

Joint Committee on GMP for Dietary Supplements

April 18, 2024

Proposed revision to NSF/ANSI 455-2 – *Good Manufacturing Practices for Dietary Supplements* (455-2i59r1)

Revision 1 of NSF/ANSI 455-2, issue 59 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 will update the language for laboratory requirements for clarity.

Background

Section 4.6.17 was removed and combined with Section 4.6.16.

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

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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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4.6 Performance evaluation

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4.6.16 Laboratory controls shall be established and have been approved by QC, including use of sampling plans, criteria for establishing specifications, testing methods or examinations, and standard reference materials, and use of test methods and examinations in accordance with established criteria. [21 C.F.R. § 111.315 (a)]

4.6.17 Parameters shall be set for laboratory controls for sampling plans, criteria for examination and testing methods, and standard reference materials. [21 C.F.R. § 111.315 (b, c, d, e)]

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