"The ISO 9000:2000 standards – some common misconceptions"

(Paper to be presented at the 46th EOQ Annual Congress, Harrogate, UK, October 2002)

Dr Nigel H Croft
Chairman - International Standardized Testing Organization A.G.
Zug, Switzerland

Synopsis

The publication of the ISO 9000:2000 series of standards at the end of 2000 necessitated a significant change in the mind-set of many quality professionals, in order to cope with a process-based, results-focused quality management system, rather than the documentation-heavy earlier versions.

Through its worldwide network of partner organizations, the International Standardized Testing Organization ("ISTO") has carried out examinations in over 30 countries around the globe, to test individuals' level of understanding of the ISO 9000:2000 standards. The examination is becoming widely recognized as an important criterion for the selection and evaluation of facilitators, internal auditors, quality managers, consultants, and third party auditors, among others. Several international certification bodies have established the ISTO examination as a minimum requirement for all their in-house and sub-contracted audit personnel.

The paper will present an analysis of the results of over 1500 examination papers, and will discuss the major misconceptions and areas of misunderstanding of the requirements and guidance of ISO 9001, ISO 9004 and ISO 9000:2000. This analysis provides feedback not only to the candidates themselves (irrespective whether or not they pass the examination), but also to training organizations, in order for them to identify key areas that need to be emphasized in future courses.

Introduction

The ISO 9000:2000 family of standards represent a significant improvement over the 1994 versions of the standards, and, if implemented in an appropriate manner within organizations, should facilitate the development of an effective, process oriented quality management system. If the focus of the 1994 versions of the standards was perceived to be "developing documented procedures, and providing evidence in the form of records", then the focus of the year 2000 standards is "understanding and managing processes, and providing evidence in the form of results". For this to happen, however, it is of fundamental importance that those individuals who are involved in the development, implementation and evaluation of an ISO 9000 – based quality management system understand not only the requirements of ISO 9001:2000, but also the underlying eight quality management principles, the concepts and terminology used in the standards (as defined in ISO 9000:2000) and the guidelines for performance improvement provided by ISO 9004:2000, which allow an organization to look beyond registration and to use the quality management system to its best advantage.

This paper provides information regarding the International Standardized Testing Organization's ISO 9000:2000 examinations, and discusses some of the most common misconceptions regarding the standards, based on examination results.

The ISTO Test of Understanding of ISO 9000:2000

Background

ISO 9001:2000 (*Quality Management Systems – Requirements*), ISO 14001:1996 (*Environmental Management Systems requirements*) and the joint Environmental / Quality Management Auditing standard ISO 19011 have shifted the traditional focus away from "training" of personnel to a competence-based requirement. The way in which competence is achieved may or may not include the need for training. This concept was further reinforced by the requirements specified in the International Accreditation Forum / ISO-CASCO / ISO TC176 policy for the transition to ISO 9001:2000, where it was noted that certification body auditors and other relevant personnel must be able to demonstrate:

"**knowledge** and **understanding** of:

- the eight Quality Management Principles on which the revised standards are based;
- the requirements of ISO 9001:2000 and;
- the concepts and terminology of ISO 9000:2000."

No specific training requirements were mandated in this policy for individuals to be able to achieve the necessary knowledge and understanding, although auditor recognition schemes such as those operated by, the UK's International Register of Certificated Auditors (IRCA), the USA's Registrar Accreditation Board (RAB), Japan's Japan Register of Certificated Auditors (JRCA) and the International Auditor Training and Certification Association (IATCA) have established their own training requirements.

In a similar fashion, the new ISO Guidance Standard for the Selection of Quality Management consultants, currently under development by ISO/TC176, includes as one of the most important criteria "knowledge and understanding of ISO 9000:2000, ISO 9001:2000 and ISO 9004:2000 in order to apply these as appropriate to the overall objectives of the organization".

