



Setting Standards for Excellence

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Vice President, Medical Products

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June 13, 2002

Dockets Management Branch
HFA-305
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. OOD-1538
Guidance for Industry 21 CFR Part 11; Electronic Records; Electronic Signatures
Validation

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 on the draft *Guidance for Industry 21 CFR Part 11; Electronic Records; Electronic Signatures Validation*.

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 more than ninety-five percent 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NEMA notes that the subject Part 11 draft Guidance on Validation appears to conflict with FDA's other issued documents on the subject (e.g. FDA General Principles of Software Validation; Final Guidance for Industry and FDA Staff, January 11, 2002). As an example there is a major conflict in acceptable approaches to validating off-the-shelf software. Numerous other examples have been cited in comments to the Public Docket. Given the thorough review that has been conducted by the public, industry and FDA of the "General Principles" Guidance, NEMA urges FDA to withdraw the Part 11 Draft Guidance on Validation until it can be re-drafted to align with the "General Principles" Validation Guidance.

In addition to reconciling the Part 11 draft Validation Guidance with the "General Principles" Final Guidance, the Part 11 Validation Guidance should also address validation of hybrid systems. Hybrid document systems have been widely used for many

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Manufacturers Association

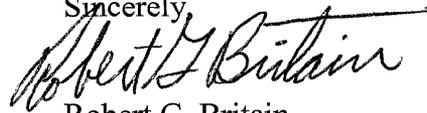
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years in industry as it has worked to comply with the requirements of 21CFR Part 11 without meaningful Part 11 implementation Guidances. FDA should provide alternative solutions allowing the validation of such systems in keeping with the spirit of the “Least Burdensome” principles adopted in the FDA Modernization Act of 1997.

Part 11 Guidances were adopted solely to regulate records or record-keeping software as specified in predicate rules. Of particular concern to industry is the point at which an electronic document or quality record becomes subject to Part 11. Practices acceptable prior to the Part 11 Rule did not accept draft documents as objective evidence of compliance. Part 11 appears to subject electronic drafts to the full requirements of released records. NEMA believes the implementation approach taken with Design Controls merits consideration. As the QSR rolled out Design Controls, FDA permitted the manufacturer the opportunity to declare the point where Research progressed to the point of becoming Development and thus subject to Design Controls. Similarly, industry would like electronic records to be permitted to be exempt from Part 11 until the manufacturer declares them to be a released or approved record. The disposition of this issue among others creates an urgent need for Part 11 Scope Guidance. NEMA urges FDA to accelerate the promulgation of a draft Part 11 Scope Guidance.

NEMA appreciates the opportunity to submit these comments.

Sincerely,



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