Quality Management Systems

Compliance Driven or Quality Driven?

Overview

ISO standards have been around for quite some time now and the concept behind these standards is to assist companies in creating quality management systems that ensure quality practices are deployed throughout their entire organization from the top down. Many of the requirements ensure that management is providing quality leadership that supports quality at the production level. One of the basic underpinnings of the standards is that companies need to create repeatable and predictable business processes at every level of the organization.

In fact, meeting these standards and obtaining ISO certification has become a necessary rite of passage for companies that want to work in certain markets. Unfortunately, ISO registration has become so widespread today that it is becoming difficult to differentiate which companies are committed to quality and which ones are gaining compliance just to be able to serve a certain market. Although many companies rely on the ISO certification as a seal of approval, compliance to these standards does not guarantee that a company will produce quality product.

So what differentiates a quality driven company from a compliance driven company? To be quality driven rather than compliance driven, employees at every level of a company must accept quality as their responsibility. Quality expectations must be understood by both the supplier and the customer. The company must develop business processes that make sense to the leadership and to each employee. There must be effective communication to resolve any conflicts and to arrive at solutions. Finally, companies must have an effective way to measure their strengths and weaknesses.

Who does quality begin with?

Presumably everyone within a company that is quality driven should have the same voice and same objectives. In reality that is often not the case. Too often we hear companies refer to quality as a separate department. The result is that the goals of the "quality" department are at odds with the goals of the other departments. If your organization was truly quality driven and you had good sound quality practices and procedures in place, would you need a quality department at all?

Quality begins and ends with me.

If you are planning on becoming ISO certified; have you done an effective job of making sure that every person in every department understands that quality begins and ends with them? Quality within an organization starts from the top down. A company should adopt quality standards based on sound principles that no customer or external organization should be able to alter or take exception to. Those principles need to be in place from the time a quotation is provided through to the time an order is shipped. What if the customer requests something you are not capable of achieving and you accept the order including all the customer's terms? What if your entire organization agrees that your company cannot meet the requirements and you allow your sales department to accept the order as is? What kind of message about quality does this send to your employees?

What does quality mean?

The word quality has been used for many years in the manufacturing world. Years ago people could shop for a product and see the fine workmanship and attention to detail in a product and

would even be willing to pay more for a product if they had a previous positive experience using other products from the same manufacturer. Consumers today no longer shop and compare quality. They expect it. But what does quality mean? Is it just a perception that varies from customer to customer or is it a standard that is set by some external organization? The word quality has become so over-used that it has, in many cases, become undervalued.

Before ISO standards, companies would choose a supplier based on the customer's satisfaction with the quality of the supplier's workmanship and attention to detail. But in today's ISO world, a company that is compliance driven rather than quality driven risks compromising quality workmanship and the pride of its highly skilled workers by putting too much emphasis on compliance with standards set by an external organization.

When we discuss quality, we hear phrases like "voice of the customer"; but, who is the customer? Is the customer the end user or the tiers and sub-tiers of suppliers and all the accompanying levels of bureaucracy in between? Does the end user really have a choice at all? We are often told that we need to satisfy every customer internal and external. What happens when the customer requirements are either overstated (creating a bottleneck somewhere in the supply chain) or understated (introducing more risk somewhere along the supply chain)? Overstated and/or understated requirements typically lead to some sort of conflict.

Lack of communication is the root cause of all problems.

The old adage, "Rule Number One: The customer is always right, and Rule Number Two: if the customer is wrong, refer to rule number one" has no place in a quality driven organization. Too often mandates are passed along down the supply chain. Depending on the product application, these mandates may not be feasible or may not create significant value for the product. If issues are not resolved up front, the supplier and ultimately the customer will bear the burden. No matter what business processes you have in place or how repeatable and predictable they are, you cannot deliver quality if you accept an order with requirements that you cannot meet. To consistently and repeatedly make quality parts, quality expectations must be both realistic and feasible. Otherwise we set our workforce up for failure. Communicating your commitment to quality, including not accepting unattainable requirements, is critical to quality.

Quality means making acceptable parts.

In the past when you heard the term "*quality standard*" you would think of a product specific quality standard. One thing that has been misconstrued and has confused many people over the years is that ISO quality standards are not product specific but are process specific. The whole concept behind many ISO quality standards is that if you create sound and reliable businesses processes that are predictable and repeatable, the risk of errors occurring will be greatly reduced, which in turn will make a business more efficient and profitable. This of course assumes that you have good and sound robust manufacturing processes in place. If you are not capable of making an acceptable part, a good quality management system will only assure you would consistently make bad parts. The danger for smaller companies trying to implement ISO is that compliance to the ISO standard requires a lot of oversight. Sometimes this oversight comes at the expense of managing the manufacturing processes.

