Awareness Training on ISO 17020

"General Criteria for the operation of various types of bodies performing inspection"

1

About Qdot

Qdot managed by a team of experienced professionals, is committed to promote quality & excellence culture in GCC (UAE, QATAR, KSA, Oman, Kuwait, Bahrain)by providing below mentioned services.

Management System Services
- ISO 9001, ISO 14001, ISO 45001, HACCP, ISO 22000, FSSC 22000, BRC GS, Halal, ISO 22716 (GMP),Organic Certification, ISO 27001, ISO 41001, ISO 37001, ISO 50001, ISO 55001, ISO 17020 & ISO 17025 etc

Training Services
- IRCA Approved Lead Auditor
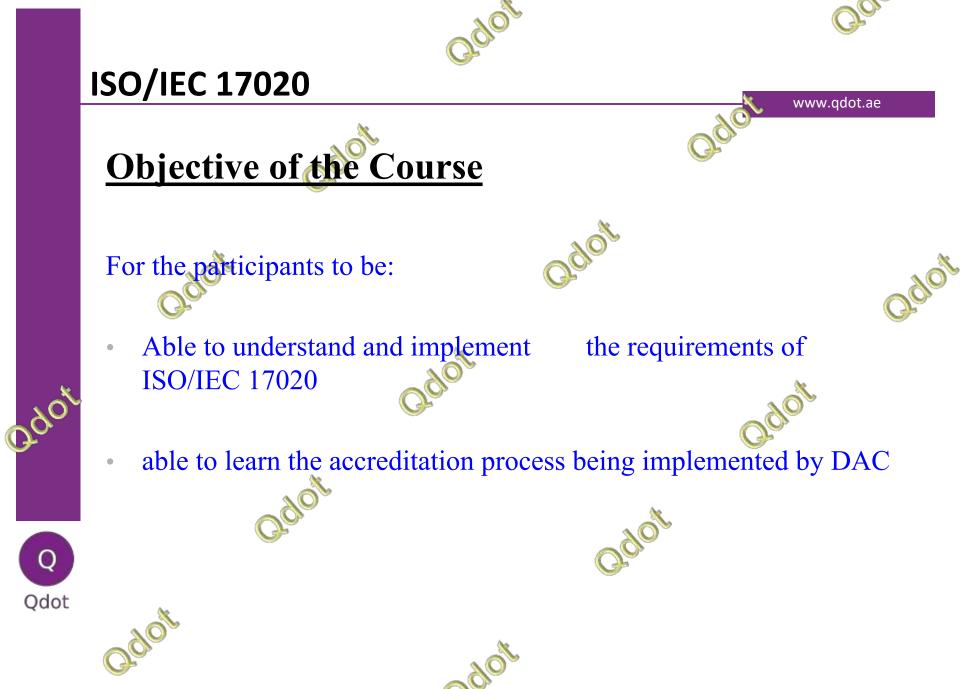- Awareness & Trainings on ISO Standards

Product Registration
- SABER, SQM, SFDA, CITC, IECEE, ECAS, EQM, RoSH, EESL, SLCP, G-Mark etc

Social Compliance
- SEDEX-SMETA, SA 8000, amfori BSCI, ISO 26001, WRAP, GRLI, ESG, CTPAT etc

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ISO/IEC 17020

<u>Objective of the Course</u>

For the participants to be:

- Able to understand and implement   the requirements of ISO/IEC 17020

- able to learn the accreditation process being implemented by DAC

ISO/IEC 17020

INTRODUCTION TO ACCREDITATION OF INSPECTION BODIES

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What is Accreditation?

- A procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks.

Accreditation is applicable for:

- Laboratories
- Inspection Bodies
- Certification Bodies (e.g. BVQI, TUV,SGS, Lloyds, BSI etc.)
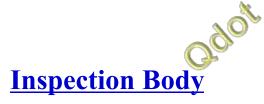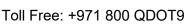- Personnel Certification Bodies, etc.

