DeuZert® Deutsche Zertifizierung in Bildung und Wirtschaft GmbH

Hochschulring 2

15745 Wildau

Certification procedure of quality managementsystems according to ISO 9001:2015

Document WP04 A - D02e

SUMMARY

- Examination regulations for certification of quality management systems
- Procedures for certification of quality management systems according to ISO 9001:2015

Content

Introduction

This document summarizes the procedure of certifying quality management systems according to ISO 9001: 2015 (see Figure No. 1).
The aim of this document is to ensure a secure, standard-compliant certification in accordance with ISO 9001:2015 including the correct determination of the necessary audit times at all times and to inform the organization to be certified about the relevant regulations.
This procedure summarizes the "Examination Regulations for the Certification of Management Systems and Products" and the procedural instruction "VA WP04 A - Certification of Quality Management Systems according to ISO 9001: 2015".
This procedure was developed in accordance with the relevant standard ISO/ IEC 17021-1:2015.

To note:

When the word "auditor" is used below, it is meant to be a qualified ISO 9001: 2015 auditor with the specific scope.

Certification application

After receiving the order for certification, the organization receives the application form for certification and other certification documents. Only when the organization has submitted the signed application for certification together with the necessary evidence (documents/documents) of compliance with the certification requirements to the certification body and a successful check for completeness and plausibility has been carried out, can the audit procedure be started.

Initial certification audit

The certification audit of a quality management system consists of the audit stage 1 and the audit stage 2. In addition, an optional pre-audit can be carried out pre-switched.

Pre-audit

The procedure of a pre-audit is optional and unique. The intention of a pre-audit is to deter-mine the readiness for certification by a review of documents and, if necessary, an on-site inspection. The auditor conducts the audit according to an audit plan that leads to an audit report. The costs for the pre-audit are not included in the costs for the initial certification audit.

Stage 1 audit

The aim is to evaluate to what extent the requirements of ISO 9001: 2015 for the implementation of the audit stage 2 are fulfilled by the organization. During the stage 1 audit the quality management documentation of the organization and the conditions on site are audited. If multiple sites are to be certified, the stage 1 audit will take place in the organization`s head-quarter.

