
Guidance for Industry

Part 11, Electronic Records; Electronic Signatures — Scope and Application

**U.S. Department of Health and Human Services
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Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)
Center for Food Safety and Applied Nutrition (CFSAN)
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Office of Regulatory Affairs (ORA)**

**August 2003
Pharmaceutical CGMPs**

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Part 11, Electronic Records; Electronic Signatures — Scope and Application

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33 As an outgrowth of its current good manufacturing practice (CGMP) initiative for human and
34 animal drugs and biologics,⁴ FDA is re-examining part 11 as it applies to all FDA regulated
35 products. We anticipate initiating rulemaking to change part 11 as a result of that re-
36 examination. This guidance explains that we will narrowly interpret the scope of part 11. While
37 the re-examination of part 11 is under way, we intend to exercise enforcement discretion with
38 respect to certain part 11 requirements. That is, we do not intend to take enforcement action to
39 enforce compliance with the validation, audit trail, record retention, and record copying
40 requirements of part 11 as explained in this guidance. However, records must still be maintained
41 or submitted in accordance with the underlying predicate rules, and the Agency can take
42 regulatory action for noncompliance with such predicate rules.

43
44 In addition, we intend to exercise enforcement discretion and do not intend to take (or
45 recommend) action to enforce any part 11 requirements with regard to systems that were
46 operational before August 20, 1997, the effective date of part 11 (commonly known as legacy
47 systems) under the circumstances described in section III.C.3 of this guidance.

48
49 ***Note that part 11 remains in effect*** and that this exercise of enforcement discretion applies only
50 as identified in this guidance.

51
52 FDA's guidance documents, including this guidance, do not establish legally enforceable
53 responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should
54 be viewed only as recommendations, unless specific regulatory or statutory requirements are
55 cited. The use of the word *should* in Agency guidances means that something is suggested or
56 recommended, but not required.

57 58 59 **II. BACKGROUND**

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61 In March of 1997, FDA issued final part 11 regulations that provide criteria for acceptance by
62 FDA, under certain circumstances, of electronic records, electronic signatures, and handwritten
63 signatures executed to electronic records as equivalent to paper records and handwritten
64 signatures executed on paper. These regulations, which apply to all FDA program areas, were
65 intended to permit the widest possible use of electronic technology, compatible with FDA's
66 responsibility to protect the public health.

67
68 After part 11 became effective in August 1997, significant discussions ensued among industry,
69 contractors, and the Agency concerning the interpretation and implementation of the regulations.
70 FDA has (1) spoken about part 11 at many conferences and met numerous times with an industry
71 coalition and other interested parties in an effort to hear more about potential part 11 issues; (2)
72 published a compliance policy guide, CPG 7153.17: Enforcement Policy: 21 CFR Part 11;
73 Electronic Records; Electronic Signatures; and (3) published numerous draft guidance
74 documents including the following:

⁴ See *Pharmaceutical CGMPs for the 21st Century: A Risk-Based Approach; A Science and Risk -Based Approach to Product Quality Regulation Incorporating an Integrated Quality Systems Approach* at www.fda.gov/oc/guidance/gmp.html.

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- *21 CFR Part 11; Electronic Records; Electronic Signatures, Validation*
- *21 CFR Part 11; Electronic Records; Electronic Signatures, Glossary of Terms*
- *21 CFR Part 11; Electronic Records; Electronic Signatures, Time Stamps*
- *21 CFR Part 11; Electronic Records; Electronic Signatures, Maintenance of Electronic Records*
- *21 CFR Part 11; Electronic Records; Electronic Signatures, Electronic Copies of Electronic Records*

Throughout all of these communications, concerns have been raised that some interpretations of the part 11 requirements 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. These concerns have been raised particularly in the areas of part 11 requirements for validation, audit trails, record retention, record copying, and legacy systems.

As a result of these concerns, we decided to review the part 11 documents and related issues, particularly in light of the Agency's CGMP initiative. In the *Federal Register* of February 4, 2003 (68 FR 5645), we announced the withdrawal of the draft guidance for industry, *21 CFR Part 11; Electronic Records; Electronic Signatures, Electronic Copies of Electronic Records*. We had decided we wanted to minimize industry time spent reviewing and commenting on the draft guidance when that draft guidance may no longer represent our approach under the CGMP initiative. Then, in the *Federal Register* of February 25, 2003 (68 FR 8775), we announced the withdrawal of the part 11 draft guidance documents on validation, glossary of terms, time stamps,⁵ maintenance of electronic records, and CPG 7153.17. We received valuable public comments on these draft guidances, and we plan to use that information to help with future decision-making with respect to part 11. We do not intend to re-issue these draft guidance documents or the CPG.

