Customer journal no. 81 – II/2017

DQS COMPACT

Risk-based thinking and action

The revised standard ISO 9001:2015

One of the fundamental changes delivered by the revision of ISO 9001 is undoubtedly the risk-based approach. Now, the topic of „risk“ is not entirely new for ISO 9001, it was just embedded in the requirements for preventative action, which have been eliminated in the revision, and replaced by consideration of risks and opportunities.

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The starting point for considering risks and opportunities is the sharpened focus of ISO 9001:2015 on achieving "intended results" for both the quality management system as well as the processes needed. The "intended results", on the other hand, are a consequence of the scope of the management system with the goal to make available products and services that must be satisfied by customer requirements, legal requirements or an organization's own definition. Thus, this is not a comprehensive risk management system, e.g. based on ISO 31000, nor is a formal risk management process required. Neither are there any requirements regarding use of specific methods for determining or evaluating risks.

In this context, two documents published by the ISO committee responsible are highly recommended, as they explain briefly and concisely what the risk-based approach is all about. Both documents, in English, may be found at the link provided below.

Chapter 0.3.3 of the revised standard offers additional sound supplementary clarifications, explaining, inter alia, that risk-based thinking is indispensable for an effective quality management system, and is to be used to achieve improved results and avoid negative impacts.

Specific requirements of ISO 9001:2015

- Identifying (determining) risks and opportunities in order to ensure intended results are achieved, desired effects (opportunities) strengthened, undesirable effects (risks) prevented or minimized and improvements achieved.
- Evaluating the risks and opportunities identified and determined. No specific methods are listed as mandatory. Common, established tools, such as (process) FMEAs, SWOT-analyses, ABC analyses or risk matrices are quite recommended.
- Deducing actions from the risks and opportunities identified. Either these may refer to the prevention of risks or sources of risk, or they may be directed at reducing risk by changing the probability of negative events or their effects. However, this may also include an acceptance of risk on order to utilize an opportunity.
- Evaluating the effectiveness of actions, e.g. by the non-occurrence of an identified risk or the reduction of its effects e.g. by contractual safeguards in customer contracts.

With respect to the question in which form or which scope documented information on this topic is necessary, the following may be stipulated: there is no specific requirement in the relevant chapters of the standard. Rather, Annex A.4 states: "... the organization is responsible for its application of riskbased thinking and the actions it takes to address risk, including whether or not to retain documented information as evidence of its determination of risks." To put it in simpler terms: this is for each organization to determine individually - not for the standard, a certification body or its auditors.

Interested Parties and their relevant requirements

Another fundamental aspect is the consideration of relevant requirements from interested parties relevant to the quality management system. "Relevance" is in this case to be interpreted as follows: impact on the ability of the organization to continuously deliver compliant products and services, i. e. products and services that conform to statutory and other legal requirements as well as customer requirements. Hence, in the context of considering risks and opportunities, these requirements are to be considered as well (Ch. 6.1.1).

The poor relation: Opportunities

Even though ISO 9001:2015 always considers risks in relation to opportunities, many are wondering what exactly constitutes an opportunity. It does not mean achieving intended outcomes, since that is a basic requirement of quality management systems and their processes. Here, too, Chapter 0.3.3 offers good advice. In this chapter, the following possible types of opportunity are listed:

- Acquiring new customers
- Developing new products and services
- Reducing waste / rejection rates
- Improving productivity

Additional advice is found in the notes to Chapter 6.1.2, e. g.

- Adopting new practices and using new techniques
- Introducing new products to the market
- Opening up new markets
- Building new partnerships

Overall, we recommend handling opportunities with the same intensity used for determining, evaluating and deriving actions from risks; as well as determining opportunities, evaluating and taking appropriate action to realize them.

Frank Graichen
DQS GmbH Managing Director

Recommended documents of the ISO committee:

Set of slides ISO TC/176/SC2 „ISO 9001 and Risk-based thinking" and document N1284 „Risk in ISO 9001:2015", available free of charge at
www.iso.org

ISO 14001:2015

Operational Planning and Control Process orientation as a central aspect of environmental management systems

A significant intention of ISO 14001:2015 is to strengthen the process orientation. Compared to the previous version from 2008, where Section 4.4.6 was still dealing with requirements for "process control", the new environmental standard goes considerably further. The relevant Section 8.1 "Operational Planning and Control" now explicitly requires, in addition to a review and evaluation of planned and unplanned changes, the review of outsourced processes and the integration of the life-cycle concept.

