NSF/ANSI 455-2 GOOD MANUFACTURING PRACTICES FOR DIETARY SUPPLEMENTS

INFORMATION GUIDE

NSF/ANSI 455-2 GOOD MANUFACTURING PRACTICES FOR DIETARY SUPPLEMENTS INFORMATION GUIDE

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On behalf of the NSF's dietary supplements 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 455-2 Good Manufacturing Practices for Dietary Supplements.

21 CFR Part 11 Electronic Records; Electronic Signatures

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11

21 CFR Part 111 Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=111

21 CFR Part 117 Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=117

Food Safety Modernization Act (FSMA)

https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/food-safety-modernization-act-fsma

Preventive Controls for Human Food

https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-human-food

Foreign Supplier Verification Programs (FSVP)

https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-foreign-supplier-verification-programs-fsvp-importers-food-humans-and-animals

Sanitary Transportation of Human and Animal Food

https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-sanitary-transportation-human-and-animal-food

Standardized Information on Dietary Ingredients (SIDI) Protocol

https://www.sidiworkgroup.com

NSF/ANSI 455-2 Good Manufacturing Practices for Dietary Supplements*

NSF/ANSI 455-2 Good Manufacturing Practices for Dietary Supplements Audit Requirements Guideline*

NSF International Certification Policies – NSF/ANSI 455*

*Note: Available in NSF Connect

2. Certification Overview and Benefits

Overview

Good Manufacturing Practices (GMPs) are guidelines that provide a system of processes, procedures and documentation to assure a product has the identity, strength, composition, quality and purity that appear on its label. These GMP requirements are listed in NSF/ANSI 455-2 GMP standard which was developed by the dietary supplement industry in accordance with 21 CFR Part 11, 21 CFR Part 111 and Food Safety Modernization Act (FSMA).

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

Benefits

- Provides risk-based audits to 21 CFR Part 111 and FSMA (21 CFR Part 117; 21 CFR Part 1.5; 21 CFR Part 1.9)
- Prepares a facility for FDA inspections
- Allows a facility to benchmark its quality systems
- Helps facilities to build a strong quality and GMP program
- Creates eligibility to enter products into NSF's product certification program
- Serves as a communication tool between manufacturers of dietary supplements, regulators, retailers, and consumers
- ANSI logo on certificates for global acceptance

3. Certification Documents

1. NSF/ANSI 455-2 Good Manufacturing Practices for Dietary Supplements

The standard is developed by the joint committee on GMP for dietary supplements using the consensus process described by American National Standards Institute. Participation includes dietary supplements manufacturers, public health regulators, consumers and retailers of dietary supplements.

The standard is intended to define a standardized approach for auditing to determine the level of compliance of dietary supplement products to 21 CFR Part 111, Current Good Manufacturing Practices (GMPs) in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements, as well as incorporating additional industry requirements and FSMA.

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

4.1.1 Quality responsibilities shall be distinct and separate from operations. [21 CFR § 111.12(b)]

> The criteria in this standard was structured to be in the ISO 9001:2015 format, following a 7 systems approach.

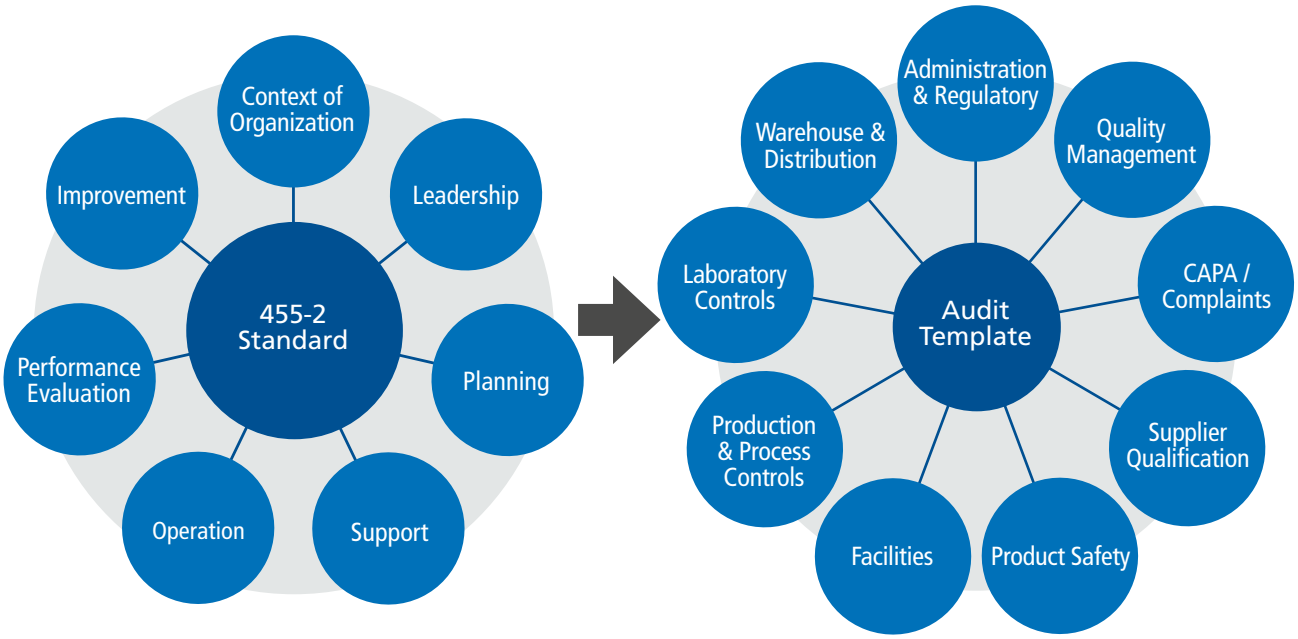
- Content of Organization
- Leadership
- Planning
- Support
- Operation
- Performance Evaluation
- Improvement

3. Certification Documents (cont'd)

2. NSF/ANSI 455-2 Good Manufacturing Practices for Dietary Supplements 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 455-2 GMP standard. See graphical representation below comparing the two. Refer to section Comparison of NSF/ANSI 455-2 GMP Standard and Audit Template for additional details.



