



**MIRION**  
TECHNOLOGIES



# Apex-Guard™ Software

---

**Productivity Spectroscopy Software implements the controls required to ensure data integrity for regulated count room, including US FDA Title 21 CFR Part 11 compliance.**



## Overview

- FDA Part 11
- Features can benefit every counting lab
- Installation considerations
- IQ/OQ
- Product offerings



## What is 21 CFR Part 11?

FDA's regulations for electronic records and electronic signatures

- Secure all data from being corrupted or lost
- Maintain approval signatures securely
- Track and changes to data
- Ensure any changes made are authorized and on record

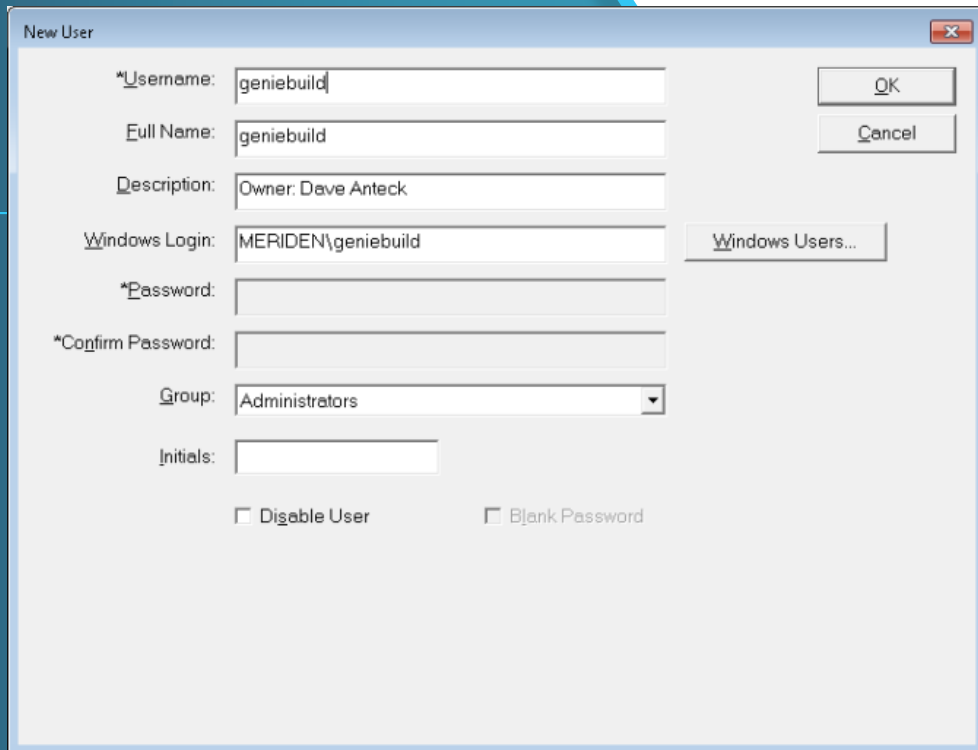


## Key Features

- Windows credentials used for log-in
- Automatic log-off
- Increased security from standard Apex-Gamma
  - Editing can only be done within Apex session
  - MCA adjustments can only be done from within Apex session
- Data Review analysis history
  - This preserves the initial analysis
- Enhanced Audit Tracking and Audit Log
  - Who, what, when and why
  - Digital signatures now included
- Electronic Signatures

# Key Feature #1

- **Windows credentials used for log-in**
  - Assigned by customer's I.T. department
  - Password has some degree of complexity
  - Password expires after some period
  - Why?
    - Eliminates “generic” Apex user log-on
    - Tightens security
    - Puts admin burden on I.T. instead of you
  - Open area PC with generic Windows log-on can still be used



