MIRION Connect 21

Annual Users' Conference

Latest in Gamma Spectroscopy Laboratory and In Vivo Counting Applications

Greg Landry
Steve Laskos

Topics

- Genie 2000 Software Developments (*In Progress*) [Genie 4.0]
- Genie 2000 and Apex Gamma Maintenance Updates
- Apex Guard (New Product)
- Intelligent Cryo-Cycle™ - Hybrid Cryostat
- Aegis™ - Portable HPGe Spectrometer
- In Vivo/Wound Counting

Genie 4.0 (development in progress)

- FWHM Calibration Improvements
- Correlations in Efficiency Calibration and Activity Calculation
- Support for opening N42 and AVA files
- Python Script Engine – Post NID Analysis Step
- Stimulsoft Reporting Engine
- Electronic Licensing (no more dongles)

Genie 4.0 - Improvements to Shape Calibration (development in progress)

- Two new FWHM functions will be included with Genie
- The current FWHM Model will be retained

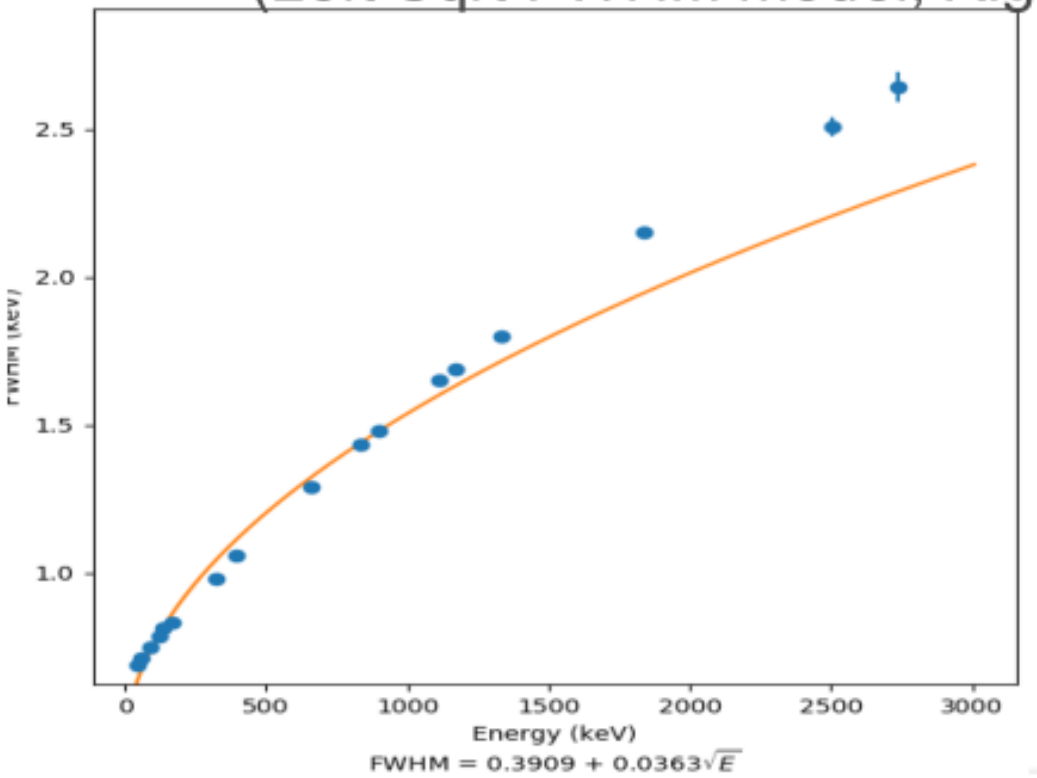
- Current FWHM fitting routine does not always successfully fit the calibration data
- New FWHM fitting routines can make extrapolation beyond measured calibration energies reliable
- Good FWHM fitting improves accuracy of MDA calculations, peak search tolerances, peak fitting (fixed FWHM setting).
- Changes required by CTBTO Comprehensive Nuclear Test-ban Treaty Organization

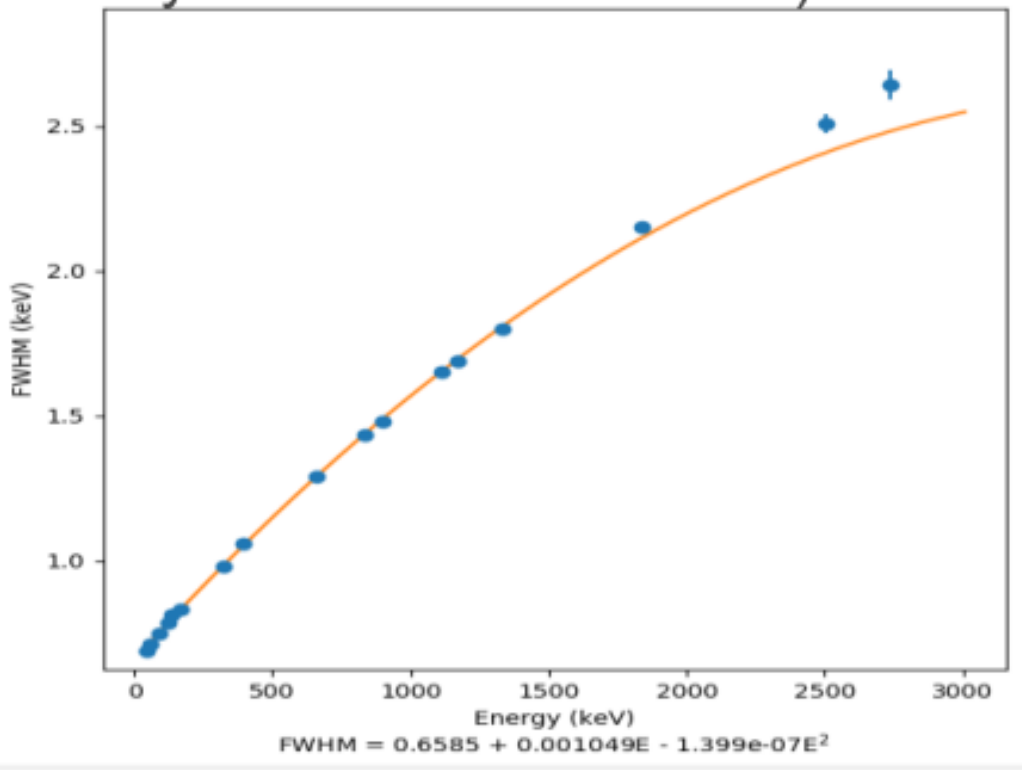
Genie 4.0 - Improvements to Shape Calibration (development in progress)

- Support a polynomial fit for the FWHM calibration:
  - FWHM = C0 + C1*Energy + C2 * Energy^2
- Support a square fit for the FWHM calibration:
  - FWHM = SQRT (C0 + C1*Energy + C2 * Energy^2)
- Retain the option to have the current Genie FWHM fit calibration:
  - FWHM = C0 + C1*Energy^(0.5)

