



ISO9001:2008

How does it affect your certification?

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2.4.2009

Why Change ISO 9001:2000?

- ISO 9001:2000 still referred to as “new standard”
- Subject to review every 5 years
- Original version: ISO 9001:1987
- ISO 9001:1994
- ISO 9001:2000
- ISO 9001:2008

“BECOME CERTIFIED TO THE NEW ISO 9001:2008”

- Certified manufacturers being “harassed” by companies attempting to “upgrade your system” to the new standard
- Their nominal fee = \$5000/\$6000!
- You can upgrade with minimal effort through comparison
- No new requirements – only clarifications to existing requirements

ISO 9001:2008 vs. ISO 9001:2000

In short, the ISO 9001 standard is a compilation of all the general elements a company's quality management system *must* contain and the associated requirements that the company *must* adhere to in order to demonstrate conformance to the standard.

How Does ISO 9001:2008 Affect *MY* Company?

Primary Effect

- Most of the text in ISO 9001:2000 has not been affected by ISO 9001:2008.
- A complete list of the changes can be found in Annex B of the new Standard.

Secondary Effect

- You will need to “transition” to the new standard at some time in the future.
- Contact your registrar for an exact timeline.
- Since there have been no changes, you have to show that you are complying to the new “clarifications.”

Brief Summary of Changes

- ISO 9001:2008 provides clarified requirements.
- Evaluate to determine if these clarifications cause you to revise how you manage your QMS.
- Certification body seeks evidence that your company has carefully considered these differences and revised your QMS as appropriate.
- Suggestion: accomplish by recording, at your next management review, what action was taken (or assign action items) following a review of Annex B of the Standard.

Brief Summary of Changes

- Section: FORWARD
 - Numerous small changes and clarifications that need review but do not require action.
- Section: INTRODUCTION
 - “The risks associated with change in the organization’s environment be considered.”
 - Risk assessment theme with both ISO and AS.
 - Statutory and regulatory.
- SECTION: Paragraph 0.2
 - Clarification of what a process is; asks that you determine rather than identify these processes.
- SECTION: Paragraph 0.3 & 0.4
 - No major changes.

Brief Summary of Changes

- Section: Paragraph 4.1, sub-clause (a)
 - Identify to “determine the processes” which have slightly different meanings. To identify is to recognize or establish something while determine implies more analysis.
- Section: Section 4.1 (outsourced processes)
 - Current note expanded; two notes added.
 - Note 1 – added “analysis and improvement to measurement which match the title for clause 8, deleting word “should”, it now states that these processes are included.
 - Note 2 – defines an outsourced process as a process that the organization needs for its quality management system, which the company chooses to have performed by an external party.
 - Note 3 – ties the outsourced process to requirements in clause 7.4, including 7.4.1 which apply to the supplier selected to perform the process.

Brief Summary of Changes

- Section 4.2.1 Documentation Requirements
 - Minor changes.
 - Clarification that you can combine processes in one procedure or may split one document into two separate documents.
- Section 4.2.3 Control of Documents
 - Sub-paragraph (f) clarifies that all external documents have to be identified.
 - Only those needed for the planning and operations of the QMS.
- Section 4.2.4 Control of Records
 - Expanded from records being maintained to having them controlled.
 - Maintaining records considered keeping them in good condition.
 - Controlling records have their use regulated.

Brief Summary of Changes

- Section 5 Management Responsibility
- Section 5.5.2 Management Representative
 - Companies have outsourced the MR position.
 - Text changed to “appoint a member of the organization’s management...”
 - Interpreted as internal resource only.
 - Consult your registrar to get feedback on this requirement.

Brief Summary of Changes

- Section 7.2.1
 - Determination of the requirements related to the product.
 - Note: post delivery activities include actions under warranty provisions, contractual obligations such as maintenance services and supplementary services such as recycling or final disposal.
 - Organizations may not have considered the breadth of post delivery as described by the note.
- Section 7.3.1 (b)
 - Added a new note that explains that although review, verification and validation have distinct goals, they can be carried out separately or in any combination.
 - New note: information for production and service provisions can include details for the preservation of product (design should consider this).

Brief Summary of Changes

- Section 7.3 Design & Development
 - 7.3.1 (b) continues to state that the organization must determine the review, verification and validation appropriate for each design and development stage.
 - New note explains that although review, verification and validation have distinct goals, they can be carried out separately or in any combination.
 - Note: design and development review, verification and validation have distinct purposes. They can be conducted and recorded separately or in any combination, as suitable for the product and the organization.

