



# NSF/ANSI 455 – FREQUENTLY ASKED QUESTIONS

## 1. WHAT IS NSF/ANSI 455?

- > NSF/ANSI 455 are a set of accredited public standards for Dietary Supplements, Cosmetics, and Over-the-Counter Drugs industries. These standards provide consistent quality management principles in these industries in which facilities may be audited. The purpose of these widely accepted industry standards is to reduce the number of audits for facilities throughout the year.
- > If you are facility that manufacturers outside of the US and does not import product to the US. You must be registered in the country of manufacturer and the country of sale.

## 2. WHY IS “NSF” IN THE STANDARD NAME?

- > NSF International is a standard-writing organization that works with industry stake holders in the development of NSF/ANSI 455 standards.

## 3. WHAT ARE THE FDA REGISTRATION REQUIREMENTS FOR EACH STANDARD?

- > FDA registration is required for the 455-2 Dietary Supplements and 455-4 Over-the-Counter Drugs standards. FDA registration is not required for the 455-3 Cosmetics standard; however, the standard requires cosmetic product and ingredient manufacturer to register through the FDA’s Voluntary Cosmetic Registration Program (VCRP). More information for the FDA VCRP can be found at <https://www.fda.gov/cosmetics/voluntary-cosmetic-registration-program>.
- > If you are facility that manufacturers outside of the US and does not import product to the US. You must be registered in the country of manufacturer and the country of sale.

## 4. WHEN WILL 455 TAKE EFFECT?

- > The applications for the NSF/ANSI 455 and GRMA programs will be available in October 2020.
- > Accredited audits can be scheduled now to take place after January 1, 2021.
- > New applications for 173GMP will no longer be accepted as of January 31, 2021.

## 5. WHY SHOULD WE SEEK NSF/ANSI 455 CERTIFICATION?

- > Third-party auditing may be required for several stakeholders, such as retailers, brand owners, etc., as well as, criteria to obtain product certification. NSF understands there several different audits that a manufacturer may require throughout the year can become quite costly and time-consuming. NSF/ANSI 455 certification audits intention is to limit the number of audits a facility must go through on an annual basis.

## 6. HOW LONG IS THE APPLICATION PROCESS?

- > The application process is a collaborative effort between the facility and NSF International. NSF has provided documents and tools to simplify the process, however, the timeline depends heavily on the facilities preparedness.
- > NSF recommends allowing a 60-90-day window from application submission to desired audit date.

## 7. WHAT DO I NEED TO APPLY?

- > Notify your NSF representative of you interest in NSF/ANSI 455.
- > In order to apply, requirements of Section 5.3 of the standards need to be met.
  - Familiarize yourself with the applicable NSF/ANSI 455 standard(s), policies and regulations;
  - Conduct a self-assessment;
  - Address identified gaps and implement corrective actions;
  - Identify products and product technologies that are within scope of the selected standard certification; and
  - Register facility with the FDA (if applicable).
  - Prepare pre-audit documentation.
- > Request an application for the new audit scope and review the audit tools, which include:
  - Application Form
  - Audit Template
  - Applicable Standard
  - Audit Requirements Guideline
  - FAQ's
  - Transition Guide
  - Training Videos

## 8. HOW LONG WILL IT TAKE ME TO GET CERTIFIED?

- > Unfortunately, there are too many variables to give a definitive timeline. If you meet all required criteria of the NSF/ANSI 455 standard(s) and NSF policies, you could be listed in as little as 4 months. But it could take up to 18 months to complete the entire process. Be sure to talk about your time line goals with your dedicated Account Manager.

