Lean, Six Sigma, Quality Transformation Toolkit (LSSQTT)*
LSSQTT Tool #6 Courseware Content

“ISO 9000 Foundational Infrastructure For Management, Assessment, and Decision Making To Standardize Improvement”

1. ISO, QS introduced, overviewed
2. ISO 9000 based requirements, QS focus
4. Environmental 14000 standard
5. Managing process: Ongoing Process Control Plan (OPCP) As One Key
6. Managing based on standardization

*Updated summer, 2006 by John W. Sinn.

ISO, QS Umbrella, Infrastructure For The Future, Lean Six Sigma

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. 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 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 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. Most important, it is essential that the actual purpose of the systems be seen clearly as improvements in quality management systems rather than simply achievement of another registration or certification plaque on the wall.

Part of the systemic changes which are occurring in the new century, as we move into 2000, is the reality that lean and six sigma are increasingly important precepts. But to view these as “buzz words of the month” anymore that ISO 9000 would be an error. The reality, and part of the reason for design of the toolkits as is the case, is that ISO 9000 will increasingly be viewed as the umbrella under which all other quality functions, including lean and six sigma, will be viewed and addressed. Given the overall infrastructure which ISO 9000 provides, it is logical to anticipate this to be the case. This will become increasingly clear as we explore relationships and structures inherent I the standards.

Key in the infrastructure of ISO and lean six sigma, is the reality that what this is about to a great extent is standardization. Standardization is one of the fundamental requirements for lean six sigma to be successful in just about any sense, and the infrastructural fabric which can help make this happen is ISO 9000. The structure and discipline inherent in ISO 9000 is parallel in principle and practice to the philosophies and conceptual realities of lean six sigma. It may even be fair to say that were it not for advances in quality systems over the past 20-30 years, primarily due to ISO 9000, we would not have the maturity and “under control” conditions requisite for doing projects and improvement oriented to lean six sigma. Thus, the umbrella comments previously introduced—ISO 9000 has served nicely as an umbrella within which to be able to take improvement to the next level. Among other things, consider the power in the documentation which is inherent in ISO 9000, and the myriad uses and opportunities (and challenges) presented to lean six sigma projects—many which were not nearly as well organized or articulated, let alone tabulated, collected and put together systemically, prior to ISO 9000.

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 changes have occurred in the basic fabric of the standard, leading to various updates, depending on specific standards and versions, including a 14000 version for 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, but at a domestic or local level, the ISO and QS movements define methods to use in documentation, specifications and in other basic but critical communications systems. This also relates to reduction in variation and good resource management in all that we do—strong basis for connecting and relating lean and six sigma improvement systems.

**ISO and QS levels, classifications, tiers.** At the outset, it should be pointed out that 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 underwriter’s 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 organizationally to lead the process. External certification is the typical end process desired by most organizations, requiring a third party approach. It is also desired in some situations, to merely be in compliance with the ISO standards, but not actually registered.1

**9000 series.** 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. 9002 and 9003 each provide more focus to 9001, 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:

- Process definition: quality system; contract review; design control; and purchasing.
- Process improvement: corrective action; and internal quality audits.
- Process measurement: purchasing; inspection and testing; control of measurement and test equipment; inspection and test status; internal quality audits.
- 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; statistical techniques.
- Administrative: management; quality system; document control; 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.

**ISO process.** The ISO 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.

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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.
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 (SOPs). The lowest level, or tier, is the form and record, details of charts and other recording devices and systems’ elements.

Regardless of tier, classification, or level, all are designed to be routinely updated for demonstrating that quality practices are properly performed. The fundamental elements are:

○ Describing what we do.
○ Defining responsibilities for those areas and activities within the organization.
○ Describing how those activities are carried out by people in the organization.
○ Describing 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.

Costs to become registered will vary based on size of the organization, complexity of the process, level of preparedness going in to the process, and other factors. Generally the immediate costs for an external auditor to perform the various functions identified above over time will be around $15,000.00-$25,000.00. The actual costs could easily be double this, including preparation costs to gain sufficient documentation at the outset, among others. The process could take 6-12 months for a typical situation, but again is largely dependent upon where we are upon starting, and how much resource we can afford to put behind the process upon beginning.

ISO 9000 Based Requirements, QS Focus

The actual focus of the QS 9000 effort is on supplier based contractual relationships. But much of the overall effort is consistent with, or parallel with, the ISO registration process. Thus, the QS guidelines contain a significant emphasis oriented to elements which are specific to the ISO requirements. The purpose of the current section is to identify the ISO specific elements, and to provide some brief explanation of the requirement within the broader context of quality improvement. Each is briefly described and discussed as:

1. Management responsibility.
2. Quality system.
4. Design control.
5. Document and data control.
6. Purchasing.
7. Control of customer supplied product.
8. Product identification and traceability.
10. Inspection and testing.
11. Control of inspection, measuring and test equipment.
12. Inspection and test status.
13. Control of non-conforming product.
14. Corrective and preventative action.
15. Handling, storage, packaging, delivery, preservation.
16. Control of quality records.
17. Internal quality audits.
18. Training.
19. Servicing.
20. Statistical techniques.

Each element will be briefly presented and discussed in the broader context of the toolkit quality system.

Management responsibility. The management responsibility element provides a statement of quality policy to be consistent with what has traditionally been called a mission statement. As part of the overall management function, organizational responsibility and authority for quality issues and operations as defined in the broader system is identified and explained. The overall system for interfacing organizational entities and resources are described and identified as part of the management responsibility. The key reason for identifying and describing various organizational functions is to assure that, as a supplier, the organization can deliver product as stated. A major focus of this delivery is the ability to bring a concept to production with all development activities in between, as well as review systems and mechanisms for improvement and adjustments as needed over time to meet customer demands. This requires a multidisciplinary approach between and among technical and business functions within the organization, similar to what is described throughout the toolkit.

Part of the management responsibility is identification and explanation of a business plan. The comprehensive plan must provide the suppliers' goals and objectives which are 1) short term for one to two years, and 2) long term for three or more years. Appropriate mechanisms for implementing, tracking, updating, and reviewing the plan by all
persons on empowered teams should also be included as part of the planning process. This process would provide evidence that data and documentation systems are actually being used in the broader system to conduct affairs of the organization. A key part of this element is the ability to involve suppliers with customers in constructive team arrangements.

**Quality system.** Element 4.2 in the system is the establishment of the broad quality system. This is providing for the mechanism, in the form of a quality manual to assure that the supplier is meeting the customer specifications. This also allows for providing implementation of the quality system per the documented procedures as stated in the quality manual. The range and detail involved in the procedures of the quality system will be a direct function of the complexity of the work and methods used by the supplier in achieving the customers' demands. Documented procedures in the manual and broader quality system may also be referenced to other work instructions with finer detail and added definition at the work place.

