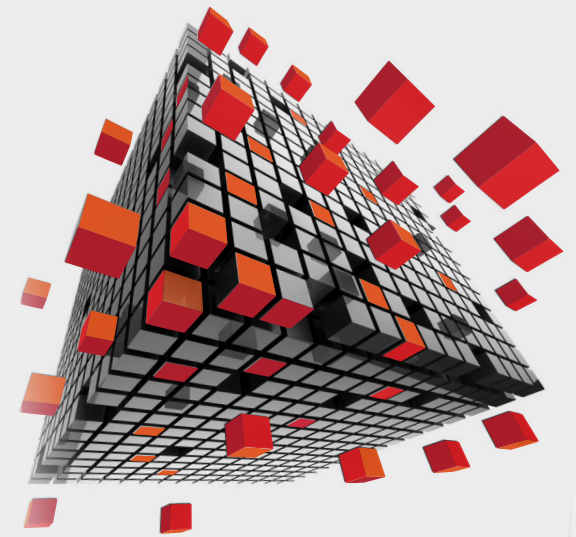# Implementation Checklist

This checklist is intended for use by those organizations who are either looking at implementing an Integrated Management System (IMS) for the first time or by those who currently have an integrated management system and would like to ensure they are on the right track during transition to revised ISO standards following Annex SL.

While this checklist is set up by elements of the ISO 9001 and ISO 14001 standards, it should be noted that the standards are intended to be used – and will be audited by the Certification Body – as a whole. Concepts of planning, management of change, and risk are woven throughout the standards and are expected to be implemented throughout the business.

Risk planning from the business perspective will differ from risk planning at the operational level – whether it be the design process for quality (FMEAs) or the aspect analysis – going from "big picture" to detailed analysis.

The audit process will begin and end with top management – defining what the organization is about, where it is, where it wants to go, how it plans to get there and how it will evaluate its progress and the effectiveness of its efforts. That "line of sight," starting from the top, will be applied as a measure throughout the audit; the results will then be delivered to top management to help them understand if they are on track and if their planning will bring intended results.

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ISO 9001:2015 & ISO 14001:2015 Requirements	Objective	Minimum Expectation	Meets Expectations
4. Context of the organization	Please use text in the **Meets Expectations** column to capture procedure numbers, process information, or additions required to ensure all requirements are met and fully integrated.		
4.1 Understanding the organization and its context	The organization must determine external and internal issues relevant to its purpose and strategic direction that may affect its ability to achieve intended outcomes as well as monitor and review information regarding these issues. Every location has a high-level, conceptual understanding of the important issues that can affect, either positively or negatively, the way the organization manages its business, from a quality and environmental perspective – covering all responsibilities.	• Is the scope documented for quality and environmental? Even in an integrated system, these may differ. • Are external and internal issues defined, so they can be considered throughout the planning process and the organization can monitor how well they are addressing or dealing with the issues? • Can Top Management explain what the concerns of the organization are from a quality and environmental perspective? • Does Top management understand how the management system is a support and critical part of the overall business system and a vehicle to help achieve overall strategic goals, both short and long term.	
4.2 Understanding the needs and expectations of interested parties	The organization has determined its important stakeholders and has defined the Scope of the QMS/EMS. The location understands who the important internal and external stakeholders are, their expectations and which of these are compliance obligations. Note: these are not necessarily legal compliance requirements, but are QMS/EMS compliance obligations.	• Has a stakeholder analysis been completed and documented to determine key stakeholders whom have an impact on the requirements of the IMS? • Have these stakeholders' expectations been considered for incorporation into the IMS? • Are expectations identified as compliance obligations?	
4.3 Determining the scope of the quality/environmental management system	The organization has defined the scope of its quality/environmental management system and considered the internal and external issues, requirements of interested parties and the products/services of the organization. The scope needs to be documented and available to interested parties.	• Is the documentation suitable and appropriate? • Has an appropriate documented system been established, with procedures, instructions, permits etc. in place where required?	
4.4 Quality/Environmental management system and its processes	Senior management has defined and communicated its Quality and Environmental Policy and demonstrates commitment to it. The organization's quality and environmental policy establishes the framework upon which objectives and targets are set.	• Are the required elements from the quality and environmental policy readily identifiable (e.g. preventing pollution or ensuring customer satisfaction)? Even in an integrated system, the policy for quality may be separate from environmental.	

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5. Leadership			
5.1 Leadership and commitment	Senior management demonstrates its commitment to the QMS/EMS with actions and behaviors and takes responsibility for its implementation and continual improvement.	• Interview management representatives in various levels to verify how and when they demonstrate their commitment • Interview employees and review meeting minutes of strategic and tactical teams. Is leadership perceived to be visible on the floor on behalf of quality, environmental, health and safety issues or events, and involved in key decisions and interacts with groups?	
5.2 Policy	Top management has established an environmental and quality policy and communicated the policy to the entire organization. The policy shall be appropriate to the purpose and context of the organization and provide a framework for setting objectives. The organization's intentions and principles for the implementation and continual improvement of the management system are formally stated in the policy. The policy is periodically reviewed and revised to ensure its continuing adequacy and effectiveness.	• Is the QMS/EMS policy is posted, readily accessible and communicated to employees, contractors and other interested stakeholders? • While there is no defined requirement for senior management to personally sign and endorse the policy, it is considered best practice. • Interview a representative number of employees in all levels of the organization, including contractors. Have eemployees seen and understand the QMS/EMS policy and the organization's expectations concerning the policy? • Review the facility's records associated with the IMS policy. Is the policy periodically reviewed and revised as needed to ensure its continuing adequacy and effectiveness?	
5.3 Organizational roles, responsibilities and authorities	Senior management ensures responsibilities and relevant roles are assigned, communicated and understood within the organization.	• Can senior management explain how they keep abreast of quality and environmental management system needs, how they ensure the needs are met, and their methods of communicating during an interview in the audit?	

ISO 9001:2015 & ISO 14001:2015 Requirements	Objective	Minimum Expectation	Meets Expectations
6. Planning			
6.1 Actions to address risks and opportunities	The organization needs to consider the scope, as well as issues (4.1) and requirements (4.2), when planning for the management system and risks and opportunities should be defined and addressed. While environmental aspects and impacts, and compliance obligations, may be identified and managed by the same process used to determine business risks and opportunities, they are normally kept separate. Business risks and opportunities may be identified by management discussion and brainstorming, while a formal FMEA-type process is applied to aspects and impacts. See Annex A6.1.1 for more information.	• Are customers and other interested parties' expectations defined and linked to business issues? Note: The larger or more complex an organization, the more probable this process will be documented. A formal risk analysis process is not required to define these issues under 4.1 • Are aspects and impacts defined in relation to compliance obligations with a risk assessment methodology for use in prioritizing aspects?	
6.2 Quality/Environmental objectives and planning to achieve them	The organization needs to establish objectives at relevant functions, levels and processes needed for the integrated management system and plan actions to achieve these objectives. This includes considering risks and opportunities associated with environmental aspects and impacts as well as associated compliance obligations.	• Are objectives set based on data collected and analyzed in relation to customers' needs and satisfaction, market changes, environmental performance, best practices, changes in regulations, etc.? • Are objectives meaningful, realistic, achievable and measurable, and most importantly, do they have a positive impact on the business? • Are objectives dynamic and easy to change/update to keep current to the organization needs and ever-changing environment the organization operate in?	
6.3 Planning of changes	Any changes needed from the management system should be planned with consideration given to availability of resources as well as the potential consequences and integrity of the integrated management system.	• How is the management of change defined, managed and measured for success and can you ensure lessons learned are incorporated into future actions? • Do processes defined identify and plan for changes related to customers, products, new equipment, new processes, new materials, changed equipment, amended processes, new uses applied to current materials, new compliance obligations, changes in personnel responsible, etc. that can impact quality or environmental?	

ISO 9001:2015 & ISO 14001:2015 Requirements	Objective	Minimum Expectation	Meets Expectations
7. Support			
7.1 Resources	The organization must determine and provide resources needed for the establishment, implementation, maintenance and continual improvement of the integrated management system. This includes determining and providing the necessary people, infrastructure, environment, monitoring/measurement resources, and organizational knowledge required for operations.	• Are key roles within the management system defined and duties assigned? • Is required training identified by position? • Are succession plans identified for key resources/positions? • Are calibration needs for both quality and environmental purposes must be identified and defined? Criteria may not be the same, but will take into account industry-standard calibration processes, ISO standard requirements, regulatory requirements, and customer requirements as applicable.	
7.2 Competence	The organization must first determine the necessary competence and ensure that the relevant people have proper training and experience and that there is proper documentation as evidence.	• Is criteria for competence defined by responsibilities? • Is there a process for tracking training and development? • Does the process for competency ensure consistency and effectiveness in evaluation of competency?	
7.3 Awareness	People working for the organization need to be aware of the policy and objectives as well as their contribution to the effectiveness of the integrated management system and the implications of not conforming to requirements.	• Can you define what is needed from persons working for the organization? • Have you determined potential for impacting quality or the environment.? • Have you determined what needs to be communicated in order to avoid negative impacts?	
7.4 Communication	Relevant internal and external communications need to be established, implemented and maintained, including what will be communicated as well as timing, audience, method and who will deliver the message.	• Is the process defined and responsibility for communication assigned? • Does the process define documented evidence of communications required, where appropriate?	
7.5 Documented information	The management system must include documented information required by the standards as well as any necessary information contributing to the effectiveness of the integrated management system. This information should be controlled to ensure availability, usability and protection.	• Is there evidence that the locations have reviewed regulatory, corporate or other external requirements to identify documentation that is required to be part of the management system?	

ISO 9001:2015 & ISO 14001:2015 Requirements	Objective	Minimum Expectation	Meets Expectations
8. Operation			
8.1 Operational planning and control	Necessary processes need to be established, implemented, controlled and maintained to meet system requirements. Actions identified in 6.1 and 6.2 need to be implemented by establishing operational criteria and implementing control of processes.	• Have you defined critical control points in operations from both a quality and environmental perspective? • Is control criteria established? • After implementation of the control process, use monitoring or the audit process to ensure it is maintained, and is adequate and effective in achieving customer satisfaction and preventing of pollution/consumption of nonrenewable resources	
8.2 Requirements for products and services (ISO 9001:2015) 8.2 Emergency preparedness and response (ISO 14001:2015)	8.2 Requirements for products and services lends itself to integration. 8.2 Emergency preparedness and response will remain separate due to legal implications.	• Implement and plan the criteria for products and services to meet standard and customer requirements. • Analyze the established criteria to determine in which areas risk of material use and disposal could lead to environmental impacts that must be controlled, and add these controls to the process, in support of 8.1.	
8.3 Design and development of products and services (ISO 9001:2015)	Gather all the information needed to ensure products and services are understood and properly planned, including communication with the client to ensure their expectations are met.	• Establish the design criteria per the ISO 9001:2015 standard, determine the process required, ensuring all standard and customer requirements are met. • If environmental criteria within the design were not set by the client, determine the environmental controls your organization wishes to establish for the design criteria and process and establish them within the quality process. • Establish a process to ensure the quality and environmental criteria will be considered in each product or process change going forward, if such criteria has been established. • Note: Look at 8.1 of 14001 for life cycle perspective and the impact of design on that life cycle.	
8.4 Control of externally provided processes, products and services (ISO 9001:2015)	This may be excluded from the integration process.	Should this be a consideration, selection of contracted services may include environmental considerations, or contractor's environmental performance, as a criteria.	
8.5 Production and service provision (ISO 9001:2015)	These requirements may be integrated with environmental criteria, if the provisions of 8.3 have been integrated.	Ensure defined process to control quality and environmental criteria is considered in each product design or process change going forward, if such criteria has been established.	

ISO 9001:2015 & ISO 14001:2015 Requirements	Objective	Minimum Expectation	Meets Expectations
8. Operation *(continued)*			
8.6 Release of products and services (ISO 9001:2015)	These requirements may be integrated with environmental criteria, such as packaging, if the provisions of 8.3 have been integrated.	Ensure defined process to control quality and environmental criteria is considered in each product design, design change, or process change going forward, if such criteria has been established.	
8.7 Control of nonconforming outputs (ISO 9001:2015)	*See 8.6*	*See 8.6*	
9. Performance evaluation			
9.1 Monitoring, measurement, analysis and evaluation	The organization must determine what needs to be monitored and measured as well as the criteria, method and timing for analysis. This includes monitoring customer satisfaction as well as evaluating performance, effectiveness and compliance of the integrated management system.	• Are critical control points determined in operation, regulatory requirements for monitoring, weaknesses identified through customer feedback, and system requirements for monitoring in both quality and environmental? • Establish acceptable criteria parameters, where applicable. • Are monitoring requirements defined in relation to method and timing? • Analyze and ensure sufficient information is captured and provided for Management Review to determine adequacy, suitability and effectiveness of the system.	
9.2 Internal audit	Internal audits need to be planned regularly to provide information on the integrated management system's conformance and effectiveness.	• Is risk considered when determining the audit plan frequency and content/processes for both quality and environmental? • While there is an expectation that individuals will not audit work for which they are responsible, individuals with specialized skill can be utilized as "consultants" in areas for which they are responsible to ensure the competency of the auditors is sufficient to provide depth and breadth of audit.	
9.3 Management review	The integrated management system needs to be reviewed at planned intervals and, if needed, action should be taken to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization.	• Is management provided with sufficient data to ensure decisions made in review are satisfactory? They must understand results of customer satisfaction measurements, progress on objectives, trends in internal audit findings, and current regulatory compliance status for quality and environmental before they can make decisions on suitability, adequacy and effectiveness of the management system, and whether the organization is performing as expected.	

ISO 9001:2015 & ISO 14001:2015 Requirements	Objective	Minimum Expectation	Meets Expectations
10. Improvement			
10.1 General	Opportunities for improvement need to be identified and necessary actions should be implemented to meet customer requirements and enhance customer satisfaction.	•What are the processes for gathering information on opportunities? These are critical to ensure good input – for quality and environmental management.	
10.2 Nonconformity and corrective action	Any nonconformity should be dealt with by taking action to correct and control it and evaluated to determine and eliminate root cause. This will ensure that the nonconformity does not recur or occur elsewhere in the system.	• Is containment of any condition of nonconformity handled immediately? • Without cause analysis, you cannot determine the issue or issues that led to the nonconforming condition. • Once determined and implemented, is corrective action verified to ensure it not only eliminated the nonconforming condition, but that it didn't cause another issue? • Are customer complaints, agency notices of violation, process conditions that cause work stoppages, incidents, etc. all conditions of nonconformity, and require analysis, correction and corrective action?	
10.3 Continual improvement	The organization needs to consider the evaluation and management review to determine any actions needed to continually improve the suitability, adequacy and effectiveness of the integrated management system.	• Is continual improvement expected throughout the organization's process – from product improvements to capitol improvements – for quality and environmental? • Note: data analyzed for continual improvement can be quantitative or qualitative, but must demonstrate targets have been met.	

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