

CENTUM CS 1000/CS 3000

Production Control Systems Meeting 21 CFR Part 11,
the U.S. Food and Drug Administration's Regulation



What is 21 CFR Part 11?

A set of regulations issued by the U.S. Food and Drug Administration (FDA) which provide criteria for acceptance of electronic records, electronic signatures, and handwritten signatures executed to electronic records.

CENTUM CS 1000/CS 3000 process control systems meet FDA 21 CFR Part 11 requirements

In 1997, the Food and Drug Administration (FDA) promulgated a code of federal regulations, 21 CFR Part 11, "Electronic Records; Electronic Signatures." 21 CFR Part 11 defines criteria for users who control records in electronic form instead of paper documents, to provide their systems with tighter security to assure integrity of system operations and information, such as data protection against unauthorized modifications.

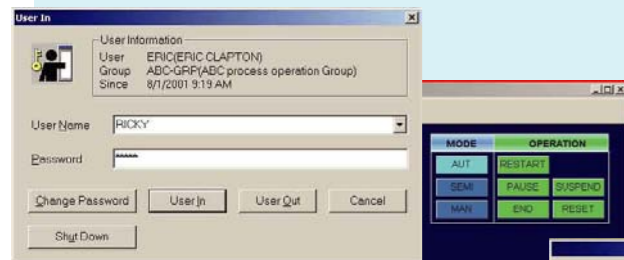
Yokogawa's CENTUM CS 1000/CS 3000 features highly reliable management of data directly input from the processes and records of operator actions, which are the basis of production records. CENTUM CS 1000/CS 3000 are ideal solutions for production control systems that require adherence to 21 CFR Part 11.

POINT 1 Privileges on System Access (Personnel Authentication)

Identifying individuals and limiting system access

The CENTUM CS 1000/CS 3000 can restrict operation by operators, system maintenance by system engineers, and recipe creation/modifications by recipe authors, all by authenticating individuals by user ID and password, or by user ID and fingerprint. Moreover, privilege levels can be assigned to individuals and set detailed limitations set on the objects (function blocks and windows) which can be operated by individuals for each level.

Dialog box requesting username and password for logging on to CENTUM CS 1000/CS 3000 system



Dialog box warning of an operator action not allowed under the privileges assigned



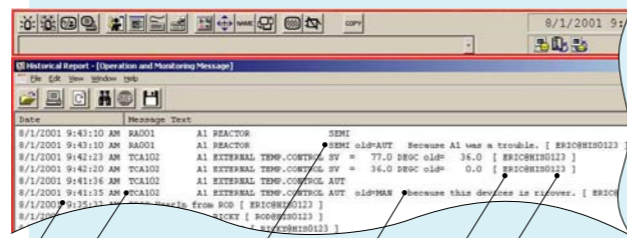
Biometric device for personnel authentication (Example: fingerprint ID device) (*1)



POINT 2 Secure Computer Generated Audit Trail

Automatically recording actions by operators and engineers

The CENTUM CS 1000/CS 3000 automatically records the when, who, what, where, why, and how of each operator entry or modification to data including actions by operators, system maintenance by system engineers, and recipe creation/modifications/deletions by recipe authors.



Historical report

Dialog box for confirmation of action (allowing the reason to be entered)



