TÜVNORD

Certification Rules

For the Certification of Management Systems

310-01-001 version 3.0, 2023-05-01

All copies of these certification rules are non-managed copies. The current version is published via the website www.tuv.nl. This version supersedes all previous versions of these Certification Rules.

TÜV®

TÜVNORDGROUP

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1. General provisions

1.1 General

These certification rules were issued by TÜV NORD Nederland B.V.
(trade name: TÜV NORD Nederland).

Contact details:

TÜV NORD Nederland B.V.
Ekkersrijt 4401
5692 DL Son en Breugel

Tel. +31-(0)499 - 339 500
Email: info-nl@tuv-nord.com
www: www.tuv.nl

1.2 Structure of these certification rules

Chapter 1 of the certification rules describes the general topics related to the rules. Chapter 2 provides an explanation of a certification cycle. Chapter 3 describes the responsibilities for both parties in the phase of the *certification* application. Chapter 4 covers *audit* planning. Chapter 5 sets out the responsibilities when conducting the assessment. Chapter 6 focuses on the *certificate* and the responsibilities that apply after the certificate is issued. Chapter 7 describes the activities required to verify the validity of the certificate.

Chapter 8 lists key terms and definitions. Every time one of the terms listed is used for the first time in Chapters 2 through 7, it is printed in *italics*. Furthermore, in Chapters 2 through 7, the responsible party for a specific topic is printed **bold**.

1.3 Purpose of these rules

The purpose of these certification rules is to inform all organizations that are or wish to be certified by TÜV NORD Nederland about the procedure and the applicable mutual agreements.

1.4 Scope

These certification rules apply to all activities performed by TÜV NORD Nederland within the scope of certification of management systems and processes of organizations. TÜV NORD Nederland is accredited to assess products (ISO/IEC 17065) and management systems (ISO/IEC 17021) by Raad voor Accreditatie (Dutch Accreditation Council). TÜV NORD Nederland is also supported by the Dutch government and European Union on several *instructions* for assessment based on national and European legislation.

1.5 Status of these certification rules

A certification agreement is concluded between TÜV NORD Nederland and the existing or prospective *certificate holder*. This certification agreement refers to these certification rules. For this reason, the full set of these certification rules are an integral part of the certification agreement between the two parties. Both parties are therefore responsible for compliance with the requirements pursuant to these rules.

Additional provisions may have been adopted by a *(Central) Board of Experts* ([C]CvD). If these provisions are in addition to or in conflict with the provisions of these certification rules, those of the (C)CvD shall prevail. As part of its accreditations and instructions, TÜV NORD Nederland must adhere to several guidelines. TÜV NORD Nederland is responsible for compliance with these guidelines. These guidelines are not directly applicable to the customers of TÜV NORD Nederland. However, these can be translated into requirements for the organization to be certified via the certification agreement, the *certification outline* and/or these certification rules.

1.6 Duration of certification agreement

The contract concluded between the organization to be (re)certified and TÜV NORD Nederland is also a certification agreement. This agreement is concluded on a non-temporary basis with the option of termination after notice.

1.7 General responsibilities TÜV NORD Nederland

1.7.1. Confidentiality and conflicts of interest

TÜV NORD Nederland is responsible for ensuring confidentiality by any person working for or on behalf of TÜV NORD Nederland involved in the certification process who has become aware of confidential company information as a result of the work.

Every internal and external employee of TÜV NORD Nederland has signed a confidentiality statement.

TÜV NORD Nederland does not perform advisory work in the field of (management) systems in order to avoid conflicts of interest in certification activities.

1.7.2. Confidentiality

By signing the certification agreement, **TÜV NORD Nederland** is committed to maintaining confidentiality. This confidentiality obligation focuses on all information/data that TÜV NORD Nederland receives from organizations during its audits and assessments. A number of exceptions apply to this confidentiality obligation, namely:

1. The information on the certificate and the status of certification may be published and provided to third parties.
2. If TÜV NORD Nederland has a contractual obligation to disclose data to a plan administrator, then it is permitted to do so.
3. Accreditation bodies and other regulators may inspect records of individual organizations as part of their audits.
4. If an instruction decree includes an obligation to disclose information to a government agency, TÜV NORD Nederland may do so.
5. Audit findings (unless confidential) (e.g. after complaints) may be disclosed to stakeholders.

1.7.3. Introducing amendments to these regulations

If amendments applied to these rules affect the certification cycle of customers and certificate holders, **TÜV NORD Nederland**:

- gives these organizations an opportunity to comment on such proposed change(s);
- establishes a date by which the change(s) will be effective in order to allow these organizations sufficient time to adjust the management system and/or process;
- notifies these organizations of the effective date of the change and the actions required of those organizations.

Failure to take the required action by the established effective date may result in suspension under Section 6.8.2 in these rules or suspension and revocation of the certificate under Section 6.8.3 in these rules.

1. Explanation of certification cycle

This section explains how a full certification cycle is set up. A certification cycle usually starts with an organization's application for certification. After the organization and TÜV NORD Nederland have signed the certification agreement, TÜV NORD Nederland plans the audit to be conducted in consultation with the organization.

The audit involves document research in order to obtain the evidence used to assess the correct application of a *normative document*. This audit evidence includes the documented information that an organization maintains during its operations and the statements of facts that employees make to the audit team auditors.

If all activities that are part of the *certification audit* have been completed to full satisfaction and all requirements of the normative document are met and this is adequately proven on the basis of the audit evidence, the audit team will issue a positive opinion. The audit team's report is then reviewed by a qualified colleague not involved in conducting the audit.

Upon approval of the audit report, it is up to a qualified certification decision-maker to determine whether all certification requirements have been met. Upon a positive decision, the organization receives the certificate.

After awarding the certificate, compliance monitoring activities are conducted to periodically assess the certificate holder's compliance with all applicable requirements.

Figure 1 - A certification cycle

A certification cycle spans three (3) years for most standards. In the first year, the certification audit (CA) is conducted. Based on a positive certification decision, the organization receives the certificate for three (3) years. The validity of the certificate begins on the date of the positive certification decision.

In the subsequent two years, compliance monitoring activities (Y1 and Y2) are completed to confirm the validity of the certificate. Some standards include optional interim audits on a project site, whether announced or not. At the end of the certification cycle, a new cycle is started with a recertification audit (HCA) as the first activity, and the organization receives a new certificate upon passing the certification audit. This cycle also includes the annual compliance monitoring activities.

A certification audit consists of two phases: the preliminary audit (Phase 1) and the *implementation audit* (Phase 2).

The (re)certification audit involves an assessment of the entire management system and/or process and certification outline. Combined, the *compliance audits* also cover the entire management system and/or process and the entire certification outline.

The scope of the full audit program is in line with the scope of certification.

2. Application for certification

2.1 Introduction

A certification cycle starts with an organization's application for certification. This section describes how an organization can submit an application and how TÜV NORD Nederland processes it.

2.2 Submission of an application

Upon receipt of the application, **the organization** provides the information necessary to assess its eligibility for certification. This can be done verbally, by phone, via email and/or the application form on the TÜV NORD Nederland website: www.tuv.nl. At a minimum, the information includes:

- (the (desired) scope of the certification (processes or activities that the organization performs), described in such a way that:
  - there can be no deception or confusion.
  - no value terms (for example: high quality, effective, high-tech) are assigned to products and or services.
  - it gives clarity on any additional *(branch) sites* to be certified, including the associated operating area of these (branch) sites.
  - no company name is included.
  - no references to other normative documents are included.
- relevant details of the applicant as required by the specific certification outline, including its name and the address(es) of its *branch(es)* (see also Section 8.1.29); its processes and activities, human and technical resources, functions, contacts/(sub)contractors and any relevant legal obligations;
- identification of outsourced processes applied by the organization that affect compliance;
- the *normative documents* (see also Section 8.1.22) or other requirements for which the applicant seeks certification;
- whether consulting services related to the management system or process to be certified were provided and, if so, by whom;
- any available third-party inspection reports, such as reports from previous certification bodies (see also Section 3.5), healthcare (IGZ) and industry inspections.

2.3 Assessment of an application

TÜV NORD Nederland evaluates the application and additional information related to certification to ensure that:

- the information about the organization and its management system and/or process is sufficient to develop an audit program;
- any potential misunderstandings about the information provided between TÜV NORD Nederland and the organization have been resolved;
- TÜV NORD Nederland has the competence and capability to perform the certification activities;
- the scope of the certification sought, the establishment(s) where the organization operates, the time required to conduct the audits and any other issues that affect the certification activity have been considered (language, security conditions, potentially compromised objectivity, etc.).

On the basis of an application, **TÜV NORD Nederland** shall:

- indicate whether TÜV NORD Nederland or its parent organization has the required *accreditation* or *designation* for the indicated scope of certification;
- decide whether to accept or reject the application;
- in case of rejection of the application, announce this to the organization and justify the reason for the rejection;
- send an offer to the organization (provided the application has not been rejected).

The organization conveys its approval of the quotation by signing and returning it to TÜV NORD Nederland. This signed quotation then serves as the certification agreement.

TÜV NORD Nederland then sends an order confirmation to the organization.

2.4 Determination of audit time

2.4.1. Introduction

TÜV NORD Nederland bases the *audit lead time* on guidelines established by plan administrators. Variables that affect the final audit time include size of the organization in effective number of employees, number of sites, scope to be certified and complexity.

If, during the audit, the data provided by the organization is found to be incorrect, incomplete or altered, which may result in additional audit time in order to reach a sound conclusion, this additional time will be charged to the organization based on actual cost at the agreed hourly rate per person.

TÜV NORD Nederland records the required audit time of each assessment within the certification cycle in the quotation. An assessment consists of the preliminary audit work[1], the actual audit (the implementation audit), reviewing the results and making the certification decision.

TÜV NORD Nederland has the following arrangements to reduce the time commitment of a certification cycle:

- Rules regarding limited time allocated to the preliminary audit;
- Rules relating to *multi-site certification*;
- Rules relating to integrated audits.

