



OPTIMIZE OPERATIONS

# Apex-Gamma™

## Lab Productivity Suite



**Upon its initial release, the Apex-Gamma Lab Productivity Suite broke the mold of conventional gamma spec operations. Workflow gains continue today.**

Upon introduction, Apex-Gamma software enabled the integration of the gamma counting system into the complete operation of the laboratory. With this advance, we moved beyond the system as a functionally-isolated instrument offering only basic counting, calibration and QA capabilities. Instead, we set a foundation for replacing manual and offline processes with seamless, built-in functionality (Figure 1 on next page).

With Apex-Gamma software, users can easily access the complete status of a multi-detector system, quickly find samples to be counted, and log them directly from the sample preparation area. The software also helps ensure calibration and QA schedules are met, and monitors results. If something goes wrong, it automatically takes appropriate action.

### FEATURES

- ✓ Comprehensive operation and management for the production-oriented gamma spectroscopy sample-counting lab
- ✓ Designed for labs with large numbers of routine gamma samples
- ✓ Distributed, multi-user functionality provides access and control of the system from any client workstation
- ✓ Sample database tracks samples through log-in, counting and data review
- ✓ Flexible calibration capabilities, including scheduling, confirmation report and cross-check reports
- ✓ Broad QA capabilities, including scheduling, failure response and intra-lab comparison reporting
- ✓ Data review and reanalysis capabilities, for routine and non-routine evaluation of assay results
- ✓ Comprehensive event logging records every event on the system – with flexible recall
- ✓ Granular, role-based security system controls to manage access to system functions
- ✓ Genie™ Gamma Spectroscopy Software provides industry-proven analysis capabilities
- ✓ Support for Oracle and SQL Server database facilities

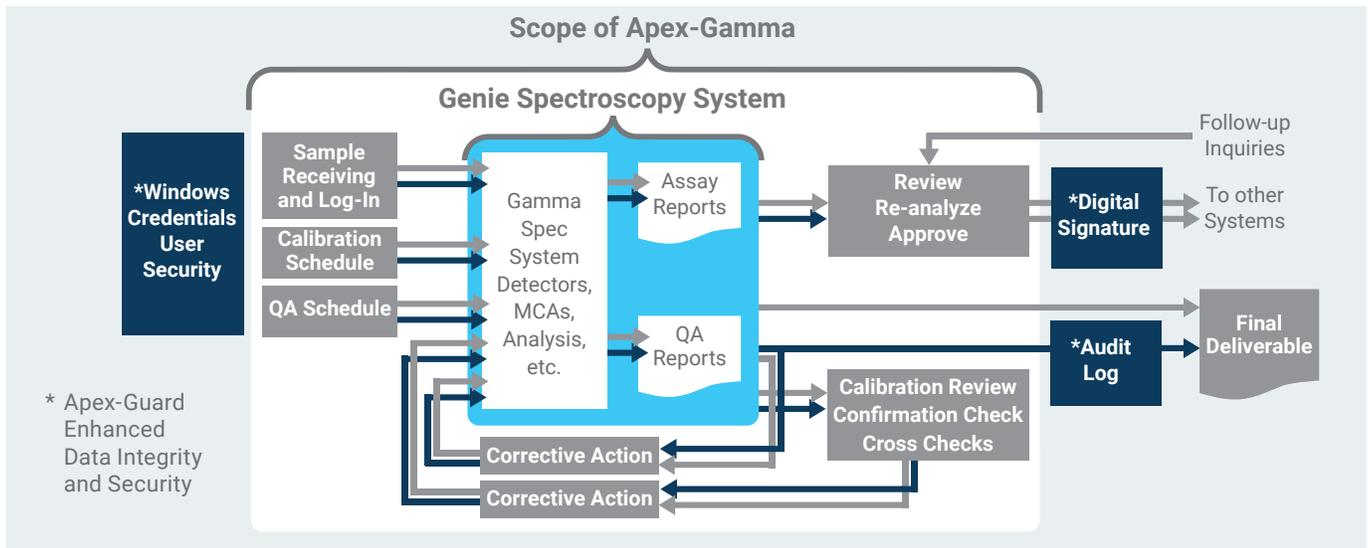


Figure 1. Schematic Workflow and Scope of Software Applications

## DATA REVIEW AND REPORTING

The key to Apex-Gamma software is its extensive database. As samples are logged, a record is created which remains in the system as the sample goes through various stages of processing – from counting to analysis, reporting, review and approval.

