ISO 9001:2000
Interpretation and Upgrading

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INTRODUCTION

I learned about the ISO 9000 group of standards in about 1990 when this gal (whom I admit - I really didn't like - she was 'commercial', I was a Mil-Spec kind of guy) gave me a copy of the standard. She told me they would be a bed-rock standard in the 1990's (she was obviously right). Well, by golly, I picked up the copy and read it. I pretty much laughed at the time. Being involved in government work, these things were all givens considering a contract taken as a whole. I saw ISO 9001:1987 (I did not particularly consider ISO 9004:1987 'suggestions') as a minor, yet significant, sub-set of every government contract I had ever worked on. It was 'Good Business Practices' to me. No more and no less. No sweat. "This is it?" I said to my self back then... I read it, studied it, and talked to people about it. I focused on it. Not much here I told myself. The basics were evident almost every place I have worked. The documents didn't seem very demanding or explicit. ISO 9001 was the most comprehensive, yet it only specified that elements basic to a minimal Quality Assurance program be in place. But there was one overlying theme - documentation must exist to support systems and processes. This was not particularly exciting to me. Working in military electronics manufacturing, intensive documentation was a given.

At that point I joined the documents with a matrix I had developed earlier in a systems integration effort. The matrix expanded slightly, however most of the ISO 9001 elements were already customer requirements. I kept coming back to the documentation theme. I spoke with numerous people about the ISO 9000 documents. Most were ignorant of their existence. The ones who knew of ISO 9000 and had the actual documents all had differing criticisms. Most said things like "Well, ISO 9000 doesn't really relate or compare to ....". I spoke with one fellow and as we were talking, he brought up the subject of traceability. The fellow told me he believed ISO 9001 would force him to serialize each item his company produced. I told him I read the paragraph (ISO 9001:1994, para. 4.8) to say traceability is required to the extent the process and product warrant traceability. Obviously a metal stamper putting out several thousand parts a day is not going to serialize every part. Serialization typically would serve no purpose. A stamp (ink or metal impression) of a lot number would be appropriate, but not individual serialization. We bet a beer on it. My friend called the next day and said when he reread the paragraph. 'to the extent the process and product warrant traceability' was the key. I won a beer.

Since that initial exposure to ISO 9000, I have seen terror in peoples eyes. Though the document is short, people I spoke with seemed to have lost their ability to read and interpret. It was as if people would pick up ISO 9001, for example, and close their eyes before they began to read. The document took on a mystical air. What is it? What will it make us do? All of a sudden it appeared an alarm had gone off. I heard ISO 9000 this, ISO 9000 that. My amazement grew as I watched ISO 9000 become a growth business. People were running to seminars, hiring 'Top Guns' to evaluate and instruct them, and generally running amuk (as far as I'm concerned, amuk is the best description) in their pursuit of 'compliance'. I spoke with people who attended seminars - some came out with a 'revelation'. Others left the seminar in utter confusion, looking for a 'consultant'. And consultants there are - about everywhere today.

So - what is this mysterious document? What does it really ask? What does it require? I'll try to put it in perspective here.

The Key To ISO 9001 Compliance Is Matrixed, Integrated, Living Documentation and employees doing what they are supposed to be doing. It is all really just Good Business Practices.

Yes, minimal quality assurance systems and several minor related elements are necessary. For the most part, the required elements are good business practices anyway. Their form is not dictated. The main thrust of ISO 9001 is to force companies to be Consistent through 'Living' Documentation. It forces a company to define its self, its systems, and its processes.

As you start your journey, look closely. As you go through your initial GAP ANALYSIS look closely. Many times you will find that you are, in fact, already doing what is necessary for compliance.

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That's it! That's all there is to it believe it or not. Well, then again my statement should be tempered. The effort required to reach compliance depends entirely upon the state of the individual company. Many companies have all their systems documented but the documentation is not matrixed and timely. Some companies have absolutely no documentation (Frank knows exactly how to do that job...) and they produce products of excellent quality and value. Some companies have excellent documentation which was written 5 years ago, looks professional, yet has never been updated to reflect changes over the years. Everyone knows the procedures are there, but no one follows them. In one plant someone told me he 'doesn't prescribe to that procedure'. He knew he had a better way to do it, but rather than change the existing procedure, he did it his own way.

Keeping documentation current is not as formidable a task as it was even a couple of years ago. Relatively cheap technology, networked PCs, allow a company to keep documentation simple and current (Living). For example, one no longer needs a special group to produce work instructions with illustrations. Scanners can input sketches, prints, etc. with ease quickly. Distribution can be by electronic mail or masters may be kept on a network server for reference by personnel. The system still has to be overseen by someone, however if set up correctly minimal time need be spent on 'maintenance'.

An Early Implementation Flow

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[Assemble ALL Personnel and Explain The Program, Goals & Implications]
→ [Flow Chart Current Operations/System (Story Board) & Define Cost of Quality Elements]
→ [Assemble & Flow Chart All Forms and Document Systems]
→ [Rough Out Procedures, Quality Plan, Systems Manual, & Supplier Manual]
→ [Determine Missing Required System Elements]

[Propose & Flow Chart Missing Required System Elements]
→ [Evaluate & Agree On New System Elements]
→ [Begin Detailing Quality Assurance Plan, Supplier Requirements Manual]
→ [Begin Writing Formal Quality Assurance Procedures & Detail Base Training Programs]
→ [Contact Suppliers & Customers As Necessary]

[Train Personnel & Implement Major Procedures & Systems]
→ [Work On Low Level Procedures, Work & Inspection Instructions, SPC, Etc.]
→ [Maturing Process - Continuous Improvement, System Monitoring, Etc.]
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Why Now, So Suddenly?

This is not really 'all of a sudden'. We have been watching for years as Japan and other countries have embraced Quality Assurance and provided reliable products we want, often at prices lower than we can produce them for here in the United States. The drive for common standards has actually been on for over 15 years. The ISO first documents were released in 1987 - they were published as standards nearly 15 years ago. The fact is, many

companies are just now considering compliance because world markets, as well as markets internal to the United States, are demanding compliance as a basic element for doing business. Many companies are finding their customers are requiring an ISO 9001 compliant system as a condition of doing business. Compliance can be initially somewhat expensive, so many companies have held back believing compliance might not be worth the effort. But as more and more companies require ISO 9001 systems as a minimum of their suppliers, more and more companies are seeing compliance as necessary to sell their product. In short, if a company doesn't comply, fewer people will buy their product.

Why Common Standards?

As the world 'shrinks', it becomes more important for common rules and standards to exist. As an example, we can use two states. You live in Indiana and want to buy something from Utah. There are Federal regulations and standards which define safety standards for both states. This protects people in both states by defining 'common' safety requirement for products each produce. With 'common' safety standards, you can confidently buy something made in Utah and know it is safe (as defined by regulations/ standards). In fact, the ISO 9000 series was initially conceived to assure safety compliance in a unified Europe.

The ISO standards attempt to provide common definitions, directions, intentions, techniques and requirements for basic Quality Assurance Systems in manufacturing and other business systems. But they aim not only to provide these basics, they also provide a method to evaluate systems and processes while providing data which will allow for the identification of problems, as well as cost reductions. They do not yet address Continuous Improvement, but the revisions next year do.

The focus and purpose of the standards is ultimately to:

1. Continually Meet Customer Needs and Wants
2. Provide Customers With What They EXPECT
3. Provide Confidence To A Company
4. That It Is Providing The Best Possible Product
5. Provide Confidence To A Purchaser
6. That They Are Getting The Best Possible Product

So we can see two things. The standards have been around for a while and they are an attempt to provide a common basis on which to design a basic system. But what is the focus? What is the Bottom Line?

The Bottom Line is:

For compliance with ISO 9001, a company must have a documented Quality Assurance program with a demonstrated management involvement - Total Quality Management. The key word here is documented! Written policies and procedures are the significant part of the program, although it is written with guidelines. A company must have a somewhat detailed, defined Quality System, yet the main thrust is that company systems are written - which is not as easy to put together as it looks on first glance. Policies and procedures are more difficult to write than they appear to be on the surface. They must be clear, concise and fully inter-related. Some people will say writing a good, matrixed Quality Assurance Plan, company Policies, and Procedures is a true art. This has long been seen in Military Manufacturing Systems and is now significant in automotive and other progressive businesses.

For a company which has no documented systems, the first move is to flow chart systems and integrate systems within the flow charts. Next comes flow charting and integrating required systems which do not currently exist. Then comes writing procedures which describe the details of the flow charted systems. This is more time consuming and expensive than most people initially think. It is a lot like writing a book - a detailed book.

Lets look at some of the basic reasoning behind the Quality Systems elements of the standard guidelines contained in ISO 9001:

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First it says there must be a written **Quality Policy** which defines a company's objectives and commitment to Quality. By requiring a written policy, it makes a company think about its goals and forms a promise. Just as if I write you a letter and tell you I will do something, a written statement helps define what I am saying. In addition, it tends to make what I say more definite - more of a promise than if I just say I will do something.

Next, the standard says the company must be organized and defined. This part of the specification forces a company to define responsibilities. It defines responsibilities by position, not name. For example, a Quality Assurance Manager is responsible for certain things. The position is a defined element of a 'company tree' which not only shows the position, but who the position answers to, as well. And the position the QA Manager answers to is responsible for performance. A "Company Tree" delineates responsibilities from the top down.

The next part of the specification says the company must have a defined, documented **Quality Management System**. Just like defining the company organization, the Quality System must be documented to define who is responsible for what. The reason for this is to provide assurance that a company produces items which conform to specified requirements. Specified requirements? When a product is designed there are requirements stated. For example, when a door panel is pressed it must be made of a certain material. It must conform to certain standards set by the designer such as having no scratches or dents. These requirements are not just for the operations necessary to make the door panel, however. It must be pressed, packaged and shipped in a way to arrive at the customers facility with no dents or scratches. So handling, storage and shipping are included in the plan. The main point is that an over all plan must exist to encompass events from receipt of material to shipping.

Document Control is another part of the standard. This section says simply that all documents which affect manufacture of a product must be controlled. What are documents? They include procedures, specifications, drawings, forms and tags and other manufacturing paperwork. Why control? Control keeps old drawings, forms, and such from being inadvertently used. Lets say you buy something which requires assembly. If the company which makes that item does not have control over the instructions it includes to guide you in assembling it, it could send you old, outdated instructions or even instructions for another item. Which would not make you happy. It is the same with documents used inside a company. They must be controlled to assure that the latest, correct paperwork is being used. In manufacturing, work instructions, prints, inspection instructions and other product related documents must be controlled.

Purchasing. Yes, even purchased material used to manufacture a product must be controlled. As an example, lets say you want some meat for a cook-out. You go to the store and buy what you want. You assume the store has bought inspected meat which is fresh, disease free, and if the label says it's beef that it is beef and not horse meat or something else. Maybe you order ground round. You don't want to be sold cheap hamburger and pay for ground round. The same idea is important in manufacturing. If a customer wants a company to make something, they specify what materials to use. It is necessary to be absolutely sure that what the specification calls for is what is ordered.

Process Control. The goal is consistency. The specification says processes must be defined and carried out under controlled circumstances. What this means is when we make something, we must do it the same way every time. Lets take the cook-out example from earlier. You want to make potato salad to go with the meal. While you might not use a written recipe, you try to use the same ingredients every time if you want the potato salad to taste the same as last time you made it. If you find a taste you really like, you will probably write down exactly what you put in it and how you made it - a certain number of hard boiled eggs, a certain amount of mustard, etc. You may cook the potatoes for a certain amount of time and boil the eggs for a certain number of minutes. The same is true in manufacturing. To make the same thing exactly the same way every time, you have to have detailed, defined, documented controlled processes. Presses are set up the same way every time, pressures are the same, etc.

Inspection and Test is another requirement of the specification. This part is pretty self explanatory - it states that everything produced must have an inspection and, when applicable, a test plan to assure (verify) that product is being constantly produced in accordance with the specification. This includes material coming in for processing as well as what is being produced. Above we spoke about purchasing, about how we want to be sure what we buy is what we ordered and what we are told by the supplier is true. In the same way, we want to be sure what we

produce is all made the same and is what we say we will be selling to others. And we want objective evidence which verifies this. Lets say we make a part for a car. If the process gets off of center - say a punch on a die breaks and we don't notice it - we want to have a definite way to keep a documented check that every thing is going well and nothing has broken or changed. We do this by planning an inspection procedure prior to production and following it strictly through out the production process. In every day life we want meat companies to test for Salmonella bacteria contamination. That is an inspection.

Inspection, Measuring and Test Equipment. Simply put, this says that instruments we measure with - specifically tools we use in production to inspect or test with - are calibrated to the same international standard. This assures that everyone in the world who measures something is using the same unit of measurement. In short, it makes it so that "everyone is measuring the same inch" (or millimeter, or volt or whatever). We wouldn't want to buy a steak for our cook-out from a butcher shop whose pound was not as heavy as ours - we could end up paying for a pound and only getting 3/4 pound by our measure. You have seen this for years at gasoline stations, as another example. The government checks the pumps once a year and 'certifies' them to make sure the gas station is giving you a standard, defined, consistent gallon when the pump says it gave you a gallon.

Non-conformance. This system provides for identification of non-conforming (bad or out-of-specification) product, whether it is material being received or product in the manufacturing process. It says such material must be identified by a tag or other means and separated (were possible) by segregating it from everything else. In industries which make smaller products, the offending items are supposed to be segregated and put in a special room which is locked to prevent any unauthorized use. When I work with military electronics companies this is literally done - the items are locked up and must be accounted for to the government - the way the item is destroyed or otherwise disposed of. All of this has to be documented with objective evidence (proof) of what they did with it! Obviously at most companies we cannot separate everything which is non-conforming into a separate room! Many things are just too big or numerous. But they (or their container) still have to be identified with a tag (or something) which stands out to let everyone know it is non-conforming product and is not to be used in production.

Corrective Action works hand in hand with the non-conformance system. This system says that non-conformance must be investigated to determine the cause of the failure (a non-conforming item is produced by a failure of a process, operator error, etc.). The idea is simple - we want to be able to look at problems we have and find ways to stop them from happening again, or at least as often. This saves the company time and money. Lets take the potato salad example. You wrote down the recipe so that anyone can make it so that it tastes just like yours. You give me the recipe so that I can make some for you (let's say we want to sell this tasty delight), but I just cannot get the same flavor yours has. Mine would be technically non-conforming. We both have to make potato salad which tastes exactly the same if we want to sell it and have the customer get the same taste whether you made it or I made it. I just cannot get the eggs right. We investigate and find that the stove I use does not heat up as fast as yours does. So the eggs I put in are not cooked as well as yours. From there we adjust my cooking time so that we both cook the eggs to exactly the same temperature and then the potato salad I make tastes just like yours and we can sell it. The same happens in manufacturing. When we make something and a problem comes up, we investigate to determine what caused the problem so that we can prevent it from happening again.

Internal Audits are another important part of the specification. Audits are a check on the systems we document and say we use. What auditors normally do is look at what is written and then go out to the production floor and verify that what is written is what is happening. As an example, if I'm making potato salad for you, once in a while you would want to come over to my place to watch me make it so that you are sure I am making it according to the recipe (specification), to verify that the taste is the same and to verify that the environment is clean/sterile. Audits are also made by outside companies, but they must also be made within a company yearly, but by employees, of each system and procedure to make sure the company continues to do what they have written they are doing.

It is important, after systems are defined, written and in place, for everyone to know and perform in accordance with documented procedures. It is also important for everyone to know what to expect when an auditor comes in from an outside company to verify our systems.

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Training is the last major topic of ISO 9001 we'll discuss here. This area simply says that procedures for identifying the training needs of employees must be established and written. In order for an employee to be able to perform his/her job (production, inspection, purchasing, or whatever) properly, they have to be trained An example might be where one is using a lathe, or, using our earlier meat example, cutting meat from a side of beef. Even a custodial engineer must know how to wax a floor properly, however in the arena of production knowing how to do ones job is seriously important. If an employee is expected to perform a function, he/she must know how - which is the reason for training.

These are not all of the requirements, but this should provide some *basic* insight ISO 9001 and 'what it's about'.. Now. On to the meat of this standard.

THE "CONSISTENT PAIR" OF QUALITY MANAGEMENT STANDARDS

The revised ISO 900**1** and 900**4** are designed to constitute a "consistent pair" of standards. Their structure and sequence are identical in order for easy transition between the two.

The revised standards were restructured in order to provide a more 'user-friendly' introduction of Quality Management Systems into an company. The common structure of the two standards follows the typical format of the main processes of an company and enables the Quality Management System to be aligned to its operations.

Aims and Mission

The primary aim of the "consistent pair" is to relate modern quality management to the processes and activities of an company, including the promotion of continual improvement and achievement of customer satisfaction. It is intended that the ISO 9000 standards have global applicability. Therefore, the factors that are driving the revision process, among others, are:

* Applicability to all product categories and to all sizes of companies. (Note that the ISO 9001:2000 definition of "Product" also includes "services"!!)
* Simple to use, clear in language, readily translatable and easily understandable.
* Ability to connect Quality Management Systems to company processes.
* Provision of a natural stepping stone towards Total Quality Management.
* Greater orientation toward continual improvement and customer satisfaction.
* Compatibility with other management systems, such as ISO 14000 for Environmental Management.
* Need to provide a consistent basis and address the primary needs and interests of companies in specific sectors such as aerospace, automotive, medical devices, telecommunications, and others.

In this way, all companies, whether private or public, large or small, producing manufactured goods, services, or software, are being offered tools with which to achieve internal and external benefits.

In the revisions of the standards there is a single Quality Management Requirements standard, ISO 9001:2000, applicable to all companies, products and services, which will replace the former three quality assurance standards ISO 9001:1994, ISO 9002:1994 and ISO 9003:1994. ISO 9001:2000 should be used for the certification of Quality Management Systems and may also be the basis for contractual agreements. ISO 9004:2000 is the Quality Management System Guidance standard. ISO 9004 is designed to go beyond quality management requirements to a *holistic* approach to quality management in pursuit of operational improvement and benefits to all interested parties.

PERMISSIBLE EXCLUSIONS

Under the new ISO 9001:2000 standard, you may ignore or exclude some requirements. Requirements that may be ignored under special circumstances are known as permissible exclusions. According to ISO, you may ignore or exclude any of the requirements found in Section 7 (Product Realization) if you meet certain conditions.

You may exclude or ignore Section 7 requirements **if**:

* Your products are such that some Section 7 requirements don't apply n your situation.
* Your customers' requirements make it reasonable to exclude or ignore selected Section 7 requirements.
* Your regulatory requirements allow you to exclude or ignore selected Section 7 requirements.

However, you may **not** exclude Section 7 requirements if doing so reduces your ability to provide products that meet the requirements set by customers and regulators.

In other words, you may **not** ignore any Section 7 requirements if doing so will undermine your ability to provide products that meet requirements or compromise your willingness to accept the responsibility to do so.

The permissible exclusion clause is significant because it makes implementation more flexible and conformance less rigid. Now you're more likely to end up with a quality management system that not only complies with ISO's standards but also meets your company's unique needs than was formerly the case.

CLAUSE INTERPRETATIONS

The first thing to remember is:

There is a lot of overlap in the clauses where one section requires the data, another mandates you review it, and yet another makes you show what you did about the information.

4   QUALITY MANAGEMENT SYSTEM

Control of Quality Management Processes

Note the change from Quality System in the 1994 version to the current Quality Management System.

At a recent training course on implementation of ISO 9001:2000, process sequencing and interaction were, obviously, one of the major issues. According to the auditors responsible for the training course (from an international certification body), they would expect companies to go further than just identifying their processes and indicating their sequence and flow (for example, on a process map or flow chart). They understood "interaction" or "interdependence" to mean possible effects of one process on another, thereby identifying ultimate effects of the process on customer satisfaction. For example, if your design process doesn't work well - where are you going to detect this in (any or all of) the subsequent processes and what measures are you going to take to control / correct / improve it. In the exercises we were given to illustrate this, process interaction, in this light, was not an easy thing to identify!

A detailed analysis of the Standard reveals that an ISO 9001:2000 Quality Management System is made up of 21 base processes (22 if you recognize that the Quality Management System as a whole is also a process).

1.   Quality Management Process
2.   Resource Management Process
3.   Regulatory Research Process
4.   Market Research Process
5.   Product Design Process
6.   Purchasing Process
7.   Production Process
8.   Service Process
9.   Product Protection Process
10.   Customer Needs Assessment Process
11.   Customer Communications Process
12.   Internal Communications Process
13.   Document Control Process
14.   Record Keeping Process
15.   Planning Process
16.   Training Process
17.   Internal Audit Process
18.   Management Review Process

19. Measuring and Monitoring Process
20. Nonconformance Management Process
21. Continual Improvement Process

Unless you are new to ISO 9001, these should remind you of the ISO 9001:1994 structure.

Each of the 21 processes uses inputs to generate outputs. All of these processes are interconnected using these input-output relationships. The output from one process becomes the input for other processes. Because of this, inputs and outputs are, in fact, the same thing. In order to ensure that you understand what we're talking about, we've provided the following incomplete list of some general types of inputs/outputs:

1. Products
2. Services
3. Information
4. Documents
5. Reports
6. Records
7. Results
8. Needs
9. Data
10. Expectations
11. Requirements
12. Complaints
13. Comments
14. Feedback
15. Resources
16. Measurements
17. Authorizations
18. Decisions
19. Plans
20. Ideas
21. Solutions
22. Proposals
23. Instructions

In summary, an ISO 9001:2000 Quality Management System is made up of many processes, and these processes are glued together by means of many input-output relationships. These input-output relationships turn a simple list of processes into an integrated system. Without these input-output relationships, you wouldn't have a Quality Management System.

For those of you who have gone through an implementation with me, you should already have gone through process mapping and document mapping. This being the case, you should understand this input-output methodology. It is not new – it is **business as a process**. In fact, your systems should already be appropriately represented to comply with this new 'systems' model.

4.1   General Requirements

NOTE: There are no new requirements for General Requirements.
Also see: 5.4.2a, 7.1

The company ***shall*** establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of ISO 9001:2000.

2 What is a "document"? - Definitions and references

The following are some of the main objectives of an organization's documentation, independent of whether or not it has implemented a formal QMS;

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a) Communication of Information
*   as a tool for information transmission and communication. The type and extent of the documentation will depend on the nature of the organization's products and processes, the degree of formality of communication systems and the level of communication skills within the organization, and the organizational culture.

b) Evidence of conformity
*   provision of evidence that what was planned, has actually been done.

c) Knowledge sharing
*   in order to disseminate and preserve the organization's experiences. A typical example would be a technical specification, which can be used as a base for design and development of a new product.

A list of commonly used terms relating to documentation is presented in Annex A (taken from ISO 9000:2000). It must be stressed that, according to ISO 9001:2000 clause 4.2 *Documentation requirements* documents may be in any form or type of medium, and the definition of "document" in ISO 9000:2000 clause 3.7.2 gives the following examples:
*   paper
*   magnetic
*   electronic or optical computer disc
*   photograph
*   master sample

Also see ISO/TR 10013 *Guidelines for quality management systems documentation* for further guidance.

The company *shall*:

a) Identify the processes needed for the quality management system and their application throughout the company (see 1.2),

ISO 9001:2000 actually defines the minimal processes related to a company. Essentials such as a nonconformance system and control of customer supplied product.

•   Determine the sequence and interaction of these processes,

Use Process Mapping to comply. This is the reason we go through the process of asking what your products and processes are. We are looking at what is done, how it is done and what effect one system has upon another.

•   Determine criteria and methods needed to ensure that both the operation and control of these processes are effective,

This talks about criteria and methods of control. It comes into play where we discuss how checks are decided upon such as content of audits performed (e.g. Customer Service Audit Form). A 'process audit' is one methodology. The audit criteria is the audit content. Note that both effective and control are key words here.

•   Ensure the availability of resources and information necessary to support the operation and monitoring of these processes,

This requires feedback from a number of sources including management reviews. The contents of management review meetings as determined by the standard (the 'minimum') can not be static. This is to say you must be able to show that you react to information. One might interpret this to require that management reviews have information inputs from processes such as internal audits and process audits, not to mention performance and other data. Key word is availability.

e)   Monitor, measure and analyze these processes, and
(See: Section 8)

f)   Implement actions necessary to achieve planned results and continual improvement of these processes.

This is a reference to a number of sections of the requirements including corrective action. Note that continual improvement is essentially first used here. This requirement is new to the year 2000 version.

