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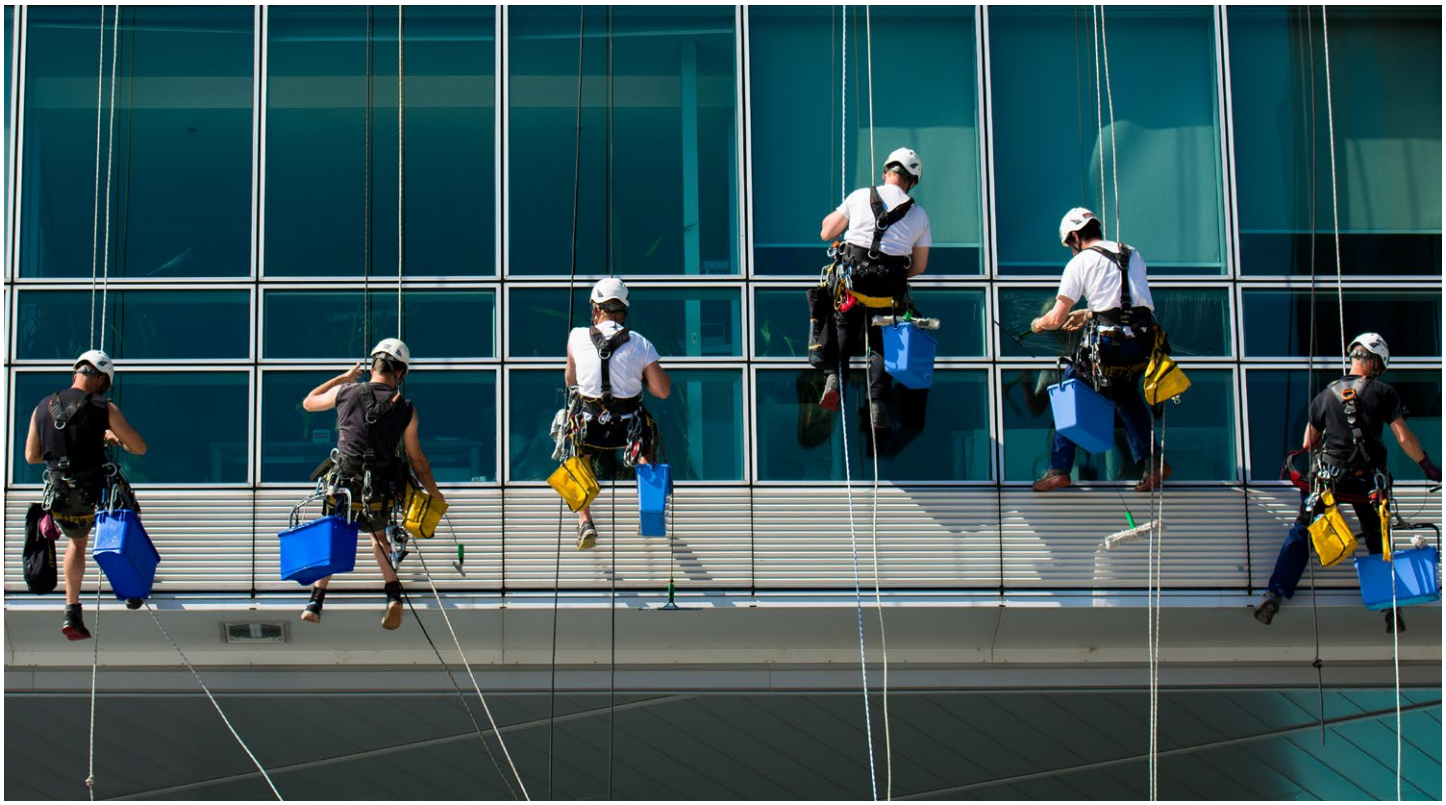
DQS COMPACT

ISO 45001 to be published on 12 March 2018!

