**TO:** Joint Committee on GMP for Dietary Supplements

**FROM:** Freddie Agyin, Chair of the Joint Committee

**DATE:** February 23, 2024

**SUBJECT:** Proposed revision to NSF/ANSI 455-2 – *Good Manufacturing Practices for Dietary Supplements* (455-2i60r1)

Revision 1 of NSF/ANSI 455-2, issue 60 is being forwarded to the Joint Committee for consideration. Please review the proposal and **submit your ballot by March 15, 2024** via the NSF Online Workspace <https://standards.nsf.org/home>.

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 group requirements together that are related to reprocessing.

## Background

4.5.80 Moved to 4.5.69 so that it is grouped with other requirements pertaining to reprocessing. Also, added reference to 21 C.F.R.§ 111.535 (b4) which was originally 4.5.82 as it is more appropriate in this requirement.

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.]**

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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**4.5.67** Treatment or in-process adjustments of components, packaging and labeling, and reprocessing of a dietary supplement in an attempt to correct a deviation or unexpected event, or specification deficiency shall be approved by Quality personnel. [21 C.F.R. § 111.90(a1, b1), 21 C.F.R. § 111.113(b), 21 C.F.R. § 111.120(d), & 21 C.F.R. 111.130(c)]

**4.5.68** Reprocessing controls shall be established. [21 C.F.R. 111.20(c2), 21 C.F.R. 111.77(b, c), 21 C.F.R. 111.123(a5), & 21 C.F.R. § 111.90(a, b)]

**4.5.69** Reprocessed material shall meet its original specification. QC personnel shall determine the appropriate disposition of the material (release or reject). [21 C.F.R. § 111.90(c) & 21 C.F.R. § 111.525 & & 21 C.F.R. § 111.535 (b4)]

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~~**4.5.80** Any reprocessed material shall meet its original specification. QC personnel shall determine the appropriate disposition of the material (release or reject). [21 C.F.R. § 111.90(c) & 21 C.F.R. § 111.525]~~

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