SSCI’s DSSC Initiative

Requirements for Certification Bodies
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1. Introduction

1.1. The Supplement Safety & Compliance Initiative (SSCI) is a non-profit foundation comprising major global retailers, distributors, raw material suppliers (including cultivators), raw material manufacturers, finished product manufacturers, certifying bodies, and experts in quality control, quality assurance, and safety of dietary supplement.

1.2. SSCI’s vision is to elevate the quality and credibility of dietary supplements globally by continuously driving improvements in quality processes. The initiative is focused on engaging and collaborating with stakeholders in the supply chain with the goal of raising standards of the entire industry.

2. Purpose

2.1. This document specifies requirements for certification bodies (CBs). Through routine assessments, SSCI-recognized accreditation bodies (ABs) verify CB conformance to the requirements of ISO/IEC 17065 and the requirements contained in this document.

2.2. SSCI monitors evaluations that CBs meet the requirements of this document. Through its relationship with ABs, SSCI is informed about CB conformance with these requirements. In addition, SSCI directly evaluates conformance of CBs with requirements of the Dietary Supplements Safety and Compliance (DSSC) initiative through its integrity initiative.

2.3. Contact information for all recognized ABs is listed on the SSCI website.

2.4. English is the official language of SSCI. All correspondence, reports, and certificates shall be submitted in English.

2.5. The following verbal forms are used (consistent with their use in ISO/IEC 17065):

- “Shall” indicates a requirement.
- “Should” indicates a recommendation.
- “May” indicates a permission.
- “Can” indicates a possibility or a capability.

2.6. Unless otherwise specified the latest version of the referenced documents apply.

3. References

3.1. ISO/IEC 17011, Conformity assessment -- Requirements for accreditation bodies accrediting conformity assessment bodies

3.2. ISO/IEC 17065, Conformity assessment -- Requirements for bodies certifying products, processes and services.
3.3. 21 CFR Part 111, Current Good Manufacturing Practice in Manufacturing, Packaging, labeling and holding operations for dietary supplements

3.4. 21 CFR Part 117, Current Good Manufacturing Practice, Hazard Analysis and Risk-Based Preventative Control for Human Food

4. Definitions

4.1. Refer to DSSC Initiative Definitions Document.

5. General Requirements

5.1. The CB must be accredited to ISO/IEC 17065 by an IAF MLA signatory AB.

5.2. The CB must obtain accreditation from an SSCI-recognized AB for ISO/IEC 17065 and DSSC initiative requirements.

   Note 1: A list of SSCI recognized ABs is available on the SSCI website.

   Note 2: A CB in the process of obtaining accreditation under the DSSC initiative may conduct certification audits and issue unaccredited certifications to DSSC initiative requirements provided a valid agreement is in place between the CB and SSCI. This period is referred to as “conditional recognition” and its duration is a maximum of 12 months.

5.3. The CB shall immediately inform SSCI of any changes in its accreditation status.

5.4. The CB shall designate a single point of contact for the DSSC initiative. Any changes in the contact or contact information shall be communicated to SSCI and the AB.

5.5. The CB shall sign an agreement with SSCI prior to providing any certification to the requirements of the DSSC initiative.

5.6. The CB shall cooperate with all requests from SSCI to provide information related to the operation of the DSSC initiative. Any information requested shall be provided within ten business days, unless agreed on otherwise by SSCI.

5.7. The CB shall actively participate in annual stakeholder meetings of SSCI. SSCI will communicate information about upcoming meetings to allow sufficient time for the CB to make appropriate arrangements.

5.8. The CB shall inform SSCI of any changes in its legal status, ownership, operational contacts, location, significant personnel, or any other changes that could have an impact on delivery of the program in a competent and conflict-free manner.
5.9. The CB shall make available to SSCI the following information:

- Any new applicants for the DSSC initiative, including the scopes of certification sought.
- Any changes in the certification status of an organization (e.g., extension, suspension, or withdrawal). Information on suspension or withdrawal shall include the basis for the action taken.
- Any validated complaints against an organization related to the DSSC initiative.

5.10. The CB shall ensure that in its contact with the certified organization, the organization agrees that the CB audit team may be accompanied by an accrediting body or members of SSCI at any time.

