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

TRANSITION GUIDE

NSF/ANSI 455-2 GOOD MANUFACTURING PRACTICES FOR DIETARY SUPPLEMENTS AND DIETARY INGREDIENTS TRANSITION GUIDE

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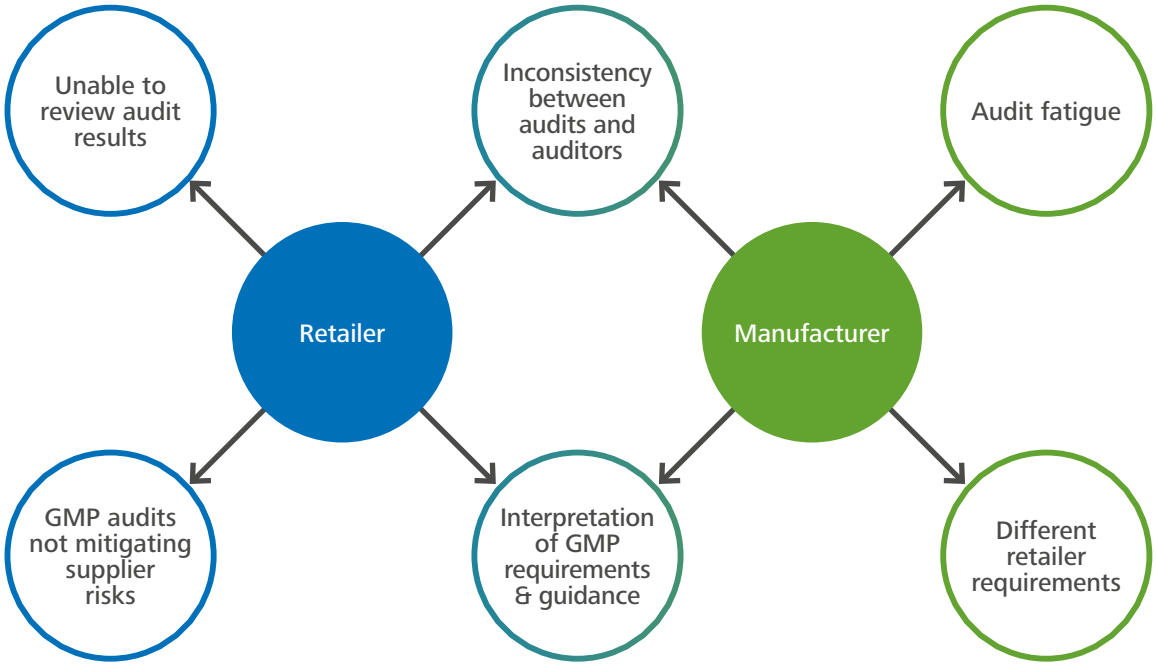
1. Overview of NSF/ANSI 455-2 GMP Certification

In January 2019, the Global Retailer and Manufacturer Alliance (GRMA) announced the publication of NSF/ANSI 455 standards, a set of consensus-based Good Manufacturing Practices (GMP) requirements for manufacturers of dietary supplements (NSF/ANSI 455-2), cosmetics and personal care products (NSF/ANSI 455-3) and over-the-counter drugs (NSF/ANSI 455-4). In addition, an Audit Requirements Guideline (ARG) were published as companion documents to assist with the interpretation of each standard. A fourth standard, NSF/ANSI 455-1 Terminology for the NSF 455 Portfolio of Standards, was also published as a supplement to the three (3) NSF/ANSI 455 GMP standards.

The NSF/ANSI 455-2 GMP for Dietary Supplement standard was developed in accordance with 21 CFR Part 11, 21 CFR Part 111, and applicable Food Safety Modernization Act (FSMA) final rules: Preventive Controls for Human Food (21 CFR Part 117), Sanitary Transportation of Human and Animal Food, and Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals. The purpose of NSF/ANSI 455-2 is to address key challenges in the dietary supplements industry by having one accepted standard.

Key Industry Challenge



1. Overview of NSF/ANSI 455-2 GMP Certification (cont'd)

Benefits of transitioning to NSF/ANSI 455-2 GMP Certification

- Public standard developed in consensus by manufacturers, retailers, public health regulators, and certification bodies
- American National Standards Institute (ANSI) accredited standard
- One industry GMP standard
- Mitigate supplier risk
- Calibration of certification bodies and auditors to one standard
- Standardized audit report
- ANSI logo on certificates for global recognition
- Prevent manufacturers' audit fatigue by reducing the number of audits in a year
- Reduce associated costs of auditing to multiple independent standards
- Assists manufacturers with continuous improvement
- Assists manufacturers with implementing industry best practices
- Greater consumer confidence in manufacturers and their products
- Accepted by retailers

Out of Scope

Warehouse and distribution centers (standalone), brokers, label designers, laboratories, office buildings, transport companies, E-Commerce, or facilities producing medical food or functional food do not qualify for certification to NSF/ANSI 455.

2. NSF ANSI 455-2 GMP Certification vs. NSF GMP Registration Programs

The NSF/ANSI 455-2 GMP Certification and NSF GMP Registration are both developed in accordance with 21 CFR Part 1.9, 21 CFR Part 11, 21 CFR Part 111 and FSMA regulations.

Key Differences

> Pre-Audit documentation

A company seeking certification to NSF/ANSI 455-2 GMP Certification must provide documents to NSF at minimum of one (1) business week prior to the scheduled audit date.

Documents required 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

2. NSF ANSI 455-2 GMP Certification vs. NSF GMP Registration Programs (cont'd)

> Document format

The NSF/ANSI 455-2 GMP standard document structure is based on an ISO 9001 format while the NSF GMP Registration Requirements document structure is based on a Quality Management Systems format.

NSF/ANSI 455-2 GMP Standard

NSF GMP Registration Requirements

2. NSF ANSI 455-2 GMP Certification vs. NSF GMP Registration Programs (cont'd)

> Audit Grade Rule

Audit grade calculation is based on the number and severity of the nonconformances defined by the standard. The result obtained in your NSF/ANSI 455-2 GMP audit may differ from your NSF GMP Registration audit.

NSF/ANSI 455-2 GMP Certification Grade Rule

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

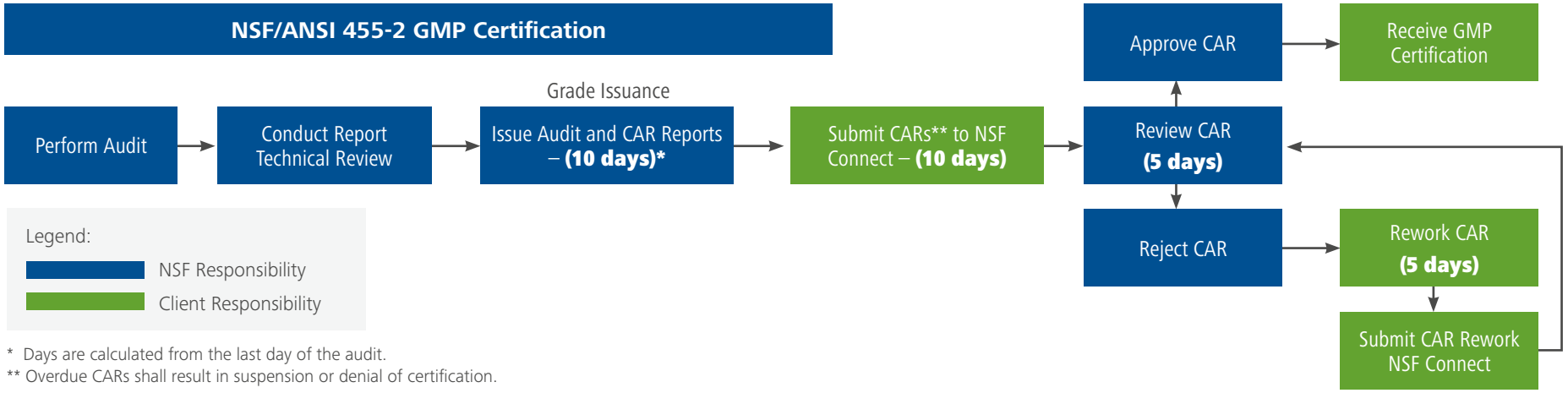
NSF GMP Registration Grade Rule

Grade	Critical	Major	Minor
A	0	0	9 or fewer
B	0	0	10 to 17
	0	1	9 or fewer
C	0	0	18 to 26
	0	1	10 to 17
	0	2	9 or fewer
Fail	0	0	27 or more
	0	1	18 or more
	0	2	10 or more
	0	3 or more	0 or more
	1 or more	0 or more	0 or more

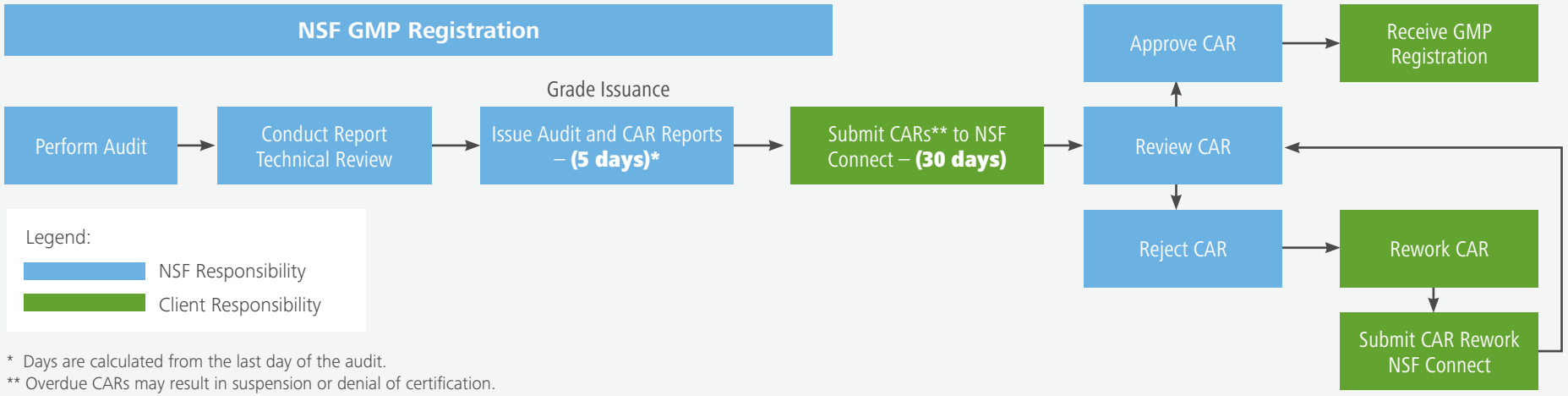
2. NSF ANSI 455-2 GMP Certification vs. NSF GMP Registration Programs (cont'd)

> Post-Audit deadlines

NSF/ANSI 455-2 GMP Certification and NSF GMP Registration have similar post audit processes, however NSF/ANSI 455-2 GMP has a shorter corrective action review timeframe, as shown in the process flow below.



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



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

2. NSF ANSI 455-2 GMP Certification vs. NSF GMP Registration Programs (cont'd)

> Repeat Nonconformances

Nonconformances cited during a previous audit that are not corrected by the next scheduled audit shall be assessed as Repeat nonconformances. Nonconformance cited are based on risk in accordance to the definition in the standard of Critical, Major and Minor.

NSF/ANSI 455-2 GMP Certification	NSF GMP Registration
> A repeat Minor nonconformance is elevated to a Major nonconformance if not closed out within three (3) months of the certification audit. > An amended report is issued with the revised nonconformance classification. This may impact the audit grade. > Failure to provide objective evidence within the three (3) month period may result in Suspension. > Monitoring audit is conducted within six (6) months of the certification audit.	> A repeat Minor nonconformance is not elevated to a Major nonconformance. > Failure to close out repeat nonconformances may result to a suspension.

3. Transition Process

> What should I do to start the transition process?

1. Review all the applicable NSF/ANSI 455-2 GMP tools.
    - NSF/ANSI 455 GMP Certification Policies
    - NSF/ANSI 455-2 GMP Standard
    - NSF/ANSI 455-2 GMP ARG
    - Audit Template
    - Training Videos
    - Transition Guide
2. Conduct a pre-assessment to the NSF/ANSI 455-2 Standard utilizing the Transition Document Annex, NSF/ANSI 455-2 GMP Standard and Auditor Requirements Guideline. This is a requirement by the Standard. The pre-assessment may be conducted by a third-party or by your organization.
    - Identify gaps / nonconformances found during the pre-assessment.
    - Apply and implement pre-assessment corrective actions.
    - Verify and ensure corrective actions are implemented and effective.
3. Close out nonconformances from your previous NSF GMP Registration audit and implement corrective actions.
4. Submit application documents to NSF.

> When can I transition from a NSF GMP Registration audit to NSF/ANSI 455-2 GMP Certification audit?

When you have determined you are ready for the NSF/ANSI 455-2 certification audit, contact your NSF Account Manager who will assist you with the next steps.

Annex: Comparison of NSF/ANSI 455-2 GMP Certification and NSF GMP Registration Audit Templates

This table provides comparison of NSF/ANSI 455-2 GMP Certification to NSF GMP Registration audit templates.

