

Requirements for verification/inspection and validation/certification

General procedures

The various standards, guidelines and methodologies developed CSI require verification/inspection and validation/certification. Validation/Certification Bodies are approved and basically trained by CSI. Validation/Certification Bodies follow the requirements of ISO 17065. Clients are treated equally, there are no different interpretations for standard, guideline, methodology requirements with different clients. The rules of equality and impartiality apply to verification/inspection and validation/certification equally. It is the responsibility of the Validation/Certification Body to train its verifiers/inspectors or ensure that if verifications/inspections are outsourced the verifiers/inspectors have the correct qualification and competence.

An annual audit and if necessary additional audits of the approved Validation/Certification Bodies, provided by the quality management department of CSI, ensures that the work is carried out on time. In addition, it is checked whether the quality specifications have been met.

The certifications are usually carried out on IT Systems developed by CSI. In exceptional cases, IT systems of the certifier may be used if agreed beforehand with CSI. Such exceptions are to be agreed in writing in the cooperation agreement between CSI and the certifier.

Deadlines for Verification/Inspection

The following table shows the deadlines for conducting and completing verifications/inspections. The starting point is the verification/inspection planning. The deadline for verification/inspection describes the period until the verification/inspection must be done and closed from the point when the client has submitted all relevant documents. If an online verification/inspection cannot be carried out within the deadline, an online verification/inspection can be decided by the validator/certifier. Once an verification/inspection date has been agreed with the operator the verification/inspection date cannot be changed anymore. If for reasons of force majeure the verification/inspection date needs to be changed this has to be communicated to CSI providing the reasons for the change.

Туре	Starting point	Deadline for verification/
		inspection
On Site Verifica-	Client expressed his interest to	20 working days if not
tion/Inspection	get verified/inspected and sub-	otherwise requested by
	mitted all relevant information	the client
Remote Verifica-	Client expressed his interest to	20 working days if not
tion/Inspection	get verified/inspected and sub-	otherwise requested by
	mitted all relevant information	the client

Quality specifications

- 1. The verification/inspection report is handed out at the end of the verification/inspection to the client
 - a. onsite verification/inspection: before the inspector leaves the client



- b. online verification/inspection: the same day
- 2. Verification/inspection reports are not adapted after they have been handed out to the client. Non-conformities can not be changed by the verifier/inspector after leaving the operator.
- 3. Non-Conformities are only issued based on the requirements of the standard, guideline, methodology. No additional non-conformities shall be recorded which are not required by the standard, guideline, methodology.
- 4. Corrective actions received from the client are sent and handled to the certifier. If the client requests changes of non-conformities after the inspection is closed, these need to be handled by the certifier in the technical review process. Corrective actions submitted after closing the inspection are handled by the certifier
- 5. Exemption permits are always issued by the certifier, no inspector or inspection body is allowed to issue exemption permits.

Deadlines for Validation/Certification

The following table shows the deadlines in which the validation/certification work must be completed. The starting point is the moment when the validator/certifier receives the closed verification/inspection report and the client has submitted his corrective actions. The deadline for validation/certification describes the period until the validation/certifications must be done and closed. If the client needs to submit further documents or information, then this period runs again after they have been submitted. The deadlines mentioned must be kept at all times.

Туре	Starting point	Deadline for validation/ certification
On Site Verification/Inspection	The client submitted the corrective actions and i.e. results of	2 weeks
tion/inspection	analysis or if no NCs have been	
	issued the date of signing the verification/inspection report.	
Online Verifica-	The client submitted the correc-	2 weeks
tion/Inspection	tive actions and i.e. results of analysis or if no NCs have been	
	issued the date of signing the verification/inspection report.	
Exemptions	The request did reach the certification body	within 3 working days
Online certifica- tion orders	The procedures request an online certification decision. The certification order is ready for work in the IT Tools and the client has provided the necessary and accurate information	within 3 working days

Quality specifications

- 1. For certification decisions, all provided data and information are considered
- 2. If a client brings evidence that a non-conformity has been closed, they will be listed as closed in the certification report

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3. Non-Conformities are only issued based on the requirements of the standard, guideline, methodology. No additional non-conformities shall be recorded which are not required by the standard, guideline, methodology.

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