Built on relational database technology, Apex-Gamma software provides a complete view of what is happening in the gamma spectroscopy portion of your lab. You can easily find out how many samples are awaiting processing, which samples require data review, and even details like which samples were counted on a particular detector, with specific parameters, and within a certain timeframe.

## DISTRIBUTED, MULTI-USER FUNCTIONALITY

Apex-Gamma software is designed with a multi-user, client-server model, allowing for networked workstations accessible from anywhere in the system. This flexibility enables users to operate from different locations within the lab, such as the counting area, sample receiving areas, or supervisor and analyst offices.

With Apex-Gamma software, you have optimal information access and system control, when and where you need it. Multiple workstations can be set up in different areas of the lab to facilitate various tasks, such as sample log-in, data review, and system counting.

Furthermore, Apex-Gamma software allows you to operate multiple facilities from a single system. This means that you can use common resources to manage separate gamma counting operations.

Whether you have separate hot lab and cold lab areas, different health physics, radiochemistry, or training areas, or a combination of HPGe and NaI detectors, all these variants can be controlled from one distributed Apex-Gamma system. The system can be partitioned to ensure easy management and secure access for each facility (Figure 2 on next page). This distributed architecture provides a centralized and efficient solution for managing multiple lab operations, streamlining processes, and maximizing productivity.

