

Transitioning to ISO 9001:2008

Profession Development for

ASQ Chapter 309

Tanzco Management Consulting, LLC

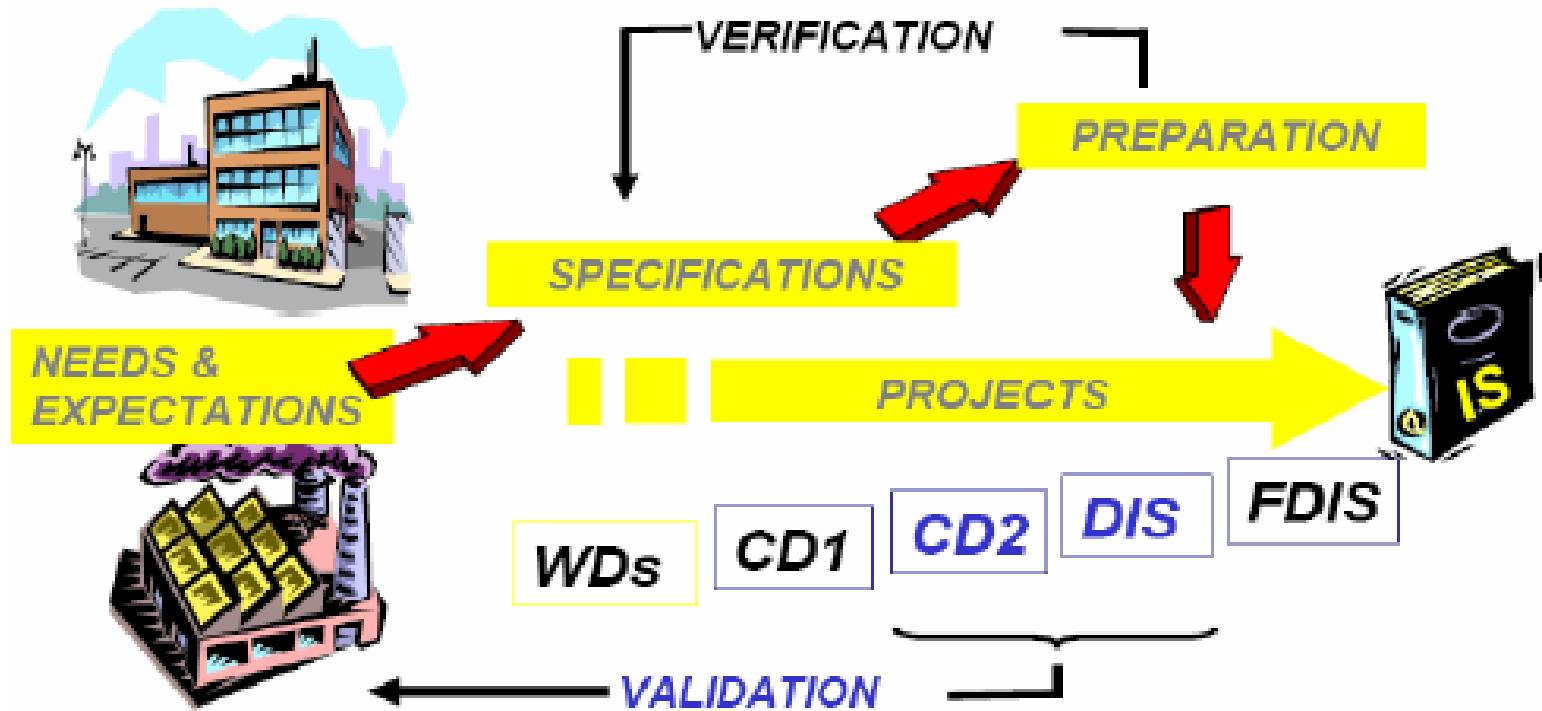
ISO 9001

- ISO 9001 is the most widely used standard for quality management systems in the world
 - Over 1,000,000 companies are certified in 170 countries
 - World-wide, certifications continue to grow at about 15% year
- Standards are reviewed and revised periodically because they must keep up to date with stakeholders expectations. Quality management is a dynamic process and evolves over time
- The ISO 9000 “family of documents” are continually reviewed and revised through the Technical Committee TC 176
 - First Edition 1987
 - Second Edition 1994
 - Third Edition 2000
 - Fourth Edition 2008 (November 15)

