

Chapter 8 - Additional rules for ISO9001 : 2008

TABLE OF CONTENTS

Article 8.1 Audit types:.....	2
Article 8.2 Classification of non-conformities	3
Article 8.3 Sanction and condition of granting certification	3
Article 8.4 Guidelines for closing a non-conformity.....	4
Article 8.5 Possible certification decisions of the certifier.....	5

Article 8.1 Audit types:

- **Initial audit:**

First ever audit of a client. Initial audit is done if the client has never been certified for ISO9001 by CU or by any other company. The initial audit starts with a stage 1 'audit/document review' which can be done on-site also and continues in a stage 2 'audit/site visit.' The stage 2 audit is always an on-site audit.

- **Re-certification audit** (re-assessment or re-evaluation):

Done in every 3 years after the initial audit or the first time if the client has already been certified. The re-assessment consists of stage 1 'audit/document review' and a stage 2 'audit/site visit.' The stage 1 audit can be , but the stage 2 audit is always an on-site audit.

- **Surveillance audit:**

Yearly follow-up audits between the initial and re-assessment audits. The surveillance audit has no separate stage 1 and 2 part. The surveillance audit is always an on-site audit.

In addition the above audit CU can perform special audits.

- **Extensions to scope**

CU will in response to an application for extension to the scope of a certification already granted undertake a review of the application and determine any audit activities necessary to decide whether or not the extension may be granted. This may be conducted in conjunction with a surveillance audit.

- **Short-notice audits**

CU reserves the right to conduct short notice audit. These audits are announced to the client 1 day before the actual visit takes place. The client can object against the audit team members but cannot object against the audit. The reasons for these short notice audits can be doubts derived from complaints, external notices or information, internal information gathered during previous audits or as follow-up on suspended clients.

- **Re-assessment of non-conformities**

Some non-conformities (or a group of non-conformities) may need to be re-assessed by an additional site visit. The auditor in consultation with the auditee decides when it is necessary. The certifier can overrule this decision but the client must be informed.

Article 8.2 Classification of non-conformities

The ISO9001 scheme has 2 NC-types:

	NC-type	Description	Deadline
	Major	The absence or the ineffective implementation of one or more required system elements, or a situation which raises significant doubt that products or services will meet the specified requirements. A major non-conformity can also be a group of minor non-conformities indicating inadequate implementation of the system relevant to an element of the standard.	1 month; verification necessary
	Minor	A lapse or either discipline or control during the implementation of the system / procedural requirements, which does not indicate a system breakdown or raise doubt that the products or services will meet the requirements.	3 months; verification might be done during next audit.
	Critical observations	Points not classified as non-conformity during the audit but will be assessed in the next audit.	
	Recommendation	Aspect that improves the quality management system.	

Article 8.3 Sanction and condition of granting certification

	Type of non-compliance	Company action and corrective action	Action by CU
	Major NC	Undertake and confirm corrective action to CU within 1 month.	If more Major NC's found making obvious the fundamental deficiencies of the system CU will revisit the company and carry out a full assessment. Initial certification Certificate cannot be granted unless compliance is demonstrated with or without a further revisit. If the corrections are submitted later than 3 months a complete new audit will take place. Re-certification New certification cannot be granted unless compliance is demonstrated with or without a

			<p>further revisit. Undertake and confirm corrective action to CU within 1 month.</p> <p>Suspension of the certificate if NC is not closed within a month.</p> <p>Surveillance audits</p> <p>Undertake and confirm corrective action to the certification body within 1 month.</p> <p>Suspension of the certificate if NC is not closed within a month.</p>
	Minor NC	Undertake and confirm corrective action to CU within 3 months,	<p>Initial certification</p> <p>Certification cannot be granted unless compliance is demonstrated with or without a further revisit. If the corrections submitted later than 3 months a complete new audit will take place.</p> <p>Re-certification</p> <p>New certification cannot be granted unless compliance is demonstrated with or without a further revisit. Undertake and confirm corrective action to the certification body within 3 month.</p> <p>Suspension of the certificate if NC is not closed within 3 month.</p> <p>Surveillance audits</p> <p>Undertake and confirm corrective action to the certification body within 3 month. Suspension of the certificate if NC is not closed within 3 month. Absolute verification of corrective action can be carried out at subsequent evaluation.</p>

Article 8.4 Guidelines for closing a non-conformity

The client needs to analyze the cause and describe the specific correction and corrective action taken, or planned to be taken, to eliminate a detected non-conformity before the above mentioned deadline.

