Go Beyond ISO 9001:2015's Requirements when Dealing with Risk

Description: ISO 9001:2015 requires "actions to address risks and opportunities" with regard to "context of the organization" and "needs and expectations of interested parties." These actions are necessary but not always sufficient to achieve organizational success or even survival because many risks and opportunities are outside the standard's explicit scope.

ISO 9001 originated because quality practitioners recognized that quality depends on a complex system rather than individual tasks and activities. The newer versions of the standard require consideration of interactions between the systems' processes. It is also, however, necessary to look beyond the scope of the organization's own processes to its supply chain and environment for additional risks and opportunities, some of which it can control only partially (e.g., the supply chain) if at all. We must often go beyond the explicit scope of ISO 9001 to recognize and address the risks and opportunities in question.

While ISO 9001 focuses on quality, poor quality is the only Toyota production system waste that makes its presence known. The other wastes are asymptomatic, which means they can hide in plain view for years or even decades. Carl von Clausewitz identified them and their effects as "friction," and Tom Peters later depicted the same principle as it applied to miss the market delays. When everybody in the workplace recognizes friction for what it is, people will initiate actions to remove it.

The Army's Risk Management Process is a free (public domain) guide for risk management, and it uses a closed loop continuous improvement cycle that should be familiar to quality practitioners. It introduces consideration of the frequency with which the organization is exposed to a risk, as well as the individual chance of occurrence. This is important because, if it is possible to do a job wrong or make a defective product, this will happen eventually if we do the job enough times or make enough of the product. This reinforces, in turn, the need to make the mistake or defect physically impossible through error proofing, poka yoke, or "can't rather than don't" as developed at the Ford Motor Company during the 1920s as a safety principle.

The supply chain is an enormous source of risk not only for poor quality (addressed by ISO 9001's purchasing clauses) but also for logistics interruptions beyond suppliers' control. Technological change can render a product or service obsolete very quickly, which is what digital photography did to Kodak's excellent film. New distribution channels can put retailers and distributors out of business, and this is hardly a new phenomenon. Vasco da Gama's circumnavigation of Africa took a lot of profit out of the Silk Road, and now the Internet is undercutting brick and mortar retailers.

ISO 9001:2015 does not explicitly define competitors as interested parties but, as shown by the EpiPen controversy, they are indeed interested much as sharks become interested in blood in the water. When a company tries to raise prices as Mylan did, competitors are eager to follow the advice shown in the Mob Museum: "Give the people what they want." This can be done by (1) creating new technology that does not infringe on intellectual property like a patent or (2) using off the shelf technology when the basic product (epinephrine) cannot be patented at all.

Why should you Attend: ISO 9001:2015 Clause 6.1 requires "actions to address risks and opportunities" with regard to the "context of the organization" and "needs and expectations of interested parties." The standard also cites the SIPOC (Supplier, Input, Process, Output, and Customer) model, but the scope of "actions to address risks and opportunities" is still not sufficiently wide to cover many existential risks and opportunities.

The true scope of organizational risks includes:

- Poor quality, which is already covered extensively by ISO 9001 as well as traditional quality management
- Friction, as defined by Major General Carl von Clausewitz's On War (1831). Friction does not necessarily manifest itself as poor quality, but it can easily degrade organizational performance. It includes inefficiencies that are built into jobs but go unnoticed because the jobs do not produce defects or scrap. Variation in transportation and processing times is another form of friction, as depicted in Goldratt's and Cox's The Goal. ISO 9001:2015 does not address this issue explicitly, although it does encourage the general consideration of risks and opportunities.
Supply chain risks. ISO 9001:2015 covers only quality-related aspects explicitly.
New distribution channels and technological change, which appear to be outside the standard's scope.

Risk = np and not just p. This means that the risk is a function not only of the individual chance of occurrence p (the criterion for an FMEA's occurrence rating) but also the frequency of exposure (n) to the risk. This requires in turn error-proofing, poka-yoke, or "can't rather than don't" for mass-produced critical to quality products or critical to quality tasks that are performed frequently.

The recent controversy over Mylan's EpiPen price hike shows meanwhile that organizations can create risks by alienating customers and simultaneously provoking reactions from competitors who will step in to meet the customer's needs. These competitors also are interested parties, albeit not defined explicitly as such by the standard.

Areas covered in the session:

- Know that ISO 9001 originated to address deficiencies in complex manufacturing and service systems rather than individual activities.
- Know that the scope of risk includes (a) internal risks such as poor quality and also friction, waste, or muda, (b) supply chain risks, and (c) external risks such as technological change and new distribution channels.
- Understand the basic concept of risk, and also the concept of friction.
- Go beyond the occurrence rating (1-10 scale) of an FMEA to understand that we must also account for the frequency of exposure to the risk. This, in turn, makes it necessary to error-proof critical to quality operations that are performed frequently.
- Know that Army Techniques Publication (ATP) 5-19, Risk Management, is a public domain off the shelf resource.
- Recognize common supply chain risks, along with risks of technological change.
- Recognize how a company can expose itself to risks, as Mylan appears to have done by hiking the price of the EpiPen in the absence of real barriers to market entry. ISO 9001:2015 does not explicitly require consideration of this risk, except with regard to the reaction of customers as interested parties.
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