With this trend towards the demonstration of ***understanding***, coupled with an ever-increasing number of self-proclaimed, and often misguided "experts" on ISO 9000, the need became apparent in late 2000 for a single, internationally recognized examination that could be used to provide evidence of an individual's understanding of the ISO 9000 standards. The publication of ISO 9000:2000 in December 2000 only added new urgency in this respect, since its correct utilization necessitates a radical change in "mind-set" for many traditional quality practitioners.

The ISTO Test of Understanding of ISO 9000:2000 is not a compulsory examination for the qualification of internal or external auditors or of personnel responsible for implementing the standards. It does, however, provide individuals with the opportunity to demonstrate their understanding of the ISO 9000:2000 standards, which may be desirable in the following circumstances:

- For quality professionals to demonstrate to their employers that they are able to take full advantage of the improvements offered by the ISO 9000:2000 standards
- As one of the criteria for the qualification of internal auditors
- As one of the criteria for the qualification of external auditors
- For consultants to demonstrate their understanding of ISO 9000:2000 to potential clients
- For job candidates to demonstrate their understanding of ISO 9000:2000 to potential employers

Examination Syllabus

The ISTO examination aims at testing individuals' understanding not only of the requirements of ISO 9001:2000, but also of the underlying concepts, terminology and principles on which the standard is based, and the opportunities provided by following the guidance of ISO 9004:2000. It has been designed specifically to ensure that successful candidates are aware of the practical realities of implementing an "ISO 9000 – based" quality management system, and have the knowledge to do this in a pragmatic, results-oriented and non-bureaucratic way.

The body of knowledge for the ISTO Test of Understanding of ISO 9000:2000 was developed in close conjunction with the American Society for Quality, and subject to consensus among recognized international experts from the following backgrounds:

- Quality managers from organizations currently registered to ISO 9001:2000 (including service organizations)
- Management representatives from organizations making the transition to or implementing ISO 9001:2000
- Experts from ISO/TC176/SC1 and SC2 involved in the development of the ISO 9000:2000 standards.
- Delegation leaders from ISO TC176 Member bodies and liaison members
- Convener and Experts from the official ISO TC176/WG19 Interpretations Group
- National Standards Bodies
- Managers from Professional Quality Institutions, including the Institute of Quality Assurance (IQA).
- International certification bodies
- Consultants
- Accreditation Bodies

Full details of the body of knowledge for the ISTO Test of Understanding of ISO 9000 may be found on the ISTO website (www.isto.ch), but in broad terms, the syllabus for the examination includes:

- The **eight quality management principles** on which the ISO 9000:2000 series of standards is based.
- The fundamentals of a quality management system, as described in ISO 9000:2000
- The terminology utilized in ISO 9001:2000 and ISO 9004:2000, as defined in ISO 9000:2000.
- The requirements of **ISO 9001:2000**, as applicable to each of the generic product categories defined in ISO 9000:2000 clause 3.4.2, and for different kinds of organization.
- The rôle of **ISO 9004:2000** guidance in helping organizations to go beyond ISO 9001:2000 requirements towards performance improvement.
- The application of ISO 9001:2000 requirements within an organization (ISO 9001:2000 clause 1.2).
- An understanding of the principles of a **Process Approach** to quality management systems.
- An understanding of the type and amount of documentation required by ISO 9001:2000, and the interpretation of these requirements to different kinds of organization.

Common misconceptions about the ISO 9000:2000 standards

Based on an analysis of answers from over 1500 candidates for ISTO ISO 9000:2000 examinations conducted around the world during the period April 2001 – April 2002, the following topics from the body of knowledge were the ones where candidates consistently experienced the greatest difficulty, and where a number of conceptual errors exist (or in some cases persist from the 1994 versions of the standards):

