Launch Data And Documentation Systems: A Model For Production Qualification

The current tool is designed to provide key techniques oriented specifically to launch of new product. The intention is to assist in building the launch system within the context of getting other existing product out the door. Each of the methods identified are typical of systems and techniques which are used ongoing in a synchronized manner within the broader system, but particularly oriented to launch of product. By design this should provide tools which can be used simultaneously by teams to launch product, without having to completely rework or rearrange the infrastructure required to do current existing products.

It is also intended that the tools should be consistent with the way current production techniques, as described throughout the various systems within the toolkit are done. This includes how we do teams and attack problems for improvement. This relates directly to the issue of synchronization in information, functions, applications and so on. It may be one thing to organize the information at the team level to serve ongoing and necessary day-to-day functions. But it will be another thing to use the same data and documentation systems to solve problems and issues which arise over the normal course of events. What the section techniques are about is not just solving problems in cost effective and competitive ways, although of course the importance of this is not discounted. Rather, use of the data and documentation to provide the base from which we launch product is vitally important. This is what the data and documentation sets of tools are about as individual and stand alone entities.

It is thought that we must certainly position our teams’ structure and infrastructure to be able to respond to daily operations first, and problems which emerge and require solutions immediately and longer term, second. But ultimately we must be able to transcend both of these essential levels and move into a third level of team opportunity which relates to product development and innovation. We must be able to rely on the same information we use at other levels for management and problem solving, for planning and launching products into the future. Remember this is not merely information, assuming we use it properly, it should become knowledge inherent in the organization at the team level.

We are also reminded that if we are not looking down the road to future opportunities we are probably slowly going out of business. We must not become so caught up in the necessary day-to-day operations or the essential act of solving various sizes and types of problems, that we forget to give birth to new ideas and products for our future production. Thus we have a third essential reason for teams, blended out of the foundations of the functional and cross functional teams used for other reasons. The synchronization of information and
functions for new product development and launch is the basis for the current set of tools, all based on the previous tools and information.

**Team Based Problem Solving Context.** Using the current tool as a backdrop, and focusing specifically on 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 below.

The more focused components within the model are shown nearby. The graphic depicts essential relationships between and among toolkit elements for team building, problem solving and improvement. This was discussed as foundational information in earlier tools. 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.

**Assessment, analysis and action.** 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. The graphic nearby provides a three tiered linear relationship 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. The relationships which are embodied provide a useful strategy for the context of bringing forward technical solutions and improvements. The applications for such relationships will be oriented toward new product launch, primarily, during the current discussion, rather than only focused on smaller scale issues inherent in data and documentation.

**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 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 indicators upon which to base measures of improvement. As baselines are established, sources of variation are determined, focused on and causes are 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 conceptualized as shown graphically nearby. As can be seen, 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. 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 was required, or better gaging needed, or shifts from one characteristic to another to be studied, identified.

A model system for production qualification. The particular focus of this tool is the identification and determination of broad issues related to qualification and capability as a production unit in the supply chain for a customer relationship. Determination of capability for production can mean many things, ranging from actual production capability in square footage, to having a broad quality system in place for determining if customer demands were met. The primary emphasis is placed on the broad quality system, alongside day to day demands for maintaining the system and getting product out the door in synchronous ways.

The system being presented here acknowledges relationships to data, documentation and other issues in the broad synchronized team environment as depicted above. But within this a more specific model must be addressed to arrive at useful relationships over time. The actual focus is to reduce lead time and increase customer satisfaction in new launches. This requires a fairly clear understanding of various relationships, many
which are complex as individual entities, let alone in total.

The total systems, represented as a model, is shown nearby. Included are most of the elements which are further developed and discussed throughout this tool. Many of the areas discussed also become entire tools in and of themselves, since they represent rather complex entities. This includes issues related to ongoing process control planning, failure mode and effects analysis, and of course the myriad of data based statistical indices related to SPC, short runs, P data, inspection planning and so on.

Following the flow of the model for qualifying a part for production, several symbols are used. The rectangle represents customer responsibility, while oval is supplier, and triangle is a combined cross functional effort. Beginning with the start point by supplier, a request for proposal is let by the customer. The potential supplier then must conduct a feasibility study and assuming feasibility is established, design and engineering functions commence. The OPCP is begun with particular emphasis on early engineering and specifications driving the documentation. It is possible that parts can be verified at this point, depending on:

1. Simplicity of part design.
2. Maturity of organization.
3. Part history and similarity to other processes and products.
4. Past documentation and data as baselines.

Generally more work must be done, as shown by the cross functional improvement of design. This includes fairly robust efforts aimed at establishing data based documentation from which enhanced design and engineering functions will occur. FMEA's and additional efforts on the OPCP, perhaps leading to enhanced or changed specifications and characteristics would be anticipated.

After production parts are verified as acceptable, tooling approvals occur. An open purchase order number will be provided, and part orders will follow part verification. Shipments will commence at the final or end point prior to invoice. As a total process this may take months of time, recognizing overall complexities. The approach discussed and illustrated in the flow chart model represents a near perfect scenario, but it is also true that suppliers and customers will mature the process together over time. The maturation process can lead to trust and ability to gain part verification in a fairly expeditious manner. This is part of what is intended to happen in the longer term.

