ISO And QS Introduced

Global issues represent some of the key driving forces world-wide, today and increasingly, in the future. As the future continues to unfold we will hear increasing amounts about this, and in particular, ISO 9000. The ISO standards as they are called, relate to much about how we will do business in the future, world-wide and at home.

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

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

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

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

The Baldrige Award is a broader framework for the total quality system and management of the total process. The Baldrige Award is commonly regarded as good stepping stones toward the broader and perhaps more practical ISO and QS systems. The original Baldrige award logic was that a few organizations would be awarded the prestigious designation based on their efforts. Indeed that was done, but recently the interest has moved on to obtaining ISO and QS designations.
establish an international quality standard that helps manage every aspect of production from design to service conditions. Sometimes referred to as a common sense approach, there are questions about paperwork required and being generated. Clearly, the ISO and QS approach is designed to establish a contractual base for customer-supplier relations.

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

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

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

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

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

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

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

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

1. Describing what we do.

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1 The majority of general information discussed in this section, and the entire tool, is condensed from the AIAG, "Quality System Requirements--QS 9000" manual.
2. Defining responsibilities for those areas and activities within the organization.
3. Describing how those activities are carried out by people in the organization.
4. Describing the records kept in the organization.

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

Costs to become registered will vary based on size of the organization, complexity of the process, level of preparedness going into 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. The 20 elements which will be briefly described and discussed within the next few paragraphs are:

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.
15. Handling, storage, packaging, preservation and delivery.
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, as with most, is the ability to involve suppliers with customers in constructive team arrangements.

Quality system. Element 4.2 in the QS 9000 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 obviously need to be consistent with the management policies and stated philosophy reflected in short and long term plans. This will typically include documentation in broad but specific terms related to:

1. Preparation of control plans or what are termed OPCP's in the toolkit.
2. Implementation of all equipment and processes to assure that the quality system is achieved.
3. Bringing together the design, production functions and all processes involved in quality.
4. Staying current in all aspects of quality, particularly focused on instrumentation for inspection and testing.
5. Identification of all measuring requirements which may have difficult to achieve capabilities, in sufficient time to enable the organization the ability to achieve the required capability level.
6. Identification and development of appropriate quality verification methods in the broader system.
7. Clarification of standards and requirements which spell out acceptability levels for the customer.
8. 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, while, by contrast, the supplier will need to add all information pertaining to total systems wide 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 provided by the customer.

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. Consistent with all other elements, the purchasing relationship system must be recorded and tracked over time.

It is also recognized that supplier or purchasing relationships take time to develop. 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. We are also reminded that 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.**

This element, 4.9, is one of those where 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, in addition to those items identified earlier, the following:

1. General part information.
2. General process information keyed to flow chart and control plan.
3. Inspection and measurement tool and method requirements and instructions.
4. Various general tooling and material identification and disposition information, particularly associated with set-up and tool changeovers.
5. Customer or other relevant standards and/or requirements, particularly as related to special characteristics.
6. Corrective action instructions or 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 improvement in process should be apparent.

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 are provided in the categories of 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. Nature of the broader documentation provided in the supplier relationship will also help determine the nature of 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 which allow for 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 should be 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 have all 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. The 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. Wherever possible, technical data generated by and/or related to the test equipment should be used to verify adequacy in the overall supplier measurement systems, consistent with customer demands.

Control procedures spelled out in the 4.11 element will typically entail several areas for supplier measurement systems. These are generally summarized below:

1. Identification of where and how to do the measuring, including equipment.
2. Identification of areas of vulnerability in equipment and the system, and methods for assuring adequacy and calibration.
3. Define the overall system for calibration of the measurement equipment and system.
4. Identify equipment with substantial calibration history, reducing uncertainty, both of current and past equipment where appropriate.
5. Maintain calibration records.
6. Provide environmental conditions, including handling, storage, and security of equipment, which will produce adequacy in measurement systems.

The total measurement system must be referenced with the overall quality system by way of the control plan. This includes a substantial capacity for analysis.
of data being generated in the documentation system. The foundations for this analysis are similar to the gage R & R tools in the toolkit. Of primary interest is 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 will include steps to take for disposal of non conforming product, as well as other corrective actions.

Other issues relevant to non conforming product control systems are:

1. How to rework non conforming product to bring it into conformance, generally in the form of work instructions.
2. How to gain approval for non conforming product, based on concessions by customers, and associated documentation.
3. What substantiates a re-inspection procedure for verifying use of concessioned product.
4. Documentation of procedures for tracking progress toward reductions in non-conformance must be provided.

Once again, this all must be part of the broader control plan documentation.

**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.

The documentation must reflect discipline and problem solving steps as addressed throughout the toolkit. Procedures in corrective and/or preventive actions should generally reflect the following steps and approaches:

1. Proper handling of customer complaints.
2. Investigation of causes of nonconformity's, and proper documentation of the same.
3. Use of systems to determine appropriate courses of action for resolving complaints.
4. Use of controls in the system to assure that repeats of what led to the need for corrective action does not occur.
5. Use of proper information within the system to resolve the concern.
6. Assurances that steps include reviews by proper levels of management to help make changes which can lead to preventing similar problems in the future.

