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Interpretations and variations of ISO 9000 in acute health care

JOHN SWEENEY[1] AND CATHERINE HEATON[2]

[1]Director, Irish Society for Quality in Healthcare, Dublin, Ireland and [2]The Health Quality Service, London, UK

Abstract

Objective. This paper aims to address two questions related to the implementation of the ISO 9000 Quality Management System standard in the acute health care sector: which countries have developed specific nationwide guidelines/interpretations? and what variances exist between the different interpretations of the ISO 9002 standard?

Design. The study was carried out via an assessment of the available guideline documents for the use of ISO 9000 in the acute health care sector. The interpretation of each document was examined for common elements and deviations from the commonly agreed terms.

Setting. Worldwide in the acute health care sector (excluding that of laboratories).

Study participants. Eighty-two international ISO members and/or quality health care organizations.

Results. The results showed variation in the interpretations of the ISO 9000 standard. In total, 16 of the clauses/subclauses note distinct variations, between one or more of the documents, which could alter the perception of the system.

Conclusion. From examination of the six identified guideline documents, the claim that ISO 9000 introduces quality systems which are comparable from one country to another is unfounded in the acute health care sector.

Keywords: certification, international standards, ISO 9000

The International Organization for Standardization (ISO) promotes the use of the ISO 9000 series of quality management system standards on two primary points. Firstly that it is an international accepted system, and secondly that it embodies worldwide standardization. This paper sets out to investigate the use of ISO 9000 standards in the acute health care sector and to ascertain how far they fulfil ISO's goal of international standardization.

With over 230 000 certificates awarded to organizations in more than 130 countries, ISO 9000 can truly be described as an internationally recognized standard. Implemented in a wide range of service industries across the globe, the influence of the ISO 9000 series of standards is unquestionable. What is more important to establish, however, is the comparability of the standard when applied to different organizations by different certifying bodies in different countries.

The International Organization for Standardization

Established in 1947 in the engineering and manufacturing industries, ISO is today a worldwide federation with member and associate member organizations in more than 130 different countries [1]. Of the 12 000 standards developed, it is the ISO 9000 series (standard ISO 9002 primarily, although not exclusively) that is seen as most applicable to the acute health care sector. ISO 9000 describes a set of individual, but related, generic standards on quality management and quality assurance. The series is divided into 9000, 9001, 9002, 9003, 9004 [2–6] with standard 9000 assisting in the interpretation and 9004 acting as a guideline for implementation of the standards 9001–9003.

Interpretation

One of the disadvantages of applying ISO 9000 to health care is that the standard is not universally held to be appropriate to the service sector. It is expected that in the year 2000, when the ISO Technical Committee 176 presents the revised, amalgamated standard, ISO 9001, it will have greater applicability to services, moving from a system-based to a process-based management approach.

Nevertheless there is already significant and increasing use of ISO certification in health care. The process is used

Address reprint requests to J. Sweeney, Director, ISQH, PO Box 6448, Dublin 9, Ireland. E-mail:jsisqh@iol.ie

by facilities to introduce a systematic quality management approach and to obtain an award which demonstrates that this approach is consistent with health care providers throughout the world. Thus the question arises how exactly an industrial standard such as ISO 9002 [4] is interpreted within health care organizations around the world implementing ISO 9002 standards.

Although some service industries have produced consensus guidelines offering specific interpretations of ISO standards, none have been developed by a central international body for the application of ISO 9002 in the acute health care sector. In order to use the standards some interpretation of ISO's technical jargon is necessary, and with a lack of officially orchestrated work in this area, interpretations are made by:

(i) Independent 'Quality Consultants', who create definitions of the clauses to suit the organization preparing for certification.
(ii) National certification/registration bodies who develop guidelines for use which organizations must follow in order to be certified by them.
(iii) Independent national bodies involved in the development of standards and/or quality programmes relating to health care, who have taken it upon themselves to create guidelines for use with ISO 9000.
(iv) A combination of some or all of the above.

