

# Lean, Six Sigma, Quality Transformation Toolkit (LSSQTT)\*

## LSSQTT Tool #19 Courseware Content

### “Quality Management Systems For Continuous Improvement”

1. LSSQTT principles underscored again
2. ISO, QS umbrella, infrastructure for the future, lean six sigma
3. Quality management system integration

\*Updated summer, 2006 by John W. Sinn.

#### LSSQTT Principles Underscored Again

As has been reinforced elsewhere, quality systems can not be thought of as an “add on”, another element of what we must attend to because someone says do it. Quality must be a way of life in all that we do, integrated from top to bottom as the overall management system. Management cannot be thought of as a separation from actual value adding elements in production. All must be viewed as value adding systems, collectively identified as the quality management system (QMS).

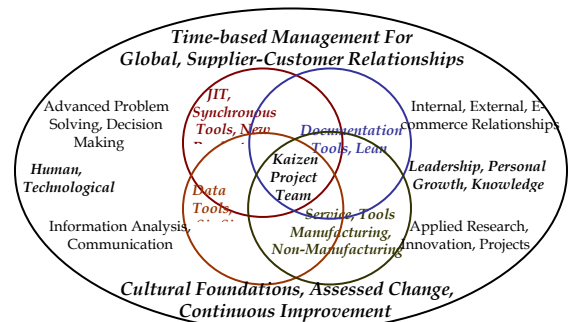
Part of the key to this rather substantial paradigm shift is to truly empower workers. Particularly at the workplace level, where product is actually having value added, directly, the workers must now increasingly be managers. Changes throughout the organization must be attended to and bring about a cultural paradigm shift necessary to actually shift control and decision-making, in doable and respectful ways, into the workplace. While some of this is at the supervisory level, much will be as teams and workers in what used to be called the shop floor, or if not in manufacturing, on the “firing line”.

The QMS focuses on production, rather than manufacturing solely, since much of what the world demands today is produced but not necessarily manufactured in the traditional sense. Production takes into account virtually any act which attempts to add value, and is not limited to only traditional manufacturing value added functions based on changes in materials. The nature of value adding has shifted to include changes in information as value added, systems for moving information, and assuring effective communications in all that we do as value added services. This is also true since any service industry function can be production, including construction, health care, transportation, recreation, academia, government entities, and so on.

QMS's are applicable to all functions and whether a traditional material based product is manufactured or produced is perhaps irrelevant. What is important is that we are adding economic value to the base of productive activity. While the main

interest is on the QMS, obviously other elements and sub-systems are relevant and important as productive outputs. Production synthesizes infrastructural and organizational methods used to produce products—relationally interconnecting the QMS.

A model to help facilitate what is being discussed is shown nearby, identified as the Lean, Six Sigma, Quality Transformation Toolkit (LSSQTT). While not a pure model for production, the LSSQTT is a blend of QMS and production elements. Based heavily around the QMS, the LSSQTT is an integrated process and system design, implementation and sustainability model.



*Lean, Six Sigma, Quality Transformation Toolkit*

The LSSQTT model describes how to add value in the process of producing products. The description as a model is deliberate to help illustrate integration of individual principles within a holistic system. Each part is not fully functional as an individual entity, and the resulting integrated model is one that is greater than the sum of it's individual elements. The LSSQTT is also a functional courseware designed to help define and do continuous improvement and change organizationally, within a context of the QMS. The LSSQTT courseware provides a template for organizations wishing to transform and change the collective culture they operate in. The seven part toolkit series was developed through work with 100's of industries since the 1980's in various environments. LSSQTT courseware, as a template in

model form, is the basis for structured discipline, explained graphically on the previous page.

The QMS has been initiated under ISO 9000 rubrics, and in many cases now serves as a “umbrella” for the broader quality system. As ISO 9000 certification and registration systems were introduced and implemented in the 1980’s and 90’s, and beyond, around the US and world, this has driven the cause of quality to new heights organizationally and functionally. What was intended to serve as a vehicle for growth and change in the global marketplace was also a catalyst for change toward a quality focus for all of us in much that we do. This includes our community-based institutions which we are part of in our local communities.

Various quality initiatives have come, and some have gone. But most have stayed in one form or another, and their impact continues to be felt as part of the broader quality movement and QMS. The quality tools which have risen to the forefront today, now a part of the broader QMS, include statistical process control tools such as variable and attribute charting, capability and gage R & R indices, generally identified as six sigma or data-based systems; industrial engineering tools such as standardized work analysis, capacity analysis, corrective action, 5’S’s, and others commonly now called lean systems; and, quality planning tools for new product development such as process control planning, quality function deployment, part qualification and others identified as synchronous.

Today’s environment of change is a strong and substantive global emphasis, with overtones that cannot and ought not be ignored. The QMS model, defined as LSSQTT, enables and helps us prepare for this global reality. Part of what we must do is use the tools we have evolved in the quality profession in novel and innovative ways to help improve well beyond our workplace only. We must be continuously changing for the good, and developing a culture of learning and transfer of knowledge, grown based on problems solved day-to-day, turned into improvements. When we solve a problem today it should be documented in ways which can be shared electronically with others to help them avoid the same pitfalls, and to therefore enable all to move forward collectively in a partnership for competitive growth. This is certainly also true at the community level. We will see an upsurge in changes at the infrastructural level in the future—changes which will need quality systems and certainly reflective of the QMS type rubrics being discussed here.

The LSSQTT uses data and documentation as the main communication vehicles, collected and housed electronically wherever possible. Data and documentation, are at the heart of the system, used to

solve problems and add value in ways which disciplined and knowledgeable workers can do. The best emphasis in the LSSQTT is at the worker and workplace level, recognizing these people are the one’s needed to be empowered and grown for future activities and leadership functions. It is suggested in the system that leaders at all levels will have been groomed out of and based on workplace functions, “where the action is”.

Everything in the LSSQTT is about teams. Since we understand that teams composed of diverse and varied talents, many whom will look and speak different from ourselves in the future, will increasingly be our strength organizationally. Teams will be electronic increasingly in the future, and while production will be fixed place, we must understand that learning and growth for individuals first, and then teams, will come increasingly not from the person next to you only in the workplace. Increasingly, we will learn from persons who we are connected to based on systemic workplace change—but done electronically—and from around the world.

