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DQS UL Management Systems Solutions

ISO 19011 – Guideline for Auditing Management Systems

In December 2011, the new Guideline for Auditing Management Systems was published. This version replaces the old Guidelines from 2002, which was called "Auditing of Quality and Environmental Management Systems", with an expanded application for the auditing of all management systems. This special edition includes a series of articles focusing on the changes in the new Guideline ISO 19011 and the subsequent effects on internal auditing.

Why this revision?

All standards and guidelines are subject to review and modification intervals. This is designed to ensure, on the one hand, that they address current practice and technological innovations; on the other hand, it allows for the experiences of users working with the standard to be included. This feedback from certified organizations, their customers, certification bodies, accreditation bodies, trade and industry associations, and other interested parties are first collected on a national level, analyzed and condensed. The national comments and change requests are then forwarded to the international councils. The members of these national and international councils also include employees of the German Society for Quality (DGQ).

If we look at the international standardization work of the past years, and at the same time observe the unbroken trend to continue to publish new or supplementary management system standards, all of which contain internal audits, it follows logically that after 10 years have passed, the ruling standard should undergo some serious renovation.

On the other hand, of course, we need to remember that techniques and methods for audit planning, audit conduct, and audit follow-up have been well established for more than two decades now, and that "auditing" does not need to be re-defined. However, there are adjustments, clarifications, detailing, and interpretations that have become necessary in order to for this Guideline to be able to fulfill the dramatically increased scope of its application. And there's another truly amazing aspect: if you ask around during an event to see who is familiar with it, the answers will disappoint you. Just one more good reason for us here at DQS to publish a series of articles on it here in our customer journal, DQS in Dialog.

Transition provisions and times

This will be a short one. There are no provisions for timeframe for transition. The Guideline came effective upon publication in December 2011, and can be used since. Of course it helps that the document has the status of a "guideline" – but more on that in the next paragraph.

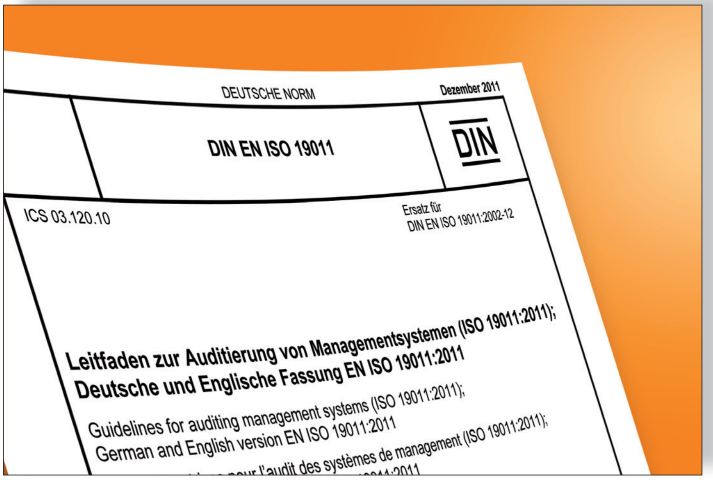
Scope of applicability and status of the document

"Applicable to all organizations that need to conduct internal or external audits of management systems or manage an audit programme." Not much needs to be added to this sentence from chapter one. But you will need to remember that for the conduct of "external audits", ISO/IEC standard 17021 applies, which has adopted many passages from ISO 19011 in its new chapter nine – but not all of them and not completely, just to mention "Remote Audit Activities" and "Risk-based Audit approach". For this reason, whenever ISO 19001 references "external audits", it should be taken to mean "second party", that is supplier audits.

Regarding the status of the document, please note this is a guideline!

What does that mean for its every-day use? A guideline provides information and orientation. A guideline does not stipulate requirements! That means, organizations are free to follow the instructions, to implement them – in whole or in part. The footnotes contained in various requirement standards for management system, which reference this standard, also do not turn it into a normative requirement. It is therefore up to each organization to decide if and which passages are practicable, useful, and can be implemented in their own company. But be careful: whenever you include statements such as "... our internal audit processes follow the principles of ISO 9011" or..

"audit programmes and audits shall be conducted based on ISO 19001", you elevate this Guideline to a document that contains requirements for your system. It may be a good idea to evaluate the formulations and wording in your own processes there. Another piece of advice: some, particularly sector-specific standards such as ISO/TS 16949, include precise requirements for planning and conducting internal audits. Here, the legal principle of precedence applies. Whenever a standard valid and applicable to your organization includes requirements, those are valid, regardless of the guideline status of comprehensive auditing standard ISO 19011.



