NEXT GENERATION AUDITING

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With millions of organisations gearing up for the release of the latest ISO 9001 revision in September 2015, the Standard is set to bring about some large-scale changes. Namely, the revision poses some serious questions concerning the new role and responsibilities of the auditor: How will the auditor’s relationship with management change? How will the auditor address the new emphasis on ‘risk based thinking’? And ultimately, how can they still deliver the right information to management when faced with increasing commercial pressures and time constraints?
Following, assessors are going to need to be able to speak the language of the boardroom.

Senior Management And Leadership – Culture of Quality

The DIS 9001:2014 requires senior management to take accountability for the effectiveness of the QMS. As stipulated in section 5.1.1 Leadership and Commitment for the Quality Management System, ‘Top management shall demonstrate leadership and commitment with respect to the quality management system’. In practice, the new clause requires management to take ownership of the management system to ensure it is effective and delivers real business improvement (and not just ISO 9001 compliance). Good communication and reporting are crucial.

“While there was always a requirement for top-level management to take accountability for the effectiveness of their QMS, there is now an increased focus on leadership skills,” says Peter Pond, Quality Manager at Qualsys Ltd. “Instead of simply relying on quality professionals, senior management must now take a more proactive approach in ensuring the QMS is integrated into the organisation’s business processes. The revision encourages a culture of quality, where management must encourage and support their organisation members to contribute towards the effectiveness of the quality management system, promoting improvement.”

The Changing Role of The Auditor

In July 2014, Richard Green, Head of IRCA Technical Services, stated he believed there will be a transition in the auditor’s role from ‘auditor’ to ‘assessor’. Green highlighted that auditors will increasingly need to deal with “shades of grey” and “new evidence sources will need to be examined”. Building on this, Green explains that auditors may transition into unknown territory and will thus have to employ an “increased use of judgment to assess the capability of the system to fulfil current and future requirements and outcomes”.

“This may mean acknowledging that ‘old friends’ such as the quality manual and the current six mandatory procedures may no longer be present in the client’s QMS,” says Green. “Instead, auditors will be faced with unfamiliar sources of documented information which they must be able to comprehend and interpret in order to discern objective evidence.”
Process Auditing for
ISO 9001:2015

1. Senior Management responsible for Culture of Quality
2. Real-time Quality and KPI data
3. Continual improvement
4. Process Auditing vs. Procedure Auditing
5. Rely on time poor Internal Auditors for actionable insight
Colin Partington, Quality Management Consultant and ISO 9001 expert (cpatraining.co.uk), believes a consistent and pragmatic dialogue between management and the auditor is essential for both management to demonstrate leadership under the new Standard, and auditors to deliver the most objective and relevant evidence to management.

“A large number of internal auditors come to me overwhelmed with increasing commercial pressures and time constraints,” says Partington. “Such issues can result in constrained or irrelevant information being delivered to senior management. To rectify this, as stated in 4.1 of DIS 9001, Understanding the Organisation and its Context, the auditor must understand what the organisation does and what influences there are upon the organisation. How the auditor will establish these factors needs to be considered, almost certainly needing the top management to be interviewed to discover these.”

This closely ties the two clauses together, with the auditor working with management to understand the context of the organisation while management demonstrates leadership and commitment by determining the required management information needed from the auditor to make informed business decisions. However, it is unlikely this new-formed relationship between management and the auditor will always be a bed of roses.

“Going forward, assessors are going to need to be able to speak the language of the Boardroom,” says Green. “They will need to engage with top management regarding strategy and context, not minor operational matters. They will need to feel comfortable challenging individuals at this level. For some existing auditors, this may prove difficult.”
The introduction of ‘risk based thinking’ into the Standard also throws forth a number of questions. “The DIS 9001:2014 brings about grey areas such as the consideration of risk and opportunities,” says Partington. “How will auditors judge if the organisation has applied an appropriate level of risk to their system when much of this topic can be very subjective? And do all auditors have sufficient skills to evaluate whether risk has been fully considered and what evidence will they look for?”

In addition, risk analysis and relations with top-level management aren’t the only areas auditors will need to approach with professional discretion and tact. When conducting a first-party audit against the new ISO 9001:2015 Standard, it may fall on the auditor’s shoulders to look to others in the organisation to ensure management is demonstrating leadership.

“Demonstrating leadership and commitment will demand more time of the senior management team during the audit – but not just them,” says Partington. “Much of this will come from asking other people in the organisation how they feel about the leadership skills of their senior management. This could be a delicate area and there may be a need for some ‘soft skills’ training for some auditors to ensure that they exercise appropriate tact and diplomacy.”

“This may sit uneasily within certain cultures (Japan for example) where the thought of challenging top management in this way is completely contrary to their beliefs,” adds Green. “You just don’t do it – but going forwards you’ll have to. This is why the dialogue between auditors and top management needs to start now. Both need to understand each other’s position. However, this will take time.”

### Process Auditing vs. Procedure Auditing

For management to be seen as effective leaders, first-party auditors must be supplying them with good-quality management information. This will require a more informed and analytical process. Whilst the 2000 version of ISO 9001 brought in the concept of developing the QMS around the organisation’s processes, the amount of detail that has been added to this clause is considerable and will require significant effort on behalf of the auditor to establish the level of compliance.
“The auditor will need to look at the processes of the organisation and check that the organisation are monitoring, measuring and evaluating them [clause 4.4 & 6.2] to determine how effective they are in helping to achieve the desired outcomes i.e. conforming products and services [clause 9.1],” says Partington.

By evaluating the processes, it will drive continual improvement, or simply ‘improvement’ as the new Standard stipulates. For Partington, this will drive a cultural shift from procedure auditing where “findings are discovered, corrective actions are made, and ultimately, boxes are ticked,” to a more analytical approach which focuses on process auditing.

“Process based auditing is more about following through a trail by taking a job from start to finish and reporting what is seen as it passes through the various departments. By taking this approach, a number of clauses can be covered in one audit.”

The Move towards Auditing Using an Electronic Quality Management System

With an increased emphasis on process control, process evaluation, risk-based thinking, and delivering the right information to management, many companies are shifting towards Electronic Quality Management Systems as a method of underpinning compliance in DIS 9001:2014 in preparation for the ISO 9001:2015 revision.

In addition to a better managed auditing process via closed-loop process control -- guaranteeing visibility of responsibilities and driving corrective actions -- Electronic Quality Management Software enables organisations to generate process efficiencies. With significantly reduced data input, duplication, printing, reliance on spreadsheets, non-conformances, and delays associated with conducting audits, this crucially provides more capacity and resource for insight, analysis and assessment.

Having recently implemented the EQMS Audit Management application from Qualsys Ltd, BT Plc aim to make the system the driving force for business improvement. With auditors sending real-time information back to management, significant time savings can be gained.

"Information will reach management much faster using an Electronic Quality Management System and auditors will be relieved from various administrative tasks associated with a paper-based process,” says Tariq Bajwa, Global Services Online Systems Lead for BT Plc. “This enables management to speed up information collection and its analysis to make better, faster decisions.”

This availability of real-time management information, including graphical KPI dashboards, empowers management to make key business decisions and demonstrate leadership under the new Standard.

Employing an Electronic Quality Management System also enables businesses to demonstrate ‘risk-based thinking’. With Electronic Risk Management Software, risks are assessed, prioritised, and mitigated, while risk reviews are automated according to the time periods set by management.

“The DIS 9001:2014 stipulates in section 6.1 Actions to address risks and opportunities, organisations must plan ‘actions to address’ risk and ‘evaluate the effectiveness’ of these actions,” says Partington. “Implementing a comprehensive Electronic Risk Management System enables organisations to proactively address, analyse and mitigate risk. It enables organisations to review the mitigation process with clear audit trails of risk statuses to see how effective it has been in reducing both strategic and operational risks.”

The Future of Auditing

With DIS 9001:2014 placing greater emphasis on the role and importance of the auditor, it is likely the auditor will need to become the ‘eyes and ears’ of senior management. The Audit Team are challenged to provide more business process / output insight in addition to traditional procedures based auditing.

This is crucial to minimising costly mistakes, driving improvement and ensuring compliance with standards and regulations. With increasing operational and commercial pressure and changing regulatory obligations, auditors will be under enormous pressures and will require additional time, resources or operational efficiencies to meet their obligations.

Senior management may consider these resource needs – such as the training needs of new and more experienced auditors, electronic QMS and auditing tools, and enabling an open culture to allow process auditing to flourish. By increasing the capability of the auditor to more deeply investigate process based topics, the auditing process more readily demonstrates compliance and, ultimately, delivers greater business value.
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