many employees.
- *Involvement of the labor unions* right from the start was an important element in keeping peace in the workplace during the difficult transition periods lasting a number of years.
- *Open and continuous communication from management to the workforce* regarding the reengineering needs, requirements, and actual processes at every stage ensured that disruptive rumor mongering was kept to an absolute minimum.
- *Stability and self-sufficiency of QI activity units before moving them to other organizations.* Separating activities from one organization to move them to another without upsetting the whole organization is successful if the part to be separated is established as a unique and self-contained entity within the organization before separation takes place.

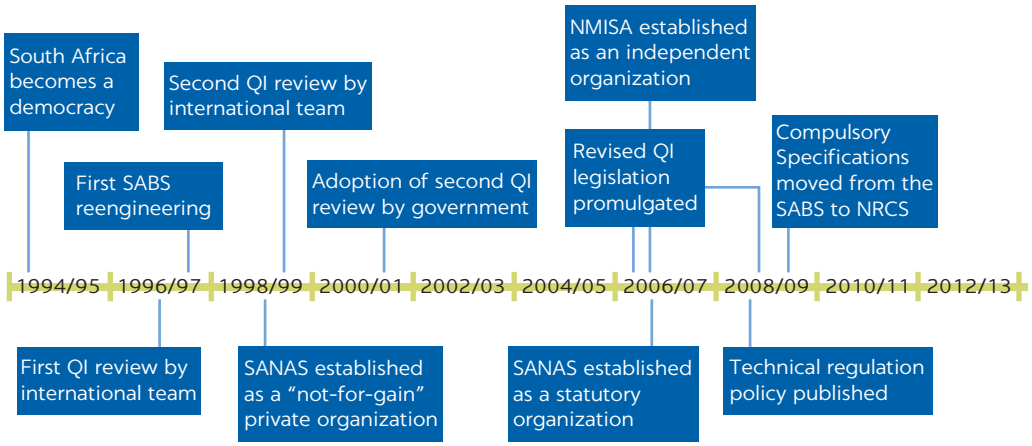
Timeline of QI reengineering

Reengineering a total system takes time—more time than is often considered adequate. Planning the time frame for such changes should take the following into consideration:

- *The development and promulgation of new or revised legislation* takes years in any society, and it is not always easy because the QI is usually not high on the sociopolitical agenda of parliaments. Hence, such revisions and the development of new legislation are frequently not undertaken, and the reengineering process is consequently compromised.
- *Massive organizational changes* require time for planning, obtaining approval from governance structures, realigning budgets, and implementation (figure 2). Separating activities from one organization to establish them within an independent organization cannot be hurried.
- *Changes have to be decisive regarding milestones.* It is not useful to have the changes take place organically, because this allows silent sabotage to creep in.

FIGURE 2

Main QI reengineering events in South Africa, 1994–2013



Note: NMISA = National Metrology Institute of South Africa; NRCS = National Regulator for Compulsory Specifications; QI = quality infrastructure; SABS = South African Bureau of Standards; SANAS = South African National Accreditation System.

CONCLUSION

Reengineering a country's total QI system is possible, given the political will and leadership to do so. Adequate time should be allowed, and all stakeholders should be involved right from the beginning. Change management is very important. It is not necessary for a low- or middle-income country to wait for donor support; a tremendous amount of the reengineering can be done by dedicated and knowledgeable individuals within the country.

NOTES

1. The Metre Convention is an international treaty signed in 1875 that created the International Bureau of Weights and Measures (BIPM), established the metric system, and addresses the base units of scientific metrology.
2. In South Africa, ministries are designated "departments."
3. The department has since been separated into the Department of Arts and Culture and the Department of Science and Technology.
4. By declaring them mandatory, these compulsory specifications are technical regulations in terms of the WTO TBT Agreement definitions.
5. NEDLAC is the vehicle by which government, labor, business, and community organizations seek to cooperate, through problem solving and negotiation, on economic, labor, and development issues and related challenges facing the country.
6. *Performance-based* technical regulations "specify the desired objective in precise terms but allow the regulated entity to determine their own technique for achieving the outcome," whereas *prescriptive* technical regulations "specify the means for attaining the specified outcome" (DTI 2006, 23–23).
7. For more information about the EU's modules for conformity assessment under its Global Approach Directive, see the summary, "CE Conformity Marking," on the EUR-Lex website: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM%3Al21013.
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INTERNATIONAL DEVELOPMENT IN PRACTICE

Turkey

QI Toolkit Case Studies

Martin Kellermann

WORLD BANK GROUP

PTB Physikalisch-Technische Bundesanstalt
Braunschweig und Berlin
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Abbreviations

CAC	Codex Alimentarius Commission
CE	Conformité Européenne
CEN	European Committee for Standardization
CENELEC	European Committee for Electrotechnical Standardization
CMC	calibration and measurement capabilities
EA	European co-operation for Accreditation
EC	European Commission
EN	European standard
ETSI	European Telecommunication Standards Institute
EU	European Union
EURAMET	European Association of National Metrology Institutes
GDP	gross domestic product
IAF	International Accreditation Forum
IEC	International Electrotechnical Commission
ILAC	International Laboratory Accreditation Cooperation
ISO	International Organization for Standardization
OECD	Organisation for Economic Co-operation and Development
PTB	National Metrology Institute of Germany (Physikalisch-Technische Bundesanstalt)
QI	quality infrastructure
SMEs	small and medium enterprises
TS	Turkish standard
TSE	Turkish Standards Institute (Türk Standardlari Enstitüsü)
TÜRKAK	Turkish Accreditation Agency (Türk Akreditasyon Kurumu)
UME	National Metrology Institute (Ulusal Metroloji Enstitüsü)

Turkey

QI Toolkit Case Studies

Abstract: Turkey reengineered its quality infrastructure (QI) as a result of the customs union established between it and the European Union (EU) in 1995 and as a precursor to EU membership later on. This major reengineering was to fundamentally change the technical regulation regime, which was based on mandatory standards and the concomitant product certification into the EU system based on the New Approach Directives for technical regulation and the Global Approach Directives for conformity assessment. The Turkish Standards Institute (TSE) and the National Metrology Institute (UME) existed but were modernized, and the Turkish Accreditation Agency (TÜRKAK) was established and gained international recognition.

EXECUTIVE SUMMARY

In 1995, a customs union was established between Turkey and the European Union (EU). The free movement of goods between these two entities became a significant driver for the socioeconomic development of Turkey. However, major differences in standardization and, especially, technical regulation practices existed between these two trading partners, leading to significant barriers to trade. Therefore, Turkey had to align its standardization and technical regulation regime with the EU's. In addition, once Turkey indicated it wished to become an EU member, Turkey had to demonstrate full compliance with the *acquis communautaire*, the body of EU legislation.

Turkey's standardization and technical regulation regime developed over many years to serve the needs of the Turkish political level and the internal market. By 2000, two public sector quality infrastructure (QI) entities—the Turkish Standards Institute (TSE) and the National Metrology Institute (UME)—had been operational for quite some time, but both needed to be modernized. A national accreditation body did not exist. The major challenge, however, was the technical regulation regime, with over 1,500 mandatory standards developed by TSE, and for which TSE operated a mandatory testing and certification scheme.

Although some efforts to reengineer the QI were made from 1995 onward, it was only after 2000 that Turkey started to dramatically reengineer its QI and its technical regulation regime. The Undersecretariat for Foreign Trade in the Prime Ministry was given overall responsibility for this massive undertaking. The reengineering of the QI and the technical regulation regime was a mixture of (a) Turkish government interventions; (b) technical support from the EU and its member countries in a variety of projects; and (c) the active involvement of the Turkish private sector in advocacy, upgrading products, meeting quality requirements, and establishing private sector conformity assessment services. Areas that required attention included the following (table 1):

- Before 1995, the TSE published national standards in accordance with national interests. Some were adoptions of international standards; many were not. By 2011, the TSE had adopted almost 99 percent of the European (EN) standards recognized by the EU. Many of the EN standards were translated into Turkish; otherwise, they were published with a Turkish cover page and an English text.
- By 1995, the UME had moved into new buildings with 21 laboratories that had appropriate environmental controls, supported by a computer center and workshops. Whereas the UME had provided much of Turkey's calibration services before 1995, private sector calibration laboratories were established thereafter and were accredited, with the result that, by 2010, UME could focus much more on research and development and the maintenance of national measurement standards.
- At the end of the 1990s, Turkey's system for controlling weights and measures was dysfunctional. Some of the national and provincial authorities were notionally responsible for market surveillance, but little of this function was in place. Personnel were trained in general legal metrology practices through a German-supported project that ran from 2006 to 2008, and some of the authorities' directorates were reorganized in 2008 to ensure a better focus on legal metrology matters. Coordination between the national and provincial authorities remained a problem, and the authorities' understanding of the EU's Legal Metrology Directives remained a challenge.
- Before 1995, accreditation in Turkey was not considered an important QI service. The TSE and the UME provided some accreditation services for testing and calibration laboratories, respectively, but these services were neither internationally recognized nor acceptable to the EU. The Turkish Accreditation Agency (TÜRKAK) was established in 1999. The accreditation activities of the TSE and the UME were transferred to TÜRKAK. TÜRKAK benefited from a German-funded technical cooperation project implemented by the National Metrology Institute of Germany (PTB) that ran from 2000 to 2005. TÜRKAK became a full member of the European co-operation for Accreditation (EA) within three years, and gained international recognition through ILAC and IAF soon afterward.