2.4.2. Rules regarding limited time allocation for preliminary audit

TÜV NORD Nederland can reduce the time allocated for a preliminary audit if the audit team already has the necessary knowledge of the organization or the design of the management system or processes has already been assessed at an earlier stage, such as during a previous certification cycle, during an audit for a different but similar normative document or a different type[2] of audit for the same plan.

Reduction of time spent on auditing will be granted only with the approval of **System Certification** management.

[1] In compliance audits and HCAs, no preliminary auditing takes place; however, concerning HCA, TÜV NORD Nederland may do so at its discretion.

[2] This includes a baseline measurement.

2.4.3. Rules relating to multi-site certification

3.4.3.1 Introduction

If the organization applying for certification has a management system that includes multiple sites performing similar work that is managed in a similar manner, then the organization may be eligible for *multi-site certification.*

The benefit of multi-site certification to the organization is that less audit time is required for the overall audit. This is based on applying random sampling on the number of establishments. Instead of visiting all sites, multi-site certification involves visiting only some of the sites. These sites effectively serve as the model for all the sites.

3.4.3.2 Multi-site eligibility requirements

To be eligible, **the organization** must meet the conditions below:

- there is a single management system applied in both the head office and (branch) offices;
- the products/services and activities at the various subsidiaries/sites are substantially of the same nature and are operated in accordance with the same methods and procedures;
- the head office has a legal or contractual relationship with the (branch) offices;
- the management system is centrally managed;
- all (branch) offices are part of the internal audit program;
- the head office collects and analyses data from all (branch) sites and demonstrates its ability to make changes when necessary:
  - documented information and system changes;
  - management review;
  - complaints;
  - evaluation of corrective actions;
  - internal audit planning and evaluation of results;
  - changes regarding aspects and related impacts (only for environmental management systems); and
  - various legal requirements.

3.4.3.3 Application for multi-site certification

When applying for certification, **the organization** indicates that it prefers to qualify for the multi-site arrangement. Also, the organization should indicate which location is the head office and which offices or subsidiaries are strongly interrelated. Once the audit is in progress, the organization cannot let any (branch) sites lapse. Later in the certification process, however, (branch) sites may be added or eliminated under certain conditions.

2.4.4. Rules relating to integrated audits

3.4.4.1 Introduction

If the organization applies for certification for two or more normative documents, it may qualify for an integrated audit. The advantage to the organization of *integrated audits* is that integrated elements of the management system are assessed only once. This reduces the time required for the overall audit. The reduction depends on the degree of integration of the two management systems and/or processes.

If the organization has two or more management systems that are not integrated, we refer to it as a combined or combi-audit. These are two separate full audits at the same time.

3.4.4.2 The conditions for applying for integrated audits

The organization must have a single management system that meets all the requirements of the two (or more) normative documents. There is a fully *integrated management system* if at least the following components are incorporated in the management system:

- the documented information, including sufficiently specified work instructions, if necessary;
- management reviews that consider overall business strategy and planning;
- the approach to internal audits;
- the approach to policies and objectives;
- the approach for system processes;
- the mechanism for improvement (corrective and preventive actions[3], measurement and continuous improvement);
- support and responsibilities.

For optimal use of audit time reduction opportunities, the certification cycles of different management systems should be at the same stage.

The organization ensures that during the audit interviews, employees are available to answer questions that relate to more than one management system.

3.4.4.3 Application for integrated audits

When applying for certification, in addition to the two or more normative documents applied, **the organization** indicates the degree of integration based on the conditions given in Section 3.4.4.2.

[3] In standards based on the High Level Structure (Annex SL), this aspect has been replaced by risk-based thinking. This is why TÜV NORD Nederland has adopted the position that there must also be an integrated approach to picking up risks and opportunities.

TÜV NORD Nederland assesses to what extent reduction of audit time is possible. Also, when planning the audit, TÜV NORD Nederland ensures that the audit activities for the various standards are sufficiently comprehensive to instill confidence in the certification.

If the organization wishes to add a certification during a compliance audit of an existing certification, TÜV NORD Nederland conducts a preliminary audit for the new certification. This limits integrated auditing. If a certification is added during a recertification, then a fully integrated audit can be applied.

2.5 Rules regarding interim transfer from another certification body

2.5.1. Introduction

If an organization has a valid certificate issued by another certification body, but for whatever reason the certification cycle is interrupted, this ongoing cycle can be taken over by TÜV NORD Nederland and is subject to certain conditions.

This option involves continuing the current certification cycle, rather than starting a new cycle. Part of this plan involves determining that the organization meets the requirements set out in the relevant plan.

2.5.2. Conditions for an acquisition

The organization must meet the following eligibility requirements:

- the certification is arguably not suspended, nor are there any suspension proceedings pending against the organization;
- all unresolved *non-conformities* were resolved before the handover from the original certification body[4].

If a certificate was issued by a certification body that has been discontinued or whose accreditation is not (or no longer) valid for any reason, TÜV NORD Nederland will consider accepting the certification.

2.5.3. Application for an acquisition

The organization provides the following with the application:

- the reasons for interrupting the certification cycle (and switching);
- the *certification documents* of the relevant certification cycle that has been or will be interrupted;
- copy of certificate.

Additional requirements may be indicated in the relevant standards or associated certification outlines.

[4] If this is not possible, TÜV NORD Nederland will take up this process with the organization before the switch becomes final.

2.5.4. Review of acquisition application

Before accepting transfer of a certificate, **TÜV NORD Nederland** conducts an assessment based on the data provided and, if necessary, visits the organization. The review is conducted on the following criteria and the outcome is fully documented:

- the activities of the applicant organization to be certified fall within the scope of TÜV NORD Nederland;
- the organization has a certificate or designation that is valid in terms of authenticity, duration and scope of activities covered by the management system certification.
- there are no unresolved non-conformities resulting from the certification cycle interrupted or to be interrupted;
- complaints received and action taken;
- the phase in the ongoing certification cycle;
- any existing engagement by the organization with regulatory bodies regarding compliance with the law.

2.5.5. Certificate issuance for an acquisition

After positive evaluation based on the aforementioned conditions, **TÜV NORD Nederland** issues a certificate and TÜV NORD Nederland and the organization enter into a certification agreement for the remainder of the current certification cycle.

In case of a negative assessment based on the aforementioned conditions, TÜV NORD Nederland assesses the application as a regular application for certification and issues an offer for a new certification cycle to be started by means of a (re)certification audit.

3. Planning an audit

3.1 Introduction

Audit planning consists of an audit program for the entire certification cycle and the *audit plan* for each separate audit. TÜV NORD Nederland distinguishes between the initial certification cycle (certification) and all subsequent certification cycles (recertification).

The actual scheduling of the audits is done by the Customer Service Center of TÜV NORD Nederland. Also, upon completion of an audit, the auditor conducting an audit will schedule a date for the next audit.

3.2 The audit programme

3.2.1. The audit programme of an initial certification cycle

TÜV NORD Nederland draws up an audit program based on the information obtained.
The audit program for the full certification cycle consists of a certification audit and two compliance audits (Y1 and Y2). A certification audit consists of two phases, namely the preliminary audit (Phase 1) and the implementation audit (Phase 2).

The purpose of the preliminary audit (Phase 1) is to assess resource allocation, determine your organization's readiness and agree on the details (of planning) of the implementation audit (Phase 2). The purpose of the implementation audit (Phase 2) is to determine whether your management system complies with the audit criteria, whether it is effective, whether it is adequate to ensure compliance with laws and rules and whether there is room for improvement.

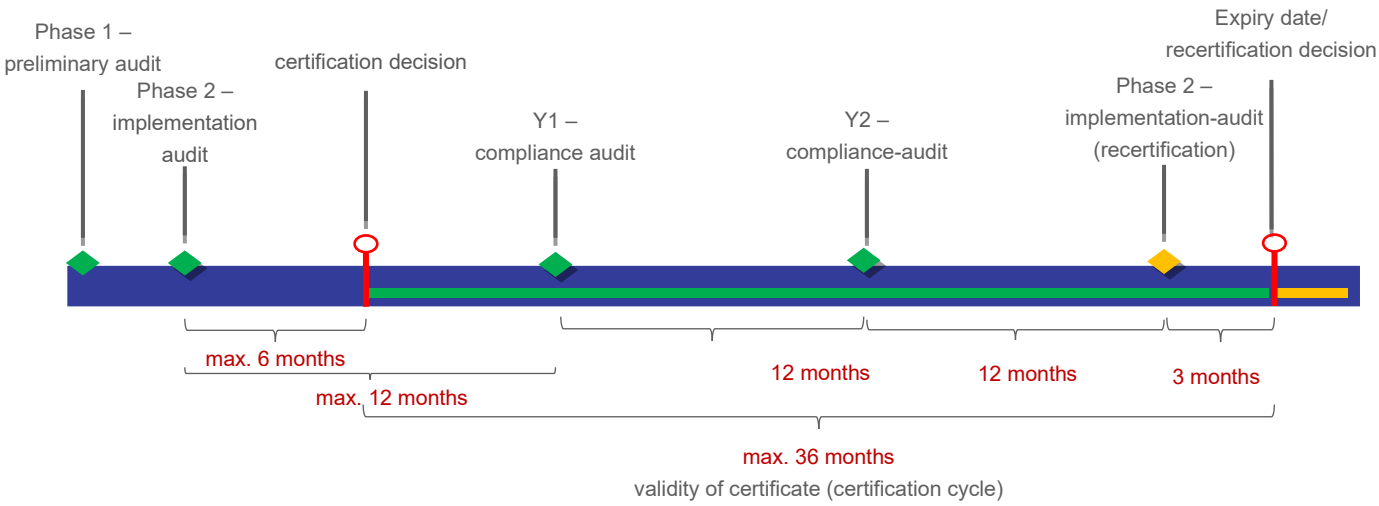

Figure 2 - Deadlines within an initial certification cycle

Figure 2 shows the main deadlines within an initial certification cycle. This cycle starts with a preliminary audit (Phase 1). The results of the preliminary audit may lead to postponement or cancellation of the implementation audit (Phase 2). The maximum lead time between the preliminary audit and an implementation audit is six (6) months. This deadline can be exceeded only on the basis of substantiation from the lead auditor involved and with the express consent of **the System Certification manager**.

