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Dockets Management Office
Food and Drug Administration
5630 Fishers Lane
Room 1061, HFA-305
Rockville, MD 20853

RE: Docket Number 03D-0060: Draft Guidance: Part 11 Electronic Records, Electronic Signatures – Scope and Application

Dear Sir or Madam:

The IBM Corporation herein is submitting comments on the draft guidance entitled "Part 11 Electronic Records, Electronic Signatures – Scope and Application". As a key services, products and technology provider to a variety of industries, including the Pharmaceutical, Biotechnology and Medical Device industries, IBM appreciates the opportunity to comment on this critical guidance document.

While many of today's FDA regulated industries are highly vocal in their response to the 21 CFR Part 11 regulations, IBM maintains that many of the requirements defined by Part 11 are not limited solely to FDA-regulated industries. The requirements defined by this regulation are generally recognized by various non-FDA regulated industries as good systems practices expected of any organization where data security, integrity, reliability & authenticity are of importance; and where records must be retained in case of a future need to re-examine transactions or decisions made on the data. Our clients in banking and securities, defense, transportation (rail, air, shipping) and communications all practice good electronic records and computer systems management as part of their approach to good business practices IBM highly suggests reviewing these



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industries as models when considering the implications of the regulation and the guidance documents moving forward.

Furthermore, IBM maintains that it should not be the intent of this guidance document to diminish the industry's responsibilities with respect to 21 CFR Part 11 and that the agency should reiterate that 21 CFR Part 11 does in fact represent viable and enforceable legislation.

Ambiguities within the Guidance Document

During IBM's review of the guidance document, three key areas of ambiguities were identified where clarification by the agency is required in order for industry to be able to respond accordingly to meet the regulation's requirements. These ambiguities are discussed below.

First, one aspect of the draft guidance of particular concern is the ambiguity around the directives for assessing 21 CFR Part 11 compliance based upon a "*justified and documented risk assessment*". It is in the best interest of public health and safety that minimal criteria for defining levels of acceptable risk be provided and that the risk assessment approach adopted be robust, defensible and scientifically based. With a shift toward a risk-based approach to compliance, FDA inspections should be driven by the impact to product quality, patient safety, and good solid IT practices. Industry's approach to compliance should seek to manage the cost to the business without diminishing the importance of product quality and patient safety.

Second, IBM is concerned that the recent draft guidance has created the misperception within industry that 21 CFR Part 11 has been softened or even significantly repealed, and that it has greatly reduced the industry's responsibility with respect to compliance to the regulation. For this reason, clarification is needed on the agency's expectations for compliance by industry. The phrases "*not normally taking action*" or "*enforcement discretion*" in the draft guidance text implies that enforcement of the regulation will be arbitrary. Statements that include these terms and phrases provide no details for the basis of future agency decisions. Organizations must now assume that while agency enforcement actions are not probable, there are still situations, of unknown definition, that could result in inspection citations.

Furthermore, if the agency intends to maintain that the potential for enforcement is optional, IBM assumes that enforcement actions would not be arbitrary, but rather that the agency would take action when circumstances warrant a response. While not all such circumstances could be known at this point in time, the principles or conditions that would trigger such actions need to be defined.



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This is necessary to enable the industry to take appropriate steps to assure compliance based upon an understanding of when and/or how these conditions will or will not be applied. The agency needs to clearly state that enforcement actions will not be taken on the specified sections, for a specified period of time, or ever, if that is the intent.

Narrow Interpretation of Scope

The draft guidance indicates that the agency intends to narrow the scope of Part 11 and that the agency's approach will be based upon the following statements.

- *Part 11 will be interpreted narrowly, we (FDA) are now clarifying that fewer records will be considered subject to Part 11*
- *For those records that we (FDA) are now clarifying are subject to Part 11, we (FDA) intend to exercise enforcement discretion with regard to Part 11 requirements for validation, audit trails, record retention and record copying, in the manner described in this guidance, and in applying Part 11 to systems that were operational before the effective date of Part 11*
- *FDA will enforce predicate rule requirements for records that are subject to Part 11*

The above statements, however, do not clarify FDA's compliance expectations nor they do they address any relationship to risk. FDA needs to provide examples to clearly express what is meant by "*narrowing the scope*". The draft guidance seems to imply, for example, that Part 11 may not be applicable to ancillary e-records supporting a batch record (e.g. HPLC data/records) or e-records supporting a dossier submission (e.g. patient case report form (CRF) data).

