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April 25, 2003

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

Re: Docket Nos. 03D-0060, 99D-1458, 00D-1538, 00D-1543, 00D-1542, and 00D-1539
Draft Guidance for Industry on "Part 11, Electronic Records, Electronic Signatures- Scope and Application;" Availability of Draft Guidance and Withdrawal of Draft Part 11 Guidance Documents and a Compliance Policy Guide

To Whom It May Concern:

On behalf of the Diagnostic Imaging and Therapy Systems Division of the National Electrical Manufacturers Association, I am pleased to submit comments relative to the Draft Guidance for Industry on "Part 11, Electronic Records, Electronic Signatures- Scope and Application.

NEMA, the National Electrical Manufacturers Association, is the nation's largest trade association representing the electro-industry. NEMA's Diagnostic Imaging and Therapy Systems Division represents the majority of the nation's manufacturers of X-ray imaging, computed tomography, diagnostic ultrasound, radiation therapy, magnetic resonance imaging, and nuclear imaging equipment. In addition, the division represents manufacturers of picture archiving and communications systems.

NEMA has been working with the "Industry 21 CFR Part 11 Coalition". We reiterate some of the points made by the Coalition as well as by Coalition-member AdvaMed to emphasize NEMA's support of these concepts.

NEMA believes that Part 11 compliance should be an outgrowth of compliance with the Quality System or Good Manufacturing Practices regulation rather than an end in itself, and in the medical device industry such compliance is driven by risk management principles. In addition, the Guidance should explicitly state that the **risk-based approach should be applied to all Part 11 activities**. This would avoid an interpretation that the guidance applies risk-based approach only to the areas singled out for enforcement discretion (Validation, Audit Trails, Legacy Systems, Copies of Records, and Record Retention). We believe that the agency's intent is for manufacturers to apply a risk-based approach to their entire compliance effort for Part 11. FDA must make this clearer in the Final Guidance.

Further, the **concept of risk** to be considered should be unambiguously clarified. As in all compliance, risk in Part 11 compliance should be clarified to mean **"risk to the consumer" and "risk to the public**

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health" as opposed to "risk to the IT/computer system". The latter is a specialized field of computer/IT-security "risk to the system" (i e. from hackers, malicious logic, etc.) NEMA strongly supports that the higher-level definition of "risk to public health/risk to consumer" should be applied to the Part 11 risk-based approach. The lack of clarity today **causes small manufacturers to avoid electronic documents and records** in design and manufacturing precisely because of the ambiguous and often extreme requirements for IT systems with little public risk.

Such higher-level risk-based approach will also acknowledge that **some records have decreasing value over time**. This will assist both the FDA and regulated industry in determining what records need to be archived and for how long for long term record maintenance is one of the most difficult problems whose high cost can be managed if realistic values are assigned to aging records.

NEMA also believes that the agency should **explain the concept of enforcement discretion in greater detail** than it might usually do. Many may find the existing language vague, resulting in excessive or deficient implementation actions. **These actions could result in additional expense**, but will most surely result in confusion and unease. More detailed explanation will ensure that the guidance is understood and implemented according to agency expectations.

NEMA reiterates AdvaMed's argument regarding **legacy systems.** The simple definition of Legacy System (a system in service prior to the effective date of Part 11) is not practical. Most, if not all, such systems have been modified in some way since the inception of the regulation. Certainly, many were modified to address Y2k concerns. If one maintains that any modification to a system removes the legacy status, then there is no value to the guidance's exclusion of legacy systems.

There is a clear need for a **broader definition of legacy systems** that takes into account the normal maintenance and changes to systems that are necessary to keep them running properly and satisfying the needs of the enterprise. We suggest the following as a starting point for FDA consideration and possible discussions with industry to refine a working definition that will satisfy the needs of all parties.

Legacy Systems:

> A Legacy System is a computer system or application in use prior to August 20, 1997 and in continuous use since that date. At this time, Legacy Systems do not need to comply with all Part 11 requirements, but must comply with predicate rules—including validation, if applicable.
>
> If a major change or radical change were made to a computer system or application since August 20, 1997, it would no longer be considered a Legacy System. One determining factor would be whether the changes were substantial enough that there was an opportunity to address Part 11 controls. (There must be a documented risk assessment addressing the controls that are in place for the Legacy System to ensure compliance with predicate rules and the justification for maintaining the system without addressing Part 11 controls.) If Part 11 controls could have reasonably been addressed during the change, the system should not be considered a Legacy System. If only changes to maintain the system operation have been made since August 20, 1997, it would be

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considered a Legacy System. Legacy Systems must comply with predicate rules and with those Part 11 controls that will ensure the system is fit for use as determined by risk assessment.

NEMA commits to participate in future dialogue on these critical issues between industry and FDA to achieve optimum compliance at a reasonable cost that minimizes risk to the consumer and to the public health.

Sincerely,

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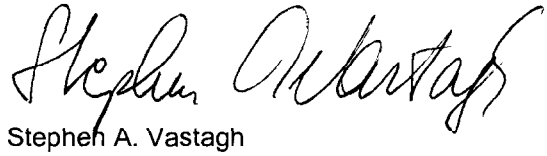

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