Published in ASQ Quality Progress and won the Paper of the Year Award in 2002.

Ten Requirements for Effective Process Control

Thomas A. Little Ph.D.

Thomas A. Little Consulting 12401 N Wildflower Lane Highland, UT 84003 1-925-285-1847 drlittle@dr-tom.com

Process control is a critical component of every manufacturing operation. Although every manufacturer requires effective process control systems, few companies are satisfied with their internal and or supplier's performance. In many cases the factory process controls fail to perform adequately due to the fragmented nature of their implementation. Partially implemented process controls will not adequately cover the range of capabilities that are required by the factory and ultimately result in a lack of control of the process and product. Failure to control the process will result in needless product recalls, extensive product loss or rework and a loss of customer confidence.

To address the need for a clear set of requirements for process control the author internally developed the 10 Requirements for Process Control. Once the requirements were defined, they were reviewed and approved by the Executive Staff of the company. They were also sent out to all the Senior Management at all company locations worldwide to allow for the opportunity to review, edit and approve the requirements. After the worldwide review and some limited document editing the 10 requirements became the basis of the internal company policy.

The reason the 10 requirements for process control were developed is due to the fact that current literature typically describes elements of a control system and not the entire set of principles required for success. The subjects vary from SPC charts to Design of Experiments, Measurement Systems Analysis etc. The company needed a single checklist that would allow the engineer and management the ability to see if all the components of an effective control system had been developed for each process step. Once the checklist was applied to each process step it was easy to see what in the process needed to be done to make more robust process controls.

The Executive Management took a very active leadership roll in management of the implementation and reengineering of the process control system. Weekly and biweekly meetings on the topic with key managers were held to determine current levels of conformance to the requirements and they reviewed the individual manager's progress to plan. This process was rolled out to all of READ-RITE's factories worldwide to assure compliance and progress.

The following is a list of 10 requirements that all process control systems were required to conform to:

1.0 Clear Product Specifications

Clear product specifications clarify for the factory operator exactly how to use the product specifications in the acceptance, rejection or rework of the product.

- 1.1 Critical to Function (CTF) sensitivities are defined for each product and process step. CTF sensitivities are those product and process features that directly affect the final product performance and are critical to achieving customer satisfaction. Sensitivity indicates that variation in the CTF product or process parameter will impact final product performance.
- 1.2 Factory floor use of specifications is clearly defined. Scrap or rework based specification limits and criteria for each process step are in place.
- 1.3 Engineering change notices (ECNs) are current in the line.
- 1.4 For non-CTF parameters product specification limits are set @ $C_p 2$, $C_{pk} 1.5$ min.
- 1.5 The goal of each process step is to achieve 6σ quality.
- 1.6 Specifications for individual measurements, yield, or mean and sigma are established and followed.

Example:

During development, product characteristics are examined to determine what is critical and where the sensitivities are. Once the product parameter sensitivities are defined appropriate targets and tolerances are established and are clearly communicated to production personnel.



2.0 Valid and Capable Metrology

Valid and capable metrology assures the measurement instrument(s) and measurement process we are using to control the process is fit for use and well controlled. Every gage needs to be profiled to make sure it is fit for use.

- 2.1 Gage capability (GR&R) for all variables test and measurement equipment must be <20% of the product tolerance; for one-sided specifications <17% of the process variation, accuracy error must be <5% of tolerance. (AIAG, 1995)</p>
- 2.2 Standards must be generated for all measurement and test equipment and common for all locations worldwide.
- 2.3 Measurement/tester controls using SPC and standards are in place and used on the line.
- 2.4 For visual criteria operational definitions for product conformance are in place with supporting job aids, photos, and or line drawings.
- 2.5 Inspection capability has been assessed and inspection effectiveness is >90%. Inspection effectiveness is the % of inspected parts correctly identified as good or bad by the inspector.

Example:

A gauge study has been competed on a Profilometer with three fixtures to determine gauge capability. The results below indicate the metrology needs improvement due to mean shifts between the fixtures.

