

# Advocacy of Accredited Organisations in Germany

Anton Blöth, Director General of German  
Independent Laboratories Association  
(VUP e.V)

Budapest, October 25th, 2017



# Outline

1. Accreditation System in Germany
2. German Independent Laboratories Association (VUP e.V.)
3. VUP and Accreditation
4. EUROLAB





# 1. Accreditation System in Germany

# Accreditation – Development Directions in Germany

## Situation before 2010

- (Quality) self-control system of the industry
- Based on (international) technical norms and regulations
- Private regulation
- Industry (associations) accreditation bodies
- since 1985 „new approach“: complementarily public accreditation bodies
- Germany: approx. 20 governmental and private accreditation bodies
- Cooperation within the German Accreditation Council (DAR)

## Situation since 2008/2010

- Accreditation as official government task
- Unified, EU-wide, horizontal regulatory framework (EG No. 765/2008) for all the accreditations of conformity assessment bodies
- Accreditation – highest control level within the conformity assessment system, one national accreditation body only
- European and international validation through EA, IAF/ILAC (multilateral agreements)
- In Germany (AkkStelleG – Accreditation Body Act):
  - Accreditation - federal task
  - National Accreditation Body - private company with limited liability, acting on behalf of the federal government (DAkKS GmbH)
  - Rigorous separation (but interaction) between accreditation (“ability”) and notification (“allowance”)



# Accreditation – Development Directions in Germany

Accreditation as a public task

heute

**20.2.1979:**  
Cassis-de-Dijon-Entscheidung (EuGH):  
Grundsätzlich alle Produkte, die in einem EU-Mitgliedstaat rechtmäßig in Verkehr gebracht wurden, sollen auch in allen anderen Mitgliedstaaten verkauft werden dürfen.

„Freier Warenverkehr“

**2008**  
**Verordnung (EG) Nr. 765 /2008 im Rahmen des „new legislative framework“**  
Zentraler Rechtsrahmen für die Erteilung und Überwachung von Akkreditierungen

**7. Mai 1985:**  
Entschließung der EU-Kommission zu einer neuen Konzeption auf dem Gebiet der technischen Harmonisierung und Normung

„new approach“

**CE-Kennzeichnung**

**01.01.2010**  
**DAkKS GmbH nimmt Arbeit auf**  
Grundlage dafür u.a. Gesetz über die Akkreditierungsstelle und Kostenverordnung der DAkKS

Accreditation (broadly) as an industry self-control system



# German National Accreditation Body (DAkkS)

## ▪ Shareholders:

- Federal Republic of Germany, represented by the Federal Ministry for Economic Affairs and Energy (BMWi)
- Federal states, represented by the states Bavaria, Hamburg and North Rhine Westphalia
- the industry represented by the Bundesverband der Deutschen Industrie e. V. (BDI; Federal Association of German Industry).

