

Specifying quality and competence requirements for medical laboratories



Within the next year, thousands of medical laboratories worldwide will have an ISO standard (developed in parallel with CEN, the European Committee for Standardization) to help improve the quality of their patient testing: ISO/DIS 15189, Medical laboratories – Particular requirements for quality and competence, is being written by ISO/TC 212, Clinical laboratory testing and in vitro diagnostic test systems. The standard matches the quality management concepts outlined in ISO 9001:2000, Quality management systems – Requirements. It also draws significantly from ISO/IEC 17025:1999, General requirements for the competence of testing and calibration laboratories, an ISO

standard used in the accreditation of all types of laboratories. This emphasis on competence requirements predetermines ISO/DIS 15189 as a standard to be used by government agencies and professional organizations for the accreditation of medical laboratories.

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Professor Keith Shinton, convener of ISO/TC 212/WG 1, first wrote about prEN ISO 15189¹ in the November 1999 issue of *ISO Bulletin*. At that time, the standard was entitled *Quality management in the medical laboratory* and the article examined the increased use of quality systems management in medical (clinical) laboratories. The last two years spent finalizing the prEN ISO 15189 have been an experience in consensus development, application of the *ISO/IEC Directives*, and the cooperation of three technical

committees [ISO/TC 212, ISO/TC 176, *Quality management and quality assurance*, and the ISO Committee on Conformity Assessment (ISO/CASCO)] operating on different timelines in developing their respective standards. The result will be a standard that, developed under the Vienna Agreement with cooperation from CEN/TC 140, *In vitro diagnostic systems*, brings together the quality systems requirements of ISO 9001, the competency requirements of ISO/IEC 17025, and melds them together to address the specific needs of medical laboratory professionals worldwide.

The demand for prEN ISO 15189

When originally proposed in 1995, prEN ISO 15189 was intended to harmonize quality management procedures and regulations for medical laboratories. The need for such a standard was clear: although a few countries had programmes or regulations that addressed quality systems for medical laboratories, most did not.

1) prEN is a “pre-European Standard”, developed by CEN, the European Committee for Standardization; ISO/DIS is an ISO draft International Standard. prEN ISO/DIS 15189 was developed by ISO and CEN in parallel, in accordance with the Vienna Agreement.

The progress of scientific medical knowledge has resulted in the need for increasingly precise and frequent information on the health status of actual and potential patients. This information to a large extent is generated by the chemical analysis of human body fluids, tissue specimens and excretions. Chemical analyses of such human material in general are performed by medical laboratories (in some countries also referred to as clinical or biological laboratories).

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As a result of the increased demand, the level of medical laboratory testing has substantially expanded worldwide. This is best reflected by the increased use of in vitro diagnostic (IVD) medical devices. IVDs are devices using human materials to detect, diagnose, manage, or prevent diseases, injuries, handicaps or physiological and pathological processes. They include: reagents for the chemical and physical analysis of material derived from the human body; equipment like clinical chemistry analyzers used to perform the analyses; portable instruments used to carry out point-of-care testing, such as blood glucose monitors; and kits like home pregnancy test kits. The IVD market is a relatively small segment of the overall medical devices market, less than 5 % of total healthcare spending, but there has been significant growth over the last 30 years. The worldwide market for IVD grew from roughly USD 450 million in 1970 to USD 19 billion in 1999, a compound annual growth rate of 15 %.

Parallel to the expansion of the quantitative demand there is a substantial increase on the qualitative demand of the services of medical laboratories: the success of a medical treatment often depends on the reliability of the result from a medical laboratory. At the same time the variety of analytical procedures that must be mastered by the laboratory continues to multiply and the time for the laboratory to respond to a request continues to shrink. Medical laboratories react to these demands by trying to organize their operation along quality management rules. This development often is being supported by hospital management and public health administrations.



