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COURSE HANDBOOK

UNDERSTANDING ISO/IEC 17020:2012

IAS Training: Training that Reaches People

Rev 1

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Introduction

Course Development

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Course Description

This course is aimed at IB staff and regulatory agencies specifying IB criteria:

- Who participate in the operation of an IB quality system – in the conduct of their inspections, and surveillance activities.
- Who participate in the management of the quality system.
- Who participate in the management of the IB.
- Who participate in the design and implementation of inspection programs.

The inspection of materials, products, installations, plants, processes, work procedures or services represents a fairly intensive conformity assessment activity. Inspection normally draws information from the following conformity assessment processes:

- ISO/IEC 17025 (testing and calibration)
- ISO/IEC 17020 (inspection)

This course will provide information to IB staff, accreditation body assessors and specifiers who seek ways to better understand the requirements behind ISO/IEC 17020 – the standard used for the inspection of product design, product, service, process or plant.

This course examines these processes within the context IAF-ILAC P15 – *Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies*.

Course Learning Objectives

The course will assist you to:

- **understand** how inspection programs operate;
- **appreciate** the needs of specifiers;
- **understand** how materials, products, installations, plants, processes, work procedures or services inspection works within the global conformity assessment approaches;
- **understand** IB requirements for impartiality;
- **understand** the requirements in ISO/IEC 17020 for an organization to operate as an IB.
- **understand** the requirements for competence of all persons involved in the inspection process, and
- **understand** the facilities and equipment requirements for inspection.
- **understand** inspection processes, and
- **appreciate** the contribution of testing and calibration to support inspection processes;
- **understand** the components of the inspection decision;
- **understand** the requirements for protection of marks/stamps/certificates of inspection, and
- **understand** the requirements for changes to inspection
- **identify** the standard management system requirements for inspection bodies;

Completing the Course

The course material is broken down into chapters. Within each chapter, specific objectives are listed as well as instructions on how to complete each chapter. Directions are provided to guide you through the readings, other reference materials, and work to be completed.

Course Content

The syllabus for this course is as follows.

Chapter 1 – Background
- Introduction to the concepts behind inspection
- Emphasis on conformity to market and regulatory needs
- Principles behind inspection
- The components of inspection programs (specifiers, inspection bodies, applicants)

Chapter 2 – Program Integrity Requirements from Clause 4
- Compatibility within the ISO/IEC family of conformity assessment disciplines
- Types of Inspection Bodies
- Inspection processes, a macro view.

Chapter 3 – Organizational Requirements from Clause 5
- Structure of the organisation

Chapter 4 – Infrastructure Requirements from Clause 6
- People and competence
- Subcontracting and external support
- Use of competent testing and calibration services
- Physical / plant / equipment requirements

Chapter 5 – Process Requirements from Clause 7
- Application and review
- Inspection processes
- Methods used for inspection
- Publication of decisions, reports and certificates
- Enforcing conformant behaviours from program participants

Chapter 6 – Management System Requirements from Clause 8
- Management system overview
- Document Control and Control of Records
- Continual Improvement
- Feedback (& Complaints)
- Disputes and Appeals
- Internal Audit
- Management Review

Supplier / Manufacturer / Provider / Applicant

It does not matter if a design, or product, or service, or process, or installed plant undergoes inspection. The term “applicant” will be used to mean all of the following; whichever one of them has submitted an application for inspection:

- applicant for inspection;

- manufacturer of the product or process, and
- provider of the product or service that is the object of inspection.

Course Grading

The quiz is at the end of the course and will allow you to measure your acquired knowledge of laboratory accreditation. Participant Inspection will be based on the result of the quiz. 70% is required in order to pass this course.

Chapter 1 – Background

1.1 Learning Objectives

Upon completion of this chapter, you should be able to:

- **understand** how inspection programs operate;
- **appreciate** the needs of specifiers, and
- **understand** how materials, products, installations, plants, processes, work procedures or services inspection works within the global conformity assessment approaches.

1.2 Completing the Chapter

Discussion Activity 1.1

Who are some of the stakeholders involved in materials, products, installations, plants, processes, work procedures or services inspection?

Discussion Activity 1.2

What are the types of inspection programs that you may be most familiar with?

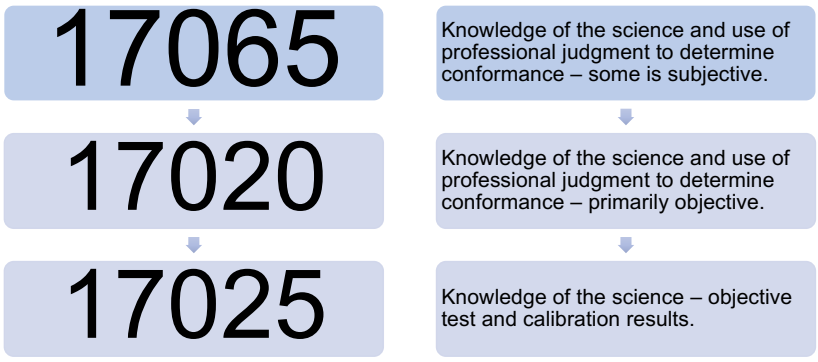
Discussion Activity 1.3

What are the common elements that appear in ISO/IEC standards?

1.3 The Hierarchy of Conformity Assessment Standards

The following diagram shows the differences in the application of the three most-common technical conformity assessment standards. They differ in the amount of subjective effort is required to deliver the attestation associated with that conformity assessment activity.

ISO/IEC 17025 and ISO/IEC 17020 can both be used as technical specifications for the provision of inspection, testing, and calibration results to be used as part of the certification of the product, process, service or plant to be examined. The top of the chain is the product certification standard and its related processes. Inspection is a close second.



1.3.1 Common Elements of Conformity Assessment Standards

Most standards now produced within ISO/CASCO (those with the ISO/IEC nomenclature) follow the criteria set out in the Publicly Available Specifications (PAS) 17001 through 17005. These specifications used to be as follows, but these standards have been withdrawn into the ISO/CASCO Part 2 Directives:

- ISO/PAS 17001 Impartiality;
- ISO/PAS 17002 Confidentiality;
- ISO/PAS 17003 Complaints and appeals;
- ISO/PAS 17004 Disclosure of information, and
- ISO/PAS 17005 Use of management systems in conformity assessment.

Because of these and other common approaches adopted, most 17000 series standards contain elements common to all of them that allow organisations to seamlessly incorporate conformity assessment standards in different disciplines.

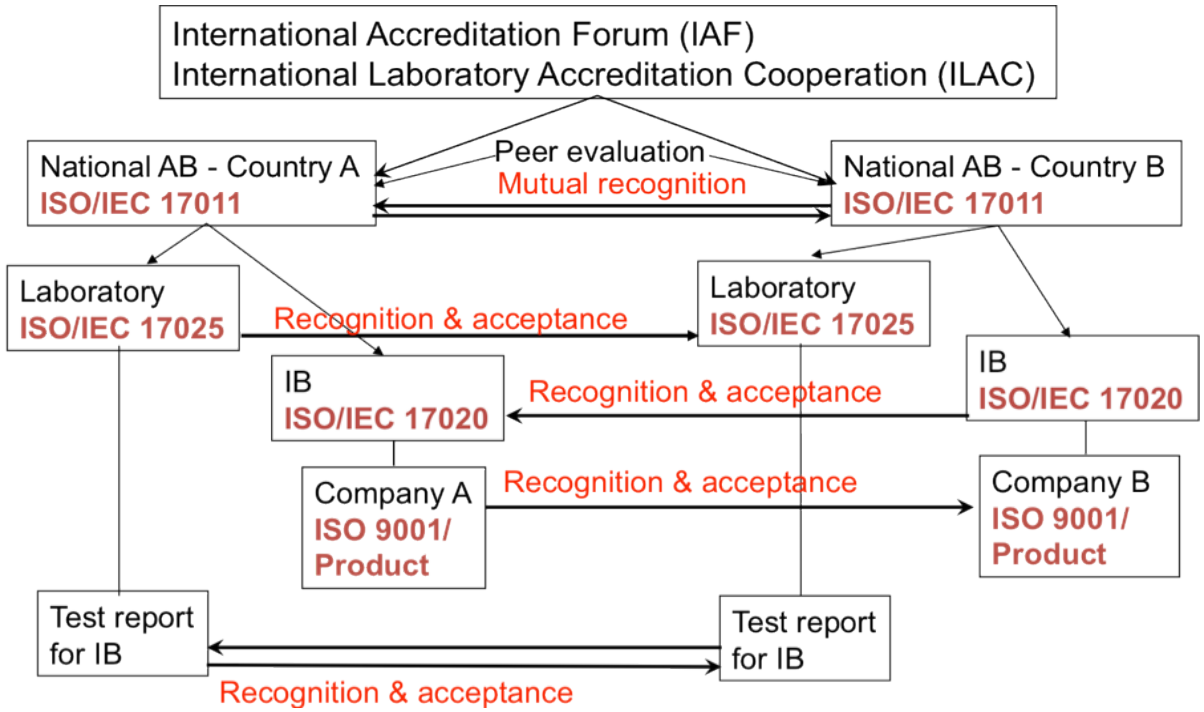
These common elements generally include the following:

- Organisation requirements;
- Management system requirements, including:
  - Technical and management system responsibilities (including both authorities and accountabilities);
  - Conflict of interest requirements;
  - Confidentiality requirements;
  - Impartiality requirements, and
  - Personnel training and qualification requirements.
- Document control;
- Control of records;
- Feedback, including complaints;
- Disputes and appeals (where applicable);
- Handling of non-conformances through to corrective action (as appropriate);
- Handling of potential non-conformances and opportunities for improvement through to preventive action (as appropriate);
- Internal audit, and
- Management review

The resulting commonality in structure is apparent in most of the documents issued by ISO/CASCO.

Informative Preliminary.	Title page Table of contents Foreword Introduction (including relationship to other standards)
Normative General	Title Scope Normative references
Normative Technical	Terms and definitions Principles Requirements Structural requirements Resource requirements (including Human resources) Process requirements (including operational functions) Management system requirements Normative annexes
Informative supplementary	Any further explanations that are not part of the normative process Informative annexes Bibliography Indexes

This commonality enhances the interoperability of these standards and promotes mutual recognition around the world. The following diagram demonstrates how mutual recognition allows inspections, inspection results, and test and calibration results to be acceptable in other nations.



