Passing Your Next ISO Audit

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INTRODUCTION

Nobody likes to be audited. Audits, however, are a way of life for an ISO-certified company. Each year, an auditor will knock on your door and will want to spend a few days with you to make sure your Quality Management System (QMS) conforms to the requirements of your ISO-based standard, such as ISO 9001:2015. The good news is, you are in complete control of how your audits go! If quality is the hallmark of your organization, and if you are committed to continual improvement, your audit will be a resounding success. Here's a quick guide that will help you pass your next ISO audit.

MANAGEMENT COMMITMENT

The foundation of a strong Quality Management System rests squarely on the shoulders of Top Management. Once an organization decides to make the commitment to the level of quality required by ISO, it is essential that leadership embraces it and demonstrates their support for it. Top Management is required to establish a Quality Policy and Quality Objectives, and to review the effectiveness of the Quality Management System at regular intervals.

RISK MANAGEMENT

A new requirement for ISO 9001:2015, Risk Management is a holistic approach to evaluating risks to the company. Once risks have been identified, you must take action to mitigate those risks, and the cycle continues indefinitely as risks change over time, and the actions you take may eliminate them completely or create new risks to be evaluated. Ensure Risk Management is an integral part of your QMS solution.

CULTURE OF CONTINUAL IMPROVEMENT

An organization's leadership is responsible for cultivating the quality culture of its company. Your ISO audit will succeed or fail based largely on culture. Make sure your people are aware of the Quality Policy, and their contribution to the Quality Objectives. When problems arise, look at them as opportunities for improvement. Think of your audit that way as well. If an auditor finds a Nonconformance (and he/she will), celebrate! You have an opportunity to strengthen your quality and separate yourself from your competition.

INTERNAL AUDIT

There is a reason why ISO incorporates a requirement for Internal Audits. You know your system better than anyone, and you can dive into the weeds and expose those underlying problems better than an auditor who spends 2-3 days onsite and doesn't have the bandwidth required to get to the deep-rooted issues. This could cause them to miss a lot of potential problems, simply because they just don't have the time to observe the "real" story.

Most auditors will lean heavily on your internal audits for direction, and if you have done a good job identifying issues and resolving them properly through Corrective Actions, it makes auditing a lot easier.

DOCUMENT CONTROL AND RECORDS

It's common for a company to struggle with Document Control, and consequently, many audit findings are due to document control issues.

Make sure your documents are identified properly, are readily accessible, and stored as per your defined requirements. Manual forms should be filled out completely, signed (as required), and records legible and readily retrievable. If a document is revised, it is imperative that anyone who needs to know about this is informed, and that all old document revisions are removed from use.

Don't make your procedures overly detailed. It is easy to write yourself into a corner when documenting your current processes, and if your people aren't working exactly the way you've documented their processes, you could have an audit finding.

A strong Document Control software solution, offering a vaulted environment for strict revision control, is essential for passing your next ISO audit. Plus a Document Control software solution can help you evolve toward a paperless system, with digital signatures and encrypted passwords.

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CORRECTIVE ACTION

Processes fail, for many reasons. Detecting those failures is easy, but an auditor cares more about how you respond to those failures. It is important to determine the root cause of the issue, take action to prevent recurrence, and most importantly verify that your actions have been effective in eliminating the problem. Done properly, a corrective action should eliminate the problem entirely.

Look beyond the person and to the process for solutions. Design your processes in such a way that would prevent the possibility that a mistake could ever be made. If there were any audit findings from the previous audit, make sure those have been effectively resolved, or a finding that was considered minor previously could be reclassified as major the second time around. When you can demonstrate that you are ruthlessly pursuing and eliminating the root causes of your problems, you are on the road to success in passing your next audit.

CALIBRATION

Testing equipment must be properly calibrated to ensure that test results are valid and reliable. These records must be readily retrievable, and if any equipment is found to be out of calibration, you must be able to trace back to all items inspected by that piece of equipment and take appropriate action. Calibration is going to be a big part of your next ISO audit, so make sure that it's effective and robust, and tied into your Inspection process.

PREPARE YOUR PEOPLE FOR INTERVIEWS

People can get nervous when being asked questions about their job. They may be afraid of saying the wrong thing, or getting themselves or the company into trouble. Reassure them that the auditor is not out to get them. The auditor is only interested in the process; no one is going to get in trouble for answering an auditor honestly.

Make sure they understand that it's important not to lie to an auditor. A good auditor will see right through a lie, and will be able to ask questions that will get to the truth. Honesty is always the best policy with an auditor. It is okay to say, "I don't know" if you truly don't know the answer to a question. Whatever you do, don't make up an answer.

