Guidance on measurements performed as part of an inspection process

ILAC-G27:06/2017

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1 INTRODUCTION

1.1 Status of this document

This guidance document provides recommendations on how to address cases where measurements are performed as part of inspection. It has been produced with the intention to give guidance to accreditation bodies facing such situations in the assessment of inspection bodies. However, this document is equally applicable to inspection bodies seeking advice on how to structure and perform its measuring activities. The main objective of producing this document is to assure the validity of measurements performed as part of inspection. The document does not intend to – and does not - place any new requirements over and above those already stipulated in ISO/IEC 17020:2012. The document only strives to interpret those requirements when used for the purpose of accreditation.

In this document no requirements are referred to except such already stipulated in ISO/IEC 17020:2012. The term “shall” is used throughout this document to indicate those provisions which, reflecting the requirements of ISO/IEC17020:2012 are considered to be mandatory. The term “should” is used to indicate those provisions which, although not mandatory, are provided by ILAC as a recognized means of meeting the requirements. The term “may” is used to indicate something which is permitted. The term “can” is used to indicate a possibility or a capability.

Whenever reference is made ISO/IEC 17020 in this document, the reference is intended to refer to ISO/IEC 17020:2012. Whenever reference is made ISO/IEC 17025 in this document, the reference is intended to refer to ISO/IEC 17020:2005.

This document covers the case when inspection is performed fulfilling the requirements of ISO/IEC 17020 and when the performance of measurements may require consideration of the requirements of ISO/IEC 17025. These two standards are both produced by ISO CASCO, following ISO CASCO principles and conventions. In the case where ISO 15189 is the most appropriate standard for testing activities (medical laboratories), the principles described in this document are equally applicable. This means that in circumstances where a general reference is made to ISO/IEC 17025, then such a reference may be read to include also ISO 15189. However, when specific references to individual clauses are made, such references are, for reasons of simplicity, only made to clauses in ISO/IEC 17025, and no effort is made to identify the corresponding clauses in ISO 15189. It should also be noted that although the general picture described for ISO/IEC 17025 in the B annexes would largely apply also for ISO 15189, the details may differ.

1.2 Background

ISO/IEC 17020 specifies requirements to be fulfilled by inspection bodies in performing inspection. Inspection may include activities referred to as “examinations”. Such examinations may include the performance of measurements. ISO/IEC 17025 specifies requirements to be fulfilled by laboratories in performing tests. Testing frequently includes the performance of measurements. Thus both ISO/IEC 17020 and ISO/IEC 17025 stipulate requirements for the performance of measurements.

This document provides recommendations on how to approach situations where examinations that form part of an inspection assignment include the performance of measurements. The document provides:

- Recommendations as to the methodology and principles that may be used in evaluating the situation. See 2.1.
- A discussion on how to use this methodology and these principles to identify the requirements that needs to be fulfilled in order for the inspection body to comply with ISO/IEC 17020. See 2.2-2.5.
- A number of case studies where the described methodology and principles are used to interpret the requirements of ISO/IEC 17020. See chapter 3.

It is important to bear in mind that as the topic of this document is inspection activities performed under accreditation all applicable requirements originate from ISO/IEC 17020. However, in certain cases described in this document, these requirements need to be interpreted with consideration to ISO/IEC 17025.

For proper implementation of the methodology described in this document it is useful to be aware of why and how ISO/IEC 17020 and ISO/IEC 17025 differ in their treatment of key aspects. To this end the traditional context of inspection and testing activities is described in Annex A. The different approaches selected by ISO/IEC 17020 and ISO/IEC 17025 for key aspects are described in Annexes B1 to B4.

1.3 Authorship

This publication was prepared under direction of the ILAC Inspection Committee (IC) by a working group with participants from the ILAC IC and the ILAC Accreditation Committee (AIC). It was endorsed for publication following a successful 30 day ballot of the ILAC voting membership in 2017.

1.4 Terminology

For the purposes of this document, the terms and definitions given in ISO/IEC 17000:2004, ISO/IEC 17020:2012, ISO/IEC 17025:2005, ISO 15189:2012 and JCGM 200:2012 apply. The following definitions are considered of particular relevance for this document:

Examination (ISO 15189:2012)
set of operations having the object of determining the value or characteristics of a property
….
Note 3 to entry: Laboratory examinations are also often called assays or tests.
….

Inspection (ISO/IEC 17020:2012)
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
….
NOTE 2 *Inspection procedures or schemes can restrict inspection to examination only*.
…

Measurement (JCGM 200:2012)
the process of experimentally obtaining one or more quantity values that can reasonably be attributed to a quantity

Testing (ISO/IEC 17000:2004)
determination of one or more characteristics of an object of conformity assessment, according to a procedure

2 METHODOLOGY

2.1 Sequence of evaluation

When considering what are the appropriate criteria to apply when assessing the performance of an inspection body it is recommended to follow the sequence described in Figure 2.1 below.