Lack of clear understanding of ISO 9001:2000 documentation requirements

- **Traditional focus on "procedures" rather than "processes"**
  - Many of the answers provided in the examinations make it clear that candidates and their organizations are still "document-driven" rather than "process-driven".
- **Tendency to "over-estimate" the documentation requirements of ISO 9001:2000**
  - Over the years, it has been common to hear criticisms of the type "Our organization has a lot of documents, because ISO 9000 requires them". In fact ISO 9001:2000 has very few explicit requirements for documented procedures. The onus is on the organization to decide where such procedures are needed in order to manage its processes, and to achieve the planned results. Thus ISO 9001:2000 has no requirement for a document called a "quality plan", although, depending on the nature of the product provided, and the size, type and culture of the organization, some organizations may find it convenient to develop specific quality plans in order to control their processes. Likewise, ISO 9001:2000 does not require a documented procedure for the management review process. Most organizations find it convenient to determine the frequency, participation, topics to be discussed, and responsibilities for the management review process in a written procedure, but this is their option. If they can demonstrate that they are carrying out the management review process without the need for a documented procedure, (in some small businesses, for example) then this should be acceptable.

- **Lack of understanding of the definition of "procedure"**
  - ISO 9000:2000 clause 3.4.5 defines "procedure" as a "specified way to carry out an activity or a process" and notes that "procedures can be documented or not". This gives organizations the opportunity to reduce the burden of documentation, whilst at the same time retaining control of their processes. This may be particularly useful in some small organizations, or for managing less critical processes

in larger, more complex organizations. The decision for a procedure to be documented or not can usually be validated over time by analysing the results achieved, and by using the "Plan-Do-Check-Act" cycle.

- **Confusion over confirmation of order where the customer provides no documented statement of requirements (ISO 9001:2000 clause 7.2.2).**
    - There is no requirement in ISO 9001:2000 for the organization to provide its customers with a ***written*** confirmation for each order. Indeed, this would be impractical for many situations.

- **Document control requirement for the quality policy**
    - There is no requirement in ISO 9001:2000 for the quality policy to be included in the organization's quality manual. Although many organizations may have traditionally chosen to include the policy in their quality manual, a "stand-alone" quality policy that meets all the requirements of ISO 9001:2000 and is controlled in accordance with ISO 9001:2000 clause 4.2.3 would be equally acceptable.

- **Confusion over "objective evidence" vs "records"**
    - Once again, there is a tendency for both organizations and auditors to be "over-bureaucratic" in their approach to records. ISO 9001:2000 defines very clearly where records are specifically required. In other circumstances where records are not specifically required, if the organization wishes to claim conformity to ISO 9001:2000, it must still provide objective evidence that it is meeting the requirements of the standard. In some cases, it may be convenient to provide this evidence in the form of records, but whilst in others, this would only add to the bureaucracy.

<u>Confusion over "processes"</u>

- **Product realization processes vs quality management system processes**
    - Many candidates for the examination do not understand that clause 4.1 of ISO 9001:2000 refers to all the processes needed for the organization's ***quality management system***, and not only to the product realization processes. The quality management system processes include, for example, the management review ***process***, the internal auditing ***process***, and the document control ***process***, among others.

- **Need for validation of processes**
    - The requirement in ISO 9001:2000 clause 7.5.2 relates only to production and service provision processes where the resulting output cannot be verified by subsequent monitoring or measurement.

This may be particularly relevant for those service provision processes that are carried out directly at the interface between the organization and its customers.

Confusion regarding ISO 9001:2000 clause 7.1 (Planning of product realization)

- **Planning of product realization processes vs product design & development**
  - Clause 7.1 of ISO 9001:2000 relates to the planning and development of the ***processes*** needed for product realization. Note 2 of clause 7.1 adds that the organization ***may*** also apply the requirements given in clause 7.3 (Design and development) to the development of product realization processes, but this is not normally something that is compulsory unless it forms a part of the customer's contractual requirements, or is required by statutory or regulatory bodies.