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. It would seem logical to assume that these type evaluative systems would also form a key part of the broad review and planning system. Appropriate follow up audit activities must also be part of the mechanism, to help assure improvement in all areas identified.

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 of the necessary techniques will be identified during planning stages, and followed through with broad control plan types of 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. 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. These areas of concern also speak directly to the toolkit and specifically the twelve tools identified as synchronous leader tools. The idea is that design, implementation and ongoing maintenance of the broader quality system is a substantial organizational issue, one that requires serious leadership and other resource commitment, as discussed throughout the toolkit.

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, as with all else in the QS 9000 requirement falls on the shoulders of the supplier.

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.
Once again, 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:

1. Facilities, equipment, and process planning and effectiveness.
2. Mistake proofing.
3. Tool design and fabrication.
4. Tooling management.

Again, most of these areas are called out in selected areas of the toolkit. This provides for enhancements in quality and productivity for improved manufacture of product, cost savings and basic quality improvements at every level and function.

**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 certainly 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 approach must also recognize 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 becoming prepared for the global market.

Unquestionably, the major force behind ISO and QS is related to better meeting the customer's needs. But many other less tangible internal reasons may exist for pursuit of ISO and QS:

1. Management and operating systems which become better tied together and linked to the day to day functions of your business.
2. Improved production process and overall efficiency through enhanced understanding.
3. Improved teamwork in virtually all facets of your organization--internal and external.
4. Enhanced flexibility and control, enabling maximum ability to meet customer demands--and response time improvement.
5. Improved ability of people in the organization to make day to day contributions through better understanding and communication.
6. Decreased liability exposure and enhanced reliability in your systems.
7. Increased marketing advantages based on external evidence of your commitment to quality.
8. Better alignment of day to day operating and management systems with strategic directions of the organization.
9. The approach provides a fundamentally healthy way of doing business--ongoing.

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

A final concern which was alluded to earlier may require additional clarification and amplification. This 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. Finally, like anything else, 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. It is probably true that your organization may be further along than it may have been originally assumed to be. No doubt, we are already doing business with numerous organizations who are either registered or becoming registered for one or both. 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:

1. Involve people throughout the organization—this is part of the intent of the process.
2. Focus on the broader purposes you are trying to achieve—improving your organization.
3. Do not do any of this in a vacuum—isolated efforts will only result in confusion and duplication.
4. Begin by focusing on the processes which are in place, to meet the needs of your business—enhanced understanding and knowledge can only help everyone.
5. Based on the enhanced understanding and knowledge, give your people increased freedom—and responsibility—to use what they learn and know. This is the true empowerment that only comes through knowledge—tools.
6. Based on the enhanced understanding and applications, study how your operations meet the intent of ISO standards.
7. If your organization is not doing something addressed by the standards, the obligation is to determine why—and then consider the value of putting it in place.
8. If the decision is made to put new or additional systems in place—based on the new levels of understanding and knowledge acquired in the process—you will be able to do a proper evaluation and possible implementation.

Obviously, part of the key is in having human resources in place to help guide the process—or to help determine other resources which may need to be brought in. It should be noted that these are quite similar to those needed resources for moving the organization forward in all areas:

1. At least one champion—someone to lead and push the process—a catalyst.
2. People who can produce results—not just muddle along—but get the job done and bring closure and produce deliverables in a less than obvious and clear situation.
3. The ability to deal with change, and evaluation of where we are and where we ought to be.
4. Expertise to guide discussions, focus groups in productive ways, and avoid false starts.
5. Expertise in building knowledge and understanding of our processes in our people—to teach and learn together in productive ways.
6. The ability to evaluate and implement standards.
7. The ability to transfer knowledge about our processes and necessary standards to our people within the context of their day to day work, ongoing.

The above is not a simple matter, and it cannot be taken lightly—but in all likelihood it must be moved into. This is simply consistent with our need to become and remain competitive in a global and changing marketplace. This is the essence of total quality and world class function in a dynamic world.

**Launch Systems For Quality**

The purpose of this section is to document and overview the definition, design, and development of typical processes used by organizations to introduce high quality new products. This includes support and information which yield a comparative advantage by creating value for our customers, delivered on time at target costs and volumes, while increasing our capability to reduce time to market.

Consistent with the entire toolkit, the "total system" is defined as the products, support and information that we, in conjunction with various delivery partners, offer to the end user customer. It includes, for example, durable and reliable products, convenient, low cost and dependable service, after
market support tools, electronic features and controls, all types of training and support systems.