The most profound reengineering took place in the technical regulation domain. Before 1995, Turkey relied heavily on a system of mandatory standards coupled with mandatory testing and certification. About 1,500 mandatory standards had been developed by the TSE over the years, and for many of them TSE was responsible for premarket inspection, testing, and certification

TABLE 1 **Snapshot of quality infrastructure (QI) reform in Turkey**

BEFORE REFORM	AFTER REFORM
The TSE, as the national standards body, develops and publishes national standards in accordance with its own system. Some standards are adoptions of ISO and IEC standards, but many are not.	The TSE standards development and publication system is fully aligned with the European system, and the TSE participates actively therein. EN standards developed and published by CEN, CENELEC, and ETSI are adopted in full as Turkish national standards.
No national accreditation body exists. Two accreditation bodies linked to the TSE and the UME provide accreditation services, but these are not internationally recognized.	TÜRKAK is established as the national accreditation body, and all other accreditation work is incorporated. TÜRKAK is accepted within three years as a full member of the EA and thereafter by ILAC and the IAF, providing Turkey with internationally recognized accreditation services.
Metrology has a long history in Turkey but did not keep up with international developments after World War II.	The UME was established as the new national metrology institute, new laboratories were built, modern measuring equipment was installed, and the UME's calibration and measurement capabilities (CMCs) were listed in the Key Comparison Database of the BIPM, thereby providing for the recognition of Turkey's metrology system at the international level.
Mandatory standards constituted the system of choice of implementing technical regulation, with the TSE responsible for mandatory testing and certification as a precondition for marketing products. More than 1,500 mandatory standards are in force.	Turkey implemented the EU technical regulation system, with the EU Directives containing essential requirements, supported by harmonized EN standards that remain voluntary. Conformity assessment is provided by accredited and designated service providers known as "notified bodies." Mandatory standards are largely withdrawn.

Note: BIPM = International Bureau of Weights and Measures; CEN = European Committee for Standardization; CENELEC = European Committee for Electrotechnical Standardization; EA = European co-operation for Accreditation; EN = European standard; ETSI = European Telecommunications Standards Institute; EU = European Union; IAF = International Accreditation Forum; IEC = International Electrotechnical Commission; ILAC = International Laboratory Accreditation Cooperation; ISO = International Organization for Standardization; TSE = Turkish Standards Institute; TÜRKAK = Turkish Accreditation Agency; UME = National Metrology Institute.

of the relevant products. This system was anathema to the EU and would have to change dramatically before Turkey complied with the EU's New Approach and Global Approach Directives. Reengineering activities included the following:

- All ministries had to reexamine all mandatory standards within their own domains and implement EU Directives in their place.
- The Ministry of Industry and Trade was responsible for about 80 percent of the mandatory standards, and it established a major program in 2004 to deal with the issue.
- The Undersecretariat for Foreign Trade allocated the responsibility for specific EU Directives to particular ministries to ensure that no overlaps or gaps developed.

In 2002, there were still 1,250 mandatory standards in operation. By the end of 2006, the number had fallen to 261, some of which had no EU Directive counterparts and most of which were used only for import controls.

By 2010, Turkey had reengineered its QI and technical regulation regime to comply with the EU's requirements. This was a major reengineering exercise that took 15 years, the last 10 years with major development partner interventions. Even though some challenges remained (particularly in legal metrology), the pre-1995 system was totally changed. It was especially the mandatory standards system—with its premarket approvals through mandatory testing and certification by the TSE—that had been replaced by a technical regulation system fully compliant with the EU Directives, EN-harmonized standards, notified bodies, and market surveillance based on risk assessments.

COUNTRY CONTEXT

General background

Turkey is a Eurasian country—located mainly in Western Asia, with a smaller portion consisting of East Thrace in southeastern Europe—with a land mass of nearly 780,000 square kilometers. Turkey is bordered by eight countries: Bulgaria to the northwest; Greece to the west; Georgia to the northeast; Armenia, Azerbaijan, and the Islamic Republic of Iran to the east; and Iraq and the Syrian Arab Republic to the southeast. The Mediterranean Sea and Cyprus are to the south, the Aegean Sea is to the west, and the Black Sea is to the north. The Sea of Marmara, the Bosporus, and the Dardanelles demarcate the boundary between East Thrace and Anatolia; they also separate Europe and Asia.

Turkey has a population of nearly 79.4 million (2016 estimate). Ethnic Turks make up the majority, estimated at 70–75 percent; Kurds are the second-largest ethnic group, estimated at 18 percent. The largest city, Istanbul, has over 13 million inhabitants; Ankara, the capital, has 4.3 million; and five other cities have populations exceeding 1 million.

Turkey has become increasingly integrated with the West through membership in organizations such as the Council of Europe, the North Atlantic Treaty Organization (NATO), the Organisation for Economic Co-operation and Development (OECD), the Organization for Security and Co-operation in Europe (OSCE), and the Group of Twenty (G-20) major economies. Turkey began full membership negotiations with the EU in 2005, having been an associate member of the European Economic Community since 1963 and having joined the EU Customs Union in 1995. Turkey has also fostered close cultural, political, economic, and industrial relations with the Middle East, the Turkic states of Central Asia, and the African countries through membership in organizations such as the Turkic Council, Joint Administration of Turkic Arts and Culture, Organization of Islamic Cooperation (OIC), and the Economic Cooperation Organization (ECO).

The economy

During the first six decades of the republic, between 1923 and 1983, Turkey mostly adhered to a quasi-statist approach with strict government planning of the budget and government-imposed limitations over private sector participation, foreign trade, flow of foreign currency, and foreign direct investment. However, in 1983 it initiated a series of reforms designed to shift the economy from a statist, insulated system to a more private sector, market-based model. Turkey gradually opened up its markets by reducing government controls on foreign trade and investment and the privatization of publicly owned industries. The liberalization of many sectors to private and foreign participation has continued amid political debate.

The reforms, combined with unprecedented amounts of foreign loans, spurred rapid economic growth. However, this growth was punctuated by sharp recessions and financial crises in 1994, 1999 (following the earthquake of that year), and 2001—resulting in average gross domestic product (GDP) growth of 4 percent per year between 1981 and 2003. Lack of additional fiscal reforms, combined with large and growing public sector deficits and widespread corruption, resulted in high inflation, a weak banking sector, and

increased macroeconomic volatility. Since the economic crisis of 2001 and the reforms initiated by the finance minister of the time in view of the looming membership negotiations for EU membership, inflation has fallen to single-digit numbers, investor confidence and foreign investment have soared, and unemployment has fallen.

GDP growth from 2002 to 2007 averaged 7 percent, which made Turkey one of the fastest-growing economies in the world during that period. However, growth slowed to 1 percent in 2008, and in 2009 the Turkish economy was affected by the global financial crisis, with a recession of −5 percent. The economy was estimated to have returned to 8 percent growth in 2010. By 2015, Turkey had the world's 17th-largest GDP by purchasing power parity (PPP) and the 18th-largest nominal GDP.

Key sectors of the Turkish economy are banking, construction, home appliances, electronics, textiles, oil refining, petrochemical products, food, mining, iron and steel, machine industry, and automotive. Turkey has a large and growing automotive industry, ranking as the 6th-largest producer in Europe (behind the United Kingdom and above Italy) and the 15th-largest producer in the world. Turkey is also one of the leading shipbuilding nations: in 2007 the country ranked 4th in the world (behind China, the Republic of Korea, and Japan) in terms of the number of ordered ships, and also 4th in the world (behind Italy, the United States, and Canada) in terms of the number of ordered megayachts. Tourism in Turkey has experienced rapid growth in the past 20 years and constitutes an important part of the economy.

BACKGROUND OF QI ISSUES

The free movement of goods played a special role in the case of Turkey because of the Customs Union between it and the EU that was established in 1995. After 1985, European legislation concerning product safety and integrity was expressed in its New Approach and Global Approach Directives.[1] The modalities of these Directives included the definition of essential requirements, compliance with which was underpinned by harmonized European standards (EN standards) and conformity assessment by designated conformity assessment bodies. The latter are known as "notified bodies," their "notification" being based on their technical competency and legal accountability in Europe.

The situation in the Turkish home market, however, was equally important, because this had to be fully aligned with EU practices before mutual recognition could be achieved. Standardization and metrology have traditionally played an important role in trade issues and were therefore important elements in the accession negotiations between Turkey and the EU.

The Undersecretariat for Foreign Trade (under the Prime Ministry) was given the oversight responsibility for the whole system. It promulgated the "Ministerial Decree on the Regime of Technical Regulations and Standardization for Foreign Trade" and its supplementary legislation, with the aim of providing transparency in the reform of the standardization and technical regulation regime—thereby assembling all the dispersed regulations regarding standardization policies in Turkey and establishing a legal base for the harmonization of Turkish legislation with that of the EU. The developments in this regard started in 1995 and intensified during the next decade as Turkey sought to comply fully with the *acquis communautaire* of the EU.[2]

PROJECT OBJECTIVES AND COMPONENTS

The EU requirements were the major driver for the more recent developments in the Turkish national QI and technical regulation regime. The *acquis communautaire* of the EU regarding standardization and technical regulation had to be implemented in full before EU accession could take place. The development of the QI and the regulatory reform of the mandatory standards system was a mixture of Turkish government interventions and technical support from foreign development partners.