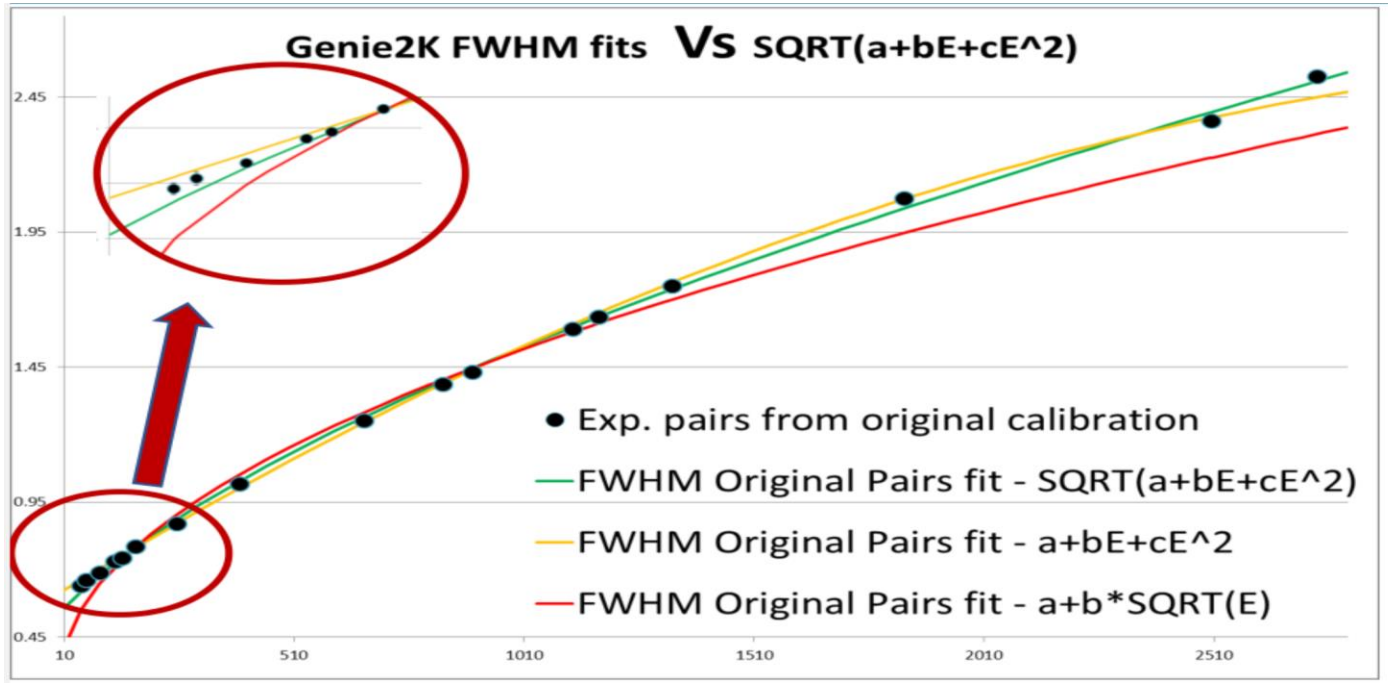
Genie 4.0 - FWHM Calibration Improvements
Genie 4.0 (development in progress)

Example of quality of model to Planar HPGe Detector
(Left Sqrt FWHM model, Right Polynomial FWHM model)





Genie 4.0 - FWHM Calibration Improvements
Genie 4.0 (development in progress)



- Original calibration pairs from station CALIBPHD (fresh source)
  Energy range of peaks in the fit:
  46.5 - 2734 keV

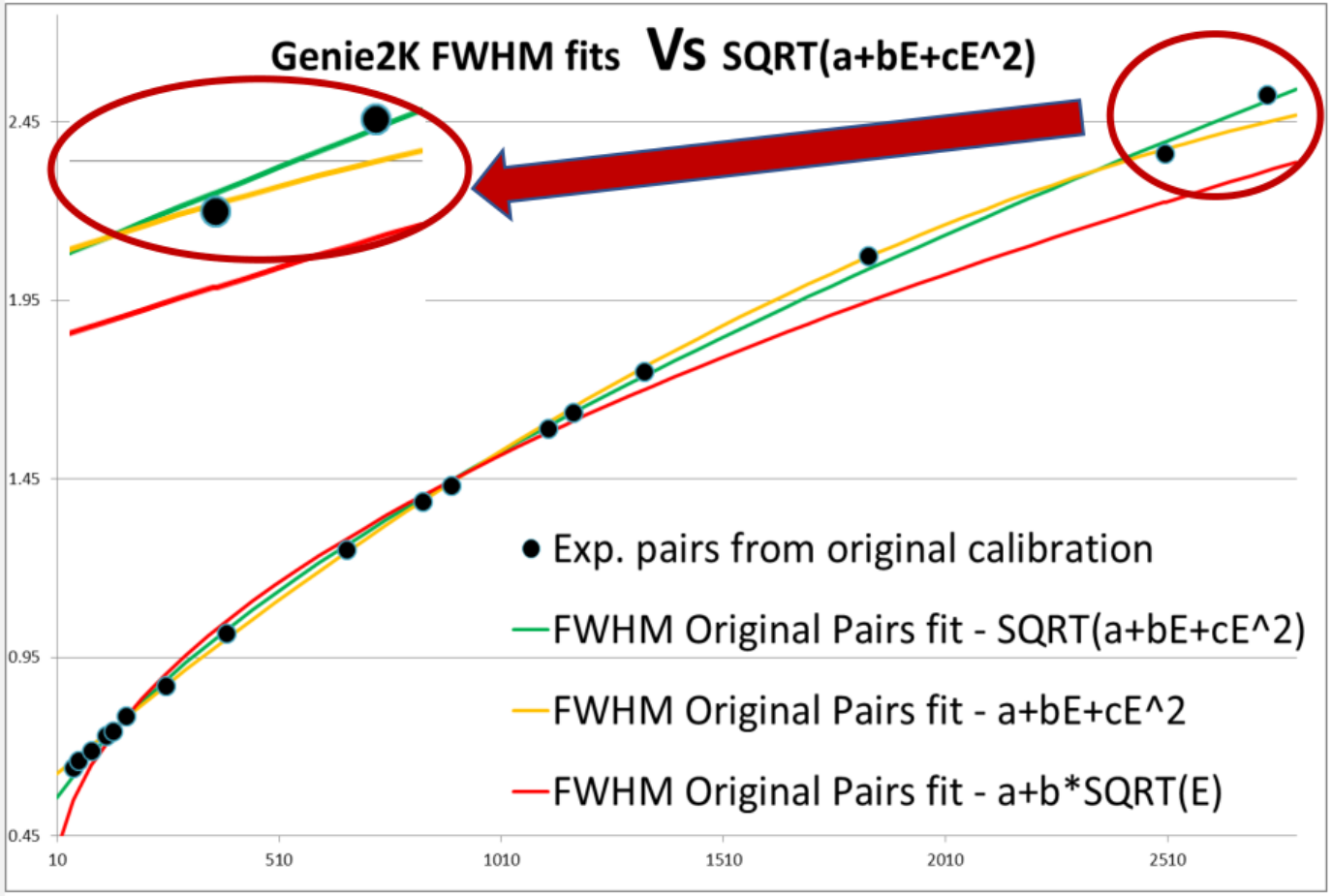
% Deviation of FWHM at 46.5 keV:

a+b*SQRT(E) Vs Exp.: **-14.4%**

a+b*E+c*E^2 Vs Exp.: **3.2%**

SQRT(a+b*E+c*E^2) Vs Exp.: **-3.7%**

Genie 4.0 - FWHM Calibration Improvements
Genie 4.0 (development in progress)



- Original calibration pairs from station CALIBPHD (fresh source)
  Energy range of peaks in the fit:
  46.5 - 2734 keV

% Deviation of FWHM at 2505 keV:

a+b*SQRT(E) Vs Exp.: **-5.7%**

a+b*E+c*E^2 Vs Exp.: **0.6%**

SQRT(a+b*E+c*E^2) Vs Exp.: **1.5%**

Genie 4.0 - Correlations in Efficiency Calibration/Activity Calculation (development in progress)

