



HOW TO SELECT A REGISTRAR SM

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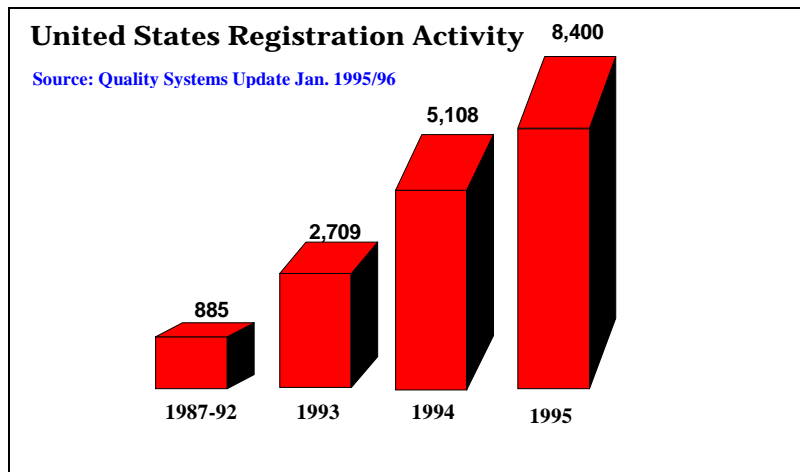
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PREFACE

ISO 9000 quality system certification¹ has skyrocketed worldwide as well as in the United States, so much that a reported 100,000 registrations have been issued internationally² and over 8,000 domestically³.



With this type of activity, existing Registrars are developing new markets, domestically and/or internationally, and new certification businesses are springing-up all over the world. Although quality system certification has been around for a couple of decades (e.g., US nuclear & petroleum industries, UK BS 5750 applications, etc.), a virtual cottage industry is developing in global proportions.

So what does this mean to a buyer of certification services? Be cautious of what you buy into! No joke, no matter the size of your company or the scope of certification, a normal contract with a Registrar is usually a three (3) year commitment with costs that run into the thousands of dollars. With an industry expanding so rapidly, the need for specialized Registrars, new Registrars coming into the market and some Registrars closing their doors⁴, it is essential for the buyer to make an informed decision. After all, can you go to your boss and say “sorry, but I just made a \$7,000 (or more) blunder”?

In today’s competitive market place, such an error is not easily forgiven. Hence the need for How To Select A Registrar, this information will help you make your informed decision efficiently.

1.0 WHY GET CERTIFIED?

There are many considerations for developing and implementing a quality system. Listed below are some of the perceived or actual pressures facing many companies in their journey toward ISO 9000. However, the need for certification is specific to each company. Some companies may not need to become certified at the present time, but could position themselves for certification sometime in the future if there is no pending need, since the main purpose of a quality system is to consistently reproduce your product or service.

A. International/Industry Movements

The following activities are being steered by specific ISO Technical Committees and specify/could specify criteria for accreditation bodies to verify Registrars against during their accreditation assessment. The purpose of such criteria is to achieve a level of confidence that the Registrar is capable of assessing a supplier against the specified criteria for a specific industry.

- ⇒ ISO TC210, General Aspects for Health Care Products is charged with taking the current ISO 9001 and 9002 standards and adding the necessary language to make them meet the needs of medical device manufacturers. This task is intended to meet the current ISO 9001/2 standards plus additional (supplementary) requirements necessary to meet industry applications. The secretariat for ISO TC210 for this activity is the American Association of Medical Instrumentation in Arlington, Virginia.

At this juncture, it is unknown as to whether or not there will be special requirements for Registrars.

- ⇒ ISO TC67, Materials and Equipment for Petroleum and Natural Gas Industries, Work Group 2, Certification Principles, has developed a series of standards for writing functional and technical specifications, equipment classification, definition of and requirements for certification activities. The certification document specifies Registrar qualification criteria which an Accreditation Body would verify. Furthermore, the work group is considering the development of an ISO 9001 standard, which applies to the petroleum and natural gas industries.
- ⇒ ISO TC207, Environmental Management has developed a series of standards, entitled the ISO 14000 series, that shares the management principles of ISO 9001. Although, there are parallels between the two series of standards, the 14000 series goes well beyond ISO 9001 in that it identifies specific requirements for environmental protection. This series of standards will also have specific accreditation body requirements for Registrars.

B. National, Regional or Industry Movements

- ⇒ Information Technology - the UK's TickIT scheme relates to the construction and formal assessment of software quality management systems for certification to the requirements of ISO 9001 through the application of ISO 9000-3 guidance. The UK's Accreditation Body has recently elevated TickIT to the level of a formal accredited sector scheme⁶ which basically means that there will be some special Registrar requirements.
- ⇒ European Union (EU) Directives - A directive is a legislative act of the Commission or Council of the European Union which sets out the scope that legislation is required to have, but leaves it to the individual Member States to determine how such scope will be translated into national law. Directives harmonize essential requirements on industrial products, with specific emphasis on essential requirements on safety and health. These products are referred to as "regulated" products, those which have an effect on health, safety and environment.

To many Europeans, ISO 9000 compliance is an essential part of the directives, while there is no stringent requirement to comply with ISO 9000, the perceptions are real! The importance of this perception is astounding when coupled with the rapid acceptance of the EU Directives - See Section 3.0 for further explanation. Therefore, your company may be impacted by EU Directives, if:

- ◆ A customer is located in an EU member country
 - ◆ A customer sells its products to an EU member country
 - ◆ A customer is located in a country which has adopted any of the EU Directives
- ⇒ Food and Drug Administration (FDA) Good Manufacturing Procedures (GMPs) - The FDA is in the process of aligning their GMPs to the requirements of ISO 9001. Draft GMPs have been issued; however, they are still in the review process.
 - ⇒ The Automotive Industry, QS-9000 - Chrysler, Ford and General Motors have developed an ISO 9001 standard with automotive specific requirements. These companies are requiring that their tier 1 suppliers are certified by a specific date. In addition, the QS-9000 document specifies Registrar qualification requirements for Accreditation Bodies to verify during their assessment of Registrars. See Appendix D for QS-9000 Specific Requirements.

C. Customer Pressure/Perception

- ⇒ A customer demand for quality system certification may exist. Customer perception of a Registrar's reputation may vary with the perceived status of a Registrar and may be a part of the Registrar decision process.
- ⇒ A customer is located in a country which has adopted ISO 9000 quality system standards - currently there are over 80 countries which have adopted ISO 9000 and many companies operating in these countries have followed by also requiring ISO 9000 certification as a condition for sale.

D. Market Position

- ⇒ International Passport - Some companies wish to strategically increase their market position and an ISO 9000 certification provides a global recognition of achievement.

E. Internal Improvement

- ⇒ Improving a basic quality system while working towards internal quality improvement is an important company goal - an ISO 9000 quality system is an excellent starting point for total quality.

These perceived or actual pressures are not an exhaustive listing since there are other specific industry certification/accreditation programs which are also moving toward being aligned with ISO 9001 or 9002. In addition to this type of movement, some industries and/or national or regional areas have existing certification or accreditation programs which have specific purposes and/or applications. Although these programs are not currently moving toward an alignment to an ISO 9000 quality system, their requirements could easily fit the ISO 9001 framework.

