Table of Contents

1. What You Need to Know .................................................................................................. 3
2. Certification Overview and Benefits .............................................................................. 4
3. Certification Documents ............................................................................................... 5
4. Certification Process ...................................................................................................... 8
5. Audit Process ................................................................................................................ 9
6. Comparison of NSF/ANSI 455-3 GMP Standard and Audit Template ......................... 13
7. Warning letters and Recalls for Cosmetics .................................................................. 15
8. What should you do? NSF/ANSI 455-3 GMP standard is here! ................................. 18
9. NSF has the tools ........................................................................................................... 19
10. Implementation Timeline for NSF/ANSI 455-3 GMP Standard .................................. 20
11. Annex 1: Detailed Comparison of NSF/ANSI 455-3 Standard and Audit Template .... 21
On behalf of the NSF Health Sciences Certification Program, we thank you for choosing NSF as your GMP certification service provider. By working with NSF, you are demonstrating your pledge to produce quality products. NSF is a public health and safety organization, committed to protecting public health and mitigating risk for our clients and consumers. This commitment means that we must continuously improve our program and incorporate the latest regulations, guidance and industry best practices.

Below are reading materials that will help you prepare for the new standard NSF/ANSI 455-3 Good Manufacturing Practices for Cosmetics.

**Regulations Related to Cosmetics from Title 21 of the Code of Federal Regulations (21 CFR)**


**FDA Draft Guidance for Industry: Lead in Cosmetic Lip Products and Externally Applied Cosmetics: Recommended Maximum Level**


**FDA Draft Guidance for Industry: Cosmetic Good Manufacturing Practices**


**Cosmetics Processors and Transporters of Cosmetics Security Preventive Measures Guidance** (Also available in other languages)


https://www.iso.org/standard/36437.html

**NSF/ANSI 455-3 Good Manufacturing Practices for Cosmetics***

**NSF/ANSI 455-3 Good Manufacturing Practices for Cosmetics Audit Requirements Guideline***

**NSF International Certification Policies – NSF/ANSI 455***

*Note: Available in NSF Connect*
Overview

Good Manufacturing Practices (GMPs) are guidelines that provide a system of processes, procedures and documentation. These GMP requirements are listed in NSF/ANSI 455-3 standard which is developed by the cosmetic industry in accordance with US FDA Guidance for Industry and ISO 22716:2007.

NSF International independently certifies manufacturers as meeting GMP requirements. The program is open not just to manufacturers of cosmetics, but also to manufacturers of ingredients, raw materials, components, and packaging and labeling companies who want to demonstrate their commitment to public safety.

Benefits

> Prepares a facility for FDA inspections
> Allows a facility to benchmark its quality systems
> Helps facilities to build a strong quality and GMP program
> Serves as a communication tool between manufacturers of cosmetics, regulators, retailers, and consumers
> ANSI logo on certificates for global acceptance
3. Certification Documents

1. NSF/ANSI 455-3 Good Manufacturing Practices for Cosmetics

This standard was developed by the NSF Joint Committee on GMP for Cosmetics using the consensus process described by the American National Standards Institute. Participation from NSF Joint Committee includes cosmetics manufacturers, public health regulators, and consumers and retailers of cosmetics.

This standard is intended to define a standardized approach for auditing to determine the level of compliance of cosmetic products to ISO 22716 – Cosmetics – Good Manufacturing Practices (GMPs) for Cosmetics – Guidelines on Good Manufacturing Practices, FDA Cosmetic GMP Guidance, as well as incorporating additional retailer requirements. It refers to the requirements for GMPs applicable to all cosmetics. It will assist in the determination of adequate facilities and controls for cosmetic manufacturers with sufficient quality to ensure suitability for intended use.

The standard has the following format and organization.

- “Shall” is used to state mandatory requirements.
- Document is written as follows:

Section (#) – Area of focus
Sub-Section (#.#) – ISO quality management principle
Requirement (#.#.#) – Standard requirement

Example:

4 Audit requirements
4.1 Context of the organization
4.1.2 Supplier (manufacturer) without VCRP registration has cosmetic product ingredient statements (CPIS) filed with the US FDA. [https://www.fda.gov/cosmetics/registrationprogram/ucm2005171.htm]

- The criteria in this standard was structured to be in the ISO 9001:2015 format, following a 7 systems approach.
  - Content of Organization
  - Leadership
  - Planning
  - Support
  - Operation
  - Performance Evaluation
  - Improvement
3. Certification Documents (cont’d)

2. NSF/ANSI 455-3 Good Manufacturing Practices for Cosmetics Audit Template

The audit template is a tool used by auditors to assist in their on-site verification activity for compliance to the standard.

To facilitate audit flow, the format of the audit template is rearranged in different sections compared to the sections in the NSF/ANSI 455-3 GMP standard. See graphical representation below comparing the two. Refer to section Comparison of NSF/ANSI 455-3 GMP Standard and Audit Template for additional details.

![Comparison of NSF/ANSI 455-3 GMP Standard and Audit Template](image-url)
3.  NSF/ANSI 455-3 Good Manufacturing Practices for Cosmetics Audit Requirements Guideline (ARG)

The document was developed to assist auditors and manufacturers to understand and interpret the requirements of the NSF/ANSI 455-3 GMP standard. The information in the guideline reflects the most current approach to achieving compliance with the standard requirements.

