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1 General

This rule applies to the accreditation of testing laboratories according to DIN EN ISO/IEC 17025 and DIN EN ISO 15189 within the framework of the activities of DAP Deutsches Akkreditierungssystem Prüfwesen GmbH (German Accreditation System for Testing Ltd – hereinafter referred to as DAP). It applies to all types of testing laboratories and medical laboratories (hereinafter referred to as testing laboratories) falling within DAP's field of competence.

The rule comprises provisions for the assessment including the check of documents, accreditation, surveillance, extension of accreditation and reaccreditation following a reassessment.

It is the aim of the assessment of a testing laboratory to establish the competence of its personnel to properly conduct unambiguously described tests and/or tests in unambiguously described testing areas within the framework of an effective and documented management system. By carrying out regular surveillance activities it is checked whether the accredited body continues to fulfil the accreditation requirements.

Testing laboratories may be accredited by DAP if they

- have submitted an application,
- have concluded a contract with DAP on conducting an accreditation procedure,
- fulfil the criteria for the work of testing laboratories according to DIN EN ISO/IEC 17025 and/or DIN EN ISO 15189, international guidelines of EA (European co-operation for Accreditation) and ILAC (International Laboratory Accreditation Cooperation) and DAP rules,
- fulfil the technical criteria set up by the appropriate sector committees.

This rule is to inform applicants and accredited bodies on the DAP assessment and accreditation process.

2 Preliminary meeting

At the request of the applicant, a preliminary meeting is conducted between the DAP assessor and the applicant to inform the applicant on the sequence of operations of an accreditation procedure and for settling any evident problems, which could influence the process of accreditation.

This preliminary meeting concentrates on:

- settling the scope of the desired accreditation
(scope of accreditation)
- the information on the content, sequence and costs of accreditation
- rights and obligations of the client and DAP after the accreditation has been granted.

Following the preliminary meeting, the testing laboratory may submit an application for accreditation. The costs for the preliminary meeting, except for travelling to be paid in any case, are levied by the DAP Office to the inquirer and are charged against the application fee on receipt of the application for accreditation.

3 Assessment and accreditation

3.1 General

The process of assessment comprises the following main steps:

- formal check of the application for accreditation and checking of the submitted documents as to correctness and completeness; assignment of the case manager and lead assessor, selection and assignment of assessors
- pre-assessment by an assigned assessor, if necessary
- assessing the documents submitted by the applicant (required documents)
- on-site assessment, handing over the non-conformity reports to the head of the laboratory, formulating corrective action by the testing laboratory to close out the non-conformities
- preparing assessment reports
- accreditation recommendation by the sector committee/committees or the Committee for Accreditation (AfA) as a rule after fulfilment of the corrective action agreed upon
- preparing surveillance action and if necessary conditions fixed in time by the assessors, the sector committee or AfA
- granting accreditation by the DAP Managing Director and issuing the certificate
- invoicing the customer and publishing the accreditation.

The lead assessor chooses assessors and technical experts suitable for the respective case from the *List of Appointed Assessors* of the respective sector committees. Subsequently, the case manager informs the customer of the assessors, their fields of activity and the date for the assessment. The applicant has the right to reject the assessors. In such a case, another assessor is to be proposed to the laboratory.

3.2 Formal checking of the application for accreditation and the submitted documents

The DAP Office checks the application of the testing laboratory for accreditation as to the fulfilment of formal prerequisites for accreditation.

Applications for an accreditation outside Germany are only accepted or dealt with if they are in compliance with the rules of the community of the European or worldwide accreditation associations (EA, ILAC). DAP recommends all foreign applicants to apply for the accreditation at the respective national accreditation body.

Once the requirements are fulfilled, further action for accreditation is taken at the DAP Office. This includes, in particular:

- acknowledgement of application, decision on the case manager, lead assessor and selection of the respective sector committee
- issuing a case number and invoicing the application fee
- concluding the contract with the applicant.

3.3 Pre-assessment

At the request of the testing laboratory, a pre-assessment may be conducted at the applicant to assess the suitability for accreditation. All necessary documents should be available and considered for the pre-assessment.