Teams will focus not only on getting product out the door in the future, required to pay bills day-to-day. But we will also work synchronously with data and documentation collected and built around day-to-day production in fairly mundane, yet sophisticated and disciplined ways. Information collected must be used for longer term planning and decision-making issues related to new products, innovations, and how to do broad-based organization change as improvement. Teams must focusing increasingly on use of what is learned day-to-day in basic production, and documented in data-driven ways, but we must also be applying what we learn and know in production, as value adding potentials to advance the organization in the future.

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

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

While ISO was designed to be an international or global entity, much of the same logic applies to QS standards. QS was designed as a primarily domestic

functional system, but relates rather directly to the ISO logic and principle, as well as functionally. Part of the intent is that duplication and waste among and between systems can, and should, be eliminated. Most important, it is essential that the actual purpose of the systems be seen clearly as improvements in quality management systems rather than simply achievement of another registration or certification plaque on the wall.

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

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

Started in the European Union in the last century, the ISO/QS movement began to pick up steam in America during the late 1980's and early 1990's. The US increasingly needed a platform for planning and conduct of increasingly complex products, and the ISO standard, in the form of QS as

related to automotive became that platform. Several changes have occurred in the basic fabric of the standard, leading to various updates, depending on specific standards and versions, including a 14000 version for environmental. The focus of the ISO movement is development of standards consistent around the world so that all parties/cultures who wish to do business can participate as full partners. This is true of the QS system, but at a domestic or local level, the ISO and QS movements define methods to use in documentation, specifications and in other basic but critical communications systems. This also relates to reduction in variation and good resource management in all that we do—strong basis for connecting and relating lean and six sigma improvement systems.

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

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

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

Both internal and external certification is used in the registration process. Internal consists of someone designated organizationally to lead the process. External certification is the typical end process desired by most organizations, requiring a third party approach. It is also desired in some situations, to merely be in compliance with the ISO standards, but not actually registered.<sup>1</sup>

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

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

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

It should also be pointed out that some of the above requirements are covered in more than one level. This is true since there are obvious relationships and overlaps which exist throughout the quality system,

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<sup>1</sup> General information discussed in this section is condensed from the AIAG, "Quality System Requirements--QS 9000" manual, publication QS9-3. Automotive Industry Action Group, Detroit, MI.

but varying degrees of detail and specificity are required depending on function.

**ISO process.** The ISO process is further detailed through what are termed tiers from most to least complex. The most complex tier of documentation is the quality manual, an overall guide to the organization's system's policies and objectives. 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, all are designed to be routinely updated for demonstrating that quality practices are properly performed. The fundamental elements are:

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

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

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

**ISO 9000 based requirements, QS focus.** The actual focus of the QS 9000 effort is on supplier based contractual relationships, consistent with, or parallel to, 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 discussed as:

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

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

**Management responsibility.** The management responsibility element provides a statement of quality policy to be consistent with what has traditionally been called a mission statement. As part of the overall management function, organizational responsibility and authority for quality issues and operations as defined in the broader system is identified and explained. The key reason for identifying and describing various organizational functions is to assure that, as a supplier, the organization can deliver product as stated.

**Quality system.** Element 4.2 provides 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.

**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. The contract, as part of the broader quality system must help assure that the supplier can actually deliver on what is specified.

**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, as part of the system.

**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. 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.

**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.

**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 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.*** The focus of element 4.9 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.

***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.

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

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

***Control of non conforming product.*** Related to 4.12, the 4.13 element is designed to substantiate good and bad, or non conforming, product disposition in production. Element 4.13 requires that suppliers provide assurances that only conforming product will

be used in product, per customer specifications. The overall documentation system, as evidenced in the control plan, tagging, environmental control, and other ways, must provide sufficient control overall identification and disposition of good and bad product. This includes steps for disposal of nonconforming product, and other corrective actions.

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

***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.

***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.

***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.

***Training.*** Although only two brief paragraphs in the QS 9000 manual, element 4.18, calls out the need for identifying and providing all persons with training in those areas which affect quality. Training is to be viewed as a strategic issue, and one of the key opportunities for improvement, as underscored throughout the toolkit. Appropriate records on training activities must be established and

maintained, and qualifications for various quality related personnel tied to training for advancement.

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

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

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

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

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

- Management and operating systems better linked to day to day functions of your business.
- Improved production process and overall efficiency through enhanced understanding.

- Real organizational teams—internal, external.
- Enhanced flexibility and control, to better meet customer demands--response time improvement.
- Overall better understanding and communication.
- Decreased liability, increased reliability.
- Increased marketing advantages based on external evidence of commitment to quality.
- Better alignment of operation and management systems to strategic directions organizationally.
- Fundamentally healthy way of doing business.

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

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

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

- Involve people throughout the organization--part of the intent of the process.
- Focus broadly on what you are trying to achieve--improving your organization.
- Do not do this in a vacuum--isolated efforts will only result in confusion and duplication.
- Build on processes in place--enhanced understanding and knowledge can only help.
- Based on enhanced understanding and knowledge, give empowerment to people.
- Based on enhanced understanding, study how your operations meet the ISO standards.

- If not compliant to standard, determine why--and consider the value of putting it in place.
- As decisions are made, carefully do a full evaluation, prior to possible implementation.

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

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

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

**TS 16949 2002 Standard.** The TS 16949 2002 standard is an updated and streamlined version of the ISO 9000 standard. It is intended to assist organizations who may be certified or those contemplating certification. Based on the original ISO rubrics and elements, it reflects maturity and a more agile system for quality management, consistent with where most organizations are in the new 2000 century. The new TS 16949 2002 standard provides a broad-based three category type logic for quality systems management at the organization level. The new quality management systems provide a seamless and integrated model for holistically managing the organization, based on three parts:

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

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

Product development would typically address such areas as quality planning from an advanced program or platform standpoint for purposes of gaining new contracts for the future. This may be called concept program and process definition, and would typically involve prototype development and readiness, design release for production, assuring readiness and capability for production, various

launch review processes and continuous improvement in all that is done. Much of this relates directly to engineering functions in manufacturing organizations. It also relates to quality directly, purchasing and other production functions indirectly for planning purposes.

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

Support processes address advanced engineering and research functions for future improvements in materials and processes, as well as plant engineering improvements to facilitate the same. Various business functions, auditing, preventative maintenance, document and record control, how corrective actions are handles, training and so on. The support services or processes are typically housed in various seemingly unrelated groups or departments, but these all relate indirectly to the broader system and the organizational ability to get product or service out the door.

