

# ANTICIPATING YOUR NEED TO KNOW MORE

TÜV Management Service realizes that choosing your Management Systems Registrar is a very important decision. This document provides answers to commonly asked questions we have received from companies actively engaged in the Registrar selection process. If you have further questions regarding TÜV's registration process, please do not hesitate to contact us. We will be pleased to address your specific issues and schedule an information meeting.

**ISO 9000**

**QS-9000**

**ISO 14001**

**TE Supplement**

**AS9100**

**VDA 6.1**

**EN 46000**

**ISO 13485 / ISO 13488**

**TL 9000**



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## 1.0 TÜV OVERVIEW

### 1.1 Who is TÜV?

TÜV, which stands for “Technical Inspection Association,” are German-based organizations authorized by the German State governments to perform a variety of mandatory and voluntary inspection, testing and certification activities.

TÜV Management Service is the global management systems certification Registrar for TÜV Süddeutschland, Munich, the largest of the TÜV’s, with over 9,000 staff and \$1 billion in annual revenues. TÜV Management Service along with TÜV Product Service, one of the world’s largest product testing and certification organizations, form the Certification Division of TÜV Süddeutschland, with over 2,500 staff at 110 locations in 30 countries.

In North America, these units, along with TÜV Automotive and our pressure & materials industry Inspection and Certification Services unit, form TÜV America Inc., employing over 250 staff in more than 10 locations throughout the continent.

### 1.2 How long has TÜV been in business?

TÜV was established in 1870. North American operations began in 1987. Today, TÜV serves thousands of North American companies in management systems and product conformity assessment activities.

### 1.3 Does TÜV offer other services in addition to Management Systems Registration?

Yes. TÜV performs a variety of product and systems related testing, inspections and certification, creating full service solution capabilities for management systems and product related testing and certification. A partial listing of additional services includes: Conformity Assessment; CE Marking assistance; EMC, product safety, electrical, mechanical, medical devices and telecommunications terminal equipment testing and certifications; 510(k) reviews; BABT 340/940 certification; Pressure Equipment and Base Materials inspection, testing and certification, and much more. TÜV is a European Union (EU) Notified and Competent Body for a variety of EU Directives, including those areas mentioned above.

### 1.4 How many companies has TÜV registered?

A global leader in ISO 9000, QS-9000 and ISO 14001 registration as well as the leader in EN 46000 and ISO 13485, we have certified thousands of companies world-wide including more than 1,000 in North America. In fact, TÜV Management Service is one of the largest third party Registrars in the world, including one of the top 10 Registrar in the US, Europe and Asia.

### 1.5 Will TÜV provide a list of clients that have achieved registration?

Yes. A current list of all companies certified by TÜV Management Service is available upon request. Our certified client list can also be viewed on our global web site at [www.tuvglobal.com](http://www.tuvglobal.com) which includes hotlinks directly to client web sites.

### 1.6 Does TÜV have additional offices in the United States and other countries?

TÜV Management Service is headquartered in Danvers, MA, offering services from offices throughout North America, including: Georgia, South Carolina, Ohio, Michigan, Ontario, Illinois, Minnesota, Colorado, Northern and Southern California, and Monterrey, Mexico. These and other new offices are staffed with TÜV Management Service auditors. Other international operations are located in Austria, China, Denmark, Germany, Egypt, Greece, Hong Kong, India, Italy, Japan, Malaysia, Mexico, Netherlands, Philippines, Republic of Korea, Russia, Saudi Arabia, Singapore, Slovakia, South Africa, South Korea, Spain, Sweden, Taiwan, United Kingdom and more.

## 2.0 ACCREDITATIONS

### 2.1 Describe TÜV’s accreditations.

TÜV Management Service is accredited by both the Registrar Accreditation Board (ANSI-RAB) and the German Accreditation Council (DAR/TGA) to provide ISO 9000, QS-9000 and ISO 14001 Registration. Additional accreditations and authorizations include ANSI-RAB for TE Supplement Registration and TL 9000 (planned), ZLG for EN 46000 and ISO 13485 / 13488, General Electric Aircraft Engines approved AS9100 Registrar and the German Department of Transportation (KBA) and the Association of German Automotive Industry (VDA) for VDA 6.1 Registration.

