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Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, HFA – 305
Room 1061
Rockville, MD 20852

**RE: Docket No. 2004N – 0133
Part 11 regulations - Electronic Records and Electronic
Signatures**

Dear Sir/Madame:

The National Electrical Manufacturers Association (NEMA) wishes to express its appreciation to the Food and Drug Administration for affording us the opportunity to submit our comments on the regulation of electronic records and electronic signatures in the Part 11 regulations, 21 CFR Part 11. We wish to commend FDA on its decision to begin a dialogue with stakeholders on proposed changes to the Part 11 regulations

NEMA is the largest U.S. trade association representing America's electroindustry. The Diagnostic Imaging and Therapy Systems Division of NEMA represents manufacturers of x-ray imaging, CT, radiation therapy, magnetic resonance, nuclear medicine imaging, diagnostic ultrasound and medical imaging informatics equipment. NEMA is a member of the Part 11 Coalition, which is comprised of manufacturers of food, drugs and medical device products and other interested parties, which have an interest in Part 11 Regulations.

While we are pleased to submit our comments on proposed changes to the Part 11 regulations, NEMA first wishes to express serious concern about FDA's announcement that it does not intend to reschedule the meeting on Part 11 Regulations which was to be held on June 11, 2004. Discussion of proposed modifications to Part 11 regulations, and the importance of the Predicate Rules in the regulation of electronic records and signatures, are issues best addressed by establishing an ongoing dialogue between FDA and industry. The complexity and far reaching implications of these regulations strongly support holding a public meeting where the views of the agency and stakeholders can be fully aired.

It is clear that the importance of FDA's initial decision to hold a public meeting was underscored by the enormous response of representatives from the food, drug and medical device industry to participate in this meeting. A decision not to reschedule this meeting would be a mistake since it would dilute the input from stakeholders on these critical issues. We strongly urge the agency to reconsider its decision and convene this important forum at a later date.

In the following comments, NEMA wishes to particularly focus attention on question # 3 of the April 8, 2004 notice, particularly Part 11 Subpart B – Electronic Records:

“Under the current part 11, the controls that apply to electronic records that are maintained also apply to electronic records that are submitted to FDA. Should the requirements for electronic records submitted to FDA be separate from electronic records maintained to satisfy predicate rule requirements? ”

This question can best be addressed by an examination of the objectives of the Part 11 regulations as compared with the scope and objectives of the Predicate Rules.

Objectives of Part 11 Regulations

The original, intended, key objectives of the Part 11 regulations were to:

- Retain and document records
- Preserve and maintain the integrity and security of records
- Enable the FDA to be able to have access to records for copying and inspection
- Ensure authentication of electronic signatures
- Establish accountability for maintaining records
- Create a means for validation of signatures

NEMA believes that the meaning and purpose of these objectives are embodied in the Predicate Rules and therefore the simultaneous existence of Part 11 regulations and Predicate Rules serves only to create a duplicative and confusing regulatory scheme.

Critically, this duplication of regulations also conflicts with “least burdensome” principles. The intent of the “least burdensome” provisions of the Food and Drug Modernization Act (FDAMA) of 2002 stressed the need for minimizing excessive regulations. This is not the case with regard to the regulations governing electronic records and signatures. Instead of being able to rely upon a clear, single regulatory pathway, manufacturers are faced with the confusing task of sorting out the complexity of two parallel sets of regulations in order to ensure compliance with Part 11 requirements.

This problem is compounded by the overly prescriptive provisions of Part 11 regulations. The prescriptiveness of these regulations deprives the manufacturers of needed flexibility in maintaining compliance with the regulations.

Scope of the Predicate Rules –comparison with Part 11 Regulations

A review of the Predicate Rules demonstrates that these rules encompass the objectives of the Part 11 regulations. This is evidenced by an examination of the Quality System Regulation

(QSR) 21 CFR 820 et seq., Medical Device Reporting Regulation (MDR) 21 CFR 803 et seq., Corrections and Removals Regulation (C & R), 21 CFR 806 et seq. and Good Laboratory Practice Regulation (GLP) 21 CFR 58 et seq. (See Appendix A attached hereto).

It is crucial to recognize that the Predicate Rules embody the same intent as the Part 11 regulations, but do so in a far less prescriptive fashion.

For example, 21 CFR 11.10(a) states that controls for closed systems shall include “ Validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records.” Validation of systems is provided for in the QSR Regulation, 21 CFR 820.70(i), and through provisions for document controls, 21 CFR 820.40.

In 21 CFR 11.10(b), the regulation requires that controls be established to ensure the ability to generate accurate and complete copies of records in human readable or electronic form suitable for inspection and review. The QSR regulation, 21 CFR 820.40(a) and 21 CFR 820.180 provides that documents shall be available at all locations for which they are designated or otherwise necessary, and all records shall be maintained so as to be accessible to FDA personnel designated to perform inspections. Similarly, comparing the MDR regulations with Part 11 regulations, the MDR regulation requires the maintenance of records and required reports and electronic reporting to FDA in its provisions, namely 21 CFR 803.1, 803.10, and 803.14. Analogous provisions for the control of records to ensure access to FDA for inspection and review exist in the C& R regulation, specifically, 21 CFR 806.10 and 806.30, and in the GLP regulations, 21 CFR 58.15.