## 9. WHAT SCOPES ARE INCLUDED IN 455? EXCLUDED? DO I QUALIFY FOR 455?

### INCLUDED Scopes:

IN SCOPE	455-2 Dietary Supplements	455-3 Cosmetics	455-4 Over-the-Counter
Manufacturing	X	X	X
Dietary Ingredients	X		
Dietary Supplements	X		
Active Pharmaceutical Ingredients (API)			X
OTC Drug			X
Cosmetic Ingredient		X	
Cosmetic		X	
Contract Manufacturer	X	X	X
Packaging Manufacturer	X	X	X

### EXCLUDED Scopes (for all standards):

- > Warehouse and Distribution (Standalone)
- > Functional Foods Manufacturers
- > Brokers
- > Label Designers
- > Laboratories (Standalone)
- > Office Buildings
- > Transport Companies
- > E-Commerce
- > Medical Food
- > Injectables
- > Prescription Drugs

Services that cover the above scopes may be offered through other NSF programs. Please contact your NSF representative for more information.

## 10. CAN WE BUNDLE MULTIPLE NSF/ANSI 455 SCOPES TOGETHER IN THE SAME AUDIT?

- > Yes. Bundling audits can be performed by NSF to save you valuable time. Products of each scope must be in production during the audit process.

## 11. CAN WE STILL BE GMP FOR SPORT REGISTERED IF WE ARE NSF/ANSI 455 CERTIFIED?

- > Yes, we can bundle GMP for Sport with the NSF/ANSI 455-2 GMP For Dietary Supplement audit. However, it is not offered for the other NSF/ANSI 455 scopes.

## 12. WHERE CAN I FIND RESOURCES FOR THE NSF/ANSI 455 STANDARD?

- > There are many different resources NSF can provide to help prepare your facility for certification. General information regarding the standards can be found at our website, NSF.org. To receive copies of the standard documents, please contact an NSF representative.
- > <https://www.nsf.org/knowledge-library/standard-transition-nsf-ansi-455>
  - Transition Guide (NSF/ANSI 455-2 Only)
  - Information Guide
  - NSF/ANSI 455 Program videos
  - GMP Tutorial videos

## 13. WHY ISN'T THERE AN AUDIT REQUIREMENT GUIDELINE (ARG) FOR THE COSMETIC STANDARD?

- > The ARGs are voted and approved through the Joint Committee and this particular ARG has not been agreed upon to publish yet. However, NSF expects that an ARG for cosmetics will be available in the future.

## 14. WHAT ARE THE CLIENT OBLIGATIONS PRIOR TO THE AUDIT TAKING PLACE?

- > Notify your NSF representative of your interest in NSF/ANSI 455;
- > Complete all requirements of Section 5.3 and send the application form to your NSF representative;
- > Review and sign your NSF/ANSI 455 proposal;
- > Attend an initial call with your NSF account manager;
- > Schedule your audit when an auditor reaches out to you; and, importantly, send written acknowledgement and acceptance of the audit plan to your account manager;
- > Provide required documentation in Section 5.4.5 to your account manager as soon as possible, but no later than 1 week prior, to your scheduled audit.
  - Organization chart
  - Site plan

- Process flow diagram
- List of products and technologies
- Typical shift schedules
- Standard operating procedure index
- Regulatory inspection history
- Site regulatory registration

## **15. WHY ARE YOU ASKING FOR SO MUCH INFORMATION BEFORE THE AUDIT?**

- > The NSF/ANSI 455 standards sections 5.3 and 5.4 require all the pre-application and pre-audit documentation as requested by the industry and agreed upon by the Joint Committee.

## **16. WHAT ARE THE GRADING CRITERIA FOR NSF/ANSI 455 STANDARDS?**

- > This is a risk-based audit and the grade is determined by the number and severity of nonconformances cited during the audit. See Table 5.2 of the applicable standard for the grading criteria.
- > If you need a copy of the standard, please reach out to your current NSF representative.

## **17. WHAT DOES THE TYPICAL AUDIT CYCLE LOOK LIKE FOR 455?**

- > The audit cycle is directly dependent on your initial audit grade. At a minimum, the facility will then need to have an annual audit to maintain certification. Additional audits may be required based on the grade and severity of nonconformances received on the previous audit. Please see the NSF/ANSI 455 standard and certification policies for additional information.
- > If you need a copy of the policies, please reach out to your current NSF representative.

