

**LOG-TEC[®] Control System...
Does FDA's new Part 11- Electronic Records; Electronic
Signatures Regulation Apply?**

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There are several control systems for food sterilization used in the food industry today. However, the most common and most powerful is the LOG-TEC control system produced by FMC Food Tech. A few years ago, FMC introduced their newest version of LOG-TEC called "LOG-TEC Momentum". Prior to that, the system in use was called the "LOG-TEC Model 9". There are nearly 1,000 LOG-TEC systems in use around the world today. Many of these are the older "model 9" systems. In light of the new FDA regulations covering Electronic Records (Part 11), the question is asked "Does Part 11 apply to LOG-TEC.

It is TechniCAL's opinion that Part 11 DOES NOT APPLY to the older LOG-TEC Model 9 systems... but it DOES APPLY to the newer LOG-TEC Momentum System. Let's take a look at Part 11....

21 CFR PART 11:

FDA published "21 CFR Part 11, Electronic Records; Electronic Signatures, FINAL RULE" on March 20, 1997. In that publication, FDA stated that it would give the industry 5 months from the publication date to be in compliance. Therefore, the rule went into effect on August 20, 1997.

However, over the past several years, there has been much discussion and debate between FDA and industry on Part 11 scope, requirements, and enforcement. FDA has not actively enforced Part 11, but had hinted that it will be doing so soon. FDA has published several documents related to Part 11, including:

- A compliance policy guideline CPG 7153.17
- An Enforcement policy
- And numerous Industry "Guidance Documents" drafts in an effort to help interpret particular sections of Part 11 for the industry

However, on February 4, 2003, FDA issued an announcement in the Federal Register that it was withdrawing one of their draft Guidance Documents

(Electronic Records; Electronic Signatures, Electronic Copies of Electronic Records).

And even more recently, on February 20, 2003, FDA issued another draft Guidance Document that stated that it was withdrawing all of the earlier draft Guidance Documents that have to do with:

- Validation
- Glossary of Terms
- Time stamps
- Maintenance of Electronic Records
- and also their FDA Compliance Policy Guideline

CP 7153.17

In that February 20, 2003 Guidance Document, FDA stated that they "*will re-examine Part 11 and we may revise provisions of that regulation. To avoid unnecessary expenditures of resources to comply with Part 11 requirements that may be revised through a rulemaking, we are issuing this guidance to describe how we intend to exercise enforcement discretion with regard to certain Part 11 requirements during the re-examination period.*"

In that Guidance Document, FDA goes on to interpret certain portions of Part 11. What they say in that document is very interesting and sheds new light on the older LOG-TEC "model 9" systems.

LOG-TEC[™] is control system product of the FMC Corporation.

In summary... after studying this new Guidance Document and going through Part 11 (regulation and preamble), it is TechniCAL's opinion that Part 11 **DOES NOT APPLY** to the older LOG-TEC Model 9 system. We make this claim based on two (2) main reasons....

REASON #1:

Part 11 applies to "paperless" computer systems. While the new LOG-TEC "Momentum" system is designed to be a paperless system, the older LOG-TEC "Model 9" system was not designed to be a paperless system. LOG-TEC Model 9 prints out a

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record of the process after each batch.... and that printed record is the official record that is used to meet the regulation.

21 CFR Part 11 states in the preamble, Part 11.1 (b) Page 13437 (March 20, 1997).....

"Part 11 is not intended to apply to computer systems that are merely incidental to the creation of paper records that are subsequently maintained in traditional paper-based systems. In such cases, the computer systems would function essentially like manual typewriters or pens and any signatures would be traditional hand-written signatures. Record storage and retrieval would be of the "file cabinet" variety. More importantly, overall reliability, trustworthiness, and FDA's ability to access the records would derive primarily from well-established and generally accepted procedures and controls for paper records.

When records intended to meet regulatory requirements are in electronic form, part 11 would apply to those records (including their creation, signing, modification, storage, access and retrieval). Thus the software and hardware used to create records that are retained in electronic form for purposes of meeting the regulations would be subject to part 11."

The February 14, 2003 Guidance Document further interprets the scope (lines 151-156)....

"...when persons use computers to generate paper printouts of electronic records, and those paper records meet all the requirements of the applicable predicate rule (such as 21 CFR 113), and persons rely on the paper records to perform their regulated activities, the merely incidental use of computers in those instances WOULD NOT trigger Part 11...."

Both of these statements by FDA (in the 1997 preamble and in the most recent Guidance Document) clearly state that if the "intent" of the computer system is to create a printed record that is used to meet the "predicate rule" requirements (such as the requirements in 113 to keep records), Part 11 DOES NOT apply to that system. Part 11 applies to computer systems that are intended to generate "paperless" records... where the need to ensure

security and change control is paramount (i.e. LOG-TEC Momentum). However, Part 11 does not apply to computer systems that are intended to generate "printed paper records" (i.e. LOG-TEC Model 9).

REASON #2

The LOG-TEC Model 9 system is considered a "Legacy System" because it was approved by FDA prior to August 20, 1997 as explained in Part 11 and, therefore, Part 11 does not apply.

The February 14, 2003 Guidance Document further interprets the term "Legacy System" as follows (lines 236-240)....

"The Agency intends to exercise enforcement discretion with regard to legacy systems that otherwise met predicate rule requirements prior to August 20, 1997, the effective date of Part 11. This means that the Agency will not normally take regulatory action to enforce compliance with any Part 11 requirements. However, all systems must comply with all applicable predicate rule requirements and should be fit for their intended use".

The LOG-TEC system was developed in the 1980's by TechniCAL and was approved by FDA to "meet the intent of the regulation 21 CFR 113" in a letter issued by FDA to TechniCAL dated June 18, 1984. This is obviously before August 20, 2997... therefore, the LOG-TEC system is considered a "legacy system" and (as stated in the 2/14/03 Guidance Document)..."*the Agency will not normally take regulatory action to enforce compliance with any Part 11 requirements*".

SUMMARY

In summary, now that FDA has further clarified their position on Part 11, it is obvious that Part 11 DOES NOT apply to the LOG-TEC Model 9 system. Therefore, validation of the system is completely "voluntary".

However, Part 11 DOES apply to the newer LOG-TEC MOMENTUM system. In that case, a complete validation program (among other requirements) is required under Part 11.



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