

ISO 9001:20000 Quotation Considerations

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Quotation Considerations

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Slide 0

Notes & Commentary

This is the 'Notes' pane or 'window'. Many slides have notes which help explain the contents in more detail.

About Implementation Quotations



Cayman Business Systems
Business Standards Compliance

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THE BEACON FOR DIRECTION THRU THE QMS FOG AND INTENT BLURRR.
Take Refuge From The Storm in the Elsmar Cove!
Elsmar.com Marc.Smith@SpamCop.net

Prepared By:
Marc T. Smith

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Notes & Commentary

Implementation Considerations

- You are not the first. Over 345,000 organizations have registered to ISO 9000 as of March 2001.
- A main point to remember as you traverse this tome is that **each company is different**.
- There is no way I can address every possible type and size of company in a document such as this one. The contents represent the basis of a methodology I have used over the last 10 years in implementing ISO 9001 and QS-9000 in facilities as large as >10,000 souls, as small as 8 folks, in companies as large and complex as Motorola Semi-Conductor, as 'unusual' as Harley-Davidson, and as unique FWSC (an insurance company). The methodology is structured. How closely you follow the path will depend upon your specific circumstances and needs as well as your own beliefs. Some companies go slowly. Some companies do not want a complex project plan. Some companies insist on a complex project plan. But, more on this later.
- As much as anything else, you will have to assess my recommendations with consideration to your circumstances.

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Notes & Commentary

Project Considerations

A Consultant?

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Notes & Commentary

I was once told that a consultant rarely does more than tell you what you already know. I have heard many 'disparaging' remarks about consultants over the years. If you're considering a consultant you should ask yourself why.

If you have the expertise in-house, and you have the time, you probably don't need a consultant. A consultant cannot do any more than advise you (an education process) on what you have to do and how to proceed. The most frequent failure I find is where I advise a client and the client declines the advice. A good consultant can save you time and money. One can help you avoid the common pitfalls.

I do not for a minute believe that all reports of consultant incompetence are incorrect. There are many consultants out there that are a problem. Making matters worse in the field of ISO consulting is that in the last 6 years it seems 'everyone' has become an ISO consultant. In fact, companies such as Strider International sell courses on how to be an ISO consultant. Anyone can join the fray! I have two friends who went through the Strider program. One called it garbage and one will not comment on it but I know he has made no money from it.

Of course, I take the position that if you need a consultant you should contact Cayman!

Basic Reasons To Consider A Consultant

- To help plan your project
 - An efficient implementation begins with a solid plan, taking into account those things you need to work on, leaving out those things which are already in place, and developing an accurate estimate of how long each implementation phase should take.
- To help interpret the standard
 - A consultant who understands the standard's requirements can prevent wasted time doing things the standard does not require, or doing things in a way that does not meet the standard. You do not want to have to undo any of your hard work.
- To allow you to benefit from experience
 - Using a consultant allows you to begin work right away without having to learn things on your own, and without having to learn by your mistakes.
- To watch your timeline
 - A consultant can work with your steering team and ISO point teams and make sure the work is done within the time allowed on the timeline.

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Types of Consulting Services

- **'Full Service'**

On-site full-time for the duration of the project. Various roles & Responsibilities.

- **Visits - As Required**

Track progress through interviews (meetings) and 'internal audits'. Address interpretations issues. Help with systems design.

- **Internet / Phone**

Verify systems documents

Discuss interpretations and systems

Answer general questions

NOTES: Training can be applied to any of the above but is on-site.
Internet / Phone help is always available at no cost.

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Notes & Commentary

Once a client referred to me as their 'Piano Teacher'. I still use the analogy. I tell clients I can help them learn how to play, but I can't play the concert for them. I can tell them what the problems to expect are. I can help with interpretations. But I can't take the audit for you.

If you're a golf person, you might want to think of this in terms of a golf pro. You are after their experience and insight. You want them to evaluate your swing. You want their advice. But - they can't play the game for you.

Some clients want someone there every day. Others want a consultant on an 'as needed' basis. Some want to keep costs as low as possible and opt to try to do almost everything by internet and phone. There are pros and cons to each method but it really depends upon how much and what you expect from a consultant with consideration to in-house resources.

As often as not, the middle of the road 'Visits as required' path is followed and is typically appropriate.

Deliverables

- Dependent Upon The Client's **Needs** and **Expectations**
- Must Be **Agreed To In Advance**
- **Cannot be determined prior to a Pre-Assessment (Gap Analysis)**
 - No one can tell you what you need until they know what you have.
- **May Change During Project**
- **May Include:**
 - Project Management
 - Systems Design
 - Systems Documentation
 - Training
 - Internal Auditing

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Notes & Commentary

Defining deliverables sounds easy -- it isn't always so. Deliverables can become a sticking point and problematic for a number of reasons. For example, a company wants to do most of the documentation in-house but lacks employees qualified / trained to produce it. One client gave flow chart training to every employee from supervisors on up at the beginning of the project to ensure they could not only map their systems and processes, but that they could also maintain them in the future.

Often there is 'adjustment' during the project as strengths and weaknesses are recognized / identified. Problems ranging from resource issues to time considerations can significantly change the actual needs and requirements. When expectations are not met, changes in the project plan are to be expected.

I was at a client facility where we had just gotten started a week earlier. We were going through the motions of finalizing a purchase order. Deliverables came up in that corporate required defined deliverables on every PO. We spent about a week discussing 'deliverables'.

Even before you contact a consultant, you should be thinking about what you expect - including deliverables. And you should expect them to change somewhat as the project proceeds.

Starting From Scratch

- Developing and managing your implementation plan
 - Developing and drafting your Quality Manual – *Level 1 documents*
 - Establishing and documenting process flows for your procedures - *Level 2 documents*
 - Interviewing your personnel and establishing detailed instruction level documents - *Level 3 documents*
 - Identifying essential records to prove compliance with your Quality System
 - Interviewing and helping select the registrar that is right for you
- The instructions we can create can incorporate a variety of visual elements to promote clarity and increase understanding, including:
 - Digital photographs
 - Drawings
 - Flow diagrams
 - Scanned images
 - Text

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Most companies are already compliant to some degree. For example, most companies control their documents in some way.

