Lean Six Sigma Quality Transformation Toolkit (LSSQTT)*
LSSQTT Tool #8 Courseware Content
“Statistical Foundations For Data-Based Improvement,
Lean, Six Sigma Solutions”

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*Updated fall, 2007 by John W. Sinn.

ISO 9000 Streamlined: TS 16949 2002 Basis For Quality Systems

Global issues represent key driving forces world-wide, today and increasingly, in the future. As the future continues to unfold we will hear increasing amounts about this, and in particular, ISO 9000. The ISO standards relate to much about doing business in the future, world-wide and at home. This is true since cultures and systems are changing, and all are becoming increasingly precise and mature in what we do. Resource shifts, economic factors, strategic plans and other major factors will all require a common playing field between and among suppliers and customers.

While ISO was designed to be an international or global entity, much of the same logic applies to QS 9000 standards. QS was designed as a primarily domestic functional system, but relates rather directly to the ISO logic and principle, as well as functionally. Part of the intent is that duplication and waste among and between systems can, and should, be eliminated. But most important in both cases, it is essential that the actual purpose of the systems be seen clearly as improvements in quality rather than simply achievement of another registration or certification plaque on the wall. This will be addressed further as related to TS 16949 2002.

Started in the European Union in the last century, the ISO/QS movement began to pick up steam in America during the late 1980’s and early 1990’s. The US increasingly needed a platform for planning and conduct of increasingly complex products, and the ISO standard, in the form of QS as related to automotive became that platform. Several major changes have occurred in the basic fabric of the standard, leading to a current 2000 version for basic operation and a 14000 version specific to environmental.

The focus of the ISO movement is development of standards consistent around the world so that all parties/cultures who wish to do business can participate as full partners. This is true of the QS system as well, but at a domestic or local level. As well, the ISO and QS movements define methods to use in documentation, specifications and in other basic but critical communications systems. This also relates to understanding and serving customer needs, and development and maintenance of good vendor/supplier relations over time.

Part of the initial confusion typically associated with ISO and QS is where they fit with the Baldridge Award. The Baldridge Award, identified and explained briefly, is a major quality award provided through the Federal Commerce Department of the United States. The focus of the Baldridge is:

1. Leadership.
2. Information and analysis.
3. Strategic quality planning.
4. Human resource development, management.
5. Management of process quality.
6. Quality and operational results.
7. Customer focus and satisfaction.

The Baldridge Award is a broader framework for the total quality system and management of the total process. The Baldridge Award is commonly regarded as a good stepping stone toward the broader and perhaps more practical ISO and QS systems. The original Baldridge award logic was that a few organizations would be awarded the prestigious designation based on their efforts. Indeed that was
done, but recently the interest has moved on to obtaining ISO and QS designations.

ISO standards are not intended to measure the quality of a product in and of itself, but rather only to help assure the organization's compliance to standards identified by the organization themselves. The ISO task is to establish an international quality standard that helps manage every aspect of production from design to in service conditions. Sometimes referred to as a common sense approach, there are questions about paper work required and being generated. Clearly, the ISO and QS approach is designed to establish a contractual base for customer-supplier relations.

While ultimately aimed at establishing a contractual basis, interestingly, ISO and QS does not focus on specifying what level of quality must be provided. They do, however, help assure compliance to a standard once identified through the process. Thus, regardless of level of defectives produced, it is important to note that this can be certified, as long as the quality system can demonstrate compliance. In other words, as long as the organization does what they document as being able to do, this is certifiable.

Generally the way the registration process works is that application is made to a registrar, a certifying body such as the underwriters labs--the registrar is selected in the same way any supplier is selected. Review by the registrar occurs, focused on the applicant's documentation--of their quality system/manual. An optional step can be a pre-assessment phase, done by either an internal auditor or external registrar. The actual assessment process is done by one or more auditors taking several days on site, leading to certification or a period of corrective action followed by re-audit. Surveillance is the final phase, including periodic re-audits to verify conformance with practices and systems.