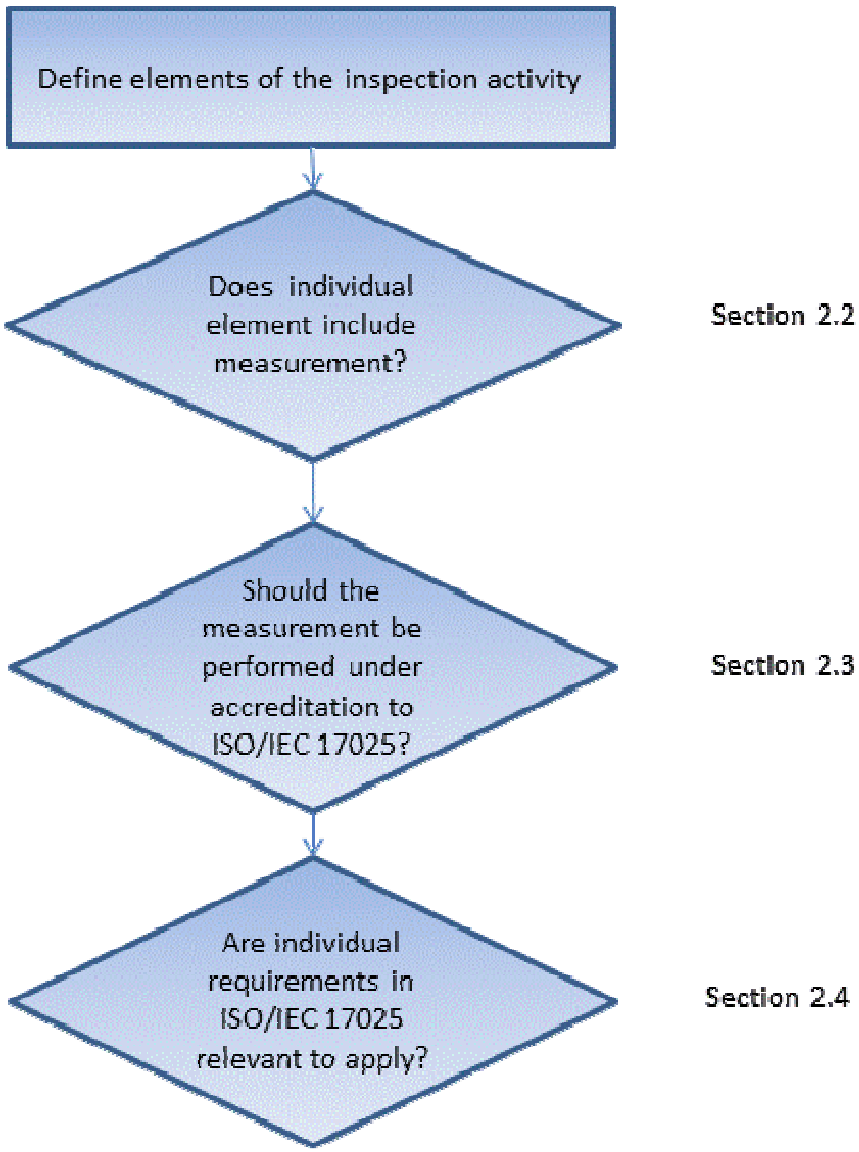

Figure 2.1. Process of determining the criteria for the performance of inspection activities.

The starting point is to define the activities included in the inspection. Having done so, the first question concerns the occurrence of activities including measurements. This question is addressed in section 2.2.

The second question concerns the case where there is an activity of the inspection which does include measurements. The issue here is if this activity is to be performed under accreditation to ISO/IEC 17025. The considerations in making this choice, and the implications, are discussed in section 2.3.

The third question concerns the case where there is an activity of the inspection which does include measurements and shall be performed under accreditation to ISO/IEC 17020. The issue here is whether certain requirements in ISO/IEC 17025 should apply to the body performing the activity. The considerations in performing this evaluation, and its implications, are discussed in section 2.4. This question will need to be addressed by the conformity assessment body (CAB), and the appropriateness of the outcome of the CAB's evaluation will have to be considered in the accreditation body's (AB's) assessment of the CAB.

2.2 Does individual element include measurements (Q1)?

The topic addressed in this document is limited to measurements. If no measurements are included in the inspection there is normally no reason to refer to ISO/IEC 17025.

2.3 Should the measurement be performed under accreditation to ISO/IEC 17025 (Q2)?

Typically, there may be four reasons why a CAB may wish to perform a measurement under accreditation to ISO/IEC 17025:

- The scheme owner/regulator has specified the measurement to be performed under accreditation to ISO/IEC 17025;
- The CAB may wish to use a subcontractor for carrying out the measurement;
- The CAB may wish to be able to offer the service of performing the measurement, under accreditation, in other contexts than inspection;
- The CAB may wish to highlight its capability to perform the measurement according to the requirements in ISO/IEC 17025.

If a measurement activity is performed by a subcontractor, it needs to be accredited in order to make it possible for the inspection to be considered as performed under accreditation. Refer to ILAC P15, application note 7.4.2a. If the subcontractor only performs the measurement activities required by the inspection, it needs to be accredited against ISO/IEC 17025.

If the inspection body performs the measurement activity in other contexts than as part of inspections covered by its accreditation certificate, it cannot claim accreditation for the measurement activity alone under ISO/IEC 17020.

When a measurement is performed under accreditation to ISO/IEC 17025, it is important to keep in mind that the inspection as a whole is still performed under accreditation to ISO/IEC 17020. As a consequence, the relevant requirements, including those for independence and impartiality, in ISO/IEC 17020 apply also for the performance of any measurement performed under accreditation to ISO/IEC 17025. If the measurement is performed by a subcontractor, it remains the responsibility of the inspection body to ensure that the requirements are fulfilled, see clause 6.3.4 of ISO/IEC 17020. The requirements specified in ISO/IEC 17020 for independence are typically more stringent than those specified in ISO/IEC 17025. For a detailed analysis, see Annex B1.

2.4 Are individual requirements in ISO/IEC 17025 relevant to apply (Q3)?

A basic principle underlying the formulation of requirements in the 17000 series of standards for CABs is that any user of their services shall find equal confidence in the outcomes produced. In other words, the services are equally reliable. The outcome of an inspection is usually a statement of conformity with a set of defined requirements, e.g. a

regulation or a product specification. The outcome of a test is often the measured value of a quantity at a specific time.

It thereby follows that in the case of an inspection comprising a single examination which includes measurements, the set of applicable requirements is intended to be equivalent whether those measurements are performed under accreditation to ISO/IEC 17020 or under accreditation to ISO/IEC 17025. This is still the case where the inspection includes several activities, one of which includes measurements that are critical to the outcome of the inspection. However, in the case where the inspection includes several activities, one of which includes measurement activities whose accuracy or performance is not considered critical, then ISO/IEC 17020 would in effect stipulate less demanding requirements for the performance of the same activity than ISO/IEC 17025 would. This is so as the reliability of the outcome of the inspection will largely be built on the diligence displayed in the performance of other activities deemed to be of more critical importance in the particular case.

Technically, the ISO/IEC 17020 standard achieves this balancing act through two key clauses which act to provide the desired flexibility:

- When the activity is performed by the inspection body itself, clauses 7.1.1 to 7.1.3 calls for the chosen inspection method to be *adequate* for its intended purpose. Whether it is adequate may depend on its ability to produce measurements of the desired accuracy. Whether it is adequate may also depend on the reliability of the method used. A situation which may require the method to be validated.

- When the activity is performed by a subcontractor, clause 6.3.1 calls for providers of testing services to fulfil *relevant* requirements of ISO/IEC 17025. Which requirements in ISO/IEC 17025 that in the individual case may be considered as "relevant" depends on the criticality of the activity and the relative importance of key aspects for a valid outcome to be produced.

ISO/IEC 17020 and ISO/IEC 17025 were formulated by different WGs, do not use the same structure and differ from each other in many details. However, the key concepts underlying the standards are the same and, as noted above, the standards are intended to produce outcomes providing the same level of confidence. The large majority of aspects covered by ISO/IEC 17020 and ISO/IEC 17025 are treated similarly or are through different paths channelled to produce equivalent results. However, a comprehensive analysis of the aspects covered reveals that a few are treated in fundamentally different ways, potentially affecting the outcome to a significant extent. These key aspects are:

- Independence (Annex B1)
- Traceability of measurement results (Annex B2)
- Validation of methods (Annex B3)
- Quality assurance initiatives to ensure proper performance of methods (Annex B4)

The issue of *independence* is covered in the last paragraph of section 2.3.

The issues of *traceability of measurement results*, *validation of methods* and *quality assurance initiatives to ensure proper performance of methods* need to be considered separately and individually for each examination including measurements.