## **18. WHEN WILL I RECEIVE MY AUDIT REPORT AFTER MY AUDIT AND HOW LONG DO I HAVE TO RESPOND TO CORRECTIVE ACTIONS?**

- > The audit and CAR report will be released within 10 business days after the conclusion of the audit.
- > You then have up to 10 business days to submit the corrective action plan for each non-conformance. The NSF technical team then has 10 days to review the plan and respond. (Section 5.7.2)
- > All corrective actions for non-fail audits are required to be closed out 30 days from receiving the audit report, per the standard.
- > The technical team will request objective evidence for implementation for major non-conformances after the corrective action plan is approved. This objective evidence needs to be completed 60 days from the last day of the audit.

## **19. WHAT HAPPENS IF I DON'T SUBMIT MY CORRECTIVE ACTIONS IN TIME, WILL I HAVE TO RESTART THE PROCESS?**

- > A critical aspect of the NSF/ANSI 455 standard is responsiveness to identified issues. Failure to respond to your corrective actions in accordance with the standard will impact the certification process which could lead to delays in obtaining your certification, additional audits, suspensions and even withdraw from the program.

## **20. WHY ARE THE TIME LINES FOR THE CORRECTIVE ACTION PROCESS SO STRICT AND SHORT?**

- > The time lines for response are detailed in the NSF/ANSI 455 standards. They were decided upon by the joint committee. It is important to understand the time lines in the standard so you can ensure you have the appropriate systems and staff to comply with the time requirements.

## **21. WHAT HAPPENS IF I FAIL THE AUDIT?**

- > Certification cannot be granted based on a failed audit. A full re-audit would need to be conducted and receive a passing grade for certification to take place.
- > A full re-audit may be conducted at any time after your failed audit with the exception of a critical finding.
- > If you receive a critical finding, you must re-apply and provide objective evidence that the critical non-conformance has been corrected.

## **22. WILL I BE ABLE TO USE THE NSF MARK ON MY PRODUCTS?**

- > No, the NSF certification mark associated with the NSF/ANSI 455 standard shall not be used in conjunction with any product advertising, or on materials, ingredients, certificates of analysis, components, or finished products, labels, or packaging.
- > The NSF/ANSI 455 Mark can be used on advertising, literature, your company's website, tradeshow booth and promotional materials as long as requirements outlined in the policies are observed. Please contact your NSF representative for review of any marketing material or to obtain a copy of NSF's co-marketing guideline and materials.
- > If you currently are producing or are seeking to produce NSF product certification to NSF/ANSI 173, please contact your NSF representative.

## **NSF INTERNATIONAL**

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# NSF/ANSI 455: GRMA FREQUENTLY ASKED QUESTIONS

## 1. WHAT IS GRMA?

- > GRMA is the Global Retailer and Manufacturer Alliance, an independent organization composed of major retailers, manufacturers, trade associations, public health and safety organizations, and certification bodies as representatives. It collaboratively assists in the development of standards and accepts the NSF/ANSI 455 GMP standards as a scheme owner. Membership is an addition to the NSF/ANSI 455 certification, but not required by NSF International. More information regarding GRMA can be found at: <https://grmalliance.org/>.

## 2. DO I HAVE TO BE A GRMA MEMBER TO APPLY FOR NSF/ANSI 455 GMP CERTIFICATION?

- > GRMA membership is not required to obtain NSF/ANSI 455 GMP certification.

## 3. WHAT ARE THE REQUIREMENTS OF GRMA?

- > Must be registered as a GRMA member;
- > This audit data consists of the audit reports, audit grade and corrective action implementation.
- > Must share their audit data to the ReposiTrak system which is accessible by retailers. Audited by an accredited certification body, such as NSF International, to NSF/ANSI 455 standards;

## 4. HOW DOES NSF HELP ME TO MEET THE ADDITIONAL GRMA REQUIREMENTS?

- > Other than registering as a GRMA member, selecting to add the GRMA services to your NSF/ANSI 455 audit will allow you to meet the GRMA requirements listed above.

