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# DAP-TM 29

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## Flexible Scope Accreditation

## **Accreditation of flexible scope**

### **Purpose and scope**

This technical note should ensure a comprehensive harmonisation of the requirements and procedures relating to the accreditation of flexible scope in all sectors of DAP's accreditation programmes. This also serves as an information and training document for DAP's case managers, assessors and laboratory staff.

The German and international guidance documents described in Para 7 as well as the vast experience of many DAP sector committees in flexible accreditation form the basis of this technical note.

### **1. General**

The scope of accreditation of a testing laboratory is the formal and exact description of the activities, for which the laboratory is accredited.

According to Clause 1.6, 5.4.3 and 5.4.4 of ISO/IEC 17025, it is permissible for accredited laboratories to modify their own in-house or laboratory developed test methods or use updated standard methods, for which they are already accredited, as well as to introduce similar or new test methods without being required to inform DAP. (Without being required to seek prior approval from DAP) This holds true only on the condition that the modifications and the updated versions or new test methods do not contain new measurement principles, which are not covered in the original description of the scope of accreditation.

Conventionally, the scope of accreditation is described using a fixed given list of all test methods. On the other hand, in terms of accreditation of flexible scopes mentioned above, there is the possibility of describing fields or areas of testing in a more general form. In doing so, there are **two different categories**, and where applicable, a combination of both, which can be used :

- I. the free selection of standard methods or their equivalent test methods within a defined field or area of testing.
- II. the modification as well as (further and new) development of test methods within a defined field or area of testing.

### **2. Definition of accreditation scope**

The field or area of testing is defined by parameters such as for example:

- physical or technological basis/principle of measurement/testing (methods, characteristic test methods)
- Measurands/measurement quantities, test parameters
- Measurement or test range
- associated measurement uncertainties (when applicable and meaningful)
- Substance types/Matrices/Products
  - Properties to be examined
  - Sample treatment/preparation
  - characteristic test methods
  - test equipment
  - measurement uncertainty of test results
- special test conditions.

The test methods and procedures can be specific or general, as well as those based on standard methods or non-standard/laboratory developed in-house methods:

- a test method that is not from a normative standard or one belonging to a set of laboratory developed methods is understood to be a test method, which was either developed by the laboratory itself (or from a third party), or one which was established from a standard method and validated
- a standard method is understood to be a test method, which was developed by a standards organisation or another recognised organisation, whose test methods are in general accepted by technical committees concerned. This also includes patented or copy right protected newly introduced test methods.

### **3. Specific requirements for testing laboratories**

When a laboratory develops a new or a modified method, this requires a fundamental technical understanding of the test method and the technology used. This competence can for example, be acquired through participation in corresponding research or development projects, test methods development projects, or through vast experience in each test area. This includes the experience of staff gleaned through involvement in scientific or authoritative committees, or through assessment/appraisal activities. Such experience must be demonstrated to be kept current.

The qualification required for the technical management staff is a scientific or engineering degree in a technical field or an equivalent qualification, and particularly for scientific laboratories, at the minimum an equivalent polytechnic degree. Staff must have at least 5 years of relevant working experience as a rule.

When a test method within the framework of the defined accreditation scope is modified, updated or introduced as a new method, it can only be used as a part of the accreditation scope only upon validation, so long as this test method is not a standard method.

In the case of the **first category** (see page 2 of 7) validation does not apply, when the use of the standard method or its equivalent methods is unchanged. However this rule does not hold, when the standard method is combined and used for a new test objective.

Administrative procedures and the responsibilities for the development, implementation and validation of such test methods must be documented. Modification and updating of test methods or the development activities including all results of validation, their supporting reasons and verification as well as other relevant details or data must be completely documented and approved for the final application or use in the testing laboratory.

The responsible staff (including those responsible for quality management) must review the modified, revised or newly introduced test methods regularly, in order to ensure that they meet the requirements satisfactorily.