The entire quality system will need to be consistent with management policies and stated philosophy reflected in short and long term plans. This will typically include documentation related to:

- Preparation of control plans.
- Implementation of all equipment and processes to assure that the quality system is achieved.
- Bringing together design and production functions and all processes involved in quality.
- Staying current in all aspects of quality, particularly focused on improvement.
- Identification of all measuring requirements to achieve capabilities, enabling the ability to achieve the required capability level.
- Identification and development of appropriate quality verification methods, systemically.
- Clarification of standards and requirements to spell out acceptability levels for the customer.
- Development of record keeping methods and procedures as a part of the broader system.

The QS standard also specifies that the work called out as satisfying the broader quality system shall be done in cross functional teams which routinely address the corrective actions, updating control plans, development and follow through of FMEA's, special characteristics, and other system wide tools. Allowances must also be acknowledged and built into the system which provide for currency and differences in product according to the three major phases of planning and control functions commonly associated with:

1. Prototype.
2. Pre-launch.
3. Production.

It is important that the broader system identify, develop and track, in accurate and timely ways, the distinctions among and between the three major product areas identified above.

**Contract review.** QS 9000 standards specify element 4.3 as contract review, allowing for procedures to conduct and provide contracts in a coordinated manner organization wide. This provides mechanisms for suppliers and customers to make sure that all requirements are adequately specified and understood by all parties. These procedures and documented methods also allow for making appropriate changes in the contracts if and when differences are found to exist between or among contracting parties. Significantly, the contract, as part of the broader quality system must help assure that the supplier can actually deliver on what is specified. As with all else in the system, appropriate procedures must be in place for tracking records of all of this, and allowances for how communications and interfaces among and between all parties, both internal and external, will occur.

**Design control.** Element 4.4 in the QS 9000 standards specify the need to control design as related to production and quality functions, system wide. This element provides a mechanism for suppliers to control all plans as related to each design and development function or activity. System wide control and responsibility for all design and development activities must be specified, tracked, recorded and implemented in ways which demonstrate broad connections to the quality system and function, and will typically be evidenced through use of tools as outlined in the toolkit as part of the system. These will typically include FMEA's, QFD's, characteristics identification and evaluation with broader connections to the geometric dimensioning and tolerancing functions, value analysis, DOE, FEA, CAD/CAM, reliability analysis, and others.

Generally it is also true that the design control element must account for broad relationships among various parties in the actual production and delivery of product from concept through broad service life concerns, spanning the life of the product. This involves what is known as design input, output, reviews, verification, validation and changes in
design. Each of these will be briefly addressed as related to the broader quality system.

Input represents the original documentation, commonly in digitized form, of the information associated with design functions. While this will most usually be CAD information in data form, it can also be merely prints, technically. This requires two-way interface and communication capability between and among internal and external customers and suppliers. Output functions will obviously relate to the input functions, but they may also be broader from the standpoint that they specify more of the production orientation possibly to include characteristics, tolerances and other specifications. The key difference between original customer inputted CAD information and supplier output design information is that the customer will increasingly provide nothing more than CAD math data in "black box" form. By contrast, the supplier will need to add all information pertaining to production and quality control in their organizational context.

Design reviews will be traditional project reviews involving appropriate cross functional team persons, and with allowances for documenting and recording progress and changes in the design as related to the broader product quality. Design verification must be performed at various stages of design to make certain that the original design input is being maintained across the total system as the product moves through various production stages. This may include comparing new designs with existing proven designs, SPC short run data comparisons to existing mature products' data, various evaluative simulations, tests and demonstrations, and other additional assurances of compliance to original CAD math data.

After various verification documentation is established and provided it will commonly be required that the supplier ensure that the product conforms to the defined customer demands as originally stated. This will generally involve validating actual functioning product under operating conditions. Several iterations in validation may be required and helpful to assure satisfactory compliance of early produced product per the original customer supplied CAD math data. Obviously, as the various stages of review, verification and validation occur, it may be necessary to make agreed to design changes. In fact it would be highly unlikely that the team would not wish to make changes over the life of the product as improvements are noted and savings overall can be made without sacrificing quality. Part of the overall element 4.4 requires that suppliers provide documentation methods and procedures for recording and controlling, systems' wide, the design changes at various stages of the overall process.

**Document and data control.** Element 4.5 provides for document and data control as part of the broader supplier system. This includes control of all internal and external document and data control for all suppliers and customers in the broader quality system being impacted. Examples of information being addressed could include drawings, CAD math data, various standards and specifications, customer specific symbols and characteristic nomenclature, work instructions and operations or procedure sheets, and of course the overall quality manual. Documents and data can be in various media and formats, obviously as long as they satisfy the customer, and as long as all internal and external customers and suppliers can accommodate and be accommodated within the broader system in efficient ways.

Approval, acceptance and issue of all documents and data must be accounted for as part of the broader system. This includes who can access, and in what ways, all information. This issue becomes increasingly important with the advent of various electronic media and formats which enable various persons to gain access. Methods for disposal of obsolete documents and data, and appropriate tracking records for the same disposition must be accounted for. Similarly, multiple site and user applications for the same documents and data must be accounted for, recognizing that when changes are made at one location or work site, problems will typically arise if we do not account for procedures to make necessary and timely changes. The ways we accept and issue changes and original information in any stage along the way in the broader quality system becomes significant, and this must be accounted for.

**Purchasing.** Element 4.6 relates purchasing to the broader quality functions and system, and acknowledges the importance of having the proper materials and components in the broader mix of producing the product. What this element focuses on is the reality that the supplier must evaluate and select subcontractors in ways which reflect their ability to deliver per customer specifications. Element 4.6 is concerned with documenting the nature of the control mechanisms and broader quality relationship which will be provided through subcontractor purchases. The purchasing relationship system must be recorded and tracked over time. Thus the element provides a desire to watch for ongoing development in the relationship over time. Evaluation of purchasing relationships, as well as other broader relational scheduling and
documentation data is addressed as important in the element. Specific desirable element issues for documentation are called out, including general identification information, specifications, drawings, inspection instructions, approval and verification procedures, applicable standards, and so on. The first tier supplier is the responsible party, and that subcontractors are responsible only to the primary supplier for their customer.

**Control of customer-supplied product.**

Similar to 4.6, element 4.7 is concerned with relationships in the supply chain in such a way to help ensure timely delivery of contracted components and services by all parties. 4.7 addresses, briefly, the purchasing type issues where the customer must provide parts of the mix for production. This places a special relational requirement into the mix where product that is lost or damaged so as to be unfit for production must be tracked and recorded for control within the quality system.

**Product identification and traceability.**

Element 4.8 provides the need to identify and provide suitable means for knowing precisely what each component is in production from receipt through delivery of finished goods. This requires decisions to be made about what are necessary traceable items, and providing means for accomplishing the same. Whether this is a tagging identification, bar code, stamp, or other procedure, the importance for knowing and tracking the components must be seen as a serious opportunity for improving production through documentation.

