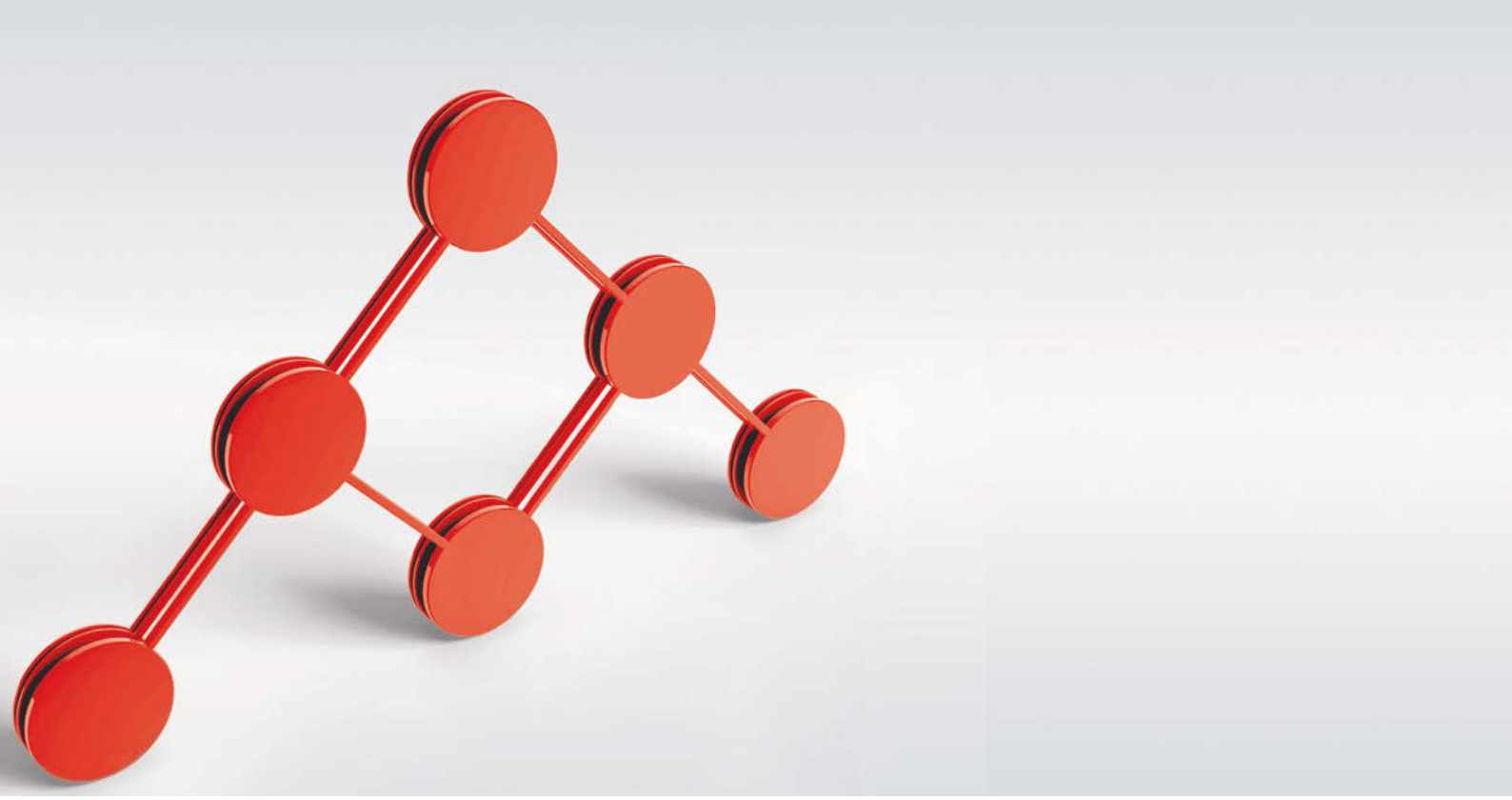

Introducing Annex SL Whitepaper

The new high level structure for all management system standards of the future

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Overview and background

Over the years ISO has published many management system standards for topics ranging from quality and environment to information security and business continuity management. In the past, despite sharing common elements, ISO management systems standards have all had different structures. This, in turn, results in some confusion and difficulties at the implementation stage.

In order to understand the importance of structure in management system standards, we will take a step back and look at ISO's definition of a management system and some of the benefits of implementing an effective management system. ISO defines a management system as a set of procedures an organization needs to follow in order to meet its objectives. A management system standard provides a model to follow when setting up and operating a management system.

Why a new high-level structure?

Most organizations have more than one management system standard to implement and certify. Doing this individually takes up a lot of extra time and resources, so there is a clear need to find a way of integrating and combining the standards in the best possible way. The management system standards to date each presents different structures, requirements and terminology, so integration has proved challenging.

In order to address this problem, ISO developed Annex SL – the framework for a generic management system and the blueprint for all new and revised management system standards going forward. To address industry specific needs, additional requirements for individual sectors will be added to this generic framework.

How will this affect organizations?

This high level structure will be rolled out across all new and revised management system standards to ensure consistency and compatibility. With Annex SL in place, management system implementers can look forward to less conflicts, duplication, confusion and the misunderstandings that took place as a result of different management system standard structures.

Management system auditors will now use a core set of generic requirements across disciplines and industry sectors.

More about Annex SL

All management system standards of the future will have the same high level structure, identical core text, as well as common terms and definitions. Whilst the high level structure cannot be changed, sub-clauses and discipline-specific text can be added.

Annex SL applies to all management system standards, such as full ISO standards, Publicly Available Specifications (PAS) and Technical Specifications (TS). Annex SL's high level structure contains 10 clauses:

Clause 1:	Scope
Clause 2:	Normative references
Clause 3:	Terms and definition
Clause 4:	Context of the organization
Clause 5:	Leadership
Clause 6:	Planning
Clause 7:	Support
Clause 8:	Operation
Clause 9:	Performance evaluation
Clause 10:	Improvement

Clause 1: Scope

The scope sets out the intended outcomes of the management system. The outcomes are industry specific and should be aligned with the context of the organization (clause 4).

Clause 2: Normative references

Provides details of the reference standards or publications relevant to the particular standard.

Clause 3: Terms & definitions

Details terms and definition applicable to the specific standard in addition to any formal related terms and definitions standard.

More about Annex SL

Clause 4: Context of the organization

Clause 4 consists of four sub-clauses:

4.1 Understanding the organization and its context

4.2 Understanding the needs and expectations of interested parties

4.3 Determining the scope of the management system

4.4 The management system

As the flagstone of a management system, clause 4 determines why the organization is here. As part of the answer to this question, the organization needs to identify internal and external issues that can impact on its intended outcomes, as well as all interested parties and their requirements. It also needs to document its scope and set the boundaries of the management system – all in line with the business objectives.

Clause 5: Leadership

Clause 5 comprises three sub-clauses:

5.1 Leadership and commitment

5.2 Policy

5.3 Organizational roles, responsibilities and authorities

The new high level structure places particular emphasis on leadership, not just management as set out in previous standards. This means top management now has greater accountability and involvement in the organization's management system. They need to integrate the requirements of the management system into the organization's core business process, ensure the management system achieves its intended outcomes and allocate the necessary resources. Top management is also responsible for communicating the importance of the management system and heighten employee awareness and involvement.

Clause 6: Planning

Clause 6 includes two sub-clauses:

6.1 Actions to address risks and opportunities

6.2 Management system objectives and planning to achieve them

Clause 6 brings risk-based thinking to the front. Once the organization has highlighted risks and opportunities in clause 4, it needs to stipulate how these will be addressed through planning. The planning phase looks at what, who, how and when these risks must be addressed. This proactive approach replaces preventative action and reduces the need for corrective actions later on. Particular focus is also placed on the objectives of the management system. These should be measurable, monitored, communicated, aligned to the policy of the management system and updated when needed.

Clause 7: Support

Clause 7 consists of five sub-clauses:

7.1 Resources

7.2 Competence

7.3 Awareness

7.4 Communication

7.5 Documented information

After addressing the context, commitment and planning, organizations will have to look at the support needed to meet their goals and objectives. This includes resources, targeted internal and external communications, as well as documented information that replaces previously used terms such as documents, documentation and records.

Clause 8: Operation

Clause 8 has one sub-clause:

8.1 Operational planning and control

The bulk of the management system requirements lies within this single clause. Clause 8 addresses both in-house and outsourced processes, while the overall process management includes adequate criteria to control these processes, as well as ways to manage planned and unintended change.

Clause 9: Performance evaluation

Clause 9 is formed of three sub-clauses:

9.1 Monitoring, measurement, analysis and evaluation

9.2 Internal audit

9.3 Management review

Here organizations need to determine what, how and when things are to be monitored, measured, analyzed and evaluated. An internal audit is also part of this process to ensure the management system conforms to the requirements of the organization as well as the standard, and is successfully implemented and maintained. The final step, management review, looks at whether the management system is suitable, adequate and effective.

Clause 10: Improvement

With two sub-clauses in place, Clause 10 looks at how non-conformities and corrective actions should be managed:

10.1 Non-conformity and corrective action

10.2 Continual improvement

In an ever-changing business world, not everything always goes according to plan. Clause 10 looks at ways to address non-conformities and corrective action, as well as strategies for improvement on a continual basis.

.....core text, common terms and definitions to aid integration.....

The benefits of using management system standards

Using standards can provide a number of key benefits to an organization:

Improved business performance

Using standards ensures all business processes are integrated and aligned with the business strategies of the organization. Used as a business management tool, this will improve performance, remove complexity, drive real value and embed continual improvement.

Improved risk and opportunity management

The requirements to identify risks and opportunities affecting an organization ensures they are managed more effectively thereby improving operational efficiency, reducing duplication, saving both time and money.

Enhanced reputation

Adopting a standard sends a clear message to existing and prospective customers that the organization is taking a leading, innovative and proactive approach to managing the business.

Increased efficiency

By providing a robust framework and focus, standards can increase operational efficiency, reducing expensive mistakes thereby saving time and money.