## ▪ Locations:

- Berlin (Headquarters), Frankfurt/Main, Braunschweig

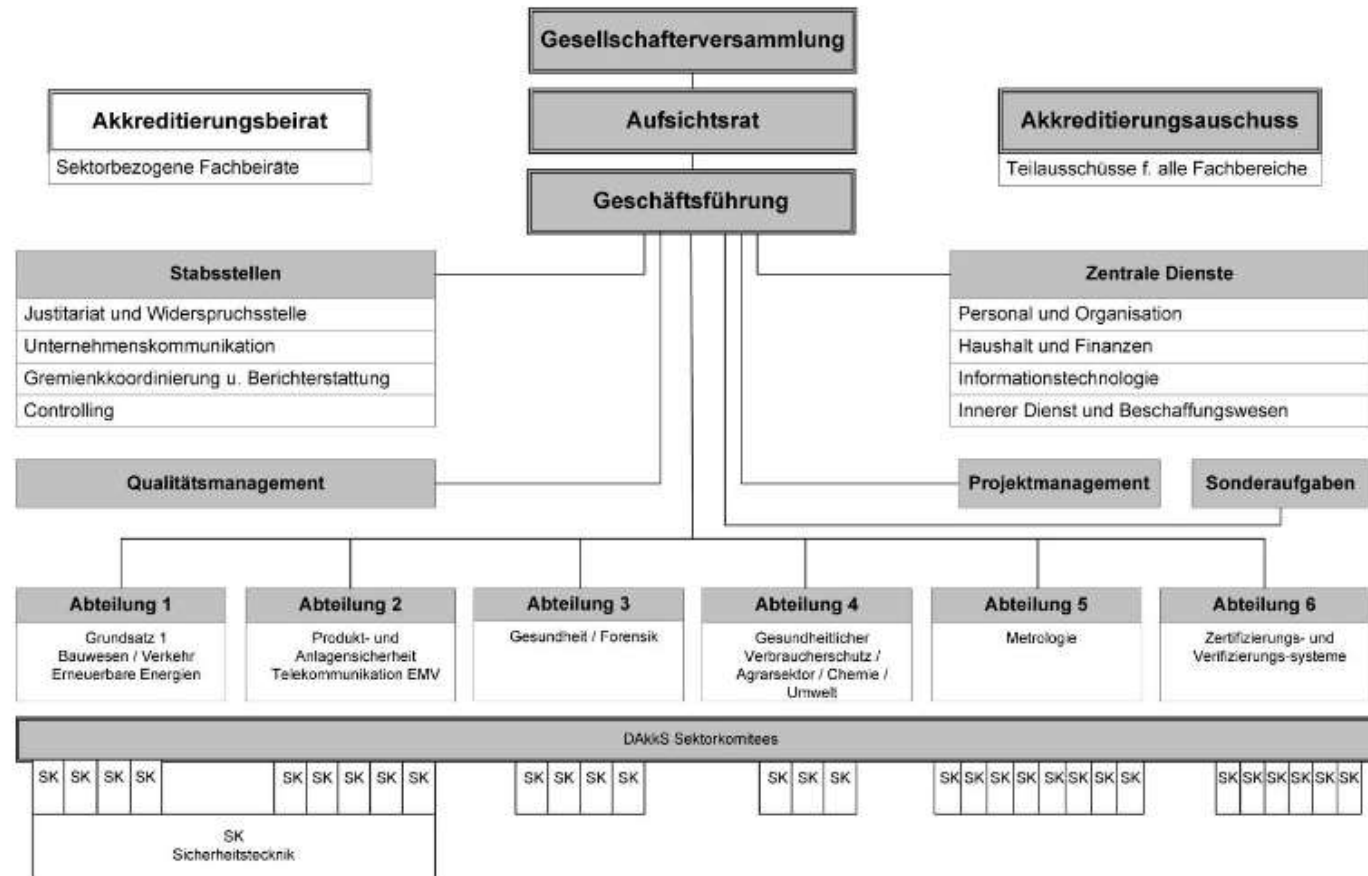
## ▪ Employees: ~ 170

## ▪ Managing Director:

- Dr.-Ing. Stephan Finke



# German National Accreditation Body (DAkkS)





# German National Accreditation Body (DAkkS)

## Number of accredited conformity assessment bodies

Akkreditierungen im Bestand (Anzahl)	31.12.2016	31.12.2015
Prüflaboratorien	2.334	2.274
Anbieter von Eignungsprüfungen	17	18
Referenzmaterialhersteller	9	8
Medizinische Laboratorien	432	433
Kalibrierlaboratorien	468	456
Inspektionsstellen	256	242
Zertifizierungsstellen für Produkte	314	289
Zertifizierungsstellen Managementsysteme	228	222
Zertifizierungsstellen Personen	54	49
Verifizierungsstellen	19	19
<b>Gesamtanzahl der Akkreditierungen</b>	<b>4.131</b>	<b>4.010</b>

Tab.: Akkreditierungen im Bestand zum 31. Dezember 2016

## Turnover by activities and markets

Tätigkeitsbereich	Umsatz
	EUR
hoheitlich	23.597.835
nicht hoheitlich	1.700.581
Gremientätigkeiten	1.172.625
Veranstaltungen und Schulungen	237.182
sonstige	266.571

Geographisch bestimmter Markt (nur aus Akkreditierungen)	Umsatz
	EUR
Inland	23.548.915
Ausland	1.801.435





A photograph of two scientists in a laboratory. A man in a white lab coat and safety glasses is holding a test tube. A woman in a white lab coat and safety glasses is looking at the test tube. The background shows laboratory equipment and shelves with bottles.