Starting From Scratch -2

- We can also help you establish new systems, fine tune existing systems and maintain those systems after implementation. Consider the following examples of how we can establish and maintain your quality system to help it remain successful:
 - Instrument Calibration
 - Establish and document your calibration system (including calibration instructions and gage R&R's)
 - Locate and identify instruments
 - Catalog instruments
 - Identify, interview, and recommend equipment and calibration suppliers
 - Track the instruments within your calibration program
- Internal Auditing
 - Establish and document your internal audit system
 - Train your internal auditors and assist with initial audits
 - Schedule and track audits
 - Monitor and track corrective actions from findings identified during both internal and external audits
 - Follow up on corrective actions to verify effectiveness
- Document and data control
 - Establish and document your document and data control system
 - Identify documents for your master list
 - Review documents when necessary
 - Monitor and track the document review process
 - Regulate hard copy or electronic distribution of all controlled material

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Project Considerations

Implementation Guarantees

- Some companies offer 'guarantees'. Consider the details / requirements carefully.
- Typical Disclaimer Example

"The ISO 9001 Network *guarantees* that your company will achieve ISO 9001, TS-16949, or ISO 14000 certification *if you follow our program.*" -
From <http://www.isonet.com/Gaurantee.htm> (sic)
- The time it takes to implement a system is inversely proportional to the company's involvement and prioritization. As involvement and/or priority increases, time decreases. Pretty much a 'no brainer'.

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Notes & Commentary

I have been working with companies in implementing ISO standards since about 1993. Since then, it seems everyone and their brother has become ISO experts. Some companies offer 'Guarantees'. The one cited above is an example. Notice where they proclaim "...if you follow our program..." Often there are sweetheart deals with registrars as well.

When I first got into ISO 9001, it was because of a gal who told me about it - in 1991. She made a very good business out of implementations. One of her initial requirements was the company had to sign an agreement which said they would do everything she said was necessary. By default, she controlled the plant manager (or whoever the top dog was). She did not want to work with a company not dedicated to the effort and she would only implement 'her way'. Her program was US\$25,000 down and US\$1500 each 1/2 day visit. She would visit once or twice a month. She did quite well, actually. But she was demanding. She had one heck of a sales pitch. She's still in business and doing well, by the way. We do implementations differently, however, to say the least.

I will offer the same guarantee to any client. If you give me control, if you will do everything I say (including providing various training programs when necessary), I will guarantee successful registration as well. I have never had a client fail a registration audit to begin with, however, so to me this isn't a significant issue.

Example Guarantee Program

8-Step Guaranteed Registration Plan

A cost effective training and consulting package to help your organization achieve registration -- GUARANTEED!

Our philosophy is to assist your company in developing and applying the skills necessary to plan, implement and achieve registration.

The 8-Step Guaranteed Registration Plan includes:

1. ISO/TS-16949 Introduction Seminar - Training
2. ISO/TS-16949 Awareness Sessions - Training
3. ISO/TS-16949 Needs Assessment - Consulting
4. ISO/TS-16949 Implementation/Documentation - Training
5. ISO/TS-16949 System Development, Consulting, Coaching, Training
6. Choosing a Registrar - Consulting
7. Part A: ISO/TS-16949 Internal Auditor Training
Part B: Internal Auditor Site Coaching - Training
8. Part A: Pre-Assessment Audit - Consulting
Part B: Registration Audit - Consulting

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Notes & Commentary

There are now many companies which give implementation guarantees. This is a typical 'guaranteed' implementation program. Please note that I do not disagree with the program they have outlined. In fact, I do endorse it as a sensible, structured approach. I do not agree that every company needs all of the training cited, however, as an example. Each company is simply too different.

Companies are each different. That is why I do not offer a 'canned' approach. Until I know what you have, I can not know what you need.

When you see a guarantee promise, remember: There is no magic answer. Be sure you understand the restrictions on any guarantee you consider.

What If You Need Training?

We have various in-house training programs, including:

- ISO / TS 16949 Executive Management Overview - The Realities
- Introduction to ISO / TS 16949 for Managers & Executive Management
- Introduction to ISO / TS 16949 for Hourly Employees
- Internal Auditing (TS or ISO Specific)
- 8 Disciplines Problem Solving (Closed Loop Corrective Action - a 7-D to some folks)
- Design/Process/Product/Device/Cell/Maintenance Failure Mode and Effects Analysis (FMEAs)
- Advanced Product Quality Planning (APQP)
- Production Part Approval Process (PPAP)
- Measurement Systems Analysis (MSA)

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Training Considerations:

We don't just leave you the books. You get the editable files for in-house course development. Course source files are in Microsoft PowerPoint, Excel, and Word from which class materials are printed. The course source data files are yours to use in-house in any way you please. There is no license or other fee - they are 'part of the course'. They may be modified in any way you choose. All we ask is that you reference the Cayman Cove! as a resource in your 'evolved and tailored' course somewhere and that you do not 'give away' the original data file(s) to those outside your company or sell the original data file(s) to anyone. Most companies take the files, tailor them to their facility and/or company and use them for structured in-house training.

Cooperation

- A consultant cannot simply come in and do everything for you. Personnel must be available and free to work with the consultant. **Planning is important!**
- Some companies 'fight' the project. This is most evident where key employees:
 - Are 'too busy today' to participate.
 - Do not complete 'assignments'.
 - Are not 'interested'.
- While some companies are 'compliant' in many areas, others are not. In many companies this means some employees will have new duties assigned them (few companies want to hire new people). However, some companies are very 'tight' with respect to personnel as is. **Place special consideration of the availability of adequate resources early in the project.**

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Notes & Commentary

I wanted to bring this slide in to briefly explain that it is important to know there is no 'silver bullet' to implementation. While the slide is titled Cooperation, I could call it The Consultant's Blues. The consultant arrives and no one is available to work with. Meetings are postponed or constantly interrupted. Little progress is made. To the consultant, this is painful. S/he is trying to get things accomplished and cannot 'get people started'. This is why many conversations about '**Management Involvement**' being crucial to an implementation. It must be clear to all that this is a project and it must be given time and attention. In addition, management must ensure early in the project that there are 'adequate resources' and that responsibilities are defined. Employees must know what they are responsible for.

This is more often a problem for smaller consultancies. Bringing in Ernst & Young commands much more attention.

A Consultant? Some Last Thoughts...

