Lean Six Sigma Quality Transformation Toolkit (LSSQTT)*
LSSQTT Tool #25 Courseware Content
“Data, Basis For Kaizen, Six Sigma, Quality Systems, Service”

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*Updated fall, 2007 by John W. Sinn.

Statistical Principles, Quality System Standards, Six Sigma, Service

The use of statistical methods enables us to make quantitative statements about data that often could not be communicated as readily by other means. Statistics refers to data, the collection of numbers that represent raw materials, products or systems we work with. These may be test scores, reaction times, frequency of rejects, numbers of product produced, or other similar numerical measures or indicators of items or behaviors. Statistics also means methods reflected in formulas, derived and developed to treat data in meaningful ways which are helpful, if not critical in technology. The task of statistics is to reduce groups of data to meaningful and useful information. These values, or information, can assist us in several ways. This includes planning, policy changes and general decision making, setting standards, and others. Based on numerical indicators and measures from production, we can take some of the guess work out of making decisions--and become increasingly competitive in the process. Without data we are less certain, less definitive, and more oriented to making "seat of the pants" types of decisions. Statistics provide a more solid, formal, base for decisions.

Based on data generated, policy can be configured or altered. If existing modes of organizing and operating prove to be problematic in quality terms, changes must be made. Changes may be based on statistical indicators, and after changes, new data generated could be used for comparative analysis. Over time and with training, persons will be exposed to data which can help make decisions, changes, and managerial issues which are being confronted. This is what data based decision making is--using data to improve.

Statistical feedback provides opportunities for standards to either be altered or created. Equally as useful, based on statistical feedback, control in processes can be pursued. Statistical analysis of the process can be pursued by gathering information which is documented/stored. This can provide a data base which is invaluable for comparative and analytical purposes related to processing, enabling better decisions and improvement.

Assuming a data base is built-up over time, much useful productivity information can be derived. For example, if the rate of the task is speeded up, how many conditional units are produced and/or rejected? Has productivity or quality actually been improved? By observing results based on statistical feedback, employees can gain insights and understanding about when they have mastered a task at a sufficient quality level. This takes a disciplined, well trained, "comfortable with numbers" work force--not quickly or easily achieved. It may be one of the most important areas for enhancing our competitiveness in the future--and now.

We should have statistics which provide documentation of quality levels as well as other general communication. Statistical information, as data, can provide an excellent communication and documentation system for internal and external purposes. Organizations are demanding clear records of the statistical process control report for a given lot or shipment, prior to accepting for production. There is a need to be able to communicate effectively and quickly with internal and external customers, upstream and downstream. Not using data properly increases chances that customers will go somewhere else with their business.
One of the key reasons for using data is to actually "know" what we are talking about. It is one thing to say "oh about half" versus saying 50%. Or if we say "well, quite a few of the products were defective", rather than saying "20% of the products were defective", it is different. If we say "10 of the products had 3 defects each, yet none of them were actually defective", it can make a significant difference. The difference is that we are being more precise when we place a proper numerical indicator into the discussion. This will increasingly be demanded by our customers--and what we must demand of our suppliers. This relates to wanting to make improved decisions, rather than "seat of the pants" decision-making. This difference is precision of communication, knowing better what and when we say something, is at the root of the need to use data.

**TS 16949 2002 ISO/QS Quality Standard.** Documented data is one of the foundations of the quality systems as defined in the TS 2002 ISO standards:

1. Quality management system
2. Management responsibility
3. Resource management
4. Product realization
5. Measurement, analysis and improvement

While there may be other elements in the new system, particularly based on where an organization may be in relation to its older quality systems, only five are now required. Many of the older elements have been subsumed within these, and each one is briefly presented below, further explained in tool 29.

Quality management system is the overall infrastructure required by the new TS 2002 standard. A major emphasis is written descriptions of how various processes in the management systems interact with one another relationally to assure quality.

Management responsibility provides a framework for management understandings, far less ambiguous than past ISO 9000 standards. The new standard requires top management to provide evidence of commitment to QMS and its continual improvement, including communication enhancements to assure that the QMS is effective internally.

Resource management is required to demonstrate that people are dedicated to, and capable of, fulfilling the new standard. Resources must increasingly be reviewed and enhanced to assure sufficiency for meeting quality objectives in quality systems.

Product realization requires that we can actually do the product in production as we contract to do within the standard. Increasing emphasis is being placed on determining quality objectives for product early in the engineering and design process.

Measurement, analysis and improvement requires that data be collected and analyzed to demonstrate that we are doing what we say we are doing. Organizations must plan and implement processes required, and actually use as well as understand the same, particularly related to data-based measures.

The new TS 2002 standard demonstrates a maturing quality system with increased flexibility and seamless relationships evolving. E-commerce methods and systems are having a positive impact, and will demand increased attention for efficient and effective improvements evolutionarily. The new standard recognizes and acknowledges that as organizations evolve there should be less need for oversight and surveillance, assuming the documentation is in place and can be reviewed in timely and routine ways.

Documentation, as defined in the new TS 2002 ISO/QS standard is also a primary foundation for lean environments and improvement. This is true since most elements in ISO/QS quality systems documentation are aimed at variation reduction based on identifying what you do, documenting this and then auditing to assure that this what is actually being done over time. Each of the documentation approaches presented in the remainder of the tool provide additional foundations for lean, via ISO/QS relationships.

**Industry Wide Terms And Other Key Statistical Indicators.** Descriptive statistics seek to accurately describe a situation through data. This deals with the present, limited to describing present conditions for numbers actually studied. Meaningful values describe the results of a particular sample of behavior. The purpose of descriptive statistics is to communicate something about a particular group of observations, as in the distribution of weights on a football team or grade point averages. If we say 90% of the product was good or 10% of the product was defective, it describes concerns which we may want to know more about. We may study types and numbers of defects contributing to defectives in the 10% group.

Inferential statistics deals with inferences, implications, and generalizations from the sample to a larger population. Inferential statistics are concerned with the future, broadening conclusions to include other groups beyond those studied, such as probability for occurrences of events. Attention shifts from describing a limited group of observations to making inferences about the population. Inferential
statistics draws inferences or makes predictions concerning the population on the basis of data from a smaller sample. An example could be a poll of one hundred (100) voters (the sample) to predict how the nation (population) voted. The sample of voters polled must be representative of all (or most) voters and citizens if we wish to make useful inferences from the sample to the broader population. If we sample without having representative data, we increase the likelihood that we can not accurately infer from the sample to the population.

Central tendency is three measures, including mean or average; median or positional value; and, mode or most frequent. Uses of central tendency occur in several ways. The average or mean is the one used most often. It is used to report average size, average yield, average percent defective, and so on. The median is used in special situations such as data that can be ranked but not easily measured including color, softness, or smoothness of a surface. The mode is the most frequent or representative value, used to eliminate effects of extreme values in a distribution.