1.4 Establishing Public Confidence

1.4.1 Driving Forces

More than testing and calibration, inspection is primarily focussed on the establishment of confidence in the operation of products, processes, services and plant. The users of goods and services that carry formal inspection marks are more interested in the results of inspection than any other aspect of the objects of inspection. For example, they are concerned about the safe installation of medical gas piping systems in hospitals than they are about the longevity of the pipes used in its manufacture and installation.

Inspection has traditionally been used to identify products deemed safe for use within a jurisdiction or economy and public confidence in the inspection has been based on conformity assessment approaches that met regulatory and market specification. Conversely, users of testing and calibration services tend to be more involved in the processes that produce these primarily objective results. They may not work within the science of the tests, but they understand more than the general public and consumer.

As a result, the processes surrounding inspection tend to involve more agencies and public sector bodies that may represent consumers and other users of products, processes, services and plant which are the objects of inspection. Depending on the scheme within which inspection is conducted, liability for the inspection decisions may be more than for other conformity assessment activities such as testing and calibration. Management and other system inspection activities involve very little liability for those inspection bodies.

Stakeholders and regulators expect and demand that all parts of the inspection processes will successfully prevent the installation and operation of unsafe, inappropriate, imprudent, unethical, and illegal goods, services and plant.

1.4.2 Market and Regulator Involvement

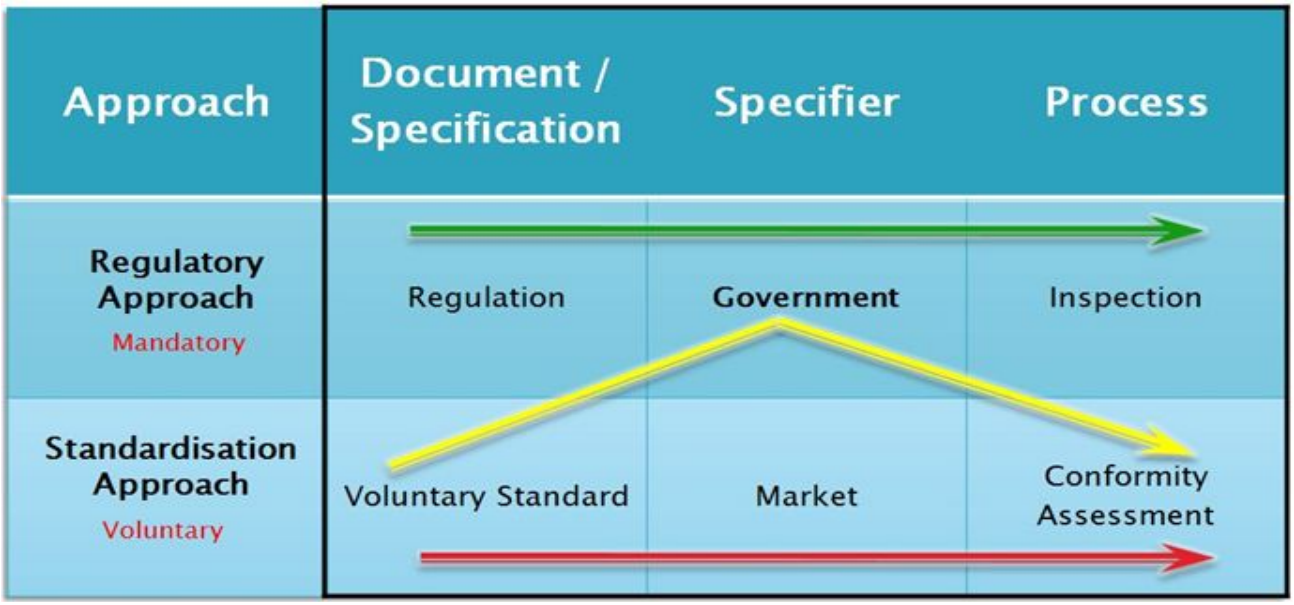
Because of the implied, if not actual, liability associated with inspection, many agencies representing various stakeholders will involve themselves in the processes surrounding inspection. Most do so as participants in the applicable inspection schemes, sometimes as the specifiers, and sometimes as scheme participants.

There are generally four methods for regulators and stakeholders to participate in the accreditation or approval of inspection schemes:

- As scheme owner;
- As a participant in the development of scheme requirements;
- As assessors of IBs within accreditation programs, and
- As reviewers and approvers in the accreditation of inspection bodies.

1.4.3 From Specification to Assessment of Conformity

There are generally two approaches to allow stakeholders to establish specifications and then ensure they have been followed.



The green line at the top shows how a government develops a regulation, then specifies its use, and finally enforces it through inspection. An example is the current laboratory-licensing program used by the US FDA.

The red line at the bottom is an example of how ISO 9001 and ISO/IEC 17025 are normally delivered without any regulator specification – “by the market, from the market, and for the market”. These two standards were developed from within their own communities. Both were developed internationally and included the input of their clients and other stakeholders, including governments. They are delivered using voluntary conformity assessment techniques.

The yellow line in the middle represents how a government can specify a voluntary standard. ISO/IEC 17025, ISO/IEC 17020, and other technically-focussed conformity assessment standards guidelines are

delivered today to organisations, which, if they wish to do business in some specific fields, must meet regulatory requirements for accreditation. These are now part of regulatory tool kits in the protection of the health, welfare and safety of citizens of many nations around the world.

Each of the three components of either type of approach involves:

- writing something that can be used to determine acceptable behaviour (standard or regulation),
- specifying the necessity for this behaviour (the market or some legislation), and
- determining how to evaluate performance against the specification (inspection or conformity assessment).

1.4.4 Third Party Conformity Assessment Principles (From ISO/IEC 17065)

As stated above, the overall aim of inspection is to give confidence to all interested parties that a materials, products, installations, plants, processes, work procedures or services fulfils specified requirements. The value of inspection is the degree of confidence and trust that is established by an impartial and competent demonstration of fulfilment of specified requirements by a third-party. Parties that have an interest in inspection include, but are not limited to:

- the clients of the inspection bodies;
- the customers of the organizations whose materials, products, installations, plants, processes, work procedures or services are inspected;
- government/regulatory authorities;
- non-governmental organizations; and
- consumers and other members of the public.

The principles for inspiring confidence are those listed below:

1.4.4.1 Impartiality

It is necessary for IBs and their personnel to be, and to be perceived as, impartial to give confidence in their activities and their outcomes.

Risks to impartiality include bias that may arise from:

a) self-interest (e.g. overdependence on a contract for service or the fees, or fear of losing the client or fear of becoming unemployed, to an extent that adversely affects impartiality in carrying out conformity assessment activities);

b) self-review (e.g. performing conformity assessment activity in which the IB evaluates the results of other services it has already provided, such as consultancy);

c) advocacy (e.g. an IB or its personnel acting in support of, or in opposition to, a given company, which is at the same time its client);

d) over-familiarity, i.e. risks that arise from an IB or its personnel being overly familiar or too trusting instead of seeking evidence of conformity (in the product inspection context, this risk is more difficult to manage because the need for personnel, with very specific expertise, often limits the availability of qualified personnel);

e) intimidation (e.g. the IB or its personnel can be deterred from acting impartiality by risks from or fear of, a client or other interested party);

f) competition (e.g. between the client and a contracted person).

1.4.4.2 Competence

Competence of the personnel supported by the management system of the IB is necessary to deliver inspection that provides confidence.

1.4.4.4 Confidentiality and openness

1.4.4.4.1 General

Managing the balance between confidentiality and transparency requirements affects stakeholders' trust and their perception of value in the conformity assessment activities being performed.

1.4.4.4.2 Confidentiality

To gain access to the information needed to conduct effective conformity assessment activities, the IB needs to provide confidence that confidential information will not be disclosed.

All organizations and personnel have the right to have protected any proprietary information that they provide unless the law or the inspection scheme applied for require disclosure of proprietary information

1.4.4.4.3 Openness

An IB needs to provide access to, and disclosure of, appropriate and timely information about its inspection processes, and about the inspection status of any design, product, service, process or plant, in order to gain stakeholder confidence in the integrity and credibility of inspection. Openness is a principle of access to, or disclosure of appropriate information.

1.4.4.4.4 Access to information

Any information held by the IB on a materials, products, installations, plants, processes, work procedures or services that is the subject of an inspection should, upon request, be made accessible to the person or organization which contracted the IB to undertake the inspection activity.

1.4.4.5 Responsiveness to complaints and appeals

The effective resolution of complaints and appeals is an important means of protection for the IB, its clients and other users of conformity assessment against errors, omissions or unreasonable behavior. Confidence in conformity assessment activities is safeguarded when complaints and appeals are processed appropriately.

1.4.4.6 Responsibility

The client, not the IB, has the responsibility for fulfillment of the inspection requirements.

The IB has the responsibility to obtain sufficient objective evidence upon which to base an inspection decision. Based on a review of the evidence, it makes a decision to issue certificates of conformance if there is sufficient evidence of conformity, or a decision not to issue such a certificate if there is not sufficient evidence of conformity.

1.4.5 Third Party Inspection programs

There are many examples available to describe how regulatory agencies deliver inspections in support of their own regulations. Municipal building inspections and the USDA food inspection programs are such examples.

In order to provide more transparency and confidence in the actual inspections, the use of third party inspection programs has largely overtaken this approach over the last 40 years or so for those designs, products, services, processes or plant that are delivered to markets in a ready-to-use condition. In the building industry, third party inspection of electrical panels and light fixtures to performance standards referenced in national building codes are examples.

Such an approach also allows regulatory agencies to concentrate on the actual requirements for inspection and approval of inspection bodies, and leave the conformity assessment work to others. In other words, these organizations become "specifiers."

1.4.6 Third Party Inspection Specifiers

Specifiers can be any of the following:

- product certification bodies;
- governments and regulators;
- non-government organisations;
- industry and retail associations; and
- consumer organisations.