This procedure and system sets forth the scope, work flow and deliverables for new products, support and information from program definition to product introduction. The launch system procedure applies across new product programs of all sizes and types in manufacturing and non-manufacturing industries as well. The types of new products to which these launch system procedures apply include several classes as outlined here. These are classes I, II and III, further defined below as new platforms, derivatives and tailoring.

**Class I, new platform.** New platforms may include entirely new products unrelated to our existing product line. But new platforms may also frequently refer to innovation spin off's from the existing product line, typically called major derivatives. New platforms are the most substantial in terms of financial commitment and change throughout the organization, and are generally referred to as class I type programs.

**Class II, derivatives.** Derivatives obviously relate to existing products and technologies which are common to the core business. Existing knowledge in process and product terms would be fully utilized with common derivatives. Derivatives are also frequently referred to as major tailoring type applications or programs since while substantial change must occur, it will not likely be as significant as new platforms. Thus derivatives are generally labeled as class II.

**Class III, tailoring.** Tailoring type programs provide changes to existing products but are designed to upgrade and enhance performance based on customer demands. This is also referred to as current product support programs, and will provide additional resources and organizational commitments to existing products. Labeled as class III, tailoring will typically provide the least amount of change and disruption to the organization.

While the launch system procedure applies to all new products, it is implemented differently for class I, II and III programs. These procedures incorporate the following six principles:

1. **Cross-functional team focus on total system customer needs.** Assimilate market research, customer demands and data in the forms of various documentation. Integrate customer contact and interaction throughout all dimensions of the program. Ensure the best fit of the products, support and information with the end-user customers' total business needs.
2. **Prevention versus failure driven.** Emphasize quality of total quality system design in all phases and functions. This includes a primary utilization of all toolkit preventative systems and tools such as FMEA, QFD, OPCP, and others as fundamental building blocks and approaches in all of the launch systems.
3. **PDSA cycle.** Plan is focused primarily on a cross-functional program plan, frequently identified as a contract. Do would become functional and cross-functional work activities. See provides the common measures, audits and prototyping functions. Act would result in data based corrective actions and issue resolutions such as FMEA.
4. **Self-managed discipline.** Cross-functional team focus on creating a product plans evidenced in a contract. Self directed team responsibility lies in managing and measuring its progress versus the plan as stated in the contract.
5. **Flexibility for program needs.** Cross-functional team tailors application of the program to meet the customer needs. Different cross-functional team approaches will be based on class I, II or III program types as specified by actual customer needs and demands.
6. **Continuous improvement.** Measures and audits provide data based improvement within and across programs, and document the same. Corrective actions taken based on available data result in improvements which can be used elsewhere over time in the synchronous environment.

### Fundamental Launch Definitions, Classifications And Phases

Several definitions are important to understanding launch systems. These also relate to several classifications and phases in launch, to be explained later in this section.

**Charter or vision.** The charter or vision is an output of the customer led planning process and could likely be solidly based on quality function deployment or other exercises. It is a concise document written by a cross-functional management team that specifies the business goals, objectives, constraints and leadership (program sponsor, manager or leader, as appropriate) for a specific program. Supported by market and or customer research, the intent of the charter or vision document is to set clear, high-level targets for the program and create a vision of what we are striving to achieve.

**Comparative advantage.** Products, support and information advantage as judged in the marketplace by the end-user customer. Total system product quality, technology leadership (real and perceived), and timely market introduction are all key
factors in establishing and maintaining a comparative advantage. By focusing on customer business needs our total system product will become consistently better than competition.

**Contract.** The contract, prepared by the program team, is a program plan to meet the business objectives of the charter. It includes "what" the team will deliver and "how" the work will get done. The contract defines the program scope, system profile, quality plan, schedule of work resource plan, measures plan, financial plan, and risk assessment. The contract is the mechanism for gaining agreement between all program stakeholders. Once approved, the contract becomes a two way agreement between management and the program team.

**Customer led planning process (CLPP).** A cross-functional process to identify and evaluate world-wide business and market opportunities and to formulate a plan which defines and integrates our technical plan, product plan, operating plan and capability improvement plan in order to provide the greatest value to our customers. This process determines the business goals and objectives for each market and creates a coordinated business plan for the company based on assessments of customers/markets, competitors, the regulatory environment, technology trends and capabilities. The CLPP is administered by planning on behalf of senior management. Participants include management from all functions.

**Management reviews.** A concise, cross-functional management meeting which charters a program, approves the contract and regularly reviews program progress versus contract and corrective action plans.

**Managed introduction.** The period of time in a program beginning with ship #1. During managed introduction, volumes are ramped up to full production levels. The program team is responsible for establishing the criteria against which the introduction is managed.

**New product planning (NPP).** The NPP process encompasses all sections of quality systems planning procedure. The procedure documents the definition, design, and development process to introduce high quality new products, support and information which yield a comparative advantage, by creating value for our customers, by delivering on time at target costs and volumes, while increasing our capability to reduce time to market.

