Chapter 38

Control Plan, Poka-Yoke, Realistic Tolerancing, and Project Completion

Introduction

• A control plan that documents the control mechanism as mistake-proof as possible.
• Tracking of KPIVs is at the 50-foot level. This control chart tracking involves frequent sampling and reporting such that changes to input levels are quickly detected. Timely corrective action can then be made following the procedure described in the reaction plan section of the control plan.
• This chapter discusses control plans, error-proofing, realistic tolerances, and $S^4$/IEE project completion.
38.1 Control Plan: Overview

- A control plan is a written document created to ensure that processes are run so that products or services meet or exceed customer requirements at all times. It should be a living document that is updated with both additions and deletions of controls based on experience from the process.
- A control plan is an extension of the control column of an FMEA. The FMEA is an important source for the identification of KPIVs that are included within a control plan.
- Other sources for the identification of KPIVs are process maps, cause-and-effect matrices, multi-vari studies, regression analysis, DOE, and S4/IEE project execution findings.

38.1 Control Plan: Overview

- A control plan offers a systematic approach to finding and resolving out-of-control conditions. It offers a troubleshooting guide for operators through its documented reaction plan. A good control plan strategy should reduce process tampering, provide a vehicle for the initiation/implementation of process improvement activities, describe the training needs for standard operating procedures, and document maintenance schedule requirements.
- Control plans should be created from the knowledge gained from other S4/IEE phases and use not only control charts but also error-proofing.
38.1 Control Plan: Overview

- KPIVs considerations should include monitoring procedures, frequency of verification, and selection of optimum targets/specifications.
- Uncontrollable noise inputs considerations should include their identification, control procedures, and robustness of the system to the noise.
- Standard operating procedure (SOP) issues include documentation, ease-of-use, applicability, utilization, updating, and training.
- Maintenance procedure issues include identification of critical components, scheduling frequency, responsibility, training, and availability of instructions.

38.1 Control Plan: Overview

- AIAG (1995a) lists three types of control plans: prototype, pre-launch, and production.
- A prototype control plan is a description of measurements, material, and performance tests that are to occur during the building of prototypes.
- A pre-launch control plan is a description of measurements, material, and performance tests that are to occur after prototype and before normal production.
- A production control plan is a comprehensive documentation of product/process characteristics, process controls, tests, and measurement systems occurring during normal production.
38.2 Control Plan: Entries

- Control plans should be available electronically within the organization. Companies often tailor control plans to address their specific needs.
- Categories that AIAG (1995a) includes in a control plan are noted below. The general control plan layout is shown in Table 38.1, where the term characteristics in the table means a distinguishing feature, dimension, or property of a process or its output (product) on which variable or attribute data can be collected.

Header Information

1. Control plan type: Prototype, pre-launch, production.
2. Control plan number: A tracking number, if applicable.
3. Part number/latest change: Number to describe the system, subsystem or component that is to be controlled, along with any revision number.
4. Part name or description: Name and description of the product or process that is to be controlled.
5. Supplier/plant: Name of company and appropriate division, plant, or department that is preparing the control plan.
7. Key contact and phone: Name and contact information for primary person who is responsible for control plan.
### 38.2 Control Plan: Entries

**Header Information**

8. Core team: Names and contact information for those responsible for preparing the control plan and its latest revision.

9. Supplier/plant approval date: If required, obtain approval from responsible facility.

10. Date (original): Date the original control plan was compiled.

11. Date (revision): Date of latest update to the control plan.

12. Customer engineering approval and date: If required, obtain the approval of the responsible engineer.

13. Customer quality approval and date: If required, obtain approval of supplier quality representative.

14. Other approvals and dates: If required, obtain approvals.

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**Line-by-Line Items**

15. Part or process number: Usually referenced from process flowchart. When there are multiple assembled parts, list individual part numbers.

16. Process name/operation description: All steps in the manufacturing of a system, subsystem, or component, which are described in a process flow diagram. This line entry contains the process/operation name that best describes the activity that is addressed.

17. Machine, device, jig, tools for manufacturing: Identification of the processing equipment for each described operation; e.g., machine, device, jig, or other tools for manufacturing.
18. Number characteristic: Cross-reference number from which all applicable documents can be referenced; e.g., FMEA.
19. Product characteristic: Features or properties of a part component, or assembly that are described on drawings or other primary engineering information. All special characteristics need to be listed in the control plan, while other product characteristics for which process controls are routinely tracked during normal operations may be listed.

20. Process characteristic: Process characteristics are the process input variables that have a cause-and-effect relationship with the identified product characteristics. A process characteristic can only be measured at the time it occurs. The core team should identify process characteristics for which variation must be controlled to minimize product variation. There could be one or more process characteristics listed for each product characteristic. In some processes one process characteristic may affect several product characteristics.

21. Special characteristic classification: Customers may use unique symbols to identify important characteristics such as those affecting safety, compliance with regulations, function, fit, or appearance. These characteristics can be determined, for example, critical, key, safety, or significant.
38.2 Control Plan: Entries

22. Product/process specification/tolerance: Sources can include various engineering documents such as drawings, design reviews, material standard, computer-aided design data, manufacturing, and/or assembly requirements.

23. Evaluation/measurement technique: Identifies measurement system that is used. Could include gages, fixtures, tools, and/or test equipment that is required to measure the part/process/manufacturing equipment. An analysis of linearity, reproducibility, repeatability, stability, and accuracy of the measurement system should be completed prior to relying on a measurement system, where improvements are made as applicable.