Therefore, any company who is even remotely considering ISO 9000 as a means of documenting their quality system, should research their marketplace and/or industry specific activities to determine what, if any, movements could impact their business. Additional consideration should be given to whether or not these industry specific movements have requirements placed upon Accreditation Bodies and subsequently the Registrars.

2.0 SURVEY RESULTS - REASONS FOR CERTIFICATION

Based upon past certifications issued, specific reasons for certification, as well as the external and internal benefits have been identified by the marketplace in an industry-wide survey described in Quality Systems Update, January 1996 edition and summarized below. These results depict the actual reasons many companies have chosen to go for ISO 9000 certification.

Reasons For Certification

| | |
|-----|--|
| 77% | Quality Benefits |
| 73% | Market Advantage/Preferred Supplier Status |
| 68% | Customer Demands/Expectations |
| 27% | Corporate Mandate/Strategy |
| 23% | EU Requirements |

External Benefits of Registration

| | |
|-----|---|
| 83% | Higher Perceived Quality |
| 70% | Competitive Advantage |
| 56% | Reduced Customer Audits |
| 29% | Improved Customer Demand |
| 18% | Increased Market Share |
| 6% | Quicker Timer Brining Product to Market |

Internal Benefits of Registration

| | |
|-----|---|
| 88% | Better Documentation |
| 83% | Greater Quality Awareness by Employees |
| 53% | Enhanced Internal Communications |
| 40% | Increased Operational Efficiency/Productivity |
| 19% | Reduced Scrap/Rework Expenses |
| 5% | Documented Sales Gain |

3.0 MANDATED ISO 9000 COMPLIANCE/EUROPEAN DIRECTIVES

The increasing number of US-based companies offering ISO 9000 series quality system certification/certification services (see Appendix A for an explanation of terms) has made the process of selecting the best service for a particular industry or type of business a significant challenge.

The number of companies offering ISO 9000 series quality system certification (see Appendix B for different Registrar backgrounds) is driven primarily by manufacturers/suppliers, and specific industries scrambling to meet perceived and actual requirements for quality system certification (or an alternative means) expected to be imposed by the European Union (EU).

Those requirements which will affect the import of products into the EU are handed down through European Directives which include specific product requirements as well as the requirements, in some cases, for the supplier to demonstrate proof of compliance to the directive. Supplier certification to the ISO 9000 series is one method for suppliers to meet the directives requirements - directives usually give other options, but the quality system certification option is usually more economical. These directives are for regulated products - in short, those products which in the event of a failure, could have an adverse effect on the health and safety of the general populous or the environment.

Although, there are no current EU requirements applicable to unregulated products, the current impetus for the quality system certification is clearly market driven (e.g., self-imposed market positioning or a customer expressed requirement).

The EU Directives are effected into law in the EU member countries, Member States, and will be implemented into law in those countries that will be joining the EU.

In 1986 the adoption of the Single European Act brought together twelve (12) European Union (EU) countries: Spain, Portugal, Luxembourg, The Netherlands, Italy, Germany, Greece, United Kingdom, Belgium, Denmark, Ireland and France. This joining of countries surpassed previous movements to unite Europe and offset economic competition from the United States, Japan and other emerging economies with a goal of achieving a single market by 1992 and a timetable for implementation.

In the past, Europe was criticized for country-by-country trade barriers. The Single European Act and subsequent actions brought together a unified approach for product standards, testing, certification and quality system certification, including a single monetary unit, tax structure, passport system and much, much more.

To further its strength, the European Communities is joined with six (6) European Free Trade Association (EFTA) members: Sweden, Norway, Iceland, Austria, Finland and Liechtenstein, to create the European Economic Area (EEA). Three of the EEA nations, Austria, Finland and Sweden formally joined the EU on January 1, 1995 bringing the total number to fifteen (15).

The EU will be expanding in the future, thereby broadening the geographical area in which compliance to the EU Directives will become law. Future movements will reportedly encompass Bulgaria, the Czech Republic, the Slovak Republic, Hungary, Poland and Romania, who are currently associate EU members, but will be full EU members before the end of this century. Three Baltic countries have been added to this group : Estonia, Latvia and Lithuania, including Slovenia, Cyprus and Malta. These Nations will join within 10 years, increasing the EU population by 130 million, which in turn will increase the total EU Area population to over 500 million.

Currently the EU countries represent approximately 375 million consumers, compared to the 250 million consumers in the United States and 120 million consumers in Japan. The size of this arena will snowball into a multi-trillion dollar marketplace with over 500 million people as more countries join the ranks of the EU.

Additionally, North and West Africa, South Africa and several countries in the Caribbean have also been given an associate member status to the EU, further broadening the realm of requirements and consumers.

If your company is doing business in any of these areas, you will need to know of the upcoming EU Product requirements which will eventually be imposed upon your products. A real possibility exists that some of these countries may require compliance to the EU Directives or at least the EU Product Safety Standards (e.g., CEN, CENELEC, etc.). For example, several EU standards are being considered by various countries around the world, for instance: India, Malaysia and Singapore have adopted the EU Telecommunication Standards and several countries in South America are considering the same.

4.0 TIES TO THE EU

Some 60 plus companies are currently offering ISO 9000 quality system certification here in the US. Some of these companies have direct ties to one of the EU countries. Other companies offer ISO 9000 series quality system certification under a Memorandum of Understanding (MOU), with EU member country Registrars, (certified bodies) while others are in the start-up process and not yet accredited.

Accreditation (initial evaluation and periodic monitoring of a Registrar) is performed by an Accreditation Body. The EU Accreditation Bodies have representatives on their board from their member state government (i.e., from one of the EU countries). When a Registrar is accredited by more than one Accreditation Body, a supplier has an opportunity to choose which certification scheme they wish to participate under (i.e., a scheme of a specific country).

Regardless of the accreditation scheme a quality system certification company operates under, all must be evaluated against the requirements of EN 45012, "General Criteria for Certification Bodies Operating Quality System Certification" (see Appendix C). Further guidance related to EN 45012 implementation is contained in the ISO/IEC Guide 40, "General Requirements for the Acceptance of Certification Bodies," and ISO/IEC Guide 48, Guidelines for Third-Party Assessment and Certification of a Supplier's Quality System."

Not all accreditation bodies have adopted EN 45012, but US and European accreditation bodies use these requirements as well as other accreditation schemes globally. Manufacturers or suppliers operating in the international marketplace should ensure that the accreditation of any quality system Registrar meets these internationally accepted requirements.

An additional link in the tie to the EU includes Notified Bodies. A Notified Body is a certification body appointed by an EU member government that is authorized to certify product and supplier conformance to the applicable directive requirements. In order to affix the CE Mark, on regulated products, the supplier must involve a Notified Body in product certification if specified in the directive. Currently Notified Bodies do not have to be accredited to the EN 45000 series, but if the Notified Body is not accredited, they will have to supply considerable proof of their competence to that member government.

So where does all of this activity leave the US? It is unlikely that any US Accreditation Body(ies) or Notified Body(ies), when named, will have any clear ties to the EU unless there is government involvement. US government involvement is in-progress through Mutual Recognition Agreement discussions (product and quality system alike) between the US and EU. Although discussions have been on-going for some time, there has been no formal US government acceptance of the American National Standards Institute (ANSI)/ASQC's Registrar Accreditation Board (RAB) as the US accreditation authority. In order to off-set any negative press of not having a formal US thumbs-up, ANSI/RAB has formulated a Memorandum of Understanding with a European based Accreditation Body. This association has helped to equalize any negative opinions by providing an ANSI/RAB tie to the EU.

