

ISO 9000

Summary:

ISO-9000 is the generic reference for a family of standards on quality management. Compliance with an appropriate standard from this family is required by members of the European Economic Community (EEC) as a prerequisite for suppliers of a broad, and increasing, range of product types described in EEC Directives. Suppliers wanting to sell these products to the EEC must be registered as compliant by a "third party" who has audited the supplier's quality management system. The "third party" auditors are also known as "Notified bodies" and are accredited by a designated authority of an EEC member state.

ISO-9000 itself is titled "Quality Management Standards" and presents guidelines for the selection and use of ISO-9001, 9002, and 9003. Part 3 of ISO-9000 guides the

application of ISO-9001 to software products. ISO-9001, "Quality Systems - Model for Quality Assurance in Design/Development, Production, Installation and Servicing," is the most comprehensive of the three quality systems standards with ISO-9002 containing only the portions of ISO 9001 concerned with production and installation, and ISO-9003 containing only those portions of ISO-9001 and 9002 pertaining to final inspection and test. A supplier would be registered to one of these three standards, depending on his role in the sale. ISO-9004 discusses quality system elements as a guide to managers and auditors. Part 2 of ISO-9004 provides guidelines on the application of quality management standards to services. Other documents cover accreditation of auditors and other ancillary topics.

ISO-9000 registration applies only to an audited site, not to all locations of a company. It is not a trivial pursuit. It has been estimated that only 30% of all applicants pass the on-site audit on the first attempt.

While ISO-9000 registration is not required for all European imports, and for few products outside of Europe, it is generally considered a marketing advantage. There are critics who consider ISO-9000 registration as an exercise in bureaucracy with little technical merit, but even these critics recognize that it can be a business necessity. Japanese companies, who built a reputation for quality without recourse to ISO-9000, are applying for ISO-9000 registration, and have in some instances accepted ISO-9000 registration of their suppliers in lieu of a quality audit.

Expert Commentaries:

"ISO 9000 is the wave of the future. For a while, certification to ISO 9000 will be a competitive advantage; sooner or later it will become a prerequisite for doing business." Anthony Coppola (1993 Annual Reliability Symposium).

"ISO 9000 does nothing to ensure actual quality of products or services. Registration merely indicates a 'system' which fulfills the often vague requirements of the standard." P.D.T. O'Conner (Quality and Reliability International, Sept. - Oct. 1992).

"ISO 9000 really sets the minimum acceptable system that all organizations should meet to be in business today. Once the basics are in place, the organization can start to bring about continuous improvement." H. James Harrington (Quality and Reliability International, July - August 1992).

"There are many certifiers of quality systems available and their qualifications are extremely varied. Selecting a certifier is a critical decision to a company, particularly

since the relationship is long-term." ABS Quality Evaluations, Inc. (White paper, "What is ISO 9000 and Why Should I Care?").

"ISO 9000, Q90, BS-5750 and EN 29000 are essentially equivalent documents. As of today, ISO 9000 has been adopted or incorporated by most industrial countries as their national standard for quality management systems." Coopers & Lybrand (White paper, "ISO 9000 Background and Current Status," Sept. 1991).

Bibliography:

ISO 9000 Standards:

ISO 9000, Quality Management and Quality Assurance Standards - Guidelines for Selection and Use. Identical to United States standard ANSI/ASQC Q9000-1.

ISO 9001, Quality Systems - Model for Quality Assurance in Design/Development, Production, Installation and Servicing. Identical to ANSI/ASQC Q9001.

ISO 9002, Quality Systems - Model for Quality Assurance in Production and Installation. Identical to ANSI/ASQC Q9002.

ISO 9003, Quality Systems - Model for Quality Assurance in Final Inspection and Test. Identical to ANSI/ASQC Q9003.

ISO 9004, Quality Management and Quality System Elements - Guidelines. Identical to ANSI/ASQC Q9004-1.

ISO standards are available from ANSI (see sources). ANSI/ASQC standards are available from ASQC (see sources).

Books:

ISO 9000 and Strategies to Compete in the Single European Market, by Costin and Dargie. 675 pages. Available from Goal/QPC (see sources).

The ISO 9000 Implementation Manual, by Greg Hutchins. 1994, 256 pages. ISBN 0-939246-63-5.

The ISO 9000 Answer Book, by Rob Kanter. 1994, 224 pages. ISBN 0-939246-60-0.

ISO 9000: Preparing for Registration, by J.L. Lamprecht. 1992, 241 pages. ISBN 0-8247-2.

Implementing the ISO 9000 Series, by J. L. Lamprecht. 1993, 262 pages. ISBN 0-8247-9134-7.

The 90-Day ISO Manual, by Mauch, Stewart, and Straka. 1994. Includes ISO Basics (150 pages) and ISO Implementation Guide (120 pages). ISBN 1-884015-11-5.

