START

Selected Topics in Assurance Related Technologies

ISO 9000-2000

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Introduction

This START sheet is in essence an update to **START 94-1, ISO** originally written by former staff member (now retired) Anthony Coppola. Portions of **START 94-1, ISO** are in fact reproduced here. But much has changed since the original ISO 9000:1994 and the purpose of this START is to update the reader to make them aware of the significant changes in ISO 9000:2000 and the possible need for industry-specific add-ons.

Background

ISO-9000[1] 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 manage-ment system. The "third party" auditors are also known as "Notified bodies" and are accredited by a designated author-ity of an EEC member state.

ISO 9000:2000 has been renamed and is now titled ***Quality management systems – Fundamentals and vocabulary***. Other documents within the series cover accreditation of auditors and other ancillary topics. ISO-9000 registration applies only to an audited site, not to all of the locations of a company.

Companies could not be certified to ISO 9001:2000 until it was actually issued in December 2000. Until then, compa-nies continued to be certified as compliant to the 1994 ver-sions of ISO 9001, 9002, and 9003. Certification to the 1994 standards expires three years after publication of the 2000 version. Thus ISO 9000:2000 is becoming to be increasing-ly relevant to industry.

Major ISO 9000:2000 Changes

The ISO 9000 series of documents has undergone a radical change from the 1994 version to the 2000 version. The total number of standards was reduced from 27 to just 4 docu-ments. In the 2000 revision, the emphasis has been shifted from a focus primarily upon up-front ISO 9000 certification to actually using the standard now to improve quality. Some of the other benefits of ISO 9000:2000 are a more user-friendly language, a smaller set of interlocking documents, and more universal applicability.

Table 1 shows how the original twelve key documents have been replaced by three new documents. These remaining documents were also extensively revised.

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[1] ISO, the name of the international standards body, is not an acronym. It is from the Greek term signifying equality, such as used in the word "isobars" referring to lines on a weather map designating equal air pressure.

Table 1. ISO 9000:1994 Elements Versus ISO 9000:2000 Elements

ISO 9000:1994		ISO 9000:2000	
ISO 9000-1: ISO 8402:	Guidelines for selection and use Vocabulary	ISO 9000:	Quality management systems – Fundamentals and vocabulary
ISO 9004-1: ISO 9004-2: ISO 9004-3: ISO 9004-4:	Guidelines for managing quality system elements Guidelines for managing the quality of service activities Guidelines for managing the quality of processed materials Guidelines for creating quality improvements	ISO 9004:	Quality management systems – Guidelines for performance improvements
ISO 9001: ISO 9002: ISO 9003:	Quality assurance – Design, manufacturing, installation, and servicing systems Quality assurance – Production and installation Quality assurance – Final product inspection and test	ISO 9001:	Quality management systems – Requirements

ISO 9001:2000 and It's Changes

This document entitled, *Quality Management Systems Requirements* is now the key remaining standard used for certification purposes, i.e., to assess a producer's ability to meet customer and applicable regulatory requirements. It is also now used specifically to address and to quantify customer satisfaction. New requirements were added to this document, existing requirements were significantly changed, and the paragraph-numbering scheme itself was completely revised as shown in Table 2. Sections 4 through 8 of the new standard now include all the requirements of Section 4 of the previous standard plus the new requirements.

Table 2. ISO 9001:1994 Versus ISO 9001:2000 Tables of Contents

ISO 9001:1994	ISO 9001:2000
1. Scope 2. Normative References 3. Definitions 4. Required Tasks (4.1 – 4.20 Individual Tasks)	1. Scope 2. Normative References 3. Terms and Definitions 4. Quality Management System 5. Management Responsibility 6. Resource Management 7. Product Realization 8. Measurement, Analysis, and Improvement

Measurements Metrics

A major new requirement of ISO 9001:2000 is for organizations to actually implement actions necessary for achieving continual improvement of processes and the quality management system itself. This change has placed a much greater emphasis on the continued improvement of processes, and on the quantitative assessment of product quality.

Thus, one important new element in ISO 9001:2000 is the requirement to actually measure processes, products, and quality objectives. The 2000 edition recognizes that measurements are important, vital in fact, if organizations are going to have any chance of assessing, monitoring, and improving the quality of their product or service.

ISO 9001:2000 thus implies that the quality objectives be measurable - this is the first basic requirement for an organization.

Whatever product and process measurements are applied, however, must be compatible with that industry and therefore contribute positive support to the quality objectives.

Measurement needs to be done with clear objectives in mind, the parameters to be measured must be carefully chosen so that both quantitative and qualitative benefits are obtained. A measurement program that shows no comprehensible evidence of benefit will soon be discarded, or, possibly worse, it may be continued by personnel with no clear understanding of what is required, simply because it has become proceduralized. This will waste time and effort and thus degrades the prime objectives of measurement.

ISO 9001 now is the only standard in the ISO 9000 family against which third-party certification are carried out. The focus of this document, however, is on the requirements themselves, and not on details of the actual measurements. Thus concern with the metrics, e.g., the identification and actual measurement of specific parameters is one of the prime reasons for the development of industry-specific add-ons. If the basic parameters and their associated metrics are clearly identified for a specific industry, a template for more focused measurement can then be established.

The Need for Industry-Specific Derivatives

There are, at present, four generally recognized industry-specific quality system derivatives. Each one was prepared by a different professional organization using industry experts with the intent of addressing perceived weakness in ISO 9001 relative to that specific industry. Thus, one goal of the industry-specific documents is to further enhance the certification process within that specific industry. These documents, however, identify with and represent quite diverse industries. Three of these four derivative documents deal with industries producing hardware, while the fourth one deals with software products.