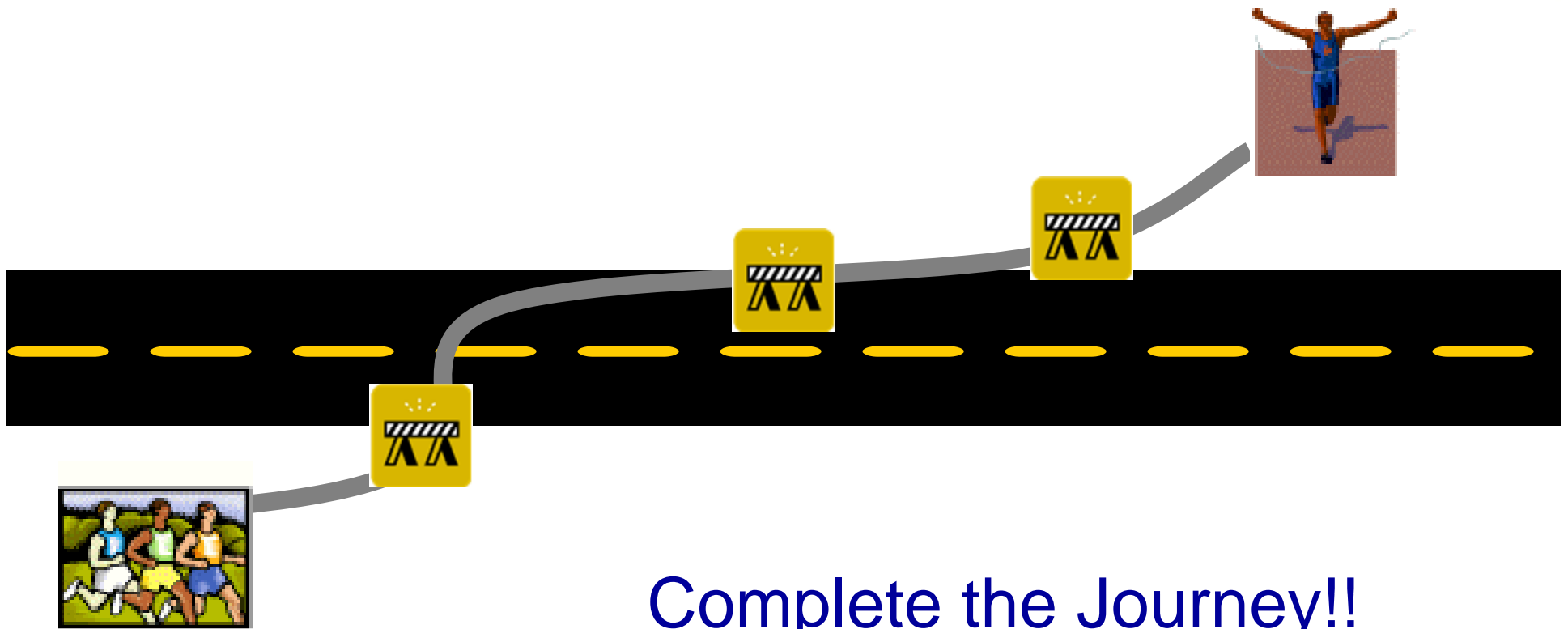
Brief Summary of Changes

- Section 8.2.1
 - Customer satisfaction added a new note clarifying the different methods that can be used to measure customer perception.
- Section 8.2.3
 - Added note that aids in determining what is a suitable method for monitoring and measuring processes.

What Does It All Mean?

- In a nutshell, the transition to ISO 9001:2008 should be relatively painless and cost free.
- Companies need to review and comply with the clarifications, working with certification body for guidance.

Road Map to ISO Registration



Complete the Journey!!

Road Map to ISO Registration

- Accredited third party certification, to any of the ISO family of standards, is the result of a company's successful implementation and a proof positive audit by an accredited third party, to a particular standard.
- Accredited certification provides evidence, to customers, of your compliance to a particular international standard.
- Where should you begin?
- This is a TEAM Effort!!!
Buy in from TOP MANAGEMENT is ESSENTIAL for SUCCESS!!



Road Map to ISO Registration

The certification process differs slightly with each standard:

- ISO 9001:2008
- AS 9100 B
- ISO 14001:2004
- ISO / TS 16949:2002

Where do I begin?

Establish a timeline (Gantt Chart) to measure benchmarks.

- Allocate “ENOUGH” resources to ensure the timetable is kept.



Road Map to ISO Registration

Preparation for accredited certification and method of implementation:

A guide on the road to certification:
ISO 9001:2008 and AS 9100 B Certification.