NSF GMP Registration Requirements Document may be more detailed in some sections than NSF/ANSI 455-2 GMP Certification. In the following table, where the "Differences" column mentions "Comparable requirements," the intention is the same. The requirements will be enforced in a same manner for both programs.

This table is applicable for both dietary supplements and dietary ingredients.

NSF/ANSI 455-2 GMP Certification					NSF GMP Registration			Differences
Audit Template Question #	Audit Template Section	Standard #	Question	NSF/ANSI 455-2 Standard Section	Audit Template Section	Requirement #	Question	
1-7	Visit summary and client logistics	NA	Client information	NA	Visit summary and client logistics	NA	Client information.	Comparable requirements.
8	Administration and Regulatory	4.1.3	US FDA facility and Bioterrorism registrations and process filings shall be current and maintained. (physical address, scope, expiration dates, etc.)	Context of the organization	Administration and Regulatory	A.1.3	Facility shall be registered with the US Food & Drug Administration (USFDA).	Comparable requirements.
						A.1.4	Procedures to register all required processes and products with the USFDA shall be documented, implemented and maintained.	
9	Quality Management	4.2.9	Hygienic practices shall be established to include appropriate garments, personal hygiene, hand washing, and sanitization, etc. prior to starting work and at any time whereby personnel can become soiled or contaminated. [21CFR111.10(b1),(b2),(b3)]	Leadership	Administration and Regulatory	A.3.1	There shall be procedures for personal hygienic practices. Procedures include but are not limited to donning appropriate garments, and exercising personal hygiene (i.e.; hand washing, sanitization, etc.) prior to starting work, returning from break (restroom or otherwise) and following any event whereby personnel may become soiled or contaminated.	Comparable requirements.

NSF/ANSI 455-2 GMP Certification					NSF GMP Registration			Differences
Audit Template Question #	Audit Template Section	Standard #	Question	NSF/ANSI 455-2 Standard Section	Audit Template Section	Requirement #	Question	
10	Quality Management	4.2.10	Procedures shall be in place for use of impermeable gloves, hairnets, caps, beard covers, etc. and for restrictions on the use of food, drinks, tobacco, etc. in areas whereby product contamination could occur. Procedures shall be established to prevent contamination from all potential sources. [21CFR111.10(b5),(b6),(b8),(b9)]	Leadership	Administration and Regulatory	A.3.1	There shall be procedures for personal hygienic practices. Procedures include but are not limited to donning appropriate garments, and exercising personal hygiene (i.e.; hand washing, sanitization, etc.) prior to starting work, returning from break (restroom or otherwise) and following any event whereby personnel may become soiled or contaminated.	Comparable requirements.
						A.3.2	The facility GMP Program shall include protections against contamination, including but not limited to: smokeless tobacco or chewing tobacco; cigarettes or e-cigarettes, food, beverages, outside bags/clothing, personal items, etc.	
						A.3.3	A written dress code including shoe policy shall exist stating appropriate attire for workers (including temporary), supervisors, managers, contractors, vendors and visitors to all parts of the GMP areas including but not limited to production, storage, packaging and testing facilities. Dress code shall include use of captive uniforms, shoes and use of disposable outer garments, where applicable.	

NSF/ANSI 455-2 GMP Certification					NSF GMP Registration			Differences
Audit Template Question #	Audit Template Section	Standard #	Question	NSF/ANSI 455-2 Standard Section	Audit Template Section	Requirement #	Question	
11	Quality Management	4.2.8	Procedures shall be established that define work requirements for personnel to prevent microbial contamination due to a health condition. [21CFR111.10(a)]	Leadership	Administration and Regulatory	A.3.1	There shall be procedures for personal hygienic practices. Procedures shall include but are not limited to donning appropriate garments, and exercising personal hygiene (e.g.; hand washing, sanitization, etc.) prior to starting work, returning from break (restroom or otherwise) and following any event whereby personnel may become soiled or contaminated.	Comparable requirements.
12	Quality Management	4.2.11	Procedures shall be in place for the control of jewelry and other personal care items. [21CFR111.10(b4)]	Leadership	Administration and Regulatory	A.3.1	There shall be procedures for personal hygienic practices. Procedures shall include but are not limited to donning appropriate garments, and exercising personal hygiene (e.g.; hand washing, sanitization, etc.) prior to starting work, returning from break (restroom or otherwise) and following any event whereby personnel may become soiled or contaminated.	Comparable requirements.
13	Quality Management	4.2.2	Management shall conduct biennial reviews to assess the suitability and effectiveness of the quality system.	Leadership	Quality Management	B.1.1	Management is responsible for Quality Management.	Comparable requirements.
						B.1.2	Senior management shall have a process for reviewing the Quality System and performance indicators on at least an annual basis.	> 455-2: 4.2.2 defines **biennial reviews** by management. > NSF GMP: B.1.2 defines **annual review** by senior management.

NSF/ANSI 455-2 GMP Certification					NSF GMP Registration			Differences
Audit Template Question #	Audit Template Section	Standard #	Question	NSF/ANSI 455-2 Standard Section	Audit Template Section	Requirement #	Question	
14	Quality Management	4.2.12	Visitor (regulator, contractor, customer, non-site employee, etc.) policy and procedures shall be established.	Leadership	Administration and Regulatory	A.2.1	There shall be Standard Operating Procedure (SOP) and records of regulatory visit, inspections, or both.	Comparable requirements.
					Administration and Regulatory	A.2.2	SOPs for regulatory visit or inspection shall include provisions for reporting regulatory citations to impacted customers and NSF International.	Comparable requirements.
					Quality Management	B.1.4	There shall be a visitor procedure applicable to all non-site employees.	Comparable requirements.
15	Quality Management	4.2.1	Procedures shall be established for the responsibilities of the QC operations. [21CFR111.103 and 21CFR111.105]	Leadership	Quality Management	B.2.3	Quality Personnel shall have established roles and responsibilities.	Comparable requirements.
					Laboratory Controls	H.1.9	Procedures for managing analytical, microbiological and physical instrument calibration and maintenance results shall be implemented.	> 455-2 does not define a timeframe to report OOS results. > NSF GMP: H.1.9 defines OOS results shall be sent to the facility based on an agreed timeframe, which shall not exceed **one (1) business day** from the result confirmation.
16	Quality Management	4.1.2	Quality control (QC) operations shall be identified and implemented. [21CFR111.65]	Context of the organization	Quality Management	B.2.3	Quality Personnel shall have established roles and responsibilities.	Comparable requirements.
17	Quality Management	4.1.1	Quality responsibilities shall be distinct and separate from operations. [21CFR111.12(b)]	Context of the organization	Quality Management	B.1.3	Quality shall not report directly to Operations, or other areas functions that pose a conflict of interest; to ensure that quality decision making remains distinct and independent.	Comparable requirements.
18	Quality Management	4.2.5	QC operations and responsibilities shall include the authority to reject any component or product if any specification is not met. [21CFR111.113(a)]	Leadership	Quality Management	B.2.3	Quality Personnel shall have established roles and responsibilities.	Comparable requirements.
19	Quality Management	4.4.33	Procedures shall be established to determine the requirements and qualifications (such as education, training, or experience) for personnel who will supervise activities. [21CFR111.13(a), (b) & 21CFR 117.4]	Support	Quality Management	B.2.4	There shall be defined supervisor training and responsibilities.	Comparable requirements.

NSF/ANSI 455-2 GMP Certification					NSF GMP Registration			Differences
Audit Template Question #	Audit Template Section	Standard #	Question	NSF/ANSI 455-2 Standard Section	Audit Template Section	Requirement #	Question	
20	Quality Management	4.4.32	Personnel shall be qualified and have adequate training, experience and/or education necessary to perform job functions. [21CFR111.12(c) & 21CFR 117.4]	Support	Quality Management	B.2.2	Personnel shall have the appropriate qualifications; and have adequate training, experience, and education necessary to perform identified job functions.	Comparable requirements.
					Quality Management	B.2.8	There shall be an assessment of learning following training to document effectiveness.	Comparable requirements.
21	Quality Management	4.4.31	Controls shall be in place to verify the backgrounds of new, contracted, seasonal and temporary employees prior to hiring. Temporary employees prior to hiring.	Leadership	Quality Management	B.2.1	Background check procedures shall be defined and implemented for all personnel, including but not limited to contracted, temporary, seasonal personnel as part of the new hiring process. Criminal background checks are not required.	Comparable requirements.
22	Quality Management	4.2.6	Sanitation supervisors shall be assigned and shall be qualified. [21CFR111.15(k)]	Leadership	Quality Management	B.2.5	Qualified sanitation supervisors shall be assigned.	Comparable requirements.
23	Quality Management	4.2.7	Competent supervisory personnel shall be responsible for ensuring transportation operations are conducted in compliance with 21CFR 1.908. [21CFR1.908]	Support	Quality Management	B.2.4	Supervisor training and responsibilities shall be defined.	Comparable requirements.
24	Quality Management	4.4.35	Job descriptions shall be available for all personnel and personnel have received food safety, GMP, and appropriate training for their assigned functions. [21CFR111.12(a) & 21CFR117.4]	Support	Quality Management	B.2.2	Personnel shall have the appropriate qualifications; and have adequate training, experience, and education necessary to perform identified job functions.	Comparable requirements.
						B.2.6	All personnel including temporary staff and contractors shall be trained in appropriate policies and procedures.	
						B.2.7	Refresher training shall be conducted at least annually.	> 455-2: 4.4.35 does not define the frequency of refresher training. > NSF GMP: B.2.7 defines the frequency as **annually**.

NSF/ANSI 455-2 GMP Certification					NSF GMP Registration			Differences
Audit Template Question #	Audit Template Section	Standard #	Question	NSF/ANSI 455-2 Standard Section	Audit Template Section	Requirement #	Question	
25	Quality Management	4.4.34	Records shall be maintained documenting compliance to established procedures that ensure that supervisors are appropriately qualified by education, training, or experience. [21CFR111.14(a), (b) & 21CFR 117.4]	Support	Quality Management	B.2.9	Training records shall be maintained.	Comparable requirements.
26	Quality Management	4.4.36	A document control program shall be established and followed outlining the initiation, formatting, review, approval, distribution (to include personnel training requirements), document storage, change control, retention, and disposal of documents and records. [21CFR111.105]	Support	Quality Management	B.6.1	A document management program shall be established.	Comparable requirements.
						B.6.2	Most recent revisions of documents shall be accessible to appropriate personnel and positions.	
						B.6.3	Review of documents shall occur on a defined frequency, at least once every three years, unless otherwise justified.	> 455-2: 4.4.36 does not define the frequency of document review. > NSF GMP: B.6.3 defines the frequency as **at least once every three years**.
27	Quality Management	4.4.37	Good documentation practices shall be established and followed concerning paper and electronic documents and records. [21CFR111.105]	Support	Quality Management	B.6.4	Good Documentation Practices (GDP) shall be established and implemented.	Comparable requirements.
28	Quality Management	4.4.41	Procedures shall be established that describe the requirements for record retention under Subpart P – Records and Recordkeeping. [21CFR111.605]	Support	Quality Management	B.6.7	Records retention policy shall be defined, documented and implemented.	Comparable requirements.
29	Quality Management	4.4.43	All records shall be maintained as original record, as true copies or as electronic records. [21CFR111.605(b)]	Support	Quality Management	B.6.8	Quality records shall be maintained and available for review.	Comparable requirements.

NSF/ANSI 455-2 GMP Certification					NSF GMP Registration			Differences
Audit Template Question #	Audit Template Section	Standard #	Question	NSF/ANSI 455-2 Standard Section	Audit Template Section	Requirement #	Question	
30	Quality Management	4.4.45	Electronic GMP inventory records that are created, modified, maintained, archived, retrieved, or distributed by a computer system, shall be 21CFR11 compliant. [21CFR11]	Support	Quality Management	B.6.5	Electronic forms shall be included in the document management program, and shall be compliant with 21 CFR Part 11, and §B.6.1.	Comparable requirements.
					Electronic Records & Signatures	J.1.1	Electronic signatures and handwritten signatures associated with electronic records shall be linked to their respective electronic records to ensure that the signatures cannot be excised, copied, or otherwise transferred to falsify an electronic record by ordinary means.	
31	Quality Management	4.4.46	Backup electronic files shall be maintained of the following; current software programs, outdated software programs that may be necessary to retrieve past records, and data that was entered. Backup files shall be an exact and complete record and are secure from alterations, erasures, or loss and damage. [21CFR111.35(b5i), (b5ii)]	Support	Electronic Records & Signatures	J.1.2	Each electronic signature shall be unique to one individual. It shall not be reused by or reassigned to anyone else.	Comparable requirements.
						J.1.3	Electronic signatures shall be protected to ensure that they are only used by their genuine owners.	
32	Quality Management	4.4.38	QC operations shall prepare and maintain all records required by Subpart F – Production and Process Control System: Requirements for Quality Control. [21CFR111.140]	Support	Quality Management	B.6.6	Record management shall be documented and implemented.	Comparable requirements.
33	Quality Management	4.4.44	QC operations shall maintain appropriate records as required. [21CFR111.325]	Support	Quality Management	B.6.6	Record management shall be documented and implemented.	Comparable requirements.

