

International Accreditation Service

COURSE HANDBOOK

UNDERSTANDING ISO/IEC 17020:2026

IAS Training: Training that Reaches People

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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 17025:2017 (testing and calibration)
- ISO/IEC 17020:2026 (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 17020:2026 – the standard used for the inspection of product design, product, service, process or plant.

Course Learning Objectives

The course will assist you to:

- **explain** how inspection programs operate;
- **identify** the needs of specifiers;
- **explain** how materials, products, installations, plants, processes, work procedures or services inspection works within the global conformity assessment approaches;
- **identify** IB requirements for impartiality;
- **explain** the requirements in ISO/IEC 17020:2026 for an organization to operate as an IB.
- **identify** the requirements for competence of all persons involved in the inspection process, and
- **identify** the facilities and equipment requirements for inspection.
- **determine** inspection processes, and
- **explain** the contribution of testing and calibration to support inspection processes;
- **document** the components of the inspection decision;
- **describe** the requirements for protection of marks/stamps/certificates of inspection, and
- **describe** 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 inspection body 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:

- **explain** how inspection programs operate;
- **identify** the needs of specifiers;
- **explain** 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?

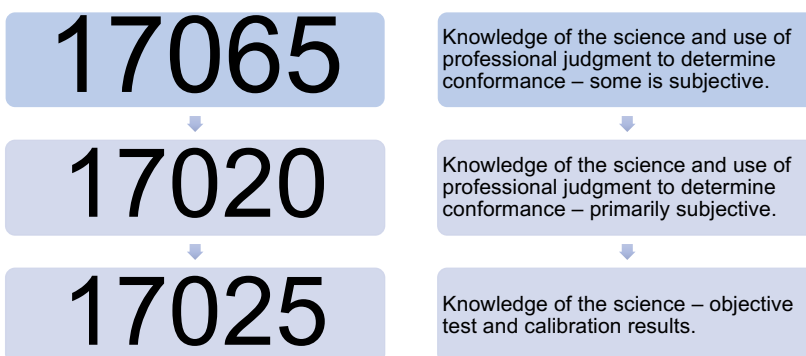
Discussion Activity 1.3

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 17025:2017 and ISO/IEC 17020:2026 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 ISO/CASCO QA PROC 33 (Procedure 33). This procedure details the required wording in CASCO standards.

Because of these 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 inspections 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 inspections 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

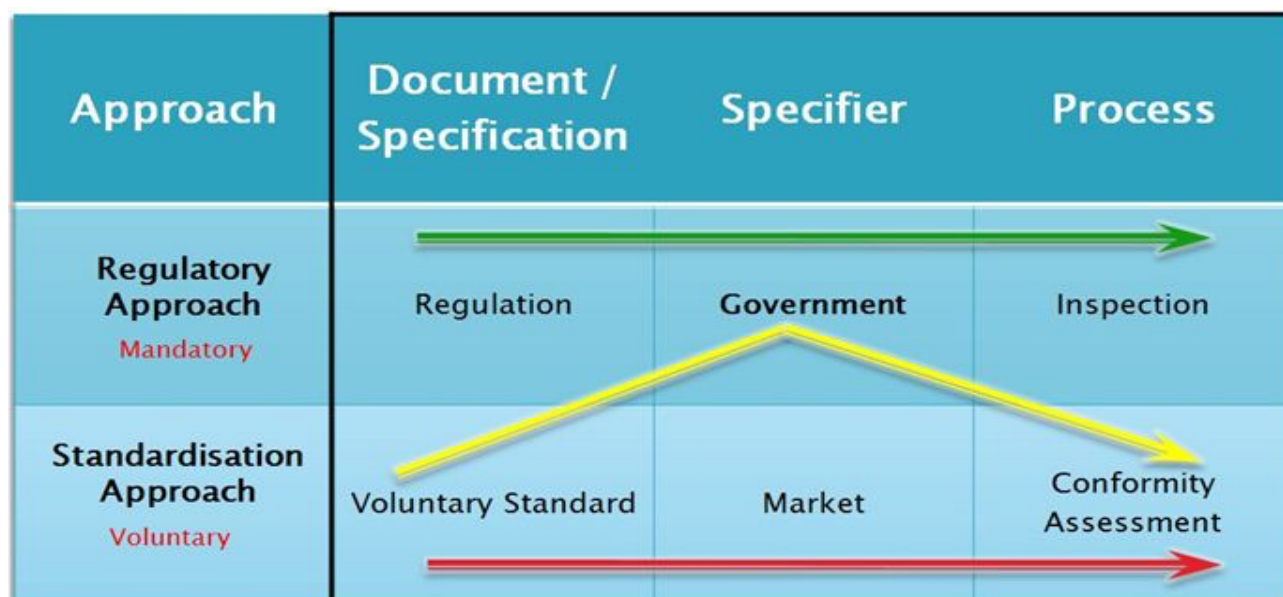
Because of the implied, if not actual, liability associated with inspection, many agencies representing various stakeholders will involve themselves in the processes surrounding inspection. Most do so as participants in the applicable inspection schemes, sometimes as the specifiers, and sometimes as 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 inspection body-licensing program used by the US FDA.

The red line at the bottom is an example of how ISO 9001 and ISO/IEC 17020:2026 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 17020:2026, 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 inspections bodies;
- the clients 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 impartially 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.

1.4.4.3 Confidentiality and openness

1.4.4.3.1 General

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

1.4.4.3.2 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

1.4.4.3.3 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.

1.4.4.3.4 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.

1.4.4.4 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.

1.4.4.5 Responsibility

The client, not the IB, has the responsibility for fulfilment of inspections requirements.

The sole work of the IB is to provide information on the conformance of the object of inspection to requirements – not to solve conformance issues.

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 regarding conformance based on sufficient evidence of conformity, or an adverse decision 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:

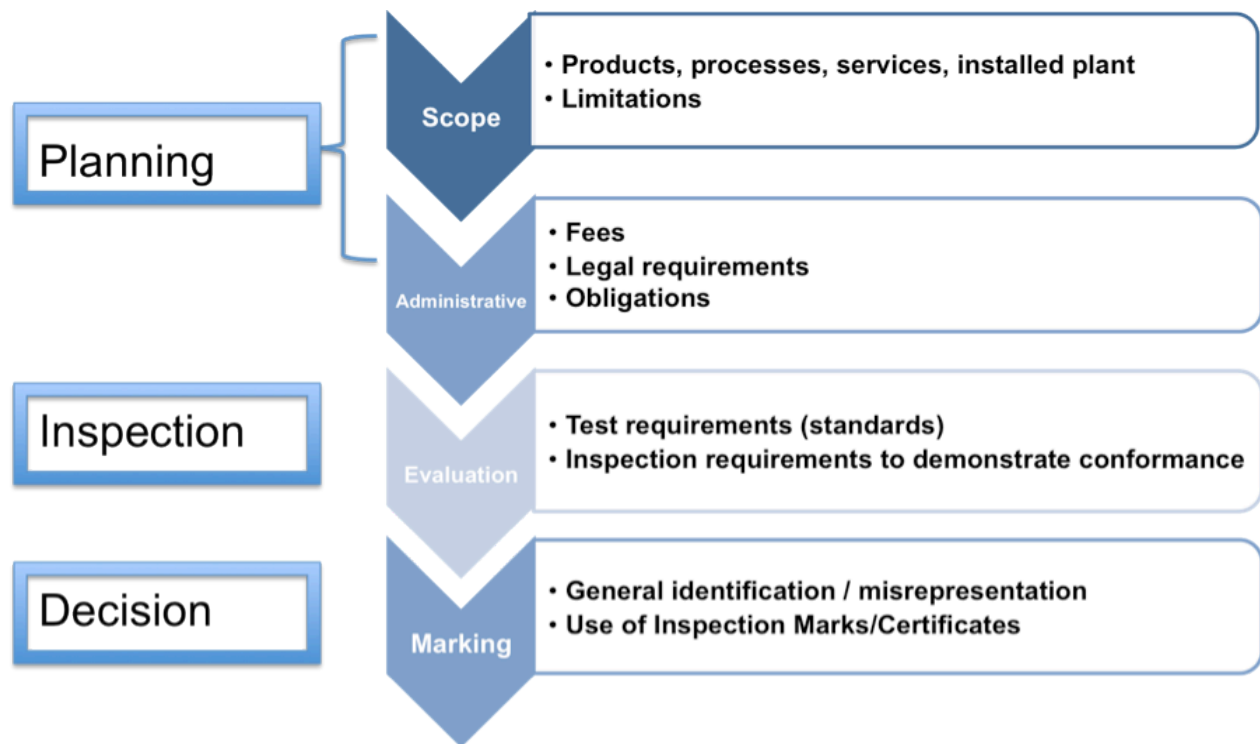
- pre-requisites for participation as a third party IB;
- pre-requisites for the inspection of conformant materials, products, installations, plants, processes, work procedures or services;
- scheme owner participation in the processes leading to either of the above;
- surveillance of materials, products, 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



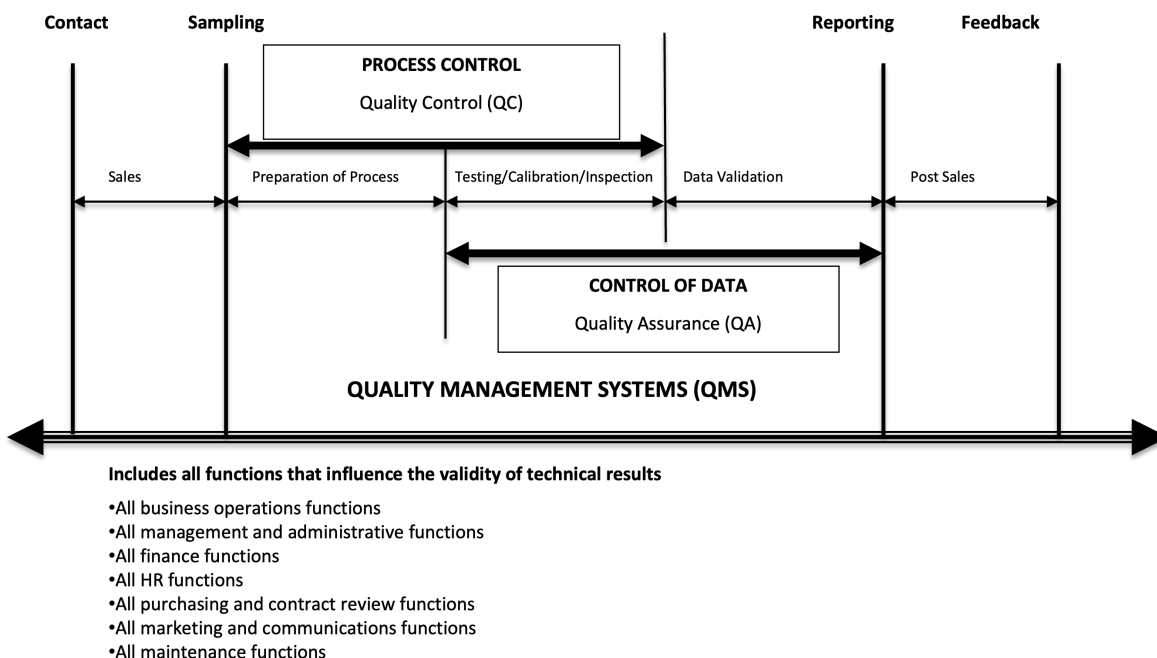
ISO/IEC 17020:2026 articulates the process of inspection to contain the 3 main steps shown.

