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Joint Committee on GMP for Dietary Supplements

April 18, 2024

Proposed revision to NSF/ANSI 455-2 – *Good Manufacturing Practices for Dietary Supplements* (455-2i65r1)

Revision 1 of NSF/ANSI 455-2, issue 65 is being forwarded to the Joint Committee for consideration. Please review the proposal and **submit your ballot by May 9, 2024** via the NSF Online Workspace.

Please review all ballot materials. When adding comments, please include the section number applicable to your comment and add all comments under one comment number whenever possible. If you need additional space, please use the attached blank comment template in the reference documents and upload online via the browse function.

Purpose

The proposed revision is to remove multiple separate requirements for records in the standard.

Background

There are a few requirements in the standard that pertain to records. However, these do not need to be called out individually as it is already implicit in the requirement that if the procedure or regulation requires evidence of compliance, records should be available. In addition, there is inconsistency in the standard as not all requirements that require records as evidence have a corresponding records requirement. (e.g. 4.4.28 Personnel qualification and training, 4.6.27 Internal audits, etc.)

The requirements for records are also updated to reflect the intent and align with regulation.

4.4.37 - Updated language and added reference to 21 C.F.R. § 111.610(a).
4.4.38 - Added overarching requirement for all records.
4.4.38.1 - Removed. Duplicate of 4.6.14.7
4.4.38.2 - Removed. Covered in 4.6.16.5
4.4.39 - Moved from 4.5.60.

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

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[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.]

NSF/ANSI Standard
for GMP for Dietary Supplements –

Good Manufacturing Practices for Dietary Supplements

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4 Audit requirements

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4.4 Support

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~~4.4.22~~ ~~Records shall be maintained for plant cleaning and pest control in accordance with Subpart P – Records and Recordkeeping. [21 C.F.R. § 111.23(a, b)]~~

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~~4.4.30~~ ~~Records shall be maintained documenting compliance to established procedures that ensure that supervisors are appropriately qualified by education, training, or experience. [21 C.F.R. § 111.14(a, b) & 21 C.F.R. § 117.4]~~

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~~4.4.35~~ ~~Records shall be maintained of specifications, supplier qualification, and testing to ensure product meets purity, strength and composition. [21 C.F.R. § 111.95]~~

~~4.4.36~~ ~~Receiving records shall be made and kept for components, packaging, and labels, and for products received for packaging and labeling. [21 C.F.R. § 111.180]~~

4.4.37 ~~Procedures shall be established that describe the requirements for record retention under Subpart P – Records and Recordkeeping~~. Procedures for record maintenance and retention shall be established. [21 C.F.R. § 111.605 ~~(a, b)~~ & 21 C.F.R. § 111.610(a)]

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

4.4.38. Records of compliance to internal procedures and regulatory requirements shall be available.

4.4.39 Records shall be maintained to allow a complete history and control of the packaged and labeled dietary supplement through distribution. [21 C.F.R. § 111.410(d)]

~~**4.4.39**~~ **4.4.40** Electronic GMP records that are created, modified, maintained, archived, retrieved, or distributed by a computer system, shall be 21 C.F.R. Part 11 compliant. [21 C.F.R. Part 111.605(c)]

~~**4.4.40**~~ **4.40.41** 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 be secure from alterations, erasures, and loss and damage. [21 C.F.R. § 111.35(b5i, b5ii)]

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4.5 Operation

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~~**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) & 21 C.F.R. § 111.113 (a4)]~~

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~~**4.5.37** 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)]~~

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~~**4.5.60** Records shall be maintained to allow a complete history and control of the packaged and labeled dietary supplement through distribution. [21 C.F.R. § 111.410(d)]~~

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~~**4.5.76** Product distribution records shall be retained. [21 C.F.R. § 111.475(b2)]~~

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~~**4.5.82** Documentation shall be maintained for material reviews and dispositions. This shall include all testing results and any reevaluations by QC personnel for reprocessed materials. [21 CFR § 111.535 (b1, b2, b3, b4)]~~

~~**4.5.83** Records for returned dietary supplements shall be maintained. Records shall be maintained for at least 1 y after the shelf life date, if shelf life dating is being used, or at least 2 y beyond the date of distribution of the last batch associated with those records. [21 C.F.R. § 111.535]~~

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4.6 Performance evaluation

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~~**4.6.23** Records for each product complaint and investigation shall be maintained. Records shall be maintained for at least 1 y after the shelf life date, if shelf life dating is being used, or at least 2 y beyond the date of distribution of the last batch associated with those records. [21 C.F.R. § 111.570(a)]~~

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