This is a 'standard' intro. In general the standard defines the required elements. However, those in section 7 may be 'opted out of [See 5.4.2 (a) and 1.2 herein]. But beware – if you decide one or more of the paragraphs in section 7 are not applicable to your company, **you will have some explaining to do**.

Design is one area often opted out of particularly by companies in a service industry. I suggest that you take a serious look at design in your company. There are several basic discussions on design in the service industry at http://Elsmar.com/Forums/showthread.php?s=&threadid=2691. Food for thought.

These processes *shall* be managed by the company in accordance with the requirements of ISO 9001:2000.

Where a company chooses to outsource any process that affects product conformity with requirements, the company *shall* ensure control over such processes. Control of such outsourced processes *shall* be identified within the quality management system.

NOTE   Processes needed for the quality management system referred to above *should* include processes for management activities, provision of resources, product realization and measurement.

The General Requirements of clause 4.1 are met if the specific requirements of clauses 5 through 8 are met (i.e. have you established a system that meets the requirements of ISO 9001:2000) - Could be audited as follows:

Review quality manual to determine if a systematic approach is defined for:

1) Identifying and managing QMS processes (or elements) in accordance with the "process approach" defined in clause 0.2 and Figure 1 of ISO 9001:2000 identifying and showing the relationship between the following QMS processes (or elements) and their related sub-processes: Clause:

*   Management Responsibility
*   Resource Management
*   Product Realization
*   Measurement, Analysis and
*   Improvement

2) Ensuring the criteria, methods, information and responsibilities for managing QMS processes are in place.

3) Ensuring that data is collected, analyzed and used to assess QMS process effectiveness and to identify needed actions or improvements.

Likewise, The General Documentation Requirements of clause 4.2 could be audited as follows:

Review quality manual to ensure required procedures are included or referenced.

Review QMS documentation to determine if documented procedures are appropriate for the size and type of the company, the complexity and interaction of processes, and competence of personnel.

Review QMS processes to ensure they are adequately defined in procedures, process or job descriptions,

work instructions, or other appropriate system documentation.

Procedures may also be "needed" for:
* Planning (5.4, 7.1, 8.1, 8.5.1)
* Communications 7.2.3
* Management Review (5.6)
* Resource Management (6)
* Training (6.2.2)
* Customer Processes (7.2)
* Design and Development (7.3)
* Purchasing(7.4)
* Operations Control (7.5.1)
* Product ID/Traceability (7.5.2)
* Customer Property (7.5.4)
* Preservation of Product (7.5.5)
* Validation of Processes (7.5.2)
* Process Measurement/Monitoring (8.2.3)
* Product Measurement/Monitoring (8.2.4)
* Analysis/ Improvement (8.4, 8.5)

Review applicable standards and statutory/regulatory documents to determine if the QMS identifies required documentation and records.

Review other external or internal documents to ensure QMS identifies documentation and records needed to effectively manage the company's products, processes and activities.

Your QMS can be illustrated in a number of ways. One way to think of it is as a standard fishbone. You have quote review to customer receives product. Along the way there are various inputs. In the extreme, as in starting an entirely new and unrelated product, there will be basics of design including determining processes, inspections and tests, etc. Once established you still review these basics - typically during contract review or RFQ review. Are current inspections and tests sufficient, etc. Your design change process should handle a lot of the documentation (assuming it's not a 'catalogue' item). I.e.: Special length, special hydraulic fittings, special attachments at each end, etc.

If you look at your business as a set of processes and inter-relate them this is not all that hard. The important part is ensuring you are clear about inputs and outputs and intra / inter-system communications.

Remember - if you are looking at a sub-contracted process, you are still responsible for determining critical characteristics and such. While you send the item out for sub-processing (for example plating), it is still a process step and is subject to QMS requirements.

-> 5.5.3 Internal Communication
->
-> Top management shall ensure that appropriate
-> communication processes are established within the
-> company and that communication takes place regarding the
-> effectiveness of the quality management system.

Communications channels are represented in procedures. Management reviews, for example, are communication conduits. Staff meetings are conduits. Shift meetings are conduits. This should be only an issue of being ready to discuss the issue and to be ready with specific examples.

Remember - communication with suppliers is as important as communication with customer and internal communication.

You may want to look through process mapping.

Your QMS is a sub-set of all processes, so if you can illustrate your company processes they will be there. Most of your processes will be QMS related with the exception of some finance and such.

If you're making specialty items on a low volume level your 'process documentation' will be a lot different than in a high volume operation. Other factors are important as well, such as how much training your company does or does not do. My point here is only to say each company is different in how their systems are designed - which is a big reason I warn against canned documentation solutions.

You can do this from the product view, but my recommendation is you do it from a process view.

Documentation Requirements

Guidance on Clause 4.2

a) *Quality Policy and Objectives:*

* Requirements for the quality policy are defined in clause 5.3 of ISO 9001:2000. Because the quality policy is a document, it must be controlled according to the requirements of clause 4.2.3. Some companies that may be revising their quality policy for the first time, in order to meet ISO 9001:2000 requirements will need to pay particular attention to clause 4.2.3 (c), (d) and (g).
* Requirements for the quality objectives are defined in clause 5.4.1 of ISO 9001:2000. They are also subject to the document control requirements of clause 4.2.3.

b) *Quality Manual:*

* Clause 4.2.2 of ISO 9001:2000 specifies the minimum content for a quality manual. The format of the manual is a decision for each company, and will depend on the company's size, culture and complexity.
* A small company may find it appropriate to include the description of its entire QMS within a single manual, including all the documented procedures required by the standard.
* Large, multi-national companies may need several manuals at the global, national or regional level, and a more complex hierarchy of documentation.

c) *Documented procedures:*

* ISO 9001:2000 specifically requires the company to have "documented procedures" for the following six activities:

    4.2.3 Control of documents
    4.2.4 Control of quality records
    8.2.2 Internal audit
    8.3   Control of nonconformity
    8.5.2 Corrective action
    8.5.3 Preventive action

* Some companies (particularly larger companies, or those with more complex processes) may require additional documented procedures in order to implement an effective QMS.
* Other companies may require additional procedures, but the size and/or culture of the company could enable these to be effectively implemented without necessarily being documented.
* In order to demonstrate compliance with ISO 9001:2000, however, the company must be able to

provide objective evidence that its QMS has been effectively implemented.

d) Documents required by the company

To ensure the effective planning, operation and control of its processes:
In order for a company to demonstrate the effective implementation of its QMS, it may be necessary to develop documents other than documented procedures. However, the only documents specifically mentioned in ISO 9001:2000 are:
*   Quality Policy   (clause 4.2.1 a)
*   Quality Objectives   (clause 4.2.1 a)
*   Quality Manual   (clause 4.2.1 b)

*   There are several requirements of ISO 9001:2000 where an company could add value to its QMS and demonstrate conformity by the preparation of other documents, even though the standard does not specifically require them. Examples may include:
*   Process Maps
*   Company Charts
*   Internal Communications
*   Production Schedules
*   Approved Supplier Lists
*   Quality Plans

e) Quality Records

*   Examples of quality records specifically required by ISO 9001:2000 are listed in the list 'Records Required' herein.
*   Companies are free to develop other records that may be needed to demonstrate conformity of their processes, products and quality management system.
*   Requirements for the control of records are different from those for other documents, and all quality records must be controlled according to clause 4.2.4.

Objective evidence that planned document / data control activities were accomplished and/or results achieved in compliance with documented procedures and the requirements of the standard.

For example -

1. Evidence that documented procedures to control documents and data, including those of external origin, related to the requirements of the standard were established and maintained.

2. Evidence of review and approval for adequacy by authorized personnel prior to issue.

3. Evidence that a master list or equivalent document control procedure - to indicate the current revision status of documents - has been established.

4. Evidence that review and approval of changes to documents and data occurred in compliance with the documented control procedures and the requirements of the standard.

5. Evidence that people are prevented from using invalid or obsolete documents.

If a process is documented, then reviewed and approved for use, then in some manner the company needs to make a 'record' of the approval - and that could be any one of a number of ways that they can define themselves. Whatever the method, the result of this activity (document, review, approve, create evidence of results) becomes a 'record', since it's information that isn't going to change - and forever more will remain as proof that the process was documented, reviewed and approved for use on some particular date by an

authorized person, and the revision status of the documented process was stated in some manner. Your choice how you do it. Just show me the evidence and I'll be happy for you.

Documents change - Records do not... (see 3.15 in ANSI/ISO/ASQC A8402-1994 - it refers to a 'document' that furnishes objective evidence (2.19 - which uses the word 'information') , and 3.15 also says the record can be written or stored on any data medium...so with some minor substitutions - a record is a document written or stored on any data media that furnishes information of activities performed or results achieved.

4.2.1   General

The quality management system documentation **shall** include

a) Documented statements of a (1) quality policy and (2) quality objectives,
b) A quality manual,
c) *Documented procedure*s required by ISO 9001:2000,
d) Documents needed by the company to ensure the effective planning, operation and control of its processes, and

This is a decision, or rather decisions, a company makes internally system by system, department by department. The company decides exactly what documentation is needed. Beware an auditor suggesting what documentation s/he believes your company needs. A question to ask yourself is "Does this make good business sense?" Many times 'On-The-Job Training' is quite sufficient. There is no 'Black-and-White' in regard to this which is often the reason auditors take it upon themselves to 'suggest' what documentation is appropriate for YOUR company and YOUR systems.

Several other areas of the standard require documentation as records, but these requirements are a little more vague and can be in forms other than procedures. Does this mean we are off the hook?

No. Note that the standard states that your quality system documentation must include BOTH the procedures required by the standard as well as the documents REQUIRED by YOUR company to ensure the effective operation and control of your processes. As a minimum, 'processes' as defined by the standard, include the things that happen in your company that directly impact the satisfaction of your customer and your company's ability to continually improve. Remember in element 4.1, General requirements, it stated that your company is required to establish, document, implement. And maintain a QMS in accordance with the requirements of ISO 9001:2000. To implement the QMS, the company must identify processes needed for the QMS. So, 4.2 now furthers that intent by requiring you to DOCUMENT those processes that are needed for the quality management system.

This is an intentional(?) gray area left by the standard. Beyond what is stated in the standard, documentation requirements will differ for every company.

As an added aspect to the whole documentation arena, the standard has given us three conditions that the extent of the quality system documentation shall be dependent on. These conditions include the size and type of the company, the complexity and interaction of your processes and the competence of your personnel. Obviously the larger and more complex your company is the more complex your documentation should be, but exactly how complex is up to you and the needs of your company. Time should be spent on deciding just how complex you need you documentation to be, remember that the intent of the standard is not to create and maintain meaningless procedures but to assist in documenting the procedures that will help you to continually improve and best satisfy your customers.

From a client who had just finished their registration audit:

    --> Date: Thu, 24 Jun 1999 16:29:21 -0500
    --> From: XXXX
    --> To: marc@Elsmar.com
    -->

--> Well, as you anticipated, we "passed" with relatively few problems.
--> We had only 7 isolated non-conformities across 5 elements. Details
--> are in the attached file. The auditor said that this was a very
--> good result when compared to other registration audits he has
--> performed. All I can say is I am glad it was successful and Marty
--> said that she was happy to finally win! Once again, thanks for the
--> help. You're advice was extremely important. Especially important,
--> at least in my opinion, was your help in determining where we did
--> not need to document every last thing (by using training, etc.). I
--> think that without this input, we would have spent a lot more time
--> writing things that we did not need and wasted a lot of peoples'
--> time. We were able to get the audit done in a year while we are
--> achieving record sales and profits. Who can argue with that?

Whatever you document, make sure you really need it. If you didn't have documentation up to this point for something, it is highly likely you don't need any now. Use your common sense in approaching documentation needs. This is one of the most dangerous areas of understanding in the standard and is the most common failure mode in registrations (Also see http://Elsmar.com/level2/failure.html for more registration failure information).

Potential Audit Questions:

1. How complex is your quality system documentation now? How many pages are in your quality manual, standard operating procedures, operational instructions and quality system forms? What type "form or type of medium" do you most typically use for your documentation?

2. What is the most important component of your quality system documentation? Are there procedures that you rely upon now that were originally written merely to meet the requirements of the standard? Are there documents that you maintain merely to meet the requirements of the standard but in reality serve no useful purpose?

3. Do you feel that the new standard will require more documentation, less documentation or just a bit of restructuring of what you've already got? Do you like the new approach to documentation in the standard?

e) Records required by ISO 9001:2000 (see 4.2.4).

NOTE 1   Where the term "*documented procedure*" appears within ISO 9001:2000, this means that the procedure is established, documented, implemented and maintained.

NOTE 2   The extent of the quality management system documentation can differ from one company to another due to:

a) The size of company and type of activities,
b) The complexity of processes and their interactions, and
c) The competence of personnel.

Note that these three items allow a company quite a bit of flexibility in deciding what systems, as well as what parts of systems, to document.

Thoughts about 'Objective Evidence':
Objective evidence does not necessarily depend on the existence of documented procedures, records or other documents, except where specifically mentioned in ISO 9001:2000. In some cases, (for example, in clause 7.1(d) *Planning of product realization,* and clause 8.2.4 *Monitoring and measurement of product*), it is up to the organization to determine what records are necessary in order to provide this objective evidence.

See ISO 9001:2000 para 3.8.1.

NOTE 3   Documentation can be in any form or type of medium.

4.2.2   Quality Manual

Also see: 4.2.1b

The company **shall** establish and maintain a quality manual that includes

a) The scope of the quality management system, including details of and justification for any exclusions (see 1.2),

The scope is very important. This scope defined here will be matched against the scope of your registration. Do note that should you plan an exclusion from section 7 you will have to give a documented explanation (reason) rather than a verbal explanation.

b) The *documented procedure*s established for the quality management system, or reference to them, and

Technically by saying "…or reference to them…" this almost allows you to have an index of your procedures with a scope statement. In the strictest sense of the words here - you explicitly have to have reference to your procedures. To comply you simply make a matrix, if you have one, part of the quality manual.

c) A description of the interaction between the processes of the quality management system.

Line item 'c' can best be illustrated through Flow Charts. This is discussed in more detail in 4.1 herein. Key word: Interaction. A top level flow chart is an 'easy fix' to ensure compliance.

A Word About Quality Manuals

I try to pressure client companies to write their own manuals. They almost always do. It's really pretty simple. One key is to not try to write your quality manual and then write procedures to fit it. Start with a matrix and document mapping with consideration to your gap analysis results. Have the main body of the manual (the ISO text) set up and ready. As your matrix fills out, you go to the appropriate section of your manual and insert the appropriate reference. Again, I admit this is redundant because technically you have the matrix.

A Word of Serious Caution

Many companies do insert some additional details in their quality manuals. In fact, some companies have all the relevant level 2 'procedures' in their quality manual. The folks I worked with last winter did exactly this. They inserted flow charts in the MS Word document which was their 'systems manual' (as opposed to calling it a 'quality' manual) in the 'appropriate' sections of their manual. It was still relatively short - maybe 50 pages - and just about everything was there. Departments controlled their own work instructions and such, but for all intents and purposes the main systems are defined entirely within their systems manual.

When I work with a client I often do, in fact, suggest clarification statements here and there throughout the manual.

Look at how your system is structured (including corporate, if you're in a big company - they have many documents which apply to your location {and other locations}, I would bet). Ask yourself what you need in your manual. But - don't go overboard. Don't complicate issues and Don't be redundant!

Take a quick read through http://Elsmar.com/Forums/showthread.php?s=&threadid=2713 for some more thoughts on 'quality' manuals.

4.2.3   Control of Documents

NOTE: There are no new requirements for Control of Documents from the 1994 version.

Documents required by the quality management system **shall** be controlled. Records (*Also see: 4.2.1e*) are a special type of document and **shall** be controlled according to the requirements given in 4.2.4.

A *documented procedure shall* be established to define the controls needed

   a)   To approve documents for adequacy prior to issue,

The originator or whoever is 'responsible' for the document content is the person to approve. It is best to state a departmental functionary rather than a specific name. Some companies, however, are bigger and more complex and may require multiple approvals on one or more documents. There is no requirement, however, for multiple people to approve a document.

   b)   To review and update as necessary and re-approve documents,

The key words are "...as necessary..." Your company may decide procedures are only reviewed when changed. This fulfills the requirement.

The secondary 'qualifier' which confuses people is where it says: "...and re-approve..." which on its face appears to be implying a review unrelated to a change in the document. With some QS registrars the requirement is a minimum yearly review of procedures.

But the ISO document does not say that nor does it give an 'appropriate' timeframe for such review. So - it's up to you.

A discussion may come up from the auditor in how often a document is reviewed for relevance. There is no single answer. What the auditor is looking for is that you ensure that documents do not 'get lost'. Some companies put a 1 year review on certain documents. Some 2 years. Many companies reference documents which were changed within the last year or two and try to explain that this is evidence that documents are being reviewed and changed. But that is **reactive**. The auditor will be looking for some sort of plan or policy (e.g. **policy**: "All departmental managers shall review and re-approve procedures relevant to their department yearly.") They may look for evidence this is in fact happening.

   c)   To ensure that changes and the current revision status of documents are identified,

This is typically done with a database, spreadsheet listing (document matrix), document control software or the like. I have seen simple systems where a read-only directory was established and the document 'matrix' was simply a print of the directory listing. To find current revision level one only had to open the document and check it's header.

   d)   To ensure that relevant versions of applicable documents are available at points of use,

If people need them, they have to be 'readily' available. The definition of 'readily' is open for discussion. In the case of 'work instructions', typically they should be at the place the person does the work. But every company and process is different. The question really boils down to common sense. If a person has a relatively constant need for a document, it should be at hand. But – let's consider the case of a non-conformance procedure. It is not (hopefully) being utilized frequently and as such may be located away from where the person is working. Engineering specifications would most probably be located in the engineering area (yeah, I know – so much is on 'the network' anymore that in some companies this is not much of an issue). With one client the auditor had a hard time accepting the fact that a document in Chicago was readily available in Cincinnati. No, it wasn't online either. Stumped? Think FAX. It was a seldom referenced document. In today's world with all the intranets, this should not be an issue for most documents.

   e)   To ensure that documents remain legible and readily identifiable,

Legible:	This is typically not a problem except with paper documents in greasy or wet environments and the like. At the very least, have a policy on the use of white-out. White-out should NOT be allowed on 'quality records'.
Identifiable:	Title, document number or similar identifier.
Retrievable:	Can we find and get to it? See d) above as well.

One auditor gave a minor, threatened a major, for the use of 'whiteout' by a client employee recently. I lost this challenge, but not based upon "Show me where it says…". He simply said he would not argue – that the use of whiteout made the record illegible. Before you say, "Well, I think whiteout on a data record is a bad idea anyway…" -- This was a daily schedule 'copy' (the original is in the computer), not data per se. The employee explained it was her personal reminder. The auditor added that he expected to see this as a defined quality related record by the next audit. My opinion is the auditor was being an ass and over-stepped the intent. This was a service company – not a military manufacturing facility.

f) To ensure that documents of external origin are identified and their distribution controlled, and

This is an oldie from the original. It is also a sticking point with many companies and auditors. There is no Black-and-White to go by. The trigger is supposed to be "…if a document could affect the quality of the product, it has to be controlled…" This leaves many documents wide open for interpretation. Some are quite clearly applicable (e.g. customer prints). Some are not so clear (e.g. catalogues). For thought, you might want to take a read of http://Elsmar.com/Forums/showthread.php?s=&threadid=2462 (it's short).

The bottom line is: You have to take a good look at what documents and specifications you use and ensure you have identified what documents of external origin you have, which you have to control and why, and what ones you have but do not control and why. This should be an output from your in-house sweeps.

g) To prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

The heart of the matter – to prevent unintended use of the wrong (out dated) document (internal or external). How do you do this? Do you physically retrieve all outdated paper copies? Is everything on the computer? If people can do printouts of documents, how do you ensure they do not use them after the original is revised? Be realistic. The best way I believe is when a procedure is revised, ensure there is a meeting or other method to 'train' the changes. At this meeting people should be admonished to destroy and illegitimate printouts. If you do distribute paper procedures, an email or memo to each person on the distribution list detailing the change and asking them to destroy the old version should be sufficient. Many companies require some sort of response – such as a returned e-mail or a signed memo – to evidence that the person in fact did receive the e-mail or memo and understands the contents, etc.

4.2.4 Control of Records

NOTE: There are no new requirements for Control of Records from the 1994 version.
Also see: 4.2.1e, 5.6.1

Records **shall** be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records **shall** remain legible, readily identifiable and retrievable. A *documented procedure **shall*** be established to define the controls needed for the (1) identification, (2) storage, (3) protection, (4) retrieval, (5) retention time and (6) disposition of records.

The issue here for most companies has less to do with control, but rather with defining what are and what are not quality records. An old rule of thumb was that quality records were defined in procedures (forms and such). Were this always the case this would be simple. But not all are defined in procedures. The old "…does this affect quality…" trigger arises, as vague as it can be from time to time. Defining what records are quality records takes some thought in many cases. Some are obvious such as records of design reviews, purchase orders, results of inspections and internal audit results.

In smaller companies it often makes sense to have a simple Controlled Document Matrix which includes identified Quality records. This is typically simple because quality records typically start their life as a controlled form. An example of such a matrix is included with this package (see Document_Matrix_Example.xls).

On the other hand, in larger companies where everything is on computers, there are many options. There are also software solutions.

RECORDS REQUIRED

Clause	Record required
5.6.1	Management review minutes / etc.
6.2.2 (e)	Education, training, skills and experience.
7.1 (d)	Evidence that the realization processes and resulting product fulfill requirements.
7.2.2	Results of the review of requirements relating to the product and actions arising from the review.
7.3.2	Design and development inputs.
7.3.4	Results of design and development reviews and any necessary actions.
7.3.5	Results of design and development verification and any necessary actions.
7.3.6	Results of design and development validation and any necessary actions.
7.3.7	Results of the review of design and development changes and any necessary actions.
7.4.1	Results of supplier evaluations and actions arising from the evaluations.
7.5.2 (d)	As required by the company to demonstrate the validation of processes where the resulting output cannot be verified by subsequent monitoring or measurement.
7.5.3	The unique identification of the product, where traceability is a requirement.
7.5.4	Customer property that is lost, damaged or otherwise found to be unsuitable for use.
7.6 (a)	Standards used for calibration or verification of measuring equipment where no international or national measurement standards exist.
7.6	Validity of previous results when measuring equipment is found not to conform with its requirements.
7.6	Results of calibration and verification of measuring equipment
8.2.2	Internal audit results.
8.2.4	Evidence of product conformity with the acceptance criteria and indication of the authority responsible for the release of the product.
8.3	Nature of the product nonconformities and any subsequent actions taken, including concessions obtained.
8.5.2	Results of corrective actions.
8.5.3	Results of preventive actions.

THOUGHTS ON WHITE-OUT

From: Nancy Jennejohn <jennejohnn@uwstout.edu>
Date: Wed, 4 Jul 2001 10:24:07 -0500
Subject: Re: Use of White-Out on Q-Records /Robison/Madden

From: Lori Madden <lmadden@semproducts.com>

Regarding Jim Robison's email about using white-out:

It is the auditor's responsibility to determine if the organization is compliant or non-compliant. Period. In my humble opinion, unless the standard states that white-out is not permitted, the auditor has no basis on which to justify writing a finding. True, it isn't the best practice to use white-out (we do not allow it and say so), but if it hasn't prevented the organization's ability to prove they have a suitable and effective QMS, and if it hasn't caused any reason for customer dissatisfaction, leave it.

The standard does say (and I'm speaking of ISO 9000), "Any corrective or preventive action taken to eliminate the causes of actual or potential nonconformities shall be to a degree appropriate to the magnitude of problems and commensurate with the risks encountered." What are the magnitude and risks of using white-out? Sometimes the only corrective action is to do nothing. (If the customer requires that white-out not be used, this should be clearly documented and adhered to. In this case, I would have written a finding also.)

A related issue is the use of pencil. In my document control and record control procedures, it says the use of pencil is not allowed. This may sound petty, but it was brought about because supervisors were signing final approval in pencil and signatures were 'mysteriously' getting erased. We had a stack of batches that had been released without approval, or so it appeared. Our corrective action was to eliminate the use of pencil. I do

write nonconformances if this is not followed. But we have it documented, and our employees also know why it is important.

An auditor who truly is auditing for the benefit of the company will suggest that white-out is not a good idea, followed by examples of why. But write a finding? That's almost as bad as my auditor writing a finding because the page number on the bottom of one of our work instructions had been slightly cut off during copying. I believe a good auditor will also give the auditee the benefit of the doubt. Some issues are a matter of interpretation.