The development of the QI is a continuing process, and hence the narrative in this case study must of necessity be limited to a specific period, largely reflecting the changes during 2000–10. The narrative is to some extent therefore out of date, but it provides ample evidence of the major changes that were implemented in that period. Further developments will also be influenced in part by the evolving political dynamic of the relationship between the EU and Turkey.

Standards

Institutional changes

Standardization has a long tradition in Turkey. It started in 1930, when provisions controlling the quality of export products were put into force. The Turkish Standards Institute (TSE), the national standards body of Turkey, was established in 1954 as an autonomous institute affiliated with the state. The TSE is the only organization in Turkey that is authorized to develop and publish national standards.

The TSE's status was changed in 1960 by Organization Law 132, which gave it the status of a legal entity administered under the provisions of civil law. Organization Law 132 was later amended to ensure that the TSE's structure, responsibilities, and activities meet the membership requirements of the European standardization bodies, the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC). The amended law gave the TSE a more flexible organizational structure that is administratively, financially, and technically independent. The TSE had to establish new technical committee structures to achieve a balance among members from the public sector, related industry sectors, and academia. The necessary separation between standardization activities and conformity assessment, as required by the EU, was also ensured.

The TSE is an active member of the world standardization community, with full membership in the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) since 1956, and in CEN and CENELEC since 2012.

Standards development and publication

Before 1995, the TSE published national standards in accordance with national interests. Some of these were adoptions of international standards; others were more of an indigenous nature. Once the decision had been made to negotiate accession to the EU, the focus changed dramatically.

Since 1995, as in all EU member countries, the TSE has focused first on EN standards development, next on international standards, and last on national

standards, even though Turkey is not a full member of the EU. The methodology is contained in a TSE Quality Manual that also regulates the establishment of national technical committees and national mirror committees.[3] The previous custom of paying sitting fees to committee members was abolished in view of EU requirements. As of June 2011, 71 national mirror committees covering 20 sectors were actively involved in the work programs of 183 international and European technical committees and their subcommittees.

The TSE circulates the European drafts for inquiry when they are circulated in Europe and creates the country comment in the relevant national mirror committee. Although the TSE will only gain voting rights in CEN and CENELEC if Turkey becomes an EU member, it started to register dummy votes, which are kept for future evidence. After the publication of the EN standard, the TSE adopts the EN within six months (just like full CEN or CENELEC members) without asking the stakeholders again. At the same time, the TSE withdraws national standards of similar scope to promote technical harmonization and to remove technical barriers to trade, a procedure generally welcomed by both industry and regulatory authorities.

As of mid-2011, approximately 99 percent of the EN standards had been adopted as Turkish standards, and conflicting national standards were withdrawn. By then the TSE had adopted nearly 16,300 EN standards as Turkish (TS EN) standards. Of these, 45 percent had been translated into Turkish; the rest had a Turkish cover page with the document in English. The aim was to have all the EN standards translated in the future. If no EN standard is available, the adoption of international standards may be contemplated, but EN standards have priority.

Stakeholder awareness

A standards information service, fully compliant with the requirements of the 1998 revision of the EU New Approach Directive for technical regulation,[4] is operational within the TSE's Standards Preparation Centre. The TSE also acts to raise awareness among national stakeholders on the importance of participation in standardization work. In addition, ministries have created central information points between the respective bodies for the fields under their responsibility. These points are responsible for the dissemination of information within the ministries and for providing draft technical regulations to the Undersecretariat for Foreign Trade for notification to the World Trade Organization (WTO).

Standardization requires balanced representation between the various actors. It is therefore important that it be representative of all interested parties. Technical ministries and big companies deal fairly well with normative information and hence also with their participation in standardization work. This is not necessarily the case for consumer organizations, which are not really involved in the standardization process; small and medium enterprises (SMEs); and professional organizations, especially those representing SMEs. The difference between voluntary standards and technical legislation was not well known among SMEs by 2011, and the issue would need to be addressed through heightened awareness campaigns. Hence, SMEs and consumers were not yet well integrated into the standardization system by 2011.

Metrology

Scientific metrology

The Ottoman Empire was one of the 20 founding states of the Metre Convention in 1875.[5] There were, however, no significant developments in metrology in Turkey until the promulgation of the Law on Weights and Measures in 1931. After World War II, the need for an integrated system of metrology was felt strongly, but major investments had to wait until the 1980s, leading to the establishment of the National Metrology Institute (UME) in 1992 under the Scientific and Technical Research Council of Turkey (TÜBİTAK). The UME moved to new buildings in January 1994 with 21 laboratories, a computer center, an electronic workshop, conference and seminar rooms, and offices. Each laboratory has environmental controls, and all the parameters—such as temperature, humidity, and air pressure—are measured and recorded by a fully automated, computerized environmental control center. The most sensitive laboratories are underground, and special precautions are taken to minimize vibrations.

UME operations were already recognized in 2003 to be fully compatible with European practices, and subsequent progress has seen the UME developing even more. As an institute under TÜBITAK, the UME has changed its scope from being a service provider to becoming a research and development institute. The UME has redefined its mission to be a scientifically based metrology institute with responsibility for all measurement standards except those related to ionizing radiation. This also means that the UME will gradually stop delivering services that are not directly related to scientific metrology, and these services will be devolved to capable accredited laboratories (for example, the calibration department of the TSE and private sector calibration laboratories).

The single biggest new activity that the UME has taken up is in chemistry. This has been done after extensive hearings and in collaboration with the European Commission's (EC) metrology laboratory at its Joint Research Centre. In the chemical community, there was still some skepticism toward the UME's engagement in metrology in chemistry by 2010 that the UME needed to overcome. In general, though, there was respect for the UME's high technical competence and its international engagement. The UME also planned to become a major supplier of certified reference materials (CRMs) in the future.

Consistent with its new mission, the UME had intensified and broadened the scope of its training activities, and it had made several important strategic alliances to increase the impact of metrology in Turkish society. For example, the Turkish Atomic Energy Authority (TAEK) became the designated institute for metrology within ionizing radiation. Hence, TAEK participates in the Mutual Recognition Arrangement of the International Committee for Weights and Measures (CIPM-MRA), which has responsibility for ionizing radiation.

The national metrology system, represented by the UME and including TAEK, is therefore well positioned regionally and internationally, with the UME fully compliant with European practices and an active member of the European Association of National Metrology Institutes (EURAMET). Furthermore, Turkey's calibration and measurement capabilities (CMCs) are listed in the International Bureau of Weights and Measures (BIPM) Key Comparison Database (KCDB), thereby facilitating acceptance of the Turkish metrology system at the international level.

Legal metrology

Despite the substantial work on improving legal metrology in Turkey, progress up to 2006 was limited, and it was in a less favorable position than scientific metrology. The EU Measuring Instruments Directive[6] was foreseen to be difficult to handle, with its new concepts for notified bodies and for market surveillance by the Ministry of Industry and Trade. This turned out to be true, as was also manifested by the lack of national notified bodies for legal metrology.

To initiate change, the relevant ministries received general training on market surveillance, and the Ministry of Industry and Trade started working on the existing law (Law No. 3516, "Metrology and Measurement," promulgated in 1989) to incorporate EU Directives. Thereafter, the Directorate General for Measurements and Standards was reorganized in 2008. (For example, tasks other than legal metrology were transferred to the Directorate General for Industry to provide a better focus on legal metrology.) In addition, new experts were appointed at the Directorate General for Measurements and Standards.

By 2011, revised legal metrology legislation was promulgated, and market surveillance had been implemented in 10 authorities (including six ministries) responsible for this activity. But the implementation varied from authority to authority, and there was a lack of common understanding of what market surveillance really is. There was still no notified body designated for the EU Measuring Instruments Directive, but at least one candidate body had applied to the Ministry of Industry and Trade for designation and was ready for notification to the EU by the Undersecretariat for Foreign Trade.

Producers of measuring instruments in Turkey therefore expressed concern about the lack of public infrastructure for legal metrology. They were concerned that when the transition period for the EU Measuring Instruments Directive expired in 2016, foreign competitors would overrun the Turkish market because of the lack of legal metrology knowledge in the country. With no up-to-date legislation on legal metrology and no notified bodies, Turkey would appear as a weak supporter of its otherwise successful measurement industry. Eventually, the public's faith in Turkish consumer protection could be at stake. To deal with this situation, legal metrology became the subject of a specific EU-supported development project after 2016.

Calibration

By 2008, a complete data set for the calibration activities in Turkey did not exist, but with the big increase in number of accredited laboratories, it was expected to be a growing market. The market situation in calibration benefited specifically from a new policy of the Small and Medium Enterprises Development Organization (KOSGEB). According to this policy, it was possible for SMEs to get support to consult accredited laboratories for calibration, testing, and product development, provided that these SMEs had been listed in the KOSGEB database.

New calibration laboratories emerged in such diverse fields as the environment, aflatoxin in dried food, and medical instrumentation. The calibration laboratories in the newer fields such as chemistry and microbiology were less developed, as was also the case in Europe. Here, traceability was more difficult to establish, and uncertainties were more difficult to calculate, because consideration of metrology was not yet routine. When the measurements were

performed on food or the environment, the problem of sampling occurred, and none of the laboratories had yet fully integrated sampling in the measurement process.