In determining whether the requirements in ISO/IEC 17025 for traceability of measurement results are relevant to apply, it is important to consider the different

approaches for this aspect chosen in ISO/IEC 17020 and ISO/IEC 17025. An analysis of these approaches is provided in Annex B2.

In determining whether the requirements in ISO/IEC 17025 for validation of methods are relevant to apply, it is important to consider the different approaches for this aspect chosen in ISO/IEC 17020 and ISO/IEC 17025. An analysis of these approaches is provided in Annex B3.

In determining whether the requirements in ISO/IEC 17025 for quality assurance initiatives to ensure proper performance of methods are relevant to apply, it is important to consider the different approaches for this aspect chosen in ISO/IEC 17020 and ISO/IEC 17025. An analysis of these approaches is provided in Annex B4. The main difference in practice being the role assigned to proficiency testing in ISO/IEC 17025.

When it has been determined that requirements in ISO/IEC 17025 apply, for the reasons outlined above, then any non-conformities identified should refer to one of the bridging clauses in ISO/IEC 17020, i.e. clauses 6.3.1 or 7.1.1-7.1.3.

In chapter 3 a set of cases is discussed to provide guidance on how to arrive at appropriate solutions.

2.5 Summary of evaluation

The recommended approach to determine the requirements applicable in performing measurements is summarised in Figure 2.2.

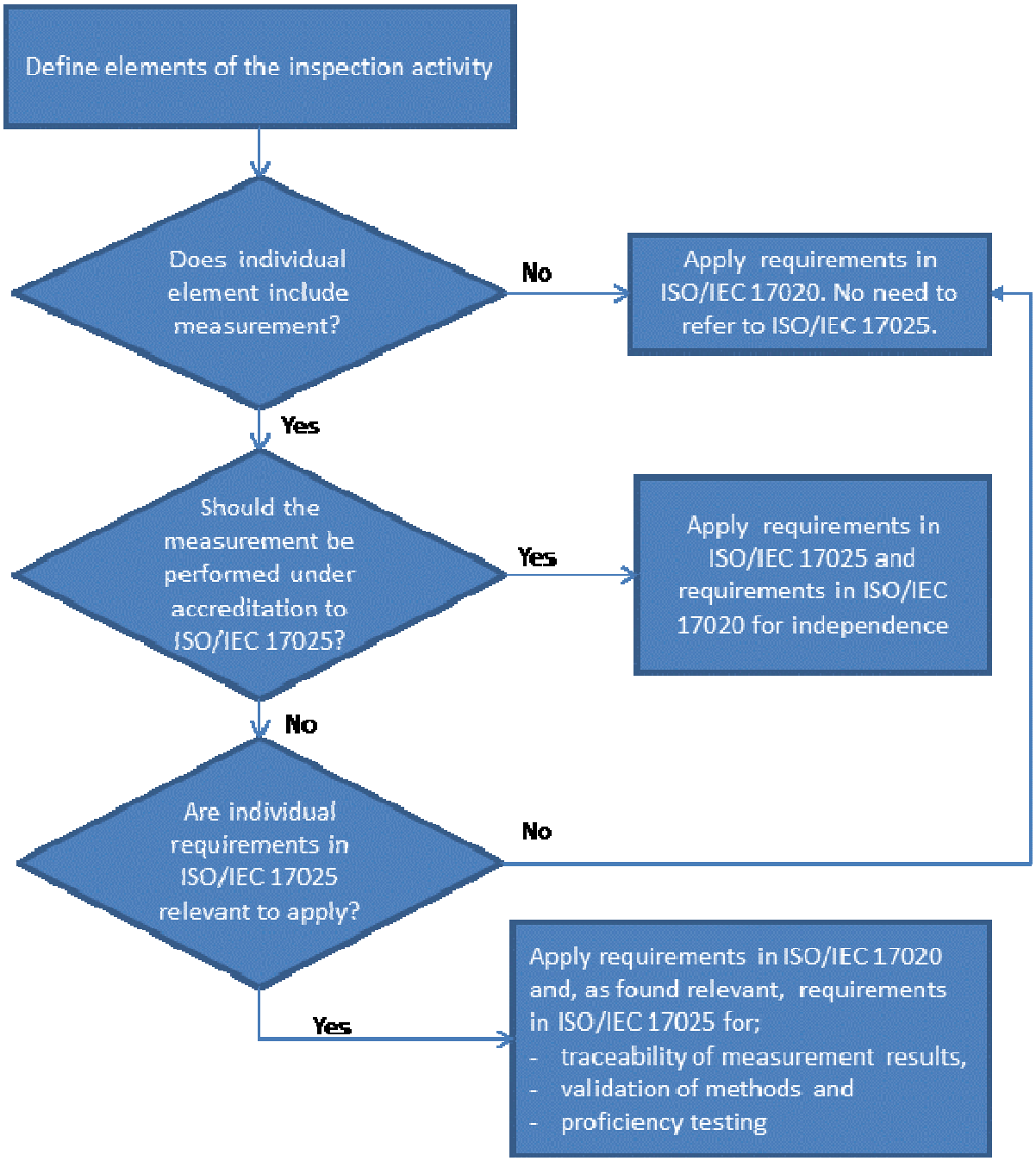

Figure 2.2. Recommended approach to determine the requirements applicable in performing measurements.

3 CASE STUDIES

3.1 General

In this chapter typical examples of examinations are described and analysed. Each case is summed up in a recommended solution based on the limited information of the case description. In real cases more complex considerations are frequently called for, and the selected approach may therefore deviate from those provided here. The cases are provided more to exemplify a methodology than to provide absolute answers.

3.2 Case 1: In-service testing of brakes in vehicles

3.2.1 Description of scheme

As part of a regulated scheme to inspect the in-service condition of vehicles, the performance of the brakes is examined. The car is put in motion on rollers, the inspector put the brakes on and the rolling resistance is measured. The procedure used gives instructions as to the force to be applied in the braking manoeuvre.

3.2.2 Analysis and recommended solution

Issue	Need to consider requirements in ISO/IEC 17025?	Comments
Metrological traceability of measurement results	Yes	The measurement uncertainty resulting from different practices and types of equipment has been found to be substantial.
Validation of methods	No	Methodology described in detail by the regulator
Quality assurance initiatives	No	

Note that in this case traceability is considered a critical factor despite the fact that a high level of accuracy is not required. But even though the requirement is low it has been established that the level achieved in practice is often even lower.

3.3 Case 2: In-service examination of structural components of vehicles

3.3.1 Description of scheme

As part of a regulated scheme to inspect the in-service condition of vehicles the structural integrity of the vehicle is examined. The examination includes visual inspection and hitting the car at selected points with a hammer. Different sizes of hammers, having one sharp and one obtuse end, are used in different cases. The extent and location of corrosion and damages are weighed to arrive at a balanced conclusion.