1. Prepare a statement outlining the nature, scope and objectives of the project.
2. Circulate this written statement to the key people in your organization inviting them to comment by a specific date in terms of whether it defines the need accurately and whether the assignment should be tackled internally or external help sought.
3. Define the expertise you will need.
4. Brief the staff who will be involved in the selection process.
5. Avoid organization jargon.
6. Convey this to the prospective consultant.
7. Invite the consultant for an interview.
8. Ask the consultant to describe how the assignment will be approached.
9. Request references, in confidence, to provide real examples of previous assignments carried out and check with the referees how successfully the assignment was carried out. Do not buy on price alone.
10. Express the assignment you wish carried out in terms of the end results, i.e. outputs, that you want to achieve.

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Notes & Commentary

If you follow these simple steps, you will avoid much heartbreak, not to mention heart burn....

IF YOU PROCEED... Provide resources and executive commitment. There is no point in seeking consultancy help unless you have the will, the resources and the organization resolve to follow the advice you get.

The Basics

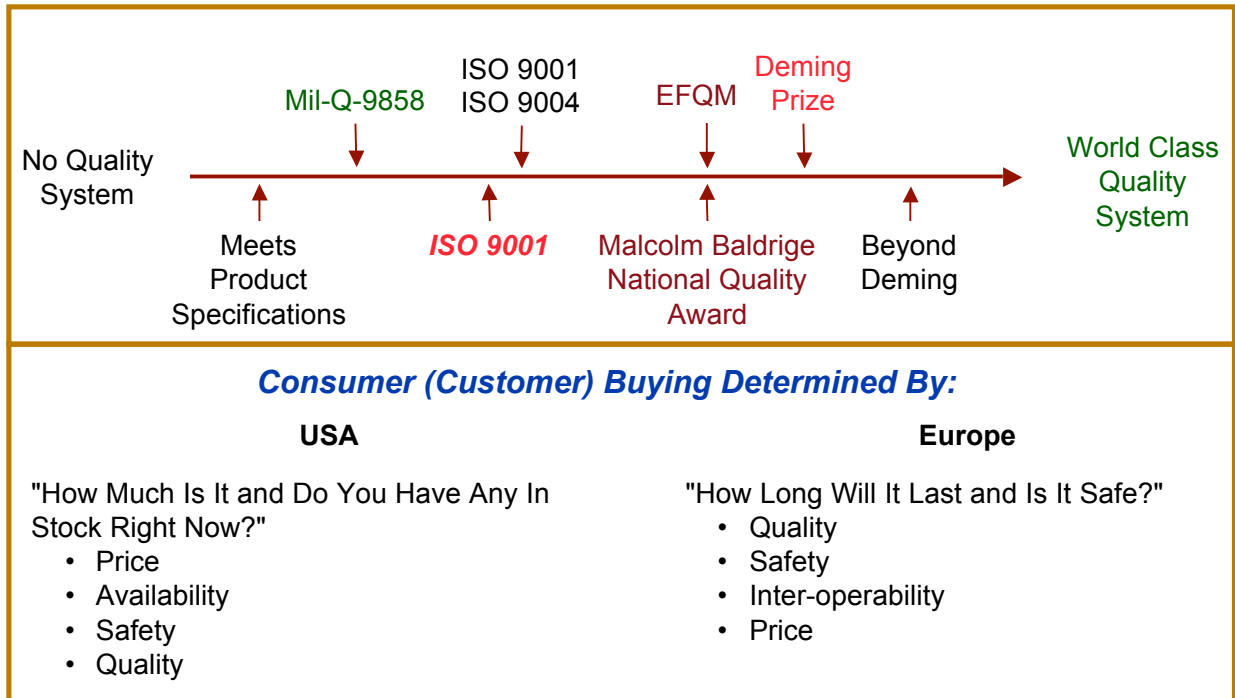
Some Thoughts About Quality Systems

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Notes & Commentary

Quality Systems



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CE Mark: The original thrust was to provide for compliance to new EC safety directives for Regulated Products. The goal is to allow for meeting product regulations in all EC countries by providing a route to gaining approval for use of the CE (Communaute Europeene) mark. The CE mark is becoming the passport for selling **regulated** products in Europe.

A. **Unregulated** Products Examples

- Paper
- Furniture

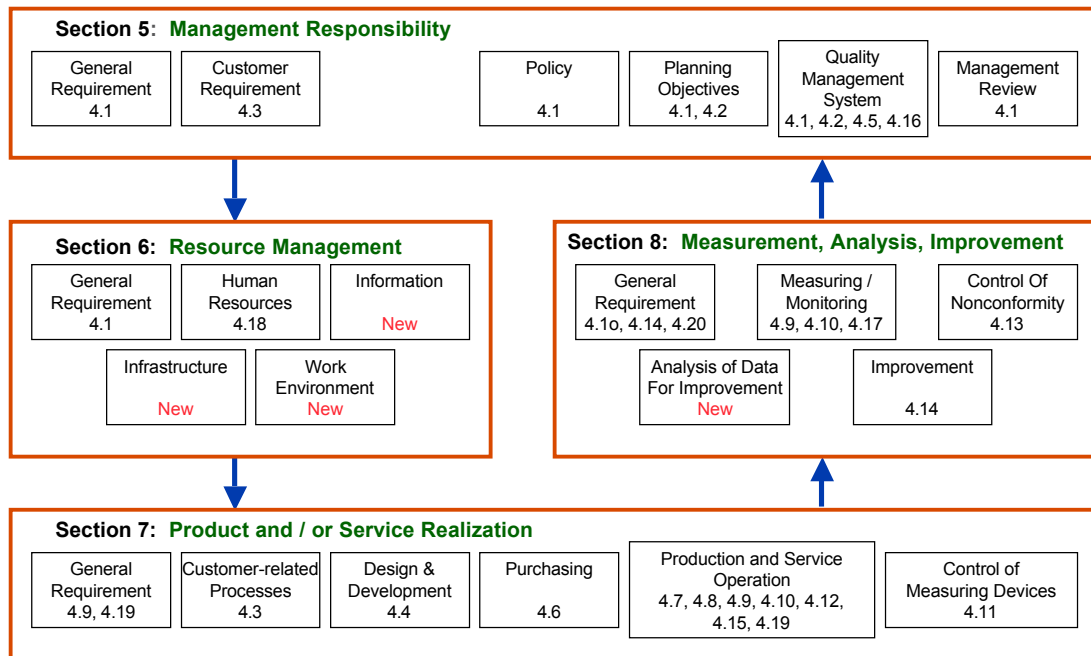
B. **Regulated** Products Examples

- Machinery
- Toys
- Personal Protection Equipment
- Medical Devices
- Telecommunications Equipment

EFQM: The organisation administering the European Quality Award in Brussels. Just for info, over 10,000 companies are using the Business Excellence Model

ISO9001:2000 DIS Structure

Section 4: Quality Management Systems Requirements 4.2



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I have included this slide as a historical perspective. Essentially it was a pictorial of the 'sections' reconciling the 1994 and 2000 versions in Appendix A in the final DIS.