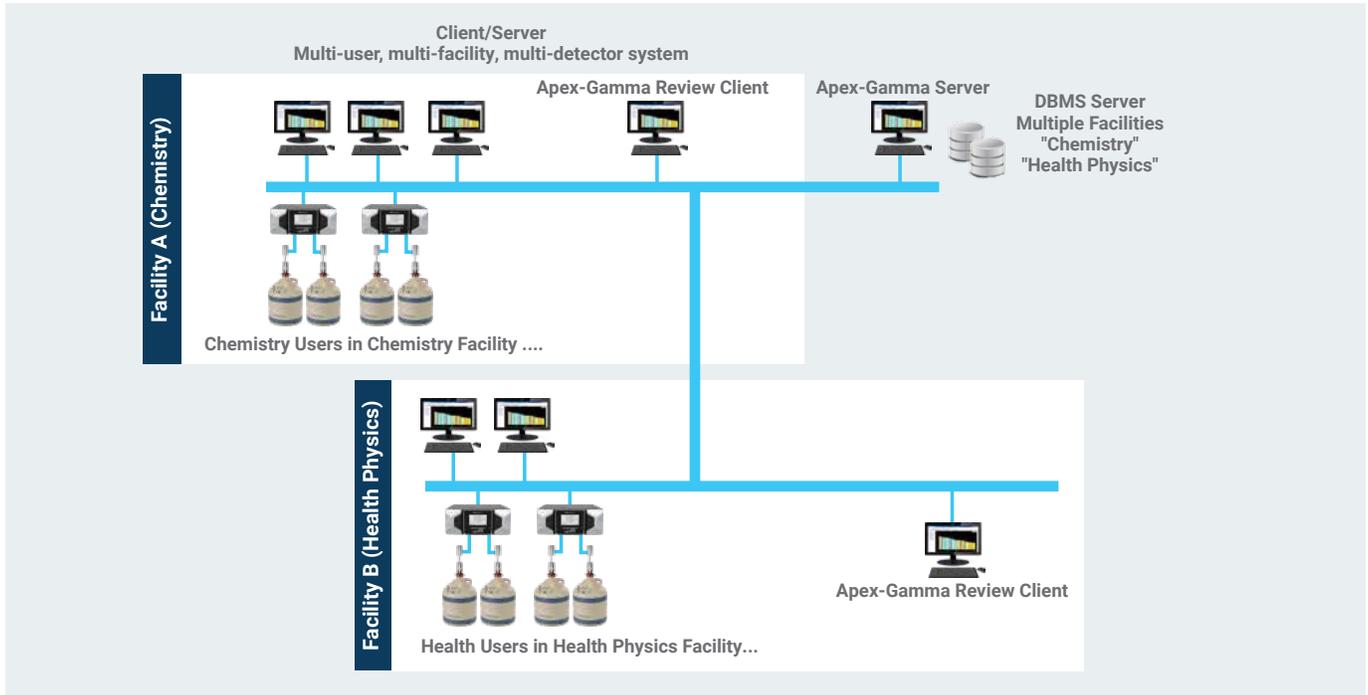


Figure 2. Apex-Gamma Multiple Facility Model

### SAMPLE COUNTING AND MANAGEMENT

Without a resource like Apex-Gamma software, samples typically were not “known” to the counting system until the moment the sample was placed on the detector. With Apex-Gamma software, a sample can be logged once the requisite sample information is available – from any location. Simply locate a client workstation in the sample receiving/preparation area and begin logging once samples arrive, enabling a more efficient, paperless approach. Other users will find a simple, customized interface allows for the download of sample lists directly from the Laboratory Information Management Systems (LIMS). In either case, Apex-Gamma software can eliminate manual processing of records, dramatically reducing transcription and data entry errors.

Once samples are logged, use Apex-Gamma software’s Main View (Figure 3) to manage sample counting and keep your detector assets working for you. Glance at a client workstation, and instantly see the status of up to six detectors on thumbnail views (more by selecting a “next” group button). Color-coded backdrops on the

spectrum views show which detectors are counting, busy, and offline or unavailable. A closer look displays estimated completion time for each measurement in progress (no elapsed/preset “mental math” required!).

Drag and drop logged-in samples to any available detector start count

“Estimated Completion Time” makes it easy to establish which detector is available next

Color code shows detector availability at a glance.  
 Green – Busy  
 Blue – Available  
 Brown – Off line  
 Red – Error (not shown)

Figure 3.

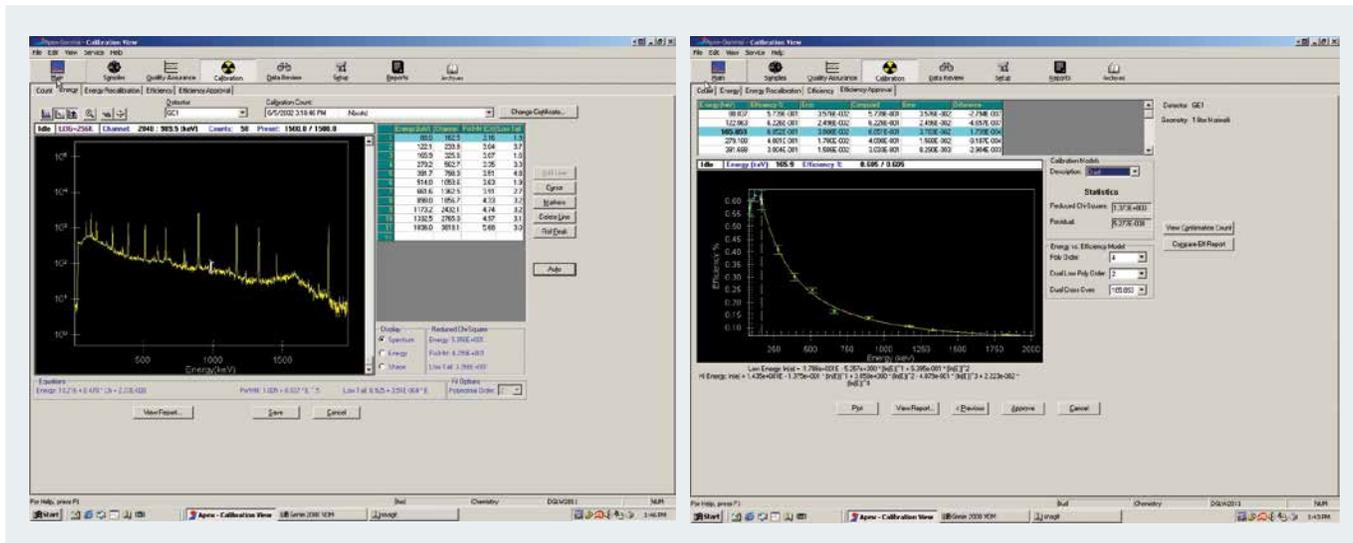


Figure 4. Interactive Efficiency Calibration

## SIMPLE AND STRAIGHTFORWARD

When a detector becomes available, users can easily drag and drop samples from the sample queue to the detector display to start counting. Defining samples is also easy. Users can enter a sample ID manually or let the system generate one automatically. They can then select a counting Procedure and enter sample information such as date, time, and quantity. The user interface is designed to be flexible and user-friendly.

