National Tooling & Machininig Association

NTMA PRECISION

Business Management Advisory

For Precision custom Manufacturers

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ISO 9000: Answers to Frequent Questions

SUMMARY

ISO 9000 is a series of international quality standards first published in 1987. As our markets and competition become increasingly global, these standards are rapidly being adopted by major tooling & machining customers and suppliers in the U.S. and abroad. This BMA addresses questions frequently raised by NTMA members on the subject.

WHAT IS ISO 9000 AND WHY SHOULD I BE CONCERNED ABOUT IT?

ISO 9000 is a series of five documents, including three standards for quality systems. The series was first published in 1987 by the International Standards Organization as a world standard for quality system assessment. The series is important because the U.S. Department of Defense intends to replace Mil-Q-9858A and its related specs with the ISO 9000 series. The European Economic Community has accepted ISO 9000 as the "EC 92" basic quality requirement. Many U.S. corporations, especially those with global markets, are adopting the ISO 9000 model for quality systems. The U.S. Food & Drug Administration is also revising its Good Manufacturing Practice (GMP) standard to conform to the ISO specifications.

WHAT'S SO SPECIAL ABOUT ISO 9000? DON'T WE HAVE ENOUGH QUALITY SPECS ALREADY?

The ISO 9000 series is unique because it depends upon a system of certification by neutral, third-party registrars (auditors). Unlike the prevalent system of customer audits, the burden of proof of non-conformance rests with the auditor, and not with the company being evaluated. Auditing registrars must be accredited by a national accreditation body.

WILL AN ISO 9000 CERTIFICATION ELIMINATE REPETITIVE & NON-PRODUCTIVE AUDITS BY CUSTOMERS?

Probably not entirely, but the widespread recognition of ISO 9000 as a minimum requirement is likely to reduce the need for customers to examine the general structure of certified suppliers' systems, permitting customers to focus only on those requirements that are specific to work at hand.

HOW CAN MY COMPANY GET CERTIFIED, AND WHAT WILL IT COST?

Your company must submit an application and fee to an accredited ISO 9000 registrar. Your quality manual and related documents will be reviewed, and a plant visit will be conducted. You will be advised of any shortcomings and asked to submit a plan to correct them within a reasonable time. Once the corrections are confirmed, a certification is issued. The registrar will conduct two-to-four surveillance visits per year, and a full reassessment is required every three or four years.

Costs will vary with different registrars, and with the circumstances of your company, but typical tooling & machining companies might expect to pay $10,000 or more for the basic certification process which usually takes from three to twelve months.

WHAT BENEFITS DO I GET FROM CERTIFICATION?

Some benefits include:

1 A reduction in number and scope of customer audits.
2 Use of the assessment process for continuous competitive improvement.
3. Use of the certification as a marketing tool for access to multinational customers, DoD, and export markets.
4. Lower operating costs through improved quality and productivity. The British Standards Institute has estimated that certified companies in the U.K. have lowered costs by an average of 10%.

MUST MY COMPANY BE CERTIFIED TO THE ENTIRE ISO 9000 SERIES?

Generally not, certifications are usually done to only one of either ISO 9001, 9002, or 9003. ISO 9001 is the most stringent and comprehensive, and applies to manufacturers that design, develop, produce, install, and service products. ISO 9001 would be appropriate if your company designs special tooling.

ISO 9002 is slightly less stringent than ISO 9001, and is intended for process industries (such as food processing, chemicals, pharmaceuticals, etc.), where requirements must meet an established design or specification. ISO 9002 is appropriate as the core of a TQM system for companies that make parts or tooling to customer specifications.

ISO 9003 applies to small shops, divisions or units of larger organizations, or equipment distributors that inspect and test supplied products. ISO 9003 is a specification for inspection systems, and does not cover many TQM elements of ISO 9001 and 9002.

The ISO 9000 document itself is a guide to the rest of the series, and offers guidance on selecting which of 9001, 9002, or 9003 is most appropriate for your company. ISO 9004 provides guidelines for implementation. Certifications are not performed to ISO 9000 nor 9004.

IF MY COMPANY IS CERTIFIED TO AN ISO 9000 STANDARD, IS THE CERTIFICATION RECOGNIZED WORLDWIDE AND BY MAJOR DOMESTIC CUSTOMERS?