If significant changes occur in the period between the preliminary audit and the implementation audit, it may be necessary for TÜV NORD Nederland to redo (part of) the preliminary audit.

Within six (6) months after the (Phase 2) implementation audit, TÜV NORD Nederland must be able to make a positive certification decision. A positive decision can be made only if the *customer* has demonstrated compliance with all the requirements of the normative document. If this deadline is exceeded for any reason, such as the customer's inability to implement any necessary corrections and corrective actions, the validity of the audit findings will expire and a new implementation audit will be required to continue the certification cycle.

The initial compliance audit (Y1) must be conducted within twelve (12) months of the last audit day of the certification audit to ensure the validity of the certification. The second compliance audit (Y2) is conducted twelve (12) months after the initial compliance audit.

3.2.2. The audit program of a subsequent recertification cycle

The audit program for the full recertification cycle consists of a recertification audit and two compliance audits (Y1 and Y2).

The purpose of the recertification audit is to determine whether your management system complies with the audit criteria, whether it is effective, whether it is adequate to ensure compliance with laws and rules and whether there is room for improvement.

To continue the validity of the certification, the recertification audit will be scheduled three (3) months before the expiry date of the certificate. Within this period, the organization must again (be able to) demonstrate compliance with all the requirements of the normative document. If successful, the customer will receive a new certificate with an expiry date based on the expiry date of the old certificate, even if the certification decision was made before the expiry date of the existing certificate. If the organization fails to demonstrate that the customer's management system and/or process continues to meet all requirements, the organization may (temporarily) have no valid certificate after expiry of the existing certificate.

The initial compliance audit (Y1) is then conducted twelve (12) months after the recertification audit to ensure the validity of the certification. The second compliance audit (Y2) is conducted twelve (12) months after the initial compliance audit.

3.3 The audit plan

TÜV NORD Nederland prepares an audit plan for each audit based on the audit program and the proposal.

The scope of an individual audit normally covers the full scope of the certification. That means all organizational units covered by the certificate are visited. However, if a (re)certification consists of multiple audits (covering multiple sites, for example) this need not be the case.

The audit criteria are used as the reference against which conformity is established. These include:

- the requirements of a standard or other normative document relating to management systems and/or processes;
- the requirements arising from the certification outline applied to establish conformity;
- the defined processes and documentation of the management system developed by the customer.

The customer will provide **TÜV NORD Nederland** with timely access to the documented information of its management system and/or process (i.e. four [4] weeks prior to the audit), if some or all of the preliminary audit is not performed on site.

TÜV NORD Nederland will send the preliminary audit plan to the customer no later than one (1) month prior to the certification audit. The (final) schedule for the implementation audit is set out in the report prepared based on the preliminary audit. The schedule for the initial compliance audit is set out in the implementation audit report. The report of the initial compliance audit includes planning for the second compliance audit.

3.4 Scheduling a recertification audit

TÜV NORD Nederland contacts the customer to continue the certification cycle and determine the date of the recertification audit. Recertification is conducted in accordance with these rules. Depending on developments within and outside the customer's organization and the results of the previous certification cycle, TÜV NORD Nederland decides whether a preliminary audit is required for the purpose of recertification. Where applicable, this is indicated in the recertification confirmation.

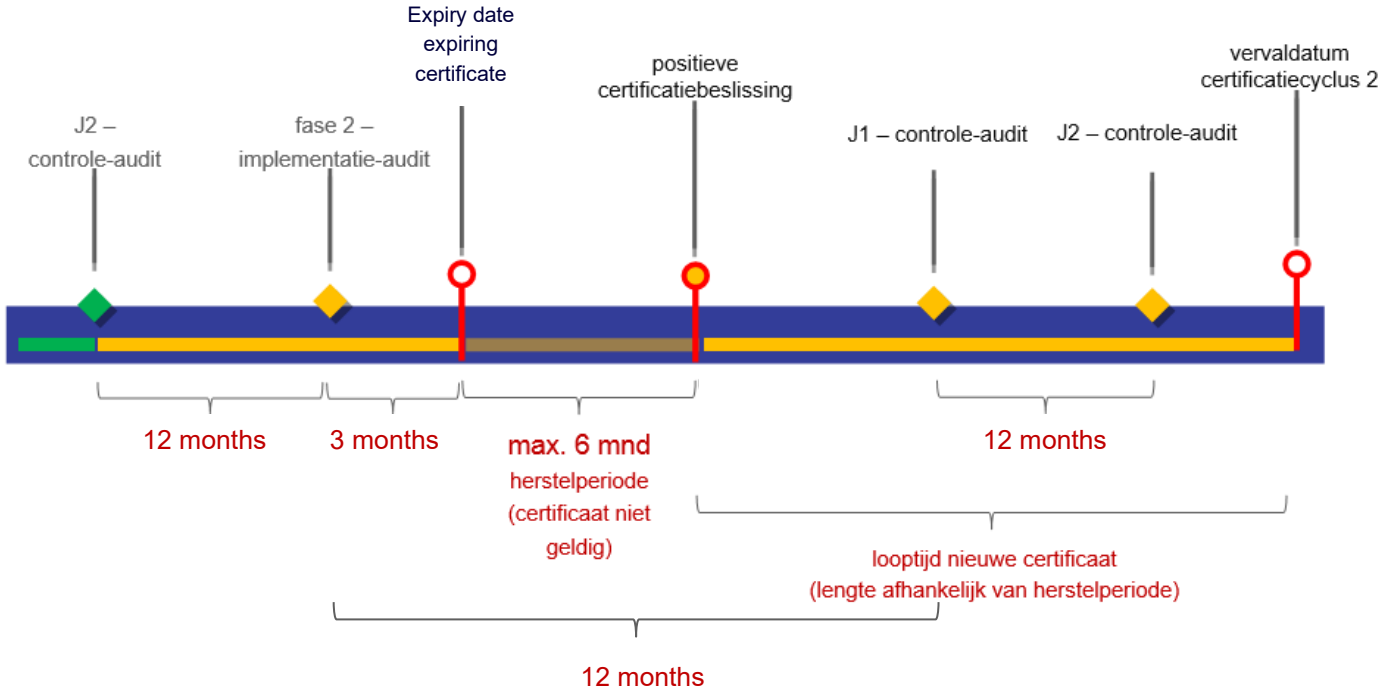

Figure 3 - Time limits in case of negative recertification decision

If, for any reason, **TÜV NORD Nederland** is unable to make a positive decision before the expiry date of the expiring certificate, the validity of the certification cannot be extended.

Figure 3 shows the consequences. If the certification has expired, TÜV NORD Nederland may restore the certification within three (3) months if the unresolved activities are completed. The effective date of the renewed certificate is on the date of the certification decision. The validity of the renewed certificate is 36 months from the expiry date of the old certificate. This then results in the renewed certificate having a shorter validity period, since the validity only takes effect at the time of the positive certification decision.

If it is not possible to restore compliance in due time, then TÜV NORD Nederland must in any case perform another implementation audit. In this case, TÜV NORD Nederland reserves the right to convert the assignment into a certification audit with a maximum of thirty percent (30%) additional audit time.

4. Conducting a (re)certification audit

4.1 Introduction

Conducting a (re)certification audit includes all activities necessary to arrive at an assessment of the management system and/or process. These are:

- Preparing the audit
- Conducting the preliminary audit
- Conducting the audit process
- Reporting the conclusion(s)
- Resolving non-conformities
- Issuing the certificate
- Suspending the certification cycle
- Complaints about TÜV NORD Nederland

4.2 Preparing for an audit

4.2.1. General

After the customer has awarded **TÜV NORD Nederland** the assignment, the practical arrangements regarding the implementation of the audit will be initiated.

TÜV NORD Nederland:

- bears responsibility for the completion of all phases of the certification cycle;
- appoints qualified auditors to conduct the audit under its authority and responsibility;
- acts in accordance with applicable accreditation or other regulatory guidelines; and

- conducts the audit within twelve (12) months of the assignment being awarded;

If completion is not possible in the latter timeframe, then the cancellation terms come into effect.

The **customer** must:

- ensure that the documented information as stated in the audit confirmation is made available in usable form to TÜV NORD Nederland by the date specified in the audit confirmation;
- allow the audit team of TÜV NORD Nederland to gather information about the activities that are within the scope of the certification, allow access to the different company premises and/or (project) sites, provide all applicable documented information of the customer and provide assistance upon the audit team's first request;
- ensure that officials - who may be stated in the audit plan - are available to participate in the investigation;
- ensure that, during the audit, the consultant(s) present serve as observers only and are limited in their duties to observation;
- provide tools and facilities for the purpose of the audit team's deliberations and the development of audit findings;
- instruct the TÜV NORD Nederland audit team on safety guidelines that apply within the organization and at any (project) sites, providing them with appropriate safety equipment as the situation requires;
- if privacy-sensitive data are part of the auditing process, agree with TÜV NORD Nederland on how an adequate sample can be taken. Consider anonymizing data and consent of individuals. Monitoring for observing privacy rules is a primary responsibility of the customer;
- provide insight into complaint records (focused on the scope of the certified management system and/or process);
- appoint a permanent point of contact for the audit team (e.g. the KAM officer); contact information must be shared with the audit team leader.

The customer must ensure that the entire management system and/or process is in place, managed and operational for at least three (3) months before TÜV NORD Nederland conducts the certification audit.

The certification outline may specify additional requirements for the certification audit.

5.2.1.1 Preparation for multi-site certification

TÜV NORD Nederland develops a sampling plan for each organization using multi-site certification and records the underlying rationale.

