EAGLE Certification Group

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ISO 45001:

Occupational Health & Safety Management Systems (OHSMS) Hazards and Risks in the ISO 45001 Standard

Hazards and Risks in the ISO 45001 Standard

ISO 45001, the international standard for Occupational Health and Safety Management Systems (OHSMS), provides a structured framework for organizations to manage workplace safety. A core component of this standard is the identification of hazards and the assessment and control of associated risks. Understanding the distinction between these terms, and how to classify them, is essential. ISO 45001 requires systematic hazard identification. This document outlines a process for defining and prioritizing them to create a hierarchy for decisions and actions. The process below is just one example of how health & safety risks may be identified. This is not a mandatory methodology.

Explanation of Hazards and Risks

ISO 45001 provides specific definitions for hazard and risk, which sound similar, but have distinct meanings within the standard. In essence, a hazard is the "thing" that can cause harm, while the risk is the "chance" and "consequence" of that harm occurring.

Hazard: A hazard is a source or situation with the potential to cause injury or ill health. It is the possibility of harm existing within a workplace or process. Examples include a live electrical supply, a slippery floor, a hazardous chemical, a machine with pinch points, extreme weather and even human factors such as work-related stress or bullying. In each case, the hazard is the source of the potential harm.

Risk: An OHS risk is the combination of the likelihood that a work-related hazardous event or exposure(s) will occur and the severity of injury or ill health that can be caused by the event or exposure(s). Risk is the possibility that harm will occur if exposed to a hazard, and it considers both how likely the event is to occur and the severity of its potential consequences. It is the overall measure of the potential harm.

Explanation of Hazards and Risks Cont.

The first step is to identify all hazards within an organization. Defining hazards requires the establishment of an ongoing, proactive process that covers physical dangers as well as social and organizational factors. Many organizations already have process-specific risk assessments, generally termed as Job Hazard Assessments (JHAs) or Job Safety Assessments (JSAs), as required by OSHA. JHAs/JSAs are a strong starting point for capturing risks within specific processes and can serve as valuable inputs to the overall risk assessment process. These assessments usually do not consider risks that are not strictly related to a specific process (i.e. plant-wide hazards such as extreme weather, workplace stress or bullying, slip/trip hazards, and more). Many organizations will refer to the site-wide OHS risk evaluation process as a "Hazard Identification Risk Assessment" (HIRA).

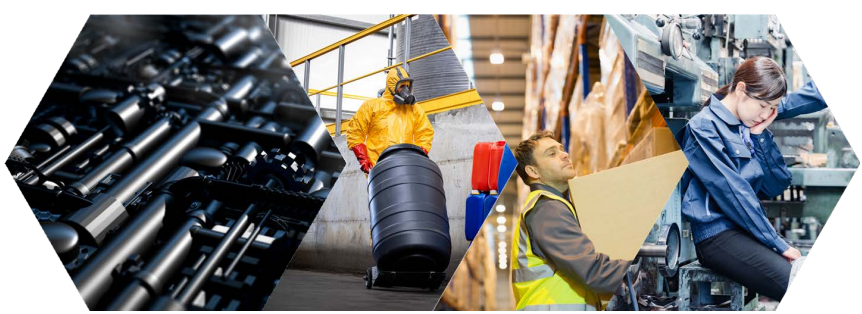
One reliable approach to identifying OHS risks is to assemble a cross-functional team including non-managerial associates. Involvement of hourly associates is both a requirement of the standard and a practical step, as they are most familiar with day-to-day OHS risks. One tactic to update and expand your risk assessment is to ensure that each JHA/JSA is current with input from the cross-functional team. From there, identify the common risks across processes and summarize them accordingly. Often, it is possible to capture the same risk identified in many processes or departments and evaluate them as "plant-wide" risks. Consolidating shared risks is a great way to ensure they are evaluated consistently.

Explanation of Hazards and Risks Cont.

Process flow diagrams are also very helpful inputs to the risk evaluation and ranking process to ensure you've not only captured individual processes, but also the linkage between those processes. Categorizing hazards into five different groups for management will help tackle the project. Consider:

1. **Physical and Environmental**: temperature, noise, lighting, extreme weather/climate change;
2. **Mechanical and Infrastructure**: mobile equipment, machinery, facilities, tools;
3. **Chemical and Biological**: chemical exposure, fumes, dust, pathogens;
4. **Ergonomic**: manual handling, repetitive tasks;
5. **Psychosocial and Social**: workload, harassment, organizational culture.

ISO 45001 also requires the identification of hazards across different operational contexts, including normal, abnormal and reasonably anticipated emergency conditions. Some examples of overall process risks to consider include receiving new equipment, process changes, and unplanned tasks such as emergency maintenance, equipment malfunction or breakdowns, spills, fires, explosions, and power outages.

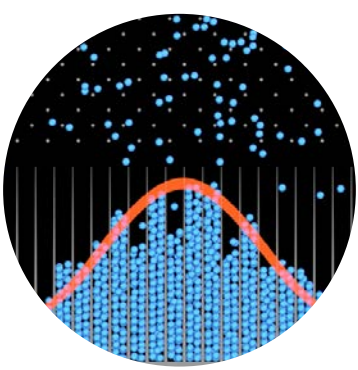


Risk Classification Based on Probability and Severity

To effectively manage hazards and risks, a hierarchy of severity should be established. ISO 45001 requires organizations to implement a process for assessing identified risks to determine which are significant enough to require attention and control measures. While the standard does not prescribe a specific methodology, it allows organizations to create their own tools to fit their processes. One common and effective approach is to use a risk matrix that classifies risks based on two primary criteria: **Probability** (likelihood) and **Severity** (consequence).

Most organizations identify the nature of the controls in place and only conduct their risk ranking based on post-control. However, some organizations choose to rank risks both pre-control and post control, and it is up to each facility to decide the best approach. One place where identifying risk pre- and post-control may be helpful is justifying a new or additional control being put into service. This may help justify the expense and help with prioritization of resources.

Probability



Severity

Risk Classification Based on Probability and Severity Cont.

In many instances, organizations add additional criteria including past performance, robustness of controls and regulatory categories, which can make the risk matrix quite complex. It is recommended to reserve this approach for facilities with high-risk processes and maintain a more streamlined approach for facilities with straightforward risks. The following information will focus on a basic likelihood vs. severity approach.

By establishing the probability and severity of a risk using a numeric designation, organizations can use this data to determine and prioritize the level of risk more effectively. It is important to note that having too many options for selection of risk may cause difficulties in defending the risk evaluation process.

The following explains how probability may be categorized using five general criteria:

1. **Rare** – unlikely to occur and/or have minor or negligible consequences
2. **Unlikely** – possible to occur and/or have moderate consequences
3. **Moderate** – likely to occur and/or have serious consequences
4. **Likely** – almost sure to occur and/or have major consequences
5. **Almost certain** – sure to occur and/or have major consequences

The criteria for the severity of a risk may also be established using a (1-5) scale by considering the potential impact of the hazard:

1. **Insignificant** – no serious injuries or illnesses expected
2. **Minor** – minor injuries or illnesses with limited impact
3. **Significant** – injuries or illnesses requiring medical attention but limited treatment
4. **Major** – serious or irreversible injuries or illnesses requiring constant medical attention
5. **Severe** – potential for fatality

Risk Classification Based on Probability and Severity Cont.

To determine the level of risk in a matrix, both the probability and severity of each hazard are designated with a numerical value such as (1-5), as outlined above. The identified hazards are then evaluated against these two criteria using a matrix (see Table 1). The total at the intersection of probability and severity determines a numerical score, which is used as a risk level. For example, a high probability and high severity hazard (such as an unguarded machine pinch point in constant use) is classified as a significant risk, requiring immediate attention and stringent control measures, whereas a low probability and low severity hazard may be managed by routine procedures. This systematic classification allows organizations to prioritize their resources, focus on the most significant threats, and plan actions to eliminate hazards and reduce risks proactively.

Risk Classification Based on Probability and Severity Cont.

To help identify a numerical score for management purposes, it can be useful to multiply **Probability** by **Severity**. In the case where the highest level of severity intersects with an almost certain likelihood of occurrence, the resulting score would be 25.

For more clarity and usability, this score could be further categorized as:

1-4: Acceptable – no further action needed; current control measures acceptable

5-9: Adequate – may be considered for further analysis

10-16: Tolerable – reviewed in a timely manner to carry out improvement strategies

17-25: Unacceptable – cease activities and endorse for immediate action

Table 1:

Risk Assessment Table					
Potential Severity Ratings ↓	Probability of Occurrence Ratings →				
	Insignificant (1)	Minor (2)	Significant (3)	Major (4)	Severe (5)
Almost Certain (5)	5	10	15	20	25
Likely (4)	4	8	12	16	20
Moderate (3)	3	6	9	12	15
Unlikely (2)	2	4	6	8	10
Rare (1)	1	2	3	4	5

Risk Classification Based on Probability and Severity Cont.

Another example is provided, customizing a risk evaluation approach to meet a site's specific needs. In this case, the company elected to skew the risk values to 1, 3, 5 and 9 instead of the traditional 1-5 scale. This allows for easier visual identification of higher risks, as the Risk Priority Number (RPN) becomes much larger as risk levels rise.

This format involved consideration of likelihood and severity. The criteria for selecting a specific value were identified as follows:

Probability

1 - Highly unlikely
3 - Low probability
5 - Medium probability
9 - Highly likely

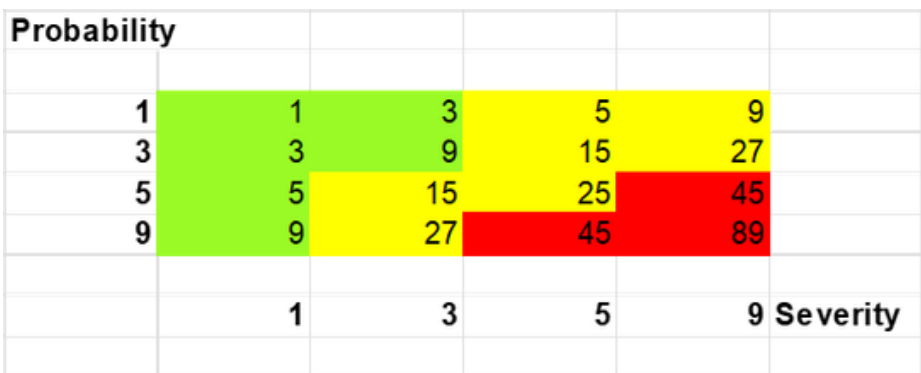
Severity

1 - Occurrence will have little or no effect on health/safety
3 - Occurrence will have minimal effect on health/safety including acute illness or isolated injury with short-term ramifications
5 - Occurrence will have significant effect on health/safety including possible chronic illness or injury
9 - Occurrence will cause permanent injury, disability or death

Risk Classification Based on Probability and Severity Cont.

Risk Priority Number

1-10 Low Risk
11-27 Medium Risk
28-89 High Risk



As illustrated in the graphic above, the lower the value, the less overall risk exists. The green areas typically would not need any further controls put into place. The yellow areas may have improvement projects planned, while the red areas will likely need immediate action. When considering appropriate corrective actions, requirements related to federal, state and local regulations must be considered. In addition, requirements of the applicable management system and company requirements, including corporate, division, facility, etc., must also be considered along with the risk level.

FMEA

If you have experience with the Failure Mode and Effects Analysis (FMEA) tool, you recognize its effectiveness for managing hazards and risks under ISO 45001. FMEA is widely recognized as a robust approach that aligns with the standard's requirements for hazard identification and risk assessment. It achieves this by identifying potential "failure modes" (what could go wrong within equipment or processes) before they lead to incidents.

Under ISO 45001, organizations must prioritize risks. FMEA uses a Risk Priority Number (RPN), calculated from Severity, Occurrence, and Detectability, to provide a clear, data-driven ranking of hazards that require immediate attention. FMEA is particularly valuable for assessing workplace processes and complex equipment, ensuring that each step is analyzed for potential safety failures.

While these models can be expanded, the principle for developing such a tool remains the same. It should function as a controlled document that captures all safety concerns, allowing them to be acknowledged and prioritized. Organizations should also consider opportunities for positive outcomes and apply the Plan-Do-Check-Act (PDCA) model to help maintain control over this tool.

FMEA Cont.

For more detailed information on risk management considerations, review IEC 31010. This International Standard provides guidance on risk assessment techniques and is designed to be used alongside ISO 31000, providing practical support for the risk assessment component of the broader risk management framework. IEC 31010 covers the process of identifying potential risks, the analysis of their causes and consequences, and the evaluation of their likelihood and severity.

About EAGLE Certification Group

Since 1994, EAGLE has built a reputation on providing third party auditing services that are objective and value-added. Based in Dayton Ohio, our competent, industry-experienced auditors are well-versed in helping clients ensure their quality, environmental, health and safety, or food safety management systems are robust and effective. EAGLE is ANAB-accredited and the North American member of IQNET, a leading international association of certification bodies and fully committed to the global IAF Cert Search database, resulting in transparency and confidence that clients can trust.

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