We are now re-examining part 11, and we anticipate initiating rulemaking to revise provisions of that regulation. To avoid unnecessary resource expenditures to comply with part 11 requirements, we are issuing this guidance to describe how we intend to exercise enforcement discretion with regard to certain part 11 requirements during the re-examination of part 11. As mentioned previously, part 11 remains in effect during this re-examination period.

III. DISCUSSION

A. Overall Approach to Part 11 Requirements

⁵ Although we withdrew the draft guidance on time stamps, our current thinking has not changed in that when using time stamps for systems that span different time zones, we do not expect you to record the signer's local time. When using time stamps, they should be implemented with a clear understanding of the time zone reference used. In such instances, system documentation should explain time zone references as well as zone acronyms or other naming conventions.

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116 As described in more detail below, the approach outlined in this guidance is based on three main
117 elements:

- 118
- 119 • Part 11 will be interpreted narrowly; we are now clarifying that fewer records will be
120 considered subject to part 11.
- 121 • For those records that remain subject to part 11, we intend to exercise enforcement
122 discretion with regard to part 11 requirements for validation, audit trails, record retention,
123 and record copying in the manner described in this guidance and with regard to all part 11
124 requirements for systems that were operational before the effective date of part 11 (also
125 known as legacy systems).
- 126 • We will enforce all predicate rule requirements, including predicate rule record and
127 recordkeeping requirements.

128 It is important to note that FDA's exercise of enforcement discretion as described in this
129 guidance is limited to specified part 11 requirements (setting aside legacy systems, as to which
130 the extent of enforcement discretion, under certain circumstances, will be more broad). We
131 intend to enforce all other provisions of part 11 including, but not limited to, certain controls for
132 closed systems in § 11.10. For example, we intend to enforce provisions related to the following
133 controls and requirements:

- 134
- 135 • limiting system access to authorized individuals
- 136 • use of operational system checks
- 137 • use of authority checks
- 138 • use of device checks
- 139 • determination that persons who develop, maintain, or use electronic systems have the
140 education, training, and experience to perform their assigned tasks
- 141 • establishment of and adherence to written policies that hold individuals accountable for
142 actions initiated under their electronic signatures
- 143 • appropriate controls over systems documentation
- 144 • controls for open systems corresponding to controls for closed systems bulleted above (§
145 11.30)
- 146 • requirements related to electronic signatures (e.g., §§ 11.50, 11.70, 11.100, 11.200, and
147 11.300)

148

149 We expect continued compliance with these provisions, and we will continue to enforce them.
150 Furthermore, persons must comply with applicable predicate rules, and records that are required
151 to be maintained or submitted must remain secure and reliable in accordance with the predicate
152 rules.

B. Details of Approach – Scope of Part 11

1. Narrow Interpretation of Scope

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158 We understand that there is some confusion about the scope of part 11. Some have understood
159 the scope of part 11 to be very broad. We believe that some of those broad interpretations could

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160 lead to unnecessary controls and costs and could discourage innovation and technological
161 advances without providing added benefit to the public health. As a result, we want to clarify
162 that the Agency intends to interpret the scope of part 11 narrowly.

163
164 Under the narrow interpretation of the scope of part 11, with respect to records required to be
165 maintained under predicate rules or submitted to FDA, when persons choose to use records in
166 electronic format in place of paper format, part 11 would apply. On the other hand, when
167 persons use computers to generate paper printouts of electronic records, and those paper records
168 meet all the requirements of the applicable predicate rules and persons rely on the paper records
169 to perform their regulated activities, FDA would generally not consider persons to be "using
170 electronic records in lieu of paper records" under §§ 11.2(a) and 11.2(b). In these instances, the
171 use of computer systems in the generation of paper records would not trigger part 11.

172 173 2. *Definition of Part 11 Records*

174
175 Under this narrow interpretation, FDA considers part 11 to be applicable to the following records
176 or signatures in electronic format (part 11 records or signatures):

- 177
178 • Records that are required to be maintained under predicate rule requirements and that are
179 maintained in electronic format *in place of paper format*. On the other hand, records (and
180 any associated signatures) that are not required to be retained under predicate rules, but
181 that are nonetheless maintained in electronic format, are not part 11 records.

