Waters™

System Policies and Privileges for Processing Data in Empower Software with Data Integrity in Mind

Explore how Empower Software System Policies and User Type Privileges can be used to control user actions when processing data, particularly when working in the Review window.

INTRODUCTION

Regulators expect Pharmaceutical Quality Risk Management (QRM)[1,2,3] systems to continuously evolve and improve over time. As pharmaceutical organizations strive to adhere to regulations and guidelines and to achieve Quality Management Maturity (QMM), it is important for Quality Units and Regulators to understand the capabilities available in Empower™ Software for processing data. It is also critical to evaluate the need for appropriate controls within your organization, together with varied levels of flexibility. While this paper explains the processing-related policies and privileges available with a focus on how this affects what an analyst can and cannot do when processing data in the Review window, it is up to your organization to configure Empower Software, User Types, User Groups, and Users as fit for your intended use. When set properly and used with appropriate corporate procedures and data governance, you can ensure compliance with 21 CFR Part 11 as well as other GxP regulations, Annex 11, ISO 17025, PIC/S Guidances, or other standards.

A common approach typically includes employing a variety of User Types to meet both your laboratory and business requirements, in addition to any specific workflow requirements. These needs often vary between laboratories and chromatographic methods. It is vital for you to perform ongoing, documented risk assessments of your workflows and against new information, including software functionality, to determine and document hazards and their effective mitigation.

For the Waters assessment of risks pertaining to Empower Software privileges and other documents related to this topic, see the Empower Compliance, Durable Data, and Functionality eBook.

SYSTEM POLICIES

System Policies control the behavior of key areas of Empower Software for the Empower environment. These settings affect all users and control specific aspects of how all users interact with the software. The Empower system administrator can set rules governing user accounts, log in procedures, full audit trail default settings, data processing techniques, Result sign off requirements, and date formats. System Policies help define peak detection and integration techniques, and calculations that Empower Software uses to process data.

There are several data processing System Policies (Figure 1) that impact processing data:

- **Use v3.0X Style Peak Width and Threshold Determination**: For Processing Methods that use the Traditional integration algorithm, this System Policy specifies the use of the legacy Peak Width and Threshold determination method used in Millennium[32] Software in versions 3.0x instead of the Auto-Peak Width and Auto-Threshold capability introduced with Empower Software. This System Policy is available for compatibility with legacy methods.

- Enabled: The Peak Width and Threshold buttons, Processing Method wizard, Processing Methods, and Results all function as previously in Millennium[32] Software.
- Not Enabled: The software uses a second derivative to set the Peak Width and Threshold values in the Processing Method. The Auto-Peak Width and Auto-Threshold functionality is available.

For more information, see Empower Software Data Acquisition and Processing Theory Guide, Section 3.1.

Note: This policy must be enabled when performing Empower SQT for Software.

- **Use v2.XX Style Retention Time Calculations**: Specifies the approach to determine peak Retention Time and Height that was used in Millennium[32] Software prior to version 3.0. This System Policy is available for compatibility with legacy methods.
  - Enabled: Uses only the highest data point from the baseline to determine retention time and height and disables fitting a quadratic curve to the top of the peak. Processing Code I09 appears in the Results table.
  - Not Enabled: Uses the inflection point of a 5-point quadratic fit to the Peak and assigns this as the Retention Time, whenever possible.

For more information, see Empower Software Data Acquisition and Processing Theory Guide, Sections 2.1, 2.5, 3.1.

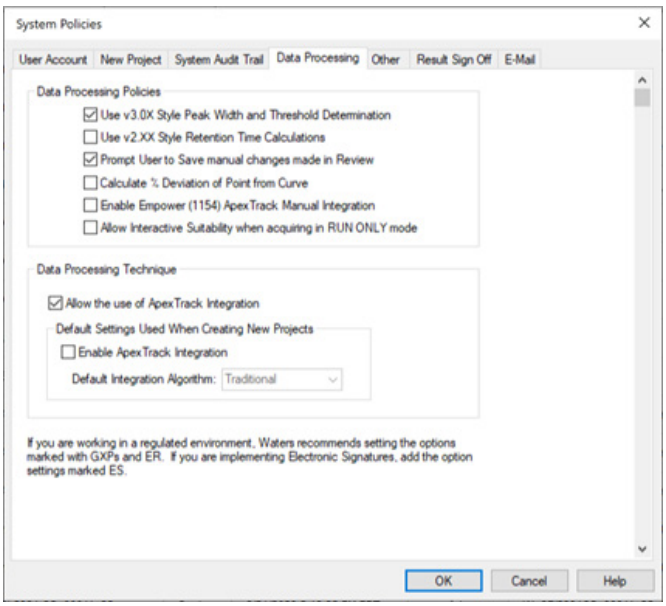


Figure 1. Data Processing System Policies options, default settings.

