

Flexible Batch Control System Description

This is a system description of a Flexible Batch System in an agile manufacturing process. This system executes batch logic in the structured (hierarchical) and sequential manner. For example,

- each recipe consists of a series of unit procedures,
- each unit procedure consists of a series of operations,
- each unit procedure consists of a series of phases,
- each phase consists of a series of states (running, holding, etc.), and
- each phase state consists of a series of steps.

The system is fully compliant to industry standards since it uses the S88.01 procedural and equipment models and terminology. System components (PLCs, HMI Software, Batch Software, relational databases, barcode readers, etc.) and interfaces (OEM skids, reporting/approval applications, Operating System based security, etc.) are seamlessly integrated and all batch parameters, activities, and results are retained in a single Electronic Batch Record.

The system includes functions we call Automated Manufacturing Procedures (AMPS). Manual operating instructions can be associated with any step in any phase and can influence the transition from one phase step to the next. Instructions can require simple acknowledgement, comments, keyboard data entry, and/or barcode data entry. Every entry must be accompanied by one or more valid electronic signature(s) with the access level(s) defined for the instruction. Electronic signatures are recorded in the Electronic Batch Record along with the instruction text, the data entered, time/date, and the context of the response (Batch ID, procedure step, etc.).

In addition to full automatic recipe-driven control, every control module (valves, pumps, PID controllers, analog instruments, etc.) can be monitored and controlled independently in manual mode. Manual control operations also require electronic signature and are recorded to the Electronic Batch Record if the control module is owned by an active batch. Control module interactions and exception handling (i.e., protection against process upsets) occur at the lowest control level in the form of PLC-coded alarms and interlocks. Monitoring and control popup windows include dynamic links to maintenance database information, including I/O addresses, drawing references, and scaling limits.

1.1 Flexible Batch Overview

The Flexible Batch Control System provides integrated control of all production and production support activities. The system integration closely follows the batch control activities model recommended by the ISA S88.01 standard. Figure 1. depicts the system context and batch control activities, including:

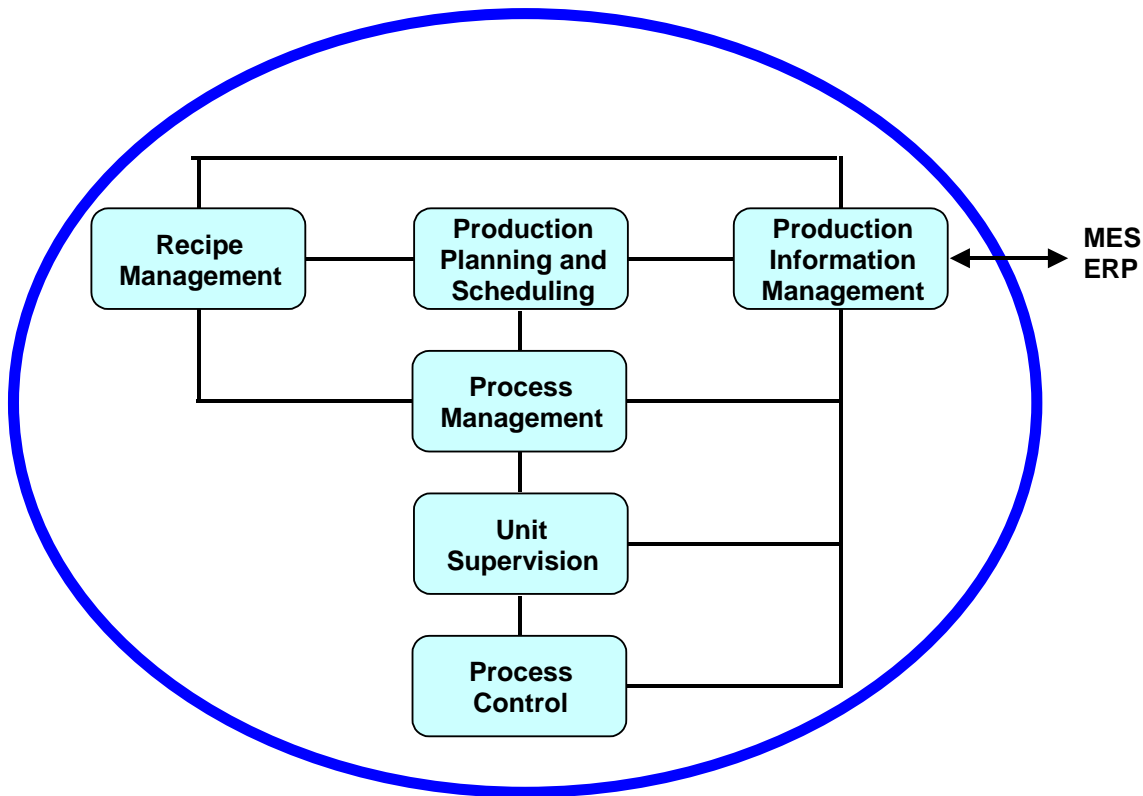


Figure 1: Context Drawing

Recipe Management

Recipe Management includes the ability to create, approve, store, and maintain master recipes. A master recipe ties together procedural elements (unit procedures, operations, and phases) with specific equipment requirements and formula information (parameters, reports, etc.). Since recipe procedural elements are described based on facility capabilities instead of discrete processing steps, virtually all procedural changes can be accomplished at the recipe level. This feature will expedite startup adjustments, control system qualification, and ongoing process optimization activities. Changes are made to the recipe rather than the PLC code so that most re-qualification steps are avoided.

Production Planning and Scheduling

Using the Batch Scheduling application program, production lots are automatically initiated upon receipt of raw material. Process equipment cleaning (CIP, SIP,

Equipment Wash Room, etc.), ingredient preparation, and weigh room activities are coordinated to reduce overall production cycle time. A key strategy in synchronizing these activities is the use of active binding and release of process equipment. This strategy permits initiation of production support activities at the earliest possible moment relative to production requirements. Procedural integration into the HMI allows operators to quickly identify and execute pending manual tasks. Providing instructions well in advance of the events that require completion of off-line manual tasks helps keep manual operations off the production “critical path”.

Process Management

The process management activity includes converting the master recipe into a control recipe, defining and tracking each batch, supervising batch execution, managing process cell resources to prevent or resolve conflicts, and collecting batch data. The Batch server is the engine for managing recipe execution and resource coordination control. Development of an effective batch process model for the product is the key consideration in optimizing the use of resources in the facility and providing an agile manufacturing process.

Unit Supervision

The S88.01 batch control standard defines unit supervision as the activity that acquires and executes procedural elements associated in the master recipe on the allocated equipment. In essence, this activity is the real-time translation of generalized recipe steps and parameters into specific operator prompts and process actions. Procedural elements (procedures, operations, and phases) are defined based on equipment capabilities rather than predefined processing steps. This object-oriented approach to batch control provides many important benefits, including:

- Integrating disparate operations (weigh room, SIP, manual steps, barcode events, etc.) into a single cohesive and detailed electronic batch record.
- Flexibility and agility for rapid control system adjustments at startup.
- Improved process utilization and throughput through integrated equipment binding to process operations.
- Modular reusable components which simplify qualification and expansion.
- Improved ability to detect, respond to, and document process upsets.

Process Control

Procedural control is tightly integrated with fully independent basic process control. With appropriate security, all control equipment is accessible for complete control from any workstation. Alarms and interlocks protect against unintended operations in manual mode. In procedural control (automatic mode), traditional alarms and interlocks are augmented by phase-specific and operation-specific alerts and hold conditions. These protect against, detect, and recover from many process upsets

that would be missed by traditional (i.e., non-batch or non-S88.01) automation schemes. In many instances, phase-specific "alerts" and "hold conditions" can also be used in place of conventional alarms and interlocks. This approach prevents nuisance alarms and complex enable/disable logic that is difficult to validate and maintain.

The human-machine interface is carefully designed to effectively focus operator attention to important process conditions. The appropriate balance of routine procedural and basic control information is developed to allow operators to maintain production efficiency. While providing an easy-to-use window to normal process operations, the HMI also allows detailed examination of batch and non-batch information for diagnostics and maintenance.

