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Application of statistical techniques in the evaluation of packaging processes

Mark Harris

Application of Statistical Techniques

In the Evaluation of Packaging Processes

By

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M.S. Degree Thesis

The M. S. Degree thesis of Mark R. Harris
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Title of Thesis: Application of Statistical Techniques in the Evaluation of Packaging Processes.

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DEDICATION

To Beth, for her loving support.

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ABSTRACT

Production processes for packaging components frequently are subject to variation that can result in the manufacture of unusable components. Significant exposure to both the component supplier and the customer is incurred when the production process capability is not established prior to the start of production. "Application of Statistical Techniques in the Evaluation of Packaging Processes" presents a program of statistical tests for problem resolution as well as for the qualification of a new process. Training of manufacturing personnel in the fundamentals is a necessary element to accurately apply and interpret the results. The successful use of statistics requires knowledge of both their strengths and weaknesses. This study highlights those aspects of the process capability index (Cpk) and a sequence of tests to assure the strengths of its predictive powers are not undermined by any weaknesses. Organizations on both sides of the supply chain must resist the temptation to speed a new product to market by eliminating or short cutting the confirmation of process control and process capability. This important step greatly reduces risk and is inexpensive insurance for a smooth new product launch into the marketplace.

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1.0 INTRODUCTION

BACKGROUND

Use of Statistical Process Control (SPC) and more advanced statistical techniques are widespread in American manufacturing. The ground swell of interest has been influenced by the work of Dr. W. E. Deming and his success with Japanese industry applying the 14 Points for Management and Continuous Improvement. These principles have subsequently formed the basis of the quality management philosophy known as Total Quality. Statistical methods are a principle component in the implementation of Total Quality.

Employing statistical methods for monitoring processes and implementing process improvements have yielded spectacular results. Statistical methods have provided a valuable tool for management confronted with determining the proper allocation of constrained resources to achieve production, product development, and quality objectives. "They (statistics) provide the principal means by which a product is sampled, tested, and evaluated, and the information in those data is used to control and improve the manufacturing process." [1] The inherent power of statistical methods to efficiently increase the information on a process has assured their continued use in the search for ways to "do more with less."

Two of the statistical methods frequently used in total quality applications are process control and process capability. They are so common

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[1]Montgomery, Douglas C., Introduction to Statistical Quality Control, 2nd Ed., (New York: John Wiley & Sons, Inc., 1991), p. 21.

one might say process control and capability have become the meat and potatoes of statistical process measurement for industry. A control chart measuring the key characteristic of a production process and the calculation of process capability is often the method employed to measure the quality of the output from a production process and establish process reliability. The graphical representation of a process achieved with a control chart serves as a "picture" of the process over a period of time. The process capability index yields a single numeric value that represents both the combined inputs of process variability and the location of the mean relative to the specifications. These elements of visual representation and quantifying the process in a single number have tremendous value for evaluating, communicating, and managing processes. The single number yielded by the process capability index clearly defines a target objective that must be met to assure the process is robust.

AREAS OF APPLICATION

Quantifying manufacturing processes with measurements of their state of control and process capability is a commonly accepted and useful practice. The application of statistical methods varies from one organization to another. While it does not always hold true, the degree of sophistication and scope in the application of statistical methods generally increases with the size and complexity of the manufacturing operation. In addition to the prevalent use of process control and capability measurements in manufacturing, their application by customers in transactions with suppliers has also become common. Examples of process control and/or capability index applications include certification

provided by a supplier for the acceptance of a material or component, qualification and acceptance of tooling or manufacturing equipment, narrowing the field of potential suppliers in the supplier selection process, reducing the variability in a manufacturing process, and qualification of a contract manufacturer's packaging process. These are appropriate applications, providing meaningful information when properly used. The ubiquitous application has contributed to the casual use and reporting of process control and capability. This practice carries significant risk resulting in considerable cost to customers and suppliers alike. The underlying statistical assumptions necessary for use of these techniques must be validated prior to calculation of process capability to provide meaningful and actionable information.

APPLICATION ERROR

Misleading or erroneous information is reported when process control and process capability are calculated without confirming the fundamental statistical criteria on which the data is based. The following note of caution regarding statistical control appears in Juran's Quality Control Handbook: "A state of statistical control ...does not necessarily mean that the product meets specifications. " [2] A state of control is determined by statistical calculation which does not include the specification. A process which is in control may not be centered properly to produce components which meet specification.

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[2] Juran, J. M., Quality Control Handbook, With F. M. Gryna, 4th Ed., (New York: McGraw-Hill, Inc., 1988) p. 24.9.

"Conversely, a process which is not in statistical control may still be producing a product which conforms to specification." [3] This can occur when the variation in a process which is not in control does not exceed the product specifications. Verification of the product conformance to specification is still a necessary step when interpreting process control data.

The issues identified for process control are compounded in the subsequent determination of process capability. Several assumptions are made when calculating process capability which must be validated prior to the calculation. "The interpretation of these statistics, when the process is not in statistical control, when the probability distribution underlying the process is not normal, or when the observations are not independent, is highly questionable. These statistics do not indicate the capability of the process." [4] This unconcerned approach results in invalid data, wasted resources, and will ultimately impact profitability.

Practitioners' lack of knowledge in statistical theory and the fundamental assumptions necessary for application contributes to the nonchalant use and description of process control and capability. In an effort to comply with customers' expectations, suppliers have frequently pressed the methods into service after personnel have received only a minimum of training.

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[3] Ibid., p. 24.9.

[4] Pignatiello, Joseph J. Jr. and John S. Ramberg, Statistical Applications in Process Control, Ed. J. Bert Keats and Douglas C. Montgomery, (New York: Marcel Dekker, Inc., 1996), p. 408.

Furthermore, the limitations of process capability indices have been highlighted in recent literature on the topic. In a paper covering the recent developments in process capability analysis, Rodriguez noted;

> Various authors have commented on the weakness of capability indices. Gunter, for example, discuses the limitation of Cpk with non-normal data and cautions that unless the process is in control and hence predictable, the use of Cpk "becomes a kind of mindless effort that managers confuse with real statistical process control efforts."[5] Other writers have criticized standard capability indices as over-simplifications (Kitska).

In combination, the "weakness" of capability indices and application with a minimum of training increases the potential for misuse of the methods. For example, calculating the Cpk prior to establishing the data is independent yields an invalid statistic. Verifying the underlying statistical assumptions and determining the appropriateness of the application are prerequisites for use of the methods.

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[5] Rodriguez, Robert N., "Recent Developments in Process Capability Analysis.", Journal of Quality Technology, Vol. 24, No. 4, (October 1992), p.176.

2.0 STATISTICAL METHODS

PROCESS CONTROL

Variability in a process falls into one of two categories. One type of process variability is common cause variation which is also referred to as the natural variation of the process. The second form is assignable cause variation. Assignable causes are the result of an outside influence such as operator error or worn tooling. A process is said to be in a state of statistical control when the assignable cause variation has been eliminated. Control charts are used to detect the presence of assignable cause variation.

Control charts measure the process aim or the proximity to target. "It is often called centerline (CL) and is usually determined from either the midpoint of the specification range or the long-term mean (μ) for the process. "[6] The upper control limit (UCL) and lower control limit (LCL) are typically defined as plus or minus three standard deviations (σ) from the CL. The $\bar{x}$ control chart (figure 1) is widely used for charting variables as well as controlling the process average.