The fundamental aspects of environmental management have – unsurprisingly – remained the same in the new environmental standard: the consideration of environmentally relevant aspects in order to fulfil relevant requirements, the continuous improvement of environmental performance and the reduction of environmental impact. The central relevance of the process-oriented approach for the environmental management system is new, however, enabling organizations to safely measure and control environmentally relevant processes alongside their business processes. In order to measure the risks and opportunities of environmentally relevant aspects (Section 6.1.2), binding requirements (Section 6.1.3) as well as other environmentally relevant topics, a systematic analysis of the operational processes and their interactions within the scope of application of the organization is necessary. ISO 9001:2015 can be a valuable guidebook for this. If an organization orients itself by the systematic display of its own value-creating process in conformity with the quality standard, the significant environmentally relevant aspects may be systematically recognized as well. Using this approach makes it clear quickly where an organization needs to take action. These actions are derived from Sections 6.1 (Actions for managing risks and opportunities) and 6.2 (environmental objectives and planning to achieve them) and need to be designed, realized controlled and maintained.

Defining Actions Specific to an organization

An organization can, with respect to their operational processes, decide for itself about the flexibility and degree of detail of their actions. Examples of possible actions are:

- Procedure instructions, contracts or agreements with suppliers,
- Use of technical options,
- Optimization of installations,
- Technical supervision,
- Use of competent personnel,
- Or a combination thereof.

The selection of specific actions depends on various factors, such as e.g. skills, experience and qualifications of the people involved, as well as the complexity and environmental relevance of the operational implementation. However, it needs to be ensured that the actions, such as e. g. servicing, maintenance, compliance with limit values, are effective and the objectives defined during planning are achieved. For effective planning and control, operational criteria are to be determined (Section 8.1). The organisation is also obliged to supervise planned changes of actions/processes and evaluate the consequences of unintentional changes. In addition, it needs to take action, if necessary, to mitigate or prevent negative effects. The type and extent of that control should correspond to the requirements of the organization, and shall be defined within the environmental management system.

Outsourced process according to ISO 14004:2016, clause 8.1.2

An outsourced process is one that fulfils all of the following criteria:

a) the function or process is integral to the organization's functioning;

b) the function or process is needed for the environmental management system to achieve its intended outcome;

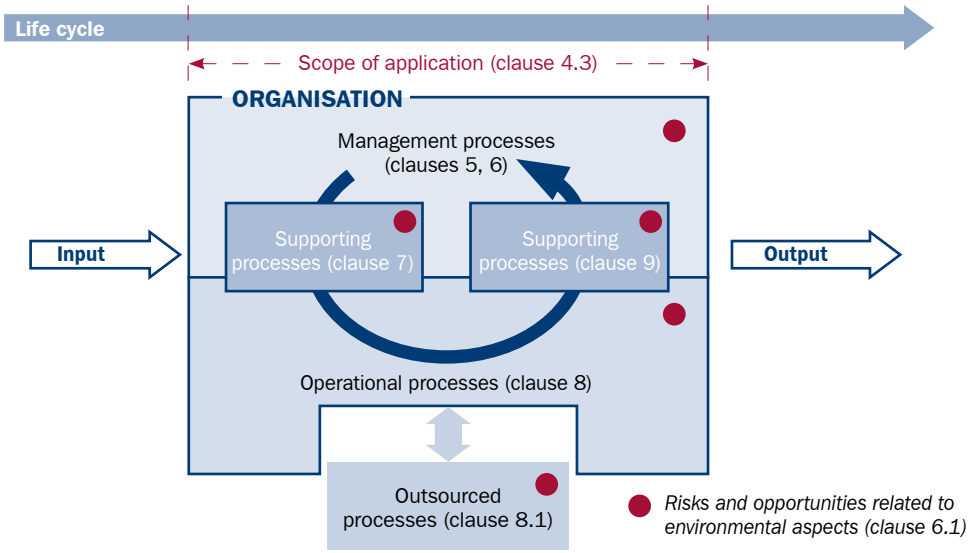
c) the liability for the function or process conforming to requirements is retained by the organization;

d) the organization and the external provider have a relationship, e.g. one where the process is perceived by interested parties as being carried out by the organization.