If there are multiple nearly identical samples, users can define the first sample and then use the "copy" feature to create more, changing only the information that varies from one sample to the next. If a sample needs to be recounted, users can simply click the recount button and navigate the sample information database using filters to locate and load the sample back into the queue.

The key to the simplicity of sample entry in Apex-Gamma software lies in the Procedure, which helps ensure counting only occurs only as long as needed to reach MDA and not beyond.

Within the Procedure editor, users can assign a friendly name for the procedure and define all the necessary parameters for a specific type of assay, from count parameters to report review requirements. Embedded within the Procedure are the count time or Count to MDA, analysis sequence, sample geometry, library, required reports, sample information, and required data reviews.

## MANAGING CALIBRATION OPERATIONS

Calibration documentation is critical to a well-run laboratory and for passing any audits. Apex-Gamma software not only provides simple and accurate calibration facilities, it offers management tools to ensure records are up to date and calibrations are properly verified, approved and performed according to the required schedule.

The calibration operation in Apex-Gamma software is rigorous. First, the calibration spectra are counted using a dedicated screen designed specifically for calibration, which includes hardware MCA adjustment facilities.

Energy and efficiency calibrations are then performed on interactive "one page" calibration screens. These screens allow users to adjust calibration parameters and inputs and instantly see the results (Figure 4). Efficiency calibrations can be performed using traditional source methods, including automatic combination of multiple counts, or using the LabSOCS™ mathematical calibration method developed by Mirion.

Efficiency calibrations may optionally require a separate approval process, typically performed at a higher security level, before they can be used. The efficiency calibration and approval screens provide advanced capabilities for adjusting the calibration.

Additionally, there are facilities to generate an Efficiency Confirmation Report, which compares the decay-corrected source certificate activity to a recount of the standard with a standard gamma analysis, calculating variances. Similarly, an Efficiency Comparison Report allows users to compare a newly generated efficiency calibration to a previous one.

To ensure that multiple detectors are performing identically, Apex-Gamma software provides a Detector Cross Check Report comparing decay corrected certificate activities to activities calculated from counting the standard on multiple detectors. Variances are calculated, as well as other figures of merit, to ensure that all of the detectors in the lab are performing comparably for a given sample geometry.

The productive gamma spec operation needs to ensure equipment is always calibrated according to a fixed schedule. Energy and efficiency calibration summaries show last calibration information (dates, by whom, etc.), as well as the date the next calibration is due – calculated automatically from a “calibration frequency” parameter entered in setup.

If a user attempts to use a detector with an overdue energy calibration, or in a detector/geometry where the efficiency calibration is past due, Apex-Gamma software can either log the error, warn the operator, or prevent counting on that configuration entirely (as specified by the System Administrator). In the case of an energy calibration past due – which means that the detector should not be used in any geometry – the detector can be taken completely offline automatically.

With Apex-Gamma software, numerous standard calibration practices – once done only manually in a time consuming, offline manner – can now be completed directly on the counting system, without manual transcription, calculators and spreadsheets.

## THE QUALITY ASSURANCE PROGRAM

Quality Assurance is an integral part of production gamma spectroscopy, and for this reason it is directly integrated with the Apex-Gamma application.

Routine QA checks for calibration and background are initiated directly from the main view. QA counting parameters are set up and defined ahead of time, making the interface exceptionally simple for the operator. Setup defines the reports and control charts to be produced automatically at the end of each QA check. An easy-to-use report and chart review tool also lets the user quickly review QA data for a given detector – paging sequentially through all control charts and reports in one operation. Most importantly, “failure responses” can be configured to log, warn, or lock a detector in case a QA count is missed or out of tolerance, ensuring samples are counted only on a detector with a successful QA count.