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[6] American Society for Quality Control, Quality Assurance for the Chemical and Process Industries: A Manual of Good Practices, (Milwaukee: ASQC Quality Press, 1987), p. 31.

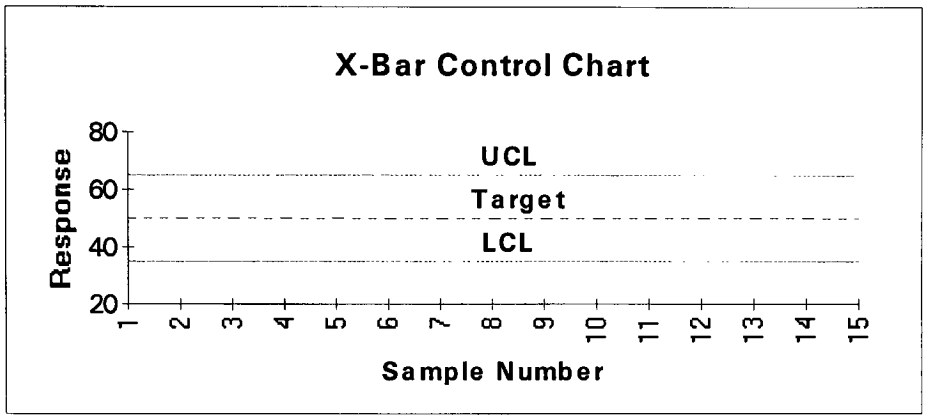

Figure 1: Example of Control Chart Format

PROCESS CAPABILITY INDICES

A process capability index is used to summarize the spread of the distribution and the process mean relative to specifications as a single number. "To most engineers, capability analysis means the use of histograms and capability indices such as Cp and Cpk. These continue to be the tools most widely taught and required by industry for this purpose."[7] Histograms provide a visual presentation of the distribution for the sample population. Figure 2 is an example of a histogram that has the mean, upper specification limit (USL), and lower specification limit (LSL) included in the diagram. Also, the bell shaped curve of the normal distribution is superimposed over the frequency distribution.

[7] Rodriguez, Robert N., "Recent Developments in Process Capability Analysis.", Journal of Quality Technology, Vol. 24, No. 4, (October 1992), p.176.

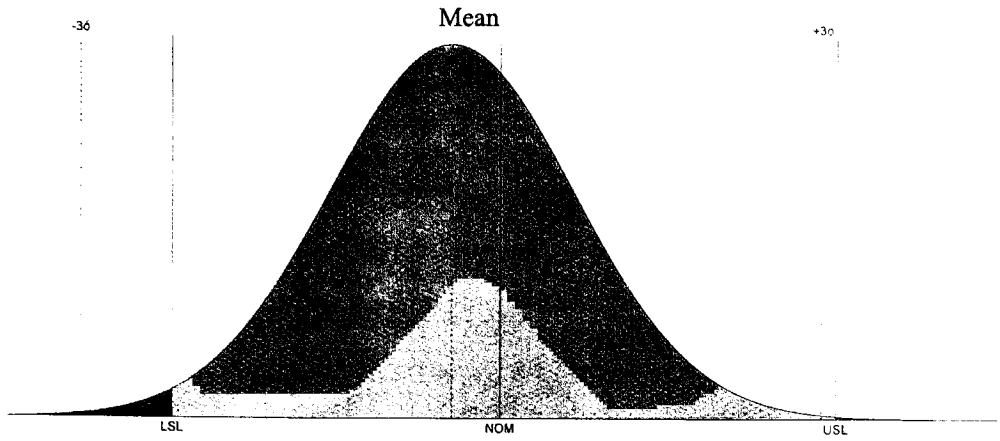

Figure 2: Example of a Histogram.

"Cp is the basic capability index. It is a ratio of the tolerance range divided by the process standard deviation.

$$Cp = (USL-LSL)/6\sigma$$

Cp does not measure the location of process; it assumes the process can be adjusted to the target. This equates to a measure of process potential."[8]

"Cpk is the capability index adjusted for location. Because it accounts for the location of the process mean relative to the specification limits, it is a measure of process capability.

$$Cpk = \text{Minimum } \{[(USL-\mu) / 3\sigma], [(\mu-LSL) / 3\sigma]\}$$

When the process is centered, a Cp of 1.00 or greater will meet specification. A value of 1.33 or greater is desired to allow for the natural variability in the process. The same minimum value of 1.33 is also desired for

[8] American Society for Quality Control, Specifications for the Chemical and Process Industries: A Manual for Development and Use, (Milwaukee: ASQC Quality Press, 1996), p. 99.

Cpk."[9] The Cpk index takes into account the spread of the process while simul-taneously evaluating the relation of the process mean to the specification limits. This concurrent calculation of process spread and location provides the assessment that identifies the capability of the process for production of an item.

Examples of process location relative to specification and the resultant Cp and Cpk values are illustrated in Figure 3. In figure 3-A, a process producing parts within a narrow range is depicted. The process mean is on the USL, however half of the production will be out of the specified tolerance on the high side. In figure 3-B the process is producing parts within the same process spread as depicted in figure 3-A. In this example, the process mean is centered within the LSL and USL and demonstrates the process is capable of ongoing production within specification. The process depicted in figure 3-C is centered within the LSL and USL, so the parts produced by this process are within specification. Of concern is the ability of the process to produce within specification over time when the natural variation of the process is taken into consideration.

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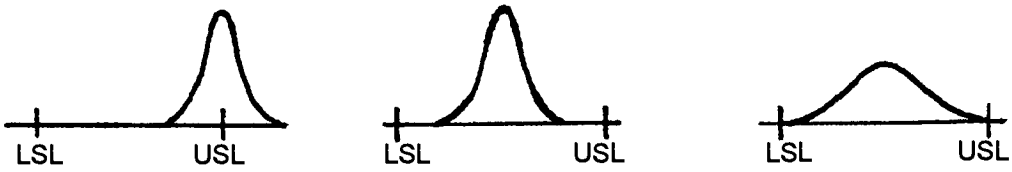
[9] Ibid.,p. 99.



Cp=2.0, Cpk=0.0 Cp 2.0, Cpk=2.0 Cp=1.0, Cpk=1.0

3-A 3-B 3-C

Figure 3: Diagrams of Cp and Cpk values.[10]

While the construction and application of the Cpk index is statistically sound it has been criticized as misleading and "fundamentally flawed."[11] This criticism has surfaced due to the broad based misuse of the index as industry searches for a holy grail to resolve process issues, employing the methods with disregard to the statistical principles required to calculate a valid Cpk.

ASSUMPTIONS

Validating assumptions when employing statistical methods is key to their successful application. In too many instances, the calculation and reporting of process control and capability statistics is done without testing the basic sta-tistical assumptions required to confirm the validity of the expressed values. The following section will identify the assumptions and their importance.

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[10] Case, Kenneth E., David H. Brooks and James S. Bigelow, "Proper Use of Process Capability Indices in SPC", 1987 IIE Integrated Systems Conference Proceedings, (Institute of Industrial Engineers, 1987), p. 107.

[11] Nelson, Peter R., "Editorial.", Journal of Quality Technology, Vol. 24, No. 4, (October 1992). p. 175.

Process control must first be verified as a precursor to calculation of process capability. Given it is a prerequisite to process capability analysis, the following factors must first be considered in identifying and validating the statistical assumptions for process capability.