Accreditation

Turkish Accreditation Agency (TÜRKAK)

The Turkish Accreditation Agency (TÜRKAK) was established in 1999 as the sole accreditation body for all accreditation activities in Turkey. Its legal framework is provided in Law No. 4457/1999 (on Establishment and Tasks of TÜRKAK) and a number of supporting regulations. Turkey notified the EC that TÜRKAK is the national accreditation body, and as a consequence it was listed in the EC's list of national accreditation bodies—but not before its technical capabilities were extensively developed under a project implemented by the National Metrology Institute of Germany (PTB) from mid-2000 through 2005. The PTB project invested just over €1 million in consultancy, training, and advocacy in the public and private sectors.

The law provides that TÜRKAK operates on a not-for-profit basis and that it neither offers any activities or services that conformity assessment bodies provide nor provides consultancy services to, owns shares in, or otherwise has a financial or managerial interest in any conformity assessment body. The Turkish government ensured that TÜRKAK had the appropriate financial and personnel resources for the proper performance of its tasks, especially during the first years of operation.

TÜRKAK has been a full member of the EA since 2006, actively participating in its scheme-specific activities. It is a signatory to multilateral agreements of the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF) for testing, calibration, inspection, personnel, and quality management system and product certification schemes—most of those agreements also since 2006. Signing the EA Multilateral Agreement with the EA changed the public perception on accreditation significantly. Accreditation is operated on a voluntary basis—that is, provided when conformity assessment bodies so request.

TÜRKAK has business relationships for assessment and accreditation with several neighboring countries: Albania, Azerbaijan, Georgia, Kazakhstan, the Kyrgyz Republic, Turkmenistan, and Uzbekistan. Applications for accreditation have also been received from countries in the Middle East like Lebanon, Saudi Arabia, and Syria, but by 2008 they had not yet been processed. When accepting and processing applications from abroad, TÜRKAK observes the cross-frontier policies of ILAC and the IAF.[7] In spite of the provision in the amended Law No. 4457, TÜRKAK does not consider establishing branches abroad.

By the end of the German project, in 2005, TÜRKAK had accredited 33 testing laboratories, 17 calibration laboratories, 17 management system certification bodies, 11 inspection bodies, 2 product certification bodies, and 3 personal certification bodies—a total of 83. By mid-2016, the numbers increased to 730 testing laboratories, 120 calibration laboratories, 18 medical laboratories, 165 inspection bodies, 53 product certification bodies, 81 management system certification bodies, 81 personal certification bodies, and 4 proficiency testing providers—a total of 1,204 bodies, some with more than one accreditation. This was remarkable growth by any measure.

By 2007, over and above the conformity assessment bodies accredited by TÜRKAK, many were still operating in Turkey that had been accredited by foreign accreditation bodies. These did not seem in a hurry to obtain TÜRKAK accreditation. The main reason stated was the significant difference in financial obligation implied by TÜRKAK accreditation (UNIDO 2013). Competition with European accreditation bodies ended in the wake of EU Regulation No. 765/2008 (to regularize accreditation across EU member states),[8] and TÜRKAK was able to take over all accreditations granted by these bodies to Turkish conformity assessment bodies. Competition continued with other national accreditation bodies, such as those from the East Asia and Pacific region, but it was kept notionally within the framework of the ILAC and IAF cross-frontier policies (IAF 2016).

Notified bodies

According to EC Regulation No. 768/2008, conformity assessment procedures can be performed by authorities, manufacturers, or conformity assessment bodies. In case authorities decide not to perform conformity assessment themselves, they may delegate this task to conformity assessment bodies, but must notify such delegation to the EC. This is what Turkey has also been practicing. TÜRKAK's role in the notification process is to assess applicant-notified bodies and report the results to the relevant ministry. By 2007, the EC had accepted three notified bodies from Turkey, and others were pursuing notification.

The Undersecretariat for Foreign Trade publishes the complete list of notified bodies, as do some ministries for their specific sectors. When the designation process started in Turkey, it was possible for a candidate conformity assessment body to apply directly to the ministry in charge without being accredited. The ministry reviewed the application and documents, and then submitted the file to TÜRKAK for evaluation. In this case, TÜRKAK's evaluation concentrated only on the conformity assessment body's competence in assessing conformity with essential requirements, which is less than an accreditation against the reference criteria plus the directive requirements. By 2008, this approach was no longer possible because the EU had changed its rules, but some remnants of the old dispensation still had to be cleared.

Mandatory standards

General

Until the early 2000s, Turkey relied heavily on the imposition of mandatory standards (which were a form of technical regulation) to control the integrity of products in the marketplace. Because of Turkey's plans to become an EU member, these had to be withdrawn in totality to meet the EU requirements. Hence the number of mandatory standards decreased considerably over the years. For example, in import controls, the number decreased from 1,250 to 261 in five years (2002–07), and a further 220 were abolished by the beginning of 2009. The remaining ones used for customs control were a mixture of TS EN standards and some national TS standards, such as gas cartridges for liquefied petroleum gas, child articles, fire protection, lighters, and roller bearings.

Mandatory application of standards is the responsibility of the concerned ministry. Therefore, each ministry had to make the necessary arrangements to withdraw the mandatory standards within its jurisdiction. The Ministry of

Industry and Trade was in charge of coordinating all information on this matter and informing the stakeholders. The TSE facilitated this process by informing the relevant ministry that the standard under mandatory implementation was revised and replaced by a European standard. Additionally, at the TSE website, superseded Turkish standards under mandatory implementation were shown as "withdrawn" with an "Important Notice" stating, "The standard is withdrawn even if it is in mandatory implementation."

European Directives

By 2007, the responsibility for implementation of the EU Directives had been officially allocated to specific ministries, for example:

- *Ministry of Industry and Trade* is responsible for directives in the fields of motor vehicles, agricultural and forestry tractors, legal metrology, electrical risk and electrical equipment, pressurized equipment, and other manufactured product groups.
- *Information and Communication Technologies Authority* is a member of the European Telecommunication Standards Institute (ETSI) and the International Telecommunication Union (ITU). All ETSI standards are transposed and published by the TSE as TS ETS standards.
- *Ministry of Health* is responsible for the harmonization of the following directives (both old and New Approach): safety of toys, medical devices, cosmetic products, detergents, chemicals and their safe use, and ionizing radiation.
- *Ministry of Agriculture and Rural Affairs* is in charge of Codex Alimentarius Commission (CAC) standards. The Turkish Food Codex is prepared by the National Food Codex Commission and its subcommittees. As soon as the specifications prepared by the Codex Alimentarius are adopted by the Turkish Codex Committee, they are made applicable to the market.
- *Undersecretariat for Maritime Affairs* is in charge of directives on recreational crafts, marine equipment, and noise and exhaust emission measurement of the same.
- *Ministry of Public Works and Settlement* is responsible for the implementation of the directive on construction products. This, however, has not been fully implemented—and approximately 40 mandatory standards are still in place.
- *Ministry of Labour and Social Security* is in charge of the directive on personal protective equipment and on the protection of the health and safety of workers from the risks related to chemical agents. Most standards in use are ISO and EN standards.

Import inspection

Inspectors of the Directorate General Standardization, a directorate of the Undersecretariat for Foreign Trade, dealt with quality control of more than 140 agricultural produces and products such as fresh fruits and vegetables, edible oils, dry and dried produces, and pulses. The inspectors were conducting inspections of these commodities according to 80 TS standards. These standards were mandatory on both the export and import levels. They corresponded, for example, to the United Nations Economic Commission for Europe (UNECE) or CAC standards for fresh fruits and vegetables as well as dry and dried products, and the inspections were performed in accordance with OECD Scheme recommendations. These were to be withdrawn once the EU Directives were established.

Market surveillance

With the transition from the existing system of mandatory standards to the new system of EU technical legislation combined with voluntary standards, the Ministry of Industry and Trade, among others, was confronted with some new and challenging tasks. Implementation of mandatory standards was basically a premarket control system, whereas EU technical legislation relies heavily on in-market surveillance to check the compliance of products with essential requirements. The ministry's organization had to be restructured so that its responsibilities and tasks related to the transposition, preparation, and implementation of technical legislation were in line with European and international requirements. A "twinning project" between the German Federal Ministry of Economic Affairs and Technology (BMWi)[9] and the Turkish Ministry of Industry and Trade was implemented to address these challenges (BMWi 2008).

The most serious deficiency probably concerned the lack of experienced and qualified staff equipped with the necessary means and tools. New and existing personnel in both the central and provincial offices had to be trained. The training needs varied from technical assistance to consultancy on the administrative and practical issues of implementing the *acquis communautaire* of the EU. Coordination and cooperation between the Ministry of Labour and the Ministry of Industry and Trade in the field of inspections of industrial enterprises was another issue that was worked out in the short run. Furthermore, a proactive market surveillance policy and improved coordination between the various directorates general of the ministry were needed.

Conformity assessment

By 2008, conformity assessment—as a means of demonstrating that only safe products are put on the market—was slowly being appreciated by the business community in Turkey. Council Decision No. 1/2006 to implement the final phase of Turkey's Customs Union with the EU,[10] which permitted the designation of notified bodies from Turkey, opened up opportunities to trade with the EU. The number of notified bodies had increased since 2006, but Turkey still lagged behind small nations such as Romania. Despite this progress, there were still many gaps; for example, there were no notified bodies for the EU's Low Voltage Directive or Electromagnetic Compatibility Directive. The scope of coverage also needed to be increased.