**Process control.**

4.9, has special consideration for relationships inherent in data and documentation will be noted as indicated throughout the toolkit. The focus of the element is emphasizing realities in critical production processes where adverse performance can clearly affect quality immediately and certainly downstream. The documentation will include many critical references to characteristics or features which require careful consideration, as well as specific measures of performance such as capability indices. The element provides reference to what may be termed special characteristics, and the need to call these out, since they may affect safety or other performance criterion of product as in reliability, or conformance to a standard where compliance is critical to proper adherence to contract. Provisions for documenting and controlling the special characteristics, as well as all processes in production, is what element 4.9 is about.

Broad relationships to maintenance, and particularly preventive approaches, must be identified and documented in process procedures with appropriate data measures identified and tied in. This may likely be a part of the standard work procedures for the operator or others, and will call out appropriate levels of Cpk, relationships to charting, when to do maintenance and of what types, and of course, all other relevant production operation specifics. Some of this may be called out in the form of monitoring and could include:

- General part and process information.
- Inspection and measurement tool and method requirements and instructions.
- General tooling and material identification and disposition information.
- Customer or other relevant standards and/or requirements, as related to special characteristics.
- Corrective action instructions, references, and systems for tracking and recording the same.

While the above must be a part of all production information, when new product launches or program changes necessitate, we must have mechanisms for conducting and tracking special approval procedures for process control and monitoring. In the toolkit this is generally referred to as pre-control or short runs. This will increasingly require more stringent Cpk levels, shifting upward from 1.33 to 1.67, recognizing that ongoing process improvement is required.

Some of the same logic applies to general ongoing improvement in process, as called out in element 4.9. Where the customer does not specify, other criterion or defaults may be useful:

1. 1.67 Cpk levels.
2. Various creative data logging techniques where we log reductions in parts per million, defects or defectives, or other attribute related issues and circumstances.

Significantly, the main point is that ongoing improvement will need to be demonstrated. Thus, the way we measure performance as specified by the customer, and well beyond based on our own internal desire to improve, is the focus of the element. This also relates back to the broad control plan where much of the performance criterion and measurement strategy is spelled out. This ties in virtually all verification and measurement systems and procedures, and will document the appropriate changes in process over time, helping demonstrate improvement in documented ways relying on data.
**Inspection and testing.** Element 4.10 is concerned with inspection and testing of product. General concerns include provisions for methods and procedures to inspect and test, with a primary emphasis on documentation for recording and control. Acceptance criteria for sampling and procedures for the same are pivotal, as are use of equipment and laboratories. Other detailed information in the element is provided in receiving inspection and testing, in-process inspection and testing, and final inspection and testing, as well as focus on recording issues and procedures.

Receiving inspection and testing provides the need for assuring that before incoming materials or components are used they will be determined to be fit for use per customer specifications and standards. The nature and type of inspection and test will be a direct function of severity of product, nature of the work environment and other customer associated factors. Much of this is associated with statistical data received with incoming product, such as charts or test data and the integrity of the same. Broader documentation provided in the supplier relationship will also help determine the incoming inspection and test procedure, as in the form of certification or other supplier warrants of performance.

In-process inspection and testing should follow the broad guidelines as shown in the control plan and other documented work instructions or SOP’s. Procedures must be established as part of the documentation to allow holding product until first piece and last piece inspections can be performed and parts confirmed as being fit for use and /or ship. Defect prevention rather than detection is the focus, relying on techniques which will help provide this such as SPC, mistake proofing, visual controls and other systemic fault recognition methods.

Similar to other inspection systems throughout the quality system, final inspect must have and provide documentation to substantiate and improve proper production. Again, the control plan is pivotal as the base, and must be reflected and upheld over time. At the final inspect, work instructions and SOP must reflect that all upstream functions have been properly carried out, incrementally adding value to the product, and now clearly evidenced prior to ship or other customer directed disposition. The total product inspection system must have documentation which relates back to the original design and specifications evidenced in CAD math data, and the final layout per print to confirm proper production. This will all have documented recording and tracking systems for monitoring conformance over time, demonstrating improvement and enhancements in characteristics being inspected.

**Control of inspection, measuring and test equipment.** Element 4.11 provides the need to document all control procedures for equipment used in inspection, measurement and test functions. This is primarily concerned with procedures to control, calibrate and maintain inspection, measuring and test equipment. The overall emphasis is to understand the uncertainty in measurement systems and to provide capability sufficient to meet the customer demands. Measurement system procedures and documentation must include both hardware and software issues and must provide frequency and extent of procedures for verifying adequacy of the overall system. Technical data generated by and/or related to test equipment should be verify adequacy in the overall supplier measurement systems, as part of customer demands.

Control procedures spelled out in 4.11 typically entail several supplier measurement system issues, generally summarized below:

- Identification of where, how to do measuring.
- Identification of areas of vulnerability in systems, and methods to assure adequacy and calibration.
- Define the overall system for calibration of the measurement equipment and system.
- Identify equipment with substantial calibration history, reducing uncertainty.
- Maintain calibration records.
- Provide environmental conditions, including handling, storage, and security of equipment, to produce adequacy in measurement systems.

Total measurement systems are referenced with the overall quality system. This includes a substantial capacity for analysis of data being generated in the documentation system, assuring that data is provided as a key part of the documentation, and that ongoing improvement in gaging, or reductions in variation, can be identified and substantiated.

**Inspection and test status.** Satisfactory methods and procedures must be identified within the inspection system to control the product test findings as a function of the broader inspection system. The concern in element 4.12 is to assure adequacy of equipment and systems for proper test and inspection.

**Control of non conforming product.** Related to 4.12, the 4.13 element is designed to substantiate good and bad, or non conforming, product disposition in production. Element 4.13 requires that
suppliers provide assurances that only conforming product will be used in product, per customer specifications. The overall documentation system, as evidenced in the control plan, tagging, environmental control, and other ways, must provide sufficient control overall identification and disposition of good and bad product. This includes steps for disposal of nonconforming product, and other corrective actions:

○ How to rework nonconforming product to be in conformance, generally as work instructions.
○ How to gain approval of nonconforming product, with customers, and associated documentation.
○ What substantiates a re-inspection procedure for verifying use of nonconforming product.
○ Documentation of procedures for tracking progress toward reductions in nonconformance.

Corrective and preventive action. Element 4.14 provides that the supplier establish documented procedures for corrective actions. The system established for corrective and preventive action must be directly proportional in rigor and robustness relative to the overall severity in the product failure. Improvements or other results related to the corrective actions should be documented as part of the record keeping log, and used to substantiate that the broader quality system is actually working to reflect discipline and problem solving steps as good management systems. Procedures in corrective and/or preventive actions should generally reflect the following steps and approaches:

○ Proper handling of customer complaints.
○ Investigation of causes of nonconformity’s.
○ Use of systems to determine appropriate courses of action for resolving complaints.
○ Use of controls systemically to assure that repeats for corrective action does not occur.
○ Using information systemically to resolve issues.
○ Management reviews, leading to prevention.

