THE CHARACTERISTICS OF QUALITY MANAGEMENT SYSTEM IN INSPECTION BODIES IN ACCORDANCE WITH THE INTERNATIONAL STANDARD ISO/IEC 17020:2012

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SUMMARY
The international standard ISO/IEC 17020 contains the requirements for work of various inspection bodies which aim to raise the level of their activities, as well as the confidence level of clients in performing inspection activities. Furthermore, the standard is aligned with other standards of series standards ISO/IEC 17000 and contains certain parts of guideline IAF/ILAC A4 as well as the mandatory parts of ISO/PAS documents. The standard is used as the reference document during an assessment process of inspection bodies by accreditation bodies. Based on the assessment, inspection bodies prove the fulfillment of the standard requirements, respectively their competencies for performing inspection activities and gain market confidence. The paper describes all necessary steps which should be taken into account by an inspection body so that it can fulfill general and technical requirements of the standard and demonstrate the necessary competencies for performing inspection activities. Especially, the paper will pay attention to impartiality, independence and competence of personnel, traceability of equipment, inspection methods, quality management system of an inspection body, etc.

Keywords: inspection bodies, impartiality, independence, standard 17020

1. INTRODUCTION

There are various types of inspection activities which can be performed by inspection bodies. The inspection activities can be carried out on behalf of private clients as well as for parent organizations. Those activities include activities as well as inspection of materials, products, installations, facilities, working procedures, services and informing clients regarding conducted inspection activities [1]. If an inspection body offers its services on the market then some evidence should be provided to clients that its inspection activities are carried out in independent, competent and professional manner. In most cases, the professional evaluations in conducting inspection activities are demanded. The categorization of the inspection bodies is divided into three types (Type A, B, and C). The level of independence of the inspection body is given by the type of the inspection body. The most powerful tool for proving competencies of the inspection body is accreditation process. The accreditation is carried out by an accreditation body which is acknowledged in a particular state. The accreditation bodies

in Europe operate under the umbrella of the European organization for the accreditation (EA). EA has set up the rules according to which the accreditation bodies operate with the aim to ensure the equal approach in accreditation process [2]. In the accreditation process, the inspection body competencies regarding its activities in accordance with the requirements of the standard ISO/IEC 17020 are checked by the accreditation body. The last edition of this standard dates from 2012.

2. STANDARD ISO/IEC 17020 REQUIREMENTS

The standard ISO/IEC is named Conformity assessment – Requirements for the operation of various types of bodies. The standard contains the requirements which should be fulfilled by inspection bodies in order to prove its competencies for performing activities, as outlined below [1]:

- The general requirements;
- The structural requirements;
- The resource requirements;
- The process requirements;
- The management system requirements.

2.1. General requirements

The inspection body should prove that its activities are performed in independent and impartial manner. The independence level which should be proved by the inspection body, depends on the type of the inspection body (A, B and C). The inspection body independence and impartiality level can be proved by its position in the parent company organization chart as well as in its internal organization chart. The risks jeopardizing the inspection body's impartiality type should be defined, as well as countermeasures to eliminate and minimize such risks. The risks for inspection bodies can be based on ownership, governance management, personnel, shared resources, finance, etc. In table 1 the short explanation regarding fulfillment of general requirements is listed.

Table 1. The General requirements of ISO/IEC 17020 [1]

Chapter	Standard requirements	Short explanation
4.1	Independence and impartiality	Where the inspection body is a part of a larger legal entity, it should be able to demonstrate that there are no conflicts of interest. All relevant information about the activities of the other parts should be regularly updated. Risk analysis should include objectivity in performing inspection activities, financial independence, operative independence, independence of organization structure, external impartiality, threats due to a closely relationship with clients, pressures from clients, etc. [4]. Documented personnel statements as well as top management which emphasize their commitment to independence and impartiality in performing inspection activities, management conflicts of interest and ensuring objectivity in performing their activities. All above mentioned requirements are also applicable to subcontractors [5].
4.2	Confidentiality	Documented personnel statements regarding confidentiality data which are collected during inspection activities. These requirements are also applicable to subcontractors [5].