**Class I programs: New programs.** Programs categorized as "clean sheet of paper" products and managed via a specific program team structure called a system team.

**Class I programs: Major Derivative.** Only those derivative programs designated as class I by senior management. The charter will reflect the critical market/business/product characteristics that drove this classification. Major derivative programs are managed by a system team instead of a new product introduction team (NPIT).

**Class II programs: Derivative.** This involves redesign or modification of existing products, processes or support tools or services. Derivatives are commonly managed via a specific program NPIT team structure.

**Class II programs: Major tailoring.** This category will typically cover those tailoring programs designated as class II by management via the customer led planning process. Major tailoring programs are managed by a NPIT instead of product change management (PCM) processes.

**Class III programs: Tailoring.** Programs or projects involving product, support or information customization for specific customer applications (e.g. changing installation related subsystems and/or parts, special performance calibrations.) Tailoring programs/projects are chartered, approved and managed via the product change management (PCM) process.

**Class III programs: Current product support.** Programs or projects such as cost reductions, quality related improvements, source approvals and parts substitutions which are designated as class III and chartered, approved and managed via the product change management (PCM) process.

**Program definition phase.** The phase which begins with the charter and ends with contract approval by the appropriate level of cross-functional management at early management review. During this phase, the program team focuses on getting to know the customer and the customers' business needs through a variety of techniques including direct customer interaction. The goal in this phase is to select one system level design concept and multiple subsystem level design concepts, as appropriate, and develop a work plan through management review.

**Design phase.** The phase which focuses on designing and beginning to develop products, support and information that meet or exceed all customer needs and technical requirements. The output of the management review or completion of the design phase, is a high quality, single design concept (stable design) for all aspects of the total system. A total system prototype has been completed and major changes are no longer planned.

**Development phase.** This phase focuses on refining the total system stable design, coming from the design phase, through continued analysis and test and releasing the product for implementation into production. All business, performance, reliability, durability and production readiness issues of the total system stable design are addressed prior to the managed introduction decision. Specifics of a plan to
transition responsibility from the program team to the "normal" production system needs to be identified prior to the management review so this transition can begin in a timely manner.

**Program managed introduction.** The managed introduction phase which is focused on final transition of responsibility from the program team to the functional group and ends in full production of the total system at the final review.

**Program leader.** The program leader is the customer "champion" for the total system who oversees the entire program through all management reviews. As leader of the program team, he/she is responsible for the program budget, selection of core program team members with functional management, preparation of the contract, communication with senior management, development and implementation of reviews, elimination of barriers, program results and management processes to get there.

The program leader must be skilled at driving consensus decisions while encouraging and listening to individual concerns. The leader must make timely decisions in instances when consensus can not be reached.

**Program manager.** As an assistant to the program leader, the program manager helps the program leader with his/her responsibilities listed above. Each program leader and program manager discuss and document the specific split of responsibilities appropriate for their situation. In some cases the program leader assumes all responsibilities of a program manager or vice versa.

In addition, the specific functional role of the program manager is to be the team's "process architect." The program manager is a core member of the program team responsible for leading team focus on work process planning, implementation, measurement and improvement. The program manager must be skilled at application of NPP and other procedures, quality tools and process improvement methods. The program manager is responsible for evaluating the capability/skills of program team and work team members and identifying training requirements.

**Program sponsor.** As a coach, mentor and advisor to the program leader, The program sponsor provides timely resolution to barriers that the program team encounters and maintains ongoing communication between cross-functional senior management and the program team. The program sponsor stays connected to the program team by reviewing progress at each major program milestone or every three months, whichever occurs sooner. The program sponsor role applies to class I programs, is optional for class II programs and is not applicable for class III programs.

**Program team and core membership.** The cross-functional team acting as the "operating committee" for the program, responsible for successful delivery of all contract elements. Core membership is consistent with all of the synchronous functions encompassing the following roles as appropriate, given the scope and areas of change in each program:

- **Program leader**
- **Program manager**

These leaders and managers are responsible for integration of all technical elements of the total system. This will generally include installation, engineering, manufacturing processes, serviceability, electronic controls and reliability in product and process during all aspects of production.

Program teams and cross functions will likely encompass other broad service entities as appropriate over the life of the program. These may be after market including service parts, service tools, parts and service training, parts and service information, warranty, service development and technical service engineering. Obviously, various documentation systems which will broadly impact on all other functions will be various management information systems and finance.

All program team members are responsible for team results while also representing their functional perspectives on the program. This will typically include various important milestones during the program. Some of these may include the following:

**Preliminary design phases.** Based on various levels and types of customer demands, preliminary designs will be in place at some point as agreed to in the contract. This key deliverable must typically include an articulated effort between and among all technical entities associated with product and process upstream and downstream.

**Prototype.** This focuses on test and evaluation of the readiness of a product, support or information related component, subsystem, or support system. This will traditionally include physical prototypes but may also be computer modeling such as finite element systems and others. Documentation and data collection systems will generally be developed to a usable state of maturity when prototyping occurs. This will also likely include various pre-production and short run documentation for integrity of ability to actually perform as contracted.