Part of the documentation for this element involves procedures for assuring proper disposition of returned product. Records and actions associated with returned product analysis and test must be documented, and mechanisms for follow through after actions, built in.

Handling, storage, packaging, preservation and delivery. Element 4.15 provides for documentation of proper handling, storage, packaging, preservation and delivery of product. The overall aim of this element is to prevent or minimize damage and deterioration to product in processing. Proper storage and shelving methods must be demonstrated in procedures to provide proper disposition for product per customer requirements. This will include inspection and assessment at regular intervals for damages or other condition of product. Methods for tracking and managing inventory must also be part of element 4.15.

Packaging, labeling and preservation methods must be documented and provided per customer requirements. Delivery of the product to customer or next point in production may be specified and monitored. Relating to inventory and materials requirement planning, suppliers must provide for appropriate scheduling systems to adhere to lead times and articulation in production. Shipping specifications, including schedule adherence, will be part of the pull production system. Monitoring of product in production, as related to scheduling, inventory, shipment, and so on, must be a function of computerized systems.

Control of quality records. Element 4.16 addresses the need for suppliers to document and record all aspects of the overall quality system. All records must be reflective of customer requirements and readily accessible by all appropriate parties. Length of time for keeping quality records, general circumstances for storage and care, and methods for evaluation by all concerned must be documented as part of the contractually agreed procedure.

Generally, the life of product programs will determine how long records must be maintained, with one year beyond the life of the production run being the baseline rule. Quality performance records such as charts and inspection and test data should also be kept for one year beyond when they were created. Most other internal management and audit records pertaining to specific programs should generally be kept for three years from date of creation.

Internal quality audits. Element 4.17 relates to the need for the supplier to establish procedures and methods to conduct and document internal quality audits. The basic purpose of the audits will be focused on determining the overall effectiveness of the quality system. The auditing system will be governed in occurrence and rigor by the overall nature of the product, and of course various customer demands and requirements. The system must include mechanisms for bringing all findings and recommendations to the attention of appropriate personnel, both those directly impacted and management with control over affecting change for improvements. These evaluative tools also form a key part of the broad review and planning system.
Appropriate follow up audit activities must be part of the mechanism, assuring improvement where needed.

**Training.** Although only two brief paragraphs in the QS 9000 manual, element 4.18, training is one of the most important. This is evidenced by the basic design and makeup of the toolkit, all designed for training and education functions. The element simply calls out the need for identifying and providing all persons with training in those areas which affect quality. Training is to be viewed as a strategic issue, and one of the key opportunities for improvement, as underscored throughout the toolkit. Appropriate records on training activities must be established and maintained, and qualifications for various quality related personnel tied to training for advancement.

**Servicing.** Again only a brief entry in the QS 9000 manual, element 4.19 is servicing, obviously a rather important area. Element 4.19 requires that the supplier provide documentation on service functions as related to customer demands and requirements. Records of all service function communications, internal and external, and specifically focused on engineering, manufacturing and quality relationships, will be the primary area of documentation.

**Statistical techniques.** Element 4.20, the final element in the QS 9000 manual, is related to documentation oriented to statistical techniques. This element requires that statistical techniques appropriate to the product and process be identified, documented and implemented. Most necessary techniques will be identified in planning stages, and followed through with broad control plan steps.

**Sector specific requirements: Production part approval or verification process.** Part of the QS 9000 manual, section II, is focused on what are termed sector specific requirements. This is further defined as production part approval or verification process (PPAP or PVP), continuous improvement, and manufacturing capabilities. The PPAP or PVP is a systematic documentation procedure which accounts for all parts and components in the broader product. The part is labeled with a part number, and all changes or approvals are logged in such a way that the basic quality and contractual arrangements surrounding the components can be better communicated to all parties. The burden for properly implementing and documenting the system falls to the supplier. While not identified as elements, each of these three areas are thought to be important to the overall accomplishment of the QS 9000 requirements for an organization. Design, implementation and ongoing maintenance of the broader quality system is a substantial organizational issue, one that requires serious leadership and other resource commitment.

**Sector specific requirements: Continuous improvement.** The continuous improvement philosophy and approach to all that is done throughout the organization must be evidenced in the documentation of the broader quality system. Specific action plans for ongoing improvement must be evidenced where stability is noted in those areas deemed to be important to the customer. This will mean a specific focus on continuously evaluating all characteristics, whether attribute or variable data. Areas and methods for ongoing improvement are well spelled out throughout the toolkit, and all are consistent with the QS 9000 requirements.

**Sector specific requirements: Manufacturing capabilities.** This sector specific requirement, while aimed at manufacturing specifically, also recognizes the reality that cross functional teams will be required to bring forward ongoing improvements for the future. Once again, through use of the tools in the toolkit as one approach, using teams composed of persons from maintenance, engineering, quality, and so on, not only must we produce product to meet customer requirements immediately, but we must also lead new product developments for the future.

Several areas are called out as specific issues to be addressed as related to manufacturing:

- Facilities, equipment, and process
- Planning and effectiveness
- Mistake proofing
- Tool design and fabrication
- Tooling management

This provides for enhancements in quality and productivity for improved product, cost savings and basic quality improvements organizationally.

**Section III: Customer specific requirements.**

The final section in the QS 9000 manual relates to specific symbols and other requirements as required for suppliers of major automotive producers and others. The point is that selected areas of concern for communication and documentation are to be handled in customer specific ways. The emphasis in this section is heavily oriented toward CAD math data based communication in prints, relationships to characteristics, corrective actions, part approvals, and of course ongoing improvement.

**Concerns, issues, benefits.** ISO and QS 9000 systems must transcend simply creating another level of documentation or an updated quality manual to sit on a shelf in someone's office and be unused. The focus of ISO and QS must be developing new levels
of understanding of the interaction between the various management and operating systems used daily in organizations. This includes how standards help meet the needs of our business--and our customers--on a daily basis. Using standards as a benchmark--a guidepost--is the most productive approach. This recognizes the importance of getting various persons up to speed, and on the same sheet of music--internal and external to the organization.

It must also be recognized that ISO and QS goes beyond merely the European or automotive community. It is assumed in the toolkit that these standards and approaches are useful for all types of industries, both manufacturing and non-manufacturing. Driven by cooperative efforts among professional groups over several years from throughout the world, this is not simply for European or automotive applications. The idea is to create an environment worldwide for movement of goods and services--by establishing workable and useful standards between and among organizations which are interested in preparing for the global market.