## 2. German Independent Laboratories Association (VUP e.V.)

# German Independent Laboratories Association (VUP e.V.)

- established December 1993 as an association of independent, private testing laboratories
- 650 members (in 10/2017) offering testing and analytic services for five market sectors
- Chairman (president): Dr. Tilman Burggraef, Eurofins Group
- Managing Directors: Anton Blöth (Spokesperson); Sven Deeg (Market&Members)
- VUP-offices in Giessen and Berlin



# German Independent Laboratories Association Milestones and Development

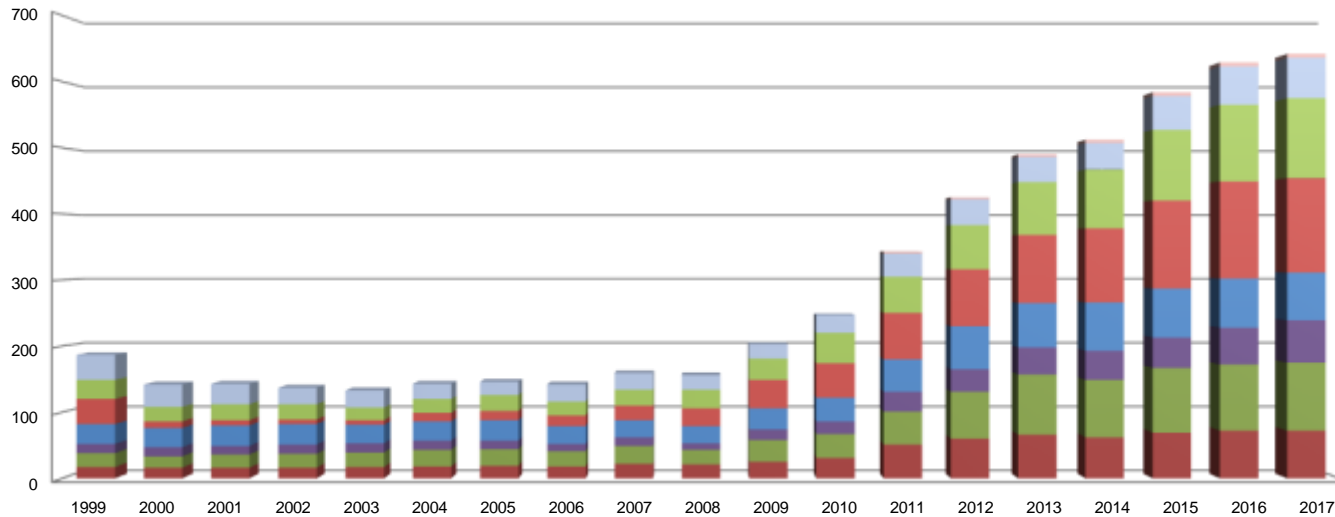
since	Market Segments
<b>Established 12.1993</b>	Environmental Analytics Consumer Protection and Food Material Analytics
<b>2000</b>	Pharmaceutical Companies
<b>2010</b>	Calibration Sector
<b>2011</b>	Medical Devices

Market Sectors	Members	Degree of organisation*
Environment	285	95 %
Consumer Protection Food, Commodities, Cosmetics, Drink Water	320	90 %
Material Analytics	311	85 %
Medical und Pharmaceutical Analytics	178	30 %
Calibration	54	20 %