These four generally recognized industry-specific derivatives are:

- **QS-9000,** *Quality System Requirements*, published by the Automotive Industry Action Group (AIAG). This is the earliest of the industry-specific derivatives, originally

published in 1994. Unfortunately this document has not yet been updated to the ISO 9000:2000 version.

- **AS 9100,** *Quality Systems – Aerospace – Model for Quality Assurance in Design, Development, Production Installation and Servicing,* published by the Society of Automotive Engineers (SAE) is very user-friendly and it retains the ISO 9001:2000 paragraph titles and numbering scheme (see Table 2).

- **TL 9000** is published by Quality Excellence for Suppliers of Telecommunications (QuEST) Forum. It breaks out the subject material into two separate documents, one dealing with "requirements" and the other with "measurements". The first TL 9000 document*, Quality Management System Requirements Handbook*, retains the ISO 9001:2000 paragraph titles and numbering scheme (see Table 2). The second document *Quality Management System Measurements Handbook* defines a minimum set of performance measurements unique to the telecommunication industry.

- *TickIT Guide*, published by the British Standards Institute (BSI) DISC office, is intended to be used as a "Software Sector Quality Certification Scheme" by the software community. Although identified as a "Guide" rather than a standard, it also retains the ISO 9001:2000 paragraph titles and numbering scheme (see Table 2).

Within the literature, reference is also sometimes (erroneously) made to a TE-9000. TE-900 is actually a shorthand nomenclature for a supplement to QS-9000. Properly identified as the "Tooling and Equipment Supplement", this document applies QS-9000 to suppliers of tooling, equipment, and related products. This "Supplement" document is an excellent example of the "tailoring" of an existing industry-specific ISO 9000 derivative to the specific needs of a somewhat different industry.

Summary

ISO 9000:2000 is a major revision. It represents a refocusing and broadening of the goals of the document. To assist the user, the RAC web site <http://rac.iitri.org> contains an extensive listing of both the documents dealt within this START Sheet and many other potential reliability, maintainability, and quality specifications and standards. These web site listings include already recognized national, international, and military documents (found under the heading: R&M Standards) that may potentially be considered for applicability for a given application. Certainly a great deal of the groundwork has already been performed in the preparation of these documents. Information has already been compiled and assembled by knowledgeable experts into potentially useful formats.

However, it is the author's opinion that, in most instances, ISO 9000 and possibly one or more of the industry-specific derivatives discussed in this START Sheet would certainly be the recommended starting point to find, convert or tailor a suitable "Quality System" specification.

To Obtain Copies/Further Study

ISO 9000:2000 *Quality Management Systems – Fundamentals and Vocabulary and* **ISO 9001:2000,** *Quality Management Systems Requirements*

Within the United States:

American National Standards Institute (ANSI)
11 West 42nd Street
New York, NY 10036
Tel: (212) 642-4900
Fax: (212) 302-1286
<http://www.ansi.org>

Or

Global Engineering Documents World Headquarters
15 Inverness Way East
Englewood, CO 80112
Tel: (800) 716-3447
Fax: (800) 716-6447
<http://www.nexdata.com/contacts.html>

Outside the United States:

International Organization for Standardization ISO
1, Rue de Varembe
CH-1211 Geneva 20 Switzerland
Tel: +(41) 22 749 0111
Fax: +(41) 22 733 3430
<http://www.iso.ch>

SAE Publication AS 9100, *Quality Systems – Aerospace – Model for Quality Assurance in Design, Development, Production Installation and Servicing* (Revision A, 2001-08)
Society of Automotive Engineers (SAE)
400 Commonwealth Drive
Warrendale, PA 15096-0001
Tel: (412) 776-4841
Fax: (412) 776-5760
<http://www.sae.org/servlets/index>

QuEST Publication TL 9000, *Quality Management System Requirements Handbook* (Release 3.0, March 31, 2001) and **QuEST Publication TL 9000,** *Quality Management System Measurements Handbook* (Release 3.0, March 31, 2001)
American Society for Quality (ASQ)
600 N. Plankinton Ave.
Milwaukee, WI 53203
Tel: (414) 272-1946
Fax: (414) 272-1734
<http://www.asq.org/>

About the Author

Norman B. Fuqua is a Senior Engineer with IIT Research Institute. His 43 years of experience in dependability, reliability, and maintainability has covered a diversity of military, space and commercial programs. Currently responsible for training he has developed and taught a variety of courses throughout his career including the RAC's PRISM Reliability Assessment Tool. His *Electronic Design Reliability* Training Course currently has been presented more than 200 times to 6,700 students in the US and a dozen other countries for a wide assortment of clients. He is a reliability textbook author, a symposium tutorial instructor and a principle contributor to many RAC publications and study programs.

Mr. Fuqua holds a B.S. in Electrical Engineering from the University of Illinois (Urbana). He is also a registered professional engineer (California).

Other START Sheets Available

Many Selected Topics in Assurance Related Technologies (START) sheets have been published on subjects of interest in reliability, maintainability, quality, and supportability. START sheets are available on-line in their entirety at <http://rac.iitri.org/DATA/START>.

For further information on RAC START Sheets contact the:

Reliability Analysis Center
201 Mill Street
Rome, NY 13440-6916
Toll Free: (888) RAC-USER
Fax: (315) 337-9932

or visit our web site at:

<http://rac.iitri.org>

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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, supportability 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, as well as 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 through 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 Research Laboratory Information Directorate (formerly Rome Laboratory).