Exactly five years after the decision to establish an international standard for occupational health and safety, ISO has now announced the approval of ISO 45001, which will replace BS OHSAS 18001:2007 in its entirety. Five years was a long time even for a comprehensive revision, even more so since it was built on top of the tried-and-tested foundation in BS OHSAS 18001, in combination with the already developed High Level Structure, which provides a uniform structure for all management system standards.



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While ISO 45001 largely stands in continuity with BS OHSAS 18001, there are a couple of **changes worth noting**:

- The standard will have the same **structure** as ISO 9001:2015 and ISO 14001:2015, and will also share the same terminology. This will make it easier to integrate OH&S management into the overall management system.
- The standard follows the normal Plan-Do-Check-Act (PDCA) model, which provides a framework for organizations to minimize the risk of harm. Although this focus on risk is not new, the emphasis in ISO 45001 on a **risk-based approach** places the standard more in line of ISO 9001:2015 and ISO 14001:2015, which also take risk as their starting point.
- Minimizing the risk of harm also requires taking into account any concerns that can lead to long term health issues and absence from work. This may include **psychosocial factors** like stress, which can be managed within the OH&S framework.
- The fact that the standard will follow the same structure as ISO 9001:2015 and ISO 14001:2015 already indicated that there will be a stronger focus on the **context of organizations**. Organizations are required to understand the needs and expectations of interested parties (commonly known as stakeholders), and to take into account all internal and external issues that my affect the ability of the organization to meet its OH&S objectives.
- The notion of context requires organizations to look beyond health and safety within their own facilities and to take into account working conditions that are not under its direct control. This reflects on the work with **subcontractors** and **suppliers**. Supply and procurement policies should address impacts on any persons that carry out activities for the organization, or produce products or deliver services for it.
- Another change we can expect is the stronger role for **top management**. Health and safety will become a central aspect of the overall management system, requiring a firm commitment from top management. At the same time it will be necessary to involve all employees in reaching OH&S objectives.
- Stronger requirement to address legal and regulatory **compliance** issues in the entire management system, throughout all phases of the PDCA-cycle.

ISO 45001 will not define specific KPIs for health and safety, but rather requires continuous improvement in the KPIs an organization has set.

Summary of changes courtesy of DQS CFS GmbH www

Just why the publication took so much time is common knowledge: the first ISO/DIS from November 2015 only met with 71 instead of the required 75% approval. And for good reasons, as evidenced by more than 3,000 comments that had been submitted. Then again, the whole development was not an easy one from the beginning: an OH&S norm issued by ISO has to formulate requirements that meet with global acceptance by all interested parties.

This ISO/DIS.1 then had to be revised in several places in order to reach a version that was agreeable to all parties. Another 1,600 comments showed that consensus on ISO/DIS.2 was indeed difficult to reach, however, in July 2017 a total of 79% of all delegates decided it would be sufficient for an FDIS.

So ISO 45001 seems to be well on its way now: a letter from the ISO/PC 283 secretariat states that the FDIS polling, which was started at the end of November, will be finalized on 25 January,

EDITORIAL

2018 now – with publication following shortly thereafter. It is definitely high time, because the advantages of this new standard are beyond doubt, in spite of its difficult gestation period.

Among other valuable input, ISO 45001 will finally see occupational health and safety capable of full integration into an existing management system, even including aspects of corporate health management. Joint topics are, e.g. context of the organization, leadership and commitment, or the risk-based approach to processes. This elevates the new standard for workplace health and safety even more into the ranks of corporate leadership subjects of strategic significance. Globally active organizations will find it easier to work within a standardized corporate OH&S management system based on an internationally recognized ISO standard – to name just some of the advantages.

Some people claim this ISO standard to be a milestone on the way to a comprehensive, holistic and globally effective occupational health and safety protection. Only time and and application will show if this is indeed true.

