JOINT COMMITTEE ISSUE PAPER

NSF Standard(s) Impacted: 455-3

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.

MoCRA identified safety of cosmetics as a primary concern and required mandatory reporting of SAE. I propose language clarifying AE documentation and reporting be moved from the ARG to the standard. Additionally, the standard does not currently reference SAEs and should directly refer to this class of AE to harmonize with new 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.

455-3 Edits

4.6 Performance evaluation

…

4.6.10 Complaint procedures shall be established~~, and complaint records shall be maintained~~ including provisions for how product complaints will be received, investigated, documented and, if necessary, reported to the appropriate authority as a serious adverse event.

4.6.11 The investigation for a product complaint is appropriately extended to other batches, products, processes, etc. [ISO 22716:2007 14.2.4]

4.6.12 Complaints are periodically reviewed for trend or recurrence of a defect. [ISO 22716:2007 14.2.5]

4.6.13 There is a system for documenting, investigating, reporting, and follow-up for complaints alleging adverse events and serious adverse events. [~~U.S. FDA Cosmetic GMP guidance~~ 21 USC 364a]

4.6.14 ~~The~~ Documentation for alleged adverse events 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 long term 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

Item #: 455-3i49 (gmpCOS-2025-3) & 455-3ARGi11)
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— the date serious adverse events are reported as required by the regulatory authority with jurisdiction over the market of distribution. ~~under Section 605 of the FD&C Act).~~

4.6.15 All product complaints shall be reviewed by a qualified person to determine if the complaint was the result of a failure of the cosmetic to meet any of its specifications or quality parameters.

455-3 ARG Edits

~~**4.6.13** 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]~~
~~***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).*~~

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: 3/21/2025

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

**Type written name will suffice as signature*

Item #: 455-3i49 (gmpCOS-2025-3) & 455-3ARGi11)
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