Process Stability

The process must be in a state of statistical control. "All statistical predictions assume a stable population. In a statistical sense, a stable population is one which is repeatable, that is, a population that is in a state of statistical control."[12] For this condition to exist, the variability in the process due to assignable causes has to be identified and removed. When assignable causes are eliminated, only the common cause variation remains and overall process variability will be reduced.

Normality

"The underlying process distribution is normal. This is needed to draw statistical inferences and construct confidence levels."[13] Several methods are used for verification of normality. The method most familiar to engineers is the histogram. Two additional methods are the normal probability plot and goodness of fit test.

The capability index adjusted for location (Cpk) is based on the normal distribution. Cpk will not be valid or adequate in application for a

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[12] Juran, J. M., Quality Control Handbook, With F. M. Gryna, 4th Ed., (New York: McGraw-Hill, Inc., 1988) p. 16.27.

[13] Pignatiello, Joseph J. Jr. and John S. Ramberg, Statistical Applications in Process Control, Ed. J. Bert Keats and Douglas C. Montgomery, (New York: Marcel Dekker, Inc., 1996), P. 413.

distribution of another form, for example a distribution that is skewed or bi-modal.

Independence

"The observations are independent of each other. For example, consecutive observations from the process must not be correlated either positively or negatively."[14] Should the independence assumption be violated the data will not yield a valid calculation of process capability. Randomization in the col-lection of the data is an important step in obtaining independence. The Durbin -Watson test is used to validate the assumption of independence.

Confidence Intervals

"All capability indices depend on the process standard deviation σ, which is almost always unknown and, therefore, replaced with the sample standard deviation *S*"[15] Use of *S* for the computation yields an estimate of the process capability. When working with a statistical estimate, the use of confidence intervals is required to accurately report the results without misrepresenting the Cpk. The confidence level is often presumed to be 100% unless identified in conjunction with the Cpk value.

Confidence intervals can be calculated for both the upper and lower bounds. The upper bound is not needed to determine capability and is not calculated. The interest in a minimum process Cpk value of 1.33 places

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[14] Ibid., p. 413.

[15] Nelson, Peter R., "Editorial.", Journal of Quality Technology, Vol. 24, No. 4, (October 1992), p.175

the focus on the lower bound. For this reason, confidence intervals have been calculated for the lower bound only.

ASSUMPTIONS SUMMARY

In order to properly apply statistical calculations to the description of a process, several common assumptions must be determined for the statement to be true. The process must be stable or "in control" with assignable cause variability identified and eliminated. The distribution must be a normal distribution, and independence of the observations has been confirmed. A confidence interval has been calculated for reporting the Cpk that appropriately describes the data set as a sample of the total population.

3.0 RESEARCH

The following example demonstrates the application of the statistical methods, including validation of the statistical assumptions and interpretation of the results.

BLOW MOLDED BOTTLE EXAMPLE

A contract filler has been engaged to produce dishwashing detergent for the consumer marketplace. Raw materials and packaging components have been delivered to the contractor's facility.

Once production is initiated, the contractor rejects several shipments of dishwashing detergent bottles. Comments from the contractor are 'the caps are stripping, this is a bad bottle design, and the bottles are out of specification."

Production data collected by the bottle supplier for the thread (T) dimension is forwarded for review. The T dimension is the measurement of diameter over the threads. Two measurements are taken 90° apart to accurately gauge a diameter dimension. This is done to check for ovality or an out of round condition. The labels used for these dimensions in this example are;

TP = T dimension at the parting line.

TO = T dimension 90° opposite the parting line.

Evaluation of the control charts (Figures 4 and 5) indicates the bottles are in specification, but trending to the low end of the specification. Dimensional evaluation of the caps indicates they are in specification with little variation.

Figure #4: X-Bar Control Chart of TP-Initial

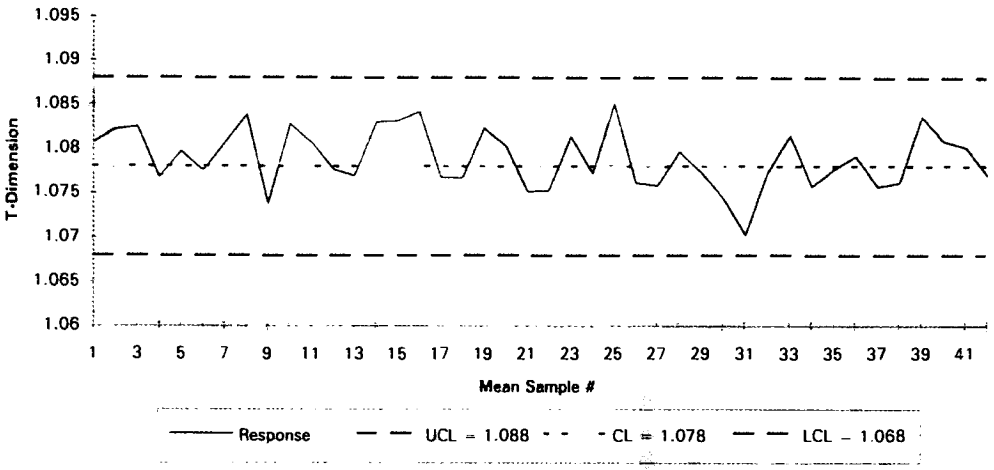
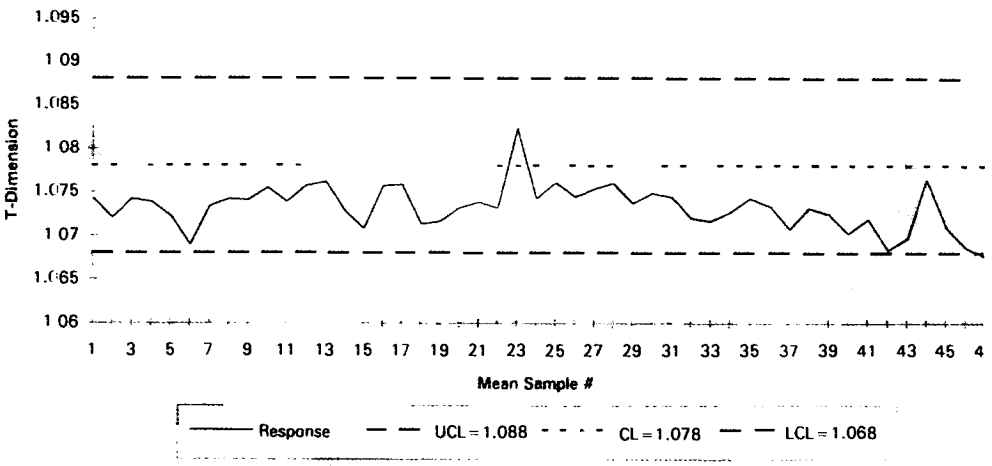


Figure #5: X-Bar Control Chart of TO-Initial



The control chart data did not support the contract filler's statement that "the bottles are out of specification." Measurements of the T dimension on a sampling of bottles did indicate a small percentage at the lower limits of the specification. Further focus was placed on investigation of the bottle produc-tion process based on the control charts trending to the lower end of the specification and the confirming dimensional check on the bottle samples.

