Figure 1: Johnson Controls Metasys for Validated Environments Campus Overlay
Metasys® for Validated Environments (MVE) is an environmental control system for facilities that may be subject to Food and Drug Administration (FDA) Title 21, Code of Federal Regulation (CFR) (more specifically, Part 11), and electronic information management requirements. MVE is a specialized application of the Johnson Controls flagship Metasys network that has built-in features to facilitate Part 11 compliance. The solution includes a data center component combined with a Web-based user interface and the proven Johnson Controls M5 Workstation components. MVE works on Windows® 2000 Professional or Server operating systems.

Features and Benefits

- **Precision Digital Environmental Control**: Maintains temperature, humidity, pressure isolation, and ventilation to tight specifications.
- **Scaleable Configuration**: Accommodates a multitude of facility sizes based on the number of tags and users.
- **System Security**: Assures the issues of Part 11 physical and logical security are addressed in a way which deals with your corporate security policies.
- **Secure Data Management and Reporting**: Collects and stores large volumes of facility data in a restricted access database.
- **Electronic Records and Signatures**: Combines the efficiency of electronic record keeping with the security of authenticated electronic signatures.
- **Time-stamped Audit Trail**: Generates traceable alarm and event transactions in a chronological manner.
- **Extensive Subsystem Integration Library**: Integrates data from a variety of environmental subsystems for streamlined operations.
- **Web-based Reporting**: Provides secure access to historical records and reports via a standard Web browser user interface.
- **Intuitive Data Visualization Tools (Optional)**: Improves the efficiency and reliability of facility operations through predictive technology and rapid analysis.
- **Turnkey Installation**: Guarantees performance from a single point of responsibility.
Areas of Application
MVE is designed for use in:
- research and development facilities
- test and stability facilities
- pilot and full-scale production facilities
- data centers
- storage facilities
- warehouse and distribution facilities
- any other regulated facility requiring critical control and secure records

Features and Benefits
Precision Control
MVE incorporates state-of-the-art controllers with continuous self-tuning using adaptive control technology. Flow, temperature, and humidity are maintained to performance specifications from the air handler to the Variable Air Volume (VAV) box. A detailed record can be kept of all critical parameters to validate performance over time.

Scalable Configuration
MVE is a robust, scalable solution designed to work with installations ranging from small buildings such as distribution centers, stability rooms, labs, or large multi-facility campus environments. The architecture consists of a robust configuration with options for 1,500, 10,000, or 50,000 tags and options for 5, 10, or 25 simultaneous Web report users.
System Security

One of the primary concerns of critical environment automation systems is system/user security. Johnson Controls is equipped to assist you in the consultation, design, and management of all physical security issues. Additionally, MVE provides a matrix password structure based on the NT security model to deal with the technical aspects of Part 11 security. All MVE features, files, and access points for the M5SAES and SAOS are configured by the system administrator and then controlled and monitored by the M-Password and M-Alarm features of MVE.

Figure 4: M-Password Configuration Window

The Password Configuration window shown in Figure 4 allows the system administrator to set up security features like:

- password aging
- password length
- account lockout, duration and reset policies
- password uniqueness
- auto lockout

M-Password is designed with Part 11 compliance in mind and with plenty of flexibility to comply to your corporate policies.

Secure Data Management and Reporting

There are two major components of the Data Management feature of MVE. The Data Collector, which queries and receives all relevant data from a variety of field control sensors and devices throughout the network, is the first component. The second component, the Data Server, uses Microsoft® SQL Server™ technology as a core and layers authentication, security, and optional redundancy/backup. The combination provides secure capture, storage, and authenticated retrieval of critical environmental data, which are required attributes of a Part 11 validated system.

Figure 5 depicts the “Exception Reports” feature of the FX Web reporting tool as used for data Outlier analysis. Going beyond alarm identification, this feature learns the response of a sampled variable over time and can identify any variation that falls outside the statistical model of “in control”.

