



National Archives and Records Administration

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm 1061
Rockville, MD 20852

Dear Sirs:

Thank you for the opportunity to comment on "Draft Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures, Glossary of Terms."

We believe that this guidance will be beneficial to Federal and non-Federal agencies and will guide them in employing procedures and controls to ensure the authenticity, integrity, and confidentiality of electronic records and electronic signatures.

A. Pertaining to the Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures Validation:

1. Under Section 5.2.1 - Validation Plan, in addition to the stated information, we recommend that review and update of the plan should occur on a regular basis and that this period of time should be stated in the plan (for example, the plan will be reviewed on an annual basis).
2. Under Section 5.2.2 - Validation Procedures, in addition to the stated information, we recommend that review and update of the procedures should occur on a regular basis and that this period of time should be stated in the Validation Plan (for example, the procedures will be reviewed on an annual basis).
3. Generally under Section 5.2 - Documentation of Validation Activity, the retention of the validation documentation is not addressed. We recommend that guidance be added stating that creation, maintenance, retention, and disposition of the documentation be addressed in the agency's records management policy and procedures, and records retention schedule. It is critical that validation documentation be retained as long as the electronic signatures and other electronic records to which the documentation relates.
4. Under Section 5.3 - Equipment Installation, the retention of the hardware and software system documentation is not addressed. We recommend that guidance be added stating that creation, maintenance, retention, and disposition of the documentation be addressed in the agency's records management policy and procedures, and records retention schedule.
5. Under the second bullet in Section 6.1.2 - Software Structural Integrity, no definition is given for the term "contemporary standards." We recommend using the same wording as appears under the first bullet in Section 5.4.2 - "consensus standards from national and international standards development organizations, such as those listed in Appendix A of this guidance."

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6. Under Section 6.2.1 – Internet Validation, the need for ensuring the confidentiality of data transfer is not stated. We recommend that the words “and if appropriate, confidential” be added to the first sentence of the second paragraph (“...when there are measures in place to ensure the accurate, complete, timely, and if appropriate, confidential transfer of data...”).

B. Pertaining to the Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures Glossary of Terms:

We recommend that two terms and their definitions be added to Section 3 – Definitions. The terms “authenticity” and “integrity” are used throughout the draft Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures Validation, but are never clearly defined in the context of electronic records. These terms are defined in the new International Standard on Information and documentation – Records management- Part 1: General (ISO 15480-1:2001(E)). The definitions from the ISO standard are:

Authenticity: An authentic record is one that is proven a) to be what it purports to be, b) to have been created or sent by the person purported to have created or sent it, and c) to have been created or sent at the time purported.

Integrity: The integrity of a record refers to its being complete and unaltered.

Thank you,



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Deputy Archivist of the United States