Newsletter

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WWISE
WORLD WIDE ISO LEARNING ACADEMY

ISO Systems Implementation & Training

WELCOME

The team at WWISE welcomes you to the sixth issue of our newsletter where we talk about all things quality.

We have all heard the term “risk management” but what is it exactly? And how is it achieved? In this issue we explore ISO3100 and how it provides organisations with the necessary principles, framework and processes for risk management.

Also in focus this month is the importance of a Business Continuity Management System for when things don’t quite go as planned.

We also look at the new Standard for Automotive Quality Management and how it addresses the three things everyone wants from their car; safety, reliability and quality.

We conclude this issue with ISO 13485:2016 and how it helps manufacturers create QMS’s that ensures the quality and safety of medical devices.

Enjoy!

The emphasis should be on why we do a job.

W. Edwards Demming

We Are The SHERQ Specialists

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Better Risk Management with ISO 31000

We have all heard the term "risk management" but what is it exactly? And how is it achieved?

ISO3100 provides organisations with the necessary principles, framework and processes for risk management.

Risk is a necessary part of the business process. With enormous amounts of data being processed daily at rapid rates, identifying and alleviating risks is a challenge for any company.

> ***"Risks within any situation can be disastrous if handled incorrectly but in an organisational context, risks affect economic performance and professional reputation."***

In light of this, effective risk management can help businesses to perform well, knowing that potential risks can and will be dealt with correctly. This is where ISO 31000 can be implemented.

ISO 31000 is the international standard providing organisations with the necessary principles, framework and processes for risk management. It provides businesses with direction on how they can integrate risk-based decision making into its planning, management, reporting, policies, values and culture.

ISO 31000:2009 and ISO 31000:2018 – what's the difference?

All ISO standards are reviewed every five years to maintain relevance. ISO 31000 was originally developed in 2009 (ISO 31000:2009) after a four-year development period during which 60 experts from 30 countries worked within an ISO international technical committee. It has since been updated to its current version, ISO 31000:2018.

ISO 31000:2018 consists of 16 pages and can be read in as little as an hour. It consists of four main sections:

Section one defines key terms such as risk, risk management, stakeholder, risk source, event, consequence, likelihood and control.

Section two outlines the principles of risk management – that it is integrated and executed by way of a structured approach.

Section three provides a framework for ensuring that risk management is properly implemented and integrated throughout the organisation and that it's carefully designed, and regularly reviewed and updated.

Section four focuses on the process of risk management itself. This includes the elements of risk identification, analysis, evaluation, and treatment. It also includes monitoring, review, communication and consultation elements.

Of the two versions, ISO 31000:2018 provides more strategic guidance than ISO 31000:2009 and emphasises the involvement of senior management.

ISO 20000-1:2018

ISO 31000:2018 recommends the development of a policy that confirms management's commitment to effective risk management and assigns authority, responsibility and accountability at the appropriate levels of the business.

Furthermore, ISO 31000:2018 recommends that risk management becomes part of the organisation's overall structure, processes, objectives, strategies and activity.

The document's content has been updated to reflect an open systems model that regularly exchanges feedback with its external environment to fulfil a wider range of needs and contexts. The key objective is to simplify business processes by using plain language to define the fundamental elements of risk management in an easy-to-understand way.

Implementing ISO 31000:2018

ISO 31000:2018 is applicable to any organisation regardless of its size or industry but it cannot be used for certification purposes; it simply provides guidance for internal or external audit programmes. Organisations that already have risk management practices in place can use the document to compare their existing practices to an internationally recognised benchmark. This provides sound principles for effective management and corporate authority.

In order to take the first step towards effective risk management with ISO 31000:2018, the following must be considered:

- The organisation's key objectives. This will help management to clarify the targets and requirements of the risk management system.
- The organisation's management structure. This will ensure that responsibilities and risk reporting procedures are allocated efficiently among management.
- The organisation's commitment to effective risk management. This includes the resources available for the implementation and maintenance of a risk management system.

The Benefits of ISO 31000:2018

While the concept of effective risk management is a benefit in itself, ISO 31000:2018 provides a reliable basis for decision making and planning while helping a business to achieve objectives, efficiently identify opportunities and risks, and comply with relevant legal and regulatory requirements.

The main goal of this document is to help businesses protect their assets while developing a risk management culture where employees and stakeholders are aware of the importance of risk monitoring and management.