TÜV is authorized to perform inspections, testing and certification on behalf of Germany and the European Union (EU). TÜV is an EU Notified Body for a multitude of mandatory and voluntary inspections, tests and certifications. The auditing and certification of management systems by TÜV Management Service is based on ISO/IEC Guide 62 and EN45012, "General Criteria for Certification Bodies Operating Quality System Certification" and ISO 10011, "Guidelines for Auditing Quality Systems."

*(Medical Device and In Vitro Diagnostic Device Manufacturers please contact us for more detailed information regarding the Management Systems registration process for the medical device industry.)*

## **2.2 Does TÜV offer Management Systems consulting services?**

No. We concentrate on the Audit activities associated with management systems registration. ISO/IEC Guide 62, "General requirements for bodies operating assessment and certification/registration of quality systems," states in part:

"...the certification/registration body shall ensure that activities of related bodies do not affect the confidentiality, objectivity or impartiality of its certifications/registrations and shall not offer or provide consulting services to obtain or maintain certification/registration."

## **2.3 What is TÜV's position regarding Memorandums of Understanding (MOU)?**

As an EU Notified Body for a number of voluntary and mandatory inspections, testing and certifications, our management systems certifications are well recognized throughout the European Union and world-wide.

Through our parent companies, TÜV Management Service has joined with six of the leading internationally accredited certification bodies to form the Independent International Organization for Certification (IIOC). These Registrars recognize accreditation as a status awarded by national bodies on the merit of individual performance, not as a transferable commodity. Other members of the IIOC include ABS Quality Evaluations, Bureau Veritas Quality International, Det Norske Veritas Certification, Germanischer Lloyd QS-Zertifizierung GmbH, Lloyd's Register Quality Assurance Ltd, and SGS International Certification Services.

## **3.0 TÜV MANAGEMENT SERVICE AUDITORS**

### **3.1 Does TÜV use all sub-contracted auditors?**

No. TÜV maintains a full time audit staff throughout North America which builds value-added, long term partnerships with our clients. However, on a limited basis, we use exclusive sub-contracted auditors based upon geographical location or technical expertise required. Our standards are high, and all auditors must go through the same TÜV training program outlined in section 3.2.

### **3.2 What are the auditor requirements in terms of training, experience and education?**

TÜV lead auditors have the following qualifications:

- An average of 15 years management systems experience
- Completion of a 36 hour RAB/IRCA approved Lead Assessor Course
- Comprehensive internal TÜV training program
- Hired based not only on their Quality or Environmental Management Systems experience, but also on their demonstrated professional conduct and teamwork skills.

### **3.4 Does the auditor training follow a national scheme such as the RAB or the IRCA?**

Auditor training exceeds the requirements of both the RAB and IRCA.

### **3.5 How are auditors assigned? Where will the auditors travel from?**

Auditors are located throughout North America. In addition, we employ over 400 auditors worldwide, should global certifications be important to our customers. The assignment of audit teams is based primarily upon industry, process and product experience, in addition to geographic considerations. Contracting with TÜV early in the process assists us in assigning the best possible teams.

### **3.6 Will the same auditors be utilized for the pre-audit, certification audit and surveillance audits?**

Yes. Our goal is to establish a long term relationship as a partnership in continuous improvement. It is always our goal to utilize the same auditors throughout the client relationship, unless the client chooses otherwise, or special circumstances require that a change be made. In fact, our audit

teams are usually assigned months in advance, and we encourage direct audit team contact throughout the certification process.

### 3.7 How would differences of opinion between the audit team and the client in standards interpretation be handled?

The issue is addressed in our contract. Among other items, these conditions include:

- Qualifications and appointment of auditors
- Handling of complaints
- Escalation process for appeals

## 4.0 REGISTRATION PROCESS

### 4.1 What are the current lead times for registration audits?

The lead time for certification audits varies, normally from 3-5 months from the date of the purchase order receipt.

### 4.2 What is the current lead time for pre-audits?

Pre-audits can usually be scheduled within 60 days.

### 4.3 What are the steps in the TÜV Management Service certification process?

There are four major steps in the certification process, outlined as follows:

As part of **Phase 1**, TÜV staff is available for on-site **Information Meetings**. The purpose of the Information Meeting is to discuss in detail the certification process and provide clarification of any specific issues.