Source: Environmental management systems – General guidelines on implementation (ISO 14004:2016); German and English version EN ISO 14004:2016

New Aspect: Considering the Life Cycle

Significant environmental effects may occur during the entire life cycle, both upstream and downstream: such as e.g. raw material extraction, development and production, transport and delivery, use, end-of-life-cycle treatment or final disposal of the product or service (ISO 14004). The life cycle should be considered as early as possible, ideally already during product development and procurement. ISO 14001 does not require a detailed life cycle analysis according to ISO 14044, however, the organization is required to evaluate to which extent outsourced processes need to be controlled and influenced. External suppliers and contractors are also to be reviewed. In addition to significant environmental aspects, all other requirements and the environmental risks and opportunities connected with them are to be evaluated. This may require acquiring suitable information about possible significant environmental effects in connection with transport or delivery, use, end-of-life-cycle treatment and final disposal of the products or services. This creates a good possibility to improve the entire environmental performance and leads to an unequivocal responsibility with regard to detrimental environmental effects and environmental protection. So as to be able to trust that the processes have been carried out as planned, ISO 14001:2015 correspondingly requires appropriately documented information.



According to Section 8.2 „Emergency Planning and Response", the organization is obliged to set up and implement such processes as are required for the emergency situations projected (Section 6.1).

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DQS at the “transport & logistic” fair featuring Qualified Carrier, qualislogistics and TAPA

The world‘s leading trade fair for logistics, mobility, IT, and supply chain management is “**transport logistic**”, and it acts as the business platform for and driving force behind the global logistics and transport industry, as well as a comprehensive conference program. Held every other year in Munich, Germany, this year’s fair featured more than 2160 exhibitors from 62 countries, as well as more than 60,000 visitors from 120 countries. One of these exhibitors was of course DQS GmbH, personally represented by colleagues from the Competence Center Logistics and the Marketing & Communication team.

One of the key points of interest for visitors at the DQS booth was the recent cooperation of DQS GmbH with the Spanish market leader for internet-based freight platforms **Wtransnet** on **qualislogistics.com**, a new freight exchange with exceptionally high standards of quality. The new platform is accessible only to those freight companies that have demonstrated their reliability in a qualified certification audit. For small freight carriers looking for an entry-level certification that can be achieved with a certain amount of effort, this cooperation also includes the “**Qualified Carrier**” Seal, which is also honored by the German freight transport association BGL, equivalent to their own **Trusted Carrier** program.

TAPA

Transported Assets Protection Association (TAPA) has authorized DQS to perform audits and issue certificates according to their FSR and TSR supply chain security standards in Europe, Middle East and Africa.

- FSR – **Facility Security Requirements** – For secure warehouse options and distribution centres
- TSR – **Trucking Security Requirements** – Protecting high value goods in transit.

Both FSR and TSR specify the minimum acceptable security standards for high value assets moving through the supply chain and the methods to maintain those standards. TAPA Security Standards are a valuable quality and security benchmark for manufacturers to use as part of their selection of logistics partners.

After the fair, Ralf Grobusch, DQS GmbH Director for Audit Systems, summarizes: *„This was a well-prepared and highly visible participation, thanks to the two dedicated teams. DQS was highly sought-after for discussions and commenting, in interviews and during the conference. We generated interest outside the fair itself, too, reporting live from a training container set up by our customer Hoyer, and in our social media channels. We also made a lot of new contacts that will be analyzed and intensified now.”*

Just before the fair, the Competence Center Logistics was proud to announce having won General Logistics Systems Germany GmbH & Co. OHG – **GLS Germany** for short – for audits according to ISO 9001:2015 und ISO 14001:2015, as well as HACCP and GDP. „With GLS Germany we have secured one of Germany’s leading parcel and express service provider for our core business services. During the talks we also met with much interest in our 2nd party services, such as subcontractor audits and Qualified Carrier“, states Ralf Grobusch confidently.

