FLUKE ®

Calibration

Metrology, Quality and ISO 9000

Application Note

What is ISO 9000?

ISO 9000 is becoming *the* internationally recognized model for the development of a documented quality system. A quality system is the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management. ISO 9000 is a generic set of standards, applicable to a wide range of companies and industries.

In addition, ISO/IEC Guide 25 addresses quality systems and competency as they apply to the calibration function.

What is its origin?

The ISO 9000 standards were developed as part of the European Community's process of elimination of trade barriers and the harmonization of technical standards known as EC'92. The ISO 9000 standards were originally published in 1987 by the International Standards Organization (ISO). Today, the ISO 9000 standards are available in local-language versions which precisely match the original ISO 9000 documents. Some examples are:

ISO	ISO 900X:1994
European Community	EN 2900X-1994
Germany	DIN ISO 900X
Netherlands	NEN-ISO 900X
USA	ANSI/ASQC Q900X-1994

where X equals the appropriate digit, 0 through 4

When does it take effect?

There is no specific date. ISO 9000 compliance becomes important when your customers begin to demand it.

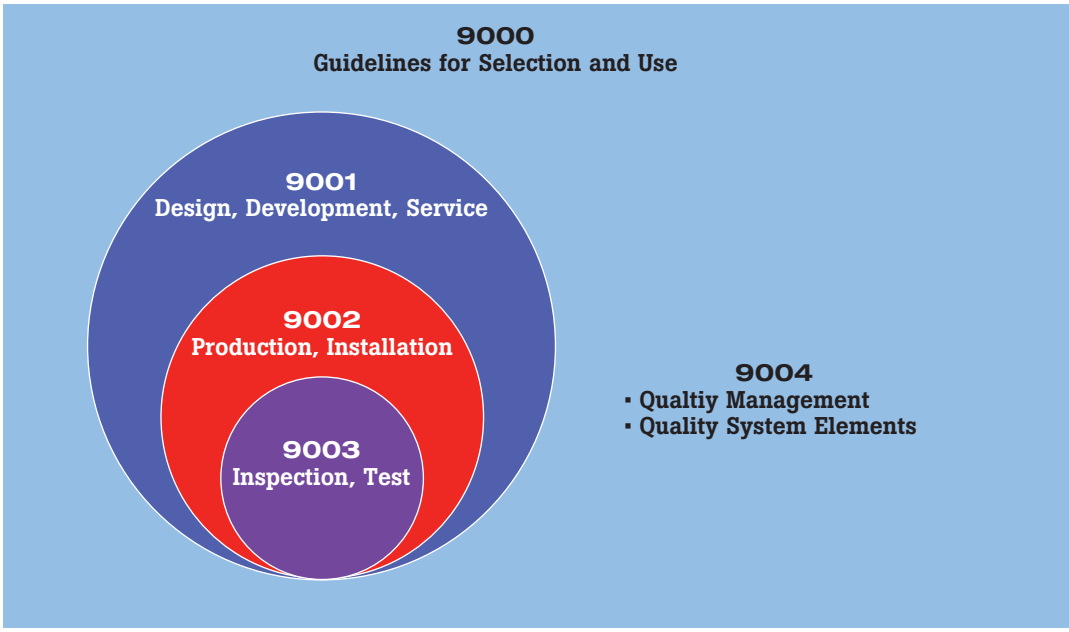

Figure 1. The relationship of the ISO 9000 standards.

How are the ISO 9000 standards organized?

ISO 9000 consists of several individual standards, each with a specific purpose. The relationship between the documents is shown in Figure 1.

ISO 8402, Quality management and quality assurance–vocabulary, serves as a glossary of quality terms.

ISO 9000 and ISO 9004 are descriptive documents. **ISO 9000**, *Guidelines for Selection and Use of Quality Management and Quality Assurance Standards*, provides information on the application of the ISO 9000 standards. **ISO 9004**, *Guidelines to Quality Management and Quality System Elements*, contains general information on quality concepts and terminology.

ISO 9001, 9002, and 9003 are the models for quality systems, and are the standards to which companies become registered or certified. **ISO 9003**, *Model for Quality Assurance in Final Inspection and Test*, is the least inclusive of three quality assurance models. **ISO 9002**, *Model for Quality Assurance in Production and Installation*, includes all elements of ISO 9003 and adds coverage of production and installation. **ISO 9001**, *Model for Quality Assurance in Design, Development, Production, Installation, and Servicing*, is the most inclusive model. It covers all aspects of an operation, from design through service.