**Ship #1.** The first commercial shipment of managed introduction is obviously an important milestone in the overall product launch program. This represents the date by which all production
processes should be in place, and tested via earlier prototyping cycles, pre-production tests and short runs. Ship # 1 is also that actual point in the program where all systems are fully capable and ready to meet actual customer demands over the long haul.

**Stable design.** Stable design is the total system design for products, support and information that has matured to the point that the critical systems program deliverables have been demonstrated. At this point one complete program system prototype has been completed, some level of short run has been accomplished, and all parts and structure are released and accepted, and major changes are no longer planned. Major durability work begins and final machine tool/supplier commitments are made. This marks the end of the design phase.

**Ongoing production.** At some point in the contract it will become obvious that we are in the ongoing production phase. Part of what is also obvious is that the capability of this phase is directly linked to the earlier planning phases and functions. Elements of the earlier team will need to remain in place over the longer term.

This procedure is meant as a guideline for the program team to use throughout the definition, design, development and introduction process. The checklists provided throughout this series of documents should not be substitutes for creativity. Each program team is challenged to find ways to improve on the NPD process, spelling out departures from the procedure in the specific contract under consideration.

Risk assessments for deviations must be noted in the contract. Enabled by management's mutual commitment, the program team has full discretion over the program and its execution. Management reviews provide key check points for the program team managing/measuring progress versus the contract and communicate the progress to management over the course of the program.

Statements of work specifying the elements of the new product planning, development and introduction procedure must be documented in several supplemental procedures. These procedures must document the charter and contract development process, cross functional team process, and product change management processes, among others.

**Special circumstances.** Special circumstances specific to each program, including deviations and/or improvements upon procedures, are highlighted in the contract by the program team. Each entity/plant function is expected to supplement documentation with local procedures as required.

**Measures of performance.** The program team is responsible for measuring and managing its performance relative to customer satisfaction, business results and process effectiveness. Performance indicators include standard measures used across all programs supplemented by specific measures the program team deems appropriate for their program. In the contract, the program team establishes management reviews and interim target values for some of the measures. Actual versus target results are visited at each management review.

### The Service Function

If an organization, or parts of an organization, do not directly make changes in physical raw materials, then that organization probably qualifies as a service organization. This is important for several reasons. First, this is a growing sector in our economy--many new jobs being created fall into the service realm. Second, many positions in technological organizations, which industrial technologists may be employed in, are of a service orientation. Third, and perhaps most important, service functions and their management provide several insights which should prove useful to improving virtually any organization and/or function.

It appears important to distinguish between service internal and external to the organization. This provides a major thrust of the current section. A second major emphasis is the overall role which service plays in technological organizations. Third, and already apparent throughout the tool, is the unique relationship enjoyed between service, maintenance, safety and other functions.

Because of the nature of technological organizations, and their particular functions, as spelled out earlier, service within the organization is presented ahead of service external to the organization. But, as will be shown throughout the section and tool, a strong relationship must exist between internal and external constituencies. That is, for most organizations to remain competitive, it is vital that service external to their customer be of paramount importance. But, this tool is also heavily focused toward making organizations, particularly technological organizations, work better internally to be more competitive.

For example, if engineering does not complete the specifications for a given component or part on schedule to coincide with production, then production may fall behind, or be forced to cut corners to meet marketing and sales commitments. Or if maintenance says they will install a new machine on a given production line, but someone in store services slipped up and forgot to process the
order for the new equipment, then how can the new equipment be installed, again to meet production commitments. The list of examples could go on and on, because in reality, virtually every component within the organization services one or more others. All are contingent to one extent or another, and all rely on one another for various services.

Similarly suppliers and customers are related to the organization in service functions, requiring a clear understanding. The relationship is illustrated nearby. The key point here is that an organization needs to pay attention to how it arranges itself, acknowledging that it is very important to realize that the service function, both internal and external, is vital to survival. Throughout the toolkit, the point has been made that perhaps traditional organizational approaches can be improved upon. The total quality and world class approach that has been presented will not necessarily prove to fit all needs, as is true of any other approach. But many of the ideas may be worth trying to integrate into other approaches.

It is also true that an organization that wants to succeed in the service arena must be structured to encourage and facilitate innovative thinking. Service relies, to a great extent, on the ability of an organization to recognize problems with the current way of dealing with internal and external customers, and use this as an opportunity to create a positive change. This requires innovative organizational structure and persons empowered to bring novel ideas forward, and see them through to implementation.

It is believed that the technological functions organizational structure provided here in the form of the technological change model, can assist in facilitating the necessary environment for innovation. This could be particularly true when combined with team empowerment for participatory management and decision making. This is sometimes referred to as the inverted pyramid structure, placing front line employees in the key decision making roles, and in terms of quality circles for problem identification and solving. This would contrast to the traditional top down management style of upper management "calling all the shots". Regardless of what it is called, it is pivotal that people have reasonable autonomy to do their work, and be able to function with sufficient authority to make and act on decisions. This forms part of the basis for teams, empowerment, and organizations of the future.