Figure 5: FX Web Reports Outlier Analysis
Alarm Reports

M-Alarm is used to capture alarms and events in addition to investigating alarms and alarm frequency of comparable systems for diagnostic purposes. Part of the standard M-Alarm Viewer Interface is seen in the upper quadrant of Figure 6. The viewer lists all active alarms in the system. The upper right corner is an application to quantify different alarm conditions currently in the system. Filters can be applied to address the most urgent alarms first. The viewer is also where the operator acknowledges alarms and events. The lower portion of Figure 4 shows the real-time trending capability, which helps operators to troubleshoot systems.
Figure 7 shows the standard M-Alarm Report interface. From master M-Alarm Report, alarms and events can be listed and filtered for review. This same logger can be used to view the audit trail of alarms and operator transactions. It gives the operator a window into all automatic and manual control actions that have occurred in the system, collected in the secure database.

All transactions contain: old and new values, date and time of occurrence, identification of the operator, event name, device tag name, units, and optionally an operator annotation of the event.

<table>
<thead>
<tr>
<th>EventTime</th>
<th>Tag</th>
<th>Value</th>
<th>Units</th>
<th>Severity</th>
<th>Message</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:00:01</td>
<td>VSS-M5-LAB-1101.T1101A</td>
<td>54.0</td>
<td>%RH</td>
<td>950</td>
<td>Alarm: Call Operator at 555-1212</td>
</tr>
<tr>
<td>8:00:01</td>
<td>VSS-M5-LAB-1101.T1101B</td>
<td>63.0</td>
<td>%RH</td>
<td>950</td>
<td>Alarm: Call Operator at 555-1212</td>
</tr>
<tr>
<td>8:00:01</td>
<td>VSS-M5-LAB-1101.T1101C</td>
<td>62.0</td>
<td>%RH</td>
<td>950</td>
<td>Alarm: Call Operator at 555-1212</td>
</tr>
<tr>
<td>8:00:01</td>
<td>VSS-M5-LAB-1101.T1101D</td>
<td>63.0</td>
<td>%RH</td>
<td>950</td>
<td>Alarm: Call Operator at 555-1212</td>
</tr>
<tr>
<td>8:00:01</td>
<td>VSS-M5-LAB-1101.T1101E</td>
<td>62.0</td>
<td>%RH</td>
<td>950</td>
<td>Alarm: Call Operator at 555-1212</td>
</tr>
</tbody>
</table>

**Figure 7: M-Alarm Reports**

**Time-stamped Audit Trails**

The ability to chronologically retrace alarm and event transactions is paramount to reproducing an audit trail during a facility system's review by the FDA. This Part 11 requirement is met by implementing the M-Alarm Logger of the MVE. In addition to logging alarms and the operator's response to those alarms, it also logs events as they occur on the network.

The secure system database contains all of these alarms and events. The entries log both the time and date of the individual operator transaction (for example, Login, Logout, Alarm Acknowledge, and Value Adjust or Override) and also log the identity of that operator, providing an audit trail of the operation of the system.
Figure 8 shows a summary of alarms and events in a bar graph format. A bar graph allows quick, focused analysis of the origin of problem areas by graphically organizing the individual alarm sources in order of frequency. This information is also available in a pie chart.
Figure 9 is an example of event-driven trending. A point is sampled once every half hour while it is in the normal state. When the point enters a non-normal state, the sample is recorded (to the second) and a more rapid sampling rate begins. This is called fast scan and allows for high resolution collection during periods of interest while keeping the total data size manageable. These subsequent fast scan samples are also recorded to the second.

Figure 9: M-Trend Graphically Displaying Data from the FX VE Secure Database

In addition to Graphical displays, tabular views of the same reports are available through M-Trend, which can view up to 6 attributes in the graphical view and 32 attributes in the tabular view.
Traceable Electronic Records

Electronic records are more efficient and easier to keep than manual records, but most electronic records can be easily altered. Therefore, the FDA requires all electronic means of record keeping incorporate traceable electronic signatures and be available only to authorized users. The use of Adobe® Acrobat® software and the MVE system authenticates electronic signatures to validate document review. Microsoft SQL C2 Security traces database alterations. These features preserve the integrity of the data and simplify Part 11 validation.