- The Efficiency Calibration Engine in Genie will be modified to accommodate correlations
  - Correlation data has historically been ignored in calculations
- A new NID Engine will be included with Genie that will accommodate correlations introduced in the efficiency calibration
  - Affects interference correction routine
  - Affects the Weighted Mean Activity calculation
- The Certificate Editor in Genie will be modified to accommodate entry of correlations
- Solves the issue that Genie reports uncertainties smaller than listed on the source certificate
  - Required for COFRAC Accreditations
  - Becoming a concern in other regulatory communities
  - RRMC Community has shown significant interest

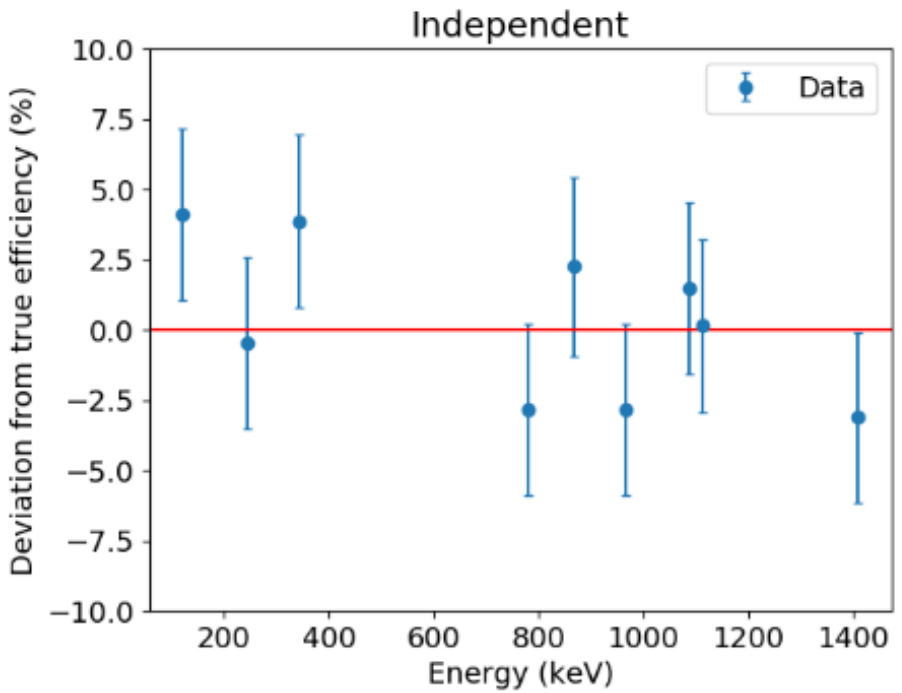
Genie 4.0 - Correlations in Efficiency Calibration/Activity Calculation (development in progress)

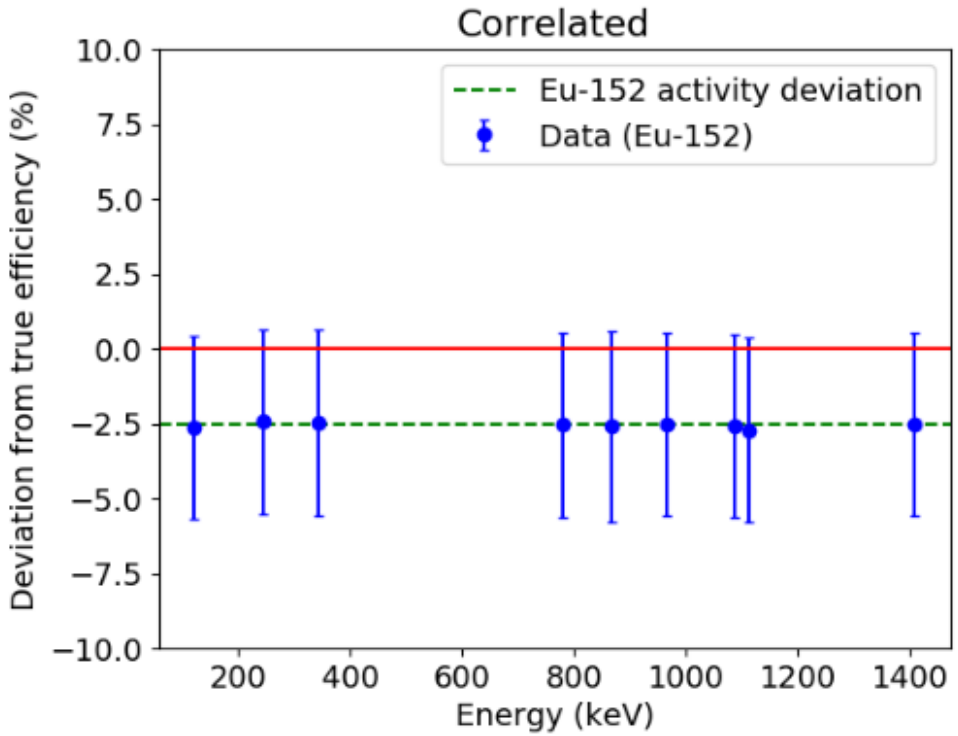
- Application: High Precision Gamma Spectrometry Laboratory Measurements

- Enhanced internal uncertainty propagation to address correlations
  - More accurate uncertainty quantification (UQ)
  - Defendable, mathematically rigorous treatment
  - High confidence in reported uncertainty values

- Enhancements focus on two key analysis stages:
  - Efficiency Calibration
  - Nuclide Identification with Interference Correction

Genie 4.0 - Correlations in Efficiency Calibration/Activity Calculation (development in progress)

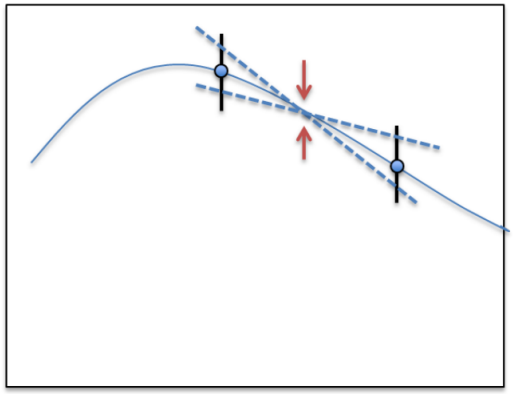




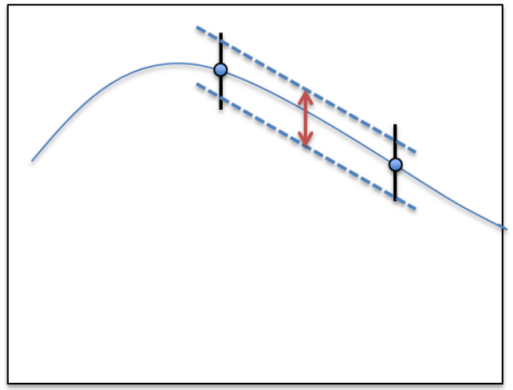
Genie 4.0 - Correlations in Efficiency Calibration/Activity Calculation (development in progress)