- **Prompt User to Save Manual Changes Made in Review**: For users executing workflows that require the flexibility to create Results in the Review Window, this policy provides a reminder to the user to save changes before exiting (Figure 2) to prevent work from being lost.

  When this System Policy is enabled, if a user attempts to exit the Review window after creating a Result, they are prompted to save the Result(s). If users save Results at this point, the last version of all Results and any related changes are automatically saved (*i.e.* calibration curves, methods).

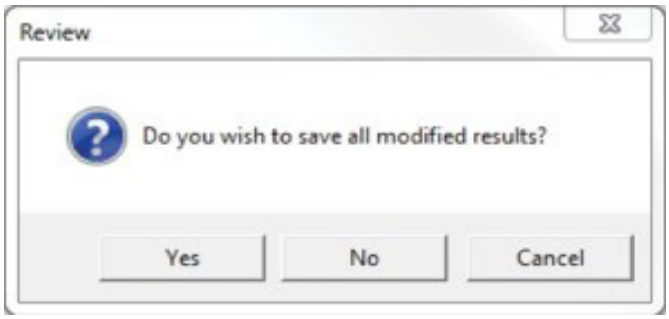


Figure 2. Save Results message when exiting from the Review window.

Note: Any Results saved in the Review window in this manner are automatically labeled as Manual regardless of whether manual integration was used.

- **Calculate % Deviation of Point from Curve:** Changes the formula for calculating % Deviation.
  - Enabled: % Deviation (Calculate % Deviation of Point from Curve) is calculated using the following formula:

    $$\% \text{ Deviation} = \frac{(\text{X Value} - \text{Calculated Value})}{\text{Calculated Value}} * 100$$

  - Not Enabled: % Deviation (Calculate % Deviation of Curve from Point) is calculated using the following formula:

    $$\% \text{ Deviation} = \frac{(\text{Calculated Value} - \text{X Value})}{\text{X Value}} * 100$$

- **Enable Empower (1154) ApexTrack Manual Integration:** Specifies that when using an ApexTrack Processing Method and applying manual integration, Empower Software will follow the rules of legacy manual integration for ApexTrack used in Empower 1 Software.

Note: In Empower 2 Software and newer versions, if this System Policy is not enabled when a baseline is manually drawn, Processing Method parameters such as Peak Width, Threshold, and Integration Events are applied to the manual peak. This allows for the creation of Gaussian and Tangential Skims, even when manually integrating rider peaks. If you draw a manual baseline from the beginning all the way to the end of a peak cluster, this will generally result in the detection and integration of multiple peaks. The automated logic that prevents the baseline from intersecting the chromatogram during automated processing also prevents the baseline from intersecting the chromatogram of manually integrated peaks.

- **Allow Interactive System Suitability when acquiring in RUN ONLY mode:** Interactive System Suitability, including Stop on Fault and Reinject on Fault, can be triggered when using Run Only mode, although Results are not saved.

  Note: It is recommended to operate in Run and Process mode when using Interactive System Suitability during acquisition in a regulated environment so that all Result(s) are saved.

PROCESSING METHOD PRIVILEGE OPTIONS

Empower Software allows users to operate under a set of defined privileges that collectively determine an overall User Type. Depending on the roles and tasks performed by the user in the laboratory and business, your Empower Software administrator should assign privileges as appropriate for the workflow the user performs. It is possible for an individual user to be assigned more than one User Type containing different privileges and the user is then able to choose the appropriate User Type upon log in depending on the workflow they are about to perform. To properly configure User Types in Empower Software it is imperative to understand how these privileges operate and to document the specific privileges that laboratory users need to perform their work.