NSF/ANSI 455-2 GMP Certification					NSF GMP Registration			Differences
Audit Template Question #	Audit Template Section	Standard #	Question	NSF/ANSI 455-2 Standard Section	Audit Template Section	Requirement #	Question	
34	Quality Management	4.4.42	Records required by 21 CFR 111 shall be maintained for at least one year after the shelf life date or at least two years beyond the date of distribution of the last batch associated with those records. [21CFR111.605(a)]	Support	Quality Management	B.5.3	Quarantine records shall be maintained for one (1) year beyond the shelf life of the product, or two (2) years beyond the date of distribution of last nonconforming batch, whichever is greater.	Comparable requirements.
35	Quality Management	4.3.6	A crisis management plan is developed to manage significant disruptive events, including, but not limited to, natural disasters and catastrophic events that may impact the ability of the manufacturer to deliver a safe product.	Planning	Quality Management	B.3.1	Crisis Management (Back-Up Plan or Disaster Recovery Plan) procedures shall be developed to address any critical situations that may occur, such as natural disasters and catastrophic events any and other emergency situations. (e.g. power outage, fires, Information Technology (IT), tampering, water interruption, etc.)	Comparable requirements.
						B.3.2	Provisions shall be in place for power backup sources to critical systems in the event of main power failure. Written procedures for recovery from power failure shall exist.	
36	Quality Management	4.6.25	Procedures shall be established to define the recall of a product. The written recall plan shall include procedures that describe the steps to be taken, and assign responsibility for taking those steps as appropriate to the facility. [21CFR117.139]	Performance evaluation	Quality Management	B.5.4	Recall and withdrawal procedure shall be established and implemented.	Comparable requirements.
						B.5.6	Records of product withdrawals and recalls, mock recall exercises shall be maintained.	

NSF/ANSI 455-2 GMP Certification					NSF GMP Registration			Differences
Audit Template Question #	Audit Template Section	Standard #	Question	NSF/ANSI 455-2 Standard Section	Audit Template Section	Requirement #	Question	
37	Quality Management	4.6.26	Procedures shall be established to define traceability and mock recall exercises at a minimum of once a year to include trace forward and trace backward.	Performance evaluation	Quality Management	B.4.3	Finished Product Lot or Batch Number shall be traceable to the customer (one forward) and to the suppliers of raw materials and packaging (one backward).	Comparable requirements.
						B.4.4	Finished product shipping records shall be available for review.	
						B.4.5	Traceability exercises shall be conducted at least twice annually, on one finished product and one raw material, including food contact packaging.	> 455-2: 4.6.26 defines **once a year** traceability exercise. > NSF GMP: B.4.5 defines **twice a year** traceability exercise.
						B.5.5	The effectiveness of the product withdrawal and recall system shall be reviewed, tested and verified at least twice annually.	> 455-2: 4.6.26 defines **once a year** mock recall. > NSF GMP: B.5.5 defines **twice a year** mock recall.
38	Corrective and Preventive Actions and Complaints	4.7.3	Procedures shall be established for a corrective and preventative action (CAPA) program for handling all nonconformances identified within the scope of this Standard.	Improvement	Corrective and Preventive Actions and Complaints	C.1.1	A corrective and preventive action (CAPA) program shall be defined to facilitate resolution of food safety and quality issues.	Comparable requirements.
						C.1.2	Triggers to initiate the CAPA Program shall be defined.	
						C.1.4	CAPAs shall be reviewed by Senior Management a minimum of monthly and shall be included as an agenda item on the management review.	> 455-2: 4.7.3 does not define the frequency of CAPA review. > NSF GMP: C.1.4 defines the frequency as **minimum monthly**.
39	Corrective and Preventive Actions and Complaints	4.6.19	QC operations shall ensure product complaints and deviations/unplanned occurrences are handled properly. [21CFR111.135]	Performance evaluation	Corrective and Preventive Actions and Complaints	C.2.1	Complaint Management Program shall be defined, and include roles and authorities, both internal and external. Complaint investigations shall be conducted by qualified personnel.	Comparable requirements.

NSF/ANSI 455-2 GMP Certification					NSF GMP Registration			Differences
Audit Template Question #	Audit Template Section	Standard #	Question	NSF/ANSI 455-2 Standard Section	Audit Template Section	Requirement #	Question	
40	Corrective and Preventive Actions and Complaints	4.6.20	Procedures shall be established describing how product complaints will be received, investigated, and documented and that the product complaint information includes adequate information. [21CFR111.553 & 21CFR111.570(b2ii)]	Performance evaluation	Corrective and Preventive Actions and Complaints	C.2.1	Complaint Management Program shall be defined, and include roles and authorities, both internal and external. Complaint investigations shall be conducted by qualified personnel.	Comparable requirements.
						C.2.2	Records of customer complaints and any associated investigations shall be maintained.	
						C.2.3	Procedures for adverse event reporting shall be established and implemented. The adverse event either discovered by or reported to the operation shall be reported to the USFDA or applicable regulatory agency, in accordance with the dietary supplement and non-prescription drug consumer protection act. Appropriate regulatory documents shall be provided to the regulatory agency	Comparable requirements.
41	Corrective and Preventive Actions and Complaints	4.6.21	All product complaints shall be reviewed by a qualified person to determine if the complaint was the result of a failure of the dietary supplement to meet any of its specifications or quality. [21CFR111.560(a)]	Performance evaluation	Corrective and Preventive Actions and Complaints	C.2.1	Complaint Management Program shall be defined, and include roles and authorities, both internal and external. Complaint investigations shall be conducted by qualified personnel.	Comparable requirements.
						C.2.2	Records of customer complaints and any associated investigations shall be maintained.	
42	Corrective and Preventive Actions and Complaints	4.6.22	The decision to investigate a complaint as well as the final decision as a result of the investigation, including corrective action, shall be approved by the QC unit. [21CFR111.560(b)]	Performance evaluation	Corrective and Preventive Actions and Complaints	C.2.1	Complaint Management Program shall be defined, and include roles and authorities, both internal and external. Complaint investigations shall be conducted by qualified personnel.	Comparable requirements.
						C.2.2	Records of customer complaints and any associated investigations shall be maintained.	

NSF/ANSI 455-2 GMP Certification					NSF GMP Registration			Differences
Audit Template Question #	Audit Template Section	Standard #	Question	NSF/ANSI 455-2 Standard Section	Audit Template Section	Requirement #	Question	
43	Corrective and Preventive Actions and Complaints	4.6.23	The investigation for a product complaint shall be appropriately extended to other batches, products, processes, etc. [21CFR111.560(c)]	Performance evaluation	Corrective and Preventive Actions and Complaints	C.1.3	A documented procedure shall exist for CAPA investigation requirements. Quality is responsible for managing and approving all CAPAs.	Comparable requirements.
						C.2.1	Complaint Management Program shall be defined, and include roles and authorities, both internal and external. Complaint investigations shall be conducted by qualified personnel.	
44	Corrective and Preventive Actions and Complaints	4.6.24	Records for each product complaint and investigation shall be maintained. Records shall be maintained for at least one year after the shelf life date, if shelf life dating is being used, or at least two years beyond the date of distribution of the last batch associated with those records. [21CFR111.570(a)]	Performance evaluation	Corrective and Preventive Actions and Complaints	C.2.2	Records of customer complaints and any associated investigations shall be maintained.	Comparable requirements.
45	Corrective and Preventive Actions and Complaints	4.6.28	An internal audit program shall be established and is conducted. QC personnel shall have established roles and responsibilities. [21CFR111.105] *NOTE: There is no specific CFR Reference regarding internal audits as it is embedded within 21 CFR 111.105*	Performance evaluation	Corrective and Preventive Actions and Complaints	C.3.1	Procedures for internal audit program including methods and responsibilities for scheduling and conducting internal audits shall be documented and implemented.	> 455-2: 4.6.28 does not define the frequency as of the internal audit. > NSF GMP: C.3.1 defines the frequency **minimum of once per year** covering all areas of quality system. Minimum frequency of once per year is best industry practice.
						C.3.2	Staff conducting internal audits shall be trained on internal audit procedures and shall be independent of the function being audited.	Comparable requirements.

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46	Supplier Qualification	4.5.24	Supplier qualification procedures shall be established and include initial qualification, periodic examination (requalification), and procedures for disqualification. [21CFR111.75(a2iiA), (b), (c), (d), (e)]	Operation	Supplier Qualification	D.1.1	Supplier/Material Qualification Program shall be established and documented. Foreign Supplier Verification Program (FSVP), if applicable, shall be established and documented.	Comparable requirements.
						D.1.2	Sources of any product or component that are brokered, or contract manufactured shall be identified.	
						D.1.3	A supplier assessment (audit) schedule shall be documented and approved and shall be managed by Quality.	
47	Supplier Qualification	4.3.2	A risk-based supplier qualification program is established and implemented for all ingredients. The program includes a supplier/ ingredient risk evaluation, appropriate qualification activities as determined by the risk evaluation, and assurance that only approved suppliers are used. [21CFR117.405 & 21CFR117.410]	Planning	Supplier Qualification	D.1.1	Supplier/Material Qualification Program shall be established and documented. Foreign Supplier Verification Program (FSVP), if applicable, shall be established and documented.	Comparable requirements.
						D.2.1	Purchasing controls shall be documented and implemented. It shall include provisions to only purchase or obtain services from an approved supplier.	
						D.2.2	A defined vetting process for chemicals, equipment, materials, suppliers, and services obtained shall be established. Quality shall be included in this process.	
48	Supplier Qualification	4.5.28	A planned deviation process shall be established to expedite the approval of raw materials, packaging materials, and other component suppliers as necessary on an emergency basis.	Operation	Supplier Qualification	D.2.3	A documented exception procedure for the receipt of raw materials received from non-approved suppliers shall exist as part of the purchasing controls.	Comparable requirements.

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49	Supplier Qualification	4.5.25	Direct importers of components, bulk dosage forms, or finished dietary supplements shall be established and implemented a foreign supplier verification program (FSVP). [21CFR1.511]	Operation	Supplier Qualification	D.1.1	Supplier/Material Qualification Program shall be established and documented. Foreign Supplier Verification Program (FSVP), if applicable, shall be established and documented.	Comparable requirements.
50	Supplier Qualification	4.5.26	Receiving, sampling, testing, release procedures shall be established to fulfill Subpart G – Production and Process Control System: Requirements for Components, Packaging, and Label. [21CFR111.153]	Operation	Supplier Qualification	D.3.1	Inspection and receipt of goods, including components, raw materials, finished product labels and packaging shall be documented and implemented, and shall include provisions to confirm that only approved suppliers were used.	Comparable requirements.
						D.3.3	A carrier inspection program for receiving and shipping shall be documented and implemented.	
					Production and Process Controls	G.5.1	A procedure shall be established for approval to use of raw materials, ingredients, packaging and finished product.	
51	Supplier Qualification	4.6.8	Dietary ingredients shall be sampled, tested, and released prior to use in production. Conduct at least one appropriate test or examination to verify the identity of the dietary ingredient (unless the company has submitted a petition for an ID test exemption that has approved by the FDA). [21CFR111.75(a1)]	Performance evaluation	Supplier Qualification	D.3.4	Each shipment of dietary ingredients shall be sampled, tested, and released prior to use in production.	Comparable requirements.
					Production and Process Controls	G.4.3	Botanical and non-botanical components shall have an identity specification.	

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52	Supplier Qualification	4.6.9	Other raw materials or components (i.e., those that are not dietary ingredients) shall be sampled, tested (or confirmed), and released prior to use in production. Conduct appropriate tests or examinations (or rely on Certificate of Analysis (COA) from the qualified supplier). [21CFR111.75(a2i)]	Performance evaluation	Supplier Qualification	D.3.5	Other raw materials or components that are not dietary ingredients (e.g. preservatives, flavors, processing aids, etc.) shall be sampled, tested or examined using appropriate methods, or confirmed through qualified CoA prior to release for use in production.	Comparable requirements.
					Production and Process Controls	G.4.4	All blends shall be identified for both incoming and finished products.	
						G.4.5	Certificate of Analysis (COA) / Certificate of Compliance (COC) shall be available for all non-botanicals, botanicals, dietary ingredients, excipients, raw materials, primary packaging materials and supplements.	
53	Supplier Qualification	4.5.34	Packaging and labeling materials shall be visually examined, at a minimum, and shall be reviewed against the supplier's invoice, guarantee, or certification to determine conformance with specifications. [21CFR111.75(f) & 21CFR111.155]	Operation	Supplier Qualification	D.3.6	Packaging and labeling materials shall be visually examined and reviewed against the supplier's invoice to determine conformance with specifications.	Comparable requirements.
54	Supplier Qualification	4.5.36	For products that are received for packaging and labeling, visual examinations shall be performed, and documentation is available to determine whether the product meets established specifications. [21CFR111.75(e)]	Operation	Supplier Qualification	D.3.6	Packaging and labeling materials shall be visually examined and reviewed against the supplier's invoice to determine conformance with specifications.	Comparable requirements.

