

## SQF Edition 8.1 Quality Code Changes

Location	Edition 8.1	Changes
<b>Part A, section 4.2</b>	Removed requirement for surveillance audits	No surveillance audit required
<b>Part A, section 2.3</b>	Change to site audit	Updated terminology
<b>System Elements 2.1.2.2</b>	<p>Ed. 8.0: The senior site management shall develop quality objectives and a process and methods by which quality performance is measured.</p> <p>Ed. 8.1: The reporting structure shall identify personnel performing key process steps and responsible for achieving quality objectives.</p>	Included reference to methods
<b>2.1.2.5 iii</b>	<p>Ed. 8.0: Be competent in statistical process control (SPC) and/or other quality tools to reduce process variation and drive root cause analysis of non-conformities.</p> <p>Ed. 8.1: Be competent in the appropriate application of or the quality tools (e.g. control charts, histograms etc.) used to meet customer requirements and specifications.</p>	Removed specific reference to SPC and more about quality tool use and competency
<b>2.1.3.1</b>	<p>Ed. 8.0: The senior site management shall be responsible for reviewing the SQF Quality System and ensuring that it includes:</p> <ul style="list-style-type: none"> <li>i. Monitoring of compliance to specifications and corrective actions taken;</li> <li>ii. Reduction and measurement of process and product variation;</li> <li>iii. Meeting customer requirements;</li> <li>iv. Sufficient resources are allocated to maintain and improve the performance of the SQF Quality System.</li> </ul> <p>Ed. 8.1: Senior site management shall be responsible for reviewing the SQF Quality System. Reviews shall include actions required to:</p> <ul style="list-style-type: none"> <li>i. Monitor compliance to specifications;</li> </ul>	Streamlined wording to emphasize requirements for senior management on reviewing the SQF Quality System

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	<ul style="list-style-type: none"> <li>ii. Measure and reduce process and product variation;</li> <li>iii. Meet customer requirements;</li> <li>iv. Take appropriate corrective action where applicable, and</li> <li>v. Ensure sufficient resources are allocated to maintain and improve the performance of the Quality System.</li> </ul>	
<b>2.2.1.1 v.</b>	<p>Ed. 8.0: v. Statistical tools and other quality tools that are used to control and reduce process variation.</p> <p>Ed. 8.1: Removed</p>	Removed reference to statistical process and modified to add statistical tools
<b>2.4.4.2 iii</b>	<p>Ed. 8.0: Be certified to a second or third party quality management system; and</p> <p>Ed. 8.1: Provide evidence that supplied product meets agreed specifications; and</p>	Removed prescriptive requirements for supplier certification
<b>2.4.5.1</b>	<p>Ed. 8.0: Non-conforming product shall include products that fail to meet quality specifications.</p> <p>Ed. 8.1: Non-conforming product shall include products that fail to meet in-process or product requirements for quality.</p>	Changed the use of "quality specification" not inclusive of in-process holds assumed only finished products

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<p><b>2.4.5.2</b></p>	<p>Ed. 8.0: Non-conforming equipment shall include equipment that is not suitable for use and is not capable of producing products that meet quality specification.</p> <p>Ed. 8.1: Non-conforming equipment shall include equipment that is not suitable for use and is not capable of producing products that meet in-process or product requirements for quality.</p>	<p>Changed the use of "quality specification" not inclusive of in-process holds assumed only finished products</p>
<p><b>2.5.3.2</b></p>	<p>Ed. 8.0: Verification activities shall include a comparison of process control limits (+/-) with specification limits to ensure alignment and appropriate process control corrections.</p> <p>Ed. 8.1: Verification activities shall include a comparison of process control limit with specification limits to ensure alignment and appropriate process control corrections. (added to 2.5.2 &amp; old 2.5.3.2 changed to 2.5.2.3)</p>	<p>Removed the reference to +/- 3 sigma, use process capability term and move under verification activities as is a better fit than CAPA</p>
<p><b>2.5.4.3</b></p>	<p>Ed. 8.0: Statistical process control methods shall be used to effectively control and optimize production processes to improve process efficiency and product quality and reduce waste. Control charts shall be in use for control of key processes and have defined upper and lower (process) control limits (+/-).</p> <p>Ed. 8.1: Process control methods shall be used to effectively control and optimize production processes to improve process efficiency and product quality and reduce waste. Control charts and/or other quality tools shall be in use for control of key processes.</p>	<p>Removed the word statistical</p>
<p><b>2.8.1.7</b></p>	<p>Ed. 8.0: The identity preserved status shall be declared in accordance with legal requirements.</p> <p>Ed. 8.1: The identity preserved status shall be declared in accordance with regulatory requirements.</p>	<p>Added regulatory to requirement</p>

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<b>2.9.2.2</b>	<p>Ed. 8.0: The employee training program shall include applicable statistical tools training for line operators, quality inspectors and supervisory staff responsible for operating and inspecting key manufacturing processes.</p> <p>Ed. 8.1: The employee training program shall include applicable process control and quality tools training for line operators, quality inspectors and supervisory staff responsible for operating and inspecting key manufacturing processes.</p>	Removed the reference to statistical and replaced with process control and quality tools
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