TO: Joint Committee on GMP for Dietary Supplements

FROM: Freddie Agyin, Chair of the Joint Committee

DATE: February 9, 2024

SUBJECT: Proposed revision to NSF 455-2ARG - *Audit Requirement Guidelines for Good Manufacturing Practices for Dietary Supplements* (455-2ARGi38r1)

Revision 1 of NSF 455-2ARG, issue 38 are being forwarded to the Joint Committee for consideration. Please review the proposal and **submit your ballot by March 1, 2024** via the NSF Online Workspace <www.standards.nsf.org>.

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 update 4.4.8 and 4.5.17 language to clarify intent and to align with the referenced applicable regulation.

Background

ARG is updated to remove 4.4.8.1 and 4.4.8.4 as these are already covered under 4.5.18.
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
Tel: (734) 827-6866
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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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4.4.8 ~~Production area walls, floors, ceilings shall be adequately cleaned and shall be kept in good repair. [21 C.F.R. § 111.20(d1i)]~~
Facility walls, floors, and ceilings shall be designed and constructed in a manner that it can be adequately cleaned, kept clean, and in good repair. [21 C.F.R. § 111.20 (d1i)]

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

~~4.4.8.1 Procedures should be established and followed for production areas.~~

4.4.8.2 *Production ceilings and walls should be constructed of smooth, nonporous, nonabsorbent, cleanable material and should be free from signs of moisture, damage, insects / pests, mold / mildew, etc.*

4.4.8.3 *Floors in areas where product is exposed should be sealed and not have exposed aggregate, cracks, peeling coating, or broken areas. Floors should be impervious and kept clean and dry.*

~~4.4.8.4 Production floors, walls, and ceilings should be on a cleaning schedule.~~

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