The 'old' standard had 20 sections or elements. These have been grouped into 4 sections in the year 2000 version of ISO 9001. This will be of more interest to those going through an 'upgrade' than to you new folks.

The relationships and all details are addressed in Clause_Interp_and_Upgrading.doc which is included with the 'Implementation Guide' package.

ISO 9001:2000 Vs Baldrige

Baldrige Criteria

ISO 9001:2000		Leadership	Strategic Planning	Customer Focus	Information Analysis	Human Resources	Process Management	Business Results
4	Quality Management System							
5.1	Management Commitment							
5.2	Customer Focus							
5.3	Quality Policy							
5.4	Planning							
5.5	Resp., Authority & Communication							
5.6	Management Review							
6.1	Provision of Resources							
6.2	Human Resources							
6.3	Facilities							
6.4	Work Environment							
7.1	Planning of Product Realization							
7.2	Customer Related Processes							
7.3	Design and/or Development							
7.4	Purchasing							
7.5	Production and Service Operations							
7.6	Control of Measuring and Monitoring Devices							
8.1	General							
8.2	Measurement and Monitoring							
8.2.1	Customer Satisfaction							
8.2.2	Internal Audit							
8.2.3	Measurement and Monitoring of Processes							
8.2.4	Measurement and Monitoring of Product							
8.3	Nonconforming Product							
8.4	Analysis of Data							
8.5	Improvement							
8.5.2	Corrective Action							
8.5.3	Preventive Action							

Aligned 
 Somewhat Aligned 
 Not Aligned 

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For those of you interested in the Baldrige program, stop by <http://16949.com> and search for Baldrige.

Malcolm Baldrige National Quality Award Criteria Circa 4/2001

1. Leadership

- Organizational Leadership
- Public Responsibility and Citizenship

2. Strategic Planning

- Strategy Development
- Strategy Deployment

3. Customer and Market Focus

- Customer and Market Knowledge
- Customer Relationships and Satisfaction

4. Information and Analysis

- Measurement and Analysis of Organizational Performance
- Information Management

5. Human Resource Development and Management

- Work Systems
- Employee Education, Training and Development
- Employee Well-Being and Satisfaction

6. Process Management

- Product and Service Processes
- Business Processes
- Support Processes

7. Business Results

- Customer Focused Results
- Financial and Market Results
- Human Resources Results
- Organizational Effectiveness Results

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Implementing ISO 9001:2000

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Notes & Commentary

Project Duration

How long will it take?

- An implementation project will typically take about 6 to 9 months, but will range from 3 to 20 months.
- Factors that will affect the timeline include:
 - Size and complexity of the organization.
 - Existing systems.
 - Existing documentation.
 - Amount of resources available for the project
 - ISO expertise available.

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Notes & Commentary

Simple Schedule

Month:	1	2	3	4	5	6	7	8	9	10	11	12
Planning												
Development												
Implementation:												
Developing processes												
Documenting processes												
Running the system:												
Collecting records												
Internal Audits												
Management review												
Registration												

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When you think about a project schedule, remember a gap analysis is Job 1. If you don't do a gap analysis you have no idea what you have to to!

Typical Costs

Annual Sales Volume	Average Annual Savings	Average Cost per Company
Less than \$11 million	\$25,000	\$62,300
\$11 million - \$25 million	\$77,000	\$131,000
\$25 million - \$50 million	\$69,900	\$149,700
\$50 million - \$100 million	\$140,000	\$188,800
\$100 million - \$200 million	\$195,000	\$208,700
\$200 million - \$500 million	\$227,000	\$321,700

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Payback

- Companies **minimize deficiencies** in supply and support of products and services.
- Companies **identify problem areas** and address them quicker.
- Companies **identify customer needs** more accurately.
- Companies **become more consistent** in their product and services.



MEASURE OF IMPACT	BEFORE	CURRENT	DIFFERENCE
• PPM Defect Level	3345	1698	49% decrease
• Number of Returns	749	346	54% decrease
• Warrantee Cost (x000)	700	667	5% decrease
• Scrap Percent	4.3	3.7	14% decrease
• Rework Percent	24	19	26% decrease
• Cost of Nonconformance	94	44	53% decrease
• Return on Investment	-	-	158%



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The above was from a real company which went through implementation. They reported the figures above.

If there is an inconsistency it is in that the figures were taken shortly after registration. I have not seen any long term studies. This is not surprising. Many companies are undergoing some type of improvement program at any given time so after implementation the next program can also affect these figures. One of my clients was undergoing TPM, 5-S and TS-16949 implementation at the same time. To try to assign cause to any one of them for better numbers observed is difficult, if not impossible.

When a company goes through the implementation process there is typically a very close look at, and an evaluation of, what is going on. While it happens, it is unusual not to see some type of spike (at least) in numbers. A heightened awareness exists. This is to say the implementation process alone is a learning experience. The question becomes '...how long will this last?'

Please do not misunderstand - I don't believe there are many companies which do not profit from implementation. Often it is hard to translate savings to \$, however.

The ISO Standards

ISO 9000:2000 Quality management systems – Fundamentals and vocabulary

Establishes a starting point for understanding the standards and defines the fundamental terms and definitions used in the ISO 9000 family which you need to avoid misunderstandings in their use.

ISO 9001:2000 Quality management systems – Requirements

This is the requirement standard you use to assess your ability to meet customer and applicable regulatory requirements and thereby address customer satisfaction.

ISO 9004:2000 Quality management systems – Guidelines for performance improvements

This guideline standard provides guidance for continual improvement of your quality management system to benefit all parties through sustained customer satisfaction.

ISO 19011 Guidelines on Quality and/or Environmental Management Systems Auditing (currently under development)

Provides you with guidelines for verifying the system's ability to achieve defined quality objectives. You can use this standard internally or for auditing your suppliers.

ISO 10005:1995 Quality management – Guidelines for quality plans

Provides guidelines to assist in the preparation, review, acceptance and revision of quality plans.

ISO 10006:1997 Quality management – Guidelines to quality in project management

Guidelines to help you ensure the quality of both the project processes and the project products.