BOTTLE PRODUCTION AND SAMPLING PROGRAM

The bottles are produced on a six cavity mold set. Samples are pulled once an hour for measurement, and data entered into an online statistical program. Measurements are taken on one bottle from each of the six cavities. This data forms a subgroup for which an average value is calculated and plotted as a single point on the control chart. When the data is charted as subgroups, one or two bottles in the sample may, in fact, be out of specification. The upper and lower limits are set at the maximum and minimum of the specification range respectively. The operator takes no action if out of control points are not observed.

Sampling in this manner is common in the molding industry. However, operator training needs to cover the implications of plotting the average and potential risk to product quality. In addition, when charting subgroups, implementing "alarm" levels is useful for an early warning. The "alarm" levels, which are set to a tighter range than the specification range, can be used to alert the operator to a potential problem prior to producing a significant quantity of out of specification parts.

APPLICATION AND INTERPRETATION

It is important that the data collected is random, or independent of each other. If the data is not random but related, the results of the study are thrown into question and may require collection of a new data set. The cost associated with collecting a new data set highlights the importance of a establishing a sound test plan from the onset. To evaluate the data for independence the practitioner will utilize a test, which yields a measure of autocorrelation within the data. For this study the Durbin-Watson test was used to measure autocorrelation.

The results of the Durbin-Watson tests validated the independence assumptions for both the TP and TO characteristics. The test results appear in Tables 1 and 2. "Output for the independence validation is located at the bottom of the table. If the value to the right of the Durbin-Watson heading is above 1 and under 2 then the data set has little evidence of autocorrelation."[16] The value for TP and TO is above 1 and less than 2 which confirms the data does not have positive or negative correlation.

"One can also look at the last line in the table which is titled 1st Order Autocorrelation, which contains a percentage value. Values close to 1 suggest that the data set is autocorrelated and the individual values are not independent."[17] The 1st Order Autocorrelation value for TP is 0.446% and for TO is 0.424%. Both of the values are less than 1 and confirms independence.

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[16] Canter, Kelly, "Memorandum." Durbin-Watson Interpretation, 3 1997 July.
[17] Ibid., 3 1997 July.

Analysis of Variance

Source	DF	Sum of Squares	Mean Square	F Value	Prob>F
Model	1	0.00018	0.00018	8.795	0.0033
Error	250	0.00509	0.00002		
C Total	251	0.00527			

Root MSE	0.00451	R - square	0.0340
Dep Mean	1.07892	Adj R – sq	0.0301
C.V.	0.41828		

Parameter Estimates

Variable	DF	Parameter Estimate	Standard Error	T for HO: Parameter=0	Prob > |T|
INTERCEP	1	1.080416	0.00057887	1866.408	0.0001
COUNT	1	-0.000069554	0.00002345	-2.966	0.0033

Durbin-Watson D	1.079
(For Number of Obs.)	252
1st Order Autocorrelation	0.446

Table 1: Independence Validation of TP - Initial.

Analysis of Variance

Source	DF	Sum of Squares	Mean Square	F Value	Prob>F
Model	1	0.00018	0.00018	13.469	0.0003
Error	280	0.00377	0.00001		
C Total	281	0.00395			

Root MSE	0.00367	R-square	0.0459
Dep Mean	1.07323	Adj R-sq	0.0425
C.V.	0.34203		

Parameter Estimates

Variable	DF	Parameter Estimate	Standard Error	T for HO: Parameter=0	Prob > |T|
INTERCEP	1	1.074653	0.00044425	2419.001	0.0001
COUNT	1	-0.000059141	0.00001611	-3.670	0.0003

Durbin-Watson D	1.151
(For Number of Obs.)	282
1st Order Autocorrelation	0.424

Table 2: Independence Validation of TO - Initial.

Normal probability plots and histograms were applied to the initial data sets to validate the assumption of normality.

"Data from normal distributions tend to plot as straight lines on normal probability plots."[18] The plots in this study were generated with SAS software which displays the data as a series of asterisks (*) and plus signs (+). "The asterisks mark the data values. The plus signs provide a reference straight line that is drawn using the sample mean and the standard deviation. If the data are from a normal distribution, the data tend to fall along the reference line".[19] The plot for the TP data set in Figure 6 is a straight line with the exception of a single data point off the line in the upper right hand corner. This indicates a distribution with a very slight tail. This is contrasted by the plot for the TO data set in Figure 7 which more closely resembles the form of an "S". The data points off the line in the lower left and upper right indicate a distribution with a slight tail. The plots demonstrate the requirement for a normal distribution has not been met.

The form and location of the distributions are visually represented in the histograms. The histogram in Figure 8 for the TP characteristic illustrates that the spread of the distribution is beyond both the USL and LSL. The histogram in Figure 9 for the TO characteristic illustrates the location of the distribution is left of center with a significant portion of the distribution below the LSL. For both characteristics, TP and TO, out of specification parts are being produced.

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[18] Pignatiello, Joseph J. Jr. and John S. Ramberg, Statistical Applications in Process Control, Ed. J. Bert Keats and Douglas C. Montgomery, (New York: Marcel Dekker, Inc., 1996), p. 414.

[19] SAS Institute Inc., SAS Procedures Guide, Version 6, Third Edition, (Cary, NC: SAS Institute Inc., 1990), p. 628.

Cp and Cpk values for both data sets are:

TP-Initial, Cp-0.73, Cpk-0.66, Cpk at a 95 % confidence interval-0.58.

TO-Initial, Cp-0.89, Cpk-0.47, Cpk at a 95 % confidence interval-0.40.

Considering the deviation from the normal distribution confirmed in the normal probability plots, continuing with the calculation of process capability values for Cp and Cpk typically would not have been done. The calculations were completed in this instance for reference in discussions with the supplier. These values have no predictive power as a statistical indicator of the process capability.

Both distributions indicate the process is producing bottles with out of specification T dimensions. Assignable cause variation must be identified and eliminated to improve the process and as a necessary step toward validating the assumptions prior to calculation of process capability.