4.  NSF International Certification Policies – NSF/ANSI 455

The document describes the framework for the administration of the program. The policies include, but are not limited to:

> Audit scope and process
> Requirements for acquiring and maintaining GMP certification
> Certification and monitoring audits
> Criteria for audit grade determination and audit frequency
> Requirements and timelines for corrective action responses
> Requirements for the correct use of NSF GMP certification marks
4. Certification Process

All clients shall go through a standardized audit process to gain certification. Below is an overview of the process.

- **Self Assessment or 3rd Party Assessment**
- **Application for Certification to CB**
- **Audit Planned & Executed**
- **Audit Report Completed**
- **CB Management Review and cGMP Rating Assigned**
- **Corrective Action Plan (if applicable)**
- **Certification Decision**
- **Certificate Issued (valid 12 months)**
- **Recertification Audit**

Legend:
- **NSF Responsibility**
- **Client Responsibility**
5. Audit Process

This is the general flow of the audit process.

1. Classification of Nonconformances

The auditor will cite a nonconformance when observations are made and evidence is collected during the audit that shows non-compliance with the standard requirement. Based on the auditor’s judgement, nonconformances are classified according to severity and risk to product safety. The severity of nonconformances are then confirmed through a technical review prior to release of the audit report.

The following are the three (3) levels of nonconformances:

- **Critical nonconformance** – A nonconformance or condition which has produced, or may lead to a significant risk of an unsafe or hazardous product which may be harmful and puts the consumer at risk of serious injury or death.

- **Major nonconformance** – A nonconformance other than critical that results in failure in one or more of the quality sub-systems; or a combination of “minor” nonconformances none of which on their own may be major, but which may together represent a major nonconformance and shall be explained and reported as such. Also, a nonconformance that has or may result in a product which does not comply with its marketing specifications or requirements; or which may result in failure or materially reduce the usability of the product for the intended purpose.

- **Minor nonconformance** – A nonconformance where an element of GMP has not been fully met or does not adversely affect the performance, reliability, or use of a product; but on the basis of objective evidence does not meet the definition of a major nonconformance. Multiple minor nonconformances when considered collectively may raise the category to a major nonconformance.

---

1 NSF/ANSI 455-3-2018 – Good Manufacturing Practices for Cosmetics, section 5.5.9
5. Audit Process (cont’d)

Where nonconformances are cited, corrective action must be submitted to NSF for review. Below is the general flow of the corrective action process, post audit.

Legend:
- NSF Responsibility
- Client Responsibility

* Days are calculated from the last day of the audit.
** Overdue CARs shall result in suspension or denial of certification.
2. Audit Grade

The auditor submits a draft report for technical review after the audit. At the technical review, the nonconformances are confirmed and the audit grade is determined based on the number and severity of nonconformances cited.

Summary of Grading Model\(^2\)

<table>
<thead>
<tr>
<th>Grade</th>
<th>Critical</th>
<th>Major</th>
<th>Minor</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>0</td>
<td>0</td>
<td>(\leq 6)</td>
</tr>
<tr>
<td>B</td>
<td>0</td>
<td>1</td>
<td>(\leq 6)</td>
</tr>
<tr>
<td>B</td>
<td>0</td>
<td>0</td>
<td>7 to 11</td>
</tr>
<tr>
<td>C</td>
<td>0</td>
<td>1</td>
<td>7 to 11</td>
</tr>
<tr>
<td>C</td>
<td>0</td>
<td>0</td>
<td>12 to 17</td>
</tr>
<tr>
<td>D</td>
<td>(\geq 1)</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>D</td>
<td>0</td>
<td>(\geq 2)</td>
<td>–</td>
</tr>
<tr>
<td>D</td>
<td>0</td>
<td>1</td>
<td>(\geq 12)</td>
</tr>
<tr>
<td>D</td>
<td>0</td>
<td>0</td>
<td>(\geq 18)</td>
</tr>
</tbody>
</table>

\(^2\) NSF/ANSI 455-3-2018 – Good Manufacturing Practices for Cosmetics, Table 5.2
3. Audit Frequency

The frequency of audits is based on the audit grade. Below is the general audit cycle. Please refer to NSF/ANSI 455-3 GMP Section 5 for a more detailed explanation.

Grades A & B *

* Grades A & B may require a monitoring audit for failure to closeout repeat nonconformance from the previous certification audit.

Certification Audit

Grade C

Monitoring Audit (6 months from initial)

Grade D

Failure

Certification Audit (12 months from previous Certification/Recertification Audit)
To facilitate audit flow, the format of the audit template is rearranged into sections different from the NSF/ANSI 455-3 GMP standard. The table below shows the distribution of NSF/ANSI 455-3 GMP standard elements in the audit template sections.