A QMS should work for the organization, not the other way around.

Lori

> From: "JIM ROBISON" <jimrobison@msn.com>
>
> I am an experienced ISO consultant and audit for a nationally recognized
> third party. A client of mine that makes commercial plastic parts,
> recently had a finding from their Registrar on using white-out to make
> minor corrections on their data entry forms, or a few of their quality
> records. The client does NOT have any customer/contractual (or
> regulatory) requirements for not using white-out. The client's procedure
> on records, clearly states that "Due to the nature of the business, that
> white-out is permitted to make corrections on q-records". The client's
> Registrar wrote that "the use of white-out prevents seeing the previous
> entry", which by the way ... was an error that was corrected, by the
> person recording the data as they do their job.
>
> With all due respect to the Registrar, I say the Registrar is incorrect
> & this is personal auditor opinion. I say my client should "appeal" the
> finding, as they feel it does not add value to "scratch through, initial
> & date the correction" as they could do... but they really do not want
> change their process of using white-out, as it makes it neater when they
> run a copy & submit a record to their customers.
>
> Also, recall that it is clearly stated in their current procedure that
> users "ARE ALLOWED" to use white-out to make corrections to data entry
> errors...
>
> In my experience as an Auditor & consultant, I believe that white out
> can be used, provided: 1) No customer or regulatory requirement exists,
> and 2) If their procedure says "it is a permitted practice", meaning it
> is documented in their procedure.
>
> I would appreciate your comments as to the use of "White-Out" & how my
> client should respond to this finding. I say it is an incorrect write-up
> and they should appeal.
>

> Does anybody know of an official ISO document/requirement or know of a
> "sanctioned statement, like in QS-9000" on the use of white-out?
>
> Any thoughts and/or suggestions?
>

****
From: Nancy Jennejohn <jennejohnn@uwstout.edu>
Date: Wed, 4 Jul 2001 10:25:54 -0500
Subject: Re: Use of White-Out on Q-Records /Robison/Solomon

From: Solomon, Jason <Jason.Solomon@EAE.Siemens.com>

I work for a sizable electronics firm, and we have used "white-out" since initial certification two years ago. Our registrar, who is quite picky, has never had an issue with our use of this universal document bandage.

I say, appeal the finding.

Jason S. Solomon

****
From: Nancy Jennejohn <jennejohnn@uwstout.edu>
Date: Wed, 4 Jul 2001 10:28:05 -0500
Subject: Re: Use of White-Out on Q-Records /Robison/Bradley

From: Mark Bradley <mbradley@Ameriqual.com>

The registrar is correct.

It doesn't matter what is written in their procedures, this is a given rule that has been around for ages in quality. If you allow white-out or use of pencils, then data can not only be corrected, but changed to the producers advantage. In other words, out-of-spec results can be changed to in-spec

results. In order to prevent this, it has always been a rule that if a correction must be made to a quality record, the previous value is crossed out, with the new value written in and initialed by the person correcting the record.

Mark A. Bradley

****
From: Nancy Jennejohn <jennejohnn@uwstout.edu>
Date: Wed, 4 Jul 2001 10:30:48 -0500
Subject: Re: Use of White-Out on Q-Records /Robison/Bogoe

From: Søren Bogø   <sb@sbconsult.net>

Use of white-out = loss of credibility - what was originally recorded? Consider these questions: when and by whom was it corrected and what was the justification to alter it ?

Reference to absence of contractual requirement not to use white-out is merely disregarding what quality records are about, and a misconception of what should be achieved by ISO.

just my 0.02$

Soren Bogoe

****

From: Nancy Jennejohn <jennejohnn@uwstout.edu>
Date: Wed, 4 Jul 2001 10:33:30 -0500
Subject: Re: Use of White-Out on Q-Records /Robison/Miller

From: Ray Miller <millerlb@dol.net>

Hmmm... I have never heard of a quality procedure that permitted the use of white-out on a quality record. The practice of casting a line through the incorrect entry, initialing and dating the correction has substantial weight in common practice, even if it is not written in the stone of ISO-9xxx or QS-9001.

A substantial part of the problem with the white-out practice is, I believe, that you now make it impossible to objectively answer the 3 questions, How wrong? How long? Who if anyone was impacted by the error?

If a quantity was transposed, for example 14 is written as 41, and it is caught right away and corrected, there is no impact. If on the other hand, the entry has already gone on into inventory and invoicing, correcting the paper copy without a corresponding transaction in the system will result in potentially serious customer service impact down the road.

I think if the procedure is tightened up to say that white- out is permitted to make corrections -- as long as the record being corrected has never left the hands of the originator or been entered into the computer -- then you would be on firmer ground. I also feel that "Due to the nature of the business" is far too ambiguous. I suggest firming up the language to give reasoning that fits the real world, such as "to ensure that records fax well when we need to send them to customers, white-out is permitted on paper records when ..."

Your problem with the auditor is not that he noticed a problem, but rather that he seems to have asserted what your customer's solution must be. This has often been a topic of debate on this list - the role of the auditor is limited to observing problems, and the job of determining the solution is strictly within the client's domain. As long as the auditor suggests a --potential-- solution that would satisfy him, fine, it's when the auditor says --this is the only solution-- then he puts himself into his client's box, which is wrong.

--Ray

****

From: Nancy Jennejohn <jennejohnn@uwstout.edu>
Date: Wed, 4 Jul 2001 10:36:07 -0500
Subject: Re: Use of White-Out on Q-Records /Robison/Mackenzie

From: James Mackenzie <qualimedd@hotmail.com>

I work in a regulated industry (Medical devices) where whiteout is effectively banned - as are pencils!

The auditor could raise an NCR by quoting from ISO 9001 1994 4.16

All quality records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss.

Retrievable suggests that whiteout conceals the original quality record.

Best Regards,

Jim Mackenzie

****

From: Nancy Jennejohn <jennejohnn@uwstout.edu>
Date: Wed, 4 Jul 2001 10:37:30 -0500
Subject: Re: Use of White-Out on Q-Records /Robison/VanDorp

From: "Darryl VanDorp" <dvandorp@westlandfasteners.com>

Ok,

In a similar vein but not specifically "white-out" we had a pile of "Costing Plans" which we use during our Contract review phase where the individual had taken a bunch of blank forms and signed and dated them, in order to save time he then proceeded to photocopy them (with signature and date) before filling them out.

I made the observation that the intention of the form was to have an original signature vs. a photocopied one. Is this something a registrar would have issues with or am I being too picky?

-Darryl

****

From: Nancy Jennejohn <jennejohnn@uwstout.edu>
Date: Wed, 4 Jul 2001 10:39:21 -0500
Subject: Re: Use of White-Out on Q-Records /Robison/Monnich

From: Herbert Monnich <canink@hal-pc.org>

The registrars auditor needs to have some training. The supplier (the company registered) is the organization that establishes the processes for their organization under ISO 9001 (either 94 or 2000). A customer may request that a particular process be used or a regulatory body may require the use of a process but these are separate from ISO 9001.

Herbert Monnich

5   MANAGEMENT RESPONSIBILITY

5.1   Management Commitment

Top management *shall* provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by:

But who IS 'Top Management'? If it's a small company and the owners do not participate on a regular basis you may want to omit them. In some smaller companies the owners really don't participate much but rather have

'handlers' (such as 'Director of Manufacturing' and 'Director of Quality'). Some companies have only 1 person watching the show (such as 'Manager of Operations'). I have had clients where the company owners were not even at the audit. Even though they 'actively' participated in the business. Their position was that they had designated who top management was and they were not part of it. This doesn't go over well with auditors in general but there's nothing they can actually do about it. Most often the **organizational chart** is what is used to define what positions 'Top Management' consists of.

> Do you think I should "Identify" for clarity sake who (by job title) is defined as TOP
> MANAGEMENT Under terms & definitions?

Depends on how often your organization chart changes and whether the positions are stable. It's a good idea, but don't get caught with something that will keep you 'on your toes'. In some companies management positions frequently change names and new ones come and old ones go. In other companies they are very stable.

a) Communicating to the company the importance of meeting customer as well as statutory and regulatory requirements,

Communicating the importance of these three compliance aspects are done in a number of ways. Company news letters, computer logon screens, from within appropriate company procedures. Some companies have TV monitors which are used for, among other things, 'indoctrination' in the importance of these. Some companies use posters (as is commonly seen in safety programs). Communication also typically takes place in an employees initial training.

Potential Audit Question: How is this done?

b) Establishing the quality policy,

Requirements for the quality policy are defined in clause 5.3 of ISO 9001:2000. The documented quality policy has to be controlled according to the requirements of clause 4.2.3. Some organizations may be revising their quality policy for the first time, in order to meet ISO 9001:2000 requirements, and will need to pay particular attention to clause 4.2.3 (c), (d) and (g).
   *   Requirements for the quality objectives are defined in clause 5.4.1 of ISO 9001:2000. These documented quality objectives are also subject to the document control requirements of clause 4.2.3.

c) Ensuring that quality objectives are established,

Note that here the operative word is objectives. The quality policy must contain objectives. These objectives must be **measurable** objectives (think data). Objectives implicitly imply that you have defined 1 or more measurables to enable you to determine whether objectives are being met or not. These will be looked at closely by your auditor. I suggest that 1 measurable is not going to be enough to satisfy an auditor.

d) Conducting management reviews, and

Management review is first mentioned here, but beware: There are places throughout the standard where the clause or paragraph specifically requires an input into management review meetings. Throughout ISO 9001 there are 'pointers' which indicate that a certain 'item' must be reviewed by or "…brought to the attention of upper management…"

The original 1987 intent of management review meetings was to ensure top management could not claim they did not know what was going on in their company. This has expanded to address issues such as control (e.g. as specified in 4.1 herein).

Management Reviews must be held a minimum of once a year. There is no requirement for 1 single, comprehensive meeting. Often different meetings cover different 'requirements'. Management reviews are typically carried out by most companies. In fact, most companies hold management meetings quarterly, monthly or more frequently. However, often these management meetings are not 'recognized as such

because of the terminology. You should note that in a number of instances this commentary will state something like "Evidence of this should be presented during Management Reviews".

The major required items which must be discussed **once a year** as a minimum are:

Business Planning
Internal Audit Status
Corrective Actions
Preventive Actions
Training Issues and Needs
M&TE & Calibration Issues and Status
Customer Complaints
Resources - Personnel
Resources - Equipment / Facilities
Supplier Quality Activities
Relevance and 'Continuing Suitability' of the Quality Policy
Quality Goals and Objectives
Customer Expectations and Satisfaction

These are typically discussed in terms of raw and statistical data. For example, in reporting on Internal Audits the Management Representative might talk about percentage of audits completed, percentage of open 'findings', and will include any specific problem areas.

Notes must be taken during Management review meetings where these issues are discussed. They need NOT be copious notes, but it is assured that your auditor will want to review at least two successive management review meeting minutes to ensure all required items are addressed. In addition, they will expect to see a carry forward and action on old business with the close out of an 'action item'. My recommendation is to use a FORM (see Mgmt_Rev_Form.xls as an example) to ensure the auditor cannot cite you for not addressing a required item. Again, we are not looking at copious notes. But - we ARE looking for a little bit more than a checklist. A checklist without comments or some type of detail will typically be rejected. At least a sentence or two is required as 'evidence' that a discussion actually did take place.

I also suggest that either a single meeting be held which focuses on the ISO requirements or that a segment of a regularly held meeting be dedicated to the ISO aspect to avoid confusion. It is perfectly acceptable to deal with different issues in different meetings - the confusion will be when evidence is requested by the auditor and knowing what was addressed in each different meeting.

About Customer Expectations

What Are Customer Expectations?

Customer expectations are the customer defined attributes of your product or service you must meet or exceed to achieve customer satisfaction.

Are There Different Types of Customer Expectations?

There are two types of customer expectations, expressed and implied.

Expressed Customer Expectations are:
· Written, e.g., terms of a contract.
· Spoken, e.g., voice of the customer.

Implied Customer Expectations are:
· Too difficult for the customer to clearly communicate.
· Not written or spoken, but very basic to the product or service, e.g., the customer expects wheels on a car.

How Are Customer Expectations Identified?

Here are several methods to help identify your customer expectations.
- · Market research
- · Contractual agreements
- · Focus groups
- · Phone calls
- · Satisfaction surveys
- · Site visits
- · Warranty records
- · Informal discussions
- · News media · competitive benchmarking

Do Customer Expectations Change Over Time?

Customer expectations change over time due to enhancements to products or services by competitors, technological innovations, or improved performance of your process.

It is important to periodically update your knowledge of customer expectations. The same methods used to identify your customer expectations can be used to update them.

e) Ensuring the availability of resources.

With regard to this issue, the auditor will look for evidence that management does consider both equipment and human resources as needs change. Typically this is evidenced in Management Review meetings.

5.1, Management Commitment, correlates with 4.1, 4.1.2.2 and 4.2.1 of the old standard.

The ISO 9001:2000 standard states that top management must provide evidence of its commitment to the development and improvement of your QMS by:

a) Communicating to your company the importance of meeting customer as well as regulatory and statutory (legal) requirements;
b) Establishing the quality policy and quality objectives;
c) Conducting management reviews;
d) Ensuring the availability of necessary resources.

The involvement of management in the new standard is more prescriptive than the old standard. First off "Top Management" is considered to have more responsibility and authority than 'management with executive responsibility'. According to the new standard the management personnel of companies that are responsible for the daily and overall operations now must specifically be committed to quality.

One of the ways top management must prove their commitment to quality is by communicating the importance of meeting customer, regulatory and statutory (legal) requirements. Your may already be communicating the importance of satisfying customer, regulatory and statutory (legal) requirements to various levels of the company. The idea here, however, is consistency, audience appeal and reach. Some companies may only be communicating to limited personnel and missing those who would also benefit from the message. Your message may not be communicated in a timely manner such as when issues are still hot, unresolved and while people still care. Try to communicate the message of quality to all levels of your company, at all times and with enthusiasm.

The second way top management must prove their commitment to quality is by use of the quality policy and quality objectives. For now we are not going to worry so much about the actually policy/objectives, but only on how are they are used by Top Management to prove their commitment. Evidence of their commitment can be as easy as the chief facility officer's signature on the quality policy and quality objectives. A more time intensive, but highly advisable method would be presentations of the quality policy and quality objectives to all personnel. The dates and attendees of such presentations would have to be recorded and kept.

The third way top management must show its commitment is through management review meetings. To record this; use management review minutes, they should record those instances where top management has taken a stand, and has ensured the development and improvement of the quality management system. Such a stand may include the allotment of new resources, the appointment of a person to a team related to quality management system, or the initiation of corrective or (especially) preventive actions. Ensure minutes glow with examples of top management commitment to the customer and continual improvement.

And the final requirement of the ISO 9001:2000 standard for top management to show their commitment to the QMS is to ensure the availability of resources. There are a multitude of occasions where resource requirements are identified throughout the standard. However, the two places that can be counted to identify most of the significant (meaning having an effect on quality) resource requirements occur during management review and quality planning. The review and provision of resource requirements is evidenced by management review minutes for management and a quality planning checklist or equivalent for Quality Planning.

Potential Audit Questions

1. How does your Top Management representative communicate the importance of meeting customer requirements? Does this message reach all personnel at your company or just a lucky few, if any at all? Do personnel believe that top management is genuinely concerned about requirements?

2. Does your top management participate keenly in management review? Is this time used well to learn and work with the quality team?

3. How committed is your top management to ISO 9001 and quality? Do they play an active part, believe in the principles and support the quality initiatives? Do they just want someone else to go get a plaque for the wall, without concern for how it is done? Please explain....

5.2   Customer Focus

NOTE: There are no new requirements in Customer Focus from the 1994 version requirements.

Top management **shall** ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1).

5.2- Customer Focus correlates somewhat with 4.3.2 of the 1994 standard.

This is a new terminology addition to ISO 9001. Currently the thought is this is *in part* evidenced during planning stages. The implementation currently appears to be that the expectation is that customer 'needs and expectations' be determined not only during quality planning but to also be re-evaluated periodically. The words NEEDS and EXPECTATIONS muddy the waters as they are quite open to interpretation. 'Converting' these to 'requirements' implies defining measurables.

The interpretation here is still murky. The question most open to discussion is how a company determines customer 'needs' and 'expectations'. In manufacturing there are tools such Quality Function Deployment. In

essence, QFD (Quality Function Deployment) is a tool to map out product characteristics with customer wants and needs, working to determine the value the customer puts on the characteristics. There is a very brief discussion on QFD with respect to service at http://Elsmar.com/Forums/showthread.php?s=&threadid=1251 . However, QFD is just one tool and it is a 'difficult' one to master. QFD is not a specific suggestion from me – just 'food for thought'.

Converting customer 'needs' and 'expectations' into requirements is less of an issue. If you determine a customer 'expects' quick service, you define what 'quick' is. For example – one service company has determined that 4 hours is the longest a customer would want to wait for a service representative to contact them after contacting the company for service. The company has integrated this requirement into its response system. The question is – How did you determine this?

The big change here is the difference between "Achieving" customer satisfaction and "Enhancing" customer satisfaction. The push for continual improvement is a global characteristic of the new standard, and 5.2 is not an exception.

The idea behind the customer focus requirement is to create a focus on your customers and their satisfaction. This is a necessary requirement for developing, planning and improving upon your company's quality management system. Of course most companies would consider themselves focused on customers and their satisfaction, but what does that mean? What do companies do to ensure their knowledge of customer requirements? How do companies work to **ENHANCE** their customer's satisfaction?

The most common way that companies gather their customer requirements is by initial and repetitive interactions with the customer. Interacting with the customer is the strongest way to get their feedback, but to enhance their satisfaction you may need to be a little more creative. Using tools such as customer surveys, market research and customer feedback forms will help if performed in the right way. Explore not only the customer's satisfaction with the current product and/or service that you provide them but also how they would like to see the product, delivery and service improve. Customers will respond positively to this type of survey as well, knowing that your interests are placed on enhancing their satisfaction.

Potential Audit Questions:

1. What does your company do to understand customer requirements? Is this a structured system? How is this information gathered?

2. Is your company focused on ACHIEVING customer requirements or ENHANCING customer satisfaction?

3. How can your company enhance customer satisfaction? Is it possible for your company to enhance customer satisfaction? If so, what will your company do to continual improve customer satisfaction?

5.3   Quality Policy

Top management *shall* ensure that the quality policy

5.3 Quality Policy
New : To include a commitment for continual improvement. What should I do for my quality policy? Do I need to change them?
Only if you have no statement at this time regarding continually improving the effectiveness of the quality management system.

a)   Is appropriate to the purpose of the company,

This is addressed in a discussion of the company (company) and why it believes that the quality policy contents are appropriate. Discussion of stated objective(s).

ISO 9001:2000
Interpretation and Upgrading

b)   Includes a commitment to (1) comply with requirements and (2) continually improve the effectiveness of the quality management system,

> Key words here are commitment and continual improvement. Continual (continuous) improvement gains a new importance in ISO 9001:2000. Yes – I know – I keep repeating this…

c)   Provides a framework for establishing and reviewing quality objectives,

> Again, we have some ambiguity on how a quality policy can "…provide a framework…". This will be an interpretation issue. As I get more information on this I will include it in this analysis.

d)   Is communicated and understood within the company, and

> Communication of the Quality Policy is carried out in many ways, from company news letters to wallet cards to signs on walls. This should never be an issue during an audit.

e)   Is reviewed for continuing suitability.

> Continuing Suitability of the Quality Policy should be a Management Review meeting item. To ensure all your bases are covered, your Management Review form should address BOTH Relevance and Continuing Suitability of the Quality Policy.

> 5.3 Quality Policy used to be element 4.1.1 of the old standard.
>
> See Quality_Policies_Samples.doc for some examples.
>
> Remember, the quality policy has to be controlled. As with other documents which are subject to revision, this is expected. This implies that the quality policy will change as objective(s) change.
>
> It should be noted here that how a company communicates the quality policy should be carefully considered. For example, if wallet cards were distributed, will you re-issue wallet cards? How will you ensure employees with wallet cards know their card is obsolete after a change? I have seen this happen and it was a distribution nightmare.
>
> The requirement for the quality policy changed a bit from the previous version of the standard. The most significant difference now is that your Quality Policy must state your commitment to continual improvement. The old standard stated the requirement to "…comply with requirements…" The new standard goes a step further and says that your must "continually improve the effectiveness of the quality management system". "Continual improvement" as a new theme continues throughout the entire standard and the quality policy is part of it.
>
> The quality policy can be compared to a company's mission statement. It clarifies why your company is in business and how it plans to stay in business. The people who write your quality policy must understand the vision and purpose of your company. This typically is Top Management. The individuals who draft the quality policy within your company must, at the very least, ensure it is appropriate to your company.
>
> When creating the quality policy remember to specifically identify the requirements that you are committed to meeting. These requirements should be centered around the characteristics your stakeholders and customers are most interested in with your company. For example, a courier service may say that on time, prompt deliver is the most critical factor as far as their customers are concerned. A government agency may include a commitment to environmental stewardship or to making services available to all constituents.
>
> You must now include in your quality policy your company's commitment to continually improve upon the above requirements. In order to do this your company must set objectives for quality. Though this is done in clause 5.4.1 Quality Objectives, the standard requires that quality objectives be directly connected to the quality policy. This connection is made by (in Quality Policy) identifying the requirements that must be met

and (in Quality Objectives) establishing the objectives that indicate whether requirements are met. You also must identify opportunities for improvement (in quality policy) and establish objectives that show the company will pursue the opportunity to improve (Quality Objectives). Confused Yet? Basically, in the quality policy you are going to state what your requirements are and the areas available for improvement, and under your quality objectives you will state how you will go about achieving them.

For the purpose of the Quality Policy requirement you do not have to set the quality objectives, you must only understand the link.

Keep your policy relatively short and sweet, this is not the appropriate forum to show off your writing skills. At the very least ensure your policy includes a statement of commitment to meet requirements (requirements should be summarized into major categories), statement of commitment to continual improvement (identify the type of things you wish to continually improve) and reference to the supporting quality objectives. You must control your quality policy when it has been finalized.

Once your policy has been drafted it must be understood, implemented, communicated and maintained. This is a good job for the CEO, no better individual at your company to color the vision. If he/she is unavailable top management will also be an excellent carrier of the message. Remember that auditors are going to ask employees what the quality policy is (or 'what it means' to them), a quick consistent answer should be available from everyone within your company.

The quality policy must also be reviewed regularly. The best forum for review is a management review meeting. Unless major changes take place within your company a yearly review is satisfactory.

Potential Audit questions....

1. What is your company's mission? Is this stated clearly in your quality policy?

2. Has your quality policy been communicated throughout your company? How is it communicated? Do employees in your company understand and believe in the quality policy? (They will be asked this)

3. What evidence do you have that the quality policy has been reviewed?

5.4   Planning

5.4.1   Quality Objectives

Top management *shall* ensure that quality objectives, including those needed to meet requirements for product [see 7.1 a)], are established at relevant functions and levels within the company. The quality objectives *shall* be *measurable* and consistent with the quality policy.

Element 5.4.1, Quality Objectives, correlates to element 4.1.1 and 4.2.1 of the old standard.

This reference requires multiple quality objectives in addition to what is stated in the quality policy. Remember, each objective requires a measurable for that objective. Most companies have quality measurables of some type established in each department. The requirement is typically met with an explanation of how one or more of these measurables is relevant to a quality objective.

NOTE: Can you distinguish between quality objectives and business objectives?

5.4.1 also states that top management must ensure that quality objectives, including those needed to meet requirements for product are established at relevant functions and levels within the company. It also says that the quality objectives shall be measurable and consistent with the quality policy.

ISO 9001:2000
Interpretation and Upgrading

This clause can be broken down into four parts:

1) Management must establish quality objectives at relevant functions and levels within the company.
2) As a minimum, the quality objectives must include those needed to meet specified product requirements.
3) The objectives must be measurable.
4) The objectives must be consistent with the Quality Policy.

Let's look at each of these in more detail...

1) Management must establish quality objectives at relevant functions and levels within the company.

This is a new requirement. High level objectives must now be supported by detailed objectives that are directly connected to the company. People and departments must now have applicable quality objectives. *The company chart should include a summary by department and level, which identifies the quality objectives of each. The quality objectives of personnel should be included as part of their job descriptions.*

2) As a minimum, the quality objectives must include those needed to meet specified product requirements.

Remember: This Requirement applies to all companies even if it does not specifically provide 'products'. According to ISO 9001:2000, the term 'product' means the result of a process and includes:
   a) Hardware;
   b) Software;
   c) Services;
   d) Processed materials.