While the major force behind ISO and QS is to better meet customer needs, other less tangible internal reasons may exist for pursuit of ISO and QS:

○ Management and operating systems better linked to day to day functions of your business.
○ Improved production process and overall efficiency through enhanced understanding.
○ Real organizational teams—internal, external.
○ Enhanced flexibility and control, to better meet customer demands--response time improvement.
○ Overall better understanding and communication.
○ Decreased liability, increased reliability.
○ Increased marketing advantages based on external evidence of commitment to quality.
○ Better alignment of operation and management systems to strategic directions organizationally.
○ Fundamentally healthy way of doing business.

Actual benefits in any given organization will need to be evaluated against the costs, both initially and over time. But most organizations can make many gains through the process, let alone the actual certification.

A final concern relates to who is chosen to certify your organization. The key is likely the extent to which the auditor actually is customer focused--is the auditor looking out for your best interest? This can be assessed up front by determining the extent to which the auditor will assess objectively against the actual standard--as opposed to their opinion or viewpoint. Also, this can be assessed by determining the flexibility and willingness of the auditor to work according to your schedule rather than their calendar. Quality of auditors will vary--you will want to seek out the views of past customers of the auditors--determine the credibility of the auditor based on the evaluation of their past customers.

Getting started on ISO and QS. Your organization may be further along than was originally assumed to be. No doubt, we are already doing business with numerous organizations who are either registered or in process. And they are likely already initiating discussions with us to pursue the process for various reasons essential to our future. If they are not, they will be--and we need to be talking with our customers about our decision any way. As we get moving over time, the following can help:

○ Involve people throughout the organization--part of the intent of the process.
○ Focus broadly on what you are trying to achieve--improving your organization.
○ Do not do this in a vacuum--isolated efforts will only result in confusion and duplication.
○ Build on processes in place--enhanced understanding and knowledge can only help.
○ Based on enhanced understanding and knowledge, give empowerment to people.
○ Based on enhanced understanding, study how your operations meet the ISO standards.
○ If not compliant to standard, determine why--and consider the value of putting it in place.
○ As decisions are made, carefully do a full evaluation, prior to possible implementation.

Part of the key is in having human resources in place to help guide the process--or to help determine other resources to be addressed in all areas:

○ At least one champion--someone to lead and push the process--a catalyst.
○ People who produce results--not just muddle along--bring closure, produce deliverables.
○ Ability to deal with change, and evaluation of where we are and where we ought to be.
○ Expertise to guide discussions, focus groups in productive ways, and avoid false starts.
○ Build knowledge of processes in people--to teach and learn together in productive ways.
○ Ability to evaluate standards, and to implement knowledge about process to meet standard.

The above is not a simple matter, and it cannot be taken lightly--but it must be moved into--consistent
with our need to become and remain competitive in a
global and changing marketplace.

**ISO 9001 Streamlined: TS 16949 2002**

**Standard For A New Century**

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. The new TS 16949 2002 standard provides a broad-based three category type logic for quality systems management at the organization level. The new quality management systems provide a seamless and integrated model for holistically managing the organization, based on three parts:

1. Product development
2. Production processes
3. Support processes

These are each discussed from a functional standpoint for day-to-day management and production purposes.

**Product development.** Product development would typically address such areas as quality planning from an advanced program or platform standpoint for purposes of gaining new contracts for the future. This may be called concept program and process definition, and would typically involve prototype development and readiness, design release for production, assuring readiness and capability for production, various launch review processes and continuous improvement in all that is done. Much of this relates directly to engineering functions in manufacturing organizations. It also relates to quality indirectly, purchasing and other production functions indirectly for planning purposes.

**Production processes.** This relates to the act of production, adding value to raw materials, assemblies, inventorying and storage, and shipping. The start of the concern with production process is receipt and verification of materials to assure specifications and fitness for production. Storage and handling of materials through actual value adding functions, including collection of appropriate necessary statistical process control data. Other inspections and management of work in process, assembly and other secondary processes through packaging and ship would typically be included in the quality management system.

**Support processes.** This addresses advanced engineering and research functions for future improvements in materials and processes, as well as plant engineering improvements to facilitate the same. Various business functions, auditing, preventative maintenance, document and record control, how corrective actions are handles, training and so on. The support services or processes are typically housed in various seemingly unrelated groups or departments, but the fact is that these all relate indirectly to the broader system and the organizational ability to get product or service out the door. Support areas also acknowledge growth and maturation in service relationships over the past 10-20 years, requisite to doing ISO and QS quality management systems.

Specific changes in quality management systems provide for fewer key elements resulting in a streamlined system, more integrated throughout all aspects of the organization. Management now realizes the importance of changing culture and systems to be more aligned with QS, becoming increasingly supportive. The 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 older elements have been subsumed within these. New elements are addressed and compared to 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. Elements in ISO 14000, due to the specificity of their intent, also clearly require additional attention. The 14000 standard is applicable to any organization that wishes to:
○ Implement, maintain and improve an 
environmental management system;
○ Assure conformance to its environmental policy;
○ demonstrate such conformance to others;
○ Seek certification/registration of environmental 
management system by external entity; and,
○ Make a self-determination and self-declaration 
of conformance with this international standard.

Six elements cover major areas of concern in the 
14000 standard, each listed and discussed briefly:

○ General requirements.
○ Environmental policy.
○ Planning.
○ Implementation and operation.
○ Checking and corrective action.
○ Management review.

**General requirements.** The organization shall 
establish and maintain an environmental management 
system, described in the remaining elements.

**Environmental policy.** Top management shall 
declare the organization’s environmental policy and 
ensure that it addresses the nature of organizational 
activities, products and services. The policy must 
include a commitment to continuous improvement 
and prevention of pollution, and assure a framework 
for setting and reviewing appropriate objectives and 
targets for improvement over time. The policy must 
include a commitment to comply with all relevant 
environmental legislation and regulations. As a 
written statement these must be documented and 
communicated to employees and the public.

**Planning.** The organization shall establish and 
maintain procedures to identify and maintain 
environmental aspects of its activities, products or 
services. The standard defines planning further as 
being related to those areas where it can control and 
influence where it can have a significant impact on 
the environment, and to using these impacts, once 
determined in setting objectives for improvement. 
The planning function shall also include 
consideration of legal aspects, legislation and 
regulations which may be appropriate to the 
organization and prevention of pollution. 
Environmental management shall include 
establishment and maintenance of programs and 
systems to assure designation and follow through of 
responsibilities, both in existing products, services 
and activities, and in new product developments.

**Implementation and operation.** The standard 
requires documentation to address and define roles 
and responsibilities which will facilitate effective 
environmental management. Resources shall be 
provided, and persons appointed, who, regardless of 
other responsibilities, will be accountable for 
implementation and operation of systems to assure 
satisfactory environmental conformance and 
performance. Documentation shall be in place to 
assure that training and education, competencies and 
experience are in place and evidenced in personnel 
for managing all systems, including emergency 
preparedness and response requirements. Systems 
must be in place to assure, demonstrate and 
document internal and external communications 
between all interested parties; and to assure accurate 
and timely review of all significant records and 
communications materials. Major environmental 
activities (real and potential) in operations must have 
written procedures identifying how to handle 
ocurrences and non-conformances in critical 
functions, and the test and improvement in 
procedures must be demonstrable. All procedures 
must include how and what to measure as key 
characteristics in operation product, services or 
activities which can have significant impact, and how 
to determine conformance and non-conformance, 
particularly based on auditing procedures, and what 
constitutes appropriate corrective actions in same 
when needed.