NORMALITY VALIDATION for TP-INITIAL

Univariate Procedure

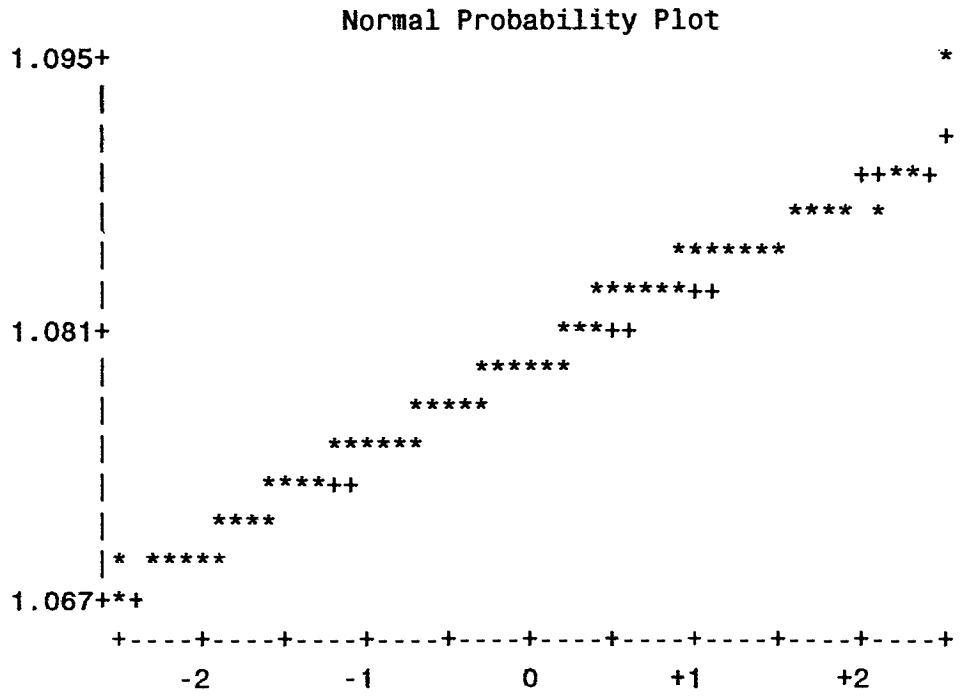


Figure #6: Normal Probability Plot of TP - Initial

NORMALITY VALIDATION for TO-INITIAL

Univariate Procedure

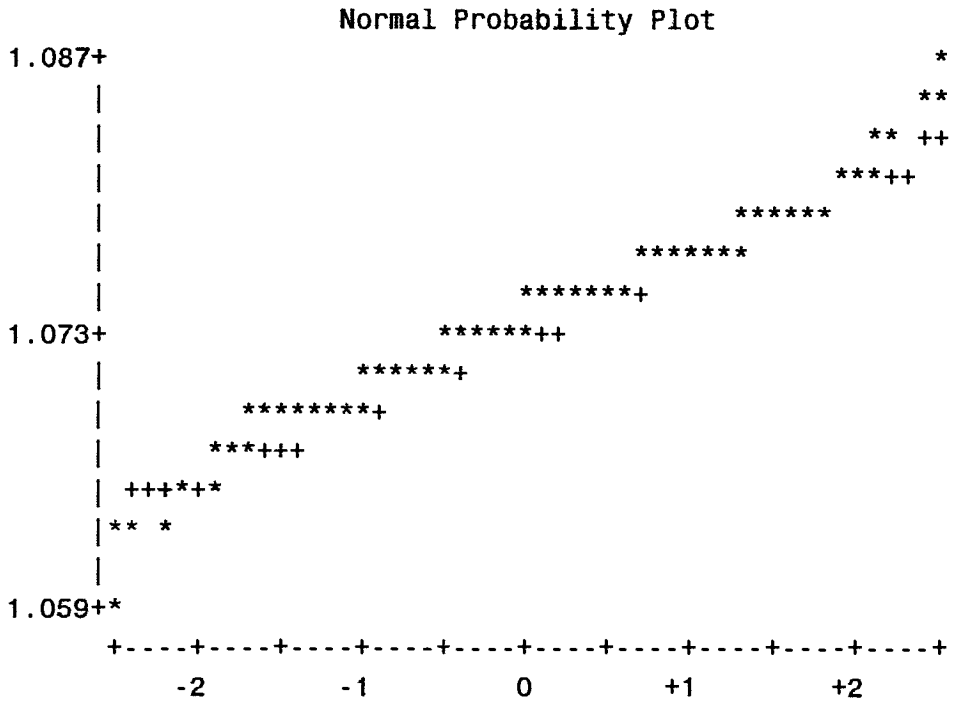


Figure #7: Normal Probability Plot of TO - Initial

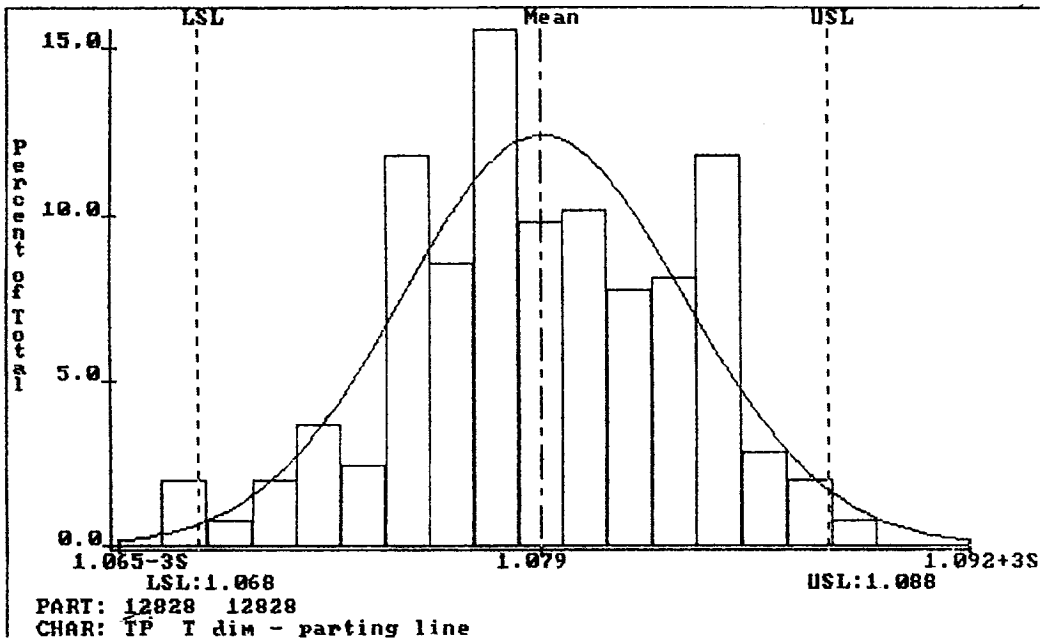


Figure #8: Histogram of TP-Initial Data

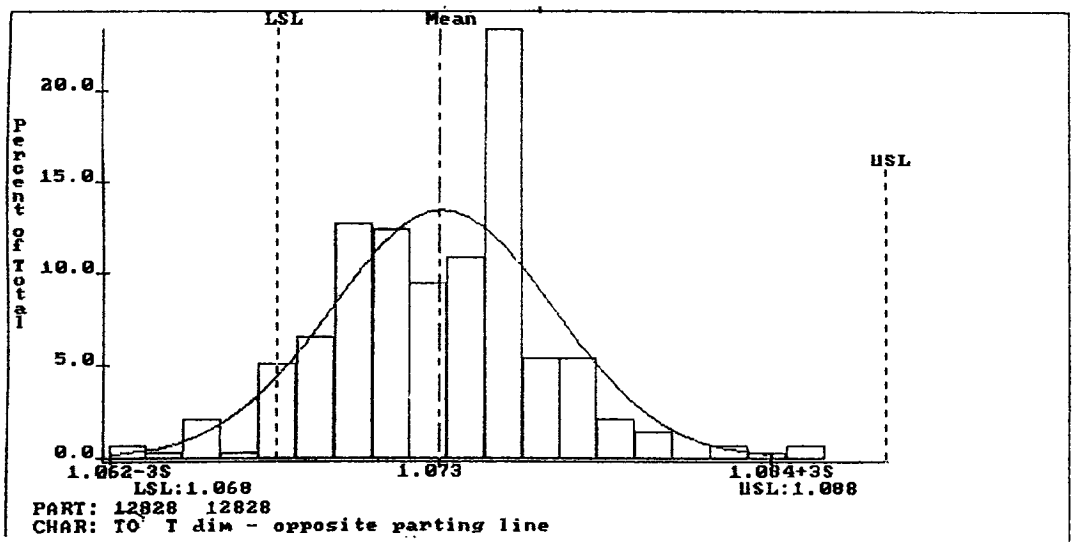


Figure #9: Histogram of TO-Initial Data

The individual data entered for each bottle was reviewed for out of specification data points. The sampling program and collection method was structured so that a pattern was identifiable. This is in contrast to the method employed by the supplier of charting only subgroup averages. This method, compounded by insufficient operator training, did not identify the issue. T dimensions for a portion of the bottles from one of the six mold cavities were below the lower specification limit. This was due to assignable cause variation that was identified and corrected. The cause was intermittent low hydraulic pressure to the single cavity producing the out of specification bottles. The blow pin did not fully seat during the periods of low hydraulic pressure resulting in the low T dimension. The control charts in Figures 10 and 11 illustrate the data after changes were made to the process to remove the assignable cause variation.