The International Accreditation Forum (IAF) has specified a three-year transition period, starting from the date of publication of ISO 45001. DQS customers will soon receive all information necessary to smoothly transition to the new ISO standard for “Occupational health and safety management systems – Requirements with guidance for us”.

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Dear reader

We live in an exciting time, characterized by ever more quickly changing, continuously more complex economic relationships. Any organizations wishing to face this situation with good prospects for success needs a suitable management system that grows with the same dynamism as the market. We at DQS see ourselves here as independent partners of management, complementing organizations with the accumulated knowledge and experience of thirty successful years as a certification body. Our neutrality allows, even demands that we hold up a mirror to management and ask: Where do you really stand?

This question is especially acute regarding the situation with the shift from the old to the new versions of ISO 9001 and ISO 14001. The transition to the new standards is already fully underway; nevertheless a number of organizations is still looking forward to transitioning in the year ahead. Where exactly do organizations stand that have not completed this step yet? If you can’t answer that yet, you should contact us now at the latest, because time is getting short. Starting on 15 March 2018, audits according to the standards ISO 9001:2008 and ISO 14001:2004 respectively may no longer be conducted.

2018 holds two additional significant events: ISO 45001, the new occupational safety standard, which, according to ISO, will finally be released in the spring of 2018 after five years of development, and is intended to replace the proven standard BS OHSAS 18001. ISO 19011, the guideline for auditing management systems, is also slated for release during the coming year after being overhauled as part of the great revision – so that will be exciting.

Last but certainly not least, I wish you from the bottom of my heart a happy new year, along with the hope that you and we will succeed in our important projects in 2018.

Stefan Heinloth
Managing Director, DQS Holding

ISO 19011 – FDIS is on the way!

Revision of the management system auditing guide is progressing well

The ISO 19011 standard, published for the first time in 2002, is known as the „Guideline for auditing management systems“. The purpose of the guide is to guide companies in conducting internal and supplier audits, „on par with“ ISO management system standards, most notably ISO 9001. The comprehensive revision of the International Quality Management Standard in September 2015 has consequently led to a corresponding revision of the ISO 19011 – what is the current status?

Early December 2017: The three-month comment

phase for the first draft standard (ISO / DIS 19011: 2017) ran from 3 August to 25 October. At the subsequent meeting of the lead project committee ISO / PC 302 in Mexico from 6 to 10 November 2017, the ISO / DIS was revised following the implementation of a number of proposed amendments. Due to the large number of comments, details have been changed or updated in almost all chapters. Many inconsistencies of the DIS were eliminated. Finally, PC 302 voted for the creation of an FDIS.

Significant changes

Compared to the current version of 2011, the structure and scope of application will be largely maintained - the focus of the guideline is on internal and external management system audits. It is also applicable for 3rd party management system certification, but here the ISO 17021 - 1 2015 ff is the requirement standard.

The systematic and extended consideration of risks and opportunities in the audit represents a substantial change in content - a new audit principle „risk based approach“ is introduced. The appropriate consideration of the risk and opportunity analysis during auditing was a topic of discussion on several occasions and was ultimately adequately implemented. This point is important because this form of auditing significantly influences the planning, execution and reporting of an audit.

Another topic of the last session was the updating and harmonization of terms and definitions. It was achieved that the most important terms of ISO 9000: 2015 should now also be used in in ISO 19011. Contents of the common basic structure of the ISO Management System Standards (HLS) published in 2012 were taken into account, but not directly referenced.

The chapters surrounding the audit program and the audit planning and implementation have been supplemented by some new content (incorporation of the strategic direction, consideration of external and internal issues as well as the interested parties and many more).

The generic competency descriptions for auditors in Chap. 7 have been structurally retained, but in many details updated and expanded - now more emphasis is placed on identifying the competencies of auditors instead of knowledge and skills. The focus is on ensuring the overall competence of the team with regard to each individual audit. The previous annex with discipline-specific competence requirements will be removed.

