



**NFPA**  
*The Food Safety People*

January 29, 2002

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

NATIONAL  
FOOD  
PROCESSORS  
ASSOCIATION

Re: Docket No. 00D-1538  
Guidance for Industry 21 CFR Part 11; Electronic Records; Electronic  
Signatures Validation

Dear Sir or Madam:

The National Food Processors Association (NFPA) is the principal scientific trade association representing the \$500 billion food processing industry. With three laboratory centers, NFPA is the leading authority on food science and safety for the food industry. For more than 90 years, the food industry has relied on NFPA for government and regulatory affairs representation, scientific research, technical services, education, communications, and crisis management.

NFPA's scientists, government affairs, regulatory, and communications experts, provide assistance to member companies and work to ensure that laws and regulations governing the food industry have a sound scientific foundation.

NFPA offers the following main points on Validation:

1) One of NFPA's roles is to provide clear guidance and direction to the food industry in complying with the regulatory rules to ensure we provide a safe product to the consumers that pose no public health hazards. A document referred to as the Bulletin 43-L, "Guidelines for Automated Control of Food Processing Systems Used for Processing and Packaging of Preserved Foods," is currently being revised in support of the technology advancements and computer integrated manufacturing advances in the food industry. This document is the result of a cooperative effort on the parts of National Center for Food Safety and Technology, our food industry members(processors and suppliers), the Center for Food Safety and Applied Nutrition, the Food Safety Inspection Services, and NFPA staff.

In this document we state, "The assurance of the accurate operation of a computerized food processing system is contingent on proper system validation.

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The computerized process control industry has recognized that a properly validated system requires properly developed standard operating procedures. This has resulted in the creation of a number of national and international standards. These standards however, are general in nature and require specific protocols in order to be implemented within a given segment of an industry. Standards such as ISO/IEC 12207, Pharmaceutical Good Automated Manufacturing Practice (GAMP), and those developed by The Institute of Electrical and Electronics Engineers (IEEE) Inc. have helped define the types of procedures that should be used when developing computerized processing systems. The need then within the food processing community is to develop procedures and recommendations **specific to the food processing industry** where by standards such as these can be implemented.”

With that said, there appears to be numerous documents already in existence by the FDA regulated industries that address computer systems and software validation. We feel that the industry needs more specific guidance for compliance with Part 11, not another guideline on how to validate computer systems. If the intention is to “...describe the FDA current thinking regarding considerations in meeting the validation requirements of Part 11...” then, this document needs to be refocused on what is required to comply with part 11 and not on general principles of computer validation that are already outlined in existing guidelines as cited in references above. What’s important to note is guidelines are in existence and we can build off of those to develop our industry specific applications as in the Bulletin 43-L we make reference to for the food industry.

2) Legacy systems need to be properly addressed since these are systems in existence in the food manufacturing area. Some aged systems have no design specifications and/or requirements in place due to the date of installation, or change of ownership. Alternative methods of validation should be applied for these systems. NFPA is currently evaluating the proper manner to address this issue.

3) Mixed systems of electronic data capturing and paper based records are also predominant in the food industry and need to be addressed. Below are a few examples of the various methods practiced in the food industry,

- Record keeping sheet of paper on which all information is entered by hand at the time the information is gathered and is signed by hand by the information gatherer and reviewed and signed by hand by the supervisor within one working day.

- Record keeping is done on a form with pre-formatted information, which is kept in a computer. The information gatherer types the information into the computer at the time the information is gathered and the control system generates data. The information gathered electronically and information typed manually are printed as soon as a group is read. The form is signed by the information gatherer and reviewed and signed by the supervisor within one working day.
- Record keeping is done on a form with pre-formatted information, which is kept in a computer. All the information is gathered electronically and the data gathered is entered into the form by a computer. The individual responsible for the data acquisition verifies the data entered. At the end of the day, the form is printed out and is signed by hand by the individual responsible for the information gathered and reviewed and signed by the supervisor within one working day.