NSF/ANSI 455-2 GMP Standard | **Audit Template**

3. NSF/ANSI 455-2 Good Manufacturing Practices for Dietary Supplements Audit Requirements Guideline (ARG)

The document was developed to assist auditors and manufacturers to understand and interpret the requirements of the NSF/ANSI 455-2 GMP standard. The information in the guideline reflects the most current approach to achieving compliance with the standard requirements.

3. Certification Documents (cont'd)

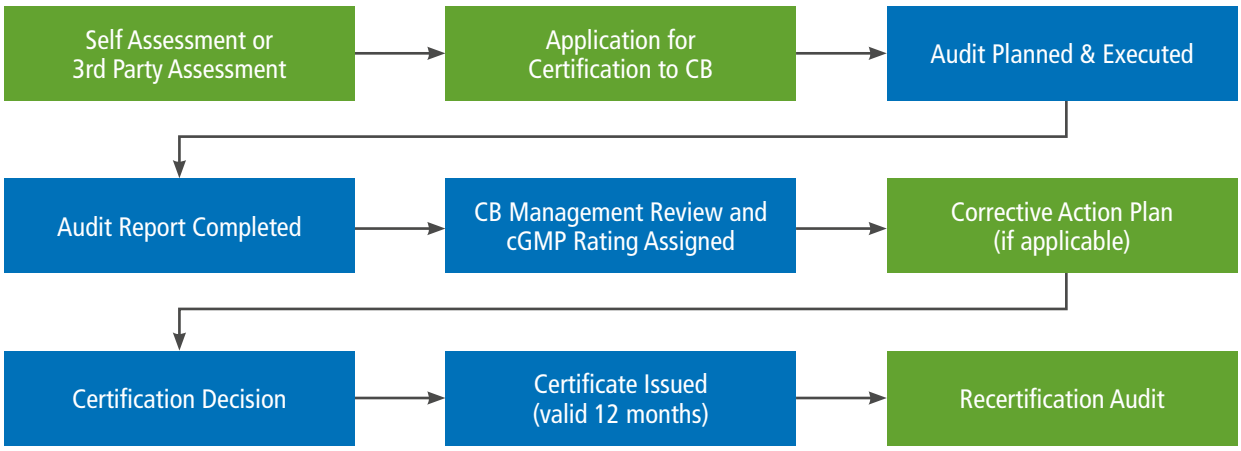
4. NSF International Certification Policies – NSF/ANSI 455

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.

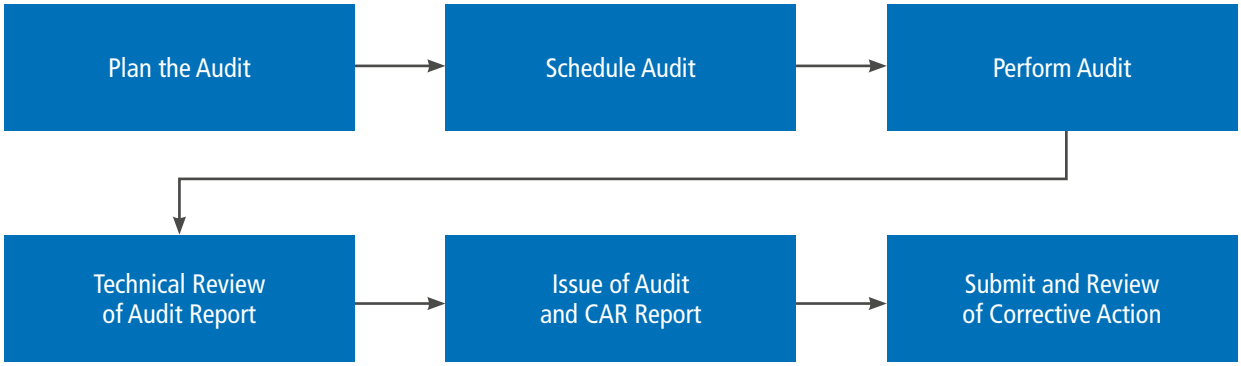


Legend:

- 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.