182 We recommend that you determine, based on the predicate rules, whether specific records
183 are part 11 records. We recommend that you document such decisions.

- 184
185 • Records that are required to be maintained under predicate rules, that are maintained in
186 electronic format *in addition to paper format*, and that *are relied on to perform regulated*
187 *activities*.

188 In some cases, actual business practices may dictate whether you are *using* electronic
189 records instead of paper records under § 11.2(a). For example, if a record is required to
190 be maintained under a predicate rule and you use a computer to generate a paper printout
191 of the electronic records, but you nonetheless rely on the electronic record to perform
192 regulated activities, the Agency may consider you to be *using* the electronic record
193 instead of the paper record. That is, the Agency may take your business practices into
194 account in determining whether part 11 applies.

195 Accordingly, we recommend that, for each record required to be maintained under
196 predicate rules, you determine in advance whether you plan to rely on the electronic
197 record or paper record to perform regulated activities. We recommend that you
198 document this decision (e.g., in a Standard Operating Procedure (SOP), or specification
199 document).

- 200 • Records submitted to FDA, under predicate rules (even if such records are not
201 specifically identified in Agency regulations) in electronic format (assuming the records
202 have been identified in docket number 92S-0251 as the types of submissions the Agency
203 accepts in electronic format). However, a record that is not itself submitted, but is used

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204 in generating a submission, is not a part 11 record unless it is otherwise required to be
205 maintained under a predicate rule and it is maintained in electronic format.

- 206 • Electronic signatures that are intended to be the equivalent of handwritten signatures,
207 initials, and other general signings required by predicate rules. Part 11 signatures include
208 electronic signatures that are used, for example, to document the fact that certain events
209 or actions occurred in accordance with the predicate rule (e.g. *approved, reviewed, and*
210 *verified*).

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C. Approach to Specific Part 11 Requirements

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1. Validation

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The Agency intends to exercise enforcement discretion regarding specific part 11 requirements for validation of computerized systems (§ 11.10(a) and corresponding requirements in § 11.30). Although persons must still comply with all applicable predicate rule requirements for validation (e.g., 21 CFR 820.70(i)), this guidance should not be read to impose any additional requirements for validation.

We suggest that your decision to validate computerized systems, and the extent of the validation, take into account the impact the systems have on your ability to meet predicate rule requirements. You should also consider the impact those systems might have on the accuracy, reliability, integrity, availability, and authenticity of required records and signatures. Even if there is no predicate rule requirement to validate a system, in some instances it may still be important to validate the system.

We recommend that you base your approach on a justified and documented risk assessment and a determination of the potential of the system to affect product quality and safety, and record integrity. For instance, validation would not be important for a word processor used only to generate SOPs.

For further guidance on validation of computerized systems, see FDA's guidance for industry and FDA staff *General Principles of Software Validation* and also industry guidance such as the *GAMP 4 Guide* (See References).

2. Audit Trail

The Agency intends to exercise enforcement discretion regarding specific part 11 requirements related to computer-generated, time-stamped audit trails (§ 11.10 (e), (k)(2) and any corresponding requirement in §11.30). Persons must still comply with all applicable predicate rule requirements related to documentation of, for example, date (e.g., § 58.130(e)), time, or sequencing of events, as well as any requirements for ensuring that changes to records do not obscure previous entries.

Even if there are no predicate rule requirements to document, for example, date, time, or sequence of events in a particular instance, it may nonetheless be important to have audit trails or other physical, logical, or procedural security measures in place to ensure the trustworthiness and

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250 reliability of the records.⁶ We recommend that you base your decision on whether to apply audit
251 trails, or other appropriate measures, on the need to comply with predicate rule requirements, a
252 justified and documented risk assessment, and a determination of the potential effect on product
253 quality and safety and record integrity. We suggest that you apply appropriate controls based on
254 such an assessment. Audit trails can be particularly appropriate when users are expected to
255 create, modify, or delete regulated records during normal operation.

3. *Legacy Systems*⁷

259 The Agency intends to exercise enforcement discretion with respect to all part 11 requirements
260 for systems that otherwise were operational prior to August 20, 1997, the effective date of part
261 11, under the circumstances specified below.

