

## The APOGEE Compliance Solution — Technological Elements for 21 CFR Part 11 Compliance

### Background

The U.S. FDA's 21 CFR Part 11 was developed to permit the widest possible use of electronic technology in support of electronic record and electronic signature systems. While the use of electronic records is voluntary, an industry trend to move to paperless records is driven by the efficiencies of electronic media and the increased reliability and data integrity potential of electronic systems over manual processes. The rule was first issued in the spring of 1997. In 1998, the Building Technologies Division of Siemens Industry, Inc. delivered the first APOGEE® Compliance Solution designed to address compliance needs. The APOGEE Compliance Solution continues to evolve and with each revision, providing users increased operational efficiency while at the same time a reduction in risk.

The APOGEE Compliance Solution is a combination of technological and procedural elements designed to ensure full compliance with 21 CFR Part 11, while minimizing the risk of failure. The cornerstones of this solution are *APOGEE Building Automation Services* and *APOGEE Building Automation Technologies* (see Figure 1).

The APOGEE Building Automation Services are a series of compliance-based services that are designed to address the procedural elements that are key components of any compliance solution. These include system validation, training, standard operating procedures and migration planning.

The APOGEE Building Automation Technologies include the combined features of the workstation software (Insight® software and the InfoCenter Suite® software) and field panel firmware that are required to address technological elements such as record security, record retention, audit trails, system security and system/device checks.

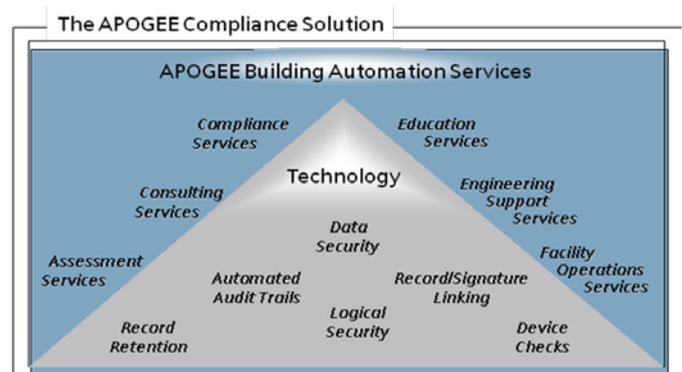
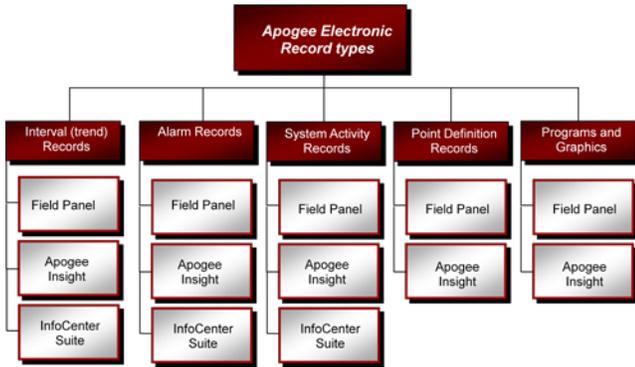


Figure 1. The APOGEE Compliance Solution.

The guiding principle of the compliance solution strategy is to increase efficiency and reduce risk by using the most effective mix of services and technologies available at any point in time.

### Electronic Records

The term *electronic records* can be applied to data from many types of systems and applications. Within the APOGEE Automation System, there are five types of records generated by the system that can be critical to compliance. Figure 2 shows these five types of records, along with the APOGEE Automation System components that are required to manage these records electronically within the APOGEE Compliance Solution.



**Figure 2. Key APOGEE Records and System Components.**

The APOGEE Compliance Solution addresses each record throughout its lifecycle, including the point of creation, transfer through the APOGEE Automation System and long-term lifecycle management and archiving. The compliance solution involves a series of components and procedures working together. The lack of any one of these significantly increases the risk of non-compliance.

### Electronic and Digital Signatures

Electronic Signatures refer to the digital representation of a signature that is used to authorize or “sign” electronic reports. This functionality is reserved for electronic authorization of compliance level reporting. Digital Signatures, which often refer to the use of such things as User ID/password to track changes or provide access to system functions, are used throughout the APOGEE Compliance Solution, but should not be confused with electronic signatures. As an example, inserting an electronic signature into a document may require a digital signature (user name/password).