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55	Supplier Qualification	4.5.27	QC operations shall review and approve components, labels and packaging materials for intended use. [21CFR111.120]	Operation	Quality Management	B.2.3	Quality personnel shall have established roles and responsibilities.	Comparable requirements.
					Supplier Qualification	D.3.5	Other raw materials or components that are not dietary ingredients (e.g. preservatives, flavors, processing aids, etc.) shall be sampled, tested or examined using appropriate methods, or confirmed through qualified CoA prior to release for use in production.	
					Production and Process Controls	G.3.1	Labels shall be accurate and comply with applicable regulations.	
						G.3.2	There shall be a process for label control in operations.	
56	Supplier Qualification	4.5.33	QC requirements shall be established for packaging materials and labels. [21CFR111.160]	Operation	Supplier Qualification	D.3.6	Packaging and labeling materials shall be visually examined and reviewed against the supplier's invoice to determine conformance with specifications.	Comparable requirements.
57	Supplier Qualification	4.5.35	QC requirements shall be established for products that are received for packaging and labeling as a dietary supplement and bulk finished product. [21CFR111.165]	Operation	Quality Management	B.2.3	Quality Personnel shall have established roles and responsibilities.	Comparable requirements.
58	Supplier Qualification	4.4.40	Receiving records shall be made and kept for components, packaging, and labels, and for products received for packaging and labeling. [21CFR111.180]	Support	Supplier Qualification	D.3.1	Inspection and receipt of goods, including components, raw materials, finished product labels and packaging shall be documented and implemented, and shall include provisions to confirm that only approved suppliers were used.	Comparable requirements.

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59	Product Safety	4.3.1	A hazard analysis shall be conducted to identify and evaluate known or reasonably foreseeable hazards for each type of dietary supplement to determine whether there are hazards requiring specifications and process controls. [21CFR111.70 & 21CFR117.130]	Planning	Food Safety * **please see the table in page 72 for the requirements for Dietary Ingredients.*	E.2.1	Hazards shall be considered and identified for each type of product manufactured, processed, packed, or held at the facility (e.g. product category, product groups, or product lines, etc.). A combined hazard analysis is acceptable for different packaging sizes of the same product.	Comparable requirements.
						E.2.2	Hazard analysis shall be conducted for each identified hazard.	
						E.2.3	Hazard analysis shall be conducted for each identified hazard.	
						E.2.4	Hazard evaluation shall consider the effect of the product's lifecycle on the safety of the finished product for the intended consumer.	
						E.2.5	There shall be a current and verified process flow diagram.	> 455-2 does not require flow diagram. > Flow diagram is best industry practice.
						E.2.6	Hazard analysis shall be reviewed at a minimum once per year.	> 455-2: 4.3.1 does not define the frequency of hazard analysis. > NSF GMP: E.2.6 defines the frequency as **minimum once per year.** Review of hazard analysis at least once every three years or when changes occur is requirement of 21CFR117 and best industry practice.
_	This has been proposed as a new addition in the next standard revision.				Food Safety	E.3.1	The facility shall have a documented and implemented Environmental Monitoring Program.	> 455-2 does not currently define environmental monitoring program.
_	This has been proposed as a new addition in the next standard revision.				Food Safety	E.3.2	Environmental monitoring program shall include the minimum requirements to ensure indicator bacteria or mold are not present in production or processing areas and equipment.	> 455-2 does not currently define environmental monitoring program.

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–	This has been proposed as a new addition in the next standard revision.				Food Safety	E.3.3	Testing requirements for the presence of environmental pathogen or appropriate indicator organism shall be defined.	> 455-2 does not currently define environmental monitoring program.
60	Product Safety	4.5.46	A food allergen control program shall be in place. [21CFR117.80]	Operation	Food Safety	E.4.1	The facility shall have a documented and implemented allergen control.	Comparable requirements.
						E.4.2	Production records and documents, batch sheets formulas, etc. shall clearly identify the presence of allergens.	
						E.4.3	Allergenic ingredients and allergen containing bulk and finished products shall be identified.	
						E.4.4	Allergen containing ingredients, Work-In-Progress (WIP), rework and finished product shall be controlled.	
						E.4.5	Allergen management control program shall include documented cleaning procedures.	
61	Product Safety	4.5.13	The production facility shall be maintained in a clean and sanitary condition and in a proper state of repair. [21CFR111.15(b1), (b2)]	Operation	Food Safety	E.5.1	Sanitation controls shall be defined and documented to mitigate product risk.	Comparable requirements.
62	Product Safety	4.5.14	Procedures shall be established for cleaning of the plant. [21CFR111.16]	Operation	Food Safety	E.5.1	Sanitation controls shall be defined and documented to mitigate product risk.	Comparable requirements.
						E.5.7	Sanitation procedures shall be validated and verified.	> 455-2 does not define sanitation validation. Sanitation validation is best industry practice.

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63	Product Safety	4.5.17	Cleaning and sanitizing compounds shall be established for cleaning the facility. These agents shall be safe and adequate under the conditions of use; and shall be free of organisms that are of public health significance. [21CFR111.15(c1), 21CFR111.27(d6), & 21CFR117.35(b1)]	Operation	Food Safety	E.5.2	Standard Sanitation Operating Procedures (SSOPs) shall be established and have procedures that include methods, frequencies and chemicals to be used when cleaning areas; and include how the cleaning shall be documented and maintained.	Comparable requirements.
64	Product Safety	4.5.18	Cleaning and sanitizing agents, lubricants, pesticides, chemicals, and fungicides shall be identified, used, and held and stored in a manner that protects against adulteration of raw materials and in-process or finished products, and against contamination of processing equipment, utensils, and packaging materials. [21CFR111.15(c3)]	Operation	Food Safety	E.5.2	Standard Sanitation Operating Procedures (SSOPs) shall be established and have procedures that include methods, frequencies and chemicals to be used when cleaning areas; and include how the cleaning shall be documented and maintained.	Comparable requirements.
						E.7.1	Food and non-food chemicals shall be approved for use, securely stored, clearly identified and used by trained personnel.	

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65	Product Safety	4.5.16	Procedures for maintenance, cleaning, and sanitization of all equipment, utensils, and contact surfaces are established and records of sanitation shall be maintained. [21CFR111.35(a), (b1iii) & 21CFR111.25(c)]	Operation	Food Safety	E.5.1	Sanitation controls shall be defined and documented to mitigate product risk.	Comparable requirements.
						E.5.2	Standard Sanitation Operating Procedures (SSOPs) shall be established and have procedures that include methods, frequencies and chemicals to be used when cleaning areas; and include how the cleaning shall be documented and maintained.	
						E.5.3	Documents, records, and check sheets for cleaning and sanitation shall be maintained.	
						E.5.4	A master sanitation schedule (MSS) shall be developed and utilized for the monitoring and recording of cleaning and sanitation activities.	
						E.5.7	Sanitation procedures shall be validated and verified.	> 455-2 does not define sanitation validation. Sanitation validation is best industry practice.

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66	Product Safety	4.5.21	Procedures shall be established for cleaning and sanitizing all filling and packaging equipment and utensils. [21CFR111.415(a)]	Operation	Food Safety	E.5.2	Standard Sanitation Operating Procedures (SSOPs) shall be established and have procedures that include methods, frequencies and chemicals to be used when cleaning areas; and include how the cleaning shall be documented and maintained.	Comparable requirements.
						E.5.4	A master sanitation schedule (MSS) shall be developed and utilized for the monitoring and recording of cleaning and sanitation activities.	
						E.5.5	Pre-operational Inspection (prior to the start of each stage of the process, i.e. weighing, mixing, packaging) shall be documented and maintained.	
						E.5.6	Manufacturing operations shall be conducted using adequate sanitation principles.	
						E.5.7	Sanitation procedures shall be validated and verified.	> 455-2 does not define sanitation validation. Sanitation validation is best industry practice.
67	Product Safety	4.5.15	All equipment, instruments, utensils, contact surfaces, etc., shall be maintained, cleaned and sanitized (to include disassembly as required by procedure) as necessary. [21CFR111.27(d)]	Operation	Food Safety	E.5.4	A master sanitation schedule (MSS) shall be developed and utilized for the monitoring and recording of cleaning and sanitation activities.	Comparable requirements.

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68	Product Safety	4.5.23	Portable equipment and utensils shall be properly stored after cleaning and sanitization. [21CFR111.27(d7)]	Operation	Food Safety	E.5.4	A master sanitation schedule (MSS) shall be developed and utilized for the monitoring and recording of cleaning and sanitation activities.	Comparable requirements.
						E.5.5	Pre-operational Inspection (prior to the start of each stage of the process, i.e. weighing, mixing, packaging) shall be documented and maintained.	
					Facilities	F.2.4	Equipment and utensils shall protect components and dietary supplements from contamination by any source.	
69	Product Safety	4.5.22	Surfaces that do not come into direct contact with components or dietary supplements shall be cleaned. [21CFR111.27(d4)]	Operation	Food Safety	E.4.1	The facility shall have a documented and implemented allergen control.	Comparable requirements.
						E.5.2	Standard Sanitation Operating Procedures (SSOPs) shall have procedures that include methods, frequencies and chemicals to be used when cleaning areas; and include how the cleaning shall be documented and maintained.	
						E.5.4	A master sanitation schedule (MSS) shall be developed and utilized for the monitoring and recording of cleaning and sanitation activities.	
70	Product Safety	4.5.44	Manufacturing operations shall be conducted using adequate sanitation principles. [21CFR111.360]	Operation	Food Safety	E.5.6	Manufacturing operations shall be conducted using adequate sanitation principles.	Comparable requirements.

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71	Product Safety	4.5.45	Throughout the manufacturing process precautions shall be taken to prevent contamination, such as microbial, filth, chemical, foreign material, etc. [21CFR111.365(a), (b), (c), (d), (e), (f), (g)]	Operation	Food Safety	E.5.6	Manufacturing operations shall be conducted using adequate sanitation principles.	Comparable requirements.
						E.6.5	Foreign material detection systems (e.g. x-ray or metal detection systems shall be in place to minimize the potential for foreign material product contamination for final consumable packaged unit.	
						E.6.6	Foreign material detection systems shall have a documented calibration program, with results maintained as a quality record.	
						E.6.7	Foreign material detection systems shall have a documented maintenance program, including validation and sanitation.	
					Production and Process Controls	G.1.4	Process cross-contamination controls shall be implemented to prevent confusion with other	Comparable requirements.

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72	Product Safety	4.5.47	Manufacturing operations shall include controls in manufacturing steps to prevent contamination, including metal detection. [21CFR111.365(h), (i)]	Operation	Food Safety	E.6.1	Exposed product, processing vessels, ingredients in use and work-in-progress (WIP) shall be adequately covered or protected to reduce the risk of contamination.	Comparable requirements.
						E.6.5	Foreign material detection systems (e.g. x-ray or metal detection systems shall be in place to minimize the potential for foreign material product contamination for final consumable packaged unit.	
						E.6.6	Foreign material detection systems shall have a documented calibration program, with results maintained as a quality record.	
						E.6.7	Foreign material detection systems shall have a documented maintenance program, including validation and sanitation.	
73	Product Safety	4.5.38	Weighing operations shall be done in a controlled area so as to not cause contamination.	Operation	Food Safety	E.6.1	Exposed product, processing vessels, ingredients in use and work-in-progress (WIP) shall be adequately covered or protected to reduce the risk of contamination.	Comparable requirements.
74	Product Safety	4.5.19	Low moisture processing: Equipment, utensils, and contact surfaces shall be dry and sanitized. If wet-cleaned, drying and sanitization shall be performed. [21CFR111.27(d2)]	Operation	Food Safety	E.5.6	Manufacturing operations shall be conducted using adequate sanitation principles.	> 455-2 specifies requirements for low moisture processing.
75	Product Safety	4.5.20	Wet processing: Contact surfaces shall be cleaned and sanitized before use and after any interruptions. [21CFR111.27(d3)]	Operation	Food Safety	E.5.6	Manufacturing operations shall be conducted using adequate sanitation principles.	> 455-2 specifies requirements for wet processing.

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76	Product Safety	4.5.3	The use of wood and non-wood pallets is controlled to prevent possible contamination of exposed raw materials and products.	Operation	Food Safety	E.6.8	Controls for use, storage, and disposal of wood pallets or porous materials shall be established.	Comparable requirements.
						E.6.9	Controls for use, storage and disposal of non-wood pallets shall be established.	
77	Facilities	4.4.1	A master site plan or facility diagram/floor plan shall be on file reflecting the current layout of the building.	Support	Facilities	F.1.1	A master site plan or facility diagram/floor plan shall be on file, readily available for review during the inspection, and accurately reflect the current layout of the building.	Comparable requirements.
78	Facilities	4.4.2	All facilities shall be of adequate size, construction, and design for their intended use. [21CFR111.20(a)]	Support	Facilities	F.1.2	All facilities shall be of adequate size, construction, and design for their intended use.	Comparable requirements.
						F.1.10	There shall be a documented process for the design and qualification of facilities and equipment.	
						F.5.6	A maintenance shop shall be in a defined area within the facility.	
79	Facilities	4.5.1	Areas shall be clearly defined with adequate space to allow for effective receiving, inspection, holding and staging, component and finished good quarantine, finished goods, dietary supplements, packaging, and labeling. [21CFR111.20(b), (c1), (c2), (c3)]	Operation	Facilities	F.1.2	All facilities shall be of adequate size, construction, and design for their intended use.	Comparable requirements.
						F.1.3	Exposed product shall be separated and protected from any operations that could cause contamination.	> 455-2: 4.5.1 does not define the space between the floor and the storage of product. Product shall not be stored on the floor. > NSF GMP: F.1.3 defines the space between the product and the floor as **minimum 6 inches.**
						F.1.4	Procedures and processes shall be established to separate different product types including but not limited to foods, cosmetics and pharmaceuticals from dietary supplements across manufacturing, packaging, labeling, holding and storage areas.	Comparable requirements.

