SSCI’s DSSC Initiative
Requirements for Accreditation Bodies
# Table of Contents

1. Introduction .......................................................................................................................... 3
2. Purpose .................................................................................................................................. 3
3. References ............................................................................................................................. 3
4. Definitions ............................................................................................................................. 4
5. Procedural Requirements ....................................................................................................... 4
6. Assessor Competence ............................................................................................................ 5
7. Accreditation Process ............................................................................................................ 5
8. Assessment Report ................................................................................................................ 6
9. Integrity Program ................................................................................................................... 7
10. Use of Logos ......................................................................................................................... 7

Annex A (Normative): Auditor Competence Requirements ...................................................... 8
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 accreditation bodies (ABs) against which SSCI will evaluate ABs seeking to recognition to provide accreditation to certification bodies (CBs) for ISO/IEC 17065 and DSSC initiative requirements.

2.2. Evaluation that an AB meets the requirements of this document shall be monitored by SSCI and feedback on conformance with these requirements shall be shared directly with the AB for discussion and action when appropriate.

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 providing audit and certification of management systems – Part 1: Requirements
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. Procedural Requirements

5.1. The AB shall be a current member and a signatory of the International Accreditation Forum (IAF) Multilateral Recognition Agreement (MLA) for Management Systems.

5.2. The AB shall immediately communicate to SSCI any changes in its IAF signatory status.

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

5.4. The AB shall sign an agreement with SSCI prior to offering accreditation to operate the DSSC initiative.

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

5.6. The AB 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.

5.7. The AB shall make available to SSCI the following information:

- Any new applicants for the DSSC initiative, including the scopes of accreditation sought.
- Any changes in the accreditation status of a CB, (e.g., extension, suspension, or withdrawal). Information on suspension or withdrawal shall include the basis for the action taken.
- Any validated complaints about a CB related to the DSSC initiative.
6. Assessor Competence

6.2. The AB shall ensure all its assessors qualified for the DSSC initiative have completed any assessor-related training specified by SSCI.

6.3. At least one AB assessor must participate in SSCI-specified technical training, and the information must be communicated to all assessors qualified under the DSSC initiative.

6.4. The AB shall maintain records demonstrating assessors meet requirements specified in Annex A of this document. Records shall be available for review by SSCI on request.

6.5. The AB shall provide refresher training on the DSSC initiative for all assessors annually. Unless otherwise specified by SSCI, the training shall be to the latest DSSC initiative requirements.

6.6 The AB shall keep records of the training provided.

7. Accreditation Process

7.1. The AB shall issue a confirmation of application for accreditation, including the detailed scope, to the applicant CB.

7.2. The AB shall notify the applicant CB if the AB declines an application for accreditation or any part thereof.

   Note: 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.

7.3. The AB must conduct a full document review and an office assessment prior to granting accreditation.

7.4. The AB should confirm the CB has signed an agreement with SSCI no later than at the document review stage.

7.5. During the process for scope extension, the AB shall confirm that SSCI has included the requested scope under the current agreement with the CB.

7.6. During its accreditation process, the AB shall cover all DSSC initiative requirements applicable to the scope of accreditation.

7.7. The AB shall witness a CB conducting an audit prior to granting accreditation.

7.8. The AB shall conduct an initial witness for each scope included in the application, unless otherwise specified by SSCI.
Note: If there is an organization seeking certification for multiple scopes then one witness could be used for more than one scope.

7.9. AB assessors assigned to witnessed audits shall be qualified for each certification scope under the DSSC initiative included in the scope of the audit.

7.10. For each office assessment, the AB shall include at least one assessor or a technical expert competent in the DSSC initiative.

7.11. The audit plan shall clearly identify which assessor is competent for the DSSC initiative and scope-specific competence, if applicable.

7.12. Upon successful completion of the accreditation process, the AB shall issue an accreditation certificate that clearly states that accreditation is for ISO/IEC 17065 and DSSC initiative requirements, including indication of the revision.

7.13. The scope of accreditation shall identify scopes recognized under the DSSC initiative for which the CB was found to be competent.

7.14. The maintenance of accreditation process shall consist of annual on-site assessments of the CB and witnessing of a CB conducting an audit to the requirements of the DSSC initiative under the scope of recognition.

7.17. The AB shall take into account previous results of witnessing to establish its witness strategy.

7.18. Whenever possible, the AB should witness an audit team that has not been witnessed previously.

7.19. The AB shall avoid repeated witnessing of the same CB client.

7.20. The AB shall provide public information on each accredited CB. In addition to the scope of accreditation, the information shall include contact name, address, telephone number, email address, and date accreditation as granted and expiration date.

8. Assessment Report

8.1. The assessment report shall be created using the SSCI audit report template.

8.2. The AB may use its own report with the permission of SSCI. The audit report at a minimum shall include:

   a. Identification of the scope subject to assessment for which technical competence was verified.
   b. Clear identification of the scope(s) for which competence was demonstrated during the assessment.
   c. Clear identification of the scope(s) for which competence was not demonstrated.
d. Clear indication that requirements of DSSC initiative were included in the assessment.

e. Identification of which assessor is competent for the DSSC initiative and scope-specific competence, if applicable.

f. Date of the report.

8.3. The AB shall maintain and provide to SSCI on request all relevant assessment information such as nonconformities issued related to the requirements of SCCI Requirements for Certification Bodies document and to ISO/IEC 17065 requirements that have an impact on the ability of the CB to deliver competent certifications for the DSSC initiative.

9. Integrity Program

9.1. SSCI may provide to the AB information collected during its integrity program.

9.2. SSCI will provide the AB access to all relevant CB outcomes of its integrity program and complaints about CB management systems related to ISO/IEC 17065.

9.3. The AB shall consider the content of the information during its audit-planning process.

9.4. ABs are invited to observe integrity program assessments conducted by SSCI.

10. Use of Logos

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

10.2. The AB 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.
Annex A (Normative): Auditor Competence Requirements

Scope-specific competence requirements

AB assessors must meet the following requirements for scope-specific competence. The AB must have documented evidence that assessors 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.

END