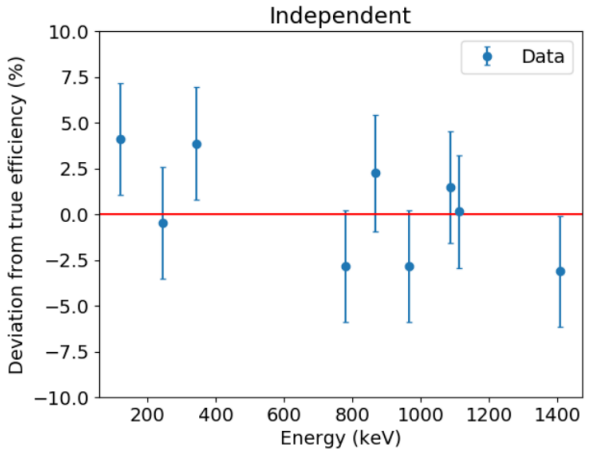
Independent vs Correlated

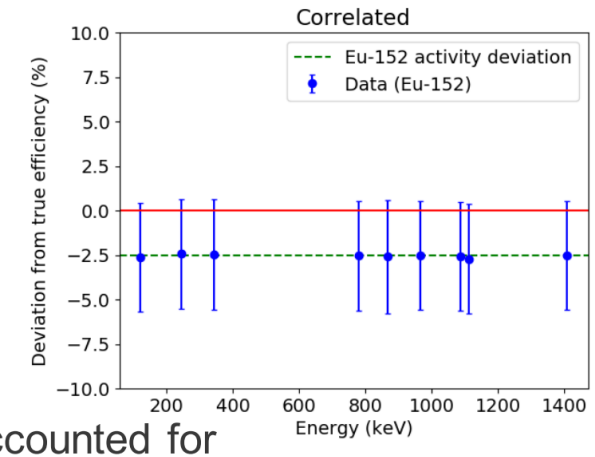
- Uncorrelated data vary independently from the true value, leading to smaller uncertainties in between data points.



- Correlated data tends to vary together – both up or down – leading to larger uncertainties in between data points.







- Measurement uncertainty can be underestimated when covariance effects are not accounted for
- Examples: Measured efficiency calibrations with multi-line nuclides, Weighted Mean Activities of multi-line sample nuclides, or Interference corrections

Genie 4.0 - Correlations in Efficiency Calibration/Activity Calculation (development in progress)

Efficiency Calibration: Examples

- Efficiency Calibrations were created using simulated data, both with and without accounting for effects of data correlations.
- Three calibration standards with differing degrees of correlation were analyzed:
  - 3% (1σ) Activity Uncertainty on each nuclide

Nuclide	Energy
Am-241	59.5
Cd-109	88.0
Co-57	122.1
Ce-139	165.9
Sn-113	391.7
Cs-137	661.7
Mn-54	834.8
Y-88	898.0
	1836.0
Co-60	1173.2
	1332.5

"Mixed Gamma"

Nuclide	Energy
Am-241	59.6
Ba-133	79.6
	81.0
	276.4
	302.8
	356.0
	383.9
Cs-137	661.7
Co-60	1173.2
	1332.5

"AmBaCsCo"

Nuclide	Energy
Am-241	59.6
Eu-152	121.8
	244.7
	344.3
	778.9
	867.3
	964.0
	1085.8
	1112.0
	1408.0

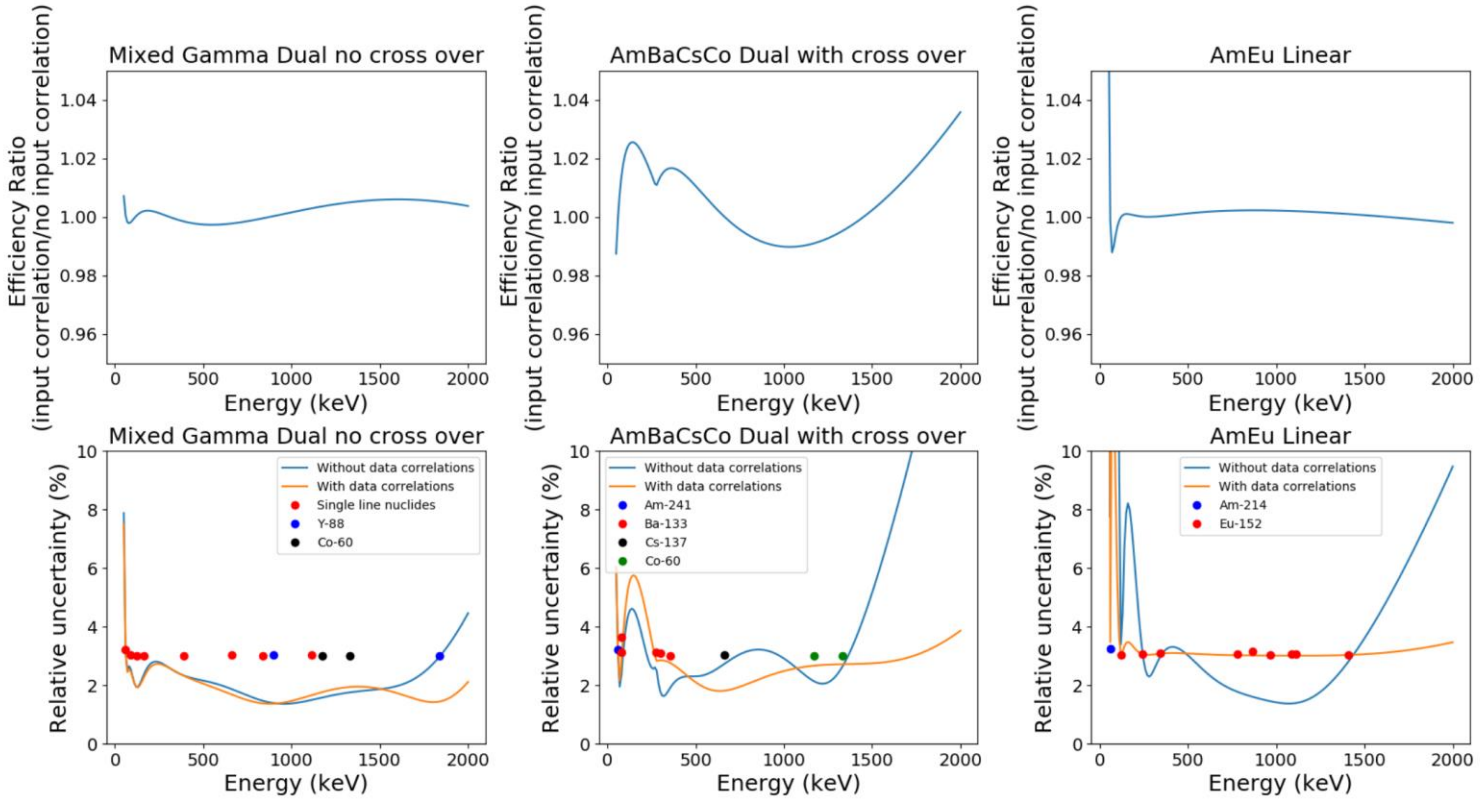
"AmEu"

Genie 4.0 - Correlations in Efficiency Calibration/Activity Calculation (development in progress)

Impact on Efficiency calibration

- Tested the effect on the efficiency calibration for three set of calibration sources for an N-type HPGe detector

- Ratios of efficiency values calculated with and without source standard correlations (top);
- Efficiency uncertainties with (orange) and without (blue) source standard correlations (bottom)



Genie 4.0 - Support for opening N42 and AVA files
Genie 4.0 (development in progress)