> ***"Ultimately, having this structure in place can improve overall business performance and reputation."***

How WWISE can help

WWISE develops systems, repairs, maintains and improves them to ensure optimal competitiveness and efficiency for the client companies. To speak to a consultant on how we can assist you to implement ISO 31000:2018 into your business operations, send us an email admin@wwise.co.za or call us on 08610 99473.

ISO 31000:2018 is not the only document covering organisational risk management but its set of principles for implementing and evaluating a risk management process is more concise than others.

Murphy's law: "Anything that can go wrong, will go wrong". That's when you need a Business continuity Management system

A business can suffer disruption at any time, how exactly this disruption is handled depends a lot on whether there is a Business Continuity Management System (BCMS) in place. Disruptions can ultimately result in revenue loss, data risk breakdowns and a failure to deliver normal client services. This is where ISO 22301:2012 becomes relevant.

> ***"Developed in 2012 by ISO Technical Committee 223 (ISO/TC 223), ISO 22301:2012 is the world's first international business continuity management standard."***

The purpose of which is to provide a guide on how to set up and manage a BCMS. By definition, business continuity is: The ability of the key operations of a firm to continue without stoppage, irrespective of the adverse circumstances or events.

How WWISE can help

WWISE develops systems, repairs, maintains and improves them to ensure optimal competitiveness and efficiency for the client companies. To speak to a consultant on how we can assist your business to prepare for ISO 22301:2012 certification, send us an email admin@wwise.co.za or call us on 08610 99473.

ISO 22301:2012
Business Continuity Management Systems

ISO 22301:2012 specifies all the requirements related to a documented management system to protect against, reduce the likelihood of an occurrence, prepare for, respond to, and recover from disruptive incidents.

This includes planning, establishment, implementation, monitoring, maintenance and ongoing improvement.

Ultimately, it cancels and replaces BS25999, the old business continuity standard.

The main goal of this standard is to ensure that the business isn't affected by any unexpected events such as a flood or cyber-attack.

It specifies the requirements for a management system to protect against disruptions and ensure that the business recovers from any disruptive incidents as quickly as possible.

Who can use it?

While ISO 22301:2012 is applicable to any organisation, regardless of its size or industry, it is particularly useful for organisations that operate in high-risk environments such as financial services, transportation, telecom, and food production.

Additionally, businesses that are unable to function properly during a disruption can benefit from this standard. An IT company, for example, will be unable to function during a power outage.

ISO 22301:2012

Structure
According to Blue Kaizen (2014), this structure is a new formulation of ISO Management System and an alignment with "Annex SL" that allows the organisation to make multiple implementations at the same time for related ISO Management Standard.

ISO 22301:2012 is structured as follows:

Clause 1: Scope

Clause 2: Normative References

Clause 3: Terms and Definitions

Clause 4: Context of the organization requires that management understands the context of the organisation, including its internal and external needs, and set boundaries for the scope of the BC management system.

Clause 5: Leadership focuses on the role and requirements of top management

Clause 6: Planning relates to the establishment of strategic objectives and guiding principles of the BCMS as a whole.

Clause 7: Support focuses on the resources required to establish, implement and maintain an effective BCMS.

Clause 8: Operations asks for proof of how the processes developed to manage the risks are being correctly implemented.

Clause 9: Evaluation covers the maintenance and review of the BCMS to ensure its ongoing relevance.

Clause 10: Improvement is about making your BCMS as effective as possible to show how effectively it is managed.

Benefits
ISO 22301:2012 covers the requirements for an efficient BCMS, which will allow the company to minimise any risks associated with disruptions and ensure that business is able to operate as usual despite an unexpected event and continue to offer a premium level of service.

Aside from this, being ISO 22301:2012 certified can benefit a business by

- Protecting key assets
- Identifying how some forms of disruption can influence daily operations
- Demonstrating commitment to key stakeholders
- Gaining a competitive advantage
- Shows the organisation's commitment to customer satisfaction.

ISO/DIS 22301:2019

> ***"In January 2019, ISO published the ISO/DIS 22301:2019 standard, which is a draft of the new version."***

Although there can be changes between the draft and the final version, it already gives a clear idea of what to expect.

The Business Continuity Management Standard lasts for three years and is subject to mandatory audits each year to ensure that the business remains compliant.

IATF 16949:2016: The New Standard for **Automotive Quality Management**

There are 3 things we all want from our cars: safety, reliability and quality.