ISO 9001:2008 in Brief

- ISO 9001:2008 clarifies
 - legal requirements
 - Outsourcing
 - Competence
 - design and development
 - Internal audit
 - Monitoring and measurement
 - Control of non-conforming product
- The goal of this version is to improve your organizations QMS and improve profitability
- It includes a 24 month implementation plan

The ISO standards development process



ISO 9001:2008

- For ISO 9001:2008, a design specification was developed (in 2005) and balloted. The purpose of the revision was specified to be limited to:
 - Enhance the clarity of ISO 9001:2000, without introducing new requirements
 - Enhance compatibility with ISO 14001:2004.
- ISO 9001:2008 was published November 15, 2008
- Content of the 4th Edition of ISO 9001 (2008):
 - **No new requirements introduced**
 - Some useful clarifications to existing requirements
 - Mainly editorial changes
 - A few examples of increased compatibility with ISO 14001:2004, but these are also mainly editorial amendments.

Compatibility with ISO 14001:2004

“Compatibility” means that common elements of the standards can be implemented by organizations in a shared manner, in whole or in part, without unnecessary duplication or the imposition of conflicting requirements.

When maintaining compatibility with ISO 14001:2004 the following do not necessarily represent potential conflicts:

- Different text in common elements or terminology
- Different numbering of the clauses
- Different models and structure
- Inclusion of guidance, notes or annexes

ISO & IAF

- ISO and the International Accreditation Forum have jointly issued the following rules for the transition:
 - Twenty four months after publication of ISO 9001:2008 any existing certifications issued to ISO 9001:2000 shall not be valid
 - One year after publication of ISO 9001:2008 all accredited certifications issued shall be to ISO 9001:2008
 - Certification of conformity of ISO 9001:2008 and /or national equivalents shall only be issued after official publication and after routine surveillance of recertification audit against ISO 9001:2008
- Transition can be done during any scheduled re-certification or periodical audit in the 24 month period