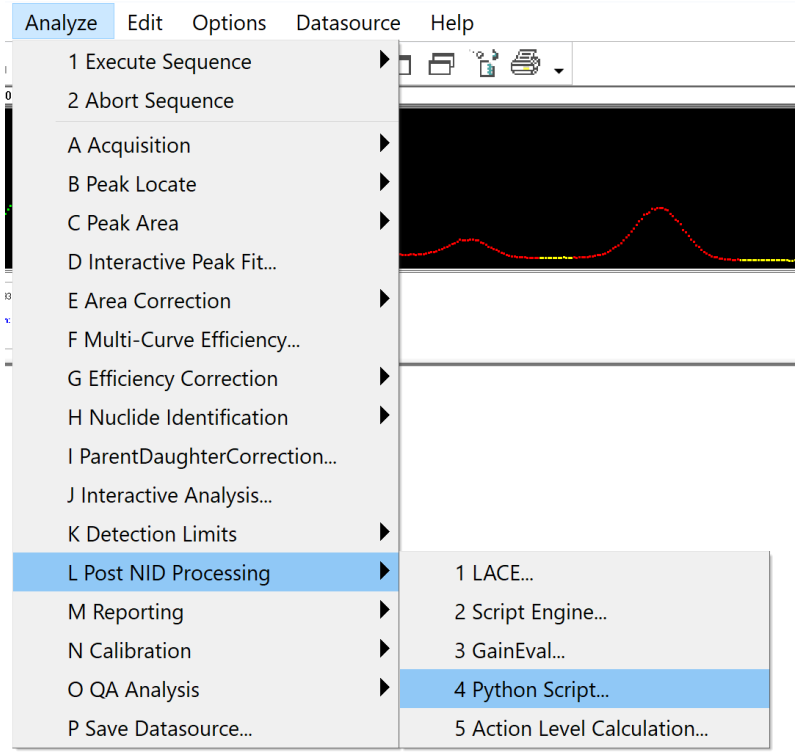
Allow the GAA File | Open dialog to open the following file types:

- N42 files
  - ANSI/IEEE N42.42 Standard
    - The ANSI/IEEE N42.42 standard specifies the XML data format that shall be used for both required and optional data to be made available by radiation measurement instruments.

- AVA file
  - PROSPECT - Gamma Spectroscopy Software

Genie 4.0 – Python Script Engine
Genie 4.0 (development in progress)

- A new Post NID Python Script Engine will be included with Genie that will accommodate custom Python scripts to be run on data sources
- CAM Parameter access will be accommodated via a Mirion python package
- All additional available python packages may be incorporated
  - Numpy
    - NumPy is a Python library used for working with arrays.
  - Scipy
    - SciPy contains modules for optimization, linear algebra, integration, interpolation, special functions, FFT, signal and image processing, ODE solvers and other tasks common in science and engineering.
  - Pandas
    - Pandas is an open source Python package that is most widely used for data science/data analysis and machine learning tasks.

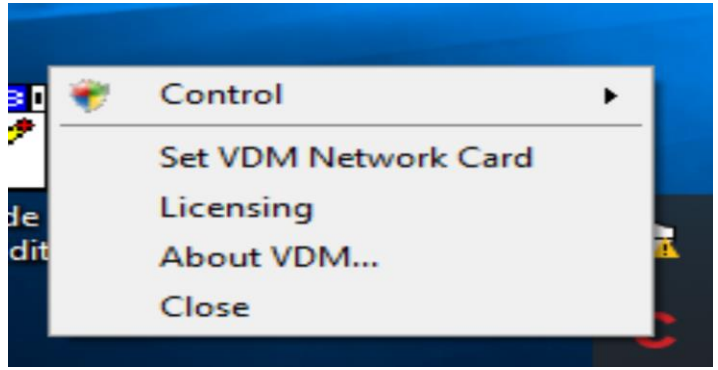


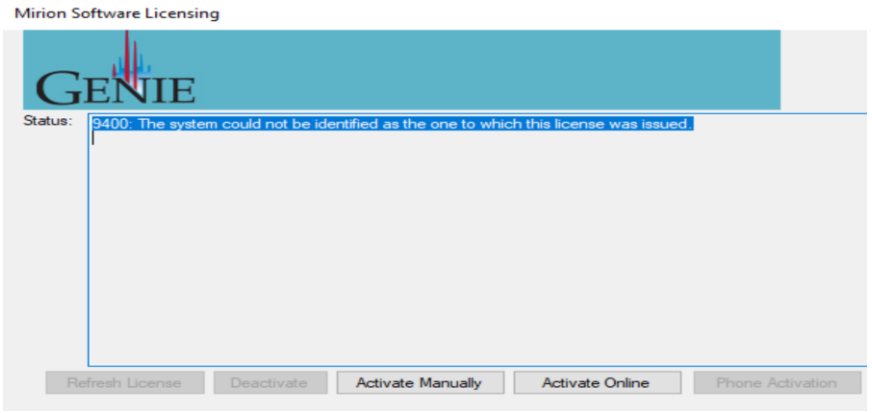
Genie 4.0 – Stimulsoft Reporting Engine
Genie 4.0 (development in progress)

- A StimulSoft engine compatible with StimulSoft Viewer and StimulSoft Editor will be added to Genie
- Requires Genie CAM file to be open prior to accessing report editor, allowing for easier previewing of report while editing.
- Cam parameters schema is referenced as a separate file, allowing updating for new CAM parameters without recompiling code
- The Stimulsoft Report engine will support:
  - Spectrum Viewing
  - Image integration
  - Geometry Composer output Integration
  - Interactive Collapsible Sections
  - Electronic Signature Integration
  - Hyperlinks

Genie 4.0 – Electronic Licensing
Genie 4.0 (development in progress)

- Genie will move to electronic licensing
  - Subscription
  - Purchase
- Physical Software Key will no longer be required
- Software packages will be consolidated
  - Separate installations and updates no longer required
    - Basic Genie
    - Gamma Analysis
    - QA
    - Interactive Peak Search
    - ISOCS/LabSOCS





Genie 2000 and Apex Gamma Maintenance Updates

- Genie 3.4.1 and Apex-Gamma were released in 2016. Since their release, a number of issues have been identified and corrected.
- Genie & Apex-Gamma Consolidated Patch Update Kit Released Sep 2020
- Apex-Gamma V1.4.1 R1 & R2 and Genie V3.4.1 R1 & R2 systems only
- Easy Installation
- 21 SPRs Addressed

