A Learning Experience from ISTO Examination

Nigel Croft*
Young Hyun Park**

*International Standardized Testing Organization A.G. Chairman
Grabenstrasse 32, CH-6301 Zug Switzerland
**Dept. of Industrial System and Information Engineering
Kangnam University, Korea

Abstract

The revised ISO9000 family of standards represents a significant improvement on the 1994 version and, if implemented well within organizations, should facilitate the development of effective, process-oriented Quality Management Systems. This paper describes how the International Standardized Testing Organization (ISTO) tests the understanding of ISO9000 : 2000, and presents an analysis of the results of the first examinations held in the UK, USA, Mexico and Hong Kong, in February and March 2001.

1. Introduction

If the focus of ISO 9000: 1994 was perceived to be developing documented procedures, and providing evidence in the form of records, then the focus of the new standard is understanding and managing processes, and providing evidence in the form of results. For this to happen, it is of cardinal importance that people involved in the development, implementation and evaluation of an ISO 9000-based Quality Management Systems understand not only the standards requirements, but also the eight underlying quality management principle, 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 certification and use the QMS to its advantage.

ISTO (International Standardized Testing Organization) based in Switzerland, provides a global examination and certification service to individuals who wish to demonstrate their understanding of ISO 9000 and other international standards. It has been identifying levels of knowledge.

2.   Shifting the focus

ISO 9001:2000 (QMS requirements), ISO 14001:1996 (EMS requirements) and the new joint environmental/ quality management auditing standard ISO 19001 (still in the drafting process) have shifted the focus from training personnel involved in management systems, to a competence-based requirement. The way in which competence is achieved may include the need for training. This concept was reinforced further 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 demonstrate knowledge and understanding of:

● Eight quality management principles of the revised standards
● Requirements of ISO 9001:2000
● Concepts and terminology of ISO 9000:2000

No specific training requirements were mandated in the policy for individuals to achieve the necessary knowledge and understanding, although auditor recognition schemes, such as those operated by IRCA, RAB, JRCA and IATCA, have established their own training requirements.

With this trend towards the demonstration of understanding coupled with an ever-increasing number of self-proclaimed experts on ISO 9000, the need became apparent for a single, internationally recognized examination that could be used to demonstrate an individuals understanding of the standards. The publication of ISO 9001:2000 added a new urgency, since it necessitates a radical change in the mindset of many quality practitioners.

The ISTO examinations facilitate:
● Focus on understanding, rather than on training.
● Possibility for professionals to demonstrate their understanding of international standards, with the ISTO certificate as objective evidence
● Demonstration of an individuals competence, with the understanding of the standard as an important component
● Opportunity for individuals to acquire knowledge by home study or distance learning
● Basis for the responsible dissemination of knowledge by training organizations
● Opportunity for professionals to acquire additional qualification, as part of CPD
● Selection of staff by employers
● Greater credibility for the standards themselves, by ensuring that those using them understand their intent

The ISTO test of understanding of ISO 9001:2000 is not intended to be a compulsory examination for the qualification of internal or external auditors. It does, however, provide individuals with the opportunity to demonstrate their understanding of the standards, which may be desirable:

- For quality professionals to demonstrate to employers that they understand the new standards
- As one criterion for the qualification of both internal and external auditors
- For consultants to demonstrate their knowledge to potential clients
- For job candidates to demonstrate their knowledge to potential employers

3. Exams in progress

The syllabus for the examination includes:
- Eight quality management principles on which the ISO 9000:2000 series of standards is based (this includes topics covered not only by ISO 9000:2000 and ISO 9004:2000, but also by the quality management principles brochure)
- Fundamentals of a Quality Management systems, as described in ISO 9000:2000
- Terminology used in ISO 9001:2000 and ISO 9004:2000, as defined in ISO 9000:2000. Candidates are also advised to