If, during the audit, the audit team finds that the organization does not meet the multi-site conditions, they still visit all sites. The additional work required to reach a fully substantiated conclusion will be charged by TÜV NORD Nederland based on actual cost at the agreed hourly rate per person to the organization.

For multi-site certification, non-conformities found at one branch office apply to all branch offices within the certification outline.

In the case of non-conformities, when auditing the cause of the non-conformity, **the organization** examines all subsidiary sites participating in the relevant certification outline in order to determine whether the non-conformities are also relevant there.

5.2.1.2 Preparation for integrated audits

During a preliminary audit, the audit team determines and confirms the degree of integration of the management system. If necessary, the required audit time, based on the information from the application, is assessed and adjusted.

If, during the audit, the audit team finds that the organization does not meet the integration requirements, the certification is converted to a *combined audit*. The additional work required to reach a fully substantiated conclusion will be charged by TÜV NORD Nederland to the organization based on actual cost at the agreed hourly rate per person.

If non-conformities are detected, **the organization** must consider the various standards related to the part of the management system and/or process in resolving the non-conformity.

4.2.2. Audit team members

TÜV NORD Nederland puts together an audit team with all the necessary qualifications to complete a full certification cycle. An audit team[5] consists of one or more auditors. Although the audit team is appointed for a full certification cycle, circumstances may require changes.

One auditor from the audit team acts as the **audit team leader**. This auditor is the primary point of contact for the organization regarding the conduct of the audit, chairs both the opening and closing meetings, is responsible for following the audit plans and prepares the audit report.

An industry (or technical) **expert** can support the audit team. This person does not serve as an auditor, but provides the audit team with advice for preparing, planning or conducting the audit.

The audit team members are revealed to the organization in the audit confirmation. If any members are replaced, this will be communicated in a timely manner.

4.2.2.1 Objection to members of the audit team

The customer may object to members of the appointed audit team if a conflict of interest may arise. The organization must communicate such objections in writing to the management of TÜV NORD Nederland within five (5) working days from the date of the audit confirmation.

[5] In the context of this document, the term 'audit team' also covers the situation where just a single auditor is assigned.

4.2.3. Observers on behalf of TÜV NORD Nederland

The audit team may be accompanied by an observer. This may be an assessor from the Dutch Accreditation Council or a designating body that evaluates whether the audit team is complying with the rules and procedures applicable to them as part of an accreditation review or designation.

The customer has a contractual obligation to provide access to these observers to perform their assessment.

The audit team may also be accompanied by a witness auditor or a trainee, respectively. A witness auditor is a (fellow) auditor who observes his or her colleague in the context of assessing qualification to perform audits. A trainee is an auditor-in-training who, as part of his or her qualification, is required to shadow a number of audits with an experienced colleague.

4.2.4. Determining the scope of an audit

TÜV NORD Nederland determines the scope of an audit based on:

- the documented information belonging to the organization's management system;
- these certification rules;
- the audit plan;
- (application of) the normative document and/or certification outline with any additional provisions of the relevant (Central) Board of Experts;
- agreed arrangements, including audit time, as per quotation.

4.3 Conducting the preliminary audit

In the case of a certification audit, **TÜV NORD Nederland** conducts a preliminary audit and in the case of a recertification audit, this is an option. During a preliminary audit, depending on the certification outline and possibly the requirements of the relevant (Central) Board of Experts, the audit team assesses at least the readiness of the organization for certification. TÜV NORD Nederland also uses the preliminary audit to get thoroughly acquainted with the customer's organization so that the implementation audit can be effectively planned.

TÜV NORD Nederland almost always conducts the preliminary audit at the customer's site. This is sometimes in combination with an off-site review of documented information, such as via a digital link. In highly exceptional cases, a preliminary audit may be conducted completely off-site.

Studying an organization's website (in relation to Chapter 4 of an HLS standard) or doing desktop research for communications concerning the organization's performance may be part of the preliminary audit. This depends on the requirements established in the relevant certification outline, accreditation standard or preferences of the organization. The manner in which the preliminary audit is conducted is defined in the quotation.

The assessment of the documented information included in the tender is focused on completeness as well as compliance with the requirements regarding documented information in the applicable normative documents.

During a preliminary audit at the main site, **the customer** is expected to give the following:

- an explanation, preferably by the customer's board or management about the organization, covering the past, present and future of the organization. This should also include discussing the specific circumstances (context) of the organization.
- an explanation of the set-up of the management system, which covers at least the documented information associated with the management system and the way in which various standards requirements have been applied.
- an explanation of the organization's products/services and its (operational) processes, including any different (branch) offices, management mechanisms and applicable laws and rules;
- if possible, a tour where the audit team can see first-hand the processes previously discussed and, where possible, be able to speak briefly with employees to learn more about the processes.

TÜV NORD Nederland ensures that sufficient information is obtained to prepare a substantiated conclusion. The conclusion depends on the nature, extent and number of the areas of *concern identified*. At the end of the preliminary audit, TÜV NORD Nederland provides the (preliminary) conclusion. TÜV NORD Nederland will send the result of the preliminary audit to the organization no later than one (1) week prior to the implementation audit.

The conclusion of a preliminary audit may be that the customer is sufficiently ready to enter the *implementation audit*. A final audit plan will be established. Here, TÜV NORD Nederland determines whether sufficient resources (including audit time) are available to conduct an effective assessment of the implementation of the management system and/or process. This may necessitate adjusting the scheduled audit time. Should this be necessary, TÜV NORD Nederland communicates this accordingly by sending an (updated) audit confirmation.

It may also conclude that the management system is still not fully compliant in a number of areas in order to successfully pass an implementation audit. This may lead to postponement or cancellation of the implementation audit. If the conclusion is that the customer is not yet ready to start the implementation audit, a new date is set to repeat the preliminary audit.

If **the customer** wishes to discontinue the certification cycle as a result of a negative conclusion, the cancellation clause stated in the quotation is binding.

Not stating any areas of concern on a particular part of the normative document does not guarantee that any non-conformity will be found during the implementation audit.

4.4 Completing the audit process

5.4.1 Introduction

The core of the audit process is the phase in which the audit team collects the *audit evidence (data and documentation).* Based on this, the audit team determines whether the customer's management system and/or process meets the requirements pursuant to the standard or normative document. This is not a question of how the customer meets the requirements, but rather that an element of the standard is met and carried out effectively.

Because the customer's cooperation is necessary to obtain the audit evidence, the procedure is coordinated in advance. Each audit therefore starts with a kick-off meeting. This is intended to allow the audit team and participants (on behalf of the customer) to get to know each other and to coordinate the method, schedule and content of the audit.

Then the actual gathering of information (audit evidence) takes place through a series of interviews, review of documented information and observations. This also includes visiting projects and (branch) offices.

Each audit concludes with a closing meeting in which the audit team's conclusion is presented to the customer.

5.4.2 Audit kick-off meeting

A kick-off meeting is held at the start of the audit activities at the customer's premises to briefly explain how the audit activities will proceed. The topics and level of detail depend on the customer's familiarity with the audit process.

This kick-off meeting is attended by:

- the **audit team**
- the **customer's board or management and**
- the customer's permanent point of contact for the audit team.

The audit team leader at the meeting ensures that the attendants of the kick-off meeting are logged.

Prior to each audit, based on communicated major and/or non-intrusive changes, **TÜV NORD Nederland** decides whether the audit program needs to be adjusted.

5.4.3 Collecting audit evidence

The necessary data is collected in cooperation between the audit team of TÜV NORD Nederland and the customer's participants.

TÜV NORD Nederland specifies the information it requires to demonstrate conformity.

The **customer's participants** provide the requested (or reasonably intended) information. Disclosure may take the form of, or a combination of:

- submitting documented information;
- making statements of fact;
- showing or demonstrating a product, service, process or activity.

In addition, the audit team from TÜV NORD Nederland can make the necessary observations on site.

Failure to provide the necessary information may result in the audit team being unable to demonstrate compliance. This leads to having to establish a non-conformity.

TÜV NORD Nederland verifies the data provided to establish validity and reliability. Only valid and reliable data will be used as audit evidence.

TÜV NORD Nederland performs the audit in accordance with the audit plan as far as possible. If this is not possible, the customer's management is notified accordingly. TÜV NORD Nederland sets out the details of any deviations from the audit plan in the final audit report.

5.4.4 Deliberations of the audit team

TÜV NORD Nederland discusses the experiences and (preliminary) audit findings at the end of each audit day. A multi-day audit will also discuss whether the audit plan followed needs to be adjusted to achieve the audit objectives.

During a multi-day audit, TÜV NORD Nederland provides brief daily feedback on the experiences of that audit day to customer representatives. The customer cannot derive any rights from not yet sharing non-conformities in areas under audit.

At the end of the final audit day, **TÜV NORD Nederland** compares all the audit evidence against the audit criteria to determine conformity. If insufficient evidence of compliance is obtained, the audit team defines one or more non-conformities.

Depending on the audit schedule, TÜV NORD Nederland first discusses such non-conformities with the customer's management before their final definition and registration. During this consultation, the customer's management is given the opportunity to provide any additional information. If this information can be verified within the available audit time, it can potentially serve as additional audit evidence. This additional audit evidence can be used to establish subsequent compliance with audit criteria.

5.4.5 Closing meeting (presentation of findings)

In the closing meeting, the **audit team leader** of TÜV NORD Nederland announces the result of the audit as well as the recommendation to the certification decision maker with regard to the issuing or renewal of the certification. The following persons attend:

- the audit team of TÜV NORD Nederland;
- the customer's board or management or designated representative,
- the customer's permanent point of contact for the audit team, and
- if needed, the customer's participants in the audit.

The **audit team leader** chairs the closing meeting and ensures that attendance records are kept.

During the discussion, **the customer** is given the opportunity to ask questions about the findings and further steps to be taken regarding the certification cycle.