Furthermore, in 21 CFR Part 11 (Summary), clearly states that this regulation was providing "*the criteria, under certain circumstances, of electronic records, electronic signatures, and handwritten signatures executed to electronic records as equivalent to paper records and handwritten signatures executed on paper*". The draft guidance seems to imply that e-records and e-signatures may not be held to the same legal standards and ramifications as paper records and handwritten signatures executed to paper.

IBM is concerned that if the agency chooses to adopt a narrow interpretation of Part 11 several unintended consequences may result. Including:

- Reducing the urgency with which industry moves to a paperless environment
- Reducing the significance of electronic records/electronic signature with respect to paper records/handwritten signature



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- Severely limiting the agency's ability to electronically manipulate or trend data due to an increased likelihood that the copy of record will be defined as the paper copy
- Severely limiting the agency's ability to review and verify the authenticity of records that do not fall under specific predicate rules

IBM suggests that the agency reconsider the impact not only to the industry but also the impact on FDA's mission to *"promote and protect the public health by helping safe and effective products reach the market in a timely way, and monitoring products for continued safety after they are in use"*.

Definition of Part 11 Records

The draft guidance suggests that computers used to generate paper printouts of electronic records represent *"merely an incidental use of computers"* and that this action would not trigger adherence to Part 11 compliance requirements. It is important to recognize, however, that a paper printout of an e-record does not diminish or neutralize the reliance on the original e-record. e-Records must be considered from two perspectives: e-records as documents (e.g. specifications, procedures) and e-records as data. Confusion occurs when the same statement logic is applied to both instances.

When the e-record is a document and the system used to generate the record is a word processor, that computer system may be *"merely incidental"* if the resulting printout is the approved paper document, which is then managed, copied/distributed, and stored as the paper original. Common practice, however, is to retain the e-record and to use that record as the basis for revision and the generation of additional copies for regulated activities (e.g. on-line display of a procedure during a task). In this case, it is not the "official" paper document, but the e-record that actually being used for the regulated activity.

When data are captured, calculated, or manipulated by a computer system, a paper printout of an e-record is only a form of displaying that e-record. The accuracy, integrity, authenticity and reliability of the paper printout are only as good as the veracity of the e-record from which the paper was generated. The e-record generating system (with its calculations, and data selection/manipulation logic) cannot be *"merely incidental"* to the paper printout, as the system is the source for the printed data.

The draft guidance should separately discuss the logic of *"merely incidental"* along the lines of e-records that are non-data-containing documents where a computer system is only an authoring tool; as opposed to a document management system that retains and distributes electronic documents. The draft



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guidance should also clarify that when data transactions are captured, generated from calculations or filtering logic, manipulated, stored, and retained by a computer system; that system cannot be "*merely incidental*" because it is the source of the paper printout.

In the draft guidance, the agency has indicated that records, which are required to be maintained by predicate rules, and which are maintained in electronic format, must be 21 CFR Part 11 compliant. IBM suggests that with the recent mandate for a system approach with a risk-based filter applied, that predicate named records and ancillary records that support product quality or patient safety should be considered within the scope of the regulation.

The draft guidance indicates that FDA is re-examining Part 11 as a result of the current good manufacturing practice (CGMP) initiative for human and animal drugs and biologics. IBM is concerned that this may create the misperception that the Part 11 regulation is focused mainly on GMPs. Regulations for maintaining records or submitting information to the agency include GMPs, GLPs, GCPs and the quality system regulation (21 CFR Part 820). In other words, the agency needs to clearly articulate, within the approved guidance document, that the electronic records/electronic signature regulation "*applies to all records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted, under any records requirements set forth in agency regulations*".