Range shows extremes in a given group of data. The range of data listed below is 3 to 21. The top of the range is 21 and the bottom is 3. Rank ordered data within the range follows:

21
15
14
12
12
10
7
3

We can determine that the mode is the number 12, appearing twice, and the average is $\frac{84}{8} = 10.5$. This was based on the sum of numbers, 84, divided by the total number of values.

Note that what started out as raw numbers has become a rather useful set of descriptive data. If this was the temperature for the first eight days in the month of January for the year 1994, it would give even more meaning to the data and to those days. This is essentially what descriptive data is about. Inferential data would reflect behavior over time in another way—still using our existing example.

If we looked at the ten year average of the same set of eight days in January and find that each of the averages is as follows:

1985 = 11
1986 = 12
1987 = 12.5
1988 = 13
1989 = 11.5
1990 = 14
1991 = 15
1992 = 18
1993 = 20
1994 = 10.5

We could then sum these and provide what is called a grand mean. This would be 137.5, and when divided by 10, it would be 13.75. We would generally say that the mean, or $X$ bar, of all of the 10 means is a grand mean, or $X$ double bar. Thus 13.75 is the grand mean of the ten year average. The inference which may be drawn from this data is that the temperature for the first eight days of January in most years will be in the range of 10.5 to 20 degrees, and on average will be 13.75 degrees.

It is increasingly important for us to be able to say that on average we can produce product with certain quality levels. We must also be able to retrieve data from our part histories and assure that we can produce products of certain types at this or that level of tolerance. Tolerance in this case means a range of values—possibly cut length of 42.5 to 43 inches on a given product line. Note the use of the term, range, used in reference to tolerance.

If the customer says they will remain a customer only as long as accuracy falls within the tolerance, how will we know if we can achieve this demand? Obtaining contracts in the future will be directly contingent upon our knowledge and understanding of range of tolerance, mean values within the tolerance, or capability, and related terms and knowledge.

Following the concept of tolerance, variable and attribute data must be introduced. Variable data is that which we can measure with a graduated instrument such as a dial indicator, ruler, micrometer or other incrementally based tool, studied as variation from tolerance. Attribute data are judgment calls based on subjective observations of defect. If we say color looks wrong or the shape is irregular, we are making attribute judgments. These are go and no-go gages, not based on graduated measures, but rather simple judgments of fit or acceptance.

**Normal Curve, Variation And Standard Deviation, Basis For Six Sigma.** Dispersion is represented by three measures including range; variance; and standard deviation. Range is the minimum value subtracted from the maximum value in a sample or set of numbers, and as a measure of variability is useful when the number of values is
small. The standard deviation as an indicator of total variation, is also reflective of what is called central tendency in and among data. Variance is the square of standard variation, providing a broader look at behavior around the mean. These values, as a function of descriptive data, fall under the broad rubric of the normal curve. The "normal curve" is illustrated nearby for further description and discussion.

While we do not necessarily use the range, standard deviation or variance directly, we do use them indirectly. Many statistical process control (SPC) calculations rely on standard deviation. This is true for attribute and variable SPC, capability, and gage repeatability and reproducibility (R & R) calculations. Concern with measures of central tendency is not only to use them directly, but understanding their role in broader applications for improvement.

Standard deviation is a calculation of dispersion among the mean, or sample total variation around the mean. Use of standard deviation allows total population to be predicted as being within + or -1 standard deviation 68% of the sample resides. within + or - 2 standard deviation 95.5% of the population resides, and within + or -3 standard deviation 99.7% of the population resides. Standard deviation is, by far, the most valuable and used measure of a frequency distribution. It expresses dispersion in a single number and as important relationships between "standard deviation" and normal curve.

Variation in product quality is the basic issue. When summed and a mean calculated, the value for the mean is a basis for further analysis. Presented graphically, it is commonly shown as a normal curve. The normal curve represents all our group of sampled data—all else is directly related back to the normal curve, and forms the basis of much of our broader SPC relationship for analysis and improvement.

Calculating the standard deviation, we can use a simple formula called the sum of squares. This provides the grouped value around the mean or average performance numerically, and if we think about the mathematics as we performed them earlier, we can understand basic relationships inherent in all of this—and when calculated, standard deviation was the average value of all deviations, represented as a mean. The average value from the mean in the normal curve is the standard deviation or variation from the mean. All other basic SPC functions rely upon this foundational statistical concept—all within the larger group of data—and the normal curve.

After determining this, we can make certain assumptions based on standard deviation from the grand mean value—generally termed sigma—and used in numerous ways. Sigma, as standard deviation, will be relied upon directly and indirectly in SPC.

Generally +3 sigma is three standard deviations on the high side of the mean or average. Three standard deviations on the low side of the mean is -3 sigma. Approximately 99.7% of all values will fall within +3 sigma and -3 sigma, of the mean, if under statistical control (plus or minus three sigma). A statistical limit set three standard deviations on the high side of the mean, or +3 sigma, is termed upper control limit. Lower control limit is a statistical limit that is set three standard deviations on the low side of the mean, or -3 sigma. Approximately 95.5% of all values will commonly fall within the range of +2 sigma on the high side of the mean to -2 sigma on the low side. The remaining +1 to -1 sigma on either side of the grand mean represent approximately 68% of all data.

The basis for six sigma as a systematic approach to improvement lies in the explanation of normal curve, variation reduction and general data-based explanations. Six sigma are represented in the normal curve, as the total population of all products or services. Our interest is to have the normal curve, or all product, be in control as represented in charting and other statistical indexes. Having an under control system requires continuous improvements and variation reduction as described throughout the toolkit, but particularly as described in the data-based tools. Relationships inherent in six sigma data-based tools and lean documentation tools are also part of the remainder of the current tool writings.
Charts, Graphs, Sampled Data As Foundational Statistical Tools

Class intervals are used to organize data by numeric groupings of equal size intervals. Rank order, as indicated earlier, refers to organizing data from most to least or highest to lowest. Distribution is the combining of frequency and intervals to organize all data in a normal curve type configuration. Each of these can be regarded as all or part of a graphical representation of statistical information.

Several other types of charts and graphical tools are useful, if not essential, in quality systems. The major chart addressed here is the histogram, although others are alluded to. Histograms, sometimes called column diagrams, are composed of a series of columns, each having a class interval as its base, and as its height, the number of cases or frequency in that class or group of data. These graphical tools provide several descriptive features. They provide automatic groupings and easier comprehension of data, taking much of the guesswork and mystery out of describing a group of data. A more penetrating analysis of a subject or issue may be provided than is possible in written/numerical form, often with a check of accuracy in reporting as part of the process. They give a different, graphical view of data in a brief and simple pictorial form, often providing powerful motivational presentation support.

Again, the power in this approach is "seen" clearly by comparing in rather straightforward ways, the larger versus smaller areas--and where we need to go to work to make improvements. This is particularly true as related to attribute data at the workplace for quick and easy analytical aids for operators. Defects and defectives, as in conformance and non-conformance, acceptance and rejection based on subjective judgments, are frequently shown in these ways with pie charts.

