

Version: 15
Date: 11/05/2016

Vérification:
Validation:

- 1) The audit programme for a standard certification cycle is shown in **Annex I**.
- 2) All information necessary to reviewing the application and planning the cycle will be provided through the form F2-2.1, in addition to F2-2.3 as required (available on www.snch.lu).
- 3) The management system shall be in conformity with the standard(s) applied for, e.g. EN ISO 9001:2015, EN ISO 13485:2012 or ISO/IEC 27001:2013.
- 4) All audits are carried out according to the requirements of standard EN ISO/IEC 17021-1:2015.
- 5) The audit duration will be determined according to:
 - a) For QMS certification according to EN ISO 9001: mandatory document IAF MD 5:2015
 - b) For QMS certification according to EN ISO 13485: mandatory document IAF MD 9:2015
 - c) For ISMS certification according to ISO/IEC 27001: international standard ISO/IEC 27006:2011
- 6) For Stage 1 of the initial audit, the client's quality manual must be sent to the lead auditor in case of a quality management system (QMS), and his policy, scope, risk evaluation and treatment as well as his statement of applicability in the case of an information security management system (ISMS). In some cases, the lead auditor may ask for additional documents from the management system.
- 7) The lead auditor may choose to carry out parts of Stage 1 on the client's premises.
- 8) The client shall carry out his management review and internal audit *before* the initial certification audit.
- 9) During on-site audits, the client shall give access to the auditors to all areas and personnel, as well as to the management system's documentation and records (including - on request - records of complaints and corresponding corrective actions).
- 10) Nonconformity system (NC):
No certification will be granted or maintained if, during an audit, at the least the following have been found:
1 Major NC
or 3 Minor NC on the same standard requirement
or 5 Minor NC in total
 with the following definitions:
Major NC: non-compliance with a requirement affecting the system's capacity to attain its objectives
Minor NC: non-compliance with a requirement not affecting the system's capacity to attain its objectives
Observation: insufficient formalization or imprecise requirement or potential for improvement
- 11) The client shall propose his corrective actions in regard to the findings within a maximum time frame of 15 working days.
- 12) In case a major NC cannot be closed within 6 months after the last day of the audit, a new Stage 2 audit will be conducted.
- 13) It should be noted that, if a minor NC is not taken into account until the next audit, it may be upgraded to a major NC.
- 14) The client commits himself to quickly inform SNCH about any modification concerning e.g. his status, his organization, the contact person, the scope of his operations as well as any major modification introduced in his certified management system or processes.
- 15) During a surveillance audit, at least the following standard clauses will always be audited: internal audit, management review, follow-up actions to non-conformities from the previous audit, complaint handling, system efficiency, continuous improvement, operational control, review of any changes, use of marks.
- 16) In order to avoid any interruption in certification, the recertification audit must be conducted and finalized before the certificate's expiry date. The recertification audit can be conducted in two stages if necessary (e.g. in case of major changes to the management system). In case all recertification activities are not completed before the certificate's expiry date (e.g. open major NCs), certification will be interrupted. If this interruption takes more than 6 months, a new Stage 2 audit will be conducted. In any case, the validity of the renewed certificate will be equal to the expiry date of the previous cycle plus 3 years.
- 17) In case a renewal audit cannot be organized before the expiry of the certificate, the next audit will be considered as an initial audit.
- 18) As soon as a certificate becomes invalid (e.g. due to suspension or expiry), the client is not allowed any longer to make any reference to this certification (notably on his website or through use of the SNCH certification mark).
- 19) Information about issued, suspended or cancelled certificates can be obtained by simple request to SNCH.



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- 20) In addition to the regular audit cycle, SNCH may need to carry out special audits (e.g. in case of complaints or in case of major modifications to the certified management system). Such audits may have a short notice. They will be duly announced to the client. All corresponding fees will be charged to the certified organization.
- 21) All SNCH auditors work under a confidentiality clause. However, SNCH may be induced by law to disclose certain confidential information on behalf of a third party, in which case confidentiality is not opposable. Unless otherwise informed by the applicant, the client will be informed about such an information transfer. Any information appearing on the certificate is not considered confidential. Specifically, in the case of ISO 13485 audits, audit report information may be released to regulators that recognize this standard.
- 22) In case of misconduct by the certified organization (e.g. inefficient management system, recurring findings, non-respect of corrective action plan, abusive certificate use, complaints, non-payment of invoices, audit refusal...) or on the organization's request, SNCH may decide to suspend the certificate which will become temporarily invalid.
- In case the reason for the suspension is not corrected within the agreed time frame, or if required by the severity of the problem, or on the organization's request, SNCH may permanently cancel the certificate. In case a suspension lasts longer than 6 months, the certificate may also be cancelled.
- In case the finding is only related to one part of the management system, and if allowed by the standards, the certificate may be maintained with a reduced scope.
- A scope reduction may also be requested by the organization (e.g. in case of cessation of part of the activities). A return to the full scope may require an additional audit.
- In any case, the organization will be informed about any suspension or cancellation decisions by registered mail. A scope reduction will result in an amended certificate.
- The organization will be informed about the obligation to cease any advertising related to the suspended/cancelled/reduced part of the certification. If necessary, SNCH will inform the competent authority.
- Any conditions and time frames for restoring the certificate will also be transmitted in writing to the organization.
- 23) Any complaint and any appeal related to SNCH 's services or decisions shall be sent in a written form (mail or e-mail) to the address below.

For further information or a quotation, do not hesitate to contact SNCH at the following address:

Société Nationale de Certification et d'Homologation s.à r.l.
2a, Kalchesbruck, L-1852 Luxembourg

Tel: +352 26 15 70 – 250 / Fax: +352 26 15 70 – 244 / E-Mail: info@snch.lu

Annex I: Standard certification cycle (ISO/IEC 17021-1:2015 Annex E):

