

## **Schutter Certification B.V.**

### **Certification criteria ISO 9001:2008**

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In regard to the wish of clients for the creation of a credible and effective quality management system, whereby the quality management system can be enforced by adequate assessment and approval, the Board of Experts at Schutter Certification B.V., established the following Certification Criteria ISO 9001:2008 on 10<sup>th</sup> of April 2009.

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## **1 Target of document**

This document contains the assessment and certification criteria in relation to the performance of audits at a registered or already certified participant for ISO 9001:2008, as described in the Regulation for Certification and Monitoring. ISO 9001:2008 is hereinafter referred to as 'the standard'.

## **2 Definitions**

Definitions applicable to this document are set out in the Regulation for Certification and Monitoring.

## **3 Applicability and conditions**

Where Schutter utilizes a certification regulation or certification mark under licence from an external organisation, the conditions agreed between Schutter and the granter of the licence will apply, even in the event of conflict with this document.

This document is supplemental to the Regulation for Certification and Monitoring. The conditions in the Regulation for Certification and Monitoring remain applicable, in addition to the conditions in these certification criteria, as do the conditions set out in the NEN-EN-ISO/IEC 17021 latest version.

This document contains the assessment and certification criteria in regard to certification of a participant against the conditions of the standard.

## **4. Assessment programme**

### **4.1 General**

#### **4.1.1 Types of audit**

The participant will be visited annually for an audit. The assessment programme is composed as follows:

- First year: two stage initial audit
- First year: supervision audit
- Second year: supervision audit
- Third year: extension audit

In addition, supplementary audits can be performed in relation to the seriousness of shortcomings identified:

1. A compliance audit, being an on-site audit at the expense of the participant, aimed at specific conditions in this matter where shortcomings were identified in the previous audit. These shortcomings fall at least into the major non-conformity category;
2. A re-examination (repeat audit), being an on-site audit at the expense of the participant, aimed all conditions of the standard. Re-examination (repeat audit) is necessary where one or more non-conformities have been identified, and where a written solution cannot be provided to Schutter, or where more than five major non-conformities are identified.

Schutter will organise performance of the audits, including planning, assessment of documents, on-site audits, reporting and certification (according to NEN-EN-ISO/IEC 17021 latest version ).

#### **4.1.2 Initial audit**

In order to assess whether the participant meets the requirements of the standard, Schutter will perform an initial audit. On the basis of this initial audit, Schutter will grant/not grant an ISO 9001:2008 certificate, depending on fulfilment of the requirements of the standard and the established certification criteria set out in this document. The certificate is valid for a maximum of 3 years.

The initial audit is an assessment in two stages of the quality management system, consisting of:

Stage 1:

- Assessing whether quality documentation meets the requirements of the standard;
- Evaluation of the company location and circumstances on-the-spot (unless unnecessary)
- Assessment of understanding and status of the certification scheme
- Collection of information on the scope of the management system, processes and locations
- Determination of subjects for stage 2 of the initial audit and putting together the audit plan
- Check whether the internal audit and management review have been planned and/or done and assure that the auditee is ready for stage 2 of the initial audit.

A part of the stage 1 audit can be performed on location.

Stage 2:

- An on-site audit, including an assessment of implementation of the quality management system.

The interval in between stage 1 and 2 depends on the needs of the auditee. Depending on the situation and the auditee, stage 1 and 2 of the audit can take place on the same day.

#### **4.1.3 Supervision audit**

In the second year of the validity of the granted ISO 9001:2008 certificate, Schutter will perform an supervision audit to assess whether the participant still fulfils the requirements of the standard. This audit needs to take place within 12 months after the previous audit.

The supervision audit is an assessment of the quality management system, consisting of:

- Assessing whether quality documentation meets the requirements of the standard;
- An on-site audit, including an assessment of implementation of the quality management system.

In the event that the results of the supervision audit give reason to do so, Schutter can decide that a supplementary audit is required to ensure fulfilment of the requirements of the standard. Types of supplementary audit are described in paragraph 4.1.1 and 4.1.4.

Past performance review

After the 2<sup>nd</sup> surveillance audit, a past performance review will be executed. The auditor will report his conclusions concerning the performance of the management system during the past certification period:

- Conclusions concerning audit time duration (increase or decrease of duration)
- Conclusions concerning focus points:
  - Aspects of the management system which might be important for the recertification.
  - Non-conformities which have to be addressed by the auditor during the recertification audit.
  - All other important information which have to be addressed by the auditor during the recertification audit.

#### **4.1.4 Extension audit**

The certificate can only be extended after an extension audit has shown that the participant fulfils the requirements of the standard, having been assessed in accordance with the conditions set out in this document.

At least 6 months before the expiry of the period of validity of the certificate, Schutter will start the process for the execution of the extension audit, to assess whether the participant still fulfils the requirements of the standard, in accordance with the conditions set out in this document.