If necessary, **TÜV NORD Nederland** can indicate *improvement opportunities* in the form of *recommendations.* However, these do not affect the certification decision presented.

TÜV NORD Nederland ensures that all documented information received is returned to the customer's permanent contact after the audit is performed or destroyed.

4.5 Reporting the conclusion(s)

TÜV NORD Nederland prepares a draft audit report. A qualified reviewer reviews this draft report. The audit report contains the audit team's recommendation to the certification decision-maker regarding issuing or renewal of the certification.

Non-conformities are always recorded and provided digitally to the customer at the end of the audit.

If one or more non-conformities are detected, the audit team leader states in the report that a final conclusion regarding a positive opinion depends on adequately resolving the relevant non-conformities. In an audit report, the audit team leader includes instructions for the next audit.

4.6 Handling non-conformities

4.6.1. Introduction

The wording of the non-conformity consists of a statement of

- **What** was observed?
- **Where** was it observed?
- **Why** is it a non-conformity?

The customer's permanent contact, in consultation with the audit team leader and taking into account applicable guidelines, determines the lead time required for the corrective action(s) and co-signs the non-conformity(ies) confirming the non-conformity(ies) identified by the audit team.

4.6.2. Deadlines for handling non-conformities

As stated in Section 4.2, TÜV NORD Nederland must be able to make a positive certification decision within six (6) months (26 weeks) after the implementation audit, otherwise the results of the implementation audit would no longer be valid and thus a new implementation audit would be required. That is why it is necessary for the **customer** to take any necessary measures in due order.

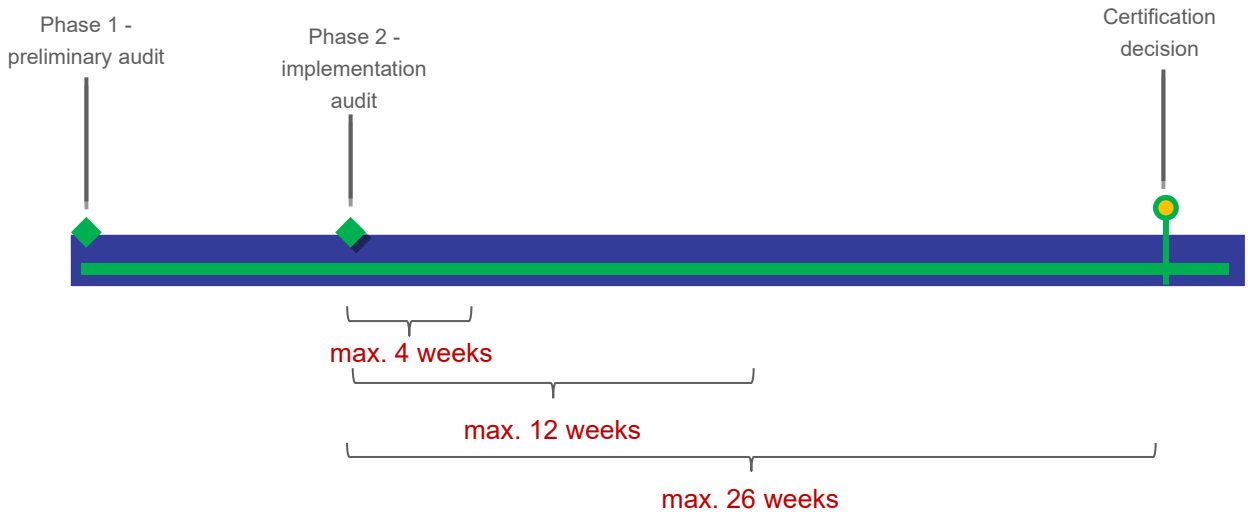

Figure 4 - Deadlines for handling A non-conformity

The maximum time period (see Figure 4) for processing by the customer (excluding acceptance of supporting documents by the audit team leader) of the measures used by TÜV NORD Nederland is twelve (12) weeks for an *A and B non-conformity*. In the case of an A non-conformity, the customer must submit a plan of action within four (4) weeks.

Acceptance of the evidence means that the audit team leader accepts it as valid substantiation of whether or not a non-conformity has been fully resolved. Acceptance does not imply final closure of the relevant non-conformity.

If a *re-audit* is to be performed on a non-conformity, the re-audit must take place within a maximum of twelve (12) weeks from the date the non-conformity was identified. After exceeding the set period, the certification cycle is stopped (in the case of a

[re]certification audit) or suspended (in the case of a compliance audit). In the case of a (re)certification audit, this also means that the file is closed. In that case, a full new certification audit must be conducted.

4.6.3. Follow-up actions for customer

For each reported non-conformity, **the customer** takes the following actions:

- determine what caused the non-conformity (root cause analysis);
- determine whether the non-conformity could occur or recur elsewhere (scope analysis);
- correct the observed non-conformity (correction, if possible);
- eliminate the cause of the observed non-conformity (if necessary);
- document the evidence of the above activities on the original non-conformity report/matrix and/or on any attachments; and
- send this documentation to TÜV NORD Nederland within the agreed deadline.

For B non-conformities, evidence of actions taken should be attached.

If the customer is unable to provide the relevant evidence within the agreed lead time (including acceptance by the audit team leader), TÜV NORD Nederland reserves the right to stop the certification cycle or to either suspend or revoke the certificate.

4.6.4. Verification of measure(s) by TÜV NORD Nederland

TÜV NORD Nederland determines whether a re-audit of the root cause analysis and non-conformities must be performed or whether a written statement of the cause analysis and corrective action(s) is sufficient. A re-audit is required for an A non-conformity and for a disproportionate amount of B non-conformities. In exceptional cases, exemption may be granted.

To verify the actions taken in response to both A and B non-conformities, **TÜV NORD Nederland** will assess whether the customer can demonstrate that the actions described in Section 5.6.3 have been effectively implemented.

If TÜV NORD Nederland considers the measures taken by the Customer to be insufficient, it may give the Customer the opportunity to demonstrate measures for completion, taking into account the deadlines by which the measure must be implemented.

TÜV NORD Nederland informs the customer in writing of the audit team's opinion and TUV NORD Nederland's subsequent certification decision.

In the case of an A non-conformity, if the customer proves unable to provide the evidence needed to verify the implementation of the corrections and corrective actions, TÜV NORD Nederland will perform the implementation audit again to obtain sufficient audit evidence to issue certification. This evidence must be available to TÜV NORD Nederland within six (6) months after the last day of the performance of the preliminary audit.

The cost of (re)verifying the measures taken will be charged to TÜV NORD Nederland. The cost of redoing the full implementation audit is charged to **the customer**.

4.7 Awarding a certificate

The certification decision-maker of **TÜV NORD Nederland** makes the decision on (re)certification of the organization after receiving the opinion of the audit team. This decision is based on the presence of all necessary audit evidence to conclusively demonstrate conformity with the normative document.

In case of a negative opinion by the audit team or a negative decision by the certification decision-maker, **TÜV NORD Nederland** will inform the customer accordingly in writing.

If the certification outline or other requirement-setting document has such a clause, then TÜV NORD Nederland also informs other bodies, such as Certification Bodies or Notified Bodies (accredited respectively designated for the work area in question) regarding this negative decision.

In the event of a positive decision, TÜV NORD Nederland:

- provides the final audit report and announces the decision to certify (and *register*) to the customer;
- registers the customer in its own register or the central register of the plan administrator;
- provides the customer with a certificate;
- authorises the customer to use the TÜV NORD Nederland *mark of conformity* in accordance with the terms of these rules;

The certificate normally has a validity of three (3) years, provided that the organization complies with all conditions and does not evade the conditions applicable to certified organizations (see Chapter 6) and compliance monitoring activities of TÜV NORD Nederland (see Chapter 7).
After certification has expired for an HCA, TÜV NORD Nederland can restore certification within six (6) months, provided that any unresolved recertification activities are completed. Otherwise, at least a new Phase 2 must be performed.

If requested by the organization, TÜV NORD Nederland produces the certificate in multiple languages. The costs for the translation of a certificate are in principle charged to the customer, unless TÜV NORD Nederland can verify the translated texts independently.

4.8 Cessation of the certification cycle

4.8.1. Cessation of certification cycle by the organization

If **the customer** cancels a scheduled appointment, the cancellation clause set out in the quotation is binding.

4.8.2. Cessation of certification cycle by TÜV NORD Nederland

TÜV NORD Nederland can stop a certification cycle in which a certificate has not yet been issued in the following cases:

- the audit team leader issues a negative opinion to the certification decision-maker regarding the certifiability of the management system and/or process.

- the (corrective) actions following non-conformities were not approved by the audit team leader of TÜV NORD Nederland.
- a period of six (6) months after the start of the audit has elapsed without the customer having demonstrated to TÜV NORD Nederland that it has met all the requirements of the normative document.
- a negative decision by certification decision-maker on other issues.

TÜV NORD Nederland announces a decision to discontinue a certification cycle in writing (paper or digital). Discontinuation of a certification cycle where a certificate has already been issued is described in Section 6.8.

4.9 Complaints about TÜV NORD Nederland

4.9.1. General

If the **customer** or **certificate holder** is dissatisfied with the way TÜV NORD Nederland conducted the assessment, a complaint can be filed. The complaint rules are available from the TÜV NORD Nederland website at https://www.tuv.nl/nl/contact/klachten/.

4.9.2. Supplement for statutory certification activities

As part of its statutory certification activities, **TÜV NORD Nederland** applies the complaints procedure for administrative bodies, as set out in Chapter 9 of the General Administrative Law Act (Awb). The above complaints procedure complies with the Awb.

Pursuant to the General Administrative Law Act, the relevant parties may file a complaint against the conduct of TÜV NORD Nederland as an administrative body and against the conduct of persons employed under the responsibility of TÜV NORD Nederland. It is not possible to file an appeal against the decision regarding the processing of the complaint.