## 5. WHAT IS THE DIFFERENCE BETWEEN NSF/ANSI 455 AND GRMA AUDITS?

- > NSF/ANSI 455 is the audit standard for which your facility will be audited. GRMA is an add on service to the NSF/ANSI 455 audit. Adding GRMA will allow your final audit report and corrective actions to be shared with the GRMA member base in ReposiTrak.
- > If you add a GRMA service, upon successful completion of the audit you will receive a GRMA certificate with the NSF/ANSI 455 audit scope selected in your application with the ANAB logo.
- > If you are not a GRMA member, you will still receive an accredited certificate with the ANAB logo with NSF. This certificate will also have the NSF/ANSI 455 audit scope selected in your application with an ANAB logo.

## 6. IF I HAVE A CUSTOMER REQUIRING THE GRMA, WHAT DOES THAT MEAN FOR ME?

- > Become a GRMA member. Please apply at <https://grmalliance.org/>.
- > You can add the GRMA service to your NSF/ANSI 455 audit

## 7. DOES ADDING GRMA CHANGE THE PRICE OF MY AUDIT?

- > There are no additional fees associated with the cost of the audit if GRMA is added, however, GRMA has a membership fee which is separate from NSF.

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# TRANSITION FROM NSF/ANSI 173 TO NSF/ANSI 455-2 DIETARY SUPPLEMENTS: FREQUENTLY ASKED QUESTIONS

## 1. WHEN CAN I TRANSITION FROM AN NSF GMP REGISTRATION AUDIT TO AN NSF/ANSI 455-2 GMP CERTIFICATION AUDIT?

### > Starting January 1, 2021

- NSF can conduct NSF/ANSI 455-2 GMP certification audits.

### > October 2020 - December 2022

- Clients can select audits to NSF/ANSI 173, Section 8 GMP registration or NSF/ANSI 455-2 GMP certification.

### > After December 31, 2022

- NSF GMP registration audits will be retired and replaced with NSF/ANSI 455-2 GMP certification.
- Warehouse & distribution facilities (standalone) will remain under the 173GMPWD (Warehouse and Distribution) program.

## 2. DO I HAVE TO TRANSITION TO THIS NEW STANDARD?

- > Not right away. You have until December 31, 2022 to apply and obtain NSF/ANSI 455-2 GMP certification, allowing you to remain in the NSF program and transition at a pace that is comfortable for your organization.
- > Not right away. You have until December 31, 2022 to apply and obtain NSF/ANSI 455-2 GMP certification, allowing you to remain in the NSF program and transition at a pace that is comfortable
- > If you are a current client who has a standalone warehouse and distribution GMP registration with NSF, you may continue with that program. That program will continue forward and not be impacted by the deadlines above at this time.

## 3. HOW SHOULD I HANDLE THE TRANSITION FROM 173GMP TO NSF/ANSI 455?

There are two general options that each facility will choose from:

- > Replace the current registration audit with an NSF/ANSI 455 audit (Replace option), minimize costs but risk losing all listings if you fail, or
- > Pursue NSF/ANSI 455 certification while maintaining your current registration, which will ensure you remain listed the entire time but would result in higher costs. This can be achieved by maintaining your current 173GMP audit cycle and pursuing NSF/ANSI 455 at another time (Self-Paced option).

The table below highlights these options with some considerations that should be made. Your NSF account Manager can assist in identifying the best option for your organization.