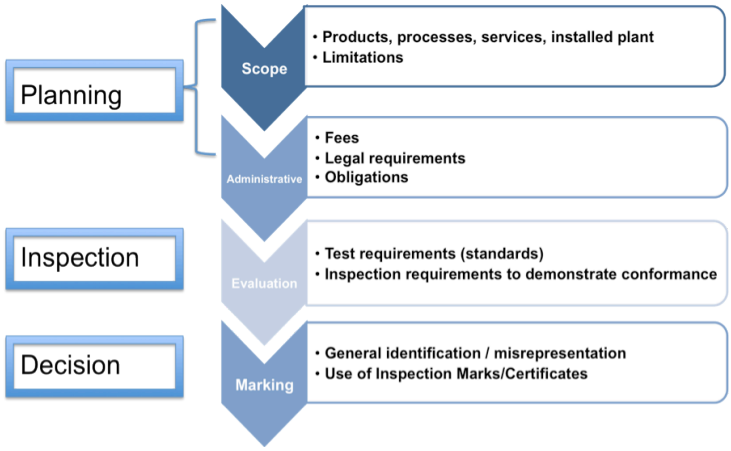
Specifiers establish requirements for the following, non-exclusive list, of aspects of third party inspection schemes:

- pre-requisites for participation as a third party IB;
- pre-requisites for the inspection of conformant materials, products, installations, plants, processes, work procedures or services;
- scheme owner participation in the processes leading to either of the above;
- surveillance of materials, products, installations, plants, processes, work procedures or services for continued inspection;
- sanctions to all other parties for failure to conform to their requirements, and
- supporting requirements such as cost recovery, legal liability, and conflict resolution.

In other words, the specifiers own the scheme. They wish to influence the processes that define trust in the designs, products, services, processes or plant inspected. **THIS IS IMPORTANT**. **IBs must meet the needs of specifiers in order to establish scheme owner trust in their inspection processes.** Accreditation bodies accrediting IBs that conduct third party inspection will work closely with specifiers to establish confidence in their accreditations of these inspection bodies.

1.5 Inspection is different than Testing

1.5.1 Inspection Processes



ISO/IEC 17020:2012 articulates the process of inspection to contain the following 3 steps.

These three steps underpin all inspection processes and therefore, the management system that supports them, in ISO/IEC 17020, is geared towards allowing the IB to issue certificates that enhance trust in the safety and performance of the products, processes, services, and plant that have been examined.

Chapter 2 – Program Integrity Requirements

2.1 Learning Objectives

Upon completion of this chapter, you should be able to:

- **understand** IB requirements for impartiality.

2.2 Completing the Chapter

Consider the following questions. Discuss your findings and those of others in your group. This can be done by seeking clarification of others, providing support to others where required and challenging responses when necessary.

Discussion Activity 2.1

How important is impartiality to the success of an inspection scheme?

Discussion Activity 2.2

What types of requirements are contained in ISO/IEC 17020 that may not be present in the other standards used in the Inspection process?

Discussion Activity 2.3

What specific steps must an IB take to ensure real and perceived impartiality in its processes?

2.3 Understanding Impartiality

Impartiality is the concept that decisions made with regard to something are **based solely on the defined merits or criteria related to it**, or its operation, or some other aspect of its being. That is to say, only those things can be used in the decision – nothing else, and certainly nothing related to the decision maker.

Conflict of interest is the concept that something other than those defined merits or criteria are influencing the decisions related to that thing. People or organizations are deemed to be in conflict of interest when they are associated with any condition or organization that might have an interest in influencing the outcome of the decisions.

Simple conflict interest is deemed to exist whenever more than one relationship connects two parties. When this occurs, it is not possible to ensure that one relationship is not being influence by the dynamics of the other.

Impartiality in inspection is more difficult to delve than simple conflict of interest considerations. It is not possible to simply identify and declare the existence of more than one relationship between parties. There may not be any, but because of the possibility of small amounts of influence being applied that may skew the inspection, all possible aspects of conditions that may jeopardize or compromise impartiality must be dealt with in a clear and transparent manner.

Failure to do so will adversely affect the integrity of the inspection scheme and its certificates, and may significantly reduce the trust placed in the IB and its stakeholders.

2.4 Types of Inspection programs (from ISO/IEC 17020)

There are three types of IBs as defined in ISO/IEC 17020. They are described below.

ISO/IEC 17020 References	ILAC P15 Interpretation
4.1 Impartiality and Independence The IB shall implement policies and procedures that prevent pressures from compromising impartiality, analyse the risks of its relationships to its impartiality, and eliminate/minimise such risks.	**4.1.3a** Risks to the impartiality of the inspection body shall be considered whenever events occur which might have a bearing on the impartiality of the inspection body or its personnel. **4.1.3b** The inspection body should describe any relationships that could affect its impartiality to the extent relevant, using organisational diagrams or other means. Examples of relationships that could influence the impartiality include: - Relationship with a parent organisation - Relationships with departments within the same organisation - Relationships with related companies or organisations - Relationships with regulators - Relationships with clients - Relationships of personnel - Relationships with the organisations designing, manufacturing, supplying, installing, purchasing, owning, using or maintaining the items inspected. **4.1.5a** The inspection body should have a documented statement emphasising its commitment to impartiality in carrying out its inspection activities, managing conflicts of interest and ensuring the objectivity of its inspection activities. Actions emanating from the top management should not contradict this statement. **4.1.5b** One way for the top management to emphasise its commitment to impartiality is to make relevant statements and policies publicly available.

2.5 Demonstrating Impartiality in Decision Processes

Rock solid demonstrations of impartiality require the IB to ensure that its own staff are not involved in any aspect of ownership, design, manufacture, or other relationship as regards the object of inspection or its manufacturer / supplier.

It may also require that all sub-contracted organizations that participate in the Inspection processes also are visibly free of such conflicts.

ISO/IEC 17020, clauses 4.1 and 4.2 specify the requirements for the independence of all persons involved in the conduct and decision of the inspection. Clause 6.1 provides specific requirements regarding the conduct of staff with respect to their activities for inspection and inspection decisions. See the table below and Chapter 4 – Infrastructure Requirements.

2.5.1 Type A Inspection Body

From 17020, Clause 4.1.6 a) *An inspection body providing third party inspections shall meet the type A requirements of Clause A.1 (third party inspection body).*

These are the simply stated requirements for a Type A Inspection Body:

- The IB shall be independent of the parties involved.
- The IB, and its staff responsible for carrying out the inspection shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the items which they inspect, nor the authorized representative of any of these parties.
- The IB and its staff shall not engage in any activities that may conflict with their independence of judgement and integrity in relation to their inspection activities. In particular they shall not become directly involved in the design, manufacture, supply, installation, use or maintenance of the items inspected, or similar competitive items.

All interested parties shall have access to the services of the IB. There shall not be undue financial or other conditions. The procedures under which the body operates shall be administered in a non-discriminatory manner.

The IB providing "third party" services shall meet the criteria from Annex A (normative).

17020 Annex A Normative Requirements

A.1 Requirements for inspection bodies (Type A)

The inspection body referred to in 4.1.6 a) shall meet the requirements below.

a) The inspection body shall be independent of the parties involved.

b) The inspection body and its personnel 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.

NOTE 1 This does not preclude exchanging technical information between the client and the inspection body (e.g. explanation of findings, or clarifying requirements or training).

NOTE 2 This does not preclude the purchase, ownership or use of inspected items that are necessary for the operations of the inspection body, or the purchase, ownership or use of the items for personal purposes by the personnel.

c) 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.

NOTE 1 This does not preclude exchanging technical information between the client and any other part of the same legal entity of which the inspection body is a part (e.g. explanation of findings, or clarifying requirements or training).

NOTE 2 This does not preclude the purchase, ownership, maintenance or use of inspected items that are necessary for the operations of another part of the same legal entity, or for personal purposes by the personnel.

17020 Annex A Normative Requirements

d) 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:

1) common ownership, except where the owners have no ability to influence the outcome of an inspection;

EXAMPLE 1 A cooperative type of structure where there are large numbers of stakeholders, but they (individually or as a group) have no ability to influence the outcome of an inspection.

EXAMPLE 2 A holding company consisting of several separate legal entities (sister companies) under a common mother company, where neither the sister companies nor the mother company can influence the outcome of an inspection.

2) 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;

EXAMPLE A bank financing a company insists on an appointee to the board who will overview how the company is managed but will not be involved in any decision-making.

3) directly reporting to the same higher level of management, except where this cannot influence the outcome of an inspection;

NOTE Reporting to the same higher level of management is permitted on matters other than design, manufacture, supply, installation, purchase, ownership, use or maintenance of the items inspected.

4) contractual commitments, or other means that may have an ability to influence the outcome of an inspection.

Annex A

Aa Annex A.1 and A.2 of ISO/IEC 17020 refer to the phrase “items inspected with respect to Type A and Type B inspection bodies. In Annex A.1 b it is stated that “In particular they shall not be engaged in the design, manufacture, supply, installation, purchase, ownership, use or maintenance of the items inspected”. In Annex A.2 c it is stated that “In particular they shall not be engaged in the design, manufacture, supply, installation, use or maintenance of the items inspected”. The reference to “they” in the above sentences is a reference to the inspection body concerned and its personnel. The items in this case are those items that are specified in the accreditation body’s certificate/annex with respect to the accredited scope of the inspection body (e.g. pressure vessels).

Ab Within sub clause d), reference is made to linkages to separate legal entities engaged in the design, manufacture, supply, installation, purchase, ownership, use or maintenance of the items inspected. Such linkages include common owners and common owners’ appointees on boards or equivalent. These linkages are acceptable if persons involved do not have the possibility to influence the outcome of an inspection. In particular there exists a possibility to influence the outcome of an inspection if the person has the ability to;

- influence the selection of inspectors for specific assignments or customers, or
- influence decisions on conformity in specific inspection assignments, or
- influence remuneration for individual inspectors, or
- influence remuneration for specific assignments or customers, or
- initiate the use of alternative work practices for specific assignments.