The privileges associated with Processing Methods have a significant effect on what users can do in the Review window:

- **Lock Methods:** A locked method can be used to generate Results; however, it cannot be modified once locked. Locking a method is a permanent action and cannot be undone in Empower 3 Feature Release 4 and prior versions.
  - Locking and unlocking a method results in the method version incrementing by one and a new Method ID is assigned.
- **Unlock Methods:** A locked method can be unlocked for modification. This privilege is available in Empower 3 Feature Release 4 Service Release 3 and newer versions. This privilege is not available in Empower 3 Feature Release 4 and prior versions.
  - Locking and unlocking a method results in the method version incrementing by one and a new Method ID is assigned.
- **Delete Processing Methods:** Allows a user to permanently delete a Processing Method only if the method is not associated with Results. After 'deletion', any Processing Method associated with Results is removed and is not present in Project Window views. This method remains associated and reportable with the Result(s) and can be made accessible again in the Project window by Saving As Current (Select Result > View As > Processing Methods > Method Properties > Save As Current).
- **Save Processing Methods:** Allows users to create new Processing Methods and/or modify existing unlocked Processing Methods. This allows users to modify all parameters in any tab of the Processing Method.

  Note: This privilege supersedes (Figure 3) the more discreet sub-privileges described below.

SUB-PRIVILEGES OF THE SAVE PROCESSING METHODS PRIVILEGE

If the Save Processing Method privilege is not granted, the ability to modify a Processing Method and save the changes (as the same Processing Method or a new Processing Method with a different name) depends on whether any of the next three privileges are granted. These sub-privileges provide granularity to grant user access to only specific parameters in the Processing Method.

- **Modify Integration Parameters:** Allows users to modify peak detection and integration parameters on the Integration tab, such as Peak Width, Detection Threshold, Minimum Area, Minimum Height, and Integration Events. This privilege is required for users to optimize integration, account for day-to-day variation in peak shape and define the Peak Area or Peak Height for LOQ (Limit of Quantitation).
- **Modify Component Times:** Allows users to modify the expected Retention Times of Named Peaks and Timed Groups on the Components tab. This privilege is required for users to account for day-to-day variation in Retention Time and ensure correct peak identification during batch processing or when applying the Processing Method in the Review window.
- **Modify Component Constants/Default Amounts:** Allows users to modify CConst fields on the Components tab. This may be required to modify constants used to capture values such as Label Claim or Moisture Content when these values periodically require updating. This also allows the user to modify existing Default Amounts.

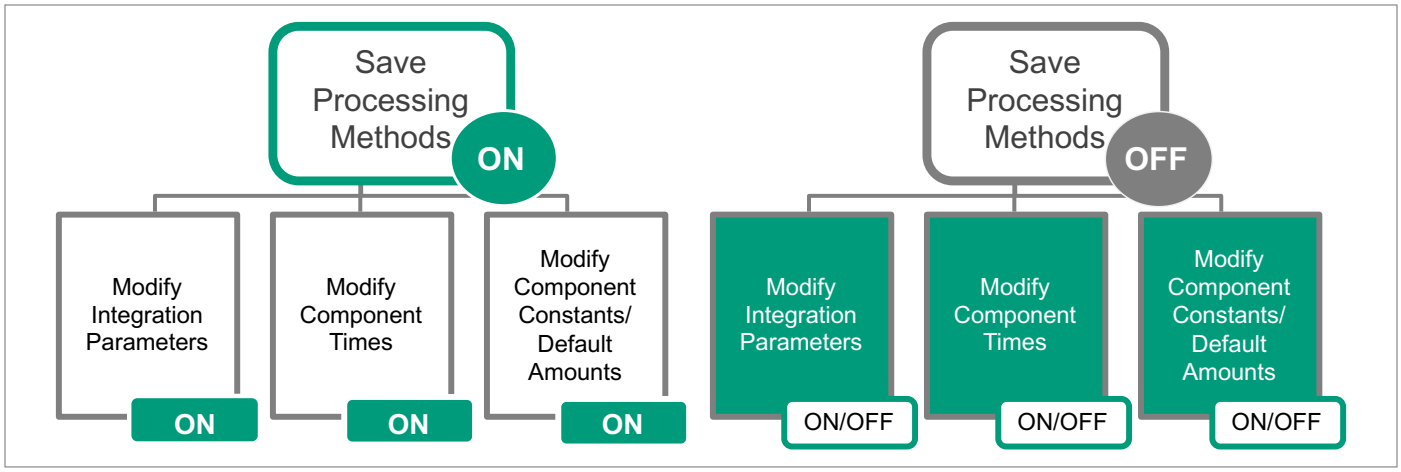


Figure 3. Hierarchy of Processing Method privileges. The Save Processing Method privilege supersedes the others. Granular control of what a user can and cannot change in a processing method is achieved by allowing any combination of the three 'modify' sub-privileges.