- **Concept of a "quality plan"**
  - ISO 9000:2000 clause 3.7.5 defines a "quality plan" as a "document specifying which procedures and associated resources shall be applied by whom and when to a specific project, product, process or contract". However, ISO 9001:2000 has no specific requirement for the organization to prepare such a quality plan, but simply states that the "output of the planning shall be in a form suitable for the organization's method of operations". For some organizations, it may be necessary, or convenient, to document this output in the form of a discrete quality plan for each project, product, process or contract, whilst for others, the output of the planning could be distributed over a number of other quality management system documents. In some cases (small or very small organizations, for example), the output of the planning may not need to be documented at all. Ironically, the word "form" in Note 2 of ISO 9001:2000 has been translated in some countries to mean "a template for filling out a record", thereby adding to the misconception. Steps are currently underway, via the official ISO 9001:2000 Interpretations Task Group, to provide definitive guidance on this matter.

Problems in understanding the application and requirements of ISO 9001:2000 clause 7.3 (Design & Development)

Some of the following problems are not specific to the new ISO 9000:2000 standards, and have also been previously recognized in the 1994 versions of the standards.

- **Definition of "Design & Development"**
  - There is a general lack of understanding about the meaning and application of design and development process, particularly as it applies to service organizations.
  - Traditionally, different geographical regions and/or industry sectors may have very different common usage of the terms "design" and "development", none of which coincide with the ISO 9000:2000 definition. ISO 9000:2000 clause 3.4.4 defines "design and development" as "the set of processes that transforms requirements into specified characteristics or into the specification of a product, process or system". This is the only definition that is valid for ISO 9001:2000.
  - Many organizations are wary of the term "design and development" which conjures up images of Research and Development departments, or the design of sophisticated hardware products, and will go to great lengths to justify the exclusion of clause 7.3 from their quality management system. In many cases, the organization's products (which might be services!) may be very simple, but are still covered by clause 7.3 of ISO 9001:2000. It is important to remember that *simple products may only require a very simple design and development process.* It is perfectly feasible for an organization to meet all the requirements of ISO 9001:2000 clause 7.3 with minimal documentation, and in a way that will benefit the organization itself, by ensuring that the product will meet all customer, statutory and regulatory requirements, as well as the organization's own objectives.

- **Application of ISO 9001:2000 requirements for design and development**
  - Clause 7.3 of ISO 9001:2000 requires the organization to "plan and control the design and development ***of product.***" By applying the definition given in ISO 9000:2000 clause 3.4.4, we can see that this means the organization must plan and control the "set of processes that transforms requirements for the product into specified characteristics for the product". Many candidates for the ISTO ISO 9000:2000 examination confuse the design and development of product with the planning of product realization processes (covered by clause 7.1 of ISO 9001:2000).

Lack of understanding of ISO 9001:2000 requirements for calibration of measuring equipment

- **Lack of understanding of the concept of monitoring vs measuring**
  - Clause 7.6 of ISO 9001:2000 refers to the control of ***monitoring*** and ***measuring*** devices. The standard dictionary definition given in the ISO/TC176 Guidance document ISO/TC176/SC2/N526R (Guidance on the terminology used in ISO 9001:2000 and ISO 9004:2000) defines "monitor" as "observe, supervise, keep under review**;** ***measure or test at intervals***, especially for the purpose of regulation or control**".** The same guidance document provides the dictionary definition of "measure" as "ascertain or determine a spatial magnitude or quantity by the application of some object of known size or capacity or by comparison with some fixed unit". In many cases, processes may be monitored simply by "observing", "supervising" or "keeping the process under review", without actually making any measurements. This is the case, for example, when calls to a hotel reservation service are "monitored for quality assurance purposes", or when a remote or dangerous/insalubrious process is monitored by video cameras. Nothing is actually being ***measured***. Further examples of this misconception have been amply demonstrated in correspondence to the IQA publication Quality World, (Jan – April 2002).
- **Monitoring customer perceptions**
  - Contrary to what many candidates of the ISTO 9000:2000 examinations believe, ISO 9001:2000 does ***not*** require an organization to measure customer satisfaction. What is required is that the organization "***"monitor*** information relating to customer perception as to whether the organization has met customer requirements."
- **What equipment needs to be calibrated?**
  - Calibration is only required for ***measuring equipment*** where necessary for valid results of measurements to demonstrate conformity of product to determined requirements. This certainly includes any measuring devices used in testing ***product*** conformity, but may also include those used to measure ***process characteristics*** in situations where the resulting output (product) cannot be verified by subsequent monitoring or measurement.