Genie 2000 and Apex Gamma Maintenance Updates

SPRs Addressed	Application(s) Affected	Description of Issue addressed
H4989776	Apex-Gamma	Addresses an issue where Apex-Gamma would crash following a specific set of steps when selecting Shape option in calibration review
H1624093	Apex-Gamma with LabSOCS	Addresses an issue where it was not possible to perform LABSOCS efficiency calibration when a space is used in the Detector.txt name
M9997482	Apex-Gamma with LabSOCS	Issue with initialization of variable geometry templates, where the symptom of failure is the error message "Variable sample material is not supported for this geometry" in geometry setup screen.
W8315480	Apex-Gamma with LabSOCS	Issue with initialization of non-English local variable geometry templates, where the symptom of failure is that the variable geometry icon in the Apex geometry setup screen would fail to launch.
W8315480	Apex-Gamma with LabSOCS	Corrects overestimated uncertainties for variable source-detector distance
D2553521	Apex-Gamma with LabSOCS	Issue with custom beaker templates used in variable geometry setup for European locals. The symptom of failure includes an error message when trying to define the variable geometry limits of fill height by mass or volume.
W7545510	Apex-Gamma Client/Server	Issue with executing cascade summing correction on Apex-Gamma Client / Server systems. The symptom of failure was that the second time a particular geometry was used for a cascade summing correction analysis, the CSC would fail and return "ERR" as a result. The root cause was a failure of the
		LabSOCS files to be copied to the correct location during the initial CSC run.
W2841306	Genie Gamma Analysis	Addresses a limitation to improve the behavior of NID when more than 200 nuclides are to be analyzed
M4983672	Genie Basic	Conversion Problem with FILECNVT utility
L1604409	Genie Basic	Autoscaling for an MCA failed to update properly for Genie V3.4.1. This is now resolved
G7382543		Issue with MVCG display window having slow response and/or crashing for certain screen aspect ratios
C10190508	Genie Basic	Maximum number of Analysis Sequence Files that could be displayed in Genie was erroneously reduced to 26. The original limit is now supported.
L1532692	Genie Basic	Analysis Sequence Files displayed in Genie were not properly sorted. Restores alphabetical sorting of ASFs in MVCG,
P8003585	Genie Basic	Certain Genie *.CAL efficiency calibration files cause a crash with Genie V3.4.1
W10772487	ISOCS	Geometry Composer Collimator type Selection Radial Buttons Fails to Show Existing Collimators
M1836957	Genie Basic	Lynx Preset time not respected when switching between live time and real time
C1974593	Genie Basic	GAA closes when executing Auto Gain Adjust Setup
J4324940	Genie Basic (V3.4.1 R1 only)	Inconsistent Peak Area Fitting for Significantly Large Multiplets
H10429922	Apex-Gamma	On a customer-specific configuration system, the Apex spectral plot window does not display
P10690089	Apex-Gamma Client/Server	Apex-Gamma limits control of Sample changer to one designated workstation. This has now been updated to allow control of a sample changer from any Apex-Gamma workstation.
G2785152	Apex-Gamma	Addresses an issue for when an efficiency count to a specified area in each peak hangs after the minimum preset is reached. This occurs when not all the peaks in the certificate have reached the specified peak area after the minimum count time and all the certificate peaks are present in the spectrum.

Apex-Guard™
Gamma Spectroscopy for Your Regulated Count Room

- Apex-Guard Lab Productivity Software integrates enhanced controls, security, and audit features with Apex-Gamma™ software for improved quality assurance and regulatory compliance

- Features and controls necessary for compliance to US FDA Title 21 CFR Part 11 Electronic Records and Electronic Signatures for pharmaceutical customers

  - 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

What is 10 CFR 21 Part 11?

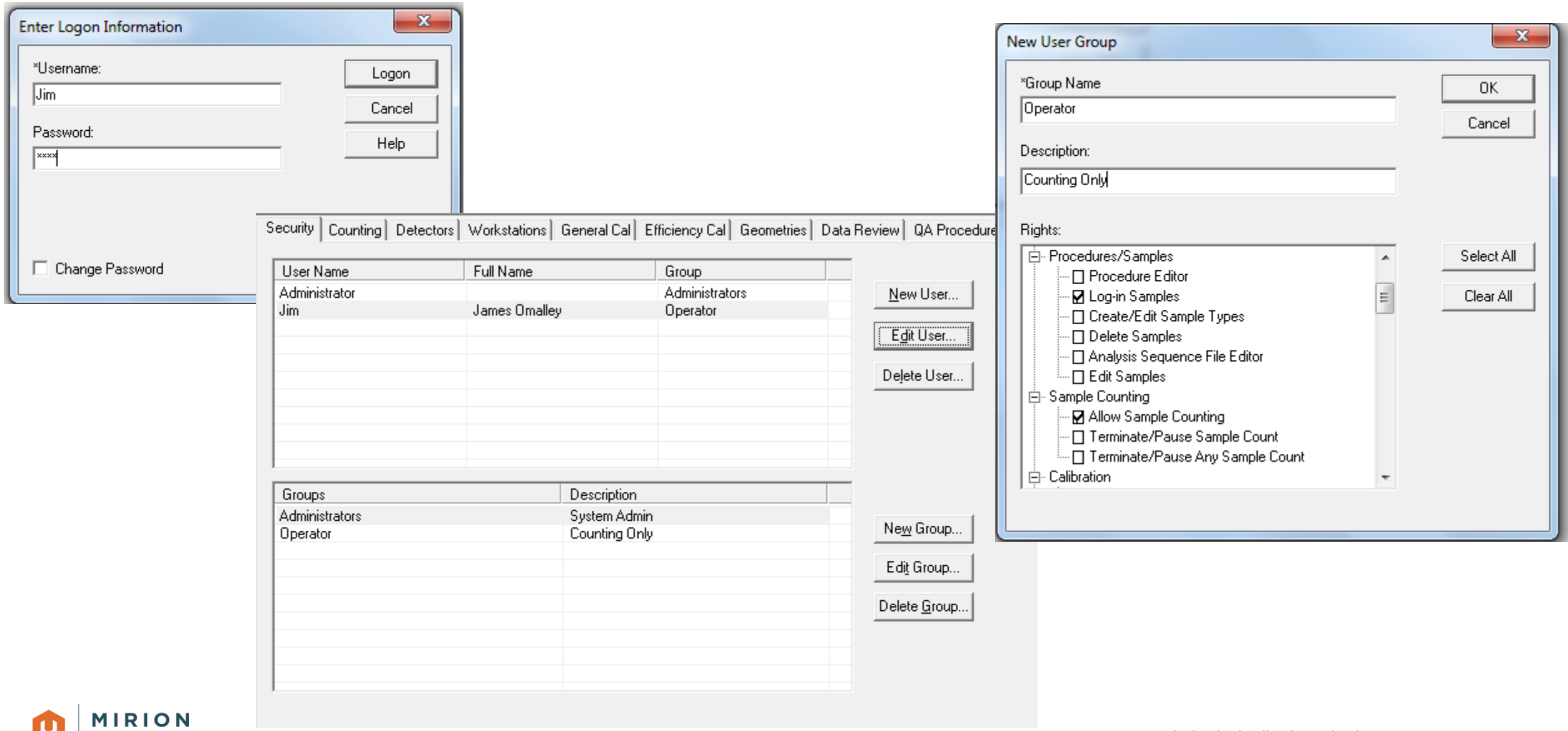
- **Title 21 CFR Part 11** is the part of Title 21 of the Code of Federal Regulations that establishes the United States Food and Drug Administration (FDA) regulations on electronic records and electronic signatures (ERES). **Part 11**, as it is commonly called, defines the criteria under which electronic records and electronic signatures are considered trustworthy, reliable, and equivalent to paper records (Title 21 CFR Part 11 Section 11.1 (a)).[1]
- Practically speaking, Part 11 applies to drug makers, medical device manufacturers, biotech companies, biologics developers, CROs, and other FDA-regulated industries, with some specific exceptions.[2] It requires that they implement controls, including audits, system validations, audit trails, electronic signatures, and documentation for software and systems involved in processing the electronic data that FDA predicate rules require them to maintain.
- Generally started to be introduced in early 2000s, starting to be enforced in our industry more regularly in past several years

"Data Integrity"