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80	Facilities	4.5.2	There shall be adequate precautions against contamination by microorganisms, chemicals, filth, or other extraneous materials. [21CFR111.20(c)]	Operation	Food Safety	E.5.1	Sanitation controls shall be defined and documented to mitigate product risk.	Comparable requirements.
81	Facilities	4.4.6	In areas where open vessels are used, there shall be adequate protection against contamination including the use of protective coverings, physical location, use of skimming equipment. [21CFR111.20(g)]	Support	Facilities	F.1.3	Product shall be separated and protected from any operations that could cause contamination.	Comparable requirements.
82	Facilities	4.5.4	Areas shall be separate for laboratory analysis and supplies. [21CFR111.20(c4), (c5), (c6), (c7)]	Operation	Facilities	F.1.2	All facilities shall be of adequate size, construction, and design for their intended use.	Comparable requirements.
83	Facilities	4.4.15	Appropriate changing rooms shall be available and have adequate storage of personal effects. [21CFR111.10(b7)]	Support	Facilities	F.1.9	Appropriate change rooms shall be available and provide adequate storage of personal effects.	Comparable requirements.
84	Facilities	4.4.3	Working areas shall have adequate access and space, aisles are clear, etc. to allow for persons to perform their duties and protect against contamination or mix-ups. Use of fans and other air-blowing equipment shall be located and operated in a manner that minimizes the potential for contamination with particulates and microorganisms. [21CFR111.20(d1v), 21CFR111.20(d2)]	Support	Facilities	F.1.5	Working areas shall have adequate access and space; aisles shall be clear to allow for personnel to perform their duties and protect against contamination or mix-ups.	> 455-2: 4.4.3 does not define the width of aisles. > NSF GMP: F.1.5 defines the width as **minimum of 5 feet.**
						F.3.12	Airborne contaminants shall be minimized.	Comparable requirements.
85	Facilities	4.4.8	Production area walls, floors, ceilings shall be adequately cleaned and shall be kept in good repair. [21CFR111.20(d1i)]	Support	Facilities	F.1.6	Walls, floors, door, windows and ceilings shall be kept in good repair and shall allow for appropriate cleaning.	Comparable requirements.

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86	Facilities	4.4.13	Toilet and hand washing facilities shall be provided, shall be of adequate number and location, shall be kept clean, and shall not be a potential source of contamination to components, products, contact surfaces, etc. [21CFR111.15(h)]	Support	Facilities	F.1.7	Bathrooms shall be provided and be of adequate number and at appropriate locations. Bathrooms shall be kept clean and shall not a potential source of contamination.	Comparable requirements.
87	Facilities	4.4.14	Hand washing facilities shall be constructed and located in appropriate areas to ensure proper hand washing of personnel. [21CFR111.15(i)]	Support	Facilities	F.1.8	Hand washing facilities shall be constructed and located in appropriate areas to ensure personnel employ proper hand washing.	Comparable requirements.

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88	Facilities	4.5.5	Equipment shall be of appropriate design and construction (corrosion-resistant, made of non-toxic materials, seamless (if seams exist, are easily cleanable and do not provide a place for accumulation of potential contaminants)) so as to not contaminate components, products, or contact surfaces with lubricants, fuel, coolants, metal or glass fragments, filth or any extraneous materials, contaminated water, or other contaminants. Equipment shall be installed and maintained to facilitate cleaning and are inspected at routine intervals for signs of wear, damage, etc. [21CFR111.27(a3i), (a3ii), (a3iii)]	Operation	Facilities	F.1.10	There shall be a documented process for the design and qualification of facilities and equipment.	Comparable requirements.
						F.2.1	Equipment shall be of appropriate design and construction so as to not contaminate components, products, or contact surfaces with lubricants, fuel, coolants, metal or glass fragments, filth or any extraneous materials, contaminated water, or other contaminants.	
						F.2.2	All product production and packaging equipment shall meet food sanitary design requirements. These shall be installed in such a manner as to permit proper operation and access for cleaning and inspection.	
						F.5.2	All equipment, utensils, utilities, parts and tools shall be included in the PM program.	
						F.5.3	Equipment and utensil surfaces shall be corrosion-resistant, made of non-toxic materials. These shall be inspected at routine intervals for signs of wear and damage.	

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89	Facilities	4.5.6	Utensil surfaces shall be corrosion-resistant, made of nontoxic materials, maintained to facilitate cleaning, and are inspected at routine intervals for signs of wear, damage, etc. [21 CFR § 111.27(a3i), (a3ii), (a3iii)]	Operation	Facilities	F.2.3	Utensils shall be designed and constructed to withstand the environment in which they are used and shall not degrade upon exposure to components, process materials and cleaning agents.	Comparable requirements.
						F.5.2	All equipment, utensils, utilities, parts and tools shall be included in the PM program.	
						F.5.3	Equipment and utensil surfaces shall be corrosion-resistant, made of non-toxic materials. These shall be inspected at routine intervals for signs of wear and damage.	
90	Facilities	4.4.12	For any automated, mechanical, or electronic equipment the manufacturer shall have established appropriate controls to ensure that equipment functions in accordance with its intended use, including power backup for critical systems. [21CFR111.30(e)]	Support	Facilities	F.2.5	Automated, mechanical, or electronic equipment shall be functioning properly and be adequately designed.	Comparable requirements.
						F.5.1	Procedures and programs shall be established for maintaining equipment.	
91	Facilities	4.5.8	Automated, mechanical, laboratory or electronic equipment shall be suitable for intended use, functioning properly, and be adequately designed. [21CFR111.30(a), (b), (c), (d),(e)]	Operation	Facilities	F.2.5	Automated, mechanical, or electronic equipment shall be functioning properly and be adequately designed.	Comparable requirements.
92	Facilities	4.5.7	Equipment logbooks shall be maintained for each equipment and include the date of use, and any documentation of cleaning, sanitization, maintenance, etc. (unless the documentation is in the batch record). [21CFR111.35(b2)]	Operation	Facilities	F.5.2	All equipment, utensils, utilities, parts and tools shall be included in the PM program.	Comparable requirements.
						F.5.5	Maintenance, inspection, cleaning and sanitation records shall be maintained for each piece of equipment.	

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93	Facilities	4.5.9	Documentation shall be maintained of the controls used that ensure that equipment functions in accordance with its intended use. [21CFR111.35(b6)]	Operation	Facilities	F.2.5	Automated, mechanical, or electronic equipment shall be functioning properly and be adequately designed.	Comparable requirements.
94	Facilities	4.5.10	Disposable items (single-service) shall be stored in appropriate containers; handled, used, dispensed, and disposed of in a manner that protects against contamination. [21CFR111.27(d5)]	Operation	Facilities	F.2.4	Equipment and utensils shall protect components and dietary supplements from contamination by any source.	Comparable requirements.
95	Facilities	4.4.9	Fixtures, ducts, piping, etc., are kept clean, shall not drip or leak or provide a source of condensation that could contaminate components, products, or product contact surfaces. [21CFR111.20(d1ii)]	Support	Facilities	F.3.7	Plumbing shall be of adequate size and design for intended usage.	Comparable requirements.
96	Facilities	4.4.10	Plumbing shall be of adequate size and design for the intended usage. [21CFR111.15(f)]	Support	Facilities	F.3.7	Plumbing shall be of adequate size and design for intended usage.	Comparable requirements.

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97	Facilities	4.5.29	The water supply and delivery system shall be safe and sanitary. Water that may contact a product contact surface or is, in fact, a component shall meet U.S. federal, state and local requirements for drinking water. [21CFR111.15(e), (f3) & 21CFR 117.37(a)]	Operation	Facilities	F.3.3	Water that comes in contact with a product contact surface or used as a product component shall meet U.S. Federal, State and Local requirements for drinking water.	Comparable requirements.
						F.3.4	The water supply shall be safe, sanitary, and under suitable temperature and pressure control. Water delivery systems shall be constructed, designed and maintained to prevent contamination of the dietary supplement.	
						F.3.5	The facility shall demonstrate that the water supply is potable and that potability is maintained.	> 455-2: 4.5.29 does not define the frequency of water testing. Risk assessment is required to determine adequate frequency and to ensure water quality is maintained. > NSF GMP: F.3.5 defines the frequency as the following: • Water used as a component is **tested weekly**. • Private water source used as a component is **tested weekly**. • Water used for cleaning is **tested monthly**.
						F.3.6	The facility shall demonstrate that ice and steam supplies are potable and that potability is maintained.	> 455-2 does not specify potability of ice and steam.
98	Facilities	4.5.30	Water sources shall not act as a potential source of contamination of the dietary supplement, either due to water purity or due to the configuration and construction of the water delivery system.	Operation	Facilities	F.3.4	The water supply shall be safe, sanitary, and under suitable temperature and pressure control. Water delivery systems shall be constructed, designed and maintained to prevent contamination of the dietary supplement.	Comparable requirements.

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99	Facilities	4.5.32	Records shall be maintained to show that the quality of water, when used as a component of the dietary supplement, meets the requirements of 111.15(e2). [21CFR111.23(c)]	Operation	Facilities	F.3.3	Water that comes in contact with a product contact surface or used as a product component shall meet U.S. Federal, State and Local requirements for drinking water.	Comparable requirements.
						F.3.5	The facility shall demonstrate that the water supply is potable and that potability is maintained.	
100	Facilities	4.4.11	Floor drainage shall be adequate providing immediate and continuous drainage, with no pooling and equipped with proper drain covers, etc. [21CFR111.15(f4)]	Support	Facilities	F.3.9	Floor drainage shall be adequate.	Comparable requirements.
101	Facilities	4.5.31	Backflow and cross-connection prevention shall be in place. [21CFR111.15(f5)]	Operation	Facilities	F.3.10	Backflow and cross-connection prevention devices shall be installed to protect potable water supplies.	> 455-2: 4.5.31 does not define the frequency of backflow checks. > NSF GMP: F.3.10 defines the frequency as **annually**. This is best industry practice.
102	Facilities	4.4.16	Waste treatment and disposal shall be adequate and does not provide a source of potential contamination. [21CFR111.15(a4)]	Support	Facilities	F.3.17	Waste treatment and disposal shall be adequate and shall not provide a source of potential contamination.	Comparable requirements.
103	Facilities	4.4.17	Solid waste and trash shall be disposed of appropriately, not allowed to accumulate, and does not provide a potential source of contamination to components, products, contact surfaces, etc. [21CFR111.15(j)]	Support	Facilities	F.3.17	Waste treatment and disposal shall be adequate and shall not provide a source of potential contamination.	Comparable requirements.
104	Facilities	4.4.18	Hazardous waste shall be properly controlled so as not to provide a potential source of contamination to components, products, contact surfaces, etc. [21CFR111.15(j4)]	Support	Facilities	F.3.18	Procedures shall be in place to address hazardous waste as appropriate.	Comparable requirements.

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105	Facilities	4.4.19	Sewage and waste disposal shall be properly plumbed from the facility and does not provide a potential source of contamination to contact surfaces, products, components, water supplies, etc. [21CFR111.15(g)]	Support	Facilities	F.3.8	Sewage and waste disposal shall be properly plumbed from the facility and shall not provide a potential source of contamination to areas including, but not limited to, contact surfaces, products, components and water supplies.	Comparable requirements.
106	Facilities	4.4.27	Adequate ventilation and airflow shall be provided in all areas of the facility. [21CFR111.20(d1iii)]	Support	Facilities	F.3.11	Adequate heating, ventilation and airflow shall be provided in all areas to maintain proper environmental and sanitary conditions for ingredients, finished product, equipment, and packaging materials.	Comparable requirements.
107	Facilities	4.5.12	Process gases that are used and contact dietary supplements, components, and contact surfaces shall be controlled so as not to cause contamination (e.g., filters). [21CFR111.27(a7)]	Operation	Facilities	F.3.13	Process gases and compressed air that are used and contact dietary supplements, components, and contact surfaces shall be controlled so as not to cause contamination.	Comparable requirements.
108	Facilities	4.4.28	Adequate lighting shall be provided in all production areas, examination areas, where equipment is cleaned, examined, etc.	Support	Facilities	F.3.14	Adequate lighting shall be provided in all production and examination areas, including warehouses.	> 455-2: 4.4.28 does not define light intensity measurements. > NSF GMP: F.3.14 defines light intensities as the following: • GMP manufacturing areas: minimum **50-foot candles**. • Light booths: minimum **100-foot candles**. • Monitor illumination minimum **monthly**. Monitoring illumination in GMP areas is expected to ensure adequate light is available.