<table>
<thead>
<tr>
<th>Audit Template Sections</th>
<th>Title</th>
<th>NSF/ANSI 455-3 GMP Standard Requirement No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section 0</td>
<td>Visit Summary</td>
<td>5.5.1, 5.5.3, 5.5.8</td>
</tr>
<tr>
<td>Section 1</td>
<td>Client Logistics</td>
<td>1.1, 1.2, 1.3, 3.24</td>
</tr>
<tr>
<td>Section A</td>
<td>Administration and Regulatory</td>
<td>4.1.1</td>
</tr>
<tr>
<td>Section B</td>
<td>Quality Management</td>
<td>4.1.5, 4.2.1, 4.4.29, 4.4.32, 4.4.35</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.1.6, 4.4.1, 4.4.31, 4.4.34, 4.4.36</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.1.7, 4.2.3, 4.4.30, 4.4.33, 4.5.12</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.1.8, 4.1.4, 4.4.26, 4.3.3, 4.6.15</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.1.3, 4.4.28, 4.4.27, 4.3.2</td>
</tr>
<tr>
<td>Section C</td>
<td>Corrective and Preventive Actions &amp; Complaints</td>
<td>4.7.4, 4.6.14, 4.6.13, 4.6.17</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.6.11, 4.6.12, 4.6.16, 4.6.18</td>
</tr>
<tr>
<td>Section D</td>
<td>Supplier Qualification</td>
<td>4.1.2, 4.5.60, 4.5.62, 4.5.19, 4.5.17</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.5.14, 4.5.61, 4.5.15, 4.5.18, 4.5.16</td>
</tr>
<tr>
<td>Section E</td>
<td>Product Safety</td>
<td>4.4.16, 4.4.17, 4.4.17, 4.5.7</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.4.20, 4.4.18, 4.4.18, 4.5.3</td>
</tr>
<tr>
<td>Section F</td>
<td>Facilities</td>
<td>4.4.4, 4.4.8, 4.5.9, 4.5.56, 4.5.41</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.4.2, 4.4.7, 4.4.12, 4.5.57, 4.4.24</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.2.2, 4.5.1, 4.5.25, 4.5.58, 4.4.25</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.4.3, 4.5.5, 4.5.26, 4.4.11, 4.4.21</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.4.15, 4.5.4, 4.4.13, 4.5.10, 4.4.23</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.4.5, 4.5.11, 4.4.14, 4.4.9, 4.4.22</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.4.6, 4.5.8, 4.5.59, 4.4.10</td>
</tr>
</tbody>
</table>
### 6. Comparison of NSF/ANSI 455-3 GMP Standard and Audit Template (cont’d)

<table>
<thead>
<tr>
<th>Audit Template Sections</th>
<th>Title</th>
<th>NSF/ANSI 455-3 GMP Standard Requirement No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section G</td>
<td>Production and Process Controls – Manufacturing, Packaging Operations &amp; Product Specification, Release and Returns</td>
<td>4.5.28, 4.5.29, 4.5.42, 4.5.30, 4.5.6, 4.5.47, 4.5.37, 4.5.38, 4.5.40, 4.5.31, 4.5.39, 4.5.24, 4.5.43, 4.6.7, 4.6.1, 4.6.2, 4.5.55, 4.5.51, 4.5.36, 4.5.2, 4.5.50, 4.5.21, 4.5.45, 4.5.9, 4.5.27</td>
</tr>
<tr>
<td>Section H</td>
<td>Laboratory Controls</td>
<td>4.5.46, 4.6.4, 4.6.8, 4.6.9, 4.7.1, 4.7.3</td>
</tr>
<tr>
<td>Section I</td>
<td>Warehouse and Distribution Controls</td>
<td>4.5.32, 4.5.34, 4.5.49, 4.5.52</td>
</tr>
<tr>
<td>Section J</td>
<td>NSF Certification Policies</td>
<td>Compliance against NSF certification policies</td>
</tr>
</tbody>
</table>

© 2019 NSF International – Unless otherwise specified, no part of this document may be reproduced or utilized in any form by any other means, electronic or mechanical, including photocopying and microfilm, without permission of NSF International.
Warning Letters

The FDA issues a warning letter for violation against the FD&C Act. The graph and table below summarize the warning letters posted on the FDA website.

For additional information, please refer to: https://www.fda.gov/cosmetics/cosmetics-compliance-enforcement/warning-letters-related-cosmetics

### Warning Letters

![Bar chart showing the number of warning letters by type of product and reason for the warning.]

### Type of Product

<table>
<thead>
<tr>
<th>Type of Product</th>
<th>Drug Claims*</th>
<th>Microbial Contamination**</th>
<th>Cosmetics vs Medical Device***</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin Care</td>
<td>25</td>
<td>2</td>
<td>11</td>
</tr>
<tr>
<td>Hair Care</td>
<td>5</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Eyelash/Eyebrow Treatment</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Make-up</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Oral Care</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Decorative Contact Lenses</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

*Warning Letters Address Drug Claims Made for Products Marketed as Cosmetics (2007-2019)

**Warning Letters Cite Cosmetics as Adulterated Due to Microbial Contamination (2005-2016)

***Warning Letters Highlight Differences Between Cosmetics and Medical Devices (2008-2016)

A company recalls a marketed product when the product is considered to be in violation of FDA requirements or FDA requests to recall. The graph and table below summarize the recalls for the past five years.