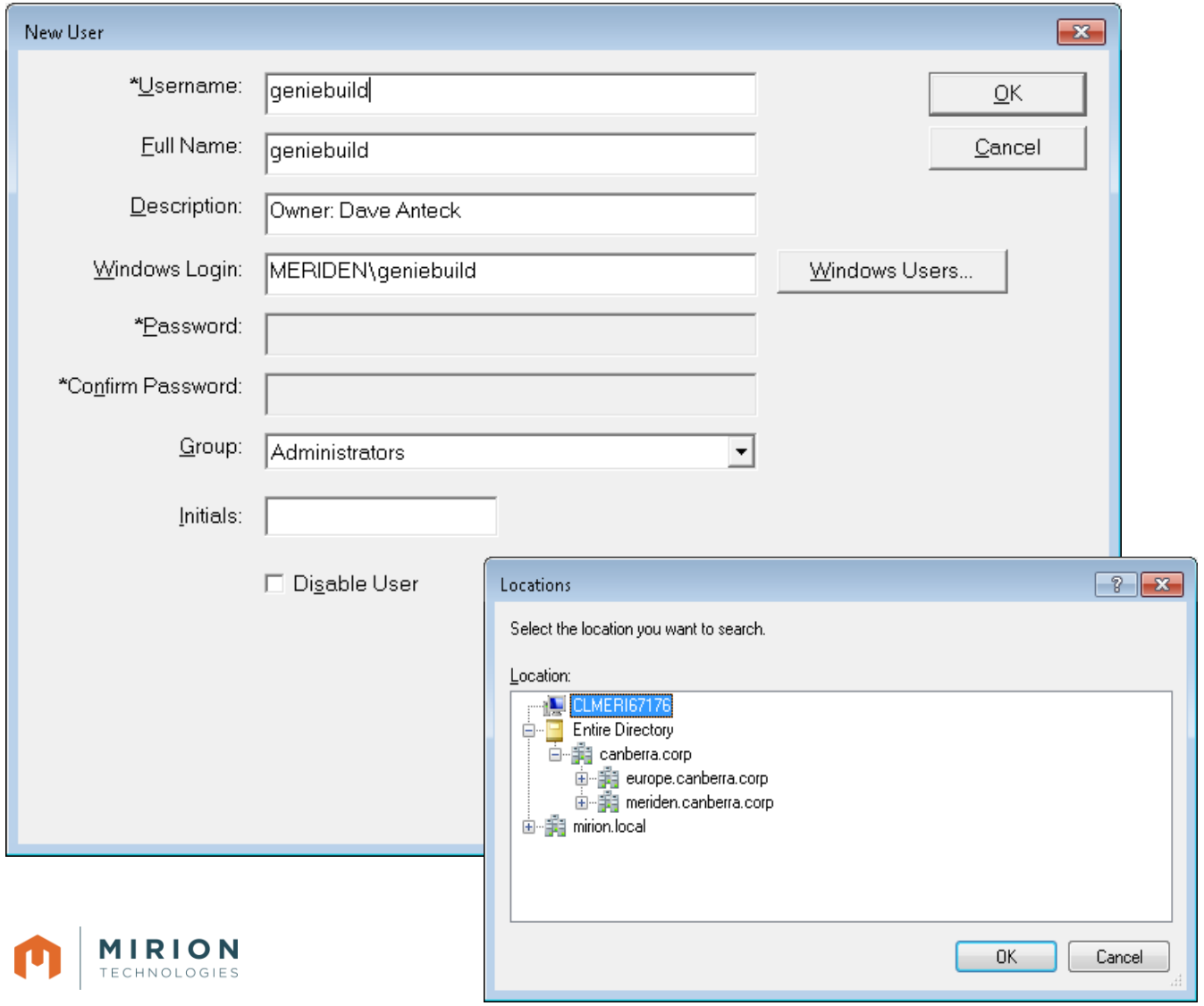
Including Radio-pharmaceutical and medical isotope Producers

Scope of Apex-Guard

User Login and Role Based Security

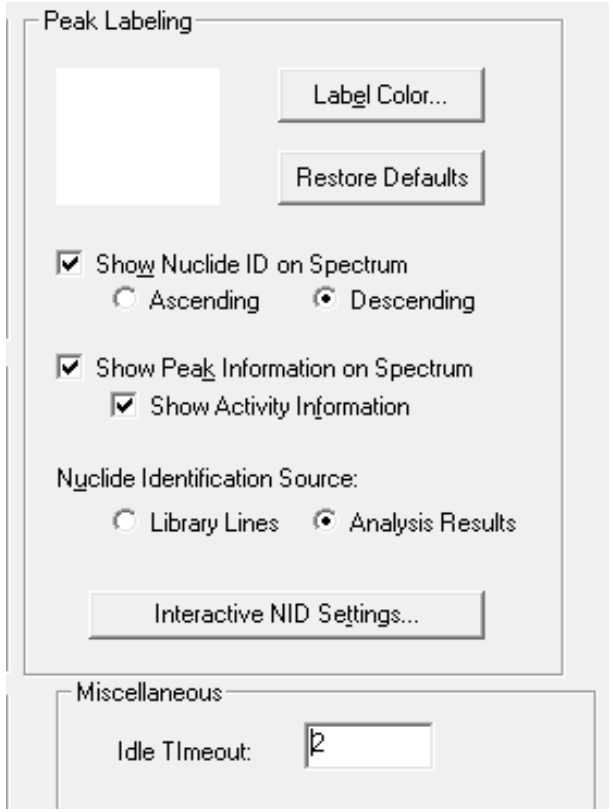


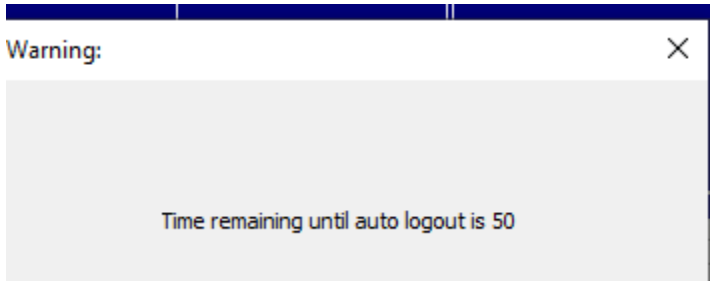
Log In Functionality w/ Windows Credentials



- New selection to browse for a Windows User
- Note the Password field is blanked. The application will use the Windows User Password
- Define a “Friendly’ Username. Note character limit is 16

