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VARIATION MANAGEMENT OF KEY CHARACTERISTICS

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Abstract:

This document describes the process for variation management of key characteristics.

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DOCUMENT CHANGE RECORD

Issue	Item	Reason for Change

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1.0 Scope

This procedure shall be applicable to all production processes that influence the variation of Key Characteristics. This procedure applies to [REDACTED]

2.0 Applicable Documents

[REDACTED]

3.0 Requirements

3.1 Variation management activities must be performed on identified Key Characteristics and processes [REDACTED] to ensure continued performance.

3.2 Appropriate documentation of Key Characteristics and manufacturing process elements that influence variation in Key Characteristics shall [REDACTED] be developed when any of the following occurs:

- a. [REDACTED]
- b. [REDACTED]
- c. [REDACTED]

3.3 The following requirements must be met if statistical process control is chosen as the method of control for the Key Characteristic:

- a. [REDACTED]
- b. [REDACTED]
- c. [REDACTED]

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[Redacted]

d. [Redacted]

e. [Redacted]

3.4 The use of other variation control methods to ensure process stability and capability may [Redacted]

3.5 Achieving stable and capable Key Characteristics does not [Redacted]

3.6 Exceptions shall be documented and may require [Redacted]

3.7 Process Model
The management of Key Characteristics shall begin with [Redacted] to control the variation of Key Characteristics; however, compliance shall be [Redacted]

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APPENDIX A: Variation Management of Key Characteristics

1.0 Understand Key Characteristics and Required Performance

1.1 Establish an appropriate cross-functional team that has [REDACTED] (if any).

1.2 Document Key Characteristics and their required performance on the [REDACTED]

1.3 Outputs from the review of key characteristics and their required performance

- [REDACTED]

Note:

Key Characteristics [REDACTED] should [REDACTED]

2.0 Plan a Manufacturing Process to Produce Acceptable Performance

2.1 Define the affected manufacturing process [REDACTED] that influence variation of Key Characteristics. Consider [REDACTED]

2.2 Perform cause and effect analysis to identify any process Key Characteristics. If substitute Key Characteristics are used, [REDACTED] Establish a minimum acceptable [REDACTED]

2.3 Identify a Process Owner for each Key Characteristic. The Process Owner shall [REDACTED]

2.4 Conduct a disciplined review of each process generating Key Characteristics to identify [REDACTED]

2.5 Develop detailed work instructions and measurement instructions to manage [REDACTED]

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2.6 [REDACTED]
(see Appendix B).

2.7 Outputs from planning the manufacturing process

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

Note:

Without the foresight necessary to design a process that is capable of meeting [REDACTED], the level of variation that is inherent in a process design may become [REDACTED] that impedes [REDACTED] and the cost [REDACTED]

3.0 Operate the Process on a Trial-Basis to Generate Data

3.1 Create a data collection plan for all Key Characteristics that reflects [REDACTED] [REDACTED] Specify who, what, where, and how [REDACTED] and under what conditions [REDACTED] and the frequency of data collection. Determine the type of control chart to be used.

3.2 Manufacture parts according to [REDACTED] [REDACTED] in a representative production environment.

3.3 Collect data on control charts according to [REDACTED] [REDACTED]

3.4 Perform a first [REDACTED]

3.5 Update the [REDACTED] as required.

3.6 Outputs from operating the process on a trial-basis

- [REDACTED]
- [REDACTED]
- [REDACTED]

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Note:

Operate the process and ensure the method to collect data [REDACTED] is relevant to the Key Characteristic. Later analysis of data could [REDACTED] on a trial basis.

4.0 Analyze Data to Identify Appropriate Action

4.1 Review control charts to determine if the process [REDACTED] capability index (e.g., Cp. and Cpk.) shall be calculated only when [REDACTED]

4.2 Investigate to determine the root cause using suitable problem resolution tools if the process is not stable, and document the results of the investigation.

4.3 Prioritize common cause sources of variation to identify [REDACTED]. Perform subsequent investigation(s) to determine root cause(s) of variability. Take no further action on the process and finalize [REDACTED] if [REDACTED].