For additional information, please refer to: https://www.accessdata.fda.gov/scripts/ires/index.cfm
### Class I

* Class I is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.

### Class II

* Class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

### Class III

* Class III is a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.

---

**FDA Recall Definition**

For additional information, please refer to:


<table>
<thead>
<tr>
<th>Code</th>
<th>Summary Reason for Recall</th>
<th>Summary of Description</th>
<th>Class I*</th>
<th>Class II*</th>
<th>Class III*</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Microbial contamination</td>
<td>Contamination of microbe, bacteria and fungi.</td>
<td>4</td>
<td>185</td>
<td>1</td>
</tr>
<tr>
<td>B</td>
<td>Non-microbial contamination</td>
<td>Contamination of asbestos, needles, wood fragments, and glass.</td>
<td>0</td>
<td>16</td>
<td>0</td>
</tr>
<tr>
<td>C</td>
<td>Misbranding</td>
<td>Defective peel out labels, incorrect information on the label, and missing information on the label.</td>
<td>0</td>
<td>8</td>
<td>5</td>
</tr>
<tr>
<td>D</td>
<td>Incorrect amount of ingredient</td>
<td>Excess amount of compound is added, ingredient not added, insufficient amount of ingredient added to assure the shelf life.</td>
<td>0</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>E</td>
<td>Others</td>
<td>Spoilage, packaging error, problematic batches, non-permitted additive was used, health claims, shattering of glass, use of undeclared ingredient, and incorrect ingredient declaration.</td>
<td>0</td>
<td>8</td>
<td>4</td>
</tr>
</tbody>
</table>
WHAT SHOULD YOU DO?
NSF/ANSI 455-3 GMP STANDARD IS HERE!

Become informed
> Review the NSF materials and tools
  - NSF/ANSI 455 GMP Policies
  - NSF/ANSI 455-3 GMP Standard
  - NSF/ANSI 455-3 GMP ARG
  - Audit Template
  - Training Videos

> Review regulations and guidelines applicable to Cosmetics
  - Draft Guidance for Industry: Cosmetic Good Manufacturing Practices

Plan your application for certification
> Review and confirm the scope applicable to your operations
> Communicate the standard requirements to your organization
> Perform a self-assessment and gap analysis of your current operations against the standard
> Contact NSF if you have questions

Submit application for certification to NSF
> Prepare the documents as required by the standard and by NSF include, but are not limited to:
  - Company organizational chart
  - Site plan
  - Process flow diagram
  - List of products and technologies included in the scope of the audit
  - Typical shift/schedule patterns
  - Standard operating procedures index/table of contents
  - Regulatory inspection history (past five years)
  - Site regulatory registration
  - Submit completed and signed documents to NSF
> Contact NSF if you have questions
NSF HAS THE TOOLS

Whether you are currently registered or are looking to newly register, we have the tools to help you prepare for your next certification audit.

- Audit Template
- FDA Warning Letters & Recalls
- NSF/ANSI 455 Certification Policies
- NSF/ANSI 455-3 GMP Standard for Cosmetics
- Webinar
- Information Guide
- NSF/ANSI 455-3 GMP ARG for Cosmetics
- Regulatory Resource Links
- FAQs
10. Implementation Timeline for NSF/ANSI 455-3 GMP Standard

Starting November 2019 NSF is offering certification to NSF/ANSI 455-3 GMP standard. Please contact your account manager to start the certification process for your company.
## Annex 1: Detailed Comparison of NSF/ANSI 455-3 GMP Standard & Audit Template