3) The objectives must be measurable.

Your company must define how it measures progress towards its objectives. Examples of specific objectives include:
   a) More efficient customer service,
   b) Faster design and development of new products,
   c) Reduction of shipping errors, and
   d) Effective production scheduling.

4) The objectives must be consistent with the Quality Policy.

The objectives should be reviewed regularly, according to Management Review, in order to ensure they remain consistent with the quality policy and commitment to continual improvement.

Potential Audit Questions

1. Has your company's top management defined Quality Objectives at each relevant function and level of the company? If so, please provide some examples of your company's quality objectives.

2. How does your company measure whether or not these quality objectives are being achieved?

3. Do you think that the addition of this requirement to the ISO 9001:2000 standard is a valuable addition?

5.4.2   Quality Management System Planning

Top management **shall** ensure that

a) The planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and
b) The integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

Quality Planning and Service aspect of the ISO 9001:2000 standard. Specifically, how you gather information to form a quality plan for a service. The following procedure is an example:

QSP 120   Service Quality Planning

1   Purpose
1.1   To describe the process to prepare and maintain Service / Quality Plans used by CO LTD.
2   Scope
2.1   A service plan is used, within the constraints of the business operating parameters, to identify the quality system activities required for product and service quality.
2.2   The service plan is typical for all contracts unless a specific contract requires the procedures to differ in which case the service plan is customized to meet the requirements of the contract.
2.3   We provide a copy of the service plan to the customer if required by the contract.
2.4   The typical service plan format is reviewed and updated during the Management Review meeting.
2.5   Unless otherwise agreed during contract negotiations, the format of the service plan is a flow chart illustrating the necessary steps required to effect the Service delivery.
2.6   The Quality Assurance Manual (QAM), the Quality System Procedures (QSP), and the Work Instructions (WI) are integral parts of the Service/Quality Plan.
2.7   Service plans and the associated parts are updated and controlled as required and described in QSP 510, Control of Documents and are retained as quality records, per QSP 1260, Control of Quality Records.
2.8   The major product service categories which follow similar practices is associated with:
   a.   Scientific Research & Experimental Development (S.R. & E.D.) services associated with components, assemblies and products for the toy industry.
   b.   Non-ferrous toy components and assemblies.
   c.   Ferrous toy components, assemblies and products.
3   Responsibility
3.1   The responsibility for the preparation and maintenance of the Service Plan for the above product categories is with the ISO Management Representative.
4   Flow Charts
4.1   Service plan flow charts, form #120-1 is shown as documentation in paragraph 6.1 of this procedure and describe a generic Service Plan for the provision of the product and service categories, per above paragraph 2.8.
4.2   For SR & ED projects, per above paragraph 2.8 a, the generic format for service plans applies. For complex projects where the activities may fall outside the flow chart service plan method, the project management planning and tracking is determined by the Sales & Marketing Manager and the customer during contract review, per QSP 610, and handled per QSP 710, Design and Development.
4.3   As applicable, service planning and the service plan flow chart #120-1, shown in paragraph 6.1, takes into consideration the following integral parts of the quality system:
   a.   the revision of documentation for an existing service plan or the preparation of a new service plan to meet the quality objectives...ref QSP 510.
   b.   the identification and allocation of specific resources, responsibilities and authority required to provide the requested services...ref QSP 310, and QSP 410.
   c.   the identification and assessment of requirements and customer communications to confirm capability to meet customer needs and requirements...ref QSP 610.
   d.   the development of process control work order instructions for the S.R. & E.D. and Production operations and the identification and acquisition of any equipment, resources and skills needed...ref QSP 710 and QSP 910.
   e.   the verification of products at the appropriate stages for incoming, in-process, and final operations...ref QSP 1220-30-40.
   f.   the clarification of acceptance criteria in the form of sketches, drawings, specifications, physical samples or written instructions...ref QSP 610 and QSP 910.
   g.   the identification of the quality records...ref QSP 1260.

4.4   When required to provide additional details the quality system procedures referenced in above par 4.3 may be outlined in flow chart format and used to supplement the main quality/service plan, form #120-1.

References

5.1   QSP 310, Deployment of Personnel
5.2   QSP 410, Management of processes
5.3   QSP 510, Document control
5.4   QSP 610, Contract review
5.5   QSP 710, Design control
5.6   QSP 910, Process control
5.7   QSP 1220-30-40, Inspection and test
5.8   QSP 1260, Quality records
6   Documentation

Service Plan Flow Chart, form #120-1.

5.5   Responsibility, Authority and Communication

5.5.1   Responsibility and Authority

Top management *shall* ensure that responsibilities and authorities are defined and communicated within the company.

Responsibilities and authorities are typically defined within the company's organizational chart(s) as well as within procedures themselves. Some companies, in fact, have no organizational chart but rather rely on procedures to fulfill this requirement. This is typically less of an actual issue than being ready to state this and to provide examples. Company organizational charts do change frequently in many companies, however, which in and of its self can become an issue. In fact, this should be a consideration when writing procedures. If a function name is changed, how will this affect your procedures which reference that functionary.

Thoughts About 'Top Management'

From a posting in the misc.industry.quality NG

The problem lies in assigning equal titles and definitions to every company in the world, which cannot be done. In some companies, a "Managing Director" may be a second tier position; in others, "top management" for the facility undergoing ISO registration may be the Plant Manager, as in the case of a large corporation with multiple sites with various certifications, where the CEO might be so far removed (logically and physically) from that site he plays no role. If my company is a small 12-person software development wing of Microsoft located in Tennessee, is Bill Gates "top management"? Of course not. (Microsoft jokes to follow....)

One of my clients has empowered divisional VP's as "top management" even though the President/CEO is headquartered out of the same site; however the practical reality is that the President's role in this company requires constant international travel and macro management, so it's not practical to have him overseeing the quality system on a regular basis. Quality managers report, during management review, to the VP's, who make all the usual "top management" decisions. A report is sent annually to the President, but no action on his part is required.

In other companies I've had certified, I run into the traditional problem where the Quality Manager/ISO Rep answers to the Production Manager. Sometimes I win that fight, and they change the reporting structure; other times I don't (like when the PM is the president's brother or cousin or something!) In those cases we devise a reporting system specific to issues related to the "quality system" where the ISO Rep has direct reporting access to the President on those issues only. It's not particularly elegant, but it meets the requirements and the culture of the companies in question.

Then there are issues with functional reporting and financial reporting, where a company built on the financial pooling of multiple members creates strange organizational relationships: the maintenance

manager, for example, may also be a full VP, or higher, because he owns 1/3 of the company! He may not be responsible for making daily quality decisions, but when it comes to certain cost factors, you can bet he's involved all of a sudden.

Early on in any implementation you need to identify (1) who is your customer and (2) who is your top management. Defining, and being able to defend that definition, sets the guidelines for implementing 5.5.2 in any company.

5.5.2   Management Representative

Top management *shall* appoint a member of management who, irrespective of other responsibilities, *shall* have responsibility and authority that includes

  a) Ensuring that processes needed for the quality management system are established, implemented and maintained,
  b) Reporting to top management on the performance of the quality management system and any need for improvement, and

This is typically accomplished through the Management Review meeting, as a minimum.

  c) Ensuring the promotion of awareness of customer requirements throughout the company.

  NOTE   The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.

You must have something official (such as a memo or letter or e-mail) which 'officially' designates someone as management representative. There have been discussions in the past with respect to the 1994 version on what level of management this person has (had) to be from. The 1994 revision specifically stated "…with executive responsibility…" As you can see, this has been relaxed in the year 2000 version.

5.5.3   Internal Communication

Top management *shall* ensure that appropriate communication processes are established within the company and that communication takes place regarding the effectiveness of the quality management system.

Communications channels are represented in procedures. Management reviews, for example, are communication conduits. Staff meetings are conduits. Shift meetings are conduits. Forms, as they flow through a system, are conduits. E-mails are another example. This is not just about talking to each other.

This should be only an issue of being ready to discuss the issue and to be ready with specific examples. Ask yourself: "How do we communicate?"

5.6   Management Review

5.6.1   General

Top management *shall* review the company's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review *shall* include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews *shall* be maintained (see 4.2.4).

5.6.2   Review Input

The input to management review **shall** include information on

a) Results of audits,
b) Customer feedback,
c) Process performance and product conformity,
d) Status of preventive and corrective actions,
e) Follow-up actions from previous management reviews,
f) Changes that could affect the quality management system, and
g) Recommendations for improvement.

5.6.3   Review Output

The output from the management review **shall** include any decisions and actions related to

a) Improvement of the effectiveness of the quality management system and its processes,
b) Improvement of product related to customer requirements, and
c) Resource needs.

What should be discussed in Management Review Meetings?

Management review is an extremely important part of the success of your quality management system and your most significant source for improvements. Management review can be used to tie together all the elements of your program and bring cohesiveness to your quality management system. You should focus your attention on "trends, objective evidence, and data based decisions" not on daily operations. As a minimum, the following topics should be included on your management review agenda:

7. Quality Assurance Report: including nonconforming/hold/rework product data, regulatory issues
8. Equipment/Maintenance: may include calibration information, repair & maintenance trending data, equipment downtime.
9. Quality Subcontractors: quality related subcontractors problems and actions, subcontractor trends
10. Customer Complaints: summary of complaints for trending of issues and actions.
11. Corrective and Preventive Actions: type & source of issues, areas most commonly having issues, trends of root causes, reoccurring problems.
12. Internal Auditing: audit results, audit schedule, nonconformances by area and clause.
13. Quality Planning: upcoming projects, status of on-going projects.
14. Resources: people & training, facility, and equipment.
15. Review of quality policy, quality objectives and over-all quality system effectiveness.

Other topics may be added as appropriate to the nature of your business. There may be some slight variations for service industries (perhaps no equipment used or no subcontracting.

6   RESOURCE MANAGEMENT

6.1   Provision of Resources

The company **shall** determine and provide the resources needed

a) To implement and maintain the quality management system and continually improve its effectiveness, and
b) To enhance customer satisfaction by meeting customer requirements.

6.2   Human Resources

6.2.1   General

NOTE: There are no new requirements in 6.2.1 General from the 1994 version.

Personnel performing work affecting product quality **shall** be competent on the basis of appropriate education, training, skills and experience.

An interesting point is that knowledge is seen as a resource - A resource to be accounted for and used efficiently and effectively. In fact, get used to the idea of using all resources in an efficient and effective manner. That is the overall theme of section 6. That, and always looking towards the future.

Potential Audit Question:
Are resources, like knowledge, materials, finances and the like carefully used to maximum efficiency and effectiveness in your company? Or, more to the point, does your company even think in these terms?

6.2.2   Competence, Awareness and Training

The company **shall**

a)   Determine the necessary competence for personnel performing work affecting product quality,
b)   Provide training or take other actions to satisfy these needs,
c)   Evaluate the effectiveness of the actions taken,
d)   Ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and
e)   Maintain appropriate records of education, training, skills and experience (see 4.2.4).

You have to maintain records of education, training, etc. You need to ensure awareness of employees on the importance of their role in the quality system. You must be able to demonstrate that employees are aware of the benefits of improved personal performance. The role of each person and their impact on the quality system must be understood. The impact of departing from the planned quality system (not doing what they are supposed to be doing) has to be made clear to employees.

Remember that there are different types of training. On-the-job, elective, orientation, etc. See the example flow chart for more specifics.

Potential Audit Question:

Does your company take pains to make employees aware of the company quality objectives and the employee,s role in obtaining these objectives? If so, how is it done?

6.3   Infrastructure

NOTE: There are no new requirements in Infrastructure from the 1994 version.

The company **shall** determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable

a)   Buildings, workspace and associated utilities,
b)   Process equipment (both hardware and software), and
c)   Supporting services (such as transport or communication).

Infrastructure is another 'new' requirement of ISO 9001:2000, but was already essentially a requirement in the 1994 version. This requires you to define, provide, and maintain the infrastructure needed to assure the quality you want from your products. But what is infrastructure?

In ISO 9004 the nature of infrastructure is explained as underlying foundation needed to keep your company going. Specifically, you would need to create a matrix to describe how you keep your infrastructure in place. Across the top of the matrix would be the issues involved, such as:

24. objectives
25. function to be performed
26. performance
27. availability
28. cost
29. safety
30. security
31. environmental issues (waste, pollution, etc.)
- maintenance plan
- reaction plan for climatic or other uncontrollable events

Down the side would be the elements of your infrastructure, such as:

16. machinery
17. workspace
18. hardware
19. software
20. tools
21. equipment
22. services
23. communication lines
24. transportation
25. facilities

Each intersecting space would be your plans for that particular part of your infrastructure and the corresponding issue. As you can see it is sort of a large quality function deployment exercise. The nature of your industry will determine what goes on each of these lists.

6.3 Infrastructure
Is the standard asking for maintenance of machines / equipment? Currently, I have a system of preventive maintenance of these equipment. Is it sufficient? OR Do I need to add something else?
With an existing PM system you are most likely meeting these requirements. the new stuff relates to 'software' and 'supporting services'. Do a gap check for these, identify or implement what is done, and that should wrap it up.

Audit Question:
1. How and how much consideration does infrastructure control get within your company? Does it deserve more or less of this amount of consideration?

6.4   Work Environment

The company *shall* determine and manage the work environment needed to achieve conformity to product requirements.

This is not typically a problem. During planning required work environment should be determined and defined. In addition, it must be kept up. If you're looking at a clean room, you have preventive maintenance involved (filter changes, etc.). Housekeeping is considered by the auditor.

7   PRODUCT REALIZATION

7.1   Planning of Product Realization

The company *shall* plan and develop the processes needed for product realization. Planning of product realization *shall* be consistent with the requirements of the other processes of the quality management system (see 4.1).

In planning product realization, the company *shall* determine the following, as appropriate:

26. Quality objectives and requirements for the product;
    Also see: 5.4.1

    b)   The need to establish processes, documents, and provide resources specific to the product;
    c)   Required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;
    d)   Records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).

The output of this planning *shall* be in a form suitable for the company's method of operations.

> The product is either a physical product, software, a process, or a service. In section 7.1 we look at the requirements for planning the realization of your product. Therefore, the actual method will be greatly affected by the type of product you produce. For example, a bank provides mostly services. They would plan the process of delivering the service.
>
> In most cases, you begin with a Quality Plan. This is the same type of Quality Plan called for in QS-9000. You need to flowchart the realization of your product through time and tasks. To this you add the quality objectives, verification methods, criteria for acceptance, and the records to be maintained. Throughout, the goal is to assure yourself that the objectives are being met and the product you intended is the product you produced.

> NOTE 1 A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan.
>
> NOTE 2 The company may also apply the requirements given in 7.3 to the development of product realization processes.

7.2   Customer-related Processes

7.2.1   *Determination of Requirements Related to the Product*

Also see: 5.2

The company *shall* determine

a)   Requirements specified by the customer, including the requirements for delivery and post-delivery activities,
b)   Requirements not stated by the customer but necessary for specified or intended use, where known,
c)   Statutory and regulatory requirements related to the product, and
d)   Any additional requirements determined by the company.

> This is a reduction in scope for this requirement from the second committee draft. Now implied is that specifications and quality characteristics are in a separate area of the standard and this part fills in the gaps in knowledge of all customer requirements.

7.2.2   Review of Requirements Related to the Product

The company **shall** review the requirements related to the product. This review **shall** be conducted prior to the company's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and **shall** ensure that

 a) Product requirements are defined,
 b) Contract or order requirements differing from those previously expressed are resolved, and
 c) The company has the ability to meet the defined requirements.

Records of the results of the review and actions arising from the review **shall** be maintained (see 4.2.4).

Where the customer provides no documented statement of requirement, the customer requirements **shall** be confirmed by the company before acceptance.

Where product requirements are changed, the company **shall** ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

 NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material.

The review of product requirements comes after all the steps you have taken to collect information on what the customer wants. Now it is time to combine internal requirements with regulations and create a written confirmation of the customer's order.

For a manufacturing company this would be the tender, contract, or order. For service companies this would be the quote for services or the creation of the standard fees list. Any difference between what the customer ordered and what you are offering has to be resolved and recorded. You must be sure you can complete the order.

The biggest change from the 1994 contract review requirements is the commitment to written contracts with most customers. No more sketching on napkins. Real written contracts have to be drawn up and confirmed.

A word about contracts. Contracts are what happen after you have reached an agreement with your customer. In other words, once you have fixed the requirements for the product or service to be delivered, then you use a contract to set the limits on that agreement. It can be as simple as the terms on an order form, or as complex as a multi-page contract.

Contract review should be relatively straightforward for all three tiers of orders. Simply identify the (minimum) information that your company needs to have to be able to complete the order. Contract review then consists of making sure the customer has provided you with that essential information. A checklist often works for simpler orders, but you probably should have different people and processes for each tier. For example, catalog orders might be handled by people who simply take orders and enter them. This may be entry on a form, into a database or other software. More complex orders probably need people who are more highly skilled, perhaps to the level of an engineer or project manager. Define the skill set required for your products and then staff to that level. A general rule is that custom orders require much more "face time" & hand-holding with the customer (because you need to get a lot of information from them), so you want people who are good at doing that. Most companies use an "account manager" or equivalent. Companies that sell very expensive products use teams of two for custom orders: an account manager who handles the people skills, and a technical guru who overcomes the technical hurdles. The greater the cost of errors, the greater the effort you should to make to avoid them.

For example, I compare simple catalog orders to taking my car for an oil change at one of those drive-through oil change businesses. They perform a limited range of well-defined services, so they take orders with a simple checklist. By contrast, I compare custom orders to taking my car to my mechanic for major

work. Every order he takes is unique, so he takes orders with a blank form and writes in, in longhand, exactly what is to be done. Well, most modern garages do this on computer now. This may be a sign I'm getting old – thinking paper…

If you really want to be cutting edge, it might be worth your while to investigate a variety of businesses in your area, and benchmark the ones that have good processes for standard, configured and custom orders. For example, for standard orders, you might benchmark a popular fast food restaurant; for configured orders, you might benchmark a regular restaurant; and for custom orders, you might benchmark a catering business. With a little imagination, you can probably find businesses near you that have solutions for each of the three tiers in your order process.

Potential Audit Questions:

1. Is every customer order documented, reviewed, and the results of that review documented?
2. Do you have a contractual agreement in writing that you have the customer sign? (If not, why not?)

7.2.3   Customer Communication

The company **shall** determine and implement effective arrangements for communicating with customers in relation to

a) Product information,
b) Inquiries, contracts or order handling, including amendments, and
c) Customer feedback, including customer complaints.

We are going through the product realization requirements. We talk about review of product requirements that imply we have an open line of communications with our customers. Now we look at element 7.2.3 which, for the first time, requires us to have a documented means of communicating with customers.

Many companies still have very informal means of communicating with customers (such as the back of napkins). What ISO 9001:2000 is getting you ready for is the reality already in place with QS-9000. That is, you need formal documented communications and in many cases electronic communications set up for full time transfer of information between you and your customers. With the internet coming on so strong, you can already perform all communications with your customers and suppliers using just e-mail and web pages.

ISO 9001:2000 is asking you to have open avenues of communication for product information, inquiries, order handling, feedback, and customer complaints.

7.3   Design and Development

In this section of ISO 9001:2000 you get a lot of the original requirements for design control from the 1994 edition. **However, it has an important subtlety, it allows for the design and development of new services as well as the design of a new physical product.** Thus, a much wider range of companies and companies can (and will be expected to) use this part of the standard.

In element 7.3.1 you get the expected requirements that you need a documented system for the planning of design and development work. In so many words, you are being told to have a strict project management system.

In 7.3.2 - Design inputs, you are now sitting down with the list of customer needs, contractual obligations, and regulatory requirements. From this you create the engineering design inputs. Specifically, the functional and performance characteristics of the product or service, a list of the statutory (legal) requirements, information from previous product designs or service methods similar to this project, and any other important design aspects to be considered.

ISO 9004:2000 lists many details to be considered. These include risk assessment, marketplace situation, codes of practice, internal policies, life cycle issues, environmental impact, operation characteristics, and disposal plan.

Potential Audit Questions

1. If your company manufactures a product, do you go to these lengths for the design process?
2. If your company delivers a service, are you using project management to design new services?

7.3.1   Design and Development Planning

The company *shall* plan and control the design and development of product.

During the design and development planning, the company *shall* determine

a) The design and development stages,
b) The review, verification and validation that are appropriate to each design and development stage, and
c) The responsibilities and authorities for design and development.

The company *shall* manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output *shall* be updated, as appropriate, as the design and development progresses.

7.3.2   Design and Development Inputs

NOTE: There are no new requirements in Design and Development Inputs from the 1994 version.

Inputs relating to product requirements *shall* be determined and records maintained (see 4.2.4). These inputs *shall* include

a) Functional and performance requirements,
b) Applicable statutory and regulatory requirements,
c) Where applicable, information derived from previous similar designs, and
d) Other requirements essential for design and development.

These inputs *shall* be reviewed for adequacy. Requirements *shall* be complete, unambiguous and not in conflict with each other.

7.3.3   Design and Development Outputs

NOTE: There are no new requirements in Design and Development Outputs from the 1994 version.

The outputs of design and development *shall* be provided in a form that enables verification against the design and development input and *shall* be approved prior to release.

Design and development outputs *shall*

a) Meet the input requirements for design and development,
b) Provide appropriate information for purchasing, production and for service provision,
c) Contain or reference product acceptance criteria, and

d) Specify the characteristics of the product that are essential for its safe and proper use.

> Many companies are performing a lot of different tests to determine design inputs. However, you have to eventually take all of the inputs and create design outputs. These are the specifications and performance characteristics of the product or service being designed and/or developed.
>
> The outputs have to meet the input requirements, provide information for the production/service operations, have acceptance criteria, and define the proper and safe use of the product and/or service. In other words, most of the time you will be creating several documents from the design output portion of design/development realization.

7.3.4   Design and Development Review

NOTE: There are no new requirements in Design and Development Review from the 1994 version.

At suitable stages, systematic reviews of design and development ***shall*** be performed in accordance with planned arrangements (see 7.3.1)

   a)   To evaluate the ability of the results of design and development to meet requirements, and
   b)   To identify any problems and propose necessary actions.

Participants in such reviews ***shall*** include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions ***shall*** be maintained (see 4.2.4).

> This is where a lot of companies fall down. During the design and development review process you need to pause to check that everything is on track, you can still fulfill requirements, and identify problems to get them out of the way (think feasibility). This is normally done on a regular basis on large-scale projects (say weekly). In the manufacturing world it takes discipline to do this. It is rarely done enough in the world of services. This revision of ISO 9001 will make it more difficult for service industries to avoid addressing the design of their services.
>
> Potential Audit Question
>
>   1.   Does your company perform a regular design review meeting during the design and development process? Please give a detailed description of how you conduct your design review meetings.

7.3.5   Design and Development Verification

NOTE: There are no new requirements in Design and Development Verification from the 1994 version.

Verification ***shall*** be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions ***shall*** be maintained (see 4.2.4).

> Potential Audit Questions
>
>   1.   What Design and Development Verification Methods does your company use to ensure the output meets the design and/or development inputs?
>
>   2.   Are the results and follow up actions recorded, and once more are these items reviewed during management review meetings? If not, why?

7.3.6   Design and Development Validation

NOTE: There are no new requirements in Design and Development Validation from the 1994 version.

Design and development validation **shall** be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation **shall** be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions **shall** be maintained (see 4.2.4).

Design validation is not always performed and when it is it is not always done at the place most people would expect. Typically when one thinks of design validation they look to the classical case. That is, after a product is designed a prototype is built and tested in-house. Often a product or service is validated in the customer's facility. Or, actual use ends up being the validation. For example, a service industry may design a service which uses a customer's equipment in one way or another (for example data communication). Sometimes until the service is performed at the customer site it cannot be validated.

I am not trying to confuse the issue here, but rather to clarify that validation is not always as clear cut as the classical system leads one to believe. The important part is to understand that where validation is done, it is done to prove the device or service works as planned and designed to. This is commonly seen in software. Validation testing is typically performed, but hardware differences and such really require a validation on the customer's equipment.

Take a good look at what you make or what you do and ask yourself if and where you prove your product works as planned.

Potential Audit Questions

1. Does your company perform Design and/or Development Validation to confirm the product is meeting the requirements of it's intended use? When does this validation occur? Prior to the implementation of the product? Prior to the delivery of the product?

2. If the validation of the product is not possible prior to implementation or delivery of the product, why not? What validation methods can be used to accommodate these special circumstances?