Test procedures or methods that are used in connection with developed or revised methods in an accredited scope must be reviewed at regular intervals by the responsible management staff. The results of internal or external quality control measures should be taken into consideration. Records of all these activities of checking and reviewing must be made available to the DAP at all times.

The laboratory must always keep a current list of test methods for which it is accredited, including those that are modified, newly introduced or developed, ready for the DAP.

#### **4. Specific requirements for the assessment**

For a defined test area, the following must be assured :

- the key test procedures or methods for the applied scope of accreditation and the staff responsible for or in-charge of these methods (testing staff and supervisory) must be assessed;
- tests must be selected so that they can be practically demonstrated during the assessment;
- the selected test methods must be suitable, in order for the laboratory to instil confidence in the assessors and demonstrate that it has the competence, being able to perform all tests and measurements related to the applied accreditation scope.

During the initial assessment or reassessment the number of test methods to be assessed must be sufficiently large so that the key or principal test methods in each test area can be drawn upon and be adequately assessed. In each test area in any case, one key or principal test method must be assessed.

During every surveillance visit, test methods that the laboratory has in the mean time modified, newly introduced, or developed must be explicitly assessed.

The assessor must be appropriately qualified in order to assess the type and extent of the applied scope of accreditation concerned and must have at the minimum the qualifications as required for the staff of the technical management of the laboratory.

#### **5. Specific requirements for the process of the accreditation case**

If the laboratory wishes to have flexible scope accreditation it must apply for it. It must present its suggestion of the presentation of the intended flexible scope of accreditation to DAP before the assessment in a timely fashion.

#### **6. Presentation of the accreditation scope**

When flexible scope of accreditation is in fact justified for a laboratory, this may be presented in some form in the accreditation certificate. However, this should not be taken as a categorisation or grading of laboratories.

For the presentation of the flexible accreditation, a tabular form can be used based on the examples given.

In addition, the accreditation certificate will contain the following remark and depending on any given case, the wordings from either 1) or 2) will apply.

**Within the given test area, the laboratory is permitted, without being required to inform and obtain prior approval from the DAP Deutsches Akkreditierungssystem Prüfwesen GmbH, the following**

- 1) - the free choice of standard methods or equivalent/similar methods.
- 2) - the modification, development and introduction of test methods.

**The listed test methods are given only as examples.**

If required, e.g. clients' request or submission in a mandatory area, a list of characteristic test methods from defined test methods within an accreditation scope can be appended. added as an annex.

*Example from the sector committee for measurement in testing*

**A. Tests of mechanical-technological equipment or instruments in the field of material testing (including calibration of measurement components)**

Type of testing	Measurement quantities / Test parameters	Measurement and test range	Measurement uncertainty <sup>*)</sup>	Characteristic test methods/ procedures
Tensile Compression Torsion Deflection Deformation	Tensile strength	0,1 N to 2,2 kN > 2,2 kN to 5,0 MN	0,05% 0,10%	StAA-S.11-3 StAA-S.11-4 StAA-S.11-100
	Compressive strength	0,1 N to 36 MN	0,10%	PZ-S110138 PZ-I61-6140A
	Rotation moment	5 Nm to 20 kNm	0,50%	
	Impact loading	Rebound Elasticity	0 to 100 %	based on DIN 53 512
	Loading energy	≤ 750 J		StAA-S.11-5
Hardness	Shore	0 to 100 Shore A/D	based on DIN 53 505	StAA-S.11-5 PZ-S110811B,C DIN 53 505

<sup>\*)</sup> smallest possible measurement uncertainty (best measurement capability)

*Example from sector committee for construction, fire protection, acoustics and vibration*

**B. Test and quantity measurement of gas equipment and its components for heat, humidity and flow behaviour, corrosion resistance, thermal resistance, gas permeability, construction, functionality and safety.**