2.5.2 Type B Inspection Body

From 17020, Clause 4.1.6 b) *An inspection body providing first party inspections, second party inspections, or both, which forms a separate and identifiable part of an organization involved in the design, manufacture, supply, installation, use or maintenance of the items it inspects and which supplies inspection services only to its parent organization (in-house inspection body) shall meet the type B requirements of Clause A.2.*

The IB which forms a separate and identifiable part of an organization involved in the design, manufacture, supply, installation, use or maintenance of the items it inspects and has been established to supply inspection services to its parent organization shall meet the following criteria from annex A (normative).

- A clear separation of the responsibilities of the inspection personnel from those of the personnel employed in the other functions shall be established by organizational identification and the reporting methods of the IB within the parent organization.

- The IB and its staff shall not engage in any activities that may conflict with their independence of judgement and integrity in relation to their inspection activities. In particular they shall not become directly involved in the design, manufacture, supply, installation, use or maintenance of the items inspected, or similar competitive items.

- **Inspection services shall only be supplied to the organization of which the IB forms a part.**

The two characteristics by which IBs can be identified as Type B IBs are the following:

- Type B IBs form a demonstrably separate and identifiable part of an organisation that is involved in the design, manufacture, supply, installation, use or maintenance of items that they inspect;

- **Type B IBs supply inspection services only to their parent organisation**. A Type B IB may form a part of a user organisation or of a supplier organisation.

When a Type B IB that forms a part of a supplier organization inspects items that are manufactured by or for its parent organisation and are to be supplied to the market or to any other party, it carries out **first party inspection**.

When a Type B IB that forms a part of a user organization inspects items to be supplied for use by its parent organisation by a supplier organisation that is not its parent organisation and not related to it, it carries out **second party inspection**.

17020 Annex A Normative Requirements
A.2 Requirements for inspection bodies (Type B) The inspection body referred to in 4.1.6 b) shall meet the requirements below. a) Inspection services shall only be supplied to the organization of which the inspection body forms a part. b) A clear separation of the responsibilities of the inspection personnel from those of the personnel employed in the other functions shall be established by organizational identification and the reporting methods of the inspection body within the parent organization. c) The inspection body and its personnel 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, use or maintenance of the items inspected. **NOTE 1** This does not preclude exchanging technical information between the inspection body and the other parts of the organization of which the inspection body forms a part, e.g. explanation of findings or clarifying requirements or training. **NOTE 2** This does not preclude the purchase, ownership or use of inspected items that are necessary for the operations of the inspection body, or the purchase, ownership or use of the items for personal purposes by the personnel.

2.5.3 Type C Inspection Body

From 17020, Clause 4.1.6 c), *An inspection body providing first party inspections, second party inspections, or both, which forms an identifiable but not necessarily a separate part of an organization involved in the design, manufacture, supply, installation, use or maintenance of the items it inspects and which supplies inspection services to its parent organization or to other parties, or to both, shall meet the type C requirements of Clause A.3.*

The IB which is involved in the design, manufacture, supply, installation, use or maintenance of the items it inspects or of similar competitive items and may supply inspection services to other parties not being its parent organization shall meet the following criteria from annex A (normative).

The IB shall provide safeguards within the organization to ensure adequate segregation of responsibilities and accountabilities in the provision of inspection services by organization and/or Type C inspection bodies are involved, in the design, manufacture, supply, installation, use or maintenance of items that they inspect. Inspections carried out by them may include first party inspections and second party inspections of the same type as carried out by Type B bodies. However, Type C inspection bodies are distinct from Type B inspection bodies for the following reasons:

- **A Type C IB need not be a separate part**, but shall be identifiable within the organisation. A Type C body may itself be the designer, manufacturer, supplier, installer, user or maintainer of items that it inspects.
- **A Type C IB may offer its inspection service on the open market or to any other party** and supply inspection service to external organisations. For example, it may inspect products supplied by it or by its parent organisation and used by another organisation. It may also supply other organisations with inspection of items that are similar to those designed, manufactured, supplied, installed, used or maintained by it or by its parent organisation, and which may therefore be regarded as competitive.

Inspections carried out by Type C inspection bodies cannot be classified as third party inspections because they do not meet the requirements of independence of operations as stipulated for Type A inspection bodies in Annex A of ISO/IEC 17020. Type C inspection bodies may conform to some of the criteria concerning independence of other economic operators, non-involvement in 'conflicting" activities and non-discriminatory operations that characterise Type A and Type B inspection bodies. Yet they remain Type C inspection bodies as long as they do not meet all of the requirements applicable to Type A or Type B inspection bodies.

- The design/manufacture/supply/installation/servicing/maintenance and the inspection of an entity carried out by a Type C IB should not be undertaken by the same person. An exception to this is where a regulatory or other authoritative requirement explicitly allows an individual person from a Type C IB to undertake multiple parts of the design, manufacture, supply, installation, servicing, maintenance, and the inspection the object of conformity using documented procedures.

17020 Annex A Normative Requirements
A.3 Requirements for inspection bodies (Type C) The inspection body referred to in 4.1.6 c) shall meet the requirements below. a) The inspection body shall provide safeguards within the organization to ensure adequate segregation of responsibilities and accountabilities between inspection and other activities. b) The design/manufacture/supply/installation/servicing/maintenance and the inspection of the same item carried out by a Type C inspection body shall not be undertaken by the same person. An exception to this is where a regulatory requirement explicitly allows an individual person from a Type C inspection body 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. **NOTE** Inspections carried out by Type C inspection bodies cannot be classified as third party inspections for the same inspection activities because they do not meet the requirements of independence of operations for Type A inspection bodies.

2.5.4 Structured for Impartiality

From 17020 Clause 5.2.1, *The IB shall be structured and managed so as to safeguard impartiality.*

ISO/IEC 17020 References	ILAC P15 Interpretation
5.1.2 An inspection body that is part of a legal entity involved in activities other than inspection shall be identifiable within that entity.	**No interpretation for this part, but it facilitates the determination of Type A or B or C discussed above.**
6.1.11 The personnel involved in inspection activities shall not be remunerated in a way that influences the results of inspections.	**6.1.11a** Remuneration methods that provide incentives to perform inspections quickly have the potential to negatively affect the quality and outcome of inspection work.
6.1.12 All personnel of the IB, either internal or external, that could influence the inspection activities shall act impartially.	**6.1.12a** Policies and procedures should assist inspection body personnel in identifying and addressing commercial, financial or other threats or inducements which could affect their impartiality, whether they originate inside or outside the inspection body. Such procedures should address how any conflicts of interests identified by personnel of the inspection body are reported and recorded. Note, however, that while expectations for inspector integrity can be communicated by policies and procedures, the existence of such documents may not signal the presence of integrity and impartiality required by this clause.
6.1.13 All personnel of the IB, including sub-contractors, personnel of external bodies, and individuals acting on the IB's behalf, shall keep confidential all information obtained or created during the performance of the inspection activities, except as required by law.	**No interpretation for this part.**

Chapter 3 – Organizational Requirements

3.1 Learning Objectives

Upon completion of this chapter, you should be able to:

- **understand** the requirements in ISO/IEC 17020 for an organization to operate as an IB.

3.2 Completing the Chapter

Consider the following questions. Discuss your findings and those of others in your group. This can be done by seeking clarification of others, providing support to others where required and challenging responses when necessary.

Discussion Activity 3.1

How can an IB document the impact of its relationships on the impartiality of its inspections?

Discussion Activity 3.2

Who are the stakeholders to consult in determining the scope of an inspection for a regulatory inspection scheme?

3.3 Detailed Organisation Requirements

ISO/IEC 17020 References	ILAC P15 Interpretation
5.1 Administrative requirement **5.1.1** The IB, or the organization of which it forms a part, shall be legally identifiable entity. **5.1.5** An IB that is part of an organization involved in functions other than inspection shall be identifiable within that organization.	**No interpretation for these clauses.**
5.1.3 The IB shall have documentation which describes its functions and the technical scope of activity for which it is competent.	**5.1.3a** The inspection body should describe its activities by defining the general field and range of inspection (e.g. categories/sub-categories of products, processes, services or installations) and the stage of inspection, (see note to clause 1 of the standard) and, where applicable, the regulations, standards or specifications containing the requirements against which the inspection will be performed.
5.1.4 The IB shall have adequate provision (e.g. insurance or reserves) to cover liabilities arising from its operations.	**5.1.4a** The level of provisions should be commensurate with the level and nature of liabilities that may arise from the inspection body's operations.

ISO/IEC 17020 References	ILAC P15 Interpretation
5.2 Organization and management **5.2.2** The IB shall be organized and managed so as to enable it to maintain the capability to perform its inspection activities. NOTE Inspection schemes can require that the IB participate in the exchange of technical experience with other inspection bodies in order to maintain this capability. The IB shall have an organization that enables it to maintain the capability to perform its technical functions satisfactorily.	**5.2.2a** The size, structure, composition and management of an inspection body, taken together, shall be suitable for the competent performance of the activities within the scope for which the inspection body is accredited. **5.2.2b** "To maintain the capability to perform the inspection activities" implies that the inspection body shall take steps to keep it appropriately informed about applicable technical and/or legislative developments concerning its activities. **5.2.2c** Inspection bodies shall maintain their capability and competence to carry out inspection activities performed infrequently (normally with intervals longer than one year). An inspection body may demonstrate its capability and competence for inspection activities performed infrequently through 'dummy inspections' and/or through inspection activities conducted on similar products.
5.2.3 The IB shall define and document the responsibilities and reporting structure of the organization.	**5.2.3a** The inspection body shall maintain an up-to-date organisational chart or documents clearly indicating the functions and lines of authority for staff within the inspection body. The position of the technical manager(s) and the member of management referenced in clause 8.2.3 should be clearly shown in the chart or documents.
5.2.4 Where the IB forms a part of a legal entity performing other activities, the relationship between these other activities and inspection activities shall be defined.	**5.2.4a** It may be relevant to provide information concerning personnel which carry out work tasks for both the inspection body and for other units and departments.
5.2.5 The IB shall have available one or more person(s) as technical manager(s) who have overall responsibility to ensure that the inspection activities are carried out in accordance with this International Standard. NOTE This person fulfilling this function does not always have the title of technical manager. The person(s) fulfilling this function shall be technically competent and experienced in the operation of the IB. Where the IB has more than one technical manager, the specific responsibilities of each manager shall be defined and documented.	**5.2.5a** In order to be considered as "available", the person shall be either employed or otherwise contracted. **5.2.5b** In order to ensure that the inspection activities are carried out in accordance with ISO/IEC 17020, the technical manager(s) and any deputy(ies), shall have the technical competence necessary to understand all significant issues involved in the performance of inspection activities.
5.2.6 The IB shall have named persons who will deputize in the absence of any manager, however named, responsible for inspection services.	**5.2.6a** In an organization where the absence of a key person causes the cessation of work, the requirement for having deputies is not applicable.

