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**Linking ISO 9001:2000 Requirements**

**to**

**Product/Service Quality**

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# LINKING ISO 9001:2000 REQUIREMENTS TO PRODUCT/SERVICE QUALITY

## Abstract:

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From the time the ISO 9000 series of quality management standards were released in 1987, there have been concerns that certification of a quality management system did not necessarily assure stakeholders that conforming product or service would be delivered to the customer on time. These concerns continued when the standards were revised in 1994 and again in 2000, and to a<sup>1</sup> large extent, continue today. In 1995, with the initial introduction of QS-9000, it was thought that things would get better. QS-9000 was followed by other sector-specific standards, e.g., TL 9000, AS9100a and ISO/TS 16949. All of these have the common goal of delivering high quality product or service on time, thereby achieving customer satisfaction. What many organizations miss or do not understand is the linkage between each requirement and product/service quality. This paper focuses on those aspects of ISO 9001:2000 that directly affect customer expectations regarding product or service quality and delivery. Insights from the view of an accredited registrar will be presented, including suggested auditing techniques that will identify those areas of a quality management system that could be weak, the goal being to make it proactive, predictive, and robust, as opposed to reactive and detection focused.

## I. INTRODUCTION

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Since its introduction in 1987, ISO 9001 has been the target of criticism and considerable debate. Much of this is due to a misunderstanding and misapplication of the requirements. Some practitioners of quality disciplines view the requirements as too generic to be of any significant value. Some organizations view certification as simply the “ticket” for doing business. Purists state that it is physically impossible to manufacture products or deliver services defect free on a continuous basis. And some organizations view certification to be just one more mandated cost, a cost for which there is no return on investment.

In 1979, Phil Crosby created quite a stir in business when his book Quality is Free<sup>1</sup> was published. What Mr. Crosby was saying is that “quality,” that is, a product or service that conforms to requirements, is the natural outcome of a well-planned and implemented manufacturing or service business. It is “non-quality” that results in the extra, profit limiting, cost to business. Simply said, if you plan correctly, make product or deliver service correctly, provide on-time delivery, you will make money – assuming your pricing is correct and affordable.

With the introduction of ISO 9001:2000, the business world now has a generic model for a quality management system that, when designed, developed and implemented, will provide the framework for assuring that customer requirements are defined, quality product or service is made or delivered on time, and that product/service and the management system are improved on a continuing basis. However, with the emphasis on the terms “system” and “process,” many readers of ISO 9001:2000 miss the linkage or tie-in between the specific requirements and

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<sup>1</sup> Quality is Free, 1979, McGraw Hill Publishing

product or service quality. This paper will provide this linkage, sometimes as an overview, sometimes with specific links. The reader will also be provided with a view of the dynamics and interactions of various processes, and hints at what to audit for when assessing the quality management system.

## II. THE INTENT OF ISO 9001:2000

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**1.1a:** *...where an organization needs to demonstrate its ability to consistently provide product (service) that meets customer and applicable regulatory requirements...*

The emphasis here is on the phrase “...consistently provide product (service) that meets customer and applicable regulatory requirements...” The process for achieving this is basically: design and implement a quality management system; define customer (regulatory) requirements; define and provide resources; produce product or deliver service in accordance with previously defined requirements; monitor/measure to assure continued conformance; improve.

Ultimately, there are three goals:

- Produce a quality product (deliver a quality service)
- Provide on-time delivery
- Do the first two at a profit

If there is an effective management system in place, one in which **all** workers (not just those in the “quality” department) play a part, quality and on-time delivery will take place. And, assuming other costs are controlled, and pricing is correct, profits will occur.

## III. THE REQUIREMENTS

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**4.1 General Requirements:** *The organization shall establish, document, implement and maintain a quality management system and continuously improve its effectiveness...*

**Linkage to product/service quality:** This requirement is often referred to as the “umbrella” requirement. It provides the big-picture of a quality management system designed to identify customer needs, produce/deliver in accordance with all applicable requirements and continually improve product, service and the management system. The key factors are: processes; sequence and interaction of processes; definition of criteria and methods to assure controlled processes; provision of resources; analysis of information; actions to implement and improve.

**Dynamics and interactions:** This requirement provides all workers with a framework for understanding the basic elements of a quality management system. It should be used to provide introductory training to all employees regarding what a quality management system is and what their individual roles are. Top management can use this as the starting point for developing the quality policy. Teams can use this when designing or modifying the quality management system. Overall, it provides a simple checklist to assure that nothing has been missed.

