

## ***In this Issue:***

### ***Is Your Internal Audit Program All It Can Be?***

The annual ISO Survey of Certifications, now in its 14th edition, provides a worldwide view of certification to ISO's quality and environmental management system standards. The latest edition reveals the situation at the end of 2004, the first full year after the three-year period allowed for transition to the ISO 9001:2000 version.

*The worldwide total of certificates to the ISO 9001:2000 quality management systems standard at the end of last year was 670,399, an increase of 35% over the previous year and 64% over 2000, the year before the transition to ISO 9001:2000 began. Certificates have been issued in 154 countries.*

For the first time, the survey provides certification data on two ISO standards that include the requirements of ISO 9001:2000, plus sector-specific requirements. It shows that at least 10,056 certificates had been issued in 62 countries to ISO/TS 16949:2002, which gives quality management systems requirements for suppliers to the international automotive industry. In addition, at least 3,068 certificates had been issued in 56 countries to ISO 13485:2003, the sector-specific quality management standard for the medical device sector.

### **AS9100 Certified Supplier OASIS Database**

The International Aerospace Quality Group (IAQG) has an Online Aerospace Supplier Information System (OASIS) database that lists AS9100, AS9110, and AS9120 certified suppliers. You can register for free to have access to this database and search for certified suppliers by country, state, registrar, or certificate.

When specific suppliers are selected from the database, their certificate details and history are displayed, including address, certificate number, issue history, registration scope, and expiration date. If you want to view the certified supplier's assessment results summary and scoring data in the database, you can submit a request to the supplier's designated OASIS administrator.

For more information, go to [OASIS](#).

### **What Does ISO 9001 Mean in the Supply Chain?**

ISO has published a short information brochure, *ISO 9001:2000 - What does it mean in the supply chain?* This document is aimed at managers who are involved in selecting suppliers and making purchasing decisions, who may well encounter suppliers that claim to have an ISO 9001:2000-based quality management system. The brochure addresses the following main topics:

- What is ISO 9001:2000?
- What does "conformity to ISO 9001:2000" mean?
- How does ISO 9001:2000 help managers to select a supplier?
- How can managers have confidence that a supplier meets ISO 9001:2000?

- Can suppliers claim that their goods or services meet ISO 9001:2000?
- What to do if things go wrong.

ISO Secretary-General Alan Bryden commented: "Within the context of the growth of international trade and global supply chains, ISO 9001:2000 is being used by suppliers and customers located in different countries to establish initial confidence, or even to select partners in the supply chain. This new brochure will help them avoid unpleasant surprises and use ISO 9001:2000 to its full potential."

It provides answers to questions they may have such as:

- Does a claim of conformity to ISO 9001:2000 mean there is a 'guarantee' that all the goods and services provided will always meet the customers' requirements?
- How can a purchaser be sure that its supplier really does have a quality management system that meets ISO 9001:2000 requirements and that is relevant to the products it is providing?
- Where does product certification fit in?

The brochure is available free of charge in the ISO 9000 section of the ISO web site:  
<http://www.iso.org/iso/en/iso9000-14000/explore/9001supchain.html>

### **Is Your Internal Audit Program All It Can Be?**

You're probably familiar with the ISO 9001:2000 requirements for an internal audit program. But, have you thought about improving your internal audits by considering the extra requirements and guidance from the different industry sector schemes? Well, read on, because after a brief review of the ISO 9001:2000 audit requirements, you'll hear about additional requirements (AS9100, TL 9000, ISO/TS 16949, ISO 13485, and ISO 14001) and guidance (ISO 9004, ISO 14004, ISO 90003, and ISO 19011) to consider for your internal audit program.

Clause 8.2.1.3 of ISO 9004:2000 states that top management should ensure the establishment of an effective and efficient internal audit process to assess the strengths and weaknesses of the quality management system. The internal audit process acts as a management tool for independent assessment of any designated process or activity. The internal audit process provides an independent tool for use in obtaining objective evidence that the existing requirements have been met, since the internal audit evaluates the effectiveness and efficiency of the organization and its systems and processes.

It is important that management ensure improvement actions are taken in response to internal audit results. Planning for internal audits should be flexible in order to permit changes in emphasis based on findings and objective evidence obtained during the audit. Relevant input from the area to be audited, as well as, from other interested parties, should be considered in the development of internal audit plans.

Examples of subjects for consideration by internal auditing include:

- Effective and efficient implementation of processes,
- Opportunities for continual improvement,
- Capability of processes,
- Effective and efficient use of statistical techniques,
- Use of information technology,
- Analysis of quality cost data,
- Effective and efficient use of resources,
- Process and product performance results and expectations,
- Adequacy and accuracy of performance measurement,
- Improvement activities, and relationships with interested parties.

### **Aerospace - AS9100**

In addition to the basic ISO 9001:2000 requirements, AS9100B:2004 states that detailed tools and techniques must be developed, such as, checksheets, process flowcharts, or similar methods to support audit of the quality management system requirements. The acceptability of the selected tools will be measured against the effectiveness of the internal audit process and overall organization performance. Internal audits must also meet contract and/or regulatory requirements.

### **Telecommunications - TL 9000**

TL 9000, Release 3.0, doesn't add any requirements to those expressed in clause 8.2.2 of ISO 9001:2000.

### **Automotive - ISO/TS 16949**

In addition to the basic ISO 9001:2000 requirements, ISO/TS 16949:2002 adds five sub-clauses:

#### 8.2.2.1 Quality Management System Audit

The organization must audit its quality management system to verify compliance with ISO/TS 16949 and any additional quality management system requirements.

#### 8.2.2.2 Manufacturing Process Audit

The organization must audit each manufacturing process to determine its effectiveness.

#### 8.2.2.3 Product Audit

The organization must audit products at appropriate stages of production and delivery to verify conformance to all specified requirements, such as, product dimensions, functionality, packaging, and labeling at a defined frequency.

#### 8.2.2.4 Internal Audit Plans

Internal audits must cover all quality management related processes, activities, and shifts, and must be scheduled according to an annual plan. When internal or external nonconformities or customer complaints occur, the audit frequency must be appropriately increased. Note: Specific checklists should be used for each audit.

#### 8.2.2.5 Internal Auditor Qualification

The organization must have internal auditors who are qualified to audit the requirements of ISO/TS 16949.

### **What is Continual Improvement?**

Continual improvement is a type of change that is focused on increasing the effectiveness and/or efficiency of an organization to fulfill its policy and objectives. It is not limited to quality initiatives. Improvement in business strategy, business results, and customer, employee, and supplier relationships can be subject to continual improvement. Put simply, it means 'getting better all the time'.

#### **A ten step sequence:**

- Determine current performance.
- Establish a need to improve.
- Obtain commitment and define the improvement objective.
- Organize the diagnostic resources.
- Carry out research and analysis to discover the cause of current performance.
- Define and test solutions that will accomplish the improvement objective.
- Produce improvement plans which specify how and by whom the changes will be implemented.
- Identify and overcome any resistance to the change.
- Implement the change.
- Put in place controls to hold new levels of performance, and repeat step one.