2.2. Structural requirements

In this standard chapter it is very important that the inspection body establishes the organization structure which enables maintaining its abilities for performing inspection

activities in independent and impartial manner. The inspection body should be the legal entity or the part of the legal entity, so that it is eligible to have the legal responsibility which it proves through organizational chart so that it has complete responsibility for performing its activities. When the inspection body is a part of a legal entity, the entity itself can be included in the process of assessment in order to check records related to inspection activities [5]. The responsibilities and reporting structure should be established in the inspection body. Furthermore, one or more technical managers, who shall have the responsibility and adequate competencies to assure that inspection activities are performed in a competent manner, shall be appointed by the inspection body [3]. All functions in the inspection body which have the influence on quality service as well as the requirements regarding educations, trainings, technical knowledge, and experiences should be listed. In table 2 the short explanation regarding the fulfillment structural requirements is listed.

Table 2. The structural requirements of ISO/IEC 17020[1]

Chapter	Standard requirements	Short explanation
5.1	Administration requirements	The legal status, organizational chart, relation with parent organization, management system, communication, documented procedures, insurance, contractual conditions…
5.2	Organization and management	Independence and impartiality of inspection body, responsibilities and authorizations personnel, relations among departments, appointment of key personnel, job descriptions in inspection body…

2.3. Resource requirements

The inspection body should have enough competent personnel with a suitable level of knowledge so that they can perform their activities in competent manner. Also, the personnel are required to have knowledge about the technology used for manufacture of the product inspected. The inspection body obligations regarding the personnel are: documented education system regarding technical competencies (induction period, mentored working period with experienced inspectors, continuing educations), personnel registers (records regarding personnel academic qualifications, trainings and experience personnel) and personnel work shall not be dependent of number of inspections performed [3, 5]. The permanent equipment suitability as well as exact rules for using measuring equipment shall be established by the inspection body. The following requirements regarding equipment such as suitability, identifications, equipment register, traceability, recalibration periods, records and equipment maintenances should be established. If one part of inspection activities is subcontracted by the inspection body in accordance with its activity scope then subcontractor competence for performing the subcontracted part should be checked. The records regarding the checked subcontractor competence should be kept by the inspection body [1, 3, 5].

Table 3. Resource requirements of ISO/IEC 17020 [1]

Chapter	Standard requirements	Short explanation
6.1	Personnel	Education, skills, monitoring, training, competence, induction period, mentored working period with experienced inspectors.
6.2	Facilities and equipment	Suitability of measuring equipment and facilities, measuring equipment register, measuring equipment identifications, measuring equipment servicing, measuring equipment traceability, monitoring of ambient conditions in facilities, manuals for using measuring equipment, procedures, validation software…
6.3	Subcontracting	Subcontractor competences, records, list, contracts,…

2.4. Process requirements

The procedures for performing inspection activities as well as the standard methods for sampling for a particular field should be in possession of the inspection body. The procedures can be written on the basis of requirements in regulations, standards or inspection instructions. In the case that no such documents exist, the inspection procedures are considered as nonstandard procedures and they shall be validated by user [1]. The standard method is a method published in international, regional or national standards. Also, the standard method is considered as standard when it is published by technical organizations or the one published in international reviewed magazines. The methods that are developed by any other means, including the inspection body itself or by the client, are considered as nonstandard methods [1]. The system regarding contracts and offers shall be established by the inspection body. The collected data during inspection activities shall be recorded and all records (calculations) shall be checked. The tested samples shall be completely marked. Any irregularity on the sample before performing inspection shall be recorded and the sample owner shall be informed about it. The record system used for identifications, collections, labeling, access, archiving, maintenances and destruction of records shall be maintained by the inspection body.

The inspection report and/or inspection certificate regarding the inspection activities are issued by the inspection body. The report and/or inspection certificate shall contain all relevant results regarding the inspection process and it shall be signed by an authorized person. The documented procedures for handling complaints and appeals should be established by the inspection body. The records regarding complaints and appeals as measures for its elimination shall be kept.

Table 4. Process requirements of ISO/IEC 17020 [1]

Chapter	Standard requirements	Short explanation
7.1	Inspection method and procedures	Selection methods, documentation, written procedures, validation of nonstandard methods, approval…
7.2	Handling inspection item and samples	Procedures (if necessary), sample type (identification) sample number, state sample, sample storage…
7.3	Inspection records	Records system should be conducted in accordance with the standard chapter 8.4.
7.4	Inspection reports and inspection certificate	Type, content, results, approval, delivering, archiving of inspection report/certificate.
7.5	Complaints and appeals	Reception, analysis, corrective actions, documentation of actions taken.
7.6	Complaints and appeals process	

2.5. Management system requirements

The management system for fulfilling the requirements of ISO/IEC 17020 in accordance with the option A or B shall be established and maintained by the inspection body [1, 3, 5]. The management system in accordance with option A refers to the following documents: management system documentation (Quality Manual, politics, and responsibilities), control of documents, control of records, management review, internal audit, corrective actions, preventive action and complaints and appeals [1, 3, 5]. If the managements system is already established in accordance with ISO 9001 then requirements regarding the management system in accordance with the option B are fulfilled [1].