3.3.2 Analysis and recommended solution

Issue	Need to consider requirements in ISO/IEC 17025?	Comments
Metrological traceability of measurement results	No	Even though area and depth of corrosion is an important factor, professional judgement is more important than numerical figures
Validation of methods	No	Examination process is subject to modifications due to the status and design of the structural components
Quality assurance initiatives	No	Monitoring would be the preferred method for evaluation of validity

This is an example where it is not obvious whether measurements are performed or not. In such cases it usually turns out that requirements in ISO/IEC 17025 do not apply.

3.4 Case 3: Leak testing of non-pressurised liquid-filled systems

3.4.1 Description of scheme

As part of a regulated scheme to inspect the in-service condition of equipment for heating and cooling containing Freon gases, the leak tightness of the liquid containing system is checked. The system is put under pressure and a pressure gauge is used to verify that an adequate level of pressure has been applied.

3.4.2 Analysis and recommended solution

Issue	Need to consider requirements in ISO/IEC 17025?	Comments
Metrological traceability of measurement results	No	Equipment status the primary variable source of measurement uncertainty
Validation of methods	No	Methodology well known and not complex
Quality assurance initiatives	No	Monitoring would be the preferred method for evaluation of validity

The examination is well covered under the framework of ISO/IEC 17020.

3.5 Case 4: Pressure testing of valves in pressurised systems

3.5.1. Description of scheme

As part of a regulated scheme to inspect the in-service condition of pressurised systems the release pressure of safety valves is measured.

3.5.2 Analysis and recommended solution

Issue	Need to consider requirements in ISO/IEC 17025?	Comments
Metrological traceability of measurement results	Yes	Pressure release at set limit critical.
Validation of methods	No, but …	Instructions and training may need to account for how system configurations affects examination set-up.
Quality assurance initiatives	No	Monitoring would be the preferred method for evaluation of validity.

3.6 Case 5: Magnetic particle inspection of welded joints in steel structures

3.6.1 Description of scheme

As part of a regulated inspection scheme for in-service inspection of offshore steel structures, selected welded joints are subject to magnetic particle inspection in order to detect crack indications. Scaffolding is erected and the joints are sand-blasted to expose a clean steel surface. The geometry of the joints exhibits large variations, the location of the joints may be physically demanding to access and the environmental conditions may be less than ideal.

3.6.2 Analysis and recommended solution

Issue	Need to consider requirements in ISO/IEC 17025?	Comments
Metrological traceability of measurement results	No	Recognised as a qualitative test, although dimensional measurements may be performed. The actual detection of crack indications is more critical than the exact dimensions of the indication.
Validation of methods	Yes, but …	Method choice subject to variations in joint configuration. Evaluation of measurement uncertainty and determination of detection limit are difficult to perform.
Quality assurance initiatives	No, but …	Certification of CAB personnel may be required. However, depending on the extent and type of practical examinations included in the certification scheme, substituting elements of monitoring for proficiency testing activities may be considered.

3.7 Case 6: Ultrasonic inspection of pressure containing structures

3.7.1 Description of scheme

As part of a regulated scheme for in-service inspection of pressure containing vessels, ultrasonic testing is carried out on critical sections. Often ultrasonic testing is performed as the first step to find defects and determining their size, location and type. The inspection conclusion may be based also on other examinations.

3.7.2 Analysis and recommended solution

Issue	Need to consider requirements in ISO/IEC 17025?	Comments
Metrological traceability of measurement results	Yes	The identification and determination of minute defects may be of critical importance.
Validation of methods	Yes	Each area/item requires special considerations as to choice of equipment and methodology.
Quality assurance initiatives	No, but …	Where such programs are available, the participation in proficiency testing programs is recommended. However, monitoring is essential to ensure individual inspector competence. Note that certification of CAB personnel may be required. The extent and type of practical examinations included in the certification scheme should be considered when defining the required extent and character of monitoring activities.

3.8 Case 7: Kinetic Energy and Door Pressure of Elevator Doors

3.8.1 Description of scheme

The majority of incidents and accidents on passenger lifts/elevators are door related. To minimize the risk of injuries, EN81-1 specifies that the kinetic energy of the closing lift/elevator doors shall not exceed 10 Joules and the door pressure shall not exceed 150 Newton. In many economies, regulations are in force which refer to this or similar standards. To determine compliance with the standard two tests are carried out with a prescribed calibrated door pressure tool, which is hand held in the closing path of the closing lift/elevator door. The first test is to be carried out at 500 mm from the fully closed position of the closing lift/elevator doors to determine the kinetic energy and the second test at 180 mm from the fully closed position to determine the door pressure. These tests are done immediately

after each other on the same landing floor and both readings are taken directly from the door pressure tool.

3.8.2 Analysis and recommended solution

Issue	Need to consider requirements in ISO/IEC 17025?	Comments
Metrological traceability of measurement results	Yes	Metrological traceability is essential.
Validation of methods	No	Assuming all elevators are inspected against a national or international standard or against regulations, validation is not an essential requirement.
Quality assurance initiatives	No	Monitoring would be the preferred method for evaluation of validity.

3.9 Case 8: Pathology test and examinations of body tissues and fluids as part of autopsy

3.9.1 Description of scheme

Pathology tests and examinations form part of a voluntary inspection scheme for the determination of cause of death (autopsy). Autopsies will involve the examination of the body including organs, tissues and fluids in situ and will also involve the taking of samples and analysis either within the mortuary service or in a separate medical laboratory. Some measurements may also be taken in situ such as length or pH. Examinations will involve taking samples, preparing samples, examining the samples (e.g. by microscopy) and comparing the observations with reference samples with known characteristics to arrive at conclusions supporting the overall determination of cause of death. The requirements of ISO 15189 also need to be considered for any pathology related tests and examinations.

3.9.2 Analysis and recommended solution

Issue	Need to consider requirements in ISO/IEC 17025 (and/or ISO 15189)?	Comments
Metrological traceability of measurement results	Yes	
Validation of methods	Yes	
Quality assurance initiatives	Yes	Comparing results from multiple sources considered to be the best means both to detect non-conforming evaluations and to harmonise best practices. If PT programs are not available then monitoring would be the preferred method for evaluation of validity.

3.10 Case 9: Examination of current dependency of electricity meter

3.10.1 Description of scheme

As part of a regulated scheme for in-service inspection of electricity meters, the current dependency of the meter is examined. The measurement uncertainty of the electricity meter shall be below a specified level at different levels of current.

It is important to point out that this Case refers to in-service inspection of electricity meters, not to legal metrology verification of electricity meters on a testing bench. Electricity regulations often call for in-service inspection as part of a maintenance program. Those inspections do not require the disassembling of electricity meters, but it requires the performance of on-site testing. The inspection is carried out by means of an injection test device connected to the line before the electricity meter.

In many economies inspection bodies tend to be type C, as in-service inspection is sometimes carried out by electricity distribution companies.