Some questions to consider regarding a Registrar's accreditation include:

- ◆ Which country or countries have accredited the Registrar?
- ◆ What is the scope of their accreditation(s)?
- ◆ If the Registrar is not currently accredited to your SIC Code, can they expand their scope of accreditation? If so, at what additional cost or inconvenience to your company?
- ◆ Is a Registrar's accreditation traceable back to the EU? This is important if your company is shipping to the EU or to customers who are shipping to the EU.
- ◆ Is your Registrar's accreditation from a single country? If so, does the government of that country have a Mutual Recognition Agreement in place with the EU?
- ◆ Can the Registrar furnish your certification mark from more than one Accreditation Body? If so, what are the additional costs?
- ◆ Does the Registrar work in affiliation with other industry certification schemes or are they contracted by an industry group to perform certification activities to ISO 9000 and the industry standard? If so, is the industry group for whom the Registrar is working accredited?

5.0 MARKETPLACE

A few years ago, selecting a Registrar was not as complex as it is today. Many marketplace forces are developing seemingly overnight. Some of those forces include international, national and industry movements such as the previously discussed ISO Technical Committees 67, 207 and 210, including the Automotive Industry's QS-9000.

Depending upon your specific industry and marketplace, your choice of Registrars may be narrowed down significantly. Some of the marketplace considerations include:

- ◆ Does a chosen quality system Registrar specialize in certification of suppliers producing specific products?

- ◆ Is a specific Registrar required by a customer or a specific industry?
- ◆ Is a specific Registrar preferred by a customer?
- ◆ Is a Notified Body Registrar required by an EU Directive?
- ◆ Is there a perception that a specific Registrar is the best suited for a specific geographic area or industry?

6.0 COMPETITOR CERTIFICATION

Some companies minimize their Registrar selection process activities by making a snap decision to chose the same Registrar as their competition and to become certified to the same ISO 9000 quality system standard. Depending upon the competition's decision making skills, their choice may be a good one or it could be one they may live to regret.

Some considerations are:

- ◆ Is your competitor certified under ISO 9001, 9002, or 9003?
- ◆ Is it appropriate for your company to choose ISO 9002, when you have specific product design responsibilities, just because your competitor did?
- ◆ Was the competitor's Registrar willing to certify them under ISO 9002 when product design responsibilities are evident?
- ◆ Is there another Registrar that may be a better fit for your company's specific needs (e.g., number of locations, scope of certification, etc.)?
- ◆ Can you better position your company by selecting a broader scope than your competition, thereby, calling attention to your competitor's "missed" business area? For example: your company manufactures a product, your scope of certification includes research & development; whereas, your competitor's scope does not.

7.0 CONSULTING VERSUS CERTIFICATION PRACTICES

Some customers (or even your competition) may perceive that a conflict of interest exists if a Registrar offers and performs consulting and assessment/certification services. In fact, many companies have openly stated that "...certification seemed to go easier since we used our Registrar's consulting arm, they really know what's required".

ISO/IEC Guide 48 states in part, "an organization that, directly or through the agency of subcontractors, advises a company how to set up its quality system, or writes its quality documentation should not provide assessment services to that company, unless strict separation is achieved to ensure that there is no conflict of interest."

Consulting and certification have been prevalent enough for some action taken both internationally and in the European Union regarding standardization of the accreditation process through the Notified Bodies. The two organizations driving the process are the European Accreditation of Certification (EAC) organization and the International Accreditation Forum (IAF)⁵.

Because of the conflict of interest typically involved, one of the topics the EAC is examining is the clear-cut division of responsibility between certification and consulting services where both are offered by a Registrar. Drawing a clear and concise line between the two is their goal along with strict enforcement of the policy. If a Registrar offers these services directly or though an affiliate, find out how separation of these activities is maintained.

The EAC (which currently represents seventeen accreditation bodies in EU & EFTA countries) has even established the "EAC Guidelines on the Application of the EN 45012 European Standard for Bodies Certifying Suppliers' Quality Systems". This guideline brings forth some interesting topics on the subject of consulting.

Some questions you may want to ask are:

- ◆ Is there a clear division of responsibilities between certification and consulting?
- ◆ Are any of the following Registrar's personnel involved in consultation?
 - * governing board member(s)
 - * certification board member(s)
 - * principal(s)
 - * owner(s) or stockholder(s)
- ◆ Do any of the Registrar's contracted personnel act as an independent consultant? If so, what provisions are made to ensure there is no conflict of interest?
- ◆ Does the Registrar and Consulting arm "swap" personnel during periods of peak load?
- ◆ Does the Registrar subscribe to the following conduct when they or their affiliate(s) jointly perform certification and consultation activities? The Registrar should have a policy in effect to address the following:
 - * a statement which specifies that the Registrar has no involvement in consultation activities.
 - * a statement which specifies that individuals involved in the certification procedure, including those acting in a managerial capacity, have not been involved in any consultancy activities toward a specific supplier, or any company related to that supplier, within the last two years.
 - * a statement which specifies that the company does not market consultancy and accredited certification together.
 - * a statement which specifies that marketing material, written or oral, does not give the impression that the two activities are linked.
 - * a statement which specifies that nothing is implied or indicated by the Registrar that would suggest that certification would be simpler, easier or less expensive if any specific consultancy services were used.
 - * a statement which specifies that the Registrar's assessors are not permitted to advise or give consultancy as part of an assessment.
 - * a statement which specifies that the Registrar does not imply that the use of both of its services, certification and consultation, would bring any business advantages to you so that the certification remains, and is seen to remain, impartial.

8.0 COSTS

Putting your name on a registration contract is a significant step since it could involve large sums of money not to mention the duration of the contract. Costs could include a multitude of activities, some of which may not be clearly identified and vary from Registrar to Registrar. Some of the considerations which will affect cost are:

- ◆ Size of an organization
 - * number of facilities
 - * number of employees
- ◆ Type of business
- ◆ ISO 9000 series number selected (i.e., 9001, 9002, 9003)
- ◆ Scope of certification, (i.e., one product, a product line, an entire family)
- ◆ Location of a facility/facilities

Additionally, costs could include the following:

- ◆ Application fee
- ◆ Preparation and initial visit
- ◆ Review of quality system manual
- ◆ Review of revisions to the quality system manual
- ◆ Initial visit and number of auditors sent
- ◆ Pre-assessment charge if a contract is signed
- ◆ Assessment charges
- ◆ The number of auditors sent by the Registrar specifically for the assessment
- ◆ Certification charges
- ◆ Report writing
- ◆ Surveillance fees
- ◆ Listing fees

Questions to consider when considering certification costs include:

- ◆ Will the Registrar grant a discount for multiple sites? If so, how can the certification scheme be structured?
 - * Will all facilities receive a stand-alone certification?
 - * Will one certification be issued for all locations?
 - * If one certification is issued for all locations, what is the danger of losing the certification if one of the locations is not diligent in maintaining their quality system?
 - * Can revolving site assessments be used as a means for achieving certification? For example: your company has 15 locations which need to be certified; however, the costs for 15 single site certifications is astronomical, could the Registrar perform assessments on 2 or 3 locations

initially, certify all 15 locations, and follow-up on remaining locations (2 at a time) during periodic surveillances?