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Leitfaden zur Auditierung von Managementsystemen (ISO 19011:2011);
Deutsche und Englische Fassung EN ISO 19011:2011

Guidelines for auditing management systems (ISO 19011:2011);
German and English version EN ISO 19011:2011

pour l'audit des systèmes de management (ISO 19011:2011);

The Guideline's basic message

If asked to summarize the basis message of the Guideline into a few words, we would probably come up with these principles:

- Invest more time and thought to determine which aspects and processes of your management system you want to invest the available auditor resources in, and that you want to audit intensively – make a selective decision.
- Give some thought to what your internal audit objectives really are (that is more than just establishing conformity!), and which audit methods are best suited in support of those objectives.
- Depending on the processes and audit methods selected, pick the persons best suited to the task. Determine the skills and competencies of internal auditors specifically for your own organization.
- Evaluate and continuously improve your audit planning, conduct, and follow-up.

The newly introduced audit principle of "confidentiality"

Audit principles are often overlooked, either because people consider them to be only platitudes, or because there are no operating procedures to go with them. That is regrettable, because these principles define the basic, practical, and ethical preconditions that characterize professional conduct in the audit context. It's not for naught that they preface the guideline. In addition to the well-established ones:

- Integrity (used to be called ethical conduct),
- Fair presentation,
- Due professional care,
- Independence,
- Evidence-based approach,

another one has been added, which deals with confidentiality. The standard illustrates as follows:

"Auditors should exercise discretion in the use and protection of information acquired in the course of their duties. Audit information should not be used inappropriately for personal gain by the auditor or the audit client, or in a manner detrimental to the legitimate interests of the auditee. This concept includes the proper handling of sensitive or confidential information."

Many readers may now exclaim: but that goes without saying! Still, allow me to ask some questions here: Which organization has truly implemented transparent, binding regulations for the handling of confidential and sensitive information? The definition of a distribution list for the audit report is not sufficient for this purpose. Most organizations have no clearly defined rules for this, or at best the "orally passed down" kind that leaves internal auditors free to decide for them how to proceed. That is not fair to the auditors, and it also not prudent in terms of risk prevention. For example, how do internal auditors handle communications amongst themselves? Does the organization event want the transfer of information (which is neither forbidden nor prohibited by the audit principle)? What exactly is the possible "personal gain" that an auditor may incur, maybe for an extra income from consultancy? From an auditor's perspective, principles, rules and guidelines for confidentiality are to be recommended especially in the context of supplier audits.

Those of us who have listened attentively in trains or airport lounges to what other travelers have been saying on their phones have noticed to our alarm just how relevant most people consider the "proper handling of sensitive or confidential information".

Remote audit methods

For the first time, ISO 19001 mentions so-called “remote audit methods” in connection with determining the extent of audit programs. Obviously, this refers to methods that do not require the physical presence of the auditor on site. First reactions to this range from “excellent, from now on audits can be conducted from the quality rep’s desk by phone” to “for heaven’s sake, long-distance auditing, how is that supposed to work, especially for environmental or workplace safety systems?” Careful here: the standard does not mention “remote audits”; it mentions the use of “remote audit methods”. And we have always had those, such as in the case of document review prior to an audit, or when closing measures by sending in evidence and their evaluation by mail, without being on site. So the standard only describes something that has been in use for a while already. Still, we should take this mention as an opportunity to reconsider just which areas, subjects, and people really need to be on site in order to conduct a meaningful audit. Take, just for example, a conference call with an expert via phone, Skype, or Netviewer; or maybe a phone call with a sales team member at a remote location, provided all audit participants have access to the same data. Interestingly enough, Annex B of ISO 19011, which addresses audit methods on the whole, makes reference to a certain “level of confidence” that is prerequisite for the use of remote audit methods.

Whatever the extent may be to which organizations will in the future make use of this opportunity, they need to consider very carefully what information cannot be supplied by way of a remote audit method, which are, among others, those that arise from personal human contact or direct visual perception. Speaking for myself and as an auditor, I cannot readily imagine increased use of such audit methods in the context of production processes, environmental or workplace safety systems.