Collectively these privileges allow you to tailor a user's ability to modify specific parameters of the Processing Method as required by their analytical test methods, workflows, and intended use.

REVIEW WINDOW PRIVILEGE OPTIONS

Limiting these three privileges (Figure 4) to certain user roles offers an opportunity to reduce potential risk of analyst bias influencing integration during data processing. With the flexibility to employ multiple approaches when leveraging processing privileges, your organization has a choice of appropriate technical controls to use depending on your scientific methods, analytical workflows, business needs, business processes, and risk analysis. These privileges must be carefully evaluated against company procedures and risk assessments to ensure information that users require during data processing is understood and documented, and that users have the appropriate privileges and information needed to adjust Processing Methods for their intended workflows and to produce accurate Results during both automated and manual processing.

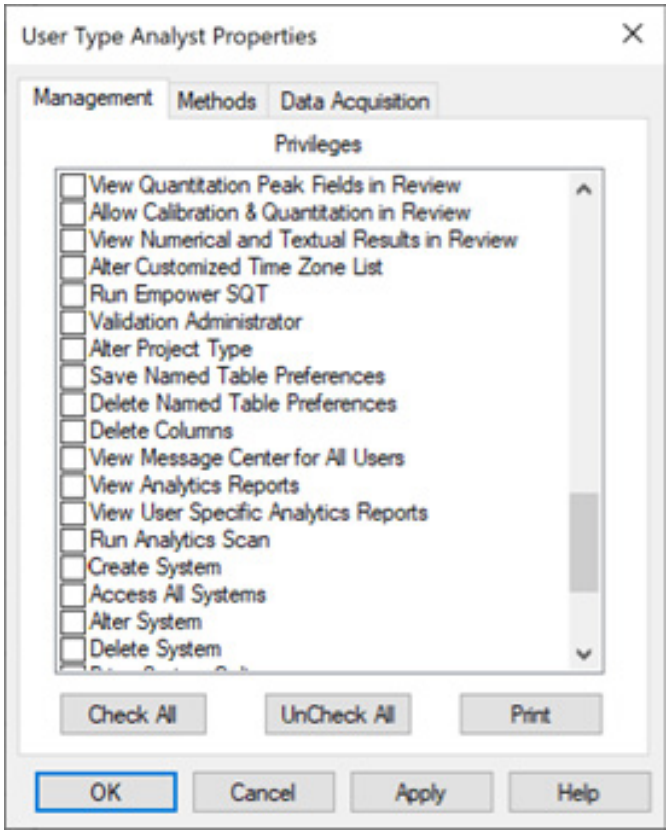


Figure 4. Privileges available that are associated with actions in the Review window.

VIEW QUANTITATION PEAK FIELDS IN REVIEW (VQPFR)*

This processing technical control, introduced in Empower 2 Software, is updated starting with Empower 3.8.1. It is critical to understand how these changes impact you and your organization, regardless of your Empower Software version in use.

**Given the name of this privilege, fields hidden when a user does not have this privilege are referred to as 'quantitation fields'.*

Empower 3.8.0 and prior versions

Determines whether a user is able to view the following quantitation fields in the Review window Peaks table:

- Area
- % Area
- Height
- % Height
- Amount
- % Amount
- Response
- Concentration
  - Enabled: With this privilege, a user can view these fields in the Review window and can use these fields as labels and legends on plots.
  - Not Enabled: Without this privilege, in the Review window a user cannot view these fields nor will the fields be visible in the properties of the Peaks table however these fields can be used as labels and legends on plots.

Empower Software version 3.8.1 and newer

Determines whether a user is able to view the fields listed above, plus these additional quantitation fields in the Review window Peaks table or Result table:

- Time Corr. Area (Capillary Electrophoresis field)
- % Time Corr. Area (Capillary Electrophoresis field)
- Relative Response
- Impurity Response
- Adjusted Total Area
- % Adjusted Area
- Corrected Area~
- Dissolved Amount (Dissolution field)
- Dissolved Percent (Dissolution field)
- Maximum Impurity Response
- All Peak and Result type Custom Fields

Additionally, without this privilege, these fields are not visible in the properties of the Peaks table or Result table and cannot be used as labels or legends on plots in the Review window.