3. Is this validation recorded and followed-up on?

NOTE: Validation is typically being done, but the review of the results is often not seen through. A serious, consistent point that comes up is the resource restraints that arise from this process.

7.3.7   Control of Design and Development Changes

NOTE: There are no new requirements in Design and Development Changes from the 1994 version.

Design and development changes **shall** be identified and records maintained. The changes **shall** be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes **shall** include evaluation of the effect of the changes on constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions **shall** be maintained (see 4.2.4).

The ISO 9001:2000 standard states that all design and/or development changes must be identified, documented and controlled. This should not be an issue. Any basic design system should address documentation and tracking of changes. In the extreme, there is configuration management.

Potential Audit Questions

1. Does your company document ALL design/ development changes? If you document some, but not all, what characteristics qualify a change for documentation?

2. If your company does document your changes, are these documents controlled in your QMS

document control system? If not, why?

7.4 Purchasing

7.4.1 *Purchasing Process*

The company **shall** ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product **shall** be dependent upon the effect of the purchased product on subsequent product realization or the final product.

The company **shall** evaluate and select suppliers based on their ability to supply product in accordance with the company's requirements. Criteria for selection, evaluation and re-evaluation **shall** be established. Records of the results of evaluations and any necessary actions arising from the evaluation **shall** be maintained (see 4.2.4).

This section is included to ensure that all purchased products, materials and services conform to purchaser requirements as well as any regulatory requirements. In effect, this section focuses on minimizing incoming non-conformances by the effective selection of suppliers, specifications / requirements and evaluation of performance.

Specifically, requirement 7.4.1 states that your company must control its purchasing processes to ensure purchased product conforms to the company's requirements. The type and extent of the control over the subcontractor / supplier is dependent upon the type of the product or service and the impact of the sub-contracted product or service on the quality of the final product or service. Your company must also evaluate and select suppliers based on their ability to meet your requirements needs. And, as is most often the case, the results of the evaluations and follow-up actions must be recorded.

One suggestion for assessing suppliers is:

Supplier approval:

Suppliers are approved by one or more of the following methods:
    Supplier Assessment Survey
    On-site Audit / Review
    Satisfactory History
    Customer Specified
    Specified by manufacturer (distributorships)

For supplier performance:

There may be suppliers that are sole source for supplies or services which have been below standard supplier rating. After all avenues of corrective action are exhausted we may revert to 100% inspection and corrective action measure may be suspended.

Potential Audit Questions

1) What approach does your company take to ensure that your supplied product conforms to your requirements?

2) What process is used to evaluate and select suppliers. Is this process used for All suppliers, and if not what criteria is used to identify applicable suppliers?

3) Are the results and follow-up actions of these evaluations documented and recorded? What is done when a key supplier does not meet your evaluation criteria (what are the follow-up actions?)

7.4.2   Purchasing Information

NOTE: There are no new requirements in Purchasing Information from the 1994 version.

Purchasing information **shall** describe the product to be purchased, including where appropriate

- a)   Requirements for approval of product, procedures, processes and equipment,
- b)   Requirements for qualification of personnel, and
- c)   Quality management system requirements.

The company **shall** ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

7.4.2 is included to provide guidance on the information that should be included on purchasing documents. The requirement asks you to include information describing the product to be purchased on the purchasing document. This includes information relating to the requirements for approval or qualification of: products, procedures, processes, equipment and personnel. It is also looking for the Quality Management System Requirements to be included. These documents must be reviewed to ensure their adequacy before they are released.

The more information you provide to your suppliers when placing an order, the more likely it is that you will get what you ordered. Think of stressful situations where your supplier provided what they thought you wanted, based on insufficient information and/or lack of communication. Put yourself in their shoes. If you are ordering standard products or services from your supplier, it may be sufficient simply to mention the part or product number; or it may be necessary to make reference to a product / material specification or supplier, quotation, which will describe all the technical data. If the items being ordered are made to your specifications, it may be necessary to make reference to a drawing and its revision number.

In any case, in addition to cost and payment conditions, it may be necessary to include the following details: the required shipping date, method of packaging, transportation, and the use of a specific customs broker.

You should as a minimum include:
    The product or service description
    Grade and quantity
    The price and any payment conditions
    The requested shipping or receiving date,

And as appropriate:
    The quality standard to be applied (such as ISO 9001 registration)
    Testing or inspection and release conditions, (by the supplier, or by your representative)
    A sample approval process
    Conditions concerning your acceptance of the product
    Special packing, packaging or marking requirements
    Special shipping requirements
    Warranty conditions.

Regardless of the type of information you include, ensure that it is clear and correct, and can be completely understood by your supplier. Meetings with your supplier prior to the release of your purchase order may be necessary.

Potential Audit Questions

1)   Do your company purchasing documents contain data clearly describing the product or service ordered, including where applicable:
        a)   The type, class, grade or other precise identification;

b) The title or other positive identification, and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical data, including requirements for approval or qualification of product [or service], procedures, process equipment and personnel;

c) The title, number and issue of the quality system standard to be applied?

2) Does your company review and approve purchasing documents for adequacy prior to release?

7.4.3 Verification of Purchased Product

NOTE: There are no new requirements in Verification of Purchased Product from the 1994 version.

The company *shall* establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Where the company or its customer intends to perform verification at the supplier's premises, the company *shall* state the intended verification arrangements and method of product release in the purchasing information.

This states that your company shall identify and implement the activities necessary for verification of purchased product. It adds that where the company or its customer performs verification activities at the supplier's premises, the company shall specify the intended verification arrangements and the release method of the product in the purchasing information.

The following are samples of how some companies document their processes of verifying the processes of suppliers or their products/services at the supplier's premises.

Sample A – No verification is performed or required.

Verification at our Suppliers Premises
At this time Company X does not perform verification at any of our supplier's premises. Should the need be identified through Management Review (as part of our procedure for Management Responsibility) or Quality Planning (as part of our procedure for our Quality System), designated personnel will develop, document and implement suitable procedures.

Sample B – Verification of product is performed, but is limited:

Verification at our Suppliers Premises
Company X performs verification of suppliers as indicated on the Approved Supplier Listing. Verification is performed on product whenever the supplier has to re-start their processes. The requirement for verification activities at the supplier's premises is included as part of the specified requirements contained in our Purchase Order. Refer to paragraph #.#, Purchasing Data.

Sample C – Verification of product is performed:

Verification is performed and recorded using a checklist provided by the supplier.
Company X ensures it has the most current version and is notified of changes according to our procedure for Document and Data Control. Where the results are unsatisfactory a Nonconformance Report is initiated according to our procedure for Element 8.3, Control of Nonconforming Product. The Checklist and copy of the Nonconformance Report are kept according to our procedure for Control of Quality Records.

Potential Audit Questions

1) Does your company identify and implement the activities necessary for verification of purchased product?

2) Where your company verifies purchased product or services at its supplier's premises, does your company specify verification arrangements and the method of product release in the purchasing documents?

7.5   Production and Service Provision

7.5.1   Control of Production and Service Provision

NOTE: There are no new requirements in Control of Production and Service Provision from the 1994 version.

The company **shall** plan and carry out production and service provision under controlled conditions. Controlled conditions **shall** include, as applicable

- a) The availability of information that describes the characteristics of the product,
- b) The availability of work instructions, as necessary,
- c) The use of suitable equipment,
- d) The availability and use of monitoring and measuring devices,
- e) The implementation of monitoring and measurement, and
- f) The implementation of release, delivery and post-delivery activities.

This is a big one. Simply put, 7.5 establishes the controls that are required to meet the defined specifications and requirements of both the company and its customers. This clause can be difficult to understand, and the one that presents the greatest challenge to document and implement. It deals with most of the processing or value-adding activities that your company carries out.

The requirement contains much of the same requirements of 4.9, 4.10, 4.12 and 4.19 of the 1994 standard. Specifically 7.5.1 states that your company shall control production and services operations through:

- a) Making information that specifies the characteristics of the product available;
- b) Making work instructions available (where necessary);
- c) Maintaining equipment for production and service operations;
- d) Using measuring and monitoring devices;
- e) The implementation of monitoring activities;
- f) Implementing defined processes for release, delivery and post-delivery activities (where needed).

The above are particular conditions under which you should operate. By doing so activities will be carried out in a consistent way. It implies control over all the factors that affect your processes, including documented procedures, process parameters, process or product monitoring, operator qualification, personnel, materials and the processing environment.

I recommend the use of flow charts (process mapping) as a starting point for this requirement. Flow Charting your primary and secondary process will ensure that you have addressed all parts of your operations. Involve a team of people who are responsible for your product/services process(es) and a cross functional mixture of people who perform them. Identify and plan all processes that effect quality and then determine the controls necessary to ensure your processes are consistent. Remember, operations control deals with the value added parts of your business and the operational controls are different in EVERY company.

Potential Audit Question

How does your company control production and services operations through:
a) Making information that specifies the characteristics of the product available?

b) Making work instructions available?
c) Maintaining equipment for production and service operations?
d) Using devices for monitoring and measurement?
e) Implementing monitoring devices?
f) Implementing defined processes for release, delivery and post-delivery activities (where applicable)?

7.5.2   Validation of Processes for Production and Service Provision

The company *shall* validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.

Validation *shall* demonstrate the ability of these processes to achieve planned results.

The company *shall* establish arrangements for these processes including, as applicable

a) Defined criteria for review and approval of the processes,
b) Approval of equipment and qualification of personnel,
c) Use of specific methods and procedures,
d) Requirements for records (see 4.2.4), and
e) Revalidation.

Validation of Processes is similar to the requirements of 4.9 Process Control of the 1994 standard.

Who is best to handle this requirement?
> This activity closely aligns with the process of production / process control from a service delivery or manufacturing perspective; therefore the responsibility is best focused between the quality manager, and the production / operations (or equivalent) managers. In a service company this responsibility may fall to a product line manager.

Day to day implementation of "Validation of Processes" must rest with those responsible for the actual management of the individuals and equipment involved in the manufacture / delivery process for the products and services. Therefore implementation will be focused on front line supervision and operational staff.

This Clause will require a high degree of co-ordination with many other departments, and is often best implemented as a team effort. Process structures and inputs are often sourced from manufacturing or design engineering (or service marketing / development) staff. Final delivery is often executed by customer service, sales or field support staff. The process will also include integration of production / service management with materials management staff, scheduling, purchasing and many others.

The Requirement
> Validation of Processes states that your company must validate any production and service processes where the output from those processes cannot be verified by monitoring and measuring activities. This includes processes where deficiencies are only apparent after the product is in use or the service is delivered. The validation must demonstrate the ability of your processes to achieve the planned results. The standard states that your company must define arrangements for validation that include the following (where applicable):
> a) Qualification of processes;
> b) Qualification of equipment and personnel;
> c) Use of defined methodologies and procedures;
> d) Requirements for records;
> e) Re-validation.

"Special Processes"

 This deals with a portion of the old 4.9 of the ISO 9001:1994 standard, specifically the "special processes" referred to in the 2nd paragraph of the requirement. You may have had instances of "Special Processes" in your Quality System based on the 1994 version, and if so, this requirement expands on the requirements of the 1994 version by requiring validation of those processes. "Special Processes" as noted in the old standard, refer to processes where the results cannot be fully verified by monitoring and measurement activities (test and inspections from the old standard) and deficiencies may only become apparent only after the product is in use.

The ISO 9001:2000 standard will now require you to go further than just qualifying your "special processes". You must now validate them. The validation is performed to ensure that your processes are able to achieve planned results. This is the major difference in the two standards, a more specific approach to monitoring your "special processes". The documented procedure for the qualification of special process is now superceded by validation. Qualification now becomes only a component of validation.

Service has been included in the new standard as well. Services will have to be more intensely planned and documented especially where their conformance to specified requirements is difficult to determine or impossible until after it has been delivered. Documented methods for implementing and measuring conformance of services should specifically define sub-processes, inputs/outputs, critical characteristics and controls. For example, services that are supposed to provide savings to the customer will now have to have short-term measures, not just the savings in the end.

Your company must now make arrangements (and document them) that ensure qualification of processes, qualification of equipment and personnel, use of defined methodologies and procedures, requirements for records and re-validation for your "special processes". These are the particular conditions under which you should operate in respect to these processes, because by doing so activities will be carried out in a consistent way. It implies control over all the factors that affect your "special processes", including documented procedures. These are not new to the 9001:2000 standard and should all be listed as a minimum requirement of validation.

Timing during implementation

 This should be started early in the development of the overall quality system. A great deal of attention and thought must be given to the development, documentation and implementation of this Clause.

Potential Audit Questions

1) Describe examples of any production or service processes you may have that the resulting output cannot be verified by monitoring and measurement activities. Why is it impossible to identify deficiencies prior to use or delivery?

2) How does your company ensure validation for...qualification of processes; qualification of equipment and personnel, use of defined methodologies and procedures; requirements of records and re-validation?

3) Has your company had difficulties in the quality of your products in which the quality cannot be verified before use or delivery? What accommodations do you currently make to ensure that processes achieve planned results? Do these processes work inline with the requirements of 7.5.5 validation of processes from the ISO 9001:2000 standard? What changes must be made?

7.5.3   Identification and Traceability

NOTE: There are no new requirements in Identification and Traceability from the 1994 version.

Where appropriate, the company **shall** identify the product by suitable means throughout product realization.

The company **shall** identify the product status with respect to monitoring and measurement requirements.

Where traceability is a requirement, the company **shall** control and record the unique identification of the product (see 4.2.4).

> NOTE In some industry sectors, configuration management is a means by which identification and traceability are maintained.

Identification and Traceability is similar to element 4.8 (Identification and Traceability) and 4.12 (Inspection and Test Status) of the old standard.

7.5.3 states that your company must identify the product throughout production and service operations (where appropriate). It also states that you must identify the status of the product with respect to monitoring and measurement activities. You must also record and control the unique identification of the product where traceability is required.

It is best to think of 7.5.3 as having three distinct components, as follows:

1. The need to identify products or services in order to differentiate between products with similar characteristics.

2. The inspection and test status of products (and services) to be identified by a suitable means, that identify the conformance or nonconformance of the product (or service) to the inspections and tests performed.

3. To provide a means of tractability so that the processing history of identical products can be distinguished, especially in cases of nonconformances, or to carry out Corrective or Preventive Action.

Of all elements in the standard, this generally should cause the least difficulty when developing or implementing procedures because most companies already identify product in a manner that meets the requirements of the standard.

Requirement Summary
>   This Requirement deals with three issues. First, the need (where appropriate) to have procedures that allow identification of product or service from receipt of materials through all stages of production to delivery and installation. Second, the need to perform inspection and test status of products and services to be identified in a suitable way as to identify the conformance or nonconformance of the product or service. And third it covers the need that exists in some industries for positive traceability of unique products or batches. These issues should be considered early, as the requirements will impact several other areas (e.g. process control, inspection).

Key Components
*   A process / method for identification of products and services.
*   A process to allow traceability of unique product or batch where required.
*   Procedure to ensure the use of the system agreed, and how this will relate to nonconformance reporting, inspection and testing.

Who should be involved?

This element is usually related to the individual with materials management responsibility. In production operations this will usually fall within the manufacturing and operations area. In service companies it could be part of customer service responsibility.

Recommended Format

The requirements of the standard start with "Where appropriate..." This allows companies to meet this requirement in a way that is realistic and practical for the 'reality' of the business. The method used will also relate to the reality of the production processes.

Methods used can include job cards; batch traveler cards; or individual product identifiers. Identification can be achieved through the use of tags, colored bins or separate processing areas.

Service companies will often identify the 'service' by the documentation that accompanies the transaction (e.g. a customs "entry" number; a freight "waybill" number; a mortgage or loan application number; or a service call).

The goal is to allow positive identification of all materials or services so that during process, mistakes will be avoided through misidentification of similar products or services.

In the area of traceability, individual process lot or batch numbers are often used. The goal is the ability to trace materials from the finished product identifier, back through the process, in a way that can positively identify all the materials, operations, operators, and process characteristics. This is often a requirement in areas such as the food and drug industry. Positive traceability can be very expensive to achieve, and should be carefully considered from a cost effectiveness viewpoint.

Even if traceability is not a specified requirement, if it makes sense to your company and helps prevent or resolve problems, then it makes sense to include your system of traceability in your quality documentation.

If traceability is a customer or regulatory requirement, your company should only maintain traceability to the required inputs and/or those that can have an effect on the product or service quality. There are different degrees of traceability.

For instance, the highest degree of traceability is required in the aerospace, aircraft, nuclear and pharmaceutical industries. Virtually every key product or component in an aircraft has a UNIQUE serial number, which allows it to be tracked through every processing step, back to raw materials and subcontracted processing and services. This is considered to be a high degree of traceability, because of the risk to life and the high cost associated with failure. The cost of maintaining a high degree of traceability can be substantial.

Every pharmaceutical container and most food containers have a traceability BATCH or LOT code attached, to allow for process tracking and validation, or for quarantine or recall in case of problems.

Companies often trace their products with varying degrees of precision, even if there is no contractual or statutory (legal) obligation to do so, because it helps them control their processes. However, this usually extends only from the receiving of raw materials to the production of final product; it is often lost when the goods are placed into inventory, as items often do not have a batch code attached. Traceability is often maintained through the use of a production job card, work order or bundle ticket, that includes the item description and often a lot code.

Potential Audit Questions

1. Where appropriate, does your company establish and maintain documented procedures for identifying the product (or service) by suitable means from receipt and during all stages of production, delivery, and installation? If so, please describe the procedure components or provide a

sample.

2. Does your company identify the status of the product with respect to measurement and monitoring requirements? How is this done?

3. Where, and to the extent that traceability is a specified requirement, does your company establish and maintain documented procedures for unique identification of individual product or batches? Does your company record this identification? If so, please describe the procedure components. If not, why does this not apply to your company?

7.5.4   Customer Property

The company *shall* exercise care with customer property while it is under the company's control or being used by the company. The company *shall* identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this *shall* be reported to the customer and records maintained (see 4.2.4).

NOTE Customer property can include intellectual property.

7.5.4 is the equivalent of 4.7 Control of Customer Supplied Product from the 1994 standard.

Who is best to handle this requirement?
This requirement will normally follow the same route as 7.4 (Purchasing Control). The focus is mainly on "Operations Management" in that the responsibility to deal with this issue will fall into the core of the processes that the company uses to manage materials from all sources.

There are 4 Key Components for this requirement...
* Methods of incoming examination and identification.(similar to the old 4.10, 4.8, and 4.12)
* Periodic examination while awaiting use. (4.15)
* Compliance with any contractual requirements (e.g. re-inspection) (4.13)
* Methods of handling and safeguarding materials / supplies. (4.15)

Treat it like it is your own.
This Element of your Quality System will include product (or services) provided to you by your Customer to be incorporated into the products or services that you are providing for that Customer. In fact, you should consider the products or services in the same way you would if your company was purchasing them.

The main difference is that (in the case of product or materials):

1. You will have to take extra care to mark or identify and store them in a way that will prevent them from being used in error.

2. Tell your Customer if / when there is a problem; or, if services are being provided by your Customer that are substandard (e.g. the customer is improperly servicing equipment supplied to you), then a procedure to inform the Customer must be in place.

Note that the standard recognizes that although your company must inspect Customer supplied product, your Customer is still ultimately expected to supply acceptable product to you in the first place.

This element covers situations where your company receives materials (or services) from your customer for incorporation into the product or service. This often includes 'free issue materials'. The object is to ensure that these items not belonging to the "supplier" are verified and then identified. And that they are protected from damage through effective maintenance, storage and handling.

This Element can be developed and implemented when practical. The timing will depend upon the degree of importance of this type of "supply or material" to the suppliers company.

Upgrading your 1994 System to be 2000 compatible

> One requirement is that your company must exercise care with customer property while it is under the company's supervision or being used by the company. This is an enhancement to the ISO 9001:1994 standard. According to ISO 9001:2000, your company must care for all customer supplied product in its possession, not just that which is incorporated into supplies. You may have to expand your procedure for 4.7, Customer Supplied Product to cover all products on hand, such as samples, equipment and even intellectual property such as confidential information.

Another requirement is that the company must ensure identification, verification, storage and maintenance of customer property provided for use or incorporation. The difference from ISO 9001:1994 is that the ISO 9001: 2000 now requires that companies specifically identify customer property. The procedure you had for 4.7, Customer Supplied Product of the old standard will now have to specify or reference the method of identifying customer property.

Another requirement is that any customer property that is lost, damaged or otherwise found to be unsuitable for use must be recorded and reported to the customer. This requirement is identical to the old standard and no changes need to be made for this requirement from your procedure for the old standard.

Recommended Documentation Format

> In some companies this practice may not exist; if so, the documentation should note this, and identify that, "...if required documentation and procedures will be developed to ensure that… " so that it can be seen that any situation that does arise will be dealt with in line with the ISO requirements.
>
> Where the practice does exist, the procedure should be developed using a flow chart model. What happens today and how is it controlled. From this gaps can be identified and dealt with, and the required procedures documented.

Key to this procedure, will be the coverage of the four points (A, B, C, D) identified above as well as the actions to be taken if problems are found. Communications with the "owner" is very important.

Potential Auditor Questions

1) Does your company exercise care with customer property while it is under your company's control or being used by the company? How does your company define "care" (what is the level of "care" given to the property)? How does your company ensure this "care" is performed?

2) Does your company identify, verify, protect and maintain customer property provided for use or incorporation into the product? How is this done? Please provide examples for the group.

3) Is occurrence of any customer property that is lost, damaged or otherwise found to be unsuitable for use recorded and reported to the customer? How is this done? Who is responsible for recording and reporting unsuitable customer supplied product in YOUR company?

7.5.5 Preservation of Product

NOTE: There are no new requirements in Preservation of Product from the 1994 version.

ISO 9001:2000
Interpretation and Upgrading

The company **shall** preserve the conformity of product during internal processing and delivery to the intended destination. This preservation **shall** include identification, handling, packaging, storage and protection. Preservation **shall** also apply to the constituent parts of a product.

This is very similar to the requirements of clause 4.15 - Handling, Storage, Packaging, Preservation and Delivery of the 1994 standard.

Who is best to handle this requirement?
> This Clause is usually covered by those closest to materials handling in production facilities, or customer service / administration in service companies.

Key Components
> Within each of the following components consideration should be given to all phases of the movement - such as raw materials or incoming supplies, in process materials or activities, and completed products and services.
> * Methods of identification, handling, packaging, and protection of products and partial products and services during internal processing.(4.15.1 through 4.15.6 of old standard)
> * Method of storage for product or partial product to ensure conformity. (4.15.3)
> * Method to ensure safe delivery of product where needed (4.15.6)

Taking care of the product
> This Clause covers the requirements for protection of incoming, in process and finished products and services (which can include up to the time that they are received by the customer).

One effective way to start developing this Clause is to draw a flow chart of how the product or service flows through the company and identify "transit" or "resting" locations during the process. Each of these points will probably have an impact on this Clause - either the way items are moved, stored, protected or otherwise handled.

A physical "walk through" the operation, tracking the flow of the service or the product is also an effective way to map out the items that must be covered.

The type of issues that are addressed here cover items such as:
1. Methods used to move materials (pallets, hand trucks, etc.);
2. Methods used to "group" materials (as above);
3. Methods used to identify transactions in a service business e.g. a client record or transaction file;
4. Methods used to store items (cold storage, controlled environment etc.) also items such as racking used, methods of stacking etc;
5. Methods of protecting items (e.g. packing materials, protective film etc.);
6. Methods related to preservation (e.g. shelf life issues, stock rotation);
7. Shipping methods of materials / products to customers;
8. Incoming shipping and packaging requirements.

The key question to ask is what methods are used (or should be used) to ensure that causes of damage and spoilage are eliminated through effective controls. (And you can be sure it will be asked!)

Timing during implementation
> This Clause can be worked on at any point; however physical protection can be dealt with early in the process, and can often bring fast results by avoiding damage.

Upgrading your 1994 System to be 2000 compatible

Point 1 (includes sentence 1 and sentence 2) of the ISO 9001:2000 standard states the company shall ensure that during internal processing and final delivery of product and/or service to the intended destination that the identification, packaging, storage, preservation, and handling do not affect conformity with product

and/or service requirements. ISO 9001:2000 has simplified its requirements for handling, storage, packaging, preservation, and delivery from the old standard. The repetition of requirements from the 1994 standard has been removed. For those of you with a service oriented company, service is now specifically covered in the new standard. Service companies will likely have to add process to their procedure for their old 4.15, Handling, Storage, Packaging, Preservation and Delivery.