**Audit for:** Since this is the “big-picture” requirement, it is not common to execute specific audit actions. Rather, each of the requirements will be viewed in much more detail as the other requirements are assessed. (These assessments will include: determination of conformance, input, transformations actions, output, monitoring and measurements, interactions, effectiveness and, as applicable, objectives.) The user is encouraged to take the time to link each of the requirements in 4.1 to other, more detailed and defined requirements throughout the standard.

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**4.2 Documentation requirements:** *...shall include quality; policy; objectives; manual; documented procedures; needed documents; records.*

**Linkage to product/service quality:** Documentation provides several benefits to all organizations, as listed here:

- Writing things down helps the writer think about what is being documented. In so doing, it is common to identify practices that are not current, stumbling blocks, voids, inconsistencies, and errors.
- Documents provide a vehicle for training new employees.
- Documents provide a vehicle for communicating changes to requirements.
- Documents provide a means to refresh one’s memory, especially for activities that are non-routine.
- Documents can provide consistency in approach among multiples of workers.

All of the following activities serve as communication tools to employees regarding the needs of the customer: product/service directed, as they serve to define the specifics of the product or service; process directed, as they relate to actions needed to provide defect free product/service; improvement related, as they define the monitoring and measuring actions needed to improve product/service and the management system.

**Dynamics and interactions:** Each employee uses documents. Policies provide guidance and direction; drawings and engineering specifications provide technical information needed to make the product or deliver the service; purchase orders provide suppliers with information for materials needed to build quality products or deliver quality service; procedures and work instructions provide information regarding the correct methods for performing work; and so on. Additionally, records provide proof that required actions were taken and that final results met all applicable requirements.

**Audit for:** Effective definition of needed documents (internal and external sources); distribution of documents to those that need to know; control of documents for current revision level, with emphasis on the control of customer-driven changes; dissemination of changes throughout all affected documents; change implementation dates, including disposition of existing material (et. al.) made obsolete by the change; implementation of training necessitated by changes; effective definition of needed records; and detail of records such that conformity of product/service is evident.

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**5.1-5.3 Management commitment; Customer focus; Quality policy:** *Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness; policy; objectives; management review; resources; determination of customer requirements; enhance customer satisfaction.*

**Linkage to product/service quality:** In any organization, the effectiveness of the quality management system is only as good as those persons that are entrusted with executive management authority and responsibility. If they fully understand the importance of a well-defined and implemented quality management system in defining and meeting customer requirements, then all employees will benefit and the needs of customers will be met. However, if top management is focused on other issues and generally relegates “quality stuff” to the quality department, the effectiveness of the quality management system will be compromised. This is not to say that top management must be intimately involved in the day-to-day activities of the quality management system. It is, however, extremely important that top management sets the “organizational compass” on a heading that leads to quality of products/service, all the time, including on-time delivery. Establishing an effective quality policy, setting achievable objectives and never settling for “good enough,” accomplishes this and ensures customer satisfaction.

**Dynamics and interactions:** Top management is the organizational source for delegation of authority and provision of resources. They also control the finances of the organization. When an organization has personnel that are competent and empowered to make decisions, quality resources, and robust processes, the needs of the customer can be met in an effective and efficient manner.

**Audit for:** These requirements are somewhat like 4.1 in that they are an overview of top management responsibilities. Many of the elements of these three clauses will be expanded upon in subsequent clauses. For these clauses, review the quality policy to assure that it addresses customer needs and continual improvement, and ask for evidence of the means that top management took to communicate the importance of customer requirements and applicable statutory and regulatory requirements.

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**5.4 Planning:** *...establish quality objectives; plan the quality management system; maintain the integrity of the quality management system when changes are planned and implemented.*

**Linkage to product/service quality:** It should be obvious to anyone in business that, on a consistent basis, quality of product/service cannot be achieved via happenstance. Yet, many organizations do just that. They take orders based upon potential sales dollars, assuming that “those guys in production will get it done.” However, without a plan, “those guys in production” have to rely upon their wits and determination. It would be far better if there was a plan, one in which: all affected parties participated in its development; where materials were correct in composition and quantity; where workers were trained; where processes were defined, robust and reliable; where customers’ needs were defined and understood by all. And, as with all good plans, objectives need to be defined so that it is not necessary to wait for input from the customer to know how well (or not well) the organization is performing. And lastly, as we all know,

changes occur. Dealing with changes in such a manner that the quality of product/service is not compromised is the mark of an effective quality management system.

**Dynamics and interactions:** Planning for quality is best accomplished via team effort. Input should be gained from the customer, engineering, manufacturing (service), purchasing, sales, and human resources. Only when input from each of these functions (processes) is obtained, evaluated and integrated into the overall scheme will quality be assured.