**Feasibility Analysis For Production Capability**

One of the first parts of the process for qualifying as an organization to supply products for a customer is relates to a feasibility analysis for production capability. The feasibility analysis is an internal supplier conducted self study which defines conditions under which production must be performed and general requirements which must be met to perform satisfactorily for the customer. The purpose of the self study is to help a potential supplier determine and substantiate their ability to respond over a long term period in a supplier relationship with the customer. Questions which must be addressed are rather straight forward, as summarized on the form shown nearby. The form and questions would become part of the basis for the supplier to convince the customer of overall appropriateness as a potential supplier. Other information which relates would be supplier evaluation survey relationships shown elsewhere.

The form contains general areas of questioning which are designed to be answered as a simple yes or no type checklist. Yet, while fairly simple and straight forward, the questions also can lead to strengthening the potential supplier position for future business, depending on how it is handled. Several categories also provide opportunities for cost issues to be broached relative to capital equipment, tooling and other systems.

A strong component in the reply to a request for proposal to bid on the part production, is the statistical basis from which we can demonstrate our production capability. Identified as statistical indices, this relates to use of existing charting, gage R & R, capability studies, short runs, and other data which can be transferred due to similarities in material, process and design. The existing data, due to similarities, can be used to demonstrate our ability to move into the new product under proposal. Discussion and reference to training requirements for the new scenario is also identified as a question.

Final areas of discussion address whether we think, internally, if we should respond to this proposal. This is provided as simple check offs for whether we think we are feasible. Categories can also be identified with feasible but adjustments are required, and not feasible without substantial
changes in fundamental design. Final sign-offs are required by persons from quality, production and engineering as well as others as appropriate.

**Broad Quality Systems, Sampling And Inspection Procedures, Launch Issues**

Specific inspection procedures are essential to providing optimum quality. These procedures typically rely on general information such as that provided throughout this tool and section. The focus here is on providing mature inspection guidelines. This is done to assist in designing SOP's and work instructions as new product launches occur. The fundamental issues for launch and inspection, not much different from all other production, is to assure compliance to customer specification. Also vitally important to the overall improvement system is the collection of accurate data and documentation by operators and others.

Inspection is usually organized around specific phases such as receiving, in-process, final and shipping inspection procedures, but incorporated into the overall production plan and quality system. As indicated earlier, it is important that people perform these inspections as part of their routine work rather than being done by roving inspectors. The bottom line is that inspection, as part of the quality system, is not a separate added on function. Rather, it is integral to the act of producing the product, virtually a part of the standard operating procedure (SOP).

But inspection must also be regarded as "adding value" wherever possible. Inspection must not be a simple added on activity which takes more time and adds possible opportunities for damaging product. As with any other task in production, we wish to do inspection in the least intrusive and most productive manner possible. Examples of this could include such simple acts as:

1. Waiting to close the package until final ship functions, allowing one more quick observance of the shipping labels and contents, original order and scheduling/routing slips, among other important functions.
2. Use of poka yoka fixtures which will only allow setups and preparatory assembly and "next step" functions in the right way--causing inspection and production to occur in simultaneous ways.
3. Continued development of SOP's to seek better ways to accommodate inspections by operators at the point of production with charting functions and other disciplined and empowered steps, without taking away from getting product out the door. This should occur particularly where flow charts demonstrate bottlenecks, WIP buildups, non-conformities or other problems/opportunities.
4. Simple use of checklists and sheets which require individuals such as operators and supervisors to study important parts of a work site or project, prior to moving forward, signing off and in effect certifying compliance to a standard or norm.

Much of the above can best be accomplished by determining capacity as a function of SOP's in the broader context of flow and layout of the total production analysis. Although this is at the core of the Kaizen systems for quality improvement, and is covered in much detail in several other tools, the key charting and documentation methods are provided again nearby for use and consideration.

Organizations and products will require varying levels and types of inspection for quality. For example, aviation, nuclear-related, and many government programs will require 100% inspection. A typical rule of thumb for many other products and organizations, however, is 10% inspection of appropriate pre-determined characteristics. Certainly, a minimal number of inspections should occur, but without reducing or jeopardizing quality. It is also worth pointing out that given statistical process control and other on-going improvement techniques, it should be true that inspection can occur less over time, and be justified and defended through documentation and charts.

The typical inspection system will involve, at minimum, receiving, in-process, and final/shipping elements or steps. As part of this the component which we are generally most concerned with, due to the production relationship overall, is the in-process component. The charting, tracking and measuring components are oriented primarily to in-process functions. Even so, attributes can and should be tracked and logged in final ship inspection where packaging, labeling, and overall quality are observed as a function of the last steps in production. Similarly, as the raw materials and parts are received for production, we can inspect attributes and variables which are important start up characteristics.
The basic system is shown graphically as application forms. Receiving inspection provides that all subcontracted materials, parts and assemblies should be subjected to a receiving inspection prior to acceptance from vendors. Purchased material should be inspected by an appropriate sample plan using standard organizational procedures unless otherwise mandated by the customer. If necessary, vendor supplies should be verified by statistical process charts where feasible to prove control within specific limits. It may also be necessary for material or assembled components to be verified by an independent lab on a random basis periodically depending on the nature of the product or service being produced. If any of the above are non-conforming, the material should be tagged and sent to an area for non-conformance. The supplier must be notified and a request for disposition, corrective action, and date of corrective action provided. If an organization can not meet production schedules without rework, the cost of the same should be at the expense of the vendor. Statistical process control is a requirement for all suppliers and they must insure their process is in control and provide charts and records for filing and customer examination.