Auto Log-Off Functionality



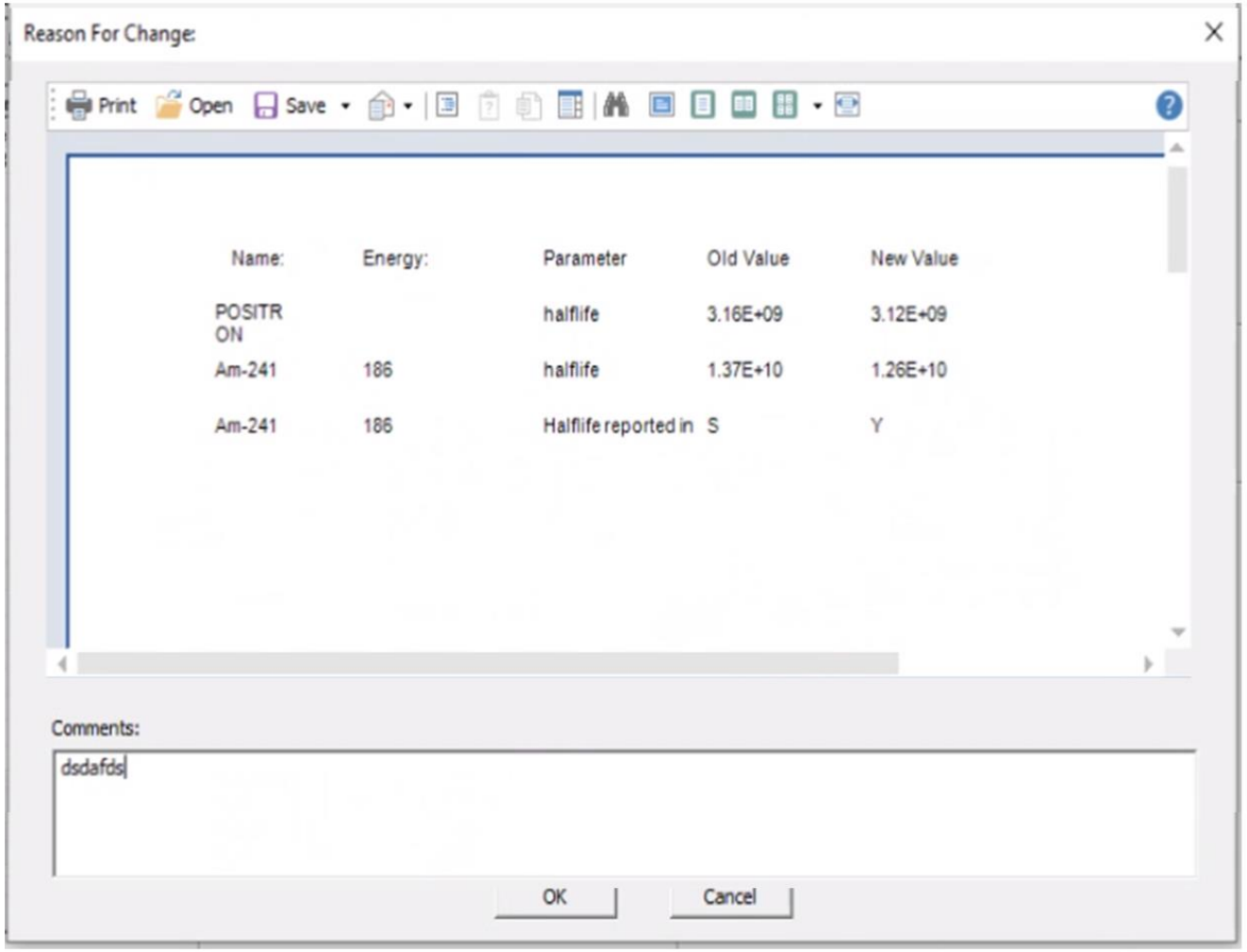


- The minimum value for the default is 2 minute
- The logoff tracks time since last mouse movement in Windows
- At 1 minute left, the warning message is generated
- If no mouse clicks during this time, the application is exited
  - Any changes in an application screen (such as an editor or procedure modification) that are not saved by the user will not take effect

Electronic Signature

- Showing NAME, TIMESTAMP, and PURPOSE/ROLE

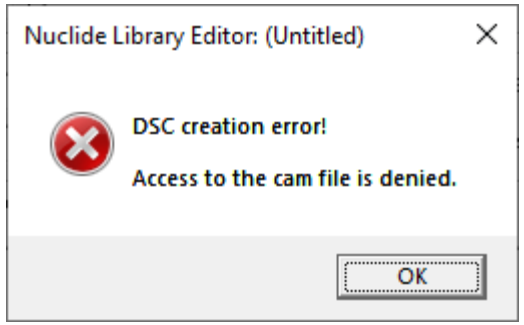
Recording Changes with a Justification



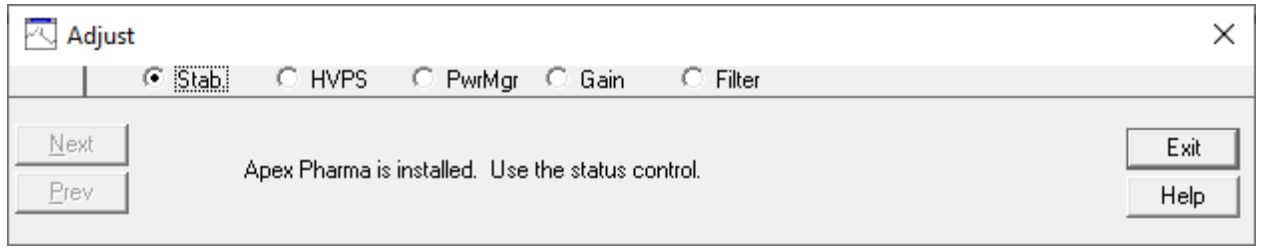
- This dialog gets generated after exiting an edit session
- So, one comment per editing *session*
- Each change is tracked via the Genie CAM parameters.
- Flexibility on what gets displayed via an editable schema (for expert users)

Ensuring the configuration cannot be modified outside Apex

- A file (for example, a library file) will not be allowed to be modified outside of Apex. An error message will be generated.
- Hardware adjust dialog now locked down outside of Apex when the Apex-Pharma option is enabled
- Using standard SQL Database protection for locking down the sample data.



- Certificates
- Nuclide Libraries
- Geometries
- QA files
- Analysis Sequence Files
- materials library
- ISOCS detector characterization
- beaker file
- calibrations



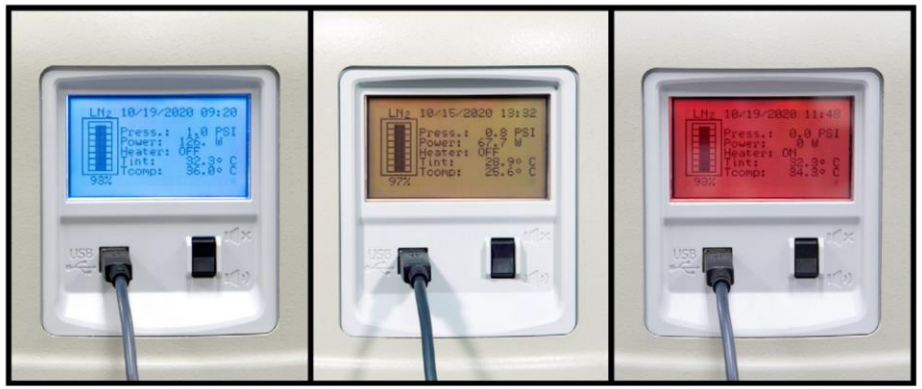
Intelligent Cryo-Cycle™
Hybrid Cryostat

FEATURES

- Low-vibration/low electrical noise even at low energies (no spectral resolution degradation)
- Low audible noise (<50 dB(A) at 1 m)
- LN_2 redundancy
- Non-CFC/non-flammable refrigerant
- Same footprint as standard LN_2 Dewar
- Low power demand (130 W nominal for typical detector configuration)
- Local (via LCD Screen) and remote State-of-Health monitoring
- Four years of onboard system memory for State-of-Health storage
- Lab-Pulse™ Ready
- No maintenance required

BENEFITS

- Low operating cost
- Designed for maximized detector uptime
- Field installable (dipstick version)
- Extremely quiet (<50 dB(A) at 1 m)
- No compromise on detector specifications



Blue LCD backlight: Unit operates normally, no action is required.

Yellow LCD backlight: Unit operates but requires attention, see error message for details.

Red LCD backlight: Unit does not operate properly, see error message for details.

Aegis™
Portable HPGe Spectrometer

FEATURES

- Thermal-cycle free cryostat
- Laboratory-grade energy resolution
- Choice of large 40% and 50% HPGe crystals
- RDC option enabling backshielding
- Easy to deploy all-in-one design
- System control via Genie™ 2000 software
- Designed to meet IP65 ingress protection rating
- Operational in -20 °C to 50 °C (-4 °F to 122 °F) ambient temperature when cooled down

Wound Counting/Locating Applications In Vivo

Articulating Arm Wound Counter

Tablet-based Portable MCS Wound Locator

Discussion

- Questions?
- Comments?