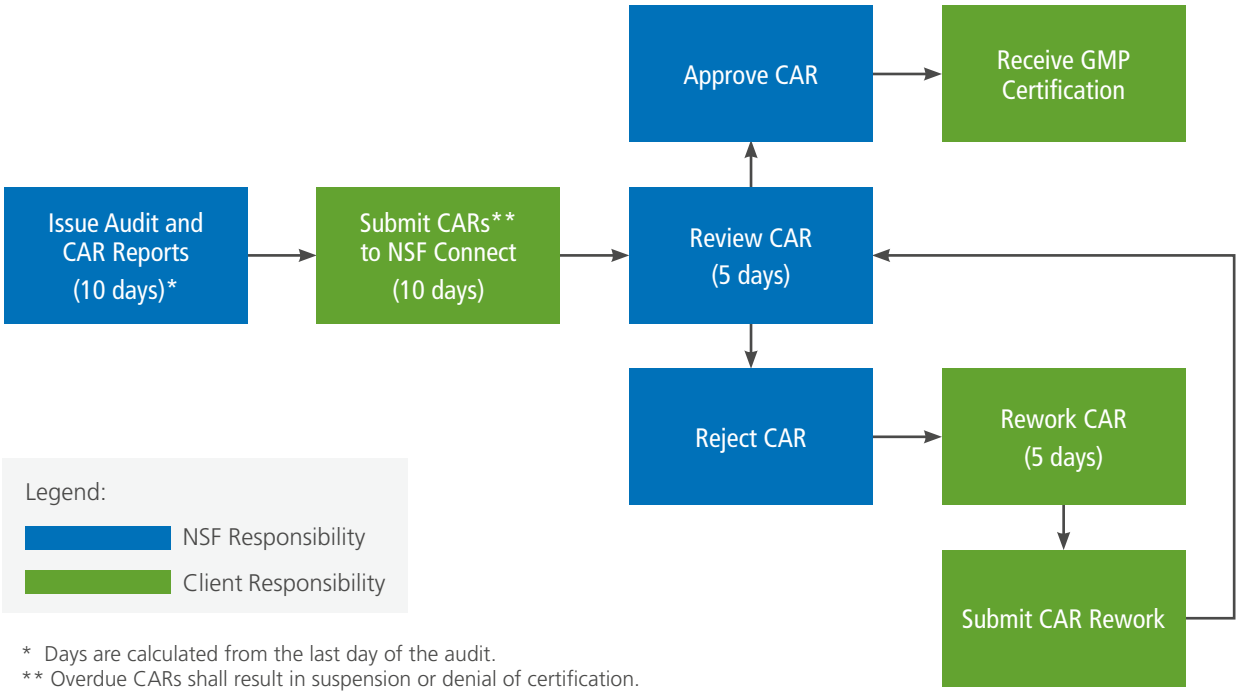
The following are the three (3) levels of nonconformances[1]:

- 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 subsystems; 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.
- 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 shall raise the category to a major nonconformance.

[1] NSF/ANSI 455-2-2018 – Good Manufacturing Practices for Dietary Supplements, 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 after the audit.



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

5. Audit Process (cont'd)

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]

Grade	Critical	Major	Minor
A	0	0	≤ 7
B	0	1	≤ 7
B	0	0	8 to 15
C	0	1	≤ 15 *(8 to 15*)*
C	0	0	16 to 22 *(16 to 23*)*
D	≥ 1	–	–
D	0	≥ 2	–
D	0	1	≥ 18 *(≥ 16*)*
D	0	0	≥ 27 *(≥ 24*)*

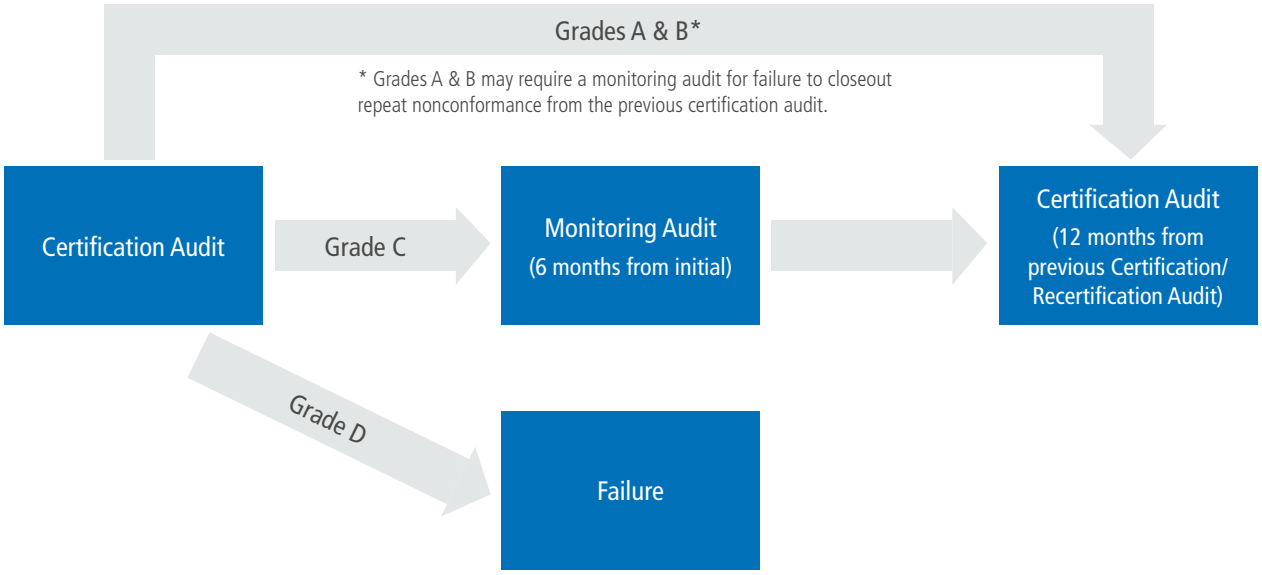
** Recommended changes by NSF submitted to NSF/ANSI 455-2 Joint Committee to remove the gaps and/or overlap of grades. NSF will follow the recommended changes when determining audit grade.*

[2] NSF/ANSI 455-2-2018 – Good Manufacturing Practices for Dietary Supplements, Table 5.2

5. Audit Process (cont'd)

3. Audit Frequency

The frequency of audits is based on the audit grade. Below is the general audit cycle. Please refer to NSF/ANSI 455-2 GMP Section 5 for a more detailed explanation.



6. Comparison of NSF/ANSI 455-2 GMP Standard and Audit Template

To facilitate audit flow, the format of the audit template is rearranged into sections different from the NSF/ANSI 455-2 GMP standard. The table below shows the distribution of NSF/ANSI 455-2 GMP standard requirements in the audit template sections.

