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ISO 2200 audit is performed by external auditors to evaluate your organization if you are eligible for certification. It is conducted to assess business compliance with:applicable statutory and regulatory food safety requirements;risk management and corrective actions;sanitary and safe environment programs; andleadership and management systems.What is an ISO 22000 Checklist?An ISO 22000 checklist is a tool used to prepare for, implement and assess Food Safety Management Systems (FSMS). It can be used in the last stage of the internal audit and self-assessment processes in preparation for external auditor certification.What does an ISO 22000 Checklist Include?To assess if your Food Safety Management System satisfied ISO 22000 standards, a ISO 22000 checklist should be able to cover the evaluation of the following clauses:Clause 4: Food Safety Management SystemClause 5: Management ResponsibilityClause 6: Resource ManagementClause 7: Planning and Realization of Safe ProductsClause 8: Validation, Verification and Improvement of FSMSISO 22000 vs FSSC 2200 vs BROne of the most frequently asked questions about ISO 22000 is how different it is from two other renowned food safety standards: FSSC 22000 (Food Safety System Certification) and BRC, now called BRCGS (British Retail Consortium Global Standard for Food Safety). Refer to the table below in order to spot the main differences between ISO 22000, FSSC 22000, and BRC:Benefits of Implementing ISO 22000ISO 22000 helps in improving organizations' food safety performance. It is a systematic way of addressing food safety issues such as unsafe food importation, foodborne illnesses, food contamination, and insufficient food security. Implementing ISO 22000 will benefit your organization with the following:Compliance with global regulatory requirementsISO 22000 sets internationally-recognized food safety standards for controlling food hazards. It helps the organization to grow globally with a recognized food safety processes and prevents costly ramifications, such as fines, penalties, product recalls, or business shutdown.Promote health and safety regulationHealth and safety regulation is paramount to any businesses. It is implemented across industries to protect and secure your consumers as well as your employees. ISO 22000 helps minimize health and safety risks such as chemical contamination, diarrhoeal diseases, food risks, and work-related incidents and injuries.Improve food risk response rateFSMS in place helps businesses to respond immediately to any unexpected food safety issues. It diminishes the time to investigate food safety breaches which can give businesses more time to solve the problem.Improve business credibility and transparencyBusiness credibility relies on product expertise and customer feedback. ISO 22000 allows the business to showcase their food safety management systems to ensure and deliver high-quality food products and services.Increase business development and growthISO 22000 helps secure business continual improvement plans on food safety systems. It is used to identify improvement needs and develop new strategies to deliver remarkable products to satisfy the consumer's needs. An effective ISO 45001 audit checklist is structured around the 7 clauses of the standard. The ISO 45001 requirements checklist includes the following key elements:Context of the OrganizationIssues: Identify factors affecting OH&S performance.Stakeholders: Determine interested parties and their OH&S needs.Leadership and Worker ParticipationCommitment: Ensure management demonstrates commitment to OH&S.Policy: Verify a communicated safety policy is in place.Participation: Establish processes for worker involvement in safety.PlanningRisks: Identify safety risks and improvement opportunities.Hazards: Implement hazard recognition processes.Legal Requirements: Ensure access to current legal obligations.Objectives: Set measurable OH&S performance goals.SupportResources: Confirm availability of necessary resources.Training: Ensure personnel are trained and aware of responsibilities.Communication: Establish internal and external OH&S communication processes.OperationControl Procedures: Maintain procedures to meet OH&S requirements.Change Management: Control changes impacting safety performance.Emergency Preparedness: Document emergency procedures and conduct drills.Performance EvaluationMonitoring: Track performance against objectives and compliance.Audits: Conduct regular internal audits of the OH&S system.Reviews: Review the system regularly for ongoing suitability.ImprovementIncident Management: Create processes for reporting and investigating incidents.Corrective Actions: Address non-conformities from audits or incidents.Continuous Improvement: Promote ongoing enhancement of OH&S practices.How to Prepare for ISO 45001 CertificationBelow are key steps involved in the preparation for ISO 45001 