Sampling Issues--Defining The Source Of Information. Sampling is the act of deriving sufficient numbers of product to be studied and inspected, based on quality characteristics previously determined. It should be obvious that the sample must be representative of the total population being produced, if the sample is going to be valid. But sampling takes time and costs money to perform, and thus cannot be done any more than is absolutely necessary. Sampling is important for several reasons:

1. Reduced cost--By sampling only a portion of the entire population, relative to looking at all units, costs are reduced.
2. Productivity--If all pieces are inspected, too much production time is lost.
3. Complete and accurate data--By gathering an adequate sample, a useful "picture" of production is provided.
4. Less damaged product--Since inspection can damage the product, the fewer products to be inspected by virtue of a sample rather than inspecting all products.

Sampling can occur in various ways, ranging from random and with very little structure, to a highly structured procedurally oriented act within the quality system. Factors governing sampling relate to cost and degree of quality required. Some considerations follow:

1. Taking all measurements at the beginning of the day, or at any set time throughout the day should be avoided in most situations. Generally, if it is important to get a well rounded look at production and we would need to be more randomized.
2. Taking all measurements at a set hour, and under specified conditions, may be necessary in process control analysis. Consistency must be observed.
3. If some items are more likely to be selected, or less than a full range of quality characteristics can be observed, it may be necessary to change the sampling plan.
4. The only good sample is a representative and accurate picture of the population.
5. Samples must come from the entire lot and all population conditions must be represented.
6. Every item must have an equal chance of being selected for the sample.
7. Personnel who are gathering data and samples must be properly trained regarding documentation and reporting.
8. Adequate time must be allowed for sampling to occur. If workers are pushed too hard, quality of data may suffer.
9. Proper measuring tools must be provided to enable a proper sample to be taken.

Consistent with other quality systems' design and functioning, it is important for sampling to occur at the point of production, and to be a standard part of the production procedure for workers. Individuals who want the best sample are persons responsible for
maximum quality and productivity, persons on the line.

An additional point relates to characteristics for sampling and measuring over time. This is true since much time and general resource will be aimed at measuring a particular characteristic, once identified. It is important to make sure that they are carefully identified and justified through the customer, suppliers, quality personnel, operators, supervisors and others. As improvement is noted over time, based on statistical process control, it is important to continuously re-evaluate quality characteristics. It may be possible over time to discontinue tracking a given characteristic, as it comes under control, thus enabling the charting process to move on to another characteristic for analysis.

**Accurate Data Plus--Defects And Defectives.**

We must gather and handle data carefully and accurately. During collection and manipulation, such as organizing in forms, it is vitally important that we be mindful of the need to use extreme care and precision in our work. Increasingly, data will formulate the basis of decisions in the workplace.

The sample we use as the basis upon which to draw all of our conclusions must be carefully accomplished. How frequently to measure, when and where, how to measure, size of subgroup, who should do it, and what to do with the data, are all the beginnings of questions to ask about sampling. This must be done through careful interaction and team work with persons in quality, engineering, and manufacturing--accurate sampled data is not easy.

Following the introduction of attribute data and characteristics in quality, it is important to distinguish between defects and defectives. The two are generally different as related to data, attributes and quality. This is because the defect may be one of many which contribute to what then may or may not be a defective product. By tracking occurrences in production, we can sort the types and significance of defects versus defectives.

Even with multiple and different types of defects, product can remain sufficient for use. This also indicates the need to be precise in quality judgments, leading to the desire for variable database measures. A defect is defined as any characteristic which is not in conformance with standards or requirements identified by the customer. A defective is a part which possesses more than the allowable number of nonconformity's, usually the presence of one or more defects, again identified by the customer. Defective also constitutes product which cannot be shipped, while the individual defect may or may not qualify for non shipment.

**Attribute Charting Systems**

The need to track and chart various attributes, under different types of circumstances, has lead to the development of several types of attribute control charting systems. These are further defined as the p, np, c, and u charts. Part of the discussion focuses on general concerns which must be attended to regarding attribute charting systems. The primary emphasis will be p charting since p charting provides a good general basis from which to initiate and pursue attribute charting, and build broad SPC systems.

P charting is generally regarded as the most used attribute chart among those being discussed. It will be presented as the basis for the others. Based on the p chart, c, np and u charting will be discussed. Similarities will be drawn, and differences noted, where appropriate to aid in the broader understanding of attributes tracking and analysis, leading to variable charting systems.

As with any charting effort, it should be clearly determined what the actual purpose of the chart is at the outset, prior to proceeding. Part of this relates to determining where and how the actual inspection will occur, and the specific characteristics to be addressed--do we fully understand the details? What size is the sample and when should it be taken--and is it to remain constant over time or can it change without affecting the system? What other information should be placed on the chart and the attribute study in general--and how should it be used over time?

The general steps associated with attribute p charting include collecting data, calculating fraction defective, and the upper and lower control limits. Based on the calculations we will wish to plot the results for analysis, over time, and complete appropriate analysis and corrective actions if needed--depending on the findings at the operator workstation.

**The P Chart Steps For Constructing Attribute Data**

The p charting approach, generally regarded as the most common attribute statistical control chart system, will be briefly defined and explained, the calculations provided, and examples shown, as related to the short form presented in the companion workbook. The p chart is used where it is necessary or advantageous to know if the numbers of rejected sub components or products is acceptable or unacceptable in a given situation. While the focus is primarily on p, most of the steps and procedures are also generalizable to all attribute charting systems.
**Attribute Step 1: Collect Data.** Data are collected on the number inspected, generally identified as n, and the number found to be defective in the total sample (n) inspected. Data would typically be divided into subgroups according to some predetermined logic system, per the customers request, or based on some inspection SOP, consistent with the type product or process under study. SOP inspection strategy would frequently be identified by date or lots for future documentation and tracking needs. Subgroup size is consistent with attributes being studied, typically no less than 50 to facilitate generalizations to larger populations.

**Attribute Step 2: Collect/Calculate Each Fraction Defective.** The second major attribute step is to calculate the fraction defective or non-conforming for each subgroup. This information should be entered on the chart or some type of collection form for tracking and further analysis purposes. Fraction defective is determined by dividing number of defectives (np) by subgroup size (n), expressed as np/n mathematically.

**Attribute Step 3: Calculate Average Fraction Defective.** The average fraction defective is a function of summing pn and dividing by the total n for an average or mean value, commonly expressed as p bar. As noted in the example from the short form, this step is converting the individual subgroups to the grouped data, reflecting normal curve behavior.