While individual medical laboratories move towards their individual quality management system, a need for a more general, or, if possible, global systems for their quality management and competence requirements becomes apparent:

- Potential and actual patients are increasingly mobile. The systems to collect medical data on these individuals therefore must operate according to the same standards independent from their geographic location.
- The mobility of modern society allows dangerous infectious diseases to easily and quickly spread in different geographic areas. The fast and unequivocal identification of diseases and of infected individuals by different laboratories in different areas requires common standards.

- Requirements for quality improvements and cost control are similar in medical laboratories around the world. The application of common standards will facilitate the exchange of experiences and the introduction of improvements.
- For cost reasons IVD to a large extent are developed and produced on a global scale. To maximize the safety and efficiency of these devices, the operations of medical laboratories should follow equally global standards.

Drawing on the ISO 9000 Series

In developing prEN ISO 15189, any existing quality management documents/standards for the medical laboratory field as well as the ISO 9000:1994 series were utilized. ISO/TC 212 Working Group 1 followed clause 6.8.2 of the *ISO/IEC Directives* (formerly 6.6.4) and was careful not to add to, delete from, or in any way change the ISO 9001 requirements while incorporating their concepts into prEN ISO 15189. ISO/TC 212 was not the first technical committee to work at developing a sector-specific quality management standard; ISO/TC 210, *Quality management and corresponding general aspects for medical devices*, followed the ISO/IEC Directives regarding use of ISO 9001 and 9002 while developing ISO 13485 and 13488, *Quality systems – Medical devices – particular requirements for the application of ISO 9001 and ISO 9002*, respectively. There was no worry about ISO/TC 212 overlapping its activities with those of ISO/TC 210, as ISO/TC 210's scope dealt with manufacturing medical devices and prEN ISO 15189 covered the process of medical laboratory testing.

To have prEN ISO 15189 proceed, ISO/TC 212 needed to have ISO/TC 176 confirm to the ISO Central Secretariat that the standard met the requirements of the *ISO/IEC Directives*. Timing and circumstances worked against ISO/TC 212 in this regard, mainly due to the finalization of ISO 9000:2000 this time last year. Once the new ISO 9001 edition was complete

however, ISO/TC 176's Secretariat and experts energetically cooperated with ISO/TC 212 to ensure that prEN ISO 15189 reflected the requirements on ISO 9001:2000, leading to a meeting in Vancouver, Canada, in March 2001. In doing so, however, a second challenge of utilizing the revised ISO 9001 and its new terminology and requirements in prEN ISO 15189 appeared.

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The ISO 9001:2000 edition refined 20 quality system requirements in the 1994 version into five main chapters: quality management system; management responsibility; resource management; product realization; and measurement, analysis and improvement. In addition, the revision introduced a new process-oriented structure; a continual improvement process as a step in enhancing the quality management system; increased emphasis on the role of top management; a requirement for the organization to monitor information on customer satisfaction as a measure of system performance; as well as terminology changes. Experts on ISO/TC 212/WG 1, however, felt that medical laboratory professionals would not be comfortable in accepting many of the terms used by quality management experts in ISO 9001:2000 while they fully endorsed the

philosophy of ISO 9001:2000. For example, “product realization” would be a difficult concept to introduce to the medical laboratory community where “product” is the results of medical tests. The new terminology would slow or even inhibit the adoption of a document that was so badly needed. So, working with ISO/TC 176 experts, WG 1 was able to develop a draft version of prEN ISO 15189 by June 2001 that satisfied the *ISO/IEC Directives*.

