IMPROVE QA & COMPLIANCE

Apex-Guard™

Lab Productivity Suite

FEATURES

Apex-Guard software integrates enhanced controls, security, and audit features with Apex-Gamma™ software to advance gamma spectroscopy for your regulated count room.

The Apex-Guard application builds on Apex-Gamma software to provide extra security, audit log, and data integrity to meet specific needs for the radiopharmaceutical field. These features are also of interest to many of our non-pharmaceutical customers.

The following features are implemented in Apex-Guard application, above and beyond the current functionality of Apex-Gamma software:

- **Role-based security with Windows Credentials Authentication:** User profiles are linked to the Windows domain user which allows Windows Policy settings to manage the password complexity and renewal frequency.

- **Automatic timed log-off feature:** Administrator user setting defines an inactivity time limit and logs the user off the system when the limit is exceeded.

- **Enhanced security for analysis and data processing files:** Editing permissions on essential files for analysis and data are allowed only within the application. This includes calibration, nuclide library, ISOCS™ and LabSOCS™ associated files (for efficiency calibration and cascade summing correction), QA, and scripts.

- ✔ Enhanced data integrity and security features integrated into lab productivity suite
- ✔ Features and controls necessary for compliance to US FDA Title 21 CFR Part 11 Electronic Records and Electronic Signatures for pharmaceutical customers
- ✔ Role-based security for user log-ons using MS Windows Policy settings for password and renewal
- ✔ Automatic timed log-off feature
- ✔ Enhanced security for analysis and processing files
- ✔ Enhanced security on detector and MCA configuration
- ✔ Dramatically improved audit capability with comprehensive audit log
- ✔ Enhanced data review features to view and restore analysis records
- ✔ Electronic Signatures
- ✔ Electronic software licensing with flexible terms and activation methods
- ✔ Comprehensive Service Bundle

- **Enhanced security on detector and MCA controls:** Modification of detector settings configured and active in an Apex-Guard system is not possible outside the Apex-Gamma application, including from Genie™ Acquisition and Analysis software.
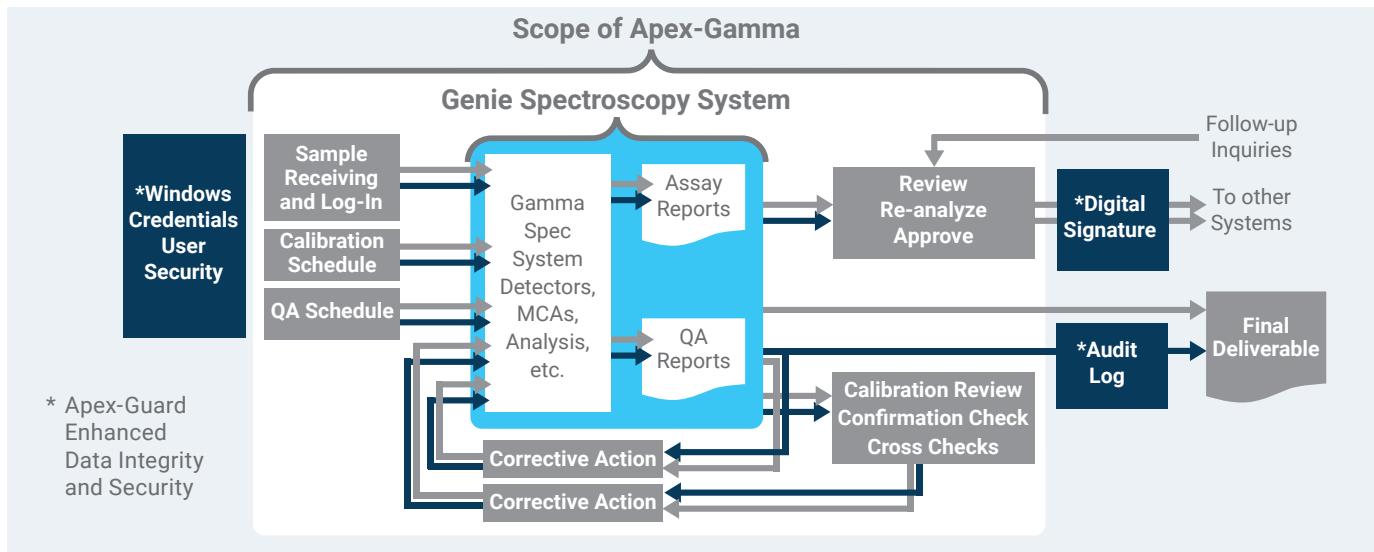
Figure 1. Schematic Workflow and Scope of Software Applications

- **Dramatically improved auditing capabilities:** For each change in an application editor, procedure, or QA file, the user is presented with a dialog summarizing the changes during the editing session as well as a free form text field to record a justification for the changes, which will be saved to the audit log along with a record of the changes made. The text field has optional input and mandatory text input settings. There is also a setting to enable requesting of user credentials and password at the time of authorizing the modification.

