ISO 9001: IMPROVED APPLICABILITY TO ENGINEERING, PROFESSIONAL SERVICES AND GOVERNMENT ORGANISATIONS

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The clock is counting down on the three-year transition period from ISO 9001:2008 to ISO 9001:2015. The latest edition of this quality management system standard, the foundation of ISO management systems worldwide, was released on 15 September 2015.

ISO 9001 first became an ISO standard in 1994 and, today, more than 1 million organisations are certified to ISO 9001.[1] The standard, which is predominantly about the enhancement of customer satisfaction, has had a major revision in arriving at the latest edition. It introduces new concepts, terminology and current thinking.

If you're in a service-based industry, rely on service-based industries or outsource a significant amount of services or functions, some key changes carry particular significance.

With reference to engineering, professional services and government organisations, this whitepaper outlines those key changes, explains the benefits in applying the revised standard and provides practical guidance on preparing for the change.

IMPROVED APPLICABILITY FOR SERVICE-BASED ORGANISATIONS (AND THOSE WHO RELY ON THEM)

IMPROVED APPLICABILITY EXPLAINED

ISO 9001 previously included services only by definition: goods were defined to include services. The revised standard takes a more refined and explicit approach to the inclusion of services throughout the entire standard.

This means that service-based organisations can more readily adopt the standard and enjoy the many benefits of being certified, including:

- Improved efficiency and reduction in costs

- Better customer experience and management

- Effective risk-management strategy

- Competitive advantage and broadened market scope for contracts and tenders (especially government)

CONTROL OF EXTERNAL SERVICE PROVIDERS

Since the revised standard specifically mentions products and services, it will potentially impact your supply chain because you'll need to manage your services as well as the products of your organisation.

Organisations will be required to put controls in place to manage their external service providers. While there has always been a level of control over their purchasing process, the revised standard makes it clear that the control extends to a service or something you're outsourcing. For example, if you obtain legal advice from a law firm, the control of this remains within the scope of your own management system.

Another focus of the revised standard is on design and development of products, which is particularly relevant for the engineering industry. If your organisation designs and manufactures something

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1. The ISO Survey of Management System Standard Certifications 2015.

for an ISO 9001-certified client, that client will need to ensure that they are managing this outsourced process and meet the requirements of the standard's design clauses.

Government organisations that put large volumes of work out to tender will now be required to manage that as part of their own quality management system. When awarding tenders for things such as IT support, logistical services, cleaning and legal services, government organisations will need to think carefully about evaluating their suppliers. They may need to put more controls on parts of their supply chain and place more emphasis on the inspection of service-based work. They must have a way of evaluating and re-evaluating the supply chain.

WHAT ELSE IS CHANGING?

STRUCTURE

ISO 9001 follows Annex SL, which contains the high-level structure common to other ISO standards such as ISO 14001 (environmental) and the soon-to-be-released ISO 45001 (occupational health and safety (OHS)). This common framework ensures consistency, applies common language and means ISO 9001 can easily integrate with these other standards, as well as a specific requirement to fully integrate the management system into your business rather than being standalone.

This integration promotes efficiency and better management of your contractors and supply chain; it can also lower your costs by reducing duplication of documentation and process control. It's a big step forward in mitigating risks and realising the upside of risk: opportunity.

ANNEX SL HIGH-LEVEL STRUCTURE

1. Scope
2. Normative references
3. Terms and definitions
4. Context of the organisation
5. Leadership
6. Planning
7. Support
8. Operation
9. Performance evaluation
10. Improvement

ORGANISATIONAL CONTEXT

The revised standard adds context to quality management systems, requiring an understanding of both the internal and external factors that may affect the business and the intended outcomes of the quality management system. This broadens the scope of the quality management system – external factors for engineering, professional services or government organisations may range from Britain's decision to leave the European Union to the growing threat of cyberattacks to the rise of the gig economy.

For many organisations, this is not a new idea. The revised standard will simply mean forging a link between business planning and the quality management system.

LEADERSHIP

Top management – defined in the standard as people or persons who lead and direct an organisation at the highest level – will have greater accountability and involvement in the organisation's quality management system. Top management will be responsible for ensuring quality management systems are compatible with the organisation's strategic direction, and ensuring policies and objectives are established and align with the strategic direction.