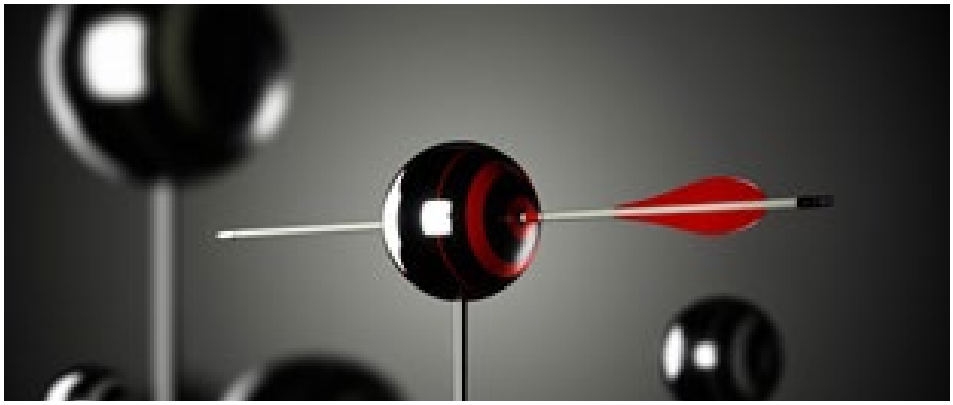
For more information about DQS services in the transport and logistics sector, please contact your local DQS office or visit:

http://www.dqs.de/en/dqs-audit-systeme/dienstleistungen/tapa
http://www.tapaonline.org
https://www.qualislogistics.com

Honesty lasts

Effective compliance management reduces liability risks

Compliance is nowadays the hot topic, but top manager often find the term and what is behind it rather difficult. Yet it means nothing less than „conformity in fulfilling official requirements, ethical behavior“ - something that goes without saying, doesn‘t it?



If you look up the definition of „compliance“ in a dictionary, it seems entirely clear and simple and above all, self-explanatory. The people responsible for an organization need only abide by all relevant (legal) requirements and act in an ethically correct fashion, and compliance is assured - so where is the problem? The answer is: reality is different. Many responsible persons (and employees) do not even know the rules they are supposed to follow. Others know them well enough, but ignore them on purpose. Some things are not non-conformities at first glance, but ethically not very valuable, and hardly acceptable by modern CSR standards. Quite a few entrepreneurs are operating in a grey area that is at times lighter, and at times rather darker. Nevertheless: the need to bring light into this semi-darkness is increasingly being recognized - not least because of the liability issues associated with it.

A good compliance system creates clarity

Organizations thus need a system that ensures that all (legal) requirements are known and obeyed. An effective compliance management system (CMS) provides clarity, legal certainty and helps top management to establish and breathe life into a corporate culture in which non-compliances of any sort are no longer an option. This corporate culture, called the „tone at the top“ in the US, is ultimately the key to effectively and appropriately diffusing the notion of compliance throughout the entire organization.

Minimizing liability risks effectively

A formal assurance of conformity with regulations by way of an established CMS helps materially to reduce liability risks and simultaneously reduces the extent of any liabilities and this may be existential for organizations. This is particularly true for the persons actually acting, since German criminal law has no „criminal law for organizations“

Another management system?

There is almost no way to avoid introducing a CMS, at least for organizations that want to be on the safe side with regard to liability issues arising from non-compliance. Many organizations are „afraid“, however, that with the CMS, another management system needs to be introduced. This widely found misunderstanding is driven by a misunderstanding, since organizations fundamentally have just one management system, most commonly based on ISO 9001 into which the requirements of other standards are integrated as necessary. This is also one of the great advantages of the common fundamental structure that ISO 9001:2015 and ISO 14001:2015 have since the great revision, and which ISO/IEC 27001 already received in 2013 as one of the first ISO standards. Within the foreseeable future, all ISO management systems, including among others ISO 45001 and ISO 50001, will have this fundamental structure.

The CMS as a „clamp“

Thus, a CMS according to ISO 19600 is integrated into the existing management system (if present). It acts like a clamp for all compliance topics addressed by other standards. Quality management deals primarily with product liability risks, whereas environmental management deals with relevant environmental laws, etc. All information and risk analyses are unified in the CMS and so give the organization a secure legal basis for their operations. All legal topics and risks that have so far been only inadequately taken into account are now covered, evaluated and controlled by the CMS.

An overarching codex of values, additional internal reviews and adjustments of risk evaluations provide safety for the organization and the persons responsible.