Point 2 (which is the third sentence) states that the above identification, packaging, storage, preservation, and handling must also apply to parts or components of a product and elements of a service. You will have to handle, store, package, preserve and deliver partial products and services to ensure they do not affect quality. The procedure for 4.15, Handling, Storage, Packaging, Preservation and Delivery will have to be expanded to cover partial products and services to be ISO 9001:2000 compatible.

Potential Audit Questions

1) What methods are used (or should be used) to ensure that causes of damage and spoilage are eliminated through effective controls?

2) How does your product or service flow through your company? Identify "transit" or "resting" locations during the process. Let us know the way items are moved, stored, protected or otherwise handled.

3) How does your company preserve conformity of "partial products" or "constituent parts"? Service companies, how does this apply to you?

Control of Monitoring and Measuring Devices

NOTE: There are no new requirements for Control of Monitoring and Measuring Devices from the 1994 version.
The company **shall** determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1).

The company **shall** establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment **shall**

a) Be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification **shall** be recorded;
b) Be adjusted or re-adjusted as necessary;
c) Be identified to enable the calibration status to be determined;
d) Be safeguarded from adjustments that would invalidate the measurement result;
e) Be protected from damage and deterioration during handling, maintenance and storage.

In addition, the company **shall** assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The company **shall** take appropriate action on the equipment and any product affected. Records of the results of calibration and verification **shall** be maintained (see 4.2.4).

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application **shall** be confirmed. This **shall** be undertaken prior to initial use and reconfirmed as necessary.

NOTE See ISO 10012-1 and ISO 10012-2 for guidance.

This element requires that documented and implemented procedures be established to control, calibrate and maintain inspection, measuring and test equipment used by the company to demonstrate compliance /

conformance to specified requirements. This generally requires that equipment that is used to measure and control specified process variables, or to check product or service characteristics, be tested on a regular basis to ensure that the readings are correct.

Element 7.6 deals with the selection, control and calibration of measuring devices that are used to do the inspection and testing. Don't forget to assess the need for calibration and control of process measurement devices, however, such as pressure gages and such.

Essentially, this clause says: to select the measuring devices carefully, according to the actual measurements needed and the accuracy required and to ensure that they maintain their ability to measure according to a predetermined degree of accuracy.

It is an element that must be approached carefully from a practical and common sense point of view. The procedures need to be developed so that they meet all the many requirements of the standard, while at the same time ensuring that they reflect what REALLY needs to happen in YOUR company to assure quality.

You must remember that the specific scope of this Element includes "…measuring and monitoring devices required to assure conformity of product to specified requirements…". Therefore, all the measuring devices in your company probably do not have to be calibrated to the same degree of accuracy as set out in the standard. Often devices are used for rough approximations, to help identify product, as tools in Process Control to check machines, or to check the process, rather than to verify that the product meets the specified requirements.

Typical equipment requiring calibration includes: devices for measuring length, distance, weight, temperature, humidity, loudness, hardness, color, gloss, voltage, resistance. Test software must be calibrated as well.

Timing
> This element is best prepared in the latter part of implementation. The test equipment involved will be defined as the operations control and inspection and test elements are developed.

Key components
* Selection of the equipment to be included, and creation of a master log
* Determine calibration required, traceable to International standards
* Define processes for calibration; timing, methods, acceptance criteria, etc
* Physically identify the test equipment included to show status
* Maintain calibration records of all equipment
* Define process to be followed when results reveal out of calibration condition
* Ensure environmental conditions are adequate for calibration
* Ensure handling assures continued fitness for use
* Safeguard equipment from adjustments that would invalidate settings

Responsibility
> This element is usually the responsibility of the Quality Manager, although it may be a Laboratory Manager, or an Engineering Manager - or another.

Recommended Format
> There are several "generic" calibration control systems that can be purchased to run on personal computers that provide the required structure to meet this ISO element. However documented procedures of how this is to be managed are still required.

Key steps in implementing this standard generally follow these main activities:

1. Create master list of test equipment containing details of the equipment, including items such as

calibration intervals, procedures etc.

2. Ensure all equipment is covered by calibration procedures (internal or specified where external calibration is used).

3. Identify each selected piece of test equipment with a small "calibration" sticker, that identifies the equipment, and the last and next calibration dates.

4. Ensure that all test equipment has been calibrated and is current.

5. Ensure all methods used for calibration allow validation against a certified national standard.

When these steps have been considered and developed, write procedures as to how this process will actually work and address the remaining points such as dealing with out of calibration equipment, storage, handling, and protection against misuse.

This is often a difficult process to maintain, and care should be taken to ensure that both the documented process as well as the on going implementation are monitored carefully.

Potential Audit Questions

1. Explain your process for ensuring the control, calibration and maintenance of inspection, measuring and test equipment (including test software) that is used by your company to demonstrate the conformance of your product to the specified requirements? Please explain any procedures involved.

2. Where test software or comparative references such as test hardware are used as suitable forms of inspection, how are they checked?

3. How do you safeguard equipment from adjustments that would invalidate settings?

8   MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1   General

The company *shall* plan and implement the monitoring, measurement, analysis and improvement processes needed

   a) The demonstrate conformity of the product,
   b) The ensure conformity of the quality management system, and
   c) The continually improve the effectiveness of the quality management system.

This *shall* include determination of applicable methods, including statistical techniques, and the extent of their use.

Your company must plan, define and implement the activities (inspection and testing/measurement and monitoring) to assure conformity and achieve improvement throughout your company. Processes are now subject to the same inspection and test requirements as products and services. Any process that is deemed to have an impact on conformity is subject to verification. However, not only do products, processes and services have to conform, they must improve.

Inspection and Test Plans will have to be set up for critical processes. Acceptance criteria, as part of your procedure for the old 4.10, or its reference documents (i.e.: Inspection and Test Instructions) will also have to include improvement specifications.

Element 8.1 also states that your company shall determine the need for, and use of, applicable methodologies including statistical techniques. In comparison to the old standard, statistical techniques are no longer a separate element. But the significance of this requirement is its application to improvement and non-product/service related process. Companies still only require techniques that are appropriate. If there are not techniques that are appropriate to your company, then no techniques are required. Statistical tools such as chart and table analysis should be used as a minimum to measure the achievement of quality objective and goals. Your procedure should reference the procedures that use statistical tools or it could reference a list that identifies the tool and the person responsible for its implementation.

Timing
> This activity can be developed in conjunction with the operations control activity and will generally be started quite early in the development and implementation of an ISO system.

Key Components
A. Receiving inspection and testing
B. In process inspection and testing
C. Final inspection and testing
D. Inspection and testing records

Note in all of the above, the reference back to the actual process involved - especially the integration of the "in process" area of inspection and testing.

Responsibility
> This area is normally the responsibility of the quality assurance manager, however in many cases actual implementation will fall into the production or operations management role.

Potential Audit Questions

1. What verification activities are in place to ensure processes that effect quality are in conformity? Please explain the verification processes.

2. How does your company define and measure "improvement"? Please include details regarding your improvement specifications.

3. What statistical tools are used within your company to ensure conformity of processes? How does your company utilize statistical techniques (or any other methodologies) to improve quality?

8.2   Monitoring and Measurement

8.2.1   *Customer Satisfaction*

Also see: 5.2

As one of the measurements of the performance of the quality management system, the company *shall* monitor information relating to customer perception as to whether the company has met customer requirements. The methods for obtaining and using this information *shall* be determined.

The ISO 9001:2000 standard now states that you must monitor information on customer satisfaction (and or dissatisfaction) as one of the measurements of performance of your quality system. You must also determine how you are going to obtain and use this information. This is a new requirement in the ISO 9001:2000 standard.

The 1994 version of the standard stated that the requirements that it entailed were specified primarily to achieve customer satisfaction. Now the standard is taking a different tone to that goal and specifically states

that we must monitor customer satisfaction.

Do a lot of us currently do this now? Well, hopefully so, but it may not be likely. The primary method of monitoring customer satisfaction: "Hey John, did we get the order?" many companies can be falsely drawn into the conclusion that the customer is completely satisfied merely because they receive repeat business, but this may not be the case.

How many of you have continued shopping at a store which has poor service because it is convenient? Maybe it is close by to your work/home, maybe the store carries a product that you cannot find elsewhere, maybe they are cheap. Whatever the reason, you go back because of some reason other than you are happy with their service, and if given another option you would be more than willing to try it.

Though an exaggeration, this is an example of how repeat business may be false security.

Element 8.2.1 of the ISO 9001:2000 standard is in place to NOT allow this to happen. The standard requires that you define ways of obtaining and using information pertinent to your customer's satisfaction and monitoring this information as a minimum form of measuring quality management system performance. Being proactive and finding out issues before they arise is the idea, how you do it is up to you.

The new ISO 9001:2000 standard helps clarify whose opinion is most important in regards to your Quality System, Your Customer's. The new standard requires the "monitoring" of customer satisfaction information, it does not require the implementation of an entirely new measurement system. The extent that you want to take this is up to you.

8.2.1 Monitoring & Measuring customer satisfaction.
Can I just use customer complaint to measure this? What kind of measurement the standard required? Please give some example?
No. the "no news is good news" adage as related to customer complaints is not enough to satisfy this particular requirement. Key questions you must be able to answer: ***Is information relating to customer perception monitored by the organization as to whether customer requirements have been met?***
and second: ***Have the methodologies for obtaining and using information related to customer perception been determined?***
Unless you have a business where customers come in and everyone leaves smiling giddily because they are so satisfied, you'll have to come up with other measurables.
examples: Customer complaints, direct communication with customers, questionnaires and surveys, reports from consumer organizations, reports in the media, sector studies, focus groups, market share info, etc...

Potential Audit Questions

1. How does your company currently assess customer satisfaction? There must be some form or another in your company, whether it be based on repeat sales, customer surveys or by word of mouth, describe how this information gets into your company.

2. What is done with information regarding customer satisfaction once it is received? If it is dissatisfaction are corrective actions pursued? Who is the highest level of management to receive word about customer satisfaction? Who is responsible for communicating with customers?

3. How will your company satisfy the requirement for customer satisfaction in the ISO 9001:2000 standard? If it was a perfect world, how would you collect this information and use it?

-> "Measurement and monitoring Customer Satisfaction is
-> based on review of customer-related information. The
-> collection of such information may be active or passive."
-> There's probably a simple explanation of the difference

-> between the two methods. To me, passive means let the
-> information flow to you. Active would mean going after
-> it.

I think you're reading it right. If you send out a survey you're being active. If you rely on, or include, unsolicited letters from customers and such it's passive.

-> Passive looks too easy. Like, " I don't have that information because I never got it."

First – can you define what, in your company, you consider passive?

I would say most companies have some form of active aspect. I see both as important parts. If I went into a company and they said they had no passive customer feedback I would really begin to seriously wonder. No letters of appreciate? No letters from dissatisfied customers at all? Ever?

I had a client which was quite small – 12 employees. They explained they had not had a customer complaint for over 8 years. No letters. No phone calls. Nothing. But when we talked they better understood what a complaint is – to them – in their company. One aspect is that a sales rep visits every customer every month for at least a day to monitor the process and help in any way possible. The visits are, not that I agree, not documented (I think they'll have to do that for the 2000 version 'upgrade'). The problem for them initially was defining exactly what a customer complaint is. They restricted customer complaints (their definition) to a phone call, a FAX or other communication (of dissatisfaction or nonconformance) not originating in the customer facility with a rep. And by that definition they had not had a complaint in over 8 years. For a more complete understanding, the product is metal cleaning chemicals and phosphatizers. Not complex.

Another aspect of the problem is identifying measurables within either type (passive or active) of information gathered. Let's say you do a survey. First of all you won't get all of them back. next is the subjectivity of the questions you ask. This said, I think the most problematic aspect for you will be addressing issues of metrics. It says "Measuring and monitoring of..." and the measuring and associated aspects will be the 'hard' part.

8.2.2   Internal Audit

NOTE: There are no new requirements in Internal Audit from the 1994 version.

The company **shall** conduct internal audits at planned intervals to determine whether the quality management system

  a)   Conforms to the planned arrangements (see 7.1), to the requirements of ISO 9001:2000 and to the quality management system requirements established by the company, and
  b)   Is effectively implemented and maintained.

An audit program **shall** be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods **shall** be defined. Selection of auditors and conduct of audits **shall** ensure objectivity and impartiality of the audit process.

Auditors **shall** not audit their own work.

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) **shall** be defined in a *documented procedure*.

The management responsible for the area being audited *shall* ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities *shall* include the verification of the actions taken and the reporting of verification results (see 8.5.2).

NOTE See ISO 10011-1, ISO 10011-2 and ISO 10011-3 for guidance.

8.2.2 correlates to the old 4.17 of ISO 9001:1994. The new standard states that your company must plan and conduct periodic internal audits to determine whether your quality management system:

a) Conforms to the ISO 9001:2000 standard, and
b) Has been effectively implemented and maintained.

Your company may take into consideration the status and importance of the activities and areas to be audited and the results of previous audits when planning your audit program. You must define the audit scope, frequency and methodologies. Your audits must be conducted by someone other than the personnel who perform the activity being audited.

You must also have a documented procedure that includes the responsibilities and requirements for conducting audits, ensuring the audit is independent, recording the results of the audit and reporting the results of the audit to management.

Summary

Internal Quality Audits are required to ensure that the quality system is working effectively and is in conformance with the ISO 9001:2000 standard. Internal Audits are a key component of your QMS, they provide a means for measuring, analyzing and improving your management system. Audits are also a very important input to the Management Review process. The accuracy, scope and reporting of the results of your internal audits are critical in enabling your management to identify the need for corrective actions and preventive action.

The ISO 9001:2000 standard has helped to clarify the auditing requirement. ISO 9001:94 was a little vague when it called for audits to "determine the effectiveness of Quality System". The new standard now is more prescriptive, pointing to the purpose of the audit as to "determine whether the quality management system a) conforms to the requirements of this (ISO 9001:2000) International Standard, and b) has been effectively implemented and maintained." The use of checklists is still a valuable tool for auditing.

You must define the audit scope, frequency and your audit method, in doing this you must place into consideration the importance of activities and areas within your company to be audited, obviously placing the most importance on the areas having the most effect on quality. This is not a new requirement of ISO 9001:2000.

When choosing your auditor you must select an individual other than one who performs the activity being audited. The Internal Quality Audits are often assigned to the financial manager. however the quality manager, as the management representative, will usually maintain responsibility for the development of, and implementation of the quality audit activity. Internal quality auditors will require training; in addition those performing audits can start their activity during development and implementation, to ensure that the quality system reflects reality and is being deployed effectively.

Being Audited

In the course of seeking conformance, concerns or nonconformances may become evident, but it is important that everyone involved understand that the intent is to seek conformance. Conclusions must be based on objective evidence, observation, interview and documents.

If auditing is understood as a staff persecution or a 'witch-hunt,' then do not be surprised when (not if, but when) the members of your company respond with suspicion, distrust and even hostility. It is extremely

important that management appreciate the purpose and principles of quality system auditing and that the auditors conduct themselves accordingly.

The results of an audit should indicate whether the quality system is properly implemented and maintained. These results are considered by management for action as necessary.

A positive and constructive attitude toward auditing can make the exercise enjoyable for both the auditor and the auditee. Most people enjoy telling you what they know and how good they are at their job. In addition, without an air of suspicion and distrust, auditees are likely to confide concerns or suggestions that are in the company's best interest to address and not simply lay blame.

One way to ensure that everyone understands and retains a good perspective on the intent of a management system audit, is to develop an audit mission statement. A two or three sentence statement that captures the positive and constructive intent of your company's audit program can help keep the auditor and auditee on track.

Finally, Quality System audits are not surprise audits! They are planned and everyone knows when it will happen, and what elements or departments will be audited. There should be no surprises, as this tends to foster mistrust towards the audit process, and a feeling of "them versus us" between your company and the auditors.

Potential Audit Questions

1. Who in your company is responsible for auditing your Quality Management System? Who reports the result of the audits? If non-conformances arise from an audit, who is notified and who is responsible for following up?

2. How are audits received in your company? Do employees take them negatively or positively? Describe what is done in your company to try to curtail negativity arising from internal audits? In a perfect world, what would you do to ensure a positive response to audits?

3. How will your company determine whether the quality system has been "effectively implemented and maintained"? Will you treat this requirement differently than the requirement to determine the "effectiveness of your quality system"? Please explain your interpretation.

-> My concern is: Is the Lead Auditor Training Course a
-> requirement in the new standard?

No. To be clear, there is no requirement in ISO 9001:2000 that there be a designated 'Lead Auditor' at all. Nor is there a requirement for an internal auditor to have attended a course, although that is pretty common anymore. You could do this by pairing a 'trainee' with a 'qualified' auditor - thus you would have 'On-The-Job' training as the basis for that person's qualification as an internal auditor. There is no requirement for classroom training, for what its worth.

The bottom line is: The requirement is that your internal auditors know what they're doing. It may be from training, experience, education or an 'appropriate' combination of one or more.

-> Can the result of our examination from the
-> Internal/External Auditing Course for ISO9001:2000 would
-> be a valid evidence that would earn me as a Lead Auditor
-> for the new standards?

You can be Lead Auditor in your company, but that does not extend to the definition of Lead Auditor with respect to the RAB or IRCA with respect to working for a registrar. That is, if you are appointed as Lead

Auditor of the internal auditors in your company that does not mean you could go to work for a registrar as a Lead Auditor.

-> Or Is it the MR would recommend me as the Lead Auditor in
-> our company?

That is perfectly acceptable.

-> Does it need a memo that recognizes me and my team as
-> Internal Quality Auditors of the company?

You should have the team defined somewhere - typically you have lists of people qualified to do certain things - whether running a specific machine or performing certain tasks. Internal auditing shouldn't be any different. How you represent it is up to you. Some companies have departmental lists of who is qualified to do what. Other companies have qualifications only in individual records. Either way, you should be able to say who is qualified to do what. This applies to internal auditors as well. A memo would work as well.

8.2.3   Monitoring and Measurement of Processes

The company *shall* apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods *shall* demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action *shall* be taken, as appropriate, to ensure conformity of the product.

8.2.3 is closely tied with 8.2.4 Measurement and monitoring of product. Keep in mind the product requirement and how it relates to this discussion.

Element 8.2.3 states that your company must apply suitable methods for measurement and monitoring of those processes specific to your company that allow you to deliver your product to your customer/s (realization processes). The standard states that these methods must confirm the continuing ability of each of these processes to satisfy its intended purpose. This requirement is similar to that of 4.20 Statistical Processes and also 4.9 Process Control, of the old standard.

Summary
> The ISO 9001:2000 standard now has more emphasis on measuring product quality (we'll get into this more with element 8.2.4) and the processes that relate to product quality. In the past, there has been some criticism that a company could create an ISO system that would still allow you to ship bad product 'consistently'. According to the new standard, companies will have to measure and prove the continued ability of their processes to meet their customers' requirements for the use of the product or service. The methods of measurement must be defined. A documented procedure as part of Process Control will have to define or reference the customer requirements, the intended purpose of the process, the measures of its continued ability and method of assurance, such as a review. How you react to these requirements will be greatly determined by the industry you are in and the regulations that you must follow.

The creation of a product occurs through the operation of one or more processes. You have to make sure that the processes are set up to meet customer requirements (i.e. capability studies). You continually monitor these processes (i.e. SPC) and make sure they are always set for meeting customer requirements. At the same time you use the data you are collecting to look for opportunities for improvement.

By measuring the process (for feed, speed, rate, temperature, etc.) you are utilizing the best method for helping to prevent defects your products may have. By waiting to measure a product once it has been produced, you can still prevent defects from getting to the customer, but it may too little too late. Ensuring quality in your processes goes to say that you are on the right track to ensuring quality in your products. You

have to control your processes in order to produce a product that is in control.

One critical point of the new standard is the monitoring component. When one "monitors" a process, one must compare the collective variance from one set of measurements to the next, or a series of measurements, and not just make measurements and let the data sit unanalyzed. I've heard of this requirement being missed in the old standard, with measurement data being taken for ISO reasons, but not actually used as a tool for improvement (or at least used to its full extent).

The new standard is somewhat more clear on how this data must be used. A new requirement of the standard is that processes measure and show the continual ability to satisfy customer requirements (monitoring is an obvious component in identifying this). Action will have to be initiated when processes fail to satisfy requirements. Process capability must be part of the company's stated overall and specific objectives for quality. Such objectives could be included as part of the Quality Policy, measured as part of Management Review and followed-up according to Corrective and Preventive Action.

Potential Audit Questions

1. How does your company identify which processes are critical to product realization. Describe the criteria for identifying these processes.

2. What methods are used to measure processes? Who is responsible for defining and conducting these measurements in your company?

3. What measures will you use to confirm the continuing ability for your processes to satisfy their intended purpose? Please describe.

8.2.4   Monitoring and Measurement of Product

NOTE: There are no new requirements in Monitoring and Measuring of Product from the 1994 version.

The company **shall** monitor and measure the characteristics of the product to verify that product requirements have been met. This **shall** be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1).

Evidence of conformity with the acceptance criteria **shall** be maintained. Records **shall** indicate the person(s) authorizing release of product (see 4.2.4).

Product release and service delivery **shall** not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

8.2.4 relates to element 4.10 - Inspection and Testing as well as 4.20 - Statistical Techniques, of the 1994 standard.

The first paragraph of element 8.2.4 Measurement and monitoring of product states that your company must measure and monitor the characteristics of your product that verify that the requirements of the product are met. You have to do this at appropriate stages of the product realization process.

The second paragraph states that evidence of conformity to the characteristics of your product that verify the requirements must be documented. The standard also states that you must indicate the "authority" responsible for the release of the product.

The third and final paragraph of element 8.2.4 states that product release and service delivery must not proceed until all the "monitoring and measurement of product" activities have been completed, unless of course your customer says it is ok. (or otherwise is approved by them).

ISO 9001:2000
Interpretation and Upgrading

Summary

The new ISO 9001:2000 standard is more specific and comprehensive regarding ensuring quality product leaves your facility. The new standard now requires you to "measure and monitor the characteristics of the product" to ensure the product requirements are met, as oppose to requiring "inspection and testing activities" to verify the requirements are met, as in the old standard.

Measurement and monitoring' implies a larger scope than 'inspection and testing'. I'm going to use the dictionary to do a comparison here:

Measurement (9K/Y2K) is: The act of taking dimensions, quantity, or capacity as ascertained by comparison with a standard,

Testing (9K/94) is: A procedure for critical evaluation; a means of determining the presence, quality, or truth of something

Monitoring (9K/Y2K): To test or sample on a regular or ongoing basis, to keep close watch over; supervise

Inspection (9K/94) is: The act of examining something closely (as for mistakes)

As you can see, the ISO 9001:2000 standard demands closer control of those characteristics of your product that verify the requirements of your product have been met. You now have to "measure" the characteristics of your product, which implies comparing your results to a "standard" (however recognized that standard may be is not of issue here), where before you were required to "test" the characteristics of your product, which, by definition, is less prescriptive a requirement.

Now the big question, what characteristics am I going to monitor and measure? To some companies this will be obvious, but others (service industry in particular) will have a tougher time with this, especially because it must be done prior to release of product or delivery of the service (and during appropriate times in product realization).

Your company will have to identify the significant product / service characteristics that effect quality and then develop methods to verify conformity to these characteristics. This includes characteristics that may not be identified by your customers.

A documented process should be developed to identify critical characteristics of the product (even ones that are not identified by the customer) and their impact on the customer. In order to ensure 'suitable' methods are developed, the documented process should rate the significance of the impacts on quality (a bit like rating your Aspect and Impacts in ISO 14001). The more significant the impact (assuming it can be verified), the more the method will have to be defined and documented. You will also have to define, and indicate on your records, the authority for final release of the product (not a new requirement).

Potential Audit Questions

1. How do you intend to identify the product/service requirements NOT specified by your customers but necessary for intended use? If you feel your customer will specify all requirements, what will you do to show that you have considered ALL characteristics? (Please identify if you are a service/product company in your response)

2. Will your company approach the requirement to "monitor and measure" the characteristics of your product differently then the old requirement to "test and inspect" the product characteristics? Please describe any possible or expected changes to your system.

> 3. If you monitor and measure all of your PROCESSES and they confirm the requirements of the product are met, how will this affect your monitoring and measurement of your PRODUCTS? What are your thoughts on the relation of the two requirements, too much, too little or just right?

8.3   Control of Nonconforming Product

The company *shall* ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product *shall* be defined in a *documented procedure*.