ISO/IEC 17020

Inspection Body

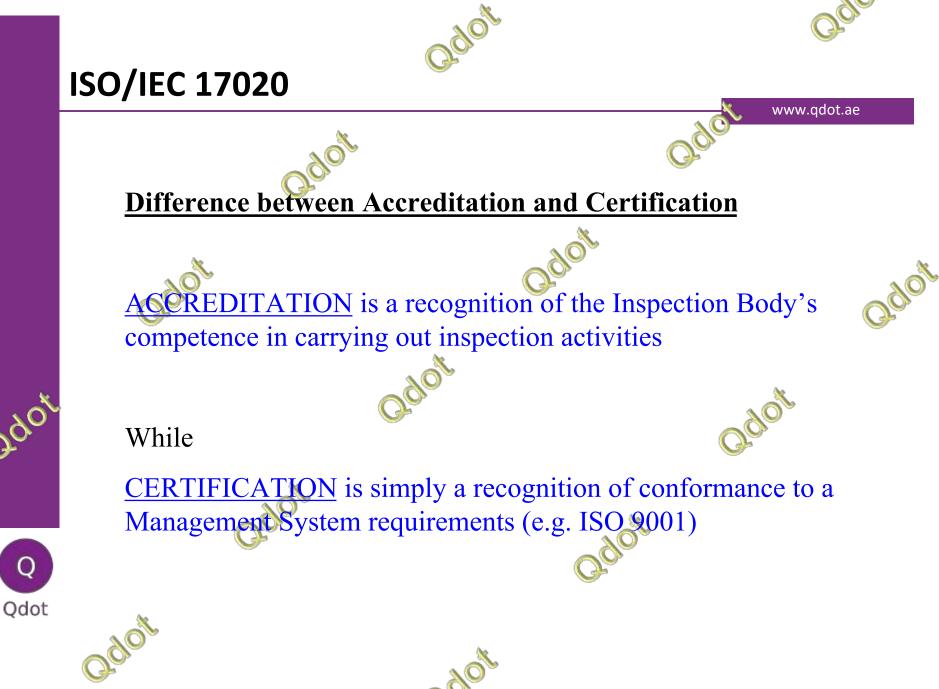Organization that performs Inspection

ISO/IEC 17020:2012

Inspection

Examination of a product, design, service, process or plant, and determination of their conformity with specific requirements or, on the basis of professional judgment, general requirement

ISO/IEC 17020:2012

ISO/IEC 17020

Difference between Accreditation and Certification

ACCREDITATION is a recognition of the Inspection Body's competence in carrying out inspection activities

While

CERTIFICATION is simply a recognition of conformance to a Management System requirements (e.g. ISO 9001)

ISO/IEC 17020

Evaluating technical competence requires additional technically focused activity:

- Use of Technical Expert

- Assessment against technical criteria

- Identification of specific capabilities
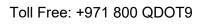
- Evaluation of results/reports/opinions

8

ISO/IEC 17020

<u>Requirements for Accreditation</u>

ISO/IEC 17020:2012 - What the Standard Requires

- Impartiality and independence
- Organizational structure
- Resource requirements including equipment and personnel
- Process requirements including inspection methods and reports
- Management system requirements
- Traceability
- The auditing and accrediting process

ISO/IEC 17020

<u>Benefits of Accreditation</u>

- A recognition of competence
- A recognition of reliability of inspection results
- A marketing advantage
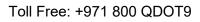- International Acceptance of inspection results

ISO/IEC 17020

General Requirement of ISO 17020

- Quality System aligned with ISO 9001

- Adequate Facilities and Equipment

- Competence of Staff

- Reliable Inspection Report / Certificate

- Efficient Records Management

- Effective management of Complaints & Appeals

- Independence, Impartiality and Integrity of Inspection Body

ISO/IEC 17020

■ **Accreditation Process**

> Submission of Application form, Quality Manual and Procedures Manual

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> Review of Quality Manual and Procedures

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> Assessment of the Quality System and Technical Competence

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> Preparation of the Assessment Report

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> Awarding of Accreditation Certificate after payment of applicable fees

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> Surveillance every year and Reassessment after 3 years

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ISO/IEC 17020

WHAT IS IT?

