HOW DOES THE DRAFT GUIDANCE ON 21 CFR PART 11 AFFECT MY EUROTHERM SYSTEM?

invensys
EUROTHERM

Which new guidance?

On 20 February 2003, the FDA published a new draft guidance document describing its current thinking regarding the scope and application of Part 11 of Title 21 of the Code of Federal Regulations; Electronic Records; Electronic Signatures. The guidance states that the FDA is embarking on a re-examination of Part 11 and that they may revise the provisions of Part 11 as a result of that re-examination. The draft guidance explains how the FDA intend to define the scope of Part 11 and exercise enforcement discretion over certain parts of the rule whilst this re-examination is under way.

Where can I find it?

The document can be found at http://www.fda.gov/cder/guidance/5505dft.doc

Why was it needed?

Concerns have been raised that some interpretations of the Part 11 requirements (particularly as applied to validation, audit trails, record retention, record copying, and legacy systems) would:

(1) unnecessarily restrict the use of electronic technology in a manner that is inconsistent with FDA's stated intent in issuing the rule,

(2) significantly increase the costs of compliance to an extent that was not contemplated at the time the rule was drafted, and

(3) discourage innovation and technological advances without providing a significant public health benefit.

So what has happened to the original rule and all the guidance related to it?

21 CFR Part 11 is still in force and it is important to note that the FDA's exercise of enforcement discretion is limited to the specified Part 11 requirements. All other provisions of Part 11 will still be enforced.

In order to avoid possible confusion, the previous draft guidance documents covering validation, glossary of terms, timestamps, maintenance of electronic records, electronic copies of electronic records have been withdrawn; as has the compliance policy guide 7153.17.

What is meant by a 'guidance document'?

The guidance is drafted as a Level 1 guidance document. Guidance documents reflect 'current thinking' and do not establish legally enforceable rights or responsibilities for either the public or the FDA. An alternative approach can be used provided it complies with the relevant statutes and regulations.

What is the current status?

At present the guidance is in draft form with comments and suggestions invited within 60 days of its publication. It is expected that any comments received will be reviewed and a final version prepared, published and implemented.

What changes are proposed?

A. Overall Approach to Part 11 Requirements

* Part 11 will be interpreted more narrowly with fewer records considered subject to Part 11 (see B below)
* Where records are subject to Part 11, enforcement discretion will be exercised over requirements for validation, audit trails, record retention, and record copying and in applying Part 11 to legacy systems (see C below).
* Predicate rule requirements will continue to be enforced.

B. Details of Approach – Scope of Part 11

The scope is narrowed to exclude merely incidental use of computers to generate paper printouts of electronic records provided that the paper records meet all the requirements of the predicate rules and are used to perform any regulated activities.

Part 11 still applies to:

* records required by predicate rules that are maintained in electronic format in place of paper format;
* records required by predicate rules that are maintained in electronic format in addition to paper format and are relied on to perform regulated activities;
* records submitted to FDA in electronic format,
* electronic signatures intended to be the equivalent of hand-written signatures, initials, and other general signings required by predicate rules .

C. Approach to Specific Part 11 Requirements

All of the closed system requirements from section 11.10 listed here also apply to the equivalent for open systems in 11.30:

1. Validation

Enforcement discretion will be exercised over the validation requirements in 11.10(a) ("to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records"). This does not remove the need for validation if it is required by a predicate rule.

2. Audit Trail

Enforcement discretion will be exercised over the audit trail requirements in 11.10 (e) ("Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records..."); and 11.10(k)(2) ("...procedures to maintain an audit trail that documents time-sequenced development and modification of systems documentation"). This does not remove the need to comply with predicate rule requirements related to documenting date, time, or sequencing of events. Even if there are no predicate rule requirements, it is recommended that a decision on whether to apply audit trails should be based on a justified and documented risk assessment.

3. Legacy Systems

Enforcement discretion will be exercised over legacy systems that otherwise met predicate rule requirements prior to August 20, 1997, the effective date of Part 11.

4. Copies of Records

Enforcement discretion will be exercised over the requirements in 11.10(b) ("The ability to generate accurate and complete copies of records in both human readable and electronic form..."). The emphasis is now on 'reasonable and useful access to records during an inspection' and on the use of (or automated conversion to) 'common portable formats' - for example pdf - whilst preserving the ability to search / sort / trend if it is technically feasible.

5. Record Retention

Enforcement discretion will be exercised over the requirements in 11.10(c) ("Protection of records to enable their accurate and ready retrieval throughout the records retention period"). Archival to another format during the retention period (eg to paper or to a standard electronic format such as pdf) will be permitted provided that predicate rule requirements for retention and availability are met and context and meaning are preserved. Any format change (which might, for example, result in reduced ability to search or sort data) should be based on a justified and documented risk assessment taking into account any change in the value of the records over time. Hybrid systems where data has both an electronic and a paper component will be permitted as long as predicate rule requirements are met and the content and meaning are preserved.