<table>
<thead>
<tr>
<th>NSF/ANSI 455-3 GMP Audit Template Question Number</th>
<th>NSF/ANSI 455-3 GMP Audit Template Section</th>
<th>NSF/ANSI 455-3 GMP Standard Requirement Number</th>
<th>NSF/ANSI 455-3 GMP Standard Section</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-7</td>
<td>Visit Summary and Client Logistics</td>
<td>NA</td>
<td>N/A</td>
</tr>
<tr>
<td>8</td>
<td>Administration and Regulatory</td>
<td>4.1.1</td>
<td>Context of the organization</td>
</tr>
<tr>
<td>9</td>
<td>Quality Management</td>
<td>4.1.5</td>
<td>Context of the organization</td>
</tr>
<tr>
<td>10</td>
<td>Quality Management</td>
<td>4.1.6</td>
<td>Context of the organization</td>
</tr>
<tr>
<td>11</td>
<td>Quality Management</td>
<td>4.1.7</td>
<td>Context of the organization</td>
</tr>
<tr>
<td>12</td>
<td>Quality Management</td>
<td>4.1.8</td>
<td>Context of the organization</td>
</tr>
<tr>
<td>13</td>
<td>Quality Management</td>
<td>4.1.3</td>
<td>Context of the organization</td>
</tr>
<tr>
<td>14</td>
<td>Quality Management</td>
<td>4.2.1</td>
<td>Leadership</td>
</tr>
<tr>
<td>15</td>
<td>Quality Management</td>
<td>4.4.1</td>
<td>Support</td>
</tr>
<tr>
<td>16</td>
<td>Quality Management</td>
<td>4.2.3</td>
<td>Leadership</td>
</tr>
<tr>
<td>17</td>
<td>Quality Management</td>
<td>4.1.4</td>
<td>Context of the organization</td>
</tr>
<tr>
<td>18</td>
<td>Quality Management</td>
<td>4.4.28</td>
<td>Support</td>
</tr>
<tr>
<td>19</td>
<td>Quality Management</td>
<td>4.4.29</td>
<td>Support</td>
</tr>
<tr>
<td>20</td>
<td>Quality Management</td>
<td>4.4.31</td>
<td>Support</td>
</tr>
<tr>
<td>21</td>
<td>Quality Management</td>
<td>4.4.30</td>
<td>Support</td>
</tr>
<tr>
<td>22</td>
<td>Quality Management</td>
<td>4.4.26</td>
<td>Support</td>
</tr>
<tr>
<td>23</td>
<td>Quality Management</td>
<td>4.4.27</td>
<td>Support</td>
</tr>
<tr>
<td>24</td>
<td>Quality Management</td>
<td>4.4.32</td>
<td>Support</td>
</tr>
<tr>
<td>25</td>
<td>Quality Management</td>
<td>4.4.34</td>
<td>Support</td>
</tr>
<tr>
<td>26</td>
<td>Quality Management</td>
<td>4.4.33</td>
<td>Support</td>
</tr>
<tr>
<td>27</td>
<td>Quality Management</td>
<td>4.3.3</td>
<td>Planning</td>
</tr>
<tr>
<td>28</td>
<td>Quality Management</td>
<td>4.3.2</td>
<td>Planning</td>
</tr>
<tr>
<td>29</td>
<td>Quality Management</td>
<td>4.4.35</td>
<td>Support</td>
</tr>
<tr>
<td>30</td>
<td>Quality Management</td>
<td>4.4.36</td>
<td>Support</td>
</tr>
<tr>
<td>31</td>
<td>Quality Management</td>
<td>4.5.12</td>
<td>Operation</td>
</tr>
<tr>
<td>32</td>
<td>Quality Management</td>
<td>4.6.15</td>
<td>Performance evaluation</td>
</tr>
<tr>
<td>33</td>
<td>Corrective and Preventive Actions and Complaints</td>
<td>4.7.4</td>
<td>Improvement</td>
</tr>
<tr>
<td>34</td>
<td>Corrective and Preventive Actions and Complaints</td>
<td>4.6.11</td>
<td>Performance evaluation</td>
</tr>
<tr>
<td>NSF/ANSI 455-3 GMP Audit Template Question Number</td>
<td>NSF/ANSI 455-3 GMP Audit Template Section</td>
<td>NSF/ANSI 455-3 GMP Standard Requirement Number</td>
<td>NSF/ANSI 455-3 GMP Standard Section</td>
</tr>
<tr>
<td>-------------------------------------------------</td>
<td>------------------------------------------</td>
<td>-----------------------------------------------</td>
<td>-----------------------------------</td>
</tr>
<tr>
<td>35</td>
<td>Corrective and Preventive Actions and Complaints</td>
<td>4.6.14</td>
<td>Performance evaluation</td>
</tr>
<tr>
<td>36</td>
<td>Corrective and Preventive Actions and Complaints</td>
<td>4.6.12</td>
<td>Performance evaluation</td>
</tr>
<tr>
<td>37</td>
<td>Corrective and Preventive Actions and Complaints</td>
<td>4.6.13</td>
<td>Performance evaluation</td>
</tr>
<tr>
<td>38</td>
<td>Corrective and Preventive Actions and Complaints</td>
<td>4.6.16</td>
<td>Performance evaluation</td>
</tr>
<tr>
<td>39</td>
<td>Corrective and Preventive Actions and Complaints</td>
<td>4.6.17</td>
<td>Performance evaluation</td>
</tr>
<tr>
<td>40</td>
<td>Corrective and Preventive Actions and Complaints</td>
<td>4.6.18</td>
<td>Performance evaluation</td>
