ISO 9001:2015
Self-assessment questionnaire

How ready are you?

This document has been designed to assess your company's readiness for an ISO 9001:2015 Quality Management System certification assessment. By completing this questionnaire your results will allow you to self-assess your organization and identify where you are in the process in relation to the main requirements of the standard.

Context of the organization

Have you determined the external and internal issues that are relevant to your organization's purpose and its strategic direction and those that affect your ability to achieve the intended results of the QMS?

Do you have a way of reviewing and monitoring these on a regular basis?

Have you determined the needs and expectations of interested parties that are relevant to the Quality Management System (QMS) and review these on a regular basis?

Has the scope of the QMS been determined taking into account the external and internal issues, interested parties and your products and services?

Has your QMS been established including the processes needed and their sequence and interaction?

Have the criteria for managing these been established together with responsibilities, methods, measurements and related performance indicators needed to ensure the effective operation and control?

Leadership

Has top management taken accountability for the effectiveness of the QMS?

Have the policy and objectives for the QMS, which are compatible with the context and strategic direction of the organization, been established and communicated?

Have the objectives been established at relevant functional, process, departmental and individual levels with the business?

Continued >>

bsi.

...making excellence a habit.™

Leadership – *continued*

Have the requirements for the QMS been integrated into the business processes and have management promoted awareness of the process approach and risk based thinking?

Have customer requirements and applicable statutory and regulatory requirements been determined, met and communicated throughout the organization?

Have the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction been determined and addressed?

Has the organization established and communicated the responsibilities and authorities for the effective operation of the QMS?

Planning

Have the risks and opportunities that need to be addressed to give assurance that the QMS can achieve its intended result(s) been established?

Has the organization planned actions to address these risks and opportunities and integrated them into the system processes?

Has the organization established quality objectives at relevant functions, levels and processes?

Is there a plan for the determining the need for changes to the QMS and managing their implementation?

Support

Has the organization determined and provided the resources needed for the establishment, implementation, maintenance and continual improvement of the QMS (including people, infrastructure and environment for the operation of processes)?

If monitoring or measuring is used for evidence of conformity of products and services to specified requirements, has the organization determined and provided the resources needed to ensure valid and reliable results?

Has the organization determined, provided and maintained the infrastructure necessary for the operation of processes and to achieve conforming products or services

Has the organization determined the knowledge necessary for the operation of its processes and achievement of conformity of products and services?

Has the organization ensured that those persons who can affect the performance and effectiveness of the QMS are competent on the basis of appropriate education, training, or experience or taken action to ensure that those persons can acquire the necessary competence?

Support – *continued*

Has the organization ensured that people doing work under their control are aware of the quality policy and objectives, their contribution to these and the implications of not conforming?

Has the organization determined internal and external communications relevant to the QMS?

Has the documented information required by the standard and necessary for the effective implementation and operation of the QMS been established?

Operation

Are there defined processes for the provision of products and services that meet the specified requirements for the products and services?

When changes are planned are they carried out in a controlled way and actions taken to mitigate any adverse effects?

Is there a process for reviewing and communicating with customers in relation to information relating to products and services, enquiries, contracts or order handling?

Is this review conducted prior to the organization's commitment to supply products and services?

If you design and develop products or services, are there processes established and implemented in line with the requirements of the standard?

Do you ensure that externally provided processes, products, and services conform to specified requirements?

Do you have criteria for the evaluation, selection, monitoring of performance and re-evaluation of external providers?

Is the provision of products and services carried out in controlled conditions which include:

- the availability of documented information that defines the characteristics of the products to be produced or the services to be provided

- the availability of documented information that defines the results to be achieved?

- monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met?

- ensuring the people carrying out the tasks are competent?

Operation – *continued*

Do you have appropriate methods of ensuring identification and traceability of the outputs during production and service provision?

Where property belonging to customers or external providers is used in the provision of the products or services, is this controlled effectively?

If there is a requirement for post-delivery activities associated with the products and services such as warranty, maintenance services, recycling or final disposal, are these defined and managed?

Are any nonconforming outputs managed so as to prevent their unintended use or delivery?

Performance evaluation

Has the organization determined

• what needs to be monitored and measured and

• the methods for monitoring, measurement, analysis and needed evaluation to ensure valid results?

Has it established when the results from monitoring and measurement shall be analyzed and evaluated?

Have methods of monitoring customer perceptions of the degree to which their needs and expectations have been fulfilled been established?

Performance evaluation – *continued*

Has the organization established a programme for an internal audit of the QMS?

Has it determined the need or opportunities for improvements within the QMS and how these will be fed into management reviews?

Has an approach to perform management reviews been established and implemented?

Improvement

Has the organization determined and selected opportunities for improvement and implemented the necessary actions to meet customer requirements and enhance customer satisfaction?

Has the organization appropriate processes for managing nonconformities and the related corrective actions?

Has the organization decided on how it will address the requirement to continually improve the suitability, adequacy, and effectiveness of the QMS?

At BSI we create excellence by driving the success of our clients through standards. We help organizations to embed resilience, helping them to grow sustainably, adapt to change, and prosper for the long term.

We make excellence a habit.

bsi.

Find out more
Call: +27 (0)12 004 0270
Visit: bsigroup.com/en-ZA