- ◆ Will you be required to pay if the Registrar performs a follow-up visit to verify the implementation of corrective action related to deficiencies identified during the assessment?
- ◆ Will the cost of surveillance be included in the certification fee, or will each surveillance be an additional charge? How many surveillances will be performed over the life of the certification? How many quality system elements are covered during each surveillance? How long will each surveillance (or periodic inspection) last?
- ◆ What is the cost of modifying the scope of a certification? What is the cost of reassessment after the expiration of the original certification? Will it be the same as the initial assessment? Will it take as long as the initial assessment?
- ◆ What are the cancellation charges?
- ◆ What is the billing rate? Is it regulated by the man-day or by the hour? Is overtime applicable? What is the billing rate for travel time? Are travel expenses and lodging billed at reasonable rates?
- ◆ Will the Registrar's auditors be traveling from a location within the US or from Europe?

9.0 Standard Industrial Classification (SIC) Code

The standard industrial classification code is a code used to identify the type of business you are in. All Registrars will want to know your SIC Code for various reasons, of which listing your business in published listing is probably the most important.

The SIC Code is the means by which each Registrar assures they can actually service your company. If a Registrar has not been approved for a specific SIC Code by their Accreditation Body, they are not permitted to assist your company. Some questions to ask include:

- ◆ Will the Registrar assist you in identifying your SIC Code?
- ◆ Is the Registrar approved to provide services to your company based upon your SIC Code?
- ◆ Does the Registrar have internal expertise with your SIC Code (e.g., auditors and members of their governing or certification boards)?
- ◆ Can you list your company under multiple SIC Code listings?
- ◆ If so, will your company have multiple entries in published lists?

10.0 FINANCIAL SECURITY

It is undetermined if all Accreditation Bodies check the Registrar's financial status during the accreditation process. If your Registrar goes into bankruptcy or ceases business, it's possible that your certification will become void. The exception to this case is if the Registrar has MOU's with other Registrars with this contingency. Considering the impact this could have on you, you will probably want to do your own checking on a Registrar's financial security.

Questions to ask concerning a Registrar's financial security include:

- ◆ Does the Registrar publish information on their financial security?
- ◆ If the Registrar goes out of business, is the supplier's certification secured?

- ◆ Does the Registrar have provisions in place to assure that another Registrar can pick-up the company's they have certified?
- ◆ If so, what additional costs can be expected?

11.0 BACKGROUND CHECK

One of the most important activities when selecting a Registrar is performing the background check. The background check includes asking the Registrar specific questions and contacting Registrar candidate current customers. Many ISO 9000 certified companies claim that this exercise has indeed assured that a wise decision has been made. Questions to ask Registrars about company policy and background include:

- ◆ How long has the company been in business?
- ◆ Is a list of previously certified companies available including contact names and telephone numbers?
- ◆ Is a complete description of a quality system certification system available including an application, the appeals process and policy regarding certification suspension, withdrawal, or cancellation?
- ◆ How will clients be notified of any rule changes? Are clients permitted to comment on any of the changes? How long do clients have to implement changes once notified?
- ◆ Does the Registrar require notification of any applicable customer complaints?
- ◆ Will the Registrar grant quality system certification to ISO 9001, 9002 or 9003? Some Registrars will not grant certification to ISO 9003.
- ◆ What is the source of a Registrar's accreditation? Is the source an EU member state, or one recognized by the EU? If not, when will the accreditation entity be recognized? Has the accreditation entity adopted EN 45012? If not, does it have plans to do so?

Other questions to consider when selecting a Registrar:

- ◆ With which other Registrars does the Registrar have a memorandum of understanding? Such understandings may provide recognition of the ISO 9000 certification issued.
- ◆ Which US state laws govern the agreement with a Registrar? Where would any legal differences occur?
- ◆ Does the Registrar subcontract any of its certification activities to another organization? If so, does the subcontracted service follow the Registrar's policies and regulations? Is the use of a subcontracted service agreeable?
- ◆ Does the Registrar have a confidentiality agreement with:
 - * Employees
 - * Contract assessors
 - * Subcontracted organizations/personnel
 - * Members of its governing board
 - * Members of its certification committee

- ◆ Does the Registrar allow the use of its symbol or logo? What are the restrictions/requirements governing its use?

Questions to ask of existing Registrar customers:

- ◆ What are the things that you most liked about the Registrar?
- ◆ What are the things that you least liked about the Registrar?
- ◆ If you had to go through the Registrar selection process again, what would you do differently?
- ◆ Are you going to renew your contract with your Registrar?

12.0 PRE-ASSESSMENTS

After the quality system is developed and implementation begins, the pre-assessment is one of the most crucial functions prior to the actual assessment. If the pre-assessment is not performed accurately and provide “value-added” results, your certification assessment could end up costing you more money.

Simply stated some past pre-assessments have resulted in a mere “walk through” which identified only superficial quality system disconnects; whereas, the actual certification assessment ended up in a catastrophe.

Therefore, you should ask yourself who should perform the pre-assessment. Options? The pre-assessment could be performed by yourself, a consultant or similar auditing company or by the Registrar. The bottom line is who will give you the best value for the service? No matter who performs the pre-assessment the following considerations should made:

- ◆ How many ISO 9000 related pre-assessments have you/they performed?
- ◆ Have you/they had adequate auditor training?
- ◆ Do you/they have sufficient audit experience?
- ◆ Does your/their experience include a sufficient number of comprehensive audits in various business environments?
- ◆ Do you/they have a recognized auditor certification?

Sometimes companies want the Registrar to perform the pre-assessment so they can “get to know the Registrar” or “understand their point of view”. This is an internal decision and whatever the reason for selecting your pre-assessors, the following should be considered”

- ◆ What is the customer's perception?
- ◆ Could your customer’s perceive a conflict of interest (e.g., perception of buying your certification)?
- ◆ Will the Registrar re-focus on problematic areas found in the pre-assessment during the certification assessment?
- ◆ Do you consider recommendations important? If so, this would be a conflict of interest for a Registrar since recommendations could be perceived as consulting.
- ◆ Are you interested in ISO 9000 related interpretations? If so, Registrars can make interpretations based upon their internal procedures and/or their Accreditation Body(ies) recommendations, but not always in the best interest of your business.

- ◆ Are you concerned about problem resolution? If so, this could also be considered to be consulting.
- ◆ Are you interested in training your internal auditors during the pre-assessment? If so, on-the-job training of auditors not only includes training, but consulting and ISO 9000 interpretations.
- ◆ Are you interested in putting your employees through a “mock” assessment, which includes role playing? If so, do you want the Registrar to do this?
- ◆ Do you want your pre-assessment report to not only identify findings, but recommendations and opportunities for improvement? If so, this could also be considered to be consulting.
- ◆ Are you interested in categorizing your pre-assessment results in the order of most important to the least important with a schedule for implementation at some point after the assessment? If so, do you think a Registrar is going to recommend this action?