These three steps underpin all inspection processes and therefore, the management system that supports them, in ISO/IEC 17020:2026, 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.

1.5.2 Inspection Body Operations

Inspection bodies operate the same type of processes that are in labs, certification bodies and other types of conformity assessment bodies (CABs).

These are shown below.



The top lines show the operational processes and the difference between QA and QC is that the former seeks to determine the fitness for purpose of results while the former seeks to determine the fitness for purpose of processes.

The QMS exists solely to help people in their conduct of inspection processes. Its aim is to support them produce only technically valid results and decisions.

Chapter 2 – Program Integrity Requirements

2.1 Learning Objectives

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

- **identify** 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 17020:2026 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 17020:2026)

There are two types of IBs as defined in ISO/IEC 17020:2026 that are characterised by their independence, the most visible indicator of impartiality and integrity. The 2026 version of 17020 lists them as:

- Type A and
- Not Type A.

2.4.1 Type A Inspection Bodies

A.1 a) The inspection body shall be independent of the parties involved.

NOTE 1 The parties involved can include, but are not limited to, the client, either the owner or the user, or both, of the item inspected, or the organization involved in the design, manufacture, supply, installation, or maintenance of the items. The parties involved also include potential purchasers of the item inspected, and possibly a relevant regulatory authority or other statutory authority.

NOTE 2 While the results of an inspection can have implications for the public, the public is not considered to be a "party involved".

A.1 b) The inspection body and its personnel shall not engage in any activities that can 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, maintenance of the item inspected, or similar competitive items.

NOTE 3 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 4 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.

NOTE 5 "Similar competitive" means an item that is an alternative (in terms of price, quality and other technical specifications) to the item inspected and competing in the market.

A.1 c) The inspection body shall not be a part of a legal entity that is engaged in the design, manufacture, supply, installation, purchase, ownership, use or maintenance of the item inspected or similar competitive items.

NOTE 6 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 7 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.

A.1 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 item inspected or similar competitive items 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 3 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; reporting to the same higher level of management is permitted on matters other than the design, manufacture, supply, installation, purchase, ownership, use or maintenance of the item inspected or similar competitive items;
- 4) any means that can establish the ability of the separate legal entity to influence the outcome of an inspection, including but not limited to contractual commitments that establish the separate legal entity's control or authority over the inspection body.

2.4.2 Non-Type A Inspection Bodies

This is any inspection body that does not meet the requirements shown for a Type A inspection body. Any inspection body that does not meet the requirements shown for a Type above, is required to meet the following requirements:

- A.2 a)** The legal entity of the inspection body is required to ensure adequate segregation of responsibilities and accountabilities between inspection and other activities, within their own organization.
- A.2 b)** No person conducting an inspection is allowed to also participate in the design, manufacture, supply, installation, servicing, or maintenance of the object of inspection. An exception to this requirement is whenever a scheme explicitly allows an individual person from an inspection body to undertake both the design, manufacture, supply, installation, servicing, maintenance and inspections of the same item, as long as this exception does not compromise inspections results.

2.5 Demonstrating Impartiality in Decision Processes

Rock solid demonstrations of impartiality require the Type A 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. This is different for non-Type A IBs where scheme requirements do allow such activities, but care must be taken to ensure that each inspection is free from compromising influence.

All sub-contracted organizations that participate in inspections processes must also meet these requirements.

ISO/IEC 17020:2026, clauses 4.1 and 5.1 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 Chapter 4 – Infrastructure Requirements.

2.5.1 Structured for Impartiality

From 17020:2026 Clauses 4.1.5, 4.1.6 and 4.1.7, The IB shall be structured and managed so as to safeguard impartiality.

2.5.2 Staff must act impartially

From 17020 Clause 4.1.7, All persons, whether part of the IB, or contracted to it, or belonging to organisations sub-contracted to it are required to act impartially. The best way to implement this is to have all persons sign the IB's own impartiality policy, giving them the responsibility to report any potential conflicts of interest. Evidence gathered to support implementation can be the reports of persons who have submitted such reports.

2.5.3 Impartiality considerations “Under the Law”

From 17020 Clause 4.2.2, When the inspection body is **required by law** or authorized by contractual arrangements to release confidential information, the client concerned shall be notified of the information released, unless **prohibited by law**.

What does “Required by Law” mean? It means that legal instruments are being used in the gathering of information and these legal instruments have been signed by a judge, such as:

- A subpoena to appear or present
- A court order to deliver information or a person
- A search warrant to allow law enforcement to conduct a search of a premises, vehicle or person.

Chapter 3 – Organizational Requirements

3.1 Learning Objectives

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

- **understand** the requirements in ISO/IEC 17020:2026 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?

Discussion Activity 3.3

What is the job description of the Quality Manager and which 17020 clause contains it?

3.3 Detailed Organisation Requirements

3.3.1 Legal Entity

The organization is required to be a legal entity that allows it to be “treated as a person under the law.” Simple business registration, full scale incorporation or being part of a government all meet this requirement.

IBs that are part of an organization involved in functions other than inspection shall be identifiable within that organization, meaning that it is considered “visible” within the larger organization.

IBs must have documentation which describes its functions and the technical scope of activity for which it is competent.

3.3.2 Legal Liability

The IB is also required to have adequate provision (e.g. insurance or reserves) to cover liabilities arising from its operations, including:

- analysis of the risks arising from inspection activities;
- assessment of potential liabilities associated with identified risks, and
- assurance that the adequacy of provisions established is consistent with those liabilities.

3.3.3 Organization and Management

The IB is required:

- to define its organization and management structure,

- to define its place within any parent organization and the relationship between management, technical activities and support services;
- to document the responsibilities and accountabilities, including interrelationships, of all personnel who manage or perform work affecting the results of its inspection activities;
- to maintain its capability to perform inspection activities as described above, and
- to document its procedures so as to ensure consistent delivery of its inspection services, including ensuring the validity of its inspection decisions.

3.3.4 Technical Management

IB technical management is required to have sufficient authority and competence to:

- develop inspection activities, including inspection methods and associated processes;
- perform the monitoring of inspectors conducting inspections on their behalf;
- access to the resources necessary for the conduct of their duties;
- determine and document their requirements for personnel competence;
- enforce technical aspects of contractual arrangements;
- perform inspection activities themselves;
- operate the inspection body;

3.3.5 Implementation and Management of the Management System

Like the laboratory management requirements shown in 17025:2017, IB management is required to have personnel who, irrespective of other responsibilities, have the authority and resources needed to perform their duties, including the following. Essentially, this is the job description of the quality manager.

- implementation, and maintenance of the management system;
- identification of deviations from the management system;
- initiation of actions to prevent or minimize such deviations;
- reporting to inspection body's management on the performance of the management system and any need for improvement, and **(THIS IS THE MOST IMPORTANT OF THESE REQUIREMENTS)**
- ensuring the effectiveness of the inspection body's activities.

The IB must also have a job description or other documentation for each function within its organization involved in inspection activities.

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 17020:2026?

Discussion Activity 4.3

What are the traceability requirements contained in ISO/IEC 17020:2026?

Discussion Activity 4.4

How does an IB ensure the competence of subcontractors?

4.3 Detailed People Requirements

4.3.1 General

The IB is required to employ, or have employment 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.

4.3.2 Managing Personnel Competence

The IB must manage and document the competence requirements for all personnel involved in inspection activities, including the following:

- determining the competence requirements including, where needed, for making professional judgement (e.g. education, training, technical knowledge, skills or experience);
- selection of personnel;
- initial training of personnel;
- authorization of personnel;
- monitoring of competence of personnel;
- continual training.

IB personnel responsible for inspection must have appropriate qualifications, training, experience and a satisfactory knowledge of the requirements of inspections to be carried out. They must 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, and
- the significance of deviations found with regard to the normal use of the products, the operation of the processes and the delivery of services.

Initial training of IB personnel must include an induction period and a mentored working period with authorized and competent personnel for the relevant inspection activity.

4.3.2 Monitoring Inspectors

Inspectors are to be monitored at a defined frequency by authorized and competent personnel in accordance with a monitoring programme. Previously, ILAC (now Global A-C-I) specified frequency of monitoring in ILAC P15, but this version of the standard now leaves the decision entirely with the IB.

IBs should consider the following in designing their monitoring program. Accreditation bodies are almost guaranteed to ask to see the documentation of such considerations during an assessment:

- the risks and complexities of inspections;
- results of previous monitoring activities;
- technical, procedural or legislative developments relevant to inspections;
- inspection activities which use new technology.

Each inspector must be observed on-site, unless there is sufficient supporting evidence that the inspector is continuing to perform competently. If necessary, more than one monitoring session may be required for each inspector to cover all of their own inspection competencies.

It is expected that on-site observations are performed in a way that minimizes the disturbance of inspections, especially from the client's viewpoint.

Evidence of inspector's continuous competence can include:

- results of examinations and inspection decisions;
- onsite monitoring;
- evaluations to confirm the outcome of inspections;
- mentoring and training results, and
- results of examination by a competent body, e.g. a body operating certification of persons.

Inspection body training programs must include developing inspection requirements, methods and issues that affect competence, and the results of monitoring. The competence of personnel must be documented.

4.4 Detailed Physical Requirements for Inspection

4.4.1 General

The inspection body must have suitable and adequate facilities and equipment to permit all activities associated with inspections services to be carried out competently and safely. It ensures the continued suitability of the facilities and the equipment for their intended use and has clear rules for the access to and the use of these facilities and equipment.