Drawing on ISO/IEC 17025

As prEN ISO 15189 was in early development, ISO/CASCO was revising ISO/IEC Guide 25 to become a standard, ISO/IEC 17025. Originally it was felt that ISO/IEC 17025 would be useful also for medical laboratories and in fact, some accreditation bodies used ISO/IEC 17025 to accredit all types of laboratories, including medical laboratories. As ISO/TC 212 Working Group 1 began reviewing ISO/IEC 17025 to add selected requirements into prEN ISO 15189, however, it became clear that the special needs of medical laboratories called for additional requirements:

In contrast to ISO/IEC 17025, prEN ISO 15189:

- focuses on the patient outcome without downgrading the need for accuracy of measurements;
- emphasizes not only the quality of the measurement but of the total service of a medical laboratory (consultation, turn around time, cost effectiveness etc.),
- uses a language and terms that are familiar in the profession;
- highlights important features of pre- and post investigational issues; and
- addresses ethics and information needs of the medical laboratory.

John Donaldson, Chair of ISO/CASCO, complimented ISO/TC 212 Working

Group 1 saying: “I think you have succeeded, and our CASCO representatives are pleased to have been able to contribute to your extremely important work.”

Accreditation bodies have also indicated their acceptance of the medical laboratory standard. Dr. Jos G. Leferink of the Dutch Accreditation Council writes: “Some people believe that the ISO/IEC 17025, the laboratory competence standard, is a perfect standard that can be interpreted for the medical sector, including clinical laboratories. In principle this could be a correct position, but a medical interpretation document would have to be so comprehensive that it would only lead to large differences between those who apply it.



The medical sector, larger than the total of the other laboratories disciplines together, deserves a standard through which harmonization can be achieved much better. Difficult subject, as the pre- and post clinical phases in testing and the sensible use of calibration can be directly and uniformly addressed. ISO 15189 seems a very good dedicated standard that can easily be used, if the sector so desires, for accreditation purposes and for subsequent mutual recognition across borders. In the recent International Laboratory Accreditation Cooperation (ILAC) meeting in Kyoto, this position was accepted.”

Further, at the recent World Association of Societies of Pathology and Laboratory Medicine (WASPaLM) World Congress held in Dusseldorf in November, 2001, Dr. Kenneth McClatchey, WASPaLM's Secretary General, stated that prEN ISO 15189 was a vehicle for global accreditation of medical laboratories. “Within two years,” he said, “there would be no other

acceptable standard for laboratory accreditation.”

Outlook – a second sector-specific quality management standard usable for accreditation of medical laboratories

The months ahead are challenging for ISO/TC 212 Working Group 1 and prEN ISO 15189. The standard was overwhelmingly approved in a DIS vote in September 1999, but due to delays and changes since then, it was distributed for a second abbreviated (two-month) DIS vote by the ISO Central Secretariat in January 2002. Following approval and resolution of comments, ISO and CEN will have a second sector-specific quality management standard that can be used for accreditation of medical laboratories.

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It will have come about as the result of at times intense consensus development and the merging of the requirements of several standards developed along different timelines. And the work will not be complete then: ISO/TC 212 Working Group 1 has an approved new work item for a guidance document on application of EN ISO 15189 and will also need to revise the standard early to match the revision of ISO/IEC 17025. Medical laboratory professionals and government agencies worldwide, however, are eagerly anticipating the long-awaited approval of the first edition of prEN ISO 15189 for use in medical laboratories worldwide. □

Developing and maintaining an effective records management programme

The new ISO 15489, Information and Documentation – Records Management, clearly shows how any organization can systematically and effectively improve their record keeping – and do so in such a way that the business objectives are supported.

Robert J McLean, Records Manager/Archivist, at The Wellcome Trust in the United Kingdom, explains why this standard is not “just another” document offering advice on records management issues. Good records management practice is essential to create, capture and use information essential for the organization. He demonstrates that this new standard presents best practice drawn from an expert international community using terms and concepts familiar to and of great interest to all managers. ISO 15489 identifies the key issues involved in retaining the information and making it available in a useable and

reliable way as well as how it may be selectively and securely disposed of at the appropriate time.