Specific changes in quality management systems provide for fewer key elements resulting in a streamlined system, more integrated throughout all aspects of the organization. Management now realizes the importance of changing culture and systems to be more aligned with QS. The key elements in TS 16949 2002 are:

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

While there may be other elements in the new system, particularly based on where an organization may be in relation to its older quality systems, only five are now required.

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

The new standard requires top management to provide evidence of commitment to QMS and its

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

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

Increasing emphasis is being placed on determining quality objectives for product early in the engineering and design process. Requirements are not necessarily stated by the customer as has traditionally been the case, but still must be determined, but in a more "shared vision" context. Capacity to produce product and deliver per contract must be documented to demonstrate feasibility and must include risk analysis. Methods for communicating with customer must be clearly established, including establishing how to use internet. Establishment and management of multidisciplinary teams must be discussed with emphasis on how to do FMEA's, control plans, corrective actions and other key documents and methods to assure effective communications. Purchasing, production and service provisions must be accounted for in increasingly demonstrable ways. Increased emphasis on management reviews and signoff's based on and around verification and validation procedures must be noted in systems per customer program demands. Advanced planning

documentation must be inclusive of all suppliers, with them registered to compatible standards as part of supply chain. Performance of suppliers must be beyond delivery to include data-based measurables. Verification and validation of production processes and tooling applies to all, not just special tooling. Calibration must be recorded to include identification and assessment of impacts, with labs doing calibration accredited to ISO compatible standards.

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

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

- Implement, maintain and improve an environmental management system;
- Assure conformance to its environmental policy;
- demonstrate such conformance to others;

- Seek certification/registration of environmental management system by external entity; and,
- Make a self-determination and self-declaration of conformance with this international standard.<sup>1</sup>

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

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

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

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

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

The standard requires documentation to address and define roles and responsibilities which will facilitate effective environmental management.

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

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

## **Quality Management System Integration**

Quality management system (QMS) comprises the collective effort of all workers in the organization to achieve zero-defect processes, products and performances in all related functions. Quality management of robust processes and products means that systemically we are capable of achieving predictable, stable and controllable results. QMS also refers to designing products that can be fabricated within the specified tolerances, timeframes and other associated new product development parameters identified internally and externally with all in the feedback loop. Customers demand perfect products and services and in order to meet these requirements we need to produce built-in quality the first time. This requires a QMS focused mindset from all workers, organizationally.

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<sup>1</sup> ANSI/ISO 14001-1996, Environmental management systems – specification with guidance for use. Publication T 65, American Society For Quality, Milwaukee, WI.

Therefore preventive thinking and personal responsibility on the part of workers is expected and encouraged in all we do. Workers are heavily involved in the overall process in their operations' roles focused on their own task and equipment, but they all must be concerned beyond only their own small part of the production puzzle. No defective part should be produced or procured, let alone released into the next process, and reliable processes are essential for a material flow without excessive buffers or other hidden wastes to assure continuity in production. A key overriding technique involved in QMS overall is to quickly determine and identify abnormalities and respond with effective analysis and countermeasures as decisions made and implemented. The key methods and tools discussed as part of the QMS are:

- Quality feedback loops
- Root cause analysis
- Information display boards
- Production validation, test and inspection
- Error proofing, mistake proofing
- Statistical process control
- Certification and other audit
- Single point lesson
- Problem solving, 8-D approach
- Failure modes and effects analysis
- Quality agreement, prevention planning
- Measuring, production equipment capability
- Man-machine analysis
- Ongoing process control plan
- Quality function deployment

Each of these will be briefly discussed and described as an integrative QMS element.

**Quality feedback loops.** Quality feedback loops are checks introduced at the end of various production sections. This could be at the process, line, center, or plant level. The quality checks are conducted according to the PDCA. Sub-standard results in every feedback loop are documented before being delivered to the subsequent customer. Abnormal conditions are avoided in the future by the consistent introduction of countermeasures. Quality checks at the end of various production sections ensure the reliability of the processes in the plant. Data analysis is routinely performed to recognize repetitive faults and trends, and to assist in addressing any issues which may arise in the loop. The effectiveness of the corrective actions introduced are reviewed and new actions agreed on if necessary.

There may be some cases of individual production and/or unit/component fabrication, where not every feedback loop may be used. Quality feedback loops are structured on the basis of the

PDCA where the operator checks for any defects, and has the capability to stop production if necessary. Worker does the SOP at the work place, and in the usual course of events any defects noted are repaired at the work area within the team. Based on the nature of the situation, a determination is made regarding if higher level problem solving is required. Generally at the lowest level of the quality system, the worker checks a random sample of products

If a defect is noted at the end of the production zone by a worker, the defect is noted and passed on to the next zone. Rework or corrections to repair the defect are completed in line or, if severe enough, note the defect for central rework, and arrange to have it taken there. Again, it is important to determine if problem solving is required

At still a higher level, quality management checks random samples of products routinely at various locations throughout the production system. Results of all feedback loops are documented and fed back to teams and management. As with all feedback loops, determination is made if some level of problem solving is required. Throughout the process, we will perform and track problem solving processes, should they be required.

Quality feedback loops cannot be introduced until a quality alert system has been introduced. Quality alerts are generally in the form of a checklist or simple audit which reflects customer demands. Workers and checkers must use checklists as key parts of the feedback loops. The results from the feedback loops must be communicated to the relevant groups of people (work teams, team leaders, work areas, plant level management). A problem solving or corrective action process must be initiated if repetitive problems occur.

Quality feedback loops provide relatively quick resolution of process-related defects. Stabilization of production process can occur since communications are enhanced, and based on rapidity in the system. Transparency in process increases since less defective product becomes "hidden" in the system, and thus waste is reduced. Quality feedback, based on quality alerts, promotes systematic analysis through the possibility of performance of problem solving or corrective action processes.

**Root cause analysis.** This helps identify the true cause of a problem, getting to the root of the problem. The goal is to establish the causal chain through to the root cause. Root cause analysis involves the following steps, all which are routinely documented: First a description of the problem is written stating what happened, when, who discovered it, who reported it, and so on. Second, it will be important to identify the cause, requiring an actual analysis. Based on the analysis, we must establish

appropriate corrective actions to eliminate the cause of the defect along with deadlines and responsibilities for when all of the analysis will be done.