Documenting Quality for ISO 9000 and Other Industry Standards, by Gary E. MacLean. 1993, 200 pages. ISBN 0-87389-212-7.

The Quality Manager's Complete Guide to ISO 9000, by Richard B. Clements, Published by Prentice-Hall.

ISO 9000 for Software Developers, by Charles Schmauch. 1994, 168 pages. ISBN 0-87389-246-1.

ISO 9000: An Implementation Guide for Small to Mid-Sized Businesses, by Voehl, Jackson, and Ashton. 1994, 250 pages. ISBN 1-884015-10-7.

Reports:

NISTIR 4721, Questions and Answers on Quality, the ISO 9000 Standard Series, Quality Systems Registration, and Related Issues, by Maureen Breitenberg. U.S. Dept. of Commerce, National Institute of Standards and Technology (NIST), Gaithersburg, MD 20899.

Videos:

Building Quality Excellence with ISO 9000. 90 minutes, Society of Manufacturing Engineers (SME) PO Box 6028, Dearborn, MI 48121.

ISO 9000 for Electronics Manufacturers. 46 minutes, With Handbook. Society of Manufacturing Engineers (SME) PO Box 6028, Dearborn, MI 48121.

ISO 9000 International Quality standards, by International Quality Systems. 1992. Two tapes, 45 minutes each. With workbook and set of ISO standards. Available ASQC.

Joint ISO, ANSI and ASQC 9000 Forum Application Symposium. Edited from 1993 Symposium. Two hours. Available ASQC.

ISO 9000: Executive Briefing, by International Quality Systems. 1993, 25 minutes. Available ASQC.

Software:

How to Implement ISO 9000, by LearnerFirst™. Available from ASQC

The Strategic Analyst, a software program which scores a quality system against ISO 9000 criteria. Society of Automotive Engineers (SAE) Dept. 2785, 400 Commonwealth Drive, Warrendale, PA 15096-0001.

ANSI/ASQC Q9000-1994 Series Standards. Q9000 on-line. Available ASQC.

Training:

Course on Achieving ISO 9000 Compliance offered by the American Management Association, PO Box 319, Saranac Lake, NY 12983. Tel: (518) 891-0065. Fax: (518) 891-0368.

ASQC courses: Preparing for ISO 9000 Registration, ISO 9000 Quality System Documentation, and ISO 9000 Internal Auditing.

Six courses: Lead Assessor Training, Internal Auditor Training, ISO 9000 Implementation, ISO 9000

Documentation, All About ISO 9000, and Train the Trainer in ISO 9000, available from Perry Johnson, Inc., 3000 Town Center, Suite 2960, Southfield, MI 48075. Tel: (810) 356-4410. Fax: (810) 356-4320.

Course on ISO 9000-part 3 (Software): Two-day course, available from Software Certification Institute, PO Box 2328, Santa Maria, CA 93457.

Course on ISO 9000-part 3 (Software): One-day Seminar by Underwriters Laboratory (UL) and Research Triangle Institute (RTI). Contact RTI, 3040 Cornwallis Blvd. PO Box 12194, Research Triangle Park, NC 27709-2194

Sources:

ANSI (American National Standards Institute) 11 West 42nd Street, New York, NY 10036. Tel: (212) 642-4900. Fax: (2123) 302-1286.

ASQC Quality Press, 611 E. Wisconsin Ave. PO Box 3005, Milwaukee, WI 43201-3005. Tel: (800) 248-1946.

GOAL/QPC 13 Branch Street, Methuen, MA 01844-9916. Tel: (800) 643-4316. Fax: (508) 685-6151.

Oliver Wight/Omneo, 85 Allen Martin Drive, Essex Junction, VT 05452-9985. Tel: (800) 343-0625. Fax: (802) 878-3384.

St. Lucie Press, 100 E. Linton Blvd., Suite 403B, Delray Beach, FL 33483. Tel: (407) 274-9906. Fax: (407) 274-9927.

Support Groups:

National ISO 9000 Support Group, 9964 Cherry Valley, Bldg. 2, Caledonia, MI 49316.

Magazine/Journal Articles:

Quality in Education - ISO 9000 as a Tool? by J. Osborne in Quality and Reliability Engineering, Vol. 10, no. 3.

ISO 9000 in the Semiconductor Industry, by E. R. Hnatek in Semiconductor International, Vol. 16, no. 8.

ISO 9000 is Setting High Standards, by E. E. Sprow in Manufacturing Engineering, Vol. 111, no. 1.

Updating the ISO 9000 Quality Standards: Responding to Marketplace Needs, by Durand, Marquardt, and Peach in Quality Progress, Vol. 26, no. 7.

