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# **Comments on the draft Guidance for Industry**

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

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*Docket Numbers: 03D-0060, 99D-1458, 00D-1538,  
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Dear sirs:

After carefully reading the new draft Guidance published last Thursday, I believe that such a dramatic change on the approach of Part 11 interpretation and practical application needs to clarify some concepts for better understanding of the new guidance and future re-examination.

At this early point, two comments come up, mainly because both have immediate practical implications in a lot of the Part 11 compliance plans that a lot of companies have been developing in the last two years.

The two comments are as follows:

**Related Guidance sections:**

149 *Under the narrow interpretation of the scope of Part 11, with respect to records required to*  
150 *be maintained or submitted, when persons choose to use records in electronic format in*  
151 *place of paper format, Part 11 would apply. On the other hand, when persons use*  
152 *computers to generate paper printouts of electronic records, those paper records meet all*  
153 *the requirements of the applicable predicate rules, and persons rely on the paper records to*  
154 *perform their regulated activities, the merely incidental use of computers in those instances*  
155 *would not trigger Part 11. In such instances, FDA would generally not consider persons to*  
156 *be "using electronic records in lieu of paper records" under §§ 11.2(a) and 11.2(b).*

And also:

171 *In some cases, actual business practices may dictate whether you are*  
172 *using electronic records instead of paper records under § 11.2(a). For*  
173 *example, if a record is required to be maintained by a predicate rule and*  
174 *you use a computer to generate a paper printout of the electronic records,*  
175 *but you nonetheless rely on the electronic record to perform regulated*  
176 *activities, the Agency may consider you to be using the electronic record*  
177 *instead of the paper record. That is, the Agency may take your business*  
178 *practices into account in determining whether Part 11 applies.*  
179 *Accordingly, we recommend that, for each record required to be*  
180 *maintained by predicate rules, you determine in advance whether you*  
181 *plan to rely on the electronic record or paper record to perform regulated*  
182 *activities. We recommend that your decision be documented (e.g., in a*  
183 *Standard Operating Procedure (SOP)).*

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### **Comment 1: Narrow Interpretation of Scope**

According to these sections it can be interpreted that persons can choose whether or not they are going to use electronic records to comply with the predicate rule.

A common example: an HPLC data acquisition and management system used in a QC lab. For this system and according to the above sections, the person could choose whether the analytical reports printed on paper (from electronic records) are the records used to meet the requirements GMP. Therefore, there is no need to ensure compliance to Part 11 controls for the data, methods and result files existing in the computer system (interpreted as electronic records prior to February 20<sup>th</sup>), since those files are not used to perform any regulated activity. Only the printed paper is used to perform such activities and therefore, this is the GMP record in this case.

Would this system be out of the scope of Part 11?

The same comment could be done for a SCADA system about the requirement of keeping the electronic file containing process data if you are attaching a printout of the process data, issued by the computer to the Batch Manufacturing Record.

I think more clarification is required regarding this “freedom for choosing” whether or not we should comply with Part 11 controls. It can be clear for some systems (management systems mainly) that Part 11 would apply. For them, it can be obvious that persons can take decisions and perform regulated activities depending on information directly displayed by the computer system. The business practices determine this. But it is not so clear for the above examples. I believe a lot of companies and persons, working in the last two years to ensure Part 11 compliance would appreciate a clarification on that point.

### **Comment 2: Metadata**

Also related to narrow interpretation.

The Guidance do not make any mention about the limits of the *metadata* concept. I understand that this would be maybe entering in too much detail for an scope and application guidance, but it should be born in mind that this concept has given rise to broader interpretations on the scope of Part 11. Under the consideration of *metadata* almost any information managed by a computer system, directly or remotely related to a “regulated record”, had the consideration of candidate to comply with Part 11 controls.

A clarification of this concept would also be appreciated.