Differences shown in a different color

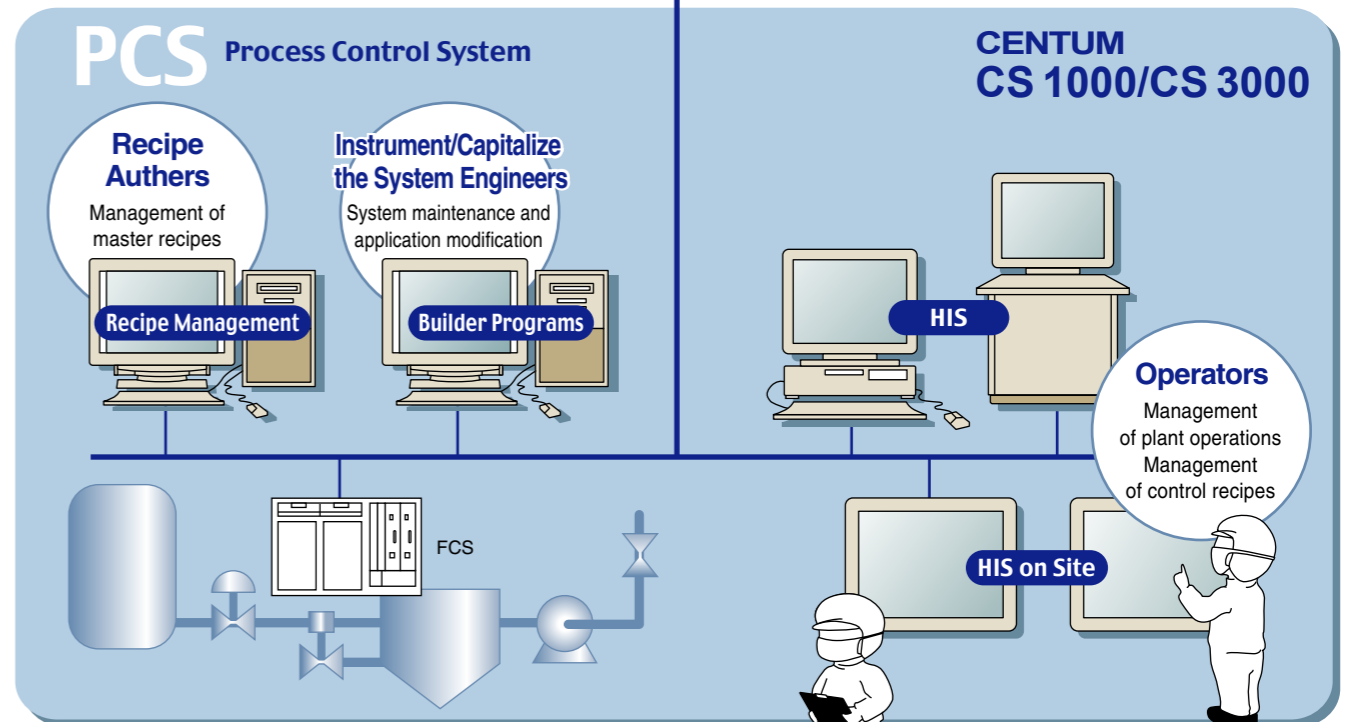
Item	Before	After
Item Name	T28-ALB001	T28-ALB001
Tag Name	X102 ALARM 001	X102 ALARM 001
Tag Comment	ON_OFF_ON	ON_OFF_ON
Switch Position	ON	OFF
Item Name	T28-ALB002	T28-ALB002
Tag Name	X102 ALARM 002	X102 ALARM 002
Tag Comment	ON_OFF_ON	ON_OFF_ON
Switch Position	ON	OFF
Item Name	T28-ALB003	T28-ALB003
Tag Name	X102 ALARM 003	X102 ALARM 003
Tag Comment	ON_OFF_ON	ON_OFF_ON
Switch Position	ON	OFF
Item Name	T28-ALB004	T28-ALB004
Tag Name	X102 ALARM 004	X102 ALARM 004
Tag Comment	ON_OFF_ON	ON_OFF_ON
Switch Position	ON	OFF
Item Name	T28-ALB005	T28-ALB005
Tag Name	X102 ALARM 005	X102 ALARM 005
Tag Comment	ON_OFF_ON	ON_OFF_ON
Switch Position	ON	OFF
Item Name	T28-ALB006	T28-ALB006
Tag Name	X102 VALVE OUT 001	X102 VALVE OUT 001
Tag Comment	ON_OFF_ON	ON_OFF_ON
Switch Position	ON	OFF
Item Name	T28-ALB007	T28-ALB007
Tag Name	X102 VALVE OUT 002	X102 VALVE OUT 002
Tag Comment	ON_OFF_ON	ON_OFF_ON
Switch Position	ON	OFF
Item Name	T28-ALB008	T28-ALB008
Tag Name	X102 VALVE OUT 003	X102 VALVE OUT 003
Tag Comment	ON_OFF_ON	ON_OFF_ON
Switch Position	ON	OFF
Item Name	T28-ALB009	T28-ALB009
Tag Name	X102 VALVE OUT 004	X102 VALVE OUT 004
Tag Comment	ON_OFF_ON	ON_OFF_ON
Switch Position	ON	OFF
Item Name	T28-ALB010	T28-ALB010
Tag Name	X102 VALVE OUT 005	X102 VALVE OUT 005
Tag Comment	ON_OFF_ON	ON_OFF_ON
Switch Position	ON	OFF
Item Name	T28-ALB011	T28-ALB011
Tag Name	X102 VALVE OUT 006	X102 VALVE OUT 006
Tag Comment	ON_OFF_ON	ON_OFF_ON
Switch Position	ON	OFF
Item Name	T28-ALB012	T28-ALB012
Tag Name	X102 VALVE OUT 007	X102 VALVE OUT 007
Tag Comment	ON_OFF_ON	ON_OFF_ON
Switch Position	ON	OFF
Item Name	T28-ALB013	T28-ALB013
Tag Name	X102 VALVE OUT 008	X102 VALVE OUT 008
Tag Comment	ON_OFF_ON	ON_OFF_ON
Switch Position	ON	OFF
Item Name	T28-ALB014	T28-ALB014
Tag Name	X102 VALVE OUT 009	X102 VALVE OUT 009
Tag Comment	ON_OFF_ON	ON_OFF_ON
Switch Position	ON	OFF
Item Name	T28-ALB015	T28-ALB015
Tag Name	X102 VALVE OUT 010	X102 VALVE OUT 010
Tag Comment	ON_OFF_ON	ON_OFF_ON
Switch Position	ON	OFF
Item Name	T28-ALB016	T28-ALB016
Tag Name	X102 VALVE OUT 011	X102 VALVE OUT 011
Tag Comment	ON_OFF_ON	ON_OFF_ON
Switch Position	ON	OFF
Item Name	T28-ALB017	T28-ALB017
Tag Name	X102 VALVE OUT 012	X102 VALVE OUT 012
Tag Comment	ON_OFF_ON	ON_OFF_ON
Switch Position	ON	OFF
Item Name	T28-ALB018	T28-ALB018
Tag Name	X102 VALVE OUT 013	X102 VALVE OUT 013
Tag Comment	ON_OFF_ON	ON_OFF_ON
Switch Position	ON	OFF
Item Name	T28-ALB019	T28-ALB019
Tag Name	X102 VALVE OUT 014	X102 VALVE OUT 014
Tag Comment	ON_OFF_ON	ON_OFF_ON
Switch Position	ON	OFF
Item Name	T28-ALB020	T28-ALB020
Tag Name	X102 VALVE OUT 015	X102 VALVE OUT 015
Tag Comment	ON_OFF_ON	ON_OFF_ON
Switch Position	ON	OFF