Audit Template Sections	Title	NSF/ANSI 455-2 GMP Standard Requirement No.					
Section 0	Visit Summary	5.5.1, 5.5.3, 5.5.8					
Section 1	Client Logistics	1.1, 1.2, 1.3, 3.28					
Section A	Administration and Regulatory	4.1.3					
Section B	Quality Management	4.2.9	4.2.1	4.4.31	4.4.37	4.4.44	
		4.2.10	4.1.2	4.2.6	4.4.41	4.4.42	
		4.2.8	4.1.1	4.2.7	4.4.43	4.3.6	
		4.2.11	4.2.5	4.4.35	4.4.45	4.6.25	
		4.2.2	4.4.33	4.4.34	4.4.46	4.6.26	
		4.2.12	4.4.32	4.4.36	4.4.38		
Section C	Corrective and Preventive Actions & Complaints	4.7.3	4.6.20	4.6.22	4.6.24		
		4.6.19	4.6.21	4.6.23	4.6.28		
Section D	Supplier Qualification	4.5.24	4.5.25	4.6.9	4.5.27	4.4.40	
		4.3.2	4.5.26	4.5.34	4.5.33		
		4.5.28	4.6.8	4.5.36	4.5.35		
Section E	Product Safety	4.3.1	4.5.17	4.5.15	4.5.45	4.5.20	
		4.5.46	4.5.18	4.5.23	4.5.47	4.5.3	
		4.5.13	4.5.16	4.5.22	4.5.38		
		4.5.14	4.5.21	4.5.44	4.5.19		
Section F	Facilities	4.4.1	4.4.8	4.5.9	4.5.31	4.4.29	4.4.5
		4.4.2	4.4.13	4.5.10	4.4.16	4.4.30	4.4.25
		4.5.1	4.4.14	4.4.9	4.4.17	4.4.20	4.4.7
		4.5.2	4.5.5	4.4.10	4.4.18	4.4.21	4.4.26
		4.4.6	4.5.6	4.5.29	4.4.19	4.4.22	
		4.5.4	4.4.12	4.5.30	4.4.27	4.4.23	
		4.4.15	4.5.8	4.5.32	4.5.12	4.4.24	
		4.4.3	4.5.7	4.4.11	4.4.28	4.4.4	

6. Comparison of NSF/ANSI 455-2 GMP Standard and Audit Template (cont'd)

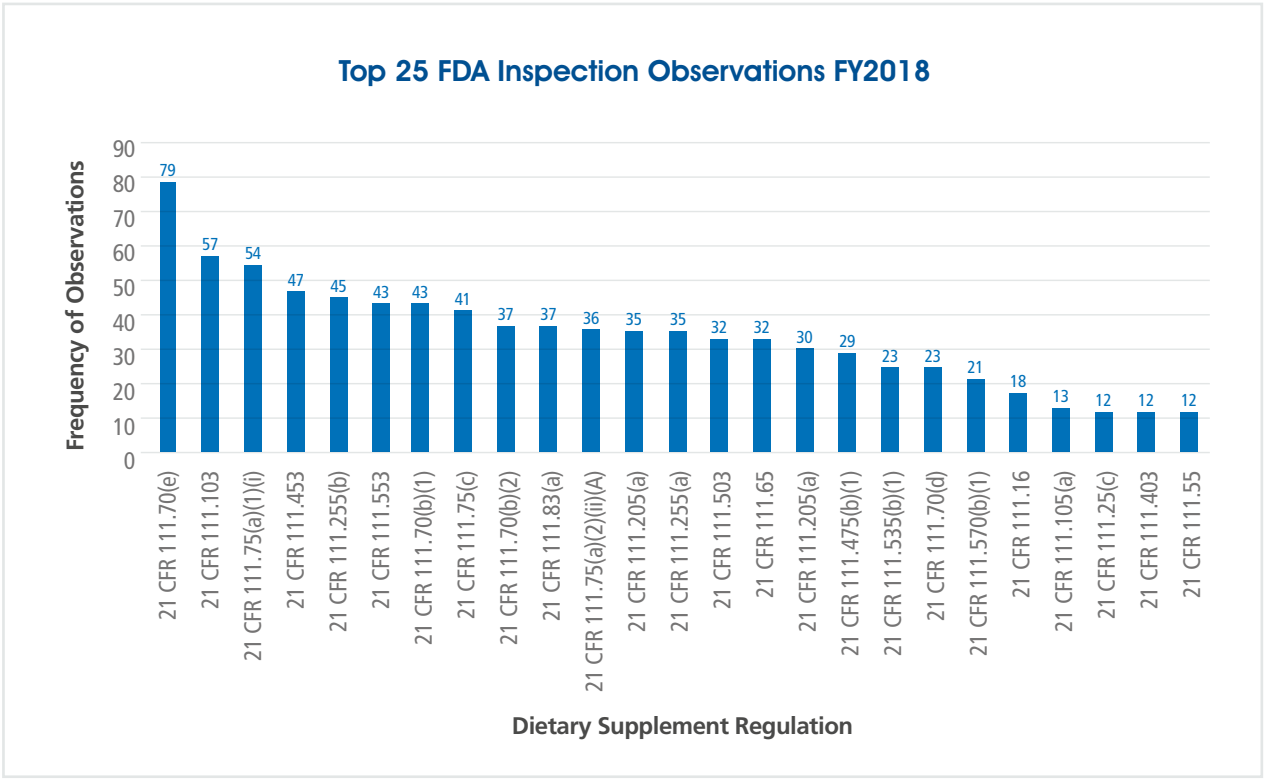
Audit Template Sections	Title	NSF/ANSI 455-2 GMP Standard Requirement No.					
Section G	Production and Process Controls – Manufacturing, Packaging Operations & Product Specification, Release and Returns	4.5.49	4.5.48	4.5.56	4.6.7	4.6.12	4.5.76
		4.2.4	4.5.50	4.5.58	4.3.5	4.6.10	4.5.78
		4.3.3	4.5.51	4.5.60	4.4.39	4.7.1	4.5.80
		4.3.4	4.6.3	4.5.61	4.6.1	4.7.2	4.5.57
		4.5.39	4.5.52	4.5.62	4.6.4	4.5.64	
		4.5.40	4.5.53	4.5.66	4.6.2	4.5.65	
		4.5.41	4.5.59	4.6.13	4.6.5	4.5.77	
		4.5.42	4.5.54	4.5.67	4.6.6	4.5.79	
		4.5.43	4.5.55	4.5.63	4.6.11	4.5.75	
Section H	Laboratory Controls	4.6.14	4.2.3	4.6.27			
		4.6.17	4.6.16	4.5.37			
		4.6.18	4.6.15				
Section I	Warehouse and Distribution Controls	4.5.70	4.5.11	4.5.72	4.5.73		
		4.5.68	4.5.69	4.5.71	4.5.74		
Section J	NSF Certification Policies	Compliance against NSF certification policies					

