INTERNATIONAL DEVELOPMENT IN PRACTICE

Germany

QI Toolkit Case Studies

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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

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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

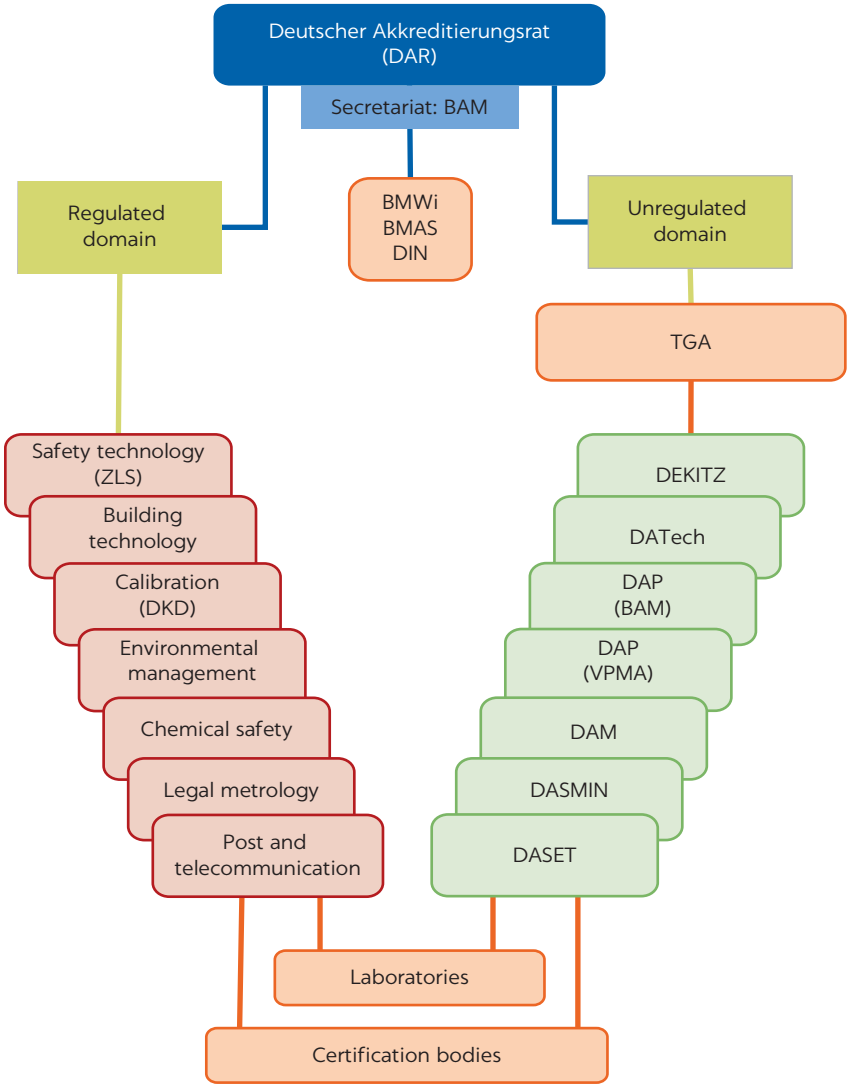
One of the key elements of an effective accreditation system is the dissemination of information to a wider audience about the accredited organizations. Over and above names and contact information, this information must provide full details of the specific areas, tests, or certification activities the 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.

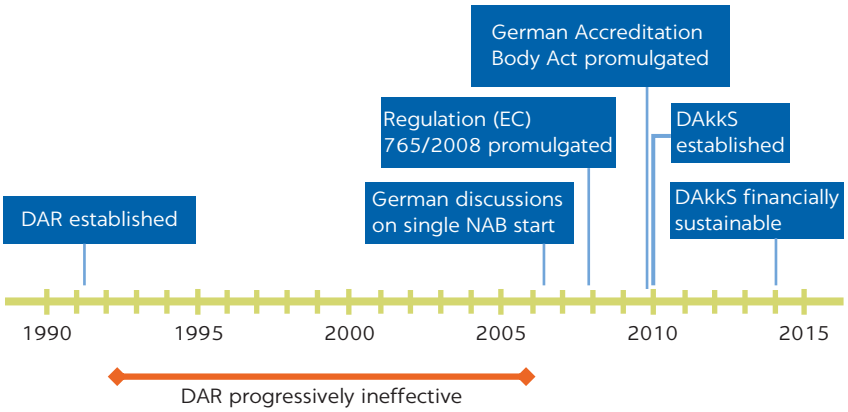
Business Development of DAkkS

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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