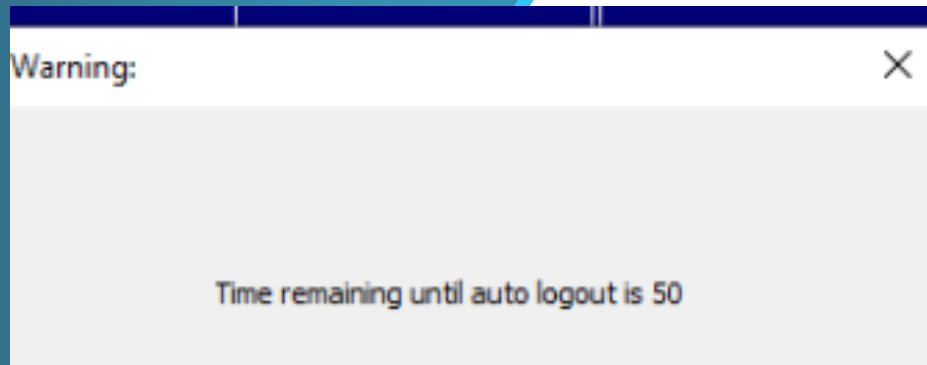
The screenshot shows a 'New User' dialog box with the following fields and options:

- \*Username:** geniebuild
- Full Name:** geniebuild
- Description:** Owner: Dave Anteck
- Windows Login:** MERIDEN\geniebuild
- \*Password:** (empty)
- \*Confirm Password:** (empty)
- Group:** Administrators (dropdown menu)
- Initials:** (empty)
- ☐ Disable User
- ☐ Blank Password
- Buttons:** OK, Cancel, Windows Users...

## Key Feature #2

### Automatic log-off

- Standard Apex allows user to remain signed on indefinitely
- New timed auto log-off for as short as 2 minutes of inactivity
- At 1 minute, a warning is displayed
- Why?
  - So Apex knows exactly who did what
- This feature can be turned off if desired



## Key Feature #3

### Enhanced security for MCA settings and analysis

Customer can now close Apex and edit nuclide libraries, certificate files, etc

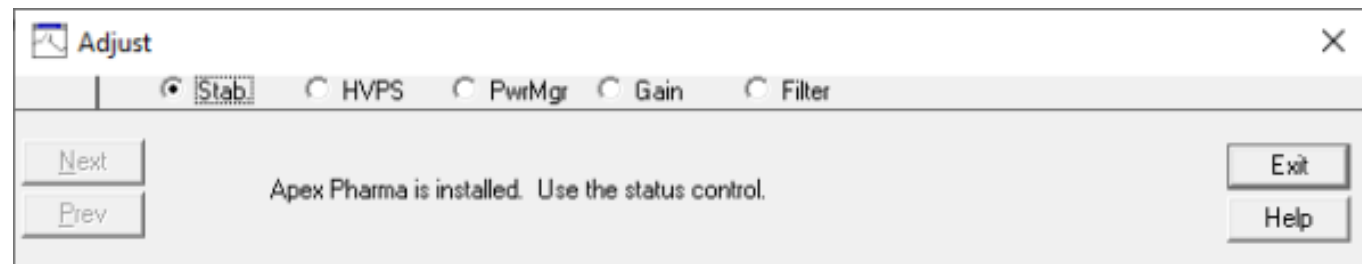
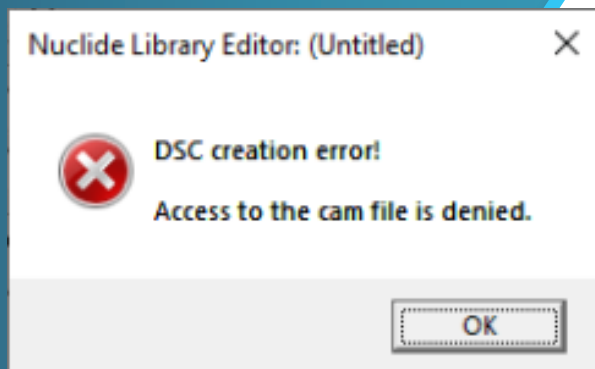
Customer can now close Apex and change Lynx settings/parameters in Genie

This loop-hole is eliminated with Apex-Guard

Why?