During Phase 1, approximately 90 percent of our clients utilize our “**Pre-Audit**” service. The purpose of the pre-audit is to assess the company’s present compliance to the applicable management system standard and evaluate the feasibility of a successful certification audit. A formal report is provided to the client which includes non-conformances. The auditor will pinpoint where non-compliance exists, but does not indicate to the client how the issue must be resolved (section 2.2).

In preparation of the formal certification audit, the client must prepare a documentation package for the audit team’s review. This package should include:

- Level I Manual
- Level II Procedures
- Samples of key Level III Work Instructions

...as well as commonly used forms, checklists, and facility information.

**Phase 2** includes an evaluation of the documentation package. The Manual and supporting documentation will be evaluated against the requirements of the applicable management system standards. Unlike many other Registrars, TÜV Management Service will review not only your Level I documentation, but also your Level II procedures and a sample of Level III work instruction documents, as well as commonly used forms.

This thorough documentation evaluation enables your company to be aware, well in advance, of any identified issues of concern in your documentation.

You are then able to address those system design issues prior to the formal certification audit.

Conducting the Documentation Evaluation in advance of the audit results in the actual certification audit being more a verification of what was documented. Our clients strongly favor this process, versus a cursory review of the Level I Manual prior to the audit. The TÜV Management Service method of documentation review dramatically reduces documentation-related findings during the Certification Audit and better prepares both the client and the auditors for a successful audit.

Upon completion of the documentation review, a **detailed report** is generated for the client outlining evaluation results. The report is returned to the client approximately one month prior to the Certification Audit date.

The formal **Certification Audit** is conducted as part of **Phase 3**. The audit is performed by an audit team consisting of at least two members (exceptions can be made for small facilities). The duration of the audits vary depending upon the size of the company, complexity of the management system, and breadth of manufacturing processes.

Upon completion, the audit team will generate a detailed report outlining the results of the audit.

At **Phase 4**, TÜV will issue a Registration certificate. This certificate is valid for three years. **Surveillance Audits** are conducted either annually

or semi-annually. When an annual surveillance schedule is chosen, a **Recertification Audit** is performed at the end of the third year.

#### **4.4 What is covered in pre-audits?**

Pre-Audits are typically conducted by one auditor during a 1 to 3 day period. The purpose of the pre-audit is to assess the company's present compliance to the applicable management system standard and evaluate the likelihood of a potentially successful certification audit. Clients will receive a verbal briefing at the closing meeting, which will be followed-up by a written report outlining non-conformances.

#### **4.5 When is the documentation review performed?**

We request that the documentation package be submitted approximately 6 to 8 weeks prior to the certification audit. This package should include Level I and II documentation as well as samples of Level III documents. This will give us ample time to report our findings back to the client well in advance of the certification audit.

#### **4.6 How long does the documentation review take?**

Documentation reviews generally require 2 to 4 days to complete, based upon a number of factors. Documentation review is normally performed at our location.

#### **4.7 Must all documentation changes be completed and implemented prior to the audit?**

Changes to documentation should be made prior to the certification audit or a plan should be developed and be accepted by the audit team.

#### **4.8 Must the Management System be 100% implemented prior to receiving registration?**

This must be handled on a case by case basis. The audit team does not necessarily require 100% implementation of a management system. However, the audit team must establish a *level of confidence* that your management system complies with the applicable standard. That level of confidence plays an important role in the registration of the facility. Implementation of the management system must be sufficient enough to demonstrate to the audit team that requirements are understood, effective and will be met in the future. In some cases, one month of records may be sufficient to assure confidence. In other cases, six months may not be sufficient. Implementation requirements may vary by management system.

For example, there must be one full internal audit cycle and a full management review cycle completed prior to the formal certification audit.

#### **4.9 How are audit findings communicated?**

Audit findings are communicated both verbally and in writing during the closing meeting. All TÜV auditors have been provided with notebook computers to maximize efficiency in client reporting and prompt auditor feedback. Our global E-mail system creates further efficiencies in client contact.

#### **4.10 How are clients notified of management system omissions or non-conformances?**

All notifications of management system deficiencies will be in writing. However, closing meetings are always used to verbally communicate issues upon completion of an audit, followed by a formal report. In all cases the written non-conformance reports are presented at the closing meeting.

#### **4.11 How much time is given to correct identified non-conformances?**

Corrective Action plans should be submitted within 30 days of the certification audit. Dates are always discussed and agreed to by both partners (the client and audit team).