  - Enabled: With this privilege, a user can view all quantitation fields in the Review window and can use these fields as labels and legends on plots.
  - Not Enabled: Without this privilege, in the Review window a user cannot view these fields in the Review window nor will the fields be visible in the properties of the Peaks table and these fields cannot be used as labels and legends on plots.

Empower Software version 3.9.0 and newer

Determines whether quantitation fields are hidden when viewing unsaved results in the Review window. Quantitation fields are not hidden when viewing saved results in the Review window, regardless of the VQPFR privilege.

Enabled: With this privilege, a user can view all quantitation fields in the Review window and can use these fields as labels and legends on plots.

Not Enabled: Without this privilege, when viewing unsaved results in the Review window, a user cannot view the quantitation fields nor are the fields visible in the properties of the Peaks table or available to be used as labels and legends on plots. Upon saving a Result, the hidden information becomes visible. Quantitation fields toggle between being visible and hidden in the Review window, as the user navigates between unsaved results and saved results.

Empower Software version 3.10.0 and newer

Quantitation fields include the following:

For data that is processed with a SEC-MALS processing method:

- Mn
- Mw
- Mp
- Mz
- Mz+1
- Polydispersity Mw/Mn
- Polydispersity Mz/Mn

For data that is processed with a GPC processing method:

- Mn
- Mw
- Mp
- Mz
- Mz+1
- Mv
- Polydispersity

For data that is processed with a GPC/V processing method:

- Mn
- Mw
- Mp
- Mz
- Mz+1
- Mv
- Polydispersity
- [n]P
- [n]w
- Mz/Mw
- Mz+1/Mw
- g'
- g' LCB
- g' SCB
- d
- f

For data that is processed with a GPC/LS processing method:

- Mn
- Mw
- Mp
- Mz
- Mz+1
- Mv
- Polydispersity
- Rg
- [n]P
- [n]w
- Mz/Mw
- Mz+1/Mw
- g'
- g' LCB
- g' SCB
- d
- f
- Mw(LS)
- Mz(LS)
- Mz+1(LS)
- Rgz
- g
- g LCB
- G SCB

Enabled: With this privilege, a user can view all quantitation fields in the Review window and can use these fields as labels and legends on plots.

Not Enabled: Without this privilege, when viewing unsaved results in the Review window, a user cannot view the quantitation fields nor are the fields visible in the properties of the Peaks table or available to be used as labels and legends on plots. Upon saving a Result, the hidden information becomes visible. Quantitation fields toggle between being visible and hidden in the Review window, as the user navigates between unsaved results and saved results.

ALLOW CALIBRATION AND QUANTITATION IN REVIEW (ACQR)

This processing technical control, introduced in Empower 2 Software, allows the user to both Calibrate and Quantitate data in the Review window when enabled in the User Type.

When this privilege is disabled, users can integrate data, but they cannot perform the following tasks to generate the associated values for any data they are working with in the Review window.

Not Enabled:

- User cannot Calibrate or Quantitate data in the Review window.
  - Calibrate (Standard type samples) - Peak Names and Amounts are determined; Amounts are added to the Calibration Curve.
  - Quantitate (Unknown and Control type samples) - Peak Names are applied and Amounts are determined from the corresponding Calibration Curves.

- User cannot add, delete, or modify points on the Calibration Curve or Individual Points table.
- User cannot create Peak/Component identification using Manually Identify Peaks.
- Manually Identify Peaks functionality allows the user to identify a peak using a sliding marker; in response Empower Software Calibrates or Quantitates the peak.

Note: Consequently, because component-specific processing values such as Amount and Peak Name cannot be determined by this user, they are not present in the Peaks table or chromatogram plot, when working with unprocessed data or when modifying previously processed data. When viewing previously processed Results in the Review window, these values, if determined, are viewable by this user. If this user subsequently re-processes the Result in the Review Window, Amounts and Peak Names are removed and are not viewable until after the data is fully processed (calibrated/quantitated by batch processing or manually by a user with the ACQR privilege) again.

It is important to consider how privileges work together and impact functionality (Figure 5).