**Attribute Step 4: Computing The Control Limits And Central Line Values.** The upper and lower control limits are calculated based on the p bar value converted to a percentage, or times 100. The p bar converted by percentage is used as the central line in the chart, centrally located between the upper and lower controls (UCL and LCL). The UCL and LCL are each calculated based on the standard deviation logic presented in earlier tools, plus or minus 3 sigma. It is also possible to work with other levels of sigma (i.e., 1, 2). Generally 3 sigma is used, and the UCL is +3 sigma, the LCL is -3 sigma, p is a function of np divided by n, and the p bar value represents sums of the total sample population.

**Attribute Step 5: Plotting The Points.** After all calculations are performed, for each subgroup, the information would typically be plotted on a form similar to what is provided with the short form. It should be noted that "ups and downs" may be observed in the step 5 charting graph as a function of varied subgroup sizes, sometimes which are unavoidable. This points to the need to consider the possibility of using consistent subgroup (n) sample sizes wherever possible to provide consistency in charting, as is typically desired (50, minimum, is the recommended sample size).

**Attribute Step 6: Analysis Of The Chart.** As data is tracked and plotted, the chart will provide a quick and generally easy-to-use tool for determining if the attribute being studied is sufficiently conforming to the desires of all concerned. Actions appropriate to the circumstances should be taken to adjust and improve over time. It should be clear that many of the same decisions made during X bar and R charting for variable data must be dealt with for attributes. Similar steps for calculating control limits, plotting the points of inspection, and interpreting this information, are applicable in principle, if not in practice.

Several basic issues are summarized specific to attribute charting, but they are also related to most other types of charting. By way of introduction, decisions/issues in preparation to completing the control chart could include:

--what is the purpose of the chart?
--where should inspection occur?
--which characteristics should be charted?
--what should the size of the sample be?
--should the sample size be constant?
--frequency of samples?
--information include on the chart?
--how does the p chart relate to Pareto?

Issues regarding startup of the chart include:

--judgments about defects and defectives
--recording accurate data--how, who, etc.?
--calculation of the p, completing forms
--plotting the points

Continuing control chart--issues could include:

--calculation of the control limits
--plotting the control limits
--plotting the sampled data points
--interpretation of control/lack of control
--comparison of current charts to past
--discipline for follow through

Possible actions based on p charting include:

--keeping process in control
--review of specifications, characteristics
--providing information to various teams
--ongoing improvements based on charts

While the above information should suffice to help get attribute charting started, it should also be stated that in some cases, similar to any form of pre-control, it is sometimes desirable to simply arbitrarily determine the upper and lower controls, rather than calculate them. Given constant improvement, we
will come to know that incremental "tightening" of the control limits will be sufficient for gaining constant improvement. This may seem to be inconsistent with the use of calculated controls, but we must recognize that as our systems mature, we can know that we are under control (or out of control) and we will know that improvement is incrementally being made. This is consistent with the "start-up" nature of attribute charting and data, often aimed broadly at longer term variable systems conversions.

Attributes, Checklists And Charting

Defects and defectives can be tracked via a simple check sheet or checklist. Whether attribute or variable, the check sheet can be used to begin the charting process, and also serve as the start of decision making. Not only is the immediate judgment on defect and defective being provided, but the broader corrective action for improvement should (and can) be noted. Checklists can be pivotal for obvious reasons relating to doing all of the things we have been trying to reinforce. They:

1. Provide indicators of defects or defectives at the point of production.
2. Are operator friendly, a good transitional mechanism on data collection.
3. Tie into basic work instruction or standard operating procedure (SOP).
4. Can be pivotal in Kaizen analysis, reinforcing data and documentation.

Examples include housekeeping and safety checklists, process flow and charting analysis, and various scheduling and balancing tools. The simplest of these are various operation checklists, and work sampling techniques. Through the use of relatively simple checklist tracking systems, we can apply traditional time and motion analysis tools as well as non-traditional Kaizen tools. Another is the determination of process capacity based on operations within the process. After individual capacities are determined, we can better balance our total organizational capacity through improvements at individual operations and ultimately collectively through improved process. All are tracking characteristics of process where checklists and other documentation techniques are powerful allies to data collection systems for improvement.

The process is commonly thought of as being more broadly based and composed of multiple operations. The process involves all activities which are involved in the production sequence, including those which appear necessary but may be wasteful, and thus, should be eliminated through Kaizen. These are separate from the process side since these are non-value adding categories of process, yet they will exist. Our function, or goal, and certainly task, in Kaizen, is to reduce these process inputs and maximize on the operations side of work, where value is added. This can be done, in part, through the use of checklists as discussed here.

Kaizen is about waste reduction. If we wish to reduce or eliminate waste, as we must do if we wish to be successful in Kaizen, we must identify the capacity of the operation for adding value, and use the operation to its optimum performance capacity. A work sheet, or checklist, is provided in reduced size, to assist in this determination, nearby. This form, essentially a reworked version of the earlier time and motion or method analysis form, is targeted to further analyze the specific operation as part of the previously determined and analyzed process. There will be delays, transports, and other wastes in the operation, needing to be identified and improved upon. But what is being pursued here is the need to identify and provide an optimum operating time for production within the broader process. All waste issues in Kaizen are essentially attribute or variable data, and may eventually be identified as characteristics.

This process analysis technique, while still macro, is beginning to be extremely close to being a micro technique. The specific application as a micro analysis technique for Kaizen and documentation purposes will be provided in a subsequent tool related to standard operating procedures (SOP). The operation capacity study is based on the assumption that we can detail out our operation processes and functions. The capacity determination tool, while quite useful as an independent technique for improvement in any isolated circumstance, is necessary to determine work loads for balancing and improvement through synchronous techniques.

Other documentation tools useful for addressing productivity are plant layout, process flow charting and inventory related approaches. Process flow charting uses symbols placed in a condensed format. The typical flow symbols, shown in the flow chart example provided, are usually placed in a progressive line format, connected, and numbers are placed in or near the symbol to correspond to a chart with all procedures for producing the product listed.
The advantage of process flow charting is that the entire enterprise system (or a sub-component) can be analyzed from a graphical schematic. Times and costs can be placed alongside each process on the chart, permitting further comparison and analysis. Typically we observe processes or tasks on the chart where the greatest time and/or cost is incurred and troubleshoot these for greater efficiency.

By placing the plant layout in schematic diagram form, analysts can readily identify obvious trouble spots. If in studying the layout diagram it is observed that some space is not being fully used, the prudent manager would attempt to better maximize on the space. As a general rule 75-80% of all space should be in use for optimum capacity planning to be prevalent. We should study various production layouts as well as the various symbols, logic systems, general relationships and so on, involved in plant layout and flow diagramming. Again, this provides the linkage for checklists and the beginnings of tracking and analyzing our work areas for improvement. Obviously this all relates to total time and costs to produce the product, much of what is driving profitability and competitiveness in the marketplace. These provide opportunities for use of checklists as analytical tools for detailing production.