Confusion over "Correction", "Corrective action" and "Preventive action"

- **General lack of understanding of the differences between these terms and their application within ISO 9001:2000.**
  - This is not a new problem associated with ISO 9001:2000, but something that has persisted over the years. The definitions given in

ISO 9000:2000 clauses 3.6.6, 3.6.5 and 3.6.4 respectively are very clear:

- "Correction" is the action taken to eliminate a detected nonconformity. This may involve reworking or regarding the product.
- "Corrective action" is the action to eliminate the ***cause*** of a detected nonconformity or other undesirable situation.
- "Preventive action" is the action to eliminate the cause of a ***potential*** nonconformity or other undesirable potential situation.

- Too often, organizations consider "rework" to be "corrective action". It is not.
- Action taken to avoid nonconformities from occurring ***again*** is corrective action, ***not*** preventive action.
- True preventive action normally results from a sound understanding of the organization's processes, and the analysis of ***trends*** or ***future plans***.

A general lack of awareness of the guidance presented in ISO 9004:2000

- **Requirements vs Guidelines**
  - ISO 9004:2000 contains only guidance for performance improvement; there are no requirements in this standard.

- **Lack of familiarity with Self-Assessment model (ISO 9004:2000 Annex A)**

- **Lack of familiarity with Improvement Methodologies (ISO 9004:2000 Annex B)**

Miscellaneous

- **Who can authorize a concession for the use of non-conforming product?**

  - A common misconception is that only the customer can authorize a concession for non-conforming product. Whilst this is generally true for any product that does not conform to ***customer*** requirements, there can be circumstances where:
    - The concession may be authorized internally within the organization, if the nonconformity relates to an internal requirement that does not affect the ability of the product to meet customer or applicable statutory and/or regulatory requirements. An example could be a product being outside the engineering department's machining tolerance, but still able to meet all customer and statutory/regulatory

requirements. In this case, it may be appropriate for the engineering department to authorize a concession
    - In cases where the requirement that is not being fulfilled is a regulatory or a statutory requirement, then even the customer cannot authorize a concession.

- **"Release of product"**
    - ISO 9001:2000 clause 3.6.13 defines "release" as "permission to proceed to the next stage of a process", and does not only relate to final release.

- **Customer property**
    - It is not always well understood that customer property not only includes tangible products supplied to the organization, such as a car that goes into the shop for servicing, but can also include intellectual property, or other intangible products, such as confidential information (credit card numbers, for example).

Conclusions

It is to be hoped that the results presented in this paper will allow individuals and training bodies to focus their attention on the areas of knowledge where deficiencies have been noted. By promoting a better and common understanding of the new ISO 9001:2000 family of standards, ISTO aims to encourage organizations to demand professionals (including quality managers, facilitators, consultants, internal and external auditors) who can provide value-adding, non-bureaucratic services. This in turn will assist organizations to take full advantage of the greater flexibility of ISO 9001:2000, (particularly in terms of the documentation requirements), to develop and improve quality management systems that focus on achieving ***results***, as a natural consequence of ***well-managed processes***, and not simply on generating unnecessary and unwelcome documentation.

Bibliography

ISO9000:2000, Quality management systems – Fundamentals and vocabulary.
ISO 9001:2000, Quality management systems – Requirements.
ISO 9004:2000, Quality management systems – Guidelines for performance improvements.
CROFT, N H, Quality World, Dec 2000, p12 “ISO 9000:2000 – a lesson in peace processes”
CROFT, N H, Quality World, June 2001, p42 “A learning experience”
CROFT, N H, in The ASQ ISO 9000:2000 Handbook, Chapter 41, ASQ Quality Press, Milwaukee, Wisconsin, USA