**Audit for:** Assess the overall approach to quality planning. Determine if teamwork was utilized. Look at the documents that result from the quality planning process, e.g., control plans, work instructions, routers, travelers. Determine if there are adequate objectives established at key points in the process that will provide early warning for those times when the processes deviate from defined criteria.

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**5.5 Responsibility, authority and communication; management representative:** *...assure that responsibilities and authorities are defined and communicated...*

**Linkage to product/service quality:** In an effective quality management system, everyone has responsibilities, but few have authority. Responsibility has to do with duty. For example, everyone is responsible to perform assigned work in accordance with the approved and authorized requirements, assuming that both are correct. Authority has to do with making decisions that are binding upon the organization. For example, the chief engineer has the authority to approve new and modified designs. Tying the two together: An operator has the responsibility to use tooling, materials, and gages to make quality products. Inspectors have the authority to accept or reject product. Once rejected by an authorized inspector, the material stays rejected until it is either corrected by approved methods or is deviated by a function that is authorized to make such determinations, such as a material review board. Responsibility and authority are typically defined and documented (communicated) in job descriptions, procedures or work instructions.

The position of a management representative is a key function within an effective quality management system. This position represents the standard and the registrar (in those cases where the organization has been certified). One of the required responsibilities of the management representative is to communicate to the workers the importance of customer requirements.

**Dynamics and interactions:** Only persons that are qualified and competent should be granted authority for decisions that affect quality. In the ideal organization, authority is driven down to the lowest level where it can be effectively implemented and controlled. Of course, implicit in granting authority is the need for defined criteria by which decisions are made. Authority without criteria will always result in inconsistency and confusion.

The management representative will often be the point of contact with the registrar and customers. As such, he/she must be competent and be granted sufficient authority such that the integrity of the quality management system is never jeopardized.

**Audit for:** Look for veto power on quality planning teams. Determine if those directly involved with production or service delivery have the authority to control further processing if nonconforming conditions are detected. Assess those decisions that involve the disposition of nonconforming conditions to be sure that those making such decisions are genuinely authorized and competent to do so. Additionally, review the qualification and authority of the management representative to assure that he/she can competently represent the standard and the registrar and has the authority to effectively implement and maintain the quality management system, especially in times of change.

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**5.6 Management review:** *...review the QMS at planned intervals; suitability, adequacy, effectiveness; opportunities for improvement; input; output.*

**Linkage to product/service quality:** Management review is one of several requirements that can be thought of as support processes – those not an integral part of product or service realization, but important nonetheless. There is an old saying “You can’t see the forest in the trees.” In an effective quality management system, management review can be thought of as looking at the forest, while internal auditing can be thought of as looking at individual trees. Just as in a forest, both views are needed to properly assess its health, so it is in an organization. Since all authority and resources flow down from top management, it is necessary for top management to periodically review the QMS – from their perspective. Customer feedback is a required and essential part of this review. The output of the review is a series of actions, some dealing with things gone wrong (corrective action) and things to do (preventive action or continuous improvement).

**Dynamics and interactions:** Management reviews are typically held two to four times per year. Since it is the entire QMS that is being reviewed, input should be obtained from all key process owners. The meeting is best executed if these process owners are also in attendance. The standard lists required input and output, however, the organization should not feel limited to these.

**Audit for:** Frequency of meetings; minutes of last two or three meetings; attendance list; actions specified and follow-up; data input; role of management representative; input regarding pending changes that could affect the QMS.

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**6.1-6.4 Provision of resources; Human resources; Infrastructure; Work environment:** *...provide resources; implement and maintain the QMS; improve its effectiveness; competent personnel; training and effectiveness of training; infrastructure (buildings, workspace, associated utilities, process equipment, support services); work environment.*

**Linkage to product/service quality:** There is another old saying, “ You can’t make a silk purse out of a sow’s ear.” In other words, if an organization wants to make quality products or deliver quality services each and every time, there needs to be: competent workers; quality materials;

capable equipment; robust processes; clean and safe work areas; good lighting; sufficient flow of utilities; ongoing training, with a means to measure effectiveness of this training.

**Dynamics and interactions:** Resources comprise the “stuff” from which a quality product or service is derived. No product can be made, or service delivered, by any one specific resource. It takes the interaction of materials, equipment, machines, buildings, utilities, and people (to name but a few). Thus, all processes and functions must work together toward the common goal of delivering a quality product or service on time, and do it consistently.

**Audit for:** Review personnel records for a cross section of employees, including top management. Assess the process whereby each has been determined to be competent – be sure to look for criteria upon which these decisions were made. Tour the facility, looking at the buildings overall, condition of equipment (office, factory, and, if service, the vehicles used for service), lighting, safety equipment. Feel free to ask for capability studies for key processes.

