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1 General

This Rule applies to the accreditation of inspection bodies pursuant to DIN EN 45004 (ISO/IEC 17020) 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 for all types of inspection bodies within the competence of DAP.

Inspection bodies, according to the above standard, are bodies performing inspections. Inspection means the examination of a product design, product, service, process or a plant and determination of their conformity with specific requirements or, on the basis of professional judgement, general requirements.

Inspection of processes includes personnel, facilities, technology and methodology.

This Rule comprises stipulations for the assessment including the assessment on-site, the accreditation, the surveillance and the reaccreditation of inspection bodies.

It is the aim of the assessment of inspection bodies to establish the competence of the inspector body to conduct, evaluate (appraise inspection results) and document inspections. Furthermore, by carrying out regular surveillance activities in accordance with rules of EA (European co-operation for Accreditation) it is checked whether the competence established at accreditation continues to exist.

Inspection bodies may be accredited by DAP, if they

- have submitted an application,
- have concluded a contract with DAP on conducting an accreditation procedure,
- fulfil all the requirements for the work of inspection bodies pursuant to DIN EN 45004, international guidelines and DAP Rules
- as well as fulfil the technical criteria set up by the appropriate sector committee.

2 Preliminary discussion

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

This preliminary meeting deals with:

- settling the scope of the desired accreditation (scope of accreditation)
- requirements for the qualification profile of the inspectors
- information on the content, sequence and cost of accreditation as well as
- obligations of the inspection body after being granted accreditation

The assessor in a suitable form shall document the preliminary meeting. Following the preliminary meeting, the inspection body may submit an application for accreditation.

3 Assessment and accreditation

The process of assessment comprises the following main steps:

- formal checking of the application for accreditation and checking the submitted documents as to correctness and completeness by the DAP Office, assigning assessors
- pre-assessment by a n assigned assessor
- assessing the documents submitted by the applicant (necessary documents)
- on-site assessment, handing over the report of non-conformities to the head of the inspection body, formulating corrective action by the inspection body on the basis of the non-conformities
- preparing assessment reports and – on request of the client - the final report by the Lead Assessor
- accreditation recommendation by the sector committee (or the sector committees respectively) or the Committee for Accreditation (AfA) respectively
- stipulating surveillance and possibly conditions fixed in time by the assessors, the sector committee and the AfA
- granting accreditation by the DAP Managing Director and issuing the certificate and
- invoicing the client 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 appropriate sector committees.

The applicant has the right to reject the assessors. The Head of the Accreditation Department issues the approval of the assessors to be engaged. Subsequently, the Case Manager informs the client on the assessors, their fields of activity and the date for the assessment.

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

The DAP Office checks the application of the inspection body for accreditation and the pertaining documents submitted as to correctness and completeness as well as to the fulfilment of formal prerequisites for accreditation.

Once the requirements posed are fulfilled, further action for accreditation is taken at the DAP Office.

This includes in particular:

- issuing a case number and invoicing the application fee
- deciding on a Case Manager, assigning the Lead Assessor and selecting the appropriate sector committee and
- coordinating the contract with the applicant

3.2 Pre-assessment

At the request of the inspection body, a preliminary assessment may be conducted at the applicant to assess the suitability for accreditation. All the necessary documents should be available and taken into consideration for the preliminary assessment.

The preliminary assessment includes the following main aspects:

- classification of the type of inspection body (A, B, C)
- appraisal of the suitability of the existing quality system for conducting qualified inspections
- fulfilling the main requirements for the qualification profile of inspectors
- appraisal of the organisational as well as administrative and technical prerequisites of the inspection body for the evaluation and appraisal of inspection results
- checking the possibly necessary equipment
- checking whether the necessary documentation is available and
- coordinating the scope of accreditation

The preliminary accreditation is conducted by the assigned Lead Assessor and in certain cases additionally by the Case Manager, coordinated with the inspection body.

