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Joint Committee on GMP for Cosmetics

August 22, 2025

Proposed revision to the ARG for NSF/ANSI 455-3: 2024 – *Good Manufacturing Practices for Cosmetics* (455-3ARGi11r1)

Revision 1 of ARG for NSF/ANSI 455-3, issue 11 is being forwarded to the Joint Committee for consideration. Please review the proposal and **submit your ballot by September 12, 2025** via the NSF Online Workspace.

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.

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.

Purpose

The proposed revision will remove ARG guidelines, which are being balloted to add to the standard as requirements in 455-3i49r1.

Background

4.6.15 The 4.6.13.2 guidance in the ARG pertaining to documentation of adverse events is moved to the standard as a mandatory requirement to harmonize with new US regulatory reporting requirements.

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
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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 Nutrition and Wellness –

ARG for 455-3: Good Manufacturing Practices for Cosmetics

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4.6 Performance evaluation

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4.6.13~~4~~ ~~There is a system for investigating, reporting, and follow-up for complaints alleging adverse events involving bodily injury. [FD&C Act §§ 604(5), 605 and U.S. FDA Cosmetic GMP guidance]~~ Procedures for handling complaints includes provisions for investigation and if necessary, reporting of serious adverse events to the appropriate regulatory authority. [USC 364a Adverse events]

~~4.6.13.1~~ *~~Complaints alleging adverse events involving bodily injury are investigated and documented.~~*

~~4.6.13.2~~ *~~The document contains, at a minimum:~~*
~~— the kind and severity of each reported injury;~~
~~— the body part involved;~~
~~— product and code numbers;~~
~~— whether medical treatment was sought, and, if so, the nature of the medical treatment and the name of the attending physician or other healthcare professional;~~
~~— whether resolution of the event occurred, with or without long-term or persistent effects (If longterm or persistent effects occurred, the nature of those effects);~~
~~— the name(s) and location(s) of any poison control center, government agency, physicians' group, etc., to whom formula information and/or toxicity data has been provided; and~~
~~— serious adverse events are reported as required under Section 605 of the FD&C Act).~~

4.6.15 Records of adverse events shall include detailed information about the incident, at a minimum:
— description of the adverse event and outcome attributed to it;
— name and description of the product;
— determination if the event qualifies as a serious adverse event;

Commented [ER1]: This suggested change is 455-3i49r1. To vote or comment on this suggested change proceed to the 455-3i41r1 ballot at: https://standards.nsf.org/higherlogic/ws/groups/39fcca33-41ff-494a-926c-018976f9b955/ballots/ballot?id=9707

Please note that the number of this requirement has changed through 455-3i49r1. Any comments or negative votes based on the standard changes in this ballot will be considered non-germane. This is only an ARG ballot.

Commented [ER2]: This suggested change is 455-3i49r1. To vote or comment on this suggested change proceed to the 455-3i41r1 ballot at: https://standards.nsf.org/higherlogic/ws/groups/39fcca33-41ff-494a-926c-018976f9b955/ballots/ballot?id=9707

Please note that the number of this requirement has changed through 455-3i49r1. Any comments or negative votes based on the standard changes in this ballot will be considered non-germane. This is only an ARG ballot.

— investigation and resolution of the adverse event, and;
— the date serious adverse events are reported to the appropriate regulatory authority.