5.12. The CB shall establish a documented policy and procedures, as applicable, outlining the steps it takes in the event its clients are affected by a natural disaster or other situation affecting business continuity. The CB should consider alternate short-term methods of audit to ensure continuing system effectiveness for such clients.

5.13. The CB shall not offer or conduct under DSSC initiative any audit activities that are not directly related to certification, such as but not limited to informational audits, pre-assessments, gap analysis, etc.

6. Auditor Competence

6.1. The CB shall have program and scope-specific documented criteria, education, and experience demonstrating auditor competence.

6.2. The CB shall define witness auditor qualification criteria.

6.3. The CB shall ensure its auditors complete training in any areas in which auditor education or experience does not meet the predefined competence criteria.

6.4. The CB shall provide supervised initial training for all auditors new to auditing or the DSSC Initiative or scope.

6.5. The CB shall witness each auditor conducting an audit prior to qualifying the auditor as competent for the DSSC Initiative.

6.6. The CB shall document the satisfactory completion of all required training and successful witnessing of the auditor conducting an audit during the qualification period.

6.7. The CB shall develop a process for ongoing competence monitoring of DSSC-qualified auditors under the DSSC Initiative. The process should incorporate technical knowledge specific to the scope of work for which the auditor is qualified.

6.8. The CB shall conduct at least one witness of an auditor conducting an audit under the DSSC Initiative every three years to confirm acceptable auditor performance.
6.9. The CB should consider auditor qualification per scope when planning witnessing Initiative.

6.10. The CB shall define criteria for increased monitoring based on aspects, complaints, questionable audit results, and other relevant concerns.

6.11. The witnessing shall be conducted by an DSSC initiative-qualified auditor who has been qualified by the CB to conduct witnessing of other auditors. The auditor conducting the witness is not considered a member of the audit team for the purposes of auditing organizational conformance to the certification requirements.

6.12. The auditor conducting a witness shall document results of the witness on an DSSC initiative template form and include a recommendation on the witnessed auditor. A decision on the recommendation shall be made by a qualified individual designated to make such decisions.

Note: The CB may use its own form with the approval of SSCI.

6.13. The CB shall ensure all auditors qualified for the DSSC initiative have completed any auditor-related training as specified by the SSCI.

6.14. All CB auditors qualified under DSSC initiative shall participate in SSCI-specified technical training, which may be offered at different times to accommodate all auditors.

6.15. The CB shall maintain records demonstrating auditors meet requirements specified in this document (refer to Annex A).

6.16. The CB shall ensure a system is in place to maintain records of auditor qualification and any training completed. The CB shall provide records of auditor competency to SSCI on request.

6.17. DSSC initiative refresher training shall be provided to all auditors annually. Unless otherwise specified by SSCI, the training shall be to the latest Initiative requirements.

6.18. The CB shall verify comprehension of any DSSC initiative related training initiative provided.

6.19. The CB shall keep a list of auditors qualified under the DSSC Initiative that identifies the scopes for which each auditor has been qualified and topics of the training provided.

6.20. If the auditor pool changes, the CB is to notify SSCI of changes (e.g. additions of new auditors).

6.21. The list shall be provided to SSCI annually no later than January 15th via email to info@ssciglobal.org. The subject line email shall be “Auditor List – NAME OF THE CB.”

7. Certification Process

7.1. The CB shall audit and certify an organization against the requirements (scopes) for which the CB’s certification scheme has been recognized by the SSCI.
7.2. The CB shall ensure that in addition to the requirements of DSSC initiative’s scope of certification the following quality requirements are audited.

a) Requirements of ISO 9001 for internal audits.

b) Requirements of ISO 9001 for management review.

c) Requirements of ISO 9001 for corrective action process.

7.3. The CB shall conduct audits of the certified organizations at least once every 12 months.

7.4. The CB shall ensure that the certification process covers all program requirements applicable to the scope of certification as defined in the DSSC initiative requirements.

7.5. The CB shall implement a documented process for conducting on-site audits. This process shall include an opening meeting at the start of the audit and a closing meeting at the conclusion of the audit. Opening and closing meeting shall meet the requirements of ISO/IEC 17021-1.

7.6. The CB shall review the corrections, identified root causes and corrective actions submitted to determine if these are acceptable.