A conformity assessment body needed accreditation from TÜRKAK based on the relevant accreditation standards as well as the relevant ministry's approval before it could be designated and notified to the EC and other member states. However, in some sectors, conformity assessment bodies felt TÜRKAK did not have the competence to assess them against the directives, and hence relevant ministries assisted TÜRKAK in the technical aspects. It was felt that TÜRKAK should be able to engage independent expertise, rather than giving the impression of a governmental group conducting the assessment.

Certification marks

By 2010, two other product certification marks besides the regulatory Conformité Européenne (CE) marking—the G mark and the TSE mark—were still in common use in Turkey. This led to confusion, and the two marks were in some cases applied

in conflict with European law, which states that only the CE marking is legally required to indicate conformity with the essential safety requirements of products.

- *The CE marking* is the demonstration of compliance with the appropriate EU Directive in terms of standards and conformity assessment procedures, and it is affixed by the manufacturer or supplier once all conformity assessment requirements stated by the relevant directive have been fulfilled.[11]
- *The G mark* (the Gulf Mark used in Gulf Coordinating Council [GCC] member countries) on construction products was introduced by the Ministry of Public Works and Settlements in 2008 as a national, compulsory safety mark for products that were not in the harmonized area or where CE marking could not be applied. Once the EU Construction Products Directive was implemented, the G mark should have been abolished where the directive applied. On the other hand, in a nonharmonized area, there may be a use for a national mark. However, the situation in Turkey gave rise to confusion among both conformity assessment bodies and end users, and the Turkish authorities were under pressure to present convincing arguments for the continued use of the G mark.
- *The TSE mark* is a quality mark given by TSE Certification that enjoyed considerable visibility and respect in Turkey. In this respect, the TSE mark is similar to the multitude of national marks that prevail in European markets. However, it was not clarified even by the TSE how the scope of the TSE mark differed from, especially, the CE marking. The EC is quite clear that there should be no confusion with the CE marking. Other marks are permissible as long as they do not purport to be equal to the CE marking. The TSE still had some public enlightenment to conduct in this regard.

Laboratories

By 2008, there was an extensive network of laboratories to cater to the needs of most industrial and food products. However, there were tensions between the private sector laboratories and the relevant ministries. The authorities showed a preference for the work to be done in their own laboratories, even when they were stretched to accommodate the testing. The private laboratories claimed that they were just as competent as the public laboratories, if not more so. They had highly qualified and trained staffs who are well versed in the necessary testing procedures. The staffs respected confidentiality and impartiality, and the testing was done independently of any knowledge of the source of the sample. Their equipment was modern, and they had the capacity. The laboratories invariably had TÜRKAK accreditation. Despite these credentials, they felt left out or picked up disproportionately less work.

System certification

Quality management system certification, especially ISO 9001 ("Quality Management Systems—Requirements"), was in place in Turkish society.[12] However, public procurement rules emphasizing ISO 9001 may have, perhaps unintentionally, opened up the market to low-quality certificates being awarded, with certified entities not in full conformity with the requirements. Authorities needed to become more vigilant in their selection of certification bodies. Environmental management system certification to ISO 14001 ("Environmental Management Systems—Requirements with Guidance for Use")[13] and occupational health and safety via OHSAS 18001 ("Occupational Health and Safety Management")[14] were commonly in use in major enterprises but not so widespread in SMEs. These needed to be promoted.

PROJECT DESIGN AND IMPLEMENTATION

Not all the outcomes were the result of specific projects supported through outside interventions. Quite a few successes were achieved by Turkish efforts within the relevant ministries. This section details some of the main projects as facets of an overall approach coordinated by the Undersecretariat for Foreign Trade.

Standards

To support Turkey, and in particular the TSE, the EU funded a technical assistance project through a grant from EuropeAid's Mediterranean Countries and the Middle East (MEDA) program, named Support to Standardisation Activities in Turkey, with the following objectives:

- *Provide technical assistance to the TSE* to contribute to the progressive alignment of national legislation and to implement the European requirements
- *Provide training to TSE staff* to enable them to become familiar and conversant with internal regulations and procedures of the European organizations CEN and CENELEC
- *Provide training of trainers* to a small team of TSE staff and some selected external consultants to enable them to work independently and train their colleagues after the completion of the project (transfer of know-how).

The project had a budget of €750,000, ran from 2005 to 2007, and was implemented by a consortium of four EU national standards bodies: the French Standardization Association (AFNOR), the Spanish Association for Standardization and Certification (AENOR), the German Institute for Standardization (DIN), and the Austrian Standards Institute (ÖN).

Mandatory standards

In 2000, the situation regarding mandatory standards was of real concern for Turkey's EU accession plans in several ways:

- The number of mandatory standards was high, but it was difficult to obtain precise statistics, and the number of mandatory standards differed according to sources (the ministries or the TSE).
- These standards existed in many sectors, including those covered by the EU New Approach Directives.
- The standards were perceived as the main technical obstacle to importing industrial products from foreign countries, particularly European countries.
- The TSE bore a large responsibility for the situation because the Technical Board of the TSE recommended to the ministries concerned the standards to be promulgated as mandatory. The TSE was also responsible for verifying conformity with mandatory standards for import control.

To address the situation, the Undersecretariat for Foreign Trade decided the following:

- The ministries concerned should reexamine all mandatory standards within their fields of competence in order to withdraw or maintain them, depending on the developments in progress—such as implementation of a New Approach Directive, obsolescence of the standard, revision of the TS standard following

the approval of the corresponding EN or ISO standard, and so on. The Ministry of Industry and Trade, which was in charge of approximately 80 percent of the mandatory standards, set up a working group at the end of 2004 in cooperation with the TSE and prepared a plan for withdrawal of mandatory standards within its field of competence.

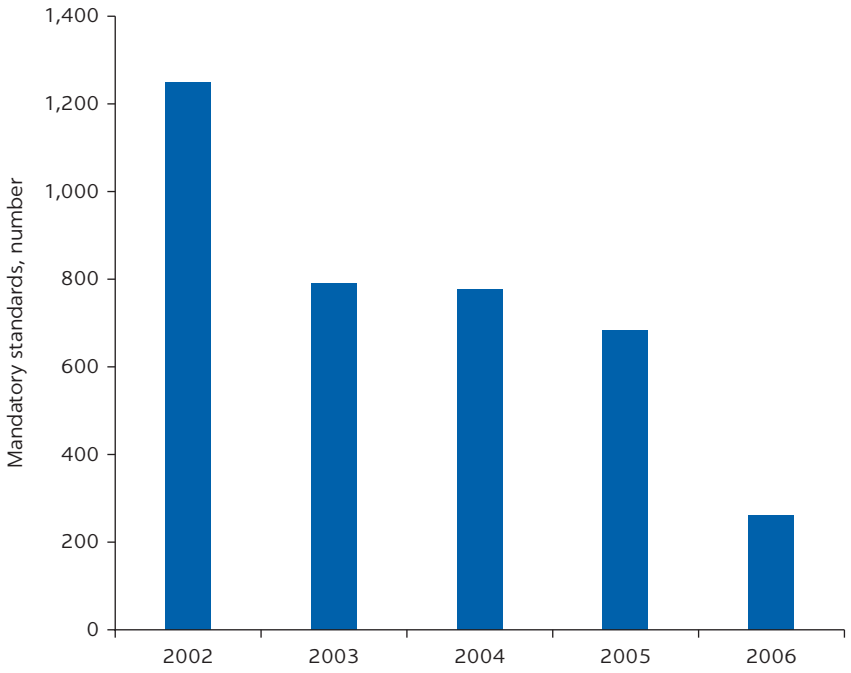
- The TSE Technical Board would no longer give any opinion on the mandatory application of a standard. Only the ministry in charge would have the responsibility for both the possible initiative and the decision, and the TSE would be excluded from the decision-making process.
- The list of mandatory standards—as established every year by the Undersecretariat for Foreign Trade in liaison with the other ministries for import control—would serve as a reference for the follow-up of all relevant actions.

The application of these decisions resulted in an important reduction in the number of mandatory standards (figure 1). Generally speaking, the trend for reduction was continuous—from 1,250 in 2002, to 777 in 2004, 683 in 2005, and finally a drastic cut in 2006, to 261. In the New Approach sectors, 29 standards were still mandatory toward the end of 2006. The Undersecretariat for Foreign Trade envisaged that these standards would be deleted from the list at the beginning of 2007. Hence, the situation concerning mandatory standards at the end of 2006 was as follows:

- *In the food sector,* 69 standards were still mandatory. These standards dealt with fruit and vegetables for which no European standards existed. Moreover, the national TS standards transposed the specifications of the Codex Alimentarius.

FIGURE 1

Number of mandatory standards in Turkey, 2002–06



Source: CEN 2007.

- *In the other sectors,* there were 163 mandatory standards. Of these, 108 standards were more or less old and purely national, whereas 55 standards were the transposition of European or ISO/IEC standards. These standards dealt with a lot of sectors: industrial equipment, automotive, road, and electrical equipment.

A study involving ministries to determine the sector distribution of remaining mandatory standards and to facilitate the repeal of the mandatory application of these standards was thereafter launched. In general, all of these changes were accepted by the relevant ministries, and suppliers got a year to change to the new TS EN standard. In special circumstances this could be extended to up to three years. The ministry inspectorates ensured that the new standards were met by the suppliers.