Both internal and external certification is used in the registration process. Internal consists of someone designated within the organization to lead and conduct the process. External certification is the typical end process desired by most organizations, requiring the third party approach indicated above. It is also desired in some situations, to merely be in compliance with the ISO standards, but not actually registered.\(^1\)

The 9000 series actually embodies a five part series of guidelines. The 9000 level is the first in the series, being a guidebook on how to apply the other materials in the series. 9001, 9002 and 9003 are those which organizations may be certified to through what are known as third party (independent) auditors. 9001 is the standard for design and development, production, installation and servicing of product, constituting the most comprehensive of the group with twenty standards cited. 9002 and 9003 each provide more focus to the 9001 series, with 9002 going into more detail on production standards while 9003 details inspection and testing.

The actual "meat" of the standards are detailed in 9001-9003, classified according to process definition, process control, process measurement, process improvement and administration:

1. Process definition: quality system; contract review; design control; and purchasing.
2. Process improvement: corrective action; and internal quality audits.
3. Process measurement: purchasing; inspection and testing; control of measurement and test equipment; inspection and test status; and internal quality audits.
4. Process control: purchasing; customer-supplier materials; process identification and traceability; process control; control of non conforming product; handling, storage, packaging and delivery; after sale service; and statistical techniques.
5. Administrative: management issues; quality system; document control; quality records; and training.

It should also be pointed out that some of the above requirements are covered in more than one level. This is true since there are obvious relationships and overlaps which exist throughout the quality system, but varying degrees of detail and specificity are required depending on function.

The ISO/QS process is further detailed through what are termed tiers from most to least complex. The most complex tier of documentation is the quality manual, an overall guide to the organization's system's policies and objectives. The next level of complexity is the procedural tier, providing process descriptions and flowcharts of the system--detailed descriptions of each process activity. The third tier is detailed in work instructions, descriptions of step by step job procedures, or standard operating procedures (SOP's). The lowest level, or tier, is the form and

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\(^1\) General information discussed in this section is condensed from the AIAG, "Quality System Requirements--QS 9000" manual, publication QS9-3. Automotive Industry Action Group, Detroit, MI.
record, details of charts and other recording devices and systems' elements.

Regardless of tier, classification, or level, these are all designed to be routinely updated for purposes of demonstrating that all quality practices are being properly performed. In all cases, the fundamental elements are:

1. Describing what we do.
2. Defining responsibilities for those areas and activities within the organization.
3. Describing how those activities are carried out by people in the organization.
4. Describing the records kept in the organization.

The above can assist any organization to enhance their overall approach to doing business through, or based on, the above elements.

**TS 16949 2002.** The TS 16949 2002 standard is an updated and streamlined version of the ISO 9000 standard. It is intended to assist organizations who may be certified or those contemplating certification. Based on the original ISO rubrics and elements, it reflects maturity and a more agile system for quality management, consistent with where most organizations are in the new 2000 century. General changes in the quality management systems provide for fewer key elements resulting in a streamlined system which is more integrated throughout all aspects of the organization. Part of what this means is that management has come to realize the importance of changing culture and systems to be more aligned with QS, and has become increasingly supportive. Key elements in TS 16949 2002 are:

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. Each of the new elements are addressed and compared to the older systems in the following section.

**Quality management system.** A major emphasis is now being placed on descriptions of how various processes in the management systems interact with one another relationally to assure quality. Sequences and where each requirement is addressed are of prime importance with new procedures required to assure document control.

**Management responsibility.** 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. Top management must have an increasing working understanding of efficiency of product realization process. Management must pursue enhancement of customer satisfaction and focus, with increased emphasis on customer requirements, including specific persons in the organization designated to assure that requirements are met. The quality policy must include a commitment to continually improve the quality management systems. Quality planning must establish measurable quality objectives for relevant functions and levels, including specific reviews to assure that all objectives are met. Greater flexibility is noted in the new management responsibilities, with less documentation required overall. FMEA’s are to be reviewed alongside safety, and environmental issues to assure broad compliance beyond only traditional quality objectives.

