

# Alcon Laboratories, Inc. Comments to FDA Docket No. 2004N-0133

## Agency: Food and Drug Administration, HHS

July 1, 2004

Thank you for the opportunity to comment on the Electronic Records/Electronic Signatures regulation and guidance during this re-exam period for Part 11.

The following are Alcon Laboratories, Inc. comments to the specified sections in Docket No. 2004N-0133:

IV. A. 1. (b) – Alcon agrees that the Part 11 Regulation should be revised to reflect the more narrow interpretation reflected in the “Scope and Application” guidance.

IV. A. 2. – Yes, revisions to definitions would help provide clarification. Examples of additional definitions and/or refined definitions are:

- ?? Clarification of “systems documentation” – for example, does this exclude vendor manuals and include system “as used” design/configuration documentation?
- ?? Definition of “predicate rule” – this definition would provide a consistent interpretation across industry
- ?? Definition of electronic signature (ESig) versus electronic identification (eID)
- ?? Clarification that an electronic record (Erecord) includes the associated metadata and accompanying audit trail info – it’s not just a stand-alone record
- ?? Definition of metadata – what is the FDA’s definition of this?
- ?? Define “records submitted to FDA”. Does this include records provided during an inspection, as well as records supplied during a product submission?

IV. A. 3. – See comments in D.2 and in A.2

IV. B. 1. – Yes, system documentation should be risk-based. Other risk-based areas of the Regulation should be operations system and device checks.

IV. B. 2. – See D.2 for example

IV. B. 3. – No – a standard approach will be less confusing to industry.

IV. B. 4. – Yes, open systems should have more stringent requirements than closed systems. But the Regulation should not dictate the specific controls to be implemented.

IV. B. 4. 1. – Yes, the validation requirements should be retained. The Regulation should clarify that validation includes requirements and testing for all of the applicable sections of Part 11.

IV. B. 4. 2. – The “Scope and Application” guidance on e-copies – section C. 4, lines 276-296 – should be incorporated into the Regulation.

IV. B. 4. 3. – Recommend the following clarifications related to audit trails:

- ?? Clarify that a full, automatic (electronic, time/date-stamped) audit trails are required when a predicate rules exists for the record and a user can create, modify, delete that record(s) during normal operations.
- ?? Clarify audit trails may be applied to non-predicate rule records based on potential effect on quality, safety and record integrity.
- ?? Clarify that the audit trails on the non-predicate rules records may be recorded by non-electronic methods
- ?? Clarify that system administrative functions which create, modify, delete predicate rule records require an audit trail of some nature (i.e., electronic or non-electronic methods are acceptable).

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- ?? Clarify that system administrative functions which create, modify, delete non-predicate rule records may require audit trails based on risk of the record.
- ?? The “Scope and Application guidance on audit trails – section C.2, lines 238-255 – should be incorporated into the Regulation.

IV. B. 4. 4. – Alcon disagrees that Part 11 be modified in this area. Alcon recommends FDA clarify the definition of “system documentation” and enable systems documentation to be risk-based (see A.2 and B.1).

IV. C. - No. Security breaches should be covered by system (risk-based) security practices and procedures and not by Part 11 specifically.

IV. D. 1. – If the Regulation is modified according to the “Scope and Application” guidance, compliance will be less costly than against the original (current) Regulation.

IV. D. 2. – Yes. Create an FDA matrix of predicate rules and applicable records/record types. For example:

Predicate rule(s)	Applicable records/record types
820.198(e)1-8	Investigation records ?? Device name ?? Date of complaint ?? Device identification ?? Investigation date ?? Investigation result ?? Etc...
211.122(c)	Shipment received records ?? Receipt ?? Exam/test ?? Acceptance/reject

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IV. D. 3. – Current industry interpretation of Part 11 discourages the use of new technology due to costs, available resources and delays from vendors. If the “Scope and Application” guidance is incorporated into the Part 11 Regulation, these factors should be reduced. If Part 11 is risk-based, the discouragement of going to new technology should be reduced.

IV. D. 4. – If FDA would standardize on a universal electronic identification methodology (i.e., SAFE) this would simplify security issues (which are current issues) and ease the burden to implement new technologies. Industry struggles with “what’s the baseline?”

IV. D. 5. – Guidance would be helpful to define that biometric methods should be employed for high-risk ESigs versus userid/password methods for lower risk ESigs.

IV. D. 6. – Interpretation of this area is that modifications can be made to legacy systems as long as the modifications do not adversely affect the system’s compliance to the predicate rules. Recommend clarifying this area within the Regulation.

IV. D. 7. – Record conversion is covered as part of computer system validation and should not be called out specifically in Part 11.

IV. D. 8. – No.