ISO/IEC 17020 References	ILAC P15 Interpretation
5.2.7 The IB shall have a job description or other documentation for each position category within its organization involved in inspection activities.	**5.2.7a** The position categories involved in inspection activities are inspectors and other positions which could have an effect on the management, performance, recording or reporting of inspections. **5.2.7b** The job description or other documentation shall detail the duties, responsibilities and authorities for each position category referred to in 5.2.7a.

Chapter 4 – Infrastructure Requirements

4.1 Learning Objectives

Upon completion of this chapter, you should be able to:

- **understand** the requirements for competence of all persons involved in the inspection process, and
- **understand** the facilities and equipment requirements for inspection.

4.2 Completing the Chapter

Consider the following questions. Discuss your findings and those of others in your group. This can be done by seeking clarification of others, providing support to others where required and challenging responses when necessary.

Discussion Activity 4.1

What are the competence requirements of people involved in inspection processes?

Discussion Activity 4.2

What are the facility requirements in ISO/IEC 17020?

Discussion Activity 4.3

What are the traceability requirements contained in ISO/IEC 17020?

Discussion Activity 4.4

How does an IB ensure the competence of subcontractors?

4.3 Detailed People Requirements

4.3.1 General

ISO/IEC 17020 References	ILAC P15 Interpretation
6.1 Personnel 6.1.1 The IB shall define and document the competence requirements for all personnel involved in inspection activities, including requirements for education, training, technical knowledge, skills and experience. NOTE The competence requirements can be part of the job description or other documentation mentioned in 5.2.7.	**6.1.1a** Where appropriate, inspection bodies shall define and document competence requirements for each inspection activity, as described in 5.1.3a. **6.1.1b** For "personnel involved in inspection activities", see 5.2.7a. **6.1.1c** Competence requirements should include knowledge of the inspection body's management system and ability to implement administrative as well as technical procedures applicable to the activities performed. **6.1.1d** When professional judgment is needed to determine conformity, this shall be considered when defining competence requirements.
6.1.2 The IB shall employ, or have contracts with, a sufficient number of persons with the required competencies, including, where needed, the ability to make professional judgements, to perform the type, range and volume of its inspection activities.	**6.1.2a** All requirements of ISO/IEC 17020 apply equally for both employed and contracted persons.
6.1.3 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. **6.1.4** The IB shall make clear to each person their duties, responsibilities and authorities.	**No interpretation for these clauses.**

ISO/IEC 17020 References	ILAC P15 Interpretation
6.1.5 The IB shall have documented procedures for the selecting, training, formally authorizing, and monitoring inspectors and other personnel involved in the inspection activities.	**6.1.5a** The procedure for formally authorising inspectors should specify that the relevant details are documented, e.g. the authorised inspection activity, the beginning of the authorisation, the identity of the person who performed the authorisation and, where appropriate, the termination date of the authorisation.
6.1.6 The documented procedures for training (see 6.1.5) shall address the following stages: a) an induction period; b) a mentored working period with experienced inspectors; c) continuing training to keep pace with developing technology and inspection methods.	**6.1.6a** The "mentored working period" mentioned in item b normally includes activities where inspections are performed.
6.1.7 The training required shall depend upon the ability, qualifications and experience of each inspector and other personnel involved in inspection activities, and upon the results of monitoring (see 6.1.8).	**6.1.7a** Identification of training needs for each person should take place at regular intervals. The interval should be selected to ensure fulfilment of clause 6.1.6 item c. The results of the review of training, e.g. plans for further training or a statement that no further training is required, should be documented.
6.1.8 Personnel familiar with the inspection methods and procedures shall monitor all inspectors and other personnel involved in inspection activities for satisfactory performance. Results of monitoring shall be used as a means of identifying training needs NOTE Monitoring can include a combination of techniques, such as on-site observations, report reviews, interviews, simulated inspections and other techniques to assess performance, and will depend on the nature of inspection activities.	**6.1.8a** A major aim of the monitoring requirement is to provide the inspection body with a tool to ensure the consistency and reliability of inspection outcomes, including any professional judgments against general criteria. Monitoring may result in the identification of needs for individual training or needs for review of the inspection body's management system. **6.1.8b** For "other personnel involved in inspection activities," see 5.2.7a.

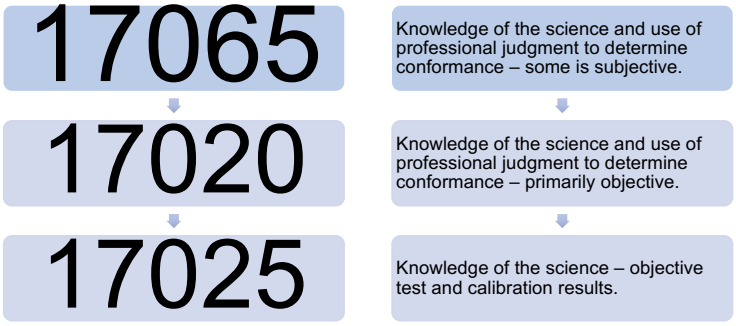
4.3.2 Monitoring Inspectors

ISO/IEC 17020 References	ILAC P15 Interpretation
6.1.9 Each inspector shall be observed on-site, unless there is sufficient supporting evidence that the inspector is continuing to perform competently. NOTE It is expected that on-site observations are performed in a way that minimizes the disturbance of the inspections, especially from the client's viewpoint.	**6.1.9a** To be considered sufficient, the evidence that the inspector is continuing to perform competently should be substantiated by a combination of information such as; • satisfactory performance of examinations and determinations, • positive outcome of report reviews, interviews, simulated inspections and other performance assessments (see note to clause 6.1.8), • positive outcome of separate evaluations to confirm the outcome of the inspections (this may be possible and appropriate in the case of e.g. the inspection of construction documentation), • positive outcome of mentoring and training, • absence of legitimate appeals or complaints, and • satisfactory results of witnessing by a competent body, e.g. a certification body for persons. **6.1.9b** An effective program for the on-site observation of inspectors may contribute to fulfil the requirements in clauses 5.2.2 and 6.1.3. The program should be designed considering; • the risks and complexities of the inspections, • results of previous monitoring activities, and • technical, procedural or legislative developments relevant to the inspections. The frequency of on-site observations depends on the issues listed above, but should be at least once during the accreditation re-assessment cycle, however see application note 6.1.9a. If the levels of risks or complexities, or the results from previous observations, so indicate, or if technical, procedural or legislative changes have occurred, then a higher frequency should be considered. Depending on the fields, types and ranges of inspection covered by the inspector's authorisations, there may be more than one observation per inspector necessary to adequately cover the whole range of required competencies. Also, more frequent on-site observations may be necessary if there is lack of evidence of continuing satisfactory performance. **6.1.9c** In inspection areas where the inspection body has only one technically competent person the internal observation on-site cannot take place. In such cases the inspection body shall have arrangements in place for external observations on-site, unless other sufficient supporting evidence that the inspector is continuing to perform competently is available (see 6.1.9a).

ISO/IEC 17020 References	ILAC P15 Interpretation
6.1.10 The IB shall maintain records of monitoring, education, training, technical knowledge, skills, experience and authorization of each member of its personnel involved in inspection activities.	**6.1.10a** Records of authorisation should specify the basis on which authorisation was granted (e.g. the on-site observation of inspections).

4.4 Acquisition of External Competence

From understanding the hierarchy of standards involved in the inspection of product design, product, service, process or plant, it is easy to appreciate the importance of competence in the production of the inspection reports, and the test and/or calibration certificates that support accredited inspection.



Most specifiers, whether or not their program conforms to other international requirements, rely on IBs to make use of accredited organisations for testing and calibration.

4.5 Detailed Subcontracting Requirements

ISO/IEC 17020 References	ILAC P15 Interpretation
6.3 Subcontracting **6.3.1** The IB shall itself normally perform the inspections that it contracts to undertake. Where an IB subcontracts any part of the inspection, it shall ensure and be able to demonstrate that the subcontractor is competent to perform the activities in question and, where applicable, complies with the relevant requirements stipulated in this International Standard or in other relevant conformity assessment standards. NOTE 1 Reasons to subcontract can include the following: • an unforeseen or abnormal overload; • key inspection staff members being incapacitated; • key facilities or items of equipment being temporarily unfit for use; • part of the contract from the client involving inspection not covered by the IB's scope or being beyond the capability or resources of the IB. NOTE 2 The terms “subcontracting” and “outsourcing” are considered to be synonyms. NOTE 3 Where the IB engages individuals or employees of other organizations to provide additional resources or expertise, these individuals are not considered to be subcontractors provided they are formally contracted to operate under the IB's management system (see 6.1.2).	**6.3.1a** Inspection activities can overlap with testing and certification activities where these activities have common characteristics (See Introduction of ISO/IEC 17020). For example, examination of a product and testing of the same product can both be the basis for the determination of conformity in an inspection process. It should be noted that ISO/IEC 17020 specifies requirements for bodies performing inspection, whereas the relevant standard to apply for bodies performing testing is ISO/IEC 17025 or ISO 15189. **6.3.1b** By definition (ISO/IEC 17011, clause 3.1), accreditation is limited to conformity assessment tasks which the inspection body has demonstrated competence to perform itself. Thus, accreditation cannot be granted for activities referred to in the fourth bullet point under note 1, if the inspection body does not have the required competence and/or resources. However, the task of assessing and interpreting the results of such activities for the purpose of determining conformity may be included in the scope of accreditation, provided adequate competence for this has been demonstrated.
6.3.2 The IB shall inform the client of its intention to subcontract any part of the inspection.	**No interpretation for these clauses.**
6.3.3 Whenever subcontractors carry out work that forms part of an inspection, the responsibility for any determination of conformity of the inspected item with the requirements shall remain with the IB.	**6.3.3a** In Note 2 to the definition of “inspection” in clause 3.1 it is indicated that in some cases inspection may be examination only, without a subsequent determination of conformity. In such cases clause 6.3.3 does not apply since there is **no determination of conformity**.
6.3.4 The IB shall record and retain details of its investigation of the competence of its subcontractors and of their conformity with the applicable requirements of this International Standard or in other relevant conformity assessment standards. The IB shall maintain a register of all subcontractors.	**6.3.4a** If the evaluation of the competence of the subcontractor is based partly or in full on its accreditation, the inspection body shall ensure that the scope of the subcontractor’s accreditation covers the activities to be sub-contracted.

