

Laboratory Products Focus



Demonstrating Integrity

Recent changes to hygiene regulations has increased the prominence of laboratory testing procedures in the food industry. UKAS explains the benefits of undertaking certification and accreditation procedures as laboratory services strive to remain competitive.

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It may be over two years since new food hygiene legislation was introduced, but its effects are still being felt by all those operating within the food industry. EU Regulations No. 852/2004, 853/2004 & 854/2004 were united in one aim; to apply suitable controls throughout the food chain. This would have the dual effect of achieving public health protection and clarifying the responsibility of food business operators to produce safe food. This legislation is supported by a plethora of Commission Regulations, chiefly concerned with microbiological criteria for foodstuffs, which specify the acceptability of food manufacturing processes. Whilst food business operators have to meet the criteria defined in the regulations, there are no prescribed requirements covering the actual testing for compliance. Testing processes and procedures may also be used to validate Hazard Analysis and Critical Control Point systems or to monitor processes. This has considerably increased the role of food testing laboratories within the food supply chain. The new regulations require a laboratory to take a wider view of the industry, so as to ensure that the test method being used is fit for the intended purpose. This change in emphasis means that testing laboratories are now required to understand their customers' needs and the precise application of the test result. In an increasingly competitive marketplace, being able to demonstrate this understanding to customers is becoming ever more important. All laboratories want to distinguish themselves from their competitors, especially with new customers where it is often difficult to establish a proven track record. The most common way for businesses generally to do this is by implementing a quality management system under certification. For the majority of food testing laboratories this is not enough. They need to demonstrate their technical competence through accreditation. Despite the introduction of the revised laboratory accreditation standard ISO/IEC 17025:2005 nearly three years ago, confusion still exists for both laboratories and their food industry customers over the differences between accreditation and certification. However, the distinctions between the two different types recognition can easily be explained. Knowing what these distinctions are will bring a range of business benefits to both laboratories and their customers, as it allows each party to make more informed choices. Certification represents a written assurance by a third party of the conformity of a product, process, person or service to specified requirements. Accreditation, on the other hand, is the formal recognition by an authoritative body of competence to work to carry out specific conformity assessment tasks, such as testing. The United Kingdom Accreditation Service (UKAS) is the sole national accreditation body recognised by Government and has over 120 certification bodies and 1,500 laboratories amongst its customers. This puts UKAS in an ideal position to be able to witness the sort of business decision that can arise from the confusion about accreditation versus certification. A key point to appreciate when weighing up the relative merits of a laboratory certified to ISO 9001:2000 for its management system or accredited to the international standard ISO/IEC 17025:2005 for its testing activities is that their purpose is different.

CERTIFICATION

The ISO series of standards is one of the most internationally recognised in the world. ISO 9001:2000 certification is a generic standard for quality management systems. It is applicable to any organisation irrespective of type, size or product, service provided or industry sector, including laboratories. The ISO 9001:2000 assessment



team will consist of auditors with the expertise to enable them to apply the generic requirements of the standard to operations of laboratory services. However, the focus is on establishing an organisation's compliance with requirements for a quality management system. This relates to what the organisation does to fulfil the customer's quality requirements and applicable regulatory requirements. It aims to enhance customer satisfaction and to achieve continual improvement of its performance in pursuit of these objectives. Unlike the ISO/IEC 17025:2005 accreditation standard, ISO 9001:2000 certification does not contain any technical requirements for laboratory personnel and operations. As such, certification against ISO 9001:2000 cannot be interpreted to mean that a laboratory has demonstrated the technical competence to produce valid data and results.

ACCREDITATION

ISO/IEC 17025:2005 is the accreditation standard applicable to all laboratories, including those in the food testing arena. Whilst there are management requirements within ISO/IEC 17025:2005, the purpose of this standard is to establish the technical competence of a laboratory for a defined set of tests, measurements or calibrations. The management requirements of ISO/IEC 17025:2005 meet the principles of ISO 9001:2000 but are written in language relevant to laboratory operations. The assessment team for laboratories is comprised of the relevant technical experts and assessors able to evaluate compliance with these management requirements. The accreditation team's major emphasis is on establishing that the laboratory being assessed meets the specific technical requirements. To achieve this, the team must determine the specific technical competence of personnel, the fitness-for-purpose of methods and the availability of all the technical resources needed to produce reliable data and results for specific tests.

BENEFITS OF CERTIFICATION

A certified ISO 9001:2000 management system can offer a food testing laboratory a number of benefits. The most obvious of these is increased customer satisfaction levels through improved product, process and service quality. As processes are made more efficient, there are internal benefits of productivity improvements and less waste. For laboratories operating in some industry sectors, it remains a contractual obligation or expectation.

BENEFITS OF ACCREDITATION

An increasing number of specifiers are stipulating the use of accredited services, whether as a legal requirement or a preferred solution. Achieving UKAS accreditation will put laboratories in a better position to win this business, particularly Government tenders. As UKAS accredited test certificates are recognised internationally the potential customer base can be increased further by providing access

to overseas customers. Whilst effective marketing will undoubtedly get a company's message across, it is accreditation that provides customers with a formal recognition of the competence, impartiality performance and capability of a particular laboratory. Customers of laboratories accredited to ISO/IEC 17025:2005 also benefit from the reliable accuracy of measurements and tests carried out by the laboratory in compliance with best practice. These can help to limit product failure and downtime and control manufacturing costs. It is also worth bearing in mind that should a problem arise which results in legal action, the use of an accredited body to carry out independent evaluations can help to demonstrate due diligence.