Study

For this study, a comparison of the guideline documents created by national bodies for ISO 9002 has been made. It was felt to be unrealistic and unproductive to attempt an assessment of the numerous interpretations made by individual consultants and organizations, or to look at interpretations of other standards in the ISO 9000 series, as ISO 9002 is generally accepted as most relevant to acute health.

The study addresses two simple questions:

- Which countries have developed specific nationwide guidelines/interpretations?
- What variances exist between the different interpretations of the ISO 9002 standard?

Methods

To assess the availability of guideline documentation, all ISO member organizations were contacted and asked whether a guideline document existed, how it had been developed and specific information on what it contained. Other quality health care organizations such as national quality health care societies and national standards authorities were also contacted.

Availability

Of the 82 countries/organizations contacted for information:

- Seven countries had developed guidelines for the interpretation of ISO 9002 (Table 1).
- Five countries had made use of ISO 9002 interpretations but had not generated direct guidelines.
- Twenty-three countries had not developed guidelines.
- Forty-seven countries did not reply.

It is interesting to note that organizations in other countries have made use of the ISO 9000 criteria to assist in outlining specific areas for consideration when producing documents to implement or assess quality in health care.

Guideline developments

The six documents that have been developed for direct translation can be roughly classified into two groups: those which were created by organizations who wished to use the interpretations for their own certification purposes {National Standards Authority of Ireland (NSAI) [8], SGS Yarsley [11], Standards Institute of Israel (SII)}; and those whose aim was to develop standards for general use {Council of Standards Australia/Council of Standards New Zealand [7], Swiss National Alliance for Quality in Health Care (SAS) [10], American Society for Quality (ASQ) [12]} (Table 2).

In most cases the guideline documents were developed in association, either directly or indirectly, with health care professionals and professional organizations. For example the NSAI document was developed via a NSAI/Health Services joint working group consisting of NSAI personnel and representatives from the medical, nursing and administrative functions of the health services. The technical committee of the Council of Standards Australia and Council of Standards New Zealand (AS/NZS) included numerous organizations, for example: Australian Private Hospitals Association; Community and Health Accreditation and Standards Program; Medical Industry Association of Australia; Sydney Adventist Hospital and The Australian Council on Health care Standards [13].

20 Clauses

The ISO 9002 standard is broken into 20 general clauses, these include: 4.1 Management Responsibility; 4.2 Quality System; 4.3 Contract Review; 4.4 Design Control (ISO 9001 only); 4.5 Document and Data Control; 4.6 Purchasing; 4.7 Control of Customer Supplied Product; 4.8 Product Identification and Traceability; 4.9 Process Control; 4.10 Inspection and Testing; 4.11 Control of Inspection and Measuring Equipment; 4.12 Inspection and Test Status; 4.13 Control of Non-Conforming Product; 4.14 Corrective and

Table 1 ISO 9002 Guideline documents available

Country	Guideline document	Organization of origin
Australia	Guide to AS/NZS ISO 9001, 9002 and 9003 for health services[1] [7]	Council of Standards Australia[1]
Ireland	Health Services application of ISO 9002 in a hospital environment [8]	National Standards Authority of Ireland (NSAI)
Israel	Check List for Assessments of Medical Service Providers [9]	Standards Institute of Israel (SII)
New Zealand	Guide to AS/NZS ISO 9001, 9002 and 9003 for health services[1] [7]	Council of Standards New Zealand[1]
Switzerland	H-9001/2 [10]	Swiss National Alliance for Quality in Health Care in association with the Swiss Accreditation Body (SAS)
UK	BS EN ISO 9000:1994 Guidance notes for its application to hospitals [11]	SGS Yarsley International (SGS)[2]
USA	The 20 Quality-System Requirements of ISO 9001/9002 Hospitals, Outpatient Clinics and Surgical Centers [12]	American Society for Quality (ASQ)

[1]The Council of Standards Australia and Council of Standards New Zealand collaborated to produce a joint document. [2]Although not the official member organization for the UK this document was deemed important as its derivatives are used in other countries under the SGS Yarsley International umbrella organization.