In-process inspection procedures should be conducted on all products, processes and production phases and equipment to insure quality. To verify proper operations, the first part can be verified 100 percent to establish conformance to specifications. All inspections must be documented and should be available upon customer request. Records should be maintained for an appropriate period of time, per the nature of the product and organization. In-process inspection, other than first piece will be performed by the operator, whenever possible, although others involved in the quality system may need to supplement this. For example it may be necessary to shut down the process, with primary responsibility remaining with the operator when the process is graphically shown as being out of control. But then others would likely become involved to assist in the analysis for corrective action, perhaps focusing through an improvement team.

Final processing inspection should be conducted per either customer instruction or general organizational standards and procedures, but focused on characteristics previously identified. Proper final documentation for certification should include all pertinent test data, sampling plans and final inspection results. If the product is approved by the operator, all documentation will be completed and a final tag attached authorizing a move to shipping. Final audits before shipment may be necessary with spot audits performed and recorded by individuals (dock audits) in the shipping function. Shipping personnel focus on the likelihood that all parts for shipment to the customers have been prepared to insure the best commercial means of packaging in order to preclude any damage.

Packaging should be reviewed on a timely basis to insure customer specifications are being met or exceeded. Components, assemblies and parts should randomly be inspected for cleanliness, any visible damage, part number, marking and packaging compliance per instructions furnished by the customer or as specified in general standards, including labeling. Any noncompliance of the packaging requirements may be cause for follow-up with operators and others, perhaps providing impetus for team involvement and problem solving.

But inspection systems and the inspection function may 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. Regardless, what is inspected must be properly documented and charted.

It should be obvious that the sample must be representative of the total population being produced, if the sample is going to be valid. But sampling takes time and costs money to perform, and thus cannot be done any more than is absolutely necessary. Yet sampling is important and essential in the quality system for several reasons. This has to do with costs, productivity, gaining an accurate picture, and reducing inspection and damage to product.

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. Generally, the factors governing amount of structure in the sampling procedure relate to cost in production and inspection and degree of quality required in the product. Considerations and guidelines for sampling presented earlier, and
summarized now in graphical form are shown in the applications section.

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. Generally, the factors governing amount of structure in the sampling procedure relate to cost in production and inspection and degree of quality required in the product.

Some specific considerations and guidelines for sampling relative to lot size and numbers for samples are provided in a graphical table nearby. It is significant to note that the table provides various levels of consideration for sample based on other important considerations. 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 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.

Picking up on the previous information about level of sampling relative to lot size in production, it is obvious that the part history and records from inspection tracking are important considerations. 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 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.

One additional point is rather important in the overall sampling mix. This relates to the characteristics for sampling and measuring over time. On the one hand this appears to be rather straightforward and simple. But the fact is that this is not only important, but it can also be rather costly. This is true since much time and general resource will be aimed at measuring that particular characteristic, once identified. Thus, it is important to make sure that they are carefully identified and justified through the customer, suppliers, engineering and quality personnel, operators, supervisors and others. Certainly, as improvement is noted over time in production, based on statistical process control, it is important to continuously re-evaluate the quality characteristics. It may be possible over time to discontinue tracking a given characteristic, as it comes under control, thus enabling the charting process to move on to another characteristic for study and analysis.

Most gages and instruments for data gathering, like all other technology have a correct method of use. This should be documented, demonstrated, and mastered by all concerned with their use. Procedures for proper use should be built by teams of operators, supervisors, quality and engineering personnel, and perhaps others such as gage vendors. If we expect integrity with and within the system, we must rely upon individuals from the start--giving them full support and all the tools they need to get the job done.

Procedures identified above are pivotal to doing business in the future. The documented procedures not only provide one of the key training vehicles, but importantly, this also forms the basis for supplier relations--most customers will want evidence that you are actually gathering the data--gage use procedures form a key part of this. Moreover, when it becomes evident that a problem requires attention, one of the keys to improvement will be knowing how we actually use gages to gather data. How can we improve without knowing how it is currently done?

Mastery of gages and instruments for data gathering starts with proper procedures for use, with full documentation built with strong operator input and guided by supervisors and others. But mastery of the gage will be a function of discipline and practice of using the gage or instrument. Much of the gaging of the future will be of a "high tech" orientation, requiring precise procedures, basic understanding of digital electronics, and confidence by and of, the operators and others in the system. All of this can be best handled through team functions with all concerned to properly demonstrate and train for the system. Ultimately, as with most other functions, "best operators" will emerge within the system, providing pivotal support persons for troubleshooting and improving the data collection system at a gage level.

The extent to which this is "put together" up front is key to proper product launches. It goes without saying that the mature organization, even while under pressure to get product out the door in launch, will reflect solid procedures for inspection.
These procedures, many from past product experience, will provide much of the base for securing the contract initially, as well as solid data for improvement over time.

