DOWNLOAD PDF ISO 9001 2015 GAP ANALYSIS CHECKLIST

Chapter 1 : ISO Gap Analysis | Simplified

This gap analysis checklist is prepared for use in evaluating your Quality Management System (QMS) against the requirements of ISO as you transition from ISO to ISO Each requirement is expressed as a question that the user (auditor / assessor) can ask to evaluate your.

Click here to see an example List of Interested parties. Have you determined and documented the boundaries and applicability of your QMS by considering external and internal issues, requirements of interested parties and your products and services? Yes No You need to determine and document the boundaries and applicability of your QMS by considering external and internal issues, requirements of interested parties and your products and services. Click here to see an example Scope of the Quality Management System. Have you established, implemented, maintained and continually improved a QMS including all processes needed; including interactions and sequences of processes and assigning resources? Yes No You need to establish, implement, maintain and continually improve a QMS including all processes needed; including interactions and sequences of processes and assigning resources. Do you maintain necessary documented information to support the processes and have confidence they are being carried out to plan? Yes No You need to maintain necessary documented information to support the processes and have confidence they are being carried out to plan. Does top management demonstrate leadership of the QMS by accounting for the efficiency of the QMS, promoting QMS principles, promoting improvement and ensuring resources are available? Does top management show leadership with respect to customer focus, customer and statutory requirements, risks and opportunities and enhancing customer satisfaction? Yes No Top management must show leadership with respect to customer focus, customer and statutory requirements, risks and opportunities and enhancing customer satisfaction. Is a quality policy established that is appropriate for the organization, provides a framework for quality objectives and shows commitment to satisfying requirements and continual improvement? Yes No A quality policy must be established that is appropriate for the organization, provides a framework for quality objectives and shows commitment to satisfying requirements and continual improvement. Click here to see an example Quality Policy. Is the quality policy available, maintained, communicated and understood by relevant interested parties? Yes The quality policy needs to be available, maintained, communicated and understood by relevant interested parties. Has top management assigned responsibilities and relevant roles for the QMS development, reporting and maintenance so that it meets the intended goals? Yes No Top management must assign responsibilities and relevant roles for the QMS development, reporting and maintenance so that it meets the intended goals. Has planning for the QMS considered issues and requirements that determine the risks and opportunities to be addressed? Yes No You need to plan for the QMS and consider issues and requirements that determine the risks and opportunities to be addressed. Click here to see an example Procedure for Addressing Risks and Opportunities. Has planning taken place to address the risks and opportunities identified and integrate these into the QMS? Yes No Planning must take place to address the risks and opportunities identified and integrate these into the QMS. Click here to see an example Registry of Key Risks and Opportunities. Have you established quality objectives for the QMS that are measurable, monitored, communicated, updated and documented? Yes No You need to establish quality objectives for the QMS that are measurable, monitored, communicated, updated and documented. Click here to see example Quality Objectives. When QMS changes are needed are they carried out in a planned manner? Yes When QMS changes are needed they must be carried out in a planned manner. Have you determined the resources needed for the QMS including internal and external resources, people, infrastructure and the environment necessary for the QMS? Yes No You need to determine the resources needed for the QMS including internal and external resources, people, infrastructure and the environment necessary for the QMS. Have you identified the resources needed for valid monitoring and measurement results for product and service conformity including measurement traceability , safeguards for measurement and organizational knowledge necessary for operations? Yes No You need to identify the resources needed for valid monitoring and measurement results for product and service conformity including