**Resource management.** Resources must increasingly be reviewed and enhanced to assure sufficiency for meeting quality objectives in quality systems. Education competencies for personnel must be based increasingly on training, skills, and experience and must be clearly established. Actions beyond training may be needed to encourage personnel to be aware of the importance of their actions to meeting quality systems objectives. More latitude is given to the organization to determine specific skills required to meet quality demands. Processes must be in place and assured to motivate quality objective achievement, continual improvements and environment for innovation, with a measurement process. Increasing emphasis on lean processes to help achieve improvements is clearly part of the new standard.

**Product realization.** Increasing emphasis is being placed on determining quality objectives for product early in the engineering and design process. Requirements are not necessarily stated by the customer as has traditionally been the case, but still must be determined, but in a more “shared vision” context. Capacity to produce product and deliver per contract must be documented to demonstrate feasibility and must include risk analysis. Methods for communicating with customer must be clearly established, including establishing how to use internet. Establishment and management of multidisciplinary teams must be discussed with emphasis on how to do FMEA’s, control plans, corrective actions and other key documents and methods to assure effective communications. Purchasing, production and service provisions must be accounted for in increasingly demonstrable ways.
Increased emphasis on management reviews and signoff’s based on and around verification and validation procedures must be noted in systems per customer program demands. Advanced planning documentation must be inclusive of all suppliers, with them registered to compatible standards as part of supply chain. Performance of suppliers must beyond delivery to include data-based measurables. Verification and validation of production processes and tooling applies to all, not just special tooling. Calibration must be recorded to include identification and assessment of impacts, with labs doing calibration accredited to ISO compatible standards.

**Measurement, analysis and improvement.** Organizations must plan and implement processes required, and actually use as well as understand the same, particularly related to data-based measures. Methods to monitor customer perception must be documented. Audits must be used, conducted by someone unrelated directly to area being audited, to show compliance with ISO TS. Each process must be audited, both in-process as well as final product audit for all shifts based on common checklists by auditors with demonstrable qualifications to audit ISO TS. Systems for taking corrective actions when non-conformity in audit is noted must be documented. Customer alerts must be built in to assure effective communications when non-conforming product is shipped. Specific types and amounts of data collected to audit and analyze quality systems must be demonstrated and documented as well as continually improved based on data collected. Process improvement must emphasize variation reduction in all functions with documentation support. Test and analysis reviews increasingly must emphasize decreased cycle times for turnarounds in data.

**TS 16949 2002 summary.** The new TS 16949 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.

**Environmental 14000 Standard.** Another recent ISO standard which is becoming increasingly important is the environmental 14000 standard. The 14000 standard is concerned with helping organizations to assess and address their environmental performance. The standard provides guidance to organizations in controlling the impact of their activities, products or services on the environment. Like all ISO standards, the 14000 standard provides a broader context, as a structure and management system, within which to assess the environmental performance. The elements for ISO 14000 are similar to other ISO standards, and there may be opportunities to overlap the management systems. However, the elements in ISO 14000, due to the specificity of their intent, also clearly require additional attention by the organization. The specific intent of the 14000 standard, along with additional details, is explained in tool 29.

**Auditing quality systems.** One way organizations will improve their quality and overall operation is through auditing. The audit is essentially a survey which raises questions about what we are doing, why we are doing it, and so on. More specifically the audit is an evaluation or assessment process used to determine the degree of adherence (or lack of) to prescribed criteria or standards, resulting in a judgment of conformance. As a practice the audit is usually a planned event which is focused on assessing documentation assembled to demonstrate the effectiveness of the quality management system, usually done by investigation, examination and analysis of documentation and other evidence provided as representative of the system.

Audits can be conducted as self audits within the organization, external audits as a customer would do of suppliers and third party audits which are conducted by an unrelated objective group. The audit may be a rather formal process with robust and extensive documentation, requiring an entire staff commitment of several days, or the audit may be rather informal and loosely conducted for purposes of evaluating ourselves for improvement in rather quiet ways. Other approaches include contractual audits which are done prior to awarding contracts, at the conclusion of specific contract stages, and so on. Finally, routine audits, both internal and external are done as part of certification and registration for ISO/QS adherence purposes.