Display example of differences between before and after system modification

ERP Enterprise Resource Planning

MES Manufacturing Execution System

Manufacturing order control, manufacturing record management, etc.



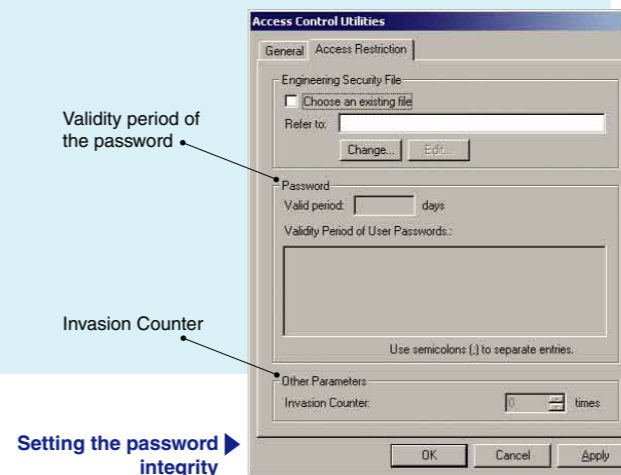
FCS: Field Control Station
HIS: Human Interface Station

POINT 3 Electronic Signatures: Control of Identification Codes and Passwords

Preventing and detecting unauthorized access

The CS 1000/CS 3000 systems:

- Display a message to request checking of a user ID and password when that user ID has been used for a specified time period in order to prevent unauthorized access.
- Display a warning message of an illegal access attempt when a wrong password is entered consecutively a specified number of times.
- Automatically records such events in the audit trail.

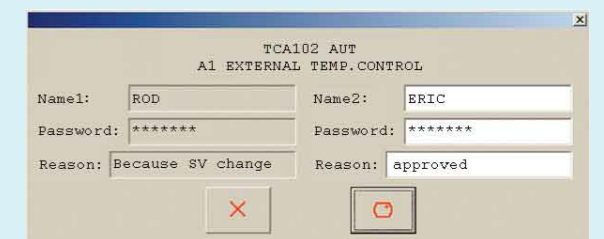


Setting the password integrity

POINT 4 Control of Critical Operations: Double Checking for Approval

Checking by two different persons or approval by a person having sufficient privileges, for operations on critical function blocks

With the CS 1000/CS 3000, manipulation of a critical function block can be permitted only when checked by two different operators or approved by a person having sufficient privileges of approval. Such double verification events are recorded in the audit trail.