Thus, the evaluation of risk is of decisive importance. Here, it is important to map out the positions and functions where legal violations are possible that may have most severe consequences for the organization. Hence, a security system needs to be installed to ensure the greatest possible degree of detection. The blithe assumption that „we don‘t have that problem“ is not very helpful.

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Introducing the DQS MED office Middle East

(DQS MED ME)

The DQS Med Middle East office in Cairo will deliver auditing and training activities for the medical devices sector. The office team has long experience working in quality and general management of leading medical devices companies, to include auditing and delivery of training programs.

The office is located in Egypt, which is home to a growing number of medical devices manufacturers, and where DQS benefits both from an established network in the market and the fact that many clients are seeking new notified bodies these days. DQS MED ME intends to fill in the gap by providing local representation and auditors. Further markets of interest are Saudi Arabia, with the second largest number of manufacturers in the Middle East region and a good network, and of course other countries in their region.

General Manager of DQS MED ME is Mr. Ahmed Shahean, B.Sc. Physics and Chemistry with Post Graduate Diploma in Quality Management. He has been working in medical devices sector since 1995 in different positions including Quality and Regulatory Manager and General Manager. His main expertise is in Clean Room technology, EO Sterilization, testing of disposable medical devices. He also has significant free-lance audit experience.

Business Development Manager is Mr. Hany El-Debeky, B.Sc. Engineering, who has been working for leading medical devices companies as quality manager. His background is in the technology, production and testing of dialysis machines, as well as active medical devices. He has significant free-lance audit experience as well.

If you are in need of their services, please feel free to contact directly:

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DQS MED

CUTOMER PROFILES

UAF celebrates 20 years with DQS Inc.

DQS Inc. recently presented a plaque to UAF for 20 years of partnership and registration to ISO 9001.

Established in 1959 and headquartered in Sauget, IL, UAF operates within the Environmental Air division of Filtration Group the world's leading filtration company. Filtration Group is a globally recognized brand, serving many of the world's best-known companies through a network of 39 facilities in North America, Europe and Asia.

UAF designs and manufactures custom air filters and EMI shielding products used to protect commercial equipment and electronics enclosures. With exceptional design and application knowledge necessary to satisfy electronics cooling requirements of increasingly powerful and complex equipment, UAF is a valuable partner for global OEMs serving all types of electronics and industrial machinery end markets. Engineering design support and quick-turn, free custom prototypes are provided to engineer prospects and customers operating under ambitious product development cycles. UAF filters are engineered to address the challenges of thermal management, dust contamination, airflow control, fire safety, EMI shielding, and size limitations in crowded electronic enclosures. Products also satisfy the most stringent end market certification standards and performance criteria.

DQS Group is proud to have been the partner of UAF for 20 years, and we hope to provide them with many more years of top-notch audit and certification services.

To start on your DQS journey, please contact any of our local office, such as the author of this article:

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UPDATES TO STANDARDS

FSSC 22000: Transition to Version 4 – Here's how it works

With over 13 000 certified sites across the globe, FSSC 22000 has firmly established itself as one of the leading food safety certification schemes. In order to stay in tune with the changing expectations of all stakeholders, a new version of the scheme was published in December 2016. As one of the leading certification bodies for the FSSC 22000 scheme, we will be happy to guide you through the transition to Version 4. In this document, you will find an overview of the transition rule.

Understanding the main changes

The main reason to revise the existing scheme has been to align the FSSC 22000 scheme with the benchmark requirements of the GFSI. With the publication of the GFSI Guidance Document Version 7 expected in the fall of 2016, two main changes to the scheme had become necessary in order to maintain status as a GFSI-benchmarked scheme: the introduction of an unannounced audit scheme as well as requirements for the prevention of food fraud. We have compiled an overview of these and other changes, which can be found here ➲

Transitioning to Version 4: The so-called Upgrade Audit

Certified sites will need to transition to Version 4 with a so-called upgrade audit, which replaces the regular surveillance or recertification audit. Please note the following points:

- Timeline: From January 1, 2018 onwards, all FSSC audits will be conducted according to Version 4. Transitioning to Version 4 before January 1, 2018 is not possible.
- If in order to maintain your certificate a surveillance audit is due in 2018, this surveillance audit will be replaced by the upgrade audit. After a successful upgrade audit, you will receive a Version 4-certificate for the remaining validity period of the replaced certificate.
- If your Version 3-Certificate expires in 2018, the recertification audit will be replaced by the upgrade audit. After a successful upgrade audit, you will receive a Version 4-certificate with a validity of three years.
- Audit Type: In Version 4, it is mandatory for at least one of the two surveillance audits to be unannounced. The upgrade audit, however, will always be an announced audit.
- Audit Duration: Regardless of whether the upgrade replaces a surveillance audit or a recertification audit, the audit duration of the upgrade audit will be increased by 0.5 audit days. This is a requirement of the Foundation FSSC 22000.

Initial Certification to the New Scopes

The new version of the FSSC 22000 scheme now also covers the following scopes:

- Catering
- Retail
- Transport and Storage

For these scopes, the possibility already exists to seek certification in the course of 2017.

Further Information

The FSSC 22000 scheme documents are available for download from the FSSC 22000 website. Contact your local DQS office to learn more about FSSC 22000. Their data can always be found on our website.

Dr. Thijs Willaert
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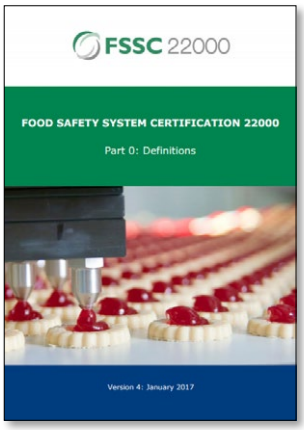
www.dqs-cfs.com



ISO/TS 22163:2017 now replaces IRIS

Transition rules until 14 Sept 2018

The new global standard for quality management systems in the railway sector, ISO/TS 22163:2017 Railway applications — Quality management system — Business management system requirements for rail organizations: ISO 9001:2015 and particular requirements for application in the rail sector was published by ISO on May 24th, 2017.

This latest evolution of the IRIS system is now in force, under the title IRIS Certification™ rev. 03. This designation encompasses the whole system, composed of different elements and responsibilities, which is now under application. The ISO/TS 22163:2017 is owned by ISO and contains the requirements of the ISO 9001:2015 Standard and the supplemental rail-specific requirements.

Transition framework

In order to provide a framework for transition, UNIFE (Union des Industries Ferroviaires Européennes) has specified that after 31 December 2017, all initial certifications will be carried out to the new technical specification, and no longer to the old and familiar IRIS standard. Customers with IRIS certificates have until 30 June 2018 to transfer to the new scheme now.

DQS recommends that customers transfer as soon as possible, in order to avoid bottlenecks and prevent problems with the transition later. Ideally, customers should aim to transfer well before the due date of 1 July, 2018.

Overview of deadlines

31 Dec 2017: Last day for initial certification to the old IRIS standard

30 June 2018: Last day for surveillance and re-certifications to the old standard for current customers

01 July 2018: From here on out, all IRIS audits have to be carried out according to ISO/TS 22163:2017

14 Sept 2018: Last validity day of old IRIS certificates

The IRIS Certification™ rules 2017 are owned by UNIFE and contain all the relevant rules relating to assessment methodology and the certification process. They govern the way audits and certification to the new ISO/TS 22163:2017 are to be carried out.

Along with the new IRIS Certification™ rev. 03 system, a new version of the Audit-Tool IRIS Certification™ Audit-Tool v 5.0.0.00 has been released, which includes the IRIS Certification™ assessment sheet version 3.0.

For more information about IRIS and the transition, contact the local DQS office near you. Their contact data can always be found on the website of DQS Group

Currently certified companies may also log in to the IRIS portal at http://www.iris-rail.org/.

Information provided by DQS GmbH, www.dqs.de

ISO 27001:2017 is no revision

It is a new European version of ISO/IEC 27001:2017 which includes approval by CEN/Cenelec. It incorporates the two corrected items from 2016 in Clause 6.1.3 and Annex A control 8.1.

This is not a change from ISO/IEC, it is a regional update that just reflects the acceptance by CEN/Cenelec and has no other modifications requiring your actions. We therefore have no current plans to update certificates to the 2017 version, so you will continue to receive an ISO/IEC 27001:2013 certificate at this stage. We will notify certification clients if this changes in the future.

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