Who has adopted ISO 9000?

As of early 1994, 73 countries have adopted one or more of the ISO 9000 standards (Figure 2). Thousands of companies have obtained registration to date worldwide.

What is a registration?

A registration is simply the audit and approval of your quality system against ISO 9000 standards by an independent registered auditor.

Is ISO 9000 the ultimate quality standard?

No. ISO 9000 is a solid base line for more comprehensive quality programs such as Total Quality Commitment (TQC). Whereas TQC is a five-step process which begins with identifying customers and culminates in measuring customer satisfaction, ISO 9000 focuses on the first four steps, identifying the customer, defining the work process, monitoring and improving that process and its results. Figure 3 shows the relationship between ISO 9000 and TQC.

What are the advantages of complying with ISO 9000?

- ISO 9000 can help your company achieve and sustain a desired level of quality.
- Many companies are consolidating their purchases from a smaller number of vendors. Often, one of the screening criteria is an ISO 9000 registration.
- Companies that are not ISO 9000 certified will find it more difficult to sell equipment in European Community (EC) countries, particularly in categories of equipment covered by EC product directives. A modular system has already evolved to mark qualified equipment, with a Confirmité Europeènne validating seal or mark (CE mark). Each EC member state must allow CE marked products into its market without further testing.[1]

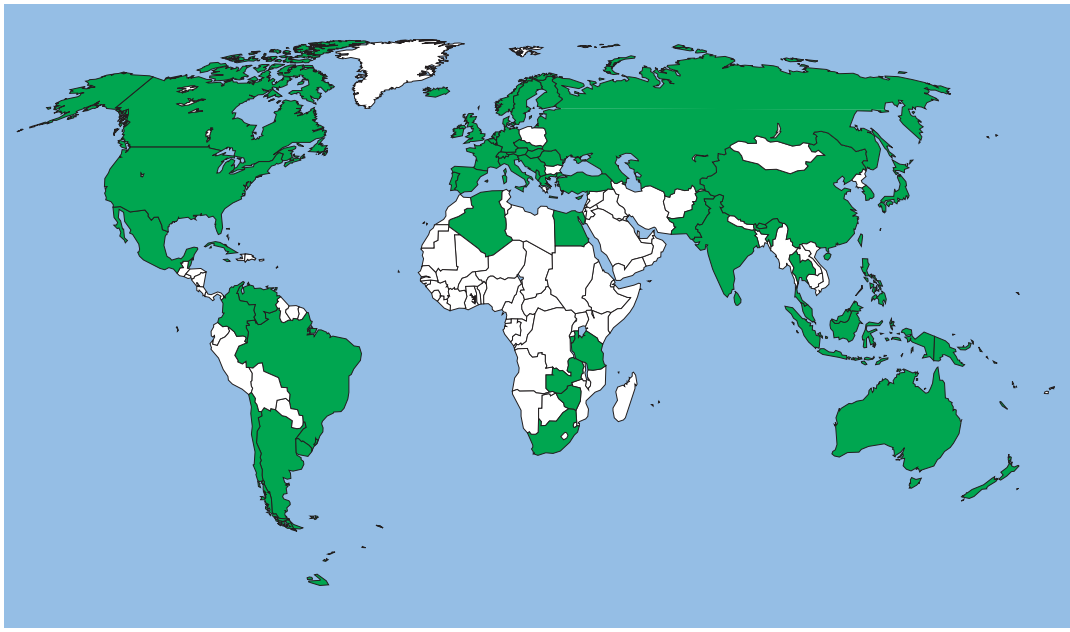

Figure 2. As of early 1994, 73 countries (shaded) had adopted one or more of the ISO 9000 standards.