Four general categories of audits are typically used. These are financial or operations, system audits, product audits, and process audits. Financial or operational audits focus on accounting practices or specific operations, frequently tied to fiscal procedures. Systemic audits are broad approaches to the system, looking at policies, general procedures and documentation approaches, standardized work instructions, and so on. The systems audit is aimed at evaluating organizational structure, responsibilities and procedures for fulfillment of the quality system. Product audits are product specific, analyzing to determine if the product is meeting specifications and design criteria established in earlier contractual agreements. The product audit is focused on
from the audit, leading to changes which are of the
and decision making inputs will often likely result
indirectly involved. Broad management information
short term improvements by persons directly and
The audit will typically encourage both long and
ultimately. Other specific reasons to audit include:

1. Compliance is assured.
2. Monitor personnel improvement.
3. Improve financial performance.
4. Measure management effectiveness.
5. Improve internal operations.
6. Helps all stay focused, centered.
7. Roles, responsibilities are flushed out.
8. Firms up the best practices.
9. Provides internal benchmarking systems.

The audit will typically encourage both long and short term improvements by persons directly and indirectly involved. Broad management information and decision making inputs will often likely result from the audit, leading to changes which are of the strategic order. The audit provides a routine gage of "where we are in our "quality journey", a tool which we can ill afford to conduct and use. It should also be recognized that while generally quality oriented, the audit can be used to address and help improve virtually all internal functions in the organization.

The goal in good auditing is fact finding, not fault finding. Good auditing systems build in the time to assure that all facts are gathered based on solid observations, and substantiated by evidence. Listening effectively to all aspects of the organization is a very important part of the process. This requires good planning and organization in the audit process, including taking away opportunities for distractions, arguments or confrontations. Being objective and non-judgmental will require careful follow-through to assure that sufficient information is gathered and analyzed. This also requires focusing on the problem, not so much the blame or fault, and use of the problem as a positive opportunity for improvement.

Basic steps and procedures used in the auditing process include initiation, planning, conducting, reporting and closing. Each of these are further detailed, along with all auditing functions, in tool 29.

Introduction, overview, data-based tools. The use of statistical and data based 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. Numerical indicators and measures from production take some of the guess work out of making decisions-and can help us 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" workforce—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.

Specific tools addressed in the data based toolkit include:

1. Basic statistical principles, standard deviation;
2. Attribute charting systems;
3. Variable charting systems;
4. Capability analysis;
5. Gage repeatability and reproducibility; and,
6. Quality characteristics, robust systems for variation reduction.

All of these concepts and principles are dealt with in a broader environment of teams, problem solving and quality improvement. Infrastructure for facilitating quality is emphasized and underscored throughout all tools and systems.

**Foundations for problem solving, improvement.** This set of tools is about knowledge based applications for technological problem solving aimed at improvement. As we make incremental improvement in various ways based on data and documentation, the quality leader in a well designed and run organization will need to be cranking up the robustness on tools and techniques. Most tools studied at the lower levels are essential to improvement, and we can make giant strides based on them. Over time, as we make incremental and disciplined change in the organizational quality with all else that must be done to fulfill our vision of a competitive organization, we will need enhanced robustness in our tools and teams to accomplish additional improvement. Individually the data based tools are highly useful since they take a small window of opportunity within a larger context for analysis. Data based tools:

1. Are detail oriented, micro looks at macro relationships--based heavily on, and requiring broader documentation foundations.
2. Force users to study various relationships tangential to the problem under study--and to have the ability as measured in experience and knowledge--to be able to do this.
3. Provide the basis for discovering relationships and issues which may prove useful to solving problems, both currently under study as well as not under study.
4. Can disclose various process and/or product improvements, incrementally, as progress is being made toward solving the problem--without never actually "solving the problem".
5. Require a rather mature organization with solid technical breadth and depth.
6. Are rather cost intensive and not to be undertaken "where we are in a hurry" to discover "the solution".
7. Require the understanding that most perennial problems are not going to be solved quickly or easily.

As we move forward into systems for data and beyond, it becomes obvious that this is important for all organizations which wish to be competitive in the future. We ought to consider that our ability or inability to move forward with data based tools will be a strong measure and indicator of where we are organizationally.