“Transition” Process

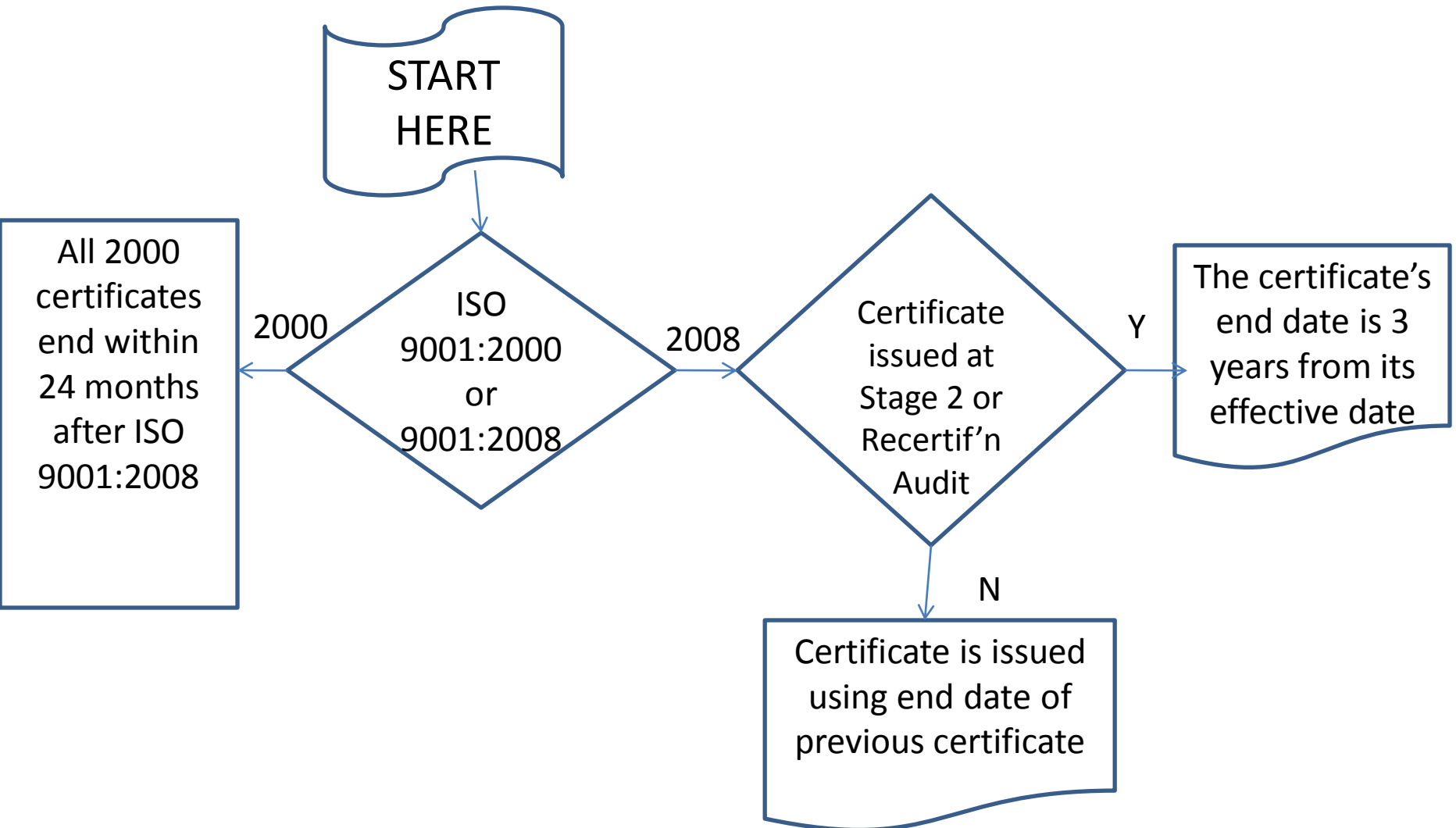
- The organization should be aware of the changes and if there is any impact upon the QMS. The organization should have reviewed the quality management system to ensure it still complies considering the clarifications made
- To reflect the limited scope of changes the term **“implementation”** is used to make a clear distinction with the former “transition” to the 2000 version.
- Consultants & Internal Auditors need to be educated in the amendments and their implications.

Implementation Process

- Certification to ISO 9001:2008 is **not an “upgrade”**, and organizations that are certified to ISO 9001:2000 should be afforded the same status as those who have already received a new certificate to ISO 9001:2008.



Decision Tree for Certificate



Management Systems

- What is a **Management System**?

ISO 9000:2005 definition:

-- “set of interrelated or interacting elements to **establish policy and objectives** and to **achieve those objectives**”

Management Systems should be *performance-based*

- ISO 9000:2005 – Clause 1.1 - “Specifies quality management system requirements for organization to:
- *demonstrate ability to consistently provide product that meets customer and applicable regulatory requirements*
-enhance customer satisfaction”
- **OUTPUT matters!** (Old story of concrete canoes)

Why “Notes?”

- Notes do not add “requirements”
- Notes are not auditable
- Notes do not affect other Standards (especially ISO 9000:2005)
- Notes can be used to explain and convey intent



Main Changes Introduced

- **Clause 0.1 (General)**

Introduces concept of organization's business environment and associated risks.