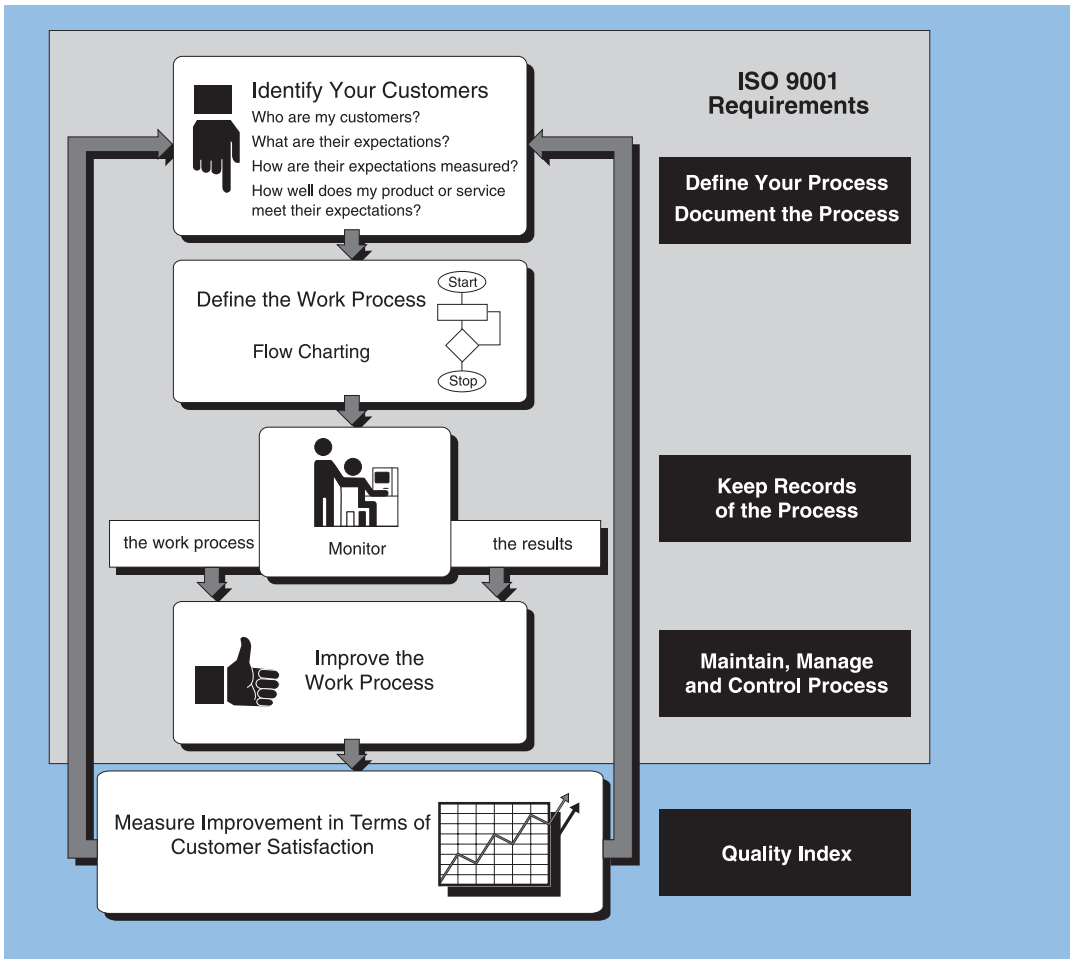

Figure 3. ISO 9000 is a good, base line quality standard which forms a solid foundation for a Total Quality Commitment program.

- ISO 9000 may simplify business by reducing the frequency and/or intensity of audits performed by customers or regulatory agencies.
- Companies certified to ISO 9000 may find they have a competitive marketing advantage over non-certified companies.
- The U.S. Department of Defense has indicated that it will shift from MIL-Q-9858 and MIL-I-45208A to the ISO 9000 quality standards.
- Companies who have implemented ISO 9000 report a positive cultural change, in which empowered employees take responsibility for quality.
- ISO 9000 registration, and the documentation to maintain it, may prove valuable in defending against product liability suits.

What areas will be probed during ISO 9000 registration?

Registration against the most comprehensive model, ISO 9001, will involve examination of these areas:

4.1 Management review
4.2 Quality systems
4.3 Contract review
4.4 Design control
4.5 Documentation control
4.6 Purchasing
4.7 Purchaser supplied product
4.8 Product identification and traceability
4.9 Process control
4.10 Inspection and testing
4.11 Inspection, measuring, and test equipment
4.12 Inspection and test status
4.13 Control of non-conforming product
4.14 Corrective action
4.15 Handling, storage, packaging, delivery
4.16 Quality records
4.17 Internal quality audits
4.18 Training
4.19 Servicing
4.20 Statistical Techniques

What must be done to pursue ISO 9000 registration?