The extension audit is an assessment of the quality management system, consisting of:

- Assessing whether quality documentation meets the requirements of the standard;
- An on-site audit, including an assessment of implementation of the quality management system.
- All non-conformities of the past audit cycle and the results of the past performance review will be part of the evaluation

When significant changes have occurred, the extension audit can also consist of 2 stages.

#### **4.1.5 Supplementary audits**

##### *4.1.5.1 Compliance audit*

If between one and four major non-conformities are identified, Schutter can perform a compliance audit. This check is supplementary to the standard audit cycle and is aimed at specific aspects of the non-conformity identified and measure(s) taken to improve it. If the non-conformities are not, or are inadequately, rectified, Schutter can decide to suspend or revoke the certificate (see paragraph 4.6).

##### *4.1.5.2 Re-examination*

In the event that a major non-conformity is identified where a rectification in writing cannot be provided to Schutter's satisfaction, or where more than five major non-conformities are identified, Schutter can carry out a re-examination (repeat audit). This examination is a repeat of the audit which gave rise to the re-examination (repeat audit). If the non-conformities identified are not, or are inadequately, rectified, Schutter can decide to suspend or revoke the certificate. When one of the above mentioned audits is necessary, the auditee will be informed.

## 4.2 Duration

### 4.2.1 Time limit for each audit

The following table provides a guideline for the time limits for audits.

Number of employees	Auditor time for initial audit (in working days)
1- 5	1,5
6- 10	2
11 – 15	2,5
16 – 25	3
26 – 45	4
46 – 65	5
66 – 85	6
86 – 125	7
126-175	8
176-275	9
276-425	10
426-625	11
626-875	12
876-1175	13
1176-1550	14
1551-2025	15
2026-2675	16
2676-3450	17
3451-4350	18
4351-5450	19
5451-6800	20
6801-8500	21
8501-10700	22
>10700	Voortgang als boven

### 4.2.2 Definitions on time limits

1. The number of employees refers to all individuals working within the scope of a certificate as described in the quality management system. The total number of employees acts as a reference point for defining the period for the audit.
2. The number of employees includes temporary personnel (for example seasonal labour, subcontractors and freelance staff).
3. Part time employees count as fulltime employees
4. The audit periods referred will be divided into 90% on site auditing and 10% reporting time.
5. One working day consists of 8 hours
6. Time allowed for the initial audit is 100% of the minimum audit time referred to under 4.2.1
7. Time allowed for the supervision audit depends on the results of the initial audit, but is at least two-thirds of the minimum audit time referred to under 4.2.1.
8. Time allowed for an extension audit depends on the results of the supervision audit, but is at least two-thirds of the minimum audit time referred to under 4.2.1.



Schutter reserves the right to extend the audit period in cases of what Schutter deems to be special circumstances, for example:

- A complicated logistical organisation with several locations where work is to be carried out;
- Personnel working in several languages, whereby an interpreter has to be employed;
- An organisation which must comply with extensive legal requirements.

Schutter reserves the right to shorten the audit period in cases of what Schutter deems to be special circumstances, for example:

- An organisation which can exclude paragraphs from the standard, such as an organisation which is not responsible for product development;
- No-risk or low-risk procedures;
- Foreknowledge of the quality system through certification by Schutter for other standards;
- A small production process for the number of employees, or a company without a production process;
- A process where there is only one main activity, for example offering a service;
- A thorough, mature quality management system.

If Schutter should decide to extend or shorten the audit period, the client will be informed accordingly. Where the audit period is adjusted, Schutter will provide reasons for doing so and provide justification for the client's file.

## **4.3 Assessment and reporting**

### **4.3.1 General procedure for performing audit**

Procedures for performing an audit have been set out in writing by Schutter in procedure schedules. These procedure schedules can be made available to the client on request.

### **4.3.2 Assessment of audit findings**

Schutter assesses the participant on fulfilment of the requirements of the standard, as set out in this document. All non-conformities identified during the audit will be registered and reported to the client. The entire findings of the audit are reported on in an audit report.

The auditor will discuss all identified non-conformities with a representative of the participant before leaving the location. The representative of the participant will perform an analysis of the cause and supply the identified rectification measures and verification of the rectification to Schutter within the agreed period for doing so.

Schutter's audit coordinator, or an authorised third party in Schutter's employ (adjudicator) will check the auditor's report of non-conformities identified and provide a final decision, and sanctions where necessary (f.e. Supplementary audits 4.1.5) . If there is any question of the auditor assessing the rectification measures, this will also be approved by the audit coordinator. The auditee will be informed on this assessment.

Within eight weeks after the audit has been performed Schutter will send the report of the audit to the company, accompanied if applicable by the certificate.

#### 4.4 Rotation of auditors

Schutter will appoint a professional audit team or a professional lead auditor to perform the audit. If the (lead) auditor has performed audits for a specific participant over three successive years, another (lead) auditor must replace the former (lead) auditor after three years.

#### 4.5 Certification

Certificates are awarded for each company location for a period of three years. A certificate will only be awarded if the conditions for certification, as set out in the standard and in accordance with the conditions set out in this document, are fully complied with. Schutter maintains a register of companies it has certified, including suspended and withdrawn certificates. The address information will be provided on request, on the condition that legal requirements are met. Remaining information will not be provided unless laid on by legal requirements or legal authorities. The certified company will be informed on the above.