Figure 10 shows an example of a Mean Kinetic Temperature report for a typical product storage cabinet. In this case, readings are collected from three different areas of the cabinet in addition to a single humidity sample. Each location provides a minimum, maximum and average reading. The Mean Kinetic Temperature is also indicated for the selected sample period. Once the researcher reviews the report for accuracy, she applies her electronic signature that is then affixed to the report. Anyone who receives the report electronically can click on the signature for verification of authenticity. Anyone who attempts to modify this report once signed nullifies the signature, and the report identifies the document was altered after signing.

Extensive Subsystem Integration Library

Through the Metasys Compatibility Program, Johnson Controls has developed the world’s largest library of software drivers to integrate third-party devices and subsystems. From air handlers and chillers to Programmable Logic Controllers (PLCs), particle counters and other vendor Building Automation Systems (BASs), integrated devices seamlessly become part of the MVE system and are granted the same data security and electronic traceability features for Part 11 as native Metasys components.
Standard Reports

Standard reports, summarizing historical data, are accessible via a common Web browser. Authenticated users can use any connected Personal Computer (PC) to access a variety of predeveloped report formats or to generate custom reports created around specific applications as seen in Figure 11.

Figure 11: Data Graph Sample Report
Data Visualization

Data Visualization is an optional tool applied to historical data help determine cause and effect and assist in a root cause analysis. Similar tools use real-time facility data to estimate the instantaneous health and performance of all critical systems. The real power of data visualization comes from predicting future events, problems, and conditions. By focusing building operators on areas of potential concern and allowing them to ignore common data noise, the reliability and overall performance of the facility are enhanced.

Figure 12 is an example of data visualization. In this example, color spectrum monitors CO₂ levels in a critical space. Each color band from top to bottom represents a day and the colors are linked to the CO₂ level at that time. Yellow is the warning condition while blue represents a zero reading. In Figure 12, CO₂ levels go into the warning level each weekday from approximately 9:00 A.M. to 1:00 P.M.
Figure 13 is an example of the optional Starfield Display. The Starfield Display relates several pieces of dynamic Heating, Ventilating, and Air Conditioning (HVAC) data into a single visual pattern. The pattern provides an overview of the operation of many pieces of HVAC equipment. Operators can quickly and easily see which equipment needs the most urgent attention. A Starfield Display is like a scatter plot, which distinguishes normal or abnormal patterns. The following star attributes can be abstracted to real data: size, brightness or color, position relative to other stars, and movement over time. Linking star attributes to system attributes like alarm condition, run status, temperature, humidity, or pressure, equipment characteristics can be represented by star clusters. Figure 13 represents six systems, which could be air handling units or production rooms.

The Starfield in the lower left indicates:

- the equipment is on, noted by the size of the center star
- the command status and the equipment status match because the center start is green
- this Starfield monitors seven variables depicted by the seven smaller dots surrounding the axis. The variables may be room temperatures or air handler control variables. Four of those variables are in a normal or non-alarm state, because they are shown in green and near the center or target while three variables are in an alarm condition, shown in blue.

At a glance, the operator can identify the variable in alarm. By hovering the cursor over this point, the operator can view the variable specifics and determine the appropriate response.

Figure 13: Starfield Display
Turnkey Installation
Each facility is unique and has distinct operational requirements. Johnson Controls, with over 300 offices around the world, is committed to creating and maintaining high performance environments to support our customers' businesses. Because building systems' technology is usually delivered from a variety of subsystems and suppliers, a single point of accountability for the final results is needed. That is why Johnson Controls assumes full systems integration responsibility and turnkey installation, including a complete suite of validation services, if desired.

Additional Information
Please refer to the following documents: Facility Explorer for Validated Environments Product Bulletin (LIT-120142), M5 Secure Architecture Engineering Station or Operator Station Product Bulletin (LIT-1201110), and Johnson Controls Validated Environments Product Bulletin (LIT-1201111).