The supplement („additional guidance for auditors for planning and conducting audits“) provides additional guidance for auditors to plan and conduct audits - addressing several new topics based on many comments on DIS: auditing of leadership engagement, supply chain, compliance, context, life cycle, virtual activities and locations are added as new chapters.

Members of the ISO PC 302 Mexico Meeting

Thomas Votsmeier, German delegate of DIN in ISO PC 302 and standardization expert assesses the new ISO 19011 2018 as follows: „A good standard set of rules for auditing management systems has been systematically reviewed and improved. The result of this revision is not fundamentally new, but a well-developed and adapted to the state of the art of the current management system standards version. Current trends and developments have been taken up, so that now a consistent set of rules is available for all questions around the auditing. This ISO 19011 contains valuable suggestions and tips on all audit-related issues - every auditor should be familiar with the contents in order to be able to audit beneficial for sustainable business success. „

Schedule

In January 2018, first the English-language FDIS will be created, so that the publication of the final version of the new guide in April 2018 can be expected. The currently valid version from the year 2011 will be replaced.

Thomas Votsmeier
DGQ Standardization expert and German delegate of DIN in ISO/PC 302
DQS Auditor

New in ISO 19011: the Life Cycle Perspective

In A.8, the Annex of the revised standard addresses internal audit from "the life cycle perspective", as introduced by ISO 14001:2015. The environmental standard also explains what is meant by this: "the consecutive and interlinked stages of a product (or service) system, from raw material acquisition or generation from natural resources to final disposal, to include acquisition of raw materials, design, production, transportation/delivery, use, end-of-life treatment and final disposal." This perspective needs to be applied to all "… aspects of its activities, products and services that the organization determines it can either control or influence…". This also applies to organizations operating an integrated management system with the current versions of ISO 9001 and ISO 14001, even though ISO 9001 does not require this explicitly. In those cases, (internal) auditors are particularly charged to keep this "life cycle perspective" in mind when it comes to product speci-fications, design and development, production, delivery and assembly.

UPDATES TO STANDARDS

DQS now accredited for ISO 50003

In addition to the requirements of ISO 17021:2016, ISO 50003:2014 governs the requirements placed upon certification bodies for the auditing and certification of energy management systems. DQS is accredited by the German accreditation body DAkkS.

The transition period for DQS certificates issued to the previous version of ISO 50001 expires on 8 June, 2020. All DQS customers undergoing initial or re-certification are being transitioned at that time.

The changes are focused around the obligatory requirement of continual improvement in energy performance to the effect that a measurable result related to energy use, energy efficiency or energy consumption has to be achieved. See chapter 5.9, *"During the recertification audit, the certification body shall review the necessary audit evidence to determine whether or not continual energy performance improvement has been demonstrated prior to making a recertification decision."*

Major changes

ISO 50003 is going to change the way we do energy management systems, from new rules for calculating audit days to the requirement for visible energy efficiency improvement. „Confirmation of continual energy performance improvement is required for granting the recertification", states ISO 50003:2016 in chapter 5.9. As innocent as this sentence may look, it signals a significant change for the audit itself, because now the auditor is required to monitor and confirm this continual improvement as part of the certification audit.

It's not only about ISO 50003

Readers of past issues of our customer journal may recall this picture from DQS Compact 80, which shows just how many different standards have been created to support organizations in their continuing efforts to manage their energy requirements in the most cost-efficient ways, and to demonstrably improve their energy performance. Annex C of ISO 50003:2016 11 provides some examples of what kind of „demonstrable" improvements auditors will be looking for.

Changes for certified organizations

For those readers looking to have their energy management system certified under the German Accreditation Body (DAkkS), their calculation requirements are based on the organization's business sector, their complexity class (number of energy sources and level of energy usage), as well as the number of effective employees (those having a significant impact on energy usage). This now replaces the previous classifications "industrial" and "not industrial".