7. Top 25 Dietary Supplements FDA Inspection Observations

During a FDA inspection of a facility, the inspector may observe conditions or practices that may be deemed to be in violation of FDA's requirements. The graph and table below summarize the top 25 observations in 2018 for dietary supplements against 21 CFR Part 111.

For additional information, please refer to:

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/inspection-observations



7. Top 25 Dietary Supplements FDA Inspection Observations (cont'd)

No.	Reference Number	Short Description	Long Description
1	21 CFR 111.70(e)	Specifications – identity, purity, strength, composition	You did not establish product specifications for the [identity] [purity] [strength] [composition] of the finished dietary supplement.
2	21 CFR 111.103	Written procedures – quality control operations	You did not [establish] [follow] written procedures for quality control operations.
3	21 CFR 111.75(a)(1)(i)	Component – verify identity, dietary ingredient	You did not conduct at least one appropriate test or examination to verify the identity of a dietary ingredient, prior to its use.
4	21 CFR 111.453	Written procedures – holding	You did not [establish] [follow written] procedures for holding and distributing operations.
5	21 CFR 111.255(b)	Batch record – complete	Your batch production record did not include complete information relating to the production and control of each batch.
6	21 CFR 111.553	Written procedures – product complaint	You did not [establish] [follow] written procedures for the requirements to review and investigate a product complaint.
7	21 CFR 111.70(b)(1)	Specifications – component identity	You did not establish an identity specification for each component.
8	21 CFR 111.75(c)	Specifications met – verify; finished batch	You did not verify that your finished batch of dietary supplement meets product specifications for [identity] [purity] [strength] [composition] [limits on contamination that may adulterate or that may lead to adulteration of the dietary supplement].
9	21 CFR 111.70(b)(2)	Specifications-component purity, strength, composition	You did not establish component specifications for [purity] [strength] [composition].
10	21 CFR 111.83(a)	Reserve sample – collect, hold	You did not collect and hold reserve samples of packaged and labeled dietary supplements that you distributed.
11	21 CFR 111.75(a)(2)(ii)(A)	Component – qualify supplier	You did not qualify a supplier of a component by establishing the reliability of the supplier's certificate of analysis through confirmation of the results of their tests or examinations.
12	21 CFR 111.205(a)	Master manufacturing record – each batch	You did not [prepare] [follow] a written master manufacturing record for each batch size of a dietary supplement that you manufactured.
13	21 CFR 111.255(a)	Batch record – every batch	You did not prepare a batch production record every time you manufactured a batch of dietary supplement.
14	21 CFR 111.503	Written procedures – returned dietary supplement	You did not [establish] [follow] written procedures for when a returned dietary supplement is received.

7. Top 25 Dietary Supplements FDA Inspection Observations (cont'd)

No.	Reference Number	Short Description	Long Description
15	21 CFR 111.65	Quality control – quality, dietary supplement	You did not implement quality control operations to ensure the quality of the dietary supplement.
16	21 CFR 111.205(a)	Master manufacturing record – unique formulation	You did not [prepare] [follow] a written master manufacturing record for each unique formulation of a dietary supplement that you manufactured.
17	21 CFR 111.475(b)(1)	Written procedures – holding; distributing	You did not make and keep written procedures for holding and distributing operations.
18	21 CFR 111.535(b)(1)	Records – returned dietary supplement: written procedures	You did not make and keep records of written procedures for fulfilling requirements for returned dietary supplements.
19	21 CFR 111.70(d)	Specifications – labels, packaging	You did not establish [label] [packaging] specifications.
20	21 CFR 111.570(b)(1)	Written procedures – product complaint; review, investigate	You did not make and keep written procedures to fulfill the requirements that apply to the review and investigation of a product complaint.
21	21 CFR 111.16	Written procedures – cleaning	You did not [establish] [follow] written procedures for cleaning the physical plant.
22	21 CFR 111.105(a)	Processes, specifications, written procedures	Your quality control personnel did not approve or reject [processes] [specifications] [written procedures] [controls] [tests] [examinations] [deviations or modifications] that may affect the identity, purity, strength, or composition of a dietary supplement.
23	21 CFR 111.25(c)	Procedures – equipment – cleaning, sanitizing	You did not [establish] [follow] written procedures for maintaining, cleaning, and sanitizing, equipment, utensils, and any other contact surfaces that are used to manufacture, package, label, or hold components or dietary supplements.
24	21 CFR 111.403	Written procedures – labeling operations	You did not [establish] [follow] written procedures for labeling operations.
25	21 CFR 111.55	Production, process controls – implement	You did not implement a system of production and process controls that covers all stages of manufacturing, packaging, labeling, and holding of dietary supplements to ensure the quality of the dietary supplement.