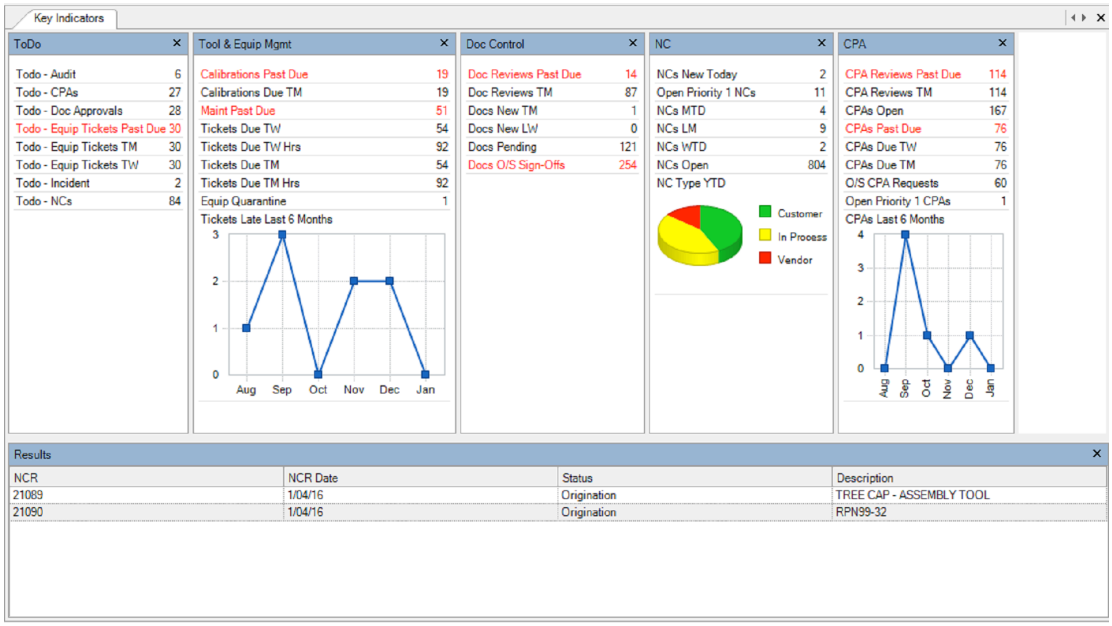
Tell them to expect questions about the Quality Policy and Quality Objectives, and give them some pointers on how to answer these questions. You can't over-prepare them for these types of questions. When people are nervous, they tend to over-talk. Listen to what an auditor is asking, and make sure you understand the question. If you don't understand, ask them to rephrase the question. When you give your answer, keep it succinct. An auditor will let you keep talking as long as you want, and will keep writing things down as you say them. Answer the question and stop. Don't feel like you need to fill the silence with more words.

STAY AUDIT-READY

Live quality, every day. Keep your organization prepared at all times. If you are doing regular internal audits, your people can be used to talking about their jobs, and that will make your external audit that much easier. If you have to hustle to get things under control at the last minute, it will be abundantly clear to a good auditor that ISO is not woven into the fabric of the organization. Make quality a part of your daily life, and ask the same of every employee. Your daily commitment to quality will shine through to your auditor.

KEY PERFORMANCE INDICATORS

Key Performance Indicators (KPI's) are measurable values that demonstrate how effectively your company is achieving its quality objectives. Auditors use KPI's to evaluate your success at reaching targets, and can often tell if you have passed the ISO Audit even before they go out into the plant! Be sure your QMS offers metrics that update live, and are visible to your entire organization.



CLOSING

Auditors are not your enemies. They are there to help you achieve the greatest success possible with your product quality, which in turn will solidify your customers' confidence in you, and should ultimately result in a increase in business. If you follow the guidelines presented here, and if your processes conform to all the requirements of the ISO standard, then passing your next ISO audit should be a breeze.

uniPoint Software

INTEGRATION

Using an ERP system with limited or no Quality Management capability? Not to worry, uniPoint can plug right in!

TECHNOLGY

What's under the hood really does matter! It impacts the ease of our installation, software upgrades, the user experience, and inter-operability with your other software systems.

SIMPLICITY

With 22 configure-to-order modules for Quality Management and Continual Improvement, uniPoint is Quality Made Simple.

Our EQMS: uniPoint is the industry leader in ERP-integrated, Enterprise Quality Management Software, offering standard integrations to over 40 leading ERP systems. This means you no longer have to run your quality system in isolation of your critical business data. Plus you can eliminate redundant data entry, reduce mistakes and show measurable efficiency improvement.

Our Solution: The cornerstone of our solution is the technology we use to develop it; the database we use to store your critical data reliably; and the reporting engine we employ to summarize your data in printed reports, graphs and charts. uniPoint uses Microsoft Visual Studio .Net; a Microsoft SQL Database; and Crystal Reporting. You will never outgrow our system, and you can rest assured that our proven technology will continue to service your growing and adapting quality compliance needs going-forward.

Our Advantage: Over 1,500 companies throughout North America agree that uniPoint is one of the easiest software applications they have ever used. That's because we use a consistent and intuitive design philosophy in every module. To support your users, our implementation consultants are ISO experts. Plus we offer FREE group training webinars every month.

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THANK YOU.

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