**Management review.** Top management of the 
organization shall review the environmental 
management system at regular intervals, to be 
determined by them, to assure that the system is 
satisfactory. Appropriate information must be 
collected as part of the review, and results shall be 
documented. The management review will address 
possible changes in policy, objectives and other 
elements of the environmental management system, 
based on audit results, for continuous improvement.

**Managing Process: Ongoing Process Control Plan (OPCP) As One Key**

This provides a focused attempt to address 
various tools and techniques which are time proven 
for helping to define the processes in production. 
Generally under the title of various engineering 
functions/personnel, these tools now must be used 
and administered (certainly understood) by various 
persons. Regardless of who completes/uses this 
information now, teams will need this information, in 
as accurate and complete a form as possible, in the 
future to solve problems for on-going improvement.

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1 ANSI/ISO 14001-1996, Environmental management systems—specification with 
guidance for use. Publication T 65, 
American Society For Quality, Milwaukee, 
WI.
This relates to another very important point about managing for problem solving and improvement. Much, if not all of it, is information based—and much of the information is numerical data. Thus, a major part of what we refer to as discipline is related to building and maintaining systems accurately, methodically, and in a timely manner. This means gathering and documenting information and data which will be used at later times and places for analyzing and solving problems, and certainly managing better in all aspects. Simply put, organizations must have processing information and communications devices and systems. Regardless of what these forms and approaches are titled, the idea is to provide basic information about building product.

The "ongoing process control plan" (OPCP) is designed to document key methods, techniques and other general information used in the processing applications for the product under discussion. This includes process name, tools for production, process parameters, product characteristics, and possibly other specific process oriented information particular to this product, the emphasis being placed on better understanding the processes involved in producing the product. Secondly, the OPCP is designed to identify and document key customer information and expectations in the form of specifications, evaluation method, sample and inspection, analysis and reaction methods, and perhaps other information vital to controlling and improving the processes involved.

Some of the information is largely the responsibility of quality personnel while other information may come from customer sources, supplier sources, standards in the industry, and so on. Particularly important in these regards are product characteristics, specifications, evaluation, inspection and analysis approaches and systems. The reason these areas are particularly important is because their determination relate to internal data collection and analysis systems by various employees. These systems and quality areas are fundamental to ongoing improvement—with a firm basis—particularly documentation and data. Equally as important, cost savings can result by re-establishing levels and methods based on documented changes—improvements in product and process. But similar to cost savings, if, due to un-disciplined approaches in processing or our manufacturing systems in general, we do not make improvements—or can not demonstrate our improvements in quality—we can/may be losing dollars.

The OPCP must be regarded as a dynamic as opposed to a static document, an important enhancement for lean management efforts. Systems which are used to maintain the information must be built to respond in a timely manner for enhancements to the system—including all involved both internal and external. This further points to the importance of the team, to be addressed further in later sections. Briefly setting the stage, the OPCP is important for procedural reasons. Some of these are:

- OPCP is a "best", "correct" way to do processing. How can we improve on, or manage, our process if we do not know the process? OPCP sets fundamental benchmarks in total process--benchmarks that can help us reduce "moving targets"—and help us know when we have improved, and why, as well as when, how to do, what must be done per customer demands.
- OPCP is based on other detailed information and documentation such as engineering drawings, customer feedback, test results, statistical process control information, gage analysis results, among others. This represents much detailed procedural work which can be reduced or redirected over time, as we make improvements—or increased if needed—but certainly changed.
- Depending on maturity of product, amount of resources directed to the product, etc., it is assumed that OPCP will become a processing summary supported by various persons, teams, departments, corporate, and others internal and external. The "total document" about processing and procedural issues for a particular product is our best defense for broad customer negotiations and relationships—business in the future.

The structure is one of causing management and communication to occur based on and around the OPCP. But all of the above assumes that we can continue building around the OPCP system to document our procedures for change and improvement. It also assumes strong "team" and "cooperative" attitudes throughout, a willingness to continue teaching and learning from one another, and a willingness to change for improvement.

We must recognize the importance of the OPCP as a documentation and communication device. While this may appear to be self evident, it is also true that many persons, depending on function, have not had a great deal of involvement in building and using the OPCP. As teamwork and cooperation become increasingly prevalent for all persons organizationally, particularly for supervisors and
operators, the use of this device will become more useful and necessary. The OPCP represents and summarizes many inputs and sources of information as a dynamic communication and management tool:

- When we, or others, wish to determine how something is being done, particularly relating to processing a product, the OPCP is the base.
- Suppliers wishing to better understand what is happening to material or component in process, the OPCP is the starting point for analysis.
- When being considered for new customer programs, OPCP is a basis for capabilities.
- OPCP is a "paper trail" for certification and verification of process, regarding management.
- OPCP is an excellent evaluation tool over time, based on strong and accurate documentation of our process at various points along the way--in the evolution of a given product.
- OPCP is a rather straight forward method for all to see and understand their involvement and role in building the product--increasingly apparent.
- OPCP is a basic communication device, internal and external, upstream and downstream, with customers and suppliers, taking guesswork out of issues to "nail down" how we do what we do.
- New product introductions use OPCP to form a basis for how implementation should be done.
- OPCP is an important training tool, helping "pass knowledge on", for future improvements.

The OPCP is a substantial document, one that forms the basis for much that is important to management for the future of the organization. The OPCP relies upon accurate and timely information gathered and compiled throughout a broad and complex network involving many persons and organizations. The OPCP can only be as good as the information upon which it is based--and the people which are providing the data--further detailed in the remaining section.

**Define the customers and suppliers of our products or services.** Traditionally we think of customers as persons or groups who buy our product or service. But we must remember that anyone who depends upon us for assistance, information, components, or service in general, downstream internal or external, is a customer. Only when we thoroughly know and understand our customers can we begin to fully meet their needs. Similarly, we must also understand our suppliers, and our role as a supplier, for our customers. Both functions require substantial effort ongoing. This requires defining and detailing the characteristics and specifications of our product or service in detailed and specific ways.

**Detail and document the process.** It is imperative that we thoroughly understand the processes we use in our production operations and functions. If we do not regularly evaluate the processes, broadly and at specific operations, we simply will not know where improvement opportunities exist. This should occur as process flow using the traditional engineering analysis symbols and time study tools, accomplished in detailed ways to include standard operating procedures at specific and detailed locations.