- Corrective action: you need to investigate the non-conformity, determine the root cause of the problem and implement some form of corrective action to prevent the problem re-occurring.
- Correction: an immediate action to solve the problem without preventing it re-occurring, a 'quick-fix' dealing only with the symptom.

	<p>Only when the client is sure that the problem has been solved he/she should submit details of the corrective action along with the evidence of the effectiveness of the solution and the correction:</p> <p>To do this in the right way the client should ask the following questions:</p> <ul style="list-style-type: none"> - Is the root cause of the problem identified. - Was the problem localized or could it have more far-reaching implications and are necessary steps taken to ensure that the corrective action has been applied through the system where such problems could also occur. - Has the system been revised so that a permanent fix has been put in place, not just for the immediate future, but on a more long term basis. <p>Submitting only a correction is not enough to close a non-conformity.</p> <p>In your response you need to detail at least the following:</p> <ul style="list-style-type: none"> - Explanation of the cause of the failure including root cause. - Description of measures that has been taken to avoid the reoccurrence of the problem. - Send evidence that the measures has been implemented.
--	--

Article 8.5 Possible certification decisions of the certifier

	<p><u>Initial certification</u> Initial certification is when CU certifies the project for the first time. It can be the result of an initial audit (when the client has not been certified before) or of a re-certification audit (when the client has already been certified by some other CB). If the decision is positive a certificate is issued for 3 years. The certificate cannot be issued until it is demonstrated that the client satisfies all the requirements of the ISO9001 quality management system standard.</p>
	<p><u>Re-certification</u> After the 3 year audit program is over, there must be a re-certification audit done. Re-certification audit is a complete audit which is reported in the Audit Report. The certifier shall make decisions on renewing certification based on the results of the re-certification audit, as well as the results of the review of the system over the period of certification and complaints received from users of certification. If the decision is positive a new certificate is issued for another 3 years.</p>
	<p><u>Maintaining certification (continued certification)</u> In the frame of the 3 year audit program, between the initial and the re-certification audit and certification CU must do annual surveillance audits. After each surveillance audit the auditor reports to the certifier. The certifier shall maintain certification based on demonstration that the client continues to satisfy the requirements of the ISO9001 quality management system standard.</p>
	<p><u>Suspension</u> The certification is suspended in cases when, for example:</p> <ul style="list-style-type: none"> - the client's certified management system has persistently or seriously failed to meet certification requirements, including requirements for the effectiveness of the management system; - the certified client does not allow surveillance or re-certification audits to be conducted at the required frequencies; or - the certified client has voluntarily requested a suspension; - certification fee has not been paid; - non-conformities have not been closed before the deadline; - failure to comply with other contractual requirements including using the CU

	<p>ISO9001 certification mark e.g.: CU ISO9001 logo.</p> <p>Under suspension, the client's management system certification is temporarily invalid. The suspended status of the certification shall be indicated on the publicly accessible client list.</p>
	<p><u>Withdrawal</u></p> <p>Suspension can be held for a maximum 6 months. Failure to resolve the issues that have resulted in the suspension within 6 months shall result in withdrawal or reduction of the scope of certification.</p>
	<p><u>Extension / reduction of the scope of certification,</u></p> <p>The certifier shall, in response to an application for extension to the scope of a certification already granted, undertake a review of the application and determine any audit activities necessary to decide whether or not the extension may be granted. This may be conducted in conjunction with a surveillance audit. After the audit with positive result a new certificate -updated with the extended scope - should be issued, but the validity should be the same as on the original certificate. Reduction of the scope can be indicated by the client or can be a consequence of the audit result. For example, reduction of the scope can be applied if a non-conformity affecting only a clearly determined part of the scope cannot be solved by the company, but QMS is functioning well for the rest of the scope. The certifier must consider whether the certificate needs to be suspended/cannot be granted or the scope of the certificate needs to be reduced.</p>