7.7. The CB shall verify the effectiveness of any correction and corrective actions taken.

7.8. The CB shall provide to SSCI, annually, information on the number of findings issued against a particular clause of certification criteria over the year. The information shall be provided no later than January 15th via email to info@ssciglobal.org. The subject line email shall be “Findings Report – NAME OF THE CB.”

Note: The information does not need to identify the facility.

7.9. The CB shall take into consideration the organization’s shifts of operation when developing its audit plan for an organization.

7.10. The CB shall ensure that technical experts, unless also qualified as auditors, audit only under direct supervision of an auditor.

7.11. The CB shall meet the requirements of IAF MD 4, Mandatory Document for the Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes, when using information and communication technology for auditing.

8. Unannounced Audits

8.1. The CB shall conduct an unannounced audit (within a 30-day window, see section 8.2) at least once in a certification cycle. The unannounced audit may not be the initial certification audit.
8.2. The CB shall obtain a 30-day operational schedule to ensure scheduling of the unannounced audit does not conflict with any situation that will prevent a CB from meeting its audit objectives, such as absence of key staff, operational shutdown, etc.

8.3 When planning and conducting an unannounced audit, the CB shall take into consideration any national holidays and known operational shutdown of the plant.

9. Increased Oversight

9.1. The CB shall have a process for increased oversight of an organization in situations in which there is a reasonable concern about the organization’s operations but suspension or withdrawal may not be appropriate. Increased monitoring may be required when there are significant organization changes, multiple nonconformities and/or complaints, recalls, or other conditions deemed appropriate.

9.2. Monitoring shall return to normal where the CB regains confidence in the organization’s system.

9.3. The CB shall inform SSCI when an organization is subject to increased monitoring.

10. Audit-Time Calculation

10.1. The CB shall have documented procedures for determining audit duration.

10.2. In determining the audit time, the certification body shall consider, among other things, the following:

a) certification requirements;

b) complexity of the client and its management system;

c) technological and regulatory context;

d) outsourcing of any activities included in the scope of the certification;

e) the results of any prior audits;

f) size and number of sites, their geographical locations and multi-site considerations;

g) any risks associated with the products, processes or activities of the organization;

10.3. The duration of the audit and its justification shall be recorded.

The CB shall document in the report the on-site audit duration in working hours. If the audit includes more than one scope, the audit duration shall be documented for each scope subject to the audit. If the audit is integrated with any other standards outside the DSSC initiative, the time spent auditing requirements of the DSSC initiative shall be clearly documented.
10.4. An audit day shall be eight working hours. The CB should take into consideration any additional factors, such as use of interpreters, and document the time allocated to accommodate them.

10.5. The audit should be conducted with a working lunch or 30 minutes built in for lunch in addition to the eight-hour audit time.

10.4. In the event the auditor must leave the site, the auditor shall inform the CB and the audit schedule shall be adjusted to account for a total of eight hours on site for the audit.

10.5. The audit time shall apply only to team members involved in auditing requirements of the DSSC Initiative.

10.6. If the audit is concluded ahead of the scheduled time, the auditor shall notify the CB.

10.7. Justification shall be documented in the audit report for the closure of the audit within less than the audit time scheduled.

11. Audit Report

11.1. The team lead shall be responsible for the content of the audit report.

11.2. The audit report shall be an accurate and clear record and provide confidence that an organization is in conformity with the requirements for certification.

11.3. The audit report shall be created using the SSCI audit report template.

11.4. The CB may use its own report with the permission of the SSCI. The audit report shall include at a minimum: facility name, address, and contact information, standard and programs (schemes) audited, scopes, CB auditor(s), date of audit, description about the facility, executive summary, what was audited, what was out of scope (not audited), restricted areas and comments about the area’s conformance, overall statement of conformity (or not conforming), recommendation, clear nonconformities cited with SSCI clauses referenced, etc.

12. Restricted Access

12.1. When the CB is denied access to information or a system or area within a facility for any reason, the following requirements apply:

   a. The CB and client shall develop an audit strategy for limited-access areas.
   b. If it is not possible to determine conformity of a limited-access area without an audit, the audit must ensure that the processes can be proven to be similar to processes in the unrestricted areas of the organization and that the same management system procedures and controls are
applied and used as within the restricted area. This should be clearly documented in the audit report, including supporting justification.

c. If a process under item b above cannot be completed, the CB shall ensure that the scope of certification clearly identifies any exclusions. The CB shall inform SSCI if this situation occurs.