- **The enhanced audit log records and displays the following data for a given change:**

  - Parameter modified
  - User who made the modification
  - Date/Time stamp of modification
  - Value prior to modification
  - Value after modification
  - Justification/comment of modification

Example Audit Log Entry: Library Modification

- **Enhanced Data Review:** Data review now has ability to display each analysis of a given sample as a separate record. This allows the user to view and restore previous analysis settings, including date/time.

Example of analysis records for a given sample

- **Electronic signatures for signing and approving sample counts:** Signatures include username, function, date/time stamp, and user comments, and conform to the requirements in US FDA Title 21 CFR Part 11, Electronic Records, Electronic Signature.

- **Installation Qualification and Operational Qualification (IQ/OQ) Services:** Mirion offers IQ/OQ, a critical component of a Title 21 CFR Part 11 compliant solution. A trained Mirion professional will install your system and review a comprehensive IQ/OQ checklist to satisfy this requirement.*

  * Apex-Guard Software and Mirion's IQ/OQ Service are designed to ensure our customers can meet Title 21 CFR Part 11 readily and easily. Please note that Apex-Guard software as a standalone product is not Part 11 compliant and must be integrated with customers' processes and procedures for laboratory Part 11 compliance.

TURN-KEY SERVICE

Our **Apex-Guard Comprehensive Service Bundle** helps keep your operations up to date and optimized with a single annual subscription service, including:

- Apex-Guard application including Apex-Gamma, Genie, LabSOCS software (3-year license, updates and support)
- IQ/OQ Services
- Virtual Training Classes
- Technical Services

The **Apex-Guard Lab Productivity Suite** adds an extra layer of security and audit-supporting documentation to the industry-standard Apex-Gamma software. The Apex-Guard application supports both the pharmaceutical (US FDA Title 21 CFR Part 11) and non-pharmaceutical customers.

SUPPORTED PLATFORMS & MCAS

The Apex-Guard application supports the following operating systems, databases, and MCAs.

Operating System	Windows 10
	Windows 11
	Windows Server 2019
	Windows Server 2022
Databases	SQL 2019
	SQL 2022
MCA Devices	Lynx® Analyzer
	Lynx® II Analyzer
	DSA-LX® Analyzer
	Osprey® MCA
	Multiport II™ Analyzer
	Sample Changers

ORDERING INFORMATION

- **Apex-Guard Software Option**
  - Available in 1-year subscription, 3-year subscription, or perpetual license (1 license required for each computer or virtual machine)
  - Requires concurrent Genie-Multi and Apex-Gamma license for each computer or virtual machine
  - For client/server configurations, Apex-Guard license required for all networked Apex-Gamma computers
  - Subscription licenses include updates as released and complimentary technical support

- **Installation Qualification & Operational Qualification Services**
  - IQ/OQ performed by a qualified Mirion support engineer
  - Deliverable includes co-signed Installation Qualification and Operation Qualification Protocol
  - Offered for desktop, client/server, and upgrade systems

Mirion **Comprehensive Service Bundles** package together software licenses and premium services for a turn-key solution to help you get operational and stay up-to-date.

- **Apex-Guard 3 Year Comprehensive Bundle: Desktop**
  - 3 Year Subscription for Genie Suite, Apex-Gamma, and Apex-Guard software for one computer
  - Includes complimentary software updates, as released
  - Includes complimentary ISOCS/LabSOCS Mathematical Calibration Software
  - Includes participation in Mirion's Customer Community Portal
  - Each year, option of one of the following services:
    - a.) IQ/OQ-1: Mirion Install and IQ/OQ Service;
    - b.) Virtual open enrollment training class credit for two people;
    - c.) 20 hours Tech Services customization or consultation credit
  - Unused Training or Service credit may roll over for one year

- **Apex-Guard 3 Year Comprehensive Bundle: Client/Server**
  - 3 Year Subscription for Genie Suite, Apex-Gamma, and Apex-Guard software for up to four computers
  - Includes complimentary software updates, as released
  - Includes complimentary ISOCS/LabSOCS Mathematical Calibration Software
  - Includes participation in Mirion's Customer Community Portal
  - Each year, option of one of the following services:
    - a.) IQ/OQ-2: Mirion Install and IQ/OQ Service;
    - b.) Four days virtual training group class (up to six participants);
    - c.) 40 hours Tech Services customization or consultation credit
  - Unused Training or Service credit may roll over for one year

MIRION TECHNOLOGIES