3.10.2 Analysis and recommended solution

Issue	Need to consider requirements in ISO/IEC 17025?	Comments
Metrological traceability of measurement results	Yes	Measurement uncertainty is critical, as the regulator requires the electricity meter to have a specified level of precision depending on the level of current.
Validation of methods	No	Methodology specified in detail by regulator
Quality assurance initiatives	No	Monitoring would be the most practical tool to check out inspectors' ability and dexterity to carry out the measurements.

4 REFERENCES

ISO 15189:2012 *Medical laboratories – Requirements for Quality and Competence*

ISO/IEC 17000:2005 *Conformity assessment – Vocabulary and general principles*

ISO/IEC 17011:2005 *Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies*

ISO/IEC 17020:2012 *Conformity assessment – Requirements for the operation of various types of bodies performing inspection*

ISO/IEC 17025:2005 *General requirements for the competence of testing and calibration laboratories*

ILAC P9:06/2014 *ILAC Policy for Participation in Proficiency Testing Activities*

ILAC P10:01/2013 *ILAC Policy on the Traceability of Measurement Results*

ILAC P15:07/2016 *Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies*

EA-3/04 G:2001 *Use of proficiency testing as a tool for accreditation in testing.*

ANNEX A: TRADITIONAL CONTEXT OF EXAMINATION AND TESTING ACTIVITIES

Although the definitions for inspection in ISO/IEC 17020 and for testing in ISO/IEC 17000 do to some extent overlap, the context of examination and testing activities has traditionally differed. The table presented below tries to describe the context by means of quantifying to which extent certain types of activities have traditionally been chosen to be considered as examination and which have traditionally been chosen to be considered as testing activities[1].

Activity …	Object of conformity assessment is …	ISO/IEC 17020 - Examination	ISO/IEC 17025 - Testing
… performed on-site		++++	+
… performed at premises of CAB		+	++++
… performed as part of type approval		++	++++
… performed as part of product certification scheme		++	++++
… performed as part of design examination		+++	++
	… gas/liquid	+	++++
	… material	++	+++
	… well defined item	++	++++
	… complex item	++++	++
	… installation	++++	+
	… service	++++	+
	… process	++++	+

\+ Seldom
++++ Often

Table 5.1. Traditional extent of use of examinations and tests for different applications.

The context described in Table 5.1 has to a significant extent provided the background for formulating the requirements in ISO/IEC 17020 and ISO/IEC 17025. In Annexes B1 to B4 the resulting differences in requirements are analysed in more detail. In these annexes the relationships between these differences in requirements and the traditional context of examinations and tests as displayed in the above table are discussed.

[1] Note that the number of plusses shown in the table is not derived from any statistical study of actual international practices. It is only an approximation based on the collective judgment of the WG which formulated this guidance document. Also note that, for the purpose of this guidance document, the trueness of the plusses is less important than the trueness of the presumption that they reflect the mind-set of the authors of the current versions of ISO/IEC 17020 and ISO/IEC 17025, of which several were members of the WG which formulated this guidance document.

ANNEX B1: INDEPENDENCE

B1.1 Context

The issue of independence is more central in the inspection context than in the testing context. One reason is that inspection often includes a decision. This decision may have substantial economic implications for the owner of the inspected object, as well as for other relevant stakeholders. Testing activities as envisaged in ISO/IEC 17025 does not include a decision stage. Another reason is that the inspector follows trails of investigation where each observation may affect the selection of the next step of the investigation. Such a process is more susceptible to bias than testing per a specific method. However, it should be borne in mind that in practise there may exist important inducements for interested parties to obtain certain outcomes also from testing activities, e.g. measurements may be performed in order to control that emissions from a plant are within permitted levels.

The issues-of-independence can be split up in two:

- Independence of the CAB, and
- Independence of CAB personnel.

B1.2 Independence of CAB

Considering first the independence of the inspection body, ISO/IEC 17020 calls for inspection bodies to be categorized as belonging to one of three types of independence; types A, B and C.

According to Annex A.2 type B inspection bodies type B shall;

- *… not engage in any activities that may conflict with its independence of judgment and integrity in relation to its inspection activities. In particular, it shall not be engaged in the design, manufacture, supply, installation, use or maintenance of the items inspected.*

According to Annex A.1 type A inspection bodies shall meet the requirements of the bullet point for inspection bodies type B above. In addition, it is stated that;

- *The inspection body shall be independent of the parties involved.*
- *An inspection body shall not be a part of a legal entity that is engaged in design, manufacture, supply, installation, purchase, ownership, use or maintenance of the items inspected.*
- *The inspection body shall not be linked to a separate legal entity engaged in the design, manufacture, supply, installation, purchase, ownership, use or maintenance of the items inspected by the following:*

    - *common ownership, except where the owners have no ability to influence the outcome of an inspection;*
    - *common ownership appointees on the boards or equivalent of the organizations, except where these have functions that have no influence on the outcome of an inspection;*
    - *directly reporting to the same higher level of management, except where this cannot influence the outcome of an inspection;*
    - *contractual commitments, or other means that may have an ability to influence the outcome of an inspection.*

According to Annex A.3 type C inspection bodies shall;

- *provide safeguards within the organization to ensure adequate segregation of responsibilities and accountabilities between inspection and other activities*

In clause 4.1.5d of ISO/IEC 17025 it is said that:

- *The laboratory shall have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity.*

Thus, ISO/IEC 17025 is content with policies and procedures, not requiring organizational safeguards. In addition, in a note to clause 4.1.4 it is said that:

- *Where a laboratory is part of a larger organization, the organizational arrangements should be such that departments having conflicting interests, such as production, commercial marketing or financing do not adversely influence the laboratory's compliance with the requirements of this International Standard.*

However, as this text is provided in a note it is not normative.

B1.3 Independence of CAB personnel

For personnel of inspection bodies type C it is stated in Annex A.3 that;

- *The design/manufacture/supply/installation/servicing/maintenance and the inspection of the same item … shall not be undertaken by the same person. An exception to this is where a regulatory requirement explicitly allows an individual person … to undertake both the design/manufacture/supply/installation/servicing/maintenance and the inspection of the same item, as long as this exception does not compromise the inspection results.*

According to Annex A.2 inspection bodies type B shall;

- *Establish a clear separation of the responsibilities of the inspection personnel from those of the personnel employed in the other functions by organizational identification and the reporting methods of the inspection body within the parent organization.*

According to Annex A.1 personnel of inspection bodies type A shall;

- *Not engage in any activities that may conflict with their independence of judgment and integrity in relation to their inspection activities. In particular, they shall not be engaged in the design, manufacture, supply, installation, purchase, ownership, use or maintenance of the items inspected.*

In addition to what is referred to in clause 4.1.5d of ISO/IEC 17025, see B1.2 above, the topic of independence also surfaces in clause 4.1.4. There it is stated that;

- *If the laboratory is part of an organization performing activities other than testing and/or calibration, the responsibilities of key personnel in the organization that have an involvement or influence on the testing and/or calibration activities of the laboratory shall be defined in order to identify potential conflicts of interest.*

Thus, measures shall be taken with the aim of revealing conflicts of interest. The requirement to take action is contained in clause 4.1.5d.