To assure only authorized users are making changes

 Apex-Guard™



## Key Feature #4

### Data Review Analysis History

- New feature introduces the ability to store, review, and reset previous analyses associated with a given sample.
- Each analysis is sequentially numbered and date stamped
- Why?
  - So you don't overwrite the initial analysis
  - So you have a record of all analysis done on a sample



Analyses for sample Sample 39203

Current	Analysis No.	Data Review User	Save Date	Sample State
*	3	Marie Curie	12/28/2020 11:06:56 AM	Done - Fully Approved
	2	Marie Curie	12/28/2020 11:03:41 AM	Done - Fully Approved
	1		12/28/2020 10:55:15 AM	Counted - Pending Review

View Analysis Cancel

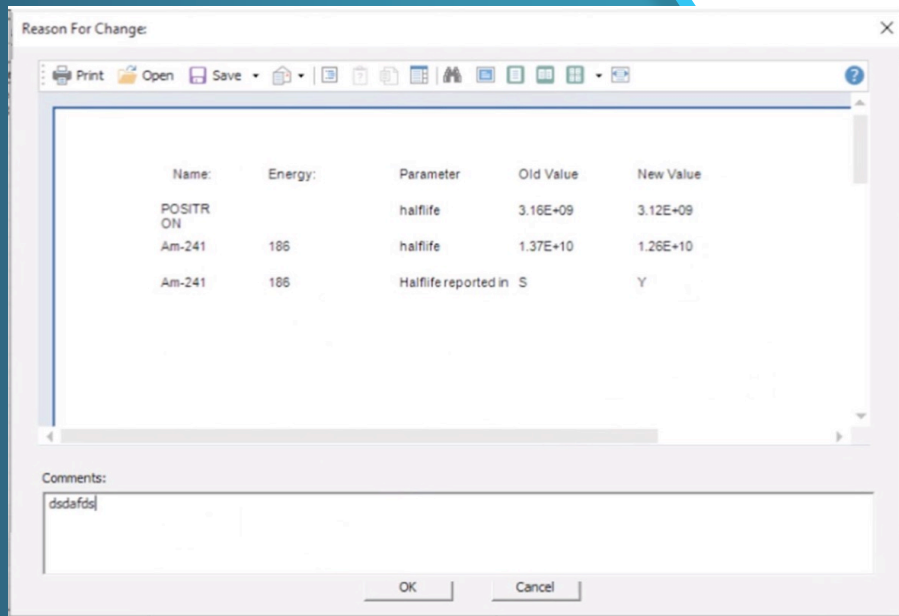


## Key Feature #5

### Enhanced Audit Tracking and Audit Log

The Audit Log is enhanced to record and display the following data for a given change:

- Parameter modified
- User who made the modification
- Date/time stamp of the modification
- **New:** Value prior to modification
- **New:** Value after the modification
- **New:** Justification/comment of the modification



## Key Feature #6

### Electronic Signatures

- Required for Part 11 compliance
- New feature now attaches name, function, time stamp and comment
- Why?
  - Get away from paper records



#### Approvals

First Approver: **Curie, Marie**

Comments: Sample approved with no additional comments

Has digitally signed this document on: 11/23/2020 3:52:12 PM



## Installation Considerations

- Installs after Apex-Gamma
  - Think of it as a bolt-on to Apex, much like the Apex-NPP package
- Desktop or Client/Server
- Must be used with latest version of Apex and Genie
  - Excellent opportunity to eliminate “technology debt”
- Requires Windows 10 !!!!!

## IQ/OQ

- Installation Qualification / Operational Qualification
  - Basically, a checklist of all relevant features of the software
  - Performed by an FSE with customer present
  - Both parties acknowledge functionality and sign document
  - Why?
    - Required by Part 11 but a “nice to have” for other customers



IQ/OQ-1

Install and IQ/OQ for Desktop System

- System installation and configuration performed by a qualified Mirion support engineer
- For single desktop systems up to two detectors
- Set-up with verification to validate system operation and specifications
- Deliverable includes co-signed Installation Qualification and Operation Qualification Checklist
- 10% discount for support agreement customers
- Firm and Fixed Price
- Includes all labor and travel expenses



## Product offering – 3 ways

- License
  - S707C is \$2,000 per copy
  - Required on each PC running Apex
- Software Subscription Bundle
  - Includes all software plus LabSOCS to sweeten the deal
  - Low cost of entry
- Comprehensive Bundle
  - Includes all software plus IQ/OC or Training or Customizations each year
  - Customer doesn't need capital equipment \$

## Product offering – 3 ways (con't.)

### Software Subscription or Comprehensive Bundle

- Lower cost of entry

- Includes LabSOCS

- Ability to use OpEx budget

- Ensures customer is always up to date with compliance

- Partners with Mirion for new features and updates



Questions?