24. Sample size and frequency: Identifies sample size and frequency when sampling is required.

25. Control method: Contains a brief description of how the operation will be controlled, including applicable procedure numbers. The described control method should be based on the type of process and an effective analysis of the process. Example operational controls are SPC, inspection, mistake-proofing, and sampling plans. Descriptions should reflect the planning and strategy that is being implemented in the process. Elaborate control procedures typically reference a procedure or procedure number. Control methods should be continually evaluated for their effectiveness in controlling the process. Significant changes in the process or its capability/performance should lead to an evaluation of the control method.
38.2 Control Plan: Entries

26. Reaction plan: Specifies the corrective actions that are necessary to avoid producing nonconforming products or operating out of control (having an unpredictable process). The people closest to the process should normally be responsible for the actions. This could be the operator, jobsetter, or supervisor, which is clearly designated in the plan. Provisions should be made for documenting reactions. Suspect and nonconforming products must be clearly identified and quarantined, and disposition made by the responsible person who is designated in the reaction plan. Sometimes this column will make reference to a specific reaction plan number identifying the responsible person.

38.2 Control Plan: Entries

A control plan checklist is given below (AIAG 1995a). Any negative comment is to have an associated comment and/or action required along with responsible part and due date.

1. Were the above control plan methods used in preparing the control plan?
2. Have all known customer concerns been identified to facilitate the selection of special product/process characteristics?
3. Are all special product/process characteristics included in the control plan?
4. Were the appropriate FMEA techniques used to prepare the control plan?
5. Are material specifications that require inspection identified?
38.2 Control Plan: Entries

6. Are incoming material and component packaging issues addressed?
7. Are engineering performance-testing requirements identified?
8. Are required gages and test equipment available?
9. If required, has there been customer approval?
10. Are gage methods compatible between supplier and customer?

38.3 Poka-Yoke

- A poka-yoke device is a mechanism that either prevents a mistake from occurring or makes a mistake obvious at a glance.
- As an industrial engineer at Toyota, Shigeo Shingo was credited with creating and formalizing zero quality control (ZQC), an approach that relies heavily on poka-yoke (mistake-proofing or error-proofing).
Lean Tools – Mistake-proofing (Poka-yoke system)

• To avoid inadvertent errors
• Poka-yoke device is any mechanism that either prevents a mistake from being made or makes the mistake obvious at a glance
  – Be inexpensive
  – Be easy to use
  – Be able to effectively prevent or significantly reduce the possibility of mistakes being made
38.4 Realistic Tolerances

- We can track process inputs through automation or manual techniques. This tracking can involve monitoring or control. Often we monitor KPOVs only because we are unable to control process inputs. When we can control KPIV characteristics, we can predict output capability/performance. Hence, we can control the process through these inputs.

- When the KPIV-to-KPOV relationship is understood, the establishment of optimum levels for KPIVs can be accomplished through the following approach:
  1. Identify the target and specification for a critical KPOV.
  2. Select from previous S^4/IEE activities KPIVs that have been shown to affect the KPOV.

3. Explain what has been learned from previous S^4/IEE activities (e.g., the DOE activities) about the levels of each KPIV that are thought to yield an optimum KPOV response.

4. Plot the relationship between each KPIV and the KPOV on an x-y plot describing not only the best-fit line but also the 95% prediction interval bounds. An approach to do this is to create 30 samples over the range of the KPIVs thought to optimize the KPOV. Plot then the relationship of each KPIV to the KPOV using statistical software to determine the 95% prediction bounds for individual points. When creating these relationships, consider not only the effect from each KPIV but also the simultaneous impact of other KPIVs.
38.4 Realistic Tolerances

5. Draw two parallel lines horizontally from the specification bounds of the KPOV to the upper and lower prediction limits.
6. Draw two parallel lines vertically from the intersection of the previously drawn lines and the prediction limits.
7. Determine the maximum tolerance permitted for each KPIV by observing the x-axis intersection points of the two vertical lines.
8. Compare the determined KPIV tolerance to existing operating levels.
9. Implement changes to the standard operating procedures as required,
10. documenting changes in the FMEA and control plan.

38.5 Project Completion

• Before a project is complete, the process owner needs to agree to the conclusions of the S³/IEE project and be willing to take over any responsibilities resulting from the project.
• One approach to accomplish this transfer is for the black belt to schedule and then lead a project turnover meeting. If the project owner accepts the project, the black belt works with the owner to finalize the presentation slides. The process owner and project team then presents the results. However, if the process owner rejects the project results/conclusions, the process owner, black belt, and champion need to discuss the project. If they agree to continue the project, agreement needs to be reach as to what specifics need to be addressed within the DMAIC procedure.
38.5 Project Completion

Other items that need to be addressed are:

• To maximize gains, a process needs to be established that leverages the results of a project to other areas of the business. A communication process needs to be established between organizations.

• Organizations need to encourage the documentation of projects such that others can understand and use the information learned. A repository needs to be established for storing project information such that others can easily search and learn from the project findings.

• Organizations need to check after some period of time to ensure that project gains are sustained after the project is completed.

38.6 S^4/IEE Assessment

• S^4/IEE complements the traditional approach that creates control plans.

• Processes that are well established and have no problems using their existing control procedures would not be good S^4/IEE project candidates.

• However, processes that are experiencing problems can be the target of S^4/IEE work if these processes impact the 30,000-fool-level and satellite-level metrics of the organization.

• Results from this S^4/IEE work can then directly impact the control plan for this process.