Not necessarily; at least, not yet. For example, in England, the only certifications officially recognized are those bearing the "Crown Stamp" issued by registrars accredited by the U.K.'s national accreditation body. Efforts are in progress to improve international acceptance.

Also, since the ISO 9000 series represents minimum quality system requirements, customers can and will impose additional specific requirements.

WHERE CAN I GET COPIES OF THESE STANDARDS?

The official U.S. editions of these standards are published as ANSI/ASQ Q90 through Q94. These are recognized by ISO as equivalent to ISO 9000 through 9004. Prices and ordering information are available by calling the American Society for Quality (Milwaukee, WI) at 1(800)248-1946.

DO I REALLY NEED TO GO THROUGH THE TIME-CONSUMING AND EXPENSIVE CERTIFICATION PROCESS?

Perhaps not. At this writing, U.S. customers of tooling & machining products and services do not appear to be pressing suppliers for the actual certification, although many major buyers are asking suppliers to have quality systems structured according to the ISO 9000 specifications.

Bruce Andres, of UNC Manufacturing Technology, (Uncasville, CT) may be the first NTMA member to have achieved certification for his 30-employee CNC machine shop. At a recent NTMA conference, Andres told an attentive audience that tooling and machining job shops "can view the ISO 9000 series as either a barrier or an opportunity," said Andres. The impact of ISO 9000 on your company will depend upon:

- What you sell,
- To whom you sell it, and,
- Your present commitment to quality.

Lack of an ISO 9000 certification will prevent you from selling in Europe only if your European customer specifically requires it, or if you make a specific end-product that requires the certification. January 1, 1993 is not a compulsory deadline for certification for the European market.

Actions by the Department of Defense, the Food & Drug Administration and various commercial customers to revise existing quality specs to conform with ISO 9000 appear at this point to be focusing on "ISO 9000-capability" versus actual certification. However, a formal certification may reduce or eliminate the need for pre-award audits.

Even without a formal certification, having your quality system conform to the ISO 9000 specifications can help respond to customer demands, and will make the certification process easier and less-costly if you decide to pursue it at a later date.

WHY MUST WE CONFORM TO A EUROPEAN STANDARD? WHAT'S WRONG WITH OUR OWN?

ISO 9000 is not strictly European. It is an international standard that has been accepted by over 50 countries around the world, including the U.S.A. ISO 9000 series was developed as a way to harmonize existing standards in various industrialized nations in order to facilitate international trade.

After the standards were published in 1987, ISO 9000 was selected by the European Economic Community (EC) as the basic quality system for doing business in the EC member-nations. Interestingly, some Europeans reportedly consider ISO 9000 an "American" standard, since much of the leadership in developing the standards came from the U.S. This may also explain the striking similarity of some elements of ISO 9000 to parts of U.S. Mil-specs on quality. Even in EC countries, your quality system requirements will remain largely determined by your individual customers.

WHERE DO I GO TO GET CERTIFIED?

Certifications must be performed by "registrars" who are accredited under ISO procedures by a national accreditation authority. In the U.S., registrars are accredited by the Registrar Accreditation Board, a unit of the American Society for Quality (ASQ). A current list of accredited registrars is available by calling ASQ (in Milwaukee, WI) at (414) 2728575.

If you are seeking certification to pursue business in a particular country, you should make sure that the registrar you select is recognized or accredited by that country. A number of U.S. registrars have accreditation or memoranda of understanding with foreign accrediting bodies.

There are some differences in the grading systems used under the various national accreditations. These differences can affect the cost of your certification process, and you should find out about them before signing a contract. Some systems use a "pass-fail" approach, while others use a point system. Under the pass-fail system, a failure requires a second visit by the audit team to assess corrective actions. In a point system, minor deficiencies may not be followed-up until the next routine audit. Once certified, routine audits are usually scheduled for every six months, and a complete reassessment is required every three years.

Ideally, you should look for a registrar with expertise in your kind of business. From a practical standpoint, however, registrars with small-company tooling & machining experience will be hard to find among the small number of accredited registrars in the U.S. If you are pursuing certification in response to customer demands, your customer's recommendation for a registrar would be valuable.

MUST I REWRITE MY ENTIRE QUALITY MANUAL TO MEET ISO 9000?

Not necessarily, although you will probably at least need to make some revisions or add some new material. Under the ISO 9000 concept, quality manuals should be kept short, and should focus on the quality system itself, not on specific procedures. Work instructions, quality-related job descriptions, inspection procedures and so on can be documented elsewhere, and referenced in the quality manual.