The total quality world class technological change model is presented again here because it is important to realize that it is designed to facilitate the service functions for enhanced quality and productivity.

**Service As An Upstream Management Function--Value Added**

Part of the key to competitiveness, built around the information previously presented, and addressed from the vantage point of documentation and Kaizen, is service within an upstream management function. Fundamentally, if we build the product properly at each operation, process or function, we will pass along a value-added product. Kaizen is about eliminating muda or waste, in gemba or the workplace. Waste is defined as the non-value added functions or activities which were identified in previous tools. The key distinction is value added as differentiated from non-value added. These are now listed again for making connections to serving customers and suppliers.

Waste can take on any shape but typically it can be classified into one of the following groups: overproduction, delay, transport, processing, inventory, wasted motions, and defective products. Identification then becomes the primary step in elimination of waste. If we don’t see something as a waste, how can we eliminate it? As production persons we must stop using the excuse that certain waste cannot be helped. It is called a positive attitude. When we see a part of the operation which does not add value we must take the attitude that it can and must be eliminated. Until we take this attitude we will miss opportunities to eliminate waste, or to improve--in this case as a service function.

One of the keys to identifying and reducing waste for service functions is what we term
upstream management. Based on the assumption that an upstream function must, by definition, service the next operation or process, downstream, we begin to recognize the importance of the upstream concept. Clearly, if each operation reduces value rather than adding value, we can create a larger problem with each added operation. Assuming each operation is functioning properly, and understands clearly its role in the total sequence, we can likely anticipate properly added value from supplier to customer. However, as may often be the case, we may have misunderstandings or lack of clarity in function between supplier and customer, or in various operations from start to finish. And we would be well advised to remember that in some cases this may be totally internal, totally external, or as is often the case, a combination of all of these, in the complex organization which most of us will be involved within the future.

The sequence of production, even when properly designed and put together, does not always function properly. As we move forward with our illustration of management upstream, we must recognize that although correction is in fact waste, it may be less wasteful relative to creating scrap. Worse yet, if we do not discover the defect or defective, we may pass it along to the next operation in a condition which is not only undesirable, but is downright unacceptable. Assuming the part is detected and corrected, it can then be passed on to operation 3, and ultimately to the downstream customer. The key concepts underlying the principles are the elimination of the wastes, or imperfections, which are currently present in delays, or non-value adding operations. This will rely on Kaizen inspection techniques, poke yoka methods, and other synchronous methods described in earlier tools, all designed to facilitate JIT in the service environment.

JIT is a process which must be supplied with the required items in the required quantity at the required time. This can result in stockless production systems, with no inventory, anywhere, period. This is one of the keys to synchronous techniques, and to becoming world class. If the JIT system is to work, everyone in the equation must be part and parcel of the system. Suppliers must deliver and customers must expect delivery in JIT fashion. If not, then the system is incomplete. This refers to internal and external suppliers and customers, up and downstream throughout the organization or process.

Kaizen is about waste reduction. If we wish to reduce or eliminate waste, as we must do if we wish to be successful in Kaizen, we must identify the capacity of the operation for adding value, and use the operation to its optimum performance capacity. A work sheet is provided nearby in the current tool to assist in this determination for purposes of relationships and applications for service functions and waste elimination for improvement. This form was targeted to analyze the specific operation as part of the previously determined and analyzed process. Again, there will be delays, transports, and other wastes in the operation, needing to be identified and improved upon as waste. But what is being pursued here is the need to identify and provide an optimum operating time for production within the broader process—all aimed at helping us service our customers in optimal manners.

Use of the form assumes that an individual or preferably team will do the following to determine capacity:

1. Make the distinction between operation and the broader process.
2. Identify and describe the distinction in writing and with flow charts and layout diagrams.
3. Detail the steps in our operations—likely based all or in part on standard operating procedures which we have in some phase of evolution.
4. Provide pertinent support/additional documentation as appropriate.
5. Analyze and detail the specific operation processes and functions in terms of manual work, processing work, and other time and/or distance related information.
6. Calculate sub totals and a total time from step three-five above, this being current capacity.
7. Based on observations and the capacity analysis activity, provide potential waste reduction possibilities to be pursued.
8. Repeat the capacity study process over time for improvements ongoing.

It should be obvious from the above that this process analysis technique, while still macro, is beginning to be extremely close to being a micro technique. The specific application as a micro analysis technique for Kaizen and documentation purposes, also provided in an earlier tool related to standard operating procedures (SOP), is also pursued later as performance standards.