In Annex A, ISO 50003 includes a formula for determining audit time, as well as tables for complexity. The challenge for both certification bodies and certified organizations lies in the determination and identification of each contributing factor, and their delineation.
Accordingly, the minimum amount of audit days for initial certifications will be three days. Increases are subject to additional sites, including un-staffed ones, higher complexity or more effective personnel and may amount to 30-50% from the previous version.

UPDATES TO STANDARDS

IFS Food Standard

As you may have heard by now, the IFS Food Standard is currently under revision. The new Version 7 of the standard was initially scheduled for publication in the spring of 2018. This now turns out to be unrealistic: Version 7 is not be expected until the last quarter of 2018. To make sure that the IFS Food Standard continues to be aligned with the GFSI requirements, IFS had to introduce a number of additional requirements, particularly in relation to the prevention of food fraud. This has resulted in the publication of intermediate version IFS 6.1, which will enter into force on July 1, 2018.

Version 6.1 has an entirely new section dedicated to the prevention of food fraud. It contains three main requirements:

- A documented food fraud vulnerability assessment shall be undertaken on all raw materials, ingredients, packaging and outsourced processes, to determine the risk of fraudulent activity in relation to substitution, mislabeling, adulteration or counterfeiting. The criteria considered within the vulnerability assessment shall be defined.
- A documented food fraud mitigation plan shall be developed, with reference to the vulnerability assessment, and implemented to control any identified risk. The methods of control and monitoring shall be defined and implemented.
- In the event of increased risk, food fraud vulnerability assessment shall be reviewed. Otherwise all vulnerability assessments shall be reviewed at least annually. Control and monitoring requirements of the food fraud mitigation plan shall be reviewed and amended when applicable.

What is next with Version 7?

While Version 6.1 is being released, IFS continues to work on Version 7. According to the latest timeline, the standard should be ready for publication no later than the last quarter of 2018. There will be a transition period of six months, meaning that the first certification audits would take place in spring 2019. Keep an eye on the website of our expert subsidiary for sustainability and food safety, **www.dqs-cfs.com** to stay informed on the latest developments.

Dr. Thijs Willaert
Communications Director
DQS CFS GmbH

CUTOMER PROFILES

DQS Serbia proudly presents

The Institute for Standardization of Serbia (ISS)

From the left: Dragana Radenkovic, Director of DQS Serbia, presents their certificate to the General Manager of ISS, Tatjana Bojanic

The competitiveness of Serbian enterprises is closely connected to their ability to manufacture products that are safe and of excellent quality, as well as conformant to the requirements of applicable technical regulations and standards. One of the prerequisites for this is an efficient and internationally recognised National Quality Infrastructure system (NQI), which provides Serbian enterprises and industries with improved conditions to implement technical regulations and standards for products and management systems, both traditional and specific.

Serbia's national standardization body ISS, which is a full member of the international and European standardization bodies ISO, IEC, CEN, CENELEC and ETSI, is one of the pillars of NQI. Harmonization of technical regulations and standards with international and European standards, as well as the strengthening of relevant institutions such as ISS is an important instrument for enhancing the competitiveness of Serbian industry. This was also recognized in the Strategy for Industrial Development for the period 2011-2020.

Commitment to standardization in general, and to quality especially, has allowed ISS to make great progress and modernize, ISS is recognized as an organization that enables a wide range of customers to fully grasp the benefits of standards application in practice. They also provide assistance, support and necessary information to the economy in general, as well as to the citizens in all areas of work and life.

Becoming certified to ISO 9001 and ISO/IEC 27001 was therefore the most logical way for ISS to demonstrate their dedication to the standardization work and quality management. As one of the beneficiaries of the CARDS Project, ISS had the pleasure of cooperating closely with DQS Serbia for the first time in December of 2010, when an international DQS audit team performed the initial certification audit. From the start, ISS and DQS enjoyed an excellent business relationship, due to DQS' exceptionally competent and experienced auditors, very useful recommendations and overall very good communication. ISS welcomed DQS' comments, resulting in improvements in both quality management and information security systems, especially regarding the relations with customers and their satisfaction.