Market surveillance

A twinning project between the BMWi and the Turkish Ministry of Industry and Trade was initiated to strengthen the Turkish ministry's capacity to establish an effective market surveillance system for the implementation of relevant EU Directives. The project was implemented from September 2006 to May 2008, with an investment of €1.297 million from the German side.

Project objectives

The main purpose of the project was to strengthen the capacity of the Ministry of Industry and Trade for market surveillance in the areas of textiles, civil explosives, protective equipment used in explosive environment, appliances burning gaseous fuels, nonautomatic weighing instruments, legal metrology and prepackaging, new hot boilers, and elevators in relation to the relevant EU Directives (BMWi 2008). The project was subdivided into three components.

Project inception (Component 1). After a public workshop with stakeholders to describe the project, an intensive benchmark study was conducted within the relevant directorates general of the Ministry of Industry and Trade to determine the available resources and deficiencies. The benchmark study led to far-reaching recommendations in four areas:

- *Organization:* (a) Reorganization of the ministry's structure to align it with responsibilities and better market surveillance; (b) establishment of a formal coordination system between the central and provincial offices; and (c) inspector identity cards to identify them during their inspections
- *Procedures:* (a) Communication of annual reports on the ministry level to the public; (b) extensive coordination of ministry resources; (c) revision of strategy and annual plans on the basis of inspection data; (d) development of specialized sectoral checklists to help inspectors in their daily work; (e) strengthening of relations with Customs; (f) precise definition of the competence of inspectors; (g) definition of decisions on critical issues like banning sales or withdrawing or stopping operation; (h) establishment of a procedure to subcontract laboratories; and (i) establishment of a cooperative method of inspection, including awareness and information (imposing a fine should always be the last step)
- *Equipment:* (a) Provision of required information technology (IT) equipment, cameras, and other tools for inspectors; and (b) establishment of a database for proper communication.

- *Special sector recommendations:* Recommendations regarding the inspection of elevators, civil explosives, and legal metrology, despite the understanding that the EU Measuring Instruments Directive would take some time to be transposed and implemented in Turkey. Legal metrology at that stage was rather weak and would become the subject of later EU-funded development projects.

Training (Component 2). The training component of the project consisted of four subcomponents: (a) identifying the training needs and designing the "train the trainers" program, (b) training the trainers, (c) designing the training program for inspectors, and ultimately (d) training the inspectors.

Initially 40 trainers were scheduled to participate, but this number was increased to 74 at the request of the beneficiary. The training of the trainers was provided on a directive-by-directive basis. These included civil explosives, gas appliances, elevators, and textiles. Training in a general sense was also provided for legal metrology, but detailed training in this area was not possible because the ministry's organizational structure was not yet supportive of the implementation of the EU Measuring Instruments Directive.

The project provided for 400 inspectors to be trained. In the end, a total of 656 inspectors participated in a program that dealt with each of the relevant directives separately. The trainers who had been previously trained instructed the inspectors under the watchful eyes of German experts. In this way, the efficacy of the trainers could also be evaluated. The training was not confined to theoretical training but continued at a practical level in the marketplace.

Enhanced enforcement of relevant EU Directives (Component 3). To ensure the sustainability of the project, the main activities carried out were the following:

- *Establishment of cooperation between the market surveillance and conformity assessment bodies* to strengthen the position of national manufacturers. This was an activity that would have to be advanced through the sectoral committees set up by the Ministry of Industry and Trade after the project.
- *Seminars to raise awareness* were a precursor to the future transposition and implementation of the General Product Safety Directive, which applies in the absence of specific European regulations on safety of certain product categories. Seminars were held in Ankara and Istanbul to explain the differences between this directive and the others focused on specific products.
- *Study tours to demonstrate market surveillance activities* as they were implemented in Germany were organized in 2007 and 2008, again organized on a directive-by-directive basis. Among the German entities visited were ministries, metrology and standards bodies, governmental bodies, producers, traders, users of equipment, and trade fairs.

Project outcomes

During the 18-month implementation period of the project, significant progress was realized in the effectiveness of market surveillance activities.

The Ministry of Industry and Trade had transposed and implemented all relevant European Directives covered by the project except the Measuring Instruments Directive. For the latter, transposition studies were initiated. Changes in the organization of the Directorate General Measurements and

Standards—changes that were proposed by the project—were implemented, namely moving the related responsibilities of the directives other than those on legal metrology from the Directorate General Measurement and Standards to the Directorate General Industry and the Directorate General Consumer Protection.

The capacity of the ministry and the provincial offices was raised considerably, leading to more effective market inspections, with a clear focus on conformity of products with the relevant EU Directives. The issue of product safety became central to market surveillance activities rather than mandatory product certification. This not only enhanced the protection of consumers and users but also improved the competitiveness of industry, which is encouraged to market only safe products.

The most significant change in practical inspections was the shift from document-based inspection to product safety inspection, clearly focusing on product properties. Taking samples and subcontracting laboratories for evidence were procedures that inspectors were trained in to enable them to better assess the risk arising from nonconformities.

The project implementation went smoothly because of the active engagement of the Ministry of Industry and Trade staff and the high commitment of both the external experts and their Turkish counterparts. Changes of key staff did not have a negative effect the overall project implementation because of the high qualifications and commitment of their successors, who easily integrated themselves into the existing project structures and took the necessary steps to ensure the fulfillment of the key outcomes. The three-month extension proved to be useful to regain lost ground resulting from initial delays in getting activities started during the first year. Because of the concerted effort of both the German and Turkish sides, the project was able to be completed within the envisaged time frame, and all the benchmarks were reached, in many cases even exceeding initial expectations.

Accreditation

To participate in international markets and for its envisaged accession to the EU, Turkey had to establish an internationally recognized accreditation body. This was of specific importance for the SME sector to access European markets. A project funded by Germany and implemented by PTB was agreed to in 1999 between the German Federal Ministry of Economic Cooperation and Development (BMZ) and the Turkish Undersecretariat for Foreign Trade. The project was worth €1.023 million and was planned for a period of five years, which at the end was extended by six months. The main objective of the project was to establish TÜRKAK as a fully operational national accreditation organization with increased use of accredited testing, calibration, and certification bodies by both the public and private sectors as a direct outcome thereof.

One of the major risks identified during the inception phase was the fact that TÜRKAK was not yet established, and there was initially some doubt as to whether the Turkish parliament would promulgate the necessary legislation in a timely manner. But the Turkish private sector actively pressured the politicians through Turkish business councils, and this effort, combined with impending EU accession negotiations, motivated the parliament to promulgate the necessary legislation in record time.

Project output and indicators

The overall project goal was a Turkish accreditation system established in accordance with international requirements and used extensively by economic operators. From the beginning of the project—initially coordinated by the Undersecretariat for Foreign Trade and later by the Ministry of Industry and Trade—several ministries and institutions were involved in the development of TÜRKAK. The project consisted of subprojects that were closely aligned, many of which were implemented in parallel:

- Revision and implementation of the TÜRKAK legislation
- Establishment of TÜRKAK steering committees and working groups
- Training and qualification of personnel
- Accreditation system rendered operational
- Advocacy in the public and private sectors
- International recognition.

The establishment of the accreditation system had a wide reach and affected civil servants; authorities; and interested parties from industry, trade, and consumer protection—over and above the many individuals in TÜRKAK, steering committees, and the personnel of organizations seeking accreditation.

The establishment and capacity building of TÜRKAK largely followed the agreed-upon planning. The project was initially overseen by a steering committee established by the Undersecretariat for Foreign Trade, but after the promulgation of the TÜRKAK legislation and the first meeting of the TÜRKAK General Assembly, the project's oversight was handed over to TÜRKAK. Two other accreditation bodies, the Accreditation Body in TSE (KAMK) and the Calibration Accreditation Body in UME (TKS), transferred their accredited entities to TÜRKAK, enabling it to become the sole accreditation body operating in Turkey. The project activities included consultancy regarding the organizational arrangements, recruitment and training of personnel, establishment of a pool of assessors, and application for EA membership, as well as support for organizations seeking accreditation—all of which were aligned with the urgent needs of the Turkish industry's calibration, testing, and certification requirements.

Project results

An increased understanding in the public and private sectors as well as by consumers and the media regarding the QI's role in economic development and consumer protection showed positive changes at a qualitative level. TÜRKAK was consistently seen as a "good for country" presence owing to an informative website, discussion forums, and a functioning complaints system. A wide range of stakeholders were reached through sector specific workshops, such as "Accreditation in the Medical Sector," "Systems, Standards, and Certification in Global Trade," and "CE-marking." The full support of important business and industry councils, with their large and wide-ranging memberships at various levels, provided TÜRKAK with a useful platform in the private sector. The looming EU accession negotiations also pushed political decision makers to instigate countrywide information campaigns with respect to the QI, consumer protection, and market surveillance.

In 2003, three years after the German-funded PTB project began, TÜRKAK became a full member of the EA and relevant EU structures. For the rest of the project, TÜRKAK's profile in these entities continued to increase.

This was an extraordinary achievement, because TÜRKAK did not even exist at the beginning of the project, and all its personnel had to be appointed and properly trained and qualified. A challenge regarding TÜRKAK's independence, due to the potential for political interference in its decision-making processes, was dealt with through an interim governmental directive. This interim directive was to be incorporated into the TÜRKAK legislation during its next revision.