OPTIONS	OPTION DESCRIPTIONS	BENEFITS	CONSIDERATIONS	CERTIFICATION SUCCESS	CERTIFICATION FAILURE
<b>Replace</b>	NSF/ANSI 455-2 GMP Certification audit replaces the NSF GMP Registration audit.	<p>Cost effective replacement.</p> <p>Certification activities reduce to one operation activity with NSF.</p> <p>Maintain current audit schedule.</p> <p>NSF/ANSI 455-2 GMP Certified facility.</p>	<p>Time preparation constraints.</p> <p>No overlap between certification and registration audits.</p> <p>Bundling product services NSF GMP for Sport, Product Certification, or Certified for Sport may impact duration.</p> <p>New NSF/ANSI 455 GMP Certification Policies.</p> <p>New NSF/ANSI 455-2 GMP standard.</p>	<p>Certification will be granted upon successful completion of the certification audit and all other requirements.</p> <p>Marketing opportunities with the NSF Certification Mark</p>	<p>NSF/ANSI 455-2 GMP Certification will not be granted and additional audits will be required.</p> <p>NSF Registration will be expired and withdrawn, including Listing.</p> <p>NSF GMP for Sport, Product Certification, or Certified for Sport will be impacted.</p>
<b>Self-Pace</b>	<p>Apply for NSF/ANSI 455-2 GMP</p> <p>Certification at any time.</p>	<p>Apply at your own pace.</p> <p>Implement NSF/ANSI 455-2 GMP Standards prior to Dec. 31, 2021.</p> <p>New audit schedule.</p> <p>NSF/ANSI 455-2 GMP Certified facility.</p> <p>More time to educate clients about NSF/ANSI 455-2 GMP Certification Program.</p>	<p>Potentially have 4 NSF audits per year depending on audit grade.</p> <p>Separate cost for NSF Registration and NFS/ANSI 455-2 GMP Certification Programs.</p> <p>New NSF/ANSI 455 GMP Certification Policies.</p> <p>New NSF/ANSI 455-2 GMP standard.</p> <p>Employee Audit Fatigue</p>	<p>Certification will be granted upon successful completion of the certification audit and all other requirements.</p> <p>Marketing opportunities with the NSF Certification Mark.</p>	<p>NSF/ANSI 455-2 GMP Certification will not be granted and additional audits will be required.</p> <p>NSF Registration may be expired and withdrawn, including Listing.</p> <p>NSF GMP for Sport, Product Certification, or Certified for Sport may be affected.</p>

#### 4. WHAT'S THE DIFFERENCE BETWEEN NSF/ANSI 455 AND CURRENT REGISTRATION?

- > The NSF/ANSI 455 program is an ISO 17065 accredited certification program through ANAB that is based off a GMP-specific standard written in collaboration by retailers, public health manufactures, and certification bodies within each industry. The NSF/ANSI 455 certificate will include the ANSI logo, which is an internationally recognized accreditation.

- > The current NSF 173GMP dietary supplements registration program is based on Section 8 of the NSF/ANSI 173 product certification standard. This was written by NSF based on industry best practices.
- > Review the transition guide on our website for an in-depth comparison between NSF/ANSI 455-2 and 173GMP.  
<https://www.nsf.org/knowledge-library/standard-transition-nsf-ansi-455>
- > Section 5.4.5 of NSF/ANSI 455 standards requires that pre-audit documentation is sent to your account manager as soon as possible, but no less than 1 week prior, to your scheduled audit. Failure to do so will result in the audit being cancelled and cancellation fees being charged.
  - Organization chart
  - Site plan
  - Process flow diagram
  - List of products and technologies
  - Typical shift and schedule
  - Standard operating procedure index
  - Regulatory inspection history
  - Site regulatory registration

## **5. WHY ARE YOU ASKING FOR SO MUCH INFORMATION BEFORE THE AUDIT?**

- > This documentation ensures that the correct scope of the audit is performed, and the auditor is prepared to evaluate the facility. This requirement can be found in the NSF/ANSI 455 standard under 5.4.5.