ISO 10007:1995 Quality management – Guidelines for configuration management

Guidelines to ensure that a complex product continues to function when components are changed individually.

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ISO/DIS 10012, Quality assurance requirements for measuring equipment – Part 1: Metrological confirmation system for measuring equipment

Give you guidelines on the main features of a calibration system to ensure that measurements are made with the intended accuracy.

ISO 10012-2:1997, Quality assurance for measuring equipment – Part 2: Guidelines for control of measurement of processes

Provides supplementary guidance on the application of statistical process control when this is appropriate for achieving the objectives of Part 1.

ISO 10013:1995, Guidelines for developing quality manuals

Provides guidelines for the development, and maintenance of quality manuals, tailored to your specific needs.

ISO/TR 10014:1998, Guidelines for managing the economics of quality

Provides guidance on how to achieve economic benefits from the application of quality management.

ISO 10015:1999, Quality management – Guidelines for training

Provides guidance on the development, implementation, maintenance and improvement of strategies and systems for training that affects the quality of products.

ISO/TS 16949:1999, Quality systems – Automotive suppliers – Particular requirements for the application of ISO 9001:1994

Sector specific guidance to the application of ISO 9001 in the automotive industry.

Required Level II Flow Charts (Procedures)

Procedures 'Required' By the 2000 Revision

- 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

Partial Listing of Procedures 'Required' By the 1994 Revision

- 4.3 Contract Review
- 4.4 Design Control
- 4.5 Document and Data Control
- 4.6 Purchasing
- 4.7 Control of Customer Supplier Product
- 4.8 Product Identification and Traceability
- 4.9 Process Control
- 4.10 Inspection and Testing
- 4.11 Control of IM&TE
- 4.12 Inspection and Test Status

Note:

A requirement for a 'documented procedure' is not a requirement for a text based document. A flow chart is readily acceptable. I've been using them in implementations for years. I personally disdain text based procedures.

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If you read through ISO 9001:2000, you will find 6 places where Documented Procedures are specifically stated to be a requirement. Some folks have been saying how nice it is that the documentation requirements have been reduced. While this is technically the case, it is really a non-issue. For the most part companies are not going to be reducing their documentation significantly if at all.

What about new implementations? Will this be a big help to you? No - not really. You will have to have the 'appropriate' documents in place regardless. Take for example 7.4 Purchasing. There is very likely that your company will need a purchasing procedure. Often there are a number of purchasing 'procedures' (systems) which will require some type of documentation. The absence of the requirement does not exempt your company from having documentation 'where appropriate'. Where appropriate will be determined by a common sense look at the process in context.

One must remember that to comply with the 1994 version, most companies adopted the Level II approach - make 20 top level procedures or flow charts to address each element of the standard.

Some Other *Expected* Process Maps

- Planning (5.4, 7.1, 8.1, 8.5.1)
- Management Review (5.6)
- Resource Management (6)
- Training (6.2.2)
- Customer Processes (7.2)
- Customer Communication (7.2.3)
- 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)

Note: Some of these may not be relevant to your company. An example is Product Identification and Traceability. If you are a *service* company, Product Preservation will *probably* not apply to your situation. Remember, however, that exclusions are limited to requirements within Element 7 - Product Realization.

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As you can see, most of the documents in the above listing are parallels to the 20 'old' ISO elements. It may be that the new standard does not specifically require a document to cover each of these, however it will most often be the case that your company will have to document these systems at least minimally.

As I have stated before, the level of documentation your company will need cannot be determined by a book or reference. Your company may have relatively simple systems and on-the-job training may be utilized more than at another company. You may be a facility which is part of a corporation where there are flow-downs you will have to comply with (some of which will probably be documentation requirements). Or, your company may only consist of 8 souls who provide a service - your documentation will probably be minimal.

You have to review, within your company, what you are doing now and making some common sense determinations of where documentation is relevant and 'necessary'.

Implementing ISO 9001:2000

- Some of you will be implementing in small companies. Some of you will be implementing in very large companies. In this document there is a mix of information. Some is appropriate to larger companies and some is targeted to smaller companies. In general it should be obvious but the rule of thumb is the bigger the company the more complex the issues become. Multi-nationals are the most complex, as one would expect.
- While this presentation is aimed at ISO 9001, it applies to ISO 14001 and TS-16949 as well, for the most part. There are a number of additional issues associated with TS-16949, however in general the intent is the same in so far as the ISO 9001:1994 requirements basis. Implementing ISO 9001 vs. TS-16949 is no different. From sweeps to document mapping, you have to determine what you have, what you need and how you want to get to the finish line.
- Do not forget that implementing a QMS is a project.

Quotation Considerations

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Notes & Commentary

Some basic tips for small companies:

Keep your documentation short and sweet. Keep a simple documentation matrix. An example is included (disk file name: Document_Matrix.xls) with the 'Implementation Guide' package.

Don't over document. Often training and/or experience will be sufficient. You have to think about what documentation people need and what they don't. If you did not have documentation before (such as work instructions), what you have will probably be sufficient. The key is knowing how to explain why you do or do not have documentation with respect to how people know how to do their jobs.

One of my former clients wrote me:

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?

I think that pretty much says it all. Remember. Simplicity. Common sense.

The Fed Ex Registration

Food for thought... Discussion at:

<http://Elsmar.com/Forums/showthread.php?s=&threadid=589>

Subject: RE: ISO 9001 *Certified Virtual Office*

Just as a point of clarification, the Fed-Ex audit approach was an exception to the rule. You are correct in stating that registrars need to follow rules for multi-site sampling. *In this unique case, the RAB did approve the unusual approach used by the registrar.* The exception was approved due to the unique design of Fed-Ex's systems. It is unlikely that another organization will duplicate these systems. Therefore, we should not expect to see this unique audit approach used for other organizations.

Indeed it was a virtual audit because *hundreds of field offices were audited without the auditor physically being there.* My agreement of confidentiality does not allow me to share more with you. Unless you fully understand how the Fed-Ex systems is set up, it is difficult to see that conducting a virtual audit is possible. It remains a controversial certification because of the approach used and the fact that *it has not yet been used at another organization.*

Quotation Considerations

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Notes & Commentary

One response:

I would be extremely cautious of using the Federal Express example for doing virtual offices. Their certificate is a joke. I have called twelve of their regional offices to find they have no procedures. They do not know what their quality policy is and they do not do customer requested corrective action because they do not know what it is. In addition a call to the corporate office in Memphis resulted in pretty much the same results except when the customer service person who answered was asked about ISO they said that I would have to talk to their sales person if I wanted to get their on line tracking software. When asked a second time the person said they didn't know what I was talking about. When finally directed to the head of the corporate customer service department the lady indicated she knew they were certified and would get a hold of the person who had implemented it to have him call me and send a copy of their certificate. That never occurred.