Integrated access to Automated Manufacturing Procedures (AMPs) is crucial to maintaining and documenting current Good Manufacturing Practices. The AMPs interface allows the operator to securely view and acknowledge individual steps within procedures. Execution of manual procedures is traceable to batch events to assure timely and appropriate operator entries.

Production Information Management

Detailed information from all batch control activities is collected and stored in an open relational database format. This information is continuously available for both pre-formatted and ad-hoc reporting. The level of detail in pre-formatted reports varies depending on the intended recipient, but may include:

- Equipment allocation and release from batches
- Start and stop times for all procedural elements
- Actual processing parameters and measurements
- Verification of appropriate use of equipment and ingredients
- All operator and supervisor actions with timestamp and User ID
- Data retrieval by equipment ID, batch ID, time, User ID, or procedural element

The open relational database format provides simple access to production data from existing and future systems.

1.2 System Architecture

Figure 2. is an overview of the hardware components included in the Flexible Batch Control System. The functionality of each component is described below.

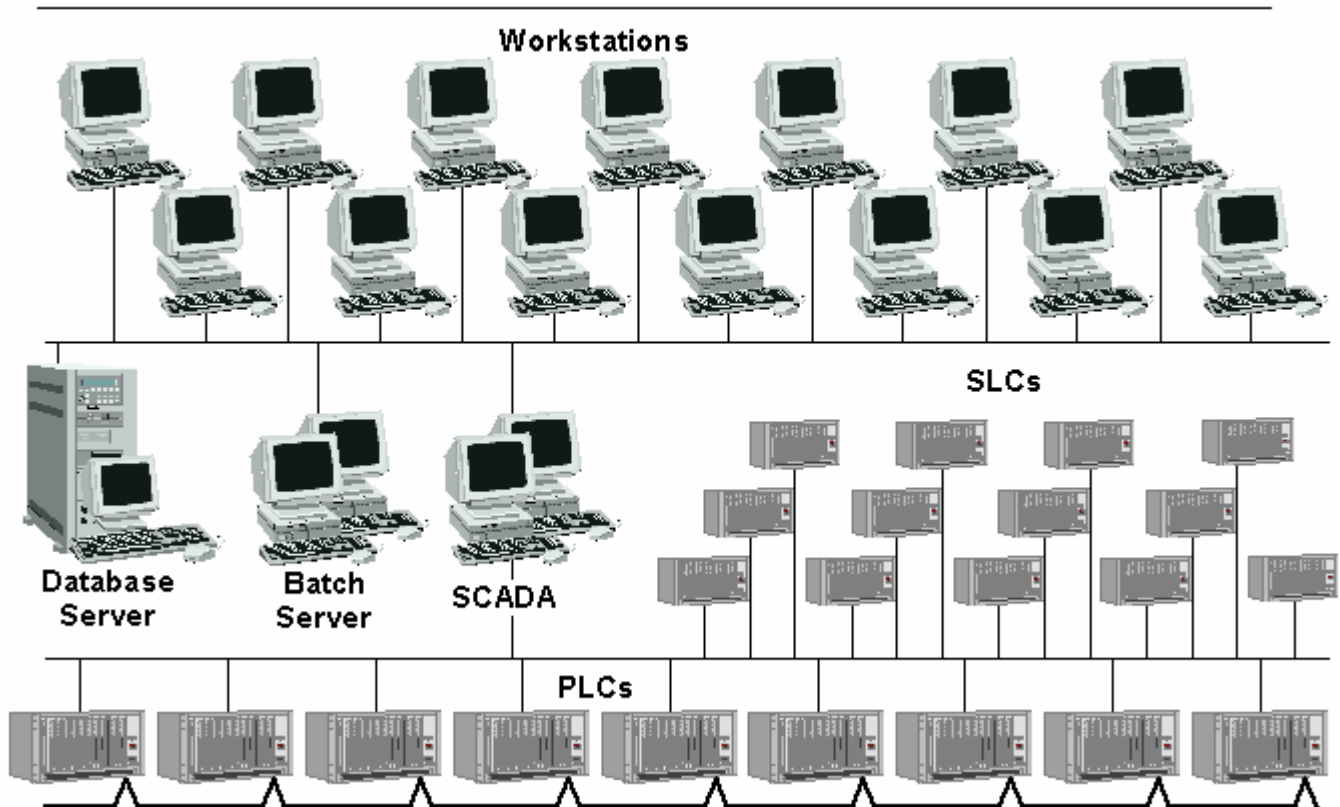


Figure 2: Control System Hardware Architecture

Relational Database Server

The primary function of the independent relational database server is to accumulate and provide access to production and production support information. Central to this function are the Electronic Batch Records stored in tables defined by the batch archivist software and the Recipe Database stored in tables defined by the Recipe Manager software. These tables receive data in SQL format via an ODBC interface from the Batch Server. The relational database server also contains one or more databases to maintain information needed to support manufacturing but outside the normal scope of the batch application software. One database is used to keep track of status and contents of each bin, and product container. Batch transactions that change records within this database are recorded in the Electronic Batch Record. Database tables are also required to link process unit phases and process feedback (e.g., proximity switch inputs) to electronic MP records. These tables describe the

location of the step instruction text, the expected feedback, and the appropriate security for each manual process step.

SCADA Server

The redundant SCADA server has primary responsibility for process communications. Third party software products provide communication between the SCADA Image Table and the PLC programs. The HMI Scan Alarm and Control (SAC) application provides communication between the Image Table and the Process Database. The Process Database Server, alarm tasks, and Historical Collect applications manage the collection and distribution of information between operators' viewing nodes.