\*estimated



# German Independent Laboratories Association Members Growth



	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
europ. Ausland													3	3	4	5	6	6	6
Ost (Sac, SaA, Thü)	38	34	31	25	26	23	20	26	25	22	22	27	35	39	38	40	51	58	61
Nordrhein-Westfalen	29	22	24	23	19	21	24	21	24	28	32	46	55	67	80	89	107	116	121
Nord (Nds.HH,HB, SwH, Mck-P.)	38	10	8	7	7	13	14	16	22	27	43	52	70	86	103	112	133	147	143
Süd-West	30	29	31	31	28	29	31	27	26	26	32	36	49	65	67	73	74	74	72
Berlin/Brandenburg	14	14	13	14	14	14	13	11	13	10	16	19	30	34	41	44	46	56	64
Bayern	21	17	20	21	22	25	25	23	27	22	33	36	50	71	91	87	98	100	103
Baden-Württemberg	17	16	16	16	17	18	19	18	22	21	25	31	51	60	66	62	69	72	72

Membership level **31.12.2016**:

ordinary members

(headquarters) 207 (175)

extraordinary members

(branches) 409 (402)

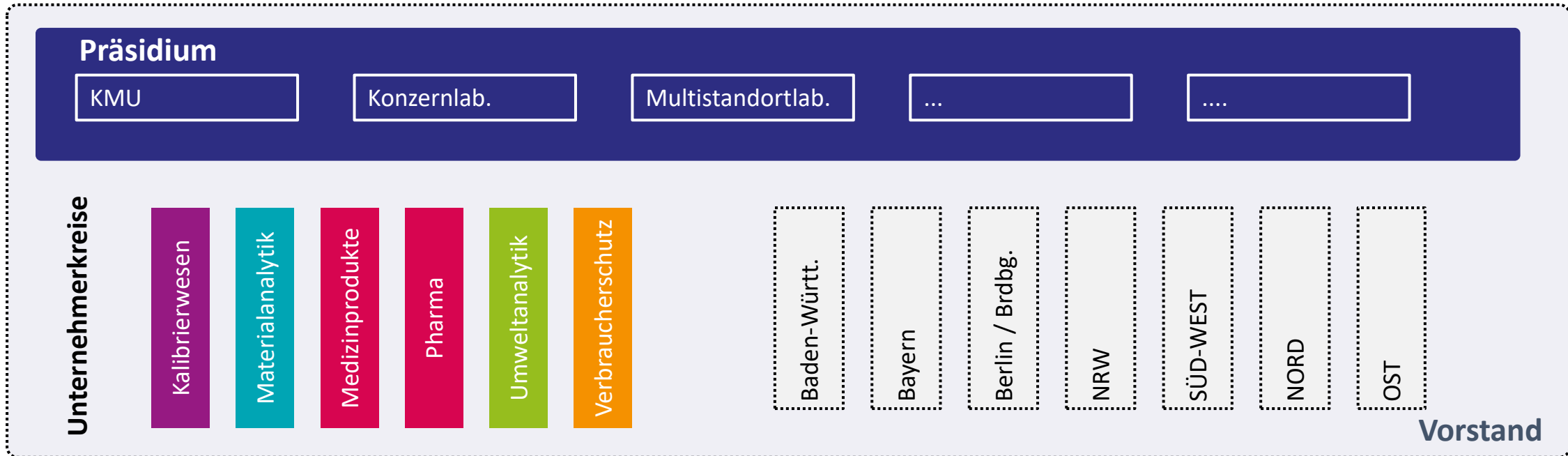
supporting members 23 (20)

**Total 639 (597)**

( ): Year 2015



# German Independent Laboratories Association Organisational Structure



# German Independent Laboratories Association

## Our Tasks

- **Advocacy (Federal, States, Europe)**
  - Legislation, Norms, Quality Protection Systems
  - Competency Assessment, Notification
  - „Harmonisation“ within the federal system
- **Information and communication**
  - Scientific, technical and legal issues
  - Cooperation with professional associations
  - News
- **Promotion of the industry**
  - Representing members' economic interests
  - Observing and evaluating market competition
  - Combating unfair market competition
- **Training and Development**
- **Services**