Table 2 The number of organizations certified to ISO 9002 standards using the specific guidelines

Guideline	Used to certify
Guide to AS/NZS ISO 9001, 9002 and 9003 for health services – Australia/New Zealand	72 acute organizations
Health Services application of ISO 9002 in a hospital environment – NSAI Ireland	3 acute units
Check List for Assessments of Medical Service Providers – SII Israel	3 hospitals, 3 health centres
H-9001/2 – SAS Switzerland	Exact figure unknown
BS EN ISO 9000:1994 Guidance notes for its application to hospitals – SGS UK	Approx. 60–70 organizations
The 20 Quality-System Requirements of ISO 9001/9002 Hospitals, Outpatient Clinics and Surgical Centers – USA	Approx. 12–20 hospitals

Preventative Action; 4.15 Handling, Storage Packaging, Preservation and Delivery; 4.16 Control of Quality Records; 4.17 Internal Quality Audits; 4.18 Training; 4.19 Servicing; 4.20 Statistical Techniques.

The interpretation of each clause, and relating subclause, was assessed, firstly by examining the common elements in the six documents, and secondly the variations. Where a guideline deviated from the generally agreed interpretation, such that it would have a direct, substantial, effect on the overall quality system, it has been included below as a variance to the norm. This list is not comprehensive but rather indicates the variances of greatest concern. As there is no centrally agreed common health care guideline, an interpretation at variance to the others does not necessarily indicate that it is less valid. However, lacking an official benchmark, and recognizing the independent way in which the guidelines were developed, it may be reasonable to consider 'normal' the interpretation most widely accepted by the seven national guideline-developing bodies.

I.S. EN ISO 9000:1994 Quality Management System

All six documents define, at varying levels of details, the key terms used in the ISO 9000 standards [14]. For example the 'Product' when ISO 9000 is applied to health care is defined as either the handling and care processes or the results of these processes, or both. In a couple of instances, the

definition offered by one guideline differs significantly from the others. Where most define the 'Supplier' as the health care or service provider, SGS include 'any supplier of goods, services or professional time to the hospital, including drug companies, cleaners, builders, locum doctors, agency nurses, etc.', but not the health service provider itself. Where most agree that the customer/client includes all patients, clients 'and other customers or clients of a health service provider . . .', SGS see the term 'Customer' as synonymous with 'patient' and does not recognize any other customer or client.

Quality System Requirements

Clause 4.1.2.2 deals with resources. It appears that there are two distinct variances in the interpretation of this subclause. The first relates to the examination of either (i) resources for 'quality' activities (ASQ) or (ii) overall resources (AS/NZS) or both (SGS). The second relates to fulfilling the subclause. NSAI requires 'consideration' of resource allocation whereas SGS and AS/NZS state that these resources 'should be' allocated, with SGS an 'annual financial plan' is expected. SII states only the need to assign a Safety Manager.

Clause 4.3 Contract Review contains two distinct lines of thought in the interpretation of what contract review refers to. The first is held by ASQ, SGS, AS/NZS and holds that contract review refers to both the patient and external agencies such as health insurers and financiers. NSAI, SAS and SII maintain that the clause refers only to the contract between the health care provider and the patient. Consequently the Amendment and Recording subclause are also dealt with differently.

Clause 4.4 Design Control is specifically related to ISO 9001 which deals with quality systems in an organization involved in research. It is included in ISO 9002 purely to synchronize the clause numbering. It is this clause which decides an organizations applicability towards ISO 9001 or 9002.