Batch Software Server

A redundant batch server houses the Batch Server application and the equipment model. The batch server coordinates and controls all procedural activities of the process (CIP, SIP, solvent preparation, weigh room, wash room, etc.). As the server executes recipes to accomplish procedural tasks, the batch publisher makes batch data available for storage in the Electronic Batch Record. The archivist creates the Electronic Batch Record as a set of records within a relational database. Other applications (and/or databases) on the batch Server support the execution of interactive procedural control tasks. These tasks include scheduling batches, "soft" phase logic, and container tracking.

HMI Workstations

Workstations will provide operator access to the Flexible Batch Control System. The principal application on each of these workstations is the HMI View Client. This application provides the graphic screens that display process information (both continuous and procedural) in a usable format. Over 70 screens are provided to clearly present all of the process information, maintenance and diagnostic information, trending, alarms, and batch integration. Screens and controls are well designed, consistent, and reflect quality construction. A robust navigation scheme, combining hierarchy (zoom in and zoom out), process sequence (next and previous), shortcut keystrokes, and menus allows rapid information retrieval.

All workstations provide an identical interface to simplify maintenance and multipurpose utilization. Controls within the application provide information filtering to focus the workstation on specific tasks. Non-batch events and alarms are carefully designed to mesh with procedural events and exception handling to provide thorough documentation without redundancy. Security is well integrated into all HMI activities. The user name is stored with each manual entry in the Electronic Batch Record.

The HMI View Client is part of an open-architecture control solution. The HMI workstations freely communicate with distributed relational databases containing batch records (Electronic Batch Record, Recipe Database, Equipment Model, etc.),

Manufacturing Procedures (AMPs), and container status information. The integration of AMPs with batch procedures is key to the success of the batch control system. The procedures interface database links procedure instructions to phase execution events. For example, a phase will notify the operator that AMPs instructions have to be executed, will record the secured acknowledgment of each instruction, and will enable automatic control actions based on the instructions accomplished. The linking of AMPs instructions to phases is database driven to provide the flexibility needed to independently modify procedures and phases.

Many operator workstations include integrated barcode readers. Scanned data from each reader is interpreted and associated with a specific batch step. This tight integration allows invalid data to be rejected and valid data is placed in context within the Electronic Batch Record.

