

# CATALOGUE OF REQUIREMENTS <sup>\*)</sup>

Sector committee – Food analyses

DAP – Deutsches Akkreditierungssystem Prüfwesen  
GmbH  
[German Accreditation System for Testing]

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<sup>\*)</sup> Translation for information purposes only. The German version is authoritative.

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## I. Scope

The sector committee – Food analyses (SC – food) of the DAP deals with the accreditation of test laboratories, which carry out physical, physical-chemical, chemical, biological, microbiological and biotechnological, virological and biomolecular, toxicological and ecotoxicological, physiological, histological, serological and sensory tests, including sample taking, on products and manufactures in the areas of

- food
- food additives
- drinking water, table, mineral and healing water, production water in the food industry
- wine
- articles of daily use
- toys
- cosmetics
- tobacco products
- animal feed
- seeds
- compost
- biological materials
- biological test systems.

## II. Flexibilisation of the accreditation scope

### 1. Purpose

The flexibilisation of the accreditation scope makes it possible for accredited laboratories

- to apply updated versions of already accredited norm methods and similar additional standardised methods as well as deviations from accredited norm methods within a competence sector (accredited test sector), maintaining at the same time the test methods and the sample preparation, if the test methods have been evidently verified before the application (**type 1**)

or

- to modify their own validated in-house methods (laboratory in-house methods) as well as apply further and newly developed in-house methods within an unambiguously specified test sector (**type 2**); type 2 can include type 1 without needing prior information, consent or assessment of the DAP.

Normally, the general acceptance of new methods as described above has to be reported to the DAP in writing on an annual basis and will be verified at the next assessment.

## 2. Objective and scope

Provided that the described flexibilisation does not entail significant deviations from the defined accredited sector and the reports to the accreditation body are submitted in the proper form, this flexibilisation attempts to accommodate technical progress and to satisfy the changing needs of the laboratories' customers.

During the accreditation procedure, this special competence of a test laboratory must be especially examined by a qualified team of assessors and is subject to an extended competence assessment.

## 3. Basics

The team of assessors has to pay special attention to the verification of the methods should a laboratory apply for a flexible accreditation according to **type 1**.

Normally, all accredited test methods should always be quoted as appendices to the certificate, if new certificates are issued.

For the accreditation of laboratories according to **type 2**, which work in research and development, the following procedures apply:

- The flexible test sectors specified in the certificates have to be unambiguously described by standardised test methods and particularly by in-house methods. In-house methods in turn are described in their title (designation) by the three cornerstones method (measurement/determination method), matrix and analyte/analyte group (species/parameters). However, it is sufficient for the description of the corresponding test sector to specify two of these cornerstones, for example the test sector: "*Chromatographic (HPLC and DC) determination of vegetable raw materials*", whereas the individual test method should be described as precisely as possible, for example: "*Determination of theobromin in cocoa by means of HPLC*" (analyte, matrix and method). The sum of the listed methods characterises the flexible sector unambiguously.
- The flexibilisation does not include the integration of new measurement principles, which had not been included in the original test sector.
- Substantially new test methods that would entail an expansion of the accreditation scope may only be included in the accreditation after the prior consent and a possible assessment by the DAP.
- The list of all valid test methods (in-house methods and norms) subject to the accreditation at the time of the assessment has to be submitted to the DAP in writing. Normally, all methods characteristic for the work of the laboratory should be quoted in the appendix of the certificate.
- The assessment of the test personnel's competence and the competence in the mastery of the test method as well as the assessment for the validation of in-house methods become especially important in this sector and have to be assessed by the team of assessors.

Test laboratories that wish to be accredited in one of the above described forms in accordance with DIN EN ISO/IEC 17025 and/or that wish to be approved and notified in accordance with the guideline 93/99 EEC, have to meet the following requirements:

### **III. General requirements**

#### **1. Personnel**

The test laboratory has to have a technical management, which is presided over by a professionally qualified technical manager.

The technical manager (manager of laboratory) has to possess a university or technical college degree and three years of professional experience. The deputy manager of laboratory has to possess a university or technical college degree and two years of professional experience. In individual cases, the degree as laboratory technician is considered the minimum qualification. Deviations from the qualifications can only be authorised by the SC – food.

The competences and substitution regulations for the executive employees have to be documented and known in the laboratory (e.g. function and job descriptions).

