I Opening Remarks

Chairperson Angela Diesch welcomed everyone and called the meeting to order. Brooker read the antitrust statement and completed roll call.

II Review of Agenda

Diesch asked for any additions to the agenda but none were voiced.

**Motion**: Ella Riggs motioned to accept the proposed agenda.

**Seconded**: Casey Coy

**Objections**: None

**Abstentions**: None

**Vote by verbal affirmation**: None apposed.

Motion passed.

III Membership Review

Brooker informed the group that JC with 3 Industry, 3 Users, and 2 Public Health (PH) members. She noted that the group is critically low on the amount PH but could use more of all categories. She noted that it is imperative that this group adds PH. Brooker requested that anyone who knows of any person or company/organization that would be an asset to this JC to please contact her after the meeting.

IV Standard Issue Papers

A. Issue 15 Section 4.5 (gmpCos-2019-1)

**Discussion**: Barbara Raji explained that this proposal was to harmonize to the 455-2 and 455-4 standards. They both have this statement, but cosmetics does not include this statement.

**Motion**: Tim Parent motioned to go to ballot.

**Seconded**: Coy

**Objections**: None

**Abstentions**: None

**Vote by verbal affirmation**: None apposed.

Motion passed.

B. Issue 16 Section 4.1.8 (gmpCos-2019-2)

**Discussion**: Raji presented that 4.1.7 and 4.1.8 were the same exact requirements and this proposal was to rectify this problem.
Motion: Coy motioned to go to ballot.
Seconded: Riggs
Objections: None
Abstentions: None
Vote by verbal affirmation: None apposed.
Motion passed.

C. Issue 17 Section 4.4.37 (gmpCos-2019-3)

Discussion: Raji explained that this proposal was to come into alignment with ISO 22716 and that it was also very similar to 455-2 and 455-4.

Motion: Fritz motioned to create a TG to discuss how to define and/or quantify this requirement.
Seconded: Finamore
Objections: None
Abstentions: None
Vote by verbal affirmation: None apposed.
Motion passed.

D. Issue 18 Section 4.5.41 (gmpCos-2019-4)

Discussion: Coy questioned if the this proposal is in alignment with ISO 22716. Raiji responded that this will make the language closer to ISO 22716.

Original:

4.5.41 On-line control equipment is checked, verified or calibrated, or both, according to a defined program. Procedures and program shall be established maintaining and calibrating equipment. [ISO 22716:2007 7.3.5]

New:

4.5.41 On-line control equipment is checked, verified or calibrated, or both, according to a defined program. Procedures and program shall be established maintaining and calibrating equipment to include online controls. [ISO 22716:2007 7.3.5]

Motion: Riggs motioned to ballot the new language above.
Seconded: Harry Bennett
Objections: None
Abstentions: None
Vote by verbal affirmation: None apposed.
Motion passed.

E. Issue 19 Section 4.6.10 (gmpCos-2019-5)

Discussion: There was much conversation questioning if this requirement should require verifying the procedure or if it is verifying the actual cleaning. The consensus was to change the language as stated below.

Original:
4.6.10 Procedures have been established for the cleaning and sanitization of all utensils and equipment. Cleaning validation studies have been completed for product contact parts and equipment. [21 CFR § 211.67] Procedures have been established for cleaning and sanitization of all utensils and equipment. [ISO 22716:2007 5.3.1]

New:

4.6.10 Procedures have been established for the cleaning and sanitization of all utensils and equipment. Cleaning validation studies have been completed for product contact parts and equipment. [21 CFR § 211.67] Procedures have been established for cleaning and sanitization, including verification and documentation thereof, of all utensils and equipment. [ISO 22716:2007 5.3.1]

**Motion:** Riggs motioned to ballot the new language above.
**Seconded:** Coy
**Objections:** None
**Abstentions:** None
**Vote by verbal affirmation:** None apposed.
Motion passed.

F. Issue 20 Section 4.6.19 (gmpCos-2019-6)

**Motion:** Bennett motioned to ballot.
**Seconded:** Riggs
**Objections:** None
**Abstentions:** None
**Vote by verbal affirmation:** None apposed.
Motion passed.

V **Tri-JC Issue Papers**

Brooker informed the new attendees that there are sections within this standard that are identical in all 455 standards and that if there are any changes proposed to those sections that change must be discussed and balloted by all 455 JCs. She explained that anything that is discussed at this meeting will then be brought up to the other JC meetings this week. If they agree to the same things that this JC agrees to we can move forward but if there are any comment, concerns, or changes then there will have to be a tri-JC teleconference to discuss.

A. Issue 1 Section 5.7.3 Scenario 1 (455MJC-2019-1)

**Discussion:** Brooker reported that both the JCs on GMP for dietary supplements and OTC already discussed this issue paper and agreed to go to ballot with the change of “…auditor’s submitted objective….” to “…client’s submitted objective….”

**Motion:** Bennett motioned to ballot the issue paper with the above edit.
**Seconded:** Coy
**Objections:** None
**Abstentions:** None
**Vote by verbal affirmation:** None apposed.
Motion passed.
B. Issue 2 Section 5.7.3 Scenario 2 (455MJC-2019-2)

Discussion: Raiji officially withdrew this issue paper since it was only created if the JC did not approve of issue 1.

C. Issue 3 Section 5.3.3 (455MJC-2019-3)

Discussion: Raiji also officially withdrew this issue paper since it was only created if the JC did not approve of issue 1 but did approve of issue 2.

D. Issue 4 Renumbering (455MJC-2019-4)

Discussion: Coy had some objections to this change stating that the reason the standards were structured the way they are is because all three JCs agreed to follow the structure of ISO 9001:2015. Raiji justified her proposed change because it was more logical on how an auditor would actually conduct an audit but Coy countered that the standards should stay in the same format and that the auditor always has his/her own checklist that he/she can order in any way he/she sees fit. Brooker noted that she will organize a tri-JC meeting to discuss this.

VI New Business & Next Meeting

Diesch asked if there was any new business, and it was noted that 4.5.24.2 and 4.5.24.2 were in conflict. After some discussion the group decided to:

4.5.28.4 – Remove the word “optional” but keep the rest of the statement
4.5.37.4– Remove the word “optional” but keep the rest of the statement
4.6.18.3 – remove

Brooker stated that she will organize a tri-JC meeting in September.

This group has a standing date of the first full week of August. There has been no objection to this date so it continues to stand.

VII Adjournment

Motion: Coy motioned to adjourn the meeting.
Seconded: Parrent
Objections: None
Abstentions: None
Vote by verbal affirmation: None apposed.
Motion Passed
### Meeting Attendance

<table>
<thead>
<tr>
<th>Company</th>
<th>Name</th>
<th>Interest Category</th>
<th>Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rutgers</td>
<td>Harry Bennett</td>
<td>Public Health / Regulatory</td>
<td>Member</td>
</tr>
<tr>
<td>NSF International</td>
<td>Casey Coy</td>
<td>User</td>
<td>Vice chair</td>
</tr>
<tr>
<td>Diesch Forrest, APC</td>
<td>Angela Diesch</td>
<td>General Interest</td>
<td>Joint Committee Chair</td>
</tr>
<tr>
<td>HEB</td>
<td>Debra Elton (by proxy)</td>
<td>User</td>
<td>Member</td>
</tr>
<tr>
<td>Whole Foods Market</td>
<td>Ella Riggs</td>
<td>User</td>
<td>Member</td>
</tr>
<tr>
<td>First Quality</td>
<td>Christopher Terpak</td>
<td>Industry</td>
<td>Member</td>
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