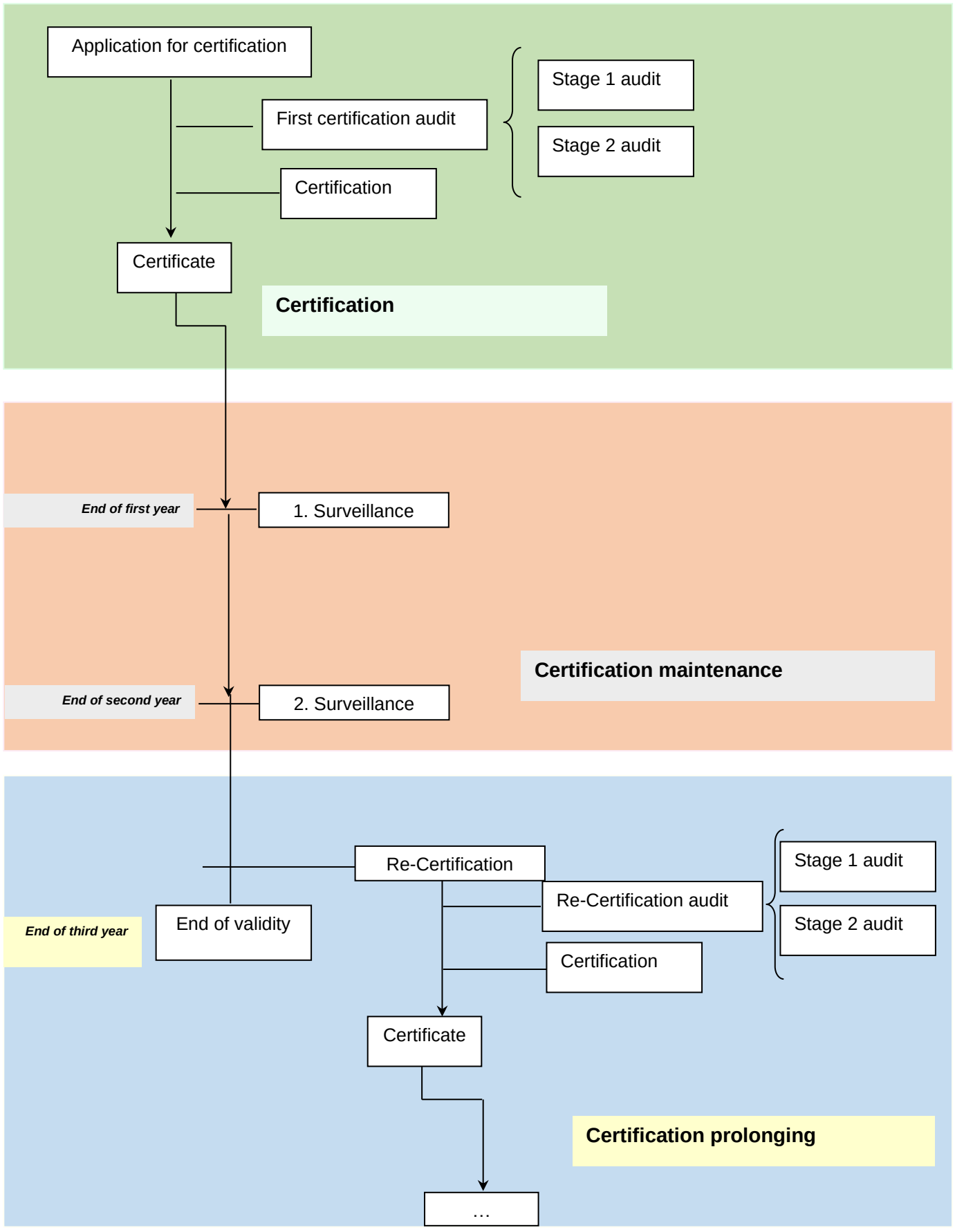
The management documentation provided by the organization has to consist of the following items:

- Documented information about the scope; it must specify types of products / services and contain justifications for any requirement declared inapplicable; Conformity with ISO 9001: 2015 may only be claimed if the requirements declared inapplicable do not compromise the ability or responsibility of the customer to ensure the conformity of their products and services as well as the enhancement of customer satisfaction. Proof of the legal form of the organization (excerpt from the commercial register, business registration, etc.), which is not older than three months, must be submitted, documented information to support the execution of the customer's processes. These include those required by ISO 9001: 2015 as well as those that the customer deems necessary for the effectiveness of his quality management system. This includes documented information of external origin.
- Documented information on the customer's quality policy.
- Documented information on measurable quality goals of the customer.
- A current organizational chart / presentation of the organizational structure,
- Relevant documented information regarding the requirements of the customer's products and services.
- Relevant documented information on the characteristics of the products to be produced by the customer / the services to be provided or the activities to be performed and the results to be achieved.
- Documented information as proof of implementation of the own audit program and the results of internal audits,
- Documented information as evidence of the results of management reviews.

In accordance with an audit plan prepared by the auditor, the auditor carries out the audit stage 1 and documents this. The auditor collects necessary (documented) information regarding the scope of application of the quality management system, the production / service processes and the site(s) of the customer, related legal as well as regulatory aspects and compliance (e.g., quality, legal aspects of the customer's activities, associated risks, etc.). The participants of the audit will be recorded in a list of signatures.

In case of nonconformities with the requirements of the standard, the organization is given an appropriate period for correction. Only, if the organization has carried out the rework within this period, the stage 2 audit can take place. In individual cases, it may be necessary to repeat the stage 1 audit. It should be noted here that the gap between the audit stage 1 and the audit stage 2 may not exceed 3 months. The auditor prepares a report on the result of the audit stage 1. The stage 2 audit can be conducted directly after the stage 1 audit. In this case, any weaknesses encountered during the stage 1 audit can be classified as nonconformities in the stage 2 audit.