</tr>
<tr>
<td>41</td>
<td>Supplier Qualification</td>
<td>4.1.2</td>
<td>Context of organization</td>
</tr>
<tr>
<td>42</td>
<td>Supplier Qualification</td>
<td>4.5.14</td>
<td>Operation</td>
</tr>
<tr>
<td>43</td>
<td>Supplier Qualification</td>
<td>4.5.60</td>
<td>Operation</td>
</tr>
<tr>
<td>44</td>
<td>Supplier Qualification</td>
<td>4.5.61</td>
<td>Operation</td>
</tr>
<tr>
<td>45</td>
<td>Supplier Qualification</td>
<td>4.5.62</td>
<td>Operation</td>
</tr>
<tr>
<td>46</td>
<td>Supplier Qualification</td>
<td>4.5.15</td>
<td>Operation</td>
</tr>
<tr>
<td>47</td>
<td>Supplier Qualification</td>
<td>4.5.19</td>
<td>Operation</td>
</tr>
<tr>
<td>48</td>
<td>Supplier Qualification</td>
<td>4.5.18</td>
<td>Operation</td>
</tr>
<tr>
<td>49</td>
<td>Supplier Qualification</td>
<td>4.5.17</td>
<td>Operation</td>
</tr>
<tr>
<td>50</td>
<td>Supplier Qualification</td>
<td>4.5.16</td>
<td>Operation</td>
</tr>
<tr>
<td>51</td>
<td>Product Safety</td>
<td>4.4.16</td>
<td>Support</td>
</tr>
<tr>
<td>52</td>
<td>Product Safety</td>
<td>4.4.20</td>
<td>Support</td>
</tr>
<tr>
<td>53</td>
<td>Product Safety</td>
<td>4.4.17</td>
<td>Support</td>
</tr>
<tr>
<td>54</td>
<td>Product Safety</td>
<td>4.4.18</td>
<td>Support</td>
</tr>
<tr>
<td>55</td>
<td>Product Safety</td>
<td>4.4.19</td>
<td>Support</td>
</tr>
<tr>
<td>56</td>
<td>Product Safety</td>
<td>4.6.10</td>
<td>Performance evaluation</td>
</tr>
<tr>
<td>57</td>
<td>Product Safety</td>
<td>4.5.7</td>
<td>Operation</td>
</tr>
<tr>
<td>58</td>
<td>Product Safety</td>
<td>4.5.3</td>
<td>Operation</td>
</tr>
<tr>
<td>59</td>
<td>Facilities</td>
<td>4.4.4</td>
<td>Support</td>
</tr>
<tr>
<td>60</td>
<td>Facilities</td>
<td>4.4.2</td>
<td>Support</td>
</tr>
<tr>
<td>61</td>
<td>Facilities</td>
<td>4.2.2</td>
<td>Leadership</td>
</tr>
<tr>
<td>62</td>
<td>Facilities</td>
<td>4.4.3</td>
<td>Support</td>
</tr>
<tr>
<td>63</td>
<td>Facilities</td>
<td>4.4.15</td>
<td>Support</td>
</tr>
<tr>
<td>64</td>
<td>Facilities</td>
<td>4.4.5</td>
<td>Support</td>
</tr>
<tr>
<td>65</td>
<td>Facilities</td>
<td>4.4.6</td>
<td>Support</td>
</tr>
<tr>
<td>NSF/ANSI 455-3 GMP Audit Template Question Number</td>
<td>NSF/ANSI 455-3 GMP Audit Template Section</td>
<td>NSF/ANSI 455-3 GMP Standard Requirement Number</td>
<td>NSF/ANSI 455-3 GMP Standard Section</td>
</tr>
<tr>
<td>-----------------------------------------------</td>
<td>------------------------------------------</td>
<td>---------------------------------------------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td>66</td>
<td>Facilities</td>
<td>4.4.8</td>
<td>Support</td>
</tr>
<tr>
<td>67</td>
<td>Facilities</td>
<td>4.4.7</td>
<td>Support</td>
</tr>
<tr>
<td>68</td>
<td>Facilities</td>
<td>4.5.1</td>
<td>Operation</td>
</tr>
<tr>
<td>69</td>
<td>Facilities</td>
<td>4.5.5</td>
<td>Operation</td>
</tr>
<tr>
<td>70</td>
<td>Facilities</td>
<td>4.5.4</td>
<td>Operation</td>
</tr>
<tr>
<td>71</td>
<td>Facilities</td>
<td>4.5.11</td>
<td>Operation</td>
</tr>
<tr>
<td>72</td>
<td>Facilities</td>
<td>4.5.8</td>
<td>Operation</td>
</tr>
<tr>
<td>73</td>
<td>Facilities</td>
<td>4.5.9</td>
<td>Operation</td>
</tr>
<tr>
<td>74</td>
<td>Facilities</td>
<td>4.4.12</td>
<td>Support</td>
</tr>
<tr>
<td>75</td>
<td>Facilities</td>
<td>4.5.25</td>
<td>Operation</td>
</tr>
<tr>
<td>76</td>
<td>Facilities</td>
<td>4.5.26</td>
<td>Operation</td>
</tr>
<tr>
<td>77</td>
<td>Facilities</td>
<td>4.4.13</td>
<td>Support</td>
</tr>
<tr>
<td>78</td>
<td>Facilities</td>
<td>4.4.14</td>
<td>Support</td>
</tr>
<tr>
<td>79</td>
<td>Facilities</td>
<td>4.5.59</td>
<td>Operation</td>
</tr>
<tr>
<td>80</td>
<td>Facilities</td>
<td>4.5.56</td>
<td>Operation</td>
</tr>
<tr>
<td>81</td>
<td>Facilities</td>
<td>4.5.57</td>
<td>Operation</td>
</tr>
<tr>
<td>82</td>
<td>Facilities</td>
<td>4.5.58</td>
<td>Operation</td>
</tr>
<tr>
<td>83</td>
<td>Facilities</td>
<td>4.4.11</td>
<td>Support</td>
</tr>
<tr>
<td>84</td>
<td>Facilities</td>
<td>4.5.10</td>
<td>Operation</td>
</tr>
<tr>
<td>85</td>
<td>Facilities</td>
<td>4.4.9</td>