Another, possibly less complex charting technique in the attribute judgment method is the simple histogram, sometimes called bar charts. These simple charts are bars, lines or other symbol which represent a corresponding number of values or observations tracked in production--attributes identified and logged--converted in to summaries which help identify key areas needing improvement. The bars can either be horizontal or vertical and are generally proportionally constructed relative to the information they represent. Like most other data collection and representation devices being discussed in the toolkit, simple computer programs are available to assist us.

Histograms are constructed by first determining the number of classes (cells) to use. Obviously, the number of cells in a histogram of data should be determined in part based on the number of values in the sample. Cells or blocks of information may also be influenced by other "common sense" information based on what we know about the situation. For example, it may be obvious that the data generally falls into groupings based on the nature of the manufacturing process, characteristics or other factors. Steps for histograms include:

1. Place all data/observations on a chart (sheet of paper) to begin organizing by determining the class (cell) intervals, based on the total group of actual data.
2. Construct a tally chart with classes in rank order. Classes should provide a category for each type of observation or attribute.
3. Tally each data observation into the appropriate class and list the total frequency for each cell.
4. Prepare the vertical and horizontal axis for the histogram. Vertical axes are frequencies of classes and horizontals will generally be classes of the frequency tally.
5. Fill in bars to the height of the total frequency for each class.
6. Based on the graphic, analyze and interpret data to determine appropriate steps for ongoing improvement.

An example histogram, based on our previous steps, is shown below: using frequencies ranging from 4 through 20, and various judgments of attributes ranging from A through H.

<table>
<thead>
<tr>
<th>freq</th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
<th>G</th>
<th>H</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
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One Type Histogram.

It should be noted that some inaccuracies exist with the approach taken, based on groupings and cells. This could be "tightened" in subsequent analysis based on actual measurements taken. This will be further explored in the next tool, and for now it should be recognized that simple judgment calls are frequently the start of the charting system.

A variation on the histogram is the bar graph. While similar in many respects, the bar graph can sometimes be constructed and/or used more readily. Bar graphs may also use horizontal groupings as shown below where TA, TB, and TC are frequencies of judgments given in more detail and sub grouping in cells. The judgments shown below reflect a simple distribution of attributes observed ranging from A to H, and could represent color, sheen, surface quality, or virtually any other common attribute or judgment, regardless of product.
Some general considerations for these types of bar graphs include their usefulness for viewing groups of information and for comparing and analyzing overlapping and similar groups of data. The groupings of information also approximate a normal curve shape, as defined earlier. This is assumed since behaviors studied as attributes are thought to occur randomly and to be representative of the broader population.

A slightly modified version of the histogram which has become increasingly popular over the last several years is the Pareto chart. Essentially, Pareto is a bar chart in histogram form, which also organizes the data according to highest to lowest percentages of behaviors. Another useful graphical chart is the pie chart as illustrated nearby. The graphic shows 100 product defects by categories, sorted and organized within the pie chart—by count and %. This analytical tool is a simple "slice out of the pie" for each area represented. The power in this approach is "seen" clearly by comparing the larger versus smaller areas—and where we need to go to work to make improvements. This is particularly true for attribute data at the workplace needing quick and easy analysis.

An additional bar type graph, related to histograms, is the Pareto chart. The reason for the Pareto popularity, similar to many of these tools, is its quick graphical analytical focus for quality improvement. The Pareto orders data, based on defects, ranks the occurrences by percentage, and gives a graphical pictorial for quick reference and ease of use. An example Pareto application is shown on the next page. General procedures to use in constructing pareto charts are as follows:

1. Identify the problem or attribute to study.
2. Collect data to support frequency of by attribute.
3. Focus on categorical or individual of attribute.
4. Identify the maximum level from among all attributes being studied, placing most from left to right, or least.
5. Individual behavior associated with the problem is generally shown as 100%.
7. Right vertical matrix is up to 100% downward.
8. Horizontal matrix represents categories of.
9. Construct vertical bars for percentages.
10. Connect vertical bars to demonstrate behaviors in groups, relationships.
11. Interpret information, provide improvements, repeat process over time.

In addition to applications of Pareto as an analysis tool, graphic communication and prioritization capabilities are underscored.

Occurrences are given their numerical value with "x's" in the vertical bar columns. It may be helpful to place the greatest to least column (item) of from left to right on the chart. The % value on the right is not always 100%—in fact it is unlikely that any one set of occurrences would ever equal 100%. Consider the power of the Pareto for teams when trying to get to the root cause of a given problem associated with a characteristic or attribute which is indicating a defect or defective.

**SPC, X-bar And R, Variable Charting**

SPC, similar to several other tools presented as part of quality systems, is a technique used during processing. SPC is a statistical technique used to help operators and others make decisions. After gathering and analyzing an initial set of data a charting process is implemented to allow operators to (a) determine when to make adjustments to process parameters, and (b) to describe how much variation exists in any particular process. In short, SPC, based on the X bar
(or mean) and R (or range), has the potential to help shift the responsibility for reducing product variation from a quality control department to the operator/processor.

The fundamental cost savings in SPC and X bar and R charts are a by-product of consistency and accuracy of production output. There are at least two situations where SPC can be implemented. The first situation involves the analysis of existing processes. In this case, SPC can be used to (1) determine how consistent and accurate a process is, (2) provide a basis for making adjustments during production to maintain control, and, (3) to establish proper production procedures. The second situation involves the introduction of a new product. In this case, SPC can be used to determine whether a process is capable of meeting predetermined design specifications. SPC can provide base line data at the onset of production, forming the basis for continuous improvement. There is an economic advantage to SPC, although typically not short term gains which will be noted quickly. Rather, SPC cost savings must be observed over time, often years.

X-bar and R charts can help define the amount of variation due solely to chance causes. If the process is operating within limits determined through charting methods, the process is generally considered stable and predictable. It represents the best that people operating the machine (i.e., operator, production supervisor, set-up person, etc.) may be able to do given the process as it exists. If this is unacceptable, then the basic system should be changed, including the type of machine, type of tools, design of the part, etc. This point is positively significant when viewed from the vantage point that the charting method has nothing directly to do with product specifications, but are calculated solely from the process data.

Perhaps one of the most important reasons for the use of control charts is to provide documentation. The documentation can be used in a variety of ways such as when to rebuild, adjust or replace machinery; when, where and how to change procedures; or for general comparative analysis between or among methods/procedures. The documentation also serves as "base-line" data which is the fundamental data used in analyzing changes/upgrades for improvement. After improvements have been attempted, and additional charts put together, based on the improvements, the new charts should be compared to the base line data. Related to documentation, charts can be shared among workers, shifts, departments, plants and so on. As such, the charts become a fundamental communication mechanism.

Control charts take some of the guess work out of process decision making. Once data are collected and tabulated we can begin to have some basis for decision making, rather than "gut feelings" only. In fact, one of the key reasons for using X-bar and R charts is to provide a systematic approach to production and its inherent problems. X-bar and R charting assists all people involved to become more rational in decision making.