##### 4.5.1 Certificate text

Schutter is obliged to place the following text on the certificate:

##### **Registration number**

## ISO 9001:2008 certificate

Company name

Street and house number

Postcode en Town

Country

##### **Scope**

Schutter Certification B.V. hereby declares that the quality management system at the above-named organisation has been examined (audit) and that this management system fulfils the requirement of the ISO standard 9001:2008 (except for {exclusions})

Valid

from: dd-mm-jjjj

to: dd-mm-jjjj

**SCHUTTER CERTIFICATION B.V.**

**Signed**

**Position**

#### **4.6 Suspension or revocation of the certificate**

If it is established that an ISO 9001:2008 certified company no longer fulfils the requirements, Schutter is obliged, in accordance with the requirements of this document, to impose sanctions and measures immediately.

If during a supplementary audit (see paragraph 4.1.4) the non-conformities identified have not been adequately rectified, Schutter can decide to impose a suspension of the certificate for three months. A new examination will be carried out after three months, whereby the non-conformities should have been rectified. If that is not the case, Schutter can decide to revoke the certificate.

Schutter can decide to suspend the certificate in the event of the following shortcomings:

- When the required demands for certification have not been met on several occasions, including the demands concerning the effectiveness of the management system;
- When in between audits or prolonged audits scheduled beforehand, are being refused;
- when voluntary suspension is requested.

Schutter can decide to revoke the certificate in the event of serious shortcomings, for example:

- Endangering the safety and health of people, animals or the environment as a result of non-operation of the quality management system;
- Supplying faulty products or services as a result of non-operation of the quality management system;
- Not rectifying major non-conformities identified.

#### **4.7 Disputes**

Disputes, objections and appeals will be dealt with in accordance with the Regulation for Objections and Appeals.

#### **4.8 Costs**

Costs for certification are set out in the tender accepted by the participant. The prices of audits in accordance with the audit cycle are set out in the tender (see 4.1.1 Types of Audit). Costs for rectification audits or re-examination (repeat audit)s will be charged at the working day hour tariff of € 1200,- per working day. Minimum costs for rectification audits or re-examination (repeat audit)s are one half working day (€ 600,-).

## **Annex 1 Assessment criteria and measures**

Audit findings are classified using these certification criteria. The following regulations apply as a minimum. Schutter reserves the right to impose more severe measures.

### **Classification: observation**

- Observations are regarded as a chance to improve and have no influence on the certification decision or the validity of the certificate.
- In the event of more than 10 observations, this will apply as a minor non-conformity.

### **Classification: minor non-conformity**

If, during audits or supplementary checks, one or more non-conformities are identified, the participant does not fulfil the requirements for certification. If one or more minor non-conformities are identified during an initial or an extension audit, the certificate cannot be awarded.

### **Examples of findings**

- A section is not fully described in the documentation, whereas this is required;
- A section which has already been described is no longer current, whereas amended conditions and regulations make it necessary;
- Quality registrations have been forgotten or are running behind (less than two months), clearly of an incidental nature;
- It can be assumed that the findings relate to one incident;
- The above is only applicable if (it can be assumed that) there is no question of serious negligence, fraudulent actions or an economic offence.

### **Measures**

- The participant is obliged to take the necessary measures for improvement to rectify the non-conformity identified within a period to be fixed by Schutter. The maximum for that period is one year.
- If the non-conformity is not improved in time, or not completely, the non-conformity will be converted into a major non-conformity.

If during audits or supplementary examinations one or more minor non-conformities is identified, the participant does not fulfil the requirements for certification. The participant is obliged to take adequate measures for improvement to improve the findings within a period to be fixed by Schutter. The maximum for that period is six weeks.

## **Classification major non-conformity**

If during audits or supplementary controls one or more major non-conformities is discovered, the participant does not fulfil the requirements for certification. If one or more major non-conformities is identified during an initial or extension audit, the certificate cannot be awarded or extended.

### **Examples of findings**

- A minor non-conformity has already been identified, but the participant has taken inadequate, or no improvement measures at all;
- A section is not described, or not completely described, in the documentation, whereby the operation of the quality management system is at stake;
- Quality registrations are more than two months behind;
- Either no, incomplete, or untimely implementation of the internal audit and management assessment;
- A serious shortcoming in regard to the conditions of the standard.

### **Measures**

The participant is obliged to take the necessary measures for improvement to improve the non-conformity within a period fixed by Schutter. The maximum period is six weeks.

- In all cases, unless otherwise stated, the participant will be the subject of re-examination (repeat audit: assessment, acceptance and verification); this will be done on location with the exception of those cases where administrative assessment is sufficient.
- If during the rectification audit or re-examination (repeat audit) it appears that the major non-conformity was not improved completely, or not in a timely manner, Schutter can decide to suspend or revoke the certification (see paragraph 4.6)