After actions are determined, carrying out the actions, in steps or other routine and methodical ways must be done. Based on actions put into place, checking the effectiveness of the actions to address the root causes will be critical as a follow through to assure that occurrences are not repeated. Use of the 5W's method is one way to enhance the robustness of the analysis. Other possible analysis methods may include cause and effect diagramming (Ishikawa) with the following themes. Systematic tests are recommended based on statistical analyses, designed experiments, and so on.

One of the key benefits of the root cause analysis is that this identifies the true cause of the problem and helps avoid focusing on a superficial cause. Root cause analysis provides a structured approach rather than a random trial and error approach to problem solving. The need to rely on assumptions can be reduced if not eliminated all together. We are fairly well assured that an effective resolution to the problem or area of concern will be resolved with root cause analysis.

**Quality tolerance limit examples** (QTLE's). These are visual tolerances such as sample products, photos or sketches, which clearly illustrate the difference between acceptable and unacceptable quality. They are commonly based on attribute type characteristics of features when passing/failing products and resources, and as the basis for initiating specific corrective actions in the event of quality alerts, defectives or failures.

QTLE's are used wherever quality requirements must not be language-dependent or would be unclear or impractical in written form due to technical complexities, length of instruction, and so on. QTLE's must be included in the quality plan and be available at the start of production. QTLE's affecting safety or customer-related issues must be agreed with the development group, based on customer demands.

When planning or modifying process, the production planning team must decide whether the use of QTLE's are to be used. QTLE's are SOP's for use when a quality alert presents itself, particularly at the front line of management, and therefore they must be up-to-date, clearly visible, and placed at workareas as part of documentation routinely used as needed. When a quality alert arises, and the QTLE SOP is used, it is critical that assurances are in place to control the discrepant item. Worker's should be instructed in the use of QTLE's and corrective actions associated with them, and when instructions

given this should be recorded and their effectiveness monitored by team leaders, supervisors or others.

Displaying QTLE's on boards in working areas directly associated with the product under consideration has proven to be a useful best practice. Placing QTLE's in close proximity to actual product's or relevant production acts increases clarity and helps prevent discrepant work from entering the workflow. During new product development programs, technical support workers must set deadlines for, and coordinate the inclusion of, QTLE's in their designs. During QTLE training, trainers should explain the samples and the action to be taken in the event of quality alerts. Regular checks to ensure worker's understood, and are still aware of, requirements can increase process safety.

Because they are by nature, generally pretty clearly defined, QTLE's enable employees to make quick and effective decisions with regard to what is and is not acceptable in terms of quality—at the point of production. Thus the QTLE can help improve quality and reduce costs, as well as reduce inventory and WIP. QTLE's are in effect standardized work methods where otherwise subjective decisions relating to quality issues would be prevalent. These become a much simpler quality standard to replace complex descriptions of products, processes, production procedures and so on. QTLE's reduce training required and stabilize quality and production levels, helping to assure an under control condition.

QTLE's are commonly part of the broader quality alert and feedback loop systems used by teams and in centers of production. Depending on the severity of the situation, a worker generally has the ability to stop production and attend to the discrepant work, something like this:

- A quality alert alarm could be readily available and activated by a team member, by pulling on a pull cord, if they cannot complete (standardized) work cycles correctly due to the discrepancy noted alongside the QTLE.
- A quality alert sends a signal to support staff, who attend to the work area concerned, are told about the problem by the team member and provide or assist with rework in the work area. The team member starts work on the next production unit.
- If the quality alert discrepancy cannot be rectified where it has occurred, the product must be transferred to the rework area and team. Faults are recorded by staff, supervisors or team members.
- After discrepancies are rectified, the worker or others acknowledge this by pulling on the pull cord again, signaling it is all right to start production.
- If the fault cannot be rectified in a defined period of time following activation of the quality alert,

production remains at standstill, to be displayed with information about the work area concerned.

- Team members, support staff and supervisors may then define action to be taken immediately to avoid similar discrepancies in the future.
- Team members, support staff and supervisors decide if a problem-solving process is needed.

Work areas where quality alert is automatically activated are indicated to team, support staff and others by visual, audible or radio signals, and is generally placed at a pre-defined location. However, non-automatic alerts (human alerts) can occur at any point in production. Some sensitivity exists regarding the possibility that supervisors and even perhaps team members may respond negatively to workers who activate quality alert during production. Organizations have internal regulations to specifically define when quality alerts can be initiated and by whom, conditions warranting, and so on.

**Information display boards.** One quick way to keep the quality focus is by using quality information display boards. Quality and production status information is displayed in as near real time as is possible to provide updates and status reports on what is happening. This type information can be displayed on an electronic panel or manually on a display board, or in various combinations. However, ideally and increasingly this will be done on electronic media to speed up the flow of information to the optimal level. Some of this information may also be implemented by use of signal lamps or audible signals. The electronic display panel will be connected to each station and type of information displayed for each individual station typically includes:

- Types of errors
- Quality alert updates
- Machine or line failure
- Shortages or overages of material
- Target vs. actual number of work in process
- Downtimes/shift
- Accident or safety/environmental issues/location
- Maintenance status and issues

Benefits of information boards and other sharing systems are many. Visualizing data relating to quality and efficiency can have a pretty sobering as well as educational effect. Understanding of what is going on in other parts of the facility and organization is enhanced many times over through these type systems, leading to enhanced understandings of roles and responsibilities, relationships, and so on. Communication in general can be greatly improved through these simple techniques.

### ***Production validation, test and inspections.***

Inspections and tests are a central improvement method in production systems to keep the quality focus where validation of the systems are necessitated. These type tests are called out in the ongoing process control plan and detailed in SOP format as one way to help achieve excellent product and production process even where reduced development time may be an issue (new product development). They are used both for new production runs and for updated products and runs (model enhancements), and for mature products in existence under selected conditions.

Production inspections and tests are carried out at various points in production, each with a varying number of workpieces depending on the nature of the situation. The production inspections and tests are used to evaluate how production factors inter-relate in order to identify weaknesses in the production process before, during and after production starts and as they mature (in the case of new products). Production inspections and tests are carried out using standard equipment.

Production inspections and tests cover all parts of a value adding process, and they are carried out on all components, at various times and in various ways as appropriate to the nature of the work area, process, and so on. Inspections and tests for new products being run early on are used primarily to evaluate how the systems interact and to test the assembly process in standard production, a sort of shake-down. A secondary level inspection and test may be used primarily to test the attainment of the required quality once production has matured and we are supplying product. Yet other levels of inspection and tests may simulate standard production.

