

## Medtronic, Inc. Responses to “Topics for Discussion” in FDA Public Meeting Notice

Date 07/08/04	Document Public Meeting Question Responses to Docket No. 2004N-0133
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Question Section	Question #	Question	Comment/Rationale
Subpart A – General Provisions	1	We are interested in comments on FDA’s interpretation of the narrow scope of part 11 as discussed in the part 11 guidance and whether part 11 should be revised to implement the narrow interpretation described in the guidance.	<p>We agree with FDA’s narrow interpretation of scope found in the “Scope and Application” guidance in regard to records; “...when persons use computers to generate paper printouts of electronic records, and those paper records meet all the requirements of the applicable predicate rules and persons rely on the paper records to perform their regulated activities, FDA would generally not consider persons to be ‘using electronic records in lieu of paper records’”.</p> <p>In addition, we suggest incorporating the concept of risk assessment to further narrow the overall scope of Part 11. While the “Scope and Application” guidance narrows scope around specific Part 11 requirements, we believe it should be allowable to use risk assessment to determine which records are in scope of the entirety of Part 11.</p>
Subpart A – General Provisions	2	We are interested in comments on whether revisions to definitions in part 11 would help clarify a narrow approach and suggestions for any such revisions.	We suggest definitions be added for legacy systems and predicate rules.

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Subpart B – Electronic Records	1	We are interested in comments on whether there are other areas of part 11 that should incorporate the concept of a risk-based approach, detailed in the part 11 guidance (e.g., those that require operational system and device checks).	<p>We do not feel there are any other specific requirements of Part 11 that should incorporate the concept of a risk-based approach beyond FDA’s “Scope and Application” guidance on the application of risk to selecting media for record retention. In particular, we do not believe that risk should be applied to audit trails since the application of audit trails should be based upon predicate rule requirements for change control. We believe either predicate rules require change control or they do not, and consequently a risk assessment is unnecessary.</p> <p>However, in addition, we would like FDA to extend a risk-based approach to the overall scope of Part 11; to determine which records are in-scope of the regulation.</p>
Subpart B – Electronic Records	3	Should the requirements for electronic records submitted to FDA be separate from electronic records maintained to satisfy predicate rule requirements?	We do not feel separate requirements are necessary for either type of record.
Subpart B – Electronic Records	4	Should part 11 continue to differentiate between open systems and closed systems?	No, we do not feel Part 11 should differentiate between open and closed systems. We do not feel the existing “open system” requirements significantly enhance control and security.
Subpart B – Electronic Records – Individual Ctrl	1	Should we retain the validation provision under § 11.10(b) required to ensure that a system meets predicate rule requirements for validation?	No. Since validation is a predicate rule requirement, the inclusion of validation in Part 11 has caused significant confusion on the part of many in industry. As is stated in FDA’s “Scope and Application” guidance, “Although persons must still comply with all applicable predicate rule requirements for validation, ... this guidance should not be read to impose any additional requirements for validation.”
Subpart B – Electronic Records – Individual Ctrl	2b	What requirements would preserve record security and integrity and ensure that records are suitable for inspection, review, and copying by the agency?	We feel current Part 11 requirements relative to record security and integrity are sufficient to maintain the suitability of records for inspection, review and copying by the agency.
Subpart B – Electronic Records – Individual Ctrl	3	Should audit trail requirements include safeguards designed and implemented to deter, prevent, and document unauthorized record creation, modification, and deletion?	We do not believe additional safeguards are needed. The current requirements contained in Part 11 provide sufficient protection for records.

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Subpart B – Electronic Records – Individual Ctrl's	4	In light of how technology has developed since part 11 became effective, should part 11 be modified to incorporate concepts, such as configuration and document management, for all of a system's software and hardware?	We do not feel this is necessary. Configuration and document management are already sufficiently covered by predicate rule validation requirements.
Subpart C – Electronic Signatures	1	Should part 11 address investigations and follow-up when these security breaches occur?	We feel that this is already adequately covered by Part 11 subsection 11.300(d). However, we suggest removing “in an immediate and urgent manner” from this subsection. The approach to detect and report unauthorized use of passwords and/or identification codes should be determined based upon the unique requirements of the system being addressed.
Additional Questions	1	What are the economic ramifications of modifying part 11 based on the issues raised in this document?	It is too early to determine economic ramifications for issues raised in this document because there is no clear indication of what the rule will contain. This is an appropriate and welcome question once a draft of the regulation has been published.
Additional Questions	3	In what ways can part 11 discourage innovation?	<p>We feel the stringent requirements for implementing electronic signatures have negatively impacted their adoption and use. We suggest simplifying the execution of electronic signatures by allowing the system to supply one of the two e-signature components. In most cases one of the components, such as user ID, is created based on a predefined format to ensure uniqueness. Individuals other than the user may easily determine this component. Entry of one component that is unknown to others, such as a password, would provide the desired control mechanism. This would also allow removal of the onerous requirements for “continuous controlled session” in subsections 11.200(i) and 11.200(ii).</p> <p>Also, some common software applications that could encourage innovation may not be used because of the difficulty in making them compliant with Part 11 requirements. Examples of such software applications include Microsoft Excel and Microsoft Access.</p>

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Additional Questions	5	What risk-based approaches would help to ensure that electronic records have the appropriate levels of integrity and authenticity elements and that electronic signatures are legally binding and authentic?	<p>We are interested in a list of risk factors similar to those that were provided in FDA’s “Scope and Application” guidance; “...base your decision on a justified and documented risk assessment and a determination of the value of the records over time.”, and “... a determination of the potential effect on product quality and safety and record integrity.”</p> <p>However, we discourage referencing or endorsing industry standard risk approaches (such as FMEA, ISO 14971, etc.) that are not well suited for Part 11 risk analysis.</p>
Additional Questions	6a	What are stakeholder concerns in regards to modifications made to legacy systems in use as of August 1997?	We suggest simplifying the scope of legacy systems by applying only the two following criteria to determine if a system is considered a legacy system. First, the system was operational prior to August 20, 1997. Second, the system currently meets all applicable predicate rule requirements. We feel the most important factor should be that the system currently meets all applicable predicate rules. This allows for a more consistent interpretation of which legacy systems are in scope of Part 11.
Additional Questions	6b	Can the use of risk mitigation and appropriate controls eliminate concerns regarding legacy systems?	Rather than introducing risk mitigation, we believe a simplified definition of the scope of legacy systems is sufficient.
Additional Questions	7	Should part 11 address record conversion?	No. Predicate rules and the current Part 11 regulation provide sufficient guidance.
Additional Questions	8	Are there provisions of part 11 that should be augmented, modified, or deleted as a result of new technologies that have become available since part 11 was issued?	We feel the regulation should be simplified wherever possible to remove specific technology references.