4.6 Detailed Physical Requirements for Inspection

ISO/IEC 17020 References	ILAC P15 Interpretation
6.2 Facilities and equipment **6.2.1** The IB shall have available to it suitable and adequate facilities and equipment to permit all activities associated with the inspection services to be carried out. NOTE The IB need not be the owner of the facilities or equipment that it uses. Facilities and equipment can be borrowed, rented, hired, leased or provided by another party (e.g. the manufacturer or installer of the equipment). However, the responsibility for the suitability and the calibration status of the equipment used in inspection, whether owned by the IB or not, lies solely with the IB.	**6.2.1a** Equipment required to carry out inspection in a safe manner may include e.g. personal protective equipment and scaffolding.
6.2.2 The IB shall have clear rules for the access to and the use of specified facilities and equipment.	**No interpretation for this clause.**
6.2.3 The IB shall ensure the continued suitability of the facilities and the equipment mentioned in 6.2.1 for their intended use.	**6.2.3a** If controlled environmental conditions are needed, e.g. For the correct Performance of the inspection, the inspection body shall monitor these and Record the results. If conditions were outside acceptable limits for the Inspection to be performed, the inspection body shall record what action was Taken. See also clause 8.7.4. **6.2.3b** Continued suitability may be established by visual inspection, functional checks and/or re-calibration. This requirement is particularly relevant for equipment that has left the direct control of the inspection body.

ISO/IEC 17020 References	ILAC P15 Interpretation
6.2.4 All equipment having a significant influence on the results of the inspection shall be defined and, where appropriate, uniquely identified.	**6.2.4a** In order to enable tracking when items are replaced, the unique identification of an item of equipment may be appropriate even when there is only one item available. **6.2.4b** When controlled environmental conditions are needed, the equipment used to monitor such conditions should be considered as equipment that significantly influences the result of inspections. **6.2.4c** When appropriate (normally for the equipment covered by clause 6.2.6) the definition shall include the required accuracy and measurement range.
6.2.5 All equipment (see 6.2.4) shall be maintained in accordance with documented procedures and instructions.	**No interpretation for this clause.**
6.2.6 Where appropriate, measurement equipment having a significant influence on the results of the inspection shall be calibrated before being put into service, and thereafter calibrated according to an established programme.	**6.2.6a** The justification for not calibrating equipment that has a significant influence on the outcome of inspection (see clause 6.2.4) should be recorded. **6.2.6b** Guidelines on how to determine calibration intervals can be found in ILAC G24.
6.2.7 The overall programme of calibration of equipment shall be designed and operated so as to ensure that wherever applicable measurements made by the IB are traceable to national and International Standards of measurement where available. Where traceability to national or International Standards of measurement is not applicable, the IB shall provide satisfactory evidence of correlation or accuracy of inspection results.	**6.2.7a** According to ILAC P10 it is possible to perform in-house calibration of equipment used for measurements. It is a requirement for accreditation bodies to have a policy to ensure that such in-house calibration services are performed in accordance with the relevant criteria for metrological traceability in ISO/IEC 17025. **6.2.7b** According to ILAC P10 the preferred routes for conformity assessment bodies who seek external services for calibration of their equipment are defined in subsections 1) and 2) of section 2 in ILAC P10. If however, it is not possible to comply with these two routes for any justifiable reason, then it is acceptable to use the routes 3a) or 3b) of section 2 of ILAC P10. It is a requirement for accreditation bodies to have a policy to ensure that such external calibration services meet the relevant criteria for metrological traceability in ISO/IEC 17025. **6.2.7c** 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.
6.2.8 Reference standards of measurement held by the IBs hall be used for calibration only and for no other purpose. Reference standards of measurement shall be calibrated by a competent body that can provide traceability to a national or International Standard of measurement.	**6.2.8a** When inspection bodies use reference standards of measurement to calibrate working instruments the reference standards of measurement should have a higher degree of accuracy than that required of the working instruments they are used to calibrate.

ISO/IEC 17020 References	ILAC P15 Interpretation
6.2.9 Where relevant, equipment shall be subjected to in-service checks between regular recalibrations.	**6.2.9a** Where equipment is subjected to in-service checks between regular recalibrations, the nature of such checks, the frequency and acceptance criteria should be defined.
6.2.10 Reference materials shall where possible be traceable to national or International Standard reference materials.	**6.2.10a** The information provided in 6.2.7a, 6.2.7b and 6.2.7c for programs of calibration of equipment is valid also for programs of calibration of reference materials.
6.2.11 Where relevant to the quality of inspection services, the IB shall have procedures for: a) selection of qualified suppliers; b) verification of incoming goods and services; **c)** ensuring appropriate storage facilities.	**6.2.11a** When the inspection body engages suppliers to perform activities which do not include the performance of part of the inspection, but which are relevant for the outcome of inspection activities, e.g. order registration, archiving, delivery of auxiliary services during an inspection, the editing of inspection reports or calibration services, such activities are covered by the term “services” used in this clause. **6.2.11b** The verification procedure should ensure that incoming goods and services are not used until conformance with specification has been verified.
6.2.12 Where applicable the condition of stored items shall be assessed at appropriate intervals to detect deterioration.	**No interpretation for this clause.**
6.2.13 If the IB uses computers or automated equipment in connection with inspections, it shall ensure that: a) computer software is validated and adequate for use; b) procedures are established and implemented for protecting the integrity and security of data, and c) computer and automated equipment is maintained in order to ensure proper functioning.	**6.2.13a** Factors that should be considered in protecting the integrity and security of data include; - backup practices and frequencies, - effectiveness in restoring data from backup, - virus protection, and - password protection.
6.2.14 The IB shall have documented procedures for dealing with defective equipment. Defective equipment shall be removed from service by segregation, prominent labelling or marking. The IB shall examine the effect of defects on previous inspections.	**No interpretation for this clause.**

ISO/IEC 17020 References	ILAC P15 Interpretation
6.2.15 Relevant information on the equipment shall be recorded. This will normally include identification, calibration and maintenance.	**No interpretation for this clause.**

Chapter 5 – Inspection Process Requirements

5.1 Learning Objectives

Upon completion of this chapter, you should be able to:

- **understand** inspection processes, and
- **appreciate** the contribution of testing and calibration to support inspection processes;
- **understand** the components of the inspection decision;
- **understand** the requirements for protection of marks/stamps/certificates of inspection, and
- **understand** the requirements for changes to inspection

5.2 Completing the Chapter

Consider the following questions. Discuss your findings and those of others in your group. This can be done by seeking clarification of others, providing support to others where required and challenging responses when necessary.

Discussion Activity 5.1

What are the three steps in Inspection?

Discussion Activity 5.2

What are the requirements for inspection imposed by IAF-ILAC that are over an above those contained in 17020?

Discussion Activity 5.3

Are there any differences in inspection requirements if a product is being resubmitted for inspection following an initial failure to meet the requirements of the inspection scheme? What are they?

Discussion Activity 5.4

What are the requirements for the protection of the certificate of inspection? Which organization is responsible for enforcing them?

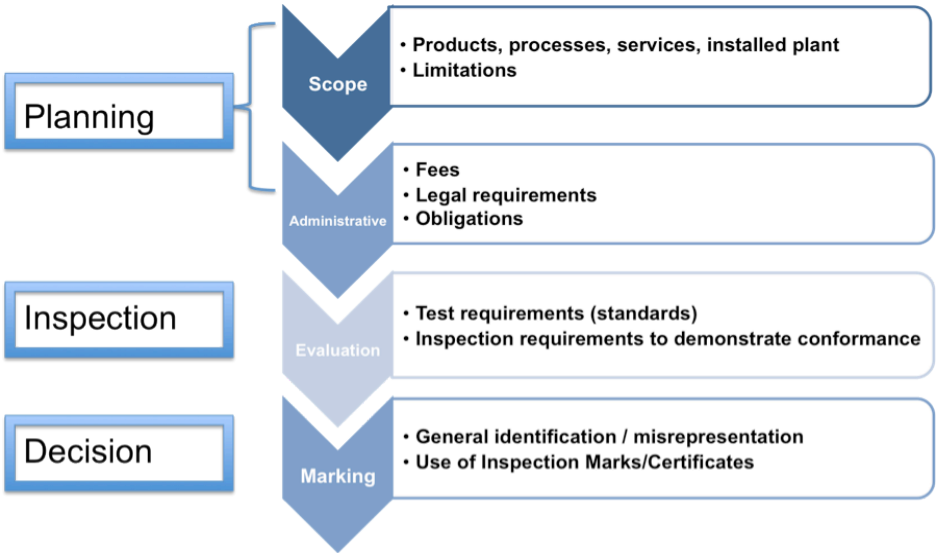
Discussion Activity 5.5

What types of changes can affect the inspection of a design, product, service, process or plant? How are these changes implemented?

Discussion Activity 5.6

What tools are available to allow an IB to suspend or withdraw an inspection certificate?

