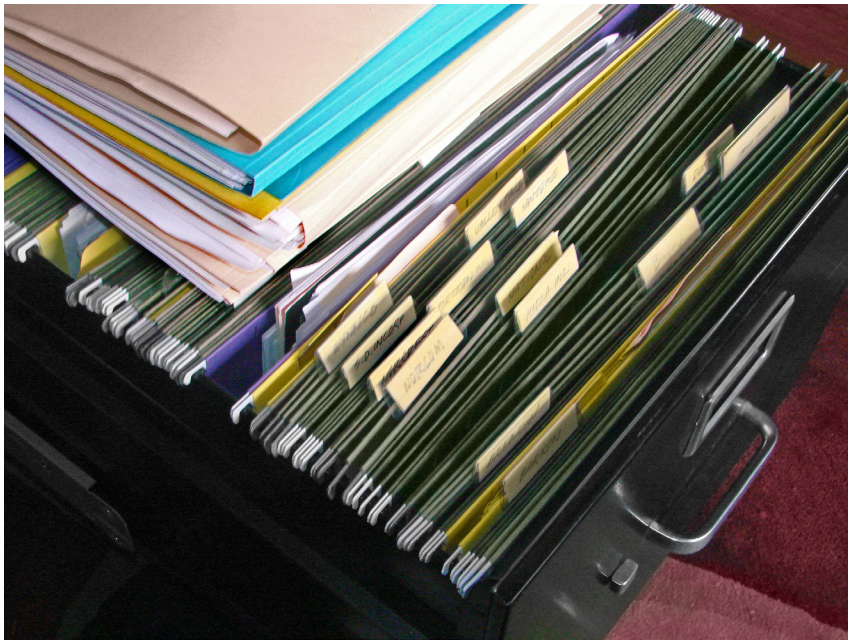
Paperless Calibration

White Paper

Bulging filing cabinets or over-full hanging files are a common office scene. But as far as calibration records are concerned, is the "paperless office" taboo? Does Agilent's free Infoline service satisfy critical record requirements?



What do You Keep in Your Drawers?

Most quality managers keep calibration results and certificates in their drawers! From discussions that have taken place with many people in industry whose responsibility includes the control of test instruments, a filing cabinet full of paper calibration 'evidence' is an integral part of the quality system — *without which audits would fail and the business would crumble*. But when pressed for a rationale for such belief, three main reasons to maintain paper records emerge:

- They believe that auditors would not accept any alternative
- They believe that product/quality certifiers or accreditation bodies demand it
- It is historical; they have always done it and it is a comfort factor

Alternative Feared

During these discussions a potential alternative option based around electronic records being retained by the calibration supplier, to be provided electronically on demand, was met with a mixed reaction.

On one hand, the positive aspects of fewer papers to handle, file, retain, refresh, retrieve, etc. were enthusiastically supported. However, the conflicting dilemma that such a change might have an impact on audit success tempered that initial enthusiasm. Equipment managers' fundamental belief is that both ISO/IEC17025 and ISO9001 auditors would not recognize or be comfortable with such a 'virtual' record system. This fear alone would deter them from seriously considering any such change.

This collective feedback formed the basis of a discussion between Agilent in Britain and senior officials from the United Kingdom Accreditation Service, the agency responsible for both accrediting calibration/test labs and overseeing quality management system registrars. The goal was to establish, for the record, whether UKAS would endorse a paperless system. The outcome of this meeting is summarized in a letter from the Technical Director of UKAS, which summarized that the responsibility of the user of calibration services (the customer)

"....is to be able to demonstrate to the assessor that it can, and does when needed, obtain evidence of calibration and that it has an effective records system enabling tracking back of full calibration data and certification for the defined period."

This doesn't mean that records are necessarily kept locally by the equipment-user in paper form but that they could, indeed, be retained by the supplier of the service and provided when needed at any time in the future. In most cases, the only data a company needs in real-time relates to parameters found to be outside the instrument's specification when initially tested (on-receipt status) so that a potential product-recall process may be invoked. But even this doesn't need to be provided on paper — it could be made available to the customer via the Internet (e.g. e-mail or a secure web server such as Agilent's Infoline) or through a variety of other electronic means (CD-ROM, memory stick, etc.).

Control is Crucial not the Mechanism

Whichever medium is most appropriate, it is the evidence of control that is imperative, not the evidence of paperwork as explained in the following extract from UKAS' letter:

"In principle, your customers would be able to contract you to retain their calibration records; this arrangement would then become part of their system for retention of records. UKAS assessment of such a customer would address whether this system provided access that was easy, quick and reliable and controlled from the point of view of security, confidentiality and accuracy. Assuming this to be so in practice then the system would be acceptable to UKAS."

This alternative solution is, therefore, one which UKAS would support provided that the customer and the supplier met some key requirements. Those requirements were concisely detailed:

"The documentation of such records and certification is acceptable in any form of medium, hard copy, electronic, etc. provided that it is legible, dated, readily identifiable, retrievable, secure and maintained in facilities that provide a suitable environment to minimize deterioration or damage and to prevent loss."

Dispelling Reluctance

So, the voice of industry is clear. It would like to take advantage of contemporary technology by contracting-out its data and certificate storage requirements and, provided that their suppliers could satisfy their needs (echoed by the needs of UKAS above), they are willing to forego historical practices by trusting virtual documentation. But the most significant reason that they are reluctant to take this step is fear of audit failure.

Agilent Technologies believe that a major step forward would be made if quality system and accreditation consultants and assessors could advise their clients that, far from impeding audit success, such a move could enhance it — *while at the same time saving space, time and ultimately money for both the equipment owner and calibration provider*.

- Find your calibration certificates on **Infoline**

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Revised: October 11, 2012

Product specifications and descriptions in this document subject to change without notice.

This white paper was originally published in June 2001 and has been republished but not updated in 2012.

Published in USA, January 25, 2012
5991-1706EN

Agilent Technologies