Tests conducted may include, but not be limited to, short runs of data with statistical indices being generated based on data gathered. These may include control charts, and could also likely require and facilitate capability indications, frequently required to be at appropriate levels (1.67) in order to achieve customer acceptance. Gage R & R values may be required to assure gaging systems are up to the task, measuring in appropriate ways per customer specifications. At the higher level, designed experiments, or DOE, would also be used in some cases to discern process and product quality. Other production data to be generated may be more associated with target timing of workpieces and flow, cycle times, target proportion of rework and rejects.

Suppliers, particularly external to the organization, should also carry out production inspections and tests to help assure capability in process and robust product. Benefits of such inspections and tests include elimination of problems

in the trial production runs. All workers can learn about standard processes and requirements, areas to be watched, where likely quality alerts may surface. This becomes a standard for how to test systems, tools, testing apparatus, and other production factors which will need to be proven time and again.

The release for standard production, based on final test results indicates if the general requirements for process and product compatible production have been met. This is particularly true in new product development, of course, but may also be applicable in process run-off's, introduction of substantial design changes, and so on. These type tests may also be applicable in the case of new suppliers whom we are trying to validate processes with, or in other cases where only very limited data and documentation exists upon which to make judgments. Also, where much information existed, but for some reason a contractual relationship was halted, and now we are trying to restart production, testing and inspection may be necessary.

Possible documentation and data, including actual production samples, used to record the results of production validation inspections and test may include the following: various checklists for suppliers; sample control charts (particularly short run charts); sample product produced; sample measurements on key characteristics; component quality history as reflected in ongoing process control planning; failure mode and effects analysis documentation; appropriate reliability testing as may deemed appropriate; and, perhaps others.

The customer generally will issue various types of follow-up reports containing data relating to their own results of process and product measurement and function tests, and other miscellaneous tests conducted independently as separate confirmation for supplier capability. Material testing and inspection properties, particularly as related to reliability analyses, may be summarized if material tests have been carried out. Components are only released if they have been approved in all customer test reports. This provides a way to test overall process compatibility in production within the context of desired customer demands for product. The processes and products are designed and maintained in a way that validates first time capability and reliably produces high quality products.

**Error proofing, mistake proofing.** Error proofing is an attempt to build into the process, systems to prevent errors occurring in production. Carrying out a risk analysis based on a tool such as FMEA in the early stages of new product planning and development enables possible errors and their significance to be assessed, along with the probability of such errors occurring and being discovered.

FMEA's can also be used in existing production scenarios to analyze for possible circumstances of higher risk. Possible reasons for incorrect actions can include forgetfulness; misunderstanding; incorrect identification; confusion; lack of practice and experience; insufficient knowledge of the operation; negligence due to inattentiveness; inability to keep up with production; lack of standards or not being aware of same; element of surprise, also related to stress from various internal and external sources.

Errors can be caused under various circumstances, including if operations are omitted and parts are incorrect or omitted based on operation missing. Operators can input the wrong information, causing malfunctions in equipment. Incorrect parts may be processed if incorrect inventories are kept or used. Equipment may be set up incorrectly and/or tools inserted and clamped incorrectly. Downstream subsequent sequences are defective due to errors in process, requiring rework. Where employees have not received sufficient training many of these scenarios are only compounded and processing operations are carried out incorrectly.

Measures for error prevention and avoidance can be developed on the basis of the results of the analysis. Examples of mistake proofing solutions may include technical solutions, which would prevent errors occurring, such as fixtures, devices or templates. Additional training and education may be in order as a part of the error proofing solution. Reduction in confusion at the work site may be required, done through isolating the systems if possible. Better articulation in all process organization may help as a error proofing strategy.

Finding solutions and prevention of errors and mistakes in systems are key parts of a continuous process of improvement. Process stability and reliability, as well as reduced errors and costs incurred are all tied to motivation for seeking error and mistake proofing. Avoidance of rejects and rework lead to waste and variation reduction, critical to forming the basis for just-in-time production. Customer good will and benefits are optimized, and complaints are reduced or eliminated. Achievement of zero defects will come about to a large measure based on and around these type principles.

If an error cannot be prevented, it should be possible to prevent it from affecting the customer (including the next process in production) in other than positive, value-adding ways. Errors can be avoided or possibly reduced if processes are designed to shut down automatically, based on sensing systems, when something is not working properly. This is why there is a need for cost-effective, reliable technical devices and sub-systems in organizations and production systems, which can identify possible

errors, or, when they occur, shut down the sub-system and/or system, or equipment where concerned. Color coding or other visual observations may be used, including various cameras and surveillance devices and systems. Positioning indicators can be used in automated movement and assembly of parts and components, as well as shapes which can only pass through/on to a next production position if properly produced to specification. Parts can also be identified using labels/designations which provide acceptance to the next level (customer) in production or value adding scenario.

While automated circumstances provide many opportunities for value adding in production, sometimes the simplest of scenarios are going to be among the most fruitful. Quality assurance measures relating to employees, such as a simple obligation to wear gloves, industrial clothing, use visual aids, adherence to test and inspection regulations, and so on as part of the work standard and procedure frequently are the concern as much as high technology issues. Moreover, these type procedural issues are directly associated with environmental safety and maintenance, and thus can place workers in harm's way if not followed.

**Statistical process control.** Statistical process control (SPC) is a statistical instrument and charting method for communicating production realities to aid in controlling processes. SPC is a system which uses data, either manually or automatically gathered, and places the data in a context of acceptable and unacceptable units of production via a control chart. The chart is drawn up by assessing the performance of actual production around selected quality characteristics. Simple mathematical methods are applied to derive upper and lower control limits based on the results of the measurements and counts.

The chart is configured on the basis of the instances of quality characteristics observed, or sampled, and not on the basis of probability, e.g. normal distribution. In fact, by configuring the production observations in the manner which is suggested, the actual production is compared statistically to the expected performance via means and standard deviations. When means are analyzed we can further derive capability indices for the process (cpk). Note that the characteristics being discussed are generally set in the engineering design process based on customer demands.

If the control limits are exceeded, or other performances are noted based on the chart, countervailing measures are put in place and tracked. Assuming changes can be made in production, such as how the measures are assessed, speed of production, training or changes in the standard work

methods, then the countervailing measures may take effect either in or on the process. If the countervailing measures are to have a positive effect in the process, they must relate to a process parameter, which must in turn have an effect on the quality characteristic. Changes may also relate to adjusting the actual characteristic being measured.