Apex-Gamma software provides a special QA study feature that allows users to initiate a series of QA counts for a given detector in a single step. This feature is particularly useful for performing QA counts over an extended period, such as a weekend. Users can request consecutive calibration QA checks at one-hour intervals, and the system will collect the necessary information without requiring manual intervention.

The Apex-Gamma QA system is designed not only to perform routine QA checks, but also to ensure that they are done and to take corrective action if the system goes out of tolerance. Each QA count type, including calibration check, background check, and long system background, has a frequency associated with it in the system setup, along with a predefined response if the specified period is exceeded. For example, if daily calibration checks and weekly background checks are required, the system can be set for 24 hours and 168 hours, respectively. When each sample count is initiated, the time since the last QA check is calculated, and if the period exceeds the defined limit, the system will automatically initiate a warning or detector lockout, depending on the setup.

Similarly, users can define specific responses to be taken if a detector goes out of tolerance. For instance, the system can be set to issue a warning for an "investigate" level violation (typically 2-Sigma) and initiate a lockout for an "action" level violation (typically 3-Sigma).

By utilizing the advanced QA facilities of Apex-Gamma software, lab operators can ensure that all assays are performed on instruments with up-to-date and successful QA checks. This significantly reduces paperwork burdens and offline activities. Moreover, the software enables easy demonstration of QA program compliance to external auditors or regulators.

## DATA REVIEW, REANALYSIS AND APPROVAL

With the Apex-Gamma Lab Productivity Suite, the data review and correction process are integrated into the software. Data reviews can be set as either optional or mandatory, based on system-wide defaults or specific procedures. If set as mandatory, a counted sample is held with a status of "pending review" until a user with the necessary security authorization reviews and approves it. Once approved, the sample status advances to "done".

In some labs, there is a need for different levels of data review based on the role of the reviewer. Apex-Gamma software addresses this by allowing two levels of sequential data review, both of which are required before a sample is considered "done". The technician who counts the sample may perform a cursory review, allowing only limited edits such as sample date or quantity. An analyst or radiochemist can then perform a more comprehensive review using advanced tools.

Retrieving samples for review is made easy with the software's database filters (Figure 5), especially when there are hundreds of samples to manage. Without the database, users would likely create a different file for each sample which would become unwieldy at some point. Having a tool to find the appropriate sample can save significant time. Filters can be applied to locate specific samples or groups of samples that need to

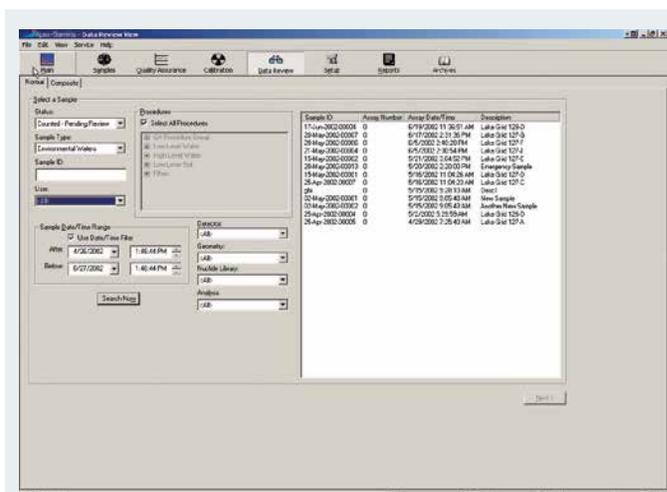
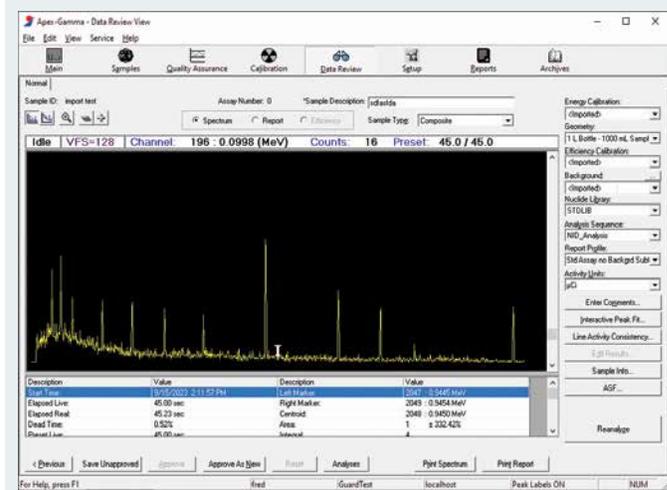