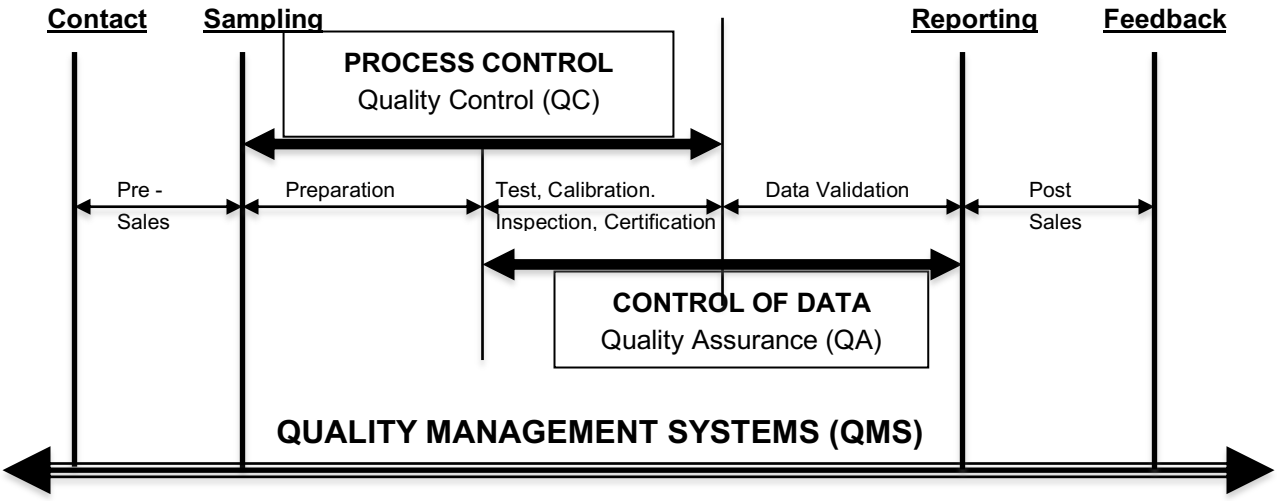
5.3 Processes involved in Inspection



This diagram shows the steps involved in inspection and the type of scheme will have a good deal of influence on the scope and complexity of each of these steps.

5.4 Inspection Body Processes

Inspection bodies inspect for conformance to specification. This activity is defined as a conformity assessment activity within ISO definitions. For all technical conformity assessment bodies, the normal scope of operations can be depicted as follows.



Includes all functions that influence the validity of technical results

- All business operations functions
- All management and administrative functions
- All finance functions
- All HR functions
- All purchasing and contract review functions
- All marketing and communications functions
- All maintenance functions

Quality control activities are aimed at ensuring the technical processes continue to be fit for purpose. Quality assurance activities are aimed at ensuring the results of the technical processes continue to be fit for purpose. A quality management system covers both of these disciplines and the other supporting procedures used to ensure that laboratories produce technically valid results, and that inspection bodies and product certification bodies issue impartial inspections and certifications.

5.5 Detailed Inspection Method Requirements

ISO/IEC 17020 References	ILAC P15 Interpretation
7.1 Inspection methods and procedures **7.1.1** The IB shall use the methods and procedures for inspection which are defined in the requirements against which inspection is to be performed. Where these are not defined, the IB shall develop specific methods and procedures to be used (see 7.1.3). The IB shall inform the client if the inspection method proposed by the client is considered to be inappropriate. NOTE The requirements against which the inspection is performed are normally specified in regulations, standards or specifications, inspection schemes or contracts. Specifications can include client or in-house requirements.	**No interpretation for this clause.**
7.1.2 The IB shall have and shall use 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. Where applicable, the IB shall have sufficient knowledge of statistical techniques to ensure statistically sound sampling procedures and the correct processing and interpretation of results.	**No interpretation for this clause.**
7.1.3 When the IB has to use inspection methods or procedures which are non-standard, such methods and procedures shall be appropriate and fully documented. NOTE 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 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 IB itself or by the client, are considered to be non-standard methods.	**No interpretation for this clause.**

ISO/IEC 17020 References	ILAC P15 Interpretation
7.1.4 All instructions, standards or written procedures, worksheets, check lists and reference data relevant to the work shall be maintained up-to-date and be readily available to the personnel.	**No interpretation for this clause.**
7.1.6 When the IB uses information supplied by any other party as part of the inspection process, it shall verify the integrity of such information.	**7.1.6a** The information referred to in this clause is not information provided by a subcontractor, but information received from other parties, e.g. a regulating authority or the client of the inspection body. The information may include background data for the inspection activity, but not results of the inspection activity.
7.1.7 Observations and/or data obtained in the course of inspections shall be recorded in a timely manner to prevent loss of relevant information.	**No interpretation for this clause.**
7.1.8 All calculations and data transfers shall be subject to appropriate checks. NOTE Data can include textual material, digital data and anything else that is transferred from one location to another where errors could be introduced.	**No interpretation for this clause.**
7.1.9 The IB shall have documented instructions for carrying out inspection safely.	**No interpretation for this clause.**

5.6 Detailed Planning/Workload/Contract Requirements

ISO/IEC 17020 References	ILAC P15 Interpretation
7.1.5 The IB shall have a contract or work order control system which ensures that: a) work to be undertaken is within its expertise and that the organization has adequate resources to meet the requirements; NOTE: Resources can include, but are not limited to, facilities, equipment, reference documentation, procedures or human resources. b) the requirements of those seeking the IB's services are adequately defined and that special conditions are understood, so that unambiguous instructions can be issued to personnel performing the duties to be required; c) work being undertaken is controlled by regular review and corrective action; d) the requirements of the contract or work order have been met.	**7.1.5a** Where appropriate the contract or work order control system should also ensure that; • contract conditions are agreed • personnel competence is adequate • any statutory requirements are identified • safety requirements are identified • the extent of any subcontracting arrangements required is identified For routine or repeat work requests the review may be limited to considerations of time and human resources. An acceptable record in such cases would be an acceptance of the contract signed by an appropriately authorised person. **7.1.5b** In situations where verbal work orders are acceptable, the inspection body shall keep a record of all requests and instructions received verbally. Where appropriate, the relevant dates and the identity of the client's representative should be recorded. **7.1.5c** The contract or work order control system should ensure that there is a clear and demonstrable understanding between the inspection body and its client of the scope of the inspection work to be undertaken by the inspection body.

5.7 Receipt and Handling of Samples

ISO/IEC 17020 References	ILAC P15 Interpretation
7.2 Handling inspection items and samples **7.2.1** The IB shall ensure items and samples to be inspected are uniquely identified in order to avoid confusion regarding the identity of such items and samples. **7.2.2** The IB shall establish whether the item to be inspected has been prepared. **7.2.3** Any apparent abnormalities notified to, or noticed by, the inspector shall be recorded. Where there is any doubt as to the item's suitability for the inspection to be carried out, or where the item does not conform to the description provided, the IB shall contact the client before proceeding. **7.2.4** The IB shall have documented procedures and appropriate facilities to avoid deterioration or damage to inspection items while under its responsibility	**No interpretation for these clauses.**

5.8 Inspection Reporting and Certificate Requirements

ISO/IEC 17020 References	ILAC P15 Interpretation
7.4. Inspection Reports and Certificates **7.4.1** The work carried out by the IB shall be covered by a retrievable inspection report and/or inspection certificate.	**No interpretation for this clause.**
7.4.2 Any inspection report/certificate shall include all of the following: a) identification of the issuing body; b) unique identification and date of issue; c) date(s) of inspection; d) identification of the item(s) inspected; e) signature or other indication of approval, by authorized personnel; f) a statement of conformity where applicable; g) the inspection results, except where detailed in accordance with 7.4.3. NOTE Optional elements that can be included in inspection reports or certificates are listed in Annex B.	**7.4.2a** ILAC P8 requires accreditation bodies to specify rules for the use of accreditation symbols on reports and certificates. It should be noted that for endorsed reports and certificates, that is reports and certificates making reference to accreditation, such rules shall include the requirement that inspection bodies include a clear disclaimer; • when not accredited for services/tests listed on reports and certificates (see full text in section 8.1), and • when reports and certificates include or are based on results from unaccredited subcontractors (see full text in section 9.3).
7.4.3 An IB shall issue an inspection certificate that does not include the inspection results [see 7.4.2 g)] only when the IB can also produce an inspection report containing the inspection results, and when both the inspection certificate and inspection report are traceable to each other.	**No interpretation for this clause.**
7.4.4 All information listed in 7.4.2 shall be reported correctly, accurately, and clearly. Where the inspection report or inspection certificate contains results supplied by subcontractors, these results shall be clearly identified.	**7.4.4a** It may be useful to identify the inspection method in the inspection report/certificate when this information supports an appropriate interpretation of the inspection results.
7.4.5 Corrections or additions to an inspection report or inspection certificate after issue shall be recorded and justified in accordance with the relevant requirements of this section.	**No interpretation for this clause.**

Chapter 6 – Management System Requirements

6.1 Learning Objectives

Upon completion of this chapter, you should be able to:

- **identify** the standard management system requirements for inspection bodies;

6.2 Completing the Chapter

Consider the following questions. Discuss your findings and those of others in your group. This can be done by seeking clarification of others, providing support to others where required and challenging responses when necessary.

Discussion Activity 6.1

Why are IBs required to deal with appeals when laboratories do not have such a requirement?

Discussion Activity 6.2

What are the continual improvement requirements in 17020?

Discussion Activity 6.3

How often is an IB required to conduct an internal audit? A management review?