All employees have to be free of internal and external commercial, financial and other restraints (remuneration on the basis of fixed salaries).

The test laboratory has to ensure that conflict situations with regard to impartiality, independence and integrity do not arise (III statement of the management).

If the test laboratory handles pathogenic germs the laboratory needs an accreditation pursuant to § 44 Infektionsschutzgesetz (Act on Prevention of Infections) (or pursuant to § 19 ff old Bundesseuchengesetz (Federal Communicable Diseases Act)). The same applies to § 2 Tierseuchen-erregerverordnung (Act on Zoonoses Agents).

If the test laboratory wishes to meet the requirements of the guideline 93/99 EEC, the laboratory has to have at least three employees in this field of activity.

The employees have to be bound by confirmed labour agreements or explicit contracts of work and labour.

The technical management of the laboratory has to provide time and funds for the implementation of internal and external training measures in a reasonable amount. The time and funds have to be documented in an approved annual training plan.

#### **2. Premises and equipment**

The premises of the laboratory may include constructionally fixed and/or mobile premises.

Besides the equipment with instruments (which have to be listed in an instrument register), technical management also has to provide and document all other necessary resources, e.g. in literature, norms and guidelines, operational safety equipment, etc.

An access regulation documented in writing has to be prepared and the technical management has to observe that it is complied with.

### **3. Quality management**

The test laboratory has to have a practise-related and flexible quality management system, which is to be specified and updated on a regularly basis in the quality management manual.

General management/technical management of the test laboratory have to appoint a competent quality management representative (QMR), who has to have access to the topmost level of management. The QMR is responsible for the planning and organisation of the audits, and he/she has to ensure that the audits are carried out by competent and qualified personnel, who are independent of the activity subject to the audit. The QMR also checks randomly the compliance with the standard operation procedures (SOP) in accordance with the guideline 93/99 EEC.

In the course of the internal audits, all relevant areas of the laboratory and all elements of the QM system, including the test activities, are audited at least once a year. The internal audits have to be planned annually.

The quality management system has to be assessed at least once a year by the technical management. In doing so, special attention has to be paid to the following points:

- reports of key support personnel
- results of the internal audits
- corrective actions carried out
- preventive actions
- results of external assessments (accreditation body, customer audits, authority audits)
- results of suitability tests, e.g. interlaboratory test results
- modification of the sphere of activity
- information feedback from the customers
- complaints
- measures for the quality control
- personnel training
- providing of personnel and technical conditions

### **4. Documented methods**

In order to meet the requirements of the guideline 93/99 EEC, the laboratory has to dispose of standard operation procedures (SOP) documented in writing for at least the following points:

samples: sample acceptance, entry registration of samples, identification, labelling, handling, extraction, storage

test and reference substances: entry, identification, labelling, handling, extraction, storage

equipment, material and reagents: operation, maintenance, cleaning, calibration, preparation of reagents

registration system and archiving

quality assurance procedure: persons, tasks, audits, assessments

regulations on biological test systems (if available)

Furthermore, procedures documented in writing and documents are required for at least the following points:

feasible regulations for the order verification and documents proving that all incoming orders have been verified technically by qualified personnel

regulations on sub-contracting as well as a list of employable sub-contractors with proof of qualification and a documentary list of actually allocated sub-contracts

regulations on supplier assessment as well as a list of all authorised suppliers relevant for the quality and documents proving a regularly conducted supplier assessment

regulations on the compliance with confidentiality of all employees together with the appropriate documents

regulations on complaint procedures with appropriate documents (e.g. complaints book), also of orally reported complaints

## **5. Documentation**

All documents used in the test laboratory have to be registered in a master list.

Information relating to the archiving place and duration have to be registered in writing for the default documents as well as for the proving documents.

Handwritten modifications in documents, especially with test methods, have to be possible but should be subject to established regulations.

## **6. Corrective and preventive actions**

The corrective actions used in the laboratory and the preventive actions for the avoidance of mistakes and for the documentation of mastered analytical processes should include at least:

determination of the tolerance range for all quality-relevant equipment parameters

plausibility tests

regularly, and where necessary, daily calibration of the equipment

reasonable verification and validation of the methods

estimation of the measurement uncertainty (without and if necessary including sample taking)

planning and participation in suitability tests like interlaboratory comparisons or intralaboratory comparisons

planning and implementation of internal and external audits

trend analyses (e.g. quality control cards)

regular qualification and exchange of experiences of the personnel

## **IV. Technical requirements on a chemical laboratory**

### **1. Personnel**

The management of the laboratory commit themselves and their employees to the compliance with a good technical laboratory practice. They have to formulate the objective with regard to the education, training and experience of the personnel.