SPC alone is not a method for improving quality characteristics, although based on the feedback inherent in this type communication tool, various analyses can play into the broader arena of information required for effective decision-making. As such, SPC is generally viewed as a fairly robust management and decision-making tool, to be used within teams and work areas. Given the substantial effect and inter-relationships which SPC, as an interdisciplinary tool brings to bear on production, it is best used within a hierarchy of various levels and types of technical specialists along with workers in the work area. It should also be noted that 100% checks can be avoided by using SPC charting techniques and samples. Given these techniques, actions in and on the process can be detected and evaluated objectively and used to increase the cost-effectiveness of processes.

**Certification and other audit.** Internal system audits generally form part of the ongoing certification process of the QMS. The internal system audit assesses processes as compliant with the QMS, and the extent to which changes may be needed for improvements. These audits apply to all direct and indirect activities in the organization and facilities, and thus are carried out on the basis of a broader systemic audit plan prepared by management. They may be referred to as certification audits or process audits, and the key is to have all systems and processes periodically reviewed on a comprehensive basis. Some key reasons for audits may be to help:

- Provide information about capability of processes, our ability to continue meeting customer demands.
- Prevent failures in processes and key functions, based on early recognition of inherent weaknesses.
- Provide a starting point, a baseline documented for process improvement.
- Develop robust processes and functions in all we do, to withstand internal and external disruptions.

While it is most desirable to have a preventative plan in place for when and how to do audits, event-oriented process and/or function audits can also be conducted, perhaps in response to current quality problems or other customer demands. Event-oriented audits may be conducted internal or external on the basis of criteria and guidelines to include: quality problems and associated corrective actions;

exceeding of defective levels as measured in some agreed upon metric such as parts per million (ppm) or other values; and perhaps exceeding of warranty and other reliability values and likely costs based on supplier issues. While there may be any number of other reasons to audit, associated with events, in all cases, an assessment of the severity and significance of consequences must be explored.

All processes and associated production factors should be routinely audited in ways appropriate to the overall work environment. This may be broken out according to suppliers of incoming materials and supplies; process steps in work cycles; personnel and training; equipment and facilities; transportation and component handling; failure analysis and corrective actions; and, customer service and overall satisfaction. This generally covers the necessary types of issues and circumstances which need internal attention to certify, via audit, a functional and cost effective QMS.

Corrective actions arising from the audit must be documented and deadlines and responsibilities assigned. Implementation of the corrective actions must be followed up on at various levels, including the team and work area. Actions that affect workers are discussed and solutions are worked out together in ways which are mutually beneficial. The long and short term results are included in management review reports. This suggests use of workers at the work area and team level to be engaged in the actual audits, directly, including the follow through for corrective actions, and in various levels of management reviews to assure the comprehensive plan is actually working as intended.

Explain the system audit to all workers and management prior to an audit in terms of an opportunity to improve processes rather than as an inspection or punitive action. Encourage all workers and managers, particularly supervisors, to report on their own work area and process conditions. Used properly, the internal system audit can prepare us for necessary certifications which are key for us to remain ISO registered and able to work and engage in the global marketplace. This also points clearly to the need for broader strategic planning and that these audits must be scheduled and aligned to the progress of broader project and activities associated with change and improvement in the QMS.

At a more practical level, the system audit will uncover hidden problems and issues, particularly those which interrelate between and among work groups and areas. The audit can confirm for us that our processes comply with the broader QMS under which we all work. The effectiveness of process controls and work standards are ensured and underscored. Process audits assess the ability of a

process to consistently and reliably produce the required product quality to meet our customer demands, and in many cases, help us all remember our relationship within the broader customer and supplier chain of production.

**Single point training lesson.** Single point training lessons (SPTL) are contrasted to kaizen workshop improvement (KWI) in that KWI's are typically day long or longer events focused on continuous improvement of a process or related element in production. SPTL's are usually one to two hours in duration and highly focused on some aspect of production which may simply be informational or require attention for any number of reasons. The aim of the SPTL method is to teach subjects quickly while KWI's are commonly identified as areas with known issues or quality concerns requiring substantial focus and breadth of worker knowledge.

SPTL's are focused on complex or far-reaching subjects which, while related, are split into small training phases and taught in short digestible and manageable sessions for workers at various levels. Commonly SPTL's are explanation of interrelations, actions, and facts, which will be put into practice or introduced through use of simple tools such as flip charts and easily read information. Each SPL training phase is followed by a practical exercise on the same subject, an application which drives the main points home.

Common materials used to teach, illustrate and/or drive the points home may be SOP's developed around new or improved processes in production. Other locally "grown" SPTL information may be documentation provided from teams engaged in 8-D problem solving, FMEA's, OPCA's or other "macro" documentation which may be continuously improved, and which should be communicated to workers regularly anyway.

SPTL activities, actions and results may likely be displayed locally, as part of a pre-post-training and informational session. Use of photos or other graphical documentation in pre-post-training sessions in order to illustrate changes quickly and to drive points home locally, may be appropriate. Fast (informal) and casual conversation, frequently done at regular quality or team meetings may provide the optimum conditions for such SPTL training. The efficiency of SPTL training can be reviewed directly after each training phase and changes to improve for additional are done on the spot by supervisors or co-workers who have presented to others.

**Problem solving, 8-D approach.** Based on fault occurrence (likely repeated) or counter-productive technical issues in production, problem solving is initiated in a worker team environment to identify the cause of the fault or issue, and to resolve

the problem. The problem solving process, in general terms is comprised of at least the following, not necessarily in a linear fashion:

- Take immediate steps to control damage and check effectiveness surrounding circumstances involved, including informing all workers directly involved.
- Accurately identify the problem and document this in appropriate ways for future reference, and to effectively communicate to others.
- Determine root cause of the fault with the help of other workers and technical experts, perhaps using brainstorming methods and root cause analysis.
- Determine corrective actions with all involved.
- Implement corrective action based on a phased plan as may be needed.
- Once implemented, check effectiveness of corrective actions to decide if successful or not, degree of success, possible additional changes, etc.
- Change existing standards/regulations and document improvements.

These steps procedurally and conceptually address the general approach to be used in solving a technical problem. Time constraints and makeup of team will vary depending on nature of the problem, production environment, amount of resources which can be dedicated, severity of the situation, and other issues.

