



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

TRANSITION GUIDE



Documents

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

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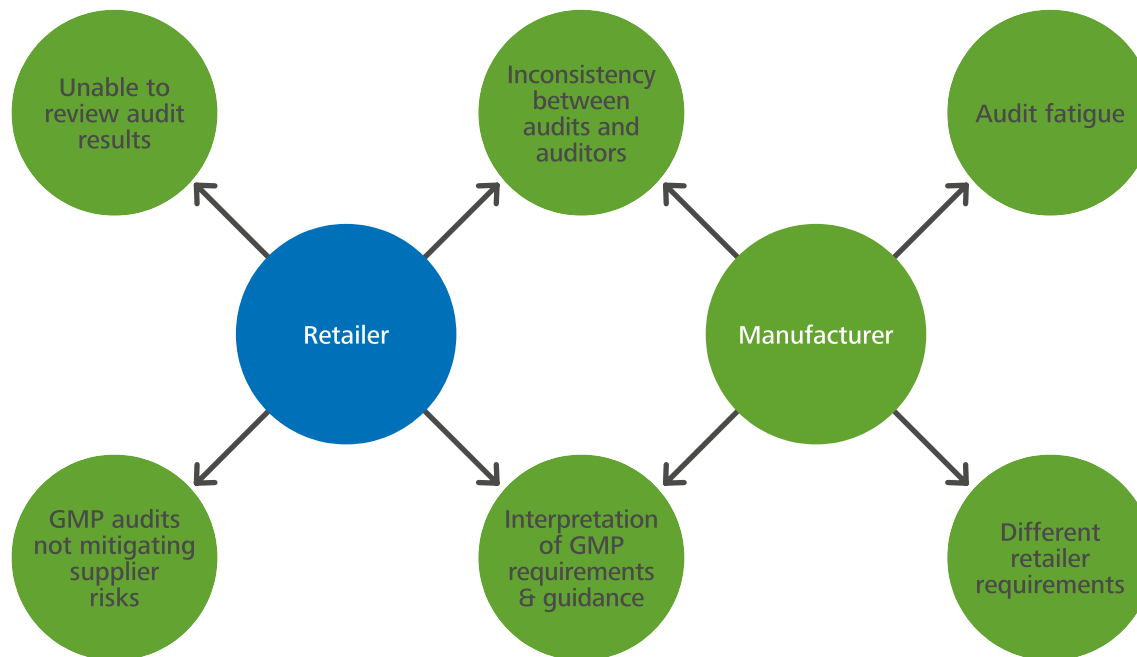
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1. Overview of NSF/ANSI 455-2 GMP Certification

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.*

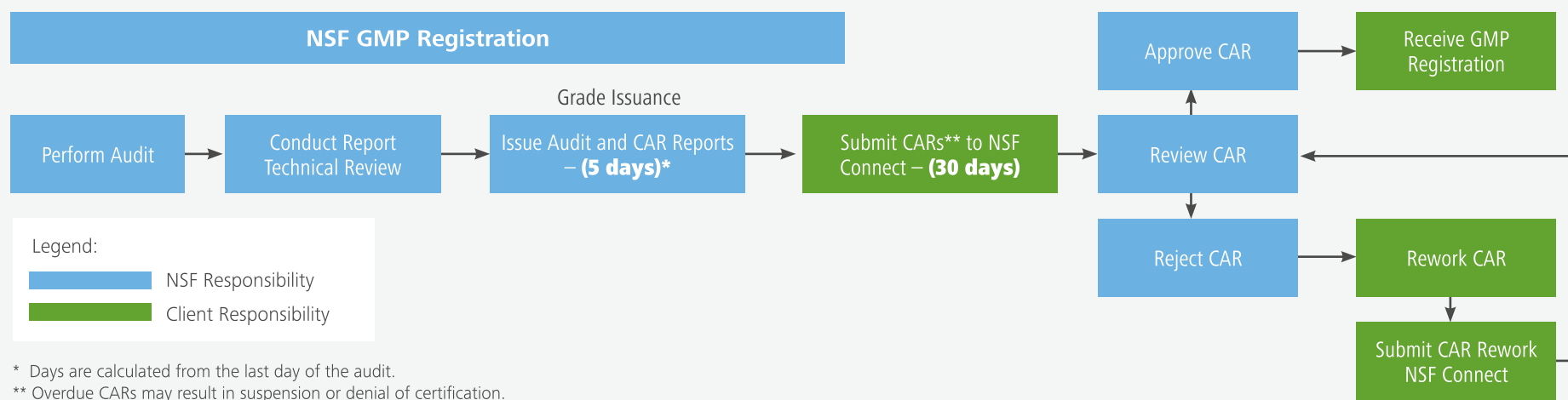
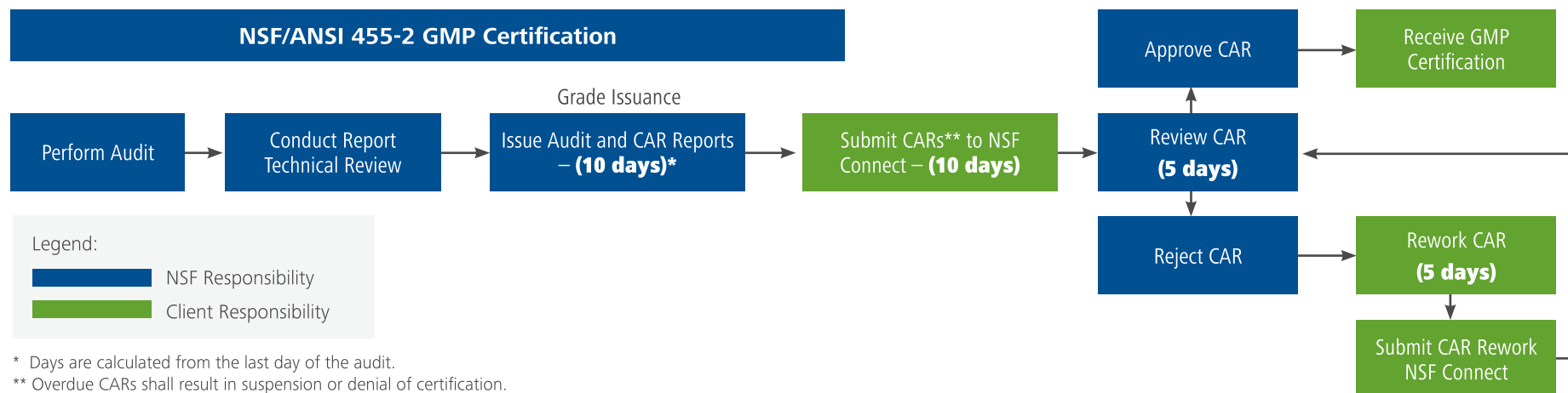
**NSF GMP Registration
Grade Rule**

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.



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

- > 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.

NSF GMP Registration

- > 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 21CFR111 compliant. [21CFR111]	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.