Test type	Measurement quantities/ Test parameters	Measurement and Test range	Measurement uncertainty *)	Characteristic Test methods
Humidity insensitivity	relative humidity	3 to 100 % r. H.	3 % r.H.	SAA 142/254 SAA142/255
Humidity transfer	Temperature	- 20 to 650 °C	3 K	SAA 142/256
Water absorption	Mass	0,1g to 30 kg	0,1 g	SAA 142/257
Humidity behaviour	Length	≥ 0,1 mm	0,1 mm	SAA 142/258
Heat conducting resistance	Humidity flow thickness	0,1 to 100 g/m <sup>2</sup> h	10 % of measurement unit	SAA 142/259 SAA 142/260
Temperature resistance				
Heat behaviour	Pressure	-100 bis +100 Pa -1000 bis +1000 Pa +2000 bis +5000 Pa	0,5 % of measurement unit 0,05 % of measurement unit 0,5% of measurement unit	SAA 142/261 SAA 142/262 SAA 142/263
Condensation permeability				
Gas permeability				
Corrosion resistance	Volume flow	2 to 20 NL/h 10 to 160 NL/h 100 to 1000 NL/h	1,5 % of measurement unit	
	Air velocity	0 to 5 m/s	1,5 % of measurement range	
	Electrical power	50 to 4000 W	1,1 % of measurement unit	
Construction	Functionality	Requirements based on standards and directives		SAA 142/254
Building integration	Intervals			SAA 142/255
geometrical characteristics	dimensions			SAA 142/256
	Surface area			SAA 142/257
	max. building height, acceptance of building materials used			SAA 142/258 SAA 142/261 SAA 142/262 SAA 142/263

\*) smallest possible measurement uncertainty (best measurement capability)

*Example from the sector committee for chemical testing*

**C. Atomic absorption spectroscopic detection of trace elements in metals, metal alloys, metal compounds, metal solution and refractory substances**

Methods	Matrix	Parameter/Analytes	Digestion	characteristic test methods
ICP-OES	nickel, nickel oxide	Ag, Ca, Co, Cr, Cu, Fe, Mn, Na	Nitric acid	StAA 201 – 203 StAA 217
ICP-OES	aluminium, gallium, indium	Be, Ca, Co, Cu, Fe, Mg, Mn, Na, Ni, Ti, Y, Zn	Nitric acid digestion	StAA 201 – 203 StAA 218
ICP-OES	cadmium, copper, zinc	Ag, Al, As, Au, Be, Bi, Ca, Cd, Ce, Co, Cr, Cu, Fe, Ga, In, Li, Mg, Mn, Mo, Na, Ni, Pb, Pt, Sc, Ti, Tl, V, Zn, Zr	Nitric acid	StAA 201 – 203 StAA 219
ICP-OES	calcium carbonate	Ag, Al, B, Ba, Be, Bi, Cd, Ce, Co, Cr, Cu, Fe, Ga, In, K, La, Li, Mg, Mn, Na, Ni, Pb, Si, Sr, Ti, V, Y, Zn, Zr	Hydrochloric acid	StAA 201 – 203 StAA 220
ICP-MS	solutions of arsonic, cadmium, chromium, copper, iron, lead	Ag, Al, B, Ba, Be, Bi, Ca, Cd, Co, Cr, Cs, Cu, Fe, Ga, Hg, In, La, Li, Mg, Mn, Na, Ni, Pb, Pd, Rb, Re, Sn, Sr, Th, Tl, U, Y, Zn, Zr		StAA 227 – 229 StAA 234
ET-AAS	aluminium	Ga, In, Tl	Nitric acid	StAA 235 – 237 StAA 246
ET -AAS	cadmium, copper, zinc	Ag, Al, Ca, Cd, Cu, Fe, K, In, Mg, Mn, Na, Ni, Pb, Sn, Te, Zn	Nitric acid	StAA 235 – 237 StAA 247
ET-AAS	nickel, nickel oxide	Ca, Cd, Co, Cu, Fe, K, Mg, Na, Pb, Zn	Nitric acid	StAA 235 – 237 StAA 248
ICP-OES	silicon carbide	Al, Ca, Co, Cr, Cu, Fe, Mg, Mn, Ni, Ti, Zn, Zr	Pressure digestion hydrofloric acid / nitric acid / sulfuric acid	StAA 201 – 203 StAA 209
ET-AAS	silicon nitride	Al, Fe, Zn	Pressure digestion hydrofloric acid / nitric acid	StAA 235 – 237 StAA 240