13. Multi-Site Certification

13.1. The CB shall follow the requirements of IAF MD 1, Mandatory Document for the Audit and Certification of a Management System Operated by a Multi-Site Organization, when certifying.

13.2. The CB shall ensure a separate report is prepared for each site.

13.3. The CB shall ensure a separate certificate is issued for each site.

14. Remote Audits

14.1. The CB shall have a written procedure for conducting remote audits.

14.2. The CB shall not conduct a remote audit of a location that has not been subject to an on-site audit.

14.3. The remote audit should be conducted by an auditor who has knowledge of the site through an on-site audit. The CB shall document justification when using auditors who are not familiar with the facility through on-site audit for remote audits.

14.4. Remote audits of sites are allowed only if the organization has a central control and the CB is able to determine full conformity with the certification requirements through a remote approach.

14.5. Use of remote assessment shall be clearly documented in the audit report. All other requirements for the content of the audit report apply.

14.6. The CB shall have a documented process for remote document and/or records reviews that are part of the physical on-site audit. The document process shall ensure that a system is in place to ensure there is a seamless transition between the document review and the on-site assessment.

15. Transfers

15.1. Transfer of Accredited Certificates

15.1.1 IAF MD 2, IAF Mandatory Document for the Transfer of Accredited Certification of Management Systems, shall be followed.

15.2. Transfer of Unaccredited Certificates
15.2.1. The CB shall have a documented process for the transfer of unaccredited certificates issued during the period of conditional recognition.

15.2.2. The process shall ensure that accredited certificates are issued only after the CB receives formal recognition of accreditation from an AB and the CB is accredited.

15.2.3. The CB is allowed to issue an accredited certification for the organization that was part of the successful witnessed audit required for the CB to become accredited, and for organizations audited after the CB’s successful first witnessed audit.

15.2.4. Organizations audited by the CB prior to the successful witnessed audit shall undergo another audit by the CB after the CB gains accreditation before the CB can issue an accredited certificate.

16. Feedback

16.1 The CB shall collect feedback from its customers on the performance of the CB and its auditors.

16.2. The CB shall provide a summary of the feedback received, including any feedback received through the complaint process, to SSCI annually no later than January 15th via email to info@ssciglobal.org. The subject line email shall be “Feedback Summary – NAME OF THE CB.”

17. Product Recalls

17.1 The CB shall have a legally binding arrangement that requires certified organizations to inform the CB within two business days of any product recall.

17.2. The CB shall have a legally binding arrangement that requires certified organizations to inform the CB within two business days of any infractions issued by the FDA such as 483, as well as inspection qualifications NAI, VAI, and OAI.

18. Use of SSCI License and Logo

18.1. The SSCI logo shall be used only on the CB’s website, printed material, and promotional material.

18.2. The CB shall not use the SSCI license or logo in any way that could bring SSCI into disrepute and shall not make any statement regarding its recognition that SSCI may consider inaccurate, misleading, or unauthorized.
19. Changes to the Requirements

19.1. Any changes to the initiative requirements or criteria released by SSCI and any amendments to existing documentation shall be implemented within the timeframe and in accordance with transition requirements specified by SSCI.
Annex A (Normative): Auditor Competence Requirements

CB auditors must meet the following requirements for scope-specific competence. The CB shall have documented evidence that auditors demonstrate competence to:

21 CFR Part 111:

- Interpret 21 CFR Part 111 through a systems-based inspection process.
- Verify establishment type and identify covered product and applicable scopes and rules.
- Understand cGMPs and their application.
- Understand production and process control systems and recordkeeping.
- Identify and report nonconformance of the Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements Rule.

21 CFR 117:

- Interpret 21 CFR 117 through a systems-based inspection process.
- Verify establishment type and identify covered product and applicable scopes and rules.
- Understand cGMPs and their application.
- Evaluate HACCP plans.
- Evaluate food safety plans for adequacy, implementation, and compliance with the PC Rule.
- Identify and report nonconformance of the Preventive Controls for Human Foods regulation.