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**7.1 Product realization:** *...plan and develop processes needed for product realization; shall be consistent with other processes; objectives and requirements of product; verification and validation; monitoring, inspection, test; criteria for acceptance; records; suitable format...*

**Linkage to product/service quality:** Clause 5.4 addressed the “big picture” of the quality management system. Clause 7.1 addresses planning activities specific to product or service. It clearly requires that processes be defined, that these processes be compatible with other, non-product related process, that criteria for product/service acceptance be established, and that the means to monitor, inspect or test be developed, implemented, and controlled. All of this is to be accomplished **prior** to the start of production or initial delivery of service.

**Dynamics and interactions:** In most organizations, there are three classifications of processes: those **directly necessary** for product or service realization (e.g., design, purchasing, receiving, steel blanking, forming, welding painting); those that **immediately support** product or service realization (e.g., human resources, gage calibration); those that are **general in nature** (e.g., internal audits, management review). Clause 7.1 pulls all of these together so that the collective effect of the planning function will be thorough to the point that the results of first-time-through actions are 100% successful.

**Audit for:** Look at how the organization has defined its processes, how planning for quality has been executed, and overall effectiveness of first-time-through production or service delivery. Assess the adequacy of product/service related objectives, monitoring and/or measurement points – all based on actual records.

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**7.2 Customer-related processes:** *...determine customer requirements; requirements not stated but necessary; statutory or regulatory; review of requirements prior to acceptance of the order, including changes; resolve differences; organizational ability; records of reviews; communication with customer, including customer feedback...*

**Linkage to product/service quality:** The sales (read – contract review) process is the starting point for all organizational transactions. It is the process whereby requirements first get defined. It may also be the process whereby changes are introduced. Based on input from this process, resources are defined and obtained, products/service get designed, product/service delivery processes get defined, and product/service realization is initiated. Requirements may include engineering specifications, quality system requirements, delivery, quantities, packaging, visual standards, communication links, and a whole range of others. From the customers’ perspective, once they execute a purchase order, they fully expect the organization to meet all requirements, all the time (read – zero defects, on-time delivery).

**Dynamics and interactions:** Information gained during the contract review process provides direct input to the quality planning activities, and where applicable, the design process. It will also provide the basis for supplier selection and evaluation. As applicable, it may also define customer-supplied materials, including software and tooling. From all of this, the product/service realization processes are defined. Once production/service commences, customer feedback will happen. The organization must address this feedback, especially if the feedback is negative (read – customer complaints).

**Audit for:** Determine how the organization assures complete and thorough contract review. (Checklists are positive tools for this purpose.) Determine how the organization integrates its own expertise into the review process – to protect the final customer from erroneous or unsafe requirements. Determine the effectiveness of contract change implementation, including disposition of existing material or product. Determine extent of customer-provided property. Assess the effectiveness of customer-organization communication, with emphasis on negative feedback, e.g., customer complaints and responses.

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**7.3 Design and development:** *...plan design and development; stages, review, verification, validation; responsibilities and authorities; manage interfaces; input (functional and performance, statutory and regulatory, information from previous designs, other; review for adequacy, completeness, unambiguous, no conflict); output (meet input requirements, provide appropriate information, contain criteria, safety and proper use); periodic reviews; verification; validation; control of changes.*

**Linkage to product/service quality:** The old adage about “starting right, finishing right” is fitting when considering design and development activities. Design personnel have key responsibility for assuring that customers receive what they want, that products work as intended, are safe, and continue to perform reliably. Similar issues are applicable to the provision of service. Of secondary concern, but also important, is the cost of materials. Design documents provide purchasing with information with which to buy quality products and manufacturing/service information regarding product/service realization. The design function is also typically responsible for administration and control of changes to the design on an ongoing basis.

**Dynamics and interactions:** In most organizations, design activities take place pretty much in the engineering department. However, the standard does require periodic reviews. It is during

these reviews that a multi-function, team approach should be taken. Recommended functions include: engineering, manufacturing, human resources, purchasing, sales, quality control, the customer, or someone to represent the customer.

**Audit for:** One of the most effective methods for assessing the effectiveness of the design process is to examine the records of a major design project, from beginning to effective implementation in manufacturing or service delivery. It is imperative that the ultimate, finished design documents (drawing, specification, instructions, etc.) meet customer requirements in all aspects. Also, assess the effectiveness of implementation of design changes. In all cases, look for how problems were identified and how they were resolved. In the vast majority of cases, verification will be executed by the organization. In some cases, validation may be shared with the customer. In rare cases, validation is executed entirely by the customer. Regardless, the organization has responsibility for both verification and validation and must have records to show the results of each activity.