The company *shall* deal with nonconforming product by one or more of the following ways:

a) By taking action to eliminate the detected nonconformity;
b) By authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;
c) By taking action to preclude its original intended use or application.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, *shall* be maintained (see 4.2.4).

When nonconforming product is corrected it *shall* be subject to re-verification to demonstrate conformity to the requirements.

When nonconforming product is detected after delivery or use has started, the company *shall* take action appropriate to the effects, or potential effects, of the nonconformity.

Element 8.3 is very similar to element 4.13 - control of nonconforming product, of the old standard. Element 8.3 states that your company must ensure that product that does not conform to requirements is identified and controlled to prevent unintended use or delivery. This activity must be defined and documented in a procedure.

Paragraph 2 of 8.3 states that nonconforming product must be corrected and subject to re-verification after correction to demonstrate conformity.

Paragraph 3 of 8.3 states that when nonconforming product is detected after delivery or use has started, your company must take appropriate action regarding the consequences of the nonconformity.

The final line of 8.3 states that it will often be required that the proposed rectification of nonconforming product be reported for concession to the customer, the end-user, regulatory body or other body.

Summary

> This element focuses on ensuring that product(s) or service(s) that do not conform to the specified requirements are prevented from unintended use, delivery or installation. It is therefore associated with Monitoring and measuring and operations control. The actual requirements for the control of nonconformity do not change from the 1994 edition of the ISO 9001 standard. The real difference are subtle, though some of the wording is better for service companies, such as the words 'corrected and subject to re-verification rather than 'reworked' so that this requirement fits better with services. The requirements of the current section 4.13 of ISO 9001:1994 are also slightly expanded to include services by changing from "nonconforming goods" to "nonconformity."

Nonconformance will be covered in two ways: firstly, quality and / or operations management will develop the procedures that define how these issues are dealt with. Secondly, implementation will cover ALL areas within the company - those having responsibility for ensuring conformance (e.g. operators, inspectors etc.) - as well as all others who may OBSERVE non conformity, such as management, internal auditors,

supervisors etc.

Responsibility includes indicating who it is that develops the procedures to handle this element, who is responsible for identification of non conformances, and who is responsible for agreement on action / disposition.

Corrective and preventive actions are now placed in several spots in the new standard. The intent is to steer away from the idea that only nonconformity should start corrective and preventive actions. Instead, your system should be proactive and seek out areas where corrective and preventive actions should be taken. The people running your processes should be encouraged to report all real and potential non-conformities.

This element should be introduced early in the development and implementation. Focusing on existing nonconformances - even before the quality system is fully completed, will assist in providing information to improve processes and other activities. It will assist management in early identification of the opportunities for improvement from current practices.

Potential Audit Questions

1. How well is your control of nonconformity working now?

2. Is your staff well trained in raising nonconformances? How thorough is your staff in raising nonconformances, do they miss potential or actual nonconformances or do they raise too many that do not add value?

3. Is your management team proactive in looking for potential problem areas?

8.4   Analysis of Data

The company **shall** determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This **shall** include data generated as a result of monitoring and measurement and from other relevant sources.

8.4 Data Analysis
Can anyone give me some examples? I'm confused between 8.4 & 8.5.1. They seem to be the same.
Includes the data accumulated through internal monitoring of processes and data collected from 8.2.1 and other sections. The data has to be relevant to customer satisfaction and/or dissatisfaction, conformance to customer requirements, product and trends, characteristics of processes, and suppliers.
8.5.1 shows more what actions you have taken from the 8.4 analysis and how they have worked - and what follow-up was done.

The analysis of data **shall** provide information relating to

a) Customer satisfaction (see 8.2.1),
b) Conformity to product requirements (see 7.2.1),
c) Characteristics and trends of processes and products including opportunities for preventive action, and
d) Suppliers.

Element 8.4, states that your company must collect data to determine the suitability and effectiveness of your quality management system and to identify and improvements to it that can be made. This includes data from measuring and monitoring activities and other relevant sources.

The standard states that you must analyze this data to provide information on:
a) Customer satisfaction
b) Conformance to customer requirements;

   c)   Characteristics of processes, product and their trends;
   d)   Suppliers

In Section 8.4 there are some new requirements. Statistical methods from the 1994 version were cut up and dropped into several new locations. This is just one of them. The idea here is that management should gather process data, internal review data, corrective action reports, preventive action results, customer complaints, and any other source of information on how your quality system is performing.

This information has to be analyzed regularly according to a written procedure. The output of such analysis should summarize, at a minimum, effectiveness of your system, process trends, customer satisfaction, and conformance to the all important customer requirements.

You get to select the appropriate statistical methods to use for the analysis. As usual ISO 9004 is full of ideas for which methods to use.

Potential Audit Questions

   1.   What is the most important data to your quality system?

   2.   Does your management team use statistical methods regularly to analyze this type of data?

   3.   What statistical method do you match up with which type of data collected? (For example: using SPC with process data, correlation analysis with customer complaints, etc.)

Thoughts on what data is:

In so far as the topic of data goes, it's the same in both standards.

->The only thing I know is that a operator of Warehousing
->Department enters the information about the incoming item
->(for example, metal tube)-price, short description,
->quantity in SKALA, and the member of supply Department can
->obtain the information about the current stocks by means
->of opportunities of SKALA.
->I can not describe the functions of our program SKALA in
->details.

I think everyone has tried to respond as closely as they can without having more details.

Go to your IS people and ask them how they control the SKALA program and the data it accumulates. Both the program and the data it accumulates must be controlled.

**However - There is a definite question as to whether this actually falls under ISO requirements if you are only looking at number of items in stock or other 'non-quality related' aspects of your systems.

This said, if you use the system to account for any customer related product, it is definitely a 'quality' related issue (4.7 in the old standard and 7.5.4 of the new standard).

If you are already ISO registered (I assume you are because you cited the 1994 standard) you should be looking at what you have defined as quality records and controlled documents. In the largest sense, data is many things, including those cited above. But also, consider the following from the 1994 standard:
****
4.6.3 Purchasing data
        Purchasing documents shall contain **data** clearly describing the product ordered, including where

applicable:

    a)   the type, class, grade or other precise identification;

****

So - in this case, data is what is input into the purchase order or other purchasing document. Now consider this:

****

4.10.4 Final inspection and testing
    ....No product shall be dispatched until all the activities specified in the quality plan and/or documented procedures have been satisfactorily completed and the associated **data** and documentation are available and authorized.

****

When I think of data, I think of a form or database where you are entering data. Data is typically **variables**. It can be a computer program or it can be inspection results. Even a pass/fail can be data. A test report can be considered data.

Consider:

****

4.11 Control of inspection, measuring and test equipment

4.11.1 General
    .....Where the availability of technical **data** pertaining to the inspection, measuring and test equipment is a specified requirement, such data shall be made available, when required by the customer or customer's representative, for verification that the inspection, measuring and test equipment is functionally adequate.

****

And:
****

4.16 Control of quality records
    ....Quality records shall be maintained to demonstrate conformance to specified requirements and the effective operation of the quality system. Pertinent quality records from the subcontractor shall be an element of these **data**.

****

The 2000 version of 9K says:

****

8.4   Analysis of Data
The company shall determine, collect and analyze appropriate **data** to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include **data** generated as a result of monitoring and measurement and from other relevant sources.

The analysis of **data** shall provide information relating to

    a)   Customer satisfaction (see 8.2.1),
    b) Conformity to product requirements (see 7.2.1),
    c)   Characteristics and trends of processes and products including opportunities for preventive action, and
    d)   Suppliers.

****

If you look at 9K as a whole, and look where the word data is used, you should be able to look at your system and decide what is appropriate.

That said, consider:

quote:

Originally posted by Al Dyer:

Listen to Roger,
Data relates to electronic media.
1. CNC programs
2. SPC programs
3. Gage programs
The best example is from Roger, CNC programming. How do you control the electronic programs that tell the process how to function?

Documents are documents. When you think data, think computers and electronics.

Well, yes, sorta. QS pressed this I believe. It is common now for data to 'include' electronic files in a broad sense.

Roger said:

->"data" refers to programming information used to run
->machines (NC machines, for example).

This correlates with my interpretation in that these are all variables.

The thing to watch is what you look at in the sense of what is a document and what is a record.

1. A purchase order (which **eventually** contains data) is **first** a **form**. Even computer screens have controlled 'forms' such as database front ends. **These forms are controllable as documents** under 4.5 (now 4.2.3).

2. Then, when you enter **data** it **becomes a 'quality record'** controllable in accordance with the old 4.16 (now 4.2.4).

Roger and Al used **control** software (such as a CNC program) which you control as a document would be controlled - it is revision sensitive. Al specifically cited **programs**.

CNC data - input into the CNC machine is an input (as opposed to 'process' software such as an SPC program which processes data). It is variable data but I would not call it a record. We want to be sure we distinguish the CNC program (call it data or call it the input – some folks call the input into a CNC the 'program whilst some call it data {either way they're variables}) from the CNC machine's interpreter.

Data taken to be analyzed in an SPC program is a process output and it is data. This data input into the SPC program is typically a 'quality record' and the data output from the SPC program is arguably also a quality record and data.

Let's look at an SPC program closer. Probably it is canned (many companies do not develop their own in-

house SPC program) so you have very little control with the exception of the yearly upgrade that software companies depend upon. Whoever installs and maintains the software are typically responsible for the control aspect. You can verify output, technically, although with canned software this is a questionable issue - usually the company which wrote the software verifies the accuracy and 'correctness' of the software output.

If you develop your SPC program in-house it's output has to be verified AND the program has to be controlled like you would a procedure - history and revision control. BUT - the output of the SPC program is **data** - again, a 'quality record'.

So data can be many things. As I said, of more importance is how you classify something which is the determining factor of what you have to do to control it.

As a procedure or as a record.

8.5   Improvement

8.5.1   Continual Improvement

The company **shall** continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

8.5.1 implies that your company must plan and manage the processes necessary for the continual improvement of the quality management system. It brings together the continual improvement cycle. Now there are better links between the continual improvement elements throughout the standard and there are also new requirements which help support continual improvement.

The basic structure for continual improvement is supported by elements throughout the ISO 9001:2000 standard. Most of the continual improvement elements were required in the old standard, but some (such as measurement of customer satisfaction) are new. Identifying the requirements that support continual improvement in your quality system is not straight forward, and it can be argued that all elements of your quality system support continual improvement.

8.5.1 serves as the locus for all of the elements that help facilitate continual improvement, and ties them together by requiring you to plan and manage all of these elements.

Potential Audit Questions

1.   How does your company use the quality policy, objectives, audit results, analysis of data, corrective and preventive action and management review to facilitate continual improvement?

2.   Please explain your most encouraging, or discouraging, experience with ISO 9001 and your quest for continual improvement. Have most of you found that your company has managed continual improvement throughout the life of your quality system, or have you managed to save a lot of improvement for later?

8.5.2   Corrective Action

NOTE: There are no new requirements in Corrective Action from the 1994 version.

The company **shall** take action to eliminate the cause of nonconformities in order to prevent recurrence.

Corrective actions **shall** be appropriate to the effects of the nonconformities encountered.

ISO 9001:2000
Interpretation and Upgrading

A *documented procedure* ***shall*** be established to define requirements for

    a)   Reviewing nonconformities (including customer complaints),

> Reviewing nonconformances is inclusive of many aspects as is illustrated by the "…including customer complaints…" verbiage. Nonconformities may be discovered internally and externally.

    b)   Determining the causes of nonconformities,

> While there is no specific mention of Root Cause, more and more auditors are looking for root cause. It is not clear how this will ultimately be interpreted (if in the extreme) so stay tuned!

    c)   Evaluating the need for action to ensure that nonconformities do not recur,

> A problem in most companies initially is how to decide what nonconformances need to be acted upon. In many companies there are lots of things which do go wrong. Some are extremely minor. One cannot do a full blown corrective action on every nonconformance. There has to be a 'gate' – someone who evaluates nonconformances and decides of the 'amount' of a reaction to follow through on. An important feature is to ensure the 'gate' person considered past history. Has this happened before? When? How often and in what timeframe?

    d)   Determining and implementing action needed,

> While the 8-D methodology is not addressed here in, nor is Root Cause specifically stated, it is expected that you will have a system which does, indeed, look for the source of the problem.
>
> The 8-D methodology is briefly described in Implementation.ppt. There is a very complete description of structured corrective action at: http://Elsmar.com/8D/.

    e)   Records of the results of action taken (see 4.2.4), and
    f)   Reviewing corrective action taken.

> There are a number of threads on corrective action in the forums of which
> http://Elsmar.com/Forums/showthread.php?s=&threadid=297 is one.
> http://Elsmar.com/Forums/showthread.php?s=&threadid=687 is another good read.
>
> You might also want to take a read through the main 8-D course file at http://Elsmar.com/8D/
>
> Summary
>   8.5.2 - Corrective Action correlates with element 4.14, corrective and preventive action, of the 1994 standard. It states that your company must take corrective action to eliminate the cause of nonconformities to prevent them from happening again. The standard states that the corrective action you take must be appropriate to the impact of the problem encountered.
>
> The standard states that you must have a documented procedure for corrective actions and that the procedure must define requirements for:
>
>   a)   Identifying nonconformities (including customer complaints);
>   b)   Determining the causes of nonconformity;
>   c)   Evaluating the need for actions to ensure that nonconformities do not recur;
>   d)   Determining and implementing the corrective action needed;
>   e)   Recording results of action taken;
>   f)   Review of corrective action taken.
>
> Basically, corrective action is aimed at preventing recurrence of a nonconformity. The purpose for this requirement is to develop a process for implementing an effective and appropriate corrective action when

needed. This is a six step process, taking you through a complete cycle with your corrective actions.

First off, you need to define your process for identifying nonconformities, including customer complaints. You will want to identify those persons who are qualified to a) identify and record problems and opportunities for improvement; and b) initiate, recommend or provide solutions through designated channels. Then you will refer to your requirements for element 8.3 - Control of Nonconformity, 8.2.2 Internal Audit, and 8.4 Analysis of data to define your processes for identifying nonconformities.

The next step in your corrective action process is to define your process for determining the cause of nonconformity. Typically, the personnel that identifies the need for corrective actions are usually aware of the cause of the problem. Try to encourage personnel who are requesting corrective action to also be suggesting solutions, they may be the most qualified to determine a solution, try to encourage constructive criticism. Your process for determining the causes of nonconformity should be timely so that any investigation takes place while the information is current and available. The results of this determination should be recorded, including the personnel who performed the determination, when the determination was conducted and the basis for the determination.

Once the cause is determined you must then determine what action is needed, if any. The required action should not be hastily determined, in some cases the cause of the problem is not fixable because it is out of your control, beyond your means of action, or the benefit of fixing the problem does not equal the cost. Ensure that the personnel that make the determination have time to make a sound judgment. It is always recommended to identify a number of suitable actions and then pick the best one. Obviously, the action should solve the problem without creating more severe problems and without an unacceptable cost - benefit ratio.

The desired course of action should be recorded. Your company may also wish to record the alternative actions which were not selected. When the required actions have been chosen, someone must approve it to ensure it is appropriate to the problem encountered and that person's signature/initial should appear on your records.

Now you must define your process for implementing, verifying and recording the corrective action needed. For the purpose of this, your company must develop a process to plan the implementation of that corrective action, including verification to ensure the action is effective. Your company should document this plan, identifying the:

a) Affected quality system processes,
b) Nature of any required document changes,
c) Subject and audience of any required training,
d) Means of verification and criteria for acceptance,
e) Personnel responsible,
f) Due dates.

After you have completed all of the above, you must review the corrective actions taken. In clause 8.5.1 - Planning for Improvement, you would have developed a process for ongoing reviews of your improvement processes, which includes the corrective action process. The frequency, personnel responsible and records of review would be defined according to that requirement. Open and verified corrective actions should be reviewed according to that process. In addition, ISO 9001:2000 requires that the results of corrective action be reviewed by top management.

Potential Audit Questions

1. How does your company decide which nonconformances become (require) corrective actions? Is the person who initiates the nonconformance involved with the corrective action?

> 2. Explain your review process for corrective actions. Does top management review them, do those who initiate the nonconformance get introduced to the review cycle?

8.5.3 Preventive Action

The company **shall** determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions **shall** be appropriate to the effects of the potential problems.

A *documented procedure shall* be established to define requirements for

- a) Determining potential nonconformities and their causes,
- b) Evaluating the need for action to prevent occurrence of nonconformities,
- c) Determining and implementing action needed,
- d) Records of results of action taken (see 4.2.4), and
- e) Reviewing preventive action taken.

Just a quick comment. There is a thread in the Cove Forums on Preventive vs Corrective Action. The thread was http://Elsmar.com/Forums/showthread.php?s=&threadid=687 and it's a doozy.

I bring this up to ensure that the difference between preventive and corrective actions is often not just blurred but an opinion.

I tell clients to base their preventive action system on data analysis and to use the corrective action system to follow through on them.

Example: A call center. One measurable is all calls answered within 40 seconds. Report is given weekly (all calls are tracked for several features including time to answer). Normally call time to answer was under 40 seconds - usually 15 to 30. It was shown slipping to 35 and 40. A 'corrective action' was started as preventative (reaction to data trend). A nonconformance (>40sec) had not been reached, but potential existed. Root cause, by the way, was increased client load without increased staff. New staff was hired, trained and put 'online'. Time-to-answer returned to <30sec.

Preventive action is a hot discussion topic. A quick read through http://Elsmar.com/Forums/showthread.php?s=&threadid=687 (linked to above as well) will give you an idea on how diverse opinion is. Another quick read is: http://Elsmar.com/Forums/showthread.php?s=&threadid=2654 which gives some examples
Element 8.5.3 of the new standard states that your company must identify preventive action to eliminate the causes of potential nonconformities to prevent them from becoming real nonconformities. The preventive action taken must be appropriate to the impact of the potential problems.

The 'old farts' out there like me may have noticed an evolution of what a preventive action is. In days of old (well, the 1980's) a preventive action was part of the result of a corrective action. It used to be what you did to ensure a problem which had already occurred would not again or would be caught through a Poke-Yoke or other mistake-proofing methodology.

Example:
   Problem: Part not machined.
   Reason: Tool broke
   Root Cause: Feed Speed set too high – Operator error
   Corrective Action: Revise tool change instruction, train operators.
   Preventive Action: Sensor to check shaft OD post-operation to ensure cut was made. A failure will stop machine. Or, Install automatic speed control to eliminate operator input requirement.

Things have changed to predictive (potential). The standard requires a documented procedure for preventive action that defines the requirements for:

a) Identifying potential nonconformities and their causes;
b) Determining and ensuring the implementation of preventive action needed;
c) Recording results of action taken;
d) Reviewing of preventive action taken.

Note that clauses 8.5.2 Corrective Action and 8.5.3 Preventive Action are almost identical, hence the processes that are developed for them will be very similar. It is strongly recommended that your company use the processes developed for corrective actions to address preventive action to standardize the approach and make it easier to implement. The personnel with overall responsibility for preventive action are likely the same personnel with overall responsibility for corrective action.

Preventive action is action taken to eliminate the cause of a potential problem that has not occurred. Your company has to ensure that the action taken is appropriate to the potential problem. The personnel who ensure it is appropriate preventive action should be the same people that ensure appropriate corrective action.

Preventive action focuses on studying your system and looking for where a problem might occur. Think data analysis, including looking for trends. Management then takes actions to ensure that the problem doesn't occur. Section 8.4.3 - Improvement processes - states that continuous improvement will be part of your management system. In other words, you look for both potential problems and opportunities for improvement at the same time. Thus, Preventive action and Continuous improvement can be easily combined.

To satisfy the requirements for preventive action you must develop a process for identifying the potential nonconformances and their causes, for determining and ensuring the implementation of the preventive action needed, then recording the results of the action taken and finally reviewing the preventive action taken. See corrective actions (8.5.2) herein for more background on this process and element.

The major difference between corrective and preventive action is that the nonconformances don't find you, you find the [potential] nonconformances. Some companies find it quite a bit easier to be reactive and not proactive – so - preventive actions are not as common as corrective actions. The secret here is the ability to identify potential nonconformances and then correct them before they become actual nonconformances. This obviously is not easy, but invested interest in identifying nonconformances before they occur is well worth it - ask anyone who has had a product recall (I am sure we are all familiar with the recent news of product recalls).

Potential Audit Questions

1. How well integrated are your preventive action and continuous improvement actions?

2. Do you feel your company seeks preventive actions enough? How could you do more to satisfy this requirement? How could your company do more to excel at this requirement?

3. How does your company identify the need for preventive actions? Do all workers identify preventive actions, or do you have a team or someone responsible for identifying preventive actions?

4. How does your company assess whether or not the preventive action is appropriate? Do many preventive actions arise without ever being implemented? Why?

Some Thoughts:

> From: ISO Standards Discussion <jennejohnn@uwstout.edu>
> Date: Fri, 29 Sep 2000 15:02:36 -0500
> Subject: Re: Q: Preventive Action /Conley/Andrews

>
> From: ea

--Patti inquired (in part);
--> We don't understand just how
--> far we need to go with preventive actions: do they need to be
--> documented & approved by someone, & then followed-up on
--> for effectiveness (similar to corrective actions)? Or is it
--> sufficient just to document what "preventive action" situations
--> have taken place & file them for later management review?"

> Patti,
>
> I have also encountered external auditors that come in looking for an entirely
> separate system for the handling of "preventive actions". What I have done to
> steer them in the right direction (toward proper interpretation of the
> 'intent' of the ISO 900X requirement) is to show the auditor where in our
> actions are incorporated. The topmost place in any QMS system
> to illustrate the presence of preventive actions is the existence of
> the system itself. The fact that you have a working QMS that requires
> management to periodically analyze the effectiveness of the system (internal
> audit results, customer complaints, internal nonconformities, etc.) with an
> eye toward undesirable trends is in and of itself a preventive measure
> (management is after all reviewing this information in order to improve the
> system where needed and thereby PREVENTING future problems). This is just one
> area of your existing system that you can use to demonstrate "preventative
> actions". I am sure that there are other areas within your existing system
> (supplier evaluations, training, etc.) that you can use as well.
>
> Hope this is helpful to get the 'ole gray matter' going.
>
> Ethan

From: Nancy Jennejohn
Date: Mon, 23 Jul 2001 22:59:17 -0500
Subject: Re: Elem 14 related to employee suggestions /../Scalies/Holtz

From: "John Holtz"

Charley Scalies wrote:

> I had a registrar's auditor tell me that since the new standard requires
> procedures for CA and also PA, he expects to see 2 separate procedures. I
> have a high regard for this guy - he usually has his head screwed on
> straight - so I figure he must have been off his feed that day.
> Has anyone else gotten the same silly "advice"?
>

Two procedures...one procedure...I can't imagine that being the issue with an auditor...but...if as an auditor I
did not see a procedural differentiation between corrective and preventive action, I'd ask for the
organization's understanding of the two concepts and follow the links or lack thereof to a process. The
differences are subtle. 9000:2000 differentiates them by "prevent occurrence" (PA) and "prevent
reoccurrence" (CA), but goes no further.. 9004:2000 implies that PA is data driven for potential events while
CA is driven by root-cause of actual events. Hmmmm. Actually, 9001:2000 may give us the most

information: from 8.5.2 "...take action to eliminate the cause of nonconformity"; From 8.5.3, "...determine action to eliminate the cause of potential nonconformity." Here's the tree-falling-in-the-woods conundrum as it relates to CA/PA: If in your corrective action you do what is necessary to assure that nonconformance will not happen again, is that a preventive measure or a corrective measure? According to what I've heard in 9001:2000 interpretation, that is CA, even though it "sounds an awful lot like" PA.

Sooo...IF that is CA, then what, pray tell, is PA? Although I fully endorse the data analysis interpretation of PA (for acting on trends before the trending actually leads to nonconformity), I go back to the concepts of mistake-proofing and FMEA at the design stage for clarification: if you design in the measures that eliminate the potential for nonconformity in the first place - and that is NOT easy to DO -- are you not practicing PA? To me, that's clear in theory and difficult-but-not-impossible in practice. My acid test is whether I can apply it to both a manufacturing and a non-manufacturing setting, and I can.

Back to wearing the auditor's hat, I'd allow some slack in interpretation, at least until there's a larger body of experience in interpreting 9000:2000. I'm known as being a "tough" auditor but also fair, and I see the value in differentiating the two processes in the manner stated above. I have also seen a lot of blank faces among my fellow quality professionals when I "talk like this," and so I'm using you all as guinea pigs in a way.