Developing ISO 9000 Implementation Plans and Quality Manuals, by W. J. Schuelke in The Fabricator, Vol. 23, no. 5.

Capture a Quality Image with ISO 9000, by Rabbitt, Bergh, and Dror in INTECH, Vol. 40, no. 4.

U. S. Diesel Manufacturers and ISO 9000, by M. Osenga in Diesel Progress Engines and Drives, Vol. 59, no. 4.

The Japanese Point of View on the ISO 9000 Standards, by H. Kume in Quality and Reliability Engineering, Vol. 9, no. 2.

ISO 9000 Quality Assurance Certification, anonymous author in Metal Matrix Composites, Vol. 1, no. 1.

The Steps Toward ISO 9000 Registration, by E. R. Hnatek in Test & Measurement World, Vol. 13, no. 2.

The European Community and the ISO 9000 Series of Quality System Management Standards, by R. G. Schueppert in the 1993 Tutorial Notes of the Annual Reliability and Maintainability Symposium.

Quality Goals, ISO 9000, and Documentation Management, by D. Gorman in Compliance Engineering, Vol. 10, no. 3.

ISO 9000 and Certification - Back to Basics, by R. T. Weightman in Valve Magazine, Vol. 5, no. 3.

About the Reliability Analysis Center

The Reliability Analysis Center is a Department of Defense Information Analysis Center (IAC). RAC serves as a government and industry focal point for efforts to improve the reliability, maintainability and quality of manufactured components and systems. To this end, RAC collects, analyzes, archives in computerized databases, and publishes data concerning the quality and reliability of equipments and systems and the microcircuit, discrete semiconductor, and electromechanical and mechanical components that comprise them. RAC also evaluates and publishes information on engineering techniques and methods. Information is distributed in data compilations, application guides, data products and programs on computer media, public and private training courses, and consulting services.

Located in Rome, NY, the Reliability Analysis Center is sponsored by the Defense Technical Information Center (DTIC). Since its inception in 1968, the RAC has been operated by IIT Research Institute (IITRI). Technical management of the RAC is provided by the U.S. Air Force's Rome Laboratory (formerly Rome Air Development Center) at Griffiss AFB.

ISO 9000 and the Military, by S. Hutchens in Compliance Engineering, Vol. 10, no. 5.

ISO 9000 Quality Systems: How to Select a Registrar, by R. T. Weightman in Valve Magazine, Vol. 5, no. 4.

Why ISO 9000 Makes Good Business Sense, by A. Saunders in Laser Focus World, Vol. 28, no. 12.

Getting off the Fence and into ISO 9000, by J. Endrijonas in Managing Automation, Vol. 7, no. 11.

ISO 9000 for the Test Engineer, by E. R. Hnatek in Test and Measurement World, Oct. 1992.

ISO 9000 and Undersea Fiber Cable: Meeting the Standard Makes a Difference, by Adame and Estenes in Photonics Spectra, Vol. 26, no. 9.

Does ISO Improve Quality? by M. Chalk in Surface Mount Technology, Vol. 6, no. 9.

Managing Your Suppliers with ISO-9000, by S. Sawin in Compliance Engineering, Vol. 9, no. 4.

Facts and Fiction of ISO 9000 Registration, by Gundlach and Deken in Compliance Engineering, Vol. 9, no. 4.

ISO 9000 Sets the Stage for Global Competition, by K. Sateesh in Controls & Systems, Vol. 39, no. 9.

ISO 9000: a Matter of Survival, by Hall, Cleaveland, and Kuhfeld in Instrumentation & Control Systems, Vol. 65, no. 6.

What You Should Know about ISO 9000, by S. L. Jackson in Training, Vol. 29, no. 5.

ISO 9000/Q90: Is itZ for You? by A. Soslow in Advanced Packaging, Vol. 1, no. 1.

Future Issues:

RAC's selected topics in assurance related technologies (START) are intended to get you started in knowledge of a particular subject of immediate interest in reliability, maintainability and quality. Some of our upcoming topics being considered are:

- Commercial Off-the-Shelf Equipment
- Reliability Predictions
- Plastic Microcircuits
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- Mechanical Reliability
- Software Reliability

Please let us know if there are subjects you would like covered in future issues of START.

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Mr. Coppola holds a Bachelor's degree in Physics and a Master's in Engineering Administration, both from Syracuse University. He also completed the Industrial College of the Armed Forces correspondence program in National Security Management, and the Air War College Seminar Program. He has been a guest instructor for the Air Force Institute of Technology, The Air Force Academy, and George Washington University. He is a fellow of the IEEE and a recipient of the IEEE Centennial medal. He also holds Air Force Medals for Outstanding Civilian Career Performance and Meritorious Civilian Service. He was the General Chairman of the 1990 Annual Reliability and Maintainability Symposium.