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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* (455-2ARGi44r1)

Revision 1 of NSF/ANSI 455-2ARG, issue 44 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 update the language in Section 4.5.84 to clarify the intent for the Environmental Monitoring Program and add guidance in the ARG.

Background

4.5.84 - The requirement is separated into two requirements to give focus on each. Also, guidance is added for establishing and implementing an environmental monitoring program as there is currently none in the ARG.

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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4.5 Operation

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4.5.84 ~~Environmental Monitoring Program shall be risk-based to include controls to evaluate and mitigate the presence of nonpathogenic microorganisms in production areas and equipment. If an environmental monitoring program includes pathogen testing in product contact zones, the production area and equipment shall not be used until the area is cleaned and proven free of pathogens~~.
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.

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

4.5.84.1 *There should be written procedures for environmental monitoring that includes*

- *Responsibilities and methods for sampling, testing, and monitoring,*
- *Target organisms (e.g. indicator organisms, pathogens, spoilage organisms),*
- *Defined levels of contamination risk for different areas in the facility (e.g. zones),*
- *Sampling locations, frequency and timing,*
- *Scientifically valid testing methods,*
- *Target levels and/or baseline for comparison of results and appropriate corrective actions,*
- *Recording and evaluation of results.*

Commented [ER1]: This suggested change is 455-2i62r1. These are only added to this ballot for context. To vote or comment on this suggested change proceed to the 455-2i62r1 ballot at:

https://standards.nsf.org/higherlogic/ws/groups/db501a6e-2381-412f-a5c0-018976f9bc62/ballots/ballot?d=8983

4.5.84.2 *Results should be monitored and trends recorded.*

4.5.84.3 *Program should be reviewed annually or whenever there are changes to the manufacturing operations, procedures, or equipment to assess the effectiveness of the program.*

4.5.85 If an environmental monitoring program includes pathogen testing and a positive result is found in product contact zones, then production area and equipment shall not be used until the area is cleaned and proven free of pathogens.

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

4.5.85.1 *Written procedures should be in place for cleaning and sanitizing the area and equipment.*

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Commented [ER2]: This suggested change is 455-2i62r1. These are only added to this ballot for context. To vote or comment on this suggested change proceed to the 455-2i62r1 ballot at:

https://standards.nsf.org/higherlogic/ws/groups/db501a6e-2381-412f-a5c0-018976f9bc62/ballots/ballot?id=8983