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**7.4 Purchasing:** ... *assure conformance of purchased product; type and extent of control; evaluate and select suppliers; re-evaluation; records; purchasing information (approval of product, procedures, processes, equipment, qualification of personnel, QMS requirements); verification of purchased product.*

**Linkage to product/service quality:** There is a computer expression that applies equally well to the issue of purchased product “GIGO – garbage in, garbage out.” In other words, the quality of the finished product or service can never be any better than the materials from which they are made. From start to finish, there is a chain of dependency that stretches from “mother-earth” all the way to the finished, delivered product or service. Any break in this chain has the potential to lead to nonconformities, some of which will be small and inconsequential, some of which have the potential to be catastrophic. Buying decisions based solely on price have, at best, a limited benefit. Without quality, these “cost-savings” decisions have the potential to undermine the outgoing product or service, and ultimately lead to the demise of the organization.

**Dynamics and interactions:** The purchasing activity does not, and cannot, perform as an island. Input typically comes from engineering, or, in the case of contract manufacturers, from customers. Supplier selection should involve quality control, engineering and manufacturing personnel. Output, in the form of RFQs, purchase orders and contracts must reflect the requirements as defined and approved. On-going monitoring of supplier performance depends upon the cooperation of many functions, primarily manufacturing or service delivery personnel.

**Audit for:** Look for evidence that the purchased product is ordered and received exactly as required by customer requirements. Assess the process whereby suppliers are originally approved and evaluated on an on-going basis. If suppliers have been “grandfathered,” look for the criteria upon which these decisions were made. Evaluate purchasing documents for clarity and completeness of requirements. Assess how the organization verifies the purchased product – typically receiving inspection, but may be source inspection at suppliers’ sites.

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**7.5 Production and service provision:** *...plan and carry out production and service provision; controlled conditions; information; work instructions; equipment; gages; inspection; release, delivery, post-delivery; special processes; identification and traceability; customer property; preservation of product.*

**Linkage to product/service quality:** As the saying goes, “This is where the rubber meets the road.” This clause puts into action those things necessary to successfully produce a product or deliver a service. If the organization has effectively implemented the requirements of the previous clauses, product provision and/or service delivery will take place in an efficient, defect-free manner, and on time. The sub-clauses in this clause address various actions that, taken collectively, provide added assurance that events will take place as planned and that customer requirements will be met. Some are aimed at providing information and/or instruction to workers regarding the applicable requirements. Some are intended to provide various degrees of control as products move through various operations. Still, others are intended to provide information to workers and management relative to the ongoing control of processes.

**Dynamics and interactions:** Contract review, design, purchasing, human resources, quality planning - to name a few functions, all work together to provide manufacturing and/or service with the resources needed to produce a quality product or deliver a quality service – on time, every time. These functions continue with their involvement long after production starts or service commences.

**Audit for:** Of all the requirements, this one should be the “easiest” to audit, and one where effective auditors will spend the lion’s share of their time. Interview personnel for competency; review machinery records for process capability status and preventive maintenance history; review in-process and final inspection and test records for evidence of product/service conformity; in cases where product/service records indicate nonconformities, assess the resultant actions for containment and, if re-work occurred, evidence that product was re-inspected or tested and subsequently found to be acceptable; check for product identification and quality status throughout the production process; if there are any special processes (e.g., welding, plating, heat treatment), determine if process controls are adequate and if personnel have been qualified against defined criteria; check product in storage for proper packaging, labeling, storage, protection; if there is customer-provided product, check to see if it is being controlled in accordance with defined procedures.

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**7.6 Control of monitoring and measuring devices:** *...determine monitoring and measurement to be undertaken; and gages; processes for monitoring and measuring; intervals; standards – traceable to national standards; adjusted...identified relative to calibration status; safeguarded; protected; assess validity of previous results if gages are found to not conform, including action with gage and affected product; records; validity of software.*

**Linkage to product/service quality:** Although all the clauses in section 7.0 are important, clause 7.6 is of special importance. This clause deals with gage calibration. Gages provide vital information about the conformance of product or services. Without this information, the organization would be “running blind,” sort of like a pilot in a plane, at night, in the fog, and no

instrumentation to serve as a guide. Even with gages, troubles can occur, especially if they are out of calibration.

**Dynamics and interactions:** Gages and test equipment provide the organization with vital product conformity information. In one sense, gages are the “ears” of quality. They “listen” to the goodness or non-goodness of a product. It is up to the employees of the organization to receive this information, analyze it, and react in accordance with approved procedures and in the best interest of customers. Remember, decisions based on bad data are almost as bad as making decisions on no data – both can have devastating results for an organization.