6.3 Detailed Management System Requirements

ISO/IEC 17020 References	ILAC P15 Interpretation
8.1.1 General The IB shall establish and maintain a management system that is capable of achieving the consistent fulfilment of the requirements of this International Standard in accordance with either Option A or Option B.	**No interpretation for this clause.**
8.1.2 Option A The management system of the IB shall address the following: • management system documentation (e.g. manual, policies, definition of responsibilities, see 8.2); • control of documents (see 8.3); • control of records (see 8.4); • management review (see 8.5); • internal audit (see 8.6); • corrective actions (see 8.7); • preventive actions (see 8.8); • complaints and appeals (see 7.5 and 7.6).	**No interpretation for this clause.**

ISO/IEC 17020 References	ILAC P15 Interpretation
8.1.3 Option B An IB that has established and maintains a management system, in accordance with the requirements of ISO 9001, and that is capable of supporting and demonstrating the consistent fulfillment of the requirements of this International Standard, fulfils the management system clause requirements (see 8.2 to 8.8)	**8.1.3a** The expression “this International Standard” is a reference to ISO/IEC 17020. **8.1.3b** Option B does not require that the inspection body's management system is certified to ISO 9001. However, when determining the extent of required assessment, the accreditation body should take into consideration whether the inspection body has been certified against ISO 9001 by a certification body accredited by an accreditation body which is a signatory to the IAF MLA, or to a regional MLA, for the certification of management systems.
8.2 Management system documentation (Option A) **8.2.1** The IB's top management shall establish, document, and maintain policies and objectives for fulfilment of this International Standard and shall ensure the policies and objectives are acknowledged and implemented at all levels of the IB's organization.	**No interpretation for this clause.**
8.2.2 The top management shall provide evidence of its commitment to the development and system and its effectiveness in achieving consistent fulfilment of this International Standard.	**No interpretation for this clause.**
8.2.3 The IB’s top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that include the following: a) ensuring that processes and procedures needed for the management system are established, implemented and maintained; and b) reporting to top management on the performance of the management system and any need for improvement.	**No interpretation for this clause.**
8.2.4 All documentation, processes, systems, records, etc. related to the fulfilment of the requirements of this International Standard shall be included, referenced, or linked to documentation of the management system.	**8.2.4a** For easy reference, it is recommended that the inspection body indicates where the requirements of ISO/IEC 17020 are addressed, e.g., by means of a cross reference table.

ISO/IEC 17020 References	ILAC P15 Interpretation
8.2.5 All personnel involved in inspection activities shall have access to the parts of the management system documentation and related information that are applicable to their responsibilities.	**No interpretation for this clause.**

6.4 Detailed Requirements for Document Control and Control of Records

ISO/IEC 17020 References	ILAC P15 Interpretation
8.3 Control of documents (Option A) **8.3.1** The IB shall establish procedures to control the documents (internal and external) that relate to the fulfilment of this International Standard.	**No interpretation for this clause.**
8.3.2 The procedures shall define the controls needed to: a) approve documents for adequacy prior to issue; b) review and update (as necessary) and re-approve documents; c) ensure that changes and the current revision status of documents are identified; d) ensure that relevant versions of applicable documents are available at points of use; e) ensure that documents remain legible and readily identifiable; f) ensure that documents of external origin are identified and their distribution controlled; g) prevent the unintended use of obsolete documents, and apply suitable identification to them if they are retained for any purpose. NOTE Documentation can be in any form or type of medium, and includes proprietary and in-house developed software.	**No interpretation for this clause.**
8.4 Control of records (Option A) **8.4.1** The IB shall establish procedures to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of its records related to the fulfilment of this International Standard. **8.4.2** The IB shall establish procedures for retaining records for a period consistent with its contractual and legal obligations. Access to these records shall be consistent with the confidentiality arrangements.	**8.4.1a** This requirement means that all records needed to demonstrate compliance with the requirements of the standard shall be established and retained. **8.4.1b** In cases where electronic seals or authorizations are used for approvals, access to the electronic media or seal should be secure and controlled.
7.3 Inspection Records **7.3.1** The IB shall maintain a record system (see 8.4) to demonstrate the effective fulfilment of the inspection procedures and to enable an evaluation of the inspection.	**7.3.1a** The records should indicate which particular item of equipment, having a significant influence on the result of the inspection, has been used for each inspection activity.
7.3.2 The inspection report or certificate shall be internally traceable to the inspector(s) who performed the inspection.	**No interpretation for this clause.**

6.5 Detailed Requirements for Continual Improvement

ISO/IEC 17020 References	ILAC P15 Interpretation
8.7 Corrective actions (Option A) **8.7.1** The IB shall establish procedures for identification and management of nonconformities in its operations. **8.7.2** The IB shall also, where necessary, take actions to eliminate the causes of nonconformities in order to prevent recurrence. **8.7.3** Corrective actions shall be appropriate to the impact of the problems encountered. **8.7.4** The procedures shall define requirements for the following: a) identifying nonconformities; b) determining the causes of nonconformity; c) correcting nonconformities; d) evaluating the need for actions to ensure that nonconformities do not recur; e) determining the actions needed and implementing them in a timely manner; f) recording the results of actions taken; g) reviewing the effectiveness of corrective actions.	**No interpretation for this clause.**
8.8 Preventive actions (Option A) **8.8.1** The IB shall establish procedures for taking preventive actions to eliminate the causes of potential nonconformities. **8.8.2** Preventive actions taken shall be appropriate to the probable impact of the potential problems. **8.8.3** The procedures for preventive actions shall define requirements for the following: a) identifying potential nonconformities and their causes; b) evaluating the need for action to prevent the occurrence of nonconformities; c) determining and implementing the action needed; d) recording the results of actions taken; e) reviewing the effectiveness of the preventive actions taken. **NOTE** The procedures for corrective and preventive actions do not necessarily have to be separate.	**8.8.1a** Preventive actions are taken in a pro-active process of identifying potential nonconformities and opportunities for improvement rather than as a reaction to the identification of non-conformities, problems or complaints.

6.6 Detailed Requirements for Feedback (& Complaints)

ISO/IEC 17020 References	ILAC P15 Interpretation
7.5 Complaints and appeals **7.5.1** The IB shall have a documented process to receive, evaluate and make decisions on complaints and appeals.	**No interpretation for this clause.**

ISO/IEC 17020 References	ILAC P15 Interpretation
7.5.2 A description of the handling process for complaints and appeals shall be available to any interested party upon request.	**No interpretation for this clause.**
7.5.3 Upon receipt of a complaint, the IB shall confirm whether the complaint relates to inspection activities for which it is responsible and, if so, shall deal with it.	**No interpretation for this clause.**
7.5.4 The IB shall be responsible for all decisions at all levels of the handling process for complaints and appeals.	**No interpretation for this clause.**
7.5.5 Investigation and decision on appeals shall not result in any discriminatory actions.	**No interpretation for this clause.**
7.6 Complaints and appeals process **7.6.1** The handling process for complaints and appeals shall include at least the following elements and methods: a) a description of the process for receiving, validating, investigating the complaint or appeal, and deciding a) what actions are to be taken in response to it; b) tracking and recording complaints and appeals, including actions undertaken to resolve them; c) ensuring that any appropriate action is taken.	**No interpretation for this clause.**
7.6.2 The IB receiving the complaint or appeal shall be responsible for gathering and verifying all necessary information to validate the complaint or appeal.	**No interpretation for this clause.**
7.6.3 Whenever possible, the IB shall acknowledge receipt of the complaint or appeal, and shall provide the complainant or appellant with progress reports and the outcome.	**No interpretation for this clause.**
7.6.4 The decision to be communicated to the complainant or appellant shall be made by, or reviewed and approved by, individual(s) not involved in the original inspection activities in question.	**No interpretation for this clause.**
7.6.5 Whenever possible, the IB shall give formal notice of the end of the complaint and appeals handling process to the complainant or appellant.	**No interpretation for this clause.**

6.7 Detailed Requirements for Disputes and Appeals

ISO/IEC 17020 References	ILAC P15 Interpretation
See Above	

6.8 Detailed Requirements for Internal Audit

ISO/IEC 17020 References	ILAC P15 Interpretation
8.6 Internal audits (Option A) **8.6.1** The IB shall establish procedures for internal audits to verify that it fulfils the requirements of this International Standard and that the management system is effectively implemented and maintained. **NOTE**: ISO 19011 provides guidelines for conducting internal audits. **8.6.2** An audit programme shall be planned, taking into consideration the importance of the processes and areas to be audited, as well as the results of previous audits. **8.6.3** The IB shall conduct periodic internal audits covering all procedures in a planned and systematic manner, in order to verify that the management system is implemented and is effective.	**No interpretation for this clause.**
8.6.4 Internal audits shall be performed at least once every 12 months. The frequency of internal audits may be adjusted depending on the demonstrable effectiveness of the management system and its proven stability.	**8.6.4a** The inspection body shall ensure that all requirements of ISO/IEC 17020 are covered by the internal audit program within the accreditation re-assessment cycle. The requirements to be covered shall be considered for all fields of inspection and for all premises where key activities are performed (see IAF/ILAC A5). The inspection body shall justify the choice of audit frequency for different types of requirements, fields of inspection and premises where key activities are performed. The justification may be based on considerations such as; • criticality, • maturity, • previous performance, • organisational changes, • procedural changes, and • efficiency of the system for transfer of experience between different operational sites and between different fields of operation.
8.6.5 The IB shall ensure that: a) internal audits are conducted by qualified personnel knowledgeable in inspection, auditing and the requirements of this International Standard; b) auditors do not audit their own work; c) personnel responsible for the area audited are informed of the outcome of the audit; d) any actions resulting from internal audits are taken in a timely and appropriate manner; e) any opportunities for improvement are identified; f) the results of the audit are documented.	**8.6.5a** Competent externally contracted personnel may carry out internal audits.

6.9 Detailed Requirements for Management Review

ISO/IEC 17020 References	ILAC P15 Interpretation
8.5.1 General **8.5.1.1** The IB's top management shall establish procedures to review its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this International Standard. **8.5.1.2** These reviews shall be conducted at least once a year. Alternatively, a complete review broken up into segments (a rolling review) shall be completed within a 12-month time frame. **8.5.1.3** Records of reviews shall be maintained.	**8.5.1a** A review of the impartiality risk identification process and its conclusions (clauses 4.1.3/4.1.4) should be part of the annual management review. **8.5.1b** The management review should take into account information on the adequacy of current human and equipment resources, projected workloads and the need for training of both new and existing staff. **8.5.1c** The management review should include a review of the effectiveness of systems established to ensure adequate competence of the personnel.
8.5.2 Review inputs The input to the management review shall include information related to the following: a) results of internal and external audits; b) feedback from clients and interested parties related to the fulfilment of this International Standard; c) the status of preventive and corrective actions; d) follow-up actions from previous management reviews; e) the fulfilment of objectives; f) changes that could affect the management system; g) appeals and complaints.	**No interpretation for this clause.**
8.5.3 Review outputs The outputs from the management review shall include decisions and actions related to: a) improvement of the effectiveness of the management system and its processes; b) improvement of the IB related to the fulfilment of this International Standard; c) resource needs.	**No interpretation for this clause.**