<td>Support</td>
</tr>
<tr>
<td>86</td>
<td>Facilities</td>
<td>4.4.10</td>
<td>Support</td>
</tr>
<tr>
<td>87</td>
<td>Facilities</td>
<td>4.5.41</td>
<td>Operation</td>
</tr>
<tr>
<td>88</td>
<td>Facilities</td>
<td>4.4.24</td>
<td>Support</td>
</tr>
<tr>
<td>89</td>
<td>Facilities</td>
<td>4.4.25</td>
<td>Support</td>
</tr>
<tr>
<td>90</td>
<td>Facilities</td>
<td>4.4.21</td>
<td>Support</td>
</tr>
<tr>
<td>91</td>
<td>Facilities</td>
<td>4.4.23</td>
<td>Support</td>
</tr>
<tr>
<td>92</td>
<td>Facilities</td>
<td>4.4.22</td>
<td>Support</td>
</tr>
<tr>
<td>93</td>
<td>Production and Process Controls – Manufacturing Operations</td>
<td>4.5.28</td>
<td>Operation</td>
</tr>
<tr>
<td>94</td>
<td>Production and Process Controls – Manufacturing Operations</td>
<td>4.5.29</td>
<td>Operation</td>
</tr>
<tr>
<td>NSF/ANSI 455-3 GMP Audit Template Question Number</td>
<td>NSF/ANSI 455-3 GMP Audit Template Section</td>
<td>NSF/ANSI 455-3 GMP Standard Requirement Number</td>
<td>NSF/ANSI 455-3 GMP Standard Section</td>
</tr>
<tr>
<td>------------------------------------------------</td>
<td>------------------------------------------</td>
<td>-----------------------------------------------</td>
<td>-----------------------------------</td>
</tr>
<tr>
<td>95</td>
<td>Production and Process Controls – Manufacturing Operations</td>
<td>4.5.42</td>
<td>Operation</td>
</tr>
<tr>
<td>96</td>
<td>Production and Process Controls – Manufacturing Operations</td>
<td>4.5.30</td>
<td>Operation</td>
</tr>
<tr>
<td>97</td>
<td>Production and Process Controls – Manufacturing Operations</td>
<td>4.5.6</td>
<td>Operation</td>
</tr>
<tr>
<td>98</td>
<td>Production and Process Controls – Manufacturing Operations</td>
<td>4.5.47</td>
<td>Operation</td>
</tr>
<tr>
<td>99</td>
<td>Production and Process Controls – Packaging Operations</td>
<td>4.5.37</td>
<td>Operation</td>
</tr>
<tr>
<td>100</td>
<td>Production and Process Controls – Packaging Operations</td>
<td>4.5.38</td>
<td>Operation</td>
</tr>
<tr>
<td>101</td>
<td>Production and Process Controls – Manufacturing Operations</td>
<td>4.5.40</td>
<td>Operation</td>
</tr>
<tr>
<td>102</td>
<td>Production and Process Controls – Packaging Operations</td>
<td>4.5.44</td>
<td>Operation</td>
</tr>
<tr>
<td>103</td>
<td>Production and Process Controls – Packaging Operations</td>
<td>4.5.31</td>
<td>Operation</td>
</tr>
<tr>
<td>104</td>
<td>Production and Process Controls – Packaging Operations</td>
<td>4.5.39</td>
<td>Operation</td>
</tr>
<tr>
<td>105</td>
<td>Production and Process Controls – Packaging Operations</td>
<td>4.5.24</td>
<td>Operation</td>
</tr>
<tr>
<td>106</td>
<td>Production and Process Controls – Packaging Operations</td>
<td>4.5.43</td>
<td>Operation</td>
</tr>
<tr>
<td>107</td>
<td>Production and Process Controls – Packaging Operations</td>
<td>4.5.13</td>
<td>Operation</td>
</tr>
<tr>
<td>108</td>
<td>Production and Process Controls – Packaging Operations</td>
<td>4.5.33</td>
<td>Operation</td>
</tr>
<tr>
<td>109</td>
<td>Production and Process Controls – Packaging Operations</td>
<td>4.5.46</td>
<td>Operation</td>
</tr>
<tr>
<td>110</td>
<td>Production and Process Controls – Packaging Operations</td>
<td>4.6.7</td>
<td>Performance evaluation</td>
</tr>
<tr>
<td>111</td>
<td>Production and Process Controls – Packaging Operations</td>
<td>4.3.1</td>
<td>Planning</td>
</tr>
<tr>
<td>112</td>
<td>Production and Process Controls – Packaging Operations</td>
<td>4.6.8</td>
<td>Performance evaluation</td>
</tr>
<tr>
<td>113</td>
<td>Production and Process Controls – Packaging Operations</td>
<td>4.6.9</td>
<td>Performance evaluation</td>
</tr>
<tr>
<td>NSF/ANSI 455-3 GMP Audit Template Question Number</td>
<td>NSF/ANSI 455-3 GMP Audit Template Section</td>
<td>NSF/ANSI 455-3 GMP Standard Requirement Number</td>
<td>NSF/ANSI 455-3 GMP Standard Section</td>
</tr>
<tr>
<td>-------------------------------------------------</td>
<td>------------------------------------------</td>
<td>---------------------------------------------</td>
<td>-------------------------------------</td>