Capacity, SOP And Other Synchronous Relationships To Kaizen In Service
When physical changes are made in value added technological functions, rather discreet and identifiable specifications can be defined as the target for performance, and the standard to be gaged against. But in service related functions it is much more ambiguous, and perhaps more difficult to determine the mark, let alone if we are hitting the mark. Yet, never before has the need been greater to set workable and useful standards for human achievement in service functions.

The basic problem in setting and measuring service standards is twofold. First, and perhaps most important, service activities are often not physical, or at least not readily measurable in the sense of a manufactured component. Second, service is fundamentally a people function, and thus the standards and gaging systems are fundamentally people evaluations. The issue of service activities not being readily measurable will be addressed as a relative type condition. That is, even in the most discreet manufacturing situation with carefully and clearly detailed specifications, and with the most advanced gaging devices, the end result will still be only as good as the person using the gages and doing the actual manufacturing work. This is relative since in service work, it is simply a matter of figuring out what, and how to, measure for quality determination.

Generally speaking, in service functions a relative degree of finiteness can be achieved. For example if the task is servicing machines we can determine that all surfaces are to be wiped and coated, all oil reservoirs topped up, belts checked for tension, floors swept in the general area, and other general observations and tasks performed. Based on past experience, time studies, and other inputs, we could determine some reasonable standard of time to be consumed to conduct the work. Follow-through to determine how well everything had been accomplished could occur via supervisors or workers on the floor, or both. And of course, most of these "judgment call" type issues or elements can be placed on check sheets or attribute tracking forms for quality purposes, or simply to track for improvement. At a more robust level, we can calculate control limits based on p charting statistical techniques, for further analysis and follow through.

As with other service functions, performance standards must be based on what is expected by the customer. This must go well beyond simply comparing our performance with similar organizations, although this is part of the way we all set standards. Equally as important, we must not let the standard become the minimum performance. Rather, we must strive to use standards as targets which are set to enhance performance and which help people strive for excellence. Thus, we are determining standards for performance, to one extent or another, based on customer input.

Common sense suggests whatever performance standards are set, that these standards should be consistent with broader objectives of the organization. It is also important that performance standards be communicated widely throughout the organization to enable all persons to understand and use the same set of criteria for performance. It would also seem reasonable to expect that standards be a part of job descriptions, and that the standards be used in a proactive manner for overall job performance evaluation, commonly called work evaluation (annual, semi-annual, and so on).

Understanding Customers And Suppliers--Kaizen Process In Action

Part of the success in servicing our customer and supplier relationships has to do with understanding their needs. This is key to the Kaizen process--understanding what is expected of us, better enabling us to know how to accomplish what is expected of us. One of the key methods for helping us understand customers and suppliers is through survey interview techniques. The purpose of the interview is to collect information about:

1. How well the current product or service being supplied meets the needs of the customer, and to learn more about what they deem to be important--and needing to be focused on. Obviously for suppliers it is necessary to determine how their process impacts on customer operations.

2. The customer or supplier measures, teaches about, and uses the product or service--this is what will give added input and enable improvements for the future.

3. How well the product/service supplied or consumed is defined and understood.

These types of surveys are generally used when it is important to determine reasons and motivation for
dissatisfaction which has resulted somewhere in the relationship. We may also wish to use interviews to determine where improvement opportunities may exist, even in the absence of complaints or problems. It should also be apparent that if we wish to acquire additional business with current customers or suppliers, we should "stay in touch" through these types of interviews and surveys. Finally, determining the best supplier will also increasingly be a function of the survey process described below.

The basic process would generally be documented in a survey type format, frequently completed by an interviewer, based on questions related to the following:

1. **Define product or service.** It is of prime importance to define the product or service. Similar to understanding our process, it is pivotal to understanding clearly what our purpose as a product or service is supposed to be, prior to trying to deliver.
2. **Form, reform team.** Based on understanding our function, form an interview/survey team, and help prepare them regarding why information is needed. What have the key problems or issues become, or what are the important issues for suppliers? Assuming this is a reasonably mature process, the team may be a standing group which is brought back together from previous iterations. Obviously, all usual rules and guidelines for forming teams are applicable.
3. **Brief/update interviewee.** Prior to the interview the interviewee should be brief regarding the purpose of the interview. This would include determining who will be interviewed at the site, particular areas of concern, and information required or helpful and requested, and so on. The survey forms shown nearby may be used as part of the preparation.
4. **Focus on key problems, opportunities.** During the interview it would be of prime importance that we focus the session on key deliverables or features which may be problematic. The opportunities for improvement are buried in the problems which have emerged between the existing or potential customer/supplier mix.
5. **Use open-ended questions.** We will generally wish to use open-ended questions which will enable the person or people to supply a broad range of information. This should likely emerge as a "survey" or "audit" type document which is pivotal in the process being described here, and which is unique to the product and organizations involved. The forms shown nearby are the start of these open ended type questions. More specificity must typically be built in based on issues and circumstances in the situation.
6. **Review, clarify.** Always reflect back on what was said, or the way responses were supplied in writing, to ensure clarity.
7. **Provide written report.** Based on the overall process, culminating around the sample survey forms, summarize in report form. This provides the usual and necessary "paper trail" which helps everyone have "better memory".
8. **Track performance trends.** As the process emerges over time, and becomes a regular iterative function toward building better customer and supplier relationships, we must observe the performance, tracking for data-based measures which will help in further future improvement efforts.
9. **Provide and implement improvements.** The data-based tracking system, and the broader inputs which the process "flushes out" must be ultimately brought forward as improvements. As we conduct the improvement process over time in the supplier/customer relationship, growing and learning together, the improvements should assist us all in becoming and remaining increasingly competitive.