By Robert J McLean, ISO/TC 46/SC 11 UK delegate, Records Manager/Archivist, The Wellcome Trust

The final quarter of the 20th century was characterized by the phenomenal growth of the personal computer and the explosive growth of information created by the individual in all organizations. The immediate and most obvious effect of this has been threefold:

- Software programmes, hardware performance and memory availability have all improved dramatically, leading to unprecedented levels of productivity and the opportunity to engage in a wide range of activities that were formally the preserve of specialists. We can now process financial data, create documentation to publishing standards, distribute our output literally to the world via the web – all at a fraction of previous costs. *The consequent growth of the volume of records thus created and stored on hard drives and networks continues to rise exponentially – as do multiple copies of documents in the form of personal copies, different versions and via attachments to e-mails. How do we find the records we are looking for in this ever-growing unstructured and un-indexed mass?*
- The application of “process driven” (word processing, publishing, spreadsheets, etc) as well as “line of business” technology typically found in

most organizations has enabled them to restructure in dramatic ways. Few of us now have secretaries and a great many clerical and support jobs have all but disappeared – *and with them the resources formerly used to organize, store and retrieve recorded information. Most of us are under enough pressure just to keep up with our workloads, without having to worry about what will happen to the records we are creating!*

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- Records created on PCs tended to stay on the PC until the hardware was upgraded – in which case only current work was taken forward to the new hard drive, or else it was consigned to floppy disks which were themselves overtaken by format changes, system changes or software upgrades. *Obsolescence has resulted in the loss of information that would otherwise still be accessible in more durable formats. Compliance and legal obligations are all the more difficult to meet in these circumstances. Future business opportunities may be lost when lessons can no longer be learned from past successes and failures.*

The scenario painted above is widespread despite the advent of document management and storage systems which tend to focus on supporting the work

process through workflow, rather than looking at the needs of the records and the record keeping systems. The new ISO 15489 standard clearly shows how any organization can systematically and effectively improve their record keeping – and do so in such a way that the business objectives are supported. Senior management will be able to identify tangible benefits such as reduced costs and better managed risks, thereby contributing to better corporate governance.

Frequently, islands of information exist in a variety of media leading to inefficiencies, increased costs and greater risk to the business. Many organizations have no broad policy for managing their corporate memory – information problems are often dealt with in isolation. With no effective records management programme, important documents are hard to find or even irretrievable. The organization has forgotten what it formerly knew.

Initiatives such as knowledge management are underpinned by well managed records. The new standard enables organizations to develop policies, strategies and programmes which will ensure that information assets have the essential characteristics of accuracy, integrity and reliability. Information thus presented to knowledge workers will be of the highest quality, currency and usefulness.

Software vendors of Electronic Document Management systems are increasingly recognizing that real business benefits can only be realized by including records management functionality in their products. ISO 15489 can be used to benchmark products claiming to fulfil record-keeping requirements so that the anticipated benefits can actually be realized.

A standard written with all managers in mind

So how does the new standard differ from the myriad of textbooks offering advice on records management issues? Quite simply, this standard is written with all managers in mind, not just the specialist information worker. It is not intended to replace textbooks, but rather present best practice drawn from an expert international com-

munity in a clear and concise way. It uses terms and concepts familiar to and of great interest to senior managers. It demonstrates why good records management practice is essential to create, capture and use information essential for the organization to fulfil its obligations and meet the expectations of its stakeholders. ISO 15489 identifies the key issues involved in retaining the information and making it available in a useable and reliable way as well as how it may be selectively and securely disposed of at the appropriate time.



“Tracking who has the latest version, who is responsible for it and therefore the holder of the official organizational copy, when and by whom additional copies should be destroyed is a complex and knotty problem.”

IT managers will be able to use the standard to identify features and functionality that systems must have in order to meet the organization’s information needs, including regulatory and audit constraints. Although the unit cost of storing electronic records has dropped dramatically in recent times, the volumes of stored data has risen to the point where storage and storage management costs now take up a significant part of the IT budget. Commercial storage companies are beginning to offer e-storage as an adjunct to traditional space for paper records and archives in recognition of the growth in this area – although few if any