**Short Run Systems, Mini Run, Pre-Control And Trending**

Short run systems are a preliminary phase of SPC, often called mini run or pre-control. This provides a system for operators and others where, given minimum data and time commitment, a reasonable indication can be provided to determine behavior of a given set of data or performance of a production run. Short runs are particularly beneficial for start-up of a process where it is simply not cost effective to run a massive amount of data prior to knowing the process behavior overall. Other examples where short runs may apply could include:

1. We are trying to achieve a target set by a customer (either internal or external)--short runs of data can give sufficient "bursts" of indication regarding process behavior.
2. Short run systems are also helpful for benchmarking, and/or conducting run-offs, for new equipment and processes.
3. Perhaps an applications improvement has been made in a piece of equipment or process, through engineering or maintenance, and we wish to determine the status of the improvement. A quick short run before and after the improvement can be a useful indicator--or comparing short run data to older established data may prove useful.
4. Short run can be useful as a preliminary approach to actual gathering/manipulating of data using standard variable or attribute data approaches. That is, if for any number of reasons we may wish to use no calculations (i.e., people are learning, time is not available, and so on).
5. The short run system can be very helpful with new employees, providing useful targets for them to strive for, and as an introduction to actual variable and attribute charting.
6. Perhaps one of the most important applications for the short run system is the use of launch in new product introductions.
7. If we have modified an SOP for improvement, or if we have the first time SOP used for any reason, we would likely test it with the short run or pre-control charting procedure.

At least two approaches can be used for short or mini runs. The typical approaches are known as "pre-control" and "trending". Pre-control is a short run system which uses the short run to establish reasonable control limits or parameters, established with the limited data collected. This pre-control information then becomes a baseline or benchmark upon which we can move forward for improvement. Pre-control has obvious applications with new product start-ups, benchmarking for possible new customers, bringing new equipment on line, bringing rebuilt equipment back on line, and so on.

Trending, by contrast, is merely the plotting of some measured or observed characteristic which is then charted over time. Most commonly used with attribute systems, it could also be a variable measure which is simply plotted but not within calculated control limits. Obvious ups and downs in the trends which are graphically plotted can be indicative of trouble spots in production--to be followed up on by the operators and others. It should be noted that the typical approach would be to begin a process with attribute trending, and gradually upgrade this to variable data with upper and lower control limits calculated.

Procedures are discussed here, based on the commonly used approaches, and example forms are presented nearby to help get the process started.

1. In most cases a standard variable or attribute data form is used, although it may be advantageous to use a "special" form designated as short run, particularly if this is the request of the customer. In both case, standard forms have been adopted.
2. Regarding sampling, the key difference here is that a smaller sample of the product is selected, commonly twenty-five or thirty pieces total (25 is shown here), generally about one third of the usual sampling approaches. Obviously, this has implications for speeding up the short run approach and for saving dollars.
3. Calculations/methods similar to standard X bar and R or p charting can be used, particularly where the computer can be used to quickly get feedback and results.
4. But it is also common to use no calculations, and simply identify based on experience, past observed behavior, or input from various sources such as external contracted
customers or internal customers (such as engineering or manufacturing personnel), the upper and lower control limits. This seemingly arbitrary approach, while not necessarily based on statistics, can be advantageous since it may actually establish a tighter target relative to calculated upper and lower control limits. It should be noted that this is actually the only way the attribute pre-control method can function.

5. The common guide for these arbitrary short run upper and lower control lines is to use 25% below the upper specification and 25% above the lower specification. This gives the main body of all sampled pieces a grouping area of 50% of the total specification band width. The range values are also arbitrarily placed.

6. Based on the 25 sampled pieces, if there were no pieces outside the 50% band width area, we would say that the short run is acceptable, and we could proceed to make additional changes, improvements and so on.

7. If however, during the 25 piece short run sample, we observe any one point out of the 50% control band area, we would consider stopping the process, making improvements/changes, and starting over with the short run.

8. At every step along the way we must diligently keep notes and records of the conditions and behaviors noted, enabling quick and effective improvements.

The short run approach has obvious time and cost advantages for observing behaviors quickly in the process. But we must also be cautious with this approach, since it generally does not give the strength of a broader sampling of data upon which to base decisions. But in terms of achieving pre-control targets efficiently, and satisfying the needs of multiple constituencies, this can often be quite satisfactory and useful--done as a short run.

It should also be indicated and underscored that several short runs, based on a systematic iterative "experimental" approach may actually demonstrate incremental improvements in the process. If for example, over a several day period of time, a team wishes to pursue possible improvements using relatively small changes to the process, the short run approach is likely a very useful way to determine if any positive change has come about. Or if a vendor is trying to sell us a "new and improved version", have them install it for purchase, contingent on the targets set and achieved with short run data. Similarly, if a team is training a new member, recently introduced, the short run approach could be very helpful in teaching the new person(s) how to do charting with minimal guidance and time commitment. Consider the power and potential if the short run approach was actually tied to standard procedure for a given operation or process!!

By way of comparison, it must be recognized that each type of charting and inspection system has advantages and disadvantages. For example, the attribute system generally requires little if any sophisticated gaging apparatus, and is relatively easy to use, since it is essentially a "judgment call". But the tradeoffs in ease of use and lowered immediate cost due to little or no equipment are balanced with less than accurate data and variation among and between operators--judgment calls.

