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Joint Committee on GMP for Dietary Supplements

April 18, 2024

Proposed revision to NSF/ANSI 455-2ARG – *Audit Requirement Guidelines for Good Manufacturing Practices for Dietary Supplements* (455-2ARGi46r1)

Revision 1 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 May 9, 2024** 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 will remove multiple separate requirements for records in the standard.

Background

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

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

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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.]

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

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

*****The suggested change above is NOT part of this ballot.*****

~~***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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Commented [ER1]: This suggested change is 455-2i65r1. 455-2i65r1 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 455-2i65r1 ballot at:

https://standards.nsf.org/higherlogic/ws/groups/db501a6e-2381-412f-a5c0-018976f9bc62/ballots/ballot?id=8982