

COMPRESSED GAS ASSOCIATION

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July 9, 2004

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

Re: Docket No. 2004N-0133: Electronic Record; Electronic Signatures; Public Meeting,
Federal Register, Vol. 69, No. 68, pgs. 18591-18593, April 8, 2004

Dear Sir or Madam:

The Compressed Gas Association (CGA), CGA's member companies, and the Gases and Welding Distributors Association (GAWDA), appreciate the opportunity to comment on this docket.

CGA, founded in 1913, is dedicated to the development and promotion of safety standards and safe practices in the industrial and medical gas industry. CGA represents over 120 member companies in all facets of the industry—manufacturers, distributors, suppliers, and transporters of gases, cryogenic liquids, and related products and services. Through the committee system, CGA creates technical specifications, safety standards, training and educational materials, and works with government agencies to formulate responsible regulations and standards and to promote compliance with these regulations.

GAWDA, founded in 1946, is dedicated to the safe operations and economic vitality of independent distributors of industrial and medical gases and equipment. It represents over 800 member companies and provides them with compliance assistance and guidance directly through internal consultants. It is also very active in providing training and educational materials that promote safe operations and cGMP compliance. GAWDA participates actively with the CGA and its activities to create and promote responsible regulations and standards for the industry.

The medical gas industry constitutes over half of all registered drug manufacturers. As an important part of the medical gas industry, the CGA applauds the initiative taken by FDA to encourage the application of science and risk assessment to meet compliance requirements. Without question, this movement will encourage innovation through technology, which, over time, should beneficially impact health care costs while assuring the high standards of product quality and public safety are maintained and potentially enhanced. Following are our comments to the specific issues identified by the Agency in the referenced notice concerning "Electronic Record; Electronic Signatures".

2004N-0133

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Issue IV A.1 page 18592

Should Part 11 be revised to implement the narrow interpretation of scope described in the guidance?

CGA Comment

Yes. Part 11 regulations should be revised to implement the narrow interpretation of scope described in the current guidance. We believe there are adequate regulations already in place to control the authenticity, integrity, and where appropriate, the confidentiality of the records that would be excluded if the scope of the regulation is narrowed consistent with that described in the current guidance. For example record authenticity and integrity is an established premise of the existing current Good Manufacturing Practice regulation (21 CFR Parts 210 and 211). By eliminating from the scope of Part 11 those documents or records that may be incidentally generated via a computer but where the generated written document (as opposed to electronic document) is utilized to perform the predicate rule's regulatory function, reduces Part 11 implementation costs without sacrificing controls on record authenticity and integrity.

Issue IV A.2 page 18592

Should the definitions in Part 11 be revised to help clarify and help narrow the approach and, if so, what are your suggested revisions.

CGA Comment

We have no specific recommendations at this time.

Issue IV A.3 page 18592

Is there a need for clarification in Part 11 regarding which records are required by predicate rule and are therefore required to be Part 11 compliant?

CGA Comment

No. To specifically delineate those predicate rule records that may be subject to Part 11 would be redundant with an appropriately revised Part 11 Scope section. Specifically clarifying which predicate rule records may be subject to Part 11 would burden the Agency by requiring a Part 11 review (and possible revision) whenever a new potentially applicable regulation was developed, or when a current predicate rule (related to records) is revised. Decisions as to what records are covered and the degree of controls appropriate for that application should be made by each individual company following a risk based approach.

Issue IV B page 18592

How should decisions for using alternate controls be made?

CGA Comment

We support the application of a scientifically based risk assessment to determine the alternate controls appropriate for a given application.

Issue IV B.1 page 18592

Are there other areas of Part 11 that should incorporate the concept of a risk-based approach?

CGA Comment

The concept of a scientifically based risk assessment approach should have broad universal application for all areas of Part 11. Although perhaps outside the scope of the comments requested, we strongly support the concept of using a scientifically based risk assessment approaches to all agency regulations such as 21 CFR Parts 210 and 211.

Issue IV B.2 page 18592

Is additional clarity needed regarding how predicate rule requirements related to subpart B can be fulfilled?

CGA Comment

Additional clarity is not needed within the regulation itself.

Issue IV B.3 page 18592

Should the requirements for electronic records submitted to FDA be separate from electronic records maintained to satisfy predicate rule requirements?

CGA Comment

Yes. The requirements for electronic records submitted to the FDA should be separate from electronic records maintained to satisfy predicate rule requirements.

Issue IV B.4 page 18592

Should Part 11 continue to differentiate between open systems and closed systems?

CGA Comment

Yes. The regulation states that in addition to the controls for closed systems (§11.10), open systems would need the controls stipulated in §11.30. The additional controls for open systems would be merited when based on any potential additional risks introduced, such as from unauthorized use.