**Team Based Problem Solving Context.**

Using the current tool as a backdrop, and focusing
specifically on enhanced and long term problem solving, this section provides a context within the broader infrastructure described. While specific steps for problem solving and actual procedures are described in detail in several parts of the overall toolkit, this section is designed to give general guidance to a technical problem solving system which is designed particularly around the various toolkits. The broad basis for the system being discussed is the toolkit technological change model, using data and documentation with teams and leadership within the proper culture as depicted in the model earlier, shown again for further discussion.

The graphic depicts essential relationships between and among toolkit elements for team building, problem solving and improvement. Appreciating that the team requires data and documentation seems less difficult to understand on the surface, relative to how to conduct the broader problem solving act. It is the synergy inherent in the relationships built around and between the data, documentation and leadership, all synchronized toward the collective team effort which can and must provide the technical solutions’ infrastructure as well as mechanism. But this will only happen if proper design consideration is given to the overall infrastructure and organizational aspects technologically and with regard to human resource issues.

The overall problem solution will be a function of three fundamental phases, each wrapped within the broader context of data, documentation and synchronized leadership as depicted throughout the toolkit. The phases are assessment, analysis and action, each to be further explored and defined within the remainder of this section. This would seem to be at the core of the concept of ongoing improvement. A three tiered linear relationship exists between assessment, analysis and action, all related and ongoing based on feedback within the context of problem solving. While depicted as a straight line linear function, obviously the functions will not always be this discreet, straight forward and simplistic. Yet the relationships which are embodied provide a useful strategy for the context of bringing forward technical solutions and improvements.

**Assessment.** During the assessment phase of problem solving, the team must document the current circumstances surrounding the problem or opportunity for improvement. This may involve demographic data such as persons and equipment involved, process flow charts of the macro process as well as the micro process. Regardless, much documentation will be involved to flush out the “who, what, where and when” type issues surrounding the way we currently do what we do. This could be a total line or production job site at the macro level and a micro work area within the broader system further analyzed. Both would likely require layouts, time and cost data, standard operating procedures, and flow charts on the current process and system.

Product design and specifications documentation would also be well advised as part of the assessment. Various tools for data analysis and documentation would begin to be formulated as a function of the nature of the product and process. It should also be clear that the data and documentation tools selected and used in the assessment phase will have a direct relationship to outcomes overall for the study in general, and subsequent phases in particular. Based on a thorough survey of all persons engaged in the work areas, it is quite likely that specific areas for further analysis will become apparent.

**Analysis.** While the major focus for assessment was to determine the current methods for processing product, the analysis phase builds on and around the assessment. Data and documentation begun in the assessment phase are fine tuned and multiple iterations may be required based on further analysis. Ultimately various experiments or trials may be run to determine optimum conditions or to further analyze what was flushed out and believed to be valid in the original assessment. Pivotal in the analysis phase is the establishment of baseline data and documentation as performance baselines upon which to base measures of improvement. As baselines are established, sources of variation are determined, focused on and causes flushed out for optimization. Stabilization in process must be achieved in reasonable ways,
facilitating a clearer understanding of broader relationships in production process. As this occurs, factors and levels appropriate for further study will begin to surface. But this all assumes that under control conditions can facilitate a sufficiently "noise free" circumstance for focused improvements. It is this analytical environment which can demonstrate optimum conditions in process.

Frequently, conflicting views or information may be found in the assessment, requiring various analytic tools and/or further clarification. Tools being required at this phase may consist of basic data such as attribute and variable charts, gage R & R, Cpk, and so on, all organized within the ongoing process control plan (OPCP) and failure mode and effects analysis (FMEA) documentation tools. When these tools are used in the team mode being described, the result might be that the overall complexity of the problem solving situation has shifted. More than likely, in most case only one or two of the tools will be used, rather than all of them at the same time. But the array of tools available for analysis should not be under stated. Likewise, the number of iterations with any one tool, to continue to interpret and understand the overall problem circumstance for improvement, will vary. Also the quality of the problem solution will determine whether further iterations will need to occur.