certification:Identify gaps in the existing OH&S Management System by conducting a gap analysis or readiness test to meet ISO 45001:2018 requirements using an ISO 45001 audit checklist.Develop an implementation plan using the Plan-Do-Check-Act (PDCA) cycle.Define your organization's competency and training requirements and provide required training for employees.Document OH&S policies and proceduresPut the documented policies and procedures into practice across the organizationConduct internal audits to identify areas for improvement and assess effectiveness of implemented OH&S management system.Select a certification body to do the external audit for ISO 45001 certification.How to Conduct an ISO 45001 Internal AuditFor an effective internal audit for ISO 45001, a systematic approach should be taken, this consists of the following:Assign internal auditors: Choose trained auditors who are not directly involved in the areas being audited to maintain objectivity.Develop an audit program: Develop a program that defines the frequency, scope, and objectives of audits, aligned with the organization's risks and opportunities.Prepare and audit plan: Create a detailed plan that includes the objectives and criteria for the audit, the methods and resources required, a schedule of activities, and a list of documents to be reviewed.Use a checklist: Use an ISO 450001 audit checklist that includes all relevant clauses of the ISO 45001 standard to guarantee a thorough evaluation.Conduct the audit: Systematically follow the audit plan, gathering evidence to verify compliance with ISO 45001 requirements, and record findings, highlighting both conformities and non-conformities.Report findings: Create a report that outlines the audit results, including the evidence collected and any issues found. Categorize the findings as either conformities or non-conformities, and designate responsibilities for corrective actions.Implement corrective actions: Promptly address any identified non-conformities, documenting the actions taken to resolve them. Set deadlines for corrective actions and follow up to ensure their effectiveness.Review and improve: Leverage the findings from the internal audit to pinpoint areas for improvement in the OHSMS. Promote a culture of continuous improvement by regularly reviewing processes and making necessary changes.Why Use a Checklist for Conducting ISO 45001 AuditsUsing a checklist for conducting ISO 45001 audits can be extremely beneficial for a number of reasons, including the following:Ensures comprehensive coverage – This checklist covers all the key ISO 45001 requirements of the standard, which ensures that no important aspect is missed during the audit, making it comprehensive and accurate.Increases efficiency – A pre-defined list of questions and requirements can help the auditor to move through the audit process logically, more quickly, and with greater ease. This can help to save time and resources, allowing the auditor to focus on areas of greater concern or interest.Improves communication – A checklist also helps keep all stakeholders involved in the audit process. By having a clear understanding of what is being audited and how the process works, communication between the auditor and the organization can be improved, leading to more effective collaboration.ISO 45001 Audit Report SampleNow that you know the most important components of an effective ISO 45001 audit checklist and how to create one for your organization, you must also know what it looks like as a completed report. Below is an example of a filled-out ISO 45001:2018 audit checklist.ISO 45001 Audit Checklist Report Sample | SafetyCulture Article byEunice Arcilla CaburaoRated 4.6/5 stars on Capterra | 3k+ app store reviewsFree Version:Available for teams of up to 10Pricing:Premium plan $24/month (with a free 30-day trial period)Platforms supported:Available as a mobile app (iOS and Android) or a web-based softwareWhy use SafetyCulture?This is a digital platform that transformed the way routine inspections are conducted by digitizing data and automating workflows. With its extensive library of customizable templates and checklists, SafetyCulture is one of the most effective tools that organizations can use to ensure they are aligned with ISO standards. The software can also help business leaders navigate the process of obtaining the coveted certification, from information dissemination and employee training to routine inspections and evaluations.Features:Use audit checklists sanctioned by the ISO, like the quality management system (QMS) or ISO 9001 series, or download ISO templates relevant to your business from the Library.Digitize salient data and store them in a central repository with role-based access controls.Report on the progress of compliance with set protocols, use analytics to obtain accurate performance metrics and share findings with the team.Monitor tasks, raise issues observed, and assign preventive or corrective