Based on Fluke's experience, a process similar to the following will be successful:

- Gather ISO 9000 information.
- Commit resources; ensure that ISO 9000 registration is a top company priority.
- Form an interdisciplinary team (operations, purchasing, engineering, marketing, etc.) to pursue registration. Specifically, develop a well trained internal audit team.
- Develop a detailed plan, schedule, and budget.
- Choose your certification agent, or registrar, carefully. Is your registrar properly accredited? Is it familiar with your industry? Is it readily accessible? Most important, is a registration granted by your chosen registrar acceptable to your key customers?
- Develop a hierarchy of quality documentation; Quality Manual, Quality Procedures, Work Instructions, and Quality Records.
- Educate employees. Strive for empowerment and commitment on the part of each employee.
- Conduct a self-assessment. Your internal audit team should conduct a complete evaluation as though it were being done by the registrar. Then, take corrective action.
- Complete a pre-assessment. Invite your registrar in to conduct a preliminary version of the final audit. Once again, take corrective action.
- Pass a site audit conducted by a certification agency.
- Pass periodic surveillance audits. Each registrar will have different policies regarding the frequency and depth of periodic audits.
- Start now! It will invariably take longer than you think.

What problems might a company encounter?

According to the June 1992 issue of *Quality System Update*, the five most common sources of trouble are:

1. Document control
2. Calibration
3. Tracking of measurement equipment
4. Training records
5. Planning for customer contacts

Where can you get more information on ISO 9000?

The ISO Compendium includes the ISO 9000 standards, additional guidelines, proposed draft standards, and a look at the future direction of the standards. Order through:

ISO Central Secreteriat
1, Rue de Varembé
CH-1211 Genève 20
Telephone: +41 (22) 749 0111
Telefax: +41 (22) 733 3430

In the U.S.A., these documents are also available through:

The American National Standards Institute (ANSI)
1430 Broadway
New York, NY 10018
Phone (212) 642-4900

Actual copies of the ISO 9000 documents are available from the national standards organizations in participating countries. In the U.S.A., the documents are available as the "ANSI/ASQC Q9000-1994 Series", Q9000 through Q9004. Order from:

The American Society for Quality Control (ASQC)
Technical Services Department
310 W. Wisconsin Ave.
Milwaukee, WI 53203
Phone (414) 272-8575

In the U.S.A. and Canada, a wealth of information on ISO 9000 is available through a monthly newsletter *Quality Systems Update*, the *Registered Company Directory*, and the *ISO 9000 Handbook*, all offered by:

CEEM Information Services
PO Box 200
Fairfax Station, VA
22039-9859
(800) 745-5565 or
(703) 250-5900

In Europe, accreditation information can be obtained from:
European Organization for Quality
Brunnhofweg 37
P.O. Box 3001, Bern
Switzerland
Telephone: + 41 31 21 61 66
Telefax: + 41 31 26 32 57

How can Fluke Calibration help?

As the world leader in DC and low frequency calibration, Fluke can help your company deal with *Inspection, Measuring, and Test Equipment*, as outlined in ISO 9001, 4.11; ISO 9002, 4.10; or ISO 9003, 4.6 and as detailed in ISO/IEC Guide 25, *General requirements for the competence of calibration and testing laboratories*.

To paraphrase ISO 9001, 4.11, one must:

a) select equipment appropriate to the measurements to be made
b) calibrate it at regular intervals to recognized standards
c) using documented procedures, and
d) ensure that equipment is capable of the necessary accuracy and precision.
e) Equipment must indicate its calibration status, and
f) calibration records must be kept.
g) When equipment is found out of cal, validity of test results must be assessed.
h) Environmental condition,
i) storage and handling, and
j) security must be adequate to protect the validity of calibrators.

Fluke Calibration provides a broad range of products and services to meet these needs. Fluke manufactures calibrators and standards to preserve an unbroken chain of traceability from your measurements to recognized standards. Fluke also offers MET/CAL® Calibration Software for the creation, execution, and documentation of automated calibration procedures. Fluke MET/TEAM™ Test Equipment Asset Management Software makes possible the efficient management of your metrological assets. Finally, Fluke offers a complete range of Calibration Services, including Direct Volt Maintenance Programs, Asset Management Agreements, and calibration/repair services. Table 1 provides a mapping between ISO 9000 issues and Fluke's products and services.

