

Security for software

Various agencies are becoming increasingly concerned over the integrity of control software, writes Martin Keay. The FDA's demand for electronic signatures is one example.

Until recently there has been an unspoken assumption that, provided critical control circuits on machines are hard-wired, it is quite acceptable for software controlling other aspects of the equipment to be written in any structure and left unprotected, allowing anyone to modify the software at a later date, leaving no record.

However, this assumption is now being challenged by safety inspectors, the American FDA and weights and measures institutions.

These agencies are responding to growing evidence that as machines become more dependent on software for their function, the integrity of the software is becoming a crucial factor in assuring the integrity of the machine.

Concerns over software integrity have led to publication of the international standard BS EN 61508 *Functional safety of electrical/electronic/programmable electronic safety related systems*, but adoption of this standard is still quite limited with most manufacturers continuing to favour the hard-wired approach for safety circuits.

Weights and measures institutions such as the UK's National Weights and Measures Laboratory are becoming aware that, as measuring instruments make more use of software, it is impossible to separate parts of the software that control metrological functions from other non-metrological functions.

Indeed, new clauses regulating the writing and protection of software in weighing instruments are being drafted for the latest versions of the documents for checkweighers (OIML IR51) and automatic weighers (OIML IR61).

However, the most immediate concern for

processing and packaging machinery and pharmaceutical manufacturers is the FDA regulation on software and drug packaging machinery: *21 CFR Part 11 Electronic records; electronic signatures*. This has been under discussion with the industry since 1992 and the rule itself actually took effect in August 1997.

While machinery manufacturers will all be taking their own approaches to compliance based on their individual experiences, the following is a brief description of how one principal industry supplier, Newman Labelling Systems, approached the subject.

To quote the FDA: "21 CFR Part 11 is intended to create criteria for electronic record-keeping technologies while preserving the agency's ability to protect and promote the public health (eg by facilitating timely review and approval of safe and effective new medical products, conducting efficient audits of required records, and when necessary pursuing regulatory actions)."

Trustworthy and reliable

In other words, the FDA wants to ensure that electronic records and signatures are as trustworthy, reliable and in essence equivalent to paper records and handwritten signatures.

Significantly, the FDA has made it clear that there is no compulsion for pharmaceutical companies to use electronic record-keeping in any of their operations. Similarly there is no requirement for companies to choose all paper or all electronic record-keeping.

However, this has not stopped some pharmaceutical companies from making compliance obligatory on their suppliers whether or not the machinery has the facility or operational requirement for electronic record-keeping. Ultimately it

is the pharmaceutical manufacturer, not its suppliers, that is responsible to the FDA (or equivalent in other countries) for compliance with regulations.

Part 11 covers companies that choose to store and/or sign records electronically in place of paper documentation. This includes records submitted electronically to the FDA as well as those stored by the company but subject to inspection by the FDA. Part 11 is designed to ensure that there will be a clear audit trail available should any investigation ever be necessary.

Audit trail of actions

Fundamental to Part 11 is the need for a system that provides an audit trail of actions and the individuals responsible for each action. Any changes or additions made electronically must only be carried out by a properly authorised employee who will take responsibility for his or her actions. Ultimately, if something does go wrong, the FDA will be able to pinpoint where the mistake was made and who made it.

The first step Newman took was to evaluate its current product range as well as products in development. For existing machinery where there is no facility for password access and no capability for electronic record-keeping, Part 11 would not apply. Therefore, in such cases the continuing use of paper-based recordkeeping would be acceptable.

For machinery that does have the facility for electronic record-keeping (and where the application specifies), validation procedures covering design qualification, installation qualification and operational qualification should all be examined to ensure compliance with Part 11.

Should customers interpret the regulation as requiring a full fault log and audit trail with levels of password access, then an optional control panel running the necessary software is available.

A good source of information on how to best implement the 21 CFR Part 11 compliance programme is *21 CFR Part 11: Electronic records and electronic signatures guidance document*, produced jointly by ISPE and PDA. This new reference guide provides practical information on how to comply with the rule while highlighting and addressing common issues of concern. ■



Validation: Supporting documentation by Newman