The “risk-based auditing” approach

The probably most interesting sentence in the new edition of ISO 19011 can be found in chapter 5.1, where it states in reference to the concept of “risk-based auditing” that: “priority should be given to allocating the audit program resources to audit those matters of significance within the management system”.

This opens up new possibilities for selection, since this expressly permits the auditing of processes in a manner that is either more or less intense, subject to their significance within the management system and the organization. It is now up to the organization to specify which criteria they want to use to determine this significance. Possible criteria might be: key characteristics for product quality, risks, significant environmental aspects or health hazards, corporate or audit objectives, or maturity of the management system. For the latter, Annex A of ISO 9004 may prove worthwhile: it contains a very practical approach for self-evaluation of the maturity level by the organization itself.

Looking at this from the perspective of an external auditor, this process of identifying the “so-called significant processes, areas of the management system” really needs to be supported by evidence, plausible descriptions, and positive proof. Then will external auditors be able to accept audit programs based on this risk-based approach without hesitation. This should put an end to audit programs built on the idea of “each year, each process, each detail”, where audits are simply hurried through. And that is definitely a good message!

Improvement of Audit Programs

Evaluating the risks associated with audit program planning

This chapter is newly developed and contains a very impressive collection of factors that may turn out to be critical in establishing, implementing, monitoring, reviewing, and improving audit programs, and for achieving the audit program's objectives. These may be associated with:

- Planning, i.e. failures to determine suitable audit objectives, or to determine the extent of an audit program. What does that mean? This relates to risks that come, for example, from supply commitments or contracts, where promises have been made relating to the conduct of and evidence from internal audits, or the obligatory auditing of defined processes. These must become part of the audit program. Ensuring that this information is made available to the person responsible for the audit program is considered a potential risk area.
- Resources, such as not having enough time to prepare the audit program or insufficient resources for conducting the audit (a real classic!). Here I would like to point out that the current trend of constantly reducing the number of internal auditors, or their availability, increasingly calls into question the effective and value- adding functionality of audits – and therefore, increases risk.
- Audit team selection, which means that the team (many of us would count ourselves lucky if we still had teams available, see the note above) as a whole does not have the qualification needed to perform the audit effectively. "Effectively" here means that the necessary skills and know-how need to be available in order to be able to achieve audit objectives and evaluate audit criteria.
- Ineffective communication of the audit program, which is to say that not enough information has been forwarded to the people involved, audit objectives and extent are not clear, the necessary interview partners are not available during the audit, and similar issues.
- The protection, storage and retrieval of audit records, which can turn out to be a significant problem if years later evidence of such records has to be provided in correlation with warranties or contractual claims (see above).
- And last but not least the monitoring, review, and improvement of the audit program: monitoring in the sense of adherence to the audit program as planned, review in the sense of achieving audit objectives, and improvement in the sense of potential adjustments of the audit program based on audit outcomes, the feedback of interested parties, or current events.

All in all, very important aspects that are often neglected or at least not taken into systematic consideration during the review of audit programs. Unfortunately, some organizations are happy enough to have prepared an audit program at all, and have it approved, then hope to have it conducted without any major incidents or other adversities, whether in-house or from the outside. But that, as they say, is another story…

Audit program review and improvement

This closing paragraph of chapter 5 is also completely new – and by now many readers may be glad to remember that ISO 19011 is a guideline and not a normative requirement. Because provision 5.6 provides orientation on the criteria to be used for evaluating the ability of an audit program to achieve its objectives. It mentions the following factors:

a) Results and tendencies inferred from audit program monitoring
b) Conformity with the audit program procedures
c) Evolving needs and expectations of interested parties
d) Audit program records
e) Alternative or new audit methods
f) Effectiveness of measures to address the risks associated with the audit program
g) Questions reference the confidentiality and information security of the audit program

This auditor is not aware of many companies that have instituted such or similar reviews of audit programs. We may safely assume – and to some extent, even understand – that this chapter will not find much concrete application especially among SMEs. Take, for example, the evaluation under c) "Prospective requirements and expectations of interested parties". The very term "interested parties" already gives rise to the question who exactly is meant by this? The answer can be found in the much ignored ISO 9004, where interested parties (in relation to comprehensive (quality) management systems) are identified as:

- Customers
- Staff members
- Suppliers
- Investors/proprietors
- Government/the public

I'd like to know which organization has already prepared a truly conclusive analysis of the needs and expectations of their interested parties, and if so, have they also deduced measures for the improvement of their audit program from it? Just to avoid any misunderstandings here: the author does consider these suggestions to be very useful and suitable for adding the interests of third parties to audit programs, and to further the development of mature internal audit processes. However, it would nevertheless overburden many other organizations. The same can be said for the recommendations at the end of chapter 5.6, which states that the continual professional development of auditors should be reviewed, and the results of the audit program reported to top management. Frequently today, this is already being done by way of the management system review (ISO 9001, clause 5.6).