- **Clause 0.2 (Process Approach)**

More emphasis on **output** from processes

- **Clause 1.1 (Scope)**

Clarification that “product” also includes intermediate product

Explanation regarding statutory, regulatory and legal requirements

Main Changes

- ...The design and implementation of an organization's quality management system is influenced by: its business environment, changes in that environment, or **risks** associated with that environment; its varying needs; its particular objectives; the products it provides; the processes it employs; its size and organizational structure...
- First time the word "**risk**" is used in ISO 9001!



Consequence

“Business environment”

- All management processes which are necessary for the realization of the process objectives must be incorporate into the QMS: for example: management meetings, performance consultation, succession mechanisms (balanced scorecards, reports, *etc.*).

The QMS as Risk Mitigation

- Top Management should design (4.1) a Quality Management System to mitigate RISK.
- What risk? The chief among them being
Customer Dissatisfaction
- Other risks are defined by the business' environment: political, social, economic...
- The auditor must ask how the process was planned and how its output mitigates risk

Main Changes

Clause 0.2 (Process Approach)

- IAF and ISO have published a document on the Desired Outcome of 9001 from the customer's perspective; namely:

“Output Matters”

Main Changes

Clause 1.1 (Scope)

- The term “statutory” added along with regulatory requirements throughout the whole of the 2008 standard
- The standard now expects that both local and national laws that are applicable to the organization in providing products and services to their customers' requirements should be considered

Implication

Statutory & regulatory requirements should be identified and considered as stated in clause 7.2.1 – Determination of requirements related to the product.



Main Changes

Clause 0.2 (Process approach)

- Text added to identify a process as “an activity **or set of activities**”
- Processes do not have to be just one step of an activity; they can be combined if they make sense; e.g., **RFQ/Quote**



Implication

- In the standard the term “product” is not solely applicable for product intended or required by the customer but also any intended output resulting from the realization process.
- This broadens the application and include *e.g.*, purchased products, products from intermediate stages in the realization process, as well as products from outsourced processes.

Main Changes

Clause 0.3 (Relationship with ISO 9004)

- Revised to emphasize **continual improvement** and to remove references to “ applicable statutory and regulatory requirements.”
- Specifies that ISO 9004 can be used to go beyond the requirements of ISO 9001
 - No longer the “consistent pair”

Main Changes

Clause 0.4 (Compatibility with other management systems)

- Added reference to Annex A, which compares ISO 9001:2008 and ISO 14001:2004



Main Changes

1.1 General

- NOTE 1

In this International Standard, the term “product” applies to the product intended for, or required by, a customer or the product realization processes. This applies to any intended output resulting from product realization processes, including purchasing.

- Clarification as to *what is a product*

Main Changes

4.1 General requirements

The organization shall

- a) **determine** the processes needed for the quality management system and their application throughout the organization (see 1.2)

Although similar, the words “Identify” and “Determine” have slightly different meanings.

- To **identify** is to recognize or establish something as being a particular thing.
- To **determine** is to apply reason and reach a conclusive decision.
Therefore, to determine the processes implies more analysis and judgment than merely identifying them = How does each process contribute to Risk Mitigation?

-- Is the process capable of achieving the desired outcome?

OUTSOURCING

“the type and extent of the control to be applied to these outsourced processes shall be defined with the QMS”

- When an organization **outsources** training, they may write specific details in the Outsourcing Process, such as:
 - “ the trainer must have attended a train-the-trainer course. The organization then requires feedback from the Master Trainer to evaluate the competency of the trainer”

Implications

- Outsourced processes have to be focused on in the audit.
- Depending on the organization's activities for monitoring the outsourced processes, the auditor has to decide how often and how long he/she needs to audit the outsourced processes (possibly at the site of the external party).

Main Changes

Product “**quality**” vs. Product
“**requirements**”

Quality is the degree to which a set of inherent characteristics fulfils requirements;

Conformity is the fulfillment of a requirement.