How is conflict resolved?

Does your Quality Management System provide a framework for effective communication, which includes knowing who, both internally and externally, has the authority to make judgment calls or resolve conflicts when necessary? If so, is the authority always in the right hands? Conflicts are especially apparent when parties focus more on making sure they comply with the quality standards instead of making sure they understand the underlying reason for the standards. The danger of focusing too heavily on compliance is that many times rather than effectively communicating and collectively getting to the root cause, the parties get consumed in focusing on complying with their piece of the process and they tend to lose sight or fail to understand the needs of all the other parties involved. It is easier to shift blame or responsibility for the problem or pass it along. Being compliance driven can give employees an excuse not to accept responsibility for or take ownership in finding a solution to the problem.

Who sets the standard?

Can there be one universal standard that defines quality for all organizations? Should the standard be industry or company specific? In fact, in today's ISO world, there are so many different standards that it has become increasingly difficult to serve more than one industry. Most standards are written at a high level so they can be flexible enough to apply to many different companies. Although many people like it this way (being told the "what" and not the "how"), it leaves the requirements of a standard open to interpretation, including by your customers, suppliers, and/or auditors. Even though in some cases the standards may be relatively the same across the different industries, the same requirement may be interpreted differently within each industry. As a result, it is virtually impossible for suppliers to meet the requirements of the same or similar standards in more than one market without getting caught up in the minutia.

You set the standard.

If you are not careful, it is easy to become compliance driven and to focus more time and resources on managing the requirements needed to comply with a standard, rather than on improving your own business processes in a way that makes sense for your business. Make sure you have robust business processes in place that make sense for your business and that are understood by all your employees. If your systems are too complex, there is a danger that employees will just "sign off" on having done something rather than try to figure out what really needs to be done.

Why do we dread the audit?

Unlike consultants, auditors technically cannot tell you how to meet a standard; but, they can tell you that you are not in compliance with the standard based on their interpretation. Some times auditors will come in to an audit with a pre-conceived notion of how a system or process should be presented. This can lead to a lot of frustration, leaving you trying to guess how to meet the standard because the requirement does not necessarily describe the expectation.

Auditing is an activity many companies perform simply for the purpose of compliance. In many cases rather than being a tool to improve your business processes it has become a vehicle that sends people into an endless loop of corrective and/or preventive actions, theoretically improving their processes, but actually adding layers of inflexible detail and complexity. The detail and

complexity can then lead to more errors. So, rather than improving the process, you may have made it more vulnerable to failure.

If not monitored, the audit process can undermine your quality management system and the credibility of the quality management system. In addition to opportunities for improvement, most audit reports will contain non conformance findings. No matter what the relevance or severity of these findings, people will take observations and findings personally and will defend their own turf at all costs to avoid going through what they believe to be a cumbersome corrective action process to fix a problem they see as nothing more than an isolated incident. The audit becomes more like a game of tag where everyone is trying not to get "caught".

The traditional audit process is negative in nature, reporting only negative findings which require documentation and proof of verification that the problem was fixed. The report may state that some systems were audited and were found to be compliant, but how good are they? There is really no way to know that if you are doing something relatively well, what it is so you can keep doing it. On the other hand, if you knew you were doing something poorly, you could focus more time and attention in that area. This is difficult to determine from a snapshot of audit findings alone. How do you know where you stand and how much you need to do in order to improve?

The audit report could be a much more valuable tool if it included a benchmark performance rating that would objectively measure the overall performance of your system. Otherwise, the problem most people will encounter is that the better they make their system, the less significant the findings become and the more of a burden they become to address. This is another way companies can become compliance driven and take their focus off of driving quality improvements into the organization.

Auditing – Make it work for you. The most valuable underutilized process for driving improvement.

Most compliance requirements are put in place for a good reason, however the method for meeting each requirement may not be not be the same for every organization or every application. The risk exposure for some things may be greater in a larger company therefore requiring more stringent controls. These same controls may not be necessary in a smaller company, yet both companies can have a very good quality system with sufficient controls in place.

Although there is often nothing you can do to change the external audit process, your internal audit is very important and should be designed for your organization's benefit. Imagine this as an alternative to driving improvement. The internal auditor will report every finding as an "observation". This provides employees the incentive to be more open and honest about their processes and procedures. The audit report will be more of a discovery process to see how robust your systems really are. Employees take the report and perform a risk analysis, rating each of the observations on factors such as severity, relevance, frequency, possible impact, and likeliness to occur or re-occur. They review the report with management and make recommendations for improvement based on the outcome of the risk analysis. The process of improvement becomes employee driven rather than auditor driven. This process may make some managers

uncomfortable as giving an employee this much freedom means losing some control. If done properly, this method will truly encourage employee involvement which in turn will gain their commitment to driving quality improvements into your organization. This approach to audit observations may not be consistent with the traditional interpretation of ISO standards, but you may find that the results from a formal compliance audit will improve as a result of performing these informal audits.