But in many cases the attribute system, with the emphasis on color, texture, smell, and so on, may be perfectly acceptable for many applications. As indicated previously, this is particularly true where we are just beginning to track a characteristic or critical dimension. And if we actually obtain more accurate data, will it do us any good? Clearly, not in all circumstances, but in many situations it is critical for us to strive to upgrade attribute systems to variable systems. This is particularly true where we recognize that the cost for obtaining the data is generally directly related to the accuracy required in measurement. It may also be reasonable to conduct a short run study using attribute tracking and logging charts, and take charting no further based on the data collected.

It is also important to recognize that the variable data affords the opportunity to provide a tolerance of acceptability and function. While the attribute approach merely "appears" acceptable or unacceptable, we can come much closer to "knowing" with reasonable certainty and definiteness, that we are actually producing product within the acceptable limits. Thus, a degree of "seat of the pants" decision-making and management style can be eliminated or upgraded through conversion to variable from attribute data and systems.

Consistent with this, it is also important to try to build the variable data collection system to be automatic as opposed to manual. That is, it may be acceptable to begin the variable system with a scale, caliper, or micrometer which is manually measured and recorded on the chart. But ultimately, it is important to extract the data via electronic gaging
systems which are automatic or semi-automatic, and "on-line". On-line in this case means that as the data is being automatically extracted it is also being electronically, or digitally, logged in for comparative analysis and enhanced control.

Closing the discussion, launch of new product will frequently require determining process behavior at various start-up stages. The short, or mini, run approach provides an excellent way to transition into full production without seriously disrupting current production and without costing substantial amounts.

Evaluation Of Quality Characteristics And Other General Statistical Indices

One of the emphases of this tool has been the focus on a clearer understanding of what characteristics are, and their relationship to other important parts of the quality system. Relationships to measurement systems, design, and certainly the act of manufacture, would be pivotal in the characteristic discussion. As well, as characteristics are better understood, this should be reflected carefully in SOP's and all documentation internal and external. Within the context of launch of new product, as knowledge builds relative to the new part or product, characteristics must be evaluated for change and improvement.

Part of the current section is also suggesting that characteristics must be evaluated over time, for upgrades in various ways. This also includes issues related to engineering design changes, within the broader approval process, discussed in various sections elsewhere. Potential upgrades in characteristics could include:

1. Redefinition of the characteristic. Perhaps some critical dimension or other specification-related information has changed over time, resulting in the need to redefine the characteristic. This may be a function of a customer driven engineering change.
2. Elimination of the characteristic. Perhaps over time it has been demonstrated that the characteristic simply does not need to be tracked any longer. This would most likely be as a result of our ability to demonstrate that it remains under control over time.
3. Expansion of a characteristic. As design and engineering changes occur, it is likely that the characteristics being tracked and charted over time will at first be expanded, and ultimately evaluated for phasing out.

The above may begin to describe some of the various conditions under which changes in characteristics can occur. It must be remembered that the primary reason for evaluating the characteristics have to do with making ongoing improvements in product, and reducing costs due to reduced tracking and monitoring. Related information is provided in the remainder of this section and two forms for analyzing and auditing the characteristics are provided.

A general approach for systematically evaluating characteristics must be based on a strong data driven charting system. The primary evaluative criteria would be questions such as:

1. Is the characteristic, as demonstrated in some numerical manner, preferably variable data, increasingly coming and remaining under control? That is, is the chart showing a trend over time which reflects data falling within calculated control limits?
2. Have there been customer complaints, internal or external, during recent times related to the characteristic in question?
3. Has this characteristic been referenced in any corrective actions recently? If yes, in what ways and why? If no, are there any internal corrective actions which we may need to do as preventative functions?
4. Does gage R & R, Cpk and other data driven information support the characteristic by showing strong repeatability and reproducibility measures and improved capability overall?
5. Do we have routine reviews of this characteristic in our quality system, supporting the possibility of its elimination for tracking, or reduction in sampling, or changes in the way we inspect--to a more cost effective method?
6. Are there customer review inputs, or issues, which support or refute our findings?
7. Has the tolerance been questioned and/or adjusted recently, and why, yes or no?
8. Have there been engineering design changes on this characteristic recently, and why?
9. Has this characteristic been audited recently and why?
There may be other inputs, depending on product, organization, suppliers and customers. But this is a reasonable place to begin evaluation systems.

This should be a regular, ongoing, and systematic process, perhaps done on a monthly routine basis. The primary goal here, similar to some of our global competition, should be the entire elimination of the SPC tracking system, based solely on our ability to demonstrate through data, that we have the process and its individual characteristics under control. It is only through proper documentation of data related to circumstances that we can demonstrate appropriate actions. Actions, broadly called improvements, should be focused on reductions in tracking of new characteristics.

