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Executive summary

The new ISO 45001 is published, and the transition from OHSAS 18001 to the new standard is ahead. One of the most important steps in the transition process, as well as in the initial implementation, is determining what documents and records are needed for an effective Occupational Health and Safety Management System (OH&SMS) based on ISO 45001. This white paper is designed to help top management and employees involved in ISO 45001 implementation or transition, and to clear up any misunderstandings regarding documents required by the standard.

In this document, you will find an explanation of which documents are mandatory according to the ISO 45001:2018 standard, and which non-mandatory documents are commonly used in the OH&SMS implementation, presented in the same order and numbered clauses as in ISO 45001.

Introduction

The documentation needed for implementation of ISO 45001 includes any documents explicitly required by the standard, plus any additional documents that the company determines to be necessary for effective maintenance of the OH&SMS based on ISO 45001. Many companies go overboard with documentation in the belief that they need to document every single process that is in place in their organization, without realizing that this is not necessary to meet the requirements of the ISO 45001 standard. While trying to fulfill standard requirements, organizations tend to generate too many documents to be on the "safe side."

Although it is sometimes helpful, this can be counterproductive, because it makes the implemented processes and respective OH&SMS harder to use and maintain, as well as making the OH&SMS a bureaucratic burden. With this approach, organizations miss opportunities to improve their processes for their own benefit, as well as that of their customers.

In this white paper, you will find, explained in plain English, what the minimum ISO 45001 requirements for the documentation are, as well as a list of documents that are commonly in place and can help you make your OH&SMS more efficient.



Which documents and records are required?

Mandatory documents

Mandatory documents	Clause of ISO 45001:2018
Scope of the OH&S management system	4.3
OH&S policy	5.2
Responsibilities and authorities within the OH&SMS	5.3
OH&S process for addressing risks and opportunities	6.1.1
Methodology and criteria for assessment of OH&S risks	6.1.2.2
OH&S objectives and plans for achieving them	6.2.2
Procedure for emergency preparedness and response	8.2

Mandatory records

Mandatory records	Clause of ISO 45001:2018
OH&S risks and opportunities and actions for addressing them	6.1.1
Legal and other requirements	6.1.3
Evidence of competence	7.2
Evidence of communications	7.4.1
List of external documents	7.5.3
Plans for responding to potential emergency situations	8.2
Results on monitoring, measurements, analysis and performance evaluation	9.1.1
Maintenance, calibration or verification of monitoring equipment	9.1.1
Compliance evaluation results	9.1.2
Internal audit program	9.2.2
Internal audit report	9.2.2
Results of management review	9.3
Nature of incidents or nonconformities and any subsequent action taken	10.2
Results of any action and corrective action, including their effectiveness	10.2
Evidence of the results of continual improvement	10.3



These are the documents and records that are required to be maintained for the ISO 45001 Occupational Health and Safety Management System, but you should also maintain any other records that you have identified as necessary to ensure your management system can function, be maintained, and improve over time.

Commonly used non-mandatory documents

ISO 45001 contains a certain number of requirements to "establish, implement and maintain a process." These requirements are not necessarily transformed into documentation; but, considering the complexity of some processes that fall under this category, it can be beneficial for the organization to take these processes into account when deciding what should be documented in addition to the mandatory documents. You can find examples of the documents that are not required by the standard, but can be beneficial to the OH&SMS:

Document title	Clause of ISO 45001:2018
Procedure for Determining Context of the Organization and Interested Parties	4.1
OH&S Manual	4
Procedure for Consultation and Participation of Workers	5.4
Procedure for Hazard Identification and Assessment	6.1.2.1
Procedure for Communication	7.4.1
Procedure for Document and Record Control	7.5
Procedure for Operational Planning and Control	8.1
Procedure for Change Management	8.1.3
Procedure for Internal Audit	9.2
Procedure for Management Review	9.3
Procedure for Incident Investigation	10.2
Procedure for Management of Nonconformities and Corrective Actions	10.2

One rule of thumb when deciding if you want to document a process is this: if there is a chance that the process won't be carried out as planned, then you should document it. In many cases, this is the best way to ensure that your Quality Management System is implemented reliably.



How to structure documents and records

ISO 45001 doesn't have a lot of requirements regarding documentation, so it is imperative that you optimize the volume of your OH&SMS documentation by trying to develop documentation that meets all requirements, while remaining simple and light. Instead of just documenting every single requirement of the standard, the organization should focus on the most important information and provide a sufficient amount of information to its employees to ensure compliance with the standard and legal requirements.

The following recommendations take into consideration the best practice in developing OH&SMS documentation:

OH&S Manual. The manual is not a mandatory document, but very often is an essential part of the OH&SMS. This document is a summary of your entire OH&S management system with reference to the procedures and records within the system, and it is a good place to put all important information that didn't fit into any other document of your OH&SMS.

For more information, see Does your organization need a health & safety manual?

Procedure for Determining Context of the Organization and Interested Parties. This is a new requirement in the Occupational Health and Safety Management System, and it can be a good idea to document not only the results of determining the context, but also the process itself. This document can define what elements of the context need to be considered, who will participate, what methodologies will be used, and how often information on the context will be revised. The Procedure for Determining Context of the Organization and Interested Parties can be of great help in initial implementation of the standard and these new requirements.

For more information, see: Defining the context of the organization according to ISO/DIS 45001 and Determining interested parties according to ISO 45001.

OH&S Scope. This document is usually rather short and is written at the beginning of the ISO 45001 implementation. Normally, it is a stand-alone document called Scope of the OH&SMS, although it can be merged into an OH&S Manual, which defines the limitations of the OH&S management system within your company, and identifies what elements are included and how they interact.

Learn more about the OH&S Scope in the article: How to determine scope of the OH&SMS.

OH&S Policy. The OH&S Policy is intended to be a company's documented intention to meet legal compliance, prevent occupational health and safety hazards, and continually improve. The Policy is a focus for the company to work toward and should readily convey the goal of the organization. It is often documented in an OH&S Manual and sometimes posted throughout the organization as a way of communicating to all employees, because it is important that every employee understand how the Policy relates to his or her job. For more information, see How to write an OH&S Policy.



Roles and responsibilities within the OH&SMS. There are two options for documenting this requirement. The first is to have a general document that will define roles and responsibilities within the OH&SMS for the entire organization. The second is to have roles and responsibilities documented within different OH&S documents, such as procedures and work instructions. Both approaches are OK, and it is up to the organization to decide what is the most appropriate approach.

For more information, see: How roles and responsibilities have changed in DIS/ISO 45001.

Consultation and participation of workers. The standard requires the organization to implement, establish, and maintain a process for consultation and participation of workers at all applicable levels and functions in development, planning, implementation, performance implementation, and actions for improvement of the OH&SMS. Although it is not required, it can be beneficial to the organization to document the mechanisms and resource provision for the consultation and participation and define the responsibilities. If you want to decrease the documentation, this procedure can be merged with the communication process into the Procedure for Communication, Participation and Consultation.

Methodology and criteria for assessment of OH&S risks. In order to address risks and opportunities, the organization needs to identify them first and assess what risks and opportunities are worth addressing. The standard requires the organization to establish criteria and methodology for assessing risks and opportunities and identifying the significant ones on which the organization needs to focus. The methodology and criteria can be merged with the Procedure for Addressing Risks and Opportunities and OH&S hazards into Procedure for Addressing Risks and Opportunities and OH&S Hazards in order to decrease the number of documents within the OH&SMS.

Process for addressing OH&S risks and opportunities. Unlike other management system standards that follow Annex SL and the High-Level Structure defined by the ISO, ISO 45001 requires the organization to document the process for addressing risks and opportunities. The procedure for addressing risks and opportunities must cover the actions taken by the organization to determine risks and opportunities and can be merged with the Procedure for Addressing Risks and Opportunities and OH&S Hazards.

Procedure for Hazard Identification and Assessment. The methodology and criteria for assessment of occupational health and safety hazards is often a legal requirement, so the standard doesn't require this procedure explicitly. In case you already have this procedure documented due to legal requirements, you can just make reference to it in your OH&S Manual and avoid writing an additional procedure. If such legal requirements do not exist, it can be beneficial for the organization to have such a procedure to assess the OH&S hazards. In this case, it can be merged with procedure for addressing risks and opportunities into the Procedure for Addressing Risks and Opportunities and OH&S Hazards.

For more information, see: How to identify and classify OH&S hazards.

Legal and other requirements. It is important for your company to know and understand the legal requirements that apply to your business practices. To make this work, you need to devise a way to ensure that you know which laws apply, and how you will keep up to date on legal changes. In addition to these legal obligations, the obligations towards other interested parties must be identified as well.



This is a part of the identification of interested parties and their needs and expectations, so it should be done during this process. The standard requires compliance obligations to be documented and evaluated on a regular basis.

OH&S objectives and plans for achieving them. The objectives are derived from the goal stated in the OH&S Policy, and are the main method used by companies to focus this goal into plans for improvement. The objectives are intended to be S.M.A.R.T. (specific, measurable, achievable, realistic, and time-based) and should have relevance at all levels of the company, meaning that all employees should understand how their jobs support meeting the OH&S objectives and the plans for achieving those objectives.

Evidence of competence. Keep records to prove that you identified what competencies are required for the crucial processes in your OH&SMS, and how employees met these competencies. If the competencies were not met by individuals responsible for the action, how did you address the training discrepancies to close the gaps?

Communication process. ISO 45001 requires the organization to perform communication, participation, and consultation with employees, subcontractors, and relevant external parties on issues regarding occupational health and safety. It is also required to process, document, and respond to relevant communication from external interested parties. Unlike ISO 14001, which requires the organization to make a decision as to whether it will inform its neighbors or not, ISO 45001 requires the organization to take into consideration information from external interested parties regarding occupational health and safety.

Procedure for Document and Record Control. How do you approve, update, and re-approve your documents? When a document is changed, how do you identify changes, and make sure that people who need the current document have it and stop using older documents? How do you make sure the documents can be read, and how do you control documents that come from outside of your organization for use? How do you maintain your records that show your OH&SMS is implemented and maintained, including how you identify, store, and protect the records so that they can be retrieved as necessary, for the correct amount of time, and destroyed when no longer needed but not before?

List of External Documents. Although this record is not explicitly required, the standard requires external documents necessary for the OH&SMS to be identified and controlled. Keeping a record of all external documents relevant to the OH&SMS is the best way to meet this requirement and demonstrate compliance with it.

Procedure for Operational Planning and Control. When you have identified that your operations can have a negative impact on occupational health and safety, you need to put controls in place to mitigate the risks and prevent the injuries and health problems from happening. In order to have a known and consistent way of doing what is needed to avoid the occurrence, you will need to create operational control procedures. If no situations are present, you need to ensure that there is no deviation from the policy and objectives, or related significant hazards, and then these procedures are not required.



Procedure for Change Management. The standard requires the organization to implement a process for controlling and planning temporary and permanent changes in the OH&SMS. The purpose of this process is to ensure compliance with the legal and the standard requirements and to review the consequences of unintended changes in order to mitigate any adverse effects on employees' occupational health and safety. Changes also can result in potential OH&S opportunities.

Emergency preparedness and response process. When there is a risk that an emergency might happen (such as a chemical spill), you need to have plans in place to respond and react to the emergency and limit the environmental damage you will cause. Also, it is necessary to ensure that the emergency plan will be followed by the employees, and this is done by testing the emergency response plans and periodically reviewing and revising the process and plans.

Monitoring, measuring and analysis of OH&S performance. When you identify a key characteristic of a process, you will also need to determine whether this characteristic can have a significant OH&S risk if it is not controlled by the company. When this is the case, the organization needs to document what information needs to be monitored so that employees can react to changes in performance and avoid the occupational health and safety hazards.

Maintenance, calibration or verification of monitoring equipment. In your processes, you may need to monitor and measure critical elements of the OH&SMS to ensure compliance with legal requirements. As an example, you may need to measure the concentration of a chemical in your workplace. When you do this, you need to use calibrated equipment to ensure your measurements are accurate and maintain records of these calibrations.

Internal audit. How do you audit your Occupational Health & Safety Management System to make sure that it is performing as planned and is effective? Who is responsible for planning and carrying out the audits? How do you report results, and what records are kept? How do you follow up on corrective actions noted in audits?

For more information, see: ISO Internal Audit - A Plain English Guide.

Management review. It is recommended for organizations to have a procedure for management review where the organization can define the inputs and outputs of the management review, as well as the persons responsible for providing the information and conducting the management review. As a result of the management review, the organization needs to produce the record with all necessary outputs of this process.

Incident investigation and reporting. Occupational health and safety incidents are big problems for the organization, even if they don't result in injuries of the employees. Such incidents need to be investigated in order to determine the cause of the incident and take measures to prevent similar incidents from happening in the future. Records about incident investigation and subsequent actions taken need to be recorded.

Management of Nonconformities and Corrective Actions. With the Occupational Health & Safety Management System, you will find that you have non-conformances occur within your processes that



you will need to correct, and when you investigate the root causes of these problems you will have corrective actions taken. You will need to keep records of these activities to show improvement.

Evidence of the results of continual improvement. This is a completely new requirement aiming to ensure that the organization takes actions towards improvement of its OH&SMS and to provide evidence that those actions are taken. In addition, this kind of record can be useful during the next management review to assess the effectiveness of the improvement actions.

Conclusion

ISO 45001 implementation can turn into a problematic project if you don't set it up correctly right from the beginning. The documentation that is required by the standard, extended by non-mandatory documents, forms a significant part of the OH&SMS implementation. Knowing what the standard requires as mandatory documentation helps the organization to be well prepared for the certification audit. On the other side, decisions regarding the addition of non-mandatory documents should represent a balance between the competence of employees, and administrative controls that can help the organization avoid nonconformities. Implementing both mandatory and non-mandatory documents in an optimal scope increases the efficiency of the OH&SMS and creates benefits for both the organization itself and its customers.

Sample documentation templates

Here you can download a free preview of the ISO 45001 Documentation Toolkit – in this free preview, you will be able to see the Table of Contents of each of the mentioned policies and procedures, as well as a few sections from each document.

References

- 45001Academy
- International Organization for Standardization











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