- It defines the general criteria for the operation of various types of bodies performing inspection

- It is an international standard adopted by DM to accredit inspection bodies operating in Dubai

- This interactive and practical course is designed to introduce delegates to the requirements of ISO/IEC 17020:2012 and how it applies to organizations who perform inspection activities.

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THE REQUIREMENTS OF ISO/IEC 17020

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ISO/IEC 17020

ISO/IEC 17020: 2012

General Criteria for the Operation of Various Types of Bodies Performing Inspection

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ISO/IEC 17020

SCOPE

- ISO/IEC 17020:2012 specifies requirements for the competence of bodies performing inspection and for the impartiality and consistency of their inspection activities.

- It also specifies the independence criteria

- It applies to inspection bodies of type A, B or C, as defined in this International Standard, and it applies to any stage of inspection.

ISO/IEC 17020

SCOPE

- **This standard does not cover testing laboratories, certification bodies or suppliers' declaration of conformity.**

- 4.1.4 If a risk to impartiality is identified, demonstrate how to be eliminated / minimised.
- 4.1.5 Top management commitment to impartiality.
- 4.1.6 Independent to the extent needed
- 4.1.6.a Type A requirements Clause A.1 Fully independent of all involvement

Consider

- Internal structures
- Consider design, manufacture, supply, installation, purchase, ownership, use or maintenance of inspected items.
- Ownership and management
- Linked companies

4.2 Confidentiality

- **4.2.1 responsible, through legally**

enforceable commitments, for the management of information obtained or created.

Inform client, in advance, of information open to public.

Generally information is proprietary and confidential.

- **4.2.2 Client notified of the information made public.**

- **4.2.3 Information about the client obtained from other sources also confidential.**

5 Structural requirements
5.1 Administrative requirements

- **5.1.1 Legal entity, can be held legally responsible for inspection activities.**

- **5.1.2 If part of a legal entity involved in activities other than inspection then identifiable within that entity.**

- **5.1.3 Documentation outlining competence.**

- **5.1.4 Adequate provision (e.g. insurance or reserves) to cover liabilities.**

- **5.1.5 Documentation describing the contractual conditions for service**

5.2 Organisation and management

- 5.2.1 Structured, managed to safeguard impartiality.
- 5.2.2 Organised, managed to maintain inspection capability.
- 5.2.3 Define and document the responsibilities and reporting structure.
- 5.2.4 Relationships within broader legal entity.
- 5.2.5 Technical manager(s), responsible for inspection activities. Technical manager available, competent and experienced.
- 5.2.6 Deputies for technical manager.
- 5.2.7 "job description" for each position involved in inspection activities.

6 Resource requirements
6.1 Personnel

- **6.1.1 Competence requirements for all personnel involved in inspection activities:**
- **education,**
- **training,**
- **technical knowledge,**
- **skills,**
- **experience.**

- **6.1.2 Sufficient number of competent persons, for type, range and volume of work.**
- **6.1.3 The personnel:**
- qualifications,
- training,
- experience, and
- satisfactory knowledge

relevant knowledge of:
- technology, processes,
- delivery of services,
- use of products,
- operation of processes,
- delivery of services,
- defects, failures and deficiencies, and
- significance of deviations.

6.1.4 Duties, responsibilities and authorities clear to each person

6.1.5 Documented procedures for training, formally authorising, and monitoring inspectors and personnel involved in inspection activities.

6.1.6 Procedures cover:

a) an induction period;

b) a mentored working period;

c) continuing training.

6.1.7 The training requirements, consider ability, qualifications and experience of each person and the results of monitoring (see 6.1.8).

- **6.1.8 Monitoring monitors familiarity with the inspection methods and procedures, for satisfactory performance, results of monitoring shall be used as a means of identify training needs(6.1.7).**

- **6.1.9 Each inspector shall be observed on-site**
- **6.1.10 records of**

monitoring,

education,

training,

technical knowledge,

skills,

experience and

authorisation

of each person in inspection activities.