The pre-assessment includes the following main aspects:

- appraisal of the prerequisites as regards to personnel, equipment and premises for accreditation
- appraisal of the management system as to its suitability
- checking of the documentation
- coordination on the scope of accreditation
- exchange of experience and clarification of open questions of the accreditation process.

In coordination with the testing laboratory, the pre-assessment is conducted by the assigned lead assessor or assessor and additionally by the case manager in certain cases.

3.4 Assessment of the documents

The lead assessor checks the underlying required documents (NU-PL-00 or NU-ML-00) to be submitted for the document review.

Already before the assessment the laboratory is to be informed on serious non-conformities as a result of the document review.

In case of initial accreditations, the date for the on-site assessment will only be fixed if the document review has resulted in no serious non-conformities to oppose an accreditation.

The lead assessor has to confirm to the DAP Office that the quality documentation is suitable.

3.5 Assessment of the testing laboratory

The assessment team consists of the lead assessor and one assessor at least. The time for the assessment is oriented on the scope of accreditation applied for, the number of personnel working in the assessed area and the number of assigned assessors and is 12 working hours on-site at least. One-day assessments can only be performed in well-founded exceptional cases.

The lead assessor in a timely manner has to communicate the applicant on the course of the assessment using an on-site assessment plan.

The assessment of the testing laboratory consists of the following steps:

- introductory meeting
- assessment of requirements as regards to the organisation and management and the verification of the technical requirements
- final meeting.

During the assessment of the testing laboratory, the processes, activities and responsibilities described in the documents are compared with their implementation in practice.

Attention focuses on:

- assessing the implementation of the activities for achieving the quality objectives
- assessing the organisational structure, the qualification of the personnel and the technical equipment as well as the cooperation with the customers
- assessing the technical competence of the body assessed, in particular the selection and use of test equipment and measuring devices, the calibration of measuring equipment, their maintenance, repair, traceability of the measured values to national standard measures, the verification and validation of test methods.

The assessor uses proforma documents for conducting the assessment such as checklists and forms, which have been released by the DAP Office.

3.5.1 Introductory meeting

The introductory meeting should focus on:

- introducing the participants to each other
- confirming the objectives, the application scope and the accreditation criteria (underlying standard and additional technical and legislative requirements)
- the approach and course of the accreditation
- confirming the confidentiality
- informing on the reporting method including the classification of non-conformities
- determining the time schedule or the assessment plan
- informing on the conditions leading to the interruption of the assessment
- the news of the accreditation body.

The introductory meeting should be attended by the:

- head of the testing laboratory,
- quality manager and responsible employees of the testing laboratory
- assessors.

The technical interviews follow the introductory meeting.

3.5.2 Assessment of the organisation, the management and technical requirements

In particular the assessors shall assess the:

- suitability of the management system
- cooperation with customers of the testing laboratory
- competence of the staff members and the ability of the head of the testing laboratory to conduct or manage the laboratory operations properly
- suitability of the accommodation and the equipment for the test methods / testing areas applied for
- control of documents and records
- subcontracting tests

- conducting of representative test methods
- maintenance and calibration condition of the test and other equipment
- participation in proficiency tests, their evaluation and documentation
- availability of reliable sample marking and sample identification systems
- availability of test or working instructions
- contents and structure of the test reports
- internal quality activities for the individual test methods
- overall process in the testing laboratory from the inquiry, the tender, receipt of samples, test till the test report
- compliance with additional requirements, e.g. EA requirements, juridical or governmental requirements (if necessary), technical notes of DAP, specific sector committee or decisions of the committee for accreditation (AfA).

The testing laboratory has to show to the assessment team documents and records to enable that the appraisal relevant to the items mentioned above is possible.

3.5.3 Final meeting

Following the internal discussion in the assessor team, the final meeting with the customer is conducted. The final meeting comprises:

- the information on the overall impression (recommendation of the assessment team on the granting of accreditation after the corrective action has been implemented or, if applicable restriction of the scope applied for)
- the information of the stated non-conformities by each assessor
- the specification of suitable corrective actions so that the customer can close out the non-conformities; confirmation by the management of the laboratory and the assessor/s (where applicable, suitable corrective actions can be made known later (max. one week))
- fixing a date until the corrective actions have been implemented (in case of initial accreditations 5 months at most, everywhere else 2 months after the assessment)
- proficiency tests where applicable
- clarification of open questions and planning of the accreditation process to continue.

