Key Elements of ISO 9001:2015
How Automated Solutions Simplify Compliance
Technology helps us centralize information, collaborate more efficiently and drive quality from all areas of the business; however, it’s visibility into data that’s needed to foster control in how information passes through overlapping processes. This visibility allows for improvements in operations based on their entirety and not just separate pieces.

The ISO 9001:2015 standard takes a broader approach in explaining the overall goals and mindset of quality that should be included in personal operations. So it is not necessarily a change in the total requirements, but a change in the approach taken to satisfy them. The new standard has no specific requirement toward a quality management representative or even a quality manual, which is different from previous iterations, but it focuses mainly on companywide commitment and the leaders within your organization that will put the effort in to achieve quality.

So to create a more common approach, especially when auditing, the 2015 standard provides a more integrated approach to standard frameworks. This way you can combine common elements of overlapping standards and then map the processes to multiple standards. You can audit an area for compliance with various standards in one event, rather than audit the same area several times for several standards of compliance. Managing the requirements of these various standards and creating a common platform for managing the process of the multiple frameworks can get complex, but technology helps to organize and automate much of the process.

Below is an overview of the new standard, and where technology fits in to simplify the process.

Section 4: Context—The Planning of How You Will Manage Quality

This section of the standard is essentially the planning of how you will manage quality. A lot of it becomes a strategic decision, but where technology fits is in 4.4, which is centered on establishing a “process-based Quality Management System (QMS).” We want to put the context of the solution to look at the processes and how we can easily map processes to our business needs. A lot of times, what’s in the standard is just a framework, and organizations have to interpret it to match their way of doing business.

When considering technology’s role in the dynamic of frameworks like ISO 9001, it’s important to look at it as what it is—a tool. Technology does not make you complaint-free; technology doesn’t inherently solve all your problems with the flick of a switch. It’s something you can use to improve what you already are doing, or what you can do manually. Technology—and more specifically QMS automation—provides you with a vehicle to move faster, more efficiently and in the right direction. Ultimately, it’s up to the leaders to drive it and give it the direction it wants it to go.

Within the context of your QMS, and how you achieve and “own” quality, we discussed that we are seeing a company-wide approach—no one person assigned to the task, but more of a collaborative and broadened scope. So when you start mapping your quality objectives and building a story of quality, how do you enroll multiple stakeholders into the process of building quality? You need to have a collaborative platform that will enable stakeholders to have not only visibility into the process, but also the control to review, approve, make comments and route policies and processes throughout these stakeholders. This way, using a platform that is centralized, records comments, feedback, and transparency, creates a culture of quality where everyone is immediately notified of changes and updates and can influence the decisions around quality.

Another consideration is in the ability of a solution to meet the needs of building processes. When it comes to mapping the process and the overall context of quality, each business is unique. There are differences in processes, workflows and roles, and each process is tailored to the uniqueness of the business. In some cases, this uniqueness is what makes us competitive. So how do you automate unique processes, and build a context of how you’re going to build a QMS, and foster this in an automated solution? This is where flexibility becomes an important component.

Technology Enabler—Flexibility: You want a solution that will adapt to your business processes, and allow for true flexibility. This is what we call “configurability”—the ability to configure a solution to your needs, without any custom programming or technical knowledge of the solution—it has to be business-friendly. You should have the ability to change the workflows, fields and forms to meet your needs. In addition, if you ever have to adjust your quality policies and processes, you want to be able to have the system adapt to those changes easily.

Flexibility helps to ensure you are meeting the requirements, and gives you the ability to make it your own. Having a workflow-based system that enables multiple departments to weigh in on a quality policy would allow one person to draft the process, then route it to the next person or team of people to review and provide comments. Each time there is feedback, it is recorded, tracked and routed. This way, everyone’s opinion is visible and is communicated to the
Section 5: Leadership—Quality is Everyone’s Responsibility

The changes that the ISO 9001:2015 standard brought, means that a single person is no longer assigned as the quality leader. It’s more about leadership of the various stakeholders and their policies and procedures around quality. The quality manual has been replaced with a broader look at each groups’ quality effort. This is really where you want to create the policies and procedures that relate to quality and how each group will commit to the quality effort. This begs the question, “how can we collaborate on quality, meet the needs of the policies and procedures we are striving for, and keep it all aligned, integrated, and common?” Having a solution that is centralized, controlled and fosters a common platform is key. This centralization of a QMS provides that single, common source for all information, specifically, Document Control.

