789 N. Dixboro Rd,
Ann Arbor, Michigan
48105-9753 USA

T +1 734 769 8010
E standards@nsf.org
nsf.org

Joint Committee on GMP for Dietary Supplements

August 1, 2025

Proposed revision to NSF/ANSI 455-2ARG – *Audit Requirement Guidelines for Good Manufacturing Practices for Dietary Supplements* (455-2ARGi46r2)

Revision 2 of NSF/ANSI 455-2ARG, issue 46 is being forwarded to the Joint Committee for consideration. Please review the proposal and **submit your ballot by August 22, 2025** via the NSF Online Workspace.

Please note that this is an ARG ballot only. ARG guidelines are denoted in italics and only the italic language is open for comments. While this ballot may include some suggested changes to the standard this ballot is NOT on those changes. They are only included so that you can see how those suggested changes impact the ARG. If you have any comments on the included standard changes you MUST make those comments on that issue paper's ballot. The link to the ballot is included in the comments in the ballot. Any comments on the suggested standard changes shown in this ballot will be considered nongermane and will not be addressed.

When adding comments, please use the comment template provided in the reference documents and upload it online via the browse function.

Purpose

The proposed revision is to combine separate requirements for records in the standard into their associated procedures.

Background

This issue was balloted in 2024. It received some comments, and the issue paper was changed accordingly. It was presented at the 2025 JC meeting, where it was motioned to go to ballot as written.

There are a few requirements in the standard that specifically call out keeping records of activities. Instead of being in a different requirement from the procedures that they refer to, they are now being incorporated into the same requirement. Applicable CFR references and ARG guidance are also moved accordingly. This makes the intent clearer by stating that documented evidence of compliance to and implementation of procedures are required to be maintained.

Additionally,

789 N. Dixboro Rd,
Ann Arbor, Michigan
48105-9753 USA

T +1 734 769 8010
E standards@nsf.org
nsf.org

4.5.7 Updated language to clarify intent.
4.5.19 Moved to a new location (4.5.9) in the same section to group together with other requirements pertaining to equipment. Language is also updated for clarity on the requirement for records.

If you have any questions about the technical content of the ballot, you may contact me in care of:

Freddie Agyin, Chair, Joint Committee on GMP for Dietary Supplements
c/o Rachel Brooker, Joint Committee Secretariat
T +1 (734) 827-6866
E rbrooker@nsf.org

[Note – the recommended changes to the standard which include the current text of the relevant section(s) indicate deletions by use of ~~strikeout~~ and additions by grey highlighting. Rationale Statements are in *italics* and only used to add clarity; these statements will NOT be in the finished publication.]

*****This is an ARG ballot only. ARG guidelines are denoted in *italics* and only the italic language is open for comments. While this ballot may include some suggested changes to the standard, this ballot is NOT on those changes. They are only included so that you can see how those suggested changes impact the ARG. If you have any comments on the included standard changes you MUST make those comments on that issue paper's ballot. The link to the ballot is included in the comments below. Any comments on the suggested standard changes shown in this ballot will be considered nongermane and will not be addressed.*****

NSF/ANSI Standard
for Nutrition and Wellness –

Audit Requirement Guidelines for Good Manufacturing Practices for Dietary Supplements

4 Audit requirements

4.3 Planning

4.3.3 Where required by regulations in the country of manufacture or sale, direct importers of components, bulk dosage forms, or finished dietary supplements shall establish and implement a foreign supplier verification program (FSVP). [21 C.F.R. § 1.511].

4.3.3.2 *Records for the foreign supplier program should be maintained and retained at least 2 yr after the documents are created or 2 yr after the product is discontinued for use. For smaller suppliers, record retention should be for at least a 3-yr period preceding the applicable calendar year to support their status as a very small supplier.*

4.4 Support

Commented [RB1]: This is a standard requirement. It is only here for context. If you have suggested changes for this requirement, please submit an issue paper.