</tr>
<tr>
<td>114</td>
<td>Production and Process Controls – Packaging Operations</td>
<td>4.6.4</td>
<td>Performance evaluation</td>
</tr>
<tr>
<td>115</td>
<td>Production and Process Controls – Packaging Operations</td>
<td>4.5.48</td>
<td>Operation</td>
</tr>
<tr>
<td>116</td>
<td>Production and Process Controls – Specifications, Product Release and Returns</td>
<td>4.5.32</td>
<td>Operation</td>
</tr>
<tr>
<td>117</td>
<td>Production and Process Controls – Specifications, Product Release and Returns</td>
<td>4.5.34</td>
<td>Operation</td>
</tr>
<tr>
<td>118</td>
<td>Production and Process Controls – Specifications, Product Release and Returns</td>
<td>4.7.1</td>
<td>Improvement</td>
</tr>
<tr>
<td>119</td>
<td>Production and Process Controls – Specifications, Product Release and Returns</td>
<td>4.6.5</td>
<td>Performance evaluation</td>
</tr>
<tr>
<td>120</td>
<td>Production and Process Controls – Specifications, Product Release and Returns</td>
<td>4.7.3</td>
<td>Improvement</td>
</tr>
<tr>
<td>121</td>
<td>Production and Process Controls – Specifications, Product Release and Returns</td>
<td>4.7.2</td>
<td>Improvement</td>
</tr>
<tr>
<td>122</td>
<td>Production and Process Controls – Specifications, Product Release and Returns</td>
<td>4.5.53</td>
<td>Operation</td>
</tr>
<tr>
<td>123</td>
<td>Production and Process Controls – Specifications, Product Release and Returns</td>
<td>4.5.54</td>
<td>Operation</td>
</tr>
<tr>
<td>124</td>
<td>Laboratory Controls</td>
<td>4.6.1</td>
<td>Performance evaluation</td>
</tr>
<tr>
<td>125</td>
<td>Laboratory Controls</td>
<td>4.6.6</td>
<td>Performance evaluation</td>
</tr>
<tr>
<td>126</td>
<td>Laboratory Controls</td>
<td>4.6.2</td>
<td>Performance evaluation</td>
</tr>
<tr>
<td>127</td>
<td>Laboratory Controls</td>
<td>4.5.55</td>
<td>Operation</td>
</tr>
<tr>
<td>128</td>
<td>Laboratory Controls</td>
<td>4.6.3</td>
<td>Performance evaluation</td>
</tr>
<tr>
<td>129</td>
<td>Warehouse and Distribution</td>
<td>4.5.22</td>
<td>Operation</td>
</tr>
<tr>
<td>130</td>
<td>Warehouse and Distribution</td>
<td>4.5.50</td>
<td>Operation</td>
</tr>
<tr>
<td>131</td>
<td>Warehouse and Distribution</td>
<td>4.5.23</td>
<td>Operation</td>
</tr>
<tr>
<td>132</td>
<td>Warehouse and Distribution</td>
<td>4.5.51</td>
<td>Operation</td>
</tr>
<tr>
<td>133</td>
<td>Warehouse and Distribution</td>
<td>4.5.21</td>
<td>Operation</td>
</tr>
<tr>
<td>134</td>
<td>Warehouse and Distribution</td>
<td>4.5.20</td>
<td>Operation</td>
</tr>
<tr>
<td>135</td>
<td>Warehouse and Distribution</td>
<td>4.5.36</td>
<td>Operation</td>
</tr>
<tr>
<td>136</td>
<td>Warehouse and Distribution</td>
<td>4.5.45</td>
<td>Operation</td>
</tr>
<tr>
<td>137</td>
<td>Warehouse and Distribution</td>
<td>4.5.35</td>
<td>Operation</td>
</tr>
<tr>
<td>NSF/ANSI 455-3 GMP Audit Template Question Number</td>
<td>NSF/ANSI 455-3 GMP Audit Template Section</td>
<td>NSF/ANSI 455-3 GMP Standard Requirement Number</td>
<td>NSF/ANSI 455-3 GMP Standard Section</td>
</tr>
<tr>
<td>-------------------------------------------------</td>
<td>------------------------------------------</td>
<td>-----------------------------------------------</td>
<td>-----------------------------------</td>
</tr>
<tr>
<td>138</td>
<td>Warehouse and Distribution</td>
<td>4.5.2</td>
<td>Operation</td>
</tr>
<tr>
<td>139</td>
<td>Warehouse and Distribution</td>
<td>4.5.49</td>
<td>Operation</td>
</tr>
<tr>
<td>140</td>
<td>Warehouse and Distribution</td>
<td>4.5.52</td>
<td>Operation</td>
</tr>
<tr>
<td>141</td>
<td>Warehouse and Distribution</td>
<td>4.5.27</td>
<td>Operation</td>
</tr>
</tbody>
</table>
NSF International is a global public health organization that operates in more than 175 countries, with worldwide laboratory testing facilities and expert resources across a wide range of professional fields including health sciences, software, food and beverages, sustainability and agriculture.

NSF INTERNATIONAL HEADQUARTERS
789 N. Dixboro Road, Ann Arbor, MI 48105 USA
T +1 734 680 7402
E 455Certification@nsf.org
www.nsf.org/info/ds