Requirements for the application of ISO/IEC 17020:2012 for the accreditation of inspection bodies

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Scope:

This Rule includes requirements for the implementation of ISO/IEC 17020:2012 for the accreditation of inspection bodies and for the presentation of the scope of accreditation.

Additional sectoral requirements may be specified in further subordinated documents.

Date of confirmation by the Accreditation Advisory Board (AKB): 09.12.2017

Substantive changes to the previous revision of this Rule are marked with a bar on the right-hand margin or highlighted in yellow.

Contents

1 Purpose / Scope

This Rule includes requirements for the implementation of ISO/IEC 17020:2012 for the accreditation of inspection bodies and for the presentation of the scope of accreditation.

Additional sectoral requirements may be specified in further subordinate documents.

2 Terms and definitions

Review	Verification of the suitability, adequacy and effectiveness of selection and determination activities, and the results of these activities, with regard to fulfilment of specified requirements by an object of conformity assessment (DIN EN ISO/IEC 17000:2005, 5.1)
Type of valuation	Distinguish the evaluation competence according to the two types of requirement definitions that are the basis of a rating (normative specific requirements or general requirements (judgement based on expertise)
Inspection	Examination of a product, process, service, or installation or their design and determination of its conformity with specific requirements, on the basis of professional judgement, with general requirements (DIN EN ISO/IEC 17020:2012, 3.1)
Inspection system	Rules, procedures, and management for carrying out inspections (DIN EN ISO/IEC 17020:2012, 3.6)
Inspection scheme	Inspection system to which the same specified requirements, specific rules and procedures apply (Clause 3.7 of ISO/IEC 17020:2012, 3.7)
Evaluation	Combination of selection and determination functions of conformity assessment activities (DIN EN ISO/IEC 17065:2013, 3.3) NOTE: The “Selection” and “Determination” functions are specified in Annexes A.2 and A.3 of ISO/IEC 17000:2004.
Examination	The terms testing and testing work refer to examinations in the sense of DIN EN ISO/IEC 17025 as well as, where applicable, to medical examinations, examination activities in the sense of DIN EN ISO 15189. This depends on the actual application area. The related explanations and requirements in this text apply mutatis mutandis.

3 Description

3.1 Testing, inspection, and certification

In the context of the conformity assessment, an inspection is an “examination of a product, process, service, or installation or their design and determination of its conformity with specific requirements or, on the basis of professional judgment, with general requirements.” (see DIN EN ISO/IEC 17020, 3.1). The examination within an inspection may include, e. g. implementation of sampling, examination according to ISO/IEC 17025 or the use of test results from test reports according to DIN EN ISO/IEC 17025, however, it may also restrict to the review of documents. Unlike the certification no certificate with a validity period is issued for an inspection.

Examinations as part of an inspection may be carried out by the inspection body itself or by one or more competent subcontractors (see DIN EN ISO/IEC 17020, section 6). The subcontracting of sampling or inspection activities is only inadmissible if the inspection system (or the inspection program) precludes this.

The assessment as part of the accreditation of inspection bodies with associated test areas according to DIN EN ISO/IEC 17025 or investigation activities according to DIN EN ISO 15189 is carried out in such a way that a multiple assessment of already accredited scopes is avoided. In these cases the assessment of Testing or medical examinations for inspection activities comprises only the interfaces between Testing/Examinations regarding DIN EN ISO/IEC 17025 and all other steps and activities within the valuation of the competent implantation of the inspection. This does not release DAkkS/assessors from its/their obligation to deviate in individual cases for being able to value the fulfilment of requirements entirely.

For testing activities, which are processed within the inspection the document ILAC G27:2017 applies.

3.2 Assessment of the evaluation competency

The assessment of the type of examination can only be performed by an assessor, who has sufficient knowledge and experience in the relevant field of inspection or in an equivalent inspection area.

The assessor shall have sufficient knowledge and experience in the application of conformity assessment procedures.

When assessing the type of examination, assessment tasks may be assigned, if necessary, in the sense of a proficiency test, which the person being assessed has to perform

3.3 Requirements for personnel

The inspection body shall ensure that the personnel involved in the inspection process is monitored on a regular basis, is competent and operates in accordance with the quality management system of the inspection body (comp. Clause 6.1.8 of ISO/IEC 17020).

In the context of performance evaluation, in general, each active inspector shall be observed during the on-site inspection activity by the inspection body once during the accreditation cycle (comp. Clause 6.1.9. of ISO/IEC 17020). Deviations from this are possible, if the observations carried out (at least two) and other records relating to the performance evaluation or further training sufficiently support evidence that the inspector is continuing to perform competently.

