Standard 6 – Minnesota’s Approach

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Snapshot of our written program

- 1 Policy
- 1 Progressive Enforcement Continuum
- 1 Progressive Enforcement Matrix
- 2 SOPs for performance review
- 4 SOPs that include field compliance
- 8 SOPs for enforcement actions
Defining the Terms

Critical Violation

A Critical Violation is a Major Violation as defined by Minn. Stat. § 28A.03 Subd.9 and includes violations of Minn. Stat. §§ 31.121, 31.123, 31.161, 31.165, 31.02, 34A.04 Subd.1, 34A.05, and 34A.11 Subd.1. For the applicable parts of 21 CFR, critical violations are violations which are directly linked to public health risk, food adulteration, and/or known contributors to foodborne illness and are identified as critical violations in USA Food Safety (USAFS) unless otherwise defined by the Manufactured Food Program.
Deﬁning the Terms

Chronic Violation (aka Repeat Violation)
A chronic violation is a speciﬁc violation observed and documented during at least two (2) inspections in a row, and/or from one (1) routine inspection to the next routine inspection, also known as a repeat violation.
Defining the Terms

Chronic Violator

A chronic violator is a legal entity that has an approved enforcement action equal to or greater than a Warning Letter and that has had a prior enforcement action equal to or greater than a Warning Letter issued in the last three (3) years.
Performance Review

• 2 types of audits:
  – Enforcement Cases
  – Field Compliance Actions

• Audit all or some?
  – Utilize the ‘statistical approach’ option (Appendix 6.2a)
  – 20 cases and actions audited each quarter
Performance Review

• Audit forms filled out and saved on SharePoint

• Each question answered based on:

<table>
<thead>
<tr>
<th>Point Scale:</th>
<th>Requirement Met (0, 1, 2)</th>
<th>Weight Multiplier (Choose 0 if Enforcement Activity not applicable to the case)</th>
<th>Points Scored</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 (Does not meet requirements)</td>
<td>2</td>
<td>5 (5)</td>
<td>10</td>
</tr>
<tr>
<td>1 (Partially meets requirements)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 (Fully meets requirements)</td>
<td></td>
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• Score is auto-calculated and overall result manually entered into Appendix 6.2 (Excel spreadsheet)
Questions?