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.

4.4.2 Equipment

All equipment having a significant influence on the results of inspections shall be defined and, where appropriate, uniquely identified, periodically checked, and calibrated. Equipment information is recorded, including maintenance and calibration information.

NOTE The term “calibrated” does not specifically state that the requirement is “metrological traceability to the SI,” but any accreditation body will see these two concepts as equivalent. See below.

When measurement results have a significant influence on the result of the inspection, or when so required by the inspection scheme, the measurement results are metrologically traceable to the International System of Units (SI) through at least one of the following: (Annex A to ISO/IEC 17025 provides guidance on the attainment of metrological traceability)

- calibration provided by a competent calibration laboratory, such as those that meet the requirements of ISO/IEC 17025 whether or not they are accredited;
- certified values of certified reference materials provided by a competent reference material producer with stated metrological traceability to the SI, such as those that meet the requirements of ISO 17034, whether or not they are accredited, and
- direct realization of the SI units ensured by comparison, directly or indirectly, with national standards or international standards, normally done by a national metrology institute (NMI).

All equipment is handled and maintained in accordance with documented procedures and instructions and is verified to conform to specified requirements before use. Defective equipment is removed from service, and the impact on previous results examined.

Information technology used in support of inspections (e.g. computers or automated equipment, data processing, artificial intelligence, augmented reality or remote inspection techniques must be:

- Suitable and adequate for use, through validation of calculations before use, periodic re-validation, re-validation following changes, and software updates as required.
- Protected from unauthorized access or manipulation of data
- Maintained to ensure proper functioning.

4.5 Externally Provided Support

4.5.1 General

The inspection body uses only suitable externally provided products and services that affect inspection activities are used, when such products and services:

- are intended for incorporation into its own inspection activities;
- are provided, in part or in full, directly to the client by the inspection body, as received from the external provider;
- are used to support the operation of the inspection body.

NOTE Products can include, for example, equipment, installations, consumable materials and reference materials. Services can include, for example, calibration services, testing services in the framework of inspection process, inspection services, facility and equipment maintenance services, IT services, expertise services and auditing services.

The inspection body has a procedure and retains records for:

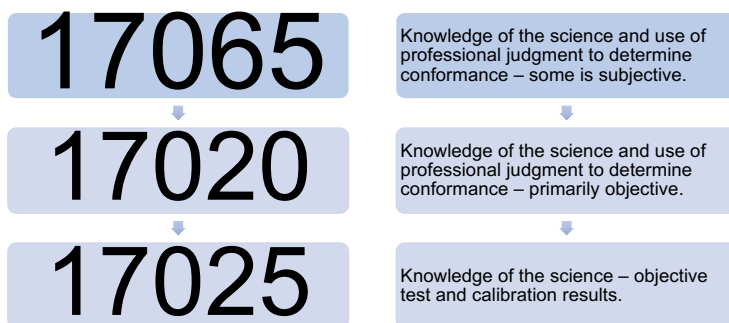
- defining, reviewing and approving the inspection body's requirements for externally provided products and services;
- defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers;

- ensuring that externally provided products and services conform to the inspection body's established requirements, or when applicable, to the relevant requirements of this document or of other relevant standards for conformity assessment bodies, before they are used;
- taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers.

4.5.2 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.



4.5.3 Detailed Subcontracting Requirements

When using external services providers, the client of the IB is to be informed of this circumstance and agree to it prior to the work being done. The IB remains responsible for all subcontracted work and the results of this work, just as if they had done the work themselves and the IB must retain records on the approved use of such subcontractors and their work.

Only those inspections, which an IB normally does itself, can be listed on an IB's scope of accreditation. The IB itself normally performs inspections that appear on its own scope of accreditation. The use of externally provided inspection activities for part of the inspection or the entire inspection can only be done in exceptional circumstances:

NOTE Reasons to subcontract can include the following:

- an unforeseen or abnormal overload;
- key inspection staff members being available;
- 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.

The terms "subcontracting" and "outsourcing" are synonymous. This term only applies to organisations, not individual persons. All external organisations providing services for testing, inspection or other conformity assessment work must meet the requirements of the applicable CASCO standard.

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. In other words, they are considered to be contracted in the same way as contracted employees.

Chapter 5 – Inspection Process Requirements

5.1 Learning Objectives

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

- **understand** inspection processes;
- **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 (Now collectively called Global A-C-I) that are over and 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?

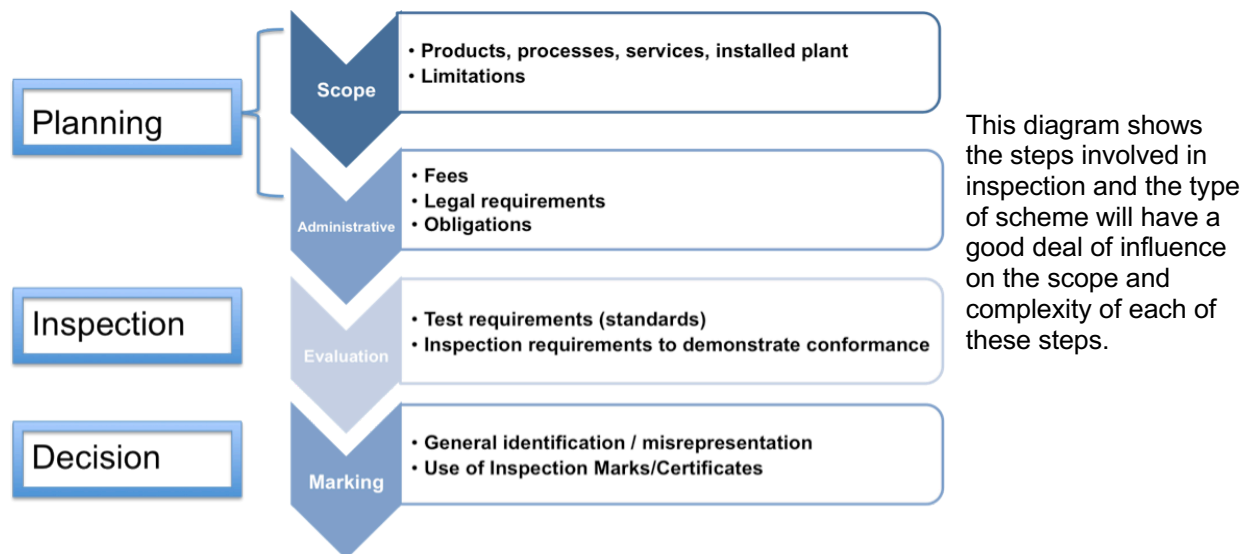
Discussion Activity 5.5

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

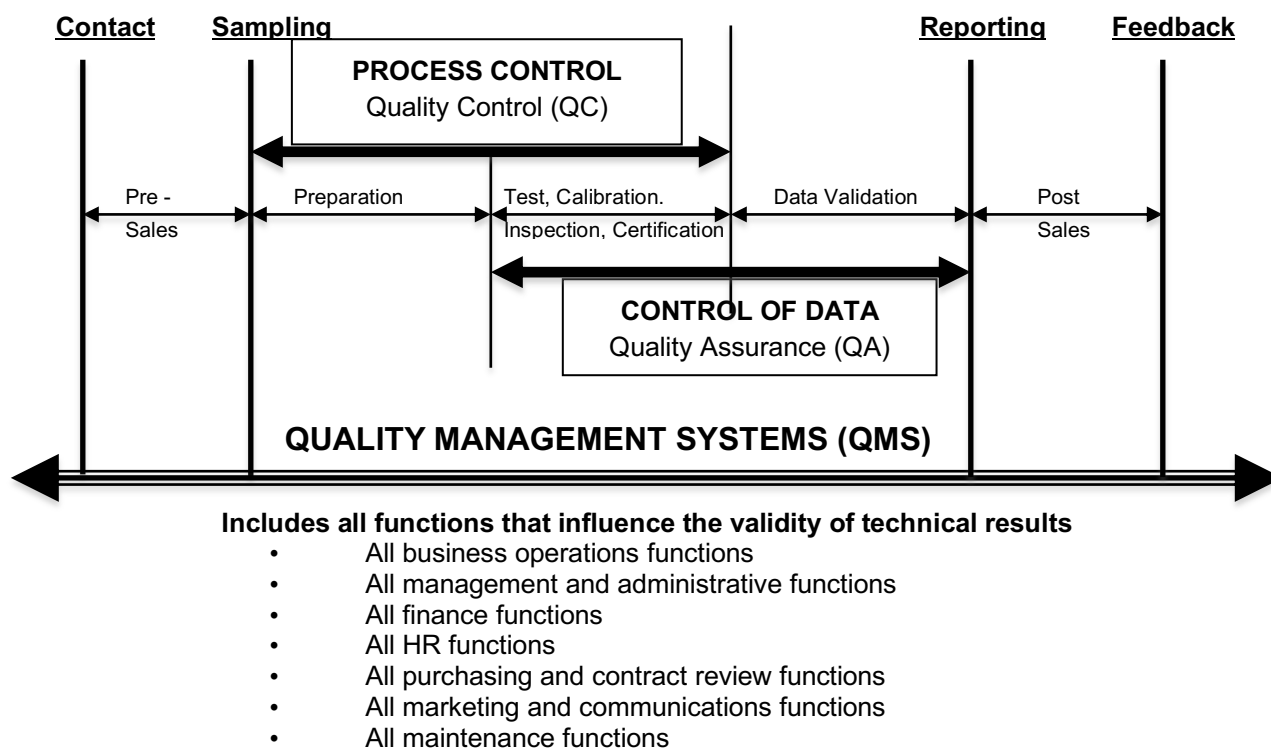
What tools are available to allow an IB to suspend or withdraw an inspection certificate?

5.3 Processes involved in Inspection



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.



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 inspection bodies produce technically valid results, and that inspection bodies and product certification bodies issue impartial inspections and certifications.

5.5 Detailed Inspection Method Requirements

5.5.1 Demonstrating Competence

IBs must have a procedure for the review of inspection requests, tenders and contracts. The procedure is to ensure that the IB has considered its own capacity and compared it with the client request. This is the first step in delivering competent inspections.