A BROADER UNDERSTANDING OF STAKEHOLDER NEEDS AND EXPECTATIONS

The revised standard requires an understanding of the needs and expectations not just of clients and suppliers, but also other stakeholders such as the local community, government bodies and trade associations. It requires organisations to understand the requirements of their stakeholders and use this information to identify any risks or opportunities that may need to be addressed. For engineering, professional services or government organisations, stakeholder analysis may not be a new consideration.

MOVING FROM PREVENTIVE ACTION TO RISK-BASED THINKING AND PLANNING

There's a stronger focus on a risk-based approach and customer satisfaction with ISO 9001:2015. Preventive action was a key concept on ISO 9001:2008 rather than risk. Although preventive action was intended as a risk-based proactive management system, it has now been

replaced with a specific requirement for an organisation to consider its risk and put a plan in place to manage those risks.

Once an organisation has highlighted risks and opportunities, it needs to indicate how these will be addressed through planning – that is, by looking at what, who, how and when these risks must be addressed. The revised standard makes risk management a critical part of policy development, strategic and operational planning and review, and change-management processes.

ORGANISATIONAL KNOWLEDGE

An organisation should be able to identify the required knowledge – that is, information about the processes, the business, and the products and services – obtain the latest knowledge and make sure it's available to people within the organisation. Here, required knowledge includes both knowledge that may or may not be documented.

DOCUMENTED INFORMATION – NEW TERMINOLOGY

ISO 9001:2008 requires, as a minimum, six documented procedures. The revised standard is more process focused. Your organisation must instead have documented information to manage its processes effectively. This documented information should cover:

1. The documented information that the standard requires, for example, information concerning the quality policy and the quality objectives
2. Information that your organisation requires to manage its business, for example, procedures, work instructions, specifications

The revised standard also encourages a full understanding of all the key processes in an organisation, where the key processes cause a risk to the business and how the organisation operates as an integrated and complete system.

ARE YOU READY FOR ISO 9001?

All certifications to the 2008 edition of ISO 9001 that have not been transitioned to the 2015 edition by 15 September 2018 will expire. Don't wait, though. If you've not yet made the transition, we encourage you to conduct a gap analysis and consult with your certification body to make arrangements for your transition at least six months before this date.

The challenges involved in transitioning to the revised quality management system standard depend on how well your organisation can answer these questions:

- How effective is your current system?
- Does it support the business?
- Is it fully integrated with your business processes?
- Does it address both risks and opportunities for the business?

You'll also need to think about management of your supply chain if you require suppliers to have certification to ISO 9001:2015.

The main transitional issues for the industries we've focused on in this whitepaper are:

- Understanding what is meant by risk-based thinking
- Understanding the new terminology of documented information
- Additional requirements on top management: leaders must be accountable for the system's effectiveness

- Risk further down the supply chain must be more tightly managed within your organisation: you can no longer discharge risk to your supply chain – you need to manage this as part of your own quality management system
- For suppliers and smaller service-based enterprises: alignment and integration mean these more onerous responsibilities will be pushed down the supply chain

Positive feedback from those who have made the transition to ISO 9001:2015

- Integration is easier
- Structure is more logical
- Terminology is clearer
- Positively received changes include risk-based thinking replacing preventive action, additional requirements for top management, requirement to manage organisational knowledge, wording change from 'product' to 'goods and services' and strategic alignment
- The requirements for purchasing, and especially outsourcing, have previously caused confusion – the new terminology for 'the external provision of goods and services' is seen as a positive

CONCLUSION

Now that ISO 9001 refers to both products and services, it is set to have a significant impact on both sectors. Engineering, manufacturing and other product-oriented organisations will need to manage their services as well as production, while service organisations will see impacts downstream (to their service suppliers) as well as upstream (to their risk management systems).

The revised standard's greater impact on service-based organisations also means that getting certified can give you a competitive advantage. Look at ISO 9001:2015 as a business improvement tool for improved efficiency and management of risks.

Are you ready for ISO 9001:2015? Has your organisation evolved from incident prevention to proactive risk management? Contact SAI Global today to learn more.

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