The requests for accreditation from testing and calibration laboratories, management system certification bodies, and inspection bodies increased slowly at the beginning, but thereafter accelerated. Only the accreditation of product certification bodies did not fulfill expectations. In the first year of the project, a total of 7 entities were accredited; in the second year, 20; and in the third year, 56—a total of 83. By the end of the project in 2005, this number had risen to 118 accredited entities. This was ample evidence of the increased relevance of accreditation in the marketplace, but it also placed additional pressures on the available capacity of TÜRKAK.

STAKEHOLDERS AND THEIR ROLES

Many stakeholders, especially public sector entities, were involved in the alignment of the Turkish QI and technical regulation system with EU requirements as a precursor to more intense negotiations for Turkish accession to EU membership.

Undersecretariat for Foreign Trade

At the political level, the Undersecretariat for Foreign Trade in the Prime Ministry was the most important entity driving and coordinating change. Early on, it was given the overall responsibility for the implementation of the EU Directives relating to trade, which included those dealing with the QI and technical regulation. It was therefore mindful of the requirements Turkey had to fulfill. It promulgated the necessary legislation to initiate and facilitate this process, and it was responsible for the notification of conformity assessment bodies to the EC. It therefore used its powerful position in the Turkish government's organizational hierarchy to good effect to get other relevant ministries and QI organizations to cooperate and initiate far-reaching organizational reform where necessary.

Ministry of Industry and Trade

The Ministry of Industry and Trade bore the brunt of the demise of the mandatory standards system and the implementation of the EU Directives. It had to reengineer its own organizational structure quite decisively to align it with new realities while also overseeing similar reengineering programs in the public standards and accreditation bodies. The support from ministry personnel was generally considered to be very high by development partners, and even when staff moved around, their replacements were of a high caliber and picked up the necessary knowledge and skills quite quickly.

Public sector QI institutions

The TSE underwent two major changes: its standards development system was totally reengineered, and its function as a regulatory authority with respect to mandatory standards disappeared.

As for the UME, it was established already in 1992, even though metrology had a long history in Turkey going back to 1875 as a founding signatory to the Metre Convention. The UME moved into new laboratories in 1994. By 2002, it was already considered to meet EU requirements. Thereafter the UME broadened its activities to also include metrology in chemistry. All of these developments indicated a high engagement of its management and metrologists.

TÜRKAK, the third fundamental of the QI, was established in 1999. Thereafter things moved quickly during the 2000–05 German support project. Within only three years, TÜRKAK had achieved recognition in Europe through the EA and internationally in ILAC and the IAF. Again, this progress indicates high commitment by management and personnel.

Private sector entities

The private sector was very much aware of the need to align the QI and the technical regulation system with EU requirements because Turkish trade within the common market depended heavily on this. Hence, when the public sector was still dallying a bit regarding the development and promulgation of the necessary legislation, the private sector, through its influential business associations, was able to pressure politicians to move much more quickly. Likewise, the private sector embraced the liberalization of the conformity assessment business; as a result, many private sector laboratories and certification bodies were established and accredited after 1995, as indicated by the growing number of accredited facilities in the years since TÜRKAK's establishment in 1999—reaching 730 by mid-2016.

The broader alignment of the Turkish QI with the EU requirements would also not have happened if the private sector had not implemented formal quality management systems and had their products tested and certified on an increasing scale to enter the European markets. Therefore, the success story of the major reengineering and modernization of the Turkish QI and technical regulation system would not have been possible without the active participation of the private sector in pushing for reform as well as implementing its outcomes.

RESULTS ACHIEVED AND OUTCOMES

The outcome of the decade of QI and technical regulation reform can be considered in two domains, albeit closely intertwined. The first is the modernization of Turkey's QI; and the second, even more profound, is the total reengineering of its technical regulation system.

Modernization of the Turkish QI

Standards. In the development and publication of standards, Turkey had to align its practices with those of the EU. The TSE became a member of the CEN, CENELEC, and ETSI committee structures, and the EN standards progressively

replaced the indigenous Turkish standards. From 1995 to 2008, more than 90 percent of the EN standards had been adopted; that is, nearly half of the approximately 35,000 Turkish national standards were full adoptions of the EN standards.

The TSE also participated fully in the voting procedures of CEN, CENELEC, and ETSI even though Turkey was not yet an EU member; and although the Turkish vote did not count in the final approval of the EN standards, the country's votes were kept on record as evidence of its active participation. The TSE technical committee structures were also fully reengineered to provide for mirror committees to the CEN, CENELEC, and ETSI technical committees.

Accreditation. As for accreditation, Turkey established the national accreditation body, TÜRKAK, and gained European acceptance for it through the EA within less than five years, in 2006. This led to TÜRKAK's international recognition through ILAC and the IAF that same year. TÜRKAK was also able to increase the number of accredited facilities from only 7 in its first year of operation to 83 in its third year, growing to over 700 by 2016. Accreditation was therefore firmly established as a fundamental of Turkey's QI, and TÜRKAK was seen as an established and prominent accreditation body in the EU.

Metrology. As the third fundamental of the QI, development of the metrology system had a mixed result. As noted earlier, scientific metrology had a long tradition in Turkey, the country (then the Ottoman Empire) having been one of the original signatories to the Metre Convention in 1875. But after World War II, it had failed to keep up with developments until the 1990s.

The UME of Turkey was established in 1992, and by 1994 it moved into new buildings with ample space for laboratories. By 2003, the UME was already considered to meet EU requirements and became a member of EURAMET. The country's CMCs were progressively listed in the Key Comparison Database of the International Bureau of Weights and Measures (BIPM), ensuring international recognition of Turkey's metrology system. Metrology in chemistry was developed, and the UME is planning to become a major supplier of certified reference materials.

As for legal metrology, some progress had been achieved, but much still needed attention before it would be considered to be at the same level of development as scientific metrology. It was especially the new EU Measuring Instruments Directive that was still poorly understood and for which the technical and market surveillance infrastructure was still to be established.

Reengineering of the technical regulation system

Before 1995, the Turkish technical regulation system was typical of systems that developed over time without policy guidance; in other words, each ministry developed and implemented technical regulations as it saw fit. Worse, the Turkish system was based largely on mandatory standards, a system that operated on a premarket approval system for products falling within the scope of these mandatory standards. This system, although favored by many low- and middle-income countries because of its simplicity from an operational perspective, became a major stumbling block to trade.

Anecdotal evidence would suggest that the regulatory authority, usually the national standards body, is prone to rent-seeking practices—for example, payment by suppliers is secured by law through a levy and for the mandatory product certification scheme, without the regulatory authority necessarily providing proper service. Other negatives of this system include (a) the propensity of the standards body to pursue the development of standards to be used as mandatory standards, rather than providing standards according to the actual needs of industry; and (b) the retesting of especially imported products in order to keep the laboratories of the national standards body busy.

Turkey, as a precursor to its negotiations on EU membership, had to reengineer the system of mandatory standards in its totality. The mandatory standards had to be replaced by the EU Directives, in which the technical regulation provides for essential requirements only. The technical requirements are provided for in harmonized EN standards that remain voluntary, and conformity assessment services can be offered by a number of designated technically competent bodies—the "notified bodies."

This reengineering had a profound impact on the finances of the national standards body, the TSE, which lost the income from mandatory testing and certification and had to compete in the marketplace with other notified conformity assessment bodies. In all, nearly 1,500 mandatory standards were withdrawn and replaced by EU Directives, and the mandatory premarket product certification system was totally replaced by an in-market surveillance system.

PROBLEMS ENCOUNTERED: CHALLENGES AND ISSUES

It is difficult to move from a system of absolute control to a system whereby the market is allowed to play an important part in the QI, and especially in the technical regulation regime. The propensity of some state organs that wished to control everything therefore led to most of the problems or challenges that were encountered.

Draft law for creating TÜRLAK, potentially weakening TÜRKAK

A project that started as an inventory of public laboratories soon morphed into one that sought to control all laboratories. Initially a database of just over 1,000 public sector laboratories was established, and work was started to increase the efficiency of public service conformity assessment bodies. This project changed direction, and a draft law was circulated whereby all laboratories, public or private, wishing to operate in Turkey would have to be registered by the to-be-established Turkish Laboratory Agency (TÜRLAK), even if they had been accredited by TÜRKAK. The functions of TÜRLAK in many instances duplicated those of TÜRKAK.

If this draft law had been allowed to pass the parliament, it would have set up an organization that would have been in direct competition with TÜRKAK on the Turkish market. Furthermore, the law would have given TÜRLAK powers that would have allowed it to act as an accreditation body without meeting the requirements of international standards. This would have damaged not only TÜRKAK but also the whole Turkish conformity assessment system that had

taken so much time and energy to build, and it would have confused a market that had only started learning the EU rules properly. The draft law was shelved after EU interventions.

Push needed to expedite accreditation legislation

At the start of the German project to build capacity in accreditation, TÜRKAK had not even been established by law. Parliament was rather lax in considering the draft legislation, and all indications were that it would take a few years to promulgate it. The business community, however, was able to harness its powerful lobbies and create enough pressure for parliament to consider and promulgate the accreditation legislation in record time.