4.4.37 Procedures ~~shall be established~~ that describe the requirements for record-retention shall be established. Records shall be maintained for at least 1 year after the shelf life date or at least 2 years beyond the date of distribution of the last batch associated with those records. ~~under Subpart P – Records and Recordkeeping~~. [21 C.F.R. § 111.605 (a, b)]

4.4.37.1 *A written records retention procedure should:*

- *address records kept in both hard copy and electronic format;*
- *specify the retention period, storage conditions, and proper disposition once the retention period for each type of record has expired; and*
- *document record destruction.*
-

4.4.37.2 *Record retention requirements apply to all records pertaining to quality as required in the standard ~~21 C.F.R. 111~~. This includes but is not limited to; MMRs, BPRs, distribution records, return records, complaint records, etc.*

~~***4.4.37.3*** *Records required by 21 C.F.R. § 111 should be maintained for at least 1 yr after the shelf life date or at least 2 yr beyond the date of distribution of the last batch associated with those records.*~~

4.4.37.4 *All records should be maintained as original record, as true copies or as electronic records.*

~~***4.4.37.5*** *Records for the foreign supplier program should be maintained and retained at least 2 yr after the documents are created or 2 yr after the product is discontinued for use. For smaller suppliers, record retention should be for at least a 3-yr period preceding the applicable calendar year to support their status as a very small supplier.*~~

~~**4.4.38** Appropriate records shall be maintained for laboratory operations. [21 C.F.R. § 111.325]~~

~~***4.4.38.1*** *Documentation at the time of performance that laboratory activities such as testing, inhouse calibrations, validations, etc., are followed.*~~

~~***4.4.38.2*** *Documentation for tests and examinations should include results.*~~

-
-
-

4.5 Operation

-
-
-

4.5.9 Procedures for preventive maintenance program shall be established and records maintained. [21 C.F.R. § 111.25 (c), 111.35(b2)]

4.5.9.1 *Procedures for maintenance of the facility and individual equipment should be available.*

4.5.9.2 *The program should designate equipment with unique identifiers (equipment numbers).*

4.5.9.3 *The program should outline what activities should be completed for the preventive maintenance and the frequency the maintenance should occur.*

4.5.9.4 *Detailed records should show that the required maintenance activities were performed as scheduled based on the established frequency. Records should list the initials of the personnel who*

Commented [ER2]: This suggested change is 455-2i65r2. 455-2i65r2 has many more suggested changes. These are only added to this ballot for context. To vote or comment on this suggested change proceed to the 455-2i65r2 ballot at: https://standards.nsf.org/higherlogic/ws/groups/db501a6e-2381-412f-a5c0-018976f9bc62/ballots/ballot?id=9662

Commented [ER3]: This suggested change is 455-2i65r2. 455-2i65r2 has many more suggested changes. These are only added to this ballot for context. To vote or comment on this suggested change proceed to the 455-2i65r2 ballot at: https://standards.nsf.org/higherlogic/ws/groups/db501a6e-2381-412f-a5c0-018976f9bc62/ballots/ballot?id=9662

Commented [ER4]: This suggested change is 455-2i65r2. 455-2i65r2 has many more suggested changes. These are only added to this ballot for context. To vote or comment on this suggested change proceed to the 455-2i65r2 ballot at: https://standards.nsf.org/higherlogic/ws/groups/db501a6e-2381-412f-a5c0-018976f9bc62/ballots/ballot?id=9662

performed the activities, the date completed, and any chemicals, parts, etc., that were used.

4.5.9.5 The PM program should include utilities such as HVAC units, dust collectors, boilers, air compressors and water treatment systems that may have direct or indirect product quality impact.

***4.5.9.6** Replacement parts which are not like-for-like should follow change control procedures.*

***4.5.9.7** Procedures should include necessary steps when equipment is taken out for maintenance and when it is returned for use in production.*

4.5.10 Procedures and programs ~~shall be established~~ for calibration of all instruments, controls, automated, mechanical, laboratory, and electronic equipment, etc. shall be established and records maintained. [21 C.F.R. §§ 111.27 (b), 111.35 (a,b), 111.113 (a4), 111.130 (c)]

-
-
-

***4.5.10.10** Records of inspections and verifications should be maintained.*

***4.5.10.11** Calibration documents should include:*

- *identity of the instrument;*
- *date of calibration;*
- *identity and certification of compliance of the reference standard;*
- *method of calibration used, including limits for accuracy and precision;*
- *calibration reading or results found;*
- *if necessary, recalibration method used and new reading or results found; and*
- *initials of the qualified person who performed the calibration and if necessary, recalibration.*

***4.5.10.12** Material review records associated with out of tolerance calibration results that may impact product quality should be maintained.*

-
-
-

4.5.12 ~~Complete records shall be made and kept of any calibration of instruments and controls that are important to product quality and safety. [21 C.F.R. §§ 111.35 (b3, b4), 111.113 (a4)]~~