Your present quality system will influence the amount of revision needed to qualify for the appropriate ISO 9000 standard. If you have a manual that conforms to Mil-I-45208A, you will be close to the requirements of ISO 9003 (ANSI/ASQ-Q93). Mil-Q-9858A and many of the leading corporate supplier quality programs share many common requirements with ISO 9001 and 9002 (Q91 & Q92). In any case, you will probably need to reorganize or re-format existing material to conform with the structure of the ISO requirements.

DO I REALLY NEED WRITTEN JOB DESCRIPTIONS TO COMPLY WITH ISO 9000? WHAT DOES THIS HAVE TO DO WITH QUALITY?

A complete set of job descriptions is not necessarily the only way to meet ISO 9000 requirements. Simply writing a description of each employee's quality responsibilities will meet the letter of the standard.

But since the Americans with Disabilities Act (ADA) has gone into effect, most employers will need job descriptions to comply with the law, as well as to defend against possible discrimination lawsuits. It simply makes sense to meet both sets of requirements with one set of job descriptions.

The ISO 9000/Q90 standards do not require job descriptions or other statements on quality responsibilities to be included in your quality manual. For convenience, job descriptions are most easily maintained on a word processor. For ready reference, a complete set of hard copies can be kept in a ring binder and individual job descriptions in each employee's personnel file.

The ISO 9000 series requires that "responsibility, authority of all personnel who manage, perform and verify work affecting quality shall be defined." This basic language is included in each of ISO 9001, 9002 and 9003 (ANSI/ASQ Q91, Q92 and 93, respectively, in their U.S. editions). The two more-stringent standards, Q91 and Q92, go on to say that quality-related responsibilities must be defined:

"...particularly for personnel who need the organizational freedom and authority to:

a. Initiate action to prevent the occurrence of product nonconformity;
b. Identify and record any product quality problems;
c. Initiate, recommend or provide solutions through designated channels;
d. Verify the implementation of solutions;
e. Control further processing, delivery or installation of nonconforming product until the deficiency or unsatisfactory condition has been corrected." [ANSI/ASQCQ91-1987 section 4.1.2.1]

None of the responsibilities listed in a) through e) may apply to some employees in your company. But it isn't unusual for all or most of the responsibilities to be expected of most journeyman-level workers in a typical job shop. Encouraging and empowering (with training and authority) employee initiative on quality is a sound management practice that will improve productivity and morale while reducing "firefighting" by supervisors and managers.

RELATED REQUIREMENTS

Several other related requirements in the ISO 9000/Q90 standards may also need to be addressed in job descriptions. Section 4.1.2.2 (identical in Q91, 92) requires that "trained personnel" be assigned for inspection work, and that "verification activities ... be carried out by personnel independent of those having direct responsibility for the work being performed." (The Q93 standard only requires training.)

The Quality system section of each of the three standards also addressed employee requirements. In Q91 and Q92, "identification and acquisition" of skills needed for required quality levels must be addressed. In Q93, documentation of "workmanship standards" is required.

Identical language in Q91 and Q92 under Process Control calls for "documented work instructions, where the absence of such instructions would adversely affect quality," and for workmanship criteria in written standards or by "representative samples."

Both Q91 and Q92 also have requirements for records of "qualified personnel" under the section on Special Processes.

Finally, all three specifications contain requirements for training. In Q91 and Q92, you must identify training needs and "provide for the training of all personnel performing activities affecting quality." People assigned specific tasks must be "qualified on the basis of appropriate education, training and/or experience." Q93 simply requires that those who perform final inspections or tests have "appropriate experience and/or training."

RESOURCES

Under a grant from the U S Department of Commerce, NTMA produced the Tooling & Machining Quality System Assessment as a useful guide to developing or refining a job-shop quality system. It addressed performance objectives of various quality system elements and provided sample statements for language in any quality manual.

The assessment followed a generic TQM approach and was useful for meeting ISO, Mil-spec, or major corporate supplier quality program requirements.

A companion package of material titled Doing Things Right served as a basic introduction to TQM systems for the typical small shop. The key elements of these two tools have since been combined into one manual called **Total Quality** by Bill Ruxton. For ordering information on this and or other products call the NTMA Publications Department @ 1-800-832-7753 or visit our online store: www.ntma.org.