measurement traceability, safeguards for measurement and organizational knowledge necessary for operations. Have you determined the necessary competence required of persons who will perform functions within the QMS processes? Yes No You need to determine the necessary competence required of persons who will perform functions within the QMS processes. Click here to see an example Procedure for Competence, Training and Awareness. Have you taken actions to ensure persons doing work within the QMS know the quality policy, quality objectives and how they contribute to the QMS including the implications of non-conformance? Yes No You need to take actions to ensure persons doing work within the QMS know the quality policy, quality objectives and how they contribute to the QMS including the implications of non-conformance. Have you determined the what, when, with whom, how and who communicates for both internal and external communications relevant to the QMS? Yes No You need to determine the what, when, with whom, how and who of QMS communication for both internal and external communications relevant to the QMS. Have you set up a process to control documented information of the QMS including creating and updating, control of use, adequate protection, control of distribution and changes? Yes No You need to set up a process to control documented information of the QMS including creating and updating, control of use, adequate protection, control of distribution and changes. Click here to see an example Procedure for Document and Record Control. Do you plan and control processes needed for your product or service including criteria for acceptance, resources needed, control necessary and what documented information is needed, including control of planned changes? Yes No You need to plan and control processes needed for your product or service including criteria for acceptance, resources needed, control necessary and what documented information is needed, including control of planned changes. Have you implemented processes for customer communication, determining requirements for products and services, reviewing requirements of products and services and updating documents when changes occur? Yes No You need to implement processes for customer communication, determining requirements for products and services, reviewing requirements of products and services and updating documents when changes occur. Click here to see an example Sales Procedure. Have you established, implemented and maintained a design and development process for your products and services that addresses design and development planning, inputs, controls, outputs and changes? Yes No You need to establish, implement and maintain a design and development process for your products and services that addresses design and development planning, inputs, controls, outputs and changes. Click here to see an example Procedure for Design and Development. Have you taken steps to ensure externally provided processes meet requirements by determining the type and extent of control needed and the information needed for external providers? Yes No You need to take steps to ensure externally provided processes meet requirements by determining the type and extent of control needed and the information needed for external providers. Click here to see an example Procedure for Purchasing and Evaluation of Suppliers. Have you implemented the controlled conditions necessary for your production and service provision including; necessary documented information, monitoring and measurement, identification and traceability if necessary , property belonging to customers or external parties, preservation of product or service, control of changes and post delivery activities associated with your product and service? Yes No You need to implement the controlled conditions necessary for your production and service provision including; necessary documented information, monitoring and measurement, identification and traceability if necessary , property belonging to customers or external parties, preservation of product or service, control of changes and post delivery activities associated with your product and service. Click here to see an example Procedure for Production and Service Provision. Have you implemented planned arrangements to verify that requirements have been met before release of products and services? Yes No You need to implement planned arrangements to verify that requirements have been met before release of products and services. Have you implemented a process to identify and control nonconforming outputs of your processes so that they are not unintentionally used until a disposition has been made? Is documented information maintained for this process? Yes No You need to implement a process to identify and control nonconforming outputs of your processes so that they are not unintentionally used until a disposition has been made and you must maintain documented information for this process.

Chapter 2 : Transition to ISO

ISO Quality Management Systems - The to Gap Analysis Checklist Page 2 of 64 3. THINGS NOT TO DO While this checklist does provide a comprehensive checklist that covers the transition, the following needs to be noted.

Even though, with good solid knowledge of the standard and of organizational processes in general, it is possible to skip this step, common sense says that to maintain discipline and more certainly assure a successful outcome, it is important to understand the current state and document it. In practice it is the next step, project planning that is really what this first step is all about and it is generally accepted that the term gap analysis generally means: Determine the current state and plan the activities necessary to change it to the desired state. Resources Needed In order to do a good job with a gap analysis project it really is important to have a strong understanding of the standard. You really need the same basic skills as an auditor to determine the current status and the same basic skills of an ISO consultant to complete a plan. Beyond a knowledge of the standard, it is ideal to have a broad understanding of organizational processes. When you identify a missing process, where you cannot see how requirements of the standard are addressed, it would be ideal if you were able to visualize how different solutions would affect the organization. Some solutions might involve the use of technology. Others can be effective with simple tools such as a whiteboard. There are different ways to bake a cake and it is important that the best option is selected for the organization. Approach The most common mistake made in gap analysis is to use a checklist of the standard. You can see it all over the internet where organizations are offering these checklists for free and advocating their use. If that approach is taken the project will start out in the wrong direction and then it will get worse from there. ISO advocates a process approach. So taking a process approach from the start is the way to go. The gap analysis should identify what processes exist within the organization and these should be investigated. They should be identified from the perspective of how well defined they are by the company procedures, what controls exist and how strong are those controls. Examples of controls include forms, software, whiteboards, and other items that cause the process to operate in a particular way. How strong the controls are in a process relates to how likely the process is to deviate from what is intended. Strong controls leave little chance of deviation and thus a great chance of success. Weaker controls leave a lot of flexibility in how things happen and may lead to failure to achieve the intended goal of the process. It is also important to understand the objectives for the process, what measurement or monitoring takes place to indicate that the process is performing correctly, and what resources are used in the process. Process theory and particular process techniques such as lean can provide more detail of what goes to make up a process and what is important in different situations. It is also important, and in the version of the standard, now mandatory, to take a risk based approach. For a really important process that has a significant impact on success and customer satisfaction, we should take a more thorough approach and we should expect stronger and more controls. After all of this is understood about each process in the organization, now and only now can we get out a copy of the standard. Finally, we look for conformance to the requirements in the standard. For each process we look to the requirements and see which apply. Now this may be the point at which we find that many of the ISO requirements are not addressed. You identified the key processes in your organization finance, sales, engineering, shipping, etc. Typically what happens is that when you do the gap analysis, you forgot to consider the supporting processes in the organization. But the standard has the answer. We can look at the standard and account for complete processes with specific clauses and requirements. For instance, the standard has section 7. You can now add them to your list and mark 7. Of course you now need to go back out into your organization and see how document control really is achieved. While document control is an easy one. There are some more complex requirements in ISO that you need to find processes for. There is no substitute, you just have to know the standard at least well enough to know generally where to look. And importantly, you have to accept that there are some instances where the requirements are addressed in multiple processes and sometimes in many processes. Sometimes there are many processes that address one or more requirements. For instance, if you have two completely separate systems for controlling procedures in your organization versus engineering drawings, then there are two