I sent a request to their registrar for verification that all offices really had been audited and was sent a nice letter indicating they did all of the offices from Memphis and they included a copy of the page out of Federal Expresses book showing they had been registered.

I have asked for corrective action no less than 5 times from Federal Express and still can not get one from anyone in the company. In addition they fail contract review but not notifying the customer when they fail to make a delivery as scheduled.

I continue to be amazed by the fact they continue to pass their audits but then again if the auditors never get out of Memphis I guess they see only what Federal Express wants them to see.

Implementation - The Process

Quotation Considerations

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Notes & Commentary

Implementation Strategies

- **Compressed Project**
 - Drop Dead Date
 - High Priority Project Management Approach
 - Intimate high level management involvement
 - Regular Scheduled Meetings
- **Business As Usual**
 - Low stress
 - Low Priority Project Management Approach
 - Slipping schedule not critical
 - Irregular Meetings
- **Meandering**
 - Slipping schedule not important
 - Low level management support / involvement
 - Irregular meetings
 - Project tends to 'Fade Away'

Quotation Considerations

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Notes & Commentary

Each company has a personality and tenor. Top management is extremely variable in how they approach, participation in and their interest in registration. Some are very involved. Some want to watch but monitor closely. Some don't want to participate at all.

Some companies are given ultimatums. Deadlines. No new business, or reduced business threats (particularly US automotive). Some companies go through the process in an attempt to improve.

These are three implementation strategies a company has to consider. It should be noted that available human resources is an important part of any implementation strategy. Unfortunately, often this aspect is a serious threat to successful implementation within the project constraints (e.g.: time).

A Plan - Think Project

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Notes & Commentary

Example Project Plan Snippet

Task ID	Project Elements	Days	Start	Finish	1999 Qtr 4, 1999 Qtr 1				
					Sep	Oct	Nov	Dec	Jan
1	Define Scope of Assessment	25d	Mon 9/20/99	Fri 10/22/99	<div><div></div></div> 0%				
2									
3	Kick-off Meeting	1d	Thu 10/7/99	Thu 10/7/99	<div><div></div></div> 100%				
4									
5	Project Set-Ups	73d	Thu 10/7/99	Mon 1/17/00	<div><div></div></div>				
6	Establish Master Binders	43d	Thu 10/7/99	Mon 12/6/99	<div><div></div></div>				
7	Procedures History Binder (Scott)	1d	Thu 10/7/99	Thu 10/7/99	<div><div></div></div> 100%				
8	Project Master Binder (Scott)	1d	Thu 10/7/99	Thu 10/7/99	<div><div></div></div> 100%				
9	Define Documentation Systems	25d	Tue 11/2/99	Mon 12/6/99	<div><div></div></div> 40%				
10	Document Company Quality Policy	35d	Tue 11/2/99	Mon 12/20/99	<div><div></div></div> 0%				
11	Tailor Company Quality Systems Manual	30d	Tue 12/7/99	Mon 1/17/00	<div><div></div></div>				
12									
13	Registrar Selection	110d	Mon 10/11/99	Fri 3/10/00	<div><div></div></div>				
14	Preparation, Initial Selection	35d	Mon 10/11/99	Fri 11/26/99	<div><div></div></div> 100%				
15	Contact, Complete Rating Sheet	30d	Mon 11/29/99	Fri 1/7/00	<div><div></div></div> 8				
16	Interviews (2 to 4)	15d	Mon 1/10/00	Fri 1/28/00	<div><div></div></div>				
17	Agree on Scope, Fees, Audit Dates	30d	Mon 1/31/00	Fri 3/10/00	<div><div></div></div>				
18									
19	Awareness & Mapping Meeting - Management	94d	Wed 10/27/99	Mon 3/6/00	<div><div></div></div>				
20	ISO Overview	1d	Wed 10/27/99	Wed 10/27/99	<div><div></div></div> 100%				
21	Process Mapping	1d	Wed 10/27/99	Wed 10/27/99	<div><div></div></div> 100%				

Quotation Considerations

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Notes & Commentary

This is a snippet from a Project Plan in project software. I am a firm believer in project plans. Even smaller companies should use a plan. I am also aware of how often they change with circumstances.

I highly recommend a tracking method. One of the worst things you can do in an implementation is lose control of the status of the project on a level of individual responsibilities. At Motorola in Guadalajara we help meetings every Thursday. It was in the 'War Room'. Chairs were removed from the conference room. Each element had been assigned to a point person. Systems documents and status were posted on the walls as well as an overall progress chart. Every 'point person' had 5 minutes to state the status of their element and 5 minutes more to answer questions. The plant manager and all upper management attended each meeting. Absences were simply not allowed and there were none.

This forced communication and an honest assessment weekly (we did the implementation in 6 months - ~4000 souls). If someone had a resource issue, this meeting is where it was to be brought up for immediate resolution (no waiting while upper management 'thinks about it').

Project Scope Considerations

- **Single Location**

- Current company / facility status
- Scope of registration
- Training needs
- Implementation strategy
- Resource allotment

- **Multiple Locations**

- Single or shared certificate
- Degree of shared documentation
- Degree of shared data / information systems
- Network Capacity / Capability

NOTE: Single location considerations all apply to multiple location projects.

Quotation Considerations

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Notes & Commentary

Different companies look at their registrations differently. Some have multiple locations on a single certificate. It's cheaper, generally, to do so. You 'make a deal' with the registrar. As with everything else, the more you want to buy in a 'chunk', the quicker they are to offer a discount.

Those who chose to have each location on a different certificate are typically looking at the weakest link aspect of a single certificate: If 1 location 'fails', all locations are affected.

The other aspects noted above should be self explanatory.

You can register 1 location in a corporation. Or you can register a corporation. You can even, theoretically, register one part of an individual facility. You address this issue in your registration **Scope** statement. You should discuss the scope of your registration very early in your contact with registrars (prior to or during the interview process).