**Drive stakes in the ground upon which to gage and manage improvements.** At some point it will be imperative that we know clearly and precisely the extent to which we have made improvements. Thus, it is important that we have clearly established and understandable measures of success for evaluation. This could be cycle times, products produced over time, defects or defectives, downtimes, maintenance schedules, and so on. This is a key part of the basis from which we set goals for improvements, moving forward for enhanced competitiveness, and the general context of lean management, all requiring strong emphasis on audits and verification of systems through tracking and data driven measurements. It is simply not acceptable to propose and implement improvements without regular follow-ups to show our continuous improvements. Assuming we have multiple improvements in motion simultaneously, it will be vitally important that documentation in a systematic manner be part of our strategy. This is part of the design of the OPCP, providing the broader format for ongoing improvement. Competitive organizations would have multiple ongoing elements of the OPCP dynamically in motion for broad improvement.

**Involve internal and external customers and suppliers.** Although it may seem obvious to involve those closest to the problem or circumstance for improvement, it is likely not always occurring. We can all gain in building the better relationship by working with our customers and suppliers, using the OPCP as the base from which we improve, collectively. This baseline, if used properly, can also provide the necessary foundation for demonstrating our potentials to current customers, for remaining and building a continuous relationship. The dynamic is part of the broader improvement system, using our information and communication to solve problems and document for future management. Several key pieces of information, and steps for completing process, are part of building the OPCP. These are briefly presented below, including descriptions of
information, step or role in the overall system for improvement and documentation:

- **Process description.** What are we doing in production, in diagrammatic form, showing relational locations of each step relative to all?
- **Tools for manufacturing.** This may be a symbol on the flow chart, but it can also be a detailed description of equipment as an addendum.
- **Process parameters.** Controlling factors in equipment and processes for production, parameters are elements of production describing why process results in good or bad product.
- **Product characteristics.** Characteristic is a detailed process or product feature being tracked at a given location in process. This is consistent with quality characteristics used in process control circumstances, providing the basis for tracking quality at the point of production.
- **Class.** The class identification in the OPCP is a customer code which provides an indication of the criticality of the characteristic.
- **Product and process specification.** Related to the characteristic at a detailed point in production, this is a technical indicator of how to measure the level of quality.
- **Evaluation method.** This is method for checking specification, a calibration device at the floor level, gage R & R system, or other.
- **Sample size/frequency of inspection.** How often do we check the process at the point of production, according to evaluation methods, to make sure the job is running correctly?
- **Analysis method.** How do we document findings based on evaluation method? Do we use trend, process control or attribute conformance charts, gage R & R results, or others?
- **Reaction program.** What is the approach when a problem is detected? If the process requires some type of corrective action, what is our method for detailing the reaction and action plan? How do we follow through to make certain we have actually taken corrective action--and made necessary improvements?
- **Revision change level.** Based on revisions which have occurred to provide ongoing improvements, this code helps communicate to all involved what the status of the change is.

Information provided can be as detailed as necessary to communicate and document sufficiently. The basic documentation format for the OPCP, with all categories shown in blank form is provided on a related page. In some cases it may be sufficient to simply fill in the blank on the OPCP form. But in other cases involving more complex processes, it may be necessary to provide added details about the process--building a substantial document for various applications--and opportunities for improvement.

### Managing Based On Standardization

This section addresses various tools and techniques which are time proven for helping to standardize processes in work, known as standard operating procedures, or SOP. Generally under the purview of various technical functions/personnel, this now must be used and administered (certainly understood) by various persons--certainly including front line workers. This is part of the key for making improvements as change, and regardless of who prepares this information, teams and individuals will need these, in accurate and complete forms, in the future. This relates to much about problem solving and improvement, since much standard information is consistent with improvement. Thus, a major part of discipline is related to building and maintaining systems accurately, methodically, and in a timely manner. Gathering and documenting information and data to be used later for analyzing and solving problems is part of our focus.

By contrast, the OPCP is a broad based and foundational document representing total knowledge about a given product or process. Generally driven by customers, the OPCP is designed to demonstrate that we either have a process under control, or that steps are being taken to bring it under control. Composed of detailed information and documentation from production, quality, customer requests, and other sources, the OPCP generally is a document based on other sources of information. For example, various charting, measurement studies, corrective actions, drawings, and others may be part of OPCP's. We will have, or be working on, at least one OPCP for each product or component, or for each major process. Part of this is a strong SOP for each of the major operations. A process is composed of numerous operations, both internal and external, and each represents opportunities for improvement--all documented with SOP's. The basic relationship of SOP to OPCP is that the OPCP requires careful detailed information about all operations which compose process--this being driven by the SOP.

Organizations must have processing information and communications devices and systems. These have various titles, but generally are titled work instructions, information sheets, or
standard operating procedure (SOP), all related to OPCP. Regardless of what these forms are titled, the idea is to provide basic information about how we build product--standard operating procedures. SOP's:

- Document key methods, techniques and other general information used in processing product in the work sequence. This includes process name, tools required, process parameters, product characteristics, and possibly other general process information for the product.
- Show step by step procedure for completion of tasks, all phases of material or component process, from supplier to a next customer.
- Identify key external customer information and expectations in the form of specifications, evaluation method, sample and inspection, analysis and reaction methods, and other.
- Provide additional important technical and quality information about operation, including drawings or sketches of parts, set-up, etc.

Most basic information is the responsibility of first line workers while other information may come from customer and supplier sources or standards in the industry. Particularly important are product characteristics, specifications and evaluation because:

- This relates to data collection and analysis systems by various workers--part of the SOP.
- These are key areas for ongoing improvement, particularly documentation and data related.
- Cost savings can result by re-establishing levels, methods based on documented changes.
- If, due to various factors in processing or systems, we do not improve procedural quality, we can/may be losing dollars.

If we are actually making progress--improvements are being made--the SOP should be changing. The SOP must be regarded as dynamic, not static document. Maintenance to this must respond in a timely manner for enhancements to the system, including all involved, both internal and external. A key reason for the SOP, and all documentation, clearly relating to standards, is the need to evaluate ourselves over time. Whether we evaluate ourselves or not, customers and others will. This is why we must have our own internal review systems, based firmly on standards like SOP's. Similar evaluation occurs with internal and external suppliers, and basis is ongoing development of detailed SOP's in work.

SOP procedural applications: Pivotal kaizen tool for lean. Briefly setting the stage for more to come in later tools, the SOP is important for several procedural reasons. Some of these are:

- **Best practices.** The SOP must represent general information related to the "best" and "correct" way to do our processing for this particular operation and product.
- **Establishes baselines.** How can we improve process if we do not know the procedure? The SOP sets a baseline in the immediate process--baselines that can help us reduce "moving targets"--and help us know we have improved, and why. Given baselines, after improvement, we can identify change in measurable ways.
- **Support documentation.** The SOP should be based on (or related to) other more detailed information and documentation such as engineering drawings, customer feedback, test results, statistical process control information, gage analysis results, among others. This represents much detailed procedural work which can be reduced or redirected over time, as we improve--or increased if needed.
- **Procedural summary.** Depending on maturity of product, amount of resources directed toward a given program, and others, it is assumed the SOP will become a procedural and processing summary supported by various persons, teams, departments, and others internal and external. SOP can be part of our "total documentation" or report about processing and procedural issues for a particular product--our best defense for broad customer negotiations and ongoing relationships--doing business in the future.