- the inspection to be performed is defined (such as in an inspection scheme), the items of inspection are clearly identified and the requirements to be fulfilled are adequately specified, documented and understood.
- the inspection body has the capability, including adequate resources, to meet the client requirements. This includes having the people with the requisite skills and knowledge, the environment with required facilities and equipment, the QA/QC/QMS, the procedures which can all lead to only producing technically valid inspection decisions.
- if new, the IB can develop inspection methods to meet the client requirements.
- requirements and any special conditions of the client, are adequately specified and understood, so that clear instructions can be issued to personnel performing required inspection activities.

NOTE For routine or repeated work, reviews of requests, tenders and contracts can be simplified.

Differences between the request or tender and the contract shall be resolved before inspection activities start. Each contract shall be acceptable to both the inspection body and the client. Deviations requested by the client shall not impact the validity of the result and records of review must be retained shall be retained.

The client must be informed if a requested inspection is considered to be inappropriate.

5.5.2 Inspection Methods

IBs must use appropriate methods and procedures. The requirements against which inspections are performed are normally specified in regulations, standards, specifications, inspection schemes or contracts. Specifications can include client or in-house requirements.

Where inspection methods and procedures are not defined, the inspection body is expected to develop specific methods and procedures to be used

Normally, standard inspection methods or procedures are used. A standard inspection method or procedure is one that has been published, in a standard, or in consensus publications or relevant scientific literature or journals. Methods or procedures that are not published in consensus publications are non-standard methods or procedures. Modifications of standard methods or procedures are also non-standard methods. In cases where non-standard methods are used, the IB is expected to ensure they are appropriate and documented

The IB is expected to validate non-standard inspection methods or procedures including when technology is used. The validation shall be appropriate to meet the needs of the given application or field of application and records are to be retained.

Method validation can include the following:

- systematic assessment of the factors influencing the result.
- testing method robustness through variation of controlled parameters, such as inspector, equipment, etc.
- comparison of results achieved with other validated methods

Any development, modification, or validation of inspection methods must be planned and assigned to competent personnel equipped with adequate resources.

Inspection methods used are required to:

- Acquire sufficient information about the conduct of the inspection for an appropriate, technically valid decision to be made. If necessary, this may include the uncertainty of any measurements made.
- Describe any activities for which the inspector's judgement may rely on the use of information technology, or other digital means such as artificial intelligence tools.
- Describe inspection planning and sampling, where the absence of such instructions can jeopardize the effectiveness of the inspection process.
- Establishment of a sampling plan when sampling is relevant to the validity of the outcome of inspection activities. Sampling plans should be based on statistical methods and records maintained, including details such as the sampling method used, date and time, personnel involved, and any deviations from the plan, to ensure traceability.
- The provision of information supplied by any other party (including the client) as part of the inspection process, and how the integrity and the validity of such information is verified to the extent appropriate.
- Record any use of safety equipment and associated processes.
- List the criteria to make decisions on the demonstrated conformity of the inspected item.
- Record any environment or equipment having significant influence (if any) on the result of the inspection and when relevant.

5.6 Sample Handling

Items to be inspected are uniquely identified to avoid confusion. A determination is made whether the items to be inspected are fit for inspection. Where there is any doubt, this is recorded and the client is contacted before proceeding.

Samples are to be protected from deterioration while in the custody of the IB.

5.7 Contents of Inspection Reports and Certificates

Inspection reports or certificates include, **at least**, the following:

- identification of the issuing body;
- unique identification of the inspection report;
- date of issue;
- date(s) of inspection;
- identification of the item(s) inspected;
- signature or other indication of approval, by authorized personnel;
- a statement of conformity, where applicable;
- inspections results, except in inspection certificates where they may be available upon request and traceable to the report;
- location of inspection when relevant.

Inspection reports normally report on the complete results of an inspection and are also considered records of the implementation of inspection processes. See **Control of Records** in **Chapter 6** below.

An inspection certificate is typically issued when there is also a statement of conformity and is then accompanied by an inspection report. Annex B contains examples of optional elements that can be included in inspection reports or certificates.

The contents of a report are correct, accurate, and clear. Where a report or inspection certificate contains results delivered by external providers, these results are clearly identified. The report or inspection certificate is traceable to the inspector(s) who performed the inspection.

Corrections, additions or amendments to an inspection report or inspection certificate after issue are to be recorded in accordance appropriate. An amended report or certificate is then issued and clearly identifies the report or certificate replaced. This is to ensure that potential fraudulent use of the report is mitigated by clear association with the report it replaces.

Inspection results can be reported in a simplified way when agreed with the client. Any information listed above, that is not reported to the client, must still be readily available.

Reporting must still meet applicable scheme, regulatory, and contractual obligations.

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

6.3.1 General

A management system must be established to meet the requirements of 17020. It has to address the following specific clause requirements in 17020:

- policies and responsibilities from clause 8.2;
- documented information from clause 8.3;
- actions to address risks and opportunities from clause 8.4;
- corrective actions from clause 8.5;
- internal audits from clause 8.6, and
- management review from clause 8.7.

Use of ISO 9001. An inspection body may establish, implement and maintain a quality management system in accordance with the requirements of ISO 9001. Regardless, this quality management system is still required to support and demonstrate the consistent fulfilment all the requirements of 17020, over an above the requirements of 9000.

No accreditation body will ever assess an inspection body against ISO 9001. That is unethical as ISO 9001 registrars are accredited by accreditation bodies and they will not compete against their own clients.

6.3.2 QMS Policies and Responsibilities

The QMS documentation must contain the policies and objectives for fulfilment of the requirements of 17020 and ensure that the policies and objectives are acknowledged and implemented at all levels of the inspection body's organization.

Policies and objectives must address the competence, impartiality and consistent operation of the inspection body.

Top management must provide evidence of its commitment to the development and implementation of the management system and its effectiveness in achieving consistent fulfilment of the requirements of this document.

6.3.3 QMS Documentation

The inspection body shall control the documents (internal and external) that relate to the fulfilment of the requirements of this document. Control of documentation normally requires the inspection body to maintain control over the **STATUS** (revision no. etc.) and **LOCATION** of all controlled documents. The procedures for the control of documents shall ensure that:

- a) documents are approved for adequacy prior to issue by authorized personnel;
- b) documents are periodically reviewed and updated as necessary;
- c) changes and current revision status of documents are identified;
- d) relevant versions of applicable documents are available at points of use and their distribution is controlled;
- e) documents are uniquely identified;
- f) documents of external origin are identified and their distribution controlled;
- g) the unintended use of obsolete documents is prevented and that suitable identification is applied to them if they are retained for any purpose.

Documentation can be in any form or medium and includes proprietary and in-house developed software. Only the most appropriate version of any document is to be made available to personnel, and these must be available to all personnel require access to them.

6.3.4 Inspection Body Records

6.3.4.1 General

Inspection records are to demonstrate conformant implementation of documents. The inspection body implements the controls needed for the identification, storage, protection, back-up, archive, retrieval, retaining and disposal of its records.

The inspection body retains records for a period consistent with its contractual obligations and any regulatory and legal requirements applicable in its jurisdiction or established in applicable schemes. Access to them is consistent with the confidentiality commitments and records is readily available as required by authorized personnel.

The management system contains references to all documentation, processes, systems and records related to the fulfilment of the requirements of 17020.

6.3.4.2 Technical Records

Observations are recorded in a timely manner. Calculations and data transfers are checked in an appropriate and systematic manner. This includes textual material, digital data and anything else that is transferred from one (physical or digital) location to another where errors can be introduced.

Any amendments to inspection records are tracked to previous versions or to original observations. Both the original and amended data, dates, and files are retained.

Records are maintained to demonstrate the effective fulfilment of inspections procedures and to enable an evaluation of inspection processes. Records identify equipment, the date of use, and when relevant, the conditions (such as environmental) under which the equipment was used.

Data collection, processing, recording, reporting, storage or retrieval is validated. Any changes, including inspection body software configuration or modifications to commercial off-the-shelf software (COTS), are authorized, documented, and validated before implementation.

Inspection records are:

- are protected from unauthorized access, tampering and loss.
- are maintained to ensure its integrity and security, and
- include information on system failures and the appropriate immediate and corrective actions.

6.3.5 Internal Audit

Internal audits are the most effective ways to recognize and identify conditions that have (or may) impede the consistent production of technically valid results or provide benefit to the organisation or its inspections. Internal audits provide the best indication of the health of the quality system and must be conducted with people trained to conduct them.

An internal audit, like all types of audits, is a comparison of what is required to what exists. This comparison is based on the gathering of “objective evidence” of current conditions and situations. This objective evidence is gathered by:

- Document review
- Observation
- Interview

The single most important criterion for the success of any internal audit is the training of staff as internal auditors.

6.3.6 Management Review

Management reviews are the best venue for top management to determine if the management system is helping attain corporate objectives. If it is, then the system does not need much modification. If it does not support corporate objectives, then either the system must be modified, or organizational expectations must be modified. This is why the leadership of top management is so important.

While the management team can make changes to the management system, only top management can modify expectations. Some findings may come from this exercise, but they are most likely to be PNCs and OFIs.

Meetings are normally chaired by top management with the quality manager acting as secretary. The agenda must include all the items shown in 17020, clauses 8.7.2 and 8.7.3.

This activity demonstrates and documents top management commitment to monitoring the quality system and its implementation.

Management review can also introduce any necessary changes or improvements; such as:

- organizational changes,
- hiring additional staff,
- providing specialised training,
- modifying the services offered,
- purchasing additional equipment, and
- modifying existing policies and procedures.

Clause 8.7 of ISO/IEC 17020 states:

“8.7.2 *The inputs to management review shall be recorded and shall include information related to the following:*

- a) *internal and external changes that are relevant to the inspection body;*
- b) *suitability of policies and procedures;*
- c) *outcome of recent internal audits;*
- d) *assessments by external bodies;*
- e) *client, personnel, and, if relevant, interested parties feedback;*
- f) *corrective actions;*
- g) *status of actions from previous management reviews;*
- h) *the fulfilment of objectives;*
- i) *changes in the volume and type of the work or in the range of inspection activities;*
- j) *appeals and complaints;*
- k) *effectiveness of any implemented improvements;*
- l) *adequacy of resources including current human and equipment resources, projected workloads and the need for training of both new and existing personnel;*
- m) *results of risk identification including impartiality threat identification process and its conclusions;*
- n) *review of the effectiveness of processes established to ensure adequate competence of the personnel, including monitoring and training of inspectors and other personnel involved in inspection activities;*
- o) *other relevant factors*

8.7.3 *The outputs from the management review shall record all decisions and actions related to at least:*

- a) *the effectiveness of the management system and its processes;*
- b) *improvement of the activities related to the fulfilment of the requirements of this document;*
- c) *provision of required resources;*
- d) *any need for change."*

Management review normally considers the types of information provided by:

- Managerial reports
- Quality system audits
- Client feedback, including complaints, compliments and appeals
- Internal quality control measures and trends
- Trends in NCs, PNCs, OFIs, and complaints.

