

Procedure for maintaining certification, re-certification, extending, re-instating, reducing, suspending or withdrawing certification

Surveillance of the QMS during the period of certification validity

Periodic surveillance audits must be conducted at least once a year during the certificate's validity period. The first surveillance audit must be no later than 12 months from the closing meeting of the certification audit.

Three months before any surveillance audit, a conformity assessment department specialist sends the client a letter notifying him that an audit has to be carried out, together with a draft Additional Agreement to the Contract.

Terms and frequency of surveillance audits are defined in the Certification Contract and in the Additional Agreement, which should be made prior to the surveillance audit. Over the whole surveillance period, audits must cover all the processes required for the QMS of the particular client.

The notified body may conduct an unscheduled audit in any of the following:

- a) the notified body receives a justified complaint about a client, or a claim against him from a regulatory authority;
- b) in response to changes relating to:
 - legal, commercial, organisational status, or ownership (if there is a significant impact on the QMS function);
 - organisation and management (e.g. changes relating to the key management that makes decisions, or to the technical personnel);
 - manufacturing site location;
 - scope of operations within the current management system;
 - major changes to the management system and processes.

If the unscheduled audit demonstrates that the management system of the client complies with the requirements of the standard, a decision is taken to maintain the certificate of conformity until the next scheduled surveillance audit. In any other case, a decision on suspension, withdrawal, etc. is made.

Unscheduled audits are carried out on the basis of a separate agreement. Should the client refuse to sign the agreement for immediate audit, this will result in cancellation of certification.

UNI-CERT may suspend a certificate if:

- the certified management system is persistently or seriously failing to meet certification requirements, in particular requirements for effectiveness of the management system;
- the certified client does not allow surveillance or recertification audits to be conducted at the required frequency;
- the certified client has voluntarily requested a suspension;
- there are justified complaints from the customers of the client (after verification);
- the certificate is misused;
- there are violations of the rules or procedures established by the notified body;
- the client fails to meet financial obligations to UNI-CERT.

If the certified client creates the circumstances that preclude the conduct of a surveillance audit within the specified timescale, then on the day following the due date of the audit, a conformity assessment department specialist will, on behalf of the director or the deputy director, send the client a notification of the certificate suspension for a maximum of 3 months. If the client fails to resolve the issue precluding the scheduled audit within 3 months, then on the day following the 3-month suspension period, a conformity assessment department specialist will, on behalf of the director or deputy director, send the client a notification of the certificate withdrawal.

In all other specified cases of suspension, a conformity assessment department specialist will, on behalf of the director or deputy director, also send the client a letter of suspension for a maximum of 6 months. If the client fails to resolve the issue that has resulted in the suspension in a time established by UNI-CERT, the certificate will be withdrawn. The timescales for correction of nonconformities are defined according to the significance of the non-conformity and risk of confidence in the client's products and services. In any other case, the notified body takes the decision to re-instate the certificate.

During the suspension period, the client is not allowed to make any references to certification.

The notified body may withdraw the management system certificate of conformity in any of the following:

- the suspension period has expired;
- a surveillance audit demonstrates that there is a major nonconformity with the current requirements;
- the client is not willing or able to remedy the nonconformities;
- the certification system rules are changed and the manufacturer cannot ensure conformance to the new requirements;
- the manufacturer ceases to supply a product or service for an extended period of time;
- the client continues to promote certification after the certificate has been suspended;
- the client uses the certification in a way that compromises the reputation of UNI-CERT;
- the client has terminated the contract with UNI-CERT;
- the manufacturer has officially requested the cancellation.

The certificate withdrawal will be communicated to the client in a letter and recorded in the Log of applications and certificates.

Extension or reduction to the scope of certification

If the applicant wishes to extend the scope of the certification, an application should be submitted to UNI-CERT, showing details of the addition.

At the discretion of the client, the scope of certification may be extended:

- in conjunction with a surveillance audit, on the basis of the application detailing the addition to the scope of certification;
- between the scheduled audits, in which case the procedure for initial certification has to be followed. However, in estimating the number of days of audit, account should be taken of a factor that reduces the efforts required, namely the previous familiarity with the management system of the client.

Based on the conclusions of the scope extension audit, a separate certificate is issued. An extended

certificate will have the same expiry date as the certificate valid at the time of the extension. Later, during recertification, a single certificate may be issued.

UNI-CERT has the right to reduce the scope of the client's certification as a result of a surveillance audit in order to exclude the parts not meeting the requirements if the client persistently or seriously fails to comply with the certification requirements for those parts of the scope of certification.

Recertification

Once the certificate has expired, the certification may be renewed. Six months prior to the certificate expiration date, a conformity assessment department specialist will send the client a letter regarding recertification, informing the client, among other things, that the certification will not be renewed if recertification activities have not been completed until the end of the validity of the certificate, and of the consequences of such decision.

If the applicant wishes to renew certification, an application has to be submitted at least 3 months before the certificate expiry date.

Recertification may have the following outcomes:

1. If recertification activities have been successfully completed before the certificate expiration, the expiry date of the new certificate should be based on the expiry date of the current certificate. The date of issue on the new certificate must be the date of the recertification decision or a later date. In this case, a decision on granting the certificate should contain the following text: “to grant certificate of conformity No.____ (version____), which supersedes certificate of conformity No.____ (version____)”.

2. If the notified body has not completed the recertification audit or cannot verify whether corrections and corrective actions have been taken for any significant nonconformity:

a) within 6 months from the expiry date of the previous certificate, the certificate can be renewed; the client must be informed that for that period of time the QMS is considered as uncertified and the client has no right to make any statements about the certification. If such situation arises during the recertification of a certificate granted following conformity assessment that followed scheme 3 as per MP 008, the client must be notified that the products manufactured during that period of time cannot be considered as conforming to the appropriate standard/regulation, and the client may not affix the identification number of the notified body on that products.

b) after 6 months and within 1 year from the expiration of the previous certificate, then the notified body repeats the Stage 2 audit; the client must be informed thereof.

This will be communicated in a letter of recertification referred to in the first paragraph of clause 7.11 of this procedure.

The effective date of the new certificate should be the date the decision on recertification is made or a later date. The expiry date of the certificate should be based on the previous cycle of certification.