### APOGEE Compliance Solution – Technological Elements

The technological elements of the APOGEE Compliance Solution represent the combined features and application of three key APOGEE components. These include field panel firmware, Insight workstation software, and InfoCenter Suite software. While a component can be implemented to be compliant within its range of functions, all components must be implemented to ensure the most comprehensive and effective compliance position.

### Insight Compliance Support Option (CSO)

The Compliance Support Option for Insight provides functionality for detailed tracking of modifications and deletions of supervised objects. With this option, you can track which property of an object was changed, its value before and after the change, why the change was made, who authorized the change and from where the change was made. The main features of CSO include supervised objects and enhanced logging.

- **Supervised Objects:** The following object types may be designated as Supervised; a point, trend definition, trend collection report, user account, or PPCL program. Modifications and deletions to a Supervised Object presents a warning that may require a user password and/or a supervisor password (user defined) in order to execute the modification or deletion. Depending on how the object is set up, users attempting to modify or delete the object will be either warned and allowed to continue, or warned and also required to enter their user password and/or have a supervisor enter a password to continue. Any modification or deletion to a Supervised Object requires the user to enter in a reason for change that is permanently attached to the electronic record.

Supervised objects have revision numbers that are automatically maintained by Insight software. Any editing of a supervised object automatically increments the revision number. You can use revision numbers as a means to track changes to objects as an alternative or supplement to keeping paper records. The revision number is displayed in the System Activity Log, on PPCL programs, printed graphics, and various reports.

- **Enhanced Logging and Audit Trails:** The following information is recorded in the System Activity Log when a Supervised Object is modified or deleted:
  - *Property* – Describes what part of a supervised object was changed.
  - *Before* – Displays the value of a supervised object’s property before the change/deletion.
  - *After* – Displays the value of a supervised object’s property after the change/deletion.
  - *Reason for Change* – Displays why a change to or deletion of a supervised object was made, or more information on why an action was performed.
  - *Authorized By* – Displays the supervisor account that authorized the change to or deletion of a supervised object. If there is no supervisor required for the supervised object, then this field is left blank.
  - *Location* – Displays the workstation or field panel where a user performed an action on a supervised object. If a user is logged in via the Terminal Server, this field will contain the name of the terminal client (that is, the computer the user was at when making the change), not the name of the Terminal Server.

## Insight Alarm Issue Management (AIM) Option

The Alarm Issue Management Option for Insight provides a structured process to manage the life cycle of an alarm issue, from initiation to resolution. AIM enforces an ordered procedure that must be followed for each point in alarm. The individual steps are: Acknowledge, Assign (to a contact), Answer, Resolve, and Clear. Each step is logged through the AIM application and a full history of all actions for a given issue is recorded in the System Activity Log.

Using the Insight Remote Notification (RENO) option for alarm notification and InfoCenter Suite for long-term data management compliments AIM as a critical alarm management application for regulated facilities.

## InfoCenter Suite Compliance-based Features

The InfoCenter Suite solution provides a robust data management platform to secure and maintain specific electronic records over their useful life. It is not simply an archiving or backup utility, but an active data management system supporting secure access to data and providing the foundation and tools to convert data to useful information. The InfoCenter Suite solution provides the horsepower for supporting long-term data management needs, freeing up the building automation system to effectively manage the building systems.

The key features of the InfoCenter Suite solution that are designed to support 21 CFR Part 11 compliance include:

- **Management of APOGEE Electronic Records** – InfoCenter applications provide long-term management and reporting of key APOGEE electronic records. These include trend records, alarm records, system activity records, and AIM records.
- **Audit Trails** – InfoCenter software provides detailed audit trails on data within the InfoCenter database and records critical changes to records. This combined with audit trail records from the Insight database, makes the InfoCenter database the central place for reviewing all audit trail information.
- **Security** – InfoCenter Suite software uses multi-layered, integrated Windows security to insure that the right people have access to the right information and allows you to extend record access to all key stakeholders.