***4.5.12.1** ~~Records of inspections and verifications should be maintained.~~*

***4.5.12.2** ~~Calibration documents should include:~~*

- ~~*identity of the instrument;*~~
- ~~*date of calibration;*~~
- ~~*identity and certification of compliance of the reference standard;*~~
- ~~*method of calibration used, including limits for accuracy and precision;*~~
- ~~*calibration reading or results found;*~~
- ~~*if necessary, recalibration method used and new reading or results found; and*~~
- ~~*initials of the qualified person who performed the calibration and if necessary, recalibration.*~~

***4.5.12.3** ~~Material review records associated with out of tolerance calibration results that may impact~~*

Commented [ER5]: This suggested change is 455-2i65r2. 455-2i65r2 has many more suggested changes. These are only added to this ballot for context. To vote or comment on this suggested change proceed to the 455-2i65r2 ballot at: https://standards.nsf.org/higherlogic/ws/groups/db501a6e-2381-412f-a5c0-018976f9bc62/ballots/ballot?id=9662

Commented [ER6]: This suggested change is 455-2i65r2. 455-2i65r2 has many more suggested changes. These are only added to this ballot for context. To vote or comment on this suggested change proceed to the 455-2i65r2 ballot at: https://standards.nsf.org/higherlogic/ws/groups/db501a6e-2381-412f-a5c0-018976f9bc62/ballots/ballot?id=9662

~~*product quality should be maintained.*~~

-
-
-

4.5.19 ~~The plant shall have a documented preventive maintenance program. [21 C.F.R. § 111.25 (c)]~~

Commented [ER7]: This suggested change is 455-2i65r2. 455-2i65r2 has many more suggested changes. These are only added to this ballot for context. To vote or comment on this suggested change proceed to the 455-2i65r2 ballot at: https://standards.nsf.org/higherlogic/ws/groups/db501a6e-2381-412f-a5c0-018976f9bc62/ballots/ballot?id=9662

~~***4.5.19.1*** *Procedures for maintenance of the facility and individual equipment should be available.*~~

~~***4.5.19.2*** *The program should designate equipment with unique identifiers (equipment numbers).*~~

~~***4.5.19.3*** *The program should outline what activities should be completed for the preventive maintenance and the frequency the maintenance should occur.*~~

~~***4.5.19.4*** *Detailed records should show that the required maintenance activities were performed as scheduled based on the established frequency. Records should list the initials of the personnel who performed the activities, the date completed, and any chemicals, parts, etc., that were used.*~~

~~***4.5.19.5*** *The PM program should include utilities such as HVAC units, dust collectors, boilers, air compressors and water treatment systems that may have direct or indirect product quality impact.*~~

~~***4.5.19.6*** *Replacement parts which are not like-for-like should follow change control procedures.*~~

~~***4.5.19.7*** *Procedures should include necessary steps when equipment is taken out for maintenance and when it is returned for use in production.*~~

-
-
-

4.5.33 The water supply shall be safe and sanitary. Records shall be maintained to show the quality of w~~W~~ater that may contact a product contact surface or ~~is~~ used as a component of the dietary supplement ~~shall~~ meets federal, state, and local requirements for drinking water. [21 C.F.R. §§ 111.15 (e), 111.23 (c), 117.37 (a)]

Commented [ER8]: This suggested change is 455-2i65r2. 455-2i65r2 has many more suggested changes. These are only added to this ballot for context. To vote or comment on this suggested change proceed to the 455-2i65r2 ballot at: https://standards.nsf.org/higherlogic/ws/groups/db501a6e-2381-412f-a5c0-018976f9bc62/ballots/ballot?id=9662

-
-
-

4.5.33.8 *Water quality trending, testing records should be maintained.*

-
-
-

~~**4.5.36** Records shall be maintained to show that the quality of water, when used as a component of the dietary supplement, meets the requirements of 21 C.F.R. § 111.15 (e2). [21 C.F.R. § 111.23 (c)]~~

Commented [ER9]: This suggested change is 455-2i65r2. 455-2i65r2 has many more suggested changes. These are only added to this ballot for context. To vote or comment on this suggested change proceed to the 455-2i65r2 ballot at: https://standards.nsf.org/higherlogic/ws/groups/db501a6e-2381-412f-a5c0-018976f9bc62/ballots/ballot?id=9662

~~***4.5.36.1*** *Water quality trending, testing, maintenance, cleaning, and sanitation records should be maintained.*~~

~~***4.5.36.2*** *Water quality records should be maintained for water that is used in a manner such that the water may become a component of the dietary supplement, e.g., when such water contacts components, dietary supplements, or any contact surface*~~.