**Action.** The final phase in the pursuit of a problem solution will be the recommendations for action. Actions may consist of new procedures to be followed uniformly in the process, new equipment based on conclusions that processes analyzed were not capable, or others. All of this will drive establishment of new standards, training and additional studies. Assuming new equipment is evaluated as being appropriate for implementation as part of the solution and improvement, new studies and iterations will be required as we move down the road. This is essentially what ongoing improvement is about, of course. It would be quite common, for example, to determine that additional training were required, or better gaging needed, or shifts from one characteristic to another to be studied identified. Unquestionably, however, the costs of such actions will need to be detailed and presented with justifications for changes, and hopefully, improvements brought forward.

**Sampling, Gathering Accurate Data**

Sampling is the act of deriving sufficient numbers of product to be studied and inspected, based on quality characteristics previously determined. 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. Considerations are:

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 random.
2. Taking all measurements at a set hour, and under specified conditions, in process control. 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, 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 to discontinue tracking a characteristic, as it comes under control, enabling charting to move to another characteristic to analyze.

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 contributes 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 data-based 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, Checklist 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 systems. 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.

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.

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.

Examples include housekeeping and safety checklists, process flow, charting, 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, eventually possibly identified 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 other data-based systems, simple computer programs are available.

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 where frequencies of judgments are given in more detail and sub grouping in cells. The judgments shown generally reflect a simple distribution of attributes observed in ranges which could represent color, sheen, surface quality, or virtually any other common attribute or judgment, regardless of product. The groupings of information also approximate a normal curve shape, as defined earlier. 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. 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 needing quick and easy analysis.

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. Additionally, applications of Pareto as an analysis tool, graphic communication and prioritization capabilities are underscored. 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 department to the operator.

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. 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 is particularly significant when viewed from the vantage point that charting 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. 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 to become more rational decision makers.

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. 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, assuming a strong, ongoing, 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 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 record measurements and other relevant data such as time of day, name of operator, machine used, and any extenuating circumstances which might explain unusual findings.

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.

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 on-going 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 certain percentages 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.

Repeatability And Reproducibility In Measurement

The following procedures are intended to assist in the analysis of gage repeatability and reproducibility (R & R), sometimes called measurement analysis. This tool is particularly appropriate and helpful for analyzing shop floor (and other) gages and instruments, and their operators, for usefulness in the broader inspection system. It is also true, however, that these R & R values will increasingly be required for documentation as suppliers and vendors--to be shipped with product and/or provided in other ways to demonstrate general capability in the inspection and quality system.

The fundamental reason for the R & R analysis is to assure as best we can that our gages are in fact accurate, and that our operators are using them correctly. Gage analysis would be a logical area of pursuit if we are seeing unexplainable variation in our X bar and R charts, or if we have eliminated virtually all other possibilities--the gages simply should be evaluated on a regular basis. This is shown graphically in summary form nearby. Other relationships include obvious connections to maintenance, indicating that when the gages do not check out as repeatable it is likely they are needing repair or calibration, or both.

Measurement error is one of the pivotal areas to focus on for variation reduction. By determining gage R & R, as baseline data, and gradually tweaking the system, significant improvement can occur. But, as has been shown earlier, the cost of inspection is such that we cannot make frivolous changes to the system. This is precisely where the measurement analysis fits in: by better knowing the error, in real percentages, or as hard data, documented over time for improvement, we can better be positioned to continue the improvement process. It is also an opportune time to place the technological change model in perspective. While measurement error is not called out as an individual entity, it must be recognized, like other data driven opportunities, that this is a key issue in the broader mix.

Although eventually data collection may occur semi-automatically via computer terminals at workstations, currently most data will be manually measured at the gage and manually recorded on forms. This establishes the basis for the system, in conjunction with the gage and procedure for use--manually collected data. It is important that all operators and others understand the importance of taking good measures and recording this data accurately. Much analysis time will be spent--and decisions made on the basis of this data, and thus, it is vitally important that it be done carefully.

Similarly, the forms are only as good as the people make them. Through use, and based on team inputs, the forms should continue to evolve toward a satisfactory collection, organization and analysis tool. Part of the point is, as we use the forms, as a key part of the system, we should be jotting down notes, talking to our supervisor about them, observing how others use them, and so on. Perhaps most important, we should be listening to what our customers are saying about the forms as well as the rest of the system. This includes people up and down the line, in quality functions, engineering personnel, other team members, and so on--all internal and external customers. This also includes the broader sampling and inspection methods as part of the quality system.