actions to ensure compliance.Provide additional instruction or training to employees when necessary.Why use ETQ Reliance?This holistic management platform developed by Hexagon aids businesses in satisfying ISO standards by lowering risk, ensuring regulatory compliance, and streamlining operations. Managers can easily integrate this into their current systems and implement changes or improvements now or in the future when their business needs evolve.Features:Pricing:Customized quote available upon requestPlatforms supported:Web, Desktop, iOS, AndroidWhy use IsoMetrix?IsoMetrix, a leader in environmental, social, and governance (ESG) management, helps companies structure their systems according to ISO standards, get certified faster, and foster a culture of social responsibility within their ranks through their all-in-one Lumina software.Features:ISO 9001 QMS standards managementData and metrics visualizationPricing:Available upon requestWhy use MasterControl Quality Excellence?With over 25 years of experience in the field, MasterContol has created an almost-perfect quality management system that supports organizations in their journey to get ISO-certified. This solution is easy to implement, understand, and use, which is why it is highly ranked in credible review sites.Features:Compliance and audit managementData analytics and insightsPricing:Available upon registrationPlatforms supported:Web, iOS, AndroidWhy use MetricStream?This comprehensive platform is sought-after by organizations across industries as it offers numerous solutions applicable to specific ISO standards and other regulatory frameworks like Health Insurance Portability and Accountability Act (HIPAA), California Consumer Privacy Act (CCPA), and Cybersecurity Maturity Model Certification (CMMC), just to name a few.Features:Continuous control monitoringIntuitive reporting with analyticsPricing:Available upon requestWhy use Secureframe?This comprehensive GRC platform built by compliance experts helps organizations stay on top of ISO standards and other mandated regulations. By digitizing information and automating processes, business operations follow global best practices, employees are kept safe, and products maintain their quality.Features:Continuous compliance monitoringPricing:Available upon requestWhy use ComplianceQuest?Powered by the Salesforce platform, ComplianceQuest is an effective QMS and EHS tool for companies who aim to be ISO-certified, maintain their certification, or be at par with ideal standards that ISO and other regulatory organizations have set.Features:Document and knowledge managementPricing:Starts at $30 per user per monthPlatforms supported:Web, iOS, AndroidDisclaimer:This list isn't ranked. Explore all options to find what works best for you.International Organization for Standardization or ISO compliance software is a digital tool that helps companies monitor, measure, and review their current management systems, ensuring that it follows ISO standards and complies with mandated regulations. Most platforms cover more popular standards concerning quality, environmental, and occupational health and safety management. Others are more comprehensive in their coverage, including lesser-known standards like language codes, medical device quality, and sustainable events.BenefitsSince 1954, the International Organization of Standardization has established global best practices in various sectors, from management to manufacturing. Getting the nod from this entity demands hard work, time, and valuable resources, but using a digital tool simplifies the workflows in acquiring certification.Improved quality of products and services – ISO 9001 (quality management systems) sets a framework businesses can follow to ascertain value in everything they produce. The software helps a great deal because it lays down the specifications of the framework in straightforward checklists that users can refer to any day, anytime. These can then be analyzed and transformed into reports that help in performance and product evaluations.Enhanced employee well-being – ISO 45001 (occupational health and safety management system) is another big-ticket standard that almost all companies aim to achieve. The software's features like continuous monitoring, issue reporting, and assigning actions help workplaces meet the standard and, more importantly, create safer working conditions for employees.Streamlined operations – Preparing for certification requires workplace inspections, performance evaluations, and routine audits. And all these tasks entail poring over tons of documents, which can be laborious and time-consuming. With computer programs, raw data is collected and analyzed in real time. And when problems arise, teams are immediately notified so they can handle them properly.Loss reduction and increased revenues – Because the software does most of the grunt work (risk identification, root cause analysis, computing metrics, etc.) to meet ISO standards, employees can focus on their actual job, which the business directly profits from. The company also saves money because errors, delays, and overhead costs are minimized.Enhanced reputation – When a company elevates products, safeguards the workplace, and cares for employees, customers know they are also on the priority list. Consumer trust and loyalty are almost definitely assured when a company is ISO-certified.Key FeaturesYou could integrate a standard-specific ISO compliance software because that is what your business currently requires, or go for a more comprehensive one just in case you expand in the future. Whatever your final decision is, make sure it has these essentials:Data digitization and document managementActivity tracking and monitoringTargeted preventive and corrective actionsTask scheduling with automated alertsInspection and audit managementInstructional or training capabilitiesSelecting the Right ISO Compliance SoftwareEvery single digital solution listed above can help your business meet the ISO standards, whether you plan to get a certification soon or ensure that your workplace follows global best practices. Review the summary below before you make your choice.*billed annuallyArticle byEunice Arcilla CaburaoSafetyCulture Content Contributor, SafetyCultureView author profile ISO 5000:2018 is an international standard that provides a framework that encourages an organization's leadership to promote the efficient use of energy in the organization through an effective EMS. This standard seeks to improve energy performance in organizations through significant changes in management practices and processes with regard to energy consumption. To implement it successfully, businesses must incorporate the standard into all aspects of their operations.However, this task is easier said than done, given how complex the standard can get and how urgent the need to be more energy efficient is based on current situations. For the given reasons, an ISO 50001 checklist proves to be a valuable tool for organizations. It offers them an organized flow of activities that they must accomplish to satisfy ISO requirements, as well as conduct internal audits effectively.Moreover, an ISO 50001 checklist can help your organization:Establish a systematic approach to internal assessment processesVerify if a business area or activity conforms to ISO's EMS frameworkReduce lapses and missed items during self-auditsEnsure consistent and complete implementation of ISO 50001 standards across all teams and departmentsWhat to Include in an ISO 50001 ChecklistThere are many ways to create an ISO 50001 checklist depending on your needs and industry. However, a typical ISO 50001 checklist should include the following sections:Context of the organization6 Steps on Using the ISO 50001 ChecklistNow that you know the advantages of using a checklist for your EMS, it's time to learn how this tool works. Here's a simple guide on completing an ISO 50001 audit checklist:1. Secure management commitment and support.The ISO 50001 checklist begins with a declaration of commitment from the organization's top management, as per the standard's Leadership Clause. After all, their role is crucial in successfully carrying out an ISO-compliant EMS.The key areas that require management support are as follows:Continuous improvement initiatives in energy performanceSufficient resources to achieve EMS goals and targets (people, financial, material, etc.)Legal compliance concerning energy consumption and use2. Set the organization's energy policy.The upper management's commitment to a world-class EMS culminates in the form of a written energy policy. This section highlights the responsibilities of the organization's leadership team to achieving energy-efficient operations and serves as a basis for setting goals, objectives, action plans, and continuous improvement efforts.3. Establish an EnMS plan.Upon creating a sound energy policy, it's time to lay out the organization's EMS plan. This plan should root itself in the provisions stated in the sixth clause (Planning) of the most recent ISO 50001 standard.An effective EMS plan consists of the following elements:Legal and other requirements relevant to energy efficiency, use, and consumptionEnergy Performance Indicators (EnPIs)Energy objectives and targetsEnergy management action plans4. Note observations about the EMS implementation.Once the groundwork is complete, it's time to carry out the EMS plan. At this point, it's a must to keep a close eye on and record every part of the organization's EMS, especially in areas with significant energy use, to see how the plan works in practice.This section covers two clauses of the ISO 50001:2018 standard: Clause 7 (Support) and Clause 8 (Operation). When writing down your observations, it's important to consider the following factors:Employee training and competency – ensuring employees understand the general concept of energy efficiency and are capable of carrying out energy management tasksOperational controls – examining business activities, processes, and practices that significantly contribute to the organization's energy consumption and identifying control procedures to regulate themDesign – determining opportunities for energy performance improvement in existing and prospective facilities, equipment, and systemsStakeholder communication – informing staff members and external stakeholders about the organization's EMS, energy policy, and energy performanceSupply chain – extending energy efficiency standards and initiatives to suppliers during the procurement process5. Measure the effectiveness of the established EMS.A functional EMS requires not only proper implementation but also robust monitoring and evaluation mechanisms. These tools allow organizations to gauge the impact of their EMS and how they measure against the established energy goals and performance indicators.For this reason, it's a must for organizations to carry out the following processes for checking their EMS and energy performance:Keeping track of energy outputs, EnPIs, and SEUsMonitoring the progress of action plans in achieving the organization's energy efficiency goals and targetsVerifying compliance with legal and similar requirements for sustainable energy useConducting regular internal audits to determine how the organization's EMS matches up against ISO standardsIdentifying nonconformities and lapses in the EMS implementationCarrying out appropriate corrective and preventive actions to resolve energy issuesMaintaining EMS records as proof of conformity and compliance with the ISO standard6. Review the EMS for continuous improvement.An ISO 50001 checklist wraps up with the final clause of the standard: a management review of the established EMS. In this section, the organization's leaders can identify opportunities for continuous improvement and evaluate if the current EMS is effective, adequate, and appropriate for the organization.Moreover, it allows them to determine external and internal issues that affect energy performance through internal audits, monitoring systems, and other indicators. This way, they can modify the EMS to address these deficiencies and find strategies that work for the organization.ExampleHere is a sample ISO 50001 checklist in use for reference:ISO 50001 Checklist – Sample Report | SafetyCulture Construction Site Complianceimg]:aspect-[2/1] data-component-image-wrapper=>Discover what site restoration is, why it matters, and the common methods used to return land to safe, useful conditions. Construction Site Complianceimg]:aspect-[2/1] data-component-image-wrapper=>Discover what site restoration is, why it matters, and the common methods used to return land to safe, useful conditions. An ISO 13485:2016 audit checklist is a tool used by quality managers to determine if the organizations' QMS for medical devices aligns with the requirements of the ISO 13485:2016 standard. The checklist includes a comprehensive list of questions, criteria, or statements that are useful in evaluating readiness for a third-party ISO 13485:2016 certification audit.Why is ISO 13485 Audits Important for your OrganizationISO 13485 audit checklists play a crucial role in ensuring the effectiveness and compliance of an organization's QMS for medical devices, as well as its process of auditing. Apart from that, here are more key reasons why using these checklists is important:Helps auditors conduct a thorough evaluation of the QMSVerifies compliance with the standard's requirementsPromotes standardization and consistency across auditsAssists auditors to identify areas of non-compliance, gaps, and areas for continuous improvement within the organization's current practicesEnsures proper documentation and evidence collection during auditsPrepares organizations for external audits and certification assessmentsWhat Should be Included in an ISO 13485 Audit Checklist?An ISO 13485 audit checklist should cover various aspects of a quality management system (QMS) for medical devices to ensure compliance with the ISO 13485 standard. While the specific items on the checklist may vary based on the organization's unique processes and activities, here are key areas that should typically be included:Management ResponsibilityDesign and Development/Design ControlsControl of Non-Conforming ProductsMedical Device Reporting (MDR)Production and Process Controls (P&PC)Monitoring and MeasurementSterilization Process ControlsDocumentation and Records5 Steps to Prepare for ISO 13485:2016 CertificationNow, what must organizations keep in mind and consider when getting ready to obtain a certification in ISO 13485? Here are some steps they can take:Obtain a copy and gain an understanding of the ISO 13485:2016 standard.Identify areas for improvement in the current QMS by conducting a gap analysis or a readiness audit to ensure compliance with the ISO 13485:2016 regulatory requirements.Perform quality monitoring audits and maintain a record of the results.Define your organization's competencies and determine training requirements for ISO 13485:2016 certification based on the internal audit results.Ensure competence needs are met and that all parties involved are kept in the loop.It's also crucial to note that these steps aim to guide your organization on what to prioritize doing toward an ISO 13485 certification. However, you may add more processes or necessary audits to complement your efforts in maintaining a working and safe QMS.How to Use a Checklist for ISO 13485 ComplianceHere's a step-by-step guide on how to use an ISO 13485 audit checklist:Familiarize yourself with the checklist to understand the questions or criteria it includes. Ensure that you have a clear understanding of the requirements of ISO 13485 to effectively use it, too.Assess your current processes and activities against the checklist. Compare your practices with the requirements outlined in the checklist and identify areas where your organization may have gaps or areas for improvement.Document evidence to demonstrate compliance with each checklist item. This may include records, procedures, work instructions, training records, or other relevant evidence.Conduct a self-assessment of your organization's QMS and determine whether your organization meets the requirements or if there are areas that need improvement.Identify specific corrective actions to address issues such as non-compliance or areas requiring improvement and develop an action plan for implementing the necessary changes and improvements.Execute the corrective actions according to the action plan to ensure that the identified improvements are implemented effectively and within the designated timelines.Validate the effectiveness of the changes by conducting internal audits or reviews to ensure that the improvements have addressed the non-compliances and have resulted in a more compliant QMS.Continuously monitor and review your QMS to ensure ongoing compliance with ISO 13485.Regularly review and update the checklist to align with any revisions in the ISO 13485 standard or changes in your organization's processes.ISO 13485 Audit Checklist Sample Report | SafetyCulture Construction Site Complianceimg]:aspect-[2/1] data-component-image-wrapper=>Discover what site restoration is, why it matters, and the common methods used to return land to safe, useful conditions. Construction Site Complianceimg]:aspect-[2/1] data-component-image-wrapper=>Discover what site restoration is, why it matters, and the common methods used to return land to safe, useful conditions. An ISO Audit is an official assessment sanctioned by the International Organization for Standardization (ISO) to determine if a company fulfills set criteria, usually for developing a product or rendering a service. An ISO certification gives merit to companies and protects consumers by ensuring that international safety, reliability, and quality standards are met. An ISO 9001 audit is conducted in two methods:Internal AuditAn internal audit is conducted by an organization member to compare the existing QMS with industry regulations and standards, such as ISO 9001. It helps prepare for certification by identifying non-conformances, evaluating progress, ensuring regulatory compliance, finding improvement areas, and reviewing QMS processes for certification readiness.External AuditAn external audit is conducted before obtaining ISO certification. An external auditor assesses the organization's documentation to ensure it meets ISO 9001 requirements. After the audit, the auditor will recommend either granting certification or requiring corrective actions. If certified, the organization must renew the certification every three years by undergoing the same external audit.ISO 9001: 2008 vs 2015 comparisonISO 9001:2015 intends to focus on the PDCA (Plan, Do, Check, Act) management method so the updated ISO 9001 template follows this structure. Refer to the table below to identify the key differences between the ISO 9001:2008 and ISO 9001:2015 structures.Furthermore, ISO 9001:2015 focuses on risk-based thinking rather than preventative measures. Therefore, the most recent ISO 9001 checklist reflects this by focusing on analyzing situations that are specific to your organization and deciding individual actions based on that risk analysis.Step-by-Step Guide for Creating an ISO 9001 Audit ChecklistThe key requirements to successfully integrating ISO 9001 into your organization are:Understand the context of the organization – Determining the external and internal factors that affect the organization's ability to achieve desired results.Ensure top management commitment – Management must demonstrate leadership by taking responsibility for the effectiveness of the QMS and ensuring the integration of QMS requirements into the organization's processes.Focus on the