The Lead Assessor offers the applicant inspection body information or hints and explanations respectively on the further preparation of the assessment of the inspection body and on the further process as well as the probable cost.

3.3 Assessment of the documents

The documents to be assessed comprise, for instance, the quality manual, documented procedures and work instructions, inspection procedures, evidence of qualification, possibly necessary equipment and procedural documents as well as evidence documents and records of the applicant.

The Lead Assessor checks the documents of the applicant on every aspect of the DIN EN 45004. If necessary, the Lead Assessor requests further documents for appraisal. In coordination with the assessors, he lays down the individual inspection areas to be assessed and the sequence of the assessment on site. The check of the documents constitutes the basis for deciding on the focus of the assessment on site.

In this connection, the assessor, checking the documents of the inspection body and performing the on-site assessment, has to pay attention to the implementation of the EA, ILAC and IAF Guides.

3.4 Assessment of the inspection body

As a rule, the assessment on site should be concluded within one working day, a several day assessment is possible. The Lead Assessor heads the assessment.

The assessment of the inspection body consists of the following steps:

- introductory meeting
- assessing the prerequisites as regards personnel, equipment and premises
- final meeting

During the assessment of the inspection body, the processes, activities and responsibilities described by the applicant in the documents are compared with their practical implementation.

Attention focuses on:

- assessing the implementation of the measures for achieving the quality objectives
- assessing the organisational structure, the qualification of the personnel and their professional experience as well as the technical facilities and the cooperation with the clients
- assessing the technical competence of the body with regard to the type of appraisal applied, differentiated as follows
 - establishing conformity with certain requirements on the basis of a simple comparison with the standards and other specifications
 - establishing conformity with certain requirements – due to professional judgement – with general requirements and
- evidence of the scheduled further training of the inspectors by the inspection body, taking into consideration the valid legal regulations within the scope of action of the inspection body.

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

In order to achieve assessment results close to reality, the conducting of an inspection may be assessed (*witness audit*) in addition to checking the documents.

3.4.1 Introductory meeting

The introductory meeting should focus on the following:

- introducing the assessors and the participants from the inspection body
- explaining the objective of the assessment and the tasks of the assessors
- mentioning of the fact that all findings and information are treated strictly confidentially by all DAP staff members and the assessor team
- explaining the quality management / quality assurance at the inspection body
- confirming the scope of the application and the scope of the accreditation
- assigning the staff members of the inspection body for accompanying the assessor as well as

- determining the time-schedule for the assessment (checking the documents and witness audit).

The introductory meeting should be attended by:

- the head of the inspection body
- the quality manager and responsible staff members of the inspection body
- the assessors

The introductory meeting then continues with the technical interviews (with the help of check-lists etc).

3.4.2 Assessment of the prerequisites as regards personnel, equipment and premises

The assessors shall assess, in particular:

- the suitability of the quality management system
- the competence of the staff members and the ability of the head of the inspection body to conduct the operation of the inspection body properly
- the suitability of the premises and the equipment for the procedures / inspection areas applied for
- the maintenance and calibration condition of the testing and other equipment possibly required and
- participation in proficiency tests possibly required, their evaluation and documentation

During the assessment on site, it is also checked whether sub-contractors are assigned for conducting the inspections. In this case, the inspection body has to prove that the sub-contracting inspection bodies meet the requirements pursuant to DIN EN 45004 and ISO/IEC 17020.

The following is checked, in particular:

- the quantity/list of the sub-contracts
- the approval of the client for passing on tasks to sub-contractors
- regulation and documentation of responsibilities in these cases and
- reference to the sub-contracting in the inspection report.

At the request of the assessor team, the inspection body shall make available to them written evaluations, expert opinions, documents, minutes, reports and so on by.

3.4.3 Witness audit

Before conducting the initial accreditation of an inspection body, at least one witness audit has to be performed. The witness audit aims at checking the work of the inspection body on site.