# German Independent Laboratories Association VUP

## Our Tasks in Detail (Business Report 2016)

### ▪ **Professional work and information**

- 27 internal consultations on different laws and regulations
- 317 industry News

### ▪ **Participation in committees**

- 241 VUP-representatives in 163 external committees
- 14 meetings of VUP-committees

### ▪ **Members services**

- 167 customer requests placements with 527 applicants
- 12 comparative measurements with 67 participants
- Members benefit programme (pay-out: ~ 130.000 €)





A photograph of two scientists in a laboratory. A man in a white lab coat and safety glasses is holding a test tube, and a woman in a white lab coat and safety glasses is looking at it. The background shows laboratory equipment and shelves.

### 3. VUP and Accreditation

# VUP and Accreditation

## § 2 Aim (VUP statute)

1. Our aim is to **represent the interests** of the **testing** and **calibration laboratories** and **other conformity assessment bodies** based in Germany operating **chemical, physical** and **biological laboratories**.

Basic requirement for membership:

**ACCREDITATION**

### § 4 Membership:

Ordinary members have got an accreditation or they fulfil the official requirements in this respect.



# VUP and Accreditation

...generates confidence in the activity of laboratories and other conformity assessment bodies in trade and economic sector

→ „Market entry prerequisite“ in the private economic trade (*„unregulated sector“*)

... prepare and ensure quality for the official authorisation of laboratories and other conformity assessment bodies

→ lever for privatising state tasks in the field of environment, consumer protection, health and product safety (*„regulated sector“*)

