Policy article

Drug Testing and Analysis

Published online in Wiley Online Library

(www.drugtestinganalysis.com) DOI 10.1002/dta.1353

Combining ISO/IEC 17025:2005 and European Commission Decision 2002/657 audit requirements: A practical way forward

Jack F. Kay*

Laboratories involved in the analyses of veterinary drug residues are under increasing pressure to demonstrate that they produce meaningful and reliable data. Quality assurance and quality control systems are implemented in laboratories to provide evidence of this and these are subject to external assessment to ensure that they are effective.

Audits to ISO/IEC 17025:2005, an internationally accepted standard, and subsequent accreditation provide laboratories and their customers with a degree of assurance that the laboratories are operating in control and the data they report can be relied on. However, national or regional authorities may place additional requirements on laboratories to ensure quality data are reported. For example, in the European Union, all official control laboratories involved in veterinary drug residue analyses must also meet the requirements of European Commission Decision 2002/657/EC which sets performance criteria for analytical methods used in this area and these are subject to additional audits by national or regional authorities.

All audits place considerable time and resource demands on laboratories and this paper discusses the burden audits place on laboratories and describes a UK initiative to combine these audits to the benefit of both the regulatory authority and the laboratory. © 2012 John Wiley & Sons, Ltd.

Keywords: audit; laboratory; accreditation; QC; QA

Introduction

Many regulatory authorities around the world implement programmes of monitoring home-produced and imported food of animal origin (e.g. muscle, liver, and kidney) for compliance with established residue limits for veterinary medicines and related substances.[1] This is done for a number of reasons including concerns over food safety for consumers and to meet regional/international standards. Some substances will be acceptable if residues determined are below prescribed limits whilst others will lead to regulatory action if any residues are detected. The consequences of mis-identification or quantification of residues can be legal penalties for producers and can have a serious impact on international trade.

Whilst it is important that residues in excess of limits can be identified, it is also important for consumer safety that analyses do not fail to detect the presence of residues in samples, particularly when the residue is of a prohibited or unauthorized substance. It is therefore essential that laboratories conducting these analyses are competent to do so and can demonstrate that the results they report are sound and defensible. This is discussed in more detail by Cannavan *et al.*[2]

To demonstrate their competence and reliability, residue-testing laboratories are increasingly turning to implementing quality assurance principles as a matter of routine into their day-to-day operations. Such principles cannot of themselves guarantee that the results generated will be correct but they increase the likelihood of correct results being reported which are scientifically based and fit for purpose.

Implementing a quality system demonstrates to its clients that the laboratory has the appropriate facilities, equipment, and technical expertise to perform the analyses. It also enables the laboratory to demonstrate that all stages of the analytical process, from sample receipt to sample disposal are controlled using documented and validated procedures and methods. Certification or accreditation of laboratory quality systems by a recognized national or international authoritative body can further reinforce confidence in the quality of the work undertaken by a laboratory.

Discussion

In an increasingly competitive and commercial market, laboratories have a powerful incentive to convince their clients that they are consistently capable of producing quality results. However, the term 'quality' is difficult to define and can be used in a number of different ways, each with a distinct but slightly different meaning.

For quality assurance purposes, ISO 9000:2005[3] defines quality as 'the degree to which a set of inherent characteristics fulfils requirements'. The term 'quality' can also be considered as a measure of fitness for purpose.[4,5] Quality is also user-dependent as it will be assessed against the specific requirements and expectations of the laboratory client. Therefore, introducing a quality system which involves quality assurance

* *Correspondence to: Jack Kay, Department of Mathematics and Statistics, University of Strathclyde, Glasgow, UK.*
E–mail: jack.kay@strath.ac.uk

University of Strathclyde, Glasgow, UK

and quality control procedures allows a laboratory to demonstrate to clients that reliable and quality results will be produced.

Quality assurance (QA) deals with the planned and systematic actions and measures used by a laboratory to ensure the quality of operations it conducts. However, operational techniques and activities used to fulfil quality requirements are covered by quality control (QC). Whilst QA and QC can often be considered as entirely separate, they are essentially linked in any laboratory quality system.

ISO/IEC 17025:2005[6] is perhaps the most appropriate and commonly followed quality standard for laboratories involved in trace residue analysis such as veterinary drug residue analysis, particularly if undertaken for regulatory purposes. It is required in some jurisdictions that laboratories will be accredited to this standard[7] if testing is to be conducted on food products for international trade. This standard sets out a framework for quality management and the technical competence of laboratories to carry out tests and calibrations.

When a laboratory implements a quality system, it may choose to claim informal compliance with the scheme if adopted from an external source, or it may have an independent assessment or endorsement of an in-house or adopted system by a neutral body through certification or accreditation.[8] In either case, to be meaningful and considered seriously by clients, any compliance claimed with a particular standard must be verified independently of the organization's management. A prerequisite to making any claim that the laboratory is following a quality system will involve the laboratory establishing an independent quality assurance unit to assume responsibility for internal evaluation and auditing to check for compliance with the standard. The unit should be led by a quality manager who has clearly defined responsibility and authority for ensuring that the quality management system is implemented.

Accreditation is a formal procedure which assures that the requirements specified in the quality standards followed by the laboratory are being met. For accreditation to ISO/IEC 17025:2005[6] as discussed above, this is a procedure whereby an authoritative body (e.g. UKAS, the United Kingdom Accreditation Service, which is recognized as the national accreditation body for the UK[9]) formally recognizes that a laboratory is competent to carry out specific tasks, in this case to conduct specific analytical tests or types of analyses.

Audits and inspections

To assess continued compliance with agreed quality standards, objective evidence must be gathered and evaluated to determine if the quality management system is effective and reliable. Periodic audits allow the necessary objective evidence to be collected for this purpose and these can be either internal or external.