Picture Nº 1


Application for certification
First certification audit
Stage 1 audit
Stage 2 audit
Certification
Certificate
Certification
End of first year
1. Surveillance
Certification maintenance
End of second year
2. Surveillance
Re-Certification
Stage 1 audit
Re-Certification audit
Stage 2 audit
End of third year
End of validity
Certification
Certificate
Certification prolonging
…

Stage 2 audit

During the stage 2 audit, the implementation and effectiveness of the organization's quality management system is assessed. It is checked if what has been set and/ or documented is actually implemented.
The auditor will conduct the audit according to an audit plan which will be provided to the organization in advance. The audit includes the questioning of employees at their workplace as well as inspecting further applicable documents, records or similar documents and the site inspection of the relevant areas.
Attendees on the audit will be recorded on an attendees list by signature. The auditor issues an audit report including all detections of the stage 2 audit as a conclusion. The organization as well as the lead auditor, both sign two copies of the report. One copy stays with the organization subject to the approval by DeuZert®. The second copy will be brought forward to DeuZert® for approval. At last, the second copy of the audit report will be filed. The right of property on the audit report stays with DeuZert®.
In a closing meeting the auditor will notify the conclusions mentioned in the report about the organization. If there are nonconformities the following measures are specified. The follow-up of the nonconformities will cause additional work and expenses.

Certification

The decision of issuing the certificate will be made by the certification board. Members of the certification board are the professional management in terms of contents of certification or deputy as well as a qualified auditor who is not involved in the certification process to be decided.
The decision by the certification board is based on the documentation of the certification pro-cess, a survey of the recommendation by the auditors and on further relevant information such as public information or a statement of the organization on the audit report.
Based on the form for the order of certificates completed by the organization, DeuZert® creates a certificate draft and sends it to the organization. With signature or any other appropriate approval, the organization confirms and returns the possibly corrected and signed draft to DeuZert®.
The certificate is issued by the date of the certification decision. The certificate is officially registered by granting a registration number. The validity of the certificate is three years from the issuing date.
The scope of services contains the issuing and registration of a maximum of 2 certificates (certificates and sub certificates) without organization logo in the format DIN A3 or DIN A4 as well as a .pdf file.
The available languages for certificates are: German, English or Russian. For other or additional requests concerning the certificates please refer to the actual bill of quantities.

Certification maintenance and prolonging

Surveillance audit

During the period of validity of the certificate, annual audits are carried out for the certified customers. The surveillance audits check whether changes have been made to the customer's quality management system and whether the customer continues to meet the standard requirements.

In advance of the annual surveillance audits, DeuZert® updates the existing information about the organization, in particular the number of employees and locations. Detected changes can lead to an adjustment to the original audit duration. In case of such a change, DeuZert® will determine the change within audit duration and/ or the contents of the audit.

Surveillance audits are covering the following issues:

- Examination of the current context of the organization (chapter 4),
- Examination of current aspects of leadership (chapter 5),
- Examination of current aspects of planning (chapter 6),
- Examination of current aspects of maintaining and retaining documented information,
- Examination of current aspects of production and service provision (chapter 8.5) with regard to ongoing operational steering,
- Examination of current aspects of performance assessment (chapter 9), including internal audits and management reviews,
- Examination of the complaint management,
- Examination of progress on planned activities aimed at continuous improvement,
- Evaluation of the measures taken based on conclusions of the previous audit,
- Evaluation of corporate data such as number of employees, number of sites and so on.
- Utilisation of signs.