Chapter 7 – Continual Improvement Requirements

7.1 Learning Objectives

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

- **identify** inspection body approaches in recognizing NCs, PNCs, and OFIs;
- **explain** the concepts of corrective and preventive action;
- **identify** the importance of, and requirements for, internal audit and management review;
- **identify** the most effective methods for implementing continual improvement
- **determine** the areas of the inspection body that must undergo internal audit;
- **determine** the considerations that must be part of management review;

7.2 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 7.1

Which of the following are appropriate approaches in implementing continual improvement? (Select all that apply.)

- Allow all persons in the inspection body to identify non-conforming and potentially non-conforming issues.
- Ensure that blame is properly placed.
- Document all actions in the continual improvement processes.
- Determine the need for full corrective or preventive action instead of simple remediation.
- Implement the solution that addresses the root cause.
- Implement corrective and preventive action for all NCs.
- Follow up to determine the effectiveness of remediations.

Discussion Activity 7.2

Which of the following are process components of continual improvement? (Select all that apply.)

- Feedback from clients, appeals, complaints and complements.
- NCs raised from employee performance reviews.
- Findings from internal audits and external assessments.
- Management review determinations.
- Workplace accidents.
- Technical work in the inspection body.

Discussion Activity 7.3

What are the differences and similarities between corrective action and preventive action? (Select all that apply.)

- Preventive action, unlike corrective action, does not require root cause analysis.
- They are exactly the same, except for when the original issue occurs.
- Corrective action is for all issues.
- Preventive action is only for OFIs
- Preventive action does not require follow up for effectiveness.

Discussion Activity 7.4

What are the requirements for the frequency of internal audit? Which documents govern?

- a. Our accreditation body policies require us to conduct internal audits once per year.
- b. The standard requires internal audits to be conducted once per year.
- c. There are no formal requirements for the frequency of internal audits.
- d. Our accreditation body requires us to do a risk analysis to determine the frequency of internal audits.

Discussion Activity 7.5

What are the requirements for the frequency of management review? Which documents govern?

- a. Our accreditation body policies require us to conduct management review once per year.
- b. The standard requires internal audits to be conducted once per year.
- c. There are no formal requirements for the frequency of management review.
- d. Our accreditation body requires us to do a risk analysis to determine the frequency of management review.

Discussion Activity 7.6

What are the benefits of internal audits? (Select all that apply.)

- a. Internal audit tells us who has made mistakes.
- b. Internal audit allows us to check the competence of our people.
- c. Internal audit is the best means to determine if our quality system is helping us produce valid decisions.
- d. Internal audit tells us if our system is: implemented, effective, and allows for improvement.

Discussion Activity 7.7

How does management review allow the inspection body to measure itself? Against what is the measurement conducted? (Select all that apply.)

- a. Management review allows top management to allocate responsibility.
- b. Management review tells top management if the system supports our corporate objectives.
- c. Management review tells the staff how the inspection body should be managed.
- d. Management review is about who gets bonuses.

7.3 Overview of Basic Concepts

7.3.1 The Purpose of Continual Improvement

Continual improvement is always difficult for someone to understand when the objective is not well explained. What is the objective of continual improvement? ISO 9000 tends to imply that there some state of perfection that is the objective for continual improvement. Not so for ISO/IEC 17020.

ISO/IEC 17020 is about only one thing – inspection body competence. Inspection bodies that have implemented a quality system that conforms to ISO/IEC 17020 should be able to produce valid results...but to what degree, or level?

Inspection bodies should be able to consistently produce results day after day after day after boring day. In the world of inspection bodies, boring stability means TRUST. This can be considered the state of perfection for a testing inspection body – or the goal of a continual improvement program.

The thing that most commonly interferes with a inspection body's ability to attain this state of perfection is change: change in personnel, change in structure, change in equipment, change in procedure, change in environment etc. The thing that best supports attaining such a state of perfection is stability.

No one can prevent change. However, standards like ISO/IEC 17020 can help us manage it. It provides a systematic method of identifying and addressing those things that would bring about some change and eventually impede the consistent production of valid results. In a good inspection body, continual improvement is mostly about the management of change. An organization may have other goals for their

continual improvement program, but these are over and above what the inspection body needs for its own purposes.

Remember that the standard addresses itself to inspection bodies. Therefore, the aim of continual improvement in an inspection body is:

“To consistently produce valid results, day after day after day after boring day.”

It is also important to understand that the tools in ISO/IEC 17020 can be used by the inspection body to exploit improvements, which start with root cause analysis.

7.3.2 Definitions

ISO 9000 defines “*non-conformity*” as “*non-fulfilment of requirement*.”

The non-fulfilment of specified requirements can be:

- failure of resources to meet either performance requirements or other specified requirements
- failure of organization to comply with documented policies and procedures or work instructions
- failure of inspection results to meet required standards; i.e.
 - failure to meet all conditions necessary to ensure the integrity and representativeness of the sample (i.e. sample history deficiencies exist)
 - failure to comply with the inspection method and supporting work instructions
 - failure in method performance as demonstrated by inspection results
 - inherent property of the sample that compromises inspection; and
 - relevant evidence as provided by method validation. (e.g. as a result of comparison with expected values, ranges or relationships).

7.4 Identifying NCs, PNCs, and OFIs

ISO/IEC 17020 contains six (6) clauses that facilitate our ability to find these different conditions. They are:

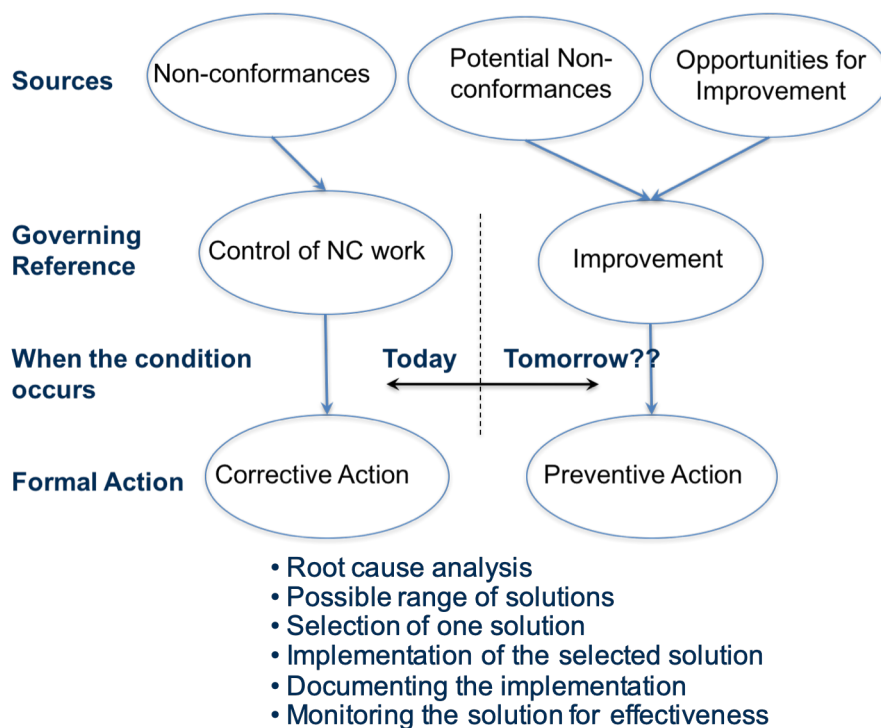
- 7.8 – Complaints
- 7.7 – Appeals
- 8.4 – Actions to address risks and opportunities
- 8.5 – Corrective actions
- 8.8 – Internal Audits
- 8.9 – Management Review

All of these clauses provide some direction on the search for NCs. Because ISO/IEC 17020 is not a perfect document, it neglects to specify that these same clauses can also be used to search for “PNCs” as well. In fact, it dedicates an entire clause on what to do when a non-conformance is discovered (identified). It has only recently included wording on what to do when a “PNC” is discovered.

The clauses cited above are the best sources of procedures against which non-conforming and PNC (OFIs) can be identified and raised.

Inspection body policies and procedures written against these clauses provide the best means of identifying circumstances that should be considered under continual improvement.

The unique clauses are those dealing with appeals, feedback and service to the client, because they may require the inspection body to undertake work to determine whether a situation is conforming or not, before any identification is made. In other words, an investigation into the validity of appeals and feedback is necessary in order to determine whether a circumstance is non-conforming (or potentially non-conforming).



7.4.1 Feedback is about Perception (Clauses 7.8 and 8.4)

One of the requirements in ISO/IEC 17020 is to actively seek the feedback of inspection body clients and do something with it to improve the management system and the technical activities. These are ambitious words.

What does this mean to an inspection body? Or to any organization that is contemplating the use of an active feedback system? Simply put, it means that the organization has to implement some method of collecting data on how their clients feel about the services they use, the treatment they receive, the interactions they experience and the expectations they take into their relationship with the inspection body.

How do the inspection body clients feel about the service and the methods used by the inspection body to interact with their clients? How do they feel about the way the inspection body treats them, or whether their expectations are being met? From the way these questions are worded, it is clear that feedback is generally used to measure perception – client perception of the inspection body, the organization, the inspection body staff, and the work of the inspection body.

7.4.1.1 Examples of Feedback from IAS

If ISO/IEC 17020 calls for this sort of activity explicitly, and IAS trains inspection bodies against this standard, it might be useful for inspection bodies to appreciate how IAS has been acquiring and using feedback.

Most North American assessors and the inspection bodies they assess are familiar with the feedback provided at the end of an assessment activity. In some accreditation bodies, all inspection body responses are collated into one document and submitted to top management as part of the measurement metrics of the accreditation program. These can be fairly large documents.

7.4.1.2 Making use of the Information Received

IAS very visible methods of feedback are used to modify goals, objectives, approaches and delivery methods in IAS assessment in accordance with the requirements of ISO/IEC 17011. That is what ISO/IEC

17020 is looking for inspection bodies to do with their own feedback mechanisms. Feedback systems can deliver valuable information to inspection bodies in real time. In good organizations, feedback can have constant, appreciable, and relevant impact on what is done, and how it is done. This approach is in line with best practices in continual improvement and is the main reason why the 2026 version of ISO/IEC 17020 includes a requirement for active acquisition of client feedback.