Audits conducted by an independent external body, as part of the process for initial accreditation or to maintain or expand the scope of accreditation, are often referred to as an assessment or inspection. Laboratory customers should reasonably expect to see copies of these audit reports if requested, together with information on how any issues identified were addressed. In addition, customers can be expected to conduct their own independent audits of laboratory services to satisfy their specific commercial or regulatory requirements.

Internal audits are carried out within the laboratory and arranged by the laboratory's quality manager to a pre-determined schedule and using suitably trained and qualified staff. Ideally auditors will be independent of the activity being audited. The purpose of internal audits is to ensure that the quality procedures are in place, are adequately documented to enable effective and consistent implementation, and are demonstrably being fully and correctly implemented. Senior laboratory management may also conduct periodic reviews to ensure that the quality system is effective and meeting its objectives, and to identify areas for improvement as customer requirements and laboratory needs evolve.

Combined audits

In the United Kingdom, the Veterinary Medicines Directorate (VMD)[10] is responsible for the post authorization residue monitoring of veterinary medicines in food-producing animals and their products to fulfil obligations under European Commission Directive 96/23/EC.[11] Laboratories conducting analyses under this programme are required to be accredited to ISO/IEC 17025:2005.[6] In addition, analytical methods used in this programme must meet the performance criteria set out in European Commission Decision 2002/657/EC.[12]

UKAS provides independent assurance that the laboratories accredited to ISO/IEC 17025:2005[6] are operating to an appropriate quality system. This in turn provides assurance to both laboratories and their customers that the results they report are fit for purpose. After initial accreditation to this standard, annual audits are conducted by UKAS and laboratories are re-accredited if found to be satisfactory. However, compliance with ISO/IEC 17025:2005[6] does not automatically ensure compliance with the analytical performance criteria set out in European Commission Decision 2002/657/EC.[12] This led the VMD to organize separate audits on an annual basis of a laboratory providing these analytical services. As can be seen from the above, there is potential for considerable time to be spent by laboratories in servicing the needs of multiple external auditors on an annual basis. UKAS and VMD audits each took two full days of laboratory time to complete, to which must be added the time spent by laboratory and audit staff preparing for each audit and following up on any issues they raised.

In discussions between VMD and the laboratory quality management team, it was suggested that auditing efficiency could be improved if UKAS and VMD audits were combined. However, this could only be considered if the integrity of the UKAS audit to ISO/IEC 17025:2005[6] was not compromised by involving a customer in a combined audit.

Discussions between UKAS and the VMD led to the production of a generic protocol which offered the assurances required that audits to ISO/IEC 17025:2005[6] would not be compromised. The protocol developed could be used by any laboratory and the laboratory providing services to the VMD was prepared to accept it. Under this audit protocol, overarching control of the combined audit remained with UKAS to safeguard the independence of the audit. In addition, it was agreed that VMD involvement would require VMD auditors to be appropriately trained to the same standard as UKAS auditors. Implementing this protocol led to successful combined audits being held annually with the laboratory concerned. There was a saving to the laboratory of two full days of auditing time plus associated preparation and follow up time per year. In addition, by introducing the specialist requirements of European Commission Decision 2002/657/EC[12] into the ISO/IEC 17025:2005[6] audit process, both the laboratory and the VMD benefited from subject specific expertise brought by

involving auditors with detailed knowledge of the specialist EU requirements.

Acknowledgement

The financial support of the OECD to permit the author to attend the SaskVal II workshop and present a paper on this topic is gratefully acknowledged.

Conflicts of interest

The author has no conflicts of interest to declare.

References

[1] Kay J.F., MacNeil J.D., In *Analyses for Hormonal Substances in Food Producing Animals*, (Ed: J.F. Kay), Royal Society of Chemistry: Cambridge, U.K. **2010**, pp. 97–128.
[2] A. Cannavan, J.F. Kay, B. Le Bizec, in *Chemical Analysis of Antibiotic Residues in Food*, (Eds: J. Wang, J.D. MacNeil, J.F. Kay), John Wiley and Sons Inc: New York, USA, **2011**, pp. 327–346.
[3] ISO 9000:2005. *Quality management systems - Fundamentals and vocabulary*. International Standards Organization, Geneva: Switzerland, **2005**.
[4] Guidelines in Analytical Terminology, CAC/GL 72–2009, Codex Alimentarius. Available at http://www.codexalimentarius.net/download/standards/11357/cxg_072e.pdf
[5] European Commission. Method validation and quality control procedures for pesticide residues analysis in food and feed. SANCO/12495/**2011**. Available at: http://www.eurl-pesticides.eu/docs/public/tmplt_article.asp?CntID=727&LabID=100&Lang=EN [18 April 2012]
[6] *General requirements for the competence of testing and calibration laboratories*, 2nd ed. ISO/IEC 17025:2005, International Standards Organization: Geneva, Switzerland, **2005**.
[7] European Commission Regulation (EC) No. 882/2004 of the European Parliament and of the Council of 29 April 2004, on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. *Off. J. Eur. Com.* **2004**, L.65/1.
[8] ISO Guide 2:2004. *Standardization and related activities - General vocabulary*. International Standards Organization: Geneva, Switzerland, **2004**.
[9] The Accreditation Regulations 2009. Statutory Instruments **2009** No. 3155. Available at: http://www.legislation.gov.uk/uksi/2009/3155/pdfs/uksi_20093155_en.pdf [18 April 2012]
[10] VMD website. Available at: http://www.vmd.defra.gov.uk/
[11] European Commission Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC. *Off. J. Eur. Com.* **1996**, L125/10.
[12] European Commission Decision 2002/657/EC of 12 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results. *Off. J. Eur. Com.* **2002**, L221/8.