- **Direct Interface to Insight** – provides a direct, secure and reliable data exchange interface between the Insight database and the InfoCenter Suite database. This interface reduces configuration time and provides increased robustness in the transmission of data from the real-time management software to the long-term data management solution.
- **Advanced Electronic Records Processing and Reporting** – InfoCenter applications provide a wide range of report and processing tools to turn data into information. These include:
  - *Summary Points* – Create statistics or formula points to refine data.
  - *Mean Kinetic Temperature* – Designed to calculate a key metric for warehousing and stability applications.
  - *Exception Reporting* – Report objects designed to highlight exceptions and audit trailed data.
  - *Statistics Reporting* – Report objects designed to show key statistical summaries.
  - *Graphs/Tables* – A range of options to show all data in human readable forms.
  - *Interactive Option* – Quickly analyze and present data without the need for creating reports.
  - *Alarm Summary Reporting* – Provides detailed alarm event totaling, average total alarm time in tabular and graphical summaries.
- **Enterprise Wide Access** – InfoCenter Suite is specifically designed for users who might not typically use the building automation systems. InfoCenter Suite also efficiently distributes information over the existing enterprise network to stakeholders who need it, when they need it.
- **Archive Management** – InfoCenter Suite provides long-term data management via its librarian feature. This feature manages online and offline data so that users can simply focus on requesting the data they need, not trying to locate it or reload it. InfoCenter's archiving flexibility ensures that an archiving strategy can be developed to meet a wide range of data management needs.

## Field Panel Firmware Compliance-based Features

To ensure that records are protected at their point of creation and to reduce the need for procedurally based service modes, the field panel firmware has multiple technical elements to maximize compliance, including:

- **BLN Operator Activity Logging** – Firmware Revision 2.6 or later can be configured to track and upload detailed operator activity to the Insight System Activity Log application and can ultimately be transferred to the InfoCenter Suite solution. Logging includes who made the change and when and where it was made.
- **Field Panel Password Expiration and “Three Strikes”** – A Field Panel’s User Account’s password can be set to “never expire” or expire every xx days, in which “xx” can be anywhere from 1 to 365 days. Additionally, with expiration enabled, users have only three chances to enter a correct password prior to being locked out. A lockout requires a reset by an administrator.
- **Trend Sample Synchronization** – Time-based trend samples can all be synchronized to the same time interval, providing better cause and effect analysis.
- **Conditional Trending** – Trend sampling frequency can be automatically adjusted when the point is in alarm.
- **Network Time Synchronization** – The field panel network time is automatically synchronized to the Insight Database Server’s time. In the event a Database Server is not on the network, then the field panel network time synchronization uses the time of the first panel on the network as the time source.
- **Buffering** – Trend and alarm buffering help to prevent data loss:
  - *Automatic Trend Collection on Buffer Full-Automatic* – Automatic trend upload to the database server will occur for time and COV trends when a field panel’s trend buffer becomes full.
  - *Adjustable Buffer Limits* – Buffer full limits can be set from 1% to 80% and combine with automatic trend collections to ensure data reliability.
  - *Alarm Buffering* – Allows up to 10 alarms per alarmable point to be stored at the panel in cases where the Insight workstation is temporarily not communicating with the panel. When communication is re-established, all buffered alarms, not just the latest, are uploaded.

## APOGEE Compliance Solution—Services

In addition to the technical elements of the APOGEE Compliance Solution, Siemens offers a series of services that are combined with the technical solutions to provide a complete 21 CFR Part 11 compliance solution. Some examples of services are:

- **Assessments** – Used to perform a gap analysis or to benchmark the current state of the building management system. Assessments are available for Part 11 and/or GXP compliance.
- **Consulting Services** – May be applied to assist in the development of a master plan for the building automation system regulatory compliance and/ or maintenance programs to ensure continual and long-term compliance.
- **Education Services** – Helps to ensure a reliable and knowledgeable facility management staff through formal training and operator coaching.
- **Compliance Services** – Employs validation services, Standard Operating Procedure (SOP) development, Factory Acceptance Testing (FAT), compliance remediation, change control for updates, and specification development to help meet compliance processes, methodology, and documentation requirements.
- **Engineering Support Services** – Supports the development, updating and proper archiving of engineering documentation.
- **Facility Operation Services** – Locks in long-term system performance in the established state of compliance with automation controls analysis and optimization, business protection and recovery services, repair and replacement services, calibration support, emergency onsite and online response, and remote facility monitoring.

## Ordering Information

Description	Part Number
Compliance Support Option for Insight	571-126
Validation Options Bundle Includes both the Compliance Support Option and the Alarm Issue Management Option	571-125
InfoCenter Suite Advanced	571-390

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