

ISO/IEC 17020:2012 Inspection Overview



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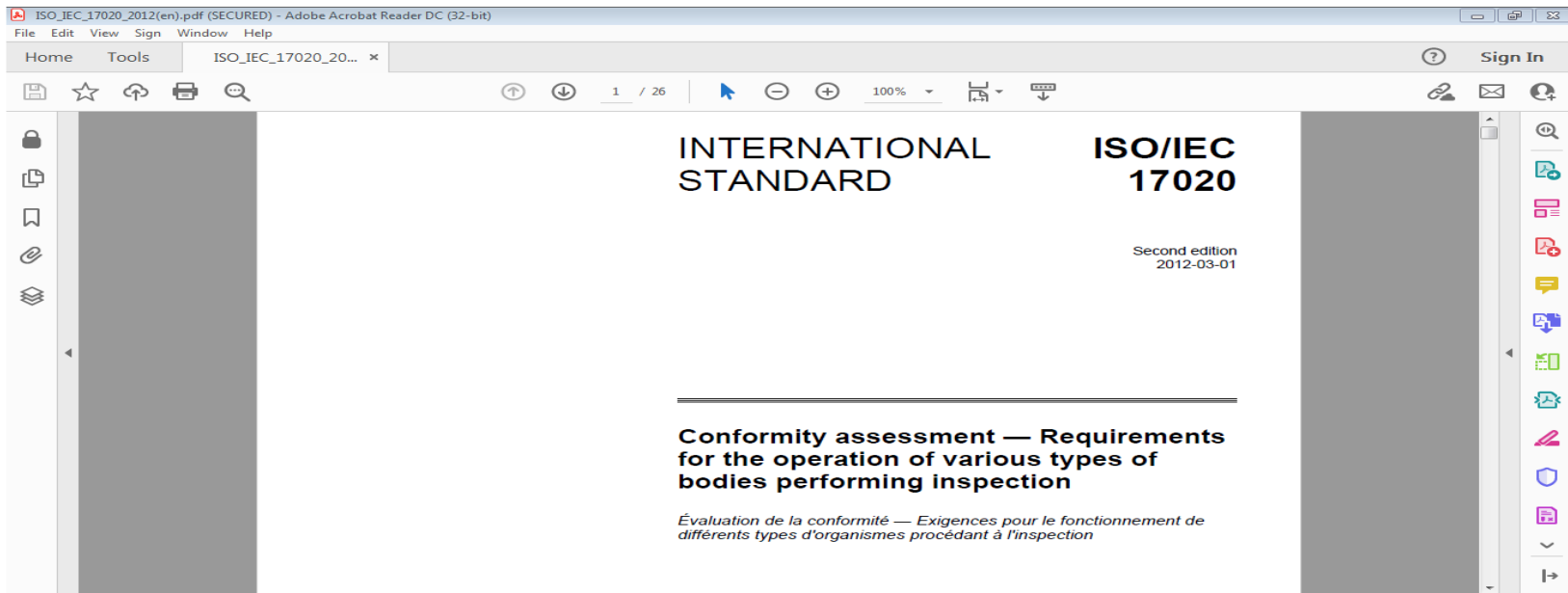
20-October-2021

ISO/IEC 17020:2012 Inspection Overview

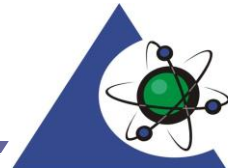
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ISO/IEC 17020:2012 Inspection Overview



This international Standards covers the activities of inspection bodies whose work can include the examination of materials , products, installations, plants, processes, work procedures or services, and the determination of their conformity with requirements and subsequent reporting of results of these activities to the clients and when required to authorities. Inspection can concern all stages during the lifetime of these items, including the design stage. Such work normally requires the exercise of professional judgement in performing inspection, in particular when assessing conformity with general requirements.



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4.1 Impartiality and independence

The inspection body shall be independent to the extent that is required with regard to the conditions under which it performs its services. Depending on these conditions, it shall meet the minimum requirements stipulated in Annex A,

Annex A

- **Independence requirements for inspection bodies**

- **A:1 Requirements for inspection bodies (Type A)**

3rd Party Inspection

- **A:2 Requirements for inspection bodies (Type B)**

Part of an organization but forms a separate part. supplying services to its parent organization

- **A: 3 Requirements for inspection bodies (Type C)**

Part of the organization and can be from the same part however will have safeguards within the organization to ensure adequate segregation of responsibility and accountabilities between inspection and other activities.