Increased engagement

By adopting a management system, an organization can ensure all employees are working to common goals driven from the business strategy.

Improved integration

The new common structure for all management system standards will ensure that integration of more than one system will be smoother, without investing a lot of extra time and money.

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ISO Revisions

ISO Revisions Whitepaper

The importance of leadership in the new ISO standards

Approaching change

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Background and overview to ISO Management system standards

ISO has over the years published many management system standards for topics ranging from quality and environment to information security, business continuity management and records management. Despite sharing common elements, ISO management system standards all have different structures. This, in turn, results in some confusion and difficulties at the implementation stage.

To help make the implementation process smoother, ISO has completed work to provide an identical structure, core text, common terms and definitions for management system standards of the future. This will ensure consistency among future and revised management system standards and make integrated use simpler. It will also make the standards easier to read and, in so doing, be understood by users.

Introducing Annex SL

ISO technical committees developing management system standards have to follow Annex SL. Annex SL harmonizes structure, text and terms and definitions, while leaving the standard's developers with the flexibility to integrate their specific technical topics and requirements.

The timetable for the core management system standards to be published in the Annex SL format is as follows:

- ISO 14001 revision: Quarter 3 2015
- ISO 9001 revision: Quarter 4 2015
- ISO 45001: Quarter 4 2016

ISO 27001 for information security has already been published using this format.

A brief overview of Annex SL's high-level structure

The new high level structure of Annex SL which will be adopted in the new version of ISO 9001, ISO 14001 and all new ISO management system standards is outlined below:

Clause 1	Scope
Clause 2	Normative references
Clause 3	Terms and definition
Clause 4	Context of the organization
Clause 5	Leadership
Clause 6	Planning
Clause 7	Support
Clause 8	Operation
Clause 9	Performance evaluation
Clause 10	Improvement

Annex SL and its new structure should not present concerns for those organizations that have embraced the management system philosophy, but could present a challenge for those that have certification for the 'badge on the wall'.

For example: There is increased reference to "organizational" context - the need to demonstrate an understanding of the internal and external issues that impact on the business. These clauses are closely linked to "leadership" which require that the management system is not held at arm's length by management, but is linked to the strategic direction of the business. This means the business has to align its processes effectively.

So Annex SL should assist management system managers by:

1. Raising the standards in the boardroom
2. Aligning standards with the needs of the business.

Why is **leadership** important in today's business environment?

Leadership, the ability to motivate groups of people towards a common goal, is an important skill in today's business world. Without strong leadership, many otherwise good businesses fail.

Many of the world's most respected leaders have several personality traits in common. Some of the most recognizable traits are the ability to initiate change and inspire a shared vision, as well as knowing how to "encourage the heart" and model the skills and behaviours that are necessary to achieve the stated objectives. Good leaders must also be confident enough in themselves to enable others to contribute and succeed.

The difference between leadership and management

Management is mostly about processes. Leadership is mostly about behaviour.

Management relies heavily on tangible measurable capabilities such as effective planning; the use of organizational systems; and the use of appropriate communications methods.

Leadership instead relies most strongly on less tangible and less measurable things like trust, inspiration, attitude, decision-making, and personal character. These are all necessary to motivate an organization to achieve its management systems objectives.

How is leadership being incorporated into today's new ISO standards?

Firstly let's understand how Leadership is defined by ISO.

'Leadership is the person or group of people who directs and controls an organization at the highest level. Top management has the power to delegate authority and provide resources within the organization. If the scope of the management system covers only part of an organization, then top management refers to those who direct and control that part of the organization.'

Defining the responsibilities of leadership according to Clause 5

This states that top management shall demonstrate leadership and commitment ... by ensuring:

- the policy and objectives are established for the management system and are compatible with the strategic direction and the context of the organization. Please note the Context of the organization, clause 4, is a new requirement compared to the current version and leadership will have to demonstrate an understanding of the business environment and its impact on the organization;
- the policy is communicated, understood and applied within the organization;
- the integration of the management systems requirements into the organization's business processes and promoting the process approach;
- the resources needed for the management system are available;
- the management system achieves its intended results;
- taking accountability of the effectiveness of the management system;
- communicating the importance of an effective management system and of conforming to the management system requirements;
- engaging, directing and supporting persons to contribute to the effectiveness of the management system;
- promoting continual improvement and innovation;
- supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

Leadership and policy

Leadership needs to establish, review and maintain a policy, but also needs to ensure that it is applied within the organization.

Roles and responsibilities

Leadership needs to ensure that responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization.

Organizational change

Leaders need to ensure - the integrity of the management system is maintained when changes are planned and implemented.

Some of the above tasks will of course be delegated, but it is the management's responsibility to ensure they are planned, implemented and achieved.

What are the **benefits**?

Let's look at what is said about leadership by ISO as one of the 8 or now 7 quality management principles that underpin existing management systems.

Leaders establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization's objectives.

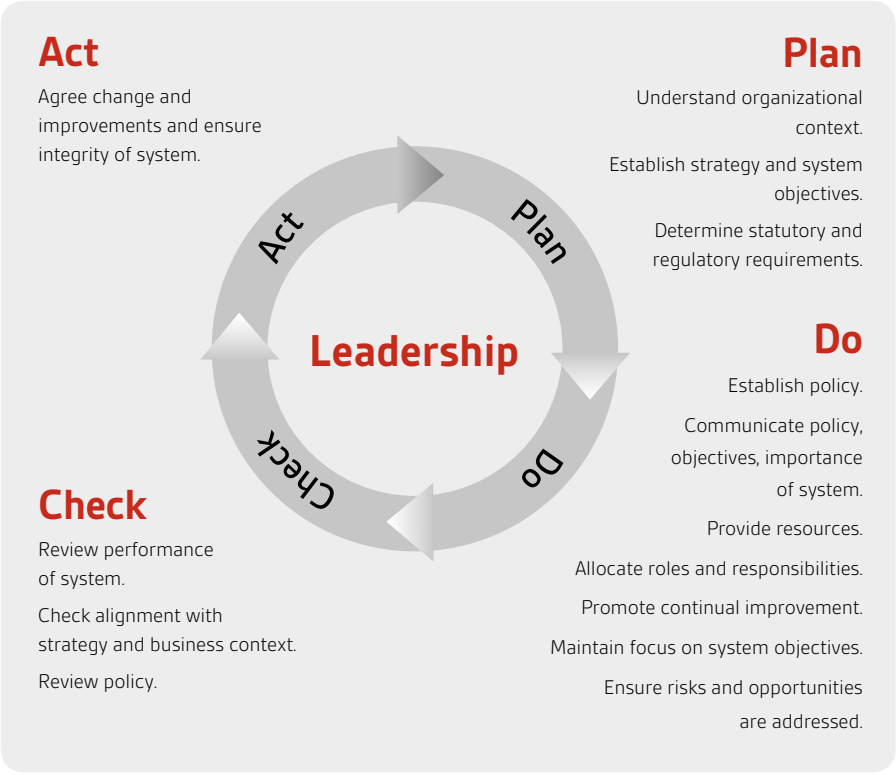
Applying the principle of leadership typically ensures that:

- People will understand and be motivated towards the organization's goals and objectives
- Activities are evaluated, aligned and implemented in a unified way
- Miscommunication between levels of an organization will be minimized
- A clear vision of the organization's future is established
- Challenging goals and targets are set
- Shared values, fairness and ethical role models are established at all levels of the organization
- Trust is established and fear is eliminated
- People are provided with the required resources, training and freedom to act with responsibility and accountability
- People are inspired, encouraged and their contributions are recognized.

What does this mean for organizations and how can they prepare?

The major additional or strengthened requirements for leadership compared to the existing management system standard requirements are:

1. The ability to demonstrate an understanding of the business environment and how it impacts on the organization's strategy. The system objectives need to be compatible with this strategy and set at relevant levels within the organization. The organization needs to be able to demonstrate alignment between system objectives and its strategic direction.
2. Ensuring they have identified the significant risks that can have an impact on the achievement of the system objectives, for instance customer satisfaction in the case of ISO 9001.
3. Review the approach to process identification and management and ensure there are clear responsibilities and authorities defined for those processes. How the processes contribute to the achievement of the system objectives needs to be clearly identified. Measures need to be established.
4. Internal communication channels need to be reviewed for their effectiveness and the policy needs to be applied within the organization.



5. The process for managing change and improvement within the organization should be reviewed and leaders need to ensure that the effectiveness of the system is maintained during improvement and other organizational changes.

Many of the leadership responsibilities are contained in the standard text of Annex SL. So the principles and requirements for the other management system standards will be very similar, but with a changed focus to for instance environmental management or health and safety management.

Next steps

After the formal publication of ISO 14001 and ISO 9001 in 2015, there will be a 3-year transition period for certified organizations. However, early planning is advisable so:

- Please talk the transition through with your BSI Client Manager at the next visit.
- Obtain a copy of the Draft International standard at http://shop.bsigroup.com
- Look out for and attend BSI seminars and training courses on the revision.
- Review your current approach to leadership as contained in the draft and identify the gaps.
- Create an implementation plan and monitor progress.
- Continually check BSI's dedicated web pages for the latest news and resources on **bsigroup.com/isorevisions**

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ISO Revisions Whitepaper

What is the difference between a procedures and a process approach?

Approaching change

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Process vs procedures: What does this mean?

The concept of process management was first introduced to the ISO 9001 series in the 2000 version of the international standard.

Whilst recognized by the experts on the standards committee as a key component of an effective management system, it caused many organizations problems with its introduction. Even now, with many organizations having certificates to confirm they meet the requirements of the standard, their approach to process can often be described as 'immature'.

ISO is not alone in recognizing the significance of process management. It is also at the heart of the EFQM Excellence Model and Baldridge Award schemes and reducing process variation is the focus of Six Sigma initiatives. Process management is also equally applicable to service and manufacturing organizations.

It can be argued that the achievement of an organization's objectives is critically affected by the performance of its people and its processes, and that successful organizations manage both effectively.

To begin to explain the approach, it may be useful to take a step backwards and reflect on the difference between policies, processes and procedures, which is often a source of confusion.

Policies

These are the guidelines that drive the organization and its processes and procedures. They may be supported or influenced by defined standards or regulations.

Processes are a high level view of the organization's activities. The key tasks within the overall process are identified. Process descriptions usually refer to several individuals or teams as processes tend to flow across the organization. ISO defines a process as a set of interrelated or interacting activities which transforms inputs into outputs. So every process will have a clearly identified input and output, and depending on whether these are internal or external, there will also be a customer or set of customers.

Procedures are the detailed steps that describe how a process step will be performed.

Understanding the process approach

This guide provides an understanding of the concepts, intent and the application of the "process approach". It also may be used to apply the process approach to any management system regardless of the type or the size of the organization. This includes, but is not limited to, management systems for:

- Environment (ISO 14000 family)
- Occupational Health and Safety
- Business Risk
- Social Responsibility

A process approach is a powerful way of organizing and managing activities to create value for the customer and other interested parties.

Organizations are often structured into a hierarchy of functional units and usually managed vertically, with responsibility for the intended outputs being divided among the functional units.

The end customer is not always visible to all involved. Consequently, problems that occur at the interface boundaries between functions and teams are often given less priority than the short-term goals of the units. The process approach introduces horizontal management, crossing the barriers between different functional units and unifying their focus to the main goals of the organization.

Shown below is a typical process used in many organizations to bring a new product to market. It typically involves several functions and teams, all who are critical to achieving an effective process.

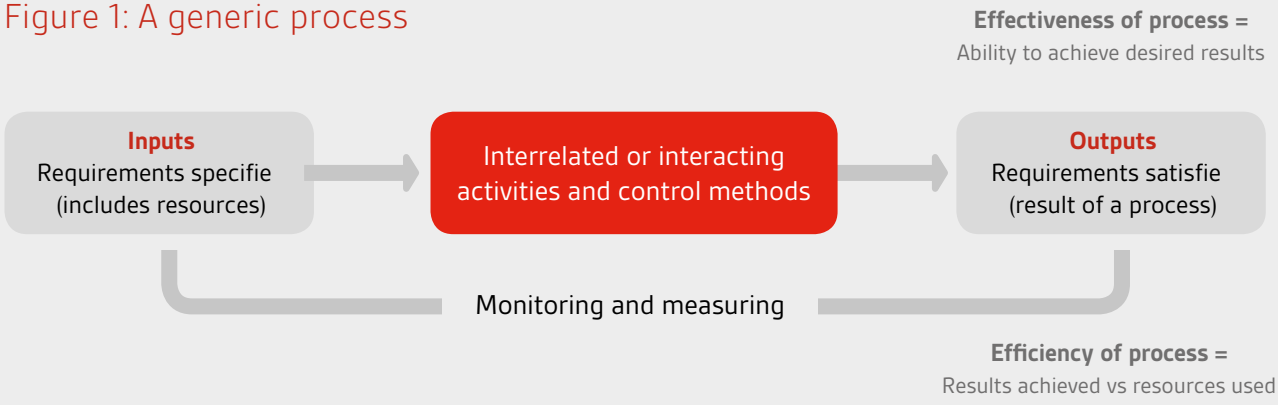
A successful new product launch requires each of the departments to operate collaboratively with a common view of what success looks like. The reality is that often individual departmental goals and priorities take precedent. That is why managing the process and giving ownership can achieve the focus required to make the process successful.

Typical process: Bringing new products to market

Process vs procedures: What does this mean?

Since "process" is a "set of interrelated or interacting activities, which transforms inputs into outputs", it is important to note that these activities require the allocation of resources such as people and materials. In the example below, the input is a customer need, while the output is a new product or service. Figure 1 shows a generic process.

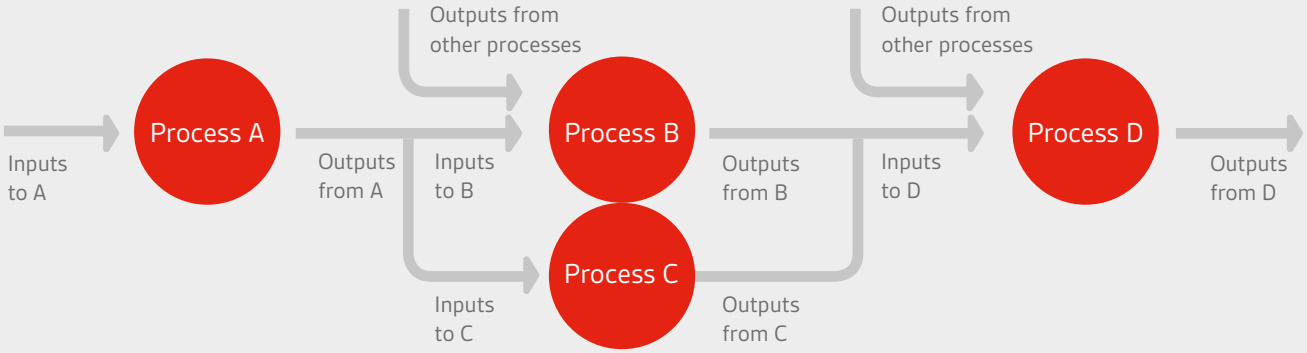
Figure 1: A generic process



Inputs and intended outputs may be tangible (such as equipment, materials or components) or intangible (such as energy or information). Outputs can also be unintended, such as waste or pollution.

Often the outputs from one process can be the inputs of other processes and are interlinked into the overall network or system.

Figure 2: Interlinked process



A system should be used to gather data to provide information about process performance, which should then be analyzed to determine if there is any need for corrective action or improvement.

All processes should be aligned with the objectives, scope and complexity of the organization, and should be designed to add value to the organization.

Types of processes

Organizations have to define the number and types of processes needed to fulfil their business objectives. While these will be unique to each organization, it is however possible to identify typical processes, such as:

Processes for the management of an organization. These include processes relating to strategic planning, establishing policies, setting objectives, enabling communication, as well as ensuring the availability of resources for the other organization's quality objectives, desired outcomes and management reviews.

Processes for managing resources. These include all the processes that are necessary to provide the resources needed for the organization's quality objectives and desired outcomes.

Operational processes. These include all processes that provide the desired outcomes of the organization.

Measurement, analysis and improvement processes. These include the processes needed to measure and gather data for performance analysis and improvement of effectiveness and efficiency.

Looking at the process-based approach in revised standards

Over the years, ISO has developed a range of management system standards for topics such as quality, environment, information security, as well as business continuity and records management.

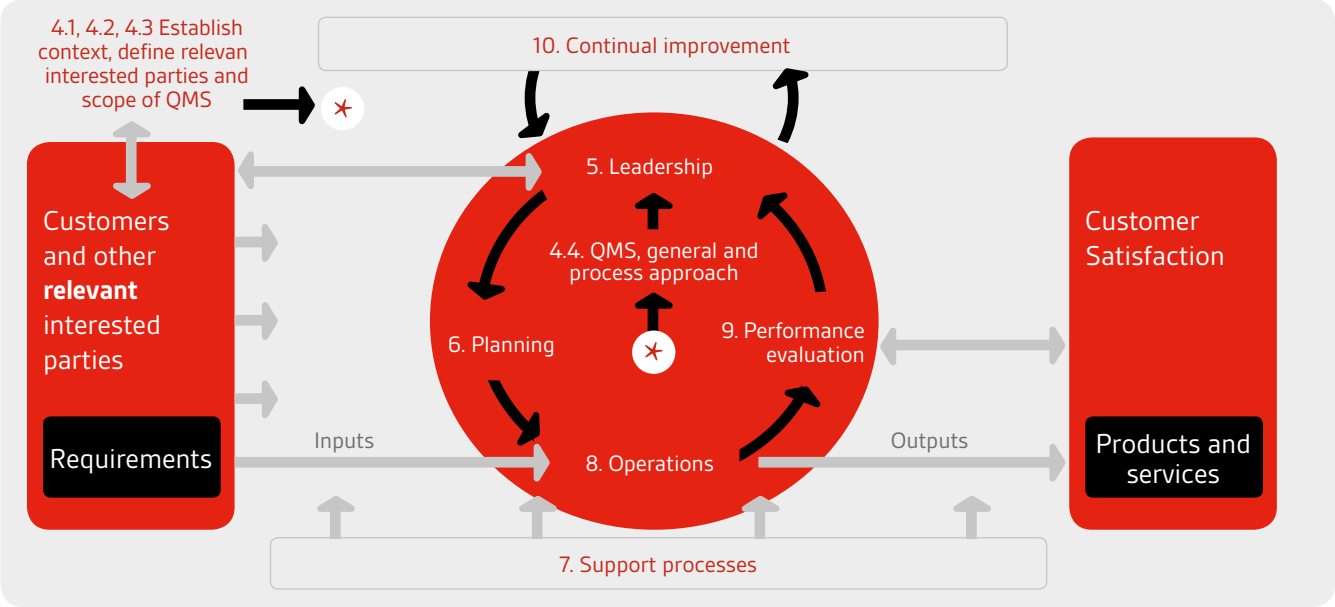
These management systems all have very different structures, despite sharing certain commonalities, which can make the implementation phase difficult and complex. To tackle this challenge, ISO has looked at ways to create an identical structure, text, common terms and definitions for management system standards of the future. The framework they developed is called Annex SL, and with its new high level structure (as set out in the table to the right), will bring consistency amongst future and revised management system standards:

Clause 1	Scope
Clause 2	Normative references
Clause 3	Terms and definitions
Clause 4	Context of the organization
Clause 5	Leadership
Clause 6	Planning
Clause 7	Support
Clause 8	Operation
Clause 9	Performance evaluation
Clause 10	Improvement

ISO 9001 Draft International Standard (DIS) contains a useful model of the clauses in Annex SL – all arranged as a process-based system.

Adopting the new framework should not be challenging for organizations that have embraced the management system philosophy, but could be a concern for those that have certification for the badge on the wall. With increased reference to "organizational" context, future management systems should be linked to the strategic direction of the business. This means an organization has to align all its processes effectively.

Figure 3: Clauses in Annex SL



How will this affect organizations?

First let's take a look at some of the specific clauses or references to process in Annex SL.

4.4 XXX management system

(Xxx allowing each committee, environment, quality etc. to insert their own description)

The organization shall establish, implement, maintain and continually improve an XXX management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard.

This is further expanded in ISO 9001:2015 DIS by adding requirements such as:

- Determining the inputs required and the outputs expected from **each process**
- Determining the sequence and interaction of **these processes**
- Determining the risks and opportunities associated with **the process**
- Determining criteria, methods and measurements needed to ensure that both the operation and control of these processes are effective
- Ensuring the availability of resources
- Allocating responsibilities and authorities for particular processes or **sets of processes**
- Monitoring, analysing and reviewing **these processes**
- Implementing necessary actions to achieve planned results and continual improvement of these processes. And ensuring new or **revised processes** continue to deliver the intended outcomes.

How will this affect organizations?

5.1 Leadership and commitment

Top management shall demonstrate leadership and commitment with respect to the XXX management system by:

- Ensuring the XXX policy and XXX objectives are established and are compatible with the strategic direction of the organization
- Ensuring the integration of the XXX management system requirements into the **organization's business processes**

8.1 Operational planning and control

The organization shall plan, implement and control the processes needed to meet requirements, and to implement the actions determined in 6.1, by:

- Establishing criteria for the processes
- **Implementing control of the processes** in accordance with the criteria
- Keeping documented information, to the extent necessary, to have confidence that the **processes** have been carried out as planned

The organization also needs to ensure that **outsourced processes** are controlled.

Whilst much of this is the same as the 2008 version of ISO 9001, there are some notable additions.

All organizations are now required to determine the risks associated with each process. This is the clause that effectively replaces PREVENTIVE action which in itself caused many questions. So whilst existing techniques are still relevant, the organization now needs to demonstrate it has applied these to all processes within the scope of the management system.

There is now a requirement to establish measures for each process to determine their effectiveness. So whilst this may just be process output measures, effective systems will also have established measures for supply inputs, in process measures, as well as outputs and customer satisfaction measures (every process, even those that are only internal, has a customer for the output).

It requires that leadership establishes responsibilities and authorities for the processes, in other words ownership needs to be clear. This may cause some cultural problems where the defined business processes cross functional and departmental boundaries.

Management have to demonstrate that they are monitoring the impact of any process changes.

And in 7.2, it requires that competences have to be established for those involved with each process.

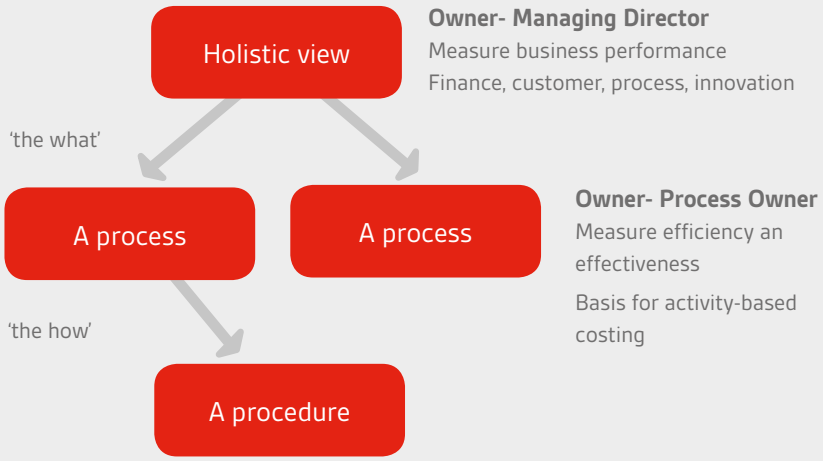
What does a process-based system look like?

A process-based system normally consists of a high level, on page, description of the business process model. This is supported by each of the processes being defined at the next level of detail.

Procedures and or work instructions are then used to define how certain tasks are carried out at each stage in the process (see the example below).

To help document and manage systems that follow this style of approach, there are many software products available and you may wish to have a look at BSI Entropy.

Typical structure



Benefits of the process approach

SO(i)* summarises the benefits of the process approach as:

- Integration and alignment of processes to enable achievement of desired outcomes
- Ability to focus effort on process effectiveness and efficiency
- Provision of confidence to customers, and other interested parties, about the consistent performance of the organization
- Transparency of operations within the organization
- Lower costs and creation of shorter cycle times, through the effective use of resources
- Improved, consistent and predictable results
- Provision of opportunities for focused and prioritized improvement initiatives
- Encouragement of the involvement of people and the clarification of their responsibilities

Additionally for those considering building an effective integrated system, a process model of the organization is often the foundation of this. This is usually supported by a set of integrated procedures and measures and ensures that when reviewing performance or change, a holistic view of the business is taken and risks reduced.

*(i) Document: ISO/TC 176/SC 2/N 544R3

Next steps

The following timetable indicates when the core management system standards will be published in the Annex SL format:

- **ISO 14001:2015**
  Revised International Standard expected to be published in July 2015.
- **ISO 9001:2015**
  Revised International Standard expected to be published in Sept 2015.
- **ISO 45001**
  NEW International Standard for Health and Safety expected to be published in Quarter 4 2016.

ISO 27001:2013 Information Security has already been revised and published using this format.

After the formal publication of the standard, each will have its own transition period. For ISO 9001 for example, there will be a 3-year transition period for certified organizations. However, early planning is advisable so:

- Please talk the transition through with your BSI Client Manager at the next visit.
- Obtain a copy of the Draft International standard at http://shop.bsigroup.com.
- Look out for and attend BSI seminars and training courses on the revision or introduction.
- Review your current approach to process as contained in the draft and identify the gaps.
- Create an implementation plan and monitor progress.
- Continually check BSI's dedicated web pages for the latest news and resources.

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White paper

Corrective action:

The closed-loop system

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Contents

The steps

The closed-loop system

Summary

The corrective action process is a fundamental process that affects all of the control points in a company's management system. Auditors tend to look deeply into companies' corrective action processes during investigations. Key questions typically asked include:

- Are corrective actions followed-up in a timely fashion?
- Do records prove that all actions have been completed successfully?
- Are all recommended changes completed and verified?
- Was the actual root cause identified? How was it validated?
- Was action taken to correct or prevent the problem and ensure it will not happen again?
- Has it been demonstrated that actions taken have no adverse effects on products or services?
- Was training performed and communications issued to ensure that all relevant parties understand the situation that occurred and the changes that have been made?

Monitor, measure, correct

To better manage the issues that launch the corrective action process, companies need to optimize their practices by implementing efficient, closed-loop corrective action processes. Every good corrective action process should have a built-in audit process to verify and validate that the corrective action system is at optimal performance.

Data and evidence tracking is a critical component of action management as well, so the organization can ensure that all non-conformity information can be confirmed, monitored, measured, and, if necessary, corrected.

Achieve success

With nearly every ISO standard, e.g. ISO 9001, ISO 13485, ISO 14001, ISO/IEC 27001, or OHSAS 18001, organizations must determine the actions they can take to eliminate the causes of potential non-conformities. A company's ability to rapidly correct existing problems and implement controls to prevent potential problems is essential to ensure customer satisfaction and achieve operational success.

While a corrective action process must meet the necessary industry compliance requirements, it must also be effective. Otherwise, managers will find themselves in a constant state of response and the corrective action process becomes a bottleneck.

How corrective action works

It's all about improvement

A preventive action is created to offset a potential problem. While the preventive action process can contribute to the overall continual improvement effort, its main objective is to eliminate potential problems before they occur. Corrective actions, on the other hand, provide managers with not only the data they need to construct an effective and efficient corrective action process, but can be used as input into preventive actions.

Using both types of actions enables a company to transform itself from an operation that is continually reacting to failures, to one with the processes in place to prevent problems in the first place. Ultimately, the company saves time and money and, most importantly, retains customers.

Continual improvement

Corrective actions are processes that may be used to achieve continual improvement. Continual improvement reflects an ongoing effort to improve products, services, or processes.

It can be incremental improvement over time or breakthrough improvement all at once. For instance, an organization's delivery processes are constantly monitored and evaluated in light of the fact that they are already considered to be effective; improvement may come in the form of making the processes more efficient. Improved efficiency could lead to a decrease in administrative and operations costs, thereby lowering the costs of goods and services and providing an opportunity to lower prices to be more competitive and win more business.

Companies that implement a closed-loop corrective action process can expect to experience satisfying and cost-effective results.

See Figure 1 for an illustration of a closed-loop corrective action process and how it ties in to the Plan, Do, Check, Act (PDCA) process. Through continuous monitoring, issues are highlighted, thereby allowing them to be addressed in real-time.

Consequently, the closed-loop process reduces the number and severity of issues that occur. Over time, organizations build an intelligent knowledge base and can implement additional preventive actions, thereby being more proactive, further improving processes and operations throughout their facilities. As a result, customer satisfaction improves and the bottom line moves in the right direction.

In addition to these advantages, a closed-loop corrective action process ensures that best practices are consistently applied to the processes that support compliance requirements. Properly documented actions provide managers with important historical data, which may be used to implement continual improvement plans; a well thought-out, integrated process can help in the capture and dissemination of operational intelligence related to these actions.

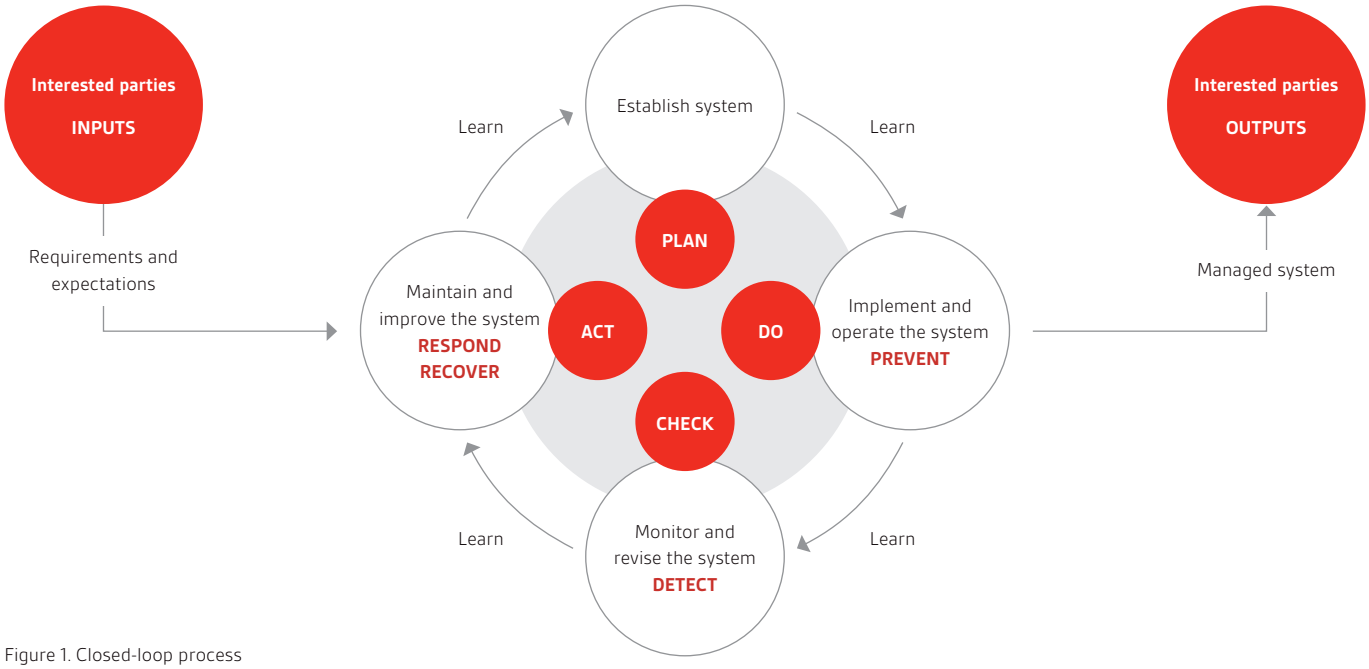


Figure 1. Closed-loop process

Step 1:

Identify non-conformities

When implementing a corrective action process, it is important to define all of the non-conformities that could impact a company's operations. Having a good grasp of the non-conformities helps managers write procedures and design actions that will be taken when a corrective action plan is launched.

But what is a non-conformity?

A non-conformity is defined as a deviation from a specific procedure, standard, stated process, or system requirement. When defining non-conformities, it is important to identify the potential severity of the impact they could have on a management system. For example, a major non-conformity could be an actual or potential deficiency that will seriously affect the management system. A minor one would be a less serious more isolated incident, such as a documentation/work instruction error or inaccuracy.

Some of the many issues related to the corrective action process are:

- Poor documentation of requirements
- Failure to document and communicate updates or process improvements following a corrective action
- Inability to trace training documents
- Corrective actions that are outdated or closed without validation
- Missing or misplaced data
- Failure to monitor critical controls

A closed-loop corrective action process enables companies to avoid or minimize the occurrence of issues, as managers are better able to characterize problems and assemble the best possible cross-functional team of people to successfully tackle them.

As illustrated in Figure 2, BSI ISO 9001 field audit results over a twelve month period reveal that the majority of non-conformities are raised in the areas of **document and record** control closely followed by **monitoring & measuring**, and **improvement**. All three are closely linked, as a good corrective action system requires good documentation and continuous monitoring in order to deliver continual improvement.

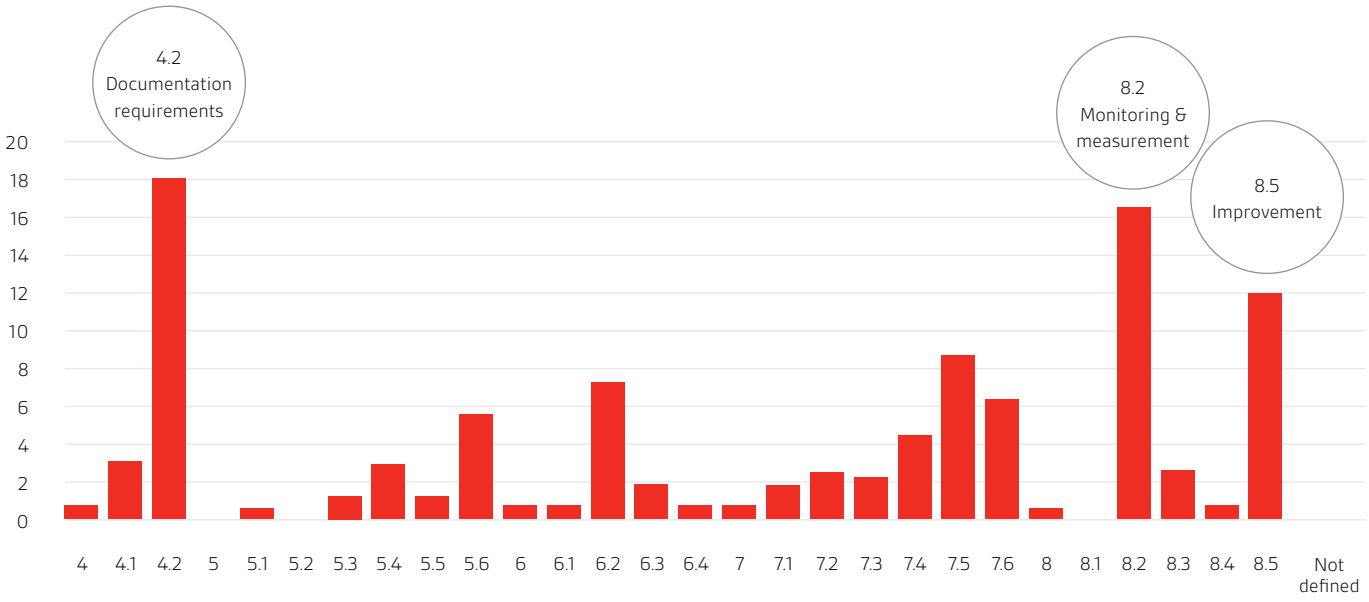


Figure 2. Non-conformities by clause for ISO 9001:2008

Step 2:

Opening a corrective action

Some organizations open a corrective action for every event, regardless of its severity or potential impact. However, this creates bottlenecks because employees become so focused on their corrective actions that they find it difficult to focus on their other day-to-day responsibilities. It also creates a feeling of chaos and concern that "the sky is falling"; continuous improvement suffers by trying to keep up with corrective actions.

ISO 9001:2008 simply states that when planned results are not achieved, appropriate corrective action shall be taken. It goes on to say that when managers are determining suitable actions, they would be wise to consider the type and extent of monitoring or measurement they plan to undertake. This is similar for many other ISO standards.

Any actions taken should be appropriate to each process related to the problem and should be considered in relation to their impact on conformity to product requirements and the effectiveness of the management system.

If the system is monitoring wrong or contaminated data, companies basing actions and assigning resources to implement those actions could find themselves wasting resources and money.

Identifying risk

Risk assessment is a good way to avoid this effect. Risk matrices* help managers and teams to clearly define risk, severity, and potential impact. They also help determine which procedures, designs, and controls best define expected performance. The higher the risk, the more likely it will be necessary to launch a corrective or preventive action. An example of high risk situations are those associated with medical device non-conformities.

In addition to predicting problematic events, risk assessment may suggest monitoring a particular aspect of a process or product. The results of the monitoring may yield measurements and analysis that help managers' spot trends that in turn will justify the opening of a corrective action. In many companies, the compilation of results is aided by software tools that provide a framework for the analysis that is critical to an effective corrective action process.

*Risk Matrices - are mainly used to determine the size of a risk and whether or not the risk is sufficiently controlled. It looks at how severe and likely an unwanted event is.

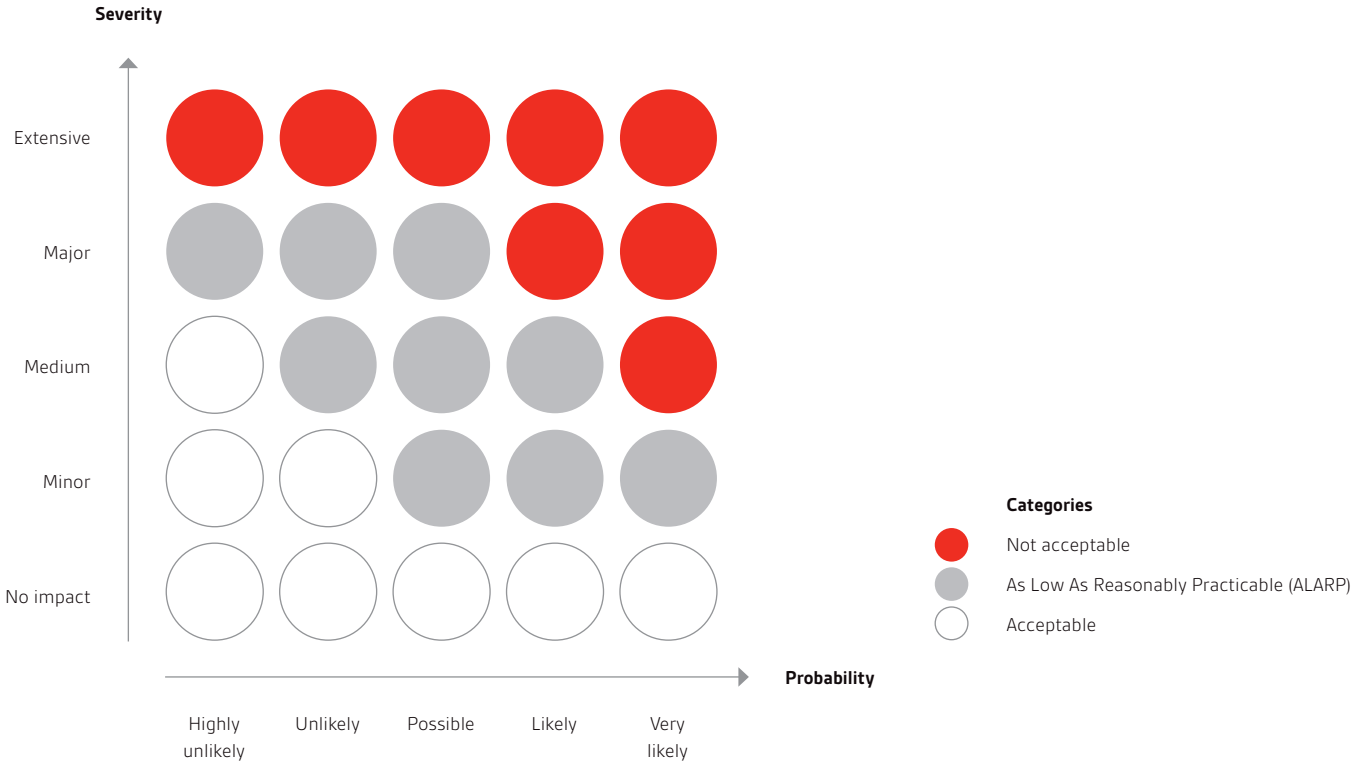


Figure 3. Example risk matrix

Step 3:

Responding to a corrective action

Once a corrective action has been opened, a cross-functional team should be assembled to respond to the event and clearly define the (potential) problem.

Team members should consider the source of the information and data. They also must obtain or draft a detailed description of the problem and consult any documentation and/or data that provides evidence that a problem exists. The team then must evaluate the situation to determine both the need for action and the level of action required.

When evaluating the problem the team should consider the potential impact of the problem in terms of its risk to the company and its customers, as well as any immediate action that may be required. They also must determine and document why the problem is a concern and what impact it may have on the company and its customers.

Typical concerns can include:

- Costs
- Functions
- Product quality
- Safety
- Reliability
- Customer satisfaction

The potential impact and risk assessment may indicate the need for some kind of immediate action to remedy the situation for the short term until a permanent solution is developed and implemented. If the remedial action solves the problem adequately, the corrective action can be closed. However, the team must document the rationale for its decision and complete appropriate follow-up to validate effectiveness of the action.

It is important to document the specific source of the information that is gathered by the team. The information collected helps with the investigation and developing an action plan. It also helps the team evaluate the effectiveness of the action and communicate how a problem has been resolved. Some sources of good information include service requests, customer complaints, internal audits, and staff observations. Trend data also can be gathered from Quality Assurance (QA) inspections, process monitoring, and risk analysis. The data gathered must be properly organized and shared through some sort of relational database. This data, when properly organized and disseminated, becomes operational intelligence that may be leveraged by the entire organization to help improve performance.

Step 4:

Defining the root cause

A problem statement is a clear concise description of the issues that need to be addressed by the assembled team, and not just a byproduct of a quick brainstorming session.

The description must contain enough information so that the specific problem statement can be easily understood. Data supporting the statement also must be easy to translate. The problem statement may have to be reviewed several times until the entire team is clear and in agreement about the task at hand.
Next, the team must conduct a detailed investigation of the circumstances that created the problem by performing root cause analysis. Eliminating the root cause is the only way to prevent the problem from recurring. Many problem-solving techniques help in this phase of the process. The most popular techniques include use of process mapping, Fish Bone, and the Five-Whys.

The Five-Whys have been criticized in the past because it is very basic. Some of the challenges include:

- Tendency for the team to stop and address symptoms rather than going on to lower-level root causes
- Inability to go beyond the team's current knowledge - cannot find causes that they do not already know
- Lack of support to help the team ask the right "why" questions
- Results are not repeatable - different people using Five-Whys come up with different causes for the same problem
- Tendency to isolate a single root cause, whereas each question could produce or uncover different associated root causes

These can be significant problems when the method is applied through deduction only. On-the-spot verification of the answer to the current "why" question, before proceeding to the next question, is recommended to avoid these issues.

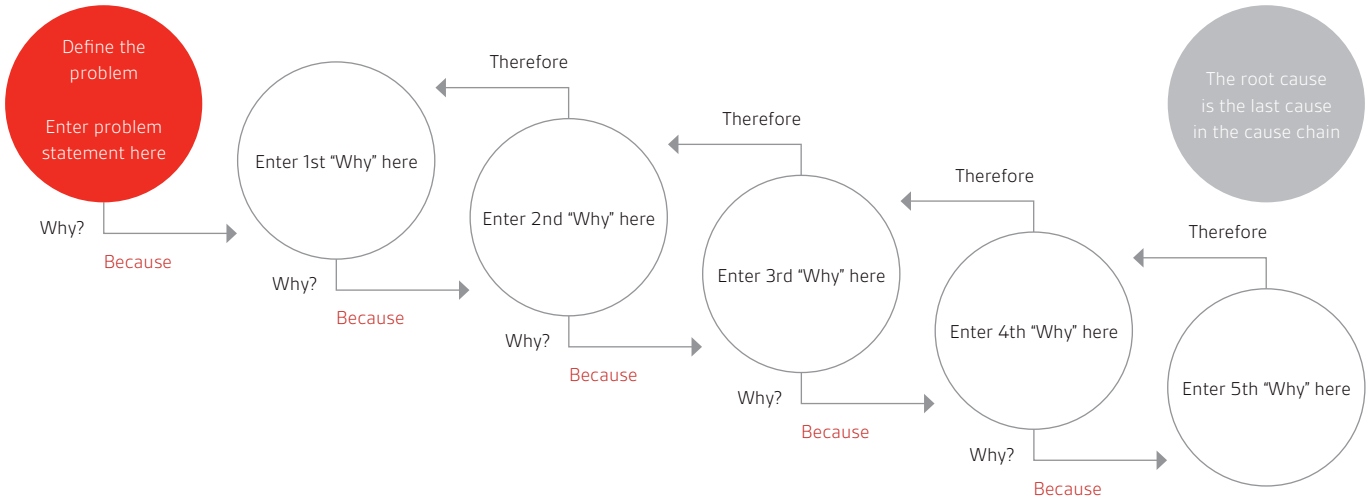


Figure 4. Five-Why's

Defining the root cause continued

The Fishbone diagram on the other hand is considered a more holistic approach to problem solving and root cause analysis. Causes in the diagram are often categorized, such as to the 5 Ms, (Model, Manpower, Machines, Methods and Measurements). Cause-and-effect diagrams can reveal key relationships among various variables, and the possible causes provide additional insight into process behavior.

Causes can be derived from brainstorming sessions. These groups can then be labelled as categories of the fishbone. They will typically be one of the traditional categories mentioned above but may be something unique to the application in a specific case. Causes can be traced back to the actual problem.

Root Cause Analysis requires asking a series of questions to identify all of the possible causes that could explain why the problem occurred. It also helps to identify why the problem was not noticed earlier. Then, all causes should be verified.

Once the root cause is established, the team should work together to create a list of required tasks and implement preproduction, process or design experiment programs to quantitatively confirm that the prescribed solution actually will resolve the problem. It is important to note if employee training should be part of the action plan.

To be effective, all modifications and changes must be communicated to all persons, departments, suppliers, etc. that were or will be affected. Automated tools can facilitate these communications to stakeholders and also ensure that communications are received and acknowledged.

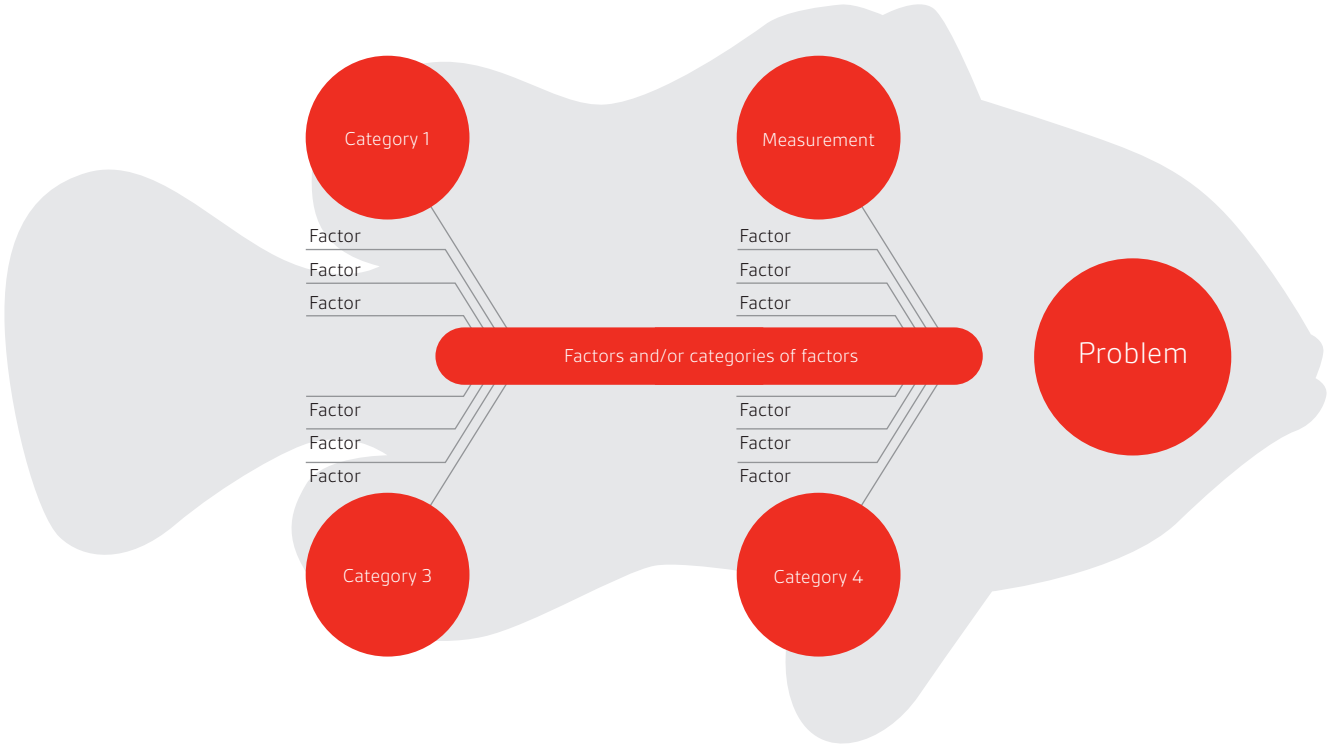


Figure 5. Fishbone diagram

Step 5:

Implementing the solution

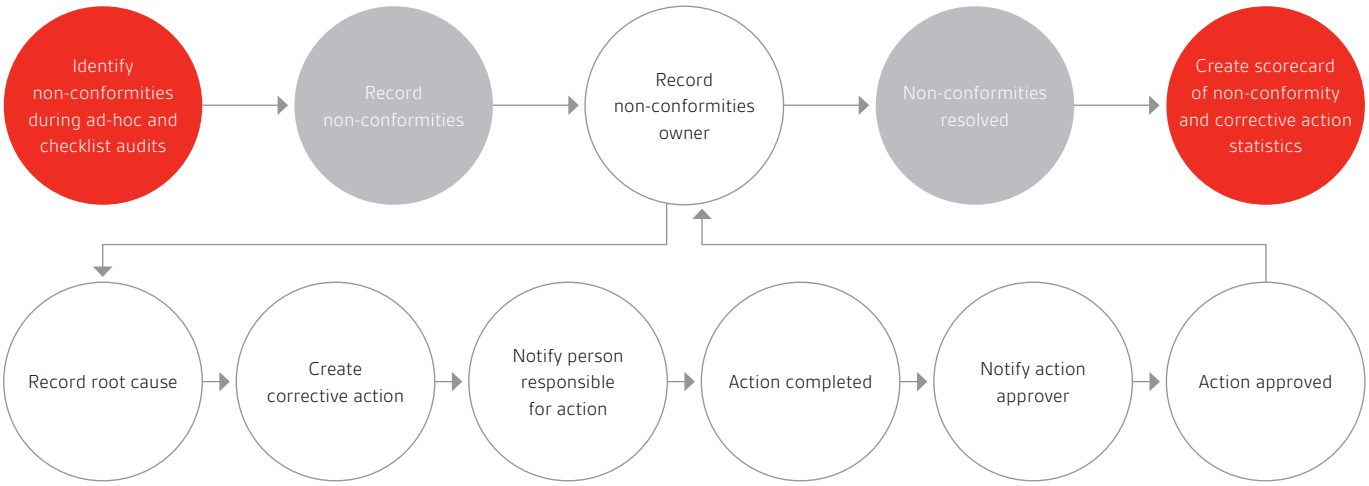
The next step is implementing the solution. It is important to confirm and verify that all of the required tasks described in the action plan are initiated, completed, and documented.

At the same time, necessary changes to documents, processes, procedures, or other system modifications must be described in a clear and concise manner and should specify the desired outcome of any changes. As one may imagine, in complex processes, discovering the potential impact of an action plan may be difficult. In this instance, a programmed tool with a comprehensive search function can ease the discovery process and help ensure that affected areas are uncovered, considered, and addressed.

Once the long term permanent action is in place, the team needs to ensure that it has records of all actions taken. It also must have a plan in place to follow-up, verify, and assess the effectiveness of the solution it has implemented after a pre-determined period of time. The team also should implement preventive measures such as modifying management systems, operation systems, practices, and procedures to prevent reoccurrence of this non-conformity and all similar types of problems.

As this is not a "one size fits all" process, it is up to the team to determine the verification method and timeline required. In some cases (depending on your industry) your customer contract may dictate a specified amount of time that processes must be monitored during and after corrective action.

Non-conformities and corrective actions



Unleashing the power of corrective action

The objective of a closed-loop system is to utilize corrective action opportunities by systematically converting them into inputs that connect to specific tasks that are assigned to process owners to be carried out until closure, verified and then redirected back into the corrective action system for final disposition and/or continuous monitoring.

The corrective action process will provide feedback to managers for necessary process improvements. This in turn enables them to continuously improve how they proactively address and prevent non-conformities.

Checking the effectiveness of a closed-loop corrective action process has to be structured and diligent. corrective action data must be easy to access and analyse, while having a continuous feedback loop. Automating forms-based processes like corrective action, facilitates compliance and saves companies' time and resources; with automation, the concerns of regulators, auditors, and other stakeholders may be easily addressed.

Without a closed-loop system, the ability for the corrective action process to effectively communicate is compromised. As a result, risk increases because there is no logical flow that can be followed. While any regulated company can ill-afford to work in such an environment, virtually every organization has to uphold customer, internal and industry standards.

In an optimal approach for a closed-loop system, resources are managed as a series of interconnecting processes. The system identifies, understands, and manages processes that have interrelationships. Inputs and outputs of the system are also monitored to ensure the process is meeting its expected performance.

This optimal approach takes a certain amount of automation to be effective. An example of a workflow element of an automated closed-loop system is shown in Figure 6. We can see that key processes are integrated and tracked to ensure that responsibility and tasks are assigned, root cause analysis is captured, and the final action plan is documented, implemented, and verified. Key owners are established, notified and documented as are the start dates and due dates. Automatic reminders and escalation notifications ensure the process and tasks are on track.

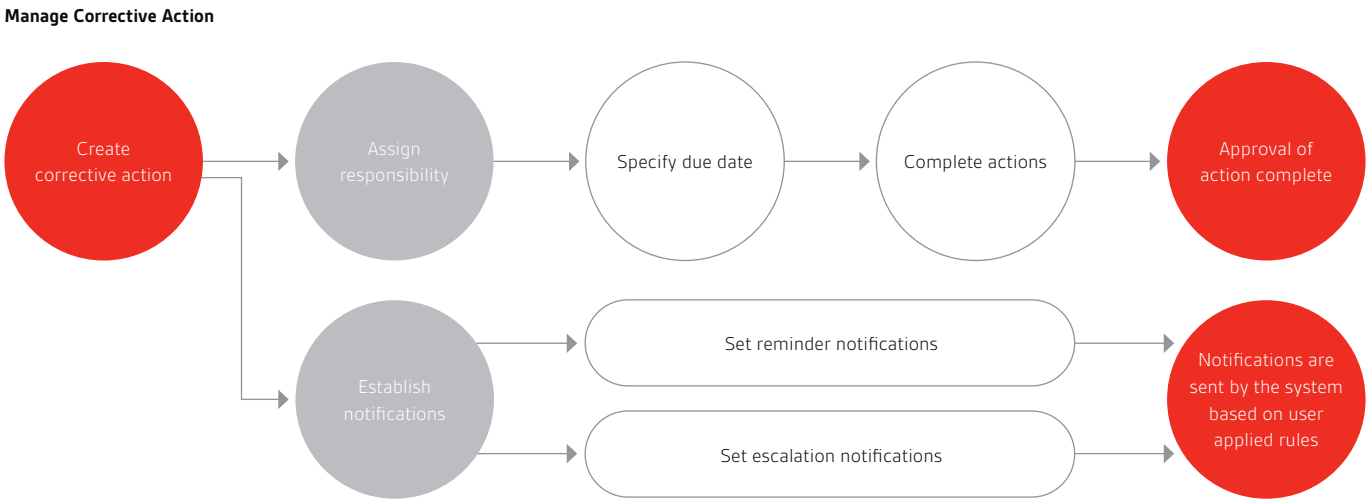


Figure 6. Example automated closed-loop corrective action

Conclusion

While implementing a closed-loop corrective action process can be an expense for companies, the cost of inaction is higher (i.e. ad hoc investigation of incidents, unclear assignment of accountability, assets over or under protected, and fines or suspensions levied by regulatory authorities).

One way to contain costs is to subject both preventive and corrective actions to the same closed-loop process. Furthermore, preventive actions, in particular, need to be thoroughly investigated and justified, both at the time of implementation and on a regular basis going forward, in order to avoid unintended consequences that could lead to non-conformities.

Manually meeting the requirements of a closed-loop system is a very daunting task, which may tax resources in a manner that can lead to the deterioration and disuse of the corrective action process. An enterprise level, role-based, automated software tool will encourage stakeholder participation in the corrective action process; the facts and figures associated with corrective action will become operational intelligence; and the organization's operational intelligence quotient can greatly improve, thereby improving the likelihood of implementing and sustaining closed-loop corrective action process.

By leveraging intelligence to drive operational excellence, companies are relying on automated closed-loop systems to implement a systematic and consistent corrective action process across the organization for increased transparency, effectiveness and efficiency.

ISO Revisions

Integrating ISO 9001 and ISO 14001
Whitepaper

What are the benefits?

Approaching change

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ISO 9001: A quick overview

As the world's most recognized quality management system standard, ISO 9001 is helping businesses of all sizes to save money, increase profits, win more business and meet customer expectations.

Designed to help organizations continually monitor and manage quality across all their operations, this internationally recognized standard sets the benchmark to achieve consistent performance and service. With ISO 9001 in place, organizations can:

- Become more consistent competitors in the marketplace
- Meet more customer needs
- Deploy more effective ways of working to save time, money and resources
- Motivate and engage staff with more efficient internal processes
- Offer better customer service and win more high level customers as a result
- Broaden business opportunities by complying with regulations

ISO 14001: A quick overview

Recognized around the globe, ISO 14001 helps organizations to reduce their environmental impact while growing their business – ultimately achieving sustainable success.

As an internationally accepted standard, ISO 14001 outlines the most effective ways to put a successful environmental management system in place. The standard was developed to help organizations remain commercially successful without overlooking their environmental responsibilities. Its high level framework allows businesses to meet increasingly demanding expectations from customers and other stakeholders, as well as regulatory requirements. With ISO 14001 in place, organizations can:

- Reduce their waste and energy use
- Cut the overall costs of running a business
- Demonstrate compliance to expand business opportunities
- Confidently prepare for the changing business landscape.

Aligning all management system standards of the future

Introducing Annex SL – the new high level structure designed to bring consistency amongst all future and revised management system standards.

ISO, the organization responsible for publishing international standards, reviews existing standards every five years to ensure they comply with an ever-changing world. After reviewing the current ISO 9001 and ISO 14001, the committees decided to revise both standards in response to important changes in the business world. The revised standards should be fully adaptable to a changing world, enhance customer satisfaction and meet the demands of all interested parties and provide a consistent foundation for the future.

In order to aid this integration, ISO has introduced a new high level framework – Annex SL – to ensure the structure of all new and future standards are consistent. In the past, management systems had very different structures despite sharing certain commonalities and this often complicated the integration process. With Annex SL in place, all management system standards will now have an identical structure as well as similar text, terms and definitions:

Clause 1:	Scope
Clause 2:	Normative references
Clause 3:	Terms and definitions
Clause 4:	Context of the organization
Clause 5:	Leadership
Clause 6:	Planning
Clause 7:	Support
Clause 8:	Operation
Clause 9:	Performance evaluation
Clause 10:	Improvement

This common structure will ensure a smoother integration with multiple management systems, saving both time and money.

Integrating ISO 9001 and ISO 14001

As discussed in previous sections of this paper, the benefits of having an effective quality/environmental management system in place are endless. For many organizations these two management systems go hand in hand and, with the new high level structure of the revised standards, integration makes more sense than ever.

With its common structure, text and terms and definitions, Annex SL enables the smoother integration of all new and revised management system standards – without investing a lot of extra time or money. Before the existence of this world-class framework, organizations had to find ways of managing multiple management systems at the same time, which often led to stretched resources, conflicting business needs and poor internal and external communication.

What is an integrated management system (IMS)?

Integrated in this sense means combined – therefore uniting all internal management systems, such as quality and environmental, to form one core business system to achieve intended objectives. This means anything that affects business results must be part of one management system, so that all processes and documents are fully integrated. This integration stretches beyond certain components merely sitting next to other components, or appearing in the same book of policies and procedures, or being managed by the same software package. All elements of an IMS are fixed to form one system.

Some organizations omit the word 'system' and focus on 'integrated management'. This concept involves the dispersion of functional management throughout an organization so that managers oversee a variety of functions. For example, a manufacturing manager could be responsible for planning, manufacturing, safety, personnel, quality and finance.

Why should organizations think about integration?

The business landscape is more competitive than ever and organizations face high expectations from internal and external customers to demonstrate good corporate social responsibility. This means implementing and maintaining robust quality, environmental and health and safety management systems. Operating these as stand-alone systems can be a heavy strain on time and resources. But with the high level structure of Annex SL in place, more organizations can benefit from merging separate management systems into one business management system that works in conjunction with business planning, HR, finance, procurement, administration, operations, audits, management reviews and other systems.

How can organizations integrate ISO 9001 and ISO 14001?

Companies have two options when considering integration. This first is conversion. If an organization already has a certified quality management system, they can expand on that by adding the necessary processes to cater for the requirements of an environmental management system standard. This means both systems will share similar processes for documented information, training, internal audits, management reviews and corrective action. In other words, integration is achieved by adding new practices to existing processes and revising documents to cover all management system requirements.

The second option is to merge systems. This involves merging two systems – such as quality and environmental management systems – followed by the integration of other systems once the formalization has started. This method allows organizations to merge all documentation where it supports the same process.

What are the benefits of integrating ISO 9001 and ISO 14001?

There are several advantages for organizations, including:

Improved business performance
Annex SL makes it easier to integrate multiple management system thereby gaining greater business benefits. It ensures all business processes for both quality and environmental performance are integrated and aligned with the business strategies of the organization, making it easier to continually improve all management systems

A holistic approach
By integrating multiple management systems standards provides a more holistic approach to business processes which increases efficiency, develops coordinated solutions to problems in different work areas and provides a complete view of the whole organization. This strategic focus will result in optimizing the performance of both management systems driving real value in the organization.

Bringing quality & environmental into the heart of the organization
The revised standards ensure that quality and environmental management are now completely integrated with the business strategies of the organization. Used as a business management tool, this will embed healthy performance improvement processes overtime and promote the importance of both quality and environmental requirements at the same time

Reduced documentation and duplication
By meeting all the standard requirements with one set of policies and procedures, integrating both ISO 9001 and ISO 14001 will highlight overlapping responsibilities or unnecessary duplication, resulting in less duplication in business processes which will be easier to manage and maintain.

Saving time and resources
With an integrated management system the audit process both internally and externally will be more effective resulting in decreased disruption, eliminating duplication of audit activity and saving time, money and other resources.

5 Key Steps for a Successful Transition

Don't delay – start working on your transition today

1 Talk to your BSI Client Manager

- Discuss your challenges and timelines
- Review the latest videos and whitepapers on the BSI website for background information

2 Attend a BSI Training Course

- Understand the new requirements faster and in greater detail by attending our training courses; from introduction through to deep dive modules which explain the new areas in greater depth.

3 Communicate with your organization

- Talk to your leadership team about the new requirements
- Communicate the revision to your wider organization to gain buy in
- Send regular updates on progress

4 Set up an Internal Project Team

- Download BSI's transition toolkit which will guide you through the transition
- Conduct a GAP analysis against your current system
- Create an implementation plan and monitor progress
- Take a fresh look at your QMS/EMS
- Implement the new requirements on leadership, risk and context of the organization
- Change your documentation to reflect the new structure

5 Gap Analysis/Transition Assessment

- BSI can conduct a GAP analysis to help you identify any weaknesses prior to formal assessment
- Consider an early assessment against the FDIS
- Transition assessments to the new standard will be available once it has been published.

Transition Timelines

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ISO 9001/ISO 14001 Transition Training Masterclass

Our new ISO transition masterclass has been designed to provide you with a detailed overview of ISO 9001:2015 and ISO 14001:2015.
The masterclass consists of 3 full days training, followed by 4 half day workshops. Attend each one in sequence to form a full weeks course, or attend individually to suit your own requirements. Click on the links below to find out more information on each course.

Day 1	Day 2	Day 3	Day 4	Day 5
Requirements	**Implementing**	**Auditing**	**Morning session Workshop 1**	**Morning session Workshop 3**
Available courses: • Understanding the requirements of ISO 9001:2015 or • Understanding the requirements of ISO 14001:2015 **Pre-requisites:** • A good knowledge of ISO 9001:2008/ ISO 14001:2004 and the principles of a QMS/EMS	**Available courses:** • Implementation of the changes to ISO 9001:2015 or • Implementation of the changes to ISO 14001:2015 **Pre-requisites:** • Understanding the requirements of ISO 9001:2015 /ISO 14001:2015	**Available courses:** • Quality Management System Auditor Transition course from ISO 9001:2008 to ISO 9001:2015 or • Environmental Management System Auditor Transition course from ISO 14001:2004 to ISO 14001:2015 **Pre-requisites:** • Understanding the requirements of ISO 9001:2015 /ISO 14001:2015 • Auditing experience	• ISO 9001:2015 and the Process Risk Approach • ISO 14001:2015 and Risk Based Process Management	• ISO 9001:2015 and the Control of External Provision • ISO 14001:2015 and the Lifecycle Perspective
			Afternoon session Workshop 2	**Afternoon session Workshop 4**
			• Leadership Auditing to ISO 9001:2015 • Leadership Auditing to ISO 14001:2015	• ISO 9001:2015 Facilitated Action Workshop • ISO 14001:2015 Facilitated Action Workshop

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ISO Revisions
Latest update

The benefits of transitioning early

Whitepaper

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Why are ISO 9001 and ISO 14001 changing?

All international standards are subject to review on a regular basis to ensure they stay relevant in today's ever-changing market place.

Following a review of the current ISO 9001 and ISO 14001 standards, the committees concluded that both standards need to be revised to ensure they:

- Reflect the increasingly complex environments in which organizations operate
- Bring quality and environmental management into the heart of businesses ensuring that they are completely integrated and aligned with business strategies.
- Are easier to integrate when implementing multiple management systems into an organization
- Provide a consistent framework for the next 10 years
- More accurately reflect of the needs of employees, customers and other stakeholders
- Improve performance across the organization

After formal publication of both standards, expected in September 2015, organizations certified to the old versions will have 3 years to transition to the new standards. However, it's better to start working on the transition sooner rather than later to gain early benefits of the new standards and improve business performance.

Benefits of transitioning early

Transitioning to the standards early can provide a number of key benefits to an organization:

Improved business performance

Both the new standards are now structured to ensure the management system is completely aligned with the business strategies of the organization. Used as a business management tool, this will improve performance and drive real value, embedding healthy performance processes into the organization earlier

Improved risk and opportunity management

The new emphasis of risk and opportunity management into your management systems now reinforces its use as a governance tool, as well as a performance accelerator This will ensure that your organization will be able to identify risks and opportunities more effectively thereby improving operational efficiency, reducing duplication, saving both time and money.

Enhanced reputation

Adopting the new standards early sends a clear message to existing and prospective customers that you are taking a leading, innovative and proactive approach to quality/environmental management through managements systems. Customer experience and stakeholder confidence will be improved.

Reduced risk of transition issues

Most organizations transition successfully to a new standard, however if you wait towards the end of the transition period there will be less time to correct any problems, increasing the time you need to resolve last minute actions. You may run the risk of your certificate expiring before actually transitioning, risking your business if you need certification for tenders.

Transition early to reduce costs

Organizations that transition over a long period of time must maintain a management system compliant to both the old and new versions throughout the time of transition. This puts an increased compliance burden on the organization and risk of non-conformance.

More flexible approach

Early adoption of the new standards means you can benefit quickly from the less prescriptive requirements of the revised standards, ie. reduced documentation saving time and resources.

Increased engagement

It will be easier to drive enthusiasm internally for making the changes within the organization if you are early adopters, rather than playing catch up to comply at the end of the period. This will ensure your organization has more time to allocate the right resources and that your existing systems will work better for the organization earlier.

Improved integration

The new common structure for all management system standards will ensure that you can integrate more than one system into your organization smoother, without investing a lot of extra time and money.

Setting the transition process in motion

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Transition Timelines

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