Assuming this process is completed on a regular and systematic basis, it is likely that we will improve our relationship with customers and suppliers. In addition to the above, it will be important to track trends in the customer and supplier perception of how well the product or service is meeting the perceived needs. As this is being tracked, it will be important to establish the perception of customers and suppliers and use this to help build our relationship. This can be done each time product exchanges hands, or it can be done through periodic visits to the customer or supplier site. It should also be recognized, we should be providing and implementing improvements, ongoing, based on the customer/supplier improvement process. As we conduct the process with customers and/or suppliers, we should be gaining input which can be turned into product improvements.
Part of the way we may wish to evaluate the customer/supplier perception, or the overall level of satisfaction, is based on several evaluative approaches alluded to earlier. These are provided in draft survey forms nearby, in three categories:

1. Potential supplier survey desirable attributes.
2. Supplier capability to potential customer.
3. Existing supplier response to enhance potentials.

While each is only the start of a system for improving relationships, they do have the basis for helping accomplish much of what is being talked about throughout the current tool. And in all cases, the documentation provided can help provide the basis for improved decisions. Each of these are designed to be used within the system being described broadly here, on a long term, ongoing basis, to assist in various types of improvement. The system should be applicable to internal and external suppliers and customers, to be modified to suit specific circumstances.

The general areas of questioning in the surveys provided are an attempt to nail down what we intend to build or deliver, how we will do it, the culture within which it will occur, and other broad areas of concern. Other areas which may be pursued in these types of survey systems would include:

1. Per cent of delivery on time.
2. Percent of rejected product.
3. Lead time requirements.
4. Order response time.
5. Specific data driven measures of capability (gage R & R, X-bar and R charts, Cpk).
6. Frequency and recency of visits required.
7. Joint work attitude and response.
8. Ability and willingness to share data and information.
9. Standard procedures for all relevant and/or related functions required.

Customer satisfaction is approached in the following steps or procedures. First the customer will need to identify their valued characteristics and features--in data driven ways. Based on the important features, we will need to work toward identifying the range of acceptability in product or service. We will also need to work with them to try to understand where and how in their process they measure to conform to their customer/supplier needs. The customer satisfaction approach under discussion can also be enhanced by asking and establishing several key questions relating to:

1. Frequency of visits desired on site--and for what purpose?
2. Nature and amount of information they will require?
3. Who should be contacted when there are problems or concerns which may arise?
4. How frequently this type of information and procedure is revisited to attempt to stay "on the same sheet of music".

Once again, this is only a start, and should not be regarded as an end-all approach. But with continued development and use, we will likely continue to improve our relationships, and move our competitive functions forward.

**Serving External Customers**

Most of the above information was generally applicable to all service circumstances, both internal and external. But several considerations related to external customers warrant further discussion. This relates to image and impression, both real and perceived, which is created and marketed for the organization. This also relates to constantly paying attention to the actual service delivery system in the organization, since no matter how well we are marketed if we do not deliver, marketing will only blow in the breeze.

Particularly in technological organizations where value is physically added to raw materials, although applicable elsewhere, if the product fails to perform as it was advertised or specified, it will tend to be problematic. This also often provides an entree for service functions. For example, if only a few short months after purchasing a new vehicle, serious mechanical problems surface, several service functions will likely be called upon to help straighten out the problems. In this case, how do we handle the customer "after the sale"? Are they rebuffed on the phone? Do they get the run-around? How are they billed, or are they billed at all? Are we defensive about our product?

Once again, the basic question becomes, how do we satisfy the customer? But perhaps equally as important, do we wish to have a customer's repeat business? Also however, we must not forget that a satisfied customer will likely only tell one, or at best, two other people. But a dissatisfied customer may easily tell eight
or ten others, further enhancing the need for our organization to consistently follow-through on service delivery systems.

Still related to the product and service, when defects or malfunctions are discovered, are they merely corrected? Or do we have established systems to effectively communicate between service functions and engineering, quality and others to affect enhanced competitiveness in the future? This may also include communicating better to marketing about the performance claims they are making in sales to customers or improving information made available to training personnel to help prepare persons internally better. If product failure information is only serviced and not used as opportunities for improvement, clearly we will miss possible situations to use to become more competitive.