Table 5. Management system requirements of ISO/IEC 17020 [1]

Chapter	Standard requirements	Short explanation
8.1	Options	Option A, Option B (the inspection body has already implemented ISO 9001)
8.2	Management system documentation	Documented policies, systems, programs, procedures, instructions, manual quality.
8.3	Control of documents	Document approval, responsibilities, authorization, documentation structure, new issues, obsolete issues, document distributions document.
8.4	Control of records	Storage, identification, protection, retrieval, retention time, and disposition of records.
8.5	Management review	Top management, management system review, records.
8.6	Internal audit	Qualified auditors, procedure, records.
8.7	Corrective actions	Identifying nonconformities, analysis, determining the causes of nonconformity, taking corrective actions, responsibilities for conducting corrective actions, procedure.
8.8	Preventive actions	Improving management system, decisions and records.

3. IMPARTIALITY, INDEPENDENCE AND INTEGRITY OF THE INSPECTION BODY

The most important task of any inspection body is to define its impartiality, independence and integrity. The inspection body shall be independent to the extent which is required in connection with conditions under which it performs its inspection activities. There are three types of the inspection bodies: Type A, Type B and Type C. The inspection body of the type A is independent from the parties involved in the inspection activities. The inspection body of the type B provides services to the parent organization and represent separate and identifiable part of the parent organization. The inspection body of Type C provides services for the parent organization and/or to other parties. The inspection body of the type C shall ensure adequate separation responsibilities and authorizations among inspections and other activities in organization. The scheme for future inspection body for determining independence level and type body is shown on figure 1. [6].

4. REALIZATION OF THE TRACEABILITY IN THE INSPECTION BODY

One of the requirements of ISO/IEC 17020 is to ensure adequate traceability of measuring equipment for performing inspection activities. All equipment with significant influence on inspection activities shall be calibrated. Traceability is the property of the measuring result or the value of the standard whereby it can be related to stated references (usually national or international standards) through unbroken chain of traceability all having stated measurement uncertainties. The measuring equipment traceability is being ensured through:

a) National measurement institutes which are signatories of the CIPM MRA (Multilateral Recognition Agreement) and which demonstrated its calibration competence by taking part in relevant inter-laboratory comparisons for adequate measurement quantity. More information about recognized calibrated and measuring capabilities of individual NMIs can be found at http://kcdb.bipm.fr.
b) Accredited calibration laboratories which are accredited by the accreditation body for the particular state which is a signatory of the MLA/MRA agreement within EA and ILAC for

calibration field. More information regarding national accreditation bodies can be found at http://www.european-accreditation.org.