B1.4 Summary

In the table below independence requirements are summarised.

Aspect of independence	Inspection body type A	Inspection body type B	Inspection body type C	Laboratory
Independent organisation	Required	Required, but only internally vis-à-vis its own identifiable part of the larger organisation	Not required	Not required
Independent CAB personnel	Required	Required	Required, unless dependency allowed for in legislation	Required

ANNEX B2: TRACEABILITY OF MEASUREMENT RESULTS

B2.1 Context

ISO/IEC 17025 gives more detailed requirements for metrological traceability of measurement results than does ISO/IEC 17020. There are several reasons for this.

As can be seen in Table 5.1 examination according to ISO/IEC 17020 is to a large extent performed on entities such as complex items, processes and installations which can be expected to exhibit a larger degree of uniqueness than do e.g. materials, gases and well defined objects. As a consequence, it is significantly costlier to estimate a measurement uncertainty valid for the individual case. Further, examination is often taking place outdoors and under less controlled conditions than typically achieved in laboratories. Note also that a test result is usually the final outcome, whereas an examination result is just one bit of information with a bearing on the outcome of the inspection. As a consequence, the measurement uncertainty connected to the individual examination yields limited information on the validity of the inspection outcome.

When the examination does not include the producing of numerical results, the need for traceability is normally minor.

B2.2 Calibration of equipment

The requirement in ISO/IEC 17020 pertaining to calibration of equipment is contained in clause 6.2.7. The requirement is that:

- *"The overall programme of calibration of equipment shall be designed and operated so as to ensure that, wherever applicable, measurements made by the inspection body are traceable to national or international standards of measurement, where available. Where traceability to national or international standards of measurement is not applicable, the inspection body shall maintain evidence of correlation or accuracy of inspection results."*

This requirement is very close to what is said in ISO/IEC 17025 clause 5.6.2.2.

A clarification concerning in-house calibration is provided in ILAC P15, application note 6.2.7a.

The requirement in ISO/IEC 17020 pertaining to calibration of reference standards is contained in clause 6.2.8. A similarly worded requirement for the traceability of reference standards is given in clause 5.6.3 of ISO/IEC 17025.

Additional guidance on how to obtain traceability is provided in ILAC P10. This document applies regardless of whether the measurements are performed under ISO//IEC 17020 or under ISO/IEC 17025.

B2.3 Calculation of measurement uncertainty

The fundamental difference between ISO/IEC 17020 and ISO/IEC 17025 with regard to traceability is that ISO/IEC 17020 requires that the performance of the equipment and reference standards used is traceable, whereas ISO/IEC 17025 requires that the measurement results are traceable. This is primarily achieved through the requirements for estimation of measurement uncertainty in clause 5.4.6. A key sub clause is 5.4.6.3:

- *When estimating the uncertainty of measurement, all uncertainty components which are of importance in the given situation shall be taken into account using appropriate methods of analysis.*

In note 1 to this clause the key considerations for estimating the uncertainty of measurement are listed:

- *Sources contributing to the uncertainty include, but are not necessarily limited to, the reference standards and reference materials used, methods and equipment used, environmental conditions, properties and condition of the item being tested or calibrated, and the operator.*

However, as this text is provided in a note it is not normative.

B2.4 Summary of analysis and possible remedial actions

In the table below a comparison is given between the requirements in ISO/IEC 17020 and in ISO/IEC 17025 related to sources of measurement uncertainty (MU).

Sources of measurement uncertainty	ISO/IEC 17020 – Traceability requirement	ISO/IEC 17025 – Traceability requirement
Reference standards and reference materials used	Traceably calibrated	Traceably calibrated and calculation of MU contribution required
Equipment used	Traceably calibrated	Traceably calibrated and calculation of MU contribution required
Methods used	None	Calculation of MU contribution required
Environmental conditions	Monitored with traceably calibrated equipment, when applicable	Monitored with traceably calibrated equipment, when applicable Calculation of MU contribution required
Properties and condition of the item being examined	None	Calculation of MU contribution required
Inspecting/testing personnel	None	Calculation of MU contribution required

A scheme owner may, in order to account for variations in measurement uncertainty, e.g. choose to:

- In detail specify the method of inspection;
- Specify limitations to acceptable environmental conditions for the performance of inspection;
- Include a safety margin when choosing the acceptance level.

ANNEX B3: VALIDATION OF METHODS

B3.1 Context

ISO/IEC 17025 gives more detailed requirements for method validation than does ISO/IEC 17020. There are several reasons for this.

As can be seen in Table 5.1 examination according to ISO/IEC 17020 is to a large extent performed on entities such as processes, installations and complex items, which can be expected to exhibit a larger degree of uniqueness than do e.g. materials, gases and well defined objects. As a consequence, it is often harder to in detail determine the exact methodology for each specific case. The increased degree of complexity typically leads the inspector to follow trails of investigation, where each observation may affect the selection of the next step of investigation. Such trails often branch out to allow for a myriad of possibilities. Arriving at the most appropriate modifications is an essential element of the ability to make professional judgements. This situation makes it more difficult, costlier and less helpful to specify the methodology in detail. In practice, check lists often replace the use of detailed method descriptions. A check list is inherently difficult to "validate", as the successful use of it is closely dependent on the ability of the inspector to make professional judgements. This is one reason why ISO/IEC 17020 puts more emphasis on knowledge and monitoring of personnel, see section 6.3.

Tests on the other hand are traditionally carried out on more well defined items or samples. This allows for the use of more detailed method descriptions, which in turn allows for a higher degree of repeatability.

Selected approaches of ISO/IEC 17020 and ISO/IEC 17025

In order to ensure the use of appropriate methods the standards put requirements on the following aspects:

- Documentation of work methodology (a)
- Validation of work methodology (b)
- Confirmation of capability of work methodology to produce correct outcomes (c)

B3.2 ISO/IEC 17020

(a) The requirement in ISO/IEC 17020 pertaining to documentation of work methodology is expressed as follows in clause 7.1.2:

- *"The inspection body shall have … adequate documented instructions on inspection planning and on sampling and inspection techniques, where the absence of such instructions could jeopardize the effectiveness of the inspection process."*

In addition, clause 7.1.3 requires inspection methods which are non-standard (see (b) below) to be "fully documented".

Thus the general requirement is linked to a judgement of what is required for the inspection case at hand in order ensure a reliable outcome.