**Audit for:** Check gages for calibration status – compare to written records; check gage calibration standards for required accuracy; if records indicate that a product was accepted with gages that exceeded their limits of accuracy, determine if subsequent containment and investigation actions were effective; pay close attention to records for gages calibrated by outside services – check “as-received” and “as-returned” data values; observe care and treatment of gages throughout the organization; if software is an integral part of measuring devices, determine if the output of these devices was validated using alternative methods

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**8.1 Measurement, analysis and improvement – General:** *...plan, implement monitoring, measurement, analysis, and improvement processes; demonstrate product conformity; ensure conformity of the QMS; continually improve effectiveness of the QMS; includes, as applicable, statistical methods.*

**Linkage to product/service quality:** There is an axiom in business that states: “If you don’t measure it, you can’t manage it.” This clause addresses the need to measure and analyze the output of systems and processes and the characteristics of products to ensure continuing conformity. This clause also requires that information obtained from these measurements be used to continually improve the effectiveness of the quality management system.

**Dynamics and interactions:** The requirements of this clause affect the entire organization to varying degrees. Based on the results of the quality planning process, objectives have been established, monitoring and measurement methods have been implemented, and data is being analyzed – from all relevant functions and levels throughout the organization. This information is then analyzed for conformance. If conformance is not present, corrective action is taken. If conformance is present, decisions are made regarding where to expend resources to achieve improvements. The focus is not just on product – it is on all facets of the organization, including systems, processes, equipment, personnel, and so on.

**Audit for:** Assess the thoroughness and effectiveness of the quality planning process relative to monitoring and measurement practices. Follow resultant audit trails to determine if conformance is present, if, as appropriate, corrective actions are taken, and if decisions are being made regarding continual improvement actions that are consistent with the quality policy.

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**8.2 Monitoring and measurement:** *...monitor customers' perception regarding organization's ability to consistently meet requirements; methods; conduct internal audits; monitor and measure processes; monitor and measure products*

**Linkage to product/service quality:** Without customers, there can be no business. Without satisfied customers, no organization can survive very long. Even if an organization produces defect-free products and delivers on time, all the time, customer dissatisfaction can occur due to undefined issues, e.g., prompt technical support, returned phones calls in a timely manner, and the way phones are answered. Hence, it is imperative that managers pay close attention to feedback from customers. The feedback can come reactively, from the customer, or the organization can take steps to proactively gain feedback. Reactive feedback from customers is, more times than not, negative in nature – something has gone wrong.

In clause 5.6, management review, the view of “forest and trees” was introduced, with the forest view being that of top management. Internal audits can be thought of as looking at the “trees,” that is, the organization’s policies, procedures, work instructions, other documents, and records. In any organization, variation is often the culprit when problems occur. If one assumes that the planning process was executed in an effective manner, and that processes are robust, then the expected outcome will be realized – a quality product or service delivered on time. An effective internal audit system will detect when planned arrangements are straying, allowing for corrective action. It will also identify areas for improvement.

All processes, to one degree or another, have in-process output, and thus can be monitored or measured. Injection molding machines have temperature and pressure indicators; heat treatment furnaces have temperature and gas mix indicators; and so on. Monitoring simply means watching, no data are recorded. Most supervisors spend a good part of their day monitoring processes via simple techniques, such as listening to the sound of a machine, looking for leaks, listening to input from process operators. Measurements, on the other hand, typically require someone to read a gage and record a measurement. This information is then subjected to analysis, perhaps via statistical process control.

All products have characteristics – size, weight, color, hardness, and so on. Those characteristics that are important to form, fit, function, reliability and safety need to be identified during the quality planning process. Also, the organization must define criteria for acceptance for each characteristic included in the quality plan, as well as at what stage in the process monitoring or measurement take place, including, as applicable, records. No product is to be released to the customer unless there are records that conformance has been achieved or, if not, that the customer is in agreement.

**Dynamics and interactions:** Of all the clauses in the standard, this one brings together many differing but related functions within an organization. Internal audits will assess the conformity and effectiveness of all processes. Processes throughout the organization will be either monitored, measured, or both. (This includes processes such as sales, purchasing, design and training, to name a few.) Products will be measured and assessments of conformity will take place. The results of all of this will be analyzed. Records will be maintained.