Vendor certification and producer liability can be better established with the use of X-bar and R charts. The reliable vendor and producer today must be prepared to provide X-bar and R charts with the product. If charts can not be provided, it may be a good indication of overall product quality and reliability. The cost involved in establishing and using the charts initially will be more than justified over time as quality of incoming materials/components as well as finished products improves, thus reducing costs over time.

X-bar and R charting methods will work best in continuous production where the same characteristics can be identified for measurement over time, and thus, charted. Continuous production, with similar characteristics provided over time, should have repeated values that can be relied on to be indicative of the process. The greater the variation in conditions under which data are gathered, the greater the likelihood of incorrect process conclusions being drawn and acted upon. Thus, continuity and repeatability in production, from measurement to measurement, are an important condition. An example of this is that a reasonably knowledgeable operator is required. If a new operator were to begin charting, clearly some error in operator control would be noted. The error would be caused by the lack of repeatability and continuity on the part of the operator. After the operator has gained experience, repeatability and continuity will improve and the likelihood is that charting will reflect "under control" conditions. Also related to repeatability and continuity, reliability in material and machinery are required and assumed to be at a level sufficient to provide "in control charting conditions". If the machine is in need of maintenance or the material inconsistent, not only will it show up in charting, but it may make charting unrealistic until maintenance is performed. Clearly, variation will be noted under these conditions.

X-bar and R charting can not be viewed as a quick fix or panacea to all production problems. The requirement is a long-term commitment to quality
and continuous quality improvement. X-bar and R charting is not a band-aid improvement project. Charting method assumes a disciplined and reasonably knowledgeable worker. Not only managers, but perhaps more importantly, the line worker must be disciplined and capable of performing routine calculations, computer applications, and analytical reasoning for quality improvement at the work station. This is the most significant requirement of all, and it assumes a strong, on-going, training effort.

Standard procedures for X-bar and R charting are necessary if reliable information is expected. Reliability of the charting technique will be affected by the extent that procedures are known and followed, generally shown as standard operating procedures (SOP). General information and guidelines include:

1. Decisions prior to beginning charting.
2. Starting the control charts.
3. Drawing conclusions from the charts.

Decisions prior to the control charts include determining objectives of the charts, but certainly knowing why they are being used by all involved. Another decision prior to the use of charts is the choice of the characteristic to be charted. As discussed earlier, this is usually a specification or variable measure which can be gaged. Also, decisions on the basis of sub grouping, sampling strategy, sizing and frequency, including setting up the forms for recording the data, must be made.

Guidelines for starting the control charts include making accurate measurements on a repeatable basis using a systematic approach (i.e., all measurements are completed following the same procedures). Operators must record the measurements and other relevant data such as time of day, name of operator, machine used, and any extenuating circumstances which might explain unusual findings in the charts.

Drawing conclusions from the charts includes getting an indication of control or lack of control based on points falling outside of the control limits/lines. Related to this, what is the apparent relationship between what the process is doing and what it is supposed to do as shown in the charts? Also, actions suggested by the control chart could include changes in the process, operator, specifications, material, etc. Certainly, with sufficient charting information, use of the charts for acceptance or rejection, and even possibly whether to stop or continue, should be viewed as standard procedure in industries wishing to stay solvent.

From the overall SPC analysis it can be determined if a machine is in control or out of control. If it is out of control, some part of the process may be modified. Regardless, however, new data will likely be collected and whether the process is in control or not, the charts become a tool for decision making. The operator, with help from others—particularly team members, can then determine when a process is running normally or is in need of adjustment or if some other type of action may be required. It should be noted, however, that prior to commencing with charting over the longer term, it is generally true that the process should be capable and under control as proven through actual start up procedures in charting.

An example process in this case involves drilling a hole .500 inch deep in a block of aluminum. While the average hole may be very close to .500 inch deep, we may find one hole drilled a few thousands too deep and others a few thousands too shallow.

**Step 1: Sampling.** Remember this is a continuous and ongoing operation. We repeat this procedure every 10 minutes for at least 16 subgroups.

**Step 2: Calculating Values.** After the data is collected statistical calculations are conducted. These involve calculating the average of the subgroup depths. Secondly the range (maximum depth - minimum depth of each subgroup are calculated. Next, the mean of all average depths (X bar) is calculated (sum of average depths divided by 16). In this example the X double bar was calculated to be .501 inches. Last, the mean range is calculated (sum of ranges divided by 16). In this example the mean range was calculated to be .006 inches.

**Step 3: Plotting X Bar Chart.** On the form provided above the values have been plotted, and the mean values for each subgroup are shown. The center of the graph is shown as the grand mean or X double bar (.501), with the vertical axis representing the depth values and the horizontal axis representing time.

**Step 4: Plotting R Bar Chart.** Similarly, the ranges for each subgroup are shown in the figure. Again, the center of the graph for R is .006, with the vertical axis representing the values associated with ranges and the horizontal axis representing time.

**Step 5: Calculating Control Limits.** Control limits represent boundaries for acceptable variation within a process. The calculations for these are based on simple formulas. The upper control limit (UCL)
and the lower control limit (LCL) for the X bar chart are calculated by:

\[ UCL = X + A2R \]
\[ LCL = X - A2R \]

In the formula A2 is a constant statistical value based on the subgroup size. In the aluminum block example it was sampled 5 times in each subgroup and therefore the factor of .58 was used in the formula. Other statistical values for different subgroup sizes vary but five is the usual subgroup as shown in the lower right hand portion of the form. Substituting appropriate values, the calculations are:

\[ ULC = .501 + .004 = .505 \]
\[ LCL = .501 - .004 = .497 \]

In the case of control limits for the range only the upper control limit is calculated. Essentially, the technical manager is not concerned where there is minimum variation in a process range, and hence there is no lower control limit. Again the general formula for the range UCL is simply a matter of multiplying the mean range times a constant statistical value, D4. In this case D4 is equal to 2.11 based on subgroup sizes of 5. Therefore, the UCL is calculated as .012.

**Step 6. Plotting the Control Limits.** The last step is to plot the control limits.

**Step 7. Interpretation of Charts.** As the ongoing process is charted and repeated, an operator can immediately determine if a machine is in control (within the boundary of the control limits). If the process is outside the limits corrective action should be taken.

**Cp And Cpk Definitions And Capability**

X-bar and R charting could be particularly difficult to use in a meaningful way if the machine or process is incapable. Technically the machine or process should first be studied for capability, and proven to be capable, prior to attempting to use X-bar and R charting. If the machine or process is not capable, it should first be adjusted or modified to become capable according to appropriate statistical measures. If the machine or process is statistically capable, X-bar and R charting can commence.