In the Part 11 regulations, 21 CFR 11.10 (c) requires that records be protected to enable their accurate and ready retrieval. Record preservation is an integral part of the Predicate Rules as well, as specified by the QSR in 21 CFR 820.20 and 21 CFR 820.180, in the MDR regulations, 21 CFR 803.1, in the C & R regulations, 21 CFR 806.1 and in the GLP regulations, 21 CFR 58.33 58.81, 58.190 and 58.195.

An important provision of the Part 11 regulations is the limitation of access to records to authorized individuals, 21 CFR 11.10(d). The limitation of access to records is incorporated in the QSR regulation 21 CFR 820.40 and 21 CFR 820.20, the document controls and management responsibility provisions, respectively. 21 CFR 820.40 document controls also addresses the use of computer-generated audit trails, as provided in the Part 11 Regulations, 21 CFR 11.10(e). Quality audit requirements for manufacturers are set forth in 21 CFR 820.22.

The Part 11 regulations are concerned also with operational system checks, 21 CFR 11.10(f) and device checks, 21 CFR 11.10(g). The QSR regulation addresses these areas in 21 CFR 820.70, Product/Process control. By virtue of 21 CFR 820.20, management has responsibility for ensuring that quality policy is understood, implemented and maintained at all levels, and that an adequate organizational structure and adequate resources are provided. Management responsibility also extends to encompass the use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or exercise other controls, as set forth in parallel in 21 CFR 11.10(g).

The duty of manufacturers to ensure that sufficient properly trained and experienced personnel to carry out the requirements of the QSR is set forth in 21 CFR 820.25. This encompasses the requirements in 21 CFR 11.10(i).

The Part 11 regulations in 21 CFR 11.10(j) require that policies be established and adhered to that hold individuals accountable and responsible for actions initiated under their electronic signatures. A corresponding duty is imposed on management under the QSR, specifically 21 CFR 820.20.

Part 11 regulations in 21 CFR 11.10(k) also require use of appropriate controls over systems documentation including adequate controls over distribution and access to and use of documentation for system operation and maintenance and putting in place revision and change control procedures to maintain an audit trail. Here again, these areas in the Part 11 regulations are covered in the QSR by 21 CFR 820.40. Similar controls exist in the MDR regulation, 21 CFR 803.10, 803.14 and 803.17 and 803.18. These areas are also addressed in the GLP regulation by 21 CFR 58.33, 58.35, 58.190 and 58.195.

In addition to satisfying the objectives of the Part 11 regulations, reliance on Predicate Rules conveys a number of other advantages. Predicate Rules are accepted by FDA and industry and are comprehensive in scope, having become an integral part of the established product approval, corrections and problem reporting processes. They are also a part of long-established medical device GMP practice. We believe the comprehensiveness of the Predicate Rules adequately protect the public health without resorting to the prescriptiveness of the Part 11 regulations.

The current Part 11 Final Guidance emphasizes the role of risk assessment for Part 11 controls dealing with validation, audit trails and record retention. In the Final Guidance it is stated that “We [FDA] recommend that you base your approach on a justified and documented risk assessment and a determination of the potential of the system to affect product quality and safety, and record integrity.”

NEMA wishes to commend FDA for taking this positive step with relation to Part 11 controls. We agree that a risk-based system is the logical and appropriate approach for the adoption of Part 11 controls. There are a number of risk-based approaches and tools, which can be employed to ensure product quality and safety, and to protect the integrity of records. Use of a risk-based approach should be defined and documented. However, it should not be too prescriptive or limited only to some areas of Part 11 controls. Manufacturers should be permitted to apply their own risk-based approach to any area pertaining to electronic records.

In conclusion, NEMA believes that based upon the comparison set forth above, the Part 11 regulations are duplicative of the Predicate Rules, and are burdensome and too prescriptive. We would propose that in order to eliminate duplication and confusion, that FDA withdraw the Part 11 regulations in favor of the Predicate Rules. As an alternative, Part 11 regulations should be converted to a less prescriptive, risk-based guidance document. This will allow manufacturers greater flexibility in complying with the Part 11 regulations while at the same time adequately protecting the public health.

NEMA appreciates the opportunity of presenting these views. NEMA's goal is to work collaboratively with FDA to achieve a practical regulatory pathway, which will satisfy the objectives of both FDA and industry.

If you have any further questions, please feel free to contact me. I can be reached at (703) 841 – 3241.

We look forward to further dialogue with you on these issues of great importance to FDA and industry.

Sincerely,

A handwritten signature in black ink that reads "Robert G. Britain". The signature is written in a cursive, flowing style.