SUMMARY

There are differences between the purpose, criteria and emphasis of the ISO 9001:2000 quality system standards and those of the accreditation standard, ISO/IEC 17025:2005. For laboratories concerned with demonstrating technical competence underpinned by

a quality system, ISO/IEC 17025:2005 is the appropriate standard. Similarly, suppliers seeking competent testing facilities should ensure that those facilities are accredited to ISO/IEC 17025:2005, with a scope of accreditation appropriate for the testing or calibration required. One of the most important considerations for any business operating in the food sector must surely be that the services offered by the testing laboratory in question should give accurate and reliable results. Achieving independent laboratory accreditation signifies that a laboratory is competent, well managed and that its customers can rely on the results of any analysis undertaken. UKAS assessments of food testing laboratories have always covered the processes in place for review of requests, tenders and contracts. However, the changes in legislation described at the beginning of this article have meant that they have received particular attention over the last couple of years to ensure that testing is always fit for purpose. This means that it is no longer enough for laboratories to simply do what the customer asks for; they have to understand and do what the customer needs. Thus, it is not merely a quality

management issue. Instead it is a technical issue, requiring the skills of trained technical assessors. A laboratory accredited by UKAS can prove its competence, impartiality and sustainable performance. This ensures that everyone from specifiers, purchasers and suppliers to consumers can have confidence in the quality of goods and in the provision of services throughout the food supply chain.

Once laboratories and their customers understand the differences between the processes of laboratory accreditation and certification, they will begin to appreciate the real benefits that accreditation can bring to their businesses.

For further information: www.ukas.com

REFERENCES:

[1] ISO 9001:2000 Quality management systems requirements

[2] ISO/IEC 17025:2005 General requirements for competence of testing and calibration laboratories



Imagine a Laboratory Printer that Thinks Like You

LabXpert has been developed and tested specifically for laboratory conditions. This label printer is ideal for lab technicians who need to be able to identify numerous samples on a daily basis, permanently, legibly and accurately. Combining customised software with advanced printing technology, LabXpert prints labels that meet the needs of a demanding lab environment.

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Circle no. 534

Innovative Biological Safety Cabinets

Thermo Fisher Scientific, Inc has introduced the new line of Thermo Scientific Safe 2020 and Thermo Scientific Maxisafe 2020 Class II biological safety cabinets. With superior personnel, product and environmental protection, these safety cabinets offer increased ergonomics creating a safer work environment for the user. Both cabinets are designed with innovative DC motor technology to maximise safety and energy efficiency. Available in four different widths (0.9, 1.2, 1.5 or 1.8 meters), the Safe and Maxisafe 2020 cabinets are ideal for labs where product and personal protection is of paramount importance. With best-in-class containment, the H14 HEPA filters guarantee a maximum filtration efficiency of 99.995% at the most penetrating particle size (MPPS). The advanced Maxisafe 2020 has an additional filter system below the work area to protect the air flow components from contamination providing 100,000 times higher filtration efficiency than standard Class II cabinets. Importantly, the filter system can be changed with minimised contamination risk while the cabinet is in operation. Pressure sensor monitoring ensures safe airflow across the entire work surface and an easy-to-read display enables convenient at-a-glance monitoring of safety parameters. When closed, the front sash window provides an aerosol tight seal for additional sample and personnel protection.

Superior DC motor technology maximises energy efficiency and reduces heat output, providing a more comfortable work environment with lower air conditioning costs. The Night-Set-Back mode decreases energy consumption by reducing blower motor speed when the front sash is closed. The transparent side glass windows maximise light and visibility, and the easily adjustable motorised front sash is angled at an optimal 10 degrees, ensuring excellent ergonomics. The sash is also hinged and can be fully opened for easy cleaning, which together with the optional cross-beam UV-irradiation, ensure thorough disinfection of the entire work chamber. A range of options and accessories enable the customisation of the workspace. Delivering maximum containment, comfort and convenience, the Thermo Scientific Safe and Maxisafe Class II biological safety cabinets are ideal for use in research laboratories, pharmacies, clinics or hospitals. They are compliant with the most stringent regulatory standards in the world and independently tested and certified to EN 12469 (Safe 2020) and to DIN 12980 (Maxisafe 2020).

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New Starter Pack Enables Productive Sample Storage

Micronic Europe has introduced a new Deluxe Starter Pack for laboratories, such as exist in Biobanking or Biorepository organisations, looking to securely and traceably store thousands of samples per month. The Micronic Deluxe Starter Pack contains everything needed to start using 2D coded sample storage tubes enabling laboratory workers to ensure a secure sample logistics system and eliminate the costly possibility of false sample identities.

Benefiting from a unique inside ring - Micronic storage tubes are designed for secure sealing and allowing customers to store the maximum sample volume. Used with the Electric Capper, supplied as part of the Deluxe Starter Pack, TPE caps are pushed into exactly the right depth of each Micronic tube to ensure a reliable, high integrity seal.

The attractively priced Deluxe Starter Pack contains an easy-to-use Electric Capper, a 2D barcode rack scanner including operating software, two cases of racked 1.4ml 2D coded tubes and enough caps, some manual cap removers and a tube selector. The Starter Pack offers a substantial saving over buying the products individually. Coming from a world leader in traceable sample storage the quality of supplied goods is second to none and all components design optimised to provide top performance.

With the ever-growing requirement for higher sample throughput in many laboratories the compact Electric Capper enables significant productivity gains to be made in the sealing of multiple sample storage tubes. The Electric Capper caps a full (or partially filled) 96-tube rack in less than 10 seconds.

Manufactured in a class 7 clean room production facility - Micronic sample storage tubes are certified RNase / DNase free and non-toxic, according to the USP class VI test, making them the ideal secure medium for storage of liquid or solid biological samples at low temperatures.

Dedicated to the design and production of innovative sample storage tubes, accessories and instruments over the last 25 years, Micronic is uniquely able to offer laboratories the expert advice to help them safeguard one of its most valuable assets - its samples.

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