- **6.1.11 Remuneration not to influence the results of inspections**

- **6.1.12 All personnel (internal and external) shall act impartially.**

- **6.1.13 All personnel (internal and external) shall maintain confidentiality**

6.2 Facilities and equipment

- **6.2.1 Available, suitable and adequate facilities and equipment**

- **6.2.2 Rules for the access to, and the use of specified facilities and equipment used to perform inspections.**

- **6.2.3 Ensure the continued suitability of the facilities and the equipment mentioned in 6.2.1 for their intended use.**

- **6.2.4 All equipment having a significant influence on the results of the inspection shall be defined and, where appropriate, uniquely identified.**

6.2.5 All equipment (see 6.2.4) shall be maintained using documented procedures and instructions.

6.2.6 Where appropriate, measurement equipment having a significant influence on the results of the inspection shall be calibrated before use, and then according to a programme.

6.2.7 Calibration of equipment so that measurements are traceable to national or international standards of measurement, where available.

6.2.8 Reference standards of measurement held by the inspection body shall be used for calibration only

6.2.9 Where relevant, equipment gets in-service checks.

6.2.10 Reference materials traceable to national /international reference materials.

6.2.11 Where relevant, procedures for

a) selection and approval of suppliers;

b) verification of incoming items;

c) appropriate storage facilities.

6.2.12 Where applicable, the condition of stored items shall be assessed at appropriate intervals to detect deterioration.

6.2.13 Computers or automated equipment :

a) software is adequate for use;

- validation of calculations before use

- periodic revalidation of hardware /software - revalidation when changes are made to hardware or software

- software updates implemented as required

b) procedures for protecting the integrity and security of data;

c) equipment is maintained in order to ensure proper functioning.

- 6.2.14 Procedures for dealing with defective equipment. removed from service by segregation, labelling or marking. consider effects on previous inspections.

- 6.2.15 Equipment and software records.

- identification

- information on calibration

- information on maintenance.

6.3 Subcontracting

- **6.3.1 The inspection body shall demonstrate subcontractor competent, complies with relevant standards.**

- **6.3.2 Client informed of subcontracting**

- **6.3.3 Responsibility for any determination of conformity remains with the inspection body.**

- **6.3.4 Records of investigation of the competence of subcontractors and of their conformity with relevant conformity assessment standards. Register of all subcontractors.**

7 Process requirements
7.1 Inspection methods and procedures

- **7.1.1 Uses methods and procedures of the requirements. Where these are not defined, the inspection body shall develop specific methods and procedures to be used**

- **7.1.3). Inform client if proposed method is considered inappropriate.**

- **7.1.2 Have and use adequate documented instructions on**

inspection planning

sampling and

inspection techniques, where needed for effective inspection.

- **Sufficient knowledge of statistical techniques supporting**

· sound sampling procedures,

· correct data processing,

· interpretation of results.

- **7.1.3 Non-standard methods appropriate and fully documented.**

- **7.1.4 All instructions, standards or written procedures, worksheets, check lists and reference data needed shall be maintained up-to-date and available.**

- **7.1.5 The inspection body shall have a contract or work order**

control system which ensures that:

a) work is within its expertise and that the organisation has adequate resources to meet the requirements;

b) the requirements adequately defined, special conditions are understood,

allowing unambiguous instructions,

c) work is controlled by regular review and corrective action;

d) the requirements of the contract or work order have been met.

- 7.1.6 Integrity of information supplied by any other party as part of the inspection process, shall be verified.

- 7.1.7 Observations recorded in a timely manner to prevent information loss.

- 7.1.8 Calculations and data transfer checks.

- 7.1.9 The inspection body shall have documented instructions for carrying out inspection in a safe manner.

