

Joint Committee on GMP for Cosmetics

August 22, 2025

## Proposed revision to NSF/ANSI 455-3 – *Good Manufacturing Practices for Cosmetics* (455-3i49r1)

Revision 1 of NSF/ANSI 455-3, issue 49 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.

## **Purpose**

The proposed revision will enhance the requirements' robustness and align them with MoCRA.

## Background

4.6.10 and 4.6.11 Added more details to the complaint procedures to make the requirement more robust.

4.6.14 MoCRA identified the safety of cosmetics as a primary concern and required mandatory reporting of serious adverse events (SAEs). The current language is updated, specifically mentioning SAEs.

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:

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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 Nutrition and Wellness –

## Good Manufacturing Practices for Cosmetics

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4.6 Performance evaluation

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- **4.6.10** Complaint procedures shall be established, and complaint records shall be maintained and include provisions for how product complaints will be received, investigated, documented.
- **4.6.11** Complaints shall be reviewed by a qualified person to determine if the complaint was the result of a failure of the cosmetic product to meet any of its specifications or quality parameters
- **4.6.12** The investigation for a product complaint is appropriately extended to other batches, products, processes, etc. [ISO 22716:2007 § 14.2.4]
- **4.6.13** Complaints are periodically reviewed for trends or recurrence of a defect. [ISO 22716:2007 § 14.2.5]
- **4.6.14** 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]
- 4.6.15 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;
- investigation and resolution of the adverse event, and;
- the date serious adverse events are reported to the appropriate regulatory authority.

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