Issue IV (For individual controls) B.1 page 18593

Should we retain the validation provision under §11.10(b) required to ensure that a system meets predicate rule requirements for validation?

CGA Comment

This may not be necessary, since computer systems already require some level of validation based upon a risk evaluation.

Issue IV (For individual controls) B.2 (question 1) page 18593

Are there any related predicate rule requirements that you believe are necessary to preserve the content and meaning of records with respect to record copying and record retention?

CGA Comment

No. Creating additional requirements within Part 11 that are not stipulated in a predicate rule may create undue burdens not warranted by risk analysis.

Issue IV (For individual controls) B.2 (question 2) page 18593

What requirements would preserve record security and integrity and ensure that records are suitable for inspection, review, and copying by the agency?

CGA Comment

The requirements stated in the guidance document, pages 7 and 8, Copies of Records and Record Retention sections, are adequate to preserve record security and integrity and ensure that records are suitable for inspection, review, and copying by the agency.

Issue IV (For individual controls) B.3 page 18593

Should audit trail requirements include safeguards designed and implemented to deter, prevent, and document unauthorized record creation, modification, and deletion?

CGA Comment

The requirements stated in the guidance document, pages 6 and 7, Audit Trails, are adequate to provide safeguards to deter, prevent, and document unauthorized record creation, modification, and deletion.

Issue IV (For individual controls) B.4 page 18593

Should Part 11 be modified to incorporate concepts, such as configuration and document management, for all of a system's software and hardware?

CGA Comment

No. Part 11 already covers the requirements for configuration and documentation management. The comment for "all systems" should be reworded to state, "all process operation systems". The configuration and documentation of "off the shelf" type software would not be available for the end user.

Issue IV C page 18593

Section 11.10(d) requires that system access be limited to authorized individuals, but it does not address the handling of security breaches where an unauthorized individual accesses the system. Should Part 11 address investigations and follow-up when these security breaches occur?

CGA Comment

No. It is not necessary that Part 11 stipulate specific corrective and preventive actions (CAPA) requirements. This is a fundamental management issue and investigations would be performed to determine the appropriate corrective and preventive actions.

Issue IV D.1 page 18593

What are the economic ramifications of modifying Part 11 based on the issues raised in this document?

CGA Comment

Any movement that embraces scientific analysis and risk assessment to determine requirements would be economically beneficial relative to a broad inflexible approach to regulatory application. Further, it would encourage the use of technology with a positive cascade effect on manufacturing efficiency and subsequent economic benefit to consumers.

Issue IV D.2 page 18593

Is there a need to clarify in Part 11 which records are required by predicate rules where those records are not specifically identified in predicate rules?

CGA Comment

Part 11 is applicable only to electronic records where the predicate rule requires a paper record, therefore further clarification is unnecessary.

Issue IV D.3 page 18593

In what ways can Part 11 discourage innovation?

CGA Comment

Validation and prescriptive requirements that are not risk based, have the potential to add significant cost with no value added. Cost/benefit analysis is typically the basis for the application of technology.

Issue IV D.4 page 18593

What potential changes to Part 11 would encourage innovation and technical advances consistent with the agency's need to safeguard public health?

CGA Comment

Application of a risk based approach would encourage innovation and technical advances and would ensure appropriate focus on our mutual concern of public health.

Issue IV D.5 page 18593

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?

CGA Comment

Any recognized, scientifically based risk assessment should address these concerns.

Issue IV D.6 (question 1) page 18593

What are stakeholder concerns in regards to modifications made to legacy systems in use as of August 1997?

CGA Comment

Modifications should be made using a Management of Change (MOC) system.

Issue IV D.6 (question 2) page 18593

Can the use of risk mitigation and appropriate controls eliminate concerns regarding legacy systems?

CGA Comment

Yes. When used as part of a scientifically based risk assessment.

Issue IV D.7 page 18593

Should Part 11 address record conversion?

CGA Comment

No. It is adequately addressed in predicate rules.

Issue IV D.8 page 18593

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?

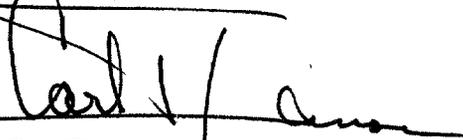
CGA Comment

Yes. See previous comment details.

The further application of science and risk assessment to meet compliance requirements will encourage innovation through technology, which, over time, should beneficially impact health care costs while maintaining and enhancing the high standards of product quality and public safety. We appreciate the opportunity to comment.

If you have any questions related to the comments we have provided, or wish to discuss them further, please do not hesitate to contact me at 703-788-2712.

Sincerely,



Carl T. Johnson
CGA President

cc: Joseph Famulare
David Horowitz