What are the potential immediate effects of all this feedback on the organization collecting and using it? For an inspection body, it would mean increased use of current data to affect the direction and methodologies of the inspection body – and less use of “that is how we have always done it.” It should not affect the underlying scientific method in any inspection, but it may affect the supporting procedures and the client interaction processes.

Feedback can also be used to identify external support for the direction of an organization and its delivery of product or service – sort of a marketing tool. However, organizations that collect, use and publish feedback may be disappointed because most of their clients will never read or be influenced by this published feedback. Such is also IAS experience. It may be surprising that clients rely so little on what other clients may have to say about the organization or the inspection body. For example, only one in 50 IAS Training Service participants admit to viewing training feedback before they purchase training. So the real advantage of feedback is not the more obvious “pat-on-the-back” from clients. It is the contribution made to improving services and delivery.

7.4.2 Appeals (Clause 7.7)

Appeals are requests for the IB to change a decision already made concerning the demonstrated conformance of the object of inspection, or lack thereof. The adjudication of an appeal is simple comparison of the circumstances surrounding the decision being appealed and confirmation that the decision either met the stated requirement, which means it can be denied, or did not meet the stated requirement and the appeal can be upheld.

Appeals require serious adjudication and it is a good idea for the quality manager to act as non-voting secretary of any appeals committee. Discussion must steer clear of any desire to punish the appellant. All information presented to the appeal panel should be used to determine whether the appeal should be upheld or denied.

Appeals under the standard do not need the formal meeting of parties outside of the appeal panel. Documentary evidence provided by the appellant is measured against the policies and procedures of the inspection body. The formal adjudication decision must be transmitted to the appellant as soon as possible. Any decision to uphold the appeal must result in the raising of a non-conformance, because the decision indicates that inspection body policies and procedures were not followed.

7.4.3 Actions to Address Risks and Opportunities (Clause 8.4)

This clause captures most of the instances of conditions in the inspection body that may impede the consistent production of technically valid results or enhance processes to the betterment of the operation of the inspection body or the production of valid results. This includes the processes for capturing both identified PNCs and OFIs.

These can be treated the same...same procedures, same forms, and same approach. The only stipulated difference is whether the condition provides a negative impact (risk) or a positive impact (benefit) to the inspection body and the conduct of its processes.

7.4.4 Corrective Action (Clause 8.5)

This clause is strictly about inspection body response to identified non-conformances. These are the conditions that have already impeded the consistent production of technically valid results or are contrary to specified policies and procedures. The processes for capturing identified NCs the same as those for capturing PNCs and OFIs...same procedures, same forms, and same approach. The only difference is Time (when they have occurred).

7.4.5 Internal Audit (Clause 8.6)

Internal audits are the most effective ways to recognize and identify conditions that have (or may) impede the consistent production of technically valid results or provide benefit to the organisation or its inspections.

Internal audits provide the best indication of the health of the quality system and must be conducted with people trained to conduct them.

An internal audit, like all types of audits, is a comparison of what is required to what exists. This comparison is based on the gathering of “objective evidence” of current conditions and situations. This objective evidence is gathered by:

- Document review
- Observation
- Interview

Contrary to popular belief, there is no “good” or “bad” result from an internal audit. There is only the objective aspect of “meeting requirement” or “not meeting requirement.” All results are “good” results, even those that demonstrate the existence of a condition that does not meet the stated requirement. Such a result gives valuable information in order to correct or improve processes. It allows top management to do their job. In short, the more findings, the better.

Top management:

- Are the owners of this process,
- Sell the requirement for internal audits to the staff,
- Approve the internal audit program and plan,
- Facilitate implementation of the requirement (remove obstacles for its accomplishment),
- Provide the Quality Manager with sufficient levels of responsibility to develop and, upon approval, implement the plan,
- Approve solutions resulting from the process, and
- Monitor the continuing effectiveness of the process.

An organization that seeks detailed knowledge about how well it is doing its own business is headed in the right direction. Such an organization is well led and not afraid to ask itself the hard questions.

In good organizations, the normal role of staff in internal audits is:

- Participate in the process, including the planning stages.
- Promote its benefits (if understood).
- Propose solutions when non-conformance / OFI challenges are encountered.
- Implement corrective- and preventive-action solutions when approved.
- Maintain the quality system as specified.
- Actively seek out OFIs.
- Make use of the benefits of the process.

The following are some of the considerations to be examined and addressed when planning and implementing internal audit programs in laboratories:

- Auditing is a “formal” process. Take no shortcuts. This ensures that all parties are treated with respect.
- The process selected must be one that can be successfully implemented. Time and resources are key.
- Avoid undue costs. Recognize the real benefits. Promote the positive aspects.
- Avoid the damage (hidden costs) of staff perceiving “failure” because of the audit process. This is a leadership challenge, but it is critical to the success of the program.
- Shorter, and more frequent, audits reinforce the requirement to maintain the quality system and result in fewer NCs. Longer and less frequent audits cost less in time and personnel.
- Quality documentation must be in place for an audit to take place. This includes:
 - Quality manual
 - SOPs
 - Inspection Methods
 - Supporting Records

7.4.6 Management Review (Clause 8.7)

Management reviews are the best venue for top management to determine if the management system is helping attain corporate objectives. If it is, then the system does not need much modification. If it does not

support corporate objectives, then either the system must be modified, or organizational expectations must be modified. This is why the leadership of top management is so important.

While the management team can make changes to the management system, only top management can modify expectations. Some findings may come from this exercise, but they are most likely to be PNCs and OFIs.

Meetings are normally chaired by top management with the quality manager acting as secretary. The agenda must include all the items shown in 17020, clauses 8.7.2 and 8.7.3.

One role of top management is to carry out regular systematic evaluations of the suitability, adequacy, effectiveness, and efficiency of the quality management system with respect to the quality policy and quality objectives. This review can include consideration of the need to adapt the quality policy and objectives in response to changing needs and expectations of interested parties.

In essence, management review allows top management to determine if the quality system is supporting the attainment of organizational objectives. If it does, all is good. If it does not, then either the system must be modified – done by the entire management team, or organisational expectations must be modified – something done only by top management.

The review includes determination of the need for actions. Amongst other sources of information, audit reports are used for review of the quality management system.

This activity demonstrates and documents top management commitment to monitoring the quality system and its implementation.

Management review can also introduce any necessary changes or improvements; such as:

- organizational changes,
- hiring additional staff,
- providing specialised training,
- modifying the services offered,
- purchasing additional equipment, and
- modifying existing policies and procedures.

Clause 8.7 of ISO/IEC 17020 states:

“8.7.2 *The inputs to management review shall be recorded and shall include information related to the following:*

- a) *internal and external changes that are relevant to the inspection body;*
- b) *suitability of policies and procedures;*
- c) *outcome of recent internal audits;*
- d) *assessments by external bodies;*
- e) *client, personnel, and, if relevant, interested parties feedback;*
- f) *corrective actions;*
- g) *status of actions from previous management reviews;*
- h) *the fulfilment of objectives;*
- i) *changes in the volume and type of the work or in the range of inspection activities;*
- j) *appeals and complaints;*
- k) *effectiveness of any implemented improvements;*
- l) *adequacy of resources including current human and equipment resources, projected workloads and the need for training of both new and existing personnel;*
- m) *results of risk identification including impartiality threat identification process and its conclusions;*
- n) *review of the effectiveness of processes established to ensure adequate competence of the personnel, including monitoring and training of inspectors and other personnel involved in inspection activities;*
- o) *other relevant factors*

8.7.3 *The outputs from the management review shall record all decisions and actions related to at least:*

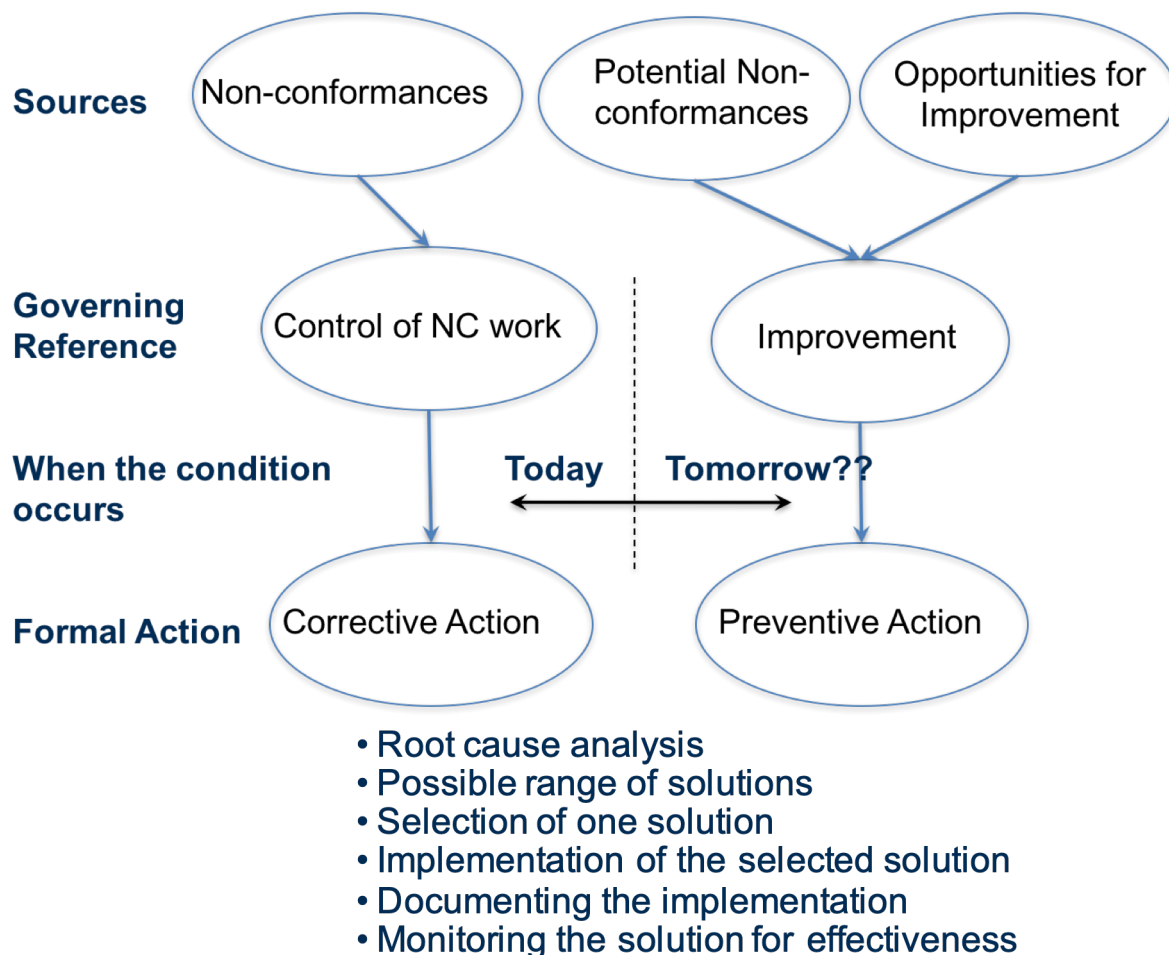
- a) *the effectiveness of the management system and its processes;*
- b) *improvement of the activities related to the fulfilment of the requirements of this document;*

- c) *provision of required resources;*
- d) *any need for change."*

Management review normally considers the types of information provided by:

- Managerial reports
- Quality system audits
- Client feedback, including complaints, compliments and appeals
- Internal quality control measures and trends
- Trends in NCs, PNCs, OFIs, and complaints.