WHAT SHOULD YOU DO?
NSF/ANSI 455-2 GMP STANDARD IS HERE!

Become informed

> Review the NSF materials and tools

- NSF/ANSI 455 GMP Policies
- NSF/ANSI 455-2 GMP Standard
- NSF/ANSI 455-2 GMP ARG
- Audit Template
- Training Videos

> Review regulations applicable to Dietary Supplements

- 21 CFR Part 11; Part 111; Part 117
- Food Safety Modernization Act (FSMA), Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans & Animals
- Sanitary Transportation of Human and Animal Food

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

Top FDA Inspection Observations

NSF/ANSI 455 Certification Policies

NSF/ANSI 455-2 GMP Standard for Dietary Supplements

Webinar

Information & Transition Guide

NSF/ANSI 455-2 GMP ARG for Dietary Supplements

Regulatory Resource Links

FAQs

10. Implementation Timeline for NSF/ANSI 455-2 GMP Standard

Starting November 2019 NSF is offering certification to NSF/ANSI 455-2 GMP standard. Please contact your account manager to start the certification process for your company.

Annex 1: Detailed Comparison of NSF/ANSI 455-2 GMP Standard & Audit Template

NSF/ANSI 455-2 GMP Audit Template Question Number	NSF/ANSI 455-2 GMP Audit Template Section	NSF/ANSI 455-2 GMP Standard Requirement Number	NSF/ANSI 455-2 GMP Standard Section
1 – 7	Visit Summary and Client Logistics	NA	NA
8	Administration and Regulatory	4.1.3	Context of the organization
9	Quality Management	4.2.9	Leadership
10	Quality Management	4.2.10	Leadership
11	Quality Management	4.2.8	Leadership
12	Quality Management	4.2.11	Leadership
13	Quality Management	4.2.2	Leadership
14	Quality Management	4.2.12	Leadership
15	Quality Management	4.2.1	Leadership
16	Quality Management	4.1.2	Context of the organization
17	Quality Management	4.1.1	Context of the organization
18	Quality Management	4.2.5	Leadership
19	Quality Management	4.4.33	Support
20	Quality Management	4.4.32	Support
21	Quality Management	4.2.6	Leadership
22	Quality Management	4.2.7	Leadership
23	Quality Management	4.4.35	Support
24	Quality Management	4.4.35	Support
25	Quality Management	4.4.34	Support
26	Quality Management	4.4.36	Support
27	Quality Management	4.4.37	Support
28	Quality Management	4.4.41	Support
29	Quality Management	4.4.43	Support
30	Quality Management	4.4.45	Support
31	Quality Management	4.4.46	Support
32	Quality Management	4.4.38	Support
33	Quality Management	4.4.44	Support

NSF/ANSI 455-2 GMP Audit Template Question Number	NSF/ANSI 455-2 GMP Audit Template Section	NSF/ANSI 455-2 GMP Standard Requirement Number	NSF/ANSI 455-2 GMP Standard Section
34	Quality Management	4.4.42	Support
35	Quality Management	4.3.6	Planning
36	Quality Management	4.6.25	Performance evaluation
37	Quality Management	4.6.26	Performance evaluation
38	Corrective and Preventive Actions and Complaints	4.7.3	Improvement
39	Corrective and Preventive Actions and Complaints	4.6.19	Performance evaluation
40	Corrective and Preventive Actions and Complaints	4.6.20	Performance evaluation
41	Corrective and Preventive Actions and Complaints	4.6.21	Performance evaluation
42	Corrective and Preventive Actions and Complaints	4.6.22	Performance evaluation
43	Corrective and Preventive Actions and Complaints	4.6.23	Performance evaluation
44	Corrective and Preventive Actions and Complaints	4.6.24	Performance evaluation
45	Corrective and Preventive Actions and Complaints	4.6.28	Performance evaluation
46	Supplier Qualification	4.5.24	Operation
47	Supplier Qualification	4.3.2	Planning
48	Supplier Qualification	4.5.28	Operation
49	Supplier Qualification	4.5.25	Operation
50	Supplier Qualification	4.5.26	Operation
51	Supplier Qualification	4.6.8	Performance evaluation
52	Supplier Qualification	4.6.9	Performance evaluation
53	Supplier Qualification	4.5.34	Operation
54	Supplier Qualification	4.5.36	Operation
55	Supplier Qualification	4.5.27	Operation
56	Supplier Qualification	4.5.33	Operation
57	Supplier Qualification	4.5.35	Operation
58	Supplier Qualification	4.4.40	Support
59	Product Safety	4.3.1	Planning
60	Product Safety	4.5.46	Operation
61	Product Safety	4.5.13	Operation
62	Product Safety	4.5.14	Operation
63	Product Safety	4.5.17	Operation
64	Product Safety	4.5.18	Operation