Implementation Commandments

- You cannot give someone a **responsibility** without publicly conferring **authority** to act.
- If top management doesn't care, no one else will care.
- If planned meetings are not attended, 'someone' isn't serious about their part in the project.
- Track the project publicly. Publicize status weekly or bi-weekly.
- Communication may not be everything, but it is the largest single stumbling block. No camps with walls.
- If people do not have enough time to begin with, they won't have time for this.

Quotation Considerations

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Notes & Commentary

A common failure or cause of delay in implementations is the failure of management to assign responsibility without authority and/or oversight of the project. If you tell someone to do something and don't give them the resources and 'power' to do it, it will probably fail. Again, different companies have different tenors.

Another major failure mode is where there really aren't enough resources (personnel, particularly) to get things done in addition to regular responsibilities. A few years ago I told the plant manager that there was no way for the company to succeed in the time expected because it was evident employees were at their limit in so far as time went. He called a meeting of upper management and middle managers and said: "I realize there is a resource issue. I will take the hit for lost productivity. Quality shall not suffer even though output may. Please put your ISO responsibilities on the top of your agenda." He authorized the war room to be stocked around the clock with sandwiches, drinks and snacks. Employees worked overtime. We had a meeting every Thursday to discuss progress including resource needs, including temporaries. This plant was 3000+ souls and completed everything in 6 months.

Often, outside help is needed with documentation. A number of clients have used temp firms to get legacy paper documentation input into their preferred software, for example.

'Standard' General Registration Path

- **Consultant?**
 - Assess your situation (**Pre-assessment**)
Also called **Gap Analysis**
 - Define a plan with time line & begin
 - Interview and choose registrar
 - Documentation processes
 - Manage transitional activities
 - Registrar document review
 - Registrar pre-assessment
 - Corrective actions
 - Registration audit
- Implementation time frame: 3 months to 2 years

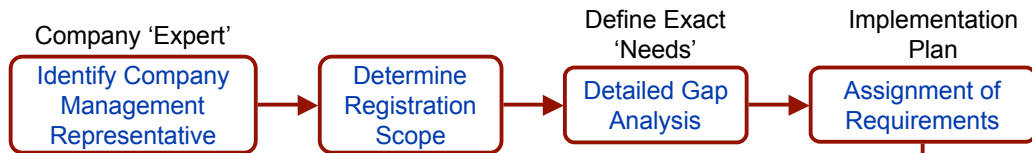
Quotation Considerations

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Notes & Commentary

Top Level Project Flow

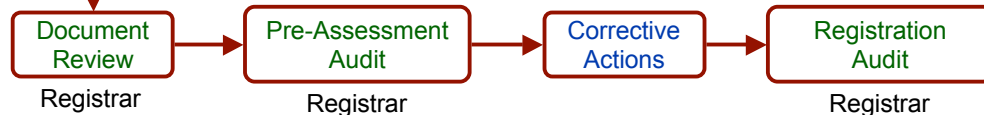
Project Definition



Project Actions



Project Fulfillment



Quotation Considerations

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Notes & Commentary

This is the basic implementation flow that I recommend. Each step is a dependency on the step before. This does not mean that steps cannot be carried out simultaneously - and they typically are. However, the completion of one step is dependent on completion of the previous step as outlined here. For example, Internal Audits are often started very early in a project. But they cannot be completed until all required documentation is trained and implemented, which in turn cannot be completed until all documentation is completed. Not rocket science - Common Sense.

'Typical' Detailed Implementation Steps Example

- | | | | |
|----|---|----|--|
| 1 | Determine Specific Requirement(s) | 31 | Buy-Offs On Master Systems |
| 2 | Define Time to Complete Requirement | 32 | De-Bug & Train Supervisors/Area Leaders (Function) |
| 3 | Define Scope of Assessment | 33 | De-Bug & Train Users (Awareness & Use Details) |
| 4 | Project Set-Ups | 34 | Implement (Final De-Bug & Formal Records [Tier 4 documents] Initiated) |
| 5 | Write Company Quality Systems Manual | 35 | Review Status |
| 6 | Document Company Quality Policy | 36 | Tier 3 and Tier 4 Documentation |
| 7 | Define Documentation Systems | 37 | Systems Documentation |
| 8 | Document Master Numbering System | 38 | Existing Systems Analysis & Flow Charting |
| 9 | Establish Master Binders | 39 | Needs Analysis from Tier 2's |
| 10 | Procedures History Binder | 40 | Documentation |
| 11 | Project Master Binder | 41 | Buy-Offs On Sub-Systems |
| 12 | Review Status | 42 | De-Bug & Train Supervisors/Area Leaders (Function) |
| 13 | Contact Registrar | 43 | De-Bug & Train Users (Awareness & Use Details) |
| 14 | Agree on Scope | 44 | Implement (Final De-Bug & Formal Records Initiated) |
| 15 | Agree On Fees (Try to Bargain) | 45 | Process Documentation |
| 16 | Agree On Audit Date(s) | 46 | Process Needs Analysis |
| 17 | Submit Required Documentation | 47 | Develop Plans to Address Deficiencies |
| 18 | Review Status | 48 | Follow Through on CA Plans (Worse Case Timing) |
| 19 | Awareness & Information Meetings - Hourly | 49 | Review Status |
| 20 | ISO 9000 Awareness | 50 | Internal Systems Audits |
| 21 | Work Instructions & Documentation | 51 | Internal Auditor Training |
| 22 | Auditee Training | 52 | Walk-Thru Audits |
| 23 | Awareness Reinforcement | 53 | Internal Audits |
| 24 | Review Status | 54 | Corrective Actions |
| 25 | Tier 2 (Systems) Documentation | 55 | Review Status |
| 26 | Gather Documentation Examples | 56 | Escorts & Area Leaders |
| 27 | Cross-Area Teams Define & Flow Chart Master Systems | 57 | Choose Escorts |
| 28 | Systemic Needs Analysis (Data From Walk-Thrus & Audits) | 58 | Train Escorts |
| 29 | Determine & Integrate Additional Systems Requirements | 59 | Choose Area Leaders |
| 30 | Systems Procedural Documentation & Flow Chart Integration | 60 | Train Area Leaders |

Quotation Considerations

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Notes & Commentary

- 61 Review Status
- 62 Pre-Audit
- 63 Corrective Actions
- 64 ISO 9000 Requirements Matrix
- 65 Internal Systems
- 66 **Registration Audit**
- 67 Corrective Actions
- 68 Submit Corrective Action Plan
- 69 ISO 9000 Requirements Matrix Failures
- 70 Internal Systems
- 71 Submit Corrective Action Results
- 72 Registration Recommendation

Typical Failure Modes

- Lack of management involvement
- Can't explain systems and/or documentation
- Lack of documentation
- Personnel not following documentation
- Poor communication and/or training
- No or inadequate document control
- Poor record keeping and systems
- More details at <http://Elsmar.com/level2/failure.html>

Quotation Considerations

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Notes & Commentary

These are typical audit failure modes.