Performar	nce Summary	1	Process Gauge Capability	Bilateral Gauge Capability	Accuracy Analysis		
Performance Summary units		=s ² gauge error/s ² process	=(5.16*s gauge)/Tolerance	Comparison:	Accuracy	% Accuracy	
Target	30.00	um	% of Process Variation	Total Gage Capability	Fixture 1	0.00	0.02%
USL	37.00	um			Fixture 2	-0.20	1.45%
LSL	23.00	um	5.53%	27.73%	Fixture 3	1.15	8.24%
Tolerance	14.00	um			Total	0.32	2.27%
Process σ	3.2	um	Fit for Use	Needs Development	Fit for Use		
			Requirement: 17% or less	Requirement: 20% or less	Requirement: 5% or less		

Source		Variance	Std. Dev.	% of Error	% of Spec.
Within Fixture	Reapeatability	0.0307	0.175	5.42%	1.50%
Between Fixture	Reproductibility	0.5352	0.732	94.58%	26.22%
	Total	0.566	0.752	100.00%	27.73%

3.0 Characterization

Characterization of the process allows the engineer to determine precisely which process factors affect the product, their relative magnitude and numerical sensitivity. A subset of the process factors must be selected for process control.

- 3.1 There is an understanding of product characteristics to process variables. This is accomplished most often based on DOE or regression analysis. (Box, Hunter & Hunter, 1978)
- 3.2 Primary and or secondary control (adjust) factors have been determined which will be used to make process adjustments when indicated by the control chart.

Example:

From the analysis the engineer can see how the process variables affect volume. The engineer can also determine exactly how changes in speed affect the volume. When the process is determined to be out of control speed will be used as the primary control factor to bring volume back to target.



4.0 Sample Plan

The process sample plan defines where to take process measurements, how many to take, and the frequency. This is often referred to as rational subgroup formation.

- 4.1 Partition of variation (POV) study is complete. POV analysis is used to understand variation patterns in the process to determine subgroup formation.
- 4.2 Process drift rate has been determined in order to understand sample frequency requirements. This is most often determined based on a regression study (Montgomery, 1996).
- 4.3 The minimum sample size that accurately approximates the mean and sigma of the process, wafer or lot has been determined. Blanket studies are used to examine larger sampling levels and then determine how it can be reduced. Blanket studies are done by mapping out a much larger number of measurements on several parts then are practical in production. By blanketing the part(s) with measurements the engineer is able to determine what is the minimum number of measurements that will correctly represent the mean and sigma.

Example:

An engineer was developing a sampling plan for a wafer parameter. She first examined production data and determined a large component of the variation was within the wafer. To see the variation pattern more clearly she conducted a blanket study of 10 wafers and 100 measurements per wafer. A contour plot of the data was developed to see the variation pattern in the product. Based on the contour plot the engineer determined a diagonal sampling pattern correctly represents the mean and sigma of the product. She then followed up with a correlation analysis of the data to determine if the sample pattern and sample size is closely correlated to the 100 measurements per wafer. Based on the correlation she determined 10 measurements gathered diagonally effectively represent the 100 readings.



5.0 Control Chart Development

Based on the data from the sample plan the correct control chart needs to be selected such that the process control rules will properly detect out of control conditions. If the correct control chart is not selected the control system will have too many charts, or it will not correctly flag out of control conditions.

- 5.1 Selection of machine based and product based control charts have been determined.
- 5.2 Leading indicator (process based) and lagging indicator (product based) control charts have been evaluated and determined for factory use.
- 5.3 Every control chart is directly associated with a single machine, tester, work cell or process line. If multiple design targets are used on a single machine, Delta-to-target or z control charts should be used as the preferred control chart method.
- 5.4 Assure the selection of the proper control chart for variables or attributes data is correct. (Grant & Leavenworth, 1996)
- 5.5 Selection of control warnings to be active. Control rules are; 1) measurements outside the control limits, 2) 6 points in a row ascending or descending, and 3) 8 in a row above or below the process centerline.
- 5.6 Assure the control system is set up using computer automation.
- 5.7 Identical, multiple tools producing products with similar features will use common control limits. Any charts indicating routine out of control

conditions require machine maintenance to improve the machine to the level of its peers.