(b) The requirement in ISO/IEC 17020 pertaining to method validation is contained in clause 7.1.3. The requirement is that:

- *"When the inspection body has to use inspection methods or procedures which are non-standard, such methods and procedures shall be appropriate".*

The expression “standard inspection method” is thus defined in a note to clause 7.1.3:

- *“A standard inspection method is one that has been published, for example, in international, regional or national standards, or by reputable technical organizations or by a co-operation of several inspection bodies or in relevant scientific text or journals. This means that methods developed by any other means, including by the inspection body itself or by the client, are considered to be non-standard methods.”*

From this it may be concluded that inspection methods published as international, regional or national standards or by reputable technical organisations or by a co-operation of several inspection bodies or in relevant scientific text or journals are assumed to be appropriate. It may also be concluded that use of the term “appropriate” in ISO/IEC 17020 is intended to mean that there should be evidence to support the ‘appropriateness’. However, there is no requirement that this evidence shall amount to a “validation” as defined in ISO/IEC 17000/ISO 9000.

(c) The primary means in ISO/IEC 17020 for confirming the capability of the chosen work methodology to produce correct outcomes is the requirements for monitoring of the performance of inspectors contained in clauses 6.1.8 and 6.1.9. In addition, clause 7.1.2 requires the consideration of needs for adequate quality control.

ISO/IEC 17020 does not explicitly refer to the concept of proficiency testing. In ILAC P15:07/2016 the following guidance to clause 6.2.7 is provided:

- *“Where traceability to national or international standards of measurement is not applicable, the participation in relevant comparison programs or proficiency tests is an example of how to obtain evidence of correlation or accuracy of inspection results.”*

In the introduction of ILAC P9:06/2014 the following is said:

- *“Proficiency testing may also be used in some types of inspection where available and justified by the inclusion of testing activities that directly affect and determine the inspection result or when required by law or by regulators. It is, however, recognised that proficiency testing is not a usual and expected element in the accreditation of most types of inspections.”*

B3.3 ISO/IEC 17025

(a) The requirement in ISO/IEC 17025 pertaining to documentation of work methodology is expressed in clause 5.4.1. This clause is analogous to clause 7.1.2 in ISO/IEC 17020. In addition, the note to clause 5.4.4 specifies what the anticipated contents of the method description are. Here it is said that it “should at least” include information on:

a) *appropriate identification;*
b) *scope;*
c) *description of the type of item to be tested or calibrated;*
d) *parameters or quantities and ranges to be determined;*
e) *apparatus and equipment, including technical performance requirements;*
f) *reference standards and reference materials required;*
g) *environmental conditions required and any stabilization period needed;*
h) *description of the procedure, including*
- *affixing of identification marks, handling, transporting, storing and preparation of items,*
- *checks to be made before the work is started,*

- *checks that the equipment is working properly and, where required, calibration and adjustment of the equipment before each use,*
- *the method of recording the observations and results,*
- *any safety measures to be observed;*

i) criteria and/or requirements for approval/rejection;
j) data to be recorded and method of analysis and presentation;
k) the uncertainty or the procedure for estimating uncertainty.

Thus, although the basic requirement for the method description is the same in ISO/IEC 17020 and ISO/IEC 17025, the latter anticipates more comprehensive and detailed contents.

(b) The requirements in ISO/IEC 17025 pertaining to method validation are contained in clauses 5.4.2 to 5.4.5. Clause 5.4.2 stipulates:

- *The laboratory shall use test … methods, including methods for sampling, which meet the needs of the customer and which are appropriate for the tests … it undertakes. Methods published in international, regional or national standards shall preferably be used. The laboratory shall ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so. When necessary, the standard shall be supplemented with additional details to ensure consistent application.*
  When the customer does not specify the method to be used, the laboratory shall select appropriate methods that have been published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment. Laboratory-developed methods or methods adopted by the laboratory may also be used if they are appropriate for the intended use and if they are validated. The customer shall be informed as to the method chosen. The laboratory shall confirm that it can properly operate standard methods before introducing the tests or calibrations. If the standard method changes, the confirmation shall be repeated. The laboratory shall inform the customer when the method proposed by the customer is considered to be inappropriate or out of date.

First, note that ISO/IEC 17025 explicitly requires the method to be appropriate whether it is a non-standard method or not. Second, also note that non-standard methods shall be appropriate *and* validated; indicating that in this standard the word “appropriate” alone is not considered to imply the need for validation. Third, note that in ISO/IEC 17025 methods developed by a co-operation of laboratories do not qualify as “standard methods”.

In clause 5.4.5 stipulations for validating methods are given. Sub-clause 5.4.5.1 provides a definition of “validation”:

- *Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.*

This is the definition given in ISO 9000 and referred to in ISO 17000. In sub clause 5.4.5.2 of ISO/IEC 17025 the requirement for the extent of validation is detailed:

- *The laboratory shall validate non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application. The laboratory shall record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use.*

In sub-clause 5.4.5.3 a definition of "appropriate" as referred to in clause 5.4.2, is given:

- *The range and accuracy of the values obtainable from validated methods (e.g. the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/test object), as assessed for the intended use, shall be relevant to the customers' needs.*

It may be concluded that both ISO/IEC 17020 and ISO/IEC 17025 require the method used to be appropriate, but that ISO/IEC 17025 is more explicit about what type of validation activities are expected to be performed in order to support the statement of appropriateness.

(c) In clause 5 of ISO/IEC 17025 under the title "Assuring the quality of test and calibration results" it is stated that:

- *The laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results. This monitoring shall be planned and reviewed and may include, but not be limited to, the following:*
  …
  participation in inter-laboratory comparison or proficiency testing programs;
  …
  NOTE: The selected methods should be appropriate for the type and volume of the work undertaken.
  Quality control data shall be analysed and, where they are found to be outside pre-defined criteria, planned action shall be taken to correct the problem and to prevent incorrect results from being reported."

In ISO/IEC 17011 it is required that accreditation bodies:

- *… ensure that their accredited laboratories participate in proficiency testing or other comparison programmes, where available and appropriate, and that corrective actions are carried out when necessary. The minimum amount of proficiency testing and the frequency of participation shall be specified in cooperation with interested parties and shall be appropriate in relation to other surveillance activities.*

ILAC P9:06/2014 give further guidance as to the specification of the minimum amount of proficiency testing required. Regional guidance documents, e.g. EA-3/04, gives further guidance on the issue.

B3.4 Summary of analysis and possible remedial actions

In the table below a comparison is given between the requirements on methodology in ISO/IEC 17020 and in ISO/IEC 17025.

Requirement on method	ISO/IEC 17020	ISO/IEC 17025
Documented	Required	Required
Contents of documentation	Contents to be "adequate" and "appropriate"	Specific contents "required"[1)]
Validated	Not required as defined in ISO 9000 and ISO/IEC 17000	Required for non-standard[2)] methods
Appropriate[3)]	Required for non-standard[2)] methods, implied for standard methods	Required

Work methodology confirmed to produce correct outcome	Required through monitoring/witnessing of inspectors and other quality checks as needed	Required through participation in PT and other quality checks as needed

1) The status of this “requirement” is not very clear. Notes in ISO standards are as a rule neither to include requirements, nor expressions such as “should at least …”.

2) The definition of “standard method” is wider in ISO/IEC 17020 than in ISO/IEC 17025 as methods developed by a co-operation of conformity assessment bodies are considered as standard methods in the former standard.