The target date of a surveillance audit shall not be performed 12/24 month after the last day of the stage 2 audit also surveillance audits shall not be performed 3 months before the target date. Surveillance audits may take place at the earliest 3 months before the scheduled date. About four months before the scheduled date, DeuZert® informs the organization about the target date of the upcoming audit.
The auditor will perform the surveillance audit in similar manner to a stage 2 audit. The surveillance audit leads to an audit report similar to the audit report of the certification. The certification board decision on the maintenance of the certification will be based on the procedural documents to be assessed, the auditor's audit review, and other relevant information (for example public information or a statement of the organization on the audit report).

Re-Certification (certification prolong)

A certification can be prolonged for further 3 years if the re-certification audit including the examination of corrective actions of nonconformities and the recommendation of the auditor for issuing the certificate are finished before the end of the validity of the former certificate.
The target date for re-certification is the end of the validity period of the certificate minus 2 months.
4 months before expiry of the validity of the certificate, the DeuZert® customer service usually contacts the customer and sends him the application for re-certification. The customer applies for the re-certification procedure about 3 months before expiry of the validity of the certificate.
Re-Certification audit activities may require a stage 1 audit if there are significant changes in the quality management system at the customer or in relation to the operation of the quality management system. In this case, the audit stage 1 is carried out as already described above.
The re-certification audit consists of a stage 2 audit similar to the stage 2 audit on page 5. The decision on the prolonging of the certificate will be similar to the decision of certification also described above.

Further regulations

- The head of sales network/ customer service or an authorised representative employee examines the inquiry on correctness and completeness. A further exam-inaction on if the inquiry meets the scope of functions and the sphere of authority as well as if there are qualified auditors available. If those preconditions are met, an offer is made based on the specifications in the inquiry. If the inquiry is denied, reason for the denial is provided to the organization in writing.
- The organization may object to any nomination of any auditor or expert. On request the organization will be provided with names and further information to every member of the audit team. The consideration on data protection in this case is mandatory.
- If during an audit is discovered that the objectives of the audit will not meet respectively an immediate considerable risk may exist (e. g. security), the auditor has to inform the organization immediately and, if possible, the certification body. Further the auditor has to initiate reasonable actions. This includes also any need for changes concerning the audit scope. Those issues are documented in the audit report. In the case of different opinions about those issues the auditor and the organization will try to resolve those differences in a common constructive manner. If this is not possible, the difference of opinion is documented in the audit report.
- There is always the possibility of objections against the certification decision as well as complaints about it. Complainants are not penalised for objecting or complaining against the certification decision. Within 4 weeks after the certification decision comes to the attention of the organization, there is the possibility of submitting a complaint in writing. Any time complaints may provide to DeuZert® in writing.
- DeuZert® provides the organization with notification of changes of the requirements concerning the certification in due time. The organization pledges oneself to implement adjustments that result out of the notification of changes.
- The utilisation of the DeuZert®-Logo is part of a stipulation. Those stipulations are part of the document WP04 – D001: Certification of management systems § 29 "Right of utilisation of token and certificates".
- DeuZert® keeps records of all valid certifications. The record consists of the name of the certified organization, the certification standard, the area of application of the certification, the certified sites and the validity of the certificate. DeuZert® has the right to reveal this register by request.
- DeuZert® has the right to provide an interested party about the status of the certification by request. Further information about the organization is handled confidential with highest priority and are only revealed to third parties if the organization has given his approval in writing. If DeuZert® is legally obligated to reveal confident information about the organization to third parties, the organization will be notified in advance about the information to be revealed, unless there are legal/official regulations to the contrary.
- The organization grants DeuZert® the right to perform trainee as well as witness audits on the part of the accreditation body. This does not lead to additional costs.
- The organization has to inform DeuZert® about any issues that could compromise the capability of the quality management system without the least delay. Such issues can be for example:

- the change of the legal form of the organization (current proof of legal form required) or the form of organisation,
- the financial conditions or land tenure,
- the organisation and their management (such as change in senior management personal in executive positions, executives or experts),
- contact address and sites inside the scope,
- significant changes to the quality management system and the processes as well as any other events which may result in certification requirements being temporarily or permanently lost among other things.