By way of definition, repeatability looks at equipment variation, based on ranges produced.
Reproducibility looks at operator or appraiser variation, based on means produced. When combined the two values (means and ranges) provide a value indicative of overall measurement ability in gages. The steps in the gage R & R procedure are focused in seven major areas, or steps, all summarized in several forms and procedures shown later in the tool dealing with gage R & R. The steps must be followed carefully to achieve accurate data and analysis for improvement.

Part of knowing whether gages and the broader quality system is capable and under control requires determining, as precisely as possible, what the quality problems are. This may include simply knowing where to look for information about process quality. This could also be traced to specific factors and includes people, materials, methods, and environment—each consisting of several subcategories within their own areas, contingent upon specific conditions.

There are various relationships to be taken into account. If gages are not repeatable, clearly, data which will be collected for various analysis and documentation applications will not only be suspicious, but wrongful conclusions could likely be arrived at. Additionally, 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. Each of these will be briefly presented and discussed in various sections, realizing this all must be built into the quality system. The results of gage R & R analyses, and other inspection related information, by machine operators and line inspectors, when properly documented, can provide early signals of quality problems. Various other related personnel in the quality system can also provide useful statistical analysis information for quality performance over time. This could include quality engineers, applications and process engineers, and others.

Material reviews (MR’s), documenting materials and parts which exceed tolerance, can be useful in tracing historical quality issues and in evaluating potential corrective actions. This, of course, assumes proper documentation as part of the quality system. Similar to MR’s, information on vendor scrap (scrap tickets, scrap cost reports, etc.) and rework (salvage costs, salvage requirements, etc.) can be useful in tracing and prioritizing quality problems based on quality costs. Also, information on warranty claims and associated costs can be useful in ensuring that prioritization of quality problems is consistent with customer requirements. This could also relate to reliability engineering information and service life data being readily available and being tracked over time. The proper quality system would provide this information routinely, or on some minimum schedule, if requested.

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 is 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 called 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. Operators, maintenance persons and
quality persons simply must do more of what
engineering once did, almost exclusively. Quality
persons must interact with customers, understanding
their demands and inputs for quality--linking this
with design and engineering, and operator input.

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.

**Six Sigma, Solving Problems, Reducing
Variation, Making Improvements**

When we begin to achieve the 1.50 type
values, incrementally--and we will--do we need to
continue studying that feature so intently? Might we
wish to change the approach taken on a given
characteristic over time when the capability value
begins to improve? The answer is yes, but only
based on careful and thorough detailed data and other
information which has been established over time--
and which we know we can believe in. This is
certainly part of how ongoing improvement is
intended to work--all based on the knowledge that
our capability in process is improving. And of
course, this is at the heart of six sigma.

As we make subtle and incremental changes in
our gaging system, or change the tolerance in our
specifications, or upgrade our SOP at the work
station, conduct various brainstorming and cause and
effect sessions, and so on, we should begin to see
gradual improvements in the capability. This is the
nature of the process, and it will only occur through
disciplined and systematic efforts over time--generally
many months. It is also true that the team
environment is thought to be the most effective
vehicle for communicating and moving these types of
issues forward for improvement, as has been alluded
to in various tools and ways.

The intention of the broader SPC system,
using all of the statistical tools and techniques, but
particularly the various charting systems, is to aid in
solving problems, controlling production and
improving the overall situation over time. But this
does not happen by chance. It is only with a
disciplined and by design, overt effort that employees
can expect to improve quality and productivity, and
reduce cost and improve customer relations in the
process, all based around the broad system being
described here--and in the seminar on world class
total quality.

Integral to making the system work are teams-
fully communicating and focused on appropriate
technical problems and issues for improvement. This
also assumes that teams have full members from the
floor, using operator expertise along with quality,
engineering, and supervisors as part of the
managerial function--and perhaps others as needed.
But pivotal to their success is the ability to spot
problems, numerically, graphically, and in other very
real day-to-day ways, in production and in other
ways. The majority of the remainder of this day's
session will focus on this--interpreting the charts and
solving problems for ongoing improvement.