Example from the sector committee for food testing

For category I:

Within the given test area indicated by \*, the laboratory is permitted, without being required to inform and obtain prior approval from the DAP Deutsches Akkreditierungssystem Prüfwesen GmbH, the use of standard methods or equivalent/similar methods that are not specifically stated in the accreditation certificate. The listed test methods are given only as examples.

**D. Physical, physical-chemical and chemical methods for the determination of parameters and content substances in milk, milk products, potable water and other selected foodstuffs.**

**D.1 Enzymatic analysis of content substances \***

**D.1.1 Official compilation of test methods (Amtliche Sammlung von Untersuchungsverfahren ASU) according to § 35 LMBG (German Act on Foodstuffs and Consumer Items )**

ASU L 01.00-17 1983-05	Determination of lactose and galactose contents in milk and milk products; Enzymatic method
ASU L 01.00-26 1987-06	Determination of the contents of L and D-Lactate in milk and milk products; Enzymatic method
ASU L 01.00-31 1988-12	Determination of Lactulose content in milk
ASU L 02.00-12 1986-05	Determination of contents of saccharose and glucose in milk products and ice-cream; Enzymatic method
ASU L 48.01-5 1985-05	Determination of strength of partly adapted milk based baby food

For category II:

Within the given test area indicated with \*\*, the laboratory is permitted, without being required to inform and obtain prior approval from the DAP Deutsches Akkreditierungssystem Prüfwesen GmbH, the modification, development and introduction of test methods. The listed test methods are given only as examples.

## **D.2 Microbiological examinations of mineral water, spring water and table water\*\***

ASU L 59.00-1 1988-05	Detection of Escherichia coli and coliform pathogens in natural mineral water, spring water and table water
ASU L 59.00-2 1988-05	Determination of fecal streptococci in natural mineral water, spring water and table water
ASU L 59.00-3 1988-05	Determination of pseudomonas aeruginosa in natural mineral water, spring water and table water
ASU L 59.00-4 1988-05	Detection of sulphite reduced, spore forming anaerobes in natural mineral water, spring water and table water
ASU L 59.00-5 1988-05	Determination of colony count in natural mineral water, spring water and table water
HM-M021 1995-03	Detection of coliform pathogens in drinking water according to Annex 1 of the German Ordinance on Drinking Water (Trinkwasser-Verordnung)
HM-M022 1995-03	Detection of E. coli in drinking water according to Annex 1 of the German Ordinance on Drinking Water (Trinkwasser-Verordnung)
HM-M019 1995-03	Determination of colony count at 20 °C for drinking water according to Annex 1 of the German Ordinance on Drinking Water (Trinkwasser-Verordnung)
HM-M020 1995-03	Determination of colony count at 36 °C for drinking water according to Annex 1 of the German Ordinance on Drinking Water (Trinkwasser-Verordnung)
HM-M023 1996-06	Determination of fecal streptococci in drinking water according to Annex 1 of the German Ordinance on Drinking Water (Trinkwasser-Verordnung)

## **7. Bibliography**

DAR-3-EM-18 : 2002-03-13 / Version 2.0

*Der Akkreditierungsbereich und Betrachtungen zu Methoden und Kriterien zur Begutachtung des Akkreditierungsbereichs im Prüfwesen*

German translation of the following EA Document: The scope of accreditation and the consideration of methods and criteria for the assessment of the scope of testing

EA-2/05 Rev.02 : 2001-08

The Scope of Accreditation and Consideration of Methods and Criteria for the Assessment of the Scope in Testing

ILAC-G18 : 2002

The Scope of Accreditation & Consideration of Methods & Criteria for the Assessment of the Scope in Testing