#### **4.12 What areas are covered if a re-audit is required?**

If a re-audit is required, the auditors will address only those areas identified within non-conformance reports.

#### **4.13 Is there a formal complaint process?**

Every client can appeal the denial, suspension, or cancellation of their certificate. Appeals must be detailed in writing to the Certification Body.

#### **4.14 How long are the registrations valid?**

Registrations are valid for a three (3) year period, assuming that the client remains in good standing during that period.

#### **4.15 What is the frequency and duration of surveillance audits.**

For most clients, a Surveillance Audit is conducted annually, typically by one TÜV auditor over a one to three day visit. Surveillance Audits may be conducted twice per year.

Visits are scheduled with the client's participation.

Surveillance audits consist of verification of internal audits, management review, corrective action, and a sample of other management system elements and changes in the management system. The elements selected for a surveillance audit are based on the previously identified non-conformances and observations. In addition, a selection of additional elements are reviewed.

#### **4.16 What is TÜV's policy on modifying the scope of a registration?**

The scope of a registration may be modified during surveillance audits or during a specially scheduled site visit/audit. The extra cost would be dependent upon the significance of the change and associated procedures review and audit time.

#### **4.17 Will a re-audit be necessary if there is a modification to the facility registration scope (from ISO 9002 to ISO 9001, for example)?**

Follow-up activity may be required depending on the changes. It is possible to perform the audit as part of surveillance visits, depending upon timing and degree.

#### **4.18 Will changes to the Level I Manual necessitate a surveillance visit?**

Most changes do not require a visit. For instance, changes implemented as a result of your continuous improvement process or internal preventative and corrective action system would not require special visits. Significant changes affecting the organization, product or process should be brought to our attention. A decision would then be made concerning the need for any follow-up activity. Examples where auditor visits could be necessary include a major acquisition, or introduction of a new product line added to the scope of certification.

#### **4.19 When should the client notify TÜV of changes in its management system?**

After the certificate has been granted, the client agrees to immediately inform TÜV of:

- Significant changes to the management system.
- Significant changes to the company structure and organization affecting the applicable management system.
- Significant changes to process equipment.

Your assigned auditor will review the changes and decide if any further action is required.

## **5.0 TÜV STRENGTHS SUMMARY**

### **5.1 Refreshing Registration Process:**

Our process includes full-scale documentation reviews well in advance of the formal certification audit. This complete evaluation better prepares the client – and our audit teams – for a successful audit, rather than leaving key documentation review until the audit itself. This is just one example of a refreshing certification process where the customer and the supplier are partners in the pursuit of continuous improvement and success. Other examples include use of full time staff, early assignment of audit teams, direct auditor contact and careful, extensive and timely reports at critical points during the audit process.

### **5.2 Auditor Consistency:**

Audit teams are assigned early in the certification process. Clients work directly with audit team members throughout the process. Auditors understand your business through pre-audit and documentation review activities. These same auditors conduct surveillance activities. We strive to build superior, long term, value-added relationships.

### **5.3 Auditor Experience:**

Lead Auditors average 15 years management systems experience. Their training and experience exceeds both RAB and IRCA requirements.

### **5.4 Reputation:**

Thousands of TÜV management system certificates have been issued throughout the world. In addition, TÜV Management Service is a true leader in environmental management systems certifications. TÜV is one of North America's leading Registrars, with over one thousand registered and contracted clients. We are well known throughout the world for highly professional management systems and product certification services.

### **5.5 A North American based, full service source for both Product and Management Systems Certification:**

We have the experience and North American based capability for both product testing and certification, as well as management systems certification.

This single source capability provides many clients with more efficient, effective and less costly international certification services.

## 5.6 Global presence:

Clients benefit from a certificate provided by a recognized international company with over 9,000 employees, \$1 billion revenues, 110 offices in over 30 countries and more than 125 years of experience in inspection, testing and certification services.

## 5.7 Client Service Philosophy:

We are your partner in continuous improvement. Our staff is comprised of team and customer oriented professionals, working hard to help you achieve your certification goals.

## How to get in touch with TÜV.

TÜV Management Service speaks one language...Yours. And your international access and success depends on your working with someone who understands your specific needs and demands. Call us today at 1-800-TUV-0123 or visit our worldwide web site at [www.tuvglobal.com](http://www.tuvglobal.com).

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