What Impact Will This Have On My Eurotherm System?

a) Narrower scope of Part 11

A Eurotherm Suite, T800 Visual Supervisor or 5000 Series Graphic Recorder system is, for many reasons, still likely to fall within the scope of Part 11:

- Any system which includes electronic signatures required by predicate rules falls within the scope.
- Any system from which records are submitted to the FDA in electronic format falls within the scope.
- Any system where the electronic version of the data is relied on to perform regulated activities falls within the scope (eg checking trends and alarm history as part of batch release)
- Any system where the electronic version of the data needs to be kept for future searching falls within the scope (eg in the event of a product recall, a search of the electronic version would be needed to identify affected batches)

A T800 Visual Supervisor used to monitor sterilisation cycles and print a cycle report might now be outside the scope provided that all required signatures are hand-written and the paper report (rather than any electronic version of it) is used for all regulated activities.

A 5000 Series Graphic Recorder used to monitor stability rooms might be within the scope (eg because electronic signatures are executed when setpoints / alarm thresholds are changed) whilst an excel template used to generate daily and weekly reports from the raw data is considered to be outside the scope (because it is merely incidental to producing a paper copy).

b) Enforcement Discretion over Validation Requirements

Most Eurotherm systems supplied to the regulated industry are covered by predicate rule 21 CFR 820.70(i) ("When computers or automated data processing systems are used as part of production or the quality system, the manufacturer shall validate computer software for its intended use according to an established protocol. All software changes shall be validated before approval and issuance. These validation activities and results shall be documented."). Validation is therefore still required, and generally needs to address issues of record integrity as well as those of process control functionality.

c) Enforcement Discretion over Audit Trail Requirements

Most Eurotherm systems are subject to predicate rules requiring people to be identified and their actions time-stamped. Run time audit trails will therefore still be needed for most applications. (For example, in a laboratory application 21 CFR 58.130(e) requires that "In automated data collection systems, the individual responsible for direct data input shall be identified at the time of data input. Any change in automated data entries shall be made so as not to obscure the original entry, shall indicate the reason for change, shall be dated, and the responsible individual shall be identified". For a production system 21 CFR 211.188 requires "Identification of the persons performing and directly supervising or checking each significant step in the operation" which, although possible to do through parallel manual recording, would be extremely cumbersome for anything but the simplest system).

d) Enforcement Discretion over Legacy Systems

For systems installed before August 20, 1997, this means that the Agency will not normally take regulatory action to enforce compliance with any part 11 requirements provided that the system complies with all applicable predicate rule requirements and is fit for the intended use.

e) Enforcement Discretion over Copies of Records

All Eurotherm Suite, T800 Visual Supervisor and 5000 Series Graphic Recorder systems already include tools which allow data to be exported in common portable formats (such as comma separated variable).

f) Enforcement Discretion over Record Retention

Decisions about what data should be retained, for how long, and in what format rest with the end user. When a Eurotherm system is to be retired, there are now many options for retention of the data without needing to keep the originating system available in order to read it:

- off-line viewing tools are often available to allow data to be viewed after the system has been retired.
- the export tools described in (e) can be used to transfer data to a portable format.
- data can be printed to paper (or to pdf format via Adobe Distiller)

EUROTHERM LIMITED UK
Faraday Close Durrington Worthing BN13 3PL United Kingdom
Tel. +44 (0)1903 268500 Fax +44 (0)1903 695666
Email info@eurotherm.co.uk
Web www.eurotherm.co.uk

EUROTHERM INC USA
741-F Miller Drive Leesburg VA 20175-8993
Tel. 1-703-443-0000 Fax 1-703-669-1300
Email info@eurotherm.com
Web www.eurotherm.com

© Copyright Eurotherm Limited 2003

All rights are strictly reserved. No part of this document may be reproduced, modified, or transmitted in any form by any means, nor may it be stored in a retrieval system other than for the purpose to act as an aid in operating the equipment to which the document relates, without the prior written permission of Eurotherm limited.

Eurotherm Limited pursues a policy of continuous development and product improvement. The specifications in this document may therefore be changed without notice. The information in this document is given in good faith, but is intended for guidance only. Eurotherm Limited will accept no responsibility for any losses arising from errors in this document.

Part No. HA027654U002 Issue 1 How does the draft guidance on 21 CFR PART 11 affect my Eurotherm System? Printed in England 03.03