Critical Success Factors

- Dedicated 'Company Knowledgebase'
(Coordinator and/or Management Representative)
- Pre-assessment (document and interview)
- Involved, supportive top management
- Receptive culture
- Focus on business rather than functional areas
- Prioritize processes based on customer needs, anticipated benefits, and potential for success

Quotation Considerations

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Notes & Commentary

Folks, if you do not have a 'dedicated company knowledgebase' - a person - who understands the standard on a sentence by sentence basis, you are in for problems. Being able and ready to explain how everything fits together, not to mention understanding the requirements as they relate to your company, business style and product(s), is extremely important.

Sooner or later there is going to be an interpretation issue with an auditor. If you are not prepared with knowledge, you have already lost.

United States - IRS Deduction Ruling

- IRS Revenue Ruling 2000-4

Implementation costs are tax deductible in the **same year**.

Registration costs and registration upkeep costs are tax deductible in the **same year**.

- Internal man hours
- Internal capital expenses
- Consultant fees

I have seen combined implementation / registrar costs as low as US\$10,000 and as high as US\$10+M.

Quotation Considerations

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Notes & Commentary

Date 1/6/2000 -- Business granted deduction for QA standards Businesses will gain a new tax deduction for the costs of meeting international quality standards under a ruling by the Internal Revenue Service, which reversed its previous position. The decision Thursday involves a series of quality guidelines known as ISO 9001 that businesses around the world use for goods and services. Companies get certified by the International Organization for Standardization by documenting their processes so all current and future employees will continue to meet the same standards.

The National Association of Manufacturers, the National Federation for Independent Business and other organizations petitioned the IRS in 1998 to permit companies to fully deduct the costs of gaining certification in a single year, instead of spreading the costs out over multiple years. Obtaining certification, the groups said in a joint letter, "can be both expensive and time consuming, particularly for small businesses." An average cost estimate was placed at \$60,000.

The IRS ruling says that costs incurred by businesses to "obtain, maintain and renew" the certification will now be fully tax deductible in one year, except for certain long-term costs such as creation of a company manual.

See <http://16949.com/Forums/showthread.php?s=&threadid=614>

Typical Audit Questions to Expect

- What is TS-16949 / ISO 9001?
- What is the quality policy?
- What does the quality policy mean to you?
- What documentation do you follow? Where is it?
- How do you know you are using the most recent documentation?
- Who is the **Management Representative**?
- How do you know what to do? Tell me about your job and your duties.
- Do you ever have problems come up? How do you handle them?
- When you find nonconforming product, what do you do?
- What are your quality responsibilities?
- What are controlled documents?
- If your documentation says you should do something a specific way and someone else tells you to do it differently, what do you do?
- What do you do if your machine jams?

If you do not know the answer to any of these questions, talk to your supervisor SOON! DO NOT WAIT!

Quotation Considerations

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Notes & Commentary

Supervisors Should Think About...

Work Instructions

- Does Every Job Have Relevant Work Instructions?
- Are Work Instructions Controlled?
- Is Each Signed & Dated?
- Who is the Keeper of a Master List & Where is it Kept?

Hand Revisions

- Have Any Work Instructions, Visual Aids, or Other Process Documentation Been Updated By Hand?
- If So, Are They Signed and Dated?

Equipment PMs

- Are All Equipment PMs Up To Date and to a Schedule?

Measurement & Test Equipment

- Is All Measurement and Test Equipment Calibrated and properly Labeled?

Defective Material

- Is Defective Material Identified and Segregated?
- Is A Defective Material HOLD Area Identified?
- Is DMR Material Dispositioned in a Timely Manner?

Quotation Considerations

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Notes & Commentary

Last Things to Think About

- **Employee Training**

Do You Know the Training Requirements Of Your Job Position?

Is Each Employee Trained?

Where Are Training Records Kept?

Are Training Records Up To Date?

- **SPC**

Are People Keeping SPC Charts Trained in SPC?

Are SPC Charts Current and Being Utilized?

Are Trends Identified and is Corrective Action Taken?

- **Work Areas**

Are Work Areas Clean and Orderly?

- **Baskets, Boxes, Racks, Shelves & Other Containers**

Is Each Properly Labeled (Identified)?

Are They Where They Are Supposed To Be?

Quotation Considerations

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Notes & Commentary

Notes & Commentary

TS-16949 / ISO 9001 Reminders

- Does **NOT** define **quality**
- Is **NOT** a **one-time** process
- Is **NOT** easy
- Requires **commitment**
- Requires **resources**

Quotation Considerations

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Notes & Commentary

Real Life

What TS-16949 / ISO 9001 Means To Employees!

Employees **MUST**:

Know Their Job Duties

Know What Training Their Job Requires

Be Able To Tell About How They Were Trained

Know What Documentation Involves THEM!

Know How To Find Out What The 'Latest' Version' Is

Know What The Documentation Says

Know How The Documentation Applies To THEM!

Know What The INTENT of the Documentation Is

Quotation Considerations

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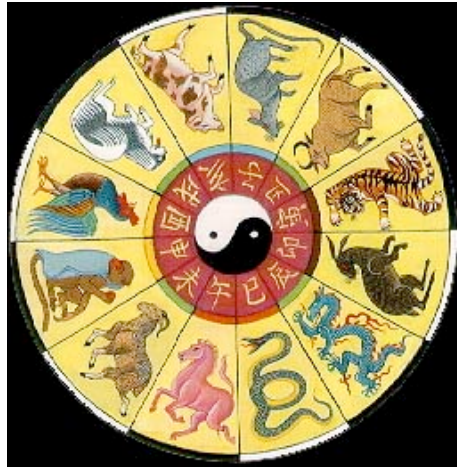
Notes & Commentary

These are items which every employee must know. The auditors will ask these questions of individual employees at all levels of the organization.

Two aspects are represented.

Job requirements, etc., and the requisite documentation.

Thank You!!!



We do hope you choose **Cayman Business Systems** as your partner in your project!

Quotation Considerations

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Notes & Commentary