3.4.4 Final meeting

Following an internal discussion among the assessor team, the final meeting is conducted with the client. Each assessor renders an oral report on his/her findings, in particular on the non-conformities established. The Lead Assessor then summarises the preliminary results of the assessment and communicates them to the management of the inspection body in the presence of the assessors. In doing so, he points out that the on-site assessment due to its spot checking character only constitutes one part of the assessment procedure and that, therefore, the results presented are not of a final nature. If required, proficiency tests are requested (see documented procedure QM-VA 10.1 *Proficiency Tests*).

On the day of the assessment, the inspection body suggests corrective action and communicates this to the Lead Assessor within a period of one week. The agreed corrective action does not exclude later conditions. The documentation on conducting the corrective action shall be handed over within an agreed time to the assessors who established the respective non-conformities.

3.5 Preparing reports

Each assessor shall submit a report on the area assessed by him within three weeks after the assessment. The reports of the assessors shall be passed on to the Lead Assessor together with further documents (filled-in checklists, forms, etc). In case of serious non-conformities, the procedure is suspended until the completion of the agreed corrective action by the inspection body.

Three weeks after having received the reports of the other assessors, at the latest, the Lead Assessor shall submit his/her report, the reports of the assessors as well as all necessary documentation to the Case Manager of the DAP Office who then forwards them to the appropriate sector committee or AfA.

3.6 Recommendation for accreditation

The assessors shall give and justify in their reports a recommendation on the procedure (accreditation, reduction, refusal) as well as suggest conditions (possibly fixed in time) and surveillance action.

The respective sector committee or in exceptional cases the AfA evaluates the reports and further necessary documents and issues its recommendation on accreditation to the DAP Managing Director.

As a rule, recommendations originated by the executive member are worked out between the meetings through a written vote calling in two members at least. One of them may be the chair or his/her deputy.

The selection of the members is based on their technical competence in the accreditation case to be assessed assuring their independence, impartiality and integrity towards the inspection body to be assessed. In cross-boundary procedures, all sector committees concerned are integrated.

From the last day of the assessment till the submitting of the documentation of the accreditation case to the sector committee or Committee for Accreditation, a period of 6 months should not be exceeded, as the status assessed may not be up-to-date anymore requiring therefore a follow-up assessment.

The assessors' reports are sent to the inspection body with the information on the stipulated conditions, at the latest. Objections to the reports have immediately to be forwarded to the DAP Office. Otherwise it is assumed that the applying inspection body does not raise any objections.

3.7 Granting accreditation and issuing the certificate

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

As a rule, the accreditation has a validity of five years.

The accreditation certificate is signed by the DAP Managing Director and a member of assessment team. The inspection body assessed has a say in the choice of the signing assessor. The Lead Assessor hands over the certificate to the client, usually by post.

Upon handing over the certificate at the latest, the client shall receive the conditions resulting from accreditation, possibly the focus of the surveillance to be expected as well as the probable next assessment date.

DAP instructs for the accreditation of the client to be published in the DAR Register of "Accredited Bodies".

On request, the Case Manager sends the client a floppy disk with the national accreditation logo (NAL) and current information on its use

3.8 Cost of assessment

The cost of assessment shall be borne by the inspection body and are invoiced by the DAP Office. They are to be paid in addition to the accreditation fees.

In preparation of the assessment, the costs are determined by the Case Manager on the basis of the valid Fee Regulations and communicated to the inspection bodies in the Supplement to the Contract along with the date of assessment and the assessors.

The Supplement to the Contract signed by the client constitutes the basis of assigning the assessors. Close in time to the assessment, a 60 % down payment on the assessment cost shall be levied.

The final invoice is sent to the inspection body two weeks after submitting the certificate, at the latest.

4 Surveillance

4.1 General

The surveillance of the inspection bodies represents a check of the continued existence of the prerequisites for accreditation.

This is reached by a regular reassessment of the accredited body on site.

The surveillance is planned by the respective Case Manager on the basis of the DAP Rules and the recommendations of the sector committee ZE / IS for the entire period of surveillance.

