Joint Committee Issue Paper

NSF Standard(s) Impacted: NSF/ANSI 455-2 and 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: Combine separate requirements for records in the standard into their associated procedures.

Background:
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,
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.

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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4.3 Planning

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4.3.2 Supplier qualification procedures ~~shall~~ that include initial qualification, periodic examination (requalification), disqualification, and as necessary, expedited approval of suppliers on an emergency basis shall be established and records maintained. [21 C.F.R. § 111.75 (a2iiA), 111.95(b2)]

4.3.2.1 *Procedure should include periodic monitoring, auditing, and review of supplier qualification verification activities, along with records of these activities, including conclusions and the approval status of each supplier.*

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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].

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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.*

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4.3.6 Specifications shall be established for components, in-process materials, labels, packaging components, and finished product, and at any point, step, or stage in the manufacturing process where control is necessary. The basis is adequately documented for how meeting the in-process specifications, in combination with meeting component specifications, will help ensure that the dietary supplement specifications will be met (e.g., hazard analysis). Records shall be maintained. [21 C.F.R. § 111.70, 111.95(b1)]

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4.4 Support

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4.4.12 For any automated, mechanical, or electronic equipment the manufacturer shall have established appropriate controls to ensure that equipment functions in accordance with its intended use, including power backup for critical systems. [21 C.F.R. § 111.30 (e), 111.35(b2)]

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4.4.29 Procedures ~~shall be established~~ to determine the requirements and qualifications (such as education, training, or experience) of personnel who will supervise activities shall be established and records maintained. [21 C.F.R. §§ 111.13 (a, b), 111.14 (a, b), 117.4]

~~**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), 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]~~

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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.~~*
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4.5 Operation

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4.5.7 ~~Equipment logbooks shall be maintained for~~ Documentation in individual logs, on the use and maintenance of each equipment shall be maintained. ~~and include the date of use, and documentation of cleaning, sanitization, maintenance, etc~~. (unless the documentation is in the batch record). [21 C.F.R. § 111.35 (b2)]
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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 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)]
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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.*

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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), 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 product quality should be maintained.*~~

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

~~***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.*~~

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4.5.21 Procedures for cleaning and sanitization of all equipment, utensils, and contact surfaces shall be established and records of sanitation shall be maintained. Equipment and utensils shall be disassembled

as necessary for thorough maintenance, cleaning, and sanitizing. [21 C.F.R. §§ , 111.25 (c), 111.27 (d1), 111.35 (a, b1iii, b2)]

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4.5.26 Procedures ~~shall be established~~ for cleaning and sanitizing all filling and packaging equipment and utensils shall be established and records maintained. [21 C.F.R. § 111.415 (a)]

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4.5.33 The water supply shall be safe and sanitary. Records shall be maintained to show the quality of water 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)]

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

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4.5.34 Water delivery systems and water treatment systems shall not act as a potential source of contamination of the dietary supplement. Records of maintenance, cleaning, sanitation shall be maintained. [21 C.F.R. § 111.15 (f3)]

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4.5.34.3 *Routine monitoring, maintenance, and sanitization procedures should be established and documented for water treatment systems.*

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~~**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)]~~

~~***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.*~~

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

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~~**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.*~~

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

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***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.*~~

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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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~~**4.5.66** Records shall be established and maintained to meet the requirements of Subpart L – Product and Process Control System: Requirements for Packaging and Labeling Operations. [21 C.F.R. § 111.430]~~

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4.5.74 Procedures ~~shall be established~~ for holding and distribution operations shall be established and records maintained. [21 C.F.R. § 111.475 (b1)]

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4.5.79 Procedures ~~shall be established~~ for the handling of returned dietary supplements shall be established and records maintained. These shall include appropriate quarantine of the returned product until QC personnel have determined its disposition. [21 C.F.R. §§ 111.503, 111.510, 111.535 ~~(a, b1)~~]

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

4.5.84 A risk-based environmental monitoring program that includes controls to evaluate and mitigate the presence of nonpathogenic microorganisms in production areas and equipment shall be established and records maintained.

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4.6 Performance evaluation

4.6.1 Procedures ~~shall be established~~ for the collection of representative samples, including collection controls (e.g., to reduce potential of contamination) and the number of units to assure compliance with specification shall be established and records maintained. [21 C.F.R. §§ 111.80, 111.415 (g)]

4.6.2 Procedures ~~shall be established~~ for the collection of reserve samples for each lot of finished material shall be established and records maintained. [21 C.F.R. § 111.83]

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4.6.5 Dietary ingredients shall be sampled, tested, and released prior to use in production. At least one appropriate test or examination shall be conducted to verify the identity of the dietary ingredient (unless the company has submitted a petition for an ID test exemption that has been approved by the U.S. FDA). Records shall be maintained. [21 C.F.R. § 111.75 (a1), 111.95(b3)]

4.6.6 Other raw materials or components (i.e., those that are not dietary ingredients) shall be sampled, tested (or confirmed), and released prior to use in production. Records shall be maintained. [21 C.F.R. § 111.75 (a2i, a2ii), 111.95(b3)]

4.6.7 Proper testing procedures or programs shall be established to determine if in-process and finished product specifications for purity, composition, and strength of the dietary supplement have been met. The basis for performing reduced testing shall be adequately documented. This shall justify how the testing procedures or program selected will help ensure that the full specification for the dietary supplement will be met. Records shall be maintained. [21 C.F.R. § 111.75 (b, c, d), 111.95(b4)]

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Joint Committee Issue Paper

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4.6.12 QC laboratory operations and procedures shall be established and records maintained. [21 C.F.R. § 111.303, 111.325]
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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.*
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4.7 Improvement
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4.7.1 Procedures and controls ~~shall be established~~ for the investigation and the handling of materials that do not meet specification shall be established and records maintained. [21 C.F.R. § 111.77]

4.7.2 Procedures ~~shall be established~~ for a corrective and preventive action (CAPA) program for handling all nonconformances identified within the scope of this standard shall be established and records maintained.
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Is this a revision of a previous Issue Paper (if yes put original issue number): Yes__
Submission Date: 11/4/2024

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

**Type written name will suffice as signature*