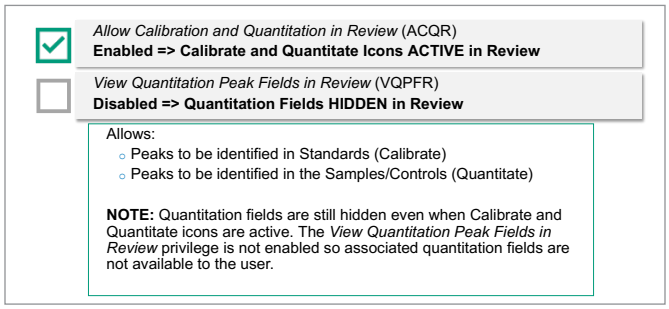


Figure 5. Empower Software behavior when the ACQR privilege is enabled for a user and the VQPFR privilege is disabled.

Key considerations:

- If your workflow may require manual Peak identification, users executing this workflow need the ACQR privilege assigned to their User Type to follow your procedure.
- The removal of this privilege from a User Type prevents the user from creating quantitative Results for named components in the Review window. It is important to understand the impact of disabling the ACQR privilege to your workflow, particularly for a user without the View Quantitation Peak Fields in Review (VQPFR) or View Numerical and Textual Results in Review (VNTRR) privileges.
- The ACQR privilege has a significant impact on workflows dependent upon manual data processing and consequently, it restricts users from fully executing a single Result in the Review window when not enabled. When the ACQR privilege is not assigned to a user, a workflow that scientifically requires or allows manual integration to ensure accurate Results typically involves the following steps:
  - Generating Results using batch processing
  - Manual integration of the Result(s) in the Review window as needed
  - Saving Results manually in the Review window
  - Batch re-processing the data with the Use Existing Integration option

Note: This typical workflow generates a minimum of three Results for each manually integrated channel of data. The number of Results generated varies based on your standard bracketing and your workflow steps.

VIEW NUMERICAL AND TEXTUAL RESULTS IN REVIEW (VNTRR)*

This processing technical control, introduced in Empower 3 Feature Release 4 Service Release 3, allows the user to view all numerical and textual fields in the Review window Peaks table. Without this privilege, users cannot see the Review window Peaks table or Results table.

** Given the name of this privilege, fields hidden when a user does not have this privilege are referred to as 'numerical and textual fields'.*

Additionally, users without this privilege cannot:

- Add numerical and textual fields as Peak labels or legends in the Chromatogram plot
- View Calibration Curve information
- View Spectrum Review for 3D PDA and MS data
- Access the Mass Analysis window
  - Enabled: With this privilege, a user can view all numerical and textual fields in the Review window and can use these fields as labels and legends on plots.
  - Not Enabled: Without this privilege, in the Review window, a user cannot view these fields nor will the fields be visible in the properties of the Peaks table and these fields cannot be used as labels and legends on plots.

Key considerations:

- When the VNTRR privilege is not enabled for a user, Peak Names and Retention Times are not visible in the Review window. If your workflow may require manual Peak identification to produce accurate Results, users executing this workflow may require the VNTRR privilege in order to efficiently follow your processes.

- It is important to understand the hierarchy of privileges and impact when assigning or disabling one or more privileges based on your workflows and risk assessments. If both the VNTRR and VQPFR privileges are disabled, the functionality of the VNTRR privilege prevails (Figure 6).
- The removal of the VNTRR privilege from a User Type prevents the user from viewing numerical and textual fields in the Review window. It is important to understand the impact of disabling the VNTRR privilege to the user workflow. The only information available to such a user in the Review window is baseline placement. Users executing a workflow which requires viewing numerical and textual information during processing may need the VNTRR privilege.

Figure 6. There is a hierarchy to VQPFR and VNTRR.

Purposeful management of these three processing technical control privileges based on workflow requirements allows users to optimize a Processing Method in the Review window and/or manually change Peak baselines as may be scientifically required to generate accurate Results within your business process. Understanding your workflow requirements and assessing your potential risk in this area for your intended use enables you to identify information that can be limited to a user during optimization, where possible, to reduce the possibility of introducing analyst bias during data processing.

In circumstances where you have identified that workflows and processes cannot be accurately and efficiently executed with technical controls in place, in addition to ongoing monitoring to ensure patient safety, you may potentially consider leveraging additional supporting activities as appropriate based on your own analysis and assessment. For example:

- Procedural controls
- Empower Software training
- Robