ISO 9001:2015

The version of ISO 9001:2015 standard related to the quality management systems is effective as of 15 September 2015.

A revision of a standard is more than just cosmetic changes; they involve a completely new structure. Changes in the ISO 9001:2015 standard were introduced in order to increase the compatibility and consistency with other ISO standards concerning management systems. A greater emphasis has been put, among others, to the organisation's context, risk-based thinking and achieving expected results in order to improve the client's satisfaction.

Processes instead of elements – process-based model

The expected results may be achieved in a more effective way if the operations and resources required are managed and supervised as processes. In order to achieve this, it is necessary to define the next actions in the processes, specified inputs and outputs as well as identified relations with other processes.

Benefits of a process-based approach

- ✓ clear presentation of the company processes;
- ✓ distinction of processes adding value;
- ✓ clear identification of relations and recognising process interactions;
- ✓ better understanding of processes, and thus, their increased acceptance by employees.

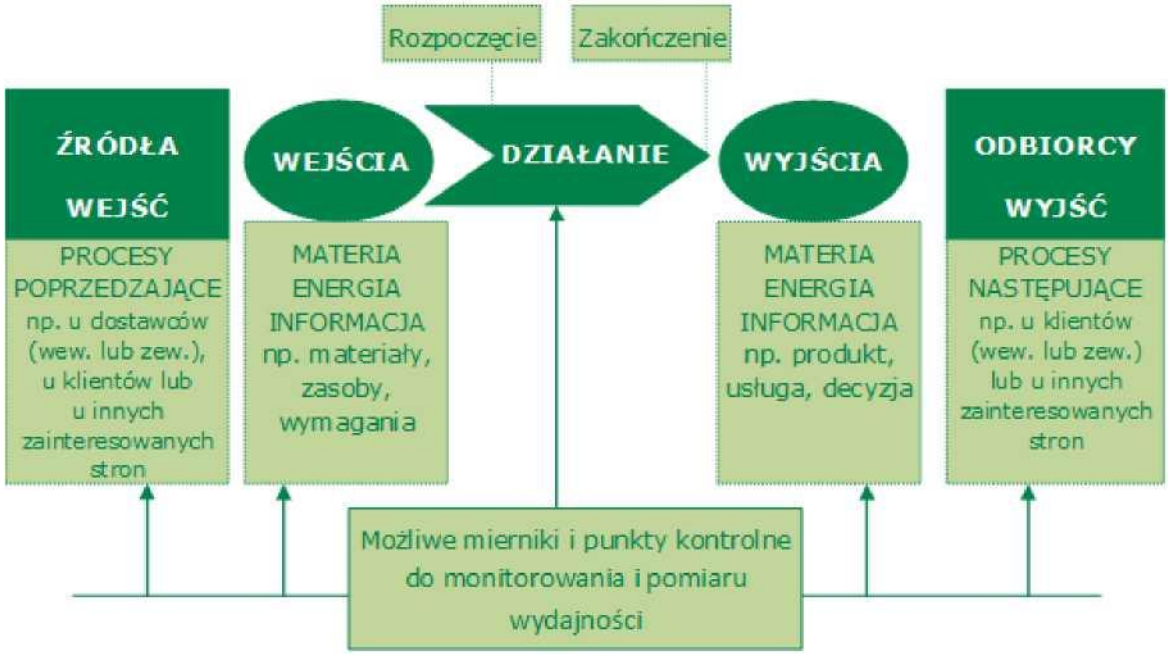

Fig. 1. Schematic representation of the elements of a single process. Source: ISO 9001:2015 standard.

Documentation of a management system

The requirements concerning the documentation (the size and scope) are dependent on the size and degree of complexity of the organisation and skills of employees. The scope of documentation for the QMS may vary between particular organisations depending on:

- ✓ the size of the organisation and type of activity,
- ✓ the complexity of the processes,
- ✓ the staff competencies.

How to obtain the certificate?

After documenting and successful implementation of the quality management system, a company may be certified by an independent certification body such as DEKRA.

The certification agreement should be concluded 4 weeks before the planned date of the certification audit.
If a company selects DEKRA to conduct the certification audit, then it also undertakes to deliver the required system documentation.