The cooperation was renewed in 2017, when DQS Serbia was selected from the ISS public procurement list for re-certification of their integrated quality management and information security system, according to ISO 9001:2015 and ISO/IEC 27001:2013. DQS' application was considered the best because it completely fulfilled all requirements and specifications of ISS in terms of accreditations for both standards, auditors' competencies, and customer references for the specific scope of ISS. As one of the leaders in the management systems arena, DQS has once again proven to be a reliable partner, providing skillful auditors who were helpful, available and competent, quick in responding to the questions and providing detailed and comprehensive analysis of ISS system. The re-certification has provided ISS with much more than just a certificate; it has helped ISS to be a modern and sustainable organization with perspectives, which employs best-practice solutions from the European and international levels.

Article courtesy of ISS

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Preparing for the Transition with A+ Corporation

When it came to preparing for the ISO 9001 transition, A+ Corporation found value in starting early. In 2014 before the standard was even finalized, the team started doing their research. We spoke with Jay St Amant, R&D Manager and ISO Representative, and Alan Martin, Director of Engineering and Manufacturing, about their company, preparing for the transition and how the implementation of ISO 9001 has benefited them.

Preparing for ISO 9001:2015

To get ready for the transition, they read through the draft online and then hired a knowledgeable internal auditor to help them understand what was coming. They did their own research and used every online tool they could get theirs hands on. They created their own gap checklist to aid in their transition as well and continued to take steps to prepare themselves as developments occurred with the standard.

Bringing in DQS

While they were working on the preparing for the transition, they were also switching registrars to come to DQS in 2015. The team said they had a Gap Assessment with DQS Auditor Craig Rice, which also helped them prepare. Then in 2017, their hard work paid off when they successfully transitioned to ISO 9001:2015.

The Difference of ISO 9001:2015

According to A+ Corporation, they were already doing risk-based thinking so it wasn't much of a change for them to transition. The company was already very process-oriented, but they were able to rewrite their manual to fit the changes they made to the new standard. They thought the new standard would help and it does. It fits them better they say.

The company was already very process-oriented since they had brought Lean thoughts to their manufacturing. They had a lot of flow charts and process charts and enhanced their process even more when they launched a new ERP system in 2008. For the team at A+ Corporation, it's all integrated together: quality and manufacturing.

About A+ Corporation

A+ is a third-generation family-owned company who designs and manufactures industry-leading analyzer sample system components and custom sample systems. These systems are used in the oil & gas, petrochemical and laboratory industries.

Some of their big customers were pushing them to get certified so they did it in 2005 to satisfy the initial requests. They say the certification has grown to be a tool to improve since then, and they now benefit greatly from being certified. "We're a worldwide company, and the certification gives us recognition for our quality. Returning customers know our quality, but it allows new customers to see it."

"We are well-known for the quality."

When asked what they are well-known for, it's the customer service in the industry as well as the quality products. Theirs is a niche market, where they sell through a distributer network and large OEMs. Testament to their products and how well they are made is the fact that no more than two or three items are returned any year.

DQS is proud to work with such an accomplished company and looks forward to our long partnership ahead

Article first published by DQS Inc. in IMPACT 3/2017

Quality under your skin

China's plastic surgeons take advantage of EN 15224

The European Union is China's most important trading partner. Even if exports still have many barriers to overcome, machinery and cars from Europe, electrical goods and textiles, even kitchen modules are highly prized. And now even standards - European standards.

DQS Auditor Maximilian May, MBA, trained paramedic and health care expert, has recently travelled to the People's Republic as a lead auditor on behalf of DQS GmbH. His customer: a center for reconstructive and cosmetic surgery. In his baggage: DIN EN 15224:2016, a standard valid throughout Europe for the specific QM requirements of health care. Read now an audit report of a slightly different kind.

