

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.

**“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.”**

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.*

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

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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!*

*“The consequent growth of the volume of records... continues to rise exponentially – as do multiple copies of documents in the form of personal copies, different versions and via attachments to e-mails.”*



- 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

offer appropriate software solutions for managing the electronic contents.

Network management regimes such as staking frequent back-ups and "archiving" data to off- or near-line storage devices are quite legitimate activities for ensuring that networks operate in an optimal fashion. However, this cannot contribute to the effective and efficient management of the underlying records if it is done without reference to the records management requirements. If this is done in isolation, as is often the case, then records properly destroyed in accordance with an agreed disposal schedule may happily live on in back up and archive copies, thereby adding unnecessary cost and potentially increasing risk during discovery actions.

Similarly, multiple copies of documents frequently exist as personally saved electronic copies, e-mail attachments and, as often as not, as paper copies in the filing cabinets of each recipient. 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. Many managers prefer not even to think about the issues if short-term measures can be implemented.

### ***A truly international standard for use by any type of organization in any sector***

ISO 15489 demonstrates how such problems can be overcome without being led by technology, by any type of organization in any sector. Indeed the standard is written in such a way that it can be applied to systems-managing information in any medium or format or in any combination of media. Whether the organization works for profit, is in the public or private sector, is large or small, it can benefit from reviewing its record-keeping

activities against the standard's best practice.

Global organizations will find particular benefits in this truly international standard. Experts from Europe, North America, Asia and Australasia forged agreement on a clear and systematic approach to the essentials of good record keeping.

ISO 15489 is published in two parts. Part 1 includes:

- definitions to clarify meaning and significance of terms commonly misunderstood;
- a summary of the benefits of records management;
- the need for and how to establish policies, procedures and practices to ensure that its business needs for evidence, accountability and information are met;
- the fundamental principles of records management and how these are realized through a comprehensive programme;
- the design and implementation of a record-keeping system and the characteristics of recorded information;
- a suggested design and implementation methodology for sustainable record keeping systems;

***"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."***



- records management processes and controls;
- monitoring, auditing and training.

Part 2 is a Technical Report which expands on the design and implementation methodology suggested in Part 1, which itself is broadly based on the DIRKS methodology (Design and Implementation of a Record Keeping System). This tried and tested methodology has been specifically adapted to implement the standard. It gives an overview of the processes and factors to consider in order to be compliant with the standard. To illustrate:

- what are the steps involved in designing and building systems for managing records?
- what are the key issues and questions when a company is involved in a mergers or acquisition or when parts of its activities are outsourced?
- how can a business activity classification scheme be developed that will provide a framework for organizing, keeping and relating records to make them accessible, usable and capable of being shared with appropriate persons or external organizations?
- what factors influence the development of a retention policy and how could it be implemented?

Annex A contains a table giving copious cross-references between the Technical Report and the standard. The

report is written in such a way that it does not have to be followed rigorously from beginning to end. After all, most organizations will have completed at least some of the steps already and may wish to strengthen certain parts of the programme before others. Above all, it is plainly shown how all of the component parts can be effectively positioned and tied

together holistically to provide greatest benefit and security.

ISO 15489 supports other ISO standards where specific record keeping requirements are indicated. For example:

The ISO 9000 family identifies “quality records” as having certain characteristics – they must demonstrate conformance to specific requirements as well as effective operation of the quality system. ISO 15489 supports quality systems by addressing why, where and how records are created and used.

ISO 9000 requires retention periods to be established and implemented. ISO 15489 shows how to develop them in support of the business needs and risks and within the external environment (including legal and regulatory).

ISO 9000 notes that records should have suitable protection. ISO 15489 shows how to identify vital records and well as create the provisions of physical and logical security.

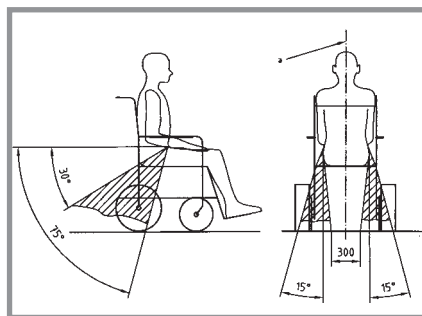
ISO 9000 states that records should be stored and retained for ready access. ISO 15489 covers record keeping system requirements for active and inactive records.

In summary, ISO 15489 can be used in a number of ways:

- to measure if existing strategies and programmes are effective in achieving their aims based on international best practice;
- to realistically offer those benefits which many technology lead projects often promise but fail to deliver;
- to provide a benchmark against which diverse and complex organizations and geographically separate systems for managing records can be measured and brought into accord;
- Most importantly, to support the translation of business plans, goals and objectives into practical information policies, strategies and programmes. □

## ✓ Technical aids for disabled or handicapped persons

Providing effective protection for the wheelchair-seated occupant of a motor vehicle usually requires that equipment be installed to secure the wheelchair and restrain the occupant of the wheelchair. ISO 10542-1 is applicable to this motor-vehicle adaptive equipment, which is referred to as wheelchair tiedown and occupant restraint systems (WTORS). The requirements and test methods of this part of ISO 10542 apply to all WTORS that use belt-type occupant-restraint systems.



*Range of required angles for pelvic belts and locations of pelvic-belt anchor points according to ISO 10542-1:2001.*

The use of only a pelvic belt as an occupant restraint is unlikely to provide adequate safety to a wheelchair user in the event of a frontal impact. Therefore, this part of ISO 10542 only includes test setups and procedures for occupant restraints that incorporate both a pelvic and an upper torso restraint.

International Standard ISO 10542-1, *Technical systems and aids for disabled or handicapped persons – Wheelchair tiedown and occupant-restraint systems – Part 1: Requirements and test methods for all systems*, specifies test methods and requirements for design and performance, for instructions and warnings to installers and users, and for prod-

uct marking and labelling for wheelchair tiedown and occupant-restraint systems (WTORS). It applies to all WTORS that use belt-type occupant restraints that are intended for adult-occupied wheelchairs used as forward-facing seats by passengers and drivers of motor vehicles.

ISO 10542 consists of 2 parts, under the general title *Technical systems and aids for disabled or handicapped persons – Wheelchair tiedown and occupant-restraint systems*.

International Standard ISO 10542-1 was prepared by ISO/TC 173, *Technical systems and aids for disabled or handicapped persons*, SC 1, *Wheelchairs*. □

## ✓ Artificial insemination of animals



The quantitative microbiological control of hygienic collection and handling of bovine semen have great importance in order to predict the efficiency of artificial insemination and to fulfil the requirements of biosecurity. For the same reason investigation of bacterial contamination and the possible presence of facultatively pathogenic micro-organisms in the preserved bovine semen is also very important.

Therefore, there is a need for an international method suitable for the determination of the microbial count in frozen