The draft guidance states "*records not required to be maintained by predicate rules, but that are nonetheless maintained in electronic format, are not Part 11 records*". While this statement would appear to be a straightforward restatement of 21 CFR Part 11.1(b), it does not resolve the issue of scope. There are different types of records that may be considered to be "required" under a predicate rule, but not specifically stated in the rule. For example:

1. Records not specifically named as a record per a predicate rule (e.g. elements of a batch record not specifically identified in §211.188)
2. Records that are captured to evidence compliance to rule sections (e.g. training records per §211.25 (a)(b); yield calculations and dual witnessing §211.103). These types of records are not specifically named as records in regulations, but are within scope of inspections and are often requested for review during an audit
3. Records not specifically named in a predicate rule at the time of creation but later used in a process. For example, records that are kept as part of the organization's quality processes, and potentially subject to inclusion in required activities such as the deviation resolution (§211.100), annual quality standards review (§211.180 (e)(1)), batch record review and



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- investigations (§211.192), CAPA analysis and investigations (§820.100) or statistical techniques (§820.250)
4. Records that do not represent observational data, but computer system management data (e.g. user profiles created by system administrators) or internally generated system records (e.g. signature/data linkages). These records are not required to meet predicate rule requirements, but are used to comply with sections of Part 11

The agency needs to clearly articulate within the approved guidance document if the agency will in fact limit the scope of auditable records to only those that are specifically named as such in a predicate rule, and not those records inferred or needed to comply with any predicate rule activities.

The draft guidance also indicates that *"a record that is not itself submitted, but is used in generating a submission is not part of a Part 11 record unless it is otherwise required to be maintained by a predicate rule and it is maintained in an electronic format"*. e-Records used in generating a submission, but not submitted directly, and which are not subject to predicate rules, are therefore not subject to an FDA audit. This is contrary to statements in 21 CFR Part 11 Preamble, comment 70. Here the agency clearly stated its desire to be able to make use of electronic means to conduct its examinations of the data *"to operate effectively, the agency must function on the same technological plane as industry. Just as firms realize efficiencies and benefits in the use of electronic records, FDA should be able to conduct audits efficiently and thoroughly using the same technology."* In other words, where firms perform computerized trend analyses of electronic records to improve their processes, FDA should be able to use computerized methods to audit electronic records to detect trends, inconsistencies, and potential problem areas. If FDA were restricted to reviewing only paper copies of those records, that process would severely impede its operations. The shift in thinking implied within the draft guidance would essentially limit the agency's ability to *"detect trends, inconsistencies, and potential problem areas"*, and therefore restrict the agency's operations. IBM therefore recommends that FDA reconsider any position that could potentially prevent the agency from using current information technologies.

System Validation

The agency has indicated in the draft guidance its intent to *"exercise enforcement discretion regarding the specific Part 11 requirements for validation of computerized systems (§11.10 (a) and corresponding requirements in §11.30)." IBM believes that validation, and in some instances installation qualification activities (e.g. database, desktop/laptop computers), is a fundamental requirement for the use of computerized systems in the*



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pharmaceutical, biotechnology and medical device industries. Furthermore, IBM strongly believes the definition of a computerized system must encompass the underlying infrastructure (networks, servers, operating systems, etc.), as well as, all operating procedures for supporting personnel and users. These concepts comprise standard good software engineering and good information technology practices which have been used in a variety of industries for several decades.

Validation provides a level of confidence that the system does what it is intended to do; is in a documented state of control; and that use of the system does not introduce any violation of the regulations. It is IBM's opinion that optional validation will lower the Public's trust in the industry overall. IBM suggests the following text for defining the scope of validation activities for inclusion in the final guidance document.