Main Changes

Clause 4.2.1 (Documentation)

- Clarification that QMS documentation also includes **records** -- All documentation requirements also apply to records
- Documents required by the standard may be combined
- ISO 9001 requirements may be covered by more than one documented procedure

Main Changes

Clause 4.2.3 (Document Control)

- Clarification that only **external** documents **relevant** to the QMS need to be controlled



Main Changes

Clause 4.2.4 (Records Control)

- Better alignment with ISO 14001
- From “*maintained*” (warehousing of records) to “*controlled*” (regulating the use of records)
- Moved documented procedure requirement up to emphasize it

Main Changes

Clause 5.5.2 (Management Rep)

- Clarifies that this must be a member of the organization's **own** management
- Implication: External parties cannot be the official management representative, even if most of his/her tasks and responsibilities are outsourced to external parties (the tasks can be delegated)

Implications

- A person appointed as management representative who does not participate in management reviews or has no managerial influence in making process owners comply with QMS requirements would likely be a finding of nonconformance

Main Changes

Clause 6.2.1 (Human resources)

- Clarification that conformity to product requirements can be affected directly or indirectly by personnel performing **any task** within the QMS.



Personnel Included

Example:

- A delivery driver would not have a direct effect on the quality of the product he is transporting, but would be responsible for the requirement of a safe and/or timely delivery of the product to the customer.
- This way, this employee is also included in the requirement for competence because **his actions could affect product requirements** even if it does not affect physical product quality.

Main Changes

Clause 6.2.2 (Competence, training and awareness)

- Clause title changed for better alignment with ISO 14001
- Clause 6.2.2 (b) changed to read *“Where applicable, ...the organization shall... provide training or take other actions **to achieve the necessary competence”***
 - Clarified “satisfy these needs”

Explanation

- Use of the phrase "**where applicable**" recognizes that training or other actions may not be necessary, since individuals may already have the necessary competence.
- Since "these needs" could be taken out of context, the requirement has been revised to specifically mention **competence**.
- "Training" *per se* is not a requirement.

Implication

- The organization must have a mechanism to ensure that personnel have been evaluated based on how well they demonstrate their knowledge and skill (*i.e.*, competence).
- It is **not enough** to merely provide training or consider an individual's experience and/or education.
- The organization must prove to itself (and auditors) that this person can, in fact, perform.
- Thus, the approach to auditing this requirement is slightly different...focus is now on determining competence, achieving competence and ensuring competence has been achieved. (P-D-C-A)
- And, at **all** levels of the organization

Main Changes

Clause 6.3 (Infrastructure)

- Includes *information systems* as example

Example:

If an organization includes any sort of order processing system, it should now be included as part of the infrastructure the organization controls within the management system as it is key to conformity to product requirements.

Main Changes

Clause 6.4 (Work environment)

- Clarifies that this includes conditions under which work is performed and includes, for example, physical, environmental and other factors such as noise, temperature, humidity, lighting, or weather
- Not EPA or OSHA regulations

Explanation

This addresses the environment relating to conditions necessary to achieve conformity to product requirements such as clean rooms, anti-static precautions and hygiene controls.

Not the EMS or ergonomics.

Implication

- Audit findings of nonconformance could include detrimental impact of work condition influence on the workers or work being performed.
- Example, if the poor lighting limited the ability of the workers to perform the work efficiently and / or effectively.
- Care must be taken to ensure that the given situation would apply to workers in general, rather than a specific person.

Main Changes

Clause 7.2.1 (Customer related processes)

- Clarifies that post-delivery activities may include:

actions under warranty provisions;
contractual obligations such as
maintenance services; and,
supplemental services such as
recycling or final disposal

The New Note: is almost identical to the current note in
ISO/TS 16949:2000

Main Changes

Clause 7.3.1 (Design & development planning)

- Clarifies that while design and development review, verification and validation have distinct purposes
 - These may be conducted and recorded separately or
 - in any combination as suitable for the product and the **process**

Main Changes

Clause 7.3.3 (Design & development outputs)

- Clarifies that information needed for production and service provision includes *preservation* of the product

Main Changes

Clause 7.5.3 (Identification and traceability)

- Clarifies that identification of product **status** must be maintained throughout *product realization*
- Dropped “*and record*” from last sentence:
Now reads: “*shall control unique identification of the product and maintain records.*”
- A process should be in place at each stage of product realization (not just production) that ensures **the identification and status of the product is known**

Example

- During a chemical treatment to be performed on an item, the paper labeling must be removed; but, the organization may use a color classification system to ensure identification is maintained during the chemical treatment process.