ISO 9000 registration at Fluke

The Fluke factory at Almelo, Netherlands, was registered to ISO 9001 in 1989 by the KEMA. Fluke's Hamburg, Germany, plant was registered to ISO 9001 in 1992 by the DQS. All North American Fluke facilities were registered to ISO 9001 through National Quality Assurance, U.S.A. (NQA) in July of 1993.

In pursuit of ISO 9001, Fluke discovered:

- The value in ISO 9000 registration was that it compelled a timely execution of a pre-existing TQC effort.
- A small, cohesive, and thoroughly trained internal audit force should be put in place early in the process, since Corrective Action Reports are highly effective at enlisting middle management commitment.
- Get the Management Review process in place as early as possible.
- Leave the detail development of the Quality Manual, the top level document hierarchy, until later in the process, when the underlying documents are well understood.
- The greatest time commitments were in Process Control (ISO 9001,4.9), Training (4.18), Document Control (4.5), and Design Control (4.4).
- Corrective action was a cultural habit at Fluke, but now corrections are fully documented, resulting in significant time savings.
- Those who have implemented ISO 9000, particularly in purchasing and on the production line, are now becoming its biggest advocates.

Calibration Requirement	ISO 9000 Reference	Fluke Calibration Products & Services
Product conformance	ISO 9001, paragraph 4.11: "The supplier shall control, calibrate, and maintain inspection, measuring, and test equipment.....to demonstrate the conformance of product to the specified requirements."	Entire Fluke line of test instrumentation, e.g., ScopeMeter® Test Tool, DMMs
Traceable calibrations	ISO 9001, paragraph 4.11b: "The supplier shall ...identify, calibrate, and adjust all inspection, measuring, and test equipment and devices that can affect product quality at prescribed intervals, or prior to use, against certified equipment having a known valid relationship to nationally recognized standards."	**Cal Products:** The Unbroken Chain of Traceability; 5500A, 5700A, 792A, 732B, 742A **Cal Services:** Direct Volt Maintenance Programs, Asset Management Agreements, Self Maintenance Services, Training, and Calibration/Repair Services
Calibration procedures	ISO 9001, 4.11c	MET/CAL Calibration Software
Adequacy of cal equipment	ISO 9001, 4.11a,d	MET/CAL Calibration Software and MET/TEAM Test Equipment Asset Management Software
Traceability documentation	ISO 9001, 4.11b	
Calibration records	ISO 9001, 4.11f	
Out-of-tolerance reporting	ISO 9001, 4.11g	
Environmental controls	ISO 9001, 4.11h	
Security of calibrations	ISO 9001, 4.11j	
Reverse traceability	ISO 9004, 13.4; 9001 4.11g	MET/TRACK Metrology Property Management Software or MET/TEAM Test Equipment Asset Management Software
Handling and storage records	ISO 9001, 4.11i	

Table 1. ISO 9000 calibration requirements and related Fluke Calibration products and services.

[1]For more information on the EC directives, ask your Fluke representative for a copy of *"The Impact of New International Quality Standards on Metrology,"* a reprint of an award-winning paper delivered at the 1991 NCSL Workshop and Symposium (B0243A).

FLUKE®
Calibration

Fluke Calibration.

Precision, performance, confidence.™

- Electrical
- RF
- Temperature
- Pressure
- Flow
- Software

Fluke Calibration
PO Box 9090, Everett, WA 98206 U.S.A.

Fluke Europe B.V.
PO Box 1186, 5602 BD
Eindhoven, The Netherlands

For more information call:
In the U.S.A. (800) 443-5853 or
Fax (425) 446-5116
In Europe/M-East/Africa +31 (0) 40 2675 200 or
Fax +31 (0) 40 2675 222
In Canada (800)-36-FLUKE or
Fax (905) 890-6866
From other countries +1 (425) 446-5500 or
Fax +1 (425) 446-5116
Web access: http://www.flukecal.com

Printed in U.S.A. 4/2013 1260343H_EN