**Engineering Design Change Documentation**

Systems for changing designs through the engineering function, in conjunction with the quality and manufacturing groups is pivotal in the launch and development sequence. More specifically, documentation for the same is the focus of the current section. Rather obviously, much of the significance of the process depends on where we are in the overall launch. The assumption in the remainder of this discussion is that the PO has been let and that the part has been committed to by both supplier and customer. Thus, financial commitments have been made in both directions, and reasons for the engineering design change documentation are to assist in careful communication about form, fit and function since we need some type of detailed reporting mechanism. This is true for internal and external communication reasons, and requires some type of form, as presented in the applications section. In addition to completion of the usual general part information, this form requires that coordinates of the product be detailed. This is true for the current part dimensions as well as the new dimensions of the part. Deviations from the original to the new dimensions are requested, to assist in clarity and detail in communication. Other general observations and information are requested in a similar manner.

Particular emphasis should be placed on submission of data and other information supporting a need for change. If data such as capability studies, variable or attribute charts, or gage R & R studies can be provided to illustrate that an improvement has been made, or should be made, and the design change is consistent with this, all should be provided and documented as a package. Short runs or DOE data are other examples of support information attached as part of the proposal for change.

**Preliminary Simplified Design Of Experiment (PSDOE)**

As the short run variable data system is being used, conversion from attribute to variable data is moving forward, and characteristics are being evaluated in the broader system, the aggregate measure of quality should be improving as evidenced in reduction in variation. While each of the elements may give indications of improvement in various ways, the total system should have improved capability as measured by Cpk and other statistical indices, all to be further explored and explained in subsequent tools. Other basic indicators of improvement aimed at variation reduction include:

1. Charting values centering around the mean.
2. Charting values becoming and remaining more stable, again around the mean.
3. Reductions in fliers and outliers within the total sample, and among individual samples.
4. Increased predictability and repeatability in the samples, lot to lot, operator to operator.

While all of these are developed and discussed further in other tools, the purpose of the current section is to show the start of a rather robust approach to problem solving and variation reduction. The ultimate approach, design of experiments, will be introduced and briefly explored now, and once again developed more fully in later tools.

Design of experiments (DOE) requires a fairly stable process, and one that is relatively under control. Yet, obviously, if we require further improvement, the process must be somewhat out of control. The point here is that most of the previously identified methods have been used and we have made substantial improvements, but now we wish to improve further. This also acknowledges that the more we improve a given process or function, the more robust and intense we must become in our improvement tools.
DOE requires a strong knowledge of the variable process as represented in data and documentation. Charting should have been done for a reasonable length of time, and data collected as baseline for comparative analysis. Documentation in the form of SOP's should be in place, affording the opportunity for various operators to similarly perform the process and achieve similar data driven results. Perhaps most important, based on this knowledge and information, we should be able to readily identify levels and factors which are needing attention, for improvement. The levels and factors are elements within key variables suspected of having room for improvement. Knowledgeable operators and others will be required to form a team around improvement issues being discussed.

A true DOE requires much time and expertise to put together and conduct. The technique being presented is not to be confused with an actual DOE, but should be considered similar to, and compatible with, a short run system for helping introduce and test various elements for improvement. The preliminary DOE is designed to be simpler and quicker, more focused, and a next logical step in the progression of improvement in process. But this is not a full blown DOE. We will refer to the method as a PSDOE, standing for preliminary simplified design of experiment.

The steps suggested as part of the PSDOE begin with the assumption that the process is measurably under control and mature at a point that can be verified through replication of data or in other ways associated with capability and repeatability (Cpk and R & R, to be discussed later). Next steps could be:

1. Conduct modified short run study, using the form provided nearby in down-sized version and full size in the companion workbook.
2. Obviously, this requires careful identification of characteristic to be studied.
3. Identify factors and levels to be studied, focusing on one or two factors at minimum, and two or three levels.
4. Fill in the blanks on the form, indicating and defining trials, and the order in which the trials are to be conducted.
5. Following trials identified, conduct multiple short runs, making minor process changes in factors and levels identified.
6. Note that only after the process has stabilized, the data should be collected and recorded on the PSDOE form shown in the applications section.
7. Following multiple iterations and completion of the trials previously designed on the form, simple comparisons should provide indications of how best to optimize the process.

It should be obvious that many variables and their levels and factors can be (and probably should be) studied. But this method, the PSDOE is only a start, leading into an eventual more robust study. Significantly, however, one of the main advantages to the PSDOE method is that it can be conducted while production is in process. This indicates that we should not be making radical changes in the set up, but rather the trials are only minor "tweaks" within the process.

The actual full blown DOE will provide the opportunity to place multiple variables and their levels and factors into a rather complex matrix for statistical comparison. The PSDOE is not designed for statistical comparison in the strict sense, but should provide for a common sense look at what effect minor changes in the process can have. This provides a disciplined and systematic approach to improvement, possibly the next logical step toward the more robust full blown DOE. The PSDOE is also a logical method to use in conjunction with short runs in introducing new product or modifying existing product or process.

Reliability Testing And Analysis, Design FMEA

Reliability and its failure relationship in quality is not a simple or easily understood area. The purpose of the following discussion is to summarize and present a few key areas related to failure and reliability for purposes of helping us be better equipped to address reliability issues. This would also typically relate to test and laboratory procedures and systems for analyzing product under rather controlled conditions. More specific to the current tool, reliability improvement is typically part of new product development to help assure customers' needs and demands are being met.