263 This means that the Agency does not intend to take enforcement action to enforce compliance
264 with any part 11 requirements if all the following criteria are met for a specific system:

- 266 • The system was operational before the effective date.
- 267 • The system met all applicable predicate rule requirements before the effective date.
- 268 • The system currently meets all applicable predicate rule requirements.
- 269 • You have documented evidence and justification that the system is fit for its intended use
270 (including having an acceptable level of record security and integrity, if applicable).

272 If a system has been changed since August 20, 1997, and if the changes would prevent the
273 system from meeting predicate rule requirements, Part 11 controls should be applied to Part 11
274 records and signatures pursuant to the enforcement policy expressed in this guidance.

4. *Copies of Records*

278 The Agency intends to exercise enforcement discretion with regard to specific part 11
279 requirements for generating copies of records (§ 11.10 (b) and any corresponding requirement in
280 §11.30). You should provide an investigator with reasonable and useful access to records during
281 an inspection. All records held by you are subject to inspection in accordance with predicate
282 rules (e.g., §§ 211.180(c), (d), and 108.35(c)(3)(ii)).

284 We recommend that you supply copies of electronic records by:

- 286 • Producing copies of records held in common portable formats when records are
287 maintained in these formats
- 288 • Using established automated conversion or export methods, where available, to make
289 copies in a more common format (examples of such formats include, but are not limited
290 to, PDF, XML, or SGML)

⁶ Various guidance documents on information security are available (see References).

⁷ In this guidance document, we use the term *legacy system* to describe systems already in operation before the effective date of part 11.

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291 In each case, we recommend that the copying process used produces copies that preserve the
292 content and meaning of the record. If you have the ability to search, sort, or trend part 11
293 records, copies given to the Agency should provide the same capability if it is reasonable and
294 technically feasible. You should allow inspection, review, and copying of records in a human
295 readable form at your site using your hardware and following your established procedures and
296 techniques for accessing records.

297 298 5. *Record Retention* 299

300 The Agency intends to exercise enforcement discretion with regard to the part 11 requirements
301 for the protection of records to enable their accurate and ready retrieval throughout the records
302 retention period (§ 11.10 (c) and any corresponding requirement in §11.30). Persons must still
303 comply with all applicable predicate rule requirements for record retention and availability (e.g.,
304 §§ 211.180(c),(d), 108.25(g), and 108.35(h)).
305

306 We suggest that your decision on how to maintain records be based on predicate rule
307 requirements and that you base your decision on a justified and documented risk assessment and
308 a determination of the value of the records over time.
309

310 FDA does not intend to object if you decide to archive required records in electronic format to
311 nonelectronic media such as microfilm, microfiche, and paper, or to a standard electronic file
312 format (examples of such formats include, but are not limited to, PDF, XML, or SGML).
313 Persons must still comply with all predicate rule requirements, and the records themselves and
314 any copies of the required records should preserve their content and meaning. As long as
315 predicate rule requirements are fully satisfied and the content and meaning of the records are
316 preserved and archived, you can delete the electronic version of the records. In addition, paper
317 and electronic record and signature components can co-exist (i.e., a hybrid⁸ situation) as long as
318 predicate rule requirements are met and the content and meaning of those records are preserved.
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⁸ Examples of hybrid situations include combinations of paper records (or other nonelectronic media) and electronic records, paper records and electronic signatures, or handwritten signatures executed to electronic records.

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2. *General Principles of Software Validation; Final Guidance for Industry and FDA Staff* (FDA, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research, 2002) (<http://www.fda.gov/cdrh/comp/guidance/938.html>)
3. *Guidance for Industry, FDA Reviewers, and Compliance on Off-The-Shelf Software Use in Medical Devices* (FDA, Center for Devices and Radiological Health, 1999) (<http://www.fda.gov/cdrh/ode/guidance/585.html>)
4. *Pharmaceutical CGMPs for the 21st Century: A Risk-Based Approach; A Science and Risk-Based Approach to Product Quality Regulation Incorporating an Integrated Quality Systems Approach* (FDA 2002) (<http://www.fda.gov/oc/guidance/gmp.html>)

Industry References

1. *The Good Automated Manufacturing Practice (GAMP) Guide for Validation of Automated Systems, GAMP 4* (ISPE/GAMP Forum, 2001) (<http://www.ispe.org/gamp/>)
2. ISO/IEC 17799:2000 (BS 7799:2000) Information technology – Code of practice for information security management (ISO/IEC, 2000)
3. ISO 14971:2002 Medical Devices- Application of risk management to medical devices (ISO, 2001)