NSF/ANSI 455-2 GMP Audit Template Question Number	NSF/ANSI 455-2 GMP Audit Template Section	NSF/ANSI 455-2 GMP Standard Requirement Number	NSF/ANSI 455-2 GMP Standard Section
65	Product Safety	4.5.16	Operation
66	Product Safety	4.5.21	Operation
67	Product Safety	4.5.15	Operation
68	Product Safety	4.5.23	Operation
69	Product Safety	4.5.22	Operation
70	Product Safety	4.5.44	Operation
71	Product Safety	4.5.45	Operation
72	Product Safety	4.5.47	Operation
73	Product Safety	4.5.38	Operation
74	Product Safety	4.5.19	Operation
75	Product Safety	4.5.20	Operation
76	Product Safety	4.5.3	Operation
77	Facilities	4.4.1	Support
78	Facilities	4.4.2	Support
79	Facilities	4.5.1	Operation
80	Facilities	4.5.2	Operation
81	Facilities	4.4.6	Support
82	Facilities	4.5.4	Operation
83	Facilities	4.4.15	Support
84	Facilities	4.4.3	Support
85	Facilities	4.4.8	Support
86	Facilities	4.4.13	Support
87	Facilities	4.4.14	Support
88	Facilities	4.5.5	Operation
89	Facilities	4.5.6	Operation
90	Facilities	4.4.12	Support
91	Facilities	4.5.8	Operation
92	Facilities	4.5.7	Operation
93	Facilities	4.5.9	Operation
94	Facilities	4.5.10	Operation
95	Facilities	4.4.9	Support

NSF/ANSI 455-2 GMP Audit Template Question Number	NSF/ANSI 455-2 GMP Audit Template Section	NSF/ANSI 455-2 GMP Standard Requirement Number	NSF/ANSI 455-2 GMP Standard Section
96	Facilities	4.4.10	Support
97	Facilities	4.5.29	Operation
98	Facilities	4.5.30	Operation
99	Facilities	4.5.32	Operation
100	Facilities	4.4.11	Support
101	Facilities	4.5.31	Operation
102	Facilities	4.4.16	Support
103	Facilities	4.4.17	Support
104	Facilities	4.4.19	Support
105	Facilities	4.4.18	Support
106	Facilities	4.4.27	Support
107	Facilities	4.5.12	Operation
108	Facilities	4.4.28	Support
109	Facilities	4.4.29	Support
110	Facilities	4.4.30	Support
111	Facilities	4.4.20	Support
112	Facilities	4.4.21	Support
113	Facilities	4.4.22	Support
114	Facilities	4.4.23	Support
115	Facilities	4.4.24	Support
116	Facilities	4.4.4	Support
117	Facilities	4.4.5	Support
118	Facilities	4.4.25	Support
119	Facilities	4.4.7	Support
120	Facilities	4.4.26	Support
121	Production and Process Controls – Manufacturing Operations	4.5.49	Operation
122	Production and Process Controls – Manufacturing Operations	4.2.4	Leadership
123	Production and Process Controls – Manufacturing Operations	4.3.3	Planning
124	Production and Process Controls – Manufacturing Operations	4.3.4	Planning

NSF/ANSI 455-2 GMP Audit Template Question Number	NSF/ANSI 455-2 GMP Audit Template Section	NSF/ANSI 455-2 GMP Standard Requirement Number	NSF/ANSI 455-2 GMP Standard Section
125	Production and Process Controls – Manufacturing Operations	4.5.39	Operation
126	Production and Process Controls – Manufacturing Operations	4.5.40	Operation
127	Production and Process Controls – Manufacturing Operations	4.5.41	Operation
128	Production and Process Controls – Manufacturing Operations	4.5.42	Operation
129	Production and Process Controls – Manufacturing Operations	4.5.43	Operation
130	Production and Process Controls – Manufacturing Operations	4.5.48	Operation
131	Production and Process Controls – Manufacturing Operations	4.5.50	Operation
132	Production and Process Controls – Packaging Operations	4.5.51	Operation
133	Production and Process Controls – Packaging Operations	4.6.3	Performance evaluation
134	Production and Process Controls – Packaging Operations	4.5.52	Operation
135	Production and Process Controls – Packaging Operations	4.5.53	Operation
136	Production and Process Controls – Packaging Operations	4.5.59	Operation
137	Production and Process Controls – Packaging Operations	4.5.54	Operation
138	Production and Process Controls – Packaging Operations	4.5.55	Operation
139	Production and Process Controls – Packaging Operations	4.5.56	Operation
140	Production and Process Controls – Packaging Operations	4.5.58	Operation
141	Production and Process Controls – Packaging Operations	4.5.60	Operation
142	Production and Process Controls – Packaging Operations	4.5.61	Operation
143	Production and Process Controls – Packaging Operations	4.5.62	Operation
144	Production and Process Controls – Packaging Operations	4.5.66	Operation

NSF/ANSI 455-2 GMP Audit Template Question Number	NSF/ANSI 455-2 GMP Audit Template Section	NSF/ANSI 455-2 GMP Standard Requirement Number	NSF/ANSI 455-2 GMP Standard Section
145	Production and Process Controls – Packaging Operations	4.6.13	Performance evaluation
146	Production and Process Controls – Packaging Operations	4.5.67	Operation
147	Production and Process Controls – Packaging Operations	4.5.63	Operation
148	Production and Process Controls – Specifications, Product Release and Returns	4.6.7	Performance evaluation
149	Production and Process Controls – Specifications, Product Release and Returns	4.3.5	Planning
150	Production and Process Controls – Specifications, Product Release and Returns	4.4.39	Support
151	Production and Process Controls – Specifications, Product Release and Returns	4.6.1	Performance evaluation
152	Production and Process Controls – Specifications, Product Release and Returns	4.6.4	Performance evaluation
153	Production and Process Controls – Specifications, Product Release and Returns	4.6.2	Performance evaluation
154	Production and Process Controls – Specifications, Product Release and Returns	4.6.5	Performance evaluation
155	Production and Process Controls – Specifications, Product Release and Returns	4.6.6	Performance evaluation
156	Production and Process Controls – Specifications, Product Release and Returns	4.6.11	Performance evaluation
157	Production and Process Controls – Specifications, Product Release and Returns	4.6.12	Performance evaluation
158	Production and Process Controls – Specifications, Product Release and Returns	4.6.10	Performance evaluation
159	Production and Process Controls – Specifications, Product Release and Returns	4.7.1	Improvement
160	Production and Process Controls – Specifications, Product Release and Returns	4.7.2	Improvement
161	Production and Process Controls – Specifications, Product Release and Returns	4.5.64	Operation
162	Production and Process Controls – Specifications, Product Release and Returns	4.5.65	Operation
163	Production and Process Controls – Specifications, Product Release and Returns	4.5.77	Operation
164	Production and Process Controls – Specifications, Product Release and Returns	4.5.79	Operation