The originator of the fault completes the appropriate documentation to initiate the problem solving process, and informs those appearing to be appropriate (supplier, previous center, own work group). The originator is responsible for rectifying the fault, and is expected to follow through on the problem solution. Appropriate documentation is displayed, routinely, kept up to date in the work area for the duration of the project (this also includes a report as part of the project at the conclusion of the work—both in traditional written format as well as in oral/physical presentations as may be deemed appropriate at the work area, to supervisors and others concerned). Originator/complainant agrees with the problem solution by signing off the effectiveness of corrective action.

Corrective actions and their effectiveness are commonly reported in regular quality meetings at the work area level, and perhaps in other venues deemed appropriate depending on the severity and complexity of the problem. The problem solving “8-D” form used to initiate the problem stays active until the problem is solved, and at that point it can be removed once the final entry has been made. A consistent, systematic and disciplined stepwise approach must be taken to the problem solving process, enabling addressing the root cause rather than the symptoms is of the utmost importance.

Finding the true cause of a problem often depends on involving the appropriate experts, and asking the 5 W’s repeatedly. Understanding what is truly the problem and what is not the problem is one of the keys to successful, value adding problem solving. Performing a problem solving process in the 8-D tradition can help prevent the recurrence of faults and set the stage for value adding improvements. The systematic approach eliminates root causes, and it can generate a problem solving sheet as reference documentation for resolving other faults.

***Failure Mode and Effects Analysis.*** Failure mode and effects analysis (FMEA) is a means of error proofing, based on identification of the potential areas of weakness in a process, product or design. Used either in the planning phase for new product development, or during ongoing operations, the FMEA is key for identifying inadequate know-how, potential errors, and problems. Additionally, once identified, the potential areas of concerns, errors or mistakes, are prioritized by means of risk priority ratings. Based on risks and other information identified, FMEA also seeks to create solutions and/or countermeasures based on expert opinion and experiences in the work group. Like many robust quality tools, based on time involved, a decision must be made regarding when the method should be used.

FMEA promotes robust processes and product, as well as strengthening the overall communication environment for improvement. Identification of opportunities for improvement that were not considered during development (or ever before in the organization, perhaps) may be explored based on the synergistic dynamic inherent in FMEA. As such, it is a structured means of ensuring that know-how is available for future planning and improvement, even while encouraging shared responsibility and cross-functional process understanding. FMEA allows for assessing at early detection levels for process risks or other deficiencies while pursuing structured planning to help avoid unnecessary changes or issues.

***Quality agreement, prevention planning.*** The quality agreement, prevention planning (QAPP) is a preventive approach for ensuring the operability and capability of critical production processes and systems. Like many parts of the QMS, the QAPP is useful both for new and existing production scenarios, and products, both new and mature. A QAPP is a defined plan of action, and agreement, which can be negotiated and put into place in order to react quickly and effectively whenever some appropriate quality type circumstance warrants or requires it—or best case, before it is needed.

Similar to a corrective action type scenario in format, the QAPP prevention application has a

more long term and systemic approach. This may be an internal or external supplier or customer circumstance where the current arrangement is not as productive as is needed to grow the larger “team”. Conditions which may warrant a quality assurance plan for prevention may be the following:

- Systemic, long term issues which have caused tension in a production agreement over time.
- Internal or external customers or suppliers, not as productive as they should, and can, be.
- Changes in production, customer demands, or others causing the need to redefine relationships.
- Consistent lower than desired levels of work from some work group, not delivering as defined previously, either unwritten or written.
- Characteristics or metrics being addressed and redefined to improve cost and other relationships.
- Broad-based cost issues which are generally tied to quality levels and metrics, needing to be redefined.

The written QAPP time span coverage should be stated in the preventative plan. QAPP use will vary depending on size of organization, nature of production, circumstances addressed, and others.

Quality agreements address internal and external customer/supplier relations to improve key interfaces in the production process based on clearly defined requirements and parameters. They are used to assess, grow and improve service relations between customers and suppliers based around functional process steps they follow, generally comprising the following elements:

- Customer demands are evaluated and supplier determines, structures, evaluates and prioritizes the customer’s requirements to include control parameters, measuring procedures and limiting values. Necessary long term escalation strategies and communication systems agreed to in writing.
- Process capability is established and work areas, both critical and non-critical, are analyzed and secured, including inspection and test systems, reaction plans, and proof of process capability.
- Adjust quality by level of severity to address process as: (1) satisfies requirements, no adjustments; (2) not satisfying requirements, adjust process/operator level; (3) not satisfying requirements, take corrective action at work area/team level; (4) not satisfying requirements, take correction action organizationally.
- Quality control over time based on reporting and controls established in the QAPP. Records to be kept, documentation maintained and in what ways, data to be collected, how this is communicated to customers, and so on over the long term.

QAPP provides sub-systems for assuring that suppliers are appropriate and able to perform in ways defined by, and agreed to with customers. This will always be important for use to drive new product development programs, but also may be useful for enhancing the robustness in existing customer-supplier relationships. This focuses on verification of the reliability and capability of critical stages of the process of supply chain management, and is comprised of the following types of elements/tools:

- Defining critical parameters in process and/or product component. This may include characteristics, measurements, equipment, etc., and is commonly called a ongoing process control plan.
- Proof of process capability. This is commonly a function of prototype production runs and data derived to determine appropriate Cpk.
- Process control and inspection/test results. Related to cpk and standard deviation derived data, this goes further to determine capacity to derive inspected or tested data in process control manner.
- Plan of action in the event corrective action is needed.
- FMEA used at various stages in production can help reduce issues with non-ability to carry through with contractual agreements.

Ideally, the contents of quality agreements are integrated into standardized communication channels over the long term based around QAPP’s. Agreements are checked and upgraded by customers and suppliers at least annually, or sooner as may be needed, continuing to improve toward a goal of zero defects. In the event non-compliance occurs, appropriate corrective action is taken and new objectives set and agreed to as may be necessary.

QAPP agreements and associated objectives are generally widely displayed and organized within the strategic planning of an organization, covering both internal and external suppliers. Policy determination and deployment as part of broader objectives, evidenced in agreed to written performance standards. Thus, the QAPP helps promote a consistent approach to quality objectives shared responsibility and accountability for achieving quality objectives, thereby promoting cooperation and cross functional enhancement in systems.

QAPP’s also naturally help establish clear agreement on escalation levels in advance, enabling sizable problems to be handled fairly quickly and effectively. Escalation, in this case, means that those areas of potential problems being identified, based on experiences in similar supplier and customer relationships, are identified and indicated with

standard procedures on how to handle circumstances, should they arise at pre-determined levels. Similarly, quality gates are used as temporary but immediate measures aimed at process stabilization to address major quality issues prior to the introduction of quality alerts or work stoppages.

