Joint Committee Issue Paper

NSF Standard(s) Impacted: NSF/ANSI 455-2 & ARG

Purpose & Background:
Please provide a brief one sentence explaining the purpose of your recommendation. Also provide a brief background statement indicating the cause and nature of concern, the impacts identified relevant to public health, public understanding, etc, and any other reason why the issue should be considered by the Committee. Reference as appropriate any specific section(s) of the standard(s) that are related to the issue.

Purpose: 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.

Recommendation:
Clearly state what action is needed: e.g., recommended changes to the standard(s) including the current text of the relevant section(s) indicating deletions by use of ~~strike-out~~ and additions by grey highlighting or underlining; e.g., reference of the issue to a Task Group for detailed consideration; etc.

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]~~

~~***4.4.38.1** 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*~~.

4.4.38. 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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Signature*: Myla Estacio
Company: NSF
Telephone Number: 734-913-5738 E-mail: mestacio@nsf.org
Is this a revision of a previous Issue Paper (if yes put original issue number):_____
Submission Date: 6/15/23

Please submit to: Joint Committee Secretariat, Rachel Brooker at rbrooker@nsf.org or to standards@nsf.org

**Type written name will suffice as signature*