IATF 1649:2016 sets the standard that helps to make sure the automotive industry delivers.

The International Organisation for Standardization (ISO) is constantly looking for ways to evaluate and adopt new concepts in the field of quality management.

> ***"The automotive industry uses international standards to ensure quality, safety and reliability in vehicle parts and assemblies - this is where IATF 16949:2016 comes into play."***

Since its initial development in 1999, ISO/TS 16949 has steadily grown into an international standard to accommodate the ongoing growth of the automotive industry.

The standard was revised in 2009, and in 2016 the International Automotive Task Force released IATF 16949:2016.

The new standard effectively replaces previous versions and certified automotive manufacturers had until the 14th of September 2018 to transition to the latest version.

Why is IATF 16949:2016 important?
IATF 16949:2016 certification is a mandatory industry requirement. This is to ensure the alignment of global automotive quality systems. It doesn't operate alone however but instead works in conjunction with ISO 9001 to define the requirements of a Quality Management System for organisations within the automotive industry.

ISO 16949:2009 vs IATF 16949:2016
When comparing ISO 16949:2009 with IATF 16949:2016, IATF 16949:2016 was written to maintain its relevance in today's automotive market.

Moreover, IATF 16949:2016 builds on this to develop a sound Quality Management System that aids ongoing improvement, defect prevention, and waste reduction. IATF 16949:2016 also relates to the design, development, manufacturing, installation and servicing of automotive-related products.

IATF 16949:2016 is based on Annex SL - the new high-level structure. This helps to maintain consistency, align various management systems, and apply common language across all standards.

Annex SL also makes it easier for organisations to incorporate their Quality Management System into their core business processes and encourage members of senior management to get involved.

IATF 16949:2016 has been updated to consider the following:

Risk-based thinking
IATF 16949:2016 outlines the specific requirements to address risk management. The goal is to identify and alleviate risk to reduce failures in program development. Organisations are also required to have processes in place to ensure a product's safety throughout its lifecycle.

Customer specific requirements
IATF 16949:2016 outlines the difference between customer requirements and Customer-specific requirements (CSR) and specifies the procedures for addressing them. This is to avoid misunderstanding.

IATF 16949:2016:

Specific requirements for products with embedded software
Technological advances and its ongoing incorporation into vehicles call for strict monitoring to detect and prevent issues; thus, the standard now explicitly addresses the electronics and software systems that are being embedded into vehicles.

Second level supplier management requirements
Organisations are required to ensure conformance of products, processes and services throughout their supply chain and effectively solve any conformity problems that may arise.

Incorporation of corporate responsibility requirements
Lastly, organisations must implement corporate responsibility policies and initiatives that address bribery and other ethical issues.

How IATF 16949:2016 is structured
The IATF 16949 structure is split into 10 sections, of which the first three are introductory, and the last seven containing the requirements for the Quality Management System.

Section 4: Context of the Organisation: The organisation must determine its context in terms of the Quality Management System. This includes interested parties, their needs and their expectations.

Section 5: Leadership: This clause requires those in top management positions to demonstrate leadership and commitment to the QMS.

Section 6: Planning: The section outlines the requirements for addressing risks and opportunities as well as the requirements for risk analysis. It also specifies the requirements for preventive actions, quality objectives and plans to achieve them.

Section 7: Support: This clause contains the requirements for the resources and supporting processes needed for an effective QMS. It defines requirements for people, infrastructure, work environment, the monitoring and measurement of resources, organisational knowledge, competence, awareness, communication, and documented information.

Section 8: Operation: The product requirements relate to all aspects of the planning and creation of the product or service. This clause specifies the requirements for planning, design, purchasing, creating a product or service, and controlling the equipment used to monitor and measure the end result.

Section 9: Performance evaluation: This section specifies the requirements needed to monitor the QMS to ensure its functionality. It involves assessing customer satisfaction, internal audits, monitoring products and processes, and management review.
Section 10: Improvement: The last section defines the requirements for continual improvement of the QMS.

The Benefits of certification
IATF 16949:2016 is applicable to any organisation that manufactures components, assemblies and parts for supply to the automotive industry. The benefits of IATF 16949:2016 cannot be highlighted enough.

Some of the benefits include:
- Improvement in reputation and credibility.
- Increased customer satisfaction.
- Fully integrated processes.
- Evidence-based decision making.
- Continued improvement.