Certification process

The certification audit consists of 2 stages. During a certification audit, an auditor checks whether the processes and procedures documented meet the requirements of the relevant standard and whether their implementation is in compliance with the system documentation.

During the audit, an auditor evaluates:

- ✓ the documentation of the QMS,
- ✓ the implementation of the processes documented and their interactions within an organisation.

If during a certification audit, any nonconformities are found, the certificate may be issued when all the nonconformities are removed. The audit result is documented in the audit report. The report is the basis for a DEKRA Certification Committee's decision on the issue of the certificate.

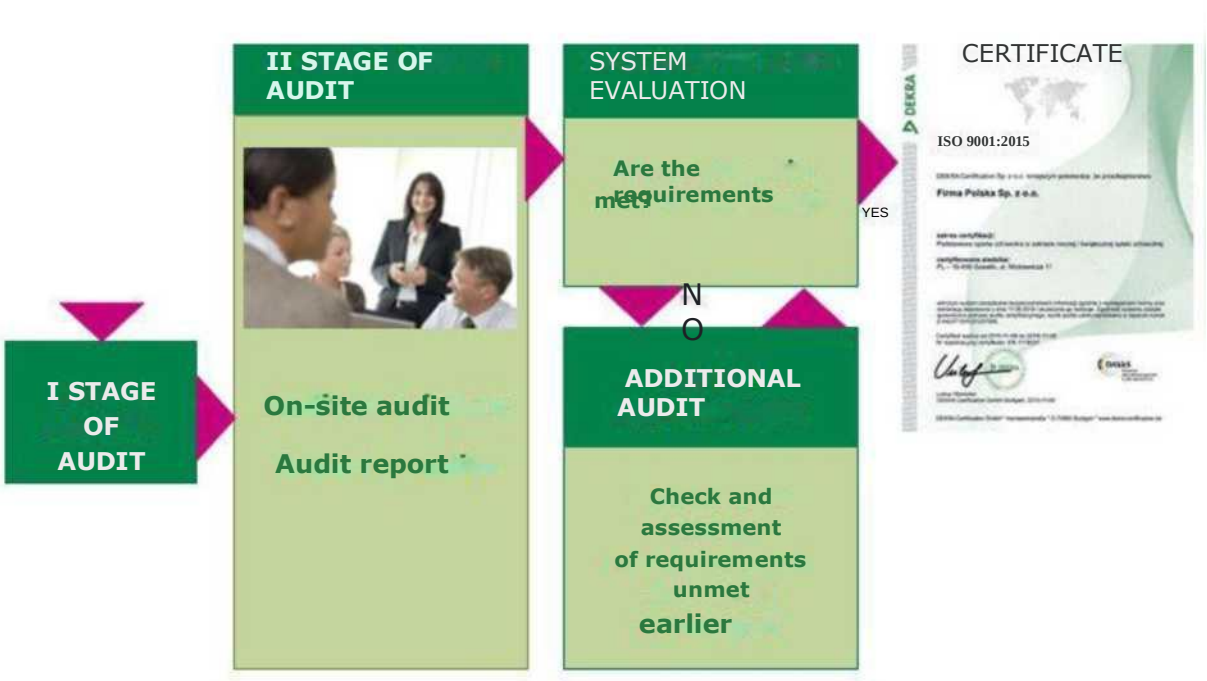

Fig. 2. Quality management system certification process in accordance with ISO 9001:2015 at DEKRA Certification.

The certificate is valid through 3 years, provided that supervision audits are completed with a positive result.

Supervision audits

During the 3-year certification validity period, annual supervision audits are conducted. The purpose of the first and second supervision audits is to check whether:

- ✓ any nonconformities determined during the previous audit are effectively removed;
- ✓ any organisational changes took place in the company;
- ✓ the quality management system changed;
- ✓ the certificate and logo are used in accordance with their intended use and whether any action is taken with regard to changes in the reference standard, legal acts and regulations.

Renewal audit (recertification)

Renewal audit is necessary to ensure the extension of the certification validity for another 3 years. Renewal audit should be conducted before the certificate expires. The requirements of the renewal audit are almost identical as in the case of a certification audit.