After the equipment corrections the following statement is valid. The process is in control and assignable cause variability has been eliminated. Further monitoring for drift or oscillation will establish if the process is stable over an extended run.

Figure #10: X-Bar Control Chart of TP-Corrected

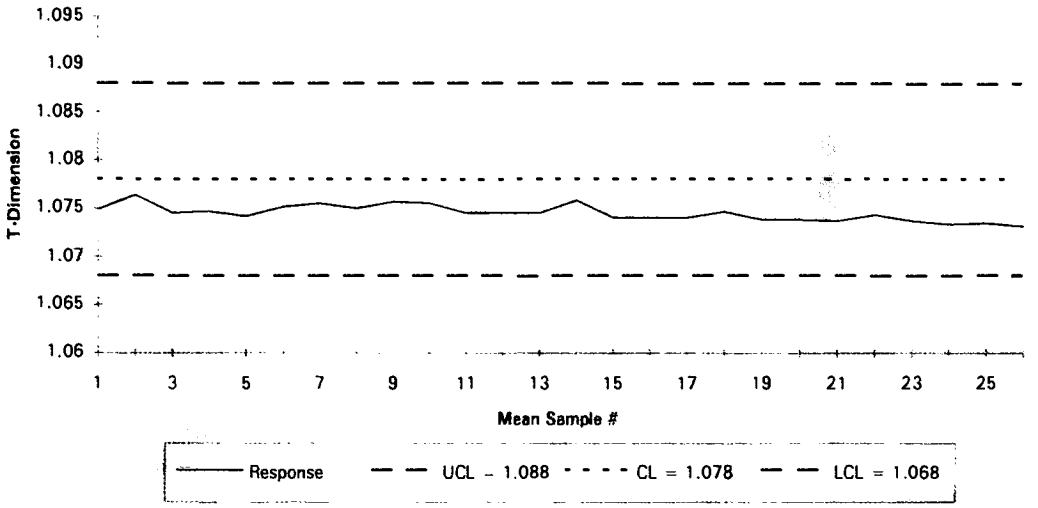
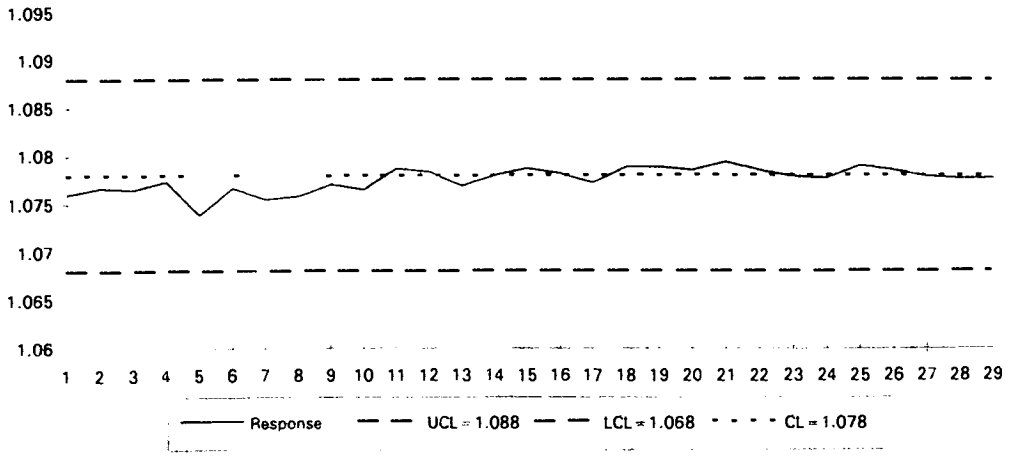


Figure #11: X-Bar Control Chart of TO-Corrected



The Durbin-Watson test was applied to the data after the assignable cause variation was eliminated from the process. The Durbin-Watson value of 1.639 for the TP characteristic and 1.650 for the TO characteristic are both between 1 and 2 and confirms the data has no evidence of auto-correlation. Further confirmation is established via 1st order autocorrelation of 0.167% for the TP characteristic and 0.161% for the TO characteristic. These values are not close to 1 which is the criteria for the following statement to be true. The Durbin-Watson tests validated the independence assumptions for both the TP and TO characteristics after the process was corrected. The test results appear in Tables 3 and 4.

Analysis of Variance

Source	DF	Sum of Squares	Mean Square	F Value	Prob>F
Model	1	0.00005	0.00005	7.129	0.0084
Error	154	0.0011382792	7.3914234E-6		
C Total	155	0.00119			

Root MSE	0.00272	R-square	0.0442
Dep Mean	1.07449	Adj R-sq	0.0380
C.V.	0.25302		

Parameter Estimates

Variable	DF	Parameter Estimate	Standard Error	T for HO: Parameter=0	Prob > |T|
INTERCEP	1	1.075533	0.00044821	2399.602	0.0001
COUNT	1	-0.000077493	0.00002902	-2.670	0.0084

Durbin-Watson D	1.639
(For Number of Obs.)	156
1st Order Autocorrelation	0.167

Table 3: Independence Validation of TP - Corrected.

Analysis of Variance

Source	DF	Sum of Squares	Mean Square	F Value	Prob>F
Model	1	0.00011	0.00011	22.134	0.0001
Error	172	0.0008305902	4.829013E-6		
C Total	173	0.00094			

Root MSE	0.00220	R - square	0.1140
Dep Mean	1.07751	Adj R – sq	0.1089
C.V.	0.20394		

Parameter Estimates

Variable	DF	Parameter Estimate	Standard Error	T for HO: Parameter=0	Prob > |T|
INTERCEP	1	1.076106	0.00034199	3146.579	0.0001
COUNT	1	0.000093678	0.00001991	4.705	0.0001

Durbin-Watson D	1.650
(For Number of Obs.)	174
1st Order Autocorrelation	0.161

Table 4: Independence Validation of TO - Corrected.

Following correction of the process, both normal probability plots and histograms were applied to the data sets to validate the assumption of normality.

The normal probability plots for both TP and TO characteristics plot as straight lines. This validates the assumption of normality. The plot for the TP data set is illustrated in Figure 12. The plot for the TO data set is illustrated in Figure 13.

The form of the frequency distribution in the TP histogram, illustrated in Figure 14, is not clearly distinct. It is visually determined to "best fit" a normal distribution. This reinforces the benefit of complementing the standard use of histograms for normality assessments with a second test. In this instance, the normal probability plot for the TP characteristic has confirmed that the distribution is normal. The distribution of the TO characteristic follows the bell shaped curve of a normal distribution (Figure 15).

The statistical assumptions required for the calculation of process capability for the TP and TO characteristics are valid.

Cp and Cpk values for both data sets:

TP - Corrected

Cp - 1.20, Cpk - 0.78, Cpk at a 95% confidence interval - 0.69.

TO - Corrected

Cp - 1.43, Cpk - 1.36, Cpk at a 95% confidence interval - 1.22.

The CP and Cpk values do not meet the minimum 1.33 value and the statement, the process is not capable, is a true statement.

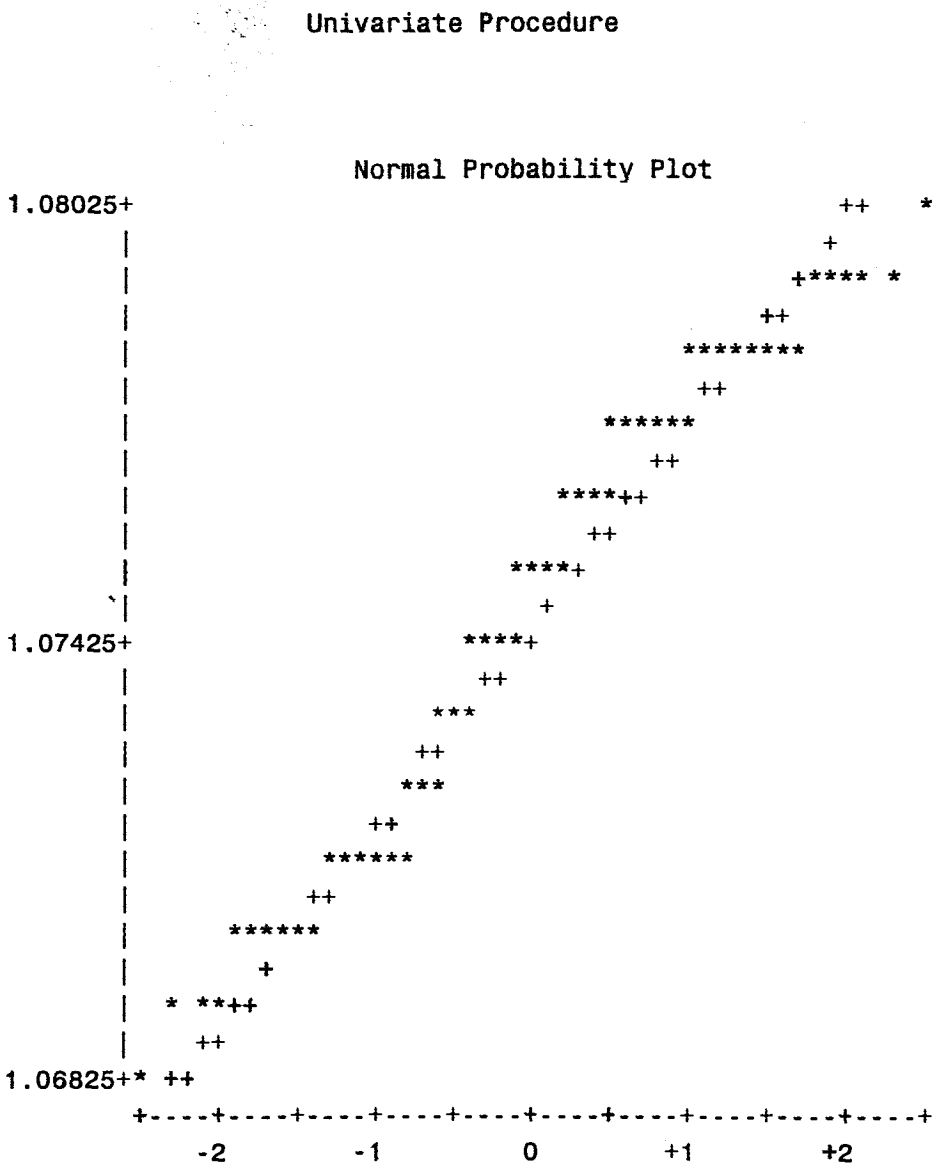


Figure #12: Normal Probability Plot for TP-Corrected

NORMALITY VALIDATION for TO-CORRECTED

Univariate Procedure

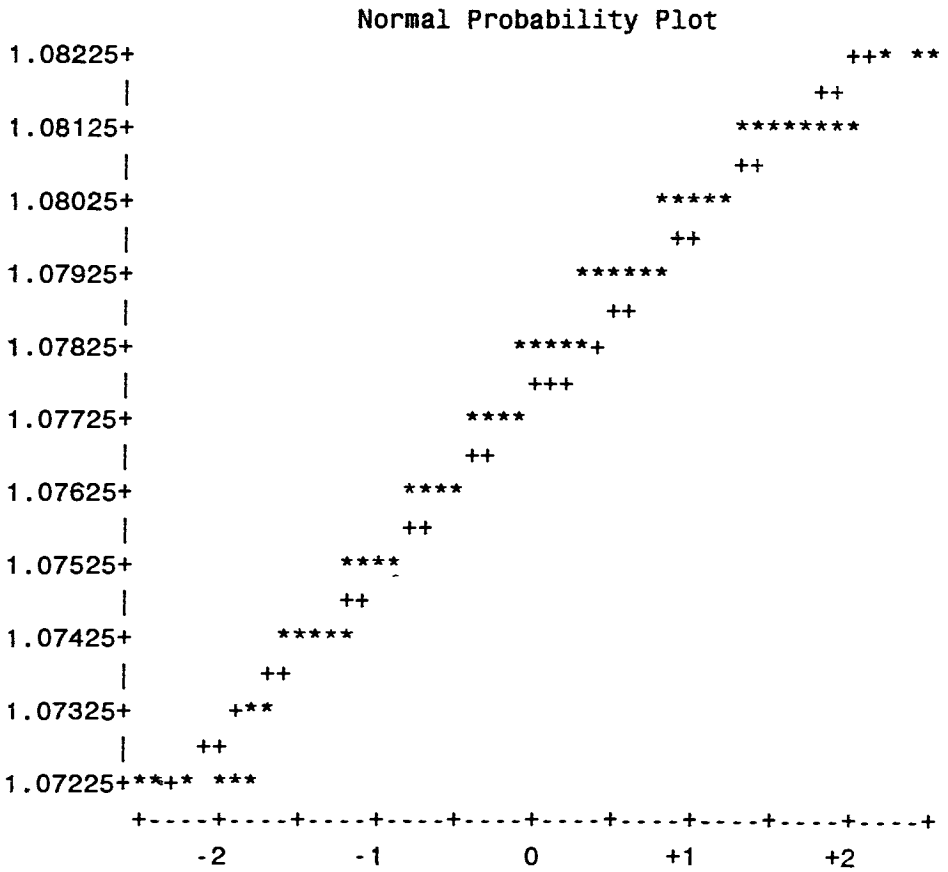


Figure #13: Normal Probability Plot for TO-Corrected

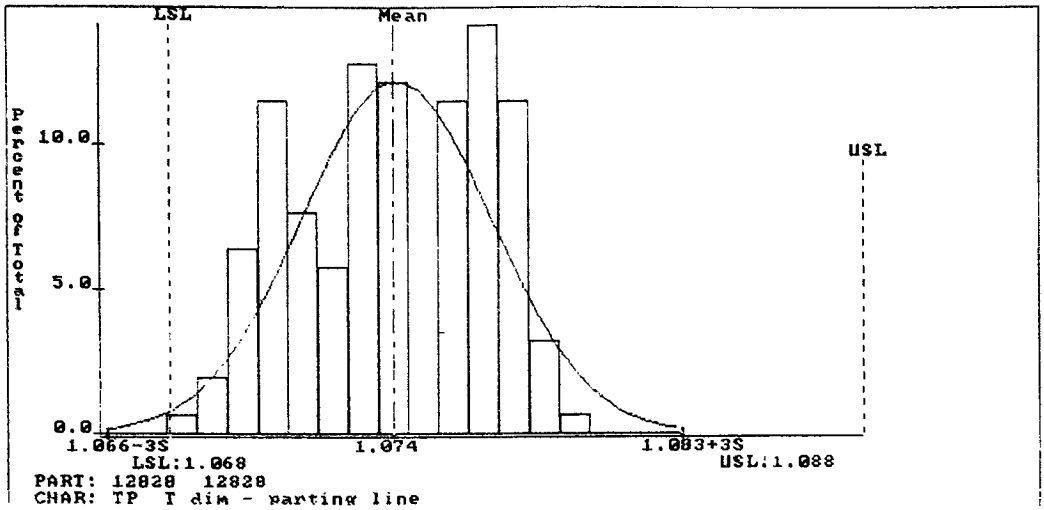


Figure #14: Histogram of TP-corrected Data

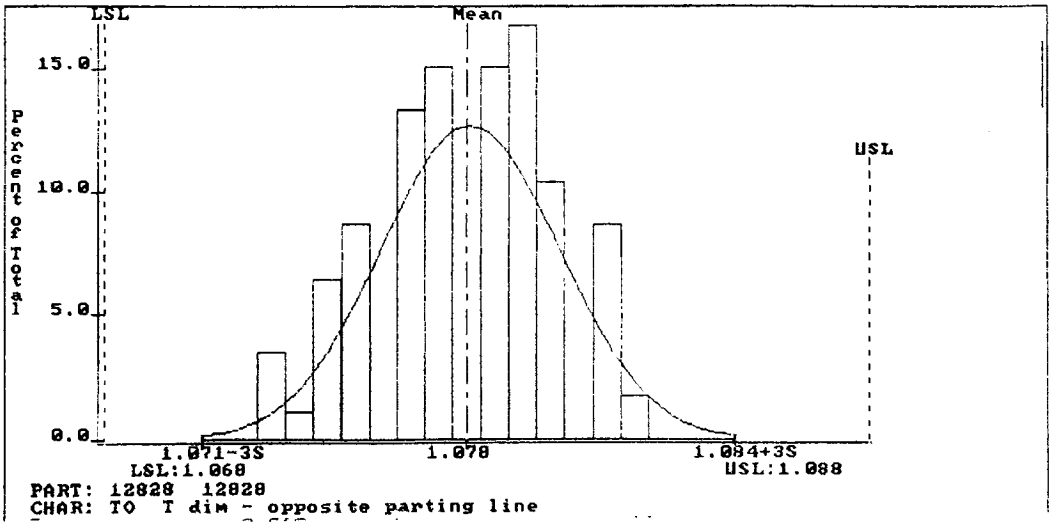


Figure #15: Histogram of TO-corrected Data

ANALYSIS SUMMARY

Criterion	Data Set			
	TP-Initial	TO-Initial	TP-Corrected	TO-Corrected
Process in Control and Assignable Causes Eliminated	No	No	Yes	Yes
Product within specification	No	No	Yes	Yes
Independence				
Durbin-Watson	1.079	1.151	1.639	1.650
% Autocorrelation	0.446	0.424	0.167	0.161
Normality				
Probability Plot	Slight Tail	Slight Tail	Straight	Straight
Histogram	X	X	Best Fit	Yes
LSL	1.0680	1.0680	1.0680	1.0680
USL	1.0880	1.0880	1.0880	1.0880
Mean	1.0789	1.0732	1.0745	1.0775
Standard Deviation	0.0046	0.0038	0.0028	0.0023
Cp	0.73 Not Valid	0.89 Not Valid	1.20	1.43
Cpk	0.66 Not Valid	0.47 Not Valid	0.78	1.36
Cpk at 95% Confidence Interval	0.58 Not Valid	0.40 Not Valid	0.69	1.22

Table 5: Analysis Summary

For the data sets TP and TO the process is in control: the data is independent and the data is from a normal distribution. All statistical assumptions required for calculation of process capability are valid.

Cpk at a 95% confidence interval for both TP and TO corrected are below the desired value of 1.33. The TP-corrected value of 0.69 indicates the process is not capable of producing bottles that meet the specification. All data collected for this characteristic is within the specification. It is the

variability and the location of the mean measured by the Cpk index which predicts the distribution of S will exceed the specification limits. The process requires modification to improve the TP characteristic prior to further production.

The TO corrected value of 1.22 indicates the process is capable of producing product that meets the specification. The value is still below the desired minimum of 1.33, and process modifications must address improving the TO characteristic as well.

Communicating the risk associated with this process capability in terms of potential out-of-specification product and the estimated cost to improve the process is needed. The risk analysis is necessary to determine if further resource expenditure to improve the process is warranted or if efforts will be redirected to qualify an alternate source.

The bottles that were originally rejected at the filling location were 100% sorted by the supplier to assure sufficient bottles were available for the product launch. This required over 250 man-hours, travel expenses, and the opportunity cost of dedicating the resources to a rework operation. Additionally, the supplier incurred the cost of production losses. This issue strained the supplier/customer relationship and put the possibility of future business in question. The risk to the customer of a delayed launch or shorting orders to their trade customers was missed by a narrow margin. This was accomplished only by accepting the cost of dedicating resources at their expense to assist in resolution of the issue.