Have I added anything positive to the discussion of CA/PA or do you view this as further muddying of the already-silt-laden waters?

Cheers...and have a great day!
John Holtz

Reference Web Sites:
    http://www.iso.ch
    http://www.isotc176.org
    http://www.Elsmar.com

ISO 9001:2000
Interpretation and Upgrading

UPGRADING FROM THE 1994 VERSION

When you study the new ISO 9001 standard, you'll notice that it is less prescriptive than the old standard. In general, the new standard tells you what to do, not how to do it. The revised standard provides a more flexible approach than the previous standard as is evidenced by 'Permissible Exclusions'.

> 1.2 Application
>
> All requirements of this International Standard are generic and are intended to be applicable to all companies, regardless of type, size and product provided.
>
> Where any requirement(s) of this International Standard cannot be applied due to the nature of an company and its product, this can be considered for exclusion.
>
> Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within clause 7, and such exclusions do not affect the company's ability, or responsibility, to provide product that meets customer and applicable regulatory requirements.
>
> This is particularly evident when you look at how many times procedures are required. When you compare the old and the new standard, you'll notice that procedures are much less often required by the new standard. This more flexible approach gives you more freedom to decide how you're going to meet the requirements. In general, this should make it easier for you to develop a more suitable and effective quality management system.

Changes Being Introduced

*   Communicate with customers (7.2.3).
*   Identify customer needs and expectations (5.2, 7.2.1).
*   Meet customer needs and expectations (5.2).
*   Measure and monitor customer satisfaction (8.2.1).
*   Meet regulatory requirements (5.1, 5.2).
*   Meet statutory (legal) requirements (5.1, 5.2).
*   Support internal communication (5.5.4).
*   Provide quality facilities (6.3).
*   Provide a quality work environment (6.4).
*   Evaluate the effectiveness of training (6.2.2 c).
*   Measure and monitor realization processes (8.2.3).
*   Evaluate the effectiveness and suitability of quality system (8.4).
*   Identify quality management system improvements (5.1, 8.4).
*   Improve quality management system (5.1, 8.5).

Structure

The revision of the ISO quality management standards includes a significant change to the structure of ISO 9001 and ISO 9004, which, while retaining the essence of the original requirements, group the original 20 elements of ISO 9001:1994 and the guidelines of ISO 9004-1:1994 into four main sections:
*   Management responsibility
*   Resource management
*   Product realization
*   Measurement, analysis and improvement

Sequence

The ISO folks believe this is a more logical sequence for the requirements and guidelines due to the process orientation of the new standards

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Top Management

More emphasis has been placed on the role of top management, which includes its commitment to the development and improvement of the quality management system, with a customer focus, consideration of statutory and regulatory requirements, and establishment of measurable objectives at relevant functions and levels.

Continual Improvement

An enhanced requirement for "continual improvement" has been introduced, as anticipated, into ISO 9001, defining a complete cycle to improve the effectiveness of the quality management system.

Application

The concept of exclusions to the requirements of ISO 9001:2000 has been introduced as a way to cope with the wide spectrum of companies and activities that are (will be?) using the new standard, via clause 1.2 "Application".

Customer Satisfaction

Another new item that has been introduced into ISO 9001:2000 is the requirement for the company to monitor information on customer satisfaction as a measure of system performance.

Resources

Attention has been placed on top management to provide and make available the necessary resources. Requirements now include evaluation of the effectiveness of training, provision of relevant information, internal and external communication, facility needs, and human and physical factors of the work environment.

Terminology

It should be noted that changes have also occurred in terminology. The most important changes concern the use of the term "company" instead of "supplier", still used in the current standards, and the use of the term "supplier" instead of "subcontractor". These changes respond to the need of being more consistent and friendly with the normal use and meaning of the words.

Documentation

The number of requirements for documented procedures has been reduced in ISO 9001:2000, and the emphasis placed on the company demonstrating effective operation.

New Definitions

In the past, companies that wished to be certified were referred to as suppliers because they supplied products and services to customers. Since many people were confused by this usage, ISO has decided to use the word company instead. Now the ISO standards focus on the company, not the supplier.

The term supplier now refers to the company's supplier. The new redefined term supplier replaces the old term subcontractor (which has now been dropped). While this may sound a bit confusing, this new usage simply reflects the way these words are normally used.

In the past, ISO seemed to say that there were four kinds of products: software, hardware, services, and processed materials. In the new standard, ISO seems to take a more abstract approach. ISO now refers to these four items as generic elements, not types of products. According to the ISO folks, most products are made up of all four elements.

Specifically, a product is referred to as a hardware product when hardware is the dominant element. However, this product may also include processed materials, services, and software elements. Similarly, a product is referred to as a service when service is the main element of that product. But this product (service) may also include processed materials, hardware, and software elements.

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While you're probably familiar with some of the previous concepts, you may not have heard of the next one. ISO now uses the phrase **product realization**. While this is a rather abstract concept, it is now central to ISO's approach. In fact, ISO devotes an entire section to this new concept (Section 7). So what does it mean?

In order to grasp what it means you need to recognize that a product starts out as an idea. The idea is realized or actualized by following a set of product realization processes. Product realization refers to the interconnected processes that are used to bring products into being. In brief, when you start out with an idea and end up with a product, you've gone through the *process of product realization*.

Summary of the Main Changes to the Standard

'Continual improvement'

A move to 'customer satisfaction' [rather than 'customer complaints']

Conceptual Changes:
   * The most significant is the movement away from a procedurally based approach to management, i.e. stating 'how' you control your activities, to a 'process' based approach which is more about 'what' you do.
   * The standard is now much simpler in its structure and approach, which makes it easier to use and understand.
   * There is now considerable flexibility within the standard which requires a balance between documenting an activity and the competence of the staff involved.

Replacement of the '20 elements' by 5 broad headings:

Quality Management System

This section details the general and documentation requirements that are the foundation of the management system. The general requirements ask you to look at the processes of the management system, how they interact with each other, what resources you need to run the processes; and how you will measure and monitor the processes. The second part of the section then sets out the requirements for the documentation needed to operate the system effectively and how the documentation should be controlled.

Management Responsibility

The management of the systems is the responsibility of the "top management" at a strategic level in the company. The "top management" must know customers' requirements at a strategic level and make a commitment to meeting these as well as statutory and regulatory requirements. "Top management" must also set policies; and to achieve these policies set objectives through planning how the objectives will be met. "Top management" should also ensure that there are clear internal communications and that the management system is regularly reviewed.

Resource Management

This covers the people and physical resources needed to carry out the process. People should be competent to carry out their tasks and the physical resources and work environment need to be capable of ensuring that the customers' requirements are met.

Product/service Realization

These are the processes necessary to produce the product or to provide the service. This is the act of converting the input of the process to the output. For a manufacturing company, this may be the process of converting iron ore to steel via a blast furnace for example. For a service company, this may be the process of moving a product or person from one place to another, for example, a taxi journey.

Measurement, Analysis and Improvement

These are the measurements to enable the systems to be monitored to provide information on how the systems are performing with respect to the customer, the management systems themselves through internal audits, the processes and the product. Analyzing these, including any defect or shortfall in performance, will provide valuable information for use in improving the systems and products where this is required.

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*The main changes in more detail that have been **introduced** are:*

* A new process-oriented structure and a more logical sequence of the contents
* A continual improvement process as an important step to enhance the quality management system
* Increased emphasis on the role of top management, which includes its commitment to the development and improvement of the quality management system, consideration of regulatory requirements, and establishment of measurable objectives at relevant functions and levels (Measurement is extended to system, processes, and product.).
* The concept of "Application" of the standard has been introduced (in clause 1.2) as a way to cope with the wide spectrum of companies and activities.
* A requirement for the company to monitor information on customer satisfaction as a measure of system performance.
* Significant reduction in the amount of required documentation.
* Terminology changes/improvements for easier interpretation.
* Increased compatibility with ISO 14001 – the environmental standard.
* Specific reference to quality management principles.
* Consideration of the benefits and needs of all interested parties.
* Addition of the concept of company self-assessment as a driver for improvement (ISO 9004).
* Increased attention to resource availability.
* Determination of training effectiveness.

27. Analysis of collected data on the performance of the quality management system.

*Summary of management requirements which have been **clarified**:*

* Management is to establish the quality policy and quality objectives. The management review must be used to evaluate the need for changes to the quality management system, quality policy and quality objectives.
* The quality policy must be communicated and understood at "appropriate" levels, rather than at "all levels," within the company.
* Top management has the responsibility and must provide evidence of their commitment to ensure the availability of resources.
* It is now possible to have more than one designated management representative.
* The company must ensure that personnel with defined responsibilities in the quality management system are competent based on appropriate levels of education, training, skills and experience.
* The company must provide resources and facilities that are specific to the product.

The following Management Responsibility requirements, are new:

* Top management must provide evidence of their commitment to the development and improvement of the system, which includes communicating to the company the importance of meeting customer, regulatory and statutory (legal) requirements.
* Top management must ensure that the quality policy shows a commitment to continual improvement, provides a framework for quality objectives and is reviewed for ongoing suitability.
* The quality objectives must be established at relevant functions and levels, be measurable and consistent with the quality policy, and include those objectives needed to meet product requirements.
* Top management must ensure that customer needs and expectations are determined and fulfilled. The company must define and communicate the responsibilities and authorities necessary to facilitate effective quality management, as well as communicating the effectiveness of the quality management system and processes.
* The management representative has the authority and responsibility to promote the awareness of customer requirements throughout the company.

*   The inputs to the management review must be explicit and must include audit results, feedback from customers, process performance and product conformance analysis, preventive and corrective actions status, follow-up actions from previous management reviews, and any changes that might affect the quality management system.
*   The outputs from the management review include actions relating to improvement of the quality management system (and its processes), product improvement (related to customer requirements) and resource needs.
*   In a timely manner, the company must determine and provide the necessary resources to implement and improve the quality management system processes and address customer satisfaction.
*   The company facilitates continual improvement through the use of the quality policy, objectives, audit results, data analysis, corrective and preventive actions, and management review.

The following requirements are the same in both versions:

*   The company must establish and document a quality policy, quality objectives and its commitment to quality.
*   The quality policy must be relevant to company goals and customer requirements. The quality policy must be disseminated throughout the company.
*   Responsibilities and authorities are to be defined and communicated.
*   Top management is responsible for allocating adequate resources relating to the quality management system.
*   The management representative must be a member of top management who has defined responsibility and authority on matters relating to the quality system.
*   Top management is responsible for the periodic quality system review to ensure its suitability and effectiveness.
*   Records of management reviews must be kept.

The following items from ISO 9001:1994 have been omitted in the revision:

1. The specific list of actions for personnel who affect quality.
2. Responsibility and authority for personnel "that affect quality."
3. The specific language regarding types of resources (i.e., trained personnel) for management, work performance and verification activities, including audits.

What's the Relationship Between the Revised ISO 9001 and ISO 14001?

The revised ISO 9001 is developed to have enhanced compatibility with ISO 14001, particularly with regard to terminology and content. There is close collaboration between the technical experts of ISO/TC176 and ISO/TC207 (the Technical Committee responsible for the ISO 14000 series of standards). A recent review of ISO 14001 and ISO 14004 by ISO/TC 207/SC1 has led to the initiation of a revision of those standards. This will provide the opportunity for further enhancement of the compatibility between the ISO 9001 and ISO 14000 standards.

Are there any guidelines covering joint implementation of ISO 9001 and ISO 14001?

It is expected that the revisions of the two standards will be compatible in terminology and content. It is not expected that an ISO guideline will be prepared on this subject at the present time. If the need for such a document arises, ISO says they will consider the request as a new project.

For the quality and environmental auditing guidance standards (ISO 10011 and ISO 14010/14011/14012) the two responsible ISO technical committees (TC 176 and TC 207) are preparing a single common auditing standard (ISO 19011), scheduled for publication in the third quarter of 2002.

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Will there be a common guideline standard for auditing QMS and EMS according to ISO 9001 and 14001?

We are told Yes. A specific agreement between the two ISO Technical Committees (TC 176 and TC 207) has set up a joint working group to prepare a single standard on auditing activities, both for quality management and environmental management systems. This new standard (ISO 19011 – see http://Elsmar.com/Forums/showthread.php?s=&threadid=2332) will replace the existing ISO 10011 and ISO 14010/14011/14012 documents. The planned publication date for this new standard is the third quarter of 2002.

Why has the requirement for monitoring of customer satisfaction been included in ISO 9001?

"Customer satisfaction" is recognized as one of the driving criteria for any company. In order to evaluate if the product meets customer needs and expectations, it is necessary to monitor the extent of customer satisfaction. Improvements can be made by taking action to address any identified issues and concerns.

How much is the transition to the new standards going to cost?

The cost of implementing any necessary changes in order to meet the new requirements of ISO 9001:2000 will vary from one company to another, depending on various factors such as the actual state of implementation of the quality management system, the size and complexity of the company, the attitude and commitment of the top management, etc. Regarding the costs of upgrading the certification, IAF guidelines provide for the incorporation of audits to the new standard into surveillance visits for existing (1994) certifications, wherever possible.

Will my company need a full reassessment?

This is primarily an issue between your company and your registration/certification body. ISO/TC 176 is working with the IAF (International Accreditation Forum) and ISO-CASCO (Committee for Conformity Assessment) in order to provide relevant information in a timely manner. ISO-CASCO is responsible for the standards to which the Certification Bodies work (ISO-Guides 61 and 62), and the Accreditation Bodies are responsible for monitoring and approving the performance of Certification Bodies within their geographical area. It is expected that conformity to the new ISO 9001:2000 standard will be evaluated by certification bodies during regular surveillance visits, and that full reassessment will only take place once current certificates expire.

Will my company have to change its quality system?

No. It is not the intention that you should have to change the whole structure of your system or re-write all your procedures; however, the revised standards include some new requirements.

Will my company have to re-write all its documentation?

No. If your current quality management system is successfully implemented, satisfies the needs and objectives of your company, reflects the way your company works, and already addresses all of the new requirements, no changes are required. However, if your current documented system does not address all of the new requirements, additional documentation may be necessary.

Only 6 documented procedures are required by the standard for administration of the system; however, other documented procedures may be required by your company in order to manage the processes which are necessary for the effective operation of the quality management system. This will clearly vary depending on the size of the company, the kind of activities in which it is involved, and their complexity.

Has the Audit Process changed?

The changes require an internal or external auditor to look at the company's processes and audit them and their output as they occur, rather than audit compliance with the requirements of the standard. The new standard requires significant changes in auditing methods for both internal and external auditors. Auditing must now be more subjective and less objective, relying more upon questioning than hard evidence. This means that opinions of an auditor will be more of a factor than ever before.

In order to carry out a "process audit" the auditor must start with the inputs, follow the process through its various stages to examine how it is controlled and verify that the outputs meet what is required.

For example, such a process might be the actions required by the company on receipt of a customer order, and the steps taken to convert that order into something that will allow a product ordered to be manufactured. The input here would be the customer order, and the output, the company's internal documents, resources and materials that allow the manufacture of the product. Another example of a process could be those steps that a dry cleaner would take to procure the chemicals required by the cleaning process itself. The input would be the need to buy chemicals, the output would be the receipt of the chemicals from the supplier. Thus the auditor will need to look at the process, determine the inputs, examine how it is controlled, and look at the outputs. The way the process is controlled may require an examination of mechanisms other than documented procedures. Such control mechanisms could be by, for example, control charts, process flow diagrams or by training of operatives to ensure they are competent. Whatever the means by which the company decides to control the process, the auditor will seek evidence that the control mechanism is indeed effective. The ultimate test of effectiveness is an examination of whether the end result of the process is in accordance with the inputs.

An example of a buying process end result could be receipt of chemicals. If the purchase order did not contain sufficient information to allow the correct product to be supplied or was deficient in some way, then the output would not be acceptable. The customer may not get the chemicals that were required. Thus the process would not be giving the output required. Some change to the process would need to occur in order that the chemicals required were received, thereby making the process output acceptable. Thus, during an audit of the process, the auditor would need to determine if the process output, i.e. the chemicals received, met the requirements of the company and the process for obtaining them was operating under the controlled conditions that the company had defined.

Auditing of processes should result in a logical audit of the activities of companies in carrying out the various functions required to supply customers with a product or service which meets their needs. This change should therefore be viewed very positively.

If I followed your implementation advice for the 1994 version, how will I be affected?

Very little, actually. Since 1994 I have encouraged every client to take a process approach to implementation. I have recommended process mapping and the use of flow charts. If you followed my implementation advice prior to the release of the 2000 revision, you should little work to do to upgrade.

Are the revised standards more compatible with national quality award criteria?

The quality management principles are now the basis for the revised standards, which will be better aligned with the philosophy and objectives of most quality award programs. These principles are:
* Customer focus,
* Leadership,
* Involvement of people,
* Process approach,
* System approach to management,
* Continual improvement,
* Factual approach to decision making, and
* Mutually beneficial supplier relationships.

Do the Revised Standards Address Financial Issues?

Financial issues are not addressed in the ISO 9001:2000 standard, which is a requirements standard.

The ISO 9004:2000 guidance standard emphasizes the financial resources needed for the implementation and improvement of a quality management system.

ISO 9001:2000
Interpretation and Upgrading

1994 VS. 2000 CROSS REFERENCE

ISO 9001:1994 Description	ISO 9001:1994	ISO 9001:2000	ISO 9001:2000 Description
Quality System	4.2 & 4.2.1	4.1 & 4.2.2	General Requirements & Quality Manual
Management Responsibility	4.1		
Quality Planning	4.2.3	5.4.2 & 7.1	Quality Management System Planning & Planning of Product Realization
Quality Policy	4.1.1	5.1 & 5.3 & 5.4.1	Management Commitment & Quality Policy & Quality Objectives
Responsibility & Authority	4.1.2 & 4.1.2.1	5.5.1	Responsibility and Authority
Resources	4.1.2.2	6.1 & 6.2.1	Provision of Resources & General
Management Representative	4.1.2.3 & 4.2.2(b)	5.5.2 & 4.2.1	Management Representative & General
Management Review	4.1.3	5.6.1 & 8.5.1	General & Continual Improvement
Quality Systems Procedures	4.2.1 & 4.2.2	4.1 & 4.2.2 & 4.2.1	General Requirements & Quality Manual & General
Quality Audit	4.17	8.2.2 & 8.2.3	Internal Audit & Monitoring and Measurement of Processes
Personnel, General	4.1.2.2	6.1 & 6.2.1	Provision of Resources & General
Training	4.18	6.2.2	Competence, Awareness and Training
Contract Review	4.3	5.2 & 7.1.1 & 7.2.2 & 7.2.3	Customer Focus & Planning of Product Realization & Review of Requirements Related to the Product & Customer Communication
Design Controls, General	4.4.1		
Design & Development Planning	4.4.2 & 4.4.3	7.3.1	Design and Development Planning
Design Input	4.4.4	7.2.1 & 7.3.2	Determination of Requirements Related to Product & Design and Development Inputs
Design Output	4.4.5	7.3.3	Design and Development Outputs
Design Review	4.4.6	7.3.4	Design and Development Review
Design Verification & Validation	4.4.7 & 4.4.8	7.3.5	Design and Development Verification
Design Transfer	4.2.3(c) & 4.4.1	7.3.6	Design and Development Validation
Design Changes	4.4.9	7.3.7	Control of Design and Development Changes
Design History File	4.16	4.2.4	Control of Records
Document & Data Control	4.5 & 4.5.1	4.2.3	Control of Documents
Document & Data Approval & Issue	4.5.2	4.2.3	Control of Documents
Document & Data Changes	4.5.3	4.2.3	Control of Documents
Purchasing Controls, General	4.6 & 4.6.1		
Evaluation of Suppliers, Contractors & Consultants	4.6.2	7.4.1	Purchasing Process
Purchasing Data	4.6.3	7.4.2	Purchasing Information
Customer Verification of Purchased Product	4.6.4.2	7.4.3	Verification of Purchased Product
Control of Customer Supplied Product	4.7	7.5.4	Customer Property
Identification & Traceability	4.8	7.5.3	Identification and Traceability
Production & Process Controls, General	4.9(a), (c), (d), (e) & (f)	6.3 & 6.4 & 7.5.1 & 7.5.2	Infrastructure & Work Environment & Control of Production and Service Provision & Validation of Processes for Production and Service Provision

ISO 9001:2000
Interpretation and Upgrading

ISO 9001:1994 Description	ISO 9001:1994	ISO 9001:2000	ISO 9001:2000 Description
Production & Process Changes	4.4.9	7.3.7	Control of Design and Development Changes
Environmental Control	4.9(b) & 4.11.2(g)	6.3 & 6.4 & 7.5.1 & 7.5.2 & 7.6	Infrastructure & Work Environment & Control of Production and Service Provision & Validation of Processes for Production and Service Provision & Control of Monitoring and Measuring Devices
Personnel	4.9(b)	6.3 & 6.4 & 7.5.1 & 7.5.2	Infrastructure & Work Environment & Control of Production and Service Provision & Validation of Processes for Production and Service Provision
Contamination Control	4.9(b)	6.3 & 6.4 & 7.5.1 & 7.5.2	Infrastructure & Work Environment & Control of Production and Service Provision & Validation of Processes for Production and Service Provision
Buildings	4.9(b)	6.3 & 6.4 & 7.5.1 & 7.5.2	Infrastructure & Work Environment & Control of Production and Service Provision & Validation of Processes for Production and Service Provision
Equipment	4.9(b) & 4.9(g)	6.3 & 6.4 & 7.5.1 & 7.5.2	Infrastructure & Work Environment & Control of Production and Service Provision & Validation of Processes for Production and Service Provision
Manufacturing Material	4.9(b)	6.3 & 6.4 & 7.5.1 & 7.5.2	Infrastructure & Work Environment & Control of Production and Service Provision & Validation of Processes for Production and Service Provision
Automated Processes	4.4.8	7.3.6	Design and Development Validation
Process Validation	4.9	6.3 & 6.4 & 7.5.1 & 7.5.2	Infrastructure & Work Environment & Control of Production and Service Provision & Validation of Processes for Production and Service Provision
Receiving, In-process & Finished Device Inspection & Testing, General	4.10.1 & 4.7	7.1 & 8.1 & 7.5.4	Planning of Product Realization & General & Customer Property
Receiving Inspection & Testing	4.10.2	7.4.3 & 8.2.4	Verification of Purchased Product & Monitoring and Measurement of Product
In-process Inspection & Testing	4.10.3	8.2.4	Monitoring and Measurement of Product
Final Inspection & Testing	4.10.4	8.2.4	Monitoring and Measurement of Product
Inspection & Testing Records	4.10.5	7.5.3 & 8.2.4	Identification and Traceability & Monitoring and Measurement of Product
Control of Measuring & Test Equipment	4.11	7.6	Control or Monitoring and Measuring Devices
Inspection & Test Status	4.12	7.5.3	Identification and Traceability
Control of Nonconforming Product	4.13.1	8.3	Control of Nonconforming Product
Review & Disposition of Nonconforming Product	4.13.2	8.3	Control of Nonconforming Product
Corrective & Preventive Action	4.14	8.5.2 & 8.5.3	Corrective Action & Preventive Action
Device Labeling	4.15.1 & 4.15.4	7.5.5	Preservation of Product
Handling	4.15.1 & 4.15.2	7.5.5	Preservation of Product
Storage	4.15.1, 4.15.3 & 4.15.5	7.5.5	Preservation of Product
Distribution	4.3, 4.15.1 & 4.15.6	7.5.1	Control of Production and Service Provision

ISO 9001:2000

Interpretation and Upgrading

ISO 9001:1994 Description	ISO 9001:1994	ISO 9001:2000	ISO 9001:2000 Description
Installation	4.9	6.3 & 6.4 & 7.5.1 & 7.5.2	Infrastructure & Work Environment & Control of Production and Service Provision & Validation of Processes for Production and Service Provision
Device Packaging	4.15.1 & 4.15.4	7.5.5	Preservation of Product
Quality Records, General	4.5, 4.5.1 & 4.16	4.2.3 & 4.2.4	Control of Documents & Control of Records
Device Master Record	4.2.2 & 4.16	4.2.1 & 7.2.4	General
Device History Record	4.16	4.2.4	Control of Records
Complaint Files	4.14.1, 4.14.2 & 4.14.3	8.5.2 & 8.5.3	Corrective Action & Preventive Action
Servicing	4.19	7.5.1	Control of Production and Service Provision
Statistical Techniques	4.20	8.1 & 8.2.3 & 8.2.4 & 8.4	General & Monitoring and Measurement of Processes & Monitoring and Measurement of Product & Analysis of Data