

ISO 9000 guidelines for health care sector

Guidelines for implementing ISO 9000 quality management systems in the health care sector were published by ISO (International Organization for Standardization) on 20 September 2001 as its first "International Workshop Agreement" (IWA).

IWA 1, *Quality Management Systems – Guidelines for process improvements in health service organizations*, 68 pages, price 74 Swiss francs, is available from ISO national member institutes (a complete list is posted on ISO's Web site: www.iso.org) and from ISO Central Secretariat (sales@iso.org).

The guidelines are based on ISO 9004:2000, *Quality management systems – Guidelines for performance improvements*. IWA 1 contains much of the text of ISO 9004:2000, supplemented by specific guidance for its

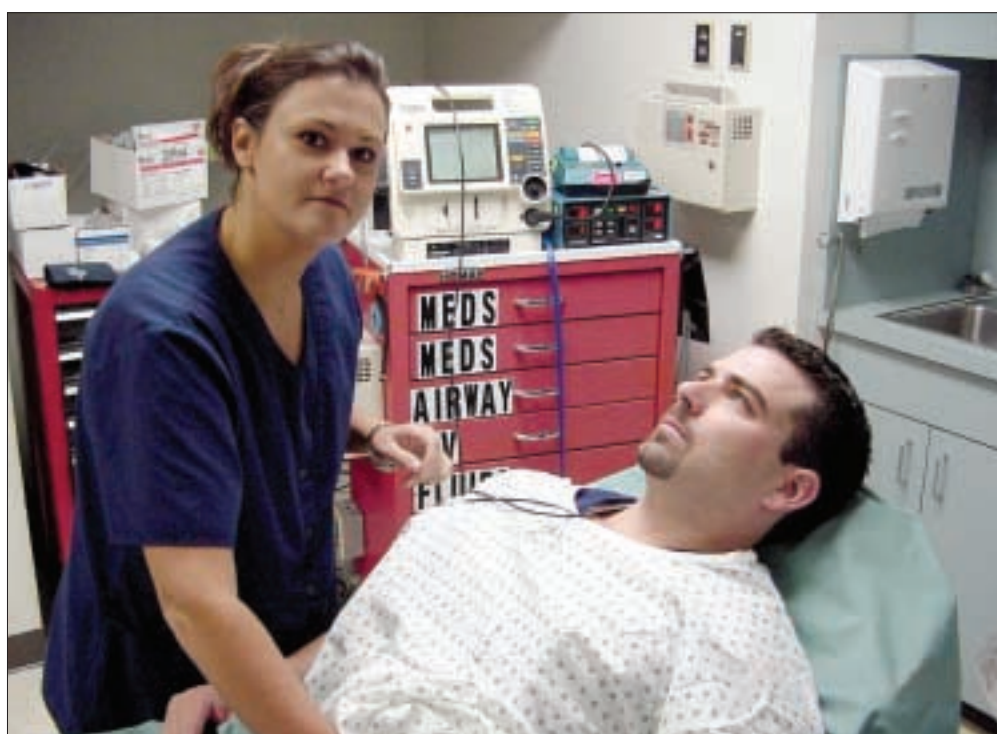
implementation in the health care sector. The document provides a framework for the design and improvement of process-based quality management systems by health care organizations. The guidelines are voluntary and they are not intended for certification or accreditation.

IWA 1 is based on an earlier draft jointly developed by the American Society for Quality (ASQ – www.asq.org) and the Automotive Industry Action Group (AIAG – www.aiag.org), which is a global industry association representing automotive companies, including the "Big Three" – Ford, DaimlerChrysler and General Motors. As a major employer, the automotive sector deals with thousands of health care providers and spends substantial amounts on health care programmes.

The generalized implementation of ISO 9000 quality management systems by health care establishments is seen as a means of rationalizing client-supplier relationships and an opportunity to improve the quality of health care while reducing the costs.



R. Dan Reid, a senior General Motors manager who was part of the team that developed the new ISO 9000 guidelines for the health sector said that the automotive sector sees the possibility of 'substantial benefits' from their implementation.



Tracie DuBose (nurse) and Conrad Breaux (patient) at the American Legion Hospital in Crowley, Louisiana, USA. The hospital is believed to be the first acute care hospital in North America to be certified to ISO 9002. The publication by ISO of guidelines for implementing ISO 9000-based quality management systems in the health care sector can be expected to encourage other establishments to follow ALH Crowley's lead.

(Photo: M.M. Christensen)

Quality improvement

"We saw a quality improvement of 85 % in five years after implementing an ISO 9000-based system for our production suppliers," commented R. Dan Reid, a senior manager with General Motors and representative of the AIAG health care project team. "Our suppliers also reported a savings of 6 % of sales as a result of registration to QS-9000. If implementation of ISO 9000 in the health service sector follows in a similar manner, the benefits should be substantial."



Mickey Christensen, Chair of the American Society for Quality's Health Care Division Standards Committee looks to the guidelines 'to improve the quality of care, improve efficiencies, and reduce errors' in the health care sector.

Mickey Christensen, Chair of ASQ's Health Care Division Standards Committee, said: "The IWA 1 is the culmination of over two years' work to have a document that helps bring ISO 9000 quality management systems criteria to health service organizations. Initial work to implement ISO 9002:1994 at the American Legion Hospital, Crowley LA, in 1995 showed that the language of the standard was not easily understood by people in health services. Now with the IWA 1, and the added text and examples for health services, this obstacle should be minimized. I hope the IWA 1 will be used to improve the quality of care, improve efficiencies, and reduce errors."

The draft was considered by health care sector stakeholder groups represented at an ISO workshop on 18-19 January 2001 in Detroit, Michigan, USA. The workshop was co-hosted and organized by the Standards Council of Canada and Canadian Standards Association (SCC – www.scc.ca / CSA – www.csa.ca) who hold the Secretariat of ISO/TC 176, the ISO technical committee responsible for the ISO 9000 standards.

At that meeting, approximately 135 health care experts from 20 countries discussed and improved the guidelines. This was followed by a 60-day consultation and vote period on the guidelines ending on 30 March 2001. The consultation period was adopted to give participants adequate time to receive input from their respective stakeholder groups.

An International Workshop Agreement is one of several new alternatives offered by ISO to developing International Standards for cases where swift development and publication takes priority. Compared to the traditional ISO process of developing International Standards through the technical committee structure, IWA's are developed in open workshops and organized by an ISO member body.

The IWA was first introduced under the designation of Industry Technical Agreement (ITA), but this was modified to reflect the fact that ISO's work addresses not only the needs of industry, but also those of numerous stakeholder groups in society as a whole. ■