Validating the production tools ahead of full-scale production and implementing an operator/quality training program would have prevented the additional cost incurred by both parties. In contrast to the relatively low

expense of the steps suggested above, the combined exposure for the supplier and customer was extremely high. Had the product launch been aborted, the investment losses would have exceeded $3MM in capital equipment, materials, and trade expenses.

4.0 CONCLUSIONS

It is important to recognize the risk associated with the use of reported process control and capability values without first validating the statistical assumptions. Frequently the recipient accepts the reported values without validating the underlying statistical assumptions. This is particularly important for the use of the Cpk index. As demonstrated in the preceding research, manufacture of packaging components without validating the underlying statistical assumptions can be a costly omission.

The recommended application of statistical methods for the evaluation of packaging processes identifies a comprehensive program that includes training of personnel in statistics and incorporating the following aspects of their use. Validation of process control must include analysis for the absence of assignable cause variation. Additionally, a process that is in control does not necessarily mean the product is also in specification. Independence of the data must be verified. Randomized sampling will help in this regard. The data must be from a normal distribution. Confirmation of normality with more than one statistical test is recommended due to the occasional difficulty of visually interpreting the distribution form illustrated in a histogram. The calculation of process capability is valid once these steps have been completed.

The Cpk value may be low even though the process is in control, and all product meets the specification. When this occurs, additional investment will be required to reach a Cpk value greater than 1.33 with a high degree of confidence. Reporting the values, including an analysis of

both the cost and risk, will provide management with the necessary information to determine the action to be taken.

The use of the process capability index Cpk has been criticized as mis-leading and "fundamentally flawed"[20]. This criticism is due in large part to the improper application of the index. Provided the statistical assumptions are validated, Cpk can be made a valuable tool for process evaluation.

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[20] Nelson, Peter R., "Editorial.", Journal of Quality Technology, Vol. 24, No. 4, (October 1992). p. 175

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