7.2 Handling inspection items and samples

- **7.2.1 Items and samples to be inspected are uniquely identified in order to avoid confusion regarding identity**

- **7.2.2 Establish whether the item to be inspected has been prepared.**

- **7.2.3 Abnormalities recorded. If item doubtful or not as described, client contacted**

- **7.2.4 Procedures and facilities to avoid deterioration or damage to items**

7.3 Inspection records

- **7.3.1 The inspection body shall maintain a record system (see 8.4) to demonstrate the effective fulfilment of the inspection procedures and enable an evaluation of the inspection.**

- **7.3.2 The inspection report or certificate shall be internally traceable to the inspector(s) who performed the inspection.**

7.4 Inspection reports and inspection certificates

- **7.4.1 The work carried out by the inspection body shall be covered by a retrievable inspection report or inspection certificate.**

- **7.4.2.a Inspection reports – Content**

- **7.4.2b. Unique identification of the report.**

- **7.4.2c. date(s) of the inspection**

- **7.4.2d. identification of the items inspected**

- **7.4.3 certificate and report cross-refer**

- **7.4.4 Reports are correct, accurate, and clear, subcontractors results identified.**

- **7.4.5 Corrections or additions to an inspection report or inspection certificate after issue shall be recorded. Amended document identify the replaced document.**
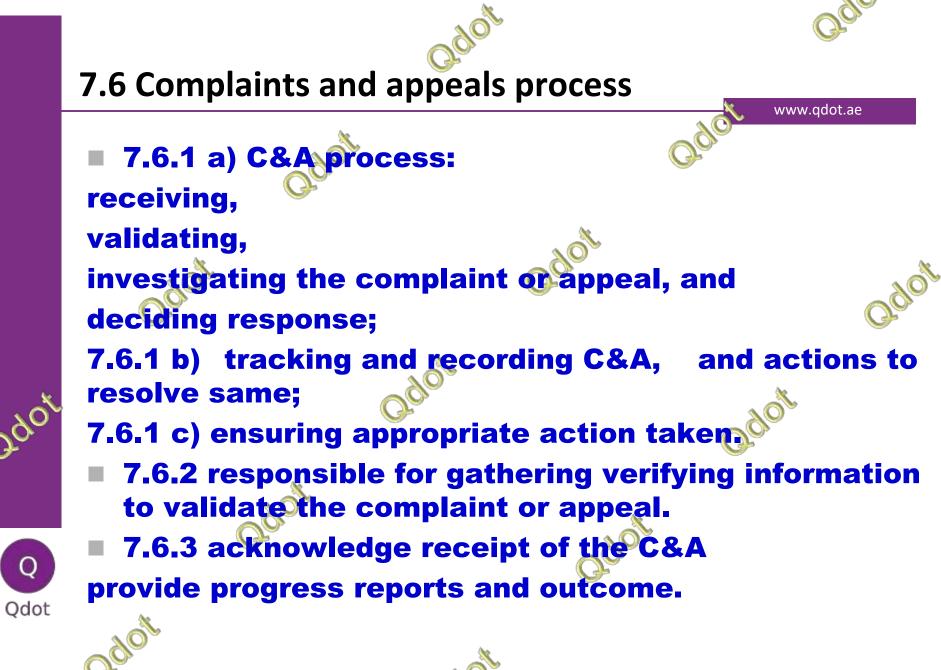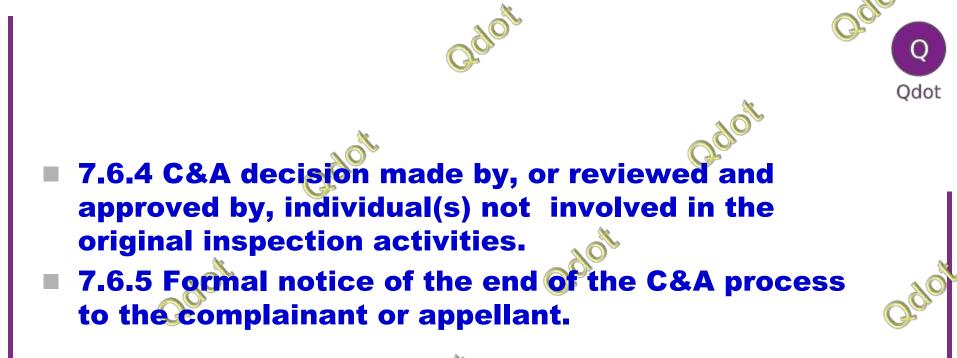
7.5 Complaints and appeals (C&A)