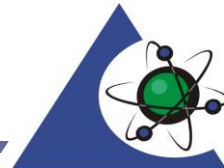


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4.2 Confidentiality

The inspection body shall be responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of inspection activities. The inspection body shall inform the client, in advance, of the information it intends to place in the public domain. Except for information that the client makes publicly available, or when agreed between the inspection body and the client (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and shall be regarded as confidential;

Confidentiality is the state of keeping or being kept secret or private



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Structural requirements

5.1 Administrative requirements

The inspection body shall have documentation which describes the activities for which it is competent;

The inspection body shall have adequate provision (e.g. insurance or reserves) to cover liabilities arising from its operations;

the level of provisions should be commensurate with the level and nature of liabilities that may arise from the inspection body's activities;

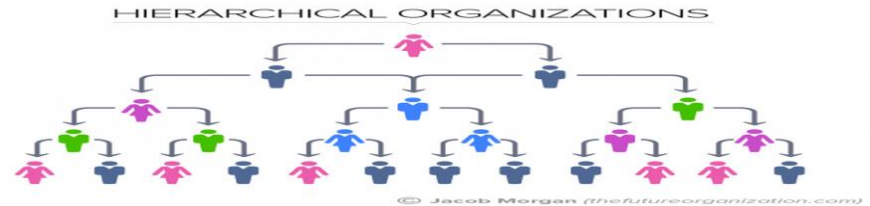
The inspection body shall have documentation describing the contractual conditions under which it provides the inspection, except when it provides inspection services to the legal entity of which it is a part;



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5.2 Organization and management

The inspection body shall define and document the responsibilities and reporting structure of the organization



The inspection body **shall** have available one or more person(s) as technical manager(s) who have overall responsibility to ensure that the inspection activities are carried out in accordance with this International Standard

NOTE This person fulfilling this function does not always have the title of technical manager.

The person(s) fulfilling this function shall be technically competent and experienced in the operation of the inspection body. Where the inspection body has more than one technical manager, the specific responsibilities of each manager shall be defined and documented



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5.2 Organization and management continued

The inspection body shall have one or more named person(s) who will deputize in the absence of any technical manager responsible for ongoing inspection activities;

In an organization where the absence of a key person causes the cessation of work, the requirement for having deputies is not applicable;



The inspection body shall have a job description or other documentation for each position category within its organization involved in inspection activities;

The job description or other documentation should detail the duties, responsibilities and authorities for each position category;



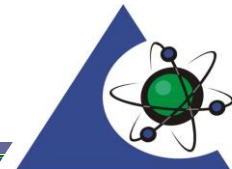
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Resource requirements Section 6

6.1 Personnel

The inspection body shall define and document the competence requirements for all personnel involved in inspection activities, including requirements for education, training, technical knowledge, skills and experience;

When professional judgment is needed to determine conformity, this shall be considered when defining competence requirements

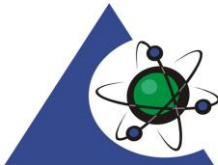


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6.1 Personnel continued

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

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



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6.1 Personnel continued

The inspection body shall have **documented procedures** for selecting, training, formally authorizing, and monitoring inspectors and other personnel involved in inspection activities

The **documented procedures** for training shall address the following stages:

- an induction period;
- a mentored working period with experienced inspectors;
- continuing training to keep pace with developing technology and inspection methods ;



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6.1 Personnel continued

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

The inspection body **shall maintain records** of monitoring, education, training, technical knowledge, skills, experience and authorization of each member of its personnel involved in inspection activities;

Records of authorization should specify the basis on which authorization was granted (e.g. the on-site observation of inspections).

The personnel involved in inspection activities shall not be remunerated in a way that influences the results of inspections;



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6.2 Facilities and equipment

The inspection body **shall have rules** for the access to, and the use of, specified facilities and equipment used to perform inspections;



All equipment shall be maintained in accordance with documented procedures and instructions;.