Supervisor Workstation

The HMI Workstation in the supervisor's office includes all of the functionality of the operator HMI workstations. In addition, this supervisor workstation includes a batch client program, for advanced batch control functions. The batch client software is used by the Supervisor to intervene in normal batch scheduling (e.g., placing entire lots in HOLD, aborting lots, etc.). The batch client may also be used to control procedural operations to a lower level of detail than is permitted from the operator HMI workstations.

Development Workstation

The remaining Workstation is dedicated to developing and maintaining the Flexible Batch Control System. Applications are available on this computer to develop the HMI application (tag database, screens, configuration, etc.), the batch application (equipment database, recipes, etc.), the custom applications, and the PLC phase logic. Network connectivity allows applications developed on this workstation to be distributed to the appropriate system nodes.

Distributed (Office) PC's

A batch reporting application is provided for installation on any PC connected to the office LAN. This application has the capability of displaying and printing data from the Electronic Batch Record. Data is available from both historical and active batches. Several pre-defined reports are selectable from a menu in the batch report generator application. On-screen forms are available for ad-hoc queries of batch record information. The same application allows entry of Quality Control lab results and batch comments. Once all lab requests are matched to lab results, the Lot End Report can be approved from this application.

PLCs

The more powerful PLCs provide the primary control logic execution for the Flexible Batch Control System. All control elements (motors, valves, controllers, phases, etc.) are developed and documented as independent modules with manual and automatic control. These PLCs provide the following functionality:

- Device Control Logic
- Alarm and Interlock Handling
- Screen Animation Logic
- Phase Logic Interface
- Phase Logic
- Network and Remote I/O Interfaces
- Peer-to-peer processor communication
- OEM SLC interface logic
- Process Simulation Logic

1.3 System Specifications and User Interface

The following information is provided to indicate the scope of the Flexible Batch Control System:

Process Components

- Unit operation process, including:
 - Process Vessels
 - Pasteurizers
 - Filtration Systems
 - CIP Skids
 - Chromatography Columns
 - Dispensing/Weighing Stations
- Hundreds of Manual Instructions per batch

Control System Components

- PLC Processors
- SLC Processors (OEM supplied)
- Redundant dual-processor SCADA server: 17,500 tags

- Redundant dual-processor batch server: 62 units, 290 phases
- Operator Workstations: 70 screens

The following screens are representative of the user interface to the Flexible Batch Control System:

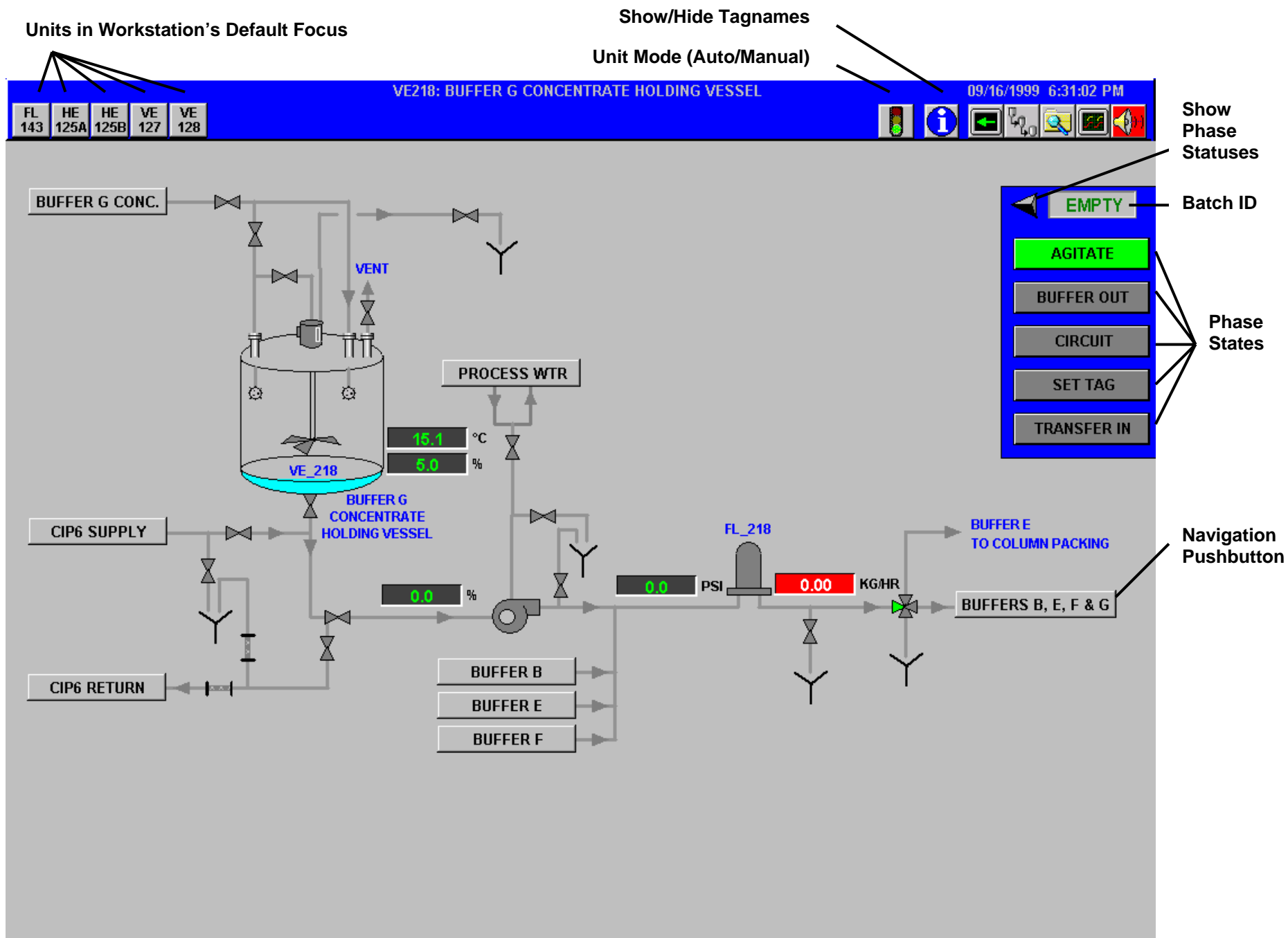










Figure 3: Typical Unit Procedure Graphic

VE127: VIRAL REDUCTION FILTER FEED VESSEL 09/16/1999 6:50:11 PM

FL 143 HE 125A HE 125B **VE 127** VE 128























Switch to Verbose

x

VE127 SIPUNIT

MP-API-7080-001608 SIPUNIT 9/03/1999 15:23:56

	SOP REF.	DATA	SIGNATURES
	1	SCAN THE FILTER FOR FL-132.	API-21 FL1234 Done By Joe Operator 09/16/1999 6:47:16 PM
	2	MANUALLY CONNECT: HOSES FROM ZS-VE127-02 TO XV-VE127-06; ZS-VE127-12 TO ZS-VE127-13; ZS-VE127-15 TO XV-VE127-14.	Done By Joe Operator 09/16/1999 6:47:53 PM Check By Susie Supervisor 09/16/1999 6:48:11 PM
	3	MANUALLY CONNECT: TX-130 U-BEND PORT D TO PORT E.	
	4	PLEASE WAIT. STEAMING PATH 1.	
	5	PLEASE WAIT. STEAMING PATH 2.	
	6	MANUALLY DISCONNECT: HOSES FROM ZS-VE127-12 TO ZS-VE127-13; ZS-VE127-02 TO XV-VE127-06; ZS-VE127-15 TO XV-VE127-14.	API-23 API-34 
	7	MANUALLY DISCONNECT: TX-130 U-BEND PORT D TO PORT E.	
	8	READ THE PRESSURE GAUGE ON THE NORTH WALL AND RECORD ITS CURRENT VALUE.	 

5079A
x

ADD BUFFER

AGITATE

CIRCUIT

HEAT/COOL

PRODUCT OUT2

SAMPLE QC

SET TAG

SIP LINE

SIP UNIT

TRANSFER IN

Figure 4: Typical Automated Manufacturing Procedure