Reliability in quality addresses quality of product service life over time. Given adequate written instructions and general support, including sufficient long term maintenance and service, the product should have overall safety and reliability considerations from concept through completion of service/use by the customer. Reliability through quality is also a fundamental concern for the length
of service life, the basic issue being how long can
the product function the way it was designed to be
used? Quality of a product when it leaves
production, and begins to be used by the consumer,
must take into account overall reliability in a
product's service life. If our only concern in the
quality system is the immediate quality at shipping
time, then over time, as the product is used by the
consumer, we may likely fall woefully short
regarding meeting all demands.

Reliability can be defined as the ability to
perform without failure in a specified function
under given service conditions for a specified
period of time. This definition provides several
general conditions required to determine reliability
in products, as related to quality:

1. Definition of successful product performance
or service.
2. Definition of the environment where the
product will perform.
3. Specified operating time and conditions.
4. Nature of the failure behavior which is
predicted.

In other words, we know that our product is going
to wear out and deteriorate over time. But through
various tests and analysis, data collected over time,
experiences both internal and external, and in other
ways, we project that our product can be expected
to perform in certain ways over time. The task then
becomes to improve on this without adding
substantially to the product cost. It should also be
clear that use of data collected in production,
various engineering data, market and customer use
information and documentation, among others, can
be very important in improving our quality over
time. This is all shown graphically in the model
presented nearby.

Several key measures are generally accepted
as part of the basis for determining and better
understanding reliability. As was indicated in the
previous introductory section, reliability has to do
with performance over time. It is also true that
reliability then has much to do with determining the
point and nature of failure. Thus, one major
analytical area associated with reliability is what is
called failure analysis. Failure analysis includes
failure rate, percentage of failures, mean life, the
exponential failure law, inverse reliability, break in
and wear out failure analysis. Reliability lab test
functions should not be underestimated, and it is
also important to document their results for
comparative analysis over time. A form is provided
for use in new product launch or other
circumstances. Formulas for calculations, explained
in a different tool, are included on the form found in
the applications section.

Production Parts Verification (PPV)

As production ramps up, and various
elements of the total organization come together
around a specific launch effort, it will be necessary
to qualify parts as being appropriate within the
context of customer specifications. Part of the
mechanism required for this effort is the production
parts verification (PPV). The PPV provides a
systematic tool for suppliers and customers to use
for communicating compliance of specifications at
various stages in the launch. While the PPV is not
designed to communicate the actual change as a
request, it may indicate the need for such a change.
Thus, as with many launch tools, from the quality
perspective, what is intended to occur is the tracking
and gathering of data for documenting the need for
change and improvement.

Most of the blanks are rather straight
forward, and simply require filling in per the void.
But some of the blanks are also demonstrative of
fairly complex issues and relationships in the launch
process. For example, several of the boxes provide
inputs which may track the number or types of
changes which have occurred. This is reflective of
the reality that many changes will occur, and that
we must carefully document the same. However,
again, the PPV should not be viewed as the change
request, but rather as the documentation reflective
of the changes, helping all to better communicate
where we are in the process. This then, as the PPV,
is a tracking and monitoring device rather than the
actual change mechanism.

As with all other forms of data driven
documentation, the PPV will also give indications
of where and when we may need to take action in
the launch process to help keep the process on track.
This could occur as related to early measurements taken per specs, and shown to be further out of the parameters than thought to be allowable. This would be clearly demonstrated by the X, Y and Z coordinates identification and verification system shown in the blanks on the PPV. And similarly, the use of this information to communicate broadly and quickly between engineering, manufacturing and quality to address capability in process, potential specification or characteristics changes, or other issues should not be under estimated.

Finally, while the PPV form does not call it out, averages of the same characteristics could be calculated based on columns of measured information. The columns could provide a more robust indication of process capability, and various statistical indices may be appropriate for use in conjunction with the same. This is used with short run systems, forms and procedures to verify Cpk in the later stages of the launch, an important element derived from early measures of key characteristics, recorded in the total launch report.

**Summary PPV Report.** As a part is submitted for approval in the iterative launch sequence, all characteristics will need to be determined to be appropriately in specification and useful within the broader customer view leading up to full production. For example, a complex part consisting of multiple characteristics would require the PPV characteristic report form for each characteristic as demanded by the customer. This assures that the characteristics as deemed important through customer demanded negotiations are upheld as being produced within proper limits in the early stages of launch.

As each characteristic is qualified on a separate form such as the one above, they should all be summarized in a master report form. This provides a mechanism for tracking the total part at various stages from early design and engineering stages through short runs and to full production. The PPV summary report approach as a form is shown in the applications section. The PPV summary report form could be used in several different ways. A customer could require this report periodically in the launch sequence to track process improvement, as a "random check". The form could be used for all characteristics of the part, or it could be used for only those characteristics deemed appropriate at a given point in the total launch process.

**GDT True Position Calculation.** Another component in the broader PPV summary report, and an application within the current discussion relates to determining allowable error in the position of part element or characteristic. For example, in the case of the true position of a hole location on a component, it is important to determine and document, during launch, where critical characteristics are relative to where they should be. This form and process is not specifically focused on determining the criticality of a given characteristic, and information provided could lead to changes in levels of criticality of various characteristics.