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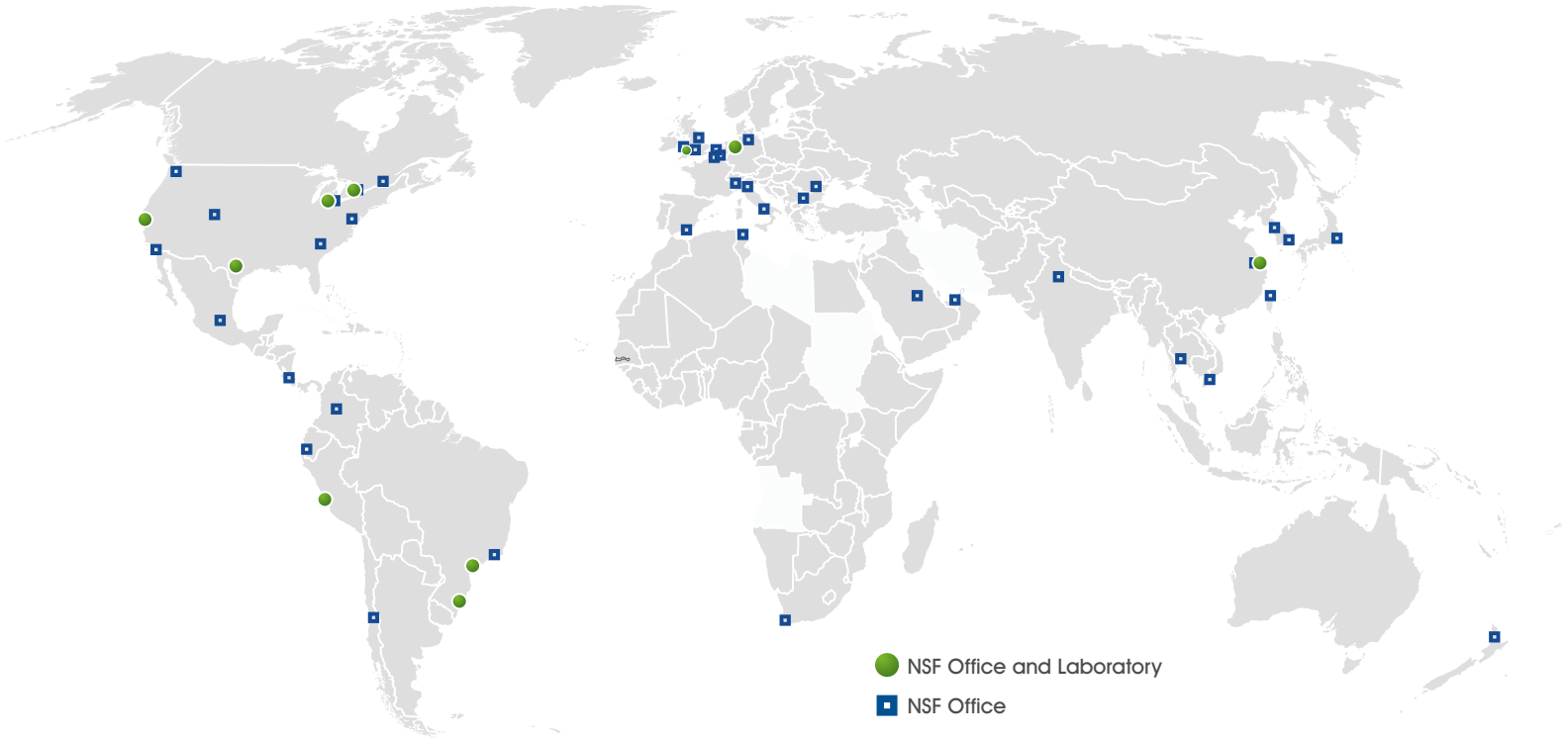
165	Production and Process Controls – Specifications, Product Release and Returns	4.5.75	Operation
166	Production and Process Controls – Specifications, Product Release and Returns	4.5.76	Operation
167	Production and Process Controls – Specifications, Product Release and Returns	4.5.78	Operation
168	Production and Process Controls – Specifications, Product Release and Returns	4.5.80	Operation
169	Production and Process Controls – Specifications, Product Release and Returns	4.5.57	Operation
170	Laboratory Controls	4.6.14	Performance evaluation
171	Laboratory Controls	4.6.17	Performance evaluation
172	Laboratory Controls	4.6.18	Performance evaluation
173	Laboratory Controls	4.2.3	Leadership
174	Laboratory Controls	4.6.16	Performance evaluation
175	Laboratory Controls	4.6.15	Performance evaluation
176	Laboratory Controls	4.6.27	Performance evaluation
177	Laboratory Controls	4.5.37	Operation
178	Warehouse and Distribution	4.5.70	Operation
179	Warehouse and Distribution	4.5.68	Operation
180	Warehouse and Distribution	4.5.11	Operation
181	Warehouse and Distribution	4.5.69	Operation
182	Warehouse and Distribution	4.5.72	Operation
183	Warehouse and Distribution	4.5.71	Operation
184	Warehouse and Distribution	4.5.73	Operation
185	Warehouse and Distribution	4.5.74	Operation



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