The first surveillance assessment shall take place within twelve months after granting the accreditation. With the second and third surveillance assessment, the interval may be extended to a maximum of 18 months respectively, subsequent to the regular date of the previous assessment. Recommendation on this is made by the sector committee of the AfA. For multiple-site accreditations, special regulations apply.

The surveillance audits may also comprise witness audits.

4.2 Procedure

The surveillance is an independent stage of the procedure of a high priority. Its sequence is similar to that of an initial accreditation with its check of documents, on-site assessment, check of the corrective action, drawing up and submitting reports as well as the recommendation on the maintenance of accreditation (compare sections 3.3 – 3.8).

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

- fulfilling 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 quality management system with regard to organisation and inspection activities as well as examination of the revision of the quality manual
- obtaining reports (audit reports, management reviews) and explanations
- requesting documentary evidence
- internal audits and quality reviews as well as originated and conducted corrective and preventive action
- participation of the accredited body in proficiency tests as well as their evaluation and documentation
- implementation of new provisions and recommendations issued by the Committee Technical Issues (ATF) of the DAR and the European co-operation for Accreditation (EA)
- customer friendliness, dealing with appeals and complaints, robustness of the quality management system, e.g. in extreme situations (peak workload, holiday times, etc.)
- documentation for realisation of conditions posed.

The Lead Assessor and the assessors for surveillance are assigned by the DAP Office. Usually, the Lead Assessor and/or an assessor conduct the surveillance.

During surveillance, individual areas may be selected and subjected to a closer assessment.

The assessor shall make a statement on the course and results of the assessment within the framework of the surveillance with reference to all issues checked. In his report, he shall make and justify a recommendation on the procedure (accreditation, reduction, refusal) as well as possibly suggest conditions fixed in time. All reports shall be submitted to the Case Manager within three weeks after the completion of the action.

The Case Manager, in order to take appropriate steps, has immediately to be informed when there are delays in fulfilling the corrective actions.

In accordance with the procedure described in 3.6, the sector committee ZE / IS, issues the technical recommendations for the maintenance of the accreditation after surveillance with extension of the accreditation.

Only if there are new areas of accreditation, cases with flexible scope of accreditation as well as in special and problematic cases, the sector committee will decide whether the case concerned is to be passed on to the Committee for Accreditation.

Along with a notification of the maintenance of accreditation, a copy of the surveillance reports are sent to the inspection body. The client has the possibility to file an objection within the period as contracted.

The cost of surveillance invoiced by the DAP Office shall be borne by the inspection body; it is.

5 Re-assessment / reaccreditation

5.1 General

The reaccreditation requires a repeat assessment. In contrast to surveillance, the scope of the reassessment corresponds more or less with an initial accreditation and has the task of checking adherence to all accreditation criteria by the accredited body and to appraise the effectiveness of the quality management system.

In case of a repeat assessment, other assessors are to be employed than in the previous accreditation case, as a rule, whereas the Lead Assessor may be the same as before.

The approach of reaccreditation is based on section 3, using all knowledge and documents already available on the inspection body. It must be ensured they are up to date.

5.2 Procedure

The last scheduled surveillance should be timed in such a way, if at all possible that it is conducted as a reassessment for reaccreditation before expiry of the accreditation, in so far as the inspection body has filed an application for reaccreditation with DAP. For this purpose, the DAP Office has to advise the inspection body of the expiry of accreditation eight months before the accreditation ceases to exist.

In principle, it is possible to conduct an extension or reduction of the accreditation within the framework of a reaccreditation.

In accordance with the procedure described in 3.6, the sector committee ZE / IS makes the technical recommendation of reaccreditation, as with the accreditation and surveillance. The respective sector committee issues. The Managing Director conducts the renewed granting of accreditation.

The provisions above analogically apply for the information of the decision on accreditation, the dispatch of the assessment reports and the possibilities to file an objection.

The cost of reaccreditation shall be borne by the inspection body and is invoiced by the DAP Office.