“Systems managing Part 11 records must be validated for accuracy, reliability, consistent intended performance and the ability to discern invalid or altered records”

“Systems generating paper records required by predicate rules should be validated for accuracy, reliability and consistent intended performance”

With respect to validation, the reference to GAMP 4 is only one of many methodologies that can be considered as a guide and particularly with respect to configurable, off-the-shelf-software (COTS), there are other methodologies industry may want to consider. The approach an organization uses to address validation and electronic references should be made by the individual organization. Numerous academic, industry, military, and state organizations have issued and recommended guidance on this subject. Examples are listed below:

Association for Computing Machinery (ACM)
American Bar Association
Carnegie Mellon University
Drug Information Association
IEEE Institute for Validation
Minnesota Historical Society, State Archives Department
National Institute of Standards and Technology (NIST), U.S. Department of Commerce
Pharmaceutical Development Association
State of Washington. *Electronic Authentication*



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Additionally, please see the following reference:

Design and Validation of Computer Protocols by Gerard J. Holzmann

"Readings in Archives and Electronic Records: Annotated Bibliography and Analysis of the Literature," in *Electronic Records Management Program Strategies*, ed. Margaret Hedstrom (Pittsburgh: Archives and Museum Informatics, 1993)

The list below contains links to web sites that are also useful references

["Collecting Computer-Based Evidence", NY Law Journal](#) (Collecting Computer-Based Evidence. [New York Law Journal](#). January 26, 1998. Feldman JE and Kohn RI)

["The Preservation of the Integrity of Electronic Records", Univ. of British Columbia](#) (The Preservation of the Integrity of Electronic Records. Eastwood TM, MacNeil H. Boston, MA. Kluwer Academic Publishers, 2002)

[A National Archives Strategy](#) for the Development and Implementation of Standards for the Creation, Transfer, Access, and Long-Term Storage of Electronic Records of the Federal Government (National Archives Technical Information Paper No. 8. June 1990. Archival Research and Evaluation Staff. National Archives and Records Administration)

[A Policy for Keeping Web-based Records in the Commonwealth Government](#) (National Archives of Australia. AtoR Project. Commonwealth of Australia, 2000)

[A Survey of Legal Issues Relating to the Security of Electronic Information](#) (Department of Justice Canada. Communications Branch, 284 Wellington Street, Ottawa, ON K1A 0H8)

[Admissibility of Electronic Records in Patent Interferences](#) (Admissibility of Electronic Records. Abstract. January 1, 1999. Intellectual Property Department. Practice Group: Electronics. Foley & Lardner Attorney at Law)

[Analysis and Development of Model Quality Guidelines for Electronic Records Management](#) (Building a National Strategy for Preservation: Issues in Digital Media Archiving. Commissioned for and sponsored by the National Digital Information Infrastructure and Preservation Program, Library of Congress, April 2002)



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[Archive Builders - Metrics for Electronic Records](#) (Measuring Scanned Documents, Born Digital Documents & Digital Storage. Gilheaney S. Archive Builders)

[Canadian Uniform Electronic Evidence Act](#) (Uniform Electronic Evidence Act. Uniform Law Conference of Canada. Ottawa, Ontario. 1997)

[Center For Electronic Recordkeeping and Archival Research](#) (CERAR, ETIA2. 1999)

[Delaware's Electronic Records Guidelines](#) (Model Guidelines for Electronic Records. The Delaware Public Archives. Dover, DE)

[Digital Storage - From Digits to Dust, Dr. John W.C. Van Bogart](#) (Magnetic Tape Life Expectancy 10-30 Years. Van Bogart JWC. National Media Lab. 13 March 1995)

[Digital to Microfilm Conversion: A Demonstration Project 1994-1996](#) (Final Report to the National Endowment of the Humanities. Digital to Microfilm Conversion. Kenney, AR. Cornell University Library Department of Preservation and Conservation, Ithaca, NY 14853)

[Digitale Archivering in Vlaamse Instellingen en Diensten](#) (Digital Archiving of the Electronic Register. Boudrez F, Van den Eynde S. Version 1.0. Legal Deposit Library D/2001/9.213/2. Antwerpen-Leuven, January 2001)

[Draft Guidelines on Managing Electronic Messages as Records, The Archives Authority of New South Wales, Australia](#) (Guidelines for Preparing a Functional Retention and Disposal Authority (DIRKS). State Records, New South Wales. February 2003)

[Electronic Records 101](#) (Electronic Records 101. Powerpoint presentation by Ruller TJ. New York State Archives and Records Administration)