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109	Facilities	4.4.29	Lighting that shall be suspended or located above areas where materials or equipment are exposed shall use safety-type bulbs or the facility shall be constructed in a manner that will protect against contamination with glass, etc. [21CFR111.20(f)]	Support	Facilities	F.3.15	Lighting that is suspended or located above areas where materials or equipment are exposed shall be safety-type or the facility shall be constructed in a manner that will protect these areas against contamination with glass.	Comparable requirements.
110	Facilities	4.4.30	Temperature and humidity control equipment shall be of adequate design for its intended function and is functioning properly. [21CFR111.20(d1iv)]	Support	Facilities	F.3.16	Temperature and humidity control equipment is of adequate design for its intended function.	Comparable requirements.
111	Facilities	4.4.20	Procedures and programs shall be established for maintaining equipment including for calibration of all instruments, controls, automated, mechanical, laboratory, and electronic equipment, etc. [21CFR111.25]	Support	Facilities	F.5.4	Procedures shall be defined for equipment taken out for maintenance.	Comparable requirements.
						F.6.1	A calibration program shall be documented and implemented.	
					Laboratory Controls	H.1.7	Laboratory instrumentation and equipment management program shall be implemented.	
112	Facilities	4.4.21	Instruments and controls that are important to product quality and safety shall be accurate and precise, adequately maintained, and adequate in number. [21CFR111.27(a6)]	Support	Facilities	F.6.2	Equipment, instruments and control devices that impact product compliance to quality and regulatory requirements shall be calibrated.	Comparable requirements.
						F.6.3	Requirements for calibration and verification activities shall be defined for all balances and scales.	
113	Facilities	4.4.22	Complete records shall be made and kept of any calibration of instruments and controls that are important to product quality and safety. [21CFR111.35(b3)]	Support	Facilities	F.6.4	Calibration record requirements shall be defined.	Comparable requirements.

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114	Facilities	4.4.23	QC operations reviews and approves all processes and/or procedures for calibrating equipment, instruments, and controls; including the periodic review of calibration records, etc. [21CFR111.117]	Support	Facilities	F.6.5	Quality shall review and approve all processes and procedures for calibrating equipment, instruments, and controls, including the periodical review of calibration records.	Comparable requirements.
115	Facilities	4.4.24	Procedures shall be established to prevent entrance to the facility by pests and animals, including screens and barriers, rodent traps, insect traps or lights, etc. [21CFR111.15(d1),(d2)]	Support	Facilities	F.4.1	Pest control program and practices shall be documented and implemented to minimize the potential entrance of pests and animals.	Comparable requirements.
116	Facilities	4.4.4	Grounds shall be properly maintained through the removal of litter and waste, cutting of grass and weeds adjacent to the plant, maintenance of roads and parking lots, providing adequate drainage, etc. [21CFR111.15(a1),(a2),(a3)]	Support	Facilities	F.3.1	Grounds shall be properly maintained.	Comparable requirements.
						F.3.2	The exterior of the facility shall be constructed and maintained to facilitate the production of product that meets customer and regulatory food safety and quality requirements.	
117	Facilities	4.4.5	Entrances to the facilities shall be properly controlled and maintained to prevent contamination. [21CFR111.15(a5)]	Support	Facilities	F.4.1	Pest control program and practices shall be documented and implemented to minimize the potential entrance of pests and animals.	Comparable requirements.
118	Facilities	4.4.25	Pest control procedures shall be established for the appropriate use of any insecticides, fungicides, fumigants, rodenticides, etc. [21CFR111.15(d3)]	Support	Facilities	F.4.1	Pest control program and practices shall be documented and implemented to minimize the potential entrance of pests and animals.	Comparable requirements.
						F.4.2	The requirements and responsibilities for the facility's Pest Control Operator (PCO) shall be defined and implemented.	> 455-2: 4.4.25 does not define the amount of liability insurance. > NSF GMP: F.4.2 defines liability insurance, **minimum $1,000,000** for US facilities.
						F.4.3	Pest control devices and chemicals shall be properly managed.	Comparable requirements.

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119	Facilities	4.4.7	Production areas shall not provide harborage for pests, pest infestation, filth, etc. (e.g., adequate screening and other measures are used). [21CFR111.20(h)]	Support	Facilities	F.4.1	Pest control program and practices shall be documented and implemented to minimize the potential entrance of pests and animals.	Comparable requirements.
120	Facilities	4.4.26	Records shall be maintained for plant cleaning and pest control in accordance with Subpart P – Records and Recordkeeping. [21CFR111.23(a),(b)]	Support	Facilities	F.4.1	Pest control program and practices shall be documented and implemented to minimize the potential entrance of pests and animals.	Comparable requirements.
						F.4.2	The requirements and responsibilities for the facility's Pest Control Operator (PCO) shall be defined and implemented.	
						F.4.3	Pest control devices and chemicals shall be properly managed.	
121	Production and Process Controls – Manufacturing Operations	4.5.49	Production and process control systems shall be implemented for each production process and/or product. [21CFR111.55]	Operation	Production and Process Controls	G.1.1	Production and process control systems shall be implemented for each production process and product.	Comparable requirements.
122	Production and Process Controls – Manufacturing Operations	4.2.4	QC operations and authority shall be established for master manufacturing record and batch production record. [21CFR111.123(a1),(a2),(a3)]	Leadership	Production and Process Controls	G.6.1	Quality shall review and approve all master manufacturing record (MMR) and batch production record (BPR) and any changes to these.	Comparable requirements.
123	Production and Process Controls – Manufacturing Operations	4.3.3	Manufacturing processes shall be designed to produce a product that consistently meets specifications. [21CFR111.355]	Planning	Production and Process Controls	G.1.2	Manufacturing processes shall be designed to produce a product that consistently meets specifications.	Comparable requirements.

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124	Production and Process Controls – Manufacturing Operations	4.3.4	Production and processes shall be designed to ensure the quality of the product and the QC unit has approved the control systems. [21CFR111.60]	Planning	Production and Process Controls	G.1.3	Process controls shall include procedures, practices, and processes to ensure the control of parameters during operations.	Comparable requirements.
						G.1.5	Production and processes shall be designed to ensure product quality and approved by the Quality.	
125	Production and Process Controls – Manufacturing Operations	4.5.39	Master manufacturing records shall be prepared for each unique formulation and batch size of the dietary supplement. [21CFR111.205(a)]	Operation	Production and Process Controls	G.6.2	MMRs and BPRs shall be prepared for each unique formulation and batch size of the dietary supplement.	Comparable requirements.
126	Production and Process Controls – Manufacturing Operations	4.5.40	The master record shall identify specifications for the control points, steps, or stages in the manufacturing process where control is necessary to ensure the quality of the dietary supplement. [21CFR111.205(b1), (b2)]	Operation	Production and Process Controls	G.4.1	Procedures shall be established for setting specifications for each raw material component, dietary ingredient, dietary supplement, finished product label, and packaging component, except for when a dietary supplement product is received for packaging or labeling and is being returned back to the supplier (e.g. contract packers who do not perform quality release and return product back to supplier).	Comparable requirements.
						G.6.2	MMRs and BPRs shall be prepared for each unique formulation and batch size of the dietary supplement.	
127	Production and Process Controls – Manufacturing Operations	4.5.41	Master manufacturing records shall contain all the required elements as defined in 21 CFR111.210. [21CFR111.210]	Operation	Production and Process Controls	G.6.3	Contents of the MMR shall be defined and implemented.	Comparable requirements.

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128	Production and Process Controls – Manufacturing Operations	4.5.42	For each manufactured batch of dietary supplement, the batch production record shall accurately follow the master manufacturing record with all steps being performed, and it shall contain complete information related to the production and control of the batch. Batch production records shall be maintained for at least one year after the shelf life date, if shelf life dating is being used, or at least two years beyond the date of distribution of the last batch associated with those records. [21CFR111.255]	Operation	Production and Process Controls	G.6.4	The batch production record (BPR) shall follow the master manufacturing record (MMR).	Comparable requirements.
129	Production and Process Controls – Manufacturing Operations	4.5.43	The batch record shall follow the master record and each step shall be performed appropriately. [21CFR111.260]	Operation	Production and Process Controls	G.6.4	The batch production record (BPR) shall follow the master manufacturing record (MMR).	Comparable requirements.
130	Production and Process Controls – Manufacturing Operations	4.5.48	Manufacturing operations shall include the identification of all process lines and major equipment used during manufacturing to indicate their contents, including the name of the dietary supplement and the specific batch or lot number, and when necessary, the phase of manufacturing. [21CFR111.365(j), (k)]	Operation	Quality Management	B.4.1	There shall be a product identification system to ensure raw materials, packaging, work in progress and finished product are clearly identified during all stages of receipt, production, storage and dispatch and that finished product is labeled to the customer specification and/or regulatory requirements.	Comparable requirements.
						B.4.2	Processes shall be implemented to ensure individual finished product lots or batches are uniquely identified.	

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131	Production and Process Controls – Manufacturing Operations	4.5.50	Records shall be established and shall be maintained to meet the requirements of Subpart K – Production and Process Control System: Requirements for Manufacturing Operations. [21CFR111.375]	Operation	Production and Process Controls	G.1.6	Product identification controls shall be defined and implemented.	Comparable requirements.
						G.2.4	Records of all rework operations including material reviews shall be maintained.	
						G.4.4	All blends shall be identified for both incoming and finished products.	
						G.4.7	Records of compliance to manufacturing and product specifications shall be available.	
						G.5.1	A procedure shall be established and implemented for the approval to use raw materials, ingredients and packaging.	
						G.6.1	Quality shall review and approve all master manufacturing record (MMR) and batch production record (BPR) and any changes to these.	
132	Production and Process Controls – Packaging Operations	4.5.51	A master manufacturing record shall include instructions for filling, assembling, packaging, labeling, and other related operations. [21CFR111.415]	Operation	Production and Process Controls	G.6.4	The batch production record (BPR) shall follow the master manufacturing record (MMR).	Comparable requirements.
133	Production and Process Controls – Packaging Operations	4.6.3	Packaging and labeling materials shall be examined before usage to determine that they conform to the master manufacturing record. [21CFR111.410(c)]	Performance evaluation	Production and Process Controls	G.6.3	Contents of the MMR shall be defined and implemented.	Comparable requirements.
134	Production and Process Controls – Packaging Operations	4.5.52	Procedures shall be established for all packaging and labeling operations. [21CFR111.403]	Operation	Production and Process Controls	G.1.8	Procedures shall be established and implemented for all packaging and labeling operations.	Comparable requirements.

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135	Production and Process Controls – Packaging Operations	4.5.53	QC operations shall be established for packaging and labeling. [21CFR111.127]	Operation	Production and Process Controls	G.1.1	Production and process control systems shall be implemented for each production process and product.	Comparable requirements.
136	Production and Process Controls – Packaging Operations	4.5.59	Filling and packaging operations shall be appropriately protected from contamination sources (e.g., airborne) by using sanitary procedures. [21CFR111.415(b), (c)]	Operation	Production and Process Controls	G.1.8	Procedures shall be established and implemented for all packaging and labeling operations.	Comparable requirements.
137	Production and Process Controls – Packaging Operations	4.5.54	Packaging and labeling of the finished packaged and labeled dietary supplement shall be visually examined, at a minimum, to determine that the correct packaging and labeling has been used. [21CFR111.75(g)]	Operation	Supplier Qualification	D.3.6	Packaging and labeling materials shall be visually examined and reviewed against the supplier's invoice to determine conformance with specifications.	Comparable requirements.
138	Production and Process Controls – Packaging Operations	4.5.55	The condition of the packaging shall meet the specifications required to ensure the quality of the dietary supplements being packaged. [21CFR111.410(a)]	Operation	Production and Process Controls	G.1.9	The packaging integrity and function shall adequately protect the product.	Comparable requirements.
139	Production and Process Controls – Packaging Operations	4.5.56	Packaging and labels shall be controlled for issuance and are reconciled after use. [21CFR111.410(b)] *NOTE: Reconciliation is not necessary for cut or rolled labels when 100% examination is performed by appropriate electronic or electromechanical equipment during or after completion of operations.*	Operation	Production and Process Controls	G.1.8	Procedures shall be established and implemented for all packaging and labeling operations.	Comparable requirements.
						G.3.2	There shall be a process for label control in operations.	
						G.3.4	Issuance of labels shall be controlled. Inventory shall be reconciled after use.	
140	Production and Process Controls – Packaging Operations	4.5.58	Separation shall be implemented to prevent mix-ups with other components and dietary supplements. [21CFR111.415(d)]	Operation	Production and Process Controls	G.1.4	Process cross-contamination controls shall be implemented to prevent confusion with other components and dietary supplements.	Comparable requirements.

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141	Production and Process Controls – Packaging Operations	4.5.60	Procedures shall be established to identify unlabeled materials that will be held for future labeling operations to prevent mix-ups. [21CFR111.415(e)]	Operation	Production and Process Controls	G.1.6	Product identification controls shall be defined and implemented.	Comparable requirements.
142	Production and Process Controls – Packaging Operations	4.5.61	Procedures shall be established for assigning a lot or batch number for each lot of packaged and labeled dietary supplement. [21CFR111.415(f)]	Operation	Production and Process Controls	G.3.3	Clearly visible production or lot codes shall be present on individual and cased product labels.	Comparable requirements.
143	Production and Process Controls – Packaging Operations	4.5.62	Disposal procedures shall be established for disposing of labels or packaging materials that are obsolete or incorrect to ensure that they are not used. [21CFR111.415(h)]	Operation	Production and Process Controls	G.3.2	There shall be a process for label control in operations.	Comparable requirements.
144	Production and Process Controls – Packaging Operations	4.5.66	All repackaging or relabeling operations shall be first approved by the QC unit. [21CFR111.420(a)]	Operation	Production and Process Controls	G.2.3	Quality personnel shall authorize a treatment, in-process treatment, or reprocessing in an attempt to correct a deviation or unexpected event, or specification deficiency.	Comparable requirements.
145	Production and Process Controls – Packaging Operations	4.6.13	Representative samples of each batch of repackaged or relabeled dietary supplement shall be examined to determine if they conform to specifications. [21CFR111.420(b)]	Performance evaluation	Production and Process Controls	G.1.7	Procedures shall be established and implemented for the collection of representative samples to verify compliance with specifications.	Comparable requirements.
146	Production and Process Controls – Packaging Operations	4.5.67	QC unit shall disposition each batch of repackaged or relabeled dietary supplement prior to release for distribution. [21CFR111.420(c)]	Operation	Production and Process Controls	G.1.7	Procedures shall be established and implemented for the collection of representative samples to verify compliance with specifications.	Comparable requirements.
147	Production and Process Controls – Packaging Operations	4.5.63	Records shall be established and are being maintained to meet the requirements of Subpart L – Product and Process Control System: Requirements for Packaging and Labeling Operations. [21CFR111.430]	Operation	Production and Process Controls	B.6.7	Records retention policy shall be defined, documented and implemented.	Comparable requirements.

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148	Production and Process Controls – Specifications, Product Release and Returns	4.6.7	A system shall be established to determine if all specifications that are established have been met. [21CFR111.73]	Performance evaluation	Supplier Qualification	D.3.2	A system shall be established to determine if all specifications that are established have been met.	Comparable requirements.
149	Production and Process Controls – Specifications, Product Release and Returns	4.3.5	Specifications shall be established for components, in-process materials, labels, packaging components, and finished product. The basis is adequately documented for how meeting the in-process specifications, in combination with meeting component specifications, will help ensure that the dietary supplement specifications will be met. [21CFR111.70]	Planning	Production and Process Controls	G.4.2	Specifications shall be established for components including but not limited to botanical/non-botanical dietary ingredients and excipients; raw materials, packaging materials, labeling, in-process and finished product.	Comparable requirements.
						G.4.6	Procedure shall be established for translating customer specifications into sample/product acceptance criteria.	
150	Production and Process Controls – Specifications, Product Release and Returns	4.4.39	Records shall be maintained of specifications, supplier qualification, and testing to ensure product meets purity, strength and composition. [21CFR111.95]	Support	Supplier Qualification	D.1.3	A supplier assessment (audit) schedule shall be documented and approved and shall be managed by Quality.	> 455-2: 4.4.39 does not define the frequency of requalification of approved suppliers. > NSF GMP: D.1.3 defines the frequency of **requalification of approved suppliers** (resubmission of the questionnaire and being audited based on the risk) **as not to exceed 3 years.** It is best industry practice to define the frequency by risk based approach.
					Production and Process Controls	G.4.7	Records of compliance to manufacturing and product specifications shall be available.	Comparable requirements.
151	Production and Process Controls – Specifications, Product Release and Returns	4.6.1	Procedures shall be established for the collection of representative samples. [21CFR111.80]	Performance evaluation	Production and Process Controls	G.1.7	Procedures shall be established and implemented for the collection of representative samples to verify compliance with specifications.	Comparable requirements.

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152	Production and Process Controls – Specifications, Product Release and Returns	4.6.4	Procedures shall be established to sample a representative number of units to assure compliance with specifications. [21CFR111.415(g)]	Performance evaluation	Production and Process Controls	G.1.7	Procedures shall be established and implemented for the collection of representative samples to verify compliance with specifications.	Comparable requirements.
153	Production and Process Controls – Specifications, Product Release and Returns	4.6.2	Samples shall be collected in a controlled area so as to not cause contamination.	Performance evaluation	Production and Process Controls	G.1.7	Procedures shall be established and implemented for the collection of representative samples to verify compliance with specifications.	Comparable requirements.
154	Production and Process Controls – Specifications, Product Release and Returns	4.6.5	Procedures shall be established for the collection of reserve samples for each lot of finished material. [21CFR111.83]	Performance evaluation	Production and Process Controls	G.5.6	Procedures shall be established and implemented for the collection of reserve or retain samples for each lot of finished product.	Comparable requirements.
155	Production and Process Controls – Specifications, Product Release and Returns	4.6.6	Reserve samples shall be held under appropriate conditions (e.g., temperature, humidity, and light) and shall not lead to a mix-up, contamination, or deterioration. [21CFR111.465]	Performance evaluation	Production and Process Controls	G.5.6	Procedures shall be established and implemented for the collection of reserve or retain samples for each lot of finished product.	Comparable requirements.

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Audit Template Question #	Audit Template Section	Standard #	Question	NSF/ANSI 455-2 Standard Section	Audit Template Section	Requirement #	Question	
156	Production and Process Controls – Specifications, Product Release and Returns	4.6.11	QC operations shall determine if process and product specifications have been met. The product shall not be released if it does not meet the specifications, unless QC approved deviations have been documented. [21 CFR § 111.123(a), (b)]	Performance evaluation	Quality Management	B.5.1	The methods and responsibilities for detection and control of nonconforming product, raw material, ingredient, work-in-progress, packaging or equipment during receipt, storage, processing, handling or delivery shall be documented and implemented. Associated records shall be maintained and made available for review.	Comparable requirements.
					Production and Process Controls	G.2.3	Quality personnel shall authorize a treatment, in-process treatment, or reprocessing in an attempt to correct a deviation or unexpected event, or specification deficiency.	
						G.5.2	A procedure shall be established and implemented for releasing product.	
						G.5.3	Product release criteria shall be defined and implemented.	
157	Production and Process Controls – Specifications, Product Release and Returns	4.6.12	The QC person shall be responsible for making the material review and disposition decision shall document the review and disposition decision at the time of performance. [21CFR111.113(c)]	Performance evaluation	Quality Management	B.2.3	Quality personnel shall have established roles and responsibilities.	Comparable requirements.
					Production and Process Controls	G.2.3	Quality personnel shall authorize a treatment, in-process treatment, or reprocessing in an attempt to correct a deviation or unexpected event, or specification deficiency.	
						G.5.7	Policies and practices for the control of returned products shall be established and implemented.	

NSF/ANSI 455-2 GMP Certification					NSF GMP Registration			Differences
Audit Template Question #	Audit Template Section	Standard #	Question	NSF/ANSI 455-2 Standard Section	Audit Template Section	Requirement #	Question	
158	Production and Process Controls – Specifications, Product Release and Returns	4.6.10	Proper testing procedures or programs shall be established to determine if in-process and finished product specifications for purity, composition, and strength of the dietary supplement have been met. The basis for performing reduced-testing shall be adequately documented and it justifies how the testing procedures or program selected will help ensure that the full-specification for the dietary supplement will be met. [21CFR111.75(b), (c), (d)]	Performance evaluation	Supplier Qualification	D.3.1	Inspection and receipt of goods, including components, raw materials, finished product labels and packaging shall be documented and implemented, and shall include provisions to confirm that only approved suppliers were used.	Comparable requirements.
					Production and Process Controls	G.5.4	Finished product microbiological compliance testing requirements shall be established.	
						G.5.5	Finished product for label claim compliance testing requirements shall be defined.	
					Laboratory Controls	H.1.12	Dietary supplements shall be sampled, tested using a standardized menthod.	
159	Production and Process Controls – Specifications, Product Release and Returns	4.7.1	Procedures and controls shall be established for investigation and handling of materials or processing that do not meet specification requirements. [21CFR111.77]	Improvement	Production and Process Controls	G.4.8	Procedures and controls shall be established for investigation and handling of materials that do not meet specification requirements.	Comparable requirements.
160	Production and Process Controls – Specifications, Product Release and Returns	4.7.2	QC personnel shall conduct a material review and make disposition decisions to approve treatments, in-process adjustments, and reprocessing when there is a deviation or unanticipated occurrence or when a specification is not met. [21CFR111.90]	Improvement	Quality Management	B.2.3	Quality personnel shall have established roles and responsibilities.	Comparable requirements.
					Production and Process Controls	G.2.3	Quality personnel shall authorize a treatment, in-process treatment, or reprocessing in an attempt to correct a deviation or unexpected event, or specification deficiency.	
161	Production and Process Controls – Specifications, Product Release and Returns	4.5.64	QC personnel shall authorize a treatment, in-process treatment, or reprocessing in an attempt to correct a deviation or unexpected event, or specification deficiency. [21CFR111.113(b)]	Operation	Production and Process Controls	G.2.3	Quality personnel shall authorize a treatment, in-process treatment, or reprocessing in an attempt to correct a deviation or unexpected event, or specification deficiency.	Comparable requirements.

NSF/ANSI 455-2 GMP Certification					NSF GMP Registration			Differences
Audit Template Question #	Audit Template Section	Standard #	Question	NSF/ANSI 455-2 Standard Section	Audit Template Section	Requirement #	Question	
162	Production and Process Controls – Specifications, Product Release and Returns	4.5.65	Reprocessing controls shall be established and meet all requirements and have been approved by the QC unit. [21CFR111.90(a), (b)]	Operation	Production and Process Controls	G.2.1	Controls for reprocessing shall be established and implemented. It shall meet all requirements for facility rework and shall be approved by Quality.	Comparable requirements.
163	Production and Process Controls – Specifications, Product Release and Returns	4.5.77	Any reprocessed material shall meet its original specification and the QC unit appropriately dispositions the material (release or reject). [21CFR111.525]	Operation	Production and Process Controls	G.2.1	Controls for reprocessing shall be established and implemented. It shall meet all requirements for facility rework and shall be approved by Quality.	Comparable requirements.
164	Production and Process Controls – Specifications, Product Release and Returns	4.5.79	Documentation shall be maintained for material reviews and dispositions, all testing results, any reevaluations by the QC unit for reprocessed materials. [21CFR111.535(b1), (b2), (b3),(b4)]	Operation	Production and Process Controls	G.2.2	Rework materials and products shall be controlled.	Comparable requirements.
						G.6.5	Documentation shall be maintained for material reviews and dispositions, all testing results, any reevaluations by Quality.	
165	Production and Process Controls – Specifications, Product Release and Returns	4.5.75	Procedures shall be established for the handling of returned dietary supplements that include appropriately quarantining the returned product until dispositioned by the QC unit. Procedures shall be established for salvage and reprocessing operations according to Subpart P – Records and Recordkeeping. [21CFR111.503, 21CFR111.510, & 21CFR111.535(a)]	Operation	Production and Process Controls	G.5.7	Policies and practices for the control of returned products shall be established and implemented.	Comparable requirements.
						G.2.4	Records of all rework operations including material reviews shall be maintained.	

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Audit Template Question #	Audit Template Section	Standard #	Question	NSF/ANSI 455-2 Standard Section	Audit Template Section	Requirement #	Question	
166	Production and Process Controls – Specifications, Product Release and Returns	4.5.76	QC operations shall be established to handle returned dietary supplements. Any returned dietary supplement shall be either destroyed or disposed of unless the QC unit has determined that the material can be salvaged or reprocessed. Any salvaged material shall be approved by the QC unit following a material review and disposition. [21CFR111.130, 21CFR111.515, & 21CFR111.520]	Operation	Production and Process Controls	G.5.7	Policies and practices for the control of returned products shall be established and implemented.	Comparable requirements.
167	Production and Process Controls – Specifications, Product Release and Returns	4.5.78	If the reason for a return implicates other batches, an investigation shall be performed to determine if those batches comply with specifications. [21CFR111.530]	Operation	Production and Process Controls	G.5.7	Policies and practices for the control of returned products shall be established and implemented.	Comparable requirements.
168	Production and Process Controls – Specifications, Product Release and Returns	4.5.80	Records for returned dietary supplements shall be maintained. Records shall be maintained for at least one year after the shelf life date, if shelf life dating is being used, or at least two years beyond the date of distribution of the last batch associated with those records. [21CFR111.535]	Operation	Quality Management	B.6.7	Records retention policy shall be defined, documented and implemented.	Comparable requirements.
					Production and Process Controls	G.5.7	Policies and practices for the control of returned products shall be established and implemented.	
169	Production and Process Controls – Specifications, Product Release and Returns	4.5.57	Records shall be maintained to allow a complete history and control of the packaged and labeled dietary supplement through distribution. [21CFR111.410(d)]	Operation	Quality Management	B.6.7	Records retention policy shall be defined, documented and implemented..	Comparable requirements.
					Production and Process Controls	G.3.2	There shall be a process for label control in operations.	
170	Laboratory Controls	4.6.14	QC laboratory operations and procedures shall be established.[21CFR111.110 & 21CFR111.303]	Performance evaluation	Laboratory Controls	H.1.1	Procedures shall be established and implemented for laboratory operations.	Comparable requirements.