-
-
-

4.5.48 Throughout the manufacturing process, precautions shall be taken to prevent contamination,

Commented [ER10]: This suggested change is 455-2i65r2. 455-2i65r2 has many more suggested changes. These are only added to this ballot for context. To vote or comment on this suggested change proceed to the 455-2i65r2 ballot at: https://standards.nsf.org/higherlogic/ws/groups/db501a6e-2381-412f-a5c0-018976f9bc62/ballots/ballot?id=9662

including by microbes, filth, chemicals, foreign material, etc. of components and dietary supplements. Records of manufacturing operations shall be maintained. [21 C.F.R. § 111.365 (a, b, c, d, e, f, g), 111.375]

4.5.48.1 *Please see 21 C.F.R. § 111.365 for a complete list.*

4.5.48.2 *Procedures should be established and implemented for:*

— designing manufacturing processes to ensure products consistently meet specifications;

— defining precautions to prevent contamination including microbes, filth, chemicals, foreign material, etc.;

— preventing the inclusion of foreign material by using filters, traps, magnets and metal detectors;

— identifying processing lines and major equipment to indicate their contents and phase of manufacturing; and

— identifying and holding materials that require material review to prevent mix-ups including returned materials.

4.5.48.3 *Records supporting required procedures should be maintained.*

-
-
-

~~**4.5.53** Records shall be established and shall be maintained to meet the requirements of Subpart K – Production and Process Control System: Requirements for Manufacturing Operations. [21 C.F.R. § 111.375]~~

~~***4.5.53.1*** *Procedures should be established and implemented for:*~~

~~*— designing manufacturing processes to ensure products consistently meet specifications;*~~

~~*— defining precautions to prevent contamination including microbes, filth, chemicals, foreign material, etc.;*~~

~~*— preventing the inclusion of foreign material by using filters, traps, magnets and metal detectors;*~~

~~*— identifying processing lines and major equipment to indicate their contents and phase of manufacturing; and*~~

~~*— identifying and holding materials that require material review to prevent mix-ups including returned materials.*~~

~~***4.5.53.2*** *Records supporting required procedures should be maintained.*~~

-
-
-

4.5.54 Procedures that include QC operations ~~shall be established~~ for all packaging and labeling operations shall be established. Records shall be maintained to allow a complete history and control of

Commented [ER11]: This suggested change is 455-2i65r2. 455-2i65r2 has many more suggested changes. These are only added to this ballot for context. To vote or comment on this suggested change proceed to the 455-2i65r2 ballot at: https://standards.nsf.org/higherlogic/ws/groups/db501a6e-2381-412f-a5c0-018976f9bc62/ballots/ballot?id=9662

Commented [ER12]: This suggested change is 455-2i65r2. 455-2i65r2 has many more suggested changes. These are only added to this ballot for context. To vote or comment on this suggested change proceed to the 455-2i65r2 ballot at: https://standards.nsf.org/higherlogic/ws/groups/db501a6e-2381-412f-a5c0-018976f9bc62/ballots/ballot?id=9662

the packaged and labeled dietary supplement through distribution. [21 C.F.R. § 111.127, 111.403, 111.410 (d), 111.430]

-
-
-

4.5.54.8 *Packaging operations should include a pre-startup inspection or line clearance approved by Quality personnel.*

~~**4.5.55** QC operations shall be established for packaging and labeling operations. [21 C.F.R. § 111.127]~~

~~***4.5.55.1*** *Packaging operations should include a pre-startup inspection or line clearance approved by Quality personnel.*~~

-
-
-

4.6 Performance evaluation

-
-
-

4.6.12 QC laboratory operations and procedures shall be established and records maintained. [21 C.F.R. § 111.303, 111.325]

-
-
-

4.6.12.3 *Documentation at the time of performance that laboratory activities such as testing, inhouse calibrations, validations, etc., are followed.*

4.6.12.4 *Documentation for tests and examinations should include results.*

-
-
-

Commented [ER13]: This suggested change is 455-2i65r2. 455-2i65r2 has many more suggested changes. These are only added to this ballot for context. To vote or comment on this suggested change proceed to the 455-2i65r2 ballot at: https://standards.nsf.org/higherlogic/ws/groups/db501a6e-2381-412f-a5c0-018976f9bc62/ballots/ballot?id=9662