The personnel has to be technically qualified and be able, within the range of the responsibility area, to determine the values analytically, to assess them and to carry out judicial interpretations, if necessary.

The personnel has to take part regularly in internal and/or external trainings and qualifications. Training plans and documents have to be documented in writing.

The responsibility areas have to be pointed out to the personnel (e.g. organisation chart, qualification matrix, job descriptions).

The laboratory has to have basic regulations, which guarantee the protection of all confidential information and property rights of its customers.

The personnel has to treat all determined data and facts with absolute confidentiality.

## 2. Premises and environmental conditions

The premises have to be sufficiently spacious, in a proper condition and clean.

Possible cross-contaminations (e.g. solvents, gases, etc.) have to be eliminated by technical and/or operation-organisational measures.

The test laboratory has to present a regulation concerning the cleaning of the premises and their housekeeping (e.g. avoidance of dust) and dispose of a cleaning/hygiene plan, if necessary. If external cleaning personnel is employed, they have to be instructed and supervised accordingly and committed with regard to the compliance with confidentiality.

## 3. Test methods and their validation as well as estimation of the measurement uncertainty

The test laboratory has to maintain and constantly update a test method list as master list containing information on the matrix, parameters and the equipment used. This is particularly applicable for a flexible accreditation, for which the methods are only exemplary listed in the current certificate.

The test laboratory has to dispose of regulations for the verification and validation of test methods (see also the validation requirement of the SC – food and the accreditation body of Hanover – **appendix I**).

The test laboratory has to dispose of regulations for the estimation of the measurement uncertainty (also making use of publications, e.g. the BgVV (Federal Institute for Health Protection of Consumers and Veterinary Medicine) or the GDCh (German Chemical Society)).

Please refer to **appendix III** (Instructions for measurement uncertainty) for further information.

## 4. Equipment

The test laboratory has to dispose of a master list of all equipment. The master list has to be updated constantly.

All quality-relevant instruments have to be calibrated regularly and, if necessary, on a daily basis or – where sensible – recalibrated and assessed statistically (e.g. by means of quality control cards (QCC)).

The reduction of the measurement categories temperature and mass has to be guaranteed by means of calibrated weight pieces or weight sets and calibrated thermometers. Furthermore, commercial laboratories and laboratories with cross-

check experts have to dispose of one or more **calibrated** scales pursuant to § 42 LMBG (Law on Foodstuff and Necessaries).

## 5. Quality assurance

The internal quality assurance is an important instrument for the determination of “correct” results and for the documentation of stable and controlled analytical processes. This includes among other things:

- calibration and recalibration of the instruments
- verification and validation of the methods used
- qualification and training of the technical personnel

The test laboratory has to employ standards, reference material (internal and certified reference material) or control tests on a regular basis in order to ensure quality and control comparability. The values have to be assessed statistically, e.g. by means of quality control cards (QCC). Promptly, the measurement values have to be registered visually as well in order to identify outliers and trends at an early stage and to be able to initiate corrective actions in time.

A list of all standards and reference materials has to be maintained and updated regularly. The application frequency has to be adopted to the sample emergence.

Within the scope of the external quality assurance, the laboratory is obligated to take part in intralaboratory comparisons, interlaboratory comparisons, individual suitability tests and suitability test systems in line with the legal requirements on a regular basis and to a reasonable extent. Furthermore, in order to meet the requirements of the guideline 93/99 EEC, it is necessary to take part in the interlaboratory comparisons listed with the Federal Institute for Health Protection of Consumers and Veterinary Medicine (BgVV) of the Coordination Body for Laboratory Suitability Tests in the Area of Official Food Inspection (DKLL). At least one interlaboratory test per year is required for every larger research division or department. Alternatively, it is possible to employ certified reference material or internal reference material (IRM), especially if no interlaboratory or intralaboratory comparisons are available for this area. If even reference material is not available, other appropriate quality assurance measures have to be documented (e.g. BSE tests).