- **7.5.1 Documented process for C&A** receive, evaluate decide

- **7.5.2 C&A process available on request.**

- **7.5.3 On receipt confirm relevant and, if so, dealt with.**

- **7.5.4 Responsible for all decisions at all levels of handling C&A.**

- **7.5.5 Investigation and decision not result in any discriminatory actions.**

7.6 Complaints and appeals process

- **7.6.1 a) C&A process:**

receiving,

validating,

investigating the complaint or appeal, and

deciding response;

7.6.1 b) tracking and recording C&A,   and actions to resolve same;

7.6.1 c) ensuring appropriate action taken.

- **7.6.2 responsible for gathering verifying information to validate the complaint or appeal.**

- **7.6.3 acknowledge receipt of the C&A**

provide progress reports and outcome.

- **7.6.4 C&A decision made by, or reviewed and approved by, individual(s) not involved in the original inspection activities.**
- **7.6.5 Formal notice of the end of the C&A process to the complainant or appellant.**

8.5 Management review
8.5.1 General

- **8.5.1.1 Review management system to ensure**
  - continuing suitability,
  - adequacy and
  - effectiveness,
  - covering the stated policies and objectives.
- **8.5.1.2 Annual review**
- **8.5.1.3 Records of reviews shall be maintained.**
- **8.5.2 Review inputs**

Input shall include:

a) results of internal and external audits;

b) feedback from clients and interested parties

c) the status of preventive and corrective actions;

d) follow-up actions from previous management reviews;

e) the fulfilment of objectives;

f) changes that could affect the management system;

g) appeals and complaints.

- 8.5.3 Review outputs

■ Outputs from management review shall include decisions and actions related to:

a) improvement of the effectiveness of the management system and its processes;

b) improvement of the inspection body related to the fulfilment of this International Standard;

c) resource needs.

8.6 Internal audits

- 8.6.1 Procedures for internal audits.
- 8.6.2 Planned audit programme considering importance of the processes/ areas to be audited, results of previous audits.
- 8.6.3 Periodic internal audits covering all procedures in a planned and systematic manner.
- 8.6.4 Start with every 12 months. Adjust based on findings and stability.
- 8.6.5 The inspection body shall ensure that:

a) auditors suitably qualified

b) auditors do not audit their own work;

c) audit outcomes are feedback gathered

d) any outcome actions are timely and appropriately done;

e) any opportunities for improvement are identified;

f) the results of the audit are documented.

8.7 Corrective actions

- **8.7.1 Procedures to identify & manage nonconformities.**

- **8.7.2 Take actions to eliminate the causes of nonconformities to prevent recurrence.**

- **8.7.3 Corrective actions shall be appropriate to the impact of the problems encountered.**

- **8.7.4 The procedures shall define**

- **requirements for the following:**

a) identifying nonconformities;

b) determining causes;

c) correcting nonconformities;

d) evaluate need for preventive actions;

e) determining the actions needed and implementing them in a timely manner;

f) recording the results of actions taken;

g) reviewing the effectiveness of corrective actions.

8.8 Preventive actions

- **8.8.1 Procedures for preventive actions.**
- **8.8.2 Preventive actions taken appropriate to probable impact of problem.**
- **8.8.3 The procedures address:**

a) identifying potential nonconformities and their causes;

b) evaluating the need for action;

c) determining and implementing the action needed;

d) recording the results of actions taken;

e) reviewing the effectiveness of the preventive actions taken.

NOTE

The procedures for corrective and preventive actions do not necessarily have to be separate.

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