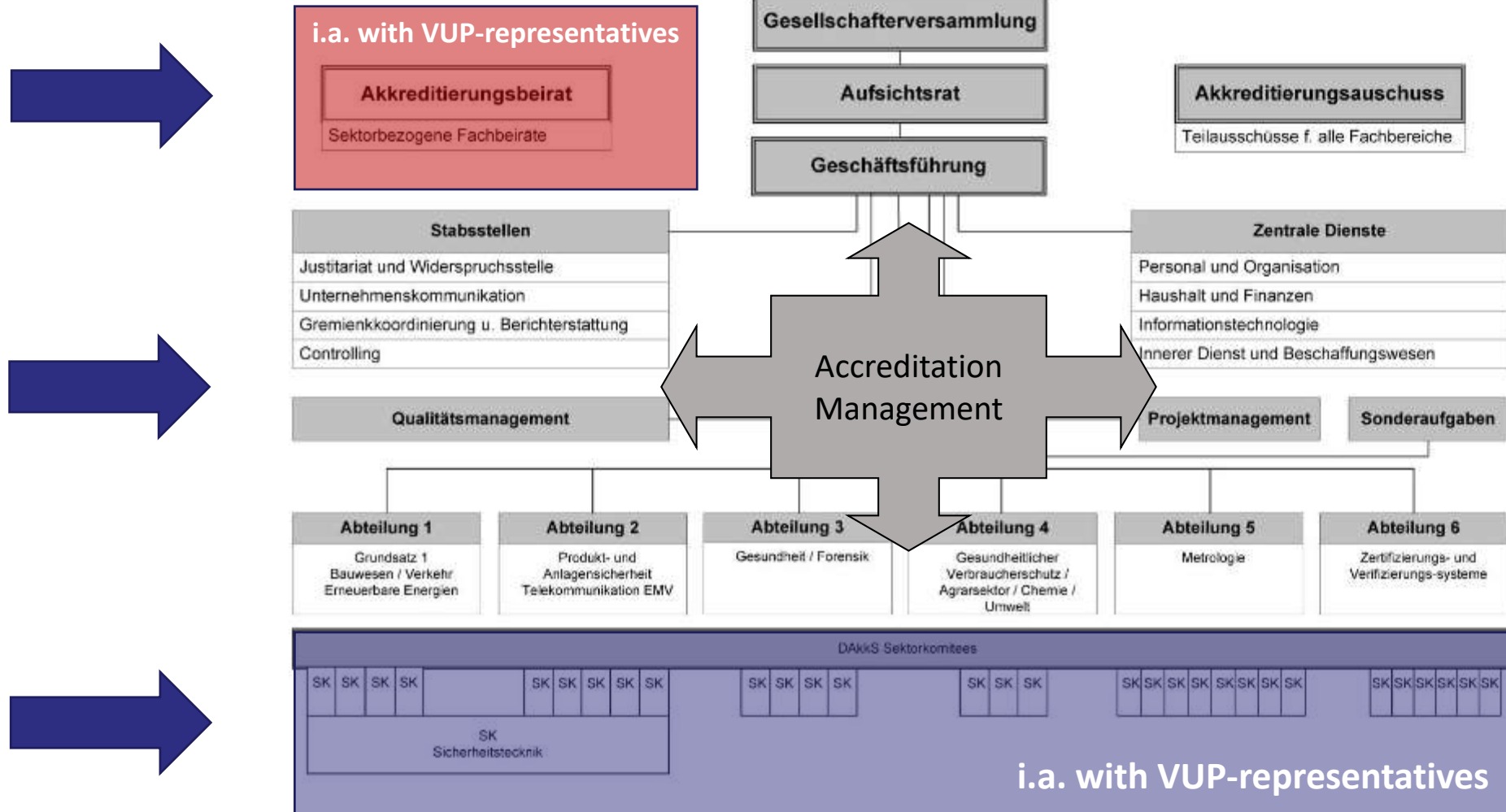


# Objections to Accreditation

- **Complexity and costs of accreditation**  
Assessment scope und detail level, level of charges/fees, cost transparency and predictability
- **Proceeding duration**  
Increase of bureaucratic procedures, „academic approach“, certificate issue, monitoring programme, assessment planning
- **New monitoring concept/ necessity for reaccreditation**  
Assessment scope, assessment rhythm, ISO/IEC 17011
- **Assessors**  
Service efficiency (costs), availability, qualification and „standardisation“
- **Balanced organisational structure of the „DAkkS“-committees**  
Sectorial Committee, Supervisory Board, Accreditation Advisory Board

