



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 455-2ARG - *Audit Requirement Guidelines for Good Manufacturing Practices for Dietary Supplements* (455-2ARGi42r1)

Revision 1 of NSF 455-2ARG, issue 42 are 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 <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 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
Email: 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.]

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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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4.5.67 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)]

The suggested change above is NOT part of this ballot.

4.5.69.1 *Reprocessed materials, including returned goods, should be reviewed for specification compliance and dispositioned by Quality.*

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Commented [ER1]: This suggested change is 455-2i60r1. To vote or comment on this suggested change proceed to the 455-2i60r1 ballot at: <https://standards.nsf.org/higherlogic/ws/groups/db501a6e-2381-412f-a5c0-018976f9bc62/ballots/ballot?id=8850>

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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]~~

The suggested change above is NOT part of this ballot.

~~4.5.80.1 Reprocessed materials, including returned goods, should be reviewed for specification compliance and dispositioned by Quality.~~

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Commented [ER2]: This suggested change is 455-2i60r1. To vote or comment on this suggested change proceed to the 455-2i60r1 ballot at:
<https://standards.nsf.org/higherlogic/ws/groups/db501a6e-2381-412f-a5c0-018976f9bc62/ballots/ballot?id=8850>