familiarize themselves with the ISO/TC176 guide to the terminology of ISO 9001:2000 and ISO 9004:2000
- 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
- Role of ISO 9004:2000 guidance in helping organizations to go beyond ISO 9001:2000 requirements towards performance improvement
- Application of ISO 9001:2000 requirements within an organization (ISO 9001:2000 clause 1.2). See also ISO/TC176 guidance on ISO 9001:2000 clause 1.2 application
- Understanding of the principles of a process approach to Quality Management Systems. Candidates are recommended to consult the ISO/TC176 guidance document on the process approach
- Understanding of the type and amount of documentation required by ISO 9001:2000, and the interpretation of these requirements. See also ISO/TC176 guidance on the documentation requirements of ISO 9001:2000
- Arrangements for the transition to ISO 9001:2000, as defined by the IAF (International Accreditation Forum). Candidates should also familiarize themselves with the relevant IAF

documents

- Implications for conformity assessment of Quality Management System based on the process approach, with reduced emphasis on documentation

The ISTO test of understanding of ISO 9001:2000 is a three-hour examination, comprising:

- 30 multiple-choice questions
- 30 questions requiring a test of logic, with true/false answers
- 30 questions based on practical cases of implication of a QMS
- Essay question

A total of 109 candidates took part in the validation program which was held worldwide in London (hosted by IQA), Hong Kong, Mexico City and Reno (hosted by ASQ). The overall distribution of marks is shown in <Figure 1>, with an average mark of 69 per cent, and a standard deviation of 13.4 per cent.

A total of 62 candidates (57per cent) were successfully in passing the examination, achieving the pass mark of 70 per cent or above. Of these, 16 (15 per cent) were awarded a distinction, for achieving a mark of 85 per cent or above.
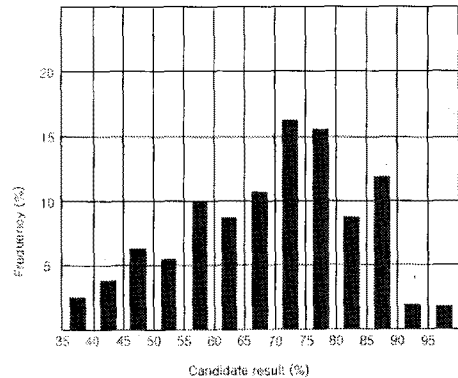

Figure 1. Results of the pilot tests of understanding of ISO 9001:2000

4. Difficulties in understanding the ISO 9000:2000 standards

Based on an analysis of the results for each individual question, the following topics from the body of knowledge presented candidates with the greatest difficulty, and constitute areas in which a number of conceptual errors persist.

Lack of clear understanding of ISO 9001:2000 documentation requirements:

- Tendency to overestimate documentation requirements
- Lack of understanding of the definition of procedure (see ISO 9000:2000 clause 3,4,5)
- Procedures may or may not be documented

- Traditional focus on procedures rather than processes
- Confusion over confirmation of orders where the customer provides no documented statement of requirements (ISO 9001:2000 clause 7,2,2)
- No requirement to include quality policy in quality manual
- Confusion over objective evidence versus records; a tendency to be over-bureaucratic

General problems with ISO 9001:2000 clause 7,3 (design and development):

- Definition of design and development (ISO 9000:2000 clause 3,4,4)
- Application of ISO 9001:2000 requirements to product development
- Lack of understanding of individual requirements within ISO 9001:2000 clause 7,3 (design and development input, output, verification and validation)

Confusion over processes:

- Product realization processes vs quality management system processes
- Need for validation only refer to special processes
- Lack of understanding regarding documentation of processes

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

- Concept of quality plan (not necessarily documented)
- Planning of product realization processes versus product design and development

Lack of understanding of exactly what measuring equipment needs to be calibrated:

- Lack of understanding of the concept of monitoring vs. measuring
- Calibration is required only where necessary for valid results of measurements to demonstrate conformity of product to determined requirements

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

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

- Requirements versus guidelines
- 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 nonconforming product?
- Release of product- does not apply only to final release

- Concept of exclusion of requirements from quality management system (ISO 9001:2000 clause 1.2- application)
- Customer property may be intellectual property

paper of Nigal Croft "A Learning Experienc e," Qualityworld, 2001, p42-44.

5. Conclusion

It is to be hoped that the results presented in this article 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 family of ISO 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 allow organizations to take full advantage of the flexibility of ISO 9001:2000, 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.

Remarks

This paper was mostly reprinted from the