JOINT COMMITTEE ISSUE PAPER

NSF Standard(s) Impacted: 455-3 and ARG

Purpose and Background:
Provide a one or two sentence statement explaining the purpose of your recommendation. Also please provide a brief background statement indicating the cause and nature of concern, the impacts identified relevant to public health, public understanding, etc., and any other reason why the issue should be considered by the Committee. Reference as appropriate any specific section(s) of the standard(s) that are related to the issue.

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 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.

Recommendation:
Clearly state what action is needed: e.g., recommended changes to the standard(s) including the current text of the relevant section(s) indicating deletions by use of ~~strike-out~~ and additions by highlighting or underlining; e.g., reference of the issue to a Task Group for detailed consideration, etc.

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]

~~***4.6.13.1*** *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;*~~

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~~— *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;
— investigation and resolution of the adverse event, and;
— the date serious adverse events are reported to the appropriate regulatory authority.
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Supplementary materials (photographs, diagrams, reports, etc.):
If not provided electronically, the submitter will be responsible to have sufficient copies to distribute to committee members.

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Is this a revision of a previous Issue Paper (if yes put original issue number): NA
Submission date: 7/17/2025

Please submit to: Joint Committee's Secretariat or to standards@nsf.org

**Type written name will suffice as signature*

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