

21 CFR Part 11

General overview

about

21 CFR Part 11

valid version from 12.May.2010





❖ In August 1997, a new regulation from FDA was introduced, 21 CFR part 11 entitled “electronic records; Electronic signatures”

❖ 21 CFR Part 11 provides criteria under which FDA will consider electronic records to be equivalent to paper records, and electronic signatures equivalent to traditional handwritten signatures



The Way Achieve

“electronic records; Electronic signatures”

- ❖ Tradition recorder plus Audit-Trail
- ❖ SCADA Central Control System
- ❖ Christ Data logger plus Audit-Trail

SCADA---Supervisor Control And Data Acquisition



21 CFR Part 11

What is 21 CFR Part 11

21 CFR Part 11 regulates the scales like process data how they have to be treated if they are archived **electronic** or will be documented.

Thereby following have to be specially noted:

Data security

Data integrity

Audit-Trail

Password protection etc.

On the content of Part 11 will not be entertained here, since these guiding principles can easily be kept on application, and this would be in this extent too much and too profounding.



21 CFR Part 11

What falls under 21 CFR Part 11

- Parameter with immediate influence on the product :
- matters relating to quality (QR) ⇒ Predicate rules 21 CFR 211 Subpart D
- safety relevant (SR) ⇒ risk analysis according Gamp 5

- all parameters with indirect influence on the product quality.



CHRIST Using Siemens PCX77

Main Menu						Guest	3:58:47 PM 1/8/2008
Plant	No.	Time	Date	State	Text	Alarm Priorities	
						OSM	LOP




CHRIST


SOFTENER

OSMOTRON

LOOP0

Project No: 72770A Revision OSM: ###
 Revision Loop: ###












Christ Christ
 Aqu@View Data
 Logger Integrate with
 PC477,577Touch PC



Christ Aqu@View DataLogger

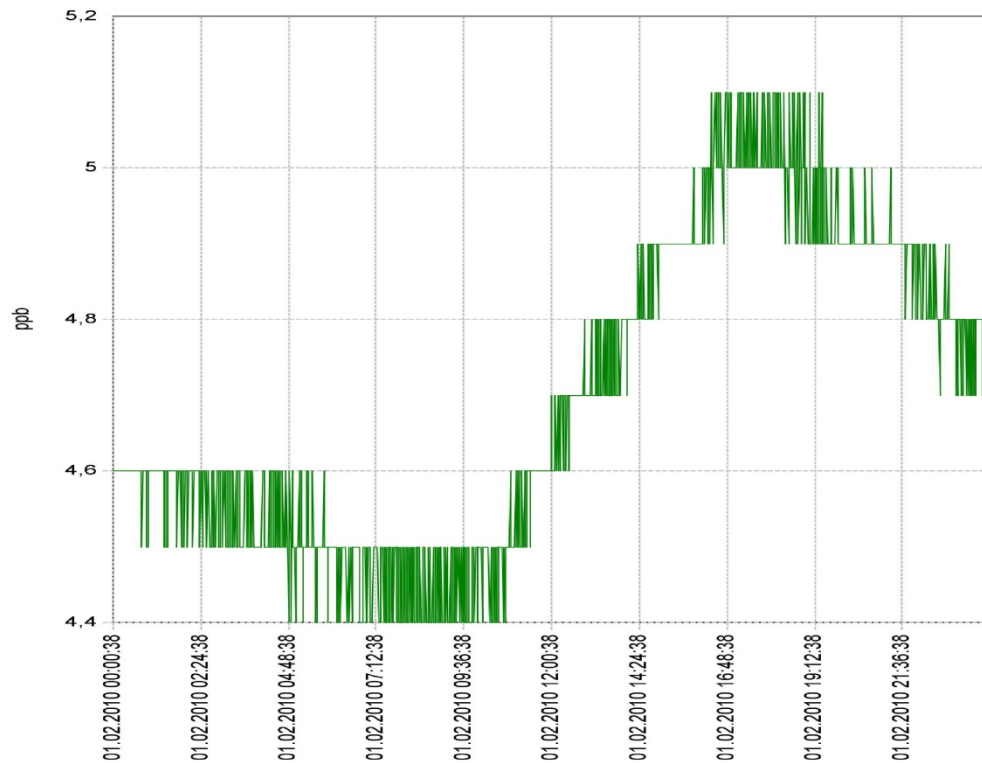


Report from CHRIST AQU@VIEW DataLogger

From: 01.02.2010 00:00:38
 To: 01.02.2010 23:59:38
 Channel: QE845.6.3 Loop Ret TOC [ppb]

Report generated at:
 02.02.2010 09:25:50
 Page: 1 / 2

Average Value: 4,7 ppb
 Minimum Value: 4,4 ppb @ 01.02.2010 09:19:38
 Maximum Value: 5,1 ppb @ 01.02.2010 17:37:38



Christ Aqu@View DataLogger



Report from CHRIST AQU@VIEW DataLogger

From: 01.02.2010 00:00:38
 To: 01.02.2010 23:59:38
 Channel: QE845.6.3 Loop Ret TOC [ppb]

Report generated at:
 02.02.2010 09:25:50
 Page: 2 / 2

Data Table:

Date	AVG [ppb]	MIN [ppb]	Timestamp	MAX [ppb]	Timestamp
2/1/2010: 00-01	4,6	4,5	00:58	4,6	00:51
2/1/2010: 01-02	4,6	4,5	01:56	4,6	01:03
2/1/2010: 02-03	4,6	4,5	02:56	4,6	02:20
2/1/2010: 03-04	4,5	4,5	03:44	4,6	03:02
2/1/2010: 04-05	4,5	4,4	04:53	4,6	04:06
2/1/2010: 05-06	4,5	4,4	05:35	4,6	05:08
2/1/2010: 06-07	4,5	4,4	06:32	4,5	06:23
2/1/2010: 07-08	4,5	4,4	07:53	4,5	07:02
2/1/2010: 08-09	4,4	4,4	08:23	4,5	08:14
2/1/2010: 09-10	4,4	4,4	09:19	4,5	09:27
2/1/2010: 10-11	4,5	4,4	10:19	4,6	10:52
2/1/2010: 11-12	4,6	4,5	11:19	4,7	12:00
2/1/2010: 12-13	4,7	4,6	12:08	4,8	12:54
2/1/2010: 13-14	4,7	4,7	13:04	4,8	13:54
2/1/2010: 14-15	4,8	4,7	14:04	4,9	14:58
2/1/2010: 15-16	4,9	4,9	15:04	5	15:53
2/1/2010: 16-17	5	4,9	16:05	5,1	16:51
2/1/2010: 17-18	5	5	17:35	5,1	17:37
2/1/2010: 18-19	5	4,9	18:45	5,1	18:06
2/1/2010: 19-20	4,9	4,9	19:37	5,1	19:24
2/1/2010: 20-21	4,9	4,9	20:48	5	20:14
2/1/2010: 21-22	4,9	4,8	21:59	5	21:17
2/1/2010: 22-23	4,8	4,7	22:38	4,9	22:04
2/1/2010: 23-24	4,8	4,7	23:52	4,8	23:11

Datum/Date

Visum/Signature



Siemens Audit Trail

Christ Audit Trail Viewer


Help

Select time frame
 Open Audit Trail file
 From: 2008-1-8
 To: 2008-1-8

Select Language
 Language 1
 Language 2
 Language 3

Filter Options
 User: [dropdown]
 Event: [dropdown]
 Object: [dropdown]

Status
 Audit Trail Integrity is OK.
 Total records: 21
 File loading finished after: 0 minutes

Integrity-Indicator 

Index	Timestamp	Timestamp	User	Real Name	User Login	Window	Event 1	Object 1	Old Value 1	New Value 1	Description 1
1	2008-1-8	2008-1-8				Alex.Zhu	License load error	SYSTEM	N/A	N/A	License loading failed: Co
2	2008-1-8	2008-1-8				Alex.Zhu	License load error	SYSTEM	N/A	N/A	License loading failed: Co
3	2008-1-8	2008-1-8				Alex.Zhu	Button clicked	btClose	N/A	N/A	
4	2008-1-8	2008-1-8				Alex.Zhu	Saving config failure	SYSTEM	N/A	N/A	Index was out of range. M
5	2008-1-8	2008-1-8				Alex.Zhu	Save config	SYSTEM	N/A	N/A	Config file saved.
6	2008-1-8	2008-1-8				Alex.Zhu	Change value	mtbUserName		christ	Config file saved.
7	2008-1-8	2008-1-8				Alex.Zhu	Button clicked	btOk	N/A	N/A	
8	2008-1-8	2008-1-8				Alex.Zhu	Change value	mtbUserName		christ	
9	2008-1-8	2008-1-8				Alex.Zhu	Change value	mtbRealName		christ	
10	2008-1-8	2008-1-8				Alex.Zhu	Button clicked	btApply	N/A	N/A	
11	2008-1-8	2008-1-8				Alex.Zhu	Button clicked	btOk	N/A	N/A	
12	2008-1-8	2008-1-8	christ	christ	1	Alex.Zhu	Logon	SYSTEM	N/A	N/A	User has logged on
13	2008-1-8	2008-1-8	christ	christ	1	Alex.Zhu	Saving config failure	SYSTEM	N/A	N/A	Index was out of range. M
14	2008-1-8	2008-1-8	christ	christ	1	Alex.Zhu	Save config	SYSTEM	N/A	N/A	Config file saved.
15	2008-1-8	2008-1-8	christ	christ	1	Alex.Zhu	Saving config failure	SYSTEM	N/A	N/A	Index was out of range. M
16	2008-1-8	2008-1-8	christ	christ	1	Alex.Zhu	Save config	SYSTEM	N/A	N/A	Config file saved.
17	2008-1-8	2008-1-8	christ	christ	1	Alex.Zhu	Saving config failure	SYSTEM	N/A	N/A	Index was out of range. M
18	2008-1-8	2008-1-8	christ	christ	1	Alex.Zhu	Save config	SYSTEM	N/A	N/A	Config file saved.
19	2008-1-8	2008-1-8	christ	christ	1	Alex.Zhu	Button clicked	btCancel	N/A	N/A	
20	2008-1-8	2008-1-8	christ	christ	1	Alex.Zhu	Open	Configuration	N/A	N/A	
21	2008-1-8	2008-1-8	christ	christ	1	Alex.Zhu	Switch back	HMI	N/A	N/A	

-- Tracking When? Who ? What?



21 CFR Part 11

Thank you for your attention