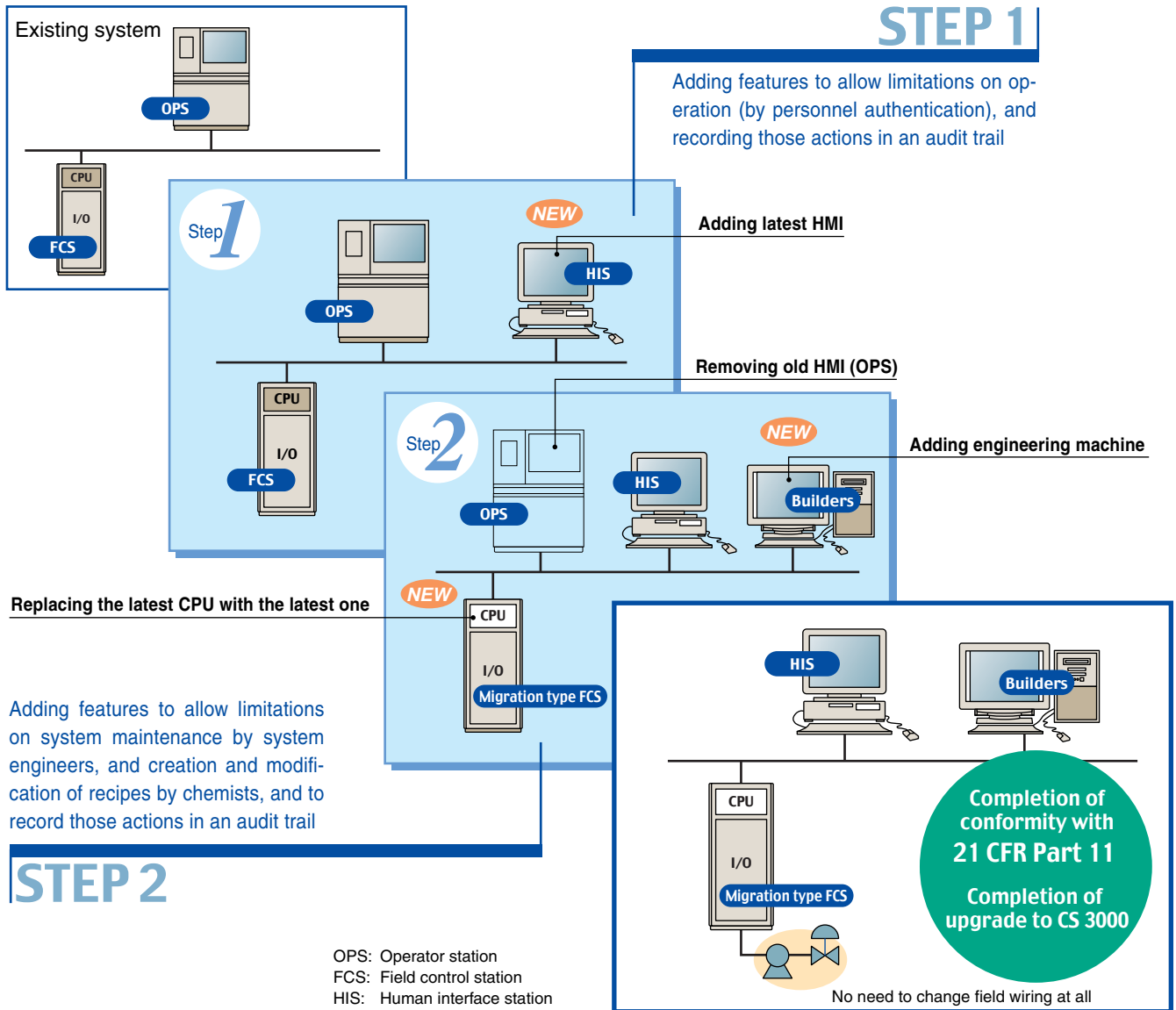


Dialog box for double check/approval for operation on a critical function block

*1: A device from Sony Corporation.

Making existing CENTUM systems conform to 21 CFR Part 11

For users of an earlier system such as a CENTUM V and CENTUM-XL, Yokogawa proposes an upgrade plan to make your existing system conform to 21 CFR Part 11. This can be done in phases while maintaining important legacy resources.



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