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*An interview with Dr Nigel Croft,
Chairman of ISO Technical Subcommittee on Quality Systems (ISO/TC 176/SC2)*

New versions of the ISO 9001 & ISO 14001 were officially launched on 15 September, 2015. ISO and the IAF have agreed that there will be a three-year transition period, where organisations currently certified to the standards can make necessary adaptations to their quality and environmental management systems. In order for organisations to have a better understanding of the new versions, HKQAA invited Dr Nigel Croft, Chairman of ISO Technical Subcommittee on Quality Systems (ISO/TC 176/SC2), to share with us the rationale behind this conversion.

What are the changes between final versions and FDIS of ISO 9001:2015 and ISO 14001:2015?

There are no technical differences between the FDIS and the final version of each standard. According to ISO rules, the FDIS ballot is a "YES/NO" ballot, and there is no opportunity for comments to be submitted or addressed.

In the new version of ISO 9001, the eight quality management principles have been reduced to seven. Why has there been such a change?

The general review of the quality management principles was actually undertaken before work started on the revision of ISO 9001. Whilst the majority of the original eight principles were maintained, with some additional clarifications or changes in emphasis, it was decided to combine the principles of the "Process Approach" and "System Approach" into a single principle, thereby reducing the number from eight to seven. The rationale for this was that some users were confused by the fact that having two separate principles implied that these were totally different concepts. The way in which the new single principle "Process Approach" is described in ISO 9000:2015 makes it clear that this is not the case: "*Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coherent system.*"

“Risk-based thinking” is incorporated into the new ISO 9001 and ISO 14001 standards. Why has this become the focus of the new standards?

This relates to the whole concept of preventive action; how to identify things that might go wrong and how to prevent or minimize the chance of that happening. Traditionally, the requirements of ISO 9001 and ISO 14001 had an implied link between “corrective action” and “preventive action”. The very positioning of the “Preventive action clause” of ISO 9001:2008 right at the end of the standard really gave the wrong impression. Prevention should be (and now **will** be) at the very heart of the quality management system, and starts with the planning of the system and its processes. The new clause on “Risks and Opportunities” near the beginning of both ISO 9001:2015 and ISO 14001:2015 aims to create that preventive “risk-based” approach to the whole system.

Which parts of the new standards are closely related to the concept of “risk-based thinking”?

There are in fact two parts of the new standard that are closely related to the concept of “risk-based thinking”. The first is the new Clause 4.1 which requires organizations to define the context in which they operate. This includes both internal factors such as the organization’s culture, know-how and resources, and external factors such as the socio-economic, and legal framework in which it operates, including local, regional and national infrastructure. No two organizations will be identical, and the potential consequences of a failure associated with, for example a manufacturer of critical aircraft components will be much more serious (and therefore “higher risk” than a small corner shop selling office supplies.

The second is determining the needs and expectations of the relevant interested parties. In the case of ISO 9001, this will focus on the direct customer, but may need to take into consideration the end-user of the product or service, regulators and others. A classic example would be a school, where the student has certain needs and expectations that must be addressed, but there are other relevant interested parties such as the student’s parents, future employers, those responsible for setting a national curriculum (if applicable), and society as a whole. All have their needs and expectations and the organization is expected to determine which of those are relevant to the quality management system.

A similar rationale might apply to environmental management if a chemical plant is to be built in an industrial zone, a semi-rural area or close to an area of virgin rain forest. In all cases, the organizations are very similar, but the contexts in which they operate and the relevant interested parties may mean that the risks associated with the business are very different.

By adopting “risk-based thinking” organizations are required to think about the relative importance of their business processes in terms of the objectives to be achieved (recognizing that not all processes have the same level of impact or potential consequences), and then take actions to address the risks and opportunities involved. There may, for example, be opportunities to improve processes and reduce costs, to develop new and innovative products or enter into new markets. These are opportunities that an organization should of

course seek out, but this needs to be done in a way that recognizes and addresses the potential risks involved.

In the new standards, why is stronger management required in all levels?

We all know that leadership from the top is vital for the success of any initiative. Unfortunately, we also know from experience that some organizations have implemented their quality or environmental management system under pressure from customers, with little, if any, true leadership from top management, or a deeper understanding of the underlying principles on which the standards are based. In some cases, the management system has been perceived to be “a system of documents” (a “necessary evil”) rather than “a documented system” that will help the organization to manage its business better and achieve its short- and long-term objectives. The new ISO 9001 standard makes it very clear - “Top Management shall ensure the integration of the quality management system requirements into the organization’s business processes.”

Why has the role of “Management Representative” been removed?

Who will then be the “project owner” or person in charge of the ISO certification?

It’s true that there is no longer any prescriptive requirement for the organization to designate a specific person as the “Management Representative”. There is, however, a requirement for top management to define the responsibilities and authorities for ensuring that the management system meets the requirements of ISO 9001 or ISO 14001, and to report back to them on the system’s performance.

That can still be done by a single person, if that is the way the organization chooses to do it and it’s effective for the organization’s particular context (in which case, the “Management Representative” role could continue unchanged - there is nothing in the new standards to say that an organization **can’t** have a single management representative to fulfill these requirements!), but it gives the organization the flexibility to meet the requirements in other ways (by designating more than one person, or a committee, or different individuals in different parts of the organization) to suit their particular circumstances. One of the main reasons that the prescriptive requirement was eliminated, though, was to avoid the possibility that top management could simply abdicate their responsibility and delegate everything to the “MR”.

In the new standards, there is less documentation and the “Quality Manual” has been eliminated, why has there been such a change?

Again, it comes back to the question of context, usefulness, and the need to be prescriptive in requiring “a quality manual”. We know from experience that some “traditional” quality manuals can be very useful (and are often required by customers in specific industry sectors). Equally, though, in a high-tech world, some organizations may choose to describe their quality management system, its processes and their interactions in, for example, an intranet domain with hyperlinks to the appropriate levels of detail to make this information available by “non-traditional” methods. It is now acceptable for them to do so.

We also know from experience that some organizations have developed quality manuals based on templates “to meet the requirements of the standard” with little or no added value, often merely regurgitating the requirements of the standard without much thought to the way the organization actually **works**. The new standard will actually require organizations to think for themselves, rather than adopting such a pro-forma approach.

How can the new ISO standards and management systems help organisations address management problems and improve performance?

I think that all of the above questions and answers point towards the fact that the new ISO 9001 and ISO 14001 are less prescriptive in nature, but focus primarily on the ability of the organizations’ processes to be effective (achieve their planned results). How an organization chooses to manage its business to achieve these results is up to the organization itself. This is in line with the ISO/IAF strategic plan from a couple of years ago that “Output Matters”. Of course it is important to have the right amount of documentation, top management leadership, competent people, calibrated equipment and so on, but we must never forget that customers and other interested parties will judge the organization on the resulting outputs (conforming products and services in the case of ISO 9001, adequate environmental performance in the case of ISO 14001).

The new standards, by being less prescriptive, will require organizations to think for themselves about what really is important; how to manage their business in order to achieve the planned results (which is the focus of ISO 9001 and ISO 14001), and how to do that efficiently, meaning in the most cost-effective way (which is up to each organization to decide for itself, so long as there is no negative impact on the system effectiveness).

To summarize, the new standards will help organizations to improve their performance by simultaneously applying a combination of the Process Approach, Risk-based Thinking, and the Plan-Do-Check-Act cycle at all levels throughout the organization.

Certification services for ISO 9001:2015 and ISO 14001:2015 are now available at HKQAA. In order to ensure that our certified customers can smoothly convert to the new version, HKQAA is providing a series of support services including training, seminars and gap assessments, to support the conversion exercise.

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