In acute health care design it is seen that design is not usually applicable. AS/NZS, ASQ, NSAI, SAS, SII agree that the health care professional or organization, in deciding on an appropriate care plan or programme of treatment or patient care, is exercising professional knowledge, skills and expertise. This is not generally considered to be design. However, SGS include 4.4 stating that 'it is essential, prior to the development/design of any new treatment that ethical approval is sought . . . The design aspects of the service are related to the design of the treatment programme, method of care and/or diagnosis . . . The design-input requirements may be very closely related to that of contract review . . .'. Unlike the other bodies, it appears that SGS accepts the development of individual treatment plans as 'design'. This may result in some organizations being certified for ISO 9001 with one body where their practices would only be accepted for ISO 9002 with another.

Clause 4.7 Control of Customer Supplied Product may be difficult to understand at first until one understands that the patient is the primary customer in the hospital setting. Therefore, anything 'owned' by the patient, either internally or externally to the body, are 'customer supplied' products. The documents breakdown this clause into three primary groups:

- Articles accompanying the patient, medication, belongings, appliances. (AS/NZS, NSAI, SAS, ASQ, SGS, SII) i.e. all documents.
- Information given by the patient (AS/NZS, SGS).
- Blood and body parts/fluids etc. (NSAI, AS/NZS, SAS, ASQ).

In this case we see the effect of variations between the different interpretations not addressing the aspects of patient information (which in some cases may be dealt with under 4.16 Control of Quality Records), to a more serious situation in which the process of dealing with blood and body parts would not be addressed.

Under **Clause 4.8 Product Identification and Traceability** it is unanimously agreed that traceability of service is addressed. However there is a high level of disagreement with regard to other aspects which would be included in this clause. Patient identification is taken on board by ASQ, SAS, SGS, but not the others, whereas the important issue of drugs and product identification is omitted under this clause by both the NSAI and SAS.

Clause 4.10 inspection and Testing possesses a lot of different interpretations in terms of its implementation. From examination of the five documents it seems that there is a variance in terms of what clause 4.10 actually deals with. In some cases it refers to the inspection and testing of the entire system (SAS, NSAI), in others it refers to the specific patient or indeed only the products or equipment being used as part of the service (SII).

In two cases we see a variation within the subclauses as to what it relates to:

- ASQ 4.10.2 Receiving Inspection and Test refers to incoming products/services but 4.10.3 'In-process Inspection and Test' refers to patient diagnosis and treatment.
- SGS 4.10.2 refers to products and equipment but 4.10.4 'Final Inspection and Test' refers to patient follow-up processes.

One would expect the overall definition of the Clause to remain constant.

Clause 4.12 Inspection and Test Status suffers from similar interpretation conflicts. It appears that there are three similar possibilities of interpretation:

- Patient Status (SGS, AS/NZS, SAS).
- Drug/equipment status (SGS, AS/NZS, ASQ, SAS).
- Service status (NSAI, SAS).

Clause 4.15 Handling, Storage Packing, Preservation and Delivery at first examination is very industry-specific with little relevance to the acute health care sector. However

a common thread throughout the documents would see this clause as applying to the handling, storage, packaging, preservation and delivery of materials, and may include environmental controls; such as patient room, treatment room, etc. This however is not uniformly accepted.

ASQ, SII and SGS make reference to supply goods/equipment as per the other documents. However ASQ, SII and SGS also include requirements to be met in relation to dealing with the patients environment. AS/NZS, NSAI ,SAS, do not make any reference to the patient under this clause.

Clause 4.19 Servicing is one of the most obvious signs of discord among the organizations interpretation of the ISO 9002 standard.There is a distinct disagreement between the guideline documents as to what clause 4.19 refers to. Some view it as dealing with post-discharge care (AS/NZS, ASQ, SAS, SGS); however, NSAI states that although it is about post-discharge care: 'Post-discharge care is viewed as a new contract rather than a service issue'. Thus NSAI does not address post-discharge care or any other aspect under this clause. It is also seen to relate to equipment servicing (AS/NZS, ASQ), which in fact has in both cases been dealt with previously under clause 4.11. SII address the aspects of complaint procedures.