This part of the PPV relates to the print as specified in GDT terms and symbols, and uses a modified version of the basic form. The modified form is shown nearby. The actual calculation required in the true position variation determination is a simple variance square function. Based on values previously determined, and differences identified as tolerances, or "DIFF", these are plugged in to the x and y values on the form. Based on the directions given on the form, the calculated values would then be compared to the actual specified requirements. Depending on calculated and required values, action may be required.

**Proprietary Tooling Relationships**

Proprietary tooling relationships are of concern because of complexities in tiers and deliverables as required through customer and suppliers. When tooling is manufactured by a supplier different from the actual part or component supplier for a final customer, care must be taken to assure compliance up and down the line. The intention is to provide documentation which can assist all involved in being accountable in appropriate ways to assist in staying in compliance with initial requirements and in being sufficiently flexible as the launch occurs. As with all parts of the launch plan, the best plans and designs will need modifications to permit improvement in the cycle as maturity occurs.

The basic tooling documentation form is designed to address key points in start up which can be developed further for specific applications and organizations. This provides potential completion of several categories of information:

1. Part description.
2. Tooling description.
4. Tooling records.
5. Sign off and update.
Each of these categories will be briefly discussed.

Part description provides basic information about the part being produced with the tooling. The obvious information has to do with part number, production location, and so on. The less obvious could be drawings or other documentation about the part. Tooling description may include drawing information, numbers and storage location. The intent is to provide sufficient general information to allow a tracking and communication vehicle for supplier and customer discussions.

Statistical indices would focus on charting systems, gage R & R, and cpk records from production characteristics associated with that particular tooling. Short run data, DOE's, maintenance and cost data, and other similar related information may provide additional insights into the overall performance of the tooling which could be useful for future reference. Other tooling records which may be helpful would be any design changes at the part or tool (or both), and details about the supplier or manufacturer of the actual tooling. Details about type and nature of insurance coverage for a particular tool may also be vital, depending on significance of tools.

**Certification Of Compliance**

Certification of compliance, sometimes called vendor certification, is an attempt to determine the quality of a vendor and certify (for legal purposes, ultimately) that what was specified is actually provided from a vendor to the user of a product or component in production. As part of the broader production qualification system, this represents a contractual agreement which provides a basis for the user to hold the vendor accountable (liable) if in fact the specifications/characteristics were contracted for but not delivered as per the certification.

Certification can help organizations realize they will be held accountable as vendors, and therefore they will make certain that their product or service is actually delivered as per specifications and certification. When products, materials, services, components and so on, are actually delivered the way they were supposed to be, it reduces transport costs (to return), rejects in production, scrappage, and so on. This all improves the overall competitive edge of the user of the certified item--our broader customer. But remember, we are the customer of our suppliers--up and down the line. And all that we must work on is based on characteristics which are essential to build into the product.

Compliance certification helps assure that all subcontracted materials, parts and assemblies should be subjected to a receiving inspection prior to acceptance from vendors. Tying in to the discussions about vendor certification, purchased material, as part of the routine standard procedure, should be inspected by an appropriate sample plan using standard organizational procedures, unless otherwise mandated by the customer. If necessary, vendor supplies should be verified by statistical process charts (suggested to be provided by the supplier) where feasible to prove control within specific limits. It may also be necessary for material or assembled components to be verified by an independent lab on a random basis periodically depending on the nature of the product or service being produced. If any of the above are non-conforming, the material should be tagged and sent to an area for non-conformance. The supplier must be notified and a request for disposition, corrective action, and date of corrective action provided. If an organization can not meet production schedules without rework, the cost of the same should be at the expense of the vendor. Statistical process control is a requirement for all suppliers and they must insure their process is in control and provide charts and records for filing and customer examination.

This is where opportunity for quality characteristics begins to take hold in the system, particularly in new product development and launch. If we have communicated effectively about our characteristics, to all involved upstream and downstream, we will enhance the likelihood that we can obtain quality in delivery. The use of several documents and charts becomes pivotal in securing and maintaining viable contractual relationships for quality--compliance certification. While possible, and maybe even necessary, to address certification as a legal issue, it is intended to be used as a trust building system. It can only lead to trust for improved relationships in quality if we go beyond the contract, using the opportunity to build documentation based on data and other communications to certify quality at all levels.

As this occurs, selection of the vendor becomes more a systematic and empirical activity, and less a "who do you know--political" situation. Vendors are chosen, then, based on their true basis for ability to deliver according to certifiability. It should be noted that certification is increasingly being specified in terms of SPC charts and capability measures, all which, if used correctly, may be useful in a court of law to assist in proving
or disproving that certification was or was not met. This requires careful understanding and detailed communication about characteristics being analyzed from incoming suppliers, and improvements in relationships. It is also extremely important that we understand that quality characteristics are at the core of the entire WC and TQ movement. As operators and others become increasingly empowered, collecting and analyzing data, and recommending, implementing, improvements through team functions, part of what they will be wanting and needing to do is to help make changes in the quality characteristics. This will include which characteristics we track, how we track and monitor them, how much sampling we do with a given characteristic, and so on. The point is, in part, what was once the primary responsibility of the engineering group—in careful consultation with the customer and others, is partly the responsibility of the operator. Customer satisfaction means that we must have operators in consultation with customers in new and innovative ways in some cases in the future, and talking about our quality characteristics.