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Audit Template Question #	Audit Template Section	Standard #	Question	NSF/ANSI 455-2 Standard Section	Audit Template Section	Requirement #	Question	
171	Laboratory Controls	4.6.17	Laboratory controls shall be established and have been approved by QC, including criteria for establishing specifications. [21CFR111.315(a)]	Performance evaluation	Laboratory Controls	H.1.1	Procedures shall be established and implemented for laboratory operations.	Comparable requirements.
						H.1.2	The laboratory and laboratory personnel shall not serve as points of potential contamination within the facility.	
172	Laboratory Controls	4.6.18	Parameters shall be set for laboratory controls for sampling plans, criteria for examination and testing methods, and standard reference materials. [21CFR111.315(b), (c),(d),(e)]	Performance evaluation	Laboratory Controls	H.1.3	Sample handling, sample preparation, and sampling plans shall be established and implemented.	Comparable requirements.
						H.1.8	A reagent and standard preparation, management, and storage program shall be implemented.	
173	Laboratory Controls	4.2.3	QC responsibilities for laboratory test methods and examinations used to test each specification requirement shall be defined, shall be appropriate for their intended use and shall be followed. Test methods and examinations shall be used according to established criteria. [21CFR111.320]	Leadership	Quality Management	B.2.3	Quality personnel shall have established roles and responsibilities.	Comparable requirements.
					Laboratory Controls	H.1.4	Quality shall define specific analytical and physical laboratory test methods and examinations used to test specifications.	
						H.1.5	Quality shall define specific analytical and physical laboratory test methods and examinations used to test specifications.	
174	Laboratory Controls	4.6.16	Laboratory facilities used shall be adequate for testing of components, in-process materials, and dietary supplements. [21CFR111.310]	Performance evaluation	Facilities	F.1.2	All facilities shall be of adequate size, construction, and design for their intended use.	Comparable requirements.

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Audit Template Question #	Audit Template Section	Standard #	Question	NSF/ANSI 455-2 Standard Section	Audit Template Section	Requirement #	Question	
175	Laboratory Controls	4.6.15	Scientifically valid methods shall be used and include at least one of the following: [21CFR111.75(h)] > gross organoleptic analysis; > macroscopic analysis; > microscopic analysis; > chemical analysis; or > another scientifically valid method.	Performance evaluation	Production and Process Controls	G.4.1	Procedures shall be established for setting specifications for each raw material component, dietary ingredient, dietary supplement, finished product label, and packaging component, except for when a dietary supplement product is received for packaging or labeling and is being returned back to the supplier (e.g. contract packers who do not perform quality release and return product back to supplier).	Comparable requirements.
					Laboratory Controls	H.1.4	Quality shall define specific analytical and physical laboratory test methods and examinations used to test specifications.	Comparable requirements.
						H.1.6	All test methods shall be validated.	
						H.1.14	The laboratory shall be monitored for accuracy and reproducibility of results.	
176	Laboratory Controls	4.6.27	For all products that bear expiration date or a statement of product shelf life, the shelf life shall be supported. [Preamble to 21CFR111 final rule]	Performance evaluation	Laboratory Controls	H.1.10	A shelf life and stability studies protocol shall be defined.	Comparable requirements.
						H.1.11	Shelf life and stability studies data shall be available (e.g. stability study results, stability summary report, etc.). For contract manufacturers, where stability studies are performed by brand owner, contract manufacturer shall have proof of stability (e.g. stability data or stability summary report) on file.	
177	Laboratory Controls	4.5.37	Written procedures shall be in place for retesting materials to extend shelf life.	Operation	Laboratory Controls	H.1.10	A shelf life and stability studies protocol shall be defined.	Comparable requirements.

NSF/ANSI 455-2 GMP Certification					NSF GMP Registration			Differences
Audit Template Question #	Audit Template Section	Standard #	Question	NSF/ANSI 455-2 Standard Section	Audit Template Section	Requirement #	Question	
178	Warehouse and Distribution	4.5.70	Procedures shall be established for the holding and distribution operations. [21CFR111.475(b1)]	Operation	Warehouse and Distribution	I.1.1	Procedures for warehouse and distribution shall be established and implemented.	Comparable requirements.
						I.1.5	Procedures for inventory control shall be established and implemented.	> 455-2: 4.5.70 does not define the frequency of inventory control system challenge. > NSF GMP: I.1.5 defines the frequency as **minimum of twice per year.** It is best industry practice to define the frequency by risk based approach.
179	Warehouse and Distribution	4.5.68	Dietary supplements, components, in-process materials, labeling, and packaging shall be held under the appropriate conditions of temperature, humidity, and light. Storage conditions shall not lead to a mix-up, contamination, or deterioration. [21CFR111.455 & 21CFR111.460]	Operation	Warehouse and Distribution	I.1.2	Raw materials, ingredients, packaging and finished product shall be secured and protected in storage.	Comparable requirements.
						I.1.3	Appropriate precautions shall be implemented to prevent contamination by microorganisms, chemicals, filth, or other extraneous materials.	
180	Warehouse and Distribution	4.5.11	All equipment including freezers, refrigerators, etc., that are used to hold components or dietary supplements shall be adequately designed and functioning properly. [21 CFR § 111.27(a5)]	Operation	Warehouse and Distribution	I.1.4	Equipment including but not limited to freezers and refrigerators that are used to hold components or dietary supplements shall be functioning properly and adequately designed.	Comparable requirements.
181	Warehouse and Distribution	4.5.69	Distribution of product shall occur under conditions that will protect against contamination and deterioration. [21CFR111.470]	Operation	Warehouse and Distribution	I.1.2	Raw materials, ingredients, packaging and finished product shall be secured and protected in storage.	Comparable requirements.

NSF/ANSI 455-2 GMP Certification					NSF GMP Registration			Differences
Audit Template Question #	Audit Template Section	Standard #	Question	NSF/ANSI 455-2 Standard Section	Audit Template Section	Requirement #	Question	
182	Warehouse and Distribution	4.5.72	Written procedures shall be in place for transportation operations and shall be conducted to prevent dietary supplements from becoming unsafe during transportation operations. [21CFR1.908]	Operation	Supplier Qualification	D.3.3	A carrier inspection program for receiving and shipping shall be documented and implemented.	> 455-2: 4.5.72 defines the following requirements of transportation procedure. • Specification and agreement for transportation of goods must be established between carrier and the client. • Records for sanitary transport shall be maintained for a minimum of 12 months beyond when the procedures or written agreements are terminated or no longer in use (12 months past the shelf life of the product). • Corrective action is required when there are temperature deviations.
183	Warehouse and Distribution	4.5.71	Vehicles and transportation equipment shall be designed and constructed of such material and workmanship to prevent dietary supplements transported therein from becoming unsafe, e.g., adulterated during transportation operations. [21CFR1.906]	Operation	Supplier Qualification	D.3.3	A carrier inspection program for receiving and shipping shall be documented and implemented.	> 455-2: 4.5.71 defines the following requirements for vehicles and transportation equipment. • Design • Construction • Workmanship
184	Warehouse and Distribution	4.5.73	Product distribution records shall be retained. Records shall be maintained for at least one year after the shelf life date, if shelf life dating is being used, or at least two years beyond the date of distribution of the last batch associated with those records. [21CFR111.475(b2)]	Operation	Warehouse and Distribution	I.1.6	Procedures for holding and distribution operations shall be established and implemented.	Comparable requirements.

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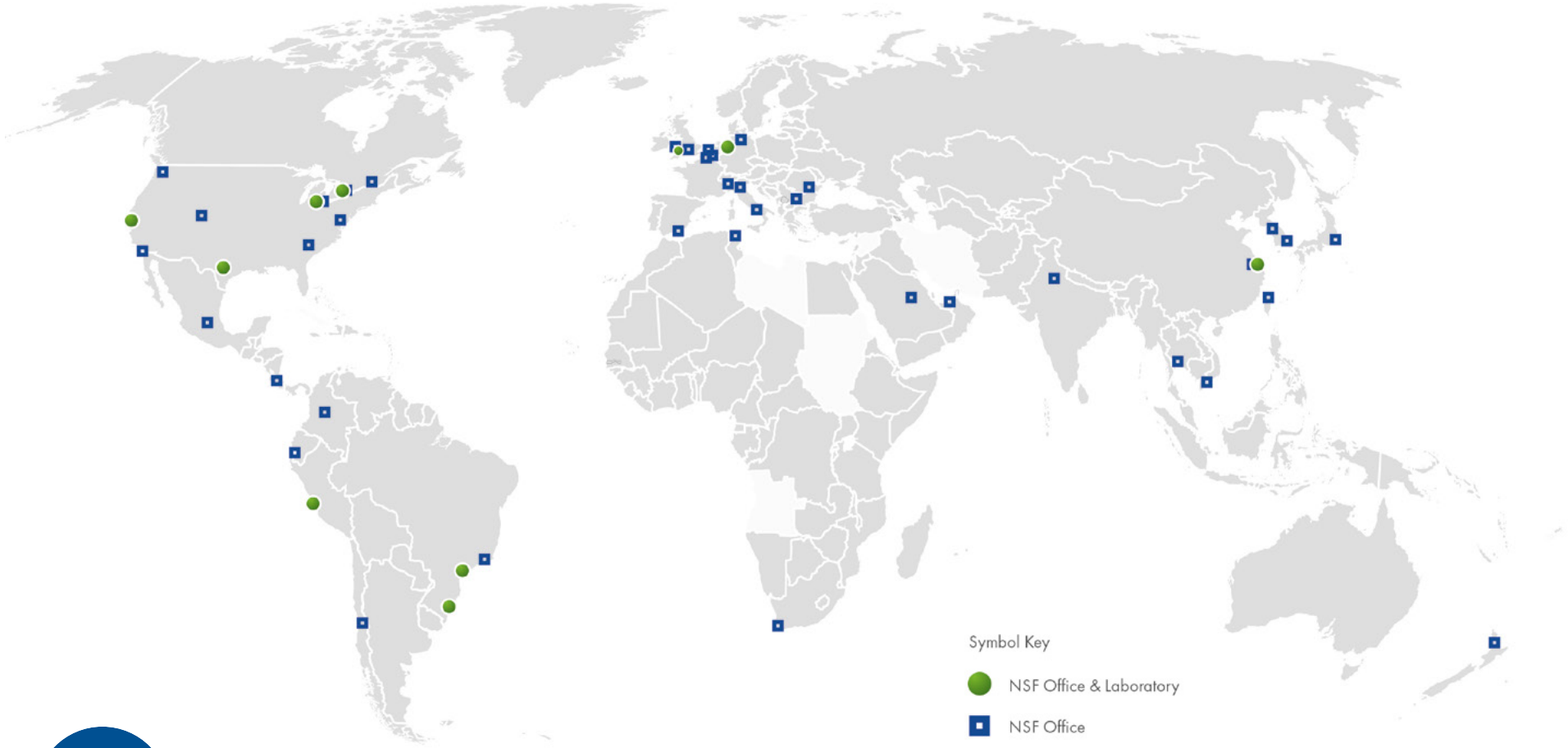
Audit Template Question #	Audit Template Section	Standard #	Question	NSF/ANSI 455-2 Standard Section	Audit Template Section	Requirement #	Question	
185	Warehouse and Distribution	4.5.74	An appropriate quarantine system shall be established and shall be demonstrated to meet the necessary requirements per procedures. Rejected dietary supplements, components, packaging, labeling, and products shall be removed from manufacturing operations and placed in quarantine until disposition is determined. Records shall be kept for the quarantine system. [21CFR111.170, 21CFR111.370, & 21CFR111.425]	Operation	Quality Management	B.5.2	Storage areas for nonconforming product, materials and equipment shall be clearly identified and separated to prevent inadvertent use of the nonconforming product or equipment.	Comparable requirements.
					Warehouse and Distribution	I.1.1	Procedures for laboratory operations shall be established and implemented.	

Comparison of Food Safety requirements in NSF Dietary Ingredient GMP Registration Requirements Document

455-2 standard is applicable to Dietary ingredients.

In addition to the previous table, the following table is applicable to dietary ingredients. The food safety plan will be assessed to ensure compliance under the hazard analysis requirement **4.3.1**.

NSF/ANSI 455-2					NSF GMP DI Registration			Differences
Audit Template Question #	Audit Template Section	Standard #	Question	NSF/ANSI 455-2 Standard Section	Audit Template Section	Requirement #	Question	
20	Quality Management	4.4.32	Personnel shall be qualified and have adequate training, experience and/or education necessary to perform job functions. [21CFR111.12(c) & 21CFR 117.4]	Support	Food Safety	E.1.1	A multidisciplinary team that includes personnel responsible for quality, production, technical, and other relevant functions in the company shall be established.	Comparable requirements.
59	Product Safety	4.3.1	A hazard analysis shall be conducted to identify and evaluate known or reasonably foreseeable hazards for each type of dietary supplement to determine whether there are hazards requiring specifications and process controls. [21CFR111.70 & 21CFR117.130]	Planning	Food Safety	E.2.1	A food safety plan specific to the manufacturing site shall be established and implemented.	Comparable requirements.
						E.2.2	There shall be a current and verified process flow diagram covering the scope of the food safety plan.	
						E.2.3	Hazards that are known or can be reasonably expected to occur shall be considered and identified for each type of product manufactured, processed, packed, or held at the facility at each step of the operation, and for other inputs.	
						E.2.4	Hazard analysis shall be conducted for each identified hazard. A combined hazard analysis is acceptable for different packaging sizes of the same product.	
						E.2.5	Preventive controls to prevent or significantly minimize hazards shall be identified, established and implemented.	



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