13.0 ASSESSMENT AND CERTIFICATION

Before the big day comes it is necessary to make sure you fully understand the implications of the actual certification assessment. Published guidelines exist which define the approximate amount of time the Registrar should spend on-site, including follow-up activities, for example the following table represents approximate audit days versus the size of a facility.⁷

| Certificated Entity: Number of Employees | Initial Assessment (Mandays) | Subsequent Annual Visits (Mandays) | Re-Assessment Visits (Mandays) |
|---|---|---|---|
| 1-4 | 2 | 1 | 1.5 |
| 5-9 | 2.5 | 1 | 1.5 |
| 10-19 | 3 | 1 | 2 |
| 20-29 | 4 | 1.5 | 3 |
| 30-59 | 6 | 2 | 4 |
| 60-100 | 7 | 2 | 4 |
| 100-250 | 8 | 2.5 | 5 |
| 250-500 | 10 | 3 | 6 |
| 500-1000 | 12 | 4 | 8 |
| 1000-2000 | 15 | 5 | 10 |
| 2000-4000 | 18 | 6 | 12 |
| 4000-8000 | 21 | 7 | 14 |

Other considerations about the quality system assessment and certification process include:

- ◆ How many companies have they certified?
- ◆ What is the Registrar’s pass/fail rate?
- ◆ In which area do most of their clientele “fail” the assessment?
- ◆ How far in advance do you have to schedule your assessment?
- ◆ Are there any cancellation or postponement fees for modifying the scheduled assessment?
- ◆ How soon can the quality system assessment be performed?
- ◆ Will there be any charges if we postpone our assessment? If so, how much?

- ◆ How long will the certification agreement last, (Generally 1 to 3 years)?
- ◆ How long will the assessment take?
- ◆ Will a controlled quality system manual be required for submission and how long will it take to review the document?
- ◆ How are clients notified of quality system omissions or deficiencies? How long will be allowed to make the necessary modifications?
- ◆ Must quality system manual amendments, (based upon the Registrar's review), be corrected and implemented prior to the assessment?
- ◆ Once accepted, will you be required to submit a quality system manual for review and approval prior to making and implementing any revisions?
- ◆ Does a quality system have to be 100 percent implemented to receive certification, or will certification be withheld until a system is fully implemented?
- ◆ Will you be notified of any deficiencies in a quality system before the assessment team leaves the site? If so, will the notification be verbal or in writing?
- ◆ How much time is given to correct identified deficiencies?
- ◆ Will a reassessment or partial assessment be performed to verify corrective action implementation of deficiencies identified during the initial assessment?
- ◆ Will changes/revisions in a quality system manual necessitate a reassessment?
- ◆ Will a reassessment be required if a modification to the certification scope is requested?
- ◆ What is the frequency of the periodic surveillances? How many quality system elements are covered during each surveillance? Will a surveillance schedule be provided?

14.0 AUDITOR QUALIFICATION

The Registrar's auditor qualification and certification program is important information to know before making a quality system Registrar decision. A recognized auditor qualification/certification program assures that manufacturers and suppliers are repeatedly audited in the same manner and at the same level of intensity.

Be sure that the method the Registrar uses provides the best assessment possible. Here are some points to consider when evaluating a Registrar's auditor certification requirements.

- ◆ Does the Registrar require its auditors to be certified to a national or international scheme?
- ◆ If not, does a Registrar's internal training program/certification follow a specific scheme that may or may not be affiliated with a national scheme?
- ◆ Certification in a national scheme such as the Institute of Quality Assurance (IQA) (e.g., Provisional Assessor, Registered Assessor or Registered Lead Assessor) or the American Society for Quality Control (ASQC) - Registrar Accreditation Board, (RAB), accreditation scheme (e.g., quality system provisional auditor, auditor or lead auditor). The IQA Administered scheme is backed by the Governing Board of the UK National Certification Scheme for Assessors of Quality Systems. This system has worldwide recognition. The RAB scheme has been recently introduced and should be parallel the IQA scheme.

Note: An upcoming certification program, the International Auditor and Training Certification Association (IATCA), is in the works. This association has been created by representatives from 12 ISO 9000 auditor certification and course accreditation bodies⁸. The purpose of this association is to bring the activity of auditor certification to common ground.

- ◆ Participation in a 36 to 40-hour ISO 9000 lead auditor training course. The course may or may not be registered to a national scheme such as the United Kingdom's Institute of Quality Assurance (IQA) or the United States Registrar Accreditation Board administered registered course.
- ◆ Is a Registrar's quality system auditor acceptance based upon The ASQC Certified Quality Auditor (CQA) program? If so, the CQA certification should be followed by an RAB-approved 16-hour ISO 9000 series course followed by an approved test.

15.0 AUDIT TEAM

Questions to ask a Registrar about its auditing team include:

- ◆ What are auditor experience, training, and educational requirements? Are auditor backgrounds verified?
- ◆ Do auditors receive training in both ISO 9000 series standards and company procedures and policies prior to certification?
- ◆ What is the standard or criteria used to qualify auditors?
- ◆ Is the standard or criteria recognized and accepted by the EU?
- ◆ What levels of auditor qualification exist (auditor in training/auditor/lead auditor) and what responsibilities do these auditors have during the assessment process?
- ◆ During the assessment process, will at least one auditor be familiar with a client's product or technology?
- ◆ Do you have the right to review auditor qualifications?
- ◆ Will you be able to meet the auditors?
- ◆ Can you object, with cause, to the audit team members?
- ◆ Will the same audit team perform the initial audit as well as all subsequent surveillances?
- ◆ If so, how is this perceived by your company? Your industry or customers? For example: If a specific auditor or group of auditors are assigned to your company, they will be familiar with your system, but does this mean they could become complacent?

16.0 SUPPLIER LIST

If the Registrar offers a list of suppliers or manufacturers it has certified, make sure the following questions are answered. The list should include an outline of the "scope" of certification.

- ◆ What is the frequency of the list publication? (At a minimum, the list should be published annually.)
- ◆ What is the charge for the list?
- ◆ Will clients be placed on a mailing list to receive the list, or will a separate request be required?

- ◆ How does the Registrar determine the technical competence of an assessor?
- ◆ Does the Registrar furnish your company's name and the relevant data to national or international source who publishes an independent registers?
- ◆ If so, will your listing include all of the SIC Codes you have chosen?

17.0 HALTING THE PROCESS

This is a point which many companies do not wish to discuss, but it is better to be prepared up front than to wait and be surprised. The certification process may be halted by either side depending upon the circumstances. Perhaps your company has too many noncompliances during a surveillance visit or perhaps you have become discontent with the Registrar.

Questions concerning quality system suspension, withdrawal, and cancellation should include:

- ◆ What is the Registrar's policy regarding the suspension, withdrawal, or cancellation of the quality system certification?
- ◆ Will the Registrar withdraw or cancel the quality system certification if a product, process, or service is not supplied for an extended period of time? Ask the Registrar to define the rules.
- ◆ How will a client be notified of quality system certification suspension, withdrawal, or cancellation?
- ◆ Will the Registrar publish the quality system certification suspension, withdrawal, or cancellation?
- ◆ Will any funds be returned to your company?

18.0 ACCREDITED VERSUS UNACCREDITED REGISTRARS

Believe it or not there are companies who refer to themselves as Registrars, but they are not accredited, and in most cases their activities are not verifiable to the conformity assessment movement. These companies are called "unaccredited" Registrars, which means they have not been audited by a government appointed Accreditation Body to En-45012, ISO Guide 40 or ISO Guide 48 and "accredited".

Sometimes such companies such companies are technically adequate, but the lack of an accreditation may hinder a customer purchasing your company's products.

If you have any questions about whether or not a Registrar is accredited, refer to Section 21 below and obtain an Accredited Registrar Listing. Some relevant questions include:

- ◆ If you are not an accredited Registrar, what would be the benefits of selecting you for ISO 9000 certification?
- ◆ How many companies have you certified?
- ◆ How many companies have you retained as clients?
- ◆ What percentage of your clientele has opted for certification by an accredited Registrar?