Clause 4.20 Statistical Techniques generically looks at the need for the supplier of the service to identify the need for statistical techniques required for establishing, controlling and verifying process capability and product characteristics. It is envisaged that this need for statistical control in areas such as clinical audit would be an integral part of the health care process. Within this clause however it is unclear whether it is an actual requirement or not. The AS/NZS states that statistics 'are needed'. NSAI states 'if it is decided'. SGS 'this could apply . . .'. SAS does state that the 'institution specifies . . .' the relevant data. SII look for a '. . . documented feedback system . . .' and ASQ is the only one who states clearly that 'the requirement for the need to use statistical techniques . . .'.

Summary of results

A review of the six guidelines verifies that they fulfil their primary directive, to interpret the technical jargon of the ISO 9002 standard into a health care-applicable language. The level of detail varies, with some dividing the standards into the individual subclauses and others grouping the subclauses under the primary clause.

The interpretations stay within the confines of 'structure' and 'process', true to the nature of the generic ISO 9002 standard. However the Swiss guideline document, in an effort to overcome what might be deemed a shortfall of ISO, also addresses the concept of 'Outcomes', adding clause 5 which refers to 'Indicators'. This states as a requirement that the organization conduct a survey of indicators. The generic ISO 9002 standard has no such clause 5.

In total 16 of the clauses/subclauses note distinct variations between one and more of the documents. Many of these variations would, in effect, have only minor altercations on the overall quality management system. In some cases, however, the variance would completely alter the perception of the system.

A major conflict is evident in 4.4 Design Control. It is primarily this clause which decides whether an organization should be looking for ISO 9001 or ISO 9002 certification. If an organization is involved in design it is applicable that it is distinguished in this fact by applying for ISO 9001 certification. However what is meant by design is interpreted in opposing ways in the different documents. A similar conflict exists with regard to the definition of 4.19 Servicing in a health care setting, whether this refers to post-discharge care or to equipment maintenance.

An even more crucial example is the definition of 'Supplier', which if seen as the organizations supplying goods to the health care provider, is in opposition to the other interpretations which point to the health care provider as the supplier. This discrepancy, together with the different definitions of the 'product', results in repercussions throughout the interpretation of the standards.

In the year 2000 the second review of the ISO 9000 series of standards will be launched. As well as merging the standards into a single 9001 standard, the revision will introduce new definitions. It is possible that the generic standard will minimize the potential for significant variance. New definitions expected include 'organization' replacing the term 'supplier', and 'customer' replacing 'purchaser'.

Discussion

In line with ISO's mission to facilitate international standardization, the document developed in conjunction with the AS/NZS in its foreword states 'Worldwide, it is now widely recognized that a quality system implementation to a standard such as AS/NZS ISO 9001, 9002 or 9003 in one country is comparable to a quality system to the same standard in another country.'

In answer to this claim, six guideline documents have been examined. Naturally it is doubtful that this list is exhaustive; however, the fact that so few were found does suggest that such documents are scarce. This prompts the question, if there are so few national documents and yet so many health care organizations around the world have ISO 9000 certification, what criteria are being used? It would appear that in the majority of cases the interpretations are organization- or consultant-specific. Having identified the differences in six nationally developed documents it seems likely that the proliferation of consultants and organizations interpreting the standards will reflect numerous variations in the way in which the standard is implemented in these organizations and in the audit mechanisms the certification bodies use to certify them. This study highlights the lack of officially orchestrated guidelines for the use of the ISO 9000 series of standards in health care. Perhaps the most important finding is that using the health care guidelines developed by national bodies throughout the world does not guarantee comparability. In fact the results lead to the conclusion that

guidelines on ISO 9000 in one country may be contradictory to those used elsewhere.

Naturally, almost all of the documents studied include a disclaimer to the effect that '. . . this document is not prescriptive and offers only a guideline of what may/should be considered under each clause.' There is recognition that the interpretation must take account of each organization's individuality as well as local legislation and regional or national cultural distinctive. Are all of the definitions valid in their own cultural context or do they contradict each other? It appears evident from this investigation that many of the variations between the guidelines cannot be explained by organizational differences or cultural factors.