4.4 Reevaluate Process Key Characteristics based on the understanding of the observed process behavior to determine [REDACTED]

4.5 Update the [REDACTED] and include references to [REDACTED]

4.6 Outputs from analysis of data

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

Note:

Informed decision based upon objective information can [REDACTED]

5.0 Take Action from Studying the Performance of Key Characteristics

5.1 Take corrective action to permanently remove or minimize [REDACTED] when a process is not [REDACTED]

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5.2 Investigate gage variation when [redacted] and verify the results if [redacted]

5.3 Investigate centering of the process if [redacted]

5.4 Take appropriate actions on sources of variation that influence [redacted]

5.5 Implement a Product/Process protection plan until such time [redacted] after performing [redacted]

5.6 A first article inspection (FAI) may be performed unless [redacted]

5.7 Take appropriate action whenever actions are taken that change the [redacted]

5.8 Finalize the [redacted] as soon as [redacted]

5.9 Outputs from study of the performance of Key Characteristics

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

Note:
Act upon information [redacted] that could introduce [redacted]

6.0 Continue to Monitor the Performance

6.1 Periodically verify that the process [redacted] after a Key Characteristic meets [redacted] Continue to measure process performance to identify [redacted]

6.2 Continually review business indicators as appropriate to ensure [redacted] which may result in [redacted] and adding [redacted]

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6.3 Outputs from continuing to monitor the process

- [REDACTED]
- [REDACTED]
- [REDACTED]

Note:

Understanding the performance of a continuous process is [REDACTED]
[REDACTED] is detrimental to [REDACTED]

7.0 Process Change Management

7.1 Document any planned change [REDACTED]

7.2 Follow the requirements of paragraph 1.0 to 5.0 prior to implementing [REDACTED]
[REDACTED] as related to the affected
Key Characteristics.

7.3 Outputs from process change management

- [REDACTED]
- [REDACTED]

Note:

Decisions must be substantiated with data [REDACTED]
[REDACTED] if the process [REDACTED]

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APPENDIX B: Process Control Document

Note: Any equivalent method of documentation is acceptable.

Instructions for completing the form:

1. [Redacted]
2. [Redacted]
3. [Redacted]
4. [Redacted]
5. [Redacted]
6. [Redacted]
7. [Redacted]
8. [Redacted]
9. [Redacted]
10. [Redacted]

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11. [Redacted]
12. [Redacted]
13. [Redacted]
14. [Redacted]
15. [Redacted]
16. [Redacted]
17. [Redacted]
18. [Redacted]
19. [Redacted]
20. [Redacted]
21. [Redacted]
22. [Redacted]
23. [Redacted]
24. [Redacted]

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- 25. [Redacted]
- 26. [Redacted]
- 27. [Redacted]
- 28. [Redacted]
- 29. [Redacted]
- 30. [Redacted]
- 31. [Redacted]
- 32. [Redacted]
- 33. [Redacted]

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APPENDIX C

Definitions

ATTRIBUTE DATA

[Redacted]

CUSTOMER

[Redacted]

DESIGN CHARACTERISTICS

[Redacted]

DRAWING REQUIREMENTS

[Redacted]

EXAMPLE

[Redacted]

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FIRST ARTICLE INSPECTION (FAI)

[Redacted]

FIRST ARTICLE INSPECTION REPORT (FAIR)

[Redacted]

FIRST PRODUCTION RUN PARTS

[Redacted]

KEY CHARACTERISTIC (KC):

[Redacted]

This definition is further explained as follows:

- [Redacted]
- [Redacted]
- [Redacted]

KEY CHARACTERISTIC OWNER

[Redacted]

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[Redacted]

KEY CHARACTERISTIC PROCESS OWNER

[Redacted]

MULTIPLE CHARACTERISTICS

[Redacted]

MUST

[Redacted]

PROCESS CONTROL DOCUMENT (PCD)

[Redacted]

PRODUCER

[Redacted]

PRODUCT

[Redacted]

REFERENCE CHARACTERISTICS

[Redacted]

SHALL

[Redacted]

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SHOULD

[Redacted]

SPECIAL CAUSE

[Redacted]

STANDARD CATALOG HARDWARE

[Redacted]

TYPICAL

[Redacted]

VARIABLES DATA

[Redacted]

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