Here is a simple approach to get more value from your auditing process.
Assess each finding as follows to determine your exposure or overall system health.
1) Probability of occurrence or recurrence;
2) Impact to business, customer or product; and
3) Recovery burden: The easier and quicker it is to recover from the occurrence, the lower the burden.

By assigning a value to each criteria then multiplying them together you can determine a risk factor for each finding. Companies can then actually see the quality of their system or its vulnerability. Without this, reports can be compared only based on the number of the findings rather than the vulnerability of the findings or the exposed risk of your quality management system. This would actually report the state of your system and would give management an objective look at how much progress they are making or where they are falling behind. This way they can take the global approach at improving the system where it needs to be improved rather than just delegating corrective action requests to address the specific findings. Here is a simple example of a risk analysis performed on findings from an audit.

QMS System Health	1=Low	Example			1-8 = Low Risk
Friday, October 01, 2010	2=Medium				9-18 = Moderate Risk
	3=High				19-27 = High Risk
Audit Results					
Finding	**Probability of Occurrence**	**Impact**	**Recovery burden**	**Risk Factor**	**Exposure**
Incorrect resin was received against P.O. 10004.	2	1	1	**2**	Moderate
Material Cert could not be located for a Medical Grade Resin.	2	2	1	**4**	Low
Six Material Certs were not reviewed by Management.	3	1	1	**3**	Low
Raw Material was observed in unmarked open container.	2	3	3	**18**	Moderate
Raw Material was purchased from an unapproved supplier.	2	2	3	**12**	Moderate
Wrong material was added to process.	3	3	3	**27**	High

These results will vary from company to company but most importantly they will be a collective representation of risk as seen by the employees directly involved in the process. This process will help management stay focused on what is important and enable them to mange priorities more effectively. Not every problem can be fixed by modifying a procedure or re-training. It takes the right leadership to support the staff in preventing most of the human-generated mistakes from happening. There is no way any management team can anticipate every possible human error from happening. After all even leaders are human. Nonetheless, no system or procedure can

compensate for the absence of good leadership. Leadership is the key in keeping everyone focused on being quality driven rather than compliance driven.

Conclusion

The best quality standard in the world is not a substitute for quality leadership. Driving quality into an organization starts from the top down and should work its way through your organization from the bottom up. This can only happen by management building a solid foundation of fundamental principles and business practices that are performed consistently. This will not happen if employees are scared to ask management for support or have given up after being denied support a number of times. A house can look beautiful from the outside, but the first place an inspector will go is to the basement to look for cracks in the foundation. Maintenance of the foundation is critical in order to sustain a quality driven organization.

If external requirements, regulations and even customer requirements interfere or conflict with your quality objectives, clarification must be communicated throughout your organization, supply chain and even customer base if necessary. This will allow you to inform other parties what can be expected from you before sacrificing the integrity of your internal quality system. Your quality management system may not and probably will not be adequate to satisfy all the requirements for all customers, but, if this is the case, policies and procedures can be put in place that are customer or product specific. It may be difficult to manage independently, but at least the integrity of your own internal quality management system will not be sacrificed and everyone internally will know that these are customer or product specific requirements only. Achieving quality in business starts with a quality relationship with your customer. If your customer has specific mandates that require you to modify your global business practices, you need to consider whether you can successfully accomplish this and create a value to your organization. If you believe you will not be able to support such mandates without creating a burden, then communicate your intentions and negotiate a solution. A supplier that can mange a customer's expectations is a quality supplier as opposed to one that says yes to everything just to get the order.

If you find that being registered to an ISO standard does not create value for your quality system, but you do not want to give up your certification, you may want to assess the value of your registrar's audit. If you reach a point where the findings are weak and become a nuisance to fix, maybe the audit process is not adding as much value as it could. Maybe it is time to talk to your registrar. They will not improve unless you hold them accountable. Your registrar wants to add value to your business. Many people do not realize that registrars need to compete for your business. They should be treated like any other supplier on your approved supplier list. If you are not giving them honest feedback, they will assume everything is alright and become complacent. Too often people are more concerned about getting the certificate of approval than ruffling any feathers. Quality in your organization is far more important than a certificate of approval. Your quality management system should go more than skin deep. Through open communication and a collaborative audit effort, your registrar should be able to help you achieve your goal of remaining a quality driven organization while maintaining compliance to a standard.