Although these documents may only proclaim to offer guidance on the implementation of ISO 9000 standards, the guidelines clearly spell out what is required by an organization in order to be certified by the corresponding national body. For example in Israel facilities must conform to the 'Check List for Assessments of Medical Service Providers' In order to be certified by the SII, and in Ireland the 'Health Services Application of ISO 9002 in a Hospital Environment' must be followed to be certified by NSAI. If an Irish hospital were transplanted to Israel would it fulfil the requirements necessary there to keep its certification? This issue may even arise within a single nation, for example would an organization certified by SGS in Ireland be 'comparable' to one certified by NSAI? This study suggests not.

So when ISO 9000 series standards are used in the health care sector, should the claim to standardize practice be dropped? Champions of ISO rally to its defence, but are they not really saying that the standards are valuable in implementing systematic quality procedures, rather than claiming that ISO 9000 can show practices in one organization to be equivalent to those in a similar department across the other side of the world?

The way forward must surely lie in an internationally co-ordinated approach towards the development of evidence based practice guidelines for the new ISO 9001 standard. In a similar way to which the International Society for Quality in Health Care's ALPHA programme attempts to link the various aspects of national accreditation programmes, perhaps a similar scheme could be created for ISO 9001. Or perhaps the answer lies in a co-ordinated approach by the ISO, in an effort to fulfil its customers requirements.

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Appendix

QUALITY SYSTEM REQUIREMENTS[1]

4.1.2.2

The supplier shall identify resource requirements and provide adequate resources, including the assignment of trained personnel (see 4.18), for management, performance of work and verification activities including internal quality audits.

4.3 Contract Review

4.3.1

The supplier shall establish and maintain documented procedures for contract review and for the co-ordination of these activities.

4.4 Design Control

The scope of this International Standard does not include quality-system requirements for design control. This subclause is included to align the clause numbering with ISO 9001.

[1] Reprinted with permission from International Organization for Standardization 9002. *Quality Systems – Model for Quality Assurance in Production, Installation and Servicing*. Geneva, Switzerland: International Organization for Standardization, 1994.

4.7 Control of customer-supplied product

The supplier shall establish and maintain documented procedures for the control of verification, storage and maintenance of customer-supplied product provided for incorporation into the supplies or for related activities. Any such product that is lost, damaged or is otherwise unsuitable for use shall be recorded and reported to the customer (see 4.16).

Verification by the supplier does not absolve the customer of the responsibility to provide acceptable product.

4.8 Product identification and traceability

Where appropriate, the supplier shall establish and maintain documented procedures for identifying the product by suitable means form receipt and during all stages of production, delivery and installation.

Where and to the extent that traceability is a specified requirement, the supplier shall establish and maintain documented procedures for unique identification of individual product or batches. This identification shall be recorded (see 4.16).

4.10 Inspection and testing

4.10.1 General

The supplier shall establish and maintain documented procedures for inspection and testing activities in order to verify that the specified requirements for the product are met. The required inspection and testing and the records to be established, shall be detailed in the quality plan or documented procedures.

4.12 Inspection and test status

The inspection and test status of product shall be identified by suitable means, which indicate the conformance or non-conformance of product with regard to inspection and tests performed. The identification of inspection and test status shall be maintained, as defined in the quality plan and/or documented procedures, throughout production, installation and servicing of the product to ensure that only product that has passed the required inspections and tests [or released under an authorized concession (see 4.13.2)] is dispatched, used or installed.

4.15 Handling, storage, packaging, preservation and delivery

4.15.1 General

The supplier shall establish and maintain documented procedures for handling, storage, packaging, preservation and delivery of product.

4.19 Servicing

Where servicing is a specified requirement, the supplier shall establish and maintain documented procedures for performing, verifying and reporting that the servicing meets the specified requirements.

4.20 Statistical techniques

4.20.1 Identification of need

The supplier shall identify the need for statistical techniques required for establishing, controlling and verifying process capability and product characteristics.

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