Where appropriate, measurement equipment having a significant influence on the results of the inspection shall be calibrated before being put into service, and thereafter calibrated according to an established program;



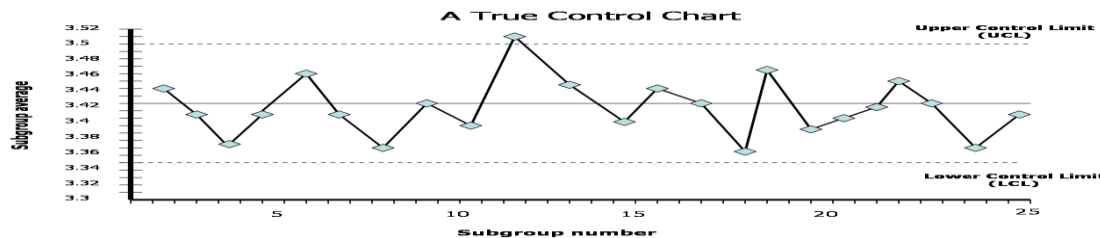
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6.2 Facilities and equipment continued

The overall program of calibration of equipment shall be designed and operated so as to ensure that, wherever applicable, measurements made by the inspection body are **traceable to national or international standards of measurement**, where available.

Where relevant, equipment shall be subjected to in-service checks between regular recalibrations;

*Where equipment is subjected to in-service checks between regular re-calibrations, the nature of such checks, the frequency and acceptance criteria **should** be defined;*



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6.2 Facilities and equipment continued

Where relevant for the outcome of inspection activities, the inspection body **shall have procedures** for the following:

- selection and approval of suppliers;
- verification of incoming goods and services;
- ensuring appropriate storage facilities;



The verification procedure should ensure that incoming goods and services are not used until conformance with specification has been verified;

Example: Use distilled or deionized water conforming grade 3 as specified in ISO 3696;



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6.2 Facilities and equipment continued

If the inspection body uses computers or automated equipment in connection with inspections, it shall ensure that:

- a) computer software is adequate for use;
- b) procedures are established and implemented for protecting the integrity and security of data;
- c) computer and automated equipment is maintained in order to ensure proper functioning;



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6.2 Facilities and equipment continued

The inspection body **shall have documented procedures for dealing with defective equipment.** Defective equipment shall be removed from service by segregation, prominent labeling or marking. The inspection body shall examine the effect of defects on previous inspections and, when necessary, take appropriate corrective action;



Relevant information on the equipment, including software, **shall be recorded.** This shall include identification and, where appropriate, information on calibration and maintenance;

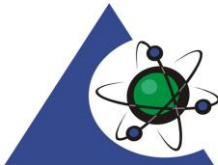


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6.3 Subcontracting

The inspection body shall itself normally perform the inspections that it contracts to undertake. Where an inspection body subcontracts any part of the inspection, it shall ensure and be able **to demonstrate** that the subcontractor is **competent** to perform the activities in question and, where applicable, **complies with the relevant requirements stipulated in this International Standard or in other relevant conformity assessment standards;**

The inspection body shall inform the client of its intention to subcontract any part of the inspection. The inspection body **shall record and retain details** of its investigation of the competence of its subcontractors;



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Section 7 Process requirements

7.1 Inspection methods and procedures

The inspection body shall use the methods and procedures for inspection which are defined in the requirements against which inspection is to be performed;

Note: The requirements against which the inspection is performed are normally specified in regulations, standards or specifications, inspection schemes or contracts. Specifications can include client or in-house requirements;

. Increasingly new technology (e.g drones, cameras, special glasses, IT, artificial intelligence, etc.) is introduced to be used during inspections. This could be as a (partly) replacement of an existing inspection method (like the human eye) or as a new inspection method.

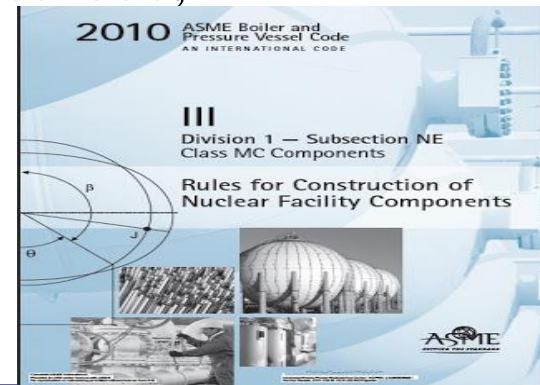


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7.1 Inspection methods and procedures continued