Main Changes

Clause 7.5.4 (Customer property)

- Explains that both intellectual property and *personal data* should be considered as customer property
- Determination of justification for a audit finding of nonconformance is whether the release of this data could or would negatively impact the customer.

Main Changes

Clause 7.6 (Now re-titled **Control of Monitoring and Measuring *equipment***)

ISO 9000:2005, 3.10.4

“measuring equipment”

- measuring instrument, software, measurement standard, reference material or auxiliary apparatus or combination thereof necessary to realize a **measurement process** (3.10.2)

Main Changes

Clause 7.6 (Now re-titled **Control of Monitoring and Measuring *equipment***)

- A change of terms: Changed “and/or” to “or in sub-clause
- a), so it now reads “**be calibrated or verified, or both**”
- The reference to paragraph 7.2.1 had been removed.

Changed c):

- **From** “*be identified to enable the calibration status to be determined*”
- **To** “have identification in order to determine its calibration status

Explanation

Stating that measuring equipment must "**be identified**" sounds as if the organization is to ***add*** identification.

However, the measuring equipment may come with the identification already; therefore the wording amendment.

Main Changes

Clause 7.6

New explanatory note added:

“Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.”

Implication

- The note regarding computers would mean that an auditor should typically check that the program can perform its intended purpose
- An example of software verification would be to check its ability to discern acceptable from reject product.
- Configuration management could possibly involve what controls to ensure the software is current and programmed parameters are up-to-date.

Main Changes

Clause 8.2.1 (Customer Satisfaction)

- Note added to explain that monitoring of customer perception may include input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, dealer reports... *etc.*

Main Change

Clause 8.2.2 (Internal audit)

- The standard now requires the area being audited to ensure that ***any necessary corrections and corrective actions*** are taken without undue delay...
- **Audit results are to be recorded**; not just nonconformances
- Records are being captured throughout the audit and should be listed before the reporting of results. The reference to 4.2.4 for record control was moved to new text.
- There is a reference to the **ISO 19011** for the qualification of internal auditors.

Main Changes

- The previous version of the standard only stated “actions” but did not specify the types of actions required of the management in response to internal audit findings
- Now, not only do you have to correct the problem by making a “correction” you also have to ensure that the problem does not recur by initiating a “corrective action” – see the Example
- Does the organization use ISO 19011? Was the auditor training based upon the Guidance document?

Example

- During an audit it was observed that Mary Smith did not have the proper competence to perform her job.
- The **correction** to the nonconformity is to train her and the **corrective action** is to develop a process to assess competencies for new employees.

Main Changes

Clause 8.2.3 (Monitoring / Measurement of process)

- Note added to clarify that when deciding on appropriate methods, the organization should consider impact on the conformity to product requirements and on the effectiveness of the quality management system = Risk!
- All QMS processes should be measured to the extent that they can affect product requirements
 - In the TS world: **SOPs**, **COPs** & **MOPs**

Implications

What is a "suitable" method for monitoring and measuring processes?

The Note says to **consider the type and extent of monitoring or measurement** based on the **impact** of the process on product conformity and system effectiveness.

How far am I required to go? As far as necessary to establish, maintain, improve, and demonstrate that your processes operate under controlled conditions to achieve output requirements.