6.0 Out of Control Action Plan (OCAP)

The OCAP is written to provide the process operator detailed guidelines for process adjustment. They are written to be specific to the control rule violated.

- 6.1 Determine the action plan for out of control conditions. Assure the OCAP is specific to the control rule violated, one OCAP for trends, one for outside of limits, etc.
- 6.2 Assure OCAPs are developed for both leading and lagging controls.
- 6.3 Provide a process adjustment matrix for operator based adjustment where appropriate. (Almost always appropriate if the control is a variable parameter)
- 6.4 Indicate responsible individuals to make adjustments and escalation procedure.
- 6.5 Develop a process log for the collection of all adjustments and process observations.
- 6.6 Assure all production personnel and Supervisors understand the OCAP and can effectively apply it.

Example:

The following OCAP is for the glue process. When the process is flagged out of control by the control chart the operator follows the OCAP and makes the corresponding change in pressure. All process adjustments are noted in a process log. The operator cannot adjust the process greater than ± 3 psi.

Process:	Adhesive dispe	nse Measurement: Smartscope		Adhe sive Dispense Adjustment Matrix		
			1	Delt	a from Target	PSI
Parameter:	Diameter		Gauge Capability 15%		0.10	-3.0
Specification: $.55 \pm .05$					0.09	-2.7
					0.08 0.07	-2.4 -2.1
Control Rules:		Primary Control Factor: Pressure			0.07	-2.1
		Deduce er ineresee Dressure*			0.05	-1.5
1: Outside limits		Reduce or increase Pressure*			0.04	-1.2
2. 6 in a row		Reduce or increase Pressure*			0.03	-0.9
0.0		Reduce or increase Pressure*			0.02	-0.6
3. 8 in a row a					0.01	-0.3
below centerline					0.00	0.0
Additional rules or warnings:					-0.01	0.3
<u>Additional raise of warmingo.</u>					-0.02 -0.03	0.6 0.9
Clean glue nozzle prior to taking sample					-0.03	1.2
If time adjustments are greater than ± 3 psi stop the adhesive					-0.05	1.5
dispense process and call Supervisor and maintenance.					-0.06	1.8
dispense process and can Supervisor and maintenance.					-0.07	2.1
*All adjustment		-0.08	2.4			
Decord all adia		-0.09	2.7			
Record all adjustments on the process control log					-0.10	3.0

7.0 Documentation

All of the process, metrology and process control procedures need to be documented to assure standardization of the process.

- 7.1 Process management plan (PMP) indicating: 1) process step, 2) measurement method, 3) sample size, 4) control chart method, 5) frequency, 6) primary control factor, and 7) machine level process control parameters (temperature, pressure, etc.). PMP must also indicate all measurement and environmental controls used in production of the product.
- 7.2 Process Instructions must provide clear detailed work instructions and process control procedures including data collection frequency, sample size, measurement location, drawings, OCAP, process adjustment matrix, and process log procedures.
- 7.3 Maintenance and calibration documentation indicating the frequency of preventive machine and tooling maintenance, measurement calibration and all associated schedules, procedures and checklists.

8.0 Training

All of the people in the process need to make sure they have a common understanding and language concerning the process and process control systems and the detailed procedures for controlling and adjusting the process. The training program provides the theories and practical knowledge for process control system design and implementation.

- 8.1 All engineers, managers, supervisors and operators are SPC trained.
- 8.2 Product specification use has been trained and disposition procedures for non-conforming products are in place.
- 8.3 Process specific operator training and certification is in place.
- 8.4 Specific process control procedures are trained for each process area which include the use of the control chart, OCAP, process adjust matrix, and process log.

9.0 Database

The database is primarily designed for Engineering and Customer use. It stores the process and product information and provides a simple and powerful interface to summarize and analyze performance.

- 9.1 Assure correct data is collected at the point of data entry for all products and processes.
- 9.2 Assure data is stored in local data tables.
- 9.3 Assure appropriate data is linked to engineering database tables in DBASE application. Information Technology group is involved to assure this connection in made.
- 9.4 Assure interested users have easy access to the raw and summary data in control charts, histograms, and correlation graphs.
- 9.5 Assure data collection maintains proper product traceability as required by internal and external customers.