Within the agreed time schedule, the testing laboratory shall hand over the documentation on conducting the corrective actions to the assessors who found the non-conformities. The corrective actions agreed upon do not exclude conditions to be specified later.

3.6 Assessment reports

Each assessor shall submit a report on the area assessed within three weeks after the assessment. The reports of the assessors shall be passed on to the lead assessor together with other documents (filled-in check-lists, forms, possibly reports on the recognition procedure).

Two weeks after the receipt of the reports of the other assessors, the lead assessor shall submit his/her final report, the reports of the assessors and all other documents needed to the case manager who forwards them to the responsible sector committee/s or AfA.

After receipt at the DAP Office, a copy of the assessment reports is immediately sent to the testing laboratory which has the right to comment on the assessment reports.

On request of the testing laboratory, a summarizing final report is to be prepared.

3.7 Recommendation for accreditation

The assessors shall include and justify in their reports a recommendation on the accreditation, reduction or possibly refusal suggesting conditions and surveillance action (where necessary time-phased).

The responsible sector committee/s or in exceptional cases the AfA evaluate the reports and other required documents and issue their recommendation on accreditation to the DAP Managing Director.

As a rule, recommendations originated by the executive member of the sector committee are worked out between the meetings through a written vote calling in two members at least. Where multidisciplinary accreditation cases are to be handled, all responsible sector committees are to be included.

From the last day of the assessment till submitting the documents of the accreditation case to the responsible sector committee or AfA, a deadline of six months should not be exceeded. Otherwise the status assessed is not up-to-date anymore requiring a follow-up-visit.

3.8 Granting accreditation and issuing the certificate

The DAP Managing Director grants the accreditation on the basis of the recommendation by the sector committee or the AfA.

The accreditation is usually valid for a period of five years.

The accreditation certificate is signed by the DAP Managing Director. The certificate is usually sent to the customer by normal mail.

Upon sending the certificate at the latest, the customer shall receive information on the conditions resulting from the accreditation, the possibly to be expected focus of surveillance as well as the probable next assessment period. On request, the usable national and/or international electronic accreditation symbols and current information on its use are sent to the customer.

The DAP arranges for the publication of the accreditation in the Register of "Accredited Bodies" of the German Accreditation Council.

3.9 Costs of assessment

The cost of assessment is to be borne by the testing laboratory and is invoiced by the DAP Office. The cost of assessment is paid in addition to the accreditation contribution.

When preparing the assessment the cost is calculated by the case manager on the basis of the valid fee regulations and is communicated to the testing laboratory in the supplement of the contract, together with the assessment date and the names of the assessors.

The supplement of the contract signed by the testing laboratory represents the basis for assigning the assessors.

Approximately one month before the on-site assessment, the testing laboratory is charged 60% of the assessment cost. The final invoice is posted two weeks at the latest after sending the certificate to the testing laboratory.

4 Surveillance

4.1 General

The surveillance procedure consists in checking periodically if the prerequisites for accreditation continue to exist. The checking is done by regular renewed on-site assessments of the accredited bodies.

Moreover, other surveillance activities may be performed as there are:

- obtaining additional information and statements
- requesting documents, test reports and proofs for the surveillance of the management system
- checking changes of the management documentation
- checking the implementation of the conditions.

The assessments for surveillance are scheduled by the case manager on the basis of the DAP rules and the recommendations of the sector committees for the entire accreditation cycle.

There is the possibility for unannounced surveillance visits.

Within the assessment for surveillance, on request of the testing laboratory the accreditation may be extended by new test areas or methods.

During the five-year validity of the accreditation by means of on-site assessments, the entire scope of accreditation shall be checked completely by representative samples. Therefore, at least three assessments have to be conducted.

