

New, improved ISO 9000 guidelines for health sector

by Roger Frost



Aftermath of Hurricane Katrina near the Gulfport, Mississippi, facility of Southern Pharmaceutical Corporation.

A US pharmaceutical home care provider hit by Hurricane Katrina was able to resume supplying patients within hours thanks to its ISO 9001:2000 quality management system (QMS) and additional ISO guidance for health sector organizations.

The additional guidance was provided by the ISO International Workshop Agreement (IWA) 1, *Guidelines for process improvements in health service organizations*. ISO has just published a new version of IWA 1. The new version has been made even more “user friendly” for organizations

in the sector by incorporating improvements based on developments in the field and comments by health care providers since the original was published in 2001,

IWA 1:2005 was developed in an international workshop¹⁾, organized under the aegis of ISO, by a joint committee of experts from the American Society for Quality (ASQ) Health Care Division and the Automotive Industry Action Group (AIAG) which is a

The **new version** has been made even more ‘user friendly’ for the health care sector

1) An International Workshop Agreement (IWA) is one of several alternatives to a full International Standard, and is offered by ISO for cases where swift development and publication take priority. Compared to the traditional ISO process of developing International Standards through voting in the technical committees, IWA’s are developed in open workshops and organized by an ISO member body.

ISO INSIDER

global industry association representing automotive manufacturers. As a major employer, the automotive sector deals with thousands of health care providers and spends substantial amounts on health care programmes.



Despite severe damage by Hurricane Katrina, the Gulfport, Mississippi, facility of ISO 9001:2000-certified Southern Pharmaceutical Corporation was back in business in a matter of hours.

The generalized implementation of ISO 9001:2000 quality management systems by health care establishments is seen as an opportunity to improve the quality of health care while reducing the costs.

The guidelines include much of the text of ISO 9004:2000, *Quality management systems – Guidelines for performance improvements*, supplemented

by text specifically aimed at assisting health service organizations to implement a QMS, regardless of whether they decide to pursue certification to ISO 9001:2000.

The objective is the systematic pursuit of process improvement in order to attain continual improvement, the prevention of error and other adverse outcomes, and the reduction of variation and organizational “waste” – such as non-value added activities.

Principal improvements

The principal improvements to the new version of IWA 1 include the following:

- the “translation” of quality-related terminology into language and situations readily understood by health care professionals;
- the addition after many of the ISO 9004:2000 requirements of paragraphs of related advice on “What to look for” and “Guidance/examples”.



Mickey Christensen is President of TQM Systems, Baton Rouge, Louisiana, USA, and was Chair of the committee that developed the proposal for the IWA-1. He consults with hospitals and other health service providers on implementing quality management systems, and was consultant to the first acute care hospital in North America to be certified to ISO 9002.

TQM Systems, 12383 Mollylea Drive, Baton Rouge, LA 70815 USA.

Tel. + 1 225 273 4972.

E-mail tqmis0@eatel.net

The experts who developed IWA 1:2005 state in the Foreword: “Implementing this guidance and maintaining the system with discipline and rigour through the organization should produce effectiveness and efficiencies with a cost benefit of up 17:1 based on experience of other sectors.”

Benefits

One of the authors, Mickey Christensen, who was Chair of the committee that developed the original proposal for IWA 1, cites the case of Southern Pharmaceutical Corporation (SPC) as an example of the benefits of ISO 9001:2000 implementation, supplemented by guidance from IWA 1.

SPC is a home care pharmacy and home medicine equipment

supplier that provides respiratory medication, home oxygen, infusion therapy devices and diabetic supplies to patients at their homes.

“This firm had a facility in Gulfport, Mississippi, that was severely damaged by Hurricane Katrina. The owner stated that because of their ISO 9001 system and having planned for disasters with documented procedures – including moving their trucks and supplies inland to a safe place – they were able to resume patient care within hours of storm subsiding.”

According to Mr. Christensen, SPC was among the first to undergo a joint audit covering ISO 9001:2000 certification and an accreditation for health care established by the Accreditation Commission for Health Care (ACHC). The agency has integrated IWA-1 criteria along with its own home care criteria, to offer ISO 9001:2000 certification or an accreditation for health care, or both.

Mr. Christensen names several other health care organizations that are promoting IWA-1 awareness by offering training to members or by providing study grants. These include the Michigan Medical Society, and the American College of Occupational and Environmental Medicine (ACOEM).

ACOEM plans to work with malpractice insurance companies and offer a substantial discount on premiums for physicians that implement IWA-1. Similarly, a bill proposed in

the State of Pennsylvania will require a 20% insurance premium discount for health service providers that implement a state approved QMS.

“Along with these efforts, a joint ASQ-Healthcare Division/AIAG Quality Award has been announced for those health care organizations deemed to have implemented IWA-1 version 2 criteria. The award process will be similar to that of the Malcolm Baldrige National Quality Award,” says Mr. Christensen.

User feedback

He cites further benefits noted by several health care establishments that have implemented ISO 9001:2000 in conjunction with IWA-1 guidelines for the health sector. One, an ISO 9001:2000-certified occupational medical facility reported:

- closure of 47,1% of open worker's compensation cases (225 to 119), representing savings of several million US dollars;
- reduction from a national industrial rehabilitation average of 8,8 visits per patient for shoulder pain to 5,1, and from 12,2 to 10,1 for rotator cuff injury, and
- elimination of redundancies and improved efficiency.

Another, a large ISO 9001:2000-certified managed care company, has identified the following benefits:

- a new “customer-centric” approach;

- the ability to provide external validation;
- generic applicability and adaptability to evolving business model;
- applicability to all departments, and compatibility with all other frameworks;
- improved efficiency and effectiveness;
- improved employee satisfaction, and
- increased performance and service quality.

Finally, he reports the following benefits achieved by an ISO 9001:2000-certified European hospital:

- fewer patient requests to meet the patient counselor;
- a largely positive attitude to quality among personnel;
- less variation in work practices, treatment methods and services;
- fewer national insurance compensation claims against treatment errors;
- improved statistical follow-up on quality indicators, and

- better control and calibration of measurement devices.

IWA 1:2005, *Guidelines for process improvements in health service organizations*, costs 93 Swiss francs and is available (English version only) from ISO national member institutes (these are listed with full contact details on ISO's web site: www.iso.org and from the ISO Central Secretariat (sales@iso.org).

ISO/PAS 28000 promises to facilitate global trade for the benefit of all



Following ISO 9001:200/IWA-1-documented procedures for disaster planning, Southern Pharmaceutical Corporation resumed patient care services out of its temporary ‘truck-office’, just hours after Hurricane Katrina struck.