10.0 Periodic Audits

Periodic audits are designed to sustain the improvements in the control system. They provide management feedback that the floor controls are carefully followed and corrective action if they are not adhered to.

10.1 Process procedure conformance.

10.2 Process control procedure compliance.

- 10.3 Product disposition per specifications and visual criteria are done correctly.
- 10.4 Measurement control system compliance.
- 10.5 Documentation revisions are current and correct.
- 10.6 Maintenance and calibration schedules are being followed.
- 10.7 Operator certifications are current.
- 10.8 Environmental, housekeeping and safety standards are followed.

Example:

Once the control system was developed, validated and documented the formal QA auditors were asked to develop a schedule to audit the process once a month to determine if the process operation and control systems were properly being followed. All audit findings are reported to management. In addition the floor Supervisors were asked to informally verify all operators were following the control charts and OCAPs for their process areas.

Rolling out the requirements

Once the 10 requirements were defined each process step in the production of a magnetic head received a detailed audit to determine the baseline level of compliance. A master plan was put together with individual process owners who were chartered to fix the process control system. In most cases the Process Engineers were selected to be the process owners and were judged capable of making the needed improvements with appropriate training and technical support. Detailed timelines were put together for both leading and lagging process controls. Managers were required to report progress to plan to Executive Management.

The internal SPC training courses were set up to assure all affected individuals received the proper level of SPC training. The training program consisted of SPC I: Foundations (4hrs), SPC II for Variables Data (8 hrs), SPC III for Yield and Defect Data (8 hrs), and SPC for Operators (4 hrs). In addition, courses were offered on DOE and regression (16 hrs), Measurement Systems Analysis (8 hrs), Partition of variation (8 hrs) and FMEA (8 hrs) where appropriate.

The training program was rolled out concurrent with the process control Hoshin objective. This made the training relevant and real world issues were brought to the classes from engineers working to apply the SPC methodology. All engineers and managers were trained on the 10 requirements to assure there was a common understanding of principles such as process drift rate, characterization, OCAPs etc. Training began with Engineers and Managers and concluded with the Operators.

As may be expected during the implementation of such an extensive company wide implementation, there were some false starts. Some Engineers failed to follow-up on their assignments, some Managers did not take the Hoshin goal

seriously and failed to make progress. This is exactly why the Executive Management of the company had to take an active leadership role during the deployment to assist in redirecting managers and directors who were struggling. To assure progress was being made and to highlight areas for concern an independent process control audit was done corporate wide on a quarterly basis to determine progress to date. This provided the Executive Management with the information needed to work with the trouble areas to get them back on track. With this level of management oversight all process areas were completed within the year time frame.

After a year of upgrading all factory process controls worldwide to comply with the 10 Process Control Requirements the results have been dramatic. In most cases a significant reduction in product sigma was achieved, fewer problems were encountered during new product introduction, a reduction in parametric drift in key product parameters, improved product yields, and higher levels of job satisfaction and involvement for line production operators was achieved. Ultimately READ-RITE's customers are the judges of its performance. Customers have noticed and commented on improvements they have observed in READ-RITE and its ability to produce a more consistent product over time.

Using the 10 requirements provided all facilities around the world a clear understanding of what is required for effective process controls. It provided a communication tool to articulate the necessary details of an effective product and process control system and became the focal point of our training and project management. The involvement of Executive Management was a key component in managing the transition. READ-RITE was able to make the transformation from a company that had less than adequate controls to a company that uses, cares about and assures process controls are effective in managing the supply of magnetic heads to the hard disk drive industry.

References:

AIAG, *Measurement Systems Analysis*, (Chrysler Motor Corporation, Ford Motor Corporation, General Motors Corporation 1995).

E.L. Grant & R.S. Leavenworth, *Statistical Quality Control* (New York: NY, McGraw Hill, 1996).

D.C. Montgomery, *Design and Analysis of Experiments.* (New York: NY, John Wiley & Sons, 1996).

G.E. Box, J.S. Hunter & W.G. Hunter, *Statistics for Experimenters: An Introduction to Design, Data Analysis, and Model Building* (New York: NY, John Wiley & Sons 1978).