In statutory certification activities, the following further applies:

- the management, or a designated staff member, will inform the complainant to contact the National Ombudsman if not satisfied with the processing of the complaint.
- TÜV NORD Nederland keeps records of complaints and the statistics are reported to the indicative Ministries.

5. The certificate

5.1 Introduction

This chapter describes the information stated on the certificate, how a certificate holder can communicate its certification to its stakeholders and further rules for maintaining certification.

5.2 The information on the certificate

Figure 1 Example of certificate

TÜV NORD Nederland states the following data on the certificate:

1. the name, including legal designation of the organization;
2. the offices / branches covered by the certificate;
3. the normative document against which the organization was assessed;
4. the scope of the certificate;
5. the registration number of the certificate;

6. the effective date of the current certificate, the end date of the current certificate, the date of issuance of the first certificate, if any;
7. the logo of the plan administrator and or RvA and mark of conformity of TÜV NORD Netherlands.

5.3 The rules for certificate holders

5.3.1. Monitor conformity with the normative document

Upon receipt of the certificate, the **certificate holder** ensures conformity with the normative document. This includes any interim changes communicated by TÜV NORD Nederland.

5.3.2. Changes in organizational registration

The **certificate holder** may request a change in registration and certification.

TÜV NORD Nederland decides whether an additional assessment must be completed and whether a new application (see Section 3.1) is required.

A change in registration and/or certification during the certification cycle incurs costs, which are charged to the certificate holder.

5.3.3. Communicate changes in the management system and/or process

Without undue delay, the **certificate holder** reports to TÜV NORD Nederland that *major changes* in the management system and/or process have taken place. These changes should be communicated via sales@tuv-nord.com or Ekkersrijt 4401, 5692 DL Son en Breugel (Attn: Sales)

Following the changes, TÜV NORD Nederland decides whether to conduct a *verification audit* or further auditing activities or whether the audit program should be adjusted.

This may incur additional costs. These costs are charged to the certificate holder.

Also, redesigning the management system and/or process from an internal need, such as by implementing new software to manage the management system and/or process, is a change that should be reported without undue delay. The same applies to changes in contact details and addresses of branches to be communicated to TÜV NORD Nederland as soon as possible.

Changes of a less significant nature must be reported by the certificate holder at the kick-off meeting of a recertification or compliance audit.

5.3.4. Cooperation with (additional) compliance monitoring activities

Without undue delay, the **certificate holder** must fully cooperate in both planned compliance monitoring activities (see Section 7) and unplanned compliance monitoring activities, such as in response to (persistent) negative publicity or complaints about the certificate holder (see Section 6.7).

5.4 Use of the TÜV NORD Nederland mark of conformity

5.4.1. Introduction

By signing the certification agreement, **TÜV NORD Nederland** gives the certificate holder the right to use the mark of conformity of TÜV NORD Nederland and possibly other logos upon certification for only as long as the certificate is valid.

During all subsequent audits, the correct application of the mark of conformity and of any other logo images is verified.

5.4.2. The TÜV NORD Nederland - mark of conformity

The certificate holder may use the mark of conformity of TÜV NORD Nederland in accordance with the provisions of the General Terms and Conditions of TÜV NORD Nederland B.V.

In addition, the following conditions apply:

- Colour combination mark of conformity TÜV NORD Nederland: The mark of conformity is manufactured in PMS colour 294 (TÜV blue) as standard, but in addition to this colour it may also be used in black (PMS process black), white (always depending on substrate to be printed) and silver (PMS 877) by organizations on printed matter; the certification mark may not be printed smaller than ø 1.8 cm on printed matter (this in order to maintain legibility).
- The mark of conformity of TÜV NORD Nederland may only be used in unaltered form. Changes in the mark of conformity and/or in the caption of the mark of conformity are not permitted.
- The mark of conformity of TÜV NORD Nederland (for processes and systems) may not be used in any form that could be interpreted as product certification. Examples include putting the mark of conformity on a product, on a calibration certificate, inspection report, laboratory results, business cards and other reports that can be seen as products in this context.
- The mark of conformity may not be used in any form where it can be interpreted as applying to non-certified (parts of) companies, sites or processes.

Figure 5 - Example mark of conformity from TÜV NORD Nederland

5.4.3. Use of other logos

The **certificate holder** has to comply with the relevant rules and regulations of the plan administrators when using plan administrator logos.

For plans without their own rules or regulations, the use of the logo is not permitted, other than when displaying the certificate (see also Section 6.8.3).

The use of the logo of the Dutch Accreditation Council is not permitted, other than when displaying the certificate (see also Section 6.8.3).

The certificate holder is also not permitted to use the (commercial) company logo of TÜV NORD Nederland.

5.5 Publicity

TÜV NORD Nederland maintains records of certificate holders and may distribute or publish information from these registers or provide this information to a plan administrator, the Dutch Accreditation Council or the government (in the context of designations).

If the certificate of a certificate holder has been temporarily suspended or revoked by TÜV NORD Nederland, this decision may be published - or passed on to a plan administrator - by TÜV NORD Nederland.

TÜV NORD Nederland will grant third parties access to this register upon request.

The **certificate holder** may:

- inform contacts such as potential customers, buyers or governments about the full and exact details of registration;

- exhibit the certificate.

The certificate holder may not:

- imply that certification covers activities outside the scope of certification;
- use the certification in such a way that it negatively affects the public trust in TÜV NORD Nederland, the certification outline or the image of TÜV NORD Nederland.

5.6 Misuse of registration

The **certificate holder** waives the display, application and use of the certificate, the mark of conformity of TÜV NORD Nederland and any logos of plan administrators (see Section 6.4) in the event that:

- the certificate expires, is suspended or revoked, (see section);
- a major change is made to the management system and/or process (see Subsection 6.3.3) that affects the suitability for registration to such an extent that it cannot be accepted by TÜV NORD Nederland in these rules);
- the certificate holder fails to implement an amendment to these certification rules issued by TÜV NORD Nederland (see Section 1.7.3);
- other circumstances adversely affect the certificate holder's management system and/or process.

5.7 Complaints about a certification holder

Stakeholders of the certificate holder can submit a complaint regarding the management system or process (depending on the scope of the certificate) of the certificate holder to TÜV NORD Nederland.

TÜV NORD Nederland researches the nature and cause of the complaint raised. The certificate holder will be notified by letter.

If TÜV NORD Nederland considers the complaint justified, one or more of the following actions will be taken:

- an additional investigation regarding the complaint with the certificate holder;
- a verification audit of the certificate holder's management system and/or process;
- suspension or revocation of the certificate, (see Section 6.8).

The costs incurred will be charged to the certificate holder.

TÜV NORD Nederland does not participate in considerations regarding compensation for the financial consequences of proven defects in delivered products, processes, services and/or management systems certified by TÜV NORD Nederland.

5.8 Suspension and revocation

5.8.1. Introduction

The **Business Unit Manager Certification** (or the designated delegate) has the decision-making authority to suspend and revoke the certificate.

If required pursuant to the certification outline or other normative document, **TÜV NORD Nederland** will also inform other bodies such as Certification Bodies, Notified Bodies (accredited and designated for the respective field of work), regulators or the relevant plan administrator regarding this negative decision.

5.8.2. Suspension of the certificate

6.8.2.1 Reasons for suspension

TÜV NORD Nederland can suspend the certificate for a certain period of time. For example, if:

- the certificate holder is unable to demonstrate that adequate corrective action has been taken concerning non-conformities from TÜV NORD Nederland;
- the certification decision-maker of TÜV NORD Nederland makes a negative decision;
- incorrect use of the registration, certificate and/or mark of conformity of TÜV NORD Nederland, the logo image of the relevant plan or if the accreditation mark logo image is not updated to the satisfaction of TÜV NORD Nederland;
- the certificate holder fails to meet its financial obligations to TÜV NORD Nederland;
- TÜV NORD Nederland is unable to complete the necessary compliance monitoring activities within the specified time frame.

6.8.2.2 The procedure for suspension

TÜV NORD Nederland notifies the certificate holder of the *suspension* of the certificate in a registered letter. This letter will state the conditions that the certificate holder must meet in order to reinstate the certificate.

The certificate can be suspended up to six (6) weeks depending on the stated and described reasons. The letter announcing the suspension will indicate the period applicable in the specific situation.

As soon as the conditions regarding the stated reasons are met within the specified period, TÜV NORD Nederland will lift the suspension of the certificate and inform the certificate holder accordingly.

6.8.2.3 Suspension in the case of multi-site certification

If the certificate of one or more branch offices is suspended, **TÜV NORD Nederland** will investigate the potential consequences for the certification of the other branches.

6.8.2.4 Suspension in integrated audits

If the certificate of one or more management systems is suspended, **TÜV NORD Nederland** will investigate the potential consequences for the certification of the other management systems.
The resulting costs are charged to the certificate holder.

6.8.2.5 Removing suspension

To reinstate a certificate, the **certificate holder** will take appropriate (corrective and/or adjustive) actions without undue delay to enable TÜV NORD Nederland to lift the suspension. The certificate holder approaches TÜV NORD Nederland in writing (on paper or digitally) regarding the proposed measure(s).

TÜV NORD Nederland verifies the effect of the measure(s) at the certificate holder's site in a re-audit.

5.8.3. Revoking a certificate

6.8.3.1 Reasons for revocation

The **Manager of the Business Unit Certification** is authorised to revoke the certificate and the use of the TÜV NORD Nederland mark of conformity in the following cases:

- the measures stated in Subsections 6.8.2 and 6.8.3.5 are not adequate in the opinion of TÜV NORD Nederland;
- the normative document and/or processes have changed and the organization cannot demonstrably meet the new requirements;
- the certificate holder does not enable TÜV NORD Nederland to complete the
- required compliance audits;
- the certificate holder stops providing the products and/or services, or processes, for more than six (6) months;
- the certificate holder fails to meet its financial obligations to TÜV NORD Nederland;
- for other reasons, provided that such reason is specifically set out in these certification rules, or such reasons have been formally agreed upon between TÜV NORD Nederland and the certificate holder;
- in the case of complaints as set out in Section 6.7 in these rules.