Technology Consideration—Document Control: You want to have a Document Control System that will not only automate the review and approval process, provide version control and foster change, but also enable you to essentially participate in the release of the documentation. Having a single solution that has the workflow, business rules and notification tools to ensure that you are not only controlling, but communicating, quality policies and procedures is vitally important. Moreover, it also enables the leaders to coordinate their efforts and provides an environment for collaboration. As an example, you want to not only make sure that your documentation goes through the proper review and approval cycles, but you also want to have the ability for all stakeholders to be involved in the process and receive notifications with comments on the document. This not only fosters tighter collaboration, but also provides a level of traceability that will show the history of this collaboration. Once approved, the entire company, or at least those affected, should be properly notified and trained.

The real power of technology is the ability to have a centralized and controlled place for an approved policy. You cannot make changes to the document—in many cases, you can have technology that effectively “hides” the editable copy, and provides only a read only copy, like a PDF or embedded document. This way, you can ensure that whatever leadership deems is the policy remains the policy—no one can edit the document. However, should you want to make a change, it shouldn’t be a matter of opinion. You need to follow a dedicated revision control process. This in itself is a workflow, going to the proper stakeholders to approve the request for a change (or changes), so that there are no errant copies floating around. It’s really about the process of releasing a policy from leadership, and revising within a controlled environment. The real value is the ability to take a policy from the top leaders, and disseminate to the entire company in real-time.

Section 6: Planning—Focus on Risk Management

This is where we see Risk Management come to the forefront of the standard. There is a shift from a preventive approach to a risk approach. It’s really several things here. You are using the risk methodology to identify and categorize your hazards by their overall risk, but you are also seeking ways to proactively control the risk. How can we mitigate our risks? What tools can we put in place to put risk at the front of our thinking throughout the entire quality lifecycle, so that we are effectively benchmarking the risks against our objectives? There are several ways to manage risk with automation.

Technology Enabler—Risk Management: With respect to risk management, there are the identification and control activities, but there is also the ability to track and measure risk operationally, within our processes. Once you’ve established a risk plan, you want to measure it against risk levels. You identify a hazard, and then categorize it, but also determine the severity and frequency or likelihood of that hazard manifesting itself as a risk. When you automate quality, you want to have these types of assessments built directly into the process. A few good ways is to do simple decision trees (if this, then that), or leverage a risk matrix. The risk matrix allows you to build systematic and objective risk rankings based on risk levels, and each event can provide decisions based on the risk levels.

The last point on risk management in planning your QMS is the ability to not only be proactive in risk planning, and operationally assessing risk, but also in the ability to track and report on risks. This is critical because while your top level executives may not “speak” quality, they do “speak risk.” Being able to put quality events and objectives into a risk context enrolls the entire company and its leaders into quality management. No longer are we speaking quality, we’re speaking in a language that anyone in the company can relate to. So one of the benefits of building risk into your processes is the idea of taking the idea of risk measurements and applying it to your processes.
For example, if you encounter a nonconformity, you want to investigate it. Now, in an investigation, there are many factors that are taken into consideration, but it’s often a case by case basis, or built upon knowledge, experience, or other means. In the end, you are making a decision based on the available qualitative information. Of course, this is not a bad thing—most people are extremely adept at the process. However, when an Auditor comes in, they may question the decision we make—it’s the nature of their job.

However, with a risk-based tool, you can set an objective method of calculating risk. It will take the severity and frequency of the event, backed by historical data, and compile a recommendation based on your past data and your identified risk levels, and create a more systematic dimension to your process. Moreover, it is repeatable, meaning one event to the next will use the same tool and compare in a common method. However, risk-based tools will not do the work for you. It is still up to the decision makers who are auctioning this event to make the final decision, and you should absolutely weigh multiple factors. What risk tools enable you to do is provide another, quantitative dimension on how you can make a more informed decision.

The last point to building risk into your process is that when you are audited, you can demonstrate that your decision, while based on multiple factors, also takes into account the risk calculations, which have been proven, repeatable and are based on quality objectives and risk management methods outlined in your quality policies. It’s another check, one that will provide you with a better way or organizing, prioritizing, and filtering your adverse events.

### Section 7: Support—People and Infrastructure

Support is all about the people who are responsible for executing on your QMS. It goes beyond one department or operational area, and extends to the entire organization. It’s also about the infrastructure of supporting the QMS. How can you ensure that not only are people competent and well versed in the quality initiatives, but you’re giving them the right documentation that is up to date and current? This is where automating documentation and controlling your records is important.

#### Technology Enablers—Document Control integrated with Training

The concept of document control is not just about document repositories; it’s about establishing a process by which documentation is created, reviewed, approved, consumed, trained on, audited and ultimately revised. It’s far more than just a simple documentation tool—it’s how you have a central location for communicating processes and information to the company. Having a solution that builds in functionality around the process of review and approval, is integrated with training, has change and revision control processes, includes periodic reviews, and takes into account collaboration on improvement of documentation is key to this element.