The first assessment for surveillance has to be carried out within 12 months following the granting of the accreditation. After the regular date of the previous assessment, the interval for the second and third assessment for surveillance may be extended to 18 months at most. In case of multi-site accreditations, the surveillance interval is 12 months.

The last assessment may be used as a reassessment for reaccreditation.

4.2 Procedure for the surveillance assessment

The surveillance assessment is an independent stage with a high priority. Its sequence is similar to the initial accreditation with its check of the documents, on-site assessment, check of the corrective action, preparing and checking reports as well as the recommendation of the sector committee (compare sections 3.4 - 3.9).

The on-site assessment is to be focused on the following:

- closing out and implementing corrective action and / or conditions determined or issued after establishing the non-conformities in the previous assessment
- comprehensive appraisal of the effectiveness of the management system with regard to the organisational structure and testing activities
- check of the continuous information to DAP by the accredited body, once the status or the mode of operations with an impact on accreditation has changed
- internal audits and management reviews as well as initiated and conducted corrective and preventive action
- ability of the accredited body to verify or validate independent laboratory-developed methods ("in-house test methods")
- participation of the accredited body in proficiency tests (interlaboratory comparisons, and bilateral proficiency tests) and their evaluation and documentation
- calibration of the measuring devices and test equipment or facilities and traceability to national or international standard measures
- implementation or recommendation of new EA and ILAC guidelines
- friendliness towards customers, handling complaints and appeals, efficiency of the management system e.g. in extreme situations (peak workload, holiday time etc.)

During the on-site assessment in the final meeting, the testing laboratory is informed on the results of the surveillance; the non-conformities established are handed over in writing.

The testing laboratory shall suggest corrective action to the assessor for closing out the non-conformities. The testing laboratory shall have closed out the non-conformities (providing evidence) within two months following the on-site assessment, at the latest. If the non-conformities have not been closed out, the accreditation may be suspended or withdrawn.

The assessor shall make a statement on the course and results of the assessment for surveillance referring to all issues checked. In his/her report, he/she shall make and justify a recommendation on the accreditation, reduction or refusal) possibly suggesting conditions fixed in time.

All reports shall be submitted to the case manager or lead assessor within three weeks. After receipt at the DAP Office and the following review, a copy of the reports is immediately sent to the testing laboratory. The testing laboratory itself has the possibility to comment on the report.

The technical recommendations on maintaining the accreditation following surveillance and possibly surveillance and extension are issued by the sector committees and are analogous to the procedure described in 3.7. Only in case of new accreditation areas, flexible scope accreditation as well as special and problematic cases, decision is to be made whether the case is also to be submitted to the AfA.

Together with the information on maintaining the accreditation, the testing laboratory is given the date for the next assessment for surveillance.

The cost of the surveillance activities shall be borne by the testing laboratory; it is invoiced by the DAP Office.

5 Reassessment / reaccreditation

5.1 General

The reaccreditation requires a reassessment. In contrast to the assessment for surveillance, the scope of the reassessment corresponds more or less with the scope of an initial accreditation and has the task to check the adherence to all accreditation criteria by the accredited body and to appraise the effectiveness of the management system. In case of a reassessment, as a rule, other assessors are to be assigned as compared to the previous accreditation procedure, whereas the lead assessor may be the same as before.

The time limit between two reassessments may not exceed 60 months.

The procedure of reaccreditation is based on section 3 whereas all available facts and documents of the testing laboratory are used and checked if they are up-to-date.

5.2 Procedure for the reaccreditation

The testing laboratory files an application for reaccreditation with the DAP Office. The reassessment should take place in time before the expiry of the accreditation to have a close connection to the previous accreditation. As in most cases it is more favourable for the testing laboratory to use the third surveillance for the reaccreditation, eight months before the reaccreditation expires, the DAP Office informs the testing laboratory on the possibility of a reaccreditation.

In principle, it is possible to have an extension or reduction of the scope of accreditation during a reaccreditation.

The responsible sector committee, analogously to the procedure described in 3.7 issues the technical recommendation for the reaccreditation. The Managing Director grants the reaccreditation, which is valid for another five years.

The cost of reaccreditation shall be borne by the testing laboratory; it is invoiced by the DAP Office.