TO: Joint Committee on GMP for Over-the-Counter Drugs

FROM: Dan Klassen, Chair of the Joint Committee

DATE: February 24, 2020

SUBJECT: Proposed revision to NSF/ANSI 455-4 – Good Manufacturing Practices for Over-the-Counter Drugs (455-4i22r1)

Revision 1 of NSF/ANSI 455-4, issue 22 is being forwarded to the Joint Committee for consideration. Please review the proposal and submit your ballot by March 16, 2020 via the NSF Online Workspace <www.standards.nsf.org>.

When adding comments, please use the comment template provided in the ‘referenced items’ section of the ballot. Please be as detailed as possible and upload your comments as a Word file.

Purpose

The proposed revision will revise the harmonized section of the three GMP Standards.

Background

The goal of the standard is to reduce the number of audits a manufacturer will obtain throughout the year. Currently, the Clause 5.7.3 states for grades A, B and C, ‘If at the next certification audit, the company has not closed their minor nonconformance(s) the company has three months to submit objective evidence that said nonconformance(s) are closed or those minor(s) shall be elevated to major nonconformance(s). The CB shall require a monitoring audit to verify that the nonconformance(s) have been closed;’

A site will have 12 months (1 year) to correct and implement minor nonconformances from the initial audit. Upon Re-certification (next certification audit cycle) the infraction remains, the firm has 90 business days (3 months) from the last day of the audit to close out minor nonconformance(s) with objective evidence; giving the manufacturer 15 months (1 year and 3 months) to close the nonconformances. However, if the site remains negligent and does not provide objective evidence within 90 business days, the technical reviewer will upgrade the minor nonconformance to major nonconformance and have a monitoring audit. This clause allows the site to have 18 months (1 year and 6 months) to fix an escalated minor infraction from the initial audit.

There are several concerns about the way the standards are written:

1. According to the standard, all Certification Bodies must issue a report within 10 days of the audit. One major nonconformance can impact the score of the site, with an issuance of a new updated report will have to be issued with a new grade. The concern is two reports will be issued and manufacturers may utilize the report with the better grade to obtain business. The standard does not give the CB an opportunity to issue a report after the 90 business days (3 month) period has expired given the site the allotted time to issue one accurate report. Which is in violation of clause 5.6.1 below:
5.6.1 Complete audit report

At the conclusion of each audit, a written report is issued in the standardized format. The report shall be written in English. The report shall be translated to another language as appropriate to the user for a fee. The audit report provides the company and customers, existing or prospective, with an accurate view of the site quality systems and performance against the requirements of the Standard.

Due to the lingering NCs for the prior year, CBs do not have a way to issue an accurate report.

2. It prohibits the Certification Body (CB) to evaluate the risk of the minor nonconformance during the technical review based on the objective evidence provided by the auditor. Infractions could potentially cause a systemic issue which could pose a public health risk or product quality.

3. Clause 5.7.3 contradicts Clause 5.6.2 stating, ‘The technical reviewer evaluates the classification of the findings, confirms the findings as nonconformances, and consults with the auditor where further clarification is needed. Where multiple findings are reported within a single system element (e.g., training), the overall classification of that system element shall be raised (e.g., multiple minor nonconformances shall be grouped into a major nonconformance).’ If a repeat nonconformance is part of other minors in a multiple system, it could not be grouped within the single system element.

4. Regardless of a grade A or B, if the nonconformance is repeated the manufacturer automatically gets a monitoring audit bring a higher cost to the manufacturer. This should be at the discretion of the CB.

If you have any questions about the technical content of the ballot, you may contact me in care of:

Dan Klassen
Chair, Joint Committee on GMP for Over-the-Counter Drugs
c/o Rachel Brooker
Joint Committee Secretariat
NSF International
Tel: (734) 827-6866
Email: rbrooker@nsf.org
5.7.3 CB determines next steps

CB determines next steps based on the grade as described below:

— a site with a grade of A and zero nonconformances is eligible for certification;

— a site with a grade of A with only minor nonconformances shall submit a corrective action plan for all nonconformances. Once the plan is approved by the CB, the site is eligible for certification. The site shall correct the minor nonconformances prior to the next certification audit. The effectiveness of the corrective actions is reviewed at the next certification audit. If at the next certification audit, the company has not closed their minor nonconformance(s) the company has three months to submit objective evidence that said nonconformance(s) are closed or those minor(s) shall be elevated to major nonconformance(s). The CB shall require a monitoring audit to verify that the nonconformance(s) have been closed;

— a site with a grade of B shall submit a corrective action plan for all nonconformances. Corrective action against major nonconformances shall be closed with objective evidence to demonstrate the corrective action is in place and effective, before consideration for certification. A site with only minor nonconformances shall be considered for certification upon acceptance of the corrective action plan by the CB. The site shall close the minor conformances prior to the next certification audit. The
effectiveness of the corrective actions against minor nonconformances shall be reviewed at the next certification audit. If at the next certification audit, the company has not closed their minor nonconformance(s), the company has three months to submit objective evidence that said nonconformances are closed or those minor(s) elevate to major nonconformance(s). The CB shall require a monitoring audit to verify that the nonconformance(s) have been closed; and

— a site with a grade of C shall submit a corrective action plan for all nonconformances. A monitoring audit is required for grade of C. For a company who receives a grade of C in their initial certification audit, corrective action against major nonconformances shall be closed at the monitoring audit with objective evidence to demonstrate the corrective action is in place and effective, before consideration for certification. A company who has already received certification from a previous certification audit who receives a grade of C, does not lose their certification but shall have a monitoring audit prior to their next certification audit to verify that they have closed their major nonconformances. In both cases, the site is to close the minor conformances prior to the next certification audit. The effectiveness of the corrective actions against minor nonconformances is reviewed at the monitoring audit or the next certification audit. If at the next certification, the company has not closed their minor nonconformance(s) the company has three months to submit objective evidence that said nonconformances are closed or those minor(s) shall be elevated to major nonconformance(s). The CB shall require an additional monitoring audit to verify that the nonconformance(s) have been closed.

The CB shall determine and communicate any additional fees associated with a monitoring audit and related activities.

— a site with a grade of D is not eligible for certification. A new certification audit is required but before that can take place, the site shall submit a corrective action plan and show completion of the corrective actions.

Repeat nonconformances identified from the previous audit will be reviewed, evaluated, reported, and may be escalated based on the risk and severity. Technical reviewer shall review client’s submitted objective evidence to ensure the classification recommended will remain as initially issued during the audit or elevate the nonconformance. The CB shall require a monitoring audit for a grade of a C and may require a monitoring audit for a grade of an A or B.

* * *

Rationale: This revision will correct contradictions with other sections of the standard.