3) The meaning of the term “appropriate” is defined in clause 5.4.5.3 in ISO/IEC 17025, whereas ISO/IEC 17020 does not provide any guidance as to the meaning of the term.

A scheme owner may, in order to control the validity of the methodology, e.g. choose to:

- In detail specify the method of inspection;
- Specify limitations to acceptable environmental conditions for the performance of inspection;
- Specify levels of performance for equipment used.

ANNEX B4: QUALITY ASSURANCE INITIATIVES TO ENSURE PROPER PERFORMANCE METHODS

B4.1 Context

The requirements for quality assurance initiatives to ensure proper performance of methods differ significantly between ISO/IEC 17020 and ISO/IEC 17025. There are several reasons for this. An inspector is typically assigned the task to weigh information from different measurements and observations in order to come to an overall conclusion. As pointed out in Annex B3, the specified procedure for each examination is sometimes lacking in detail, and the inspector is assumed to be able to shift the focus of examination when called for by observations made. A test operator is typically assigned the task of following a specified procedure as closely as possible in order to reduce bias and measurement uncertainty and to improve repeatability. Three other considerations are also important to keep in mind. First, in testing the capabilities of the method and equipment used are often perceived to be more important than the individual performance and experience of the test operator, whereas the opposite case is often the case in inspection. Second, the inspector is often required to produce a decision on whether specified requirements are fulfilled, whereas the test operator is often anticipated only to record a measurement result. Third, inspections are typically performed on-site, making opportunities for effective supervision of performance more infrequent and costlier.

B4.2 Selected approach of ISO/IEC 17020 and ISO/IEC 17025

The primary tools used in ISO/IEC 17020 and ISO/IEC 17025 to ensure the proper performance of methods are:

- Knowledge concerning the inspected object
- Training
- Qualification
- Supervision
- Monitoring
- Participation in proficiency testing schemes

The requirements for training and qualification do not differ in the two standards, so here we will focus on the four other issues.

B4.3 Knowledge

In clause 6.1.3 of ISO/IEC 17020 it is stated that:

- *"The personnel responsible for inspection shall have appropriate qualifications, training, experience and a satisfactory knowledge of the requirements of the inspections to be carried out. They shall also have relevant knowledge of the following:*

  - ♦ *the technology used for the manufacture of the products inspected, the operation of processes and the delivery of services;*
  - ♦ *the way in which products are used, processes are operated and services are delivered;*
  - ♦ *any defects which may occur during the use of the product, any failures in the operation of the process and any deficiencies in the delivery of services.*

  They shall understand the significance of deviations found with regard to the normal use of the products, the operation of the processes and the delivery of services."

This may be compared with the wording used in clause 5.2.1 in ISO/IEC 17025:

- *The laboratory management shall ensure the competence of all who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates. When using staff that is undergoing training, appropriate supervision shall be provided. Personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required.*

- *NOTE 2: The personnel responsible for the opinions and interpretation included in test reports should, in addition to the appropriate qualifications, training, experience and satisfactory knowledge of the testing carried out, also have:*

  - ♦ *relevant knowledge of the technology used for the manufacturing of the items, materials, products, etc. tested, or the way they are used or intended to be used, and of the defects or degradations which may occur during or in service;*
  - ♦ *knowledge of the general requirements expressed in the legislation and standards; and*
  - ♦ *an understanding of the significance of deviations found with regard to the normal use of the items, materials, products, etc. concerned.*

Note that the specific knowledge requirements listed in the bullet list found in clause 6.1.3 of ISO/IEC 17020 is very similar to the one found in note 2 to clause 5.2.1 of ISO/IEC 17025. However, the latter list only applies to personnel responsible for any opinions and interpretations expressed in the test report, whereas the requirement in ISO/IEC 17020 applies to all personnel responsible for inspection.

B4.4 Supervision

ISO/IEC 17020 does not explicitly include requirements for supervision of CAB personnel. However, it does include requirements for training (6.1.5/6.1.6), monitoring (6.1.8/6.1.9) and work order review (7.1.5).

In ISO/IEC 17025 clause 4.1.5 bullet item g) it is said that:

- *The laboratory shall provide adequate supervision of testing … staff, including trainees, by persons familiar with methods and procedures, purpose of each test .., and with the assessment of the test …*

Although the standards approach the issue of supervision in different ways, these could be assumed to result in corresponding levels of supervision. As noted in B4.1, however, the opportunities for effective supervision are more frequently in place under typical laboratory conditions.

B4.5 Monitoring the validity of inspections and tests

In ISO/IEC 17020 the requirement for monitoring validity is accomplished through monitoring of the performance of inspection personnel. In clause 6.1.8 it is stated that:

- *Personnel familiar with the inspection methods and procedures shall monitor all inspectors and other personnel involved in inspection activities for satisfactory performance.*

This is further elaborated upon in clause 6.1.9:

- *Each inspector shall be observed on-site, unless there is sufficient supporting evidence that the inspector is continuing to perform competently.*

The expression "sufficient supporting evidence" is explained in ILAC P15:07/2016, as are the frequencies at which on-site observation are expected to occur.

ISO/IEC 17025 does not include a specific requirement for monitoring of operators. Instead the quality of test results is monitored by other means. In clause 5.9.1 it is stated that:

- *This monitoring shall be planned and reviewed and may include, but not be limited to, the following:*

  a) regular use of certified reference materials and/or internal quality control using secondary reference materials;
  b) participation in interlaboratory comparison or proficiency-testing programs;
  c) replicate tests or calibrations using the same or different methods;
  d) retesting or recalibration of retained items;
  e) correlation of results for different characteristics of an item.

There is no corresponding requirement(s) in ISO/IEC 17020. In ILAC P9:06/2014 it is stated that

- *It is … recognized that proficiency testing is not a usual and expected element in the accreditation of most types of inspections.*

B4.6 Summary of analysis

As the requirement for monitoring in ISO/IEC 17020 applies to all CAB personnel, it can be said that it also constitutes a requirement for the CAB to arrive at correct outcomes. In ISO/IEC 17025 that requirement is put through the mechanism of quality assurance activities.

In the table below a comparison is given between the requirements for ensuring proper performance of methods in ISO/IEC 17020 and in ISO/IEC 17025.

Aspect of competence	ISO/IEC 17020	ISO/IEC 17025
General competence of CAB personnel to perform assigned tasks	Required	Required
Specific knowledge of CAB personnel about object for conformity assessment	Required	Required, but only for persons responsible for any opinions or interpretations that may be given in the test report
Monitoring of performance of CAB personnel	Required	Not required
On-site observations of CAB personnel	Required, unless other sufficient supporting evidence for satisfactory performance is available	Not required
Supervision of CAB personnel	Not explicitly required	Required through direct supervision requirement
Assuring the quality of test and calibration results	Required through work order control requirement	Required