Figure 5. Data Review: Enter sample filter criteria to locate just the sample you want...



...Then review, modify, re-analyze and approve the samples.

be reviewed. This flexibility is particularly important where the Data Review section is used to respond to follow-up needs. For example, an environmental lab may receive an inquiry about a specific type of sample from a specific project. By using date and time filters in conjunction with procedure, sample type and other information, the user can easily isolate the specific samples in question.

An additional example of use is a nuclear power plant that may discover an unknown peak in cooling water and associate it with a previously unseen corrosion product. This may result in a library change after which a review would be required to detect the exact point where the new nuclide began to appear.

For Apex-Gamma software, it's a simple problem – apply time and library filters to find the set of affected samples – reanalyze and reapprove with the new library. What was once a massive disruption to lab operation is now an efficient process. Similar procedures can be applied to recover from the impact of questionable calibrations, detectors, procedures – and even operators.

A new feature with Apex-Gamma software is the "Analyses" button, which allows a user to review and restore previous analyses and results completed for a given sample. This way a user can reanalyze while keeping record of the original result, meeting various regulatory compliance needs.

Another unique data review facility is the creation of a "composite sample" – combining results from several measurements into a single report. This can be used in any case where samples may be split for separate counts – but the need is to report the results for the original sample on a single report. Nuclear power plants often need to measure the particulate and iodine components of an integrated filter separately, then combine the results.

Similarly, a cooling water sample may need to be measured immediately, then again after decay of short half-life isotopes. Or an environmental lab may receive a large sample that must be counted in multiple containers – then recombined into a report on the total sample.

Data are combined in the Composite Sample Report by either summing or averaging the results for identical nuclides (with full error propagation). Additionally, a setup screen lets the user select which nuclides from which samples to include in the final report.

## EVENT LOGGING/AUDIT LOG

In lab operations, the ability to retrieve information, review history, and retrace steps is crucial. Whether for lab performance review or in response to a legal challenge, having rapid and complete information retrieval can save significant time and money.

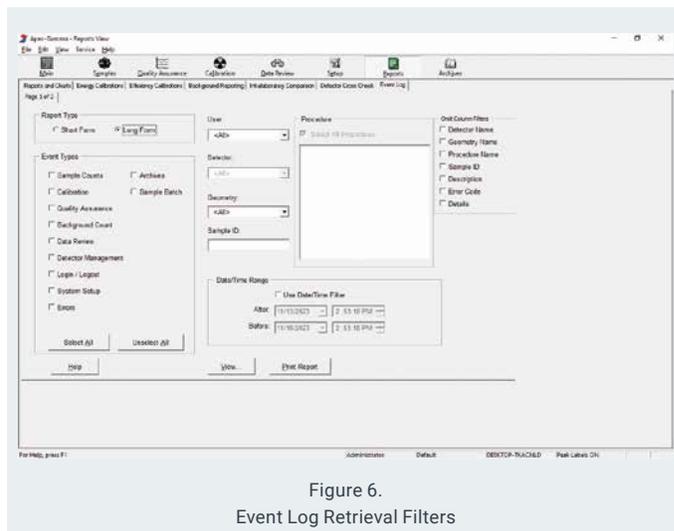


Figure 6.  
Event Log Retrieval Filters

Apex-Gamma software addresses this need by offering a consolidated event log/audit log accessible from any networked client. The consolidated log includes log-on/off events, sample counts, calibrations, QA checks, data reviews, and more. Each event is recorded and can be easily recalled when needed. Database keys enable the retrieval of specific event information, allowing users to retrieve the exact information they are looking for (Figure 6).