Capability is determined by the total variation that comes from common causes, or the minimum variation that can be achieved after all special causes have been eliminated. Thus, capability represents the performance of the process itself, as demonstrated when the process is under statistical control. Since a process in statistical control can be described by a predictable distribution, the proportion of out-of-specification parts can be estimated from this distribution. Generally, as long as the process remains in statistical control, it will continue to produce the same proportion of out-of-specification parts (or in specification parts). Management actions to reduce the variation from common causes are required to improve the process ability to meet specifications consistently, thus improving capability. But then we would be able to say that the process is capable, and predictable based on our statistical analyses over time--ongoing improvement.

The theory of capability is that as average values are generated and tracked, the grand mean can provide a relatively good picture of actual ongoing production circumstances. This average value gives a "center line" of all ups and downs of data being averaged in to the total picture on reality. Over time the average value, or grand mean, as shown in X-bar charts, is a generally good theoretical and real construct and indicator for controlling and improving production. This also relates to the standard deviation and central tendency discussion which was provided earlier related to basic statistical definitions.

When the mean value is factored into the specified upper and lower limits, or tolerance, this provides the capability index. This index or ratio as it is sometimes called provides a single numerical value which is quickly referenced against other similar values from competitors, or from suppliers as a required benchmark for components, or simply as an internal indicator of quality and improvement. Commonly, this ratio, or numerical value, has been around 1.33. But it will consistently be changing since the competition will always be striving to improve themselves--we can not sit still!! 1.33 today will likely be 1.50 or 1.66 tomorrow--and 2.00 in the not so distant future.

Capability studies deal with relationships of controlled process, as reflected in statistical process control values, to the pre-determined specification limits for the process. This is the real purpose of process control: to produce individual units of product within the specification limits or at least to minimize the amount of product outside the specification limits. If the 6 sigma spread exceeds the specification limit it is clearly shown that there are a certain percentage of the product outside the specification limit. The amount of product outside the specification limit is determined using normal curve distribution and standard deviation theory.
Quality Characteristic Foundations, Changing Relationships

Quality characteristics are important dimensions, features or parts of a component or product. Characteristics involve the classification of numerous important areas of a product, such as dimensions, speed, hardness, weight, and finish, each according to their relative importance in contributing to the quality of the product. This enables the quality effort to be directed to the matters of greatest importance, through the use of priorities. It also simplifies selection of sampling plans and increases inspection accuracy on important characteristics. This all must be greatly dependent upon customer demands or inputs.

Quality characteristics impress on individuals in the organization, the need to carefully consider the importance of each characteristic in establishing tolerances and general relationships in quality terms. It also helps to assure minimum quality cost by decreasing chances of error and aiding in general focus of issues in quality for communication. Establishment of characteristics to be addressed, and possibly inspected, may occur simply based on the key problems which have been identified. But it is also essential for quality characteristics' determination to occur based on input from the customer and perhaps others, certainly to include suppliers and technical inputs, both internal and external.

Much has been studied about data, and some elements of documentation have been introduced, based on the tools presented to date. The next set of tools provides a serious focus on documentation, built around, and upon, the data systems currently being presented. And of course, many of the data based tools currently being studied are in fact documentation type tools by default, all in healthy ways which can assist in building the robust quality system. But much of what has been presented has not been integrated as well as it should, and can, be. The total quality system can only be effective if we can envision it in its totality, tying all elements and functions together. This is all viewed through the critical component which we call the quality characteristic.

Whereas engineering was not so long ago the primary evaluator of characteristics, listening to customer demands, and inputs, it is now true that the operators and others must have a strong voice in quality. This obviously also points to shifts in what quality persons do. Perhaps the quick and easy way to address this is by saying that we have all gotten more technical. But as well the operators, maintenance persons and quality persons simply must do more of what engineering once did, almost exclusively. Quality persons must interact more with the customers, understanding their demands and inputs for quality--linking this with design and engineering functions and operator input at the floor level.

The quality person must become more of a "quality engineer", understanding the design and other technical aspects of the product, and being fully apprised of where we are in production with the process control side of SPC information. As the SPC system becomes increasingly sophisticated and mature, it is fully anticipated that we will see calculated process control limits (upper and lower) which are becoming increasingly liberal--not because we changed them--but because we have made improvements over time, bringing process and resultant data under control. This should result in improved capability measures--depending on how tight we keep the tolerances--as a direct result from quality persons and others who are in direct communication with the customer. It is vitally important for all involved to pause and recognize the importance and significance of the characteristics in the overall equation for quality. Part of the important changes that are occurring have to do with degree of specificity in determining the quality relationships throughout production--all aimed at maximum customer satisfaction as determined through assessment against characteristics.

Metrology And Inspection—Attribute, Variable And The Broader View

Metrology is the science of measurement based on some known standard. Inspection is the comparison of existing materials or components to known standards or values. If we are going to build effective quality systems it is important to first determine quality characteristics upon which standards can be based, understand the relationship to customer and supplier needs and issues through vendor certification, know the metrological tools available and how to apply them, and finally build it all around reliability principles known to be effective. The following section provides further information and helps put it all into a context appropriate for building the necessary quality system.

Measurement scales are of two types, nominal and interval. Nominal measurement scales have numbers assigned for the sole purpose of
differentiating one object from another. This could include identification of lots and locations of product in various stages of manufacture. Interval measurement scales are measurement systems for classification which includes an equality of units. This means that there are equal distances between observation points on the scale. Not only can we specify the direction of the difference but we can indicate the amount of the difference as well. This could refer to temperature scales, and any application with all the characteristics of the interval scale plus absolute zero capabilities enabling statements involving ratios of two observations, such as "twice as long" or "half as fast". Variable data is measurable with graduated scales, digital devices, or other numerical instruments and systems. This is an important difference, since while most products are measurable in variable instrumentation ways, it is not always practical and certainly not always cost effective to do so. Moreover, it is not necessarily always needed--and frequently it may not be easily done. But much of the focus of the current tool is that we will frequently wish to gradually, by design, shift to variable data collection and charting systems.

An attribute example used earlier was appearance of some types of clothing. In many cases judging the appearance of the clothing was fine as an attribute, but it is also clear that specific sizes of clothing, as variable data are quite important. Similarly, when we eat food we generally know whether it is good or bad by taste, but it may also be very important under some circumstances to determine by careful measurement, the food's temperature in preparation, or to use related variable measures to determine other characteristics in quality. If bacteria were present in undesirable quantities, we would want to quantify this, beyond the simple attribute subjective "taste test".

Building further on the food circumstance, attributes can be further defined and explained. Attributes such as overall appearance, color, texture, general taste, and others are characteristics which can be observed and tracked. Other characteristics such as size, volume, weight, temperature, and others are specific and measurable with some type of variable instrument or gage. The previous attribute characteristics are judgment calls that may or may not use a simple go or no- go gage. It is also significant to point out that in each case, attribute or variable, further definition could, and likely would, be given in characteristics. That is variable size in portions, mixtures, and so on could be specified and general appearance attributes could be further delineated as balanced, colorful, and so on.