19.0 SMALL BUSINESS CONSIDERATIONS

Small Businesses have long suffered higher costs for ISO 9000 certification. However, many Registrars have come recently come up a Small Business Program which affords such companies lower certification costs. Some Registrars quote a lump sum which includes a maximum number of employees, where others have a sliding scale which correlates with the number of employees who have responsibilities under the quality system.

Although certification costs have been reduced for Small Businesses, it must be realized that Registrars are still bound by the requirements issued by their Accreditation Body regarding the amount of days required to perform the certification assessment (see Section 7 herein for estimated days). Some question to ask:

- ◆ Do you have a lump sum certification cost? If so, what are the restrictions?
- ◆ If not, what would be the certification costs for a company of our size?
- ◆ How many assessment days will be required? Surveillance days?
- ◆ How can travel related costs be minimized?

20.0 FUTURE STATE - CONTINUITY OF REGISTRATION SERVICES

There are multiple organizations and/or movements in progress which will help bring accreditation activities, certification activities and certification recognition to an even playing field, both nationally and internationally. All of these activities will have an impact on accredited Registrars, since they intend to bring a uniformity to their services. Some of these activities are new where others are maturing and include:

- ⇒ Governmental Mutual Recognition Agreements - once all participating governments agree to trade related practices they will adopt or parallel international conformity assessment activities.
- ⇒ European Accreditation of Certification (EAC)- this is an organization made up of European Accreditation Bodies whose basic purpose is to facilitate common Registrar accreditation practices.
- ⇒ International Accreditation Forum (IAF)- this is an organization made up of International Accreditation Bodies whose purpose parallels that of the EAC.
- ⇒ Quality System Assessment Recognition (QSAR) - is a proposal that would promote the global acceptance of ISO 9000 certifications and it is currently being evaluated by the International Organization for Standardization(ISO)⁹.
- ⇒ Registrar associations - various trade groups, both nationally and internationally, have developed to bring a consistency to quality system certification activities.

21.0 BEFORE YOU BEGIN

The importance of selecting a Registrar cannot be over-emphasized since it is no simple task. The agreement is a long-term commitment and dissolving it can be costly. The purchaser of such services could help eliminate future problems by doing some up-front work and making an informed decision by asking planned questions, comparing Registrar responses and choosing the Registrar that is best suitable for their needs. Therefore, it is recommended that you treat this task as you would any other project. Some ideas for consideration include:

1. Develop a timeline for your certification activities and include Registrar selection, including the applicable sub-topics, on the timeline.
2. Obtain a listing of potential Registrars. A listing can be obtained from the following sources:
 - The US Registrar Accreditation Board (RAB) - lists only those Registrars which have been accredited by the RAB. Contact the American Society of Quality Control (ASQC) and ask for the RAB @ 1-800-248-1946.

- The US National Institute for Standards and Technology (NIST) - lists all known Registrars, both domestic and international, which are operating in the United States. The listing name is the “North American Quality System Registration Organizations” (NAQSRO) list. Contact the NIST at 301-975-4039.
3. Identify key questions to ask based upon this article, including those which are self-generated. Many Registrars have developed a marketing response to How To Select A Registrar since it was first published in QSU in January 1992.

Your questions could be listed in a matrix with each Registrar’s response in an adjoining column. Such a matrix could be developed in a word processing table, spread sheet or database format.

4. Identify cost factors. Costs could become an important issue, therefore, it is recommended that the costs become part of the questionnaire matrix you develop.
5. Create a weighted scoring mechanism and include it in your questionnaire matrix. The relative importance of each question and the subsequent Registrar response should be weighted as it applies to your company, its locations and your marketplace.

FOOTNOTES

1. ISO 9000 certification is the process by which a third party registration company, know as a Registrar or Certified Body, performs an assessment of your company’s quality management system to the requirements of the internationally acclaimed quality management system standards ISO 9001, 9002 or 9003.
2. Quality Systems Update, September 1995
3. Quality Systems Update, January 1996
4. Quality Systems Update, February 1996
5. Quality Systems Update, February 1993
6. Quality Systems Update, August 1995
7. Quality Systems Update, October 1995, from the European Accreditation of Certification
8. Quality Systems Update, February 1996
9. Quality Systems Update, July 1995

APPENDIX A . . . Explanation of Terms

1. EN 45012 defines "certified body" as the "body that issues certification of conformity."
 2. EN's, (European Standards), are promulgated by the European Committee For Standardization, (CEN), and the European Committee for Electrotechnical Standardization, (CENELEC).
 3. EN 45012 defines "certification of conformity" as an "action by a third party, demonstrating that adequate confidence is provided that a duly identified product, process or service is in conformity with a specific standard or other normative document."
 4. ISO Guide 48 defines "certification" as the "inclusion of the supplier's particulars and field of assessed capability by the assessment body in an appropriate register or list."
-

APPENDIX B . . . Different Registrar Backgrounds

There are a variety of companies offering quality system certification services. Some of these companies are established and have been performing these services prior to the concept of the European Economic Communities; whereas, others are just beginning to "get into the business". The companies providing these services include:

1. Established companies who have provided certification related services for a specific industry, national, or international scheme prior to the concept of the European Economic Communities;
 2. Established or newly founded European Certification Bodies opening new offices in the U.S.;
 3. European Certification Bodies who have formed an agreement with domestic certification companies;
 4. Industry accreditation/product certification organizations who have expanded the scope of their services;
 5. Quality-related service companies who have expanded their service base;
 6. Newly formed certification companies.
-

APPENDIX C . . . EN 45012, Outline of Requirements

1. **Object and field of application** - General Criteria for a Certification Body Operating Quality System Certification.
2. **Definitions** - definitions applicable to EN 45012.
3. **General requirements** - states that all suppliers have access to the services of the Certification Body and that the procedures under which the body operates shall be administered in a nondiscriminatory manner.
4. **Administrative structure** - requires the certification body to:
 - be impartial;

- choose the members of its governing board from among the interests involved in the process of certification without any single interest predominating;
 - safeguard impartiality and enable participation from all parties concerned regarding the functioning of a certification system;
 - have permanent personnel under the senior executive to carry out the day-to-day operations in such a way as to be free from control by those who have a direct commercial interest in the products or services concerned.
5. **Terms of reference of governing board** - addresses the functions of the governing board of the certification body:
- formulation of policy
 - overview of policy implementation
 - overview of the finances
 - setting up of committees as required.
6. **Organizational structure** - addresses the requirements for a Certified Body's organizational structure:
- a chart showing the responsibility and reporting structure of the organization and in particular the relationship between the assessment and certification functions;
 - description of the means which the Certified Body obtains financial support;
 - a documented statement of its certification systems including its rules and procedures for granting certification;
 - documentation clearly identifying its legal status.
7. **Certification personnel** - addresses the requirements for:
- personnel to be competent for the functions they undertake;
 - information to be maintained regarding relevant qualifications, training and experience;
 - records of training to be kept up-to-date;
 - personnel to have available clear documented instructions pertaining to their duties and responsibilities;
 - personnel of subcontracted sources to meet the requirements of EN 45012.
8. **Documentation and change control** - addresses the requirements for:
- the certified body to maintain a system for the control of all documentation related to the certification system:
 - * the current issues of the appropriate documentation to be available at all relevant locations;
 - * changes to documents to be covered by the correct authorization and processed in a manner which will ensure direct and speedy action at the effective point;
 - superseded documents to be removed from use throughout the organization and its agencies;