[Electronic Records Research and Development Conference](#) (Records Management Software Guidelines. NY State Archives)

[Electronic records](#) (Secure Data Logistics for e-Business. Muller Media Conversions. Syntrex Inc., 2001)

[Functional Requirements For Evidence in Recordkeeping](#) (University of Pittsburgh. School of Library and Information Sciences. 1992-1996)



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[Guidance Document for Electronic Document Management Programs](#)
[Guidance Document for Electronic Document Management Prog](#) (Intranet Site Powerpoint Presentation. Public Affairs and Corporate Communications Office. Space and Naval Warfare Systems Command)

[Kansas Electronic Records Management Guidelines](#) (Kansas Electronic Record Management Guidelines. Kansas State Historical Society)

[Missouri Department of Archives and History Draft Electronic Records Guidelines](#) (State Archives. State of Missouri)

[Model Guidelines for Electronic Records - Delaware](#) (Delaware Public Archives. Policy Statement and Guidelines. Model Guidelines for Electronic Records)

[National Archives and Records Administration Center for Electronic Records](#) (US National Archives & Records Administration, 700 Pennsylvania Ave, Washington, DC, 20408)

[New Mexico Rule on Electronic Recordkeeping](#) (Performance Guidelines for the Legal Acceptance of Public Records. State Records Center and Archives, 404 Montezuma, Santa Fe, NM, 87503, Draft May 5, 1993)

[New York Electronic Recordkeeping Project: Related Web Sites](#) (Electronic Recordkeeping Project - Related Web Sites, Work supported in part by the National Historical Publications and Records Commission under Grant No. 96023. Center for Technology in Government. 1998)

[Ohio Electronic Records Committee](#) (Ohio Electronic Records Committee. 2002)

[Preservation of Electronic Records](#) (CoOL, a project of the Preservation Department of Stanford University Libraries, is a full text library of conservation information, covering a wide spectrum of topics of interest to those involved with the conservation of library, archives and museum materials, © 1994)

[Preserving Access to Digital Information \(PADI\) - What's Happening](#) (padiforum-l is a moderated discussion list for the exchange of news and ideas about digital preservation issues. National Library of Australia. Canberra. Act 2600. Australia)



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[Protection of the Integrity of Electronic Records Project](#) (InterPARES Project, International Research on Permanent Authentic Records in Electronic Systems. © 2002)

[Records Continuum Research Group](#) (Monash University. School of Information Management & System. © 1994-2001)

[Requirements and Options for the Digitization of the Illustration Collections of the National Museum of Natural History](#) (The report, sponsored by the National Museum of Natural History's Collections and Research Information System (CRIS) Development Program, is the result of a study to understand the requirements and alternatives for digital conversion of scientific illustration collections of the Museum. The analysis was undertaken by Mitretek Systems, McLean, Virginia. Specific digitization procedures, methods, and standards are being examined by the Museum within the framework of pilot projects to test the initial recommendations contained in the report, Smithsonian Institution. © 1996)

[US Naval Archival and Inactive Records Management Services](#) (Department of the Navy. Navel Research Laboratory, Archival/Historical Records Preservation. NRL Archivist, Code 5260)

[Uniform Electronic Transactions Act](#) (Electronic Transactions Act, The National Conference of Commissioners on Uniform State Laws; Drafts of Uniform and Model Acts, The [National Conference of Commissioners on Uniform State Laws](#) , in association with the [University of Pennsylvania Law School](#), makes these drafts of Uniform and Model Acts available to help fulfill their mission to distribute information to the public. Uniform Law Commissioners, 211 East Ontario Street, Suite 1300, Chicago, IL 60611, © 2003)

[University of British Columbia - Preservation of the Integrity of Electronic Records](#) (University of British Columbia. The Newsletter of Computing and Communications. February 1996)

[Victorian Electronic Records Strategy \(VERS\) Project - Final Report](#) (The *Victorian Electronic Records Strategy* or *VERS* is a framework of standards, guidance and implementation projects which is centred around the goal of reliably and authentically archiving electronic records created or managed by the Victorian government)

[Wisconsin Guidelines for Managing Electronic Information](#) (Wisconsin Historical Society Archives. Wisconsin Guidelines for Managing Electronic Information. Public Records and Forms Board, Madison, Wisconsin, 1993.