7.5 From Identification to Action in Continual Improvement



7.5.1 What does this mean to the inspection body?

The processes for identifying and addressing both identified NCs (potentially leading to corrective action), PNCs (potentially leading to preventive action), and OFIs (potentially leading to improvement action) can be the same...same procedures, same forms, and same approach. The only stipulated difference is Time.

All personnel can now participate more effectively in identifying NCs, PNCs, and OFIs. They understand them better and they are more certain about which is which.

Implementing this approach in a formal manner also allows the inspection body to pro-actively implement continual improvement.

7.6 How to Implement Continual Improvement in an Inspection body

This is the formal method of treating NCs and PNCs/OFIs in an inspection body quality system.

Corrective Action or Preventive Action (CAPA = Continual Improvement)

- Root cause analysis
 - Determine a range of potential solutions
 - Select one
 - Implement the selected solution
 - Document the implementation
 - Monitor the implemented solution for effectiveness.
- } These two alone are only **Correction** or **Prevention**.

See the flowchart shown in section 7.13 below.

7.6.1 Correction, Prevention, and Improvement

Correction, prevention, and improvement are the simplest actions to take and they involve only the implementation and documentation of a solution that does not involve root cause analysis.

7.6.2 The Need for Corrective or Preventive Action

Whenever NCs, PNCs or OFIs are identified, the inspection body may normally address them in one of two ways:

- Correct/prevent the problem (or improve the condition) by implementing a solution and documenting both the problem and the solution. This is known as correction, prevention, or improvement and should not be confused with corrective- or preventive- or improvement-action.
- Complete full corrective- or preventive-, or improvement-action, commencing with root cause analysis.

The decision to select either approach should normally be done by asking three questions and determining, from the answers, which is the most appropriate approach – simple correction/prevention/improvement, or full-fledged corrective- or preventive-, or improvement-action.

The three questions are:

- Does the condition present the inspection body with unacceptable risk to the inspection body or to people, such as health and safety concerns?
- Does the condition cause the inspection body to produce invalid (incorrect results)? Or could it?
- Will it be easier to conduct full corrective- or preventive-, or improvement-action than simple recurring correction or prevention or improvement?

Full corrective- or preventive-, or improvement-action with root cause analysis is required **ONLY** if any of these three questions are answered with a "yes." Otherwise, the situation has little impact on the inspection body, its people, its visitors, or its ability to consistently produce technically valid results. It is easier to continually correct the situation, and no root cause analysis is required.

7.6.3 A Holistic Approach

ISO/IEC 17020 is focussed on an inspection body's ability to produce valid results, and NCs can be thought of as those circumstances that prevent this. Corrective and Preventive action, therefore, can be thought of as those activities which mitigate the adverse effects of NCs – today and tomorrow.

If we understand that PNCs are only the identification of a POTENTIAL or POSSIBLE non-fulfilment of specified requirements, then it becomes much easier to determine the best solution.

What can be done to address both NCs and OFIs/PNCs? They can be dealt with using the same formal process for corrective- or preventive-action.

- Understand that an NC is different from a PNC in only one aspect - Time.
- Understand that the inspection body quality system needs to address both of these sets of circumstances.

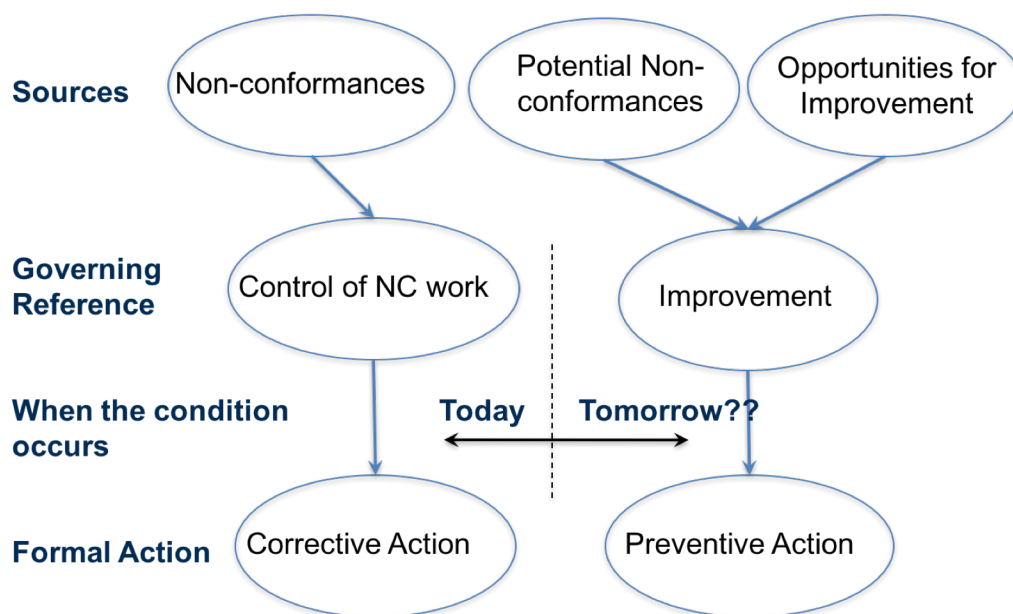
- Understand that NCs can be dealt with by simple correction or undertaking the more formal process of corrective action.
- Understand that PNCs can only be dealt with using the more formal preventive action – more about this later.
- Understand that OFIs can only be dealt with using the more formal improvement action – more about this later.
- Understand that a corrective action differs from a preventive action/improvement action in only one aspect – Time. The former is to prevent recurrence of a non-conformance that has already occurred while preventive action is to prevent the first time occurrence of a non-conformance that has not yet occurred. Improvement-action is to identify impediments to identifying other potential improvements.

ISO 9001 describes the whole process of continual improvement as having the following steps:

- identifying NCs and PNCs
- determining the need to prevent occurrence of PNCs or recurrence of NCs
- determining the causes of NCs
- determining and implementing the action that is needed
- recording the results of the action taken
- reviewing the action taken (monitoring for effectiveness)

Compare this list with that shown at the bottom of the bubble diagram in the section “*From Identification to Action*” above. They are nearly identical. This is once instance where the concept presented in ISO 9000 provides a better model for inspection bodies to follow, than simple interpretation of the wording in ISO/IEC 17020 clauses 8.4 and 8.5.

The inspection body can now formally document its continual improvement goals, processes, procedures and forms by simply pointing to its own efforts in corrective-, preventive-, and improvement-action. The graphic below, repeated from section 7.5 above shows the holistic approach of a continual improvement program.



- Root cause analysis
- Possible range of solutions
- Selection of one solution
- Implementation of the selected solution
- Documenting the implementation
- Monitoring the solution for effectiveness

7.6.4 Defining the “Root” Cause

The first step in the conduct of either preventive-, or corrective-, or improvement-action is an analysis of the root cause. Root causes are the reason that the identified condition (NC/PNC/OFI) came to exist in the first place. In order to permanently eliminate the adverse condition, or eliminate the impediment to identifying other OFIs – its root cause must be identified and then addressed/eliminated.

Organisations often treat non-conformances as “errors” when they are only indications that the quality system is not adequately supporting the work of the people within the system. It is the quality system that needs to be corrected, in most instances – not people.

At the point of discovery of a non-conformance, or a potential non-conformance, the best approach to take is to recognise that the root of the non-conforming condition is that something is “missing” from the basic list of:

People:

- *With the required skills, and*
- *With the required knowledge,*

The Environment:

- *with the required facilities, and*
- *with the required equipment,*

The Quality Control/Quality Assurance, and

The Procedures

in order to undertake the work and produce technically valid results.

This list provides us with a number of “categories” of root cause and we can select the most appropriate of these as our first approximation of the actual root cause. They are:

- Personnel Factors dealing with the demonstrated skills and knowledge of the persons involved.
- Environmental Factors dealing with the physical plant, facilities, and equipment.
- Quality Factors including quality control and quality assurance, and
- Procedural Factors including the basis and validity for the work being executed.
- *Organisational Culture (???)*

Sometimes an organisation can have all of these things in place and still have difficulties. The most common cause for this condition is its leadership and the organisation culture that emanates from the leadership.

Organisational culture and leadership are, therefore, the final category for root cause considerations. There is a catch to this final category, however. If the root cause of a non-conformance can be traced back to something missing in either the culture or leadership of the organisation, it may be very difficult to have this root cause accepted.

7.6.4.1 Root Causes based on Personnel Factors

The following list groups those root causes falling under the category of personnel factors.