Once the decision to obtain ISO certification has been made,
the following steps can help keep your company on the right path.

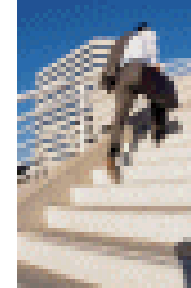
- Buy the STANDARD
- Decide how to effectively implement the QMS / Standard
- Create and keep to the implementation timeline
- Make benchmarks achievable
- Have a positive attitude
- Management commitment.
- Involve all employees



Road Map to ISO Registration

Steps To Take:

- 1.) Purchase the Standard
www.asq.org/knowledge-center/standards



- 2.) Research Implementation Options:

Upon the decision to achieve third party certification, a company must decide how to implement the standard into their organization.

- Use a consultant as a “coach” or to provide a “turn-key” solution.
- Utilize internal resources to implement and maintain certification



Road Map to ISO Registration

3.) Create a Steering Committee – To Ensure Buy-In from all level of the organization

- Achieving Third Party Certification is an enterprise wide decision.
Senior management commitment is *“imperative”* to the success this endeavor.
- Ask for and Accept Input from your employees on Work Instructions



4.) Determine Your Company's Training Needs based on Experience and Timeline:



The Implementation Team will be responsible for:

- Writing the QM, Procedures, Work Instructions and Forms
- Implementing – The Approved QMS
- Training – The employees on the QM, Procedures and Etc.
- Internal Audits of the Processes – On going Process Audits
- Corrective/Preventative Actions
- Maintaining the Management Systems' Integrity
- Management Review

Road Map to ISO Registration

5.) Draft and approve a management systems manual



The manual should include and describe;

- the policies, procedures and operations, specific to the company.

6.) Implementation of the approved documented system.



- Training records of implementation
- Verification is required for:
 - Complete round of internal audits
 - Management reviews
 - Communication of NCRs and corrective actions to address them

All facets of a successful implementation.

The “approved procedures” should demonstrate the effectiveness of the QMS.

Road Map to ISO Registration

7.) Select your registrar and surveillance cycle (6 month or 12 month visits)



The Registrar selection process should include, at a minimum, a review of the following.



- IAF Membership
- Accreditations and Traceability
- Standards - Capabilities
- Auditor Resources
- Pricing, Fees and Travel Expenses
- Customer Service
- Value Added Tools
- Reputation



Standards Council of Canada
Conseil canadien des normes

Registrar's Capabilities - Evaluation

A CBs capabilities should match your anticipated business strategy.

- Ensure the registrar has not had their accreditation suspended
- Industry specific auditors in your area.
- Single point of contact throughout the contract
- Experience - attend / participate in industry specific meetings: IAQG or IAOB
- Number of certificates issued
- Standards and scope of capability under accreditation

Pricing, Fees & Policies

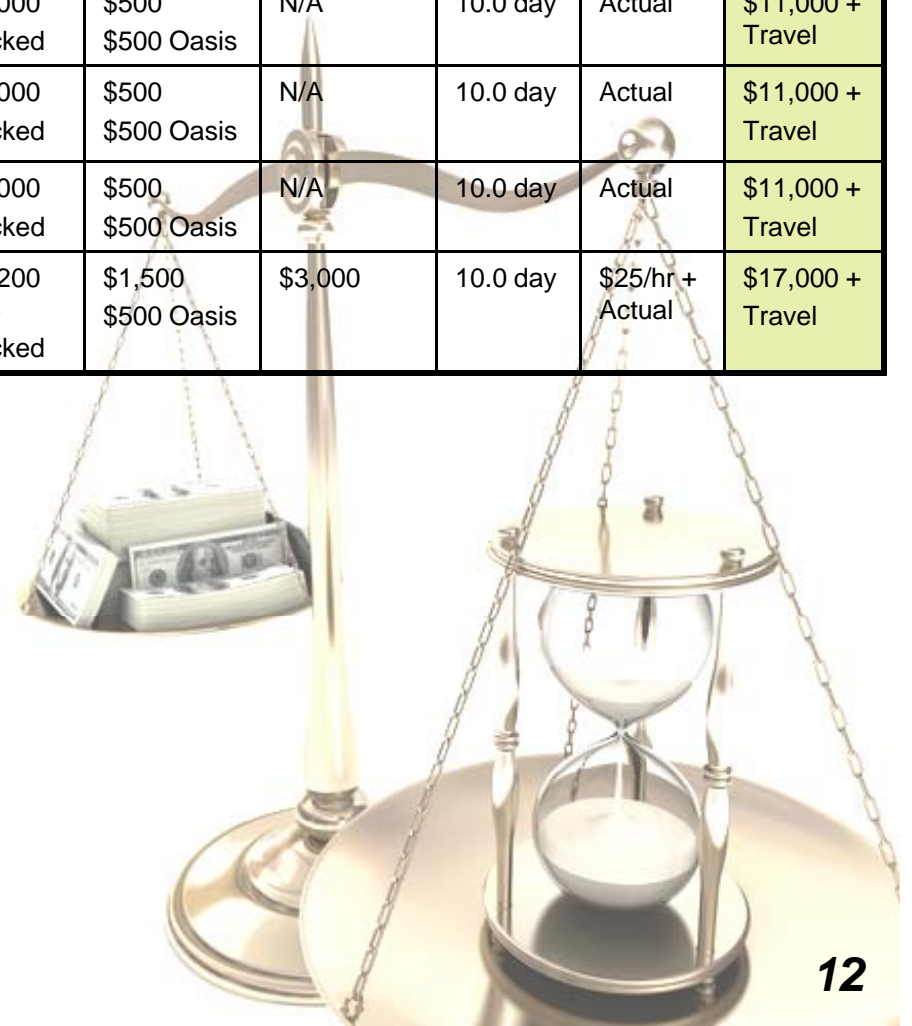
Look for the following and use metrics for a comparison of all the CBs involved in your selection process.