The food industry has traditionally captured these as paper records with appropriate manual audit trail procedures. This has been an accepted process by the FDA inspectors.

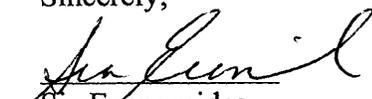
4) The validation of software and computer systems should be determined by the potential health risk that is associated with the record kept and the effect that the software/hardware have if not validated (a risk/benefit assessment of the records) and the economic burden associated with each system upgrade.

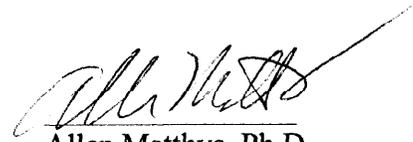
5) Overall, the comments made above reference back to understanding the scope of Part 11 in order to identify the specifics for implementation. We would recommend that the scope document be made available for comment before any final revisions are made to the already published and future guidance documents.

NFPA also offers the attached tabulated comments as they relate to the draft guidance document.

NFPA values the effort that the Agency is putting toward clarification of 21CFR Part 11 and appreciates the opportunity to share the food industries main concerns so that a workable solution is achieved and the food safety and public health safety are preserved. Thank you for providing this opportunity to comment.

Sincerely,

  
Sia Economides  
Sr. Scientist

  
Allen Matthys, Ph.D.  
V.P. Federal and State Regulations

### Comment Form

				Date	Document
				1/29/02	E-rec/sigs Validation
Commenter	Section	Paragraph Figure/ Table Line No.	Proposed Change	Comment/ Rationale	
NFPA	5.1	57 through 58	Add comment on Legacy Systems expectation and validation exceptions.	Some aged systems have no design specifications and/or requirements in place due to the date of installation, change of ownership over time from supplier to manufacturer.	
NFPA	5.2.1 to 5.2.3	88 through 102	The validation report should contain the following elements; test id, test design, expected outcome with quantifiable term, pass/fail, and comment. Likewise, the test id should be correlated to the generated objective evidence, i.e. control system electronic dataset and electronic signature printout. The validation report should be reviewed and approved by designated management.	Combine all sections, as one activity best exemplifies all of the validation tasks of 5.2.1 to 5.2.3. All logic testing is pass/fail, and it can be quantified with an objective verifiable amount.  Another comment disagreed with combining them.	
NFPA	5.4	120 through 127	Delete structural testing or Structural testing does not apply to the code of off-the-shelf software.	This type of testing is usually proprietary to the supplier and is rarely if ever shared with the end-user "manufacturer" that employs the software. To expect that the end-user is responsible for this type of testing is subjecting someone to a potential lawsuit. Software manufacturers should be responsible for supplying evidence that this activity is practised during their product development process.	
NFPA	5.4.3	135 through 137	Quantifiable test results should be recorded such that subsequent review and independent evaluation of the test results can be conducted.	All logic testing is pass/fail with the quantifiable term expressed in the expected results of the test design, and the test id correlates the test condition to objective evidence.	
NFPA	5.7	158 through 159	Add a third approach; (3) Builder to validate based on contractual agreements tied into the purchaser's user requirement specification and validation expectations or protocol.	Who better to understand the communication of the software and the interactions that the software has on hardware components that control a system than the supplier? We believe if the option of builder review is not allowed, then complete validation would be superficial. They are the "experts", and we should benefit from tapping into their expertise. The food industry does not have in-house validation departments like those found in some other industry.	
NFPA	6.1.3	210	Remove statement "that covers all functions"	Not all functions are necessary for testing; likewise some functions have no impact on public health safety.	
NFPA	6.1.3	217 through 218	Remove sentence "Note, however, we do not ... adequacy."	If functional testing "alone" is not sufficient to establish software adequacy, then what is?	
	6.2.1	223 through 239	In referencing the dynamic nature of the internet,	FDA is applying a loose validation approach which is contradictory to the remaining document.	