Attachment

APPENDIX A

PREDICATE RULES DUPLICATED BY PART 11 REGULATIONS

PART 11 REGULATIONS

21 CFR 820-QSR REGULATIONS *

21 CFR 11.10(a)

Validation of systems

21 CFR 820.70

Production/Process Controls

21 CFR 11.10(b)

Controls for closed systems
Ability to generate accurate
and complete copies of
records in both human readable
and electronic form

21 CFR 820.40

Document Controls

21 CFR 820.180

General Requirements

21 CFR 11.10 (c)

Protection of records to enable
retrieval

21 CFR 820.40, 820.180

Document controls/General
Requirements

21 CFR 11.10(d)

Limiting access to authorized individuals

21 CFR 820.40

Document Controls

21 CFR 820.20

Management responsibility

21 CFR 11.10(e)

Use of secure computer-generated
Time-stamped audit trails to
Record date/time of operator
Entries and actions which create, modify
Or delete electronic records

21 CFR 820.40

Document Controls

21 CFR 11.10(f)

Use of operational system checks
to enforce permitted sequencing of steps
and events, as appropriate

21 CFR 820.20

Management responsibility

21 CFR 11.10(g)

Use of authority checks to ensure that
only authorized individuals can use the
the operation or computer system input or
output device, alter a record, or perform
the operation at hand

21 CFR 820.20

Management responsibility

21 CFR 11.10(h)

Use of device (e.g. terminal) checks
to determine the validity of the source
of data input or operational instruction

21 CFR 820.25

Personnel

PART 11 REGULATIONS

21 CFR 11.10(i)
Determination that persons who develop, maintain or use electronic record/electronic signature systems have the education, training and experience to perform their assigned tasks

21 CFR 11.10(j)
Establishment of policies that hold individuals accountable

21 CFR 11.10(k)
System Documentation controls

- (1) Adequate controls over the distribution of, access to, and use of documentation for system operation and maintenance
- (2) Revision and change control procedures
To maintain an audit trail

PART 11 REGULATIONS

21 CFR 11.10(b)
Controls – generate copies of records for inspection

21 CFR 11.10(c)
Protection of records to enable retrieval

21 CFR 11.10(b)
Controls

21 CFR 11.10(b)
Controls

21 CFR 11.10(k)
System Documentation Controls

21 CFR 11.10(e)
Audit Trails

21 CFR 11.10(k)
System Documentation Controls

21 CFR 820 – QSR REGULATIONS *

21 CFR 820.25
Personnel

21 CFR 820.20
Management Responsibility

21 CFR 820.40
Document controls

21 CFR 803 –MDR REGULATIONS *

21 CFR 803.1
Maintain Records

21 CFR 803.1
Maintain Records

21 CFR 803.10
Required Reports

21 CFR 803.14
Electronic Reporting

21 CFR 803.17
Written MDR Procedures

21 CFR 803.18
File/Distributor
Reports (MDR events)

21 CFR 803.18
File/Distributor
Reports (MDR events)

PART 11 REGULATIONS

21 CFR 11.10(b)
Controls

21 CFR 11.10(c)
Protection of Records

21 CFR 11.10(b)
Controls

21 CFR 11.10(b)
Controls

PART 11 REGULATIONS

21 CFR 11.10(b)
Records for Inspection

21 CFR 11.10(i)
Education/Training of Personnel

21 CFR 11.10 (c)
Protection of Records

21 CFR 11.10(k)
System Documentation Controls

21 CFR 11.10(g)
Authority System Checks

21 CFR 11.10(k)
System Documentation Controls

21 CFR 11.30
Controls over Open Systems

21 CFR 11.10(c)
Protection of Records

21 CFR 806 - CORRECTION AND
REMOVALS REGULATIONS *

21 CFR 806.1
Maintain Records

21 CFR 806.1
Maintain Records

21 CFR 806.10
Corrections and Removals Reports

21 CFR 806.30
FDA Access to Records

21 CFR 58 - GOOD LAB. PRACTICE
REGULATIONS *

21 CFR 58.15
Inspection of Records

21 CFR 58.29
Personnel – Education and Training

21 CFR 58.33
Study Director -
Responsibility for Documentation

21 CFR 58.33
Study Director-
Responsibility for Documentation

21 CFR 58.35
Quality Assurance Unit

21 CFR 58.35
Quality Assurance Unit

21 CFR 58.35
Quality Assurance Unit

21 CFR 58.81
Written Standard Operating
Procedures

PART 11 REGULATIONS

21 CFR 58 - GOOD LAB. PRACTICE
REGULATIONS *

21 CFR 11.10 (c)
Protection of Records

21 CFR 58.190
Storage and Retrieval of Records

21 CFR 11.10(k)
System Documentation Controls

21 CFR 58.190
Storage and Retrieval of Records

21 CFR 11.10(c)
Protection of Records

21 CFR 58.195
Retention of Records

21 CFR 11.10(k)
System Documentation Controls

21 CFR 58.195
Retention of Records

* NOTE: Intent of Predicate Rules is the same as Part 11 Regulations, but less prescriptive.