customer – The organization must understand the needs of its customers by continuously monitoring customer perceptions about the quality of products and services.Provide adequate resources – Determine and provide the necessary resources (people, infrastructure, environment, monitoring and measuring resources, organizational knowledge) to implement and maintain the QMS.Verify employee competence – Ensure employees are competent based on, training, skills, and experience.Execute quality planning – Plan and control the processes needed to meet product and service requirements.Design of products and services effectively – Involves systematic planning and control of the design process to avoid errors and ensure the final output aligns with the intended purpose.Manage customer complaints – Organizations must ensure that they have a system in place to receive customer complaints, document them, and identify their root cause to resolve them.Implement Corrective actions – Address nonconformities, take corrective actions to eliminate the cause, and prevent recurrence.Drive continuous improvement – Continuously improve the suitability, adequacy, and effectiveness of the QMS.What should be Included in a ISO 9001 Internal Audit ChecklistBelow is an example of what a typical ISO 9001 audit checklist might look like. Using this format helps you on how to prepare for an ISO 9001 audit and adhere with ISO 9001 standards:Clause 4: Context of the OrganizationUnderstanding the organization and its contextUnderstanding the needs and expectations of interested partiesDetermining the scope of the QMSThe Quality Management System and its processesExample questions:Have all external and internal issues that are relevant to your organization's purpose and the achievement of customer satisfaction and the organization's strategic direction been determined?Are these issues reviewed and monitored on a regular basis?Have the needs and expectations of interested parties that are relevant to the QMS been determined?Clause 5: LeadershipLeadership and commitmentQuality policyOrganizational roles, responsibilities, and authoritiesExample questions:Has top management taken accountability for the effectiveness of the QMS?Have the policy and objectives for the QMS, which are compatible with the strategic direction of the organization, been established and communicated?Have the objectives been established at relevant departmental and individual levels with the business?Clause 6: PlanningActions to address risks and opportunitiesExample questions:Have the risks and opportunities that need to be addressed to give assurance that the QMS can achieve its intended result(s) been established?Has the organization planned actions to address these risks and opportunities and integrated them into the system processes?Is there a defined process for the determining the need for changes to the QMS and managing their implementation?Clause 7: SupportResources (general, people, infrastructures, environment for the operation of processes, monitoring and measuring resources, and organization knowledge)Example questions:Has the organization determined and provided the resources needed for the establishment, implementation, maintenance and continual improvement of the QMS?Is monitoring or measuring is used for evidence of conformity of products and services to specified requirements?Has the organization determined the resources needed to ensure valid and reliable monitoring and measuring of results?Clause 8: OperationOperational planning and controlDetermination of requirements for products and services (market needs and interactions with customers)Design and development of goods and servicesControl of externally provided goods and servicesProduction of goods and provision of servicesRelease of goods and servicesControl of nonconforming process outputs, products, and servicesExample questions:Is there a defined process for the provision of products and services that meet the requirements defined by the customer?Are there any changes planned?Are any outsourced processes managed and controlled?Clause 9: Performance EvaluationMonitoring, measurement, analysis, and evaluationISO 9001 Clause 10: ImprovementNonconformity and corrective actionExample questions:Has the organisation determined what needs to be monitored and measured and the methods for monitoring, measurement, analysis and evaluation, to ensure valid results?Has it established when the results from monitoring and measurement shall be analyzed and evaluated?Have methods of monitoring customer perceptions of the provision of products and services been established?ISO 9001 Audit Checklist Example PDFHere is an example of an ISO 9001 PDF in the context of a QMS gap analysis. This internal audit checklist PDF for ISO 9001 lets users visualize the report of an already answered audit for an organization's QMS.Preview ISO 9001 Audit Report PDF

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