- certified suppliers to be notified of changes which could be accomplished through direct mailing or by issue of a periodic publication.
9. **Records** - addresses the requirements for:
- maintaining a record system to demonstrate the way in which each certification procedure was applied including assessment and surveillance;
 - storing records for an adequate period;
 - holding records secure and in confidence to the client, unless otherwise required by law.
10. **Certification and surveillance procedures** - addresses the requirements for:
- the certification body to have documented procedures to enable the assessment, certification and surveillance of quality systems to be carried out;
 - the certification body to require the supplier to have a documented quality system;
 - the certification body to maintain regular surveillance of the supplier's quality system.
11. **Certification and surveillance facilities required** - addresses the requirements for:
- the certification body to have the required facilities in terms of certification personnel expertise and equipment to perform assessment, certification, and surveillance of the supplier's quality system;
 - the certification body to ensure that external bodies conform to the above requirement and that a properly documented agreement covering the arrangements including confidentiality be drawn up.
12. **Quality Manual** - addresses the requirements for the certification body to have a quality manual and documented procedures setting out the way in which it complies with the criteria. The Quality Manual shall include at least:
- a quality policy statement;
 - brief description of the legal status of the certification body;
 - a statement of the organization of the certification body, including details of the governing board, its constitution, terms of reference and rules of procedure;
 - names, qualifications, experience and terms of reference of the senior executive and other certification personnel, both internal and external;
 - details of training arrangements for certification personnel;
 - an organizational chart showing lines of authority, responsibility and allocation functions stemming from the senior executive;
 - details of the documented procedures for assessing and auditing supplier quality systems;
 - details of documented procedures for surveillance of suppliers;
 - a list of subcontractors and details of the documented procedures for assessing and monitoring their competence;
 - details of appeals procedures.

13. **Confidentiality** - addresses the requirements for the certification body to ensure confidentiality of the information obtained in the course of its certification activities at all levels of its organization, including committees.
14. **Publications** - addresses the requirements for the certification body to produce and update as necessary a list of certified suppliers with an outline of the scope of the certification of each supplier, and the requirement for the list to be available to the public. This section further requires a description of the certification system(s) to be available in published form.
15. **Appeals** - addresses the requirements for the certification body to have procedures for the consideration of appeals against its decisions.
16. **Internal audit and periodic review** - addresses the requirements for the certification body to undertake internal audits and periodic reviews of its compliance with the criteria of EN 45012. The reviews are to be recorded and are made available to persons having the right of access to this information.
17. **Misuse of certificates** - addresses the requirements for the certification body to exercise proper control on the use of its Quality System certificates. This section also requires that incorrect references to the certification systems or misleading use of certificates found in advertisements, catalogs, etc. ... be dealt with by suitable actions. A further notation states that such actions include corrective action, publication of the transgression and, if necessary, legal action.
18. **Complaints** - addresses the requirements for the certification body to require the certified suppliers to keep a record of all complaints and remedial actions relative to the quality system.
19. **Withdrawal and cancellation of certificates** - addresses the requirements for the certification body to have documented procedures for withdrawal and cancellation of quality system certificates.

* *NOTE: Refer to the latest edition of EN 45012 for the actual wording of the requirements.*

APPENDIX D . . . QS-9000 Specific Requirements¹

“Appendix B:

Code of Practice for Quality System Registrars

1. The registrar's (i.e., certification body's) local operation conducting the assessment shall be accredited by a customer-recognized national body (e.g. RvC, NACCB, RAB). Memoranda of Understanding (MOUs) are not acceptable for meeting this requirement. The registrar's scope of accreditation shall include the commodities being assessed. The scope of registration shall include all products and services being supplied to one or more of the companies subscribing to this document.
2. QS-9000 is a contractual requirement for all suppliers of: a) production materials, b) production or service parts, or c) heat treating, plating, painting or other finishing services directly to the companies using QS-9000. The registration process shall encompass QS-9000 requirements.
3. The assessment shall include all elements of the supplier's quality system implemented to meet automotive customer needs, even when these elements go beyond QS-9000.
4. The assessment shall include evaluation of all supplier quality system elements for *effective implementation* of QS-9000 requirements as well as for *effectiveness in practice*. Part of the evidence required is the results of at least one complete internal audit and management review cycle.
5. Registrars shall conform to the current European Standard EN 45012, **General Criteria for Certification Bodies Operating Quality System Certification**, and accompanying EAC guidelines, dated May 10, 1994, where not otherwise indicated in this Code of Practice and Appendix H.
6. Each on-site audit shall include a review of:
 - Customer complaints and supplier response
 - Supplier internal audit and management review results and actions
 - Progress made towards continuous improvement targets
7. The entire quality system shall be assessed at a minimum of once every three years. Each supplier design and manufacturing location shall be individually audited and referenced on a certificate. It is permissible for each surveillance audit to re-examine part of the system so that the equivalent of a total reassessment is completed within each three year cycle. Also, each such location shall receive a surveillance audit at least every six months. The Audit Report shall clearly show the part of the system that was audited on each surveillance visit.
8. The audit team shall provide a full report on the operation audited per Model B of the current RvC publication, **Guideline for Compiling Reports on Quality System Audits**, to the supplier within forty-five days of each initial and surveillance (partial) audit unless otherwise agreed by the supplier. Third party auditors will identify

opportunities for improvement (e.g. excessive scrap) as these become evident during the audit without recommending specific solutions. These opportunities shall be included in the report to the supplier.

Quality System Requirements

9. Organizations that have provided quality system consulting services to a particular client are not acceptable as registrars for that client, nor may they supply auditors. This restriction includes subsidiaries or affiliates of the same parent company.
10. Each member of a registrar's team performing audits to QS-9000 shall have satisfactorily completed QS-9000 and Quality System Assessment (QSA) training courses that have been approved by the companies issuing this document. Also, a majority of those responsible for making certification decisions, or at least one with veto power (refer to Appendix G, paragraph A.5), shall satisfactorily complete this training. Satisfactory completion will be indicated by a certificate.
11. Quality system consultants to the supplier, if present during the assessment, are limited to the role of observer.
12. Registrar's checklists shall include, but not be limited to, all questions contained in the QSA. Quality systems shall not be registered to QS-9000 if "open" major or minor nonconformances, as defined in the QSA, exist.

Registrars who:

- Contract with a supplier to follow this Code of Practice, and

- Are accredited by an OEM-recognized accreditation body, and
- Are qualified by the accreditation body (referenced above) to conduct QS-9000 registrations in accordance with the November 21, 1994

IMPLEMENTATION

REQUIREMENTS (see Appendix G) of the Chrysler, Ford, General Motors Supplier Quality Requirements Task Force

are authorized to cite conformance to QS-9000 on ISO certificates.

Instructions to Suppliers Concerning Third Party Registration

Suppliers shall review the Code of Practice with potential registrars during the negotiation process to ensure that the resulting contract specifies compliance with the Code of Practice.

