

The Quality Management System (QMS) standard ISO 9001:2008 was released on November 15, 2008. The International Organization for Standardization (ISO) rules require standards be reviewed periodically, and this work was undertaken by ISO Technical Committee 176. SRI is a member of this committee and participated in the work.

ISO 9001:2008 replaces the previous version, ISO 9001:2000.

If I already have a certified quality management system, what should I do?

Practically speaking, the changes to the standard are very minimal. Based on the November 15, 2008 release of the revised Standard, the International Organization for Standardization (ISO) has set **November 14, 2010, as the expiration date** for all current registrations to ISO 9001:2000 (two years from the publication date of ISO 9001:2008). You may purchase a complete copy of the revised standard at www.ansi.org. A summary of changes from ISO 9001:2000 to ISO 9001:2008 are outlined on page 2.

Transition of existing ISO 9001 Certificates

Even though the differences may be relatively small, they are still important and need to be taken into account. The changes and clarifications have improved the standard, and they will be beneficial to your QMS.

We recommend you **take the following steps**:

1. **Purchase a copy** of the ISO 9001:2008 standard and read it thoroughly
2. Review Annex B and **become familiar** with the specific changes
3. **Analyze** whether the changes affect your organization. **Attend training** if needed.
4. Develop an **implementation plan** for the changes
5. Discuss **transition requirements** with SRI to build into your audit timing and planning
6. Revise and **improve your QMS**, with any needed internal audits and management reviews

In order to **have a valid ISO 9001 registration**, SRI will need to conduct a registration, renewal, or surveillance audit of your quality management system under the 2008 version requirements. All registration and renewal audits after November 14, 2009, are required to be under ISO 9001:2008. Clients may also choose an ISO 9001:2008 Transition Surveillance to the new standard any time prior to the November 14, 2010, expiration.

The most **economical approach** will be to review the new standard and plan a timely implementation of the changes. Your target should be a time-line that results in SRI conducting the transition along with a regularly scheduled on-site audit visit by August 14, 2010 (90 days prior to the expiration date). Transition to the new standard at registration or renewal will not incur additional fees. **Notify your Customer Care Coordinator of your plans and anticipated timing.**

New Registration Requirements – ISO 17021:2006

Along with ISO 9001:2008, the rules governing Certification Bodies (CBs), such as SRI, have changed. Effective September 15, 2008, all CBs must be compliant and be accredited to ISO 17021:2006, replacing both ISO/IEC Guides 62 (QMS) and 66 (EMS). SRI led the industry by being among the first to comply and be accredited.

What does this mean to you?

Like the ISO 9001 update, there are some changes you will need to be aware of:

- **All new ISO registrations** (does not affect timely renewals) must be conducted in a two-stage process. An on-site Stage 1 Readiness Review is now required before the Stage 2 Registration Audit. Time must be allotted between the two stages for correction of any issues arising from the on-site Stage 1 assessment. This is now similar to ISO/TS 16949, AS9100, and ISO 14001.
- **At renewal**, SRI must issue a new certificate before the old certificate expires. This means that SRI will need to schedule renewal (re-registration) audits at least 60 days (90 days for TS-2) prior to current certificate expiration. The 60 days allows time to resolve Corrective Actions, process the renewal, and issue a new certificate. If a new certificate is not issued before the old certificate expires, certification will lapse, and a full two-stage registration audit will be required to resume certification. ANAB and RvA have said there will be no exceptions.

Section	Summary of Changes from ISO 9001:2000 to ISO 9001:2008
0.2 Process approach	<ul style="list-style-type: none"> Text added to emphasize the importance of processes being capable of achieving desired outputs
1.1 Scope	<ul style="list-style-type: none"> Explanation regarding statutory, regulatory and legal requirements
4.1 General requirements	<ul style="list-style-type: none"> Notes added to explain more about outsourcing Types of control that may be applied to outsourced processes Clarification that outsourced processes are still the responsibility of the organization and must be included in the quality management system
4.2.1 General (Documentation)	<ul style="list-style-type: none"> Clarification that QMS documentation also includes records Documents required by the standard may be combined Note added to indicate that ISO 9001 requirements may be covered by more than one documented procedure
4.2.3 Control of Documents	<ul style="list-style-type: none"> Clarification that only external documents relevant to the QMS need to be controlled
4.2.4 Control of Records	<ul style="list-style-type: none"> Editorial changes only (better alignment with ISO 14001)
5.5.2 Management Rep	<ul style="list-style-type: none"> Clarifies that this person must be a member of the organization's management
6.2.1 Human Resources	<ul style="list-style-type: none"> Clarification that competence requirements are relevant for any personnel who are involved in work affecting conformity to product requirements
6.3 Infrastructure	<ul style="list-style-type: none"> Includes information systems as a support service
6.4 Work environment	<ul style="list-style-type: none"> Note 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
7.2.1 Customer related processes	<ul style="list-style-type: none"> Note clarifies that post-delivery activities may include actions under warranty provisions, contractual obligation, such as maintenance services, and supplementary services, such as recycling or final disposal
7.3.1 Design & development planning	<ul style="list-style-type: none"> Note clarifies that design and development review, verification and validation have distinct purposes and that: These may be conducted and recorded separately or in any combination as suitable for the product and the organization
7.3.3 Design & development outputs	<ul style="list-style-type: none"> Note clarifies that information needed for production and service provision may include preservation of the product
7.5.4 Customer property	<ul style="list-style-type: none"> Note explains that both intellectual property and personal data should be considered as customer property
7.6 Monitoring and measuring equipment	<ul style="list-style-type: none"> Explanatory notes added regarding the use of computer software: "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."
8.2.1 Customer satisfaction	<ul style="list-style-type: none"> 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, warranty claims, and dealer reports
8.2.3 Monitoring/ measurement of process	<ul style="list-style-type: none"> 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

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