1. Ensure Accreditation of the CB is an IAF Member
2. Industry Norm for contract length is three years.
3. Cancellation Policy of 30 days & Fees for Audit Activity Cancelled
4. Rates Locked – For Accreditation Mark and Man day Rates
5. Customer Service – Single Point of Contact for Contracts Duration
6. Consistency of the audit team
7. Auditor Turnover and Utilization Rates



Cost Comparative Analysis

Registrar Name	Standards & Accreditation	IAF Member	Local Auditors	Number of Certificates	Loss/Suspension of Accreditation	Man day Rate	Accreditation Fees – Total	Maintenance Fees – Total	Man days over 3 yrs	Travel and Expenses	Total 3 Year Cost
CB #1	ISO / AS ANAB	Yes	Yes NY/CT	10,000+	ANAB for AS/ISO Active	\$1,000 Locked	\$500 \$500 Oasis	N/A	10.0 day	Actual	\$11,000 + Travel
CB #2	ISO / AS ANAB	Yes	Yes CT/MA	200+	ANAB for AS/ISO Active	\$1,000 Locked	\$500 \$500 Oasis	N/A	10.0 day	Actual	\$11,000 + Travel
CB #3	ISO / AS ANAB	Yes	Yes CT/MA	1,700+	ANAB for AS/ISO Active	\$1,000 Locked	\$500 \$500 Oasis	N/A	10.0 day	Actual	\$11,000 + Travel
CB #4	ISO / AS ANAB	Yes	Yes CT	700+	ANAB Suspended 3/08 to 6/08	\$1,200 Not Locked	\$1,500 \$500 Oasis	\$3,000	10.0 day	\$25/hr + Actual	\$17,000 + Travel



Road Map to ISO Registration

After Selecting the Registrar, schedule dates for each of the required audits. Keep to the timeline.

Pre-Assessment

- Optional Audit Activity



Stage I Audit

- Documentation Review & Implementation Verification
- Based upon the findings of this Audit, The Stage II Audit can be completed.



Stage II Audit

- Registrar's Certification Assessment Audit.
- Success or Failure Based on Auditor Findings (NCRs).



Certificate of Registration

- Issued – Within 4 weeks of Closing Meeting

Road Map to ISO Registration

Surveillance Visits: Select 6 or 12 month audit cycle / schedule
12 Month Schedule is Most Popular – Cost Savings of 20% Typically

Surveillance Visit #1 – Annual Cycle

- 12 Months from date of Assessment Audit



Surveillance Visit #2 – Annual Cycle

- 24 Months from date of Assessment Audit



Approximately half of the QMS is reviewed and audited at each audit.

Road Map to ISO Registration

Valuable Websites and Resources for Information:

www.jab.or.jp/english/imr/imr - Info on MLA and IAF

www.anab.org – USA Accreditation Body

www.iaqg.sae.org – OASIS Database for AS 9100 B

www.taacenters.org – DoL Grants for US Companies

www.irs.gov.org – IRS Rev. Rule 4 – ISO Tax Deductions

www.connstep.org – State Programs and Training

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