Physical capacity

- Inappropriate height, weight, size, strength, dexterity, reach, aural and visual acuity, etc.
- Restricted range of physical motion
- Restricted physical endurance
- Physiological sensitivities to conditions or substances or breathing or other impairment
- Restricted use of physical senses

Intellectual capacity (Most of these can only be determined by a doctor)

- Fears and phobias
- Emotional instability

- Inability to comprehend and collate
- Inability to exercise judgment
- Lack of situational awareness
- Lack of aptitude
- Memory failure
- Psychological medical disorder or condition

Physical or physiological stress

- Injury or illness
- Fatigue (workload or reduced physical capacity)
- Fatigue (lack of rest)
- Fatigue (sensory overload such as noise)
- Exposure to hazards
- Medication
- Working in confined spaces

Emotional or psychological stress (Most of these can only be determined by a doctor)

- Emotional overload
- Fatigue (workload or speed of work)
- Extreme judgment/decision demands
- Routine, monotony, uneventful demand for vigilance
- Extreme concentration/perception demands
- “Meaningless” or “degrading” activities
- Confusing direction and demands
- Conflicting direction/demands
- Pre-occupation with personal problems
- Frustration
- Psychological medical disorder or condition
- Inappropriate effort to gain attention

Individual skill **(SECOND MOST COMMON ROOT CAUSES)**

- Lack of formal training (initial and follow-up)
- Lack of experience
- Infrequent opportunity to exercise skill
- Lack of coaching
- Lack of review of performance

Individual knowledge **(MOST COMMON ROOT CAUSES)**

- Lack of formal training (initial and follow-up)
- Lack of experience
- Misunderstood direction
- Lack of situational awareness

Care and attention

- Unintentional improper conduct
- Intentional improper conduct (refusal to exercise care and attention)

7.6.4.2 Root Causes based on Environmental Factors

The following list groups those root causes falling under the category of environmental factors.

Physical plant and facilities

- Space not correctly sized / oriented for the work
- Lack of physical or other security
- Facility materials / construction / finishes not appropriate to tasks
- Incompatible uses within facility
- Lack of availability of facility
- Lack of appropriate access to facility

Environment

- Inappropriate environment for tasks
- Inadequate control of environmental conditions

Tools and equipment

- Inappropriate tools for tasks
- Inadequate control of tools
- Inadequate use of tools
- Inadequate conditioning / preparation of tools

Materials and supplies

- Inappropriate for tasks
- Inadequate controls
- Inappropriate uses
- Inadequate conditioning/inspection/verification

Plant, facility, tool and equipment maintenance

- Insufficient rigor in maintenance
- Inappropriate types of maintenance
- Inadequate control of maintenance activities
- Inadequate inspection or monitoring

Physical wear and tear on plant, facilities, tools and equipment

- Inadequate planning of use
- Inappropriate use (overloading/overuse/excessive/wrong task)
- Inadequate inspection or monitoring
- Use by untrained / unqualified personnel

7.6.4.3 Root Causes based on Quality Factors

The following list groups those root causes falling under the category of quality factors.

Quality control

- Insufficient controls
- Insufficient monitoring of controls
- Inappropriate use of information acquired from controls

Quality assurance

- Insufficient quality assurance
- Insufficient monitoring of quality assurance results
- Inappropriate use of information acquired from quality assurance

Quality system

- Inadequate quality planning
- Inadequate monitoring and review of quality system
- Inappropriate use of information acquired from monitoring quality system
- Inadequate implementation of continual improvement
- Insufficient monitoring for effective implementation of system

7.6.4.4 Root Causes based on Procedural Factors

The following list groups those root causes falling under the category of procedural factors.

Use of standard procedures

- Reference to inappropriate/expired standards
- Insufficient reference to appropriate standards
- Inadequate development of appropriate specifications

Development of specifications and procedures

- Inappropriate specifications included in procedures
- Insufficient use of appropriate specifications in procedures.
- Inappropriate processes to develop procedures
- Inappropriate orientation of procedures
- Insufficient consensus on content

Implementation of procedures

- Insufficient training / communication upon implementation
- Insufficient monitoring for effective implementation

Selection of vendors, personnel, supplies

- Lack of appropriate review of specifications
- Lack of application of appropriate specifications
- Lack of review of acquired supplies
- Lack of review of vendor, personnel performance

7.6.4.5 Root Causes based on Organizational Culture - Sometimes the issue is Leadership

The following list groups those root causes falling under the category of organizational and leadership factors.

Leadership

- Confusing direction and demands
- Conflicting direction/demands
- Lack of coaching
- Acceptance of (or reward for) non-conforming performance
- Lack of recognition for conforming performance
- Tolerating inappropriate peer pressure
- Inappropriate incentives
- Unintentional improper conduct that is condoned
- Intentional improper conduct that is condoned
- Inappropriate delegation (accountability without authority etc)

Communications

- Lack of review of performance
- Inadequate performance feedback
- Inappropriate treatment of disputes/complaints from all parties (external / internal)
- Inappropriate treatment of feedback from all parties

Motivation

- Reward for non-conforming performance
- Lack of recognition (reward) for conforming performance
- Inappropriate incentives, peer pressure, save time/money/effort, gain attention, etc
- Excessive frustration or aggressiveness

While the lists above are fairly comprehensive, they do not by any means cover all possible root causes. This list of missing pieces describes the holes in a quality system whose absence is a cause of non-conforming conditions.

There is a catch to the final category of Organizational Culture. If the root cause of a non-conformance can be traced back to something missing in either the culture or leadership of the organization, it may be very difficult to have this root cause accepted.

7.7 Creating Solutions that Endure

Once the actual root cause of the non-conforming condition has been determined, the work in developing solutions (corrective / preventive actions) must focus on eliminating the root cause.

Corrective action is aimed at preventing recurrence of an identified non-conformance. Preventive action is aimed at preventing the first-time occurrence of a potential non-conformance. Improvement action is aimed at removing the impediment that prevented identification of an OFI sooner than was actually done.

Examining the approach described above, the determination of root cause is most appropriately followed by the identification of a set or spectrum of solutions – any of which will address the root cause. This

The actual selection of the corrective / preventive action solution, however, is entirely dependent on others and their input. Solutions implemented in isolation do not last. They do not consider how people, other than us, work within the quality system and they cannot support people in their implementation of the quality system. The same, or similar, non-conformances may occur again.

The most appropriate approach for the selection of the corrective / preventive action address the actual root cause and endure. This approach involves the development of consensus within the group expected to implement selected corrective / preventive action. Consensus makes the solution stronger and allows others to identify problems and take preventive action as similar conditions are encountered following implementation. These types of solutions endure and prevent recurrence of non-conformances.

Organisations attempting to develop systematic approaches in this area should consider the following steps:

- 1 Develop a set of potential solutions, all of which address the identified root cause,
- 2 Determine the solution that best meets the needs of those affected by the root cause condition and those that will be required to implement it. Develop consensus.
- 3 Select the solution agreed by all.
- 4 Implement the selected solution
- 5 Monitor the selected solution for effectiveness

7.8 Documenting the Effort from Root Cause to Solution

A comprehensive quality system works best when the inspection body treats non-conformances and potential non-conformances in a congruent fashion, understanding these two are the same – except for the time of their occurrence.

Accepting this, the records created for one, can also use the same format as the other. The sample provided in this lesson can be used for any non-conformance leading to corrective action, any potential non-conformance leading to preventive action and any opportunity for improvement leading to preventive action.

7.9 Measuring and Monitoring the Quality System

7.9.1 The Need for Measurement

When an inspection body wishes to see how well an inspection process is performing, it is validated for fitness for purpose. Its ability to determine conformance is compared to other processes of known outcome. This comparison is called validation.

The same approach applies to a quality system. In order to determine if the quality system is performing as required, it must be measured. This measurement is generally in the form of an internal audit.

Normally, internal audits have three specific goals.

- The first is to determine if it has been implemented throughout the inspection body. When everyone can show the procedures they use for their work and the records generated from the use of these procedures, the system can easily be deemed implemented.
- The second is to measure the effectiveness of the system to determine if it conforms to requirements and adequately supports the ability of the inspection body to produce technically valid results and decisions. When tracking logs demonstrate that NCs have not recurred, that PNCs have been prevented from happening the first time, and when OFIs have been allowed to be identified throughout the operation of the inspection body – that root causes and solutions have supported this outcome – the system can be deemed effective.
- The third aim of an internal audit is to determine if the system allows people to identify PNCs and OFIs. Experience indicates that good QMS will show at least 30% of all findings in the tracking log are PNCs and OFIs, that system is deemed to allow for improvement.

An internal audit is the best tool an organization can use to determine how well the quality system is functioning, but it is only one of the inputs placed before top management in monitoring how well it supports the operations of the organization.

ISO/IEC 17020 separates these measurement and monitoring functions into two clauses, 8.6 – *Internal Audits* and 8.7 – *Management Review*. Note that an internal audit and an external assessment have very different aims.

- An external assessment is to determine the competence of the organization to produce technically valid results and concentrates on the requirements of the standard.
- An internal audit concentrates on the requirements articulated in the organization's own quality system.

7.9.2 International Requirements

In North America and throughout the Pacific Rim nations, assessment of laboratories is restricted by the distances involved. The assessment cycle of accreditation bodies in these areas is two years. In Europe, it is generally one year.

No international arrangement documents specify the period of both internal audits and management reviews as being one year. All conformity assessment bodies are expected to determine the level of risk imparted to the organization by the frequency of these activities and justify the frequency selected.

7.12 Monitoring Solutions, Follow up and Timelines

7.12.1 Monitoring Efforts

Quality system measurement and monitoring exercises such as internal audit and management review will produce findings requiring action on the part of all inspection body staff. These findings will most likely be NCs, PNCs, or OFIs. Management review will most likely raise no NCs but more PNCs and OFIs.

Once raised and recorded within the inspection body's continual improvement program, they become corrective and preventive actions the same as for those raised from other quality system identification

mechanisms. Within the continual improvement program of the inspection body, as with other corrective and preventive actions, the implementation of these actions should be followed up after close out, to determine if they have achieved the desired results.

Follow up activities for both corrective- and preventive-actions allow an inspection body to determine that the implemented action did what was required.

Management review findings can sometimes be treated separately, depending on the top management perception of the type of findings raised during management review. If treated separately, they must still be tracked, closed out and followed up for effectiveness within the management review processes, if not the overall continual improvement program.

7.12.2 Follow up for Effectiveness

Clause 8.5 of ISO/IEC 17020 requires the monitoring of corrective actions to ensure that, at some later date, the inspection body is able to determine that a particular corrective action has eliminated a root cause. This approach should also be used for potential non-conformances and opportunities for improvement.

These monitoring and follow-up activities are required to complete the corrective action and preventive action processes. Best practice in continual improvement for corrective and preventive action therefore includes a mechanism for tracking monitoring and follow-up.

Monitoring and follow up is aimed at a formal consideration of the effectiveness of implemented corrective and preventive actions. The simplest method of doing this is to set a date, at some time in the future, to examine the condition to see if the corrective action has effectively eliminated the underlying root cause.

This method provides semi-automatic triggers to bring the issue forward at some time in the future – and can be well supported by database applications.

7.13 Continual Improvement Flowchart

This flowchart shows the connections between inspection body activities and the sources of actions that require them.