**Audit for:** Determine the methods the organization uses to measure customer satisfaction. This may be reactive (customer provided) or proactive (organization initiated). If negative data are present, assess the effectiveness of actions taken. Review the internal audit schedule to determine if all elements of the quality management system are being assessed and if, as warranted, corrective actions are taken in an effective and timely manner. Determine which processes have been designated for monitoring and/or measurement. Assess the data generated from these actions; same for product characteristics (inspection). Pay particular attention to final inspection records – determine if all required inspections or tests have been executed and if results demonstrate conformity to requirements. If there are any cases where shipped product did not meet requirements, determine upon what authority the release occurred.

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**8.3 Control of nonconforming product:** *...nonconforming product is identified and controlled; defined controls and related responsibilities and authorities; documented procedure; action to eliminate detected nonconformities; authorized concession; actions to preclude use (if nonconformities are not corrected); records.*

**Linkage to product/service quality:** Even in the best of systems, things can occasionally go wrong, resulting in defective product. The emphasis in this clause is on preventing defective product or service from being delivered to the customer. In the case of nonconforming product, there are always two considerations: First, contain and correct the product; second, initiate positive corrective action to ensure that the root cause is identified and prevented from recurrence. Similarly for service: First, acknowledge the situation and take whatever steps are required to re-capture lost customer satisfaction; second, same as for product.

**Dynamics and interactions:** In many organizations, teams of qualified personnel are involved in the disposition of nonconforming product. These teams are often referred to as MRB teams (material review board). The requirements of sub-clause 8.5.3 (corrective action) come into play to identify root causes and institute effective and permanent corrective action. These teams often have as members the same personnel that executed the quality planning process.

**Audit for:** Tour the facility and observe for effective identification, and where warranted, isolation of nonconforming product. Assess the effectiveness of subsequent actions. Ensure that those making disposition decisions are qualified and authorized to do so. If customer or regulatory agency input is required, be sure that it was obtained as part of the decision making process. If product was reworked or repaired, check records to ensure that it was properly re-evaluated before being released for use, or, if the disposition was “scrap,” that the proper actions were taken to preclude use.

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**8.4 Analysis of data:** *...determine, collect, analyze data; demonstrate suitability and effectiveness; evaluate where continual improvement can be made; including: customer satisfaction, product conformity, characteristics and trends of processes and products; opportunities for prevention; suppliers...*

**Linkage to product/service quality:** Information is the lifeblood of any organization. Properly produced, collected and analyzed, it provides an effective status update for maintenance of processes, product and suppliers. It also provides the baseline for improvement and the means to know when improvement is either achieved or not attained. Without such information, an organization has no way of knowing whether or not it is being effective and successful. The collection of information should start with the sales function and extend through all processes, direct and support, and should include information about suppliers. Also, information about customer satisfaction is a key indicator for organizational strengths or weaknesses.

**Dynamics and interactions:** All relevant functions are to be monitored and/or measured. Information gathered from the varied functions (processes) is analyzed to determine if conformity is achieved, if corrective action is needed, or if improvement projects should be initiated. No function (process) stands alone as an island. Personnel from these various functions continually interact with each other. The output of these interactions is a quality product or service delivered to the customer on time. When either is missed, the information generated provides a means to analyze where the system failed and leads to corrective action. And after some time, when quality product and service is achieved on a continuing basis, improvements can be initiated to make the system even better. It takes involvement of all functions, at all levels, to be successful.

**Audit for:** Determine what information is being collected, the means of collection, and the process for analysis. Information should be gathered from processes throughout the system, including suppliers. Customer satisfaction information could be provided directly from customers, or it could be proactively collected by the organization. Determine if this information provides the organization with a clear picture, either positive or negative. The analysis of collected information could be accomplished by the use of various statistical techniques. If so, determine if these techniques are being utilized in accordance with sound mathematical principles. Determine what actions are taken as a result of data analysis, including corrective, preventive and improvement actions. Assess the effectiveness of these actions.

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**8.5 Improvement:**...*continually improve effectiveness; by use of policy, objectives, audits, data analysis, corrective and preventive actions, management review; corrective actions; preventive actions...*

**Linkage to product/service quality:** Continual improvement begins only when processes are working according to plan, products and/or service are in conformance and delivery is on time. If these conditions do not exist, actions taken to bring things back into conformance are deemed corrective actions. So, continual improvement means “raising the bar” on a planned basis, making good better, and better best. It is what allows an organization to maintain its competitive edge. Corrective actions must be executed in a timely and effective manner. True root causes must be identified, or else the problem will surely recur. (“Operator error” is not a root cause; it is a symptom.) Also, corrective actions must be implemented in such a way that new problems are not created. Preventive actions result from planning activities. There is a tool, developed by the aircraft industry and widely used by the automotive industry, called the FMEA or Failure Mode and Effects Analysis. It is a tool that allows users to analyze process steps or

characteristics of product/service from three perspectives: severity of effect if failure occurs, likelihood that failure will occur, and likelihood that, if failure occurred, it would be detected prior to delivery to the customer. Properly and effectively applied, this one tool can result in huge cost-avoidance savings. (Refer back to the Introduction and Phil Crosby's book, Quality is Free.)

