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# Quality management — Guidance for quality tools and their application

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# National foreword

This British Standard is the UK implementation of ISO 10009:2024.

The UK participation in its preparation was entrusted to Technical Committee QS/1/3, Quality Management - Supporting Standards.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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International Standard

# ISO 10009

First edition
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# Quality management — Guidance for quality tools and their application

*Management de la qualité — Recommandations pour les outils qualité et leur mise en oeuvre*

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# Foreword

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This document was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 3, *Supporting technologies*.

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# Introduction

The quality of products and services delivered by an organization is achieved through the processes and procedures that constitute a quality management system (QMS). The function of a QMS is, in broad terms, to enable and ensure that the resulting products and services meet the desired objectives.

Quality tools are an integral element of a QMS. This document seeks to familiarize users with a range of quality tools that potentially have useful applications in a QMS as described by ISO 9001, and to assist in the selection of quality tools appropriate to the task at hand.

In this document, the term “quality tool” is synonymous with “quality techniques”. The range of tools that could be cited is vast. Therefore, the focus of this document is on tools that have seen successful application in a wide range of activities in diverse sectors, and to draw attention to some that can be relatively less known to some users. Statistical techniques are addressed in a separate standard, ISO 10017.

This document provides a brief description of each of the selected tools to assist the user in determining whether the tool has beneficial application in a particular context. The document also provides instruction on how the tool can be used.

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# Quality management — Guidance for quality tools and their application

## 1 Scope

This document gives guidance on the selection and application of tools that can be used in a quality management system to:

a) characterize a process or a variable;

b) facilitate problem solving;

c) highlight areas for improvement;

d) improve effectiveness.

## 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9000, *Quality management systems — Fundamentals and vocabulary*

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

**3.1**
**quality tool**
**quality technique**
method or procedure to perform an operation to achieve a quality objective

## 4 Quality tools

### 4.1 General

The quality tools described in this document have been arranged in approximate alignment with the sequence of the quality system requirements of ISO 9001. This structure is intended to help the user and does not imply priority. A listing of the tools in relation to the Plan-Do-Check-Act (PDCA) approach is provided in Annex A.

Annex B gives examples of how quality tools are used together as storyboards.

Annex C provides an overview of quality tools to guide their appropriate application.

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### 4.2 Review

Each frequently used quality tool is reviewed, as applicable, including:

— a short explanation of the tool and its use within a quality system;

— how the quality tool is normally used;

— reasons to use the quality tool and guidance on its effective use.

Less frequently used tools which can be of interest are listed at the end of each clause as “Other relevant tools”.

NOTE References to the bibliography are shown by figures square brackets (e.g [27].)

## 5 Strategy

### 5.1 SWOT analysis

Strengths, weaknesses, opportunities and threats (SWOT) analysis[30-33] is a tool designed to help develop strong business strategy by consideration of key strengths, weaknesses, opportunities and threats faced when implementing the intended strategy.

SWOT is used:

— to review the impact of external and internal factors;

— to prioritize action;

— to help identify strategic options, i.e. the risks and problems to solve;

— to determine the positive points that need to be maintained, the opportunities that should be considered, and the internal and external issues that present challenges;

— to identify areas and actions to eliminate weakness.

SWOT analysis is used to:

— explore new solutions to problems;

— identify barriers that will limit achieving objectives;

— decide on the direction that will be most effective;

— reveal possibilities and limitations for change;

— prioritize actions.

Benefits and points to note for SWOT are given in Table 5.1.

**Table 5.1 — Benefits and points to note for SWOT**

| Benefits | Points to note |
|---|---|
| Focuses on actions that are most beneficial to achieve strategic objectives and sustainability. | — Should be reviewed frequently enough to recognize and react to changes. |
| Responds to new influences such as technology, legislation, market demand, etc. | — Output should be used as a basis of future actions. |
| External review includes interested parties such as competitors, customers, etc. | — Should recognize any limitations in data quality to avoid misrepresentation. |
| SWOT analysis benefits from the diversity of perspectives. Management alone will not have visibility of all interested parties’ perspectives. | — Should be carried out by the leadership team with external inputs as appropriate (not a single person). |

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## 5.2 PESTLE analysis

Political, economic, social, technological, legal and environmental (PESTLE) analysis is a tool used by an organization to determine and track the environment in which it operates. It is often used in strategic planning, sometimes with SWOT (see 5.1) and Porter's five or six forces (see 5.3).

PESTLE analysis is used:

— when developing, reviewing and updating an organization's strategic business plan;

— as a precursor to determining an organization's strategies, and risks and opportunities;

— to capture relevant external issues that impact on the organization's strategy.

Benefits and points to note for PESTLE are given in Table 5.2.

**Table 5.2 — Benefits and points to note for PESTLE**

| Benefits | Points to note |
|---|---|
| Uses a structured approach. | — Users may wish to adjust the names of some of the PESTLE factors and/or add other factors that are particularly relevant to its context. |
| Helps organizations to address factors they might not otherwise consider. | — Users should update the PESTLE information periodically to reflect incidents such as pandemic, epidemic, military situations, etc. |

## 5.3 Porter's five or six forces

Harvard Professor Michael Porter developed a strategic analysis tool[29] and also a method to understand the competing forces that organizations face.

There were originally five competing forces but a sixth was added, as follows:

1. threat of new entrants;
2. rivalry among existing firms;
3. bargaining power of buyers;
4. threat of substitute product or services;
5. bargaining power of suppliers;
6. complementors.

Porter says: "the collective strength of these forces determines the ultimate profit potential in the industry where profit potential is measured in terms of long run return on invested capital". [30]

The organization should consider the need to obtain the resources, technologies and infrastructure to support the strategic analysis activities. The importance of some competing forces can restrict opportunities to take action or experience improvements.

Porter's five or six forces model is used for analysing context to support developing strategic objectives. Benefits and points to note for Porter's five or six forces are given in Table 5.3.

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**Table 5.3 — Benefits and points to note for Porter's five or six forces**

| Benefits | Points to note |
|---|---|
| The six competing forces can provide both risk and opportunity considerations.<br>Often provides a fresh approach to strategy. | — Actions should be determined based on data gathered from reliable sources.<br>— Can be used to assess the attractiveness of the industry or sector. |

## 5.4 Vision and mission statements

### 5.4.1 Vision

A vision is the aspiration of what an organization would like to become as expressed by top management. It describes in words, or sometimes visually, how the organization wants to be perceived by the world. It can also communicate the message to the people working within it and those wanting to join it.

A vision statement should be underpinned by agreement by top management on the following three key elements:

a) the strategic goal of satisfying customers and other interested parties, e.g. what are the planned products, now and in the future and how they will be delivered;

b) the unique market it wants to secure;

c) the future horizon, e.g. the future state or end point.

### 5.4.2 Mission

A mission is the reason for the organization's being or existence as expressed by top management, what the organization does, the core competence and what it is known for. This is sometimes called a "purpose".

A mission statement:

a) gives unanimity of purpose to the organization;

b) provides a basis to derive goals and objectives;

c) provides an answer to the question: "Does this activity contribute to the organization's purpose?".

Vision and mission are used to communicate effectively at the highest level with customers, employees and other interested parties. Benefits and points to note for vision and mission statements are given in Table 5.4.

**Table 5.4 — Benefits and points to note for vision and mission statements**

| Benefits | Points to note |
|---|---|
| Provides common goals to guide all planning and direction activities.<br>Frames the values, beliefs, principles and governance disciplines and behaviours.<br>Provides a basis for distilling a complex strategy to a "plan-on-a-page". | — Should be simple and easy to communicate. |

## 5.5 Other relevant tools

Other relevant resources include the following:

— context of the organization (COTO) diagram/matrix/log;

— ISO/PAS 24644-1

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— committee of sponsoring organizations framework (COSO) shown in Figure 1.

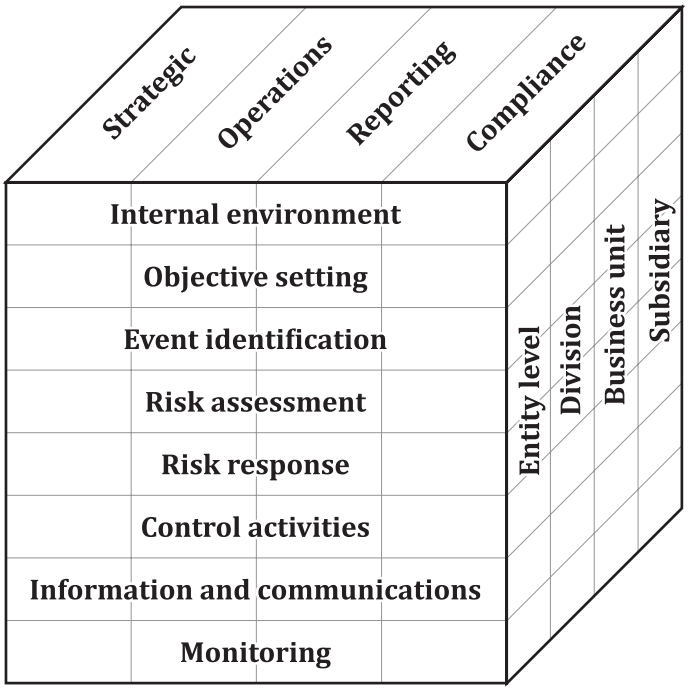


**Figure 1 — COSO**

# 6 Process approach and planning

## 6.1 SIPOC/COPIS (useful for identifying processes)

SIPOC (supplier, input, process, output, customer) is a process mapping tool that is useful in the high-level identification of the main elements of any process. COPIS is the process in reverse and is useful for identifying "customer-facing processes". It may be used to obtain high-level information about any process, and to identify inputs and outputs between suppliers, process owners and customers. It is a tool used for understanding the bounds of a process and the linked processes, related controls and how effectiveness is managed.

SIPOC is used for:

— mapping an existing or a new process;

— providing basic information regarding a process in a simple and short format;

— defining the scope of an improvement activity or project.

Benefits and points to note for SIPOC and COPIS are given in Table 6.1.

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**Table 6.1 — Benefits and points to note for SIPOC/COPIS**

| Benefits | Points to note |
|---|---|
| Simple to use and understand. | — Avoid going into too much detail (four to five key steps of the process should be identified). |
| Delivers results quickly. | — Should be completed by a team, so there is a common agreement on the start and the end of the process being analysed. |
| Provides an overview of the whole process from the beginning to the end on one page. | — Suppliers and customers can be internal.<br>— SIPOC can be hierarchical. |

## 6.2 Turtle diagram

A turtle diagram is a tool for visualizing the components or characteristics of a process. It provides the opportunity to examine a process more closely for better understanding, more effective execution and identification of areas for improvement. The diagram (see Figure 2) looks like a turtle, with the process components as the body, legs, head, and tail.

A turtle diagram is used:

— to describe the basic elements of a process for communication and understanding;

— to develop more detailed procedures and process flow diagrams (flow charts);

— to help auditors to understand and effectively assess processes.

Benefits and points to note for turtle diagrams are given in Table 6.2.

**Table 6.2 — Benefits and points to note for turtle diagrams**

| Benefits | Points to note |
|---|---|
| Uses visual and standardized methods which are easy to understand.<br>Provides a complete view of the most important elements of a process on a single page.<br>Aligns process performance to higher level business strategy and objective(s). | — The turtle diagram does not necessarily document all of the information necessary to fully describe a process, but provides a good starting point. |

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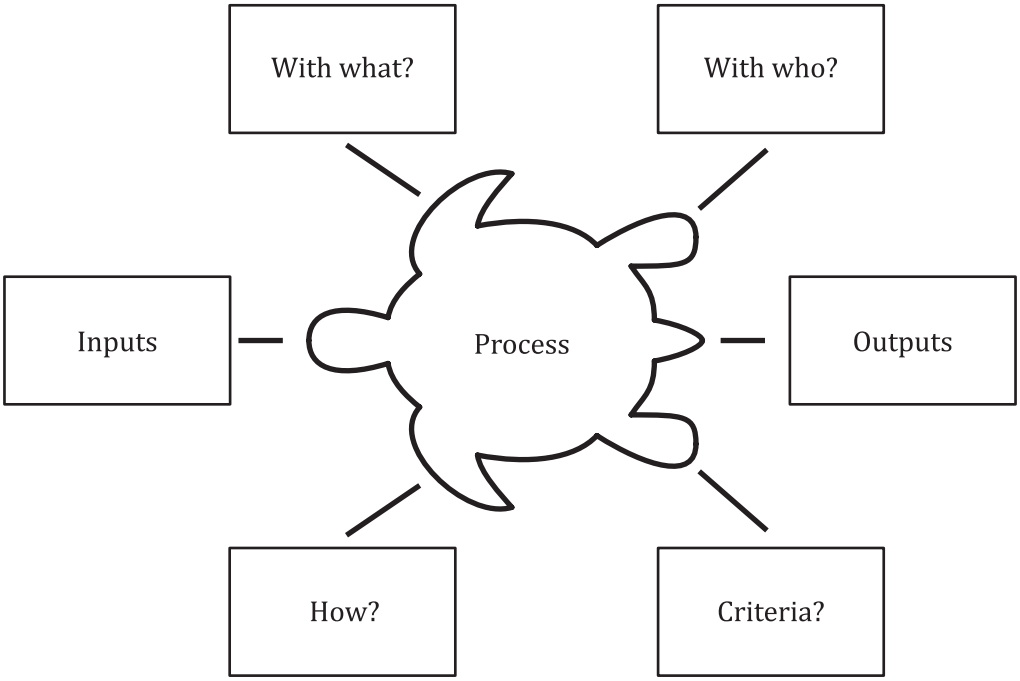


**Figure 2 — Turtle diagram**

## 6.3 Control plan

A control plan provides a structured approach to determining the controls applied to a process. Each process is listed in sequential order, typically aided by the use of a process flow diagram. Product and process criteria to be controlled are identified at each stage including special characteristics, typically using a process failure modes and effects analysis (FMEA) as an input. Controls are identified with methods of measurement, frequency, method of recording results and the reaction plan to be invoked in the event that the product or process criteria do not conform with requirements.

The objective of a control plan is to provide concise and useable information to users and minimize process and product variation.

Control plans are used:

— within manufacturing and service industries;

— where there are processes where the conformity of the resultant output cannot be verified through inspection and testing and defects would only become apparent at a later time;

— where needed for process approval on the pre-launch and production phase, with linkage and information from the design risk analysis (as necessary);

— where process/product monitoring is required to determine process capability or to assess conformity to requirements.

Benefits and points to note for control plans are given in Table 6.3.

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**Table 6.3 — Benefits and points to note for control plans**

| Benefits | Points to note |
|---|---|
| Provides a clear and structured approach to product and process control. | — Product and process characteristics should be unambiguously defined. |
| Assists in effective auditing. | — Process flows, FMEA and control plans should be reviewed and updated when nonconformities occur. |
| Helps drive conformity in processes which cannot be verified through inspection. | — The control plan does not replace work instructions which provide greater detail of the manufacturing process. |

## 6.4 Flow diagram/swim lane diagram/cross-functional flow chart

Flow charts provide a quick, visual way to show how a series of activities, tasks or processes are sequenced. [3,34,35] Swim lane diagrams (see Figure 3) add the responsibilities for activities shown on a simple flow chart.

ISO 5807:1985, 3.3 defines a flow chart as a "graphical representation of the definition, analysis, or method of solution of a problem in which symbols are used to represent operations, data, flow, equipment, etc."

In practice, they comprise symbols, text and connecting lines.

They are used:

— as a starting point in documenting activities;

— to communicate how activities are carried out;

— to identify inefficiencies and allow for analysis and improvement.

Benefits and points to note for flow charts, swim lane diagrams and cross-functional flow are given in Table 6.4.

**Table 6.4 — Benefits and points to note for flow charts/swim lane diagrams/cross-functional flow**

| Benefits | Points to note |
|---|---|
| Visual | — The direction of flow is mainly left to right, and top to bottom. |
| Can be quick to develop (depends on the complexity of the activities under consideration). | — Arrows indicating the flow should be used whenever increased clarity will result. |
| Easy for non-experts to interpret. | — Considers the position of the reader. |
| Assists in the automation and or digitalization of processes. | — Tries to anticipate the reader's problems in understanding the chart. |
| | — Swim lane diagrams (see Figure 3) are a type of flow chart which use lines (or other methods, such as shaded rectangles) to separate activities done by different departments or persons. The name comes from their appearance which looks like the lanes in a swimming pool used for competition. |
| | — Not to be confused with block diagrams which use only one shape (a block or rectangle). |
| | — Not to be confused with process charting (e.g. Graham Process Charting) which uses different symbols. |

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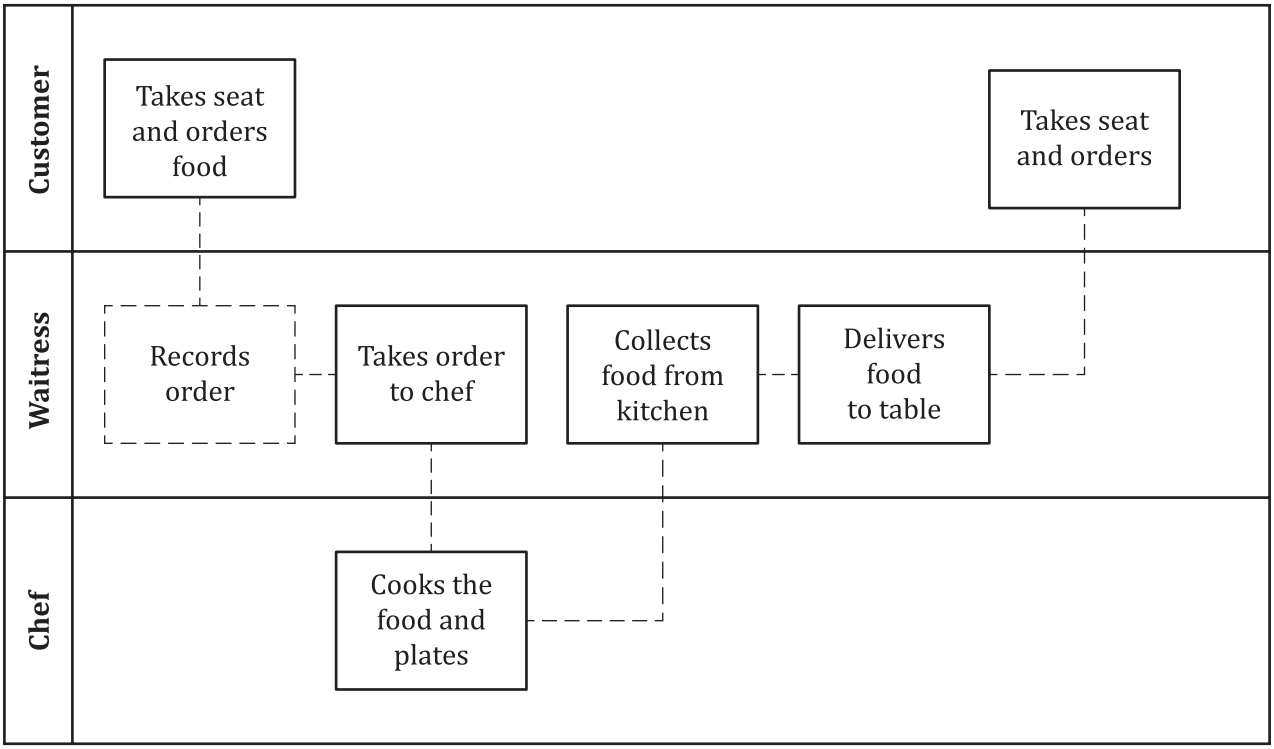


**Figure 3 — Swim lane diagram**

## 6.5 Authority matrix/RACI/RASCI

The term "authority matrix" covers a range of uses for a basic matrix that has persons (or functions) on one axis and responsibilities on the other.

When used for financial compliance, it is usually referred to as a "delegated authority matrix".

It shows the level of engagement or decision-making authority in an organization. RAC(S)I [meaning responsible, accountable, consulted, (supporting) and informed] can be used for identifying and communicating changes as necessary.

RACI/RASCI is used to clearly show responsibilities:

— responsible: the person(s) doing the work in the process;

— accountable: the member of management assigned to the process;

— consulted: other interested parties with potential input to the process or affected by outputs;

— supporting: interested parties with inputs only (e.g. IT department / engineering / laboratory);

— informed: parties who are kept informed but not directly involved.

Benefits and points to note for authority matrix/RACI/matrix diagram are given in Table 6.5.

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**Table 6.5 — Benefits and points to note for authority matrix/RACI/matrix diagram**

| Benefits | Points to note |
|---|---|
| Focuses on effective collaboration and decision-making by removing ambiguity.<br>Uses a graphical format.<br>Shows relationships between persons (or functions) in, or across, processes.<br>Supports team-building.<br>Can be used to map current-state to future-state for authorities, etc. | — Should be linked to job descriptions and updated as necessary |

## 6.6 Other relevant tools

Other relevant resources include the following:

— the IDEF0 Functional Modelling method, which was designed to model the decisions, actions and activities of an organization or system;[3][36]

— quality plans (see ISO 10005);

— advanced process and quality plan (APQP);[19,20]

— success path method (SPM).[38,39]

# 7 Risk and opportunity

## 7.1 SWIFT

The Structured What If Technique (SWIFT) is a flexible, high-level risk identification technique that may be used on a standalone basis, or as part of a staged approach to make more efficient the use of bottom-up methods such as FMEA (see 7.3).

SWIFT is used in risk assessment where a series of brainstorming prompts are used for each step of the process or component of the system being assessed. Each prompt helps to consider different types of hazards that can be present in the system.

EXAMPLE A HAZOP analysis is an example of a SWIFT.

Benefits and points to note for SWIFT are given in Table 7.1.

**Table 7.1 — Benefits and points to note for SWIFT**

| Benefits | Points to note |
|---|---|
| Structured. SWIFT can overcome the self-censorship that occurs in the brainstorming in an unstructured group, allowing members of the group to think the unthinkable. | — The process or system should be mapped out using no more than 10 steps or components (or use a P+ID). |
| Simplicity. It does not go into the same level of detail as FMEA (see 7.3) does on the process steps to be risk assessed. | — SWIFT may be used by itself, or as part of a staged approach. |

## 7.2 Risk register/risk assessment

A risk register is used to identify, prioritize, record and monitor the actions to be taken on the identified risks. A risk register is displayed in tabular format describing each risk, its nature or type, the probability of occurrence, its impact on the organization, the risk owner, mitigation measure(s), contingency action(s) and the residual risk after mitigation.

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Inputs to the risk register may come from sources such as SWOT (see 5.1), PESTLE (see 5.2) or FMEA (see 7.3). Outputs may inform improvements, objectives, human resources development, etc.

Benefits and points to note for risk register/risk assessment are given in Table 7.2.

**Table 7.2 — Benefits and points to note for risk register/risk assessment**

| Benefits | Points to note |
|---|---|
| Displays information on current risks in a single document which is easy to navigate and understand. | — It should to be regularly monitored and kept up to date. |
| Defining risks can also present opportunities for the organization. | — The use of risk priority numbers (RPN) to evaluate risks may be used as a tool to prioritize risk impact. Sometimes a cost is associated with risks and linked to insurances, contingencies or liabilities.<br>— It is often structured by categories such as financial/human resources/regulatory / customer, etc. |

## 7.3 Failure mode and effects analysis (FMEA)

FMEA[18,21,22] is a risk-based methodology for ensuring that potential problems are identified, analysed and prioritized during product or process development, and during subsequent production or service delivery and product life cycle.

Variants of the tool can be seen in:

— design (DFMEA);

— manufacturing process (PFMEA);

— design review based on failure mode (DRBFM);

— tooling;

— software;

— service design;

— service delivery;

— monitoring systems.

Benefits and points to note for FMEA are given in Table 7.3.

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**Table 7.3 — Benefits and points to note for FMEA**

| Benefits | Points to note |
|---|---|
| Enables early identification and mitigation of problems.<br>Reduces risk of late design or process changes.<br>Reduces risk of field failures and warranty costs.<br>Reduces risk of problems during production or service delivery.<br>Focuses on actions which address the most significant risks with a priority on occurrence reduction, and where possible elimination of high severity failure modes (the severity of a failure mode cannot be reduced but it can be possible to design it out). | — FMEA is a team-based activity.<br>— FMEA is a living document and should be updated when there are unexpected issues.<br>— There should be no incentive to score low to avoid high RPNs (risk priority numbers)/action priority and any need for action.<br>— The scoring criteria should use a scale where there are clear criteria for each point on the scale.<br>— The methodology considers only single failure modes and is not suitable for compound failure modes.<br>— Preparation is vital. Documented process flows or system schematics should be available or created at the start of the process.<br>— Sufficient time and resources should be allocated to the team.<br>— Facilitator competence in FMEA and team selection are critical to effectiveness.<br>— The team should represent all functions involved (and can include the customer). |

## 7.4 Traffic light/heat map

The colours red, amber and green are used to illustrate whether a situation or risk is satisfactory/unsatisfactory or high/low or positive/negative. This is often on a severity versus frequency matrix called a "heat map". This is sometimes referred to as RAG (red, amber, green).

It is used in situations such as:

— reports referencing key performance indicators (KPIs);

— risk analysis/registers;

— warning signs;

— dial gauges;

— safety signals;

— andon.[89,90]

Benefits and points to note for traffic light/heat maps are given in Table 7.4.

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**Table 7.4 — Benefits and points to note for traffic light/heat maps**

| Benefits | Points to note |
|---|---|
| Simple to use | — Care should be used with heat maps which are symmetrical as actual severity consequences can bias the outcome. |
| Easy to understand | — The colours are used to attract attention, but an indicator can change colour with a small change in data. |
| Supported by programs such as Microsoft Excel (conditional formatting). | — Will not be effective if a person is colour-blind. |
| [a] Excel is the trademark of a product supplied by Microsoft. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of the product named. Equivalent products may be used if they can be shown to lead to the same results. | |

## 7.5 Other relevant tools

Other relevant resources include the following:

— success path method (SPM);[38,39]

— failure mode, effects, and criticality analysis (FMECA);

— FMEA for monitoring and system response (FMEA-MSR).

# 8 Objectives and objective management

## 8.1 Kaizen

Kaizen means continual improvement by setting targets higher than the current level. When applied to the workplace, Kaizen means continual improvement for all human resources: managers and workers alike. Kaizen is a systematic and long-term action aimed at accumulating improvements and savings by achieving performance improvement through changes or small incremental improvements in the processes.

Kaizen may be used for any improvement project.

Benefits and points to note for Kaizen are given in Table 8.1.

**Table 8.1 — Benefits and points to note for Kaizen**

| Benefits | Points to note |
|---|---|
| Standardization<br>Waste elimination<br>Cost reduction<br>Performance improvement - See Do Check Act (SDCA)<br>— First step is to standardize or follow the procedure if in place.<br>— Then Do, Check and Act and repeat. | — Kaizen should be an ongoing process and should not be practised on an ad hoc basis as its philosophy is based on continual improvement.<br>— Changes may come from any employee anytime and are not required to happen slowly.<br>— Following the SDCA cycle, an initial 15 % improvement is possible. |

## 8.2 Hoshin Kanri (also known as the “X-matrix”)

Translated from Japanese as “compass management”, Hoshin Kanri is a seven-step process to assist organizations to chart a course and realize their strategic objectives.

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