The potential utility of this feature is vast. For example, if you need a list of work done on a specific day, shift, or week, you can request all events within a given time/date period. If you require documented proof that daily QA checks were performed on a specific detector for the last month, you can request a list of all QA events for that detector during the month. Similarly, if you need to verify the activities of a specific user or obtain a list of samples counted with a specific library, geometry, or detector, you can simply consult the Apex-Gamma Event Log.

All records are available on demand and are automatically created by the system. They can be used anytime there is a need to reconstruct activities on the system, providing a valuable resource for information retrieval and historical analysis.

For users who require even more detail in an event log, Mirion also offers the Apex-Guard™ option. With Apex-Guard software, the event or audit log capability is expanded even further to also capture the new and previous value of a parameter changed. It also has the capability for a user to enter in a comment with each change, which is displayed in the audit log as well. For applications that require justification, this feature provides ability for users to enter and record the reason for each change to a system or analysis configuration.

## **SECURITY**

Security requirements are critical in most routine sample counting facilities. It is imperative that personnel only perform operations for which they are qualified.

The security capability in Apex-Gamma software is both extensive and flexible. The system administrator plans the security setup – determining classes of operators and capabilities allowed for each class. A group profile is set up for each class of operators – lab technicians, sample preparation technicians, radiochemists, analysts, supervisors, etc. – with specific privileges assigned to each group. For example, lab technicians may be allowed to perform sample counts, but not calibrations. Sample preparation technicians may be allowed to log samples in, but not count them. Perhaps only chemists are given the capability for data review. There are over 40 security controls that can be enabled/disabled for each group, providing an extreme level of flexibility to accommodate any operational need.

There are not defined “levels” in the profiles, only access or non-access to specific functions. For example, a technician may have privilege to count a sample, but no access to data review. A chemist can be set up to perform data review, but not counting. Thus, the security profile need not be hierarchical.

Once groups are set up, individual users are assigned to the groups (Figure 7). Each user has a login, and all activities performed while a user is logged on are associated with that user in the database. With this approach, the security system is easy to maintain. As users come and go through the organization, they are simply added to or deleted from system – you do not need to re-create a complete security profile for each user. For users who would like to integrate usernames and password management with their greater IT environment, the Apex-Guard option will interface directly with the network domain and use the available Windows Credentials instead.

## **MULTI-FACILITY CAPABILITY**

Many lab operations are physically separated. A nuclear power plant may have separate health physics, chemistry, and environmental operations. A lab on a nuclear site may have separate low level and “hot” labs.

Apex-Gamma software allows these separate facilities to be operated from a single database – maintaining separation of critical structures (detectors, calibrations, procedures), while allowing sharing of others (client workstations, file and database servers). In this manner, the operation of a large counting facility can be segmented, for convenience and economy of operation. Totally separate labs within a site can be operated from one database – with most resources separated. Users will often use these facilities to have a training environment or to test new procedures before putting them into production.

## SPECIFICATIONS

For recommended system specifications, including Windows PC requirements, please refer to the *Genie™ 4.0 and Apex® Products Operating System and Database Qualifications* resource:



Data storage requirements are approximately 500 assays per 1 GB.

## ORDERING INFORMATION

- **Genie-Multi, Genie-Multi-1yr, or Genie-Multi-3yr:** Each computer, server, or virtual machine running Apex-Gamma software requires a compatible version of Genie Multi-Input Spectroscopy Software Suite.
- **Apex-Gamma, Apex-Gamma-1yr, or Apex-Gamma-3yr:** The Apex-Gamma product includes distribution of the Apex-Gamma Desktop application, the Apex-Gamma Server Application, and the Apex-Gamma Client software and license to operate any one of these software applications on one computer or virtual machine. Additional quantities may be purchased to activate the license on additional computers. Apex-Gamma NPP option (previously model S704) is included and may be optionally installed.
- **Apex-Guard, Apex-Guard-1yr, Apex-Guard-3yr:** The Apex-Guard option can be added to an Apex-Gamma system to satisfy enhanced data integrity and audit controls requirements typical of GMP regulations. If used, one Apex-Guard license activation is required for each computer of a networked Apex-Gamma Client/Server system.



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