The evaluation of "continual professional development" of auditors, on the other hand, seldom takes place – actually, it hardly ever does. But that would indeed be a significant step forward, because we do have to ask ourselves just how auditors are supposed to continue to develop if the only feedback or evaluation of their skill is anecdotal – or none at all. This also needs to include the perception of their "audit customers" in relation to e.g. audit organization, technical competence, social competence, which includes command of questioning and communication techniques. Of course, none of this should be personal and can be designed in such a way as to avoid identification of the individual auditor, in order to protect their privacy. However, it would help the auditors in their personal development, and to improve audit quality overall.

The possibly most interesting factor of this entire clause may actually be item e) "alternative or new audit methods" – why? Simply because the reader/user may be curious and ask what new or alternative methods that may be, aside from the tried-and-true ones like reviewing documents, collecting evidence, drawing samples and conducting interviews? And now they are reading this standard with renewed interest, turning pages, looking for it… but not finding it. So it falls to us to be creative, to come up with ideas on how to make audits "different", livelier maybe, more diversified, surprising even and with a touch of fun, as well as better, more useful results.

Alternative or new audit methods

Alternative or new audit methods – that is the title of the fourth part of our series of contributions on the changes of ISO 19011. To provide some background: in chapter 5.6 "Evaluating and Improving the Audit Program", you will find, amongst other aspects, such as the effectiveness of measures taken and of foreseeable requirements and expectations of interested parties, a small but very interesting suggestion regarding the use of non-standard or novel auditing methods. Those who think that ISO 19011 contains additional information will be disappointed. It is left to us to consider how this may work, to design internal audits that are "different", and possibly more exciting, more alive, more respected.

In the subsequent installment you will find a selection of possible alternative, novel audit techniques. Of course, many others are conceivable, and may actually be used by some companies. However, in this article, we want to focus on a few already successfully employed techniques.

The TOP-FLOP Approach

We all know the traditional techniques used to acquire samples for audits. Such sampling is either statistically or decision-based (cf. the highly recommended Annex B3 of ISO 19011). Both classical sampling techniques have in common that the samples so chosen are (that's how Gaussian distribution works, after all) generally "in the green", i.e. they are mostly okay, to put it colloquially. The TOP-FLOP technique consciously approaches sampling differently. It should, however, be noted from the start that this technique should not be used constantly and consistently, but rather occasionally and in order to gain a different perspective on the processes.

We begin with the choice of a TOP sample. This is chosen by the audited organization and should expressly distinguish itself by the fact that in this project, process or procedure, every conceivable aspect has gone optimally, effective and efficient. The goal is to learn which conditions obtained or coincided to produce this extraordinarily good result. The auditors' attention – as well as that of those audited – should focus on whether and how such situations are reproducible.

Subsequently, a FLOP sample should be chosen – but please in precisely that order. If you start by asking after a "flop", you will be answered by a resounding "we don't have any of those!" If, however, the employees [of the audited organization] have had an opportunity to demonstrate the sort of extraordinary performance of which they were and are capable, their willingness to look into the "poison cupboard", in which they like to store their organizational failures, increases markedly. The "FLOP" sample is then also analyzed to identify which circumstances coincided to produce this significantly bad result. Attention should now be focused on identifying whether and how to prevent a repeat of that situation (to all intents and purposes a classic prevention measure).

Substitute audits

Normally, we conduct our audit interviews with the process owners as listed in the process descriptions, as is right and proper. However, over the years, this almost necessarily creates a pool of "audit professionals", who are included in (internal and external) audits over and over again. What do you think? Is it a rather too daring thesis that some audits show similarities to the well-known film "Groundhog Day"? The employees know the aditors' questions rather too well, and the auditors could give the employees' answers by heart. So why not aim the audit consistently at the "second string", at the substitutes, at those, who assume the responsibilities of the process owners in case of their being sick, on vacation or absent for any other reason? Aside from some positive surprises, this has led employees in some companies to look up the descriptions of some processes and procedures prior to an internal audit. Not to mention that some inadequate substitution rules became clearly obvious even during the planning of the audit.