processes that are applicable to 7. Thinking more complicatedly, a production or service provision process may include many ISO requirements â€" such as those in 8. All of this makes it very complex to achieve. This comes down to experience. While this is possible document control there are instances where it is not appropriate. Nonconformance could be implemented as a single separate process with a single ISO requirement but is that really how it is addressed in the organization? Perhaps nonconformance is really customer complaints? Or perhaps it is actually discovered and addressed at receiving, in production and at final inspection. Three very different processes. The best configuration for the organization has to be defined. Perhaps another more troubling example is section 6. It is one section of the standard, but is it really one process? Are opportunities really like risks? Are they really handled the same way? And so you progress to generate a list of processes in the organization and match ISO requirements to them. You add comprehensive notes to each of these processes to indicate how conforming they are to the standard and any changes that will be necessary to meet the standard. In some instances processes will be new and there will be a single requirement assigned to it. In other instances, that approach will be too simple. You then just need to make sure that you have captured all of the ISO requirements and you have defined a management system that is meaningful to the organization but which is in conformance with requirements of the standard. Project Management All you have at this point is a roadmap. You still need to manage the success of this new structure and implement changes to processes and create brand new processes. These are two important elements of ISO success that warrant their own further discussion. We have very broad experience of different types and sizes of organizations in different industries with different technologies. We know how to optimize a management system for each individual organization so that it is meaningful, non-bureaucratic, easy to maintain, meaningful and coincidentally in conformance with the ISO standard. We guarantee ISO certification and have never had a failure. Cavendish Scott can provide you with a gap analysis and project planning audit or a full turnkey consulting project with guaranteed certification. Our 25 years of experience have made us one of the best ISO consulting and internal audit companies in the ISO industry.

Chapter 3 : ISO and Gap Analysis Checklist - KELBIX

This gap analysis checklist highlights the new requirements contained in ISO , and is not intended to cover all of the requirements from ISO comprehensively. The unique knowledge obtained about the status your existing quality management system will be a key driver of.

Chapter 4 : ISO Gap Analysis Checklist

ISO Gap Checklist is for those just creating their first ISO Management System. If you are transitioning from ISO to ISO , the Gap Transition Checklist provides you a map of where to copy some text from your existing QMS, and place it in a new QMS structure which follows Annex SL.

Chapter 5 : ISO Gap Checklist - Whittington & Associates

Larry Whittington has developed an extensive, 27 page, ISO Gap Analysis Checklist. It contains questions for organizations new to the ISO requirements standard for quality management systems.

Chapter 6 : ISO Gap Analysis Tool - Academy

Use our ISO Internal Audit Checklist to kickstart your ISO implementation. This audit checklist follows the ISO standard. Within the audit, it includes hundreds of questions to help you conduct a gap analysis between your current Quality Management System and the ISO standard.

Chapter 7 : ISO and other ISO Standards Free PDF Checklist

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ISO Quality Management System Audit Checklist Page 4 of 49 GAP ANALYSIS EVALUATION Audit Result Summary (Clausewise) Affected QMS Process.

Chapter 8 : ISO Checklist Audit for ISO

This ISO gap audit checklist is intended to be used as a tool to identify compliance with the differences between ISO and ISO

Chapter 9 : 4 ISO Gap Analysis Checklists [ISO ISO , , ,]

ISO Gap Analysis Tool. Our free gap analysis tool can help you see how much of ISO you have implemented so far - whether you are just getting started, or nearing the end of your journey.