However, it’s not just about a training tool; it’s more integrated, collaborative, it’s more around the idea that one process blends into the next. So from a technology standpoint, you want an integrated document control and training system, in which the process includes the training of people, and communication by which new information is disseminated and consumed. Being able to automate much of this is key, especially when you are looking to create a more seamless, collaborate and companywide perspective on quality.

Here’s where you can leverage the concept of automation on this link—let’s say you are releasing documentation, and you route it to its final approval and it is released to the company. While the document is released and “live”, how are you able to quantify whether another has been trained on it? If much of the quality-based training is tied to documented processes, then why not ensure that training is a part of the release process?

What many companies do is create an “awaiting release” phase in their document control workflow, which will hold the document until certain training criteria are met. Most notably, notifications get sent to the people within the company that need to be trained on it. So the system will not move forward until people have verified they have trained on it. Seems simple, but it’s often overlooked, and it’s a great way to ensure that a document doesn’t get release until the relevant workforce has had eyes on it.

But how do you automate the training? Training in any company can be time-consuming, and some documentation needs extensive classroom or on the job training. However, what about other documentation that can be reviewed online? How do you ensure people have trained on it? Integrating your Training System with Document Control will help to create the unbroken chain of release and training, but that training system should have a way to “test” the employees. This could be something as simple as self-certification—click a button to digitally sign off that you read it—or basic pass/fail quizzes to ensure they looked at the material.
The key is to make sure you are creating an infrastructure that will foster a process for providing support documentation, but also produce a competent workforce...and do it in an automated, real-time fashion, so no time is lost.

**Section 8: Operations—Traceability on How You Design, Source, Plan and Measure**

The Operations section gets into a lot of the actual processes of designing, sourcing, and monitoring your operations. The key points are that you are not only mapping processes here for each of the operational elements within your company, but you are building traceability from one process to the next. The processes are the biggest component, and whether you are building a design plan, a supplier evaluation, or establishing nonconforming material criteria, it is important to ensure that from one step within the process to the next, information is transferred.

**Technology Enabler—Automated, Integrated Processes:**

Having a solution that will take design information and communicate to production, to sourcing of suppliers, and what potential nonconforming criteria will be assessed lies in the ability of the system to provide the traceability, visibility and control. It’s about linking from one area to the next, creating that quality lifecycle where quality management is tracked, managed and assessed at each stage in the process. For example, building quality elements into the product lifecycle helps to create a full story of quality. Design and development provides risk-based analysis of the product, which then is linked to production, to sourcing, and continues to incorporate data into a single collaborative environment where all the data related to quality is contained, so that in the end, you have all the benchmarks of quality built in. Automation will help to inherit data from one process to the next, and notify users when there is a deviation in compliance.

**Section 9: Performance and Evaluation—Say What You Do and Do What You Say**

The concept of evaluation sits on its own in 2015, which certainly highlights the importance of feedback and regular assessment. The key point to take away is “how do you build a constant feedback loop from your operations to ensure that you are saying what you do, and doing what you say?” This not only includes regular auditing and feedback measures from customers, but also how you’re consuming this information as a management team.

**Technology Enabler—Audit Management:** One of the key areas is establishing a method for consuming customer feedback. You need to have an established way to build a data set from all customers and categorize and analyze the type of feedback you’re getting. There’s also auditing—you need to build both an internal and external auditing program. This is no different than requirements in previous ISO frameworks. Lastly, you still need to take the QMS data and conduct management reviews, and produce outputs against your core objectives.

It is important to “close the loop” on your QMS with your most important asset—your customer. Having a solution that can not only collect customer data and allow you to action against that data is vitally important to understanding if you are meeting your quality commitment to your customer. Having a centralized and aggregated way to organize the feedback data is essential, and an automated QMS will provide this. Another area not necessarily outlined, but certainly worth mentioning is leveraging risk to filter feedback. Some feedback is critical to the business; some is important but not as critical. How do you effectively determine what the most critical events are so you can focus on them first? This is where we go back to Risk Management. Having a risk-based filtering tool will help to prioritize how you approach events.

Most organizations are very familiar with building an auditing plan, but as a company gets more complex, it becomes more difficult to manage how much auditing, when to audit and what to audit. Having a solution that not only manages and standardizes the auditing process, but also the scheduling process is important. Centralization and harmonization play in keeping things straight; technology helps to achieve this.