> ***“ IATF 16949:2016 is a logical choice for any organisation in the automotive industry looking to improve their existing Quality Management System. ”***

Take into account that implementing and certifying IATF 16949:2016 can take a lot of effort and financial resources, but the result is a competitive advantage, increased customer satisfaction and an overall higher quality product.

How WWISE can help
WWISE develops systems, repairs, maintains and improves them to ensure optimal competitiveness and efficiency for the client companies.

ISO 13485:2016 helps manufacturers create QMS's that ensures the quality and safety of medical devices

ISO 13485:2016 : Quality Standards for **Medical Devices**

From stethoscopes to MRI Scanners all medical devices need to be made to the highest quality standards, lives could literally depend on it.

> ***A medical device is defined as any product, such as an instrument, machine, or implant that is intended for use in the diagnosis, prevention and treatment of diseases or other medical conditions.***

In the medical industry the quality and safety of devices is not negotiable which is why in 2003 The International Standards Organisation (ISO) published ISO 13485, Medical devices – Quality Management Systems – requirements for regulatory purposes. This standard has recently been revised.

ISO 13485 is an internationally recognised standard aimed at organisations involved in the medical device industry.

Its main objective is to help manufacturers create a Quality Management System that ensures the quality and safety of the finished product.

The standard provides a step-by-step infrastructure for creating a Quality Management System and/or evaluating gaps in your current system in terms of monitoring and controlling processes.

According to the ISO, ISO 13485:2016 specifies the requirements for a quality management system where an organisation needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements.

Who can use it?
ISO 13485:2016 is applicable to organisations regardless of their size and type. Where medical equipment is involved. Businesses of this nature can be involved in any number of the life-cycle stages including the design and development, production, storage and distribution, installation, or servicing of a medical equipment.

ISO 13485:2016 is considered the best internationally accepted model a medical device organisation can implement to help demonstrate compliance to laws and regulations of the medical device industry.

ISO 13485 vs ISO 9001
Taking into account the main goal, ISO 13485 and ISO 9001 are essentially the same.

ISO 13485:2016:

Aside from helping companies create safe, high-quality products, other similarities include the fact that both standards use the plan-do-check-act process approach, both are customer-centred, and in order to comply with either standard, organisations will require effective processes and tools for Document Control, Employee Training, Audits and Corrective Action.

Despite the above-mentioned similarities, it is important to note that there are significant differences between the two standards as well:

- While ISO 9001 requirements focus heavily on consumer satisfaction, ISO 13485:2016 emphasises the safety of medical devices.
- While ISO 9001 requires manufacturers to show ongoing improvement, ISO 13485:2016 merely asks that certified organisations effectively demonstrate the implementation and maintenance of the quality system.

ISO 13485:2012 vs 2016

The latest version of ISO 13485 which was published in 2016, replaces its 2012 version but is revised from its 2003 version. This is considered an evolution of its previous versions, rather than a revolution. The main differences between ISO 13485:2012 and ISO 13485:2016 are:

- Processes for sterile barrier systems and sterilisation need to be authenticated.
- Top management's responsibility is more strictly defined.
- Computer software needs to be authorised when used in the quality management system
- All medical device technical files and design and development files need to be established and maintained.

The Benefits

Being ISO 13485:2016 certified, can help to improve an organisation's overall performance, eliminate any uncertainty, and demonstrate a commitment to quality to both customers and regulators. ISO 13485 can help organisations involved in any part of a medical device's life cycle:

- Reach new clients from all over the world.
- Improve operational efficiency
- Manage risks effectively
- Improve business processes, and
- Gain a competitive advantage

> ***"The main benefit to being ISO 13485:2016 certified is that the health and safety of consumers is protected."***

While ISO 14969, ISO 14971 and ISO 9001 are similar, ISO 13485:2016 is specific to the medical device industry and is well-known and trusted by authorities, suppliers and manufacturers in the industry.

How WWISE can help

WWISE develops systems, repairs, maintains and improves them to ensure optimal competitiveness and efficiency for the client companies. To speak to a consultant on how we can assist your business to prepare for an initial ISO 13485:2016 certification or assist in transitioning from ISO 13485:2012, send us an email at admin@wwise.co.za or call us on 08610 99473. You can also visit our website at https://www.wwise.co.za for more information on other ISO standards we can assist with as well as other services we provide.