While variable data are generally the more desirable due to specificity and precision for mechanical fit and function, many quality situations and characteristics do not require this type of precision and detail. In fact in many cases if we determine how to track some characteristics with variable data when a simple attribute judgment is sufficient, we simply will not be competitive. As production becomes increasingly less oriented to artisans and craftsmen, and more mass production and repetitively oriented, we will increasingly see more variable data being generated, of necessity. This is particularly true in continuous production situations. But the start will often be attribute and judgmental in nature, later to shift to more sophisticated variable measures.

This all relates to the inspection function, driven to a great extent by the identification and understanding of quality characteristics. It is vitally important that we understand and distinguish between traditional "after the fact" inspection, and inspection for conformance to characteristics, during production, at every phase, as a regular part of the standard procedure. The typical inspection system will involve, at minimum, receiving, in-process, and final/shipping elements or steps. As part of this the component which we are generally most concerned with, due to the production relationship overall, is the in-process component. The charting, tracking and measuring components are oriented primarily to in-process functions. Even so, attributes can and should be tracked and logged in final ship inspection where packaging, labeling, and overall quality are observed as a function of the last steps in production. Similarly, as the raw materials and parts are received for production, we can inspect attributes and variables which are important start up characteristics.

We should also recognize that it is important to gain accurate and timely data for analysis, and that wherever possible we must try to convert attribute data and inspection to variable data and collection. Moreover, we will want to reduce the inspection for detection, and shift to inspection for prevention and validation of under control conditions. We are not simply inspecting because the customer says to inspect, but we are also, importantly, inspecting for ongoing improvement of our process. And again, this includes careful and detailed attention being paid to our quality characteristics--evaluating and possibly changing how we collect, evaluate and work with a given characteristic over time.

A brief discussion of what the 100% inspection method means would seem appropriate in
closing this section. This also relates to the standard methods and procedures to be discussed in the next section. As part of the standard method, every part should be viewed and carefully observed by workers closest to the point of production. But this can only happen if work in process and housekeeping in general permit us to see work clearly. 100% inspection refers to all parts being observed in clear and unobstructed work areas due to well balanced and planned production, all focused on well understood characteristics to be built in to the product. The inspection function is a part of the regular SOP, taken for granted that prevention of defects and quality problems is superior to allowing quality to slip past an operation or process.

But inspection systems and the inspection function can be expensive. It is for this (and others) reason that many organizations are conducting only first piece last piece (FPLP) inspections. This is where first and last pieces produced are inspected and compared within an entire lot, on an as needed basis. Generally speaking, if the first and last piece in a production run, or lot, are satisfactory, then it seems safe to assume that the entire group is satisfactory. Since this does not give a "total" picture by any means, it may prove totally inadequate depending on the product, lot size, and so on. But FPLP inspection may be a good place to begin.

Consistent with other quality systems’ design and functioning, as presented earlier, it is important for sampling to occur at the point of production, and to be a standard part of the production procedure for line workers. Assuming quality and production systems are working correctly, individuals who should want the best sample are persons responsible for maximum quality and productivity, persons on the line. Sampling can occur in various ways, ranging from random and with very little structure, to a highly structured procedurally oriented act within the quality system. Factors governing amount of structure in the sampling procedure relate to cost in production and inspection and degree of quality required in the product.

Quality systems, and in particular metrology and inspection, must assure form, fit, finish and function. These will be further addressed in terms of surface quality considerations, tolerances and allowances, and dimensions and shape. It must be understood that this relates considerably to design and engineering functions, as well as production functions throughout the organization, not to mention function after a product is in service, or reliability. These all provide excellent examples of quality characteristics, primarily from a manufacturing vantage point. The example of surface quality considerations include roughness, and finer irregularities in surface texture, usually resulting from processing but not necessarily limited to processing. Surface quality could also be a function of corrosion or other physical impact beyond processing. Roughness height/width waviness and other errors of form are all typical concerns when considering surface quality. Measuring surface quality is generally accomplished by moving a fine stylus or probe across the surface of the component being examined. However, a more precise method is interferometry, a quality/metrology method involving putting light on the objects' surface and measuring the interference in light waves.

When parts are designed to go together, some tolerance is typically allowed, identified as a characteristic. Tolerance says how much deviation from standard can be allowed, above or below, positive or negative. These are generally given in bilateral, unilateral or limiting tolerances. Bilateral is where the part can vary ± .003, but is ± in either direction from the specification. Unilateral allows only deviation in one direction, such as + .003 or - .003. Limiting simply says the range of dimension, as with .003, but is not directional relating to the specification. These tolerances also relate to specification (or "spec") limits in a separate section during the discussion of control charting.

Allowances indicate contact/space between mating components. Clearance is free space allowed and interference is when negative clearance is required, as in the case of press fits. Allowances also relate to specifying quality in the design function, and function in mechanical applications. These all represent characteristics in quality.

Base line dimensioning is useful in specification of quality characteristics. It is where all dimensions and measures are given from a common reference point. This eliminates tolerance build up and provides all measures to a common reference point. This is a spin off of computer numerical control, absolute programming, where all dimensions come from X and Y coordinate intersection in machining operations. Geometric dimensioning and tolerancing also relates here since all forms/shapes are treated similar to base line dimensioning. The quality system must help assure that proper information is specified in design and engineering functions, and built into the product. This all is directly related to the discussion about quality characteristics.

Part of knowing conclusively whether a process is capable requires determining, as precisely
as possible, what the quality problems are. This may include simply knowing where to look for information about process quality. Several sources of information could prove useful in determining and prioritizing product quality problems, and associated process capability problems. These sources could include inspection data, material reviews and scrap and rework data, and warranty review information. Quality characteristics must be viewed within the context of capability and the broader quality system.

No two mass produced products are exactly alike, since processes contain many sources of variability. Differences in similar products may be large, or they may be insignificant but they are always present. Production components and parts are particularly susceptible to potential variation from the machine, material, operator, methods, environment, and perhaps other factors. To reduce variation in a process, the variation must be traced back to its sources. The first step is to make the distinction between common and special causes of variation. Common causes refer to the many sources of variation within a process that is in statistical control. They behave like a constant system of chance causes. While individual measured values are different, as a group they form a predictable pattern that can be described as a distribution. Special causes (often called assignable causes) refer to any factors causing variation that cannot be adequately explained by any single distribution of the process output, as would be the case if the process were in statistical control.

Process capability issues resolution and improvement may also include simply knowing where to look for information about process quality. This could also be traced to specific factors and can often be classified as follows:

1. People.
4. Environment.

Several sources of information could prove useful in determining and prioritizing product quality problems, and associated process capability issues. These sources could include inspection data, material reviews and scrap and rework data, and warranty review information. This, of course, is at the core of the toolkit. Documentation and data are the keys to moving forward for improvement, all based on characteristics being known, understood and analyzed over time within the broader perspective of quality.