**Dynamics and interactions:** As with other activities, continual improvement, corrective action and preventive action lend themselves to the team approach. Sales personnel will be a continual source of input from customers regarding likes and dislikes. Design personnel will continually work on ways to improve product function and reliability and reduce cost. Manufacturing or service personnel will continually try to find ways to do more with less. Human resources personnel will continually seek qualified employees and develop training for changing needs. The same team that performed the quality planning function should be involved in preventive action planning. Management must provide the needed resources to all of these activities to ensure the effectiveness of the quality management system, as well as the overall success of the organization.

**Audit for:** To assess continual improvement, determine what objectives have been established by the organization. Determine if projects are on track. (Objectives may be product/service or system related.) To assess corrective actions, review inspection records and resultant corrective actions, with emphasis on customer complaints. Pay particular attention to: containment actions, rework or repair actions, root cause analysis, implementation actions, and verification actions. Assess historical data to see if problems recur. To assess preventive actions, review records from planning meetings. Investigate actions taken to see if they were effective at preventing the identified failure mode.

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#### IV. CONCLUSION

Clearly, there is a distinct link between all of the requirements of ISO 9001:2000 to product or service. The standard provides a basic format for any organization around which it can organize and develop a quality management system that is focused on defect prevention and continuous improvement. However, as with any normal population, there will be variations in the degrees to which organizations take the requirements to heart. Some will simply give it lip service, relegating the requirements to the "quality people." Others will spend some time and money to create a conforming system, obtain certification, and then let it lapse because of "more pressing issues." However, there will be a distinct group that will embrace the requirements as a way of life and, in so doing, will create a culture upon which customer satisfaction and growth can be achieved. Which group do you want your organization to fall within? The choice is yours.

## **APPENDIX – Process auditing**

Clause 0.2 talks about the process approach. What this means is that the production of product, or delivery of service, results from a series of operations, some of which are sequential and some of which are parallel. However, all are needed to be successful, and, all are linked in some manner or to some degree.

Auditing to the 1994 revision level of ISO 9001 was mostly done element-by-element or clause-by-clause. Some called this the “silo approach to business” in that the activities of the various processes within an organization could be evaluated for conformance on a stand-alone basis, oftentimes without regard for the relationship with other processes. The process auditing approach is different. Simply stated, it is an approach to auditing that can start with any process, with audit trails that can go backward, forward, or sideways. In so doing, the auditor will assess not only the conformance of the production process, but also those processes that feed or draw from it, as well as those that support it. Following are four simplified examples for demonstration purposes:

### **Example:**

The A&A Screw Machine Company designs and manufactures specialty fasteners. It has the following departments: sales, design, purchasing, manufacturing, shipping and receiving, quality control, administration (including management), human resources. The manufacturing department has the following operations: Op-1 (screw machine); Op-2 (precision machine), Op-3 (identification stamping), Op 4 (degrease and clean), Op-5 (plating), Op-6 (packaging).

**Approach 1:** The auditor may start at Op-2. Information is gathered, such as part number, operator name, identification of gages in use (if any). While at Op-2, the auditor could assess the conformance of the operation to planned arrangements. From there, the auditor could move “upstream” to Op-1 and determine if this operation was in conformance before product was moved to Op-2, or move “downstream” to assess how the product from Op-2 is handled to assure conformance. The auditor could also go to human resources and verify the qualifications of the operator and go to the quality control department to verify the calibration of gages.

**Approach 2:** Similar to Approach 1, start at Op-2, gather information, assess Op-2 for conformance. Move on to engineering (design) and assess the effectiveness of the design process. From there, go to purchasing to assess supplier qualifications. Move on to receiving to determine if the material being utilized at Op-2 was conforming as received.

**Approach 3:** Start with management review records. Take note of objectives. Move to those functions where monitoring and measurement are occurring. Compare current results with objectives. Look at the minutes of management review meetings. If there were any actions planned, follow up to determine status. Assess the process whereby resource needs are defined and allocated. Determine if planned actions have taken place and if results are as expected.

**Approach 4:** Start with customer complaint records. Determine if root causes have been identified. Assess the validity of any corrective and resultant preventive actions. If operator

training was required, move to human resources to check records. If material changes were recommended, move to engineering to determine if the specifications have been changed. Move on to purchasing to determine if revised material is ordered and if receiving criteria have been changed to reflect the revision.

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