Arizona’s ISO 17025:2017 Experience

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1:00 PM
Preparation – 2017 standard

• Checked AB website for updates constantly
• Full review to determine changes needed
  – Highlighted new items like Decision Rule, Risk, impartiality and confidentiality
• Updated Management Review SOP/Meeting
  – Ensure meeting new requirements
    • Checklist impartiality/confidentiality
    • Added Risk to list of updates required
Preparation – Adding Discipline

• Due to opioid crisis, ASPHL added Toxicology testing in forensic samples
  – Requested AB to do at same time as food
  – Thought it would be simple
  – Testing personnel were same or similar for Toxicology and Food Chemistry
  – Additional requirements which were also being updated to 2017 standard
During Inspection

• Reviews and discussions
  – Uncertainty
    • Previously qualitative was not required to have
      – Or so we thought and had written in SOP
  – Personnel/Training
    • Current process was general, needed more specificity
  – Traceability
    • More specificity required
Findings

• Total number – 13
  – Food – 6
  – Forensic – 7
  – Similar findings – 2

• Main themes
  – Traceability
  – Uncertainty
  – Final reports
  – Control charting
  – Complaints – reported back by someone not involved
  – Criminal law/civil law/testimony – review process and training
## Cross walk to responses

<table>
<thead>
<tr>
<th>ShareFile Folder #</th>
<th>Lab (Food) Finding #</th>
<th>Forensic Finding</th>
<th>ASPHL CAR #</th>
<th>Response to Jana (Forensic)</th>
<th>Uploaded to Sharefile Date</th>
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</thead>
<tbody>
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<td>1</td>
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<td>NA</td>
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<tr>
<td>3</td>
<td>3</td>
<td>7.6.3, 7.6.3.1, 7.6.4</td>
<td>MISC-2019-003</td>
<td>Effective date of 08.30.2019 allows ASPHL time to review further and add any additional language that may strengthen the SOP, QA-032. In addition it allows staff the opportunity to review and provide feedback on any section that may be confusing or unclear. Updated SOP draft to put a scheduled frequency.</td>
<td>7/11/2019</td>
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<tr>
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<td>7.8.2.1, 7.8.8.1</td>
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<tr>
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<td>NA</td>
<td>6.2.2.2, 7.7.1</td>
<td>MISC-2019-002</td>
<td>Added language to draft SOP QA-031 to indicate that if no currently trained employees, the assigned reviewer will need to go through the training prior to review, see page 4 of the draft.</td>
<td>7/11/2019</td>
</tr>
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</table>
Fun Facts

• Avoid two completely different ISO audits at the same time
  – Minimizes stress on staff
  – Makes it easier to respond

• The following seem to always come up:
  – Uncertainty
  – Traceability
  – Management Review
Contact Information

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