Thus, the QAPP functions as a “macro” level standardized checks of quality by workers in workplace, and others at other levels, helping to assure robust feedback and documentation. Concurrently, the QAPP aims for identification of all possible defects (100% check) where it may be needed, and when problems are detected, a problem-solving process is initiated immediately to help assure reductions in long term impact.

**Measuring and production equipment capability.** All equipment, as production sub-systems, must be monitored to assure satisfactory production and measurement capability. Production equipment generally is monitored in the following ways:

- Maintenance records are kept on all activities which reflect the overall condition.
- Routine maintenance plans are written and followed, clearly identifying location, age, types and history of uses and applications, and other important production details.
- TPM at the team/workplace level addresses much of this, and in fact, monitors equipment routinely.
- Longer term strategic planning with teams are built to assure new equipment as needed.
- Safety and environmental circumstances will change, requiring updates in documentation.
- Data collection and treatment according to gage R and R, cpk, and general SPC charting systems.
- Validation of data collection and treatment will occur over time based on trends determined.
- Monitoring must also take into account changes in standards and regulations over time.

While general production equipment requires documentation for various reasons, and to be done in ways which may be appropriate to one type system, the test and measurement equipment will generally need to be more robust. Thus a separate system will generally be needed, and while it may be monitored and documented primarily in the team workplace level, it will also generally require additional oversight and relational documentation to a broader quality system. The monitoring of test equipment ensures the suitability and capability of all test equipment in production as further defined below:

- Test equipment includes measuring instruments, gauges, test software, standards and any necessary setting or calibration templates.

- Monitoring covers all test equipment, assigning a unique monitoring number to each item, and other critical information recorded to assist in appropriate disposition over time.
- The monitoring system assures that equipment is calibrated and adjusted at fixed regular intervals using only certified systems for compliance with national and international standards.
- Accuracy, exactness and precision of each test and inspection item is assessed in relation to the task for which it is used, particularly assuring correct environmental conditions of use are ensured.
- Best equipment is selected according to required accuracy or permitted tolerance, and assurances that capability of the test equipment is produced under actual production conditions.
- Monitoring systems must allow and facilitate production functions within specified tolerances to avoid rejects and rework and establish certainty about the effectiveness of tests and production.

It should be clear that there is a true relationship between and among all equipment used in production, both day-to-day production, as well as test and inspection. Systems used to assure and document it's safe and reliable functioning are not trivial nor can they be marginalized in any sense. Much overlap may be derived in the cross functionality of monitoring sub-systems to assure equipment is acceptable in application.

**Quality function deployment.** Quality function deployment (QFD) is built around and upon the cause and effect logic and system, as well as the broader problem solving approach, all which help systematically and logically identify and improve on potential or real weaknesses in product quality. The emphasis in QFD is on customer input or demands as they are generally called. QFD logic also relies on matrices development to determine areas of common concern and/or areas of weakness needing to be pursued. Matrix development helps identify cross functional interests or relationships, where all gain by better understanding and articulating information or knowledge between and among groups. QFD is a communication tool for reducing lead time from concept to market--in conjunction with much other information such as cause and effect, and FMEA. The advantage of QFD is that it provides a positive system for directly placing customer inputs into the mix of information considered for product improvements, changes. Customer and supplier relationships apply both internal and external.

The QFD process encourages consensus to be built around what we really "expect" our product to be, particularly from the quality side, but also in

engineering terms. By putting all parties together, and recording all inputs over time, and repeating this, we virtually force communication and detailing of the product or issue under consideration. It is important that all parties agree that this is our objective, and various groups may use the QFD process as an evaluative tool for their own performance, rather than waiting for customers to review them. As a stand alone activity, QFD is a useful form of documentation and prioritizing for deployment of resources. These could include any number of elements in the product but are typically oriented toward specific functions, as the name implies. QFD can be similar to value engineering since both force us to consider each component function, necessity, cost, contribution to quality, safety, and so on.

QFD is a holistic way of thinking about customer needs, designing to meet those needs, and meeting them through production methods as well as design. But this is all quality focused and driven in all phases and stages of design and deployment for use. QFD is not a one time process, but it is an ongoing iterative process for systematic, incremental and disciplined improvements in product and process. It generally includes prototype development and study of performance standards and requirements, general feasibility studies, pre-market studies of quality desired and needed, and overall cost projections related to achieving quality. As organizations continue shifting toward concurrent engineering methods, this stage will also include determining and preparing control systems for production, facilitating a reduction in lead time to go to production. Finally, as design moves forward, we must determine and define quality standards and characteristics which translate into production, to be tracked and logged per customer demands and input.

QFD helps build quality into the product by verification through component and product testing under simulated operations/service conditions. This part of the QFD process requires that the product as designed must be determined to be produce-able in existing facilities. If not produce-able under existing conditions, the question becomes what will costs be involved in making changes to attain or maintain quality? The bottom line is, to determine what the functional requirements of the product or system are, we must allow quality to be built in around the requirements, and produce the product accordingly.

**Ongoing process control plan.** The "ongoing process control plan" (OPCP) is designed to document key methods, techniques and other general information used in the processing applications for the product under discussion. This includes process

name, tools for production, process parameters, product characteristics, and possibly other specific process oriented information particular to this product, the emphasis being placed on better understanding the processes involved in producing the product. Second, the OPCP is designed to identify and document key customer information and expectations in the form of specifications, evaluation method, sample and inspection, analysis and reaction methods, and perhaps other information vital to controlling and improving the processes involved.

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

The OPCP is a dynamic as opposed to a static document, an important lean management tool. Systems used to maintain the information must be built to respond in a timely manner for enhancements to the system--including all involved both internal and external. The OPCP is important procedurally:

- OPCP is a "correct" way to do processing, setting fundamental benchmarks in total process to help us know as much as possible about our own process.
- OPCP is based on other detailed information and documentation such as engineering drawings, customer feedback, test results, statistical process control information, gage analysis results, among others, all to be improved and changed over time.
- OPCP, as a "total document" about processing a particular product, is our best defense for broad customer relationships in the future.

All of this assumes we continue building around the OPCP system to document our procedures based on strong "team" and "cooperative" attitudes, and a willingness to continue teaching and learning from one another, to change for improvement.