But all of the above assumes that we can continue building around the SOP system to document our procedures for improvement. It also assumes strong "team" and "cooperative" attitudes throughout the organization, a willingness to continue teaching and learning from one another, and a willingness to change toward improvement.

Standard operating procedures provide one of the kingpins for continuous improvement. Balancing and leveling in production, leading to synchronous production and lean, is facilitated by the SOP. The basis of being able to plan and conduct production in any rational manner assumes we all perform work similarly. SOP's, with their identification and detailing of standard procedures, or methods, provide much of this need for continuity. Standards we identify, through teams and other leadership methods, are not the end in and of themselves.
Rather, standards must be ever evolving, changing for continuous improvement in our work. SOP's provide the best methods, the correct approaches, and certainly what the customer demands--and documented for all to follow and improve. While they are not fixed or permanent, the SOP must not be changed in a frivolous or light-hearted manner. There should be an SOP in the organization for how we change our SOP's. Control systems must be used for several reasons to:

- Prevent unwarranted changes which have not been made through appropriate team methods.
- Assure methods and procedures to reflect operator view, vital to the success of SOP's.
- Assure individuals and departments, customers and suppliers are involved in change.
- Facilitate upgrades provided through broader improvements to assure that we are using them.

The concept of standard methods has its basis in the need to separate the person's work from the machine. In the earlier form used to determine operation capacity, from a previous tool, this was identified as manual work and processing work. The SOP serves to provide the counter part to the machine's repetitive and consistent motion, providing the maximum capacity available, if used properly. Through the use of the SOP, operators can become standardized sufficiently to provide necessary discipline required to synchronize overall process and production system.

**Capacity determination, SOP's, kaizen.** Once individual capacities are determined, we can better balance our total organizational capacity through improvements at individual operations and ultimately collectively through improved process. Determination of capacity assumes we understand the distinction between operation and process. Process is commonly thought of as being more broadly-based and composed of multiple operations, or that the process subsumes the operations. Process involves activities involved in production sequence, including those which appear necessary but may be wasteful, and thus, should be eliminated through Kaizen. 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. After the capacity determination has been accomplished, we can rely on this to build or improve SOP's.

Part of the distinction between process and operation lies in the question of where value is being added, or if value is being added at all. Kaizen is about waste reduction, and it is assumed that by determining where process and operation are distinguished, we can then zone in on the non-value added areas. 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. Capacity determination, as related to SOP's, assumes we perform various steps to build SOP’s. Building the SOP involves use of capacity determination and process, as follows:

- **Identify coordinator.** The SOP, at the heart of Kaizen, can not be left to chance for completion or improvement. While all on the team and at the operation level must use the SOP, and interact with them, it is vitally important that we know who will actually keep the "ball rolling". The person can be from quality, engineering, operations, or elsewhere, but clearly identified.
- **Process vs. operation.** As was indicated earlier, it is assumed that we can make the distinction between operation and the broader process. It should be stated that the broader process, or any procedural function can be detailed out in SOP form. The more we know about the broader process, in documented SOP form, the better are specific operations level SOP's. Identify and describe the distinction in writing and with flow charts and layout diagrams--show how the process and operation relate--where does the operation fit into the broader scope of things? Much of this should have already been detailed in the OPCP--or it should be if not already done.
- **Operations steps.** Identify the steps in our operations--likely based all or in part on the capacity determination information, or start from scratch. This can be initiated by various persons or teams, to involve operators, quality personnel, engineering, maintenance, etc.
- **Key support documentation.** Provide pertinent support and/or additional documentation as appropriate. This involves capacity planning documentation, layouts, process flows, machine sketches/drawings, at minimum. Whether related directly to the operation under study, or whether only indirectly related, various information should be available and used to help understand and explain the SOP for a given phase of production. At each operation or machine, there should be specific minimum information all are familiar with and which they rely on--stated and used as SOP.
- **Identify detailed operations.** Analyze and detail the specific operation processes and functions in
terms of manual work, processing work, locations, and other time and/or distance related information.

- **Build standard, procedures.** Working with workers or others on the team, and based on observations and the capacity analysis, as well as the SOP functions analysis, fine tune the SOP to provide an actual working procedure, which may be actual working level information, depending on complexities in production, improvements needed, and so on.

- **Continuously upgrade SOP.** Repeat steps above to continually upgrade the SOP, based on people knowledgeable, and including key suppliers and customers, both internal and external. The rework function, over time, is repeated with regularity, perhaps every one or two months, to assure that we have current, up to date SOP's, dynamic rather than static. It is a standard work procedure that must be getting better—not worse.

- **Update/revise SOP.** If the SOP is a simple set of steps at workstation, then the SOP revision and update form may be kept in a different location such as quality or engineering, or perhaps in a resource and learning center, depending on how much documentation is included. The SOP revision and update form will likely be at least in duplicate, and whomever is responsible for the SOP function organization-wide will keep the original. This is true since these will also relate to documentation for ISO, QS or others.

Remember, the operation capacity study is based on the assumption that we can detail our operation processes, to be studied further for improvement later as we build the SOP's and use all in the broader Kaizen process. Capacity determination and SOP building, while quite useful as independent techniques, are necessities for improvement in broader Kaizen and improvement systems.

**SOP basic form.** The most functional or immediately useful assessment approach, particularly to the operator, is likely the basic SOP. This should contain the basic necessary information, in terms written and conceived by operators, for running equipment and interacting with equipment in other ways, to get product out the door. This is the most important standard procedure, since it is the actual point of contact for operators and others, in gemba or the workplace. The basic work area SOP is important since it facilitates:

- Manpower redeployment, occurring since through the SOP we can begin to see a leveling effect in all persons. This leads to idle time by some, and their opportunity for redeployment.
- WIP reduction occurring naturally since procedural leveling standardizes production, and inefficiencies are difficult to hide.
- Quality, since it is more readily built in and identified in the SOP, and since work is done with greater consistency, person to person.
- Maximizing on capacity, since we can more readily predict all aspects of production and leveling for synchronization.
- Layout improvement due to disciplined work method emerging through the SOP. As we conduct standard work over time we are increasingly likely to observe and act on this.
- Visual management techniques more readily facilitated, based on workers’ repetition. This includes work sampling, kanban, or others.

Waste, or muda, in general becomes increasingly apparent as we use SOP's. This occurs since we continually improve methods and procedures, and reflect these in the SOP. As we document, and take ownership, we will naturally analyze and assess for improvement based on enhanced process knowledge.