TO: Joint Committee on GMP for Cosmetics

FROM: Angela Diesch, Chair of the Joint Committee

DATE: February 8, 2024

SUBJECT: Proposed revision to NSF 455-3ARG - *Audit Requirement Guidelines for Good Manufacturing Practices for Cosmetics* (455-3ARGi9r1)

Revision 1 of NSF 455-3ARG, issue 9 are being forwarded to the Joint Committee for consideration. Please review the proposal and **submit your ballot by February 29, 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 add a definition in the ARG for scientifically valid test method.

Background

The standard requires test methods used to be 'scientifically valid' however, it is not defined. To provide guidance, the definition from the American Council of Independent Laboratories (ACIL) is added to the ARG.

If you have any questions about the technical content of the ballot, you may contact me in care of:

Angela Diesch
Chair, Joint Committee on GMP for Cosmetics
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 Cosmetics –

Good Manufacturing Practices for Cosmetics

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4 Audit requirements

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4.6 Performance evaluation

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4.6.3 Scientifically valid test methods are used for testing of components, packaging materials, in-process materials, and final products. [ISO 22716:2007 9.2]

4.6.3.1 *Scientifically valid methods ~~are~~ should be used for establishing that specifications have been met.*

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4.6.3.5 *A test method can be considered scientifically valid if one of the following criteria are met[1]:*

- *The test procedure is a published compendial method from AOAC, USP, or other standard setting organization. These methods should be used within the published scope of method applicability and should be documented in a company Standard Operating Procedure (SOP).*
- *The test method is a fully validated method. This validation should follow published guidelines from AOAC, USP, or other standard setting organization, and the validation study should be documented.*
- *The test method is validated using an "in-house" validation procedure. The validation procedure should be documented in a company Standard Operating Procedure (SOP) and the results of the validation should be documented.*

- *The test method is demonstrated to be scientifically valid and fit for purpose using an in-house protocol. This protocol should be documented in a company SOP and contain the following:*
  - ** Demonstration of method precision*
  - **Demonstration of method accuracy*
  - **Demonstration of the method specificity*
  - **Document range applicable concentrations*
  - **Document matrices used in validation*
- *If the test method in use does not meet the criteria listed above, there should be adequate justification and documentation to explain the reasons.*