## **6. ARE THERE DIFFERENT POLICIES FOR THE NSF/ANSI 455 STANDARD THAN WITH THE PREVIOUS NSF/ANSI 173 REGISTRATION?**

- > The policies for NSF/ANSI 455 certification and NSF GMP registration are different but have been created to align as closely as possible.
- > Contact your NSF representative to receive a copy of the NSF/ANSI 455 Certification Policies document.
- > The transition guide on NSF.org gives a complete breakdown of the differences between GMP Registration and NSF/ANSI 455-2.

## **7. WHAT'S THE DIFFERENCE BETWEEN CERTIFICATION AND REGISTRATION?**

- > NSF/ANSI 455 certification is an accredited standard where all certification bodies, like NSF International, are audited by ANAB on an annual basis. The ANAB logo will appear on all GMP certificates certified to the standard.
- > The current NSF Dietary Supplements GMP registration program is not accredited by ANAB.

## 8. WHAT DOES THE APPLICATION PROCESS LOOK LIKE?

- > The application itself is simple but serves as a critical step in making sure both NSF and you are on the same page with the work that will be performed. You may take as long as you need to familiarize yourself with the standard(s), conduct a self-assessment, implement corrective actions and address all other required fields within Section 5.3 of the standard(s).
- > Once these tasks are completed, notify your NSF representative to receive an NSF application. A formal proposal will be provided within 5-10 business days of NSF receiving a completed application.

## 9. WHAT DO I NEED TO APPLY?

- > Notify your NSF representative of your interest in NSF/ANSI 455.
- > In order to apply, requirements of Section 5.3 of the standards need to be met.
  - Familiarize yourself with the applicable NSF/ANSI 455 standard(s), policies and regulations;
  - Conduct a self-assessment;
  - Address identified gaps;
  - Identify products and product technologies that are within scope of the selected standard certification; and
  - Register facility with the FDA.
- > Request an application for the new audit scope and review the audit tools, which include:
  - Audit Template
  - Standard
  - Audit Requirements Guideline
  - FAQ's
  - Transition Guide
  - GMP Tutorial Videos
  - Webinar Videos

## 10. HOW DOES THE COST COMPARE FOR NSF/ANSI 455 AND NSF/ANSI 173? WHAT ABOUT DURATION?

- > NSF/ANSI 455-2 Dietary Supplements cost and duration are similar to NSF/ANSI 173.
- > You are able to bundle multiple scopes (Dietary Supplements, Cosmetics, and OTCs) and this may impact your cost and duration.
- > Please contact your business development manager or account manager if you have any questions or need a quote.

## 11. DO I HAVE TO TRANSITION INTO NSF/ANSI 455? OR CAN I CONTINUE WITH NSF 173GMP?

- > All currently registered facilities who are eligible for NSF/ANSI 455 will be expected to transition into the new certification program prior to January 1, 2023. This is to align NSF International with the industry and support our clients by offering a more standardized approach and reduction of audits each year.
- > New applications for 173GMP will no longer be accepted as of January 31, 2021. This includes adding additional sites to your existing account.

## 12. CAN I HAVE BOTH NSF GMP REGISTRATION AND NSF/ANSI 455-2 GMP CERTIFICATION?

- > Yes, but you must comply with the requirements and policies of both programs.
- > Audits can be combined; however, this may increase your audit duration, which will also increase the cost of the audit.
  - As an example, the typical NSF GMP registration audit duration is 3 days and the NSF/ANSI 455-2 GMP audit is 3 days.
  - The audit duration may be more than 3 days depending on the size of the facility and other factors.

## 13. IF I MOVE TO NSF/ANSI 455-2 GMP CERTIFICATION, WILL THAT IMPACT THE NSF CERTIFIED PRODUCT(S) I MAKE?

- > No, if you successfully complete NSF/ANSI 455-2 GMP certification and compliance with policies.
- > Yes, if you fail NSF/ANSI 455-2 GMP certification and are noncompliant with policies.
- > Yes, if NSF/ANSI 455-2 GMP certification is not completed within the required timeline.

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