When the inspection body has to use inspection methods or procedures which are non-standard, such methods and procedures shall be appropriate and fully documented;

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



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7.1 Inspection methods and procedures continued

The inspection body shall have a contract or work order control system which ensures that :

- work to be undertaken is within its expertise and that the organization has adequate resources to meet the requirements;
- the requirements of those seeking the inspection body's services are adequately defined and that special conditions are understood, so that unambiguous instructions can be issued to personnel performing the duties to be required;
- work being undertaken is controlled by regular review and corrective action
- the requirements of the contract or work order have been met;

For routine or repeat work requests the review may be limited to considerations of time and human resources. An acceptable record in such cases would be an acceptance of the contract signed by an appropriately authorized person;



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7.1 Inspection methods and procedures continued

Calculations and data transfers shall be subject to appropriate checks.

NOTE Data can include textual material, digital data and anything else that is transferred from one location to another where errors could be introduced.;

The inspection body **shall have documented instructions** for carrying out inspection in a safe manner;



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7.2 Handling inspection items and samples

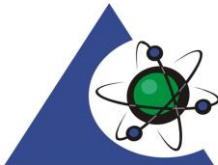
The inspection body shall ensure items and samples to be inspected are uniquely identified in order to avoid confusion regarding the identity of such items and samples;



Any apparent abnormalities notified to, or noticed by, the inspector shall be recorded;



The inspection body shall have documented procedures and appropriate facilities to avoid deterioration or damage to inspection items while under its responsibility;



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7.3 Inspection records

The inspection body shall maintain a record system to demonstrate the effective fulfilment of the inspection procedures and to enable an evaluation of the inspection;

Note: The records should indicate which particular item of equipment, having a significant influence on the result of the inspection, has been used for each inspection activity

The inspection report or certificate shall be internally traceable to the inspector(s) who performed the inspection;



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7.4 Inspection reports and inspection certificates

The work carried out by the inspection body shall be covered by a retrievable inspection report or inspection certificate;

Any inspection report/certificate **shall** include all of the following:

- a) identification of the issuing body;
- b) unique identification and date of issue;
- c) date(s) of inspection;
- d) identification of the item(s) inspected;
- e) signature or other indication of approval, by authorized personnel;
- f) a statement of conformity where applicable;
- g) the inspection results, except where detailed in accordance with 7.4.3.

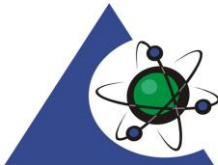
7.4.3 An inspection body shall issue an inspection certificate that does not include the inspection results only when the inspection body can also produce an inspection report containing the inspection results, and when both the inspection certificate and inspection report are traceable to each other;



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7.5 Complaints and appeals

The inspection body shall have a documented process to receive, evaluate and make decisions on complaints and appeals;



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7.6 Complaints and appeals process

The handling process for complaints and appeals **shall include at least the following** elements and methods

- a) a description of the process for receiving, validating, investigating the complaint or appeal, and deciding what actions are to be taken in response to it;
- b) tracking and recording complaints and appeals, including actions undertaken to resolve them;
- c) ensuring that any appropriate action is taken;



The decision to be communicated to the complainant or appellant shall be made by, or reviewed and approved by, individual(s) not involved in the original inspection activities in question;



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Section 8 Management system requirements

8.1 Options

The inspection body shall establish and maintain a management system that is capable of achieving the consistent fulfilment of the requirements of this International Standard in accordance with either Option A or Option B;



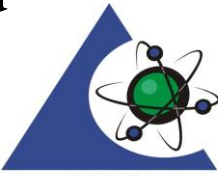
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8.1 Options continued

Option A Will be business as usual and this section will be assessed fully;

Option B An inspection body that has established and maintains a management system, in accordance with the requirements of **ISO 9001**, and that is capable of supporting and demonstrating the consistent fulfilment of the requirements of this International Standard, fulfils the management system clause requirements;

Section 8 will be assessed on a limited bases if the laboratory is part of a larger organization certified to ISO 9001 to assure that the laboratory is included in the process. PJLA assessment team has a guidance document in performing this limited assessment of Section 8 For Option B PJLA would require certification through a recognized Registrar to ISO 9001;