Lack of capacity in legal metrology

The responsibilities for legal metrology are decentralized, with public entities at both the national and provincial levels responsible. Coordination of such a decentralized system is always challenging. Over and above the coordination issues, further uncertainty stemmed from a lack of metrology skills, generally lax oversight over the implementation of the requirements in the market, and the imminent transposition and implementation of the Measuring Instruments Directive of the EU. This directive's approach to legal metrology differed from the classic weights-and-measures controls practiced by most countries, and its modalities were not understood by the relevant authorities in Turkey.

The results were great uncertainty and a lack of progress in spite of much effort invested to streamline legal metrology—so much so that the private sector became alarmed that Turkey would be overrun by other European-based legal metrology notified bodies once the directive finally replaced all national systems by 2016, to the detriment of the local metrology industry. A major support program funded by the EU was planned, and it was hoped that this would alleviate the situation to large extent.

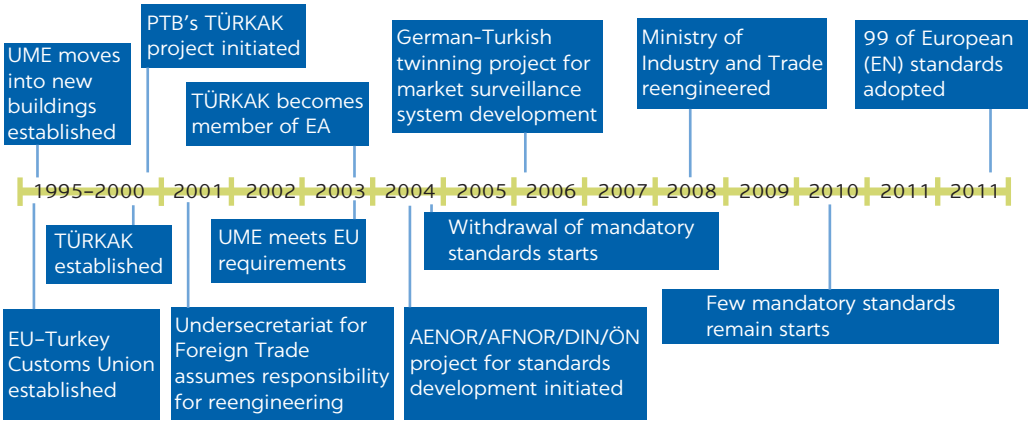
KEY SUCCESS FACTORS AND LESSONS LEARNED

The major success factors and lessons learned throughout both Turkish and foreign project implementation came down to one overarching lesson: it takes leadership to attain success (figure 2).

Political leadership. The undeniable driver of the profound QI and technical regulation system reengineering in Turkey was obviously Turkey's quest to become an EU member. This meant the full-scale, demonstrable adoption and implementation of the *acquis communautaire* of the EU. The Turkish government allocated the overall coordination and responsibility for this activity regarding the QI and technical regulations to the Undersecretariat for Foreign Trade in the Prime Ministry. This was key to the success of the whole endeavor because this undersecretariat was a governmental heavyweight able to ensure that ministries and other public sector entities implemented the radical changes as required. It is doubtful whether the Ministry of Industry and Trade, or any other ministry, would have been able to do so as successfully as the Undersecretariat for Foreign Trade.

FIGURE 2

Timeline of the Turkish QI development and notable milestones, 1995–2011



Note: AENOR = Spanish Association for Standardization and Certification; AFNOR = French Standardization Association; DIN = German Institute for Standardization; EA = European co-operation for Accreditation; EU = European Union; ÖN = Austrian Standards Institute; PTB = National Metrology Institute of Germany; QI = quality infrastructure; TÜRKAK = Turkish Accreditation Agency; UME = National Metrology Institute.

Private sector involvement. The private sector, as one of the main beneficiaries of Turkey's entry into EU markets, got involved by putting pressure on government bodies to expedite important measures such as the promulgation of relevant legislation. It did so through its powerful business associations, which politicians listened to. Later, the private sector was at the forefront of implementing the necessary requirements to satisfy EU regulatory authorities regarding product integrity, making full use of the standards, metrology, and accreditation infrastructure that was established. The private sector also made full use of the liberalization of the conformity assessment environment and established many calibration and testing laboratories as well as certification bodies. The state, except for the TSE, was no longer the main provider of such services.

Skilled and dedicated personnel. A successful QI and technical regulation system depends heavily on skilled personnel. And if they are also dedicated, things get done properly and quickly. This was certainly the case in Turkey in many instances. It was especially the donor community that commented favorably on the commitment and skills of the people involved from the Turkish side, even though they were moved around quite a bit within public entities because of the overall government reengineering exercises. New staff were mostly well educated, highly skilled, and committed to get on board quickly.

CONCLUSION

Turkey made significant progress in the decade from 2000 to 2010 toward establishing a modern, market-based technical regulation regime to facilitate its accession to the EU and other international markets. Turkey has a functioning QI in place, comprising the Turkish Standards Institute (TSE), the Turkish Accreditation Agency (TÜRKAK), the National Metrology Institute (UME), and

a fair number of testing and calibration laboratories as well as certification and inspection entities. Quality awareness among Turkish firms seems to be improving, as shown by the increasing growth rate of quality certificates, although in absolute terms Turkey is still far from other relevant comparator countries. The country had replaced almost all national standards with EN and international standards, and had significantly reduced the number of mandatory standards. The recently created accreditation body, TÜRKAK, has been accepted to the EA Multilateral Agreement (EA-MLA) for quality management systems, testing, calibration, and inspection. The UME is well equipped, has highly qualified staff, and already offers the reliable measurement traceability essential for the proper functioning of the Turkish QI.

Notwithstanding this progress in the period up to 2010, policy and institutional changes were needed to further improve Turkey's QI and foster implementation of quality standards at the company level. Furthering international recognition of the main institutions of the QI would be crucial to remove remaining constraints faced by Turkish producers and exporters. The UME, for example, should participate in more international intercomparisons of measurements, and TÜRKAK should broaden its participation in the recently signed EA-MLA by applying to also become a signatory in the areas of product certification and environmental management systems certification (which TÜRKAK achieved after 2010). Revisiting legislation regulating the functioning of these institutions could clarify responsibilities, increase flexibility, and facilitate the adoption of more efficient and transparent practices with increased participation of the private sector. Finally, it would be important to increase requests for accreditation and certification by Turkish laboratories and companies, respectively.

NOTES

1. The EU New Approach Directive for technical regulation (Council Directive 83/189/EEC of March 28, 1983) and Global Approach Directive for conformity assessment (Council Directive 90/683/EEC of December 13, 1990) have both been revised continuously and extensively over the years.
2. The *acquis communautaire* is the accumulated legislation, legal acts, and court decisions that constitute the body of EU law. The term is French—*acquis* meaning "that which has been acquired or obtained," and *communautaire* meaning "of the community."
3. Mirror committees are established as the national counterpart of either regional or international technical committees, and their objective is to develop a consolidated national position to be presented in the discussions at the regional or international level. They are also an important conduit for transferring knowledge to the national level, that is, to sensitize national stakeholders to the developments at the regional or international level at an early stage, thereby giving national stakeholders a chance to adapt more quickly.
4. Council Directive 98/34/EC of June 22, 1998.
5. The Metre Convention, an international treaty signed in 1875 that created the International Bureau of Weights and Measures (BIPM), established the metric system and addresses the base units of scientific metrology.
6. The Measuring Instruments Directive (Council Directive 2004/22/EC of March 31, 2004) set the implementation date for November 2006, with a 10-year transition period. National implementations of the new legislation started only thereafter.
7. The cross-frontier policies of ILAC and the IAF endeavor to limit competition between accreditation bodies that could be detrimental to the quality of accreditation (IAF 2016; ILAC 2012).
8. "Regulation (EC) No. 765/2008 of the European Parliament and of the Council of 9 July 2008, setting out the requirements for accreditation and market surveillance relating to the

marketing of products and repealing Regulation (EEC) No. 339/93": https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:218:0030:0047:en:PDF.

9. The BMWi is now known as the Federal Ministry for Economic Affairs and Energy (Bundesministerium fűr Wirtschaft und Energie).
10. 2006/654/EC: Decision No. 1/2006 of the EC-Turkey Association Council of May 15, 2006.
11. The CE marking is placed on the product or packaging by the manufacturer or supplier once all the requirements of the relevant EU Directive have been fulfilled, denoting that the manufacturer or supplier takes full responsibility for the compliance of the product with specified requirements. These may involve third-party conformity assessment service providers (that is, notified bodies) depending on the new directive, but the manufacturer or supplier is not licensed by a product certification body or anybody else to affix the CE marking on the product; it is done totally on that manufacturer's or supplier's own responsibility.
12. ISO 9001:1987, titled "Quality Systems—Model for Quality Assurance in Design /Development, Production, Installation and Servicing," has been revised five times. The current standard is ISO 9001:2015, "Quality Management Systems—Requirements": https://www.iso.org/standard/62085.html.
13. ISO 14001:2015, "Environmental Management Systems—Requirements with Guidance for Use": https://www.iso.org/standard/60857.html.
14. OHSAS 18001, "Occupational Health and Safety Management" (see https://www.bsigroup.com/en-US/OHSAS-18001-Occupational-Health-and-Safety/), is in the process of being replaced by ISO 45001:2018, "Occupational Health and Safety Management Systems—Requirements with Guidance for Use": https://www.iso.org/standard/63787.html.

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