Suppliers registered to an ISO 9000 standard without consideration of QS-9000 requirements shall contact their registrar and indicate that their customer(s) require(s) inclusion of QS-9000 in the registration process. The supplier shall update the quality system documentation as necessary to meet QS-9000 and identify these revisions to the registrar at the next surveillance visit. When conformance to QS-9000 has been verified (acceptance of satisfactory evidence of resolution of all major/minor nonconformities), the registrar will issue a certificate citing conformance to QS-9000. Supplier reference to QS-9000 registration may be made only after receipt of the QS-9000 certificate.

Only registration certificates citing conformance to QS-9000 will be acceptable to the companies using this document.

The registrar's reports shall be made available to customers upon request. Loss of registration by suppliers shall be reported to the companies using this document.

Supplier preparing for conformance to ISO 9001:1994 (or ISO 9002:1994) should obtain from the ISO member in their country the set of relevant ISO standards and in particular ISO 9000-1: 1994 and ISO 9004-1:1994 as these are necessary for third party registration. (Reference Appendix D).”

“Appendix G:, November 21, 1994 QS-9000 Accreditation Body Implementation Requirements

Below are requirements with regard to QS-9000 implementation including: criteria for registrar qualification, registrar auditor qualifications, certificates, and upgrading of registrar accreditation to included QS-9000. These requirements will apply to all Chrysler, Ford and General Motors-recognized accreditation bodies and the registrars qualified by those accreditation bodies to conduct QS-9000 registrations.

A. ACCREDITED REGISTRARS SHALL:

1. Provide accreditation bodies with written agreement to conduct QS-9000 registrations in compliance with QS-9000 Appendix B “Code of Practice”.
2. Provide accreditation bodies, prior to beginning QS-9000 registrations, relevant documentation showing that the registrar process complies with: a) the QS-9000 Appendix B “Code of Practice”, and b) the registrar requirements in this appendix.
3. Maintain a listing of their QS-9000 qualified auditors.
4. Have personnel on the governing board/council of experts that have

automotive industry experience as well as expertise in the appropriate SIC/EAC codes for their scope, as defined by the current accreditation body practice (ref EN 45012 items 4a. and 5).

5. Have at least one member of those responsible for their certification function successfully (pass the exam) the sector-specific training referred to in A.12 below. This member shall have veto power with regard to QS-9000 registration activities.
6. Utilize an audit team which has at least one member with relevant experience in the automotive industry.
7. Not use the QS-9000 notation on certificates until after the accreditation body has witnessed and approved a registrar’s QS-9000 audit. Approval or closure of corrective actions by the accreditation body should occur during the witness audit, if verification of effectiveness is possible at that time.
8. Be permitted, after the witness audit has been completed satisfactorily, to update the ISO 9000 certifications to QS-9000 certificates of previously-assessed companies who were found to be in compliance to QS-9000. The registrar is limited to three of these instances and subject to B.1. Where the registrar does not satisfactorily complete the witness audit, the registrar shall be responsible for remedies for any previously-assessed companies appropriate to the severity of the problems discovered, and as agreed upon by the accreditation body. No additional QS-9000 audits are permitted until the registrar corrective actions are accepted by the accreditation body.
9. Provide at least 8 weeks advanced written notification to the accreditation body of each

QS-9000 assessment scheduled, until their QS-9000 audit is satisfactorily witnessed.

10. Plan their initial four QS-9000 assessments so that no more than three occur during any consecutive four week period.
11. Be permitted to use a full QS-9000 or an ISO 9000 upgrade to QS-9000 as a witness assessment.
12. Utilize auditors that a) are recognized and qualified as ISO 9000 auditors per the accreditation body's criteria, and b) are sector-specific qualified by the Chrysler, Ford and GM Supplier Quality Requirements Task Force as evidenced by a certificate sent to the registrar (completion of the 2-1/2 day class now being offered through the Automotive Industry Action Group (AIAG) in the USA at 810-358-3003, followed by an exam. Enrollment in these classes is accomplished through a specified registrar-designate on behalf of auditors which the registrar sponsors, and is not open to consultants, or individuals); and c) have relevant industry experience as determined by the accreditation body's current SIC/EAC qualification process.
13. Provide certificates of registration to QS-9000 compliant organizations that cite the relevant ISO 9000:1994, without reference to QS-9000 sections, having been audited in accordance with the requirements of the QS-9000, Appendix B "Code of Practice".
14. Define delisting criteria, and steps for delisting QS-9000 registrants.
15. Be responsible for remedies for any QS-9000 registrants affected by the delisting of the registrar by the accreditation body, appropriate to the severity of the problems discovered. These remedies shall be agreed upon by the accreditation body.

B. ACCREDITATION BODY shall:

1. Be responsible for providing an auditor (audit team) to witness one of the first four registrar QS-9000 audits of any accredited registrar completing items A.1) and A.2 above (see A.8). The accreditation body will notify the Chrysler, Ford, and GM Supplier Quality Requirements Task Force of the date when each registrar has successfully completed the witnessing above.
2. Be responsible in the conduct of witnessing for utilizing any outside experts or observers needed. This responsibility shall include avoidance of conflict of interest, availability, and timeliness.
3. Define: a) delisting criteria, and steps for delisting QS-9000 qualified registrars, and b) an appropriate process for appeal of a witnessing decision, or any other step in the QS-9000 process.
4. Maintain a "QS-9000 Qualified Registrar Listing" kept up-to-date and distributed to the Chrysler, Ford, and GM Supplier Quality Requirements Task Force whenever the listing changes. These lists shall note new additions or deletions from previous revisions. Notice of loss of accreditation shall be formally communicated to the Task Force (above) promptly.
5. Provide a certificate, or similar formal notification, one which can be used to document the registrar's qualification, to each qualified QS-9000 registrar who has met all requirements of QS-9000 Appendix B "Code of Practice", and this document.

C. CHRYSLER/FORD/GENERAL MOTORS:

1. While continuing to enhance QS-9000 third party process and requirements, will

continue to support and respect the independence of third party system.

2. Will maintain an established, authorized QS-9000 team with whom the accreditation bodies and registrars can communicate.
3. Will share appropriate QS-9000 supplier communications with their recognized accreditation bodies.
4. Will recognize any RvC, RAB or NACCB (or other future OEM recognized accreditation bodies) witness audit of a registrar for QS-9000 launch. These accreditation bodies are end encouraged to implement a mutual recognition of each other's witness audits, described herein above, in support of the QS-9000 launch.”

Footnote

1. QS-9000 is a copyright of the Chrysler Corporation, Ford Motor Corporation, General Motors Corporation.

Appendix D information extracted from QS-9000, Second Edition, February, 1995. Complete information available through the Automotive Industry Action Group at 810-358-3003.

Biographical Sketch of RT Bud Weightman

R. T. Bud Weightman, Qualified Specialists, Inc. President & Founder, has over 26 years of experience in quality, business management and development. Bud has been an international management consultant, author and lecturer since 1989 and has extensive experience with strategic business planning, design, implementation, and assessment of management systems, including API Q1, ISO 9000/QS 9000 and ISO 14000.

He has multiple industry and cross-disciplinary experience, a wide variety of technical certifications, (including RAB/IRCA registered lead assessor and ASQ CQA) and is serving on or has served on numerous high-profile committees for economic development and standards development, including API's committee for quality and the ISO technical committees for ISO 9000 and certification principles for the oil and gas industries.

He has been an owner of various small businesses since 1980. Bud has personally assisted, over 140 businesses with implementation of their management systems and has performed quality system assessments of over 400 companies in his career.

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