This also has everything to do with variation
in process and product. 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.
Some sources of variation in the process, such as
backlash and clearances within the machine and
fixturing, cause short-term piece-to-piece differences.
Other sources of variation tend to cause changes in
the output only over a long period of time, either
gradually as with tool or machine wear, methodically
as with procedural changes, or radically, as with
environmental changes such as power surges.
Obviously, however, the time period and conditions
over which measurements are made can affect the amount of variation that will be present.

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. This distribution can be characterized by: (A) location (typical value), (B) spread or range (amount by which the smaller values differ from the larger ones), and (C) shape or pattern of variation, further defined as symmetrical, peaked, flattened, etc.

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. Unless all special causes of variation are identified and corrected, they will continue to affect process output in unpredictable ways. Special causes of variation can be detected by simple statistical techniques. The discovery of a special cause of variation, and its removal, are usually the responsibility of the operator connected with the operation. The resolution of a special cause, then, usually requires local action.

The extent of common causes of variation can generally be indicated by simple statistical techniques, but the causes themselves usually need more detailed analysis to isolate. These common causes of variation are usually the responsibility of management to correct, although other people directly connected with the operation are sometimes in a better position to identify these causes and pass them on to management for correction.

Confusion about the type of action to take can be very costly to the organization in terms of wasted effort, delayed resolution of trouble, and aggravated problems. It would be wrong, for example, to take local action (e.g. adjusting the machine) when management action on the system is required (e.g., selecting suppliers that provide consistent input materials). However, it is true that local action is frequently required prior to attaining statistical process control. It should also be understood that a team could likely identify the opportunity for improvement and bring it to the attention of various levels of management. But if the team is put together properly--and given proper decision making ability--they will not necessarily need to go to management in the traditional manner.

Once the process is statistically under control, actions to be taken are more readily known and tests for capability are possible. Determination and analysis of quality issues focused on special and common causes of variation also provide excellent opportunities for problem solving teams as defined in other areas of the manual--and also illustrated above. But this also assumes that teams can--and will--help bring processes under control over time.

Prior to being able to do anything about out of control conditions, it is important to be able to recognize problems (or opportunities for improvement) in the charts. The following summarizes variation in charts which may arise from common causes--and begins to provide helpful guides for how to improve the system:

1. Slight variations in incoming raw materials. This can also relate to inadequate testing and/or knowledge of these materials as well--all persons in the system must know the materials and processes--and pay attention to these carefully and in documented ways.

2. Slight vibration or other foreign/environmental elements in machines or equipment--proper maintenance at the operator level, and continued attention to understanding the process.

3. Lack of human control and perfection, through training, in reading instruments, setting controls, etc.--including understanding the system at all levels. This also assumes that operator knowledge and experience is matched accordingly with capability of equipment--and that supervisors are intimately aware of all this.

4. Lack of statistical feedback through the system, to the operators, for corrective action. This can also relate to inappropriate communication mechanisms, with incorrect or unreliable information, and possible demoralization at the operator level--or elsewhere.

5. Relating to all of the above, continuous attention to detailed documentation can be used to help explain variation upstream and downstream--but always before product goes out the door--disciplined and rigorous note taking, during production, similar to the way we are doing it in the seminar. Again, forms and communications systems should be improved to help accommodate the smooth and systematic--rather than confused and hurried--movement of information.
Much about the common causes of variation will be noted upstream in our pre-planning daily, weekly, monthly and program by program, for production. The key is to have the extent to which we plan for, and control, production ongoing, reflected in our downstream charting and data systems—and reflected ongoing in continuing positive customer relationships—but not by chance—rather by design. This speaks to connecting the charting systems, day-to-day, with every level of management, including operators and certainly supervisors. The only way to successfully attack opportunities for improvement, before they become problems, is to understand and recognize the circumstances of production as reflected in the charts and data.

**Metrology and inspection—attribute, variable, 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. 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 variable size in portions, mixtures, etc., 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 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.

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 product.

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. 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.