## 6. Sample taking, sample labelling, sample management

Measures for a qualified sample taking have to be taken.

Sample protocols with all necessary information as well as the appropriate working instructions (e.g. for the determination of aflatoxins in shell fruits according to the guideline 98/53 EC) have to be available on site during the sample taking.

The sample taking instruments have to be calibrated and maintained and be put in a fully functional and quality-relevant state as applies to the test equipment.

Regulations have to be available for the handling of the sample objects and samples, i.e. technical entry control, storage, keeping, protection and preparation for the relevant analytical analysis, including a possibly necessary sensory test.

A system for the labelling of the samples has to be in existence, which definitely eliminates mix-ups and permutations of the samples.

Regulations have to be available for the professional waste disposal of samples and laboratory residues.

## **7. Test reports**

Laboratory results have to be submitted in the form of norm-compliant test reports or, in case of internal audits or upon written agreements with the customers, in a simplified form.

Regulations have to be available in case test results are exclusively transferred by way of electronic data transmission.

Regulations for the preliminary transfer of test results with the obligation of appropriate documentation have to be available in writing.

Opinions, interpretations and assessments are permissible and have to be clearly identified as such in the test report. Expert opinions should differ clearly from the test report.

## **V. Technical requirements on a microbiological laboratory**

### **1. Personnel**

The technical personnel, who carries out autonomous operations, has to possess appropriate professional experience.

The laboratory has to dispose of a permit pursuant to § 19 ff Federal Communicable Diseases Act or § 44 Act on Prevention of Infections, if it works with pathogenic germs.

### **2. Environmental conditions**

#### **2.1 General**

2.1.1 The administration and laboratory areas have to be separated.

2.1.2 The chronology of the sample processing has to be reflected logically in the laboratory set-up ("no way back layout"). The test activities have to be separated spatially and chronologically, if necessary.

2.1.3 Separate areas should exist for

- sample acceptance and storage
- sample preparation
- sample analysis, incubation, assessment
- storage of the reference organisms
- medium and material preparation, including sterilisation
- analysis on sterility
- decontamination/waste disposal.

If necessary, cross-contaminations can be excluded by operation-organisational measures.

## **2.2 Environmental influences and monitoring**

2.2.1 Environmental influences have to be minimised by constructional measures.

2.2.2 The environmental conditions may not influence the test results. The measures and facilities for the minimisation of the environmental influences have to be described and documented.

2.2.3 There has to be an adequate monitoring programme for the environmental conditions (airborne germ measurements, surface analyses).

2.2.4 The working areas have to be sufficiently spacious.

2.2.5 The working areas have to be sufficiently ventilated. The ventilation has to be controlled microbiologically.

## **2.3 Environmental influences and inspection**

2.3.1 Depending on the form of the conducted tests, the access to the relevant working areas has to be limited to authorised personnel.

2.3.2 The information on the limitation of access has to be displayed clearly and visibly.

2.3.3 The access authorisations have to be registered in writing and be known to the employees.

## **2.4 Hygiene**

- 2.4.1 Protective clothing appropriate for microbiological works has to be worn and taken off when leaving the working area.
- 2.4.2 The set-up and layout of the laboratory rooms have to be designed in a way that the risk of a contamination by the environment, the working materials and the test objects is minimised.
- 2.4.3 The walls, floors, ceilings and working spaces must be easy to clean and disinfect. Possibly existing wooden surfaces have to be sealed appropriately. Measures have to be taken in order to avoid dust concentrations (sufficient storage space, preferably little paper, preferably few personal items of the personnel in the laboratory).
- There has to be a documented hygiene plan, including a cleaning programme.
- 2.4.4 A reduction of contamination sources can be achieved for example by the following measures:
- Ø smooth surfaces on walls, ceilings, floors and working tables
  - Ø rounded seams at the wall connections
  - Ø closed windows and doors during the execution of the tests
  - Ø sun protection at the outside of the windows
  - Ø easy to clean sun protection at the inside
  - Ø no open piping above the working spaces
  - Ø dust filter facility of the ventilation system
  - Ø separated wash basins (preferably with operation elements without hand contact)
  - Ø closets up to the room ceiling
  - Ø no raw, open timber
  - Ø a orderly and easy to clean sample and material storage
  - Ø no furniture, documents or other items in the test areas, which are not absolutely necessary for the test activities.
- 2.4.5 The computer facilities have to be installed in a way that the air flow from the ventilation systems cannot contaminate the working spaces.
- 2.4.6 The number of laminar flow benches has to be appropriate for the number of test activities to be carried out under sterile conditions.