6.8.3.2 Certificate revocation procedure

TÜV NORD Nederland notifies the certificate *revocation* to the certificate holder in a registered letter. Initially, this concerns a provisional revocation; after one (1) week, the revocation becomes final.

TÜV NORD Nederland may publish the notification of revocation of the certificate. If requested, TÜV NORD Nederland will always communicate to third parties the current status of the certificate (valid/suspended/revoked/restricted).

6.8.3.3 Revocation in the case of multi-site certification

If the certificate of one or more branch offices is revoked, **TÜV NORD Nederland** will investigate the potential consequences for the certification of the other branches.

6.8.3.4 Revocation in integrated audits

If the certificate of one or more management systems is revoked, **TÜV NORD Nederland** will investigate the potential consequences for the certification of the other management systems.

The resulting costs are charged to the certificate holder.

6.8.3.5 Reversing revocation

The organization cannot reverse the revocation of a certificate. If an **organization** still wants to demonstrate compliance with all the requirements of the normative document, then a completely new certification audit must be completed.

6. Compliance monitoring activities

6.1 Introduction

Following (re)certification, **TÜV NORD Nederland** conducts at least annual compliance monitoring activities to verify that the certificate holder effectively maintains compliance with the normative document. Depending on the certification outline or at the request of the certificate holder, compliance monitoring shall or may also take place semi-annually.

Compliance monitoring activities include audits at sites, assessing whether the management system and/or process of the certificate holder meets specific requirements of the normative document according to which certification is issued.

6.2 Planned compliance audits

6.2.1. Planning of compliance audits

TÜV NORD Nederland schedules the date for the following year at the end of an audit. If this is not possible, TÜV NORD Nederland will contact the representative of the certificate holder approximately three (3) months prior to the date the compliance audit is due.

The **certificate holder** ensures that the compliance audit can be conducted within the deadlines set for this purpose. If the certificate holder is unable to do so, TÜV NORD Nederland reserves the right to revoke the certificate (see Subsection 6.8.3), after the certificate holder has been notified. A delay in the date of conducting a compliance audit does not affect the date of the next compliance audit to be conducted or a recertification audit.

6.2.2. Implementation of compliance audits

7.2.2.1 General

The compliance audit is a sample that serves to verify that the certificate holder's management system and/or process is still operational and still meets the requirements of the applicable normative document. This should take into account changes in the organization and management system.

TÜV NORD Nederland conducts the compliance audits at the certificate holder's site. These are not always audits of the entire management system and may be scheduled along with other compliance monitoring activities. This allows TÜV NORD Nederland to maintain confidence that the certified management system continues to meet the requirements in the period between recertification audits.

Each compliance audit for the relevant management system standard includes:

a) internal audits and management review;
b) a review of actions taken following non-conformities identified during the previous audit;
c) resolving complaints;
d) the effectiveness of the management system in achieving the certificate holder's objectives and the intended results of the relevant management system(s);
e) progress of planned activities aimed at continuous improvement;
f) ongoing operational control;
g) assessment of any changes;
h) use of trademarks and/or other references to certification.

Conducting a compliance audit corresponds to conducting an initial audit, the main difference being that no preliminary audit is required (see Section 5.3).

7.2.2.2 Compliance and recertification audits in multi-site certification

During compliance audits and recertification audits, **TÜV NORD Nederland** visits the (branch) sites in accordance with a sampling schedule. This schedule is partly planned and partly random.

7.2.2.3 Compliance and recertification audits in integrated audits

During compliance audits and recertification audits, the **audit team** will determine each time whether the degree of integration is unchanged.

6.3 Unscheduled compliance monitoring activities

6.3.1. General

TÜV NORD Nederland may proceed with unplanned compliance monitoring activities for the following reasons:

- persistent negative publicity (related to the scope of the certificate) about the certificate holder;
- complaints about a certificate holder (see Section 6.7);
- notices or reports of investigations / shutdowns of certificate holder's operations by a competent authority;
- a notification about a change within a certificate holder's organization (see Section 6.3.3);
- suspension of certificates (see Section 6.8.2.5).

Other compliance monitoring activities may include:

- inquiries from TÜV NORD Nederland to the certificate holder regarding components of certification;
- reviewing the certificate holder's statements related to their activities (e.g. promotional materials, website);
- requests to the certificate holder to make documented information (paper or digital) available;
- any other means of monitoring the certificate holder's performance;
- conducting a verification audit.

6.3.2. Conducting verification audits

The management of TÜV NORD Nederland determines whether a verification audit is necessary. A verification audit is always announced in writing to **the certificate holder**.

If the certificate holder fails to cooperate in the performance of a verification audit, the management of TÜV NORD Nederland reserves the right to suspend and/or revoke the relevant certificate.

7. Terms and definitions

The definitions from ISO 9000:2015 "Quality Management System - Fundamentals and Glossary" apply. In addition, the following definitions and/or comments apply.

7.1 General terms

7.1.1. Recommendation

See improvement opportunity.

7.1.2. Area of concern

An observation during a *preliminary audit (8.2.2.1)* that may lead to a *non-conformity* (8.1.5) during the *implementation audit* (8.2.2.2) without action from the organization.

7.1.3. Instruction

A regulation that a lower ranking person or organization must follow in response to a (political) decision, from a hierarchically senior person, for example a Minister, or an important institution.

Note to term: TÜV NORD Nederland has been appointed by the Ministry for various subjects to conduct specific (safety) inspections in respect of laws and regulations on behalf of the government. Part of these instructions is that government agencies such as NVWA conduct regular audits to determine whether TÜV NORD Nederland is in compliance.

7.1.4. Accreditation

An independent confirmation of the competence, impartiality and independence of a conformity assessment organization that is based on (internationally) harmonised standards.

Note to term: Part of accreditation is that the Dutch Accreditation Council conducts regular audits to determine whether TÜV NORD Nederland is complying with the requirements for certification.

7.1.5. Non-conformity

Failure to meet a requirement.
(source ISO/IEC 17021-1:2015)

Note 1 to the term: In practice, TÜV NORD Nederland applies the perspective that a non-conformity is reported if an audit does not provide sufficient evidence of conformity. In other words, a non-conformity is a situation where insufficient evidence of conformity is available.

Note 2 to the term: An observation, such in nature that it is considered to have a direct negative impact on the operation of the management system and/or on the quality of an organization's products and services, processes or activities.

Resolution of a *non-conformity* (8.1.5) by taking effective corrective action is a prerequisite for certification or retention of the issued certificate.

Note 3 to the term: For definitions of non-conformities, the *plan administrator* (8.1.26) may use alternative wording; the wording in the certification outline prevails.

8.1.5.1 Class A non-conformity

A *non-conformity* (8.1.5) that affects the ability of the management system and/or process to achieve its intended results.

Note 1 to the term: *non-conformities* are classified as A non-conformities in the following circumstances:

- if there is reasonable doubt about whether effective process controls are in place, or the products or services will meet prescribed requirements;
- a number of minor non-conformities related to the same requirement or problem could indicate a structural deficiency in the management system and/or process and thus constitute an A non-conformity;
- based on objective evidence, it concludes that products and or services with deficiencies are likely or certain to be provided to customers, or do not take into account the key quality, safety, health and safety and environmental aspects of products, services or activities;
- the organization is unable to meet the principles of its own policies or relevant legislation;
- in perpetuity, the organization is unable to meet its own objective;
- an element from the normative document reviewed is missing, not implemented or not maintained at all;
- provisions in these certification rules are not met.

Note 2 to the term: in ISO/IEC 17021-1, such non-conformity is referred to as "major non-conformity".

8.1.5.2 Class B non-conformity

A *non-conformity* (8.1.5) that does not affect the management system's ability to achieve its intended results.

Note 1 to the term: non-conformities are classified as B non-conformities in the following circumstances:

- a factual observation is made that indicates a weakness in the management system, procedure, records or in the direction of an activity. Failure to take timely corrective action may result in a situation where the organization cannot comply with:
  - the principles of its own policies or relevant laws and rules;
  - achieving the objectives;
  - product requirements;
  - customer expectations;
  - the requirements of the stakeholders and environment or an element from the normative document reviewed is only partially implemented or partially not maintained.

Note 2 to the term: in ISO/IEC 17021-1, such non-conformity is referred to as "minor non-conformity".

7.1.6. Audit evidence (~material)

Records, statements based on facts or other information relevant to the *audit criteria* (8.1.7) and verifiable.

7.1.7. Audit Criteria

The set of policies, procedures or requirements used as a reference against which objective evidence is assessed.
(Source: ISO 9000:2015)

Note to term: TÜV NORD Nederland will, in case of questions of interpretation, apply standards and/or guidelines in the original language in which they were written.

7.1.8. Audit Plan

A document listing the dates of the interviews, interview times and interview locations and topics to be verified.

7.1.9. Audit time

The time required to conduct a complete and effective audit of the customer organization's management system.

Note to term: the preparation time and reporting time of the audit team also fall within this definition. The specific certification outlines specify the minimum amount of time to be spent on-site collecting *audit evidence* (8.1.6)

7.1.10. (Centraal) College van Deskundigen - (Central) Board of Experts ([C]CvD)

An independent advisory body that advises on everything related to the certification of a management system and/or process, the requirements to be applied (where applicable), the methods of audit and the rules for the use of the certificate.

College members are appointed based on their industry expertise or their specific independent expertise.

7.1.11. Certificate

A statement of conformity to a normative document, issued to the organization, showing the applicable name of the organization, location, normative document as well as the scope of work.

7.1.12. Certificate holder

An organization whose management system or a specific process has been certified.

7.1.13. Certification

The independent confirmation that management systems, products and/or services, processes or persons meet specific requirements.

Note to term: these certification rules apply only to management systems and processes.