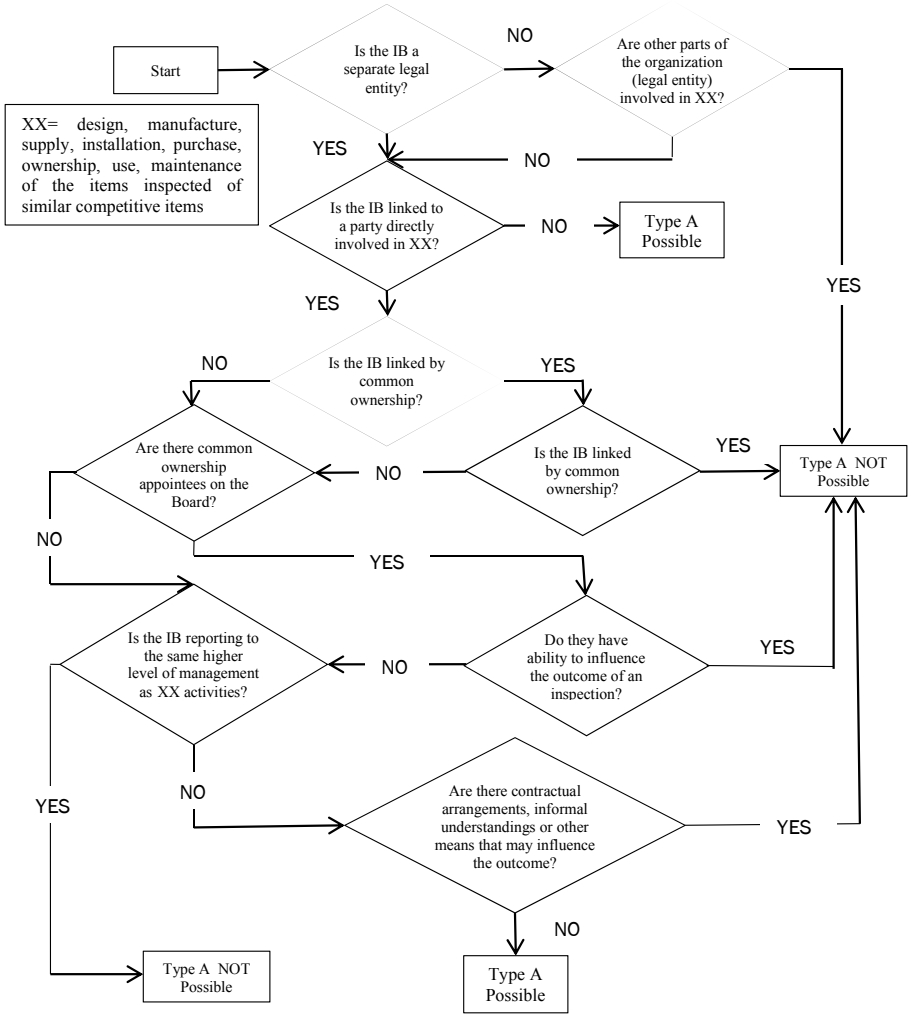

Figure 1. The inspection body classification

c) In-house calibrations by using the reference standards. In this case the inspection body shall possess competent personnel, calibration procedures and relevant traceability of reference standards for performing calibrations. During the assessment process these activities will be checked by the accreditation body in order to prove the credibility of in-house calibrations [5].

In figure 2, schematic views establishing traceability in the inspection bodies are given.

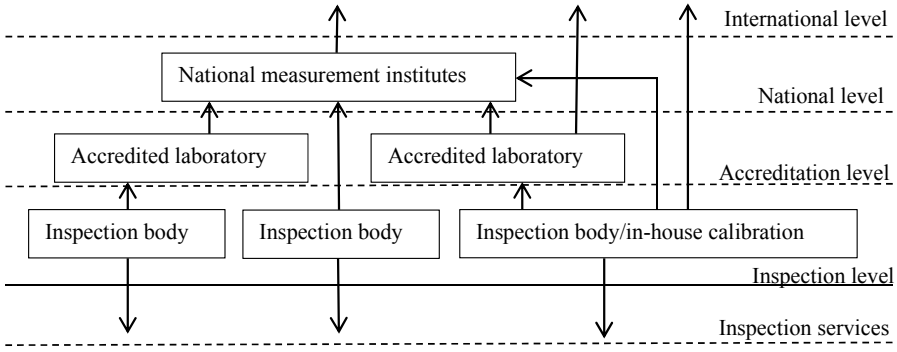

Figure 2. Establishing traceability

5. MANAGEMENT SYSTEM IN THE INSPECTION BODY

The policies and objectives shall be established by the inspection body's top management. Furthermore, the documented quality system should be established by the inspection body. The standard requirements regarding the standard should be covered by inspection body's Quality Manual. The basic requirements regarding the inspection body's quality system are: quality manager nomination, management system documentation (valid documentation on disposal to personnel, withdrawal of obsolete documentation, controlled changes), internal audits (personnel shall be competent for conducting internal audits), management review (results shall be recorded), corrective and preventive actions. Also, the nominal cross reference between ISO/IEC 17020:2012 and ISO/IEC 9001 can be found in guide [5], this greatly facilities implementation of the management system in inspection bodies in accordance with the option B.

6. CONCLUSION

The requirements arising from the standards shall be fulfilled by the inspection body in order to acquire the status of the accredited inspection body. After acquiring the status, the inspection body shall constantly maintain the system and improve it through internal audits and management reviews. The system implementation aims to improve the internal work as well as to raise the confidence of third parties in the operation of the inspection body. In this paper a short review of requirements arising from the standard, as well as the short explanation regarding them, is given. Also, a detailed inspection body assessment method, measuring equipment traceability route and quality management system is presented.

7. REFERENCES

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