Using "quiz methods"

Try to imagine this: during your usual preparations for an internal audit of any given process, take the corresponding process description and make some small changes. You may want to add a process step or delete one, change responsibilities and participation, delete quality records or replace a decision symbol by an unbroken line, remove applicable documents or create wrong connections to other processes. Now comes the interesting part: distribute this changed process to the organizational unit concerned, or maybe only to the participants in the audit, and ask them to determine the number of obvious mistakes or changes. You may want to announce a small reward for the winner(s), sweets or something similar.

You may be surprised at just how energetic they will start to look through the documentation for mistakes, and to talk to their colleagues about it, too. As a result, the documentation will not only be read and talked about, but people will actually enjoy it and ideally, they will already come up with ideas for improvements at this stage. But be careful, some people may find mistakes where there are none, or not find any of them at all. In that case, you may need to console your nerves with some chocolate.

Internal customers audit internal suppliers

This is probably the most common method; the title says it all. Add to your audit team an internal customer to serve as a bona fide expert for the internal customer's perspective. This expert does not need to have any professional audit know-how, because that is what you have, being a well-trained and qualified auditor. The internal customer's task is to review the internal supplier's actions with an eye on: how do we (the internal customers) benefit from this? What are our advantages, what would be better for us? The auditor, on the other hand, will be more in the role of a moderator (depending on how lively the dialogue is and the internal situation, it may also be more in the way of a mediator), records the results of the interview and documents the audit findings.

In addition, the auditor is also the one who has the methodology know-how and who will review and evaluate the interaction at the interfaces. All in all, organizations that have used this method tell of excellent results with real-life applications and a very cooperative audit spirit.

Ad hoc audits

This was the method most often mentioned during DQS UL customer workshops; its use seems to be spreading. What are they?

Ad hoc audits are usually unannounced audits that happen for one specific reason in order to have a quick but in-depth look at a concrete problem, a recently identified risk or an error. These audits happen right on the spot, where the problem is relevant, that is, where it may occur. These audits do not require much in the way of advance planning or extensive checklists, they also do not result in pages upon pages of reports. Some key words, quickly noted down and complemented by corresponding measures (if considered necessary) – that is all. One piece of advice for organizations just starting out with ad hoc audits: experience shows that the introduction of this particular method needs to be communicated in advance in a very open and transparent manner. Otherwise, you run the risk that employees will assume negative motives behind these ad hoc audits, and that the resulting reservations will lead to a lack of cooperation.

From Output to Input

What is more logical than to look at a sequence of events in their naturally occurring order, starting from the beginning and ending – well, at the end? Nothing, which is why audits work well that way, no question. We have learned that processes turn input into output, and that is why when auditing a process, we start with the input. But you can also try it the other way around; an auditor friend of mine put it very succinctly: "If I want to find lice in my cat's fur, I have to brush her against the grain."

So let's start at the end of the process, which is with the result, and then move forward step by step. In the case of a producing organization, for example, that would mean we start with the goods having been packed for shipping, and then work our way backwards through assembly, production – taking a short detour to metrology – then on to purchasing, work preparation all the way to sales. In doing so, we focus intensely on transfer and interaction joints within the process. In addition, that gives us the advantage of working with a sample that we know has gone through the entire production process. If we work from front to back, we naturally prefer to select procedures that are currently being worked on in this department, and therefore naturally come to an end where the department ends. In the next department, we then select another sample. This method combines well with the "internal customers audit internal suppliers" approach by simply bringing the respective internal customer "forward" to their internal supplier.
Other options

There are many more options we could address: self-assessments, mystery calls, workshop methods and group audits, using internships for audits, fairy questions, scenarios and role play. Unfortunately, there's not enough room for all of them here.

Finally, I would like to express a wish: please try just one of the methods written above, or any other change from the classic audit approach. Create your own experiences and see, how much fun you can actually have using various auditing methods with different employees, executives, and cultures within your own organization. Or to put it in the words of a famous shoe manufacturer: just do it!

specific aspects of the conduct and follow-up of audits.

There have been some notable clarifications regarding the roles and responsibilities of people who accompany the audit. ISO 19011 states: "Guides (person appointed by the auditee to assist the audit team) and Observers (person who accompanies the audit team but does not audit; can be from the auditee, a regulator or other interested party) may accompany the audit team, but should not influence or interfere with the conduct of the audit. If this cannot be assured, the audit team leader should have the right to deny observers from taking part in certain audit activities." That is of course easier said than done, but at least the standard does give auditors the right to ensure they are able to fulfill their auditing obligation.

Influencing can happen in many different ways and by a variety of observers – anything from supervisors replying in place of the actual interview partner all the way to corporate consultants trying to "defend" the results of their consultancy efforts during the audit. This also includes auditors-to-be in their observer audit getting carried away and taking charge of the audit, or official delegates overstepping their competencies and authorizations. This clause should also be applied to so-called "witness audits", that is audits accompanied by a third party such as accreditation bodies, notification authorities, or the certification body itself. Witness auditors are tasked with evaluating the performance of auditors on site. This is done by way of "observing", and they may not interfere with the audit itself.

Next to the so-called "risk-based audit approach" we already talked about in part two of this series, there was one small, but very interesting supplement to chapter 6.2.2, where it states in the last paragraph to: "determine any areas of interest or concern to the auditee in relation to the specific audit." What therefore can be more logical than contacting the area to be audited during audit planning and to determine their specific situation, interest and critical aspects? A dialog of this type can help kill two birds with one stone: it provides an opportunity to enter into a direct exchange with the responsible supervisors and/or process owners prior to the audit, and to agree on concrete audit objectives and focus areas. Audits that have been planned in this manner tend to be focused much more closely on the actual subject areas relevant to those involved in the process – instead of repeating the same approach ad nauseam, using ready-made checklists with a focus on establishing conformity.

As far as audit conduct itself is concerned, there have been only very few additions or changes in ISO 19011, which does not really come as a surprise. The basis process of audits – opening meeting/interviews/review of samples/collecting evidence/evaluating the audit findings and closing meeting – are the result of decades of tried-and-true audit practice, or to put it colloquially: there is no need to re-invent that particular wheel!

There is, however, one newly added sentence that made this author laugh: "During the meeting, an opportunity to ask questions should be provided." It makes you wonder what kind of opening meetings have been held in the past that made this addition necessary? Maybe they should have also included something along the lines of "During audits, efforts should be made to communicate as much as possible." You never know…

On a more serious note, though, the guideline includes valuable recommendations on the review of documents during the audit: "If adequate documentation cannot be provided within the time frame given in the audit plan, the audit team leader should inform both the person managing the audit program and the auditee. Depending on the audit objectives and scope, a decision should be made as to whether the audit should be continued or suspended until documentation concerns are resolved." Again, easier said than done! However, this also means a strengthening of the rights of auditors, and is an important aspect for efficient auditing. Of course the practical application of this paragraph still leaves it up to the auditor to decide on the relevance of any required document for evidence purposes, and if there is sufficient cause to abort the audit. But there are definitely situations where continuing the audit is a waste of time, such as when reference is made to a newly documented and implemented, essential process that cannot be located (neither hard-copy nor electronically), or when quality records of essential significance are not available – or if they are not meant to be available. The latter especially should give an auditor pause and may lead to the conclusion that he or she is now unable to collect the evidence required for the audit, and that a decision must be made to continue the audit – or not.

One novelty above all is really very much welcome: audit findings should include conformity and good practices along with their supporting evidence! In the draft stages of ISO 19001, they still were talking about "strengths" instead of "good practices", and that may have expressed the sentiment even better. But still, it is good to see that it is now the official function of audits to determine strengths or good practices. Hopefully, this will allow (internal) audits being more appreciated as a tool that generates value, or at least confirms and motivates. After all, the perception of many people is that audits are only focused on finding mistakes, identifying weaknesses, and discovering waste (of resources and time). When we are serious about identifying "good practices" and their supporting evidence, and when we focus our audits on this (without neglecting other aspects, of course), that changes the audit atmosphere, which in turn changes the level of acceptance. It follows logically, of course, that the identified strengths have to be documented and communicated by issuing individual, concrete findings, ideally complete with an identification of functional areas, departments, and responsible persons.

This ends my review of the new standard ISO 19011. It was my intention to provide you with helpful interpretations, practical advice, and information for implementation in your own audits, and on behalf of DQS UL Group, I hope to have been successful in that endeavor.

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