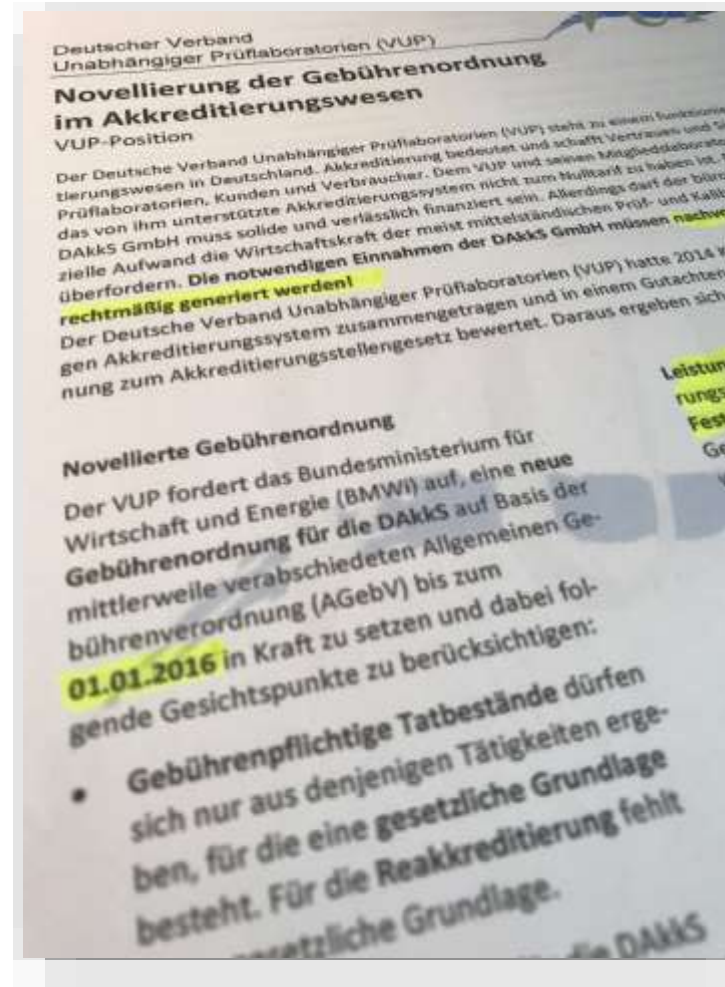
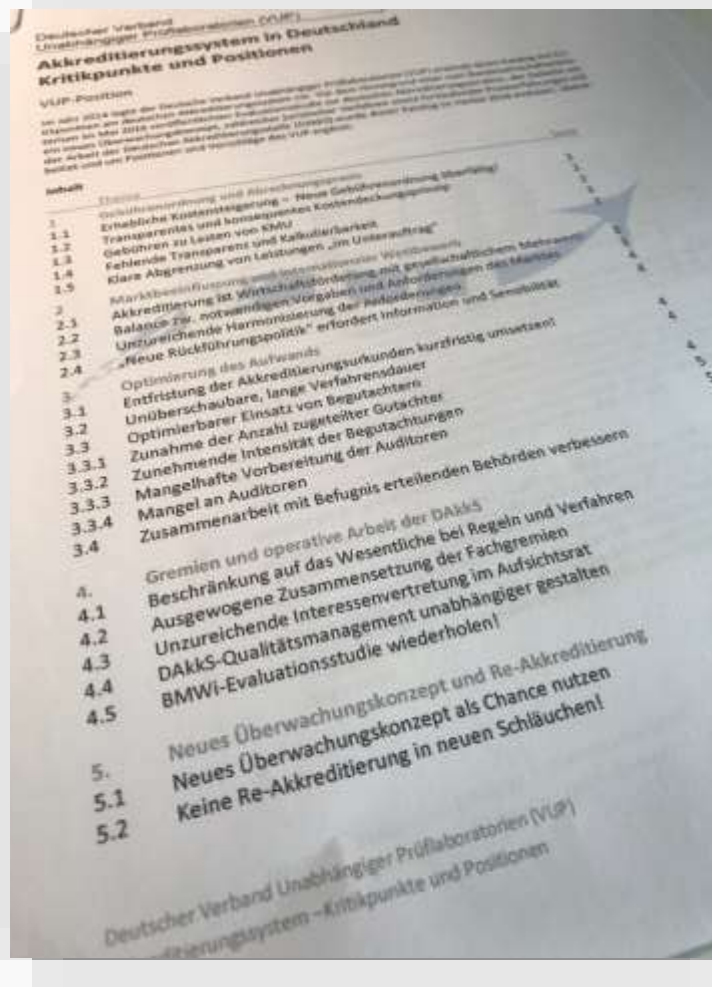


# Involvement for a customer-oriented accreditation





# Engagement for a customer-oriented accreditation



# EUROLAB

**European Federation of National Associations of  
Measurement, Testing and Analytical Laboratories**







## **EUROLAB** General Objective

**Promote cost-effective testing, calibration and measurement services, for which the accuracy and quality assurance requirements were adjusted to the actual needs.**



## EUROLAB in Brief

- EUROLAB – was set up in Brussels on 27 April 1990.
- **EUROLAB's general objective** is to promote cost-effective testing, calibration and measurement, services, for which the accuracy and quality assurance requirements are adjusted to the actual needs.
- EUROLAB represents testing, measurement and calibration laboratories and has 21 Active Members, 3 Associated Members, 1 Observer Member and 2 International Affiliates.
- Grouping over **2,000** conformity assessment bodies representing **over 100,000** technical experts and laboratory practitioners.





## EUROLAB Members

Active members



## Associated members



## Observer member



Unser Ergebnis ist Ihr Erfolg.



## Dialogue with European/International Institutions