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8.2 Management system documentation (Option A)

The inspection body's top management shall establish, document, and maintain policies and objectives for fulfilment of this International Standard and shall ensure the policies and objectives are acknowledged and implemented at all levels of the inspection body's organization

The inspection body's top management **shall appoint** a member of management who, irrespective of other responsibilities, shall have responsibility and authority that include the following

- a) ensuring that processes and procedures needed for the management system are established, implemented and maintained; and
- b) reporting to top management on the performance of the management system and any need for improvement;



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8.3 Control of documents (Option A)

The inspection body shall establish procedures to control the documents (internal and external) that relate to the fulfilment of this International Standard;

NOTE Documentation can be in any form or type of medium, and includes proprietary and in-house developed software

A document is anything that tells a person in the organization what to do or how to do it”;

Internal

QUALITY SYSTEM
PROCEDURE

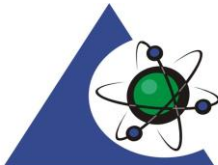
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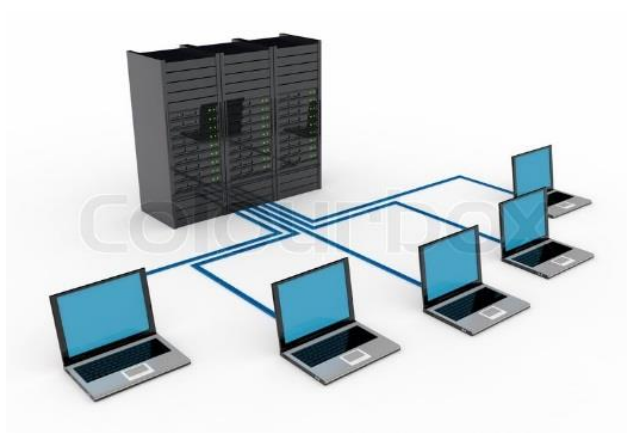
External



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8.4 Control of records (Option A)

The inspection body shall establish procedures to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of its records related to the fulfilment of this International Standard;



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8.5 Management review (Option A)

The inspection body's top management shall establish procedures to review its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this International Standard;

These reviews **shall be conducted at least once a year**. Alternatively, a complete review broken up into segments (a rolling review) shall be completed within a 12-month time frame;

This section details various inputs and outputs that need to be captured in the management review record.



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8.6 Internal audits (Option A)

The inspection body shall establish procedures for internal audits to verify that it fulfils the requirements of this International Standard and that the management system is effectively implemented and maintained. Internal audits **shall** be performed at least once every 12 months;



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8.6 Internal audits (Option A) continued

The inspection body shall ensure that:

- a) internal audits are conducted by qualified personnel knowledgeable in inspection, auditing and the requirements of this International Standard;
- b) auditors do not audit their own work;
- c) personnel responsible for the area audited are informed of the outcome of the audit;
- d) any actions resulting from internal audits are taken in a timely and appropriate manner;
- e) any opportunities for improvement are identified;
- f) the results of the audit are documented



Competent externally contracted personnel may carry out internal audits



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8.7 Corrective actions (Option A)

The inspection body shall establish procedures for identification and management of nonconformities in its operations;

The procedures shall define requirements for the following:

- a) identifying nonconformities;
- b) determining the causes of nonconformity;
- c) correcting nonconformities;
- d) evaluating the need for actions to ensure that nonconformities do not recur;
- e) determining the actions needed and implementing them in a timely manner;
- f) recording the results of actions taken;
- g) reviewing the effectiveness of corrective actions ;



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8.8 Preventive actions (Option A)

The inspection body shall establish procedures for taking preventive actions to eliminate the causes of potential nonconformities;

Preventive actions are taken in a pro-active process of identifying potential non-conformities and opportunities for improvement rather than as a reaction to the identification of non-conformities, problems or complaints;

Covers same elements of corrective actions only proactive instead of reactive;



Thank You



This time is allocated for questions. You should have a space provided for submitting questions.

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If a question is not answered, please submit directly to webinar@pjlabs.com



Save the Date

ISO/IEC 17025:2017 Section 7.10” Nonconforming Work” & Section 8.6 “Improvement”

November 2021						
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Monday, Nov 22nd 2021