7.1.14. Certification outline

A conformity assessment system related to management systems to which the same prescribed requirements, specific rules and procedures apply.

Note to term: Where these certification rules refer to schedule or certification outline, this also includes the term *normative document* (8.1.22).

7.1.15. Certification documents

The documented information related to a *certification* (8.1.13);

Note to term: The following information must be included in the certification document(s):

a) the name and geographic location of each certificate holder (or the geographic location of the principal place of business and, in the case of certification of more than one site, of each site);

b) the effective date of issuing, extending or reducing the scope of certification, or renewing certification; this date cannot be earlier than the date of the relevant certification decision;
c) the expiry date or deadline for recertification, in accordance with the recertification cycle;
d) a unique identifier;
e) the standard and/or other normative document used for auditing the certificate holder, including an indication of the issue status;
f) the scope of certification with respect to the types of activities, products and services as applicable to each establishment;
g) the name, address and mark of conformity of TÜV NORD Nederland and any other marks (e.g. accreditation symbol);
h) any further information required by the standard and/or other normative documents used for certification;
i) in the case of publication of revised certification documents, a means of distinguishing between the revised documents and previous obsolete documents.

7.1.16. Integrated management system

One management system that manages multiple aspects of organizational performance to meet more than one management standard with some degree of integration.

Note on term: a management system can range from a combined system in which different management systems are added for each set of *audit criteria* (8.1.7) or standard to an Integrated Management System that includes shared system documentation, management system elements and responsibilities.
(Source: IAF/MD 10)

7.1.17. Significant change

A change in the internal or external context of an organization affecting the management system and/or process or on the scope of a certification.

Note to term: Some examples of *significant changes* include:

- an increase or decrease in the number of sites from the previous audit (regardless of the application of multi-site certification);
- the implementation of a new software application or database (not being an update) for controlling operational processes (an Enterprise Resource Planning System, ERP);
- a reorganization within the certificate holder's organization that has changed roles, responsibilities, authority or management system and/or process-related functions;
- stopping or relocating (part of) the activities/processes;
- a merger, acquisition and/or change of ownership;
- important changes in purpose or strategy that cause the certificate holder to target a different market and/or audience.

7.1.18. Revocation

Certification discontinued voluntarily (by the certificate holder) or revocation imposed (by TÜV NORD Nederland).

7.1.19. Customer

Party where an audit of the management system or process is conducted for the purpose of certification.

Note on term 1: before the certification cycle has started, the term organization is used; after the certificate is obtained, the customer is referred to as a *certificate holder* (8.1.12).

Note to term 2: a customer must be a legal entity (such as a B.V., N.V., V.O.F. or sole proprietorship) for which a Chamber of Commerce record extract is available, or a different such record extract that shows that the legal entity exists.

7.1.20. Mark of conformity

The logo image a certificate holder may use to communicate that its management system and/or process has been positively assessed by TÜV NORD Nederland.

Note: The mark of conformity should not be confused with the company logo of TÜV NORD Nederland. Certificate holders are not authorised to use the company logo of TÜV NORD Nederland in any way or in any expression.

7.1.21. Multi-site certification

An audit at an organization where the management system and/or process extends across multiple *sites* (8.1.29), but where there is central control.

If the organization has multiple branch offices, or if, for example, a franchise organization wishes to have its branch offices certified and there is one central management system, the organization can opt for multi-site certification.

Multi-site certification always involves one main site. The audit team visits this site during each audit. For subsidiaries, the audit team takes a sample from the sites. This means that in both a (re)certification audit and a compliance audit, not all branch offices are visited each time.

Note to term: multi-site certification does not apply to all certification outlines. For more detailed information on this, see IAF/MD 1.

7.1.22. Normative document

A document that contains the requirements for a system, process or product and/or service.
Note to term: A normative document is also called a norm, standard, guideline or assessment guideline.

7.1.23. Project site

A temporary *establishment* (8.1.29) that is part of a customer or certificate holder, which an auditor has determined exists, and has activities within the scope of certification.

7.1.24. Registration

Awarding *certification* (8.1.13) to an organization, as well as including the certificate holder, and listing the activities assessed (scope) in the register of all organizations certified by TÜV NORD Nederland.

7.1.25. Registration Agreement

An agreement between TÜV NORD Nederland and the organization for the purpose of including the details of the organization's certificate in a certification register.

7.1.26. Plan administrator

An organization that develops and manages conformity assessment plans.

These plans describe the subject of assessment and the requirements that apply. Laboratories, inspection bodies and certification bodies use these plans in the performance of their evaluative task.
(Source: RvA)

7.1.27. Suspension

The temporary revocation of all or part of a certification.

7.1.28. Improvement opportunity

The finding of a situation or process that can be optimised, where the way the organization currently implements a situation, system or process does not conflict with an audited standard element. An improvement opportunity does not recommend a specific solution. The organization is free to specify these opportunities for improvement; they will not be addressed in the next audit.

7.1.29. Subsidiary (branch~)

A site that is part of a customer or certificate holder that an auditor has determined exists and has activities within the scope of certification.

Note on the term: branch offices exist when they perform the same work and are managed in the same way.

7.1.30. Preparation (audit~)

All activities of the audit team, prior to conducting the audit, that are designed to make the completion of the audit logistically effective.

Note to term: Activities related to audit content are covered by the term *preliminary audit* (8.2.2.1).

7.2 Terms related to types of audits

7.2.1. Audit

A systematic, independent and documented process for obtaining objective evidence and evaluating it objectively to determine the extent to which *audit criteria* (8.1.7) have been met.

Note to term: TÜV NORD Nederland distinguishes between several types of audits, namely:

- *certification audit (8.2.2)*
  - *preliminary audit (Phase 1 audit) (8.2.2.1)*
  - *implementation audit (Phase 2 audit) (8.2.2.2)*
- *compliance audit (8.2.3)*
- *re-audit (8.2.7)*
- *verification audit (8.2.8)*
- *recertification audit (8.2.6)*

7.2.2. Certification audit

(Alternative: initial-audit)

An audit conducted by an audit organization, independent of the customer and the parties relying on certification, for the purpose of certifying the customer's management system.

Explanation: A certification audit is designed to assess an organization's compliance with all elements of the applied *normative document* (8.1.22). This involves verifying that all measures have been established, implemented (= applied) and maintained. And that these measures are effective in relation to the purpose of the standard.

TÜV NORD Nederland conducts a *preliminary audit* (8.2.2.1) for each certification audit. A preliminary audit is necessary to obtain and verify information about the (context of the) organization so that an effective *implementation audit* (8.2.2.2) can be conducted. The outcome of the preliminary audit is used to create the (final) audit plan.

8.2.2.1 Preliminary audit (Phase 1 audit)

An exploratory study assessing an organization's readiness for certification.

Note to term: Since a preliminary audit is an assessment of limited depth that does not fully address all aspects of the *normative document* (8.1.22), it is impossible to identify *non-conformities* (8.1.5). However, the audit team may identify *areas of concern* (8.1.2) where the limited information seems to indicate that the management system needs additional attention.

8.2.2.2 Implementation audit (Phase 2 audit)

The research phase in *which audit evidence* (8.1.6) is collected and reviewed with the goal of determining the effective application of a *normative document* (8.1.22).

Note to term: The *preliminary audit* (8.2.2.1) serves to generally assess the operation of the management system. The implementation audit serves to assess the effective application of all individual components of the management system.

The purpose of the relevant normative document prevails in this context. The organization must demonstrate that the management system helps the organization achieve the goals applicable within the scope of the normative document.

The purpose of the Phase 2 audit is to assess the implementation, including the effectiveness[6], of the organization's management system. Phase 2 is conducted at the customer's site(s) and includes at least the following:

a) Information and evidence regarding compliance with all requirements in the applicable normative document(s);
b) performance monitoring, measurement, reporting and assessment against the main performance goals and targets, consistent with expectations in applicable normative documents;
c) the capability of the organization's management system and its performance in meeting applicable regulatory and contractual requirements;
d) operational control of the organization's processes;
e) internal audits and management review;
f) executive responsibility for the policies of the organization.

[6] Effective means the extent to which the purpose of the normative document is realised.

7.2.3. Compliance audit

An audit to confirm previously established conformity with a normative document.

7.2.4. Combined audit

An audit conducted at a single organization or organizational unit on two or more management systems together regardless of the number of auditors.
(Source: ISO 9000:2015, modified)

Note to term: The components of a management system that may be involved in a combined audit may be determined by the relevant normative documents applied by the organization.

7.2.5. Integrated audit

An audit on an organization's management system against two sets of audit criteria or standards conducted at the same time.
(Source: IAF/MD 10)

7.2.6. Recertification audit

An audit conducted by an auditing organization, independent of the customer and the parties relying on certification, for the purpose of renewing certification of the customer's management system.

7.2.7. Re-audit

A re-audit is an additional assessment performed on-site at the organization after non-conformities were detected during a scheduled audit, or following a suspension, for which the resolution of said non-conformities can only be adequately verified on-site.

OR
An audit to verify the effectiveness of corrections and corrective actions at the customer site. This activity is usually performed by a member of the audit team.

7.2.8. Verification audit

An additional (unscheduled) audit to assess certain aspects of a management system and/or process system that cannot be assessed fully, adequately or on time during a scheduled audit.

7.3 Abbreviations

7.3.1. RvA

Raad voor Accreditatie - Dutch Accreditation Council

7.3.2. (C)CvD

(Centraal) College van Deskundigen - (Central) Board of Experts

7.3.3. NEN

Nederlands Normalisatie-instituut - Dutch Standards Institute

7.3.4. CA

Certification audit

7.3.5. HCA

Recertification audit

7.3.6. Y1 (or Y2)

Compliance audit for year 1 (or year 2)

7.3.7. CI

Certification body

TÜVNORD

TÜV NORD Nederland

Ekkersrijt 4401
5692 DL Son en Breugel

T +31 499 - 339 500

info-nl@tuv-nord.com
www.tuv.nl