„Highly sophisticated care with quality as a unique selling point" - that is the self-image of Mege Union Medical Beauty, and has been since its founding in 2015. The organization is the center for reconstructive and cosmetic surgery and a subsidiary of a major manufacturer of cosmetics in China. With ten outpatient centers for medical beauty therapies, Mege Union Medical Beauty is represented in China's major cities, including Beijing and Tianjin. It has now established the first branch for outpatient surgical procedures.

European Standards supply a Competitive Advantage

The Chinese health care industry is marked by strong competition. In the 25-million metropolis of Shanghai alone, 450 outpatient medical beauty centers are competing for business. Quality usually enjoys the highest priority, a certification according to an international standard - including ISO 9001, which is well-known in China - is an essential competitive advantage.

Following a request by DQS China, an international project group needed to weigh the options for a suitable standard. In comparison with the US standard JCI and the German KTQ, EN 15224 was found to be most suitable. The standard is designed according to the High-Level Structure and fully compatible with ISO 9001:2015. In particular, EN 15224 is ideally balanced for the special requirements of health care due to its clinical risk management, i.e. the specific risks from patient-related medical processes.

Maximilian May,
DQS Auditor for i.a. ISO 9001,
ISO 29990, DIN SPEC 91020, EFQM

When an interpreter isn't just translating

After choosing the standard, further steps had to be planned. This included training 20 auditors of DQS China. The goal: they were to be able to handle future cases in China independently. The first on-site audit was conducted in August 2017, during which the lead auditor successfully evaluated the documentation (Stage I Audit), based on a combined schedule for ISO 9001:2015 and EN 15224. This was made more challenging by the fast that the entire documentation was written in Chinese ideographs. The interpreter hired by DQS China delivered invaluable work here. She was to reappear later in a most remarkable fashion.

During the Stage II Audit in October 2017, the specific processes were practically reproduced, both regarding minimally invasive therapy (local treatment with hyaluronic acid) as well as invasive surgical therapy (rhinoplasty with implant, buccal autologous fat re-transplantation). And „practically“ was nearly literal in this case. Because with everyone‘s agreement, the interpreter of DQS China took the role of a patient with a specific surgical-cosmetic request. From the reception area to the medical consultation and therapy planning to the medical and non-medical treatment as well as aftercare, the audit followed her through all the subsidiary processes, with the relevant process steps as well as corresponding documentation. Interventions were hinted at in the appropriate treatment theatres (intervention room, surgical theatre, including entrance and exit procedures), but of course were not carried through.

European Quality Mindset as Enrichment

As part of an accompanied monthly internal QM check, all support processes were observed. At Mege Union Medical Beauty, all parameters relevant to structure, processes or results are examined monthly by the quality manager on the basis of a comprehensive check list (254 entries). A comprehensive hygiene management - in some points going beyond German standards for outpatient care - as well as a clearly regulated and controlled handling of neurotoxins like Botox are just examples of a daily common quality practice at Mege Union Medical Beauty.

The staff at Mege Union Medical Beauty has created a comprehensive quality management system at their Shanghai branch office, and implemented many practical, quality-oriented solutions. The thorough cross-checking at all transfer points in particular demonstrates a high degree of awareness of quality and risk. In conclusion, the lead auditor was able to determine the conformity with both standards, ISO 9001:2015 as well as EN 15224:2016 during the entire audit process. Non-conformities were already closed between Stage I and Stage II. During review, all participants noted that the great efforts, especially regarding the implementation of process management, have paid off considerably. The European standard EN 15224:2016 was felt by everyone to be helpful - the European quality mindset recognizable in the standard was seen as a gain for the understanding of quality of the Chinese health experts.

Article and photos courtesy of Maximilian May

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