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This document was prepared under the joint sponsorship of the State Archives (State Historical Society of Wisconsin), the University of Wisconsin-Madison Division of Archives, and the Records Management Section of the Department of Administration. This has been endorsed by the Public Records and Forms Board)

Audit Trails

Appropriate controls (e.g. procedures) are required to ensure that electronic records are authentic and not falsified. IBM believes that audit trails are required in order for the to FDA verify the authenticity, reliability and integrity of electronic records. The draft guidance indicates that the agency intends to “*exercise enforcement discretion regarding the 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 date (e.g., §58.130(e)), time or sequence of events.* In order to meet the original intent of the regulation, IBM believes that enforcement discretion should not be considered for sections §11.10 and §11.30. IBM therefore suggest the following text for the lines 220-222:

“Persons must comply with all applicable predicate rule requirements related to documentation of (e.g., §58.130(e)) date, time or sequence of events and the non-obscuring of previously recorded information by record changes Part 11.10(e)”

Additionally, the wording for lines 224-232 seemed to be confusing and provides unclear guidance for industry. IBM therefore suggest the following text for lines 224-232:

“Records identified as Part 11 records must have audit trails or other physical, logical or procedural security measures to ensure the trustworthiness and reliability of the records”

Maintenance and Management of Legacy Systems

While many systems were "operational" prior to the rule's effective date, most systems have experienced significant changes in technology, programs, and application use since the regulation was enacted. Pre-1997 systems (legacy systems) may have the same name and primary functions as the current package, however, few systems today are of the same version. This therefore implies that these systems could (and should) have been updated for compliance



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with Part 11 during normal system upgrade processes. While the 5 month period for industry to bring their systems into compliance may have been inadequate, 6 years has now passed since 21 CFR Part 11 became federal code. Given the time that has already elapsed, IBM recommends no change to the original Part 11 requirement for legacy systems.

Copies of Records

The draft guidance suggests that organizations supply copies of electronic records *“using established automated conversion or export methods, where available, to make copies in a more common format (including PDF)”*. Due to the variety of type of records that can be generated, rather than recommending a specific format, FDA should recommend that any format utilized by industry be based upon good IT and record storage & retrieval practices. PDF is not necessarily an optimal or open format and other web based formats are available today that provide the search, sort and trending capabilities currently employed by the industry.

IBM acknowledges that copies of records must be produced using a format that minimizes the risk of falsification and that can be traced to the data stored electronically. Industry should select one or more non-proprietary formats that best apply to the record type. These may include SGML or XML for textual type of records and DB2 security for data records. Each organization should select the method for supplying records as part of their standard operating procedures.

Record Retention

The draft guidance states *“FDA normally does not intend to object if you decide to archive required records in electronic format to non-electronic media such as microfilm, microfiche, and paper, or to a standard electronic file format, such as PDF. Persons must still comply with all predicate rule requirements, and the records themselves and any copies of the required records should preserve their content and meaning. In addition, paper and electronic record and signature components can co-exist (i.e. hybrid situation) as long as predicate rule requirements are met and the content and meaning of those records is preserved”*. IBM recognizes the need for balancing declining risk with the rising cost of long-term archiving. IBM recommends FDA define a reasonable period of time after which records could be saved to another medium.

IBM also understands that all records are not necessarily created equal and that a common sense approach to record retention, based upon the criticality of the record (as it pertains to ensuring patient health & safety as well as product



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quality), needs to be addressed. IBM recommends FDA provide guidance for a balanced approach to record maintenance (retention). This approach, for example, could be based upon the varying risk to patient safety as a function of product lifecycle.



IBM appreciates this opportunity to publicly comment on the draft guidance document. IBM's intent is to highlight organizational, process and technological issues and concerns regarding the proposed changes to the scope and enforcement application of the rule.

Sincerely,

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