**Technology Enabler—Reporting:** Management Review is an important step to evaluation. However, without a way to organize and filter the data, it’s very difficult to make informed and strategic decisions. You really not only need a strong reporting tool to take all this information, you also need to ensure that you are integrating the whole process into the data collection. This is where having a closed-loop QMS solution is most valuable; it provides data from design, to production, to documentation, training and beyond. This provides a larger and more valuable view into the data, and lets management act, react or improve more efficiently.

What I think the most important element to understanding the dynamic of the new standard is that most people have a tendency to adhere to the framework, mainly to pass the audit. They are usually not thinking about how ISO will necessarily improve their operations, they have become more concerned with passing the audit. Now with the 2015,
the rules are relaxed; it’s not about how you adhere, as long as you can prove that you meet the standards. So this gives you the freedom to be more flexible in how you can implement the ISO framework that makes sense for your organization, for your people, and meet the needs and objectives that work best to improve your quality operation.

**Section 10: Improvement—Commitment to Company-Wide Improvement**

The key concept on 2015 is around a commitment to customer, to improvement and to companywide involvement. So when we look at this section there is a focus on how to foster overall improvement.

**Technology Enabler—Nonconformances Integrated with Corrective Action:** When it comes to nonconformities, you are building a process by which you are able to quickly react to nonconformances and take action on correcting them. You’re also looking to see if you need to eliminate the cause. So you first are looking to correct and control, and then determine if a corrective action is needed. If there is a systematic cause of the nonconformity, then you need to build a corrective action. Again, this is how you take an adverse event and take steps to reduce the likelihood of recurrence. Lastly, you also want to look for ways to improve your overall QMS and find trends and opportunities for improvement. So let’s break it down from an automation standpoint.

Having the ability to not only record this information in a single location, but to also have other important data linked to it is critical. You want to eliminate as much double entry of data, so importing data from other areas (product, supplier, customer, etc.) is key. They next key point is that, if you are going to issue a corrective action, it should be traceable back to the nonconformance. This is where process linking comes into play—linking a nonconformance to a corrective action, and being able to create a seamless closed loop on the process will ensure that data is not lost, or incorrect.

**Technology Enabler—Reporting:** Lastly, you want to build reporting and data collection to look for improvement areas. We’ve said that without a way to interpret the data, you are not able to make informed decisions, and impact improvement effectively. Built-in reporting engines that take the whole quality story and foster a method for dissecting and analyzing the data help to gain a full picture of the quality lifecycle and the “health” of your QMS. After you’ve made a decision, and a change is needed, what’s next? We need to initiate a change, but follow a workflow that touches the entire quality lifecycle. This is also where automation is powerful. Having a workflow-based system that will provide an automated process to touch all areas that are affected by the change is important. Managing change should be a seamless process. It’s about enrolling everyone into quality – change is no different. Improvement of quality is everyone’s responsibility.

One of the key things we all may face is the idea of an auditor or compliance officer looking at the QMS and saying “I see you had an adverse event around ‘XYZ’ – what did you do and how did you resolve it?” This is not uncommon, and most often people scramble at this point. Various records, documentation, spreadsheets, and a host of varying areas of information are used to compile the story. With automation you are able to build a true history of the event. Adverse events are linked to Corrective Action, which are then linked to updated documentation, then linked to an updated training record. This is all compiled in one report, since the data is all there in one place. So not only can you build this history to prove you are handling quality with objective evidence, but you can also leverage these histories to provide analysis and trends on how to improve quality.

**Conclusion**

ISO 9001:2015 brought with it a mindset shift. The requirements are still there, tried and true, but it’s a shift in how we view quality as an organization. While quality managers had often been labeled as the “policemen” within the organization, the changes to the standard mean the quality department is now the “champion of quality” that leads the charge, with the entire company following behind.

Quality management is about people and processes. But when you add the concept of technology, you now have a platform for automating the way the people interact with the processes and each other to detect events, correct events, report on events and ultimately improve quality throughout the business.

**About EtQ**

EtQ is the leading Quality, EHS, Operational Risk and Compliance management software provider for identifying, mitigating and preventing high-risk events through integration, automation and collaboration. At the core of EtQ’s framework is a compliance management platform that enables organizations to implement best-in-class compliance processes configured to meet their existing processes, create new compliance processes and automate and control their compliance ecosystem. EtQ’s product lineup includes traqpath™ for individual compliance users, VERSE Solutions™ for small to medium sized businesses and Reliance™ for enterprise organizations. EtQ was founded in 1992 and has main offices located in the U.S. and Europe. To learn more about EtQ and its various product offerings, visit www.etq.com or blog.etq.com.