The fulfilment of the requirements established for education and training as well as for qualification and experience for the defined inspection area (as specified for example in the job descriptions) shall be examined in the context of on-site observations.

ISO/IEC 17020 only states that a sufficient number of persons shall be available (comp. Clause 6.1.2 of ISO/IEC 17020). Therefore, there is basically no reason why the inspection bodies should not be accredited irrespective of the number of employees, provided that the requirements as set out in the standard are met.

Managerial and technical personnel for inspections may be identical but the functions and responsibilities shall be clearly regulated in written specifications.

Similarly, the management of the inspection body and the quality manager may be identical, but the functions and responsibilities shall be clearly regulated in written specifications.

Inspection bodies which are operated by one person can only be accredited if useful arrangements are implemented for the requirements set out in the clauses 5.2.6, 6.1.8, 6.1.9, 6.1.11, 8.5 and 8.6 of the standard and if external persons may be involved on a contractual basis, if necessary. In addition, this person shall have a sufficient examination competence for all activities conducted in the inspection body.

3.4 Subcontracting

According to Clause 6.3 of ISO/IEC 17020, subcontracting for an inspection body can be described in a way that subcontracts can generally be given only in exceptional cases (comp. Clause 6.3.1. of ISO/IEC 17020). Tests within the meaning of ISO/IEC 17025 or investigations within the meaning of DIN EN ISO 15189 as part of the inspection, however, can permanently be subcontracted, unless this is precluded by technical or sector-specific requirements.

The inspection body shall be able to independently assess the results of the subcontracted works. The responsibility for establishing the conformity with the requirements remains with the inspection body (comp. Notes of Clause 6.3.1 and 6.3.3 of ISO/IEC 17020).

3.5 Definition of the scope of accreditation in the accreditation certificate

The scope of accreditation shall always contain the following information:

- Items and fields of inspection (for example processes, plants, parts of plants, design, products, etc.)
- Type and range of inspection, for example inspection under operating or service conditions (in-service inspection), inspection of new products
- Designation of the type of examination

3.6 Information on the evaluation type (type of determination of the conformity with requirements) of inspection bodies

On the accreditation certificate including the annex the scope must always conclude with the information of the evaluation type of the inspection body. According the definition of inspections regarding DIN EN ISO/IEC 17020, 3.1 two evaluation types must be differentiated:

1) *Determination of compliance with certain requirements (conformity assessment on the basis of simple comparisons with standards or comparable characteristics)*

   Text on the accreditation certificate / annex:

   …and determination of its compliance with certain requirements

2) *Determination of compliance based on an expert judgement – with general requirements*

   Text on the accreditation certificate / annex

   …and determination of its compliance – based on an expert judgement with general requirements

The evaluation type must be clearly indicated for each inspection area explicitly within the scope.

3.7 Accreditation process – Selected aspects

The assessment of the competence of an inspection body is established by:

- document review
- assessing the office of the inspection body
- assessing relevant specific structures of the inspection body, such as requirements for the management system, locations, organization, work processes, etc.
- witness-audits of on-site inspections

Note: The type of independence (classification of Type A, B, C) shall be determined by the inspection body and specified in the application for accreditation.

Note: The extent of random assessment of an inspection body shall be determined before the assessment starts. The representative coverage of the locations and inspection areas shall be established and documented by the DAkkS in a monitoring matrix.

Before granting accreditation, at least one witness-audit shall be conducted. If the inspection body covers several technical inspection areas, has a large number of inspectors / locations or if certain witness-audits cannot be performed due to practical reasons, the required number of witness-audits shall be determined individually before granting the accreditation and based on sector-specific requirements.

4 Applicable documents

DIN EN ISO/IEC 17000:2005	Conformity assessment – Vocabulary and general principles
DIN EN ISO/IEC 17020:2012	Conformity assessment – Requirements for the operation of various types of bodies performing inspection
DIN EN ISO/IEC 17025:2005	General requirements for the competence of testing and calibration laboratories
DIN EN ISO 15189:2014	Medical laboratories – requirements for quality and competence
ISO/IEC 17011:2005	Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies
ILAC P10:01/2013	ILAC Policy on Traceability of Measurement Results
ILAC P15:07/2006	Application of ISO/IEC 17020:2012 for Accreditation of Inspection Bodies
ILAC G 27:06/2017	Guidance on measurements performed as part of an inspection process