Main Changes

Clause 8.3 (Control of Nonconforming Product)

- Added, “*Where applicable*” to 2nd paragraph
- Rewrote several sentences with no change in meaning to be more understandable to service organizations
- Moved the last sentence up to d) “*by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.*”

Implications

- The addition of “**where applicable**” now permits flexibility for solutions for dealing with nonconforming product
- This term does **not** mean “where practical”
- Allows for consideration of other ways and other actions that may be taken to deal with nonconforming product
- Product **can be released to other internal processes** despite planned arrangements not being satisfactorily completed as long as it conforms prior to release to the customer.
- This relaxes requirements on intermediate inspection results and records

Examples

In an organization that designs and builds automated assembly equipment, a sub-assembly was “given over” to electricians before machining was completed.

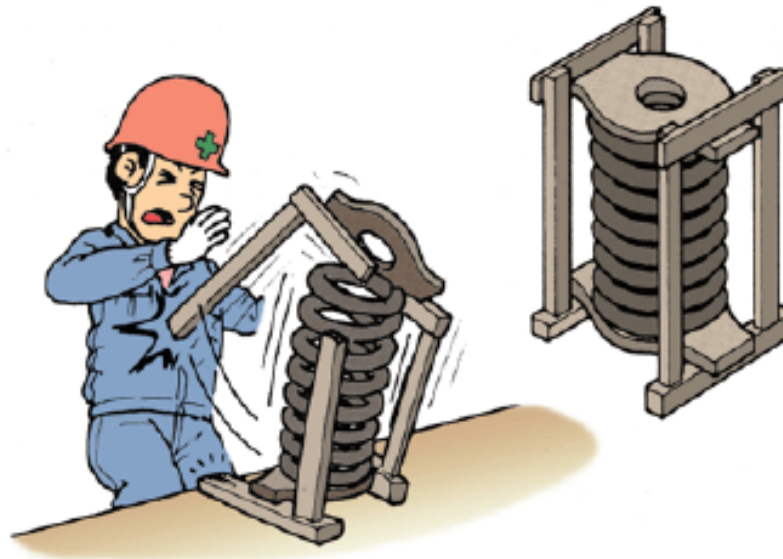
A package is misdirected during shipment and arrives late. The company decides to refund all or part of the shipping charges.

This is not a correction but a recovery action.

Main Changes

Clause 8.5.2 (Corrective action)

- Clause 8.5.2 (f) clarifies the need to review the **effectiveness** of corrective actions taken, as well as the actual results



Example

- A nonconformity was raised on a process for scanning documents. Two sided documents were only being scanned on the front side.
- The corrective action was to implement a checklist to confirm the requirements for scanning the document.
- Reviews were later carried out to show that implementation of the checklist improved the scanning process in other ways than just ensuring both sides were scanned and the new process was considered more effective.

Main Changes

Clause 8.5.3 (Preventive action)

- Clause 8.5.3 (f) clarifies the need to review the **effectiveness** of preventive actions taken, as well as the actual results



Implications

- The documented procedures for corrective action and preventive action shall contain a description of how to review the effectiveness of the corrective actions.
- Reviewing only that the corrective action or preventive action was taken does not mean that the action was effective. There should be **evidence** to support effectiveness.

Additional Resources

To help with the move from ISO 9001:2000 to the ISO 9001:2008, you may analyze the clarifications using the comparisons table, contained in annex B of ISO 9001:2008, and see the Implementation Guidance obtainable from www.iso.org or www.iso.org/tc176/sc2

To Obtain ISO 9001:2008

- You can purchase a print or an electronic copy at ASQ Standards Central at www.asq.org/standards/index.html
- The updated introduction and support package for ISO 9001 is available online for free download at www.iso.org or www.iso.org/tc176/sc2

THANK YOU!

- Feel free to contact me at any time with your questions: (914) 475-2955 or at g.tanzman@tanzco.net
- Auditors must take a transition course that meets all of the requirements of the IRCA and RABQSA.
to maintain certification.
- Copies of ISO 9001:2008 are available from ASQ at www.asq.org
- Questions?