### 3. Equipment

#### 3.1 General

The QM system of the laboratory has to include a programme for the maintenance, cleaning/sterility, calibration and monitoring of its facilities and test instruments. An appropriate documentation has to be maintained.

#### 3.2 Maintenance/cleaning

3.2.1 The maintenance of the necessary test facilities has to be carried out in predetermined intervals appropriate for the frequency of use.

3.2.2 Cross-contaminations by test facilities is to be avoided, for example by:

- Ø clean and sterile non-returnable articles
- Ø carefully cleaned reusable glass devices
- Ø ideally separated autoclaves for disposal and growing medium production and/or sterilisation of test instruments.

3.2.3 All necessary equipment items have to be included in the system of control, monitoring and possibly sterilisation. This includes among other things:

- Ø general equipment, like for example filter installations, glass and plastic containers, petri dishes, sample taking instruments and diluting loops
- Ø water baths, incubators, autoclaves, homogenisers, refrigerators, deep freezers
- Ø volumetric items: pipettes, automatic dispensers, spiral plater
- Ø measuring instruments: thermometer, clocks, weights, pH-meter, colony counter.

#### 3.3 Calibration and monitoring of the serviceability

3.3.1 For equipment, which has a direct influence on the test results, there has to be a calibration and monitoring programme. The time intervals must be founded and appropriate for the purpose of use. The time intervals should correspond to the predetermined examples in appendix B and C.

3.3.2 All measurements have to be attributed, as far as possible, to national or international standards. The corresponding

certificates for these standards have to be available.

### 3.3.3 Temperature measurement equipment

- a) The thermometers or temperature measurement equipment, which have a direct influence on the test results, have to be of an appropriate quality in order to meet the specifications laid out in the test instructions. The display scale has to correspond to the required test accuracy.
- b) The temperature control equipments have to be attributed to calibrated thermometers or temperature measurement equipments. Documented procedures have to be in existence. The measurement accuracy of the reference normal for the calibration has to be appropriate.
- c) The temperature of cooling or freezing equipment, which has no direct influence on the test results, has to be monitored with adequate thermometers.
- d) An inspection of firmly installed thermometers and temperature recording systems in for example growing medium casting machines and autoclaves has to be conducted and documented.

3.3.4 The stability, distribution and set-up time (equilibration time) of a desired temperature in incubators, water baths, hot air cabinets and tempered rooms have to be determined and documented with the commissioning for the typical purpose of use. These parameters have to be controlled after every repair or modification. The temperature measurements have to be registered and appropriately stored.

### 3.3.5 Autoclaves

- a) The autoclaves have to meet the respectively required sterilisation requirements. (Autoclaves with pressure valves are not suitable for the fabrication of media and decontamination.)
- b) With the commissioning of the autoclaves, their service capability, e.g. temperature distribution in a typical application case, has to be determined. This procedure has to be repeated after repairs or modifications (loading structure, temperature programme).
- c) The autoclave conditions have to be recorded (temperature, (pressure) and time).

Control can be achieved by means of:

1. thermo-sensors and data recorders
2. direct meter-reading and registration of the achieved temperatures and times.

In addition to direct temperature control, the functionality should be controlled with chemical or biological indicators during each cycle. Autoclave stripes should be used in order to display the execution of an autoclave process on a batch (and not the success of a process).

- 3.3.6 The scales have to be calibrated and inspected in a documented process in regular intervals. All scales have to be calibrated, and the calibration must be attributed to a national or international measurement normal.
- 3.3.7 a) In a microbiologic laboratory, volumetric equipment like automatic dispensers, dispensers/diluters, mechanical piston-stroke pipettes and non-returnable pipettes may be used. Before the initial use, the laboratory should carry out a verification of these equipments. Furthermore, the laboratory has to guarantee by inspections in regular intervals that these laboratory accessories meet the required specifications.
- b) The correspondence between the actual volume (output volume) and the target volume (set-up volume) of the equipment used must be checked. The reproducibility of the results with repeated processes has to be assessed. For non-returnable articles, the laboratory shall resort to suppliers, which can produce a relevant ISO 9000 certification.
- After the inspection before commissioning, it is recommended to carry out inspections of exactness in the context of random inspections.
- 3.3.8 As a rule, conductivity measuring instruments, oxygen measuring instruments, pH-meters and similar equipment should always be inspected before each use. The buffer solutions for their adjustment have to be stored in appropriate environmental conditions and labelled with a date of expiry.
- 3.3.9 If the air humidity is important for the result of a test, calibrated hygrometers shall be used, which can be attributed to national or international standards.
- 3.3.10 Time measuring instruments and clocks, including autoclave timers, should be controlled with a calibrated time measuring instrument or a national time signal.

#### 4. Reagents and growing media

- 4.1 The laboratory has to guarantee that the quality of the reagents used is appropriate for the intended purpose of test. Preferably, the reagents (including growing media and finished plates) should be purchased from manufacturers, which are certified according to ISO 9000. Before the first use of the products, the laboratory has to make sure that the items are suitable (inspection with positive and negative control organisms, which preferably originate from an approved national strain collection).
- 4.2 Growing media may be produced from individual chemicals or dry powder in the laboratory or may be purchased readily.
- 4.3 Reagents and buyable dry powders have to be used before the expiry date. The entry date, expiry date and opening date have to be registered. Media in store have to be used in such a way that the older media are used before the fresher media. The media must be stored under appropriate conditions, i.e. cool, dry and dark. All storage containers must be soundly locked. Dry powders that are agglutinated, welled or changed in colour, may not be used anymore.
- 4.4 Growing media, solutions and buffers produced in the laboratory itself shall be made from chemicals "for microbiological purposes/for microbiology".
- 4.5 If a laboratory uses ready-made growing media and reagents the laboratory has to demand and the manufacturer has to produce the corresponding specifications and batch certificates. Further inspections have to be carried out in irregular intervals to ensure the correspondence of the products with the required specifications. These inspections should be integrated in the QM system of the laboratory.

The manufacturer has to specify the following minimum information concerning the quality specifications of the products:

- Ø minimum durability
- Ø storage conditions
- Ø sample taking system and sample taking rate
- Ø sterility inspection including acceptance criteria
- Ø function control, including the organisms used, information on their origin and acceptance criteria
- Ø date of issue of the specifications

- 4.6 For the production of media, solutions and buffers, only distilled or deionised water or reverse osmosis produced water shall be used, which is demonstrably free from bactericidal substances or inhibitors.
- 4.7 The media, solutions and reagents have to be produced in accordance with documented procedures, which correspond to the requirements of the manufacturer/author. Support for the production and sterilisation of media or their recommended storage period can be found in the ISO 7218.
- 4.8 All growing media preparations produced in the laboratory have to be inspected for the correct detection and identification of microorganisms by means of a positive control. Additionally, it has to be checked, whether selective media reliably prevent the growing of undesired organisms. A procedure with a quantitative approach is preferred to the common smear method. With such a procedure it is recommended to work with a small amount of germs and to specify the recovery rate or to determine the necessary recovery rate.
- 4.9 All reagents (also strain solutions) have to be sufficiently labelled to display their identity, concentration, storage conditions and the expiry date. The person responsible for the production of the reagents must be either identified on the label or in the registry system of the laboratory.

## **5. Test methods**

- 5.1 A laboratory may use any kind of officially, nationally and internationally standardised test instructions as well as test methods developed in the laboratory itself (in-house methods). The methods have to be validated.
- The laboratory has to ensure that each individual test method is suitable for the respective purpose of use.
- 5.2 The reliability, repeatability/reproducibility, selectivity, sensitivity, detection limit, matrix effects and practicability have to be taken into consideration when selecting test methods.
- 5.3 The test methods used by the laboratory have to be fully documented. Concerning this, a procedure is described in ISO 78/2 "Layouts for Standards".

## 6. Validation and verification of test methods, measurement uncertainty

- 6.1 Every laboratory has to dispose of specified requirements for the application characteristics of a certain test method to verify the suitability for the intended purpose of application. However, the main characteristic of a test method should be the production of “correct” results in consideration of specified detection limits, selectivity, repeatability and reproducibility.
- 6.2 Using official methods or test methods of approved national or international standardisation committees, it is not necessary for the laboratory to carry out a complete validation before the first use. However, the laboratory has to demonstrably introduce the method in a documented training programme (verification). Basis parameters like variance, selectivity and sensitivity can be found in the respective manuals, scientific publications and guides on microbiological growing media.
- 6.3 Buyable test systems (test kits) do not require further validation, if the validation information is available from other sources, e.g. cross-validations from several laboratories. The laboratory has to enquire for the validation information and verifications for the operation in accordance with an approved quality management system with the manufacturer of such test systems.
- In case the validation information is not fully available, the laboratory is obligated to validate the method before the routine application of the method.
- 6.4. Any other test methods are subject to a complete validation to guarantee the reliability of the gained results and, if possible, to determine the measurement uncertainty.
- 6.5 Qualitative microbiological test methods (in which the results are indicated as presence/absence) have to be validated by an estimation of the following parameters, if suitable and reasonable:
- Ø selectivity
  - Ø relative reliability
  - Ø positive deviation
  - Ø negative deviation
  - Ø detection limit
  - Ø matrix effects
  - Ø repeatability
  - Ø reproducibility.

- 6.6 For quantitative microbiological test methods it is necessary to consider and, if necessary, to determine quantitatively the selectivity, sensitivity, relative reliability, positive deviation, negative deviation, detection limit, repeatability and reproducibility within a predetermined variation limit. If different samples are examined, the matrix-dependent differences have to be taken into account. The results have to be verified with suitable statistical methods.
- 6.7 The validation of the test methods has to be carried out under practice-oriented conditions. The validation may be carried out with the help of naturally contaminated products or artificially spiked products.
- 6.8 All validation information must be registered and stored for the time of the use of the test method. The archiving period is to guarantee that raw data and results may be traced back appropriately.
- 6.9 The participation in or the organisation of intralaboratory comparisons or interlaboratory comparisons is also considered a suitable method for the validation of test methods. Furthermore, the inspection of samples with the proposed new method and already introduced methods can also serve as an indicator for the assessment of the capability of the new method.
- 6.10 If a modified test method is to generate the same performance characteristics like the original test method, both methods have to be compared by testing identical samples.
- 6.11 Even if the validation is completed, the user has to check that the documented performance characteristics are achieved (e.g. by using spiked samples).
- 6.12 Measurement uncertainty
- The international definition of measurement uncertainty can be found in "ISO International vocabulary of basic and general terms in metrology: 1993".
- The test laboratory has to dispose of regulations for the estimation of the measurement uncertainty (if necessary also by using information from publications).
- Repeatability and reproducibility are aspects of the measurement uncertainty and should be determined as first steps towards the realisation of estimations. Likewise, results from participations in interlaboratory comparisons, intralaboratory comparisons and QA programmes of the

laboratory itself can be included.

Further information can be found in the **appendix III** (Instructions for measurement uncertainty).

## 7. Quality assurance of the test results/quality control

7.1 Quality assurance is the programme of all activities carried out in a laboratory, which generally wishes to enhance its laboratory performances. These activities include the promotion for the application of a permanent internal quality control, the support by external verification methods and all measures, which increase the reproducibility of results by training measures, work groups and common formulations within the laboratory and in comparison with other laboratories.

### 7.2 Internal quality control

7.2.1 The internal quality control consists of the measures of a laboratory, which are used to continuously control and assess the operation of the laboratory. The main objective is to guarantee that the daily correspondence of measurements is consistent with accepted values. This includes the comparison with approved values of molecules, cells, organisms or with designated values of control materials, if they are available. If correspondence cannot be achieved, this result has to be registered.

7.2.2 A laboratory shall apply internal control methods, which – if suitable – make use of statistical methods, e.g.:

- Ø process development
- Ø variation/regression analyses
- Ø reliability considerations/risk analyses
- Ø control of significance
- Ø quality control cards
- Ø statistical sample taking and testing.

### 7.3 Reference strains

7.3.1 In order to ensure traceability and validation, the laboratory has to obtain reference strains of microorganisms from an approved national strain collection or a body approved of by the accreditation body.

7.3.2 The reference strains may be sub-cultivated once to prepare storage batches. Appropriate purity controls and biochemical tests have to be carried out. The storage batches must be preserved by suitable technologies (e.g. freeze-drying, liquid

nitrogen cooling, deep-freezing) in such a way that the desired characteristics of the strain are maintained. The storage batches shall serve for the production of working populations. Once the storage batches have been defrosted, they may not be frozen in and used again.

7.3.3 Normally, working populations from bacteria should not be further sub-cultivated. However, under the conditions described below, working populations may be sub-cultivated:

1. A standardised method requires the sub-cultivation.
2. The laboratory can prove with documents that there has been no loss in the viability, the biochemical characteristics and/or the morphology.

The normal working populations may not be sub-cultivated in order to produce storage batches from them.

#### **7.4 Standards and certified reference material**

7.4.1 Certified reference material and standards provide for the necessary traceability of measurements. They are used for example to document the exactness of measurement results, for the calibration of the measuring instruments and methods, the effectiveness of the laboratory and the validation of test methods. They make it possible to compare methods by using them as transferable standards.

Wherever it is possible, the use of reference material must be promoted.

7.4.2 Standards and certified reference material must be stored in suitable environmental conditions, which guarantee their sound condition in accordance with documented methods and the respective test method.

#### **7.5 External quality assurance (suitability tests/interlaboratory comparisons)**

7.5.1 Externally organised suitability tests are an independent measure, the help of which a laboratory can objectively test and present to third parties the reliability of the results that have been gained using its test methods. The participation in suitability tests and interlaboratory comparisons makes it also possible for the laboratory to compare its own efficiency with the efficiency of other laboratories. The results from interlaboratory comparisons and suitability tests are an important instrument to test the efficiency of the internal quality assurance and, if necessary, to take appropriate measures.

7.5.2 The laboratories have to take part in interlaboratory

comparisons and suitability tests on a regular basis, which cover the scope of their accreditation. In special cases, the participation can be made mandatory. The accreditation body must make available information on the relevant interlaboratory test programmes.

## **8. Handling and identification of samples**

- 8.1 Sample taking activities outside the laboratory are not explicitly mentioned in the ISO/IEC 17025. However, since the microbiological flora is sensitive to temperature and transport influences as well as the storage period, it is important to register the sample taking parameters and the condition of the sample (e.g. entry temperature) in the sample taking protocol or the sample entrance protocol.
- 8.2 The laboratory has to dispose of a method for the acceptance of samples. The laboratory must reject a sample or document the conclusions on the condition of a sample in the test report, if the sample amount was too small or the sample arrived in a bad condition due to mechanical damages, inappropriate temperature conditions, torn open packages and insufficient labelling.
- 8.3 The following information has to be registered:
- (a) a unique and distinctive labelling of the sample, which ensures the traceability of the sample from order receipt to the completion of the test process
  - (b) date and – if of importance – time of the receipt of the sample
  - (c) identity of the person or institution, who has taken the sample
  - (d) sample identification information by the sample taker
  - (e) kind, characteristics and distinctive features of the sample
  - (f) list of the tests to be carried out and, if necessary,
  - (g) temperature and condition of the sample at receipt or acceptance
  - (h) information on the sample taking (date, sample taking conditions, etc.).
- 8.4 The samples to be processed have to be stored under appropriate environmental conditions to minimise the modifications of any existing microbiological population.
- 8.5 The packaging of samples can be profoundly contaminated. Therefore, they have to be stored and handled in a way that they cannot spread contaminations.
- 8.6 The preparation of the samples and the preparation of the sample amount has to follow national and international product-specific norms or standards.

- 8.7 In the simplest case, the sample preparation consists of homogenising of aliquots by stirring and bottling in case of liquids. However, the preparation can also consist of reconstitution and sub-cultivation in several steps, in case of dry products. In any case, the laboratory must prove that:
- a) the amount to be tested is, as far as possible, representative for the sample and suitable for the chemical analysis;
  - b) contaminations of the amount to be tested and the test environment have been avoided.
- 8.8 A method for the storage and disposal of samples has to exist in writing. Laboratory samples, of which it is known that they are profoundly contaminated, must be decontaminated before their disposal. Such samples have to be stored until the results are available or, if necessary, longer than that.

## **9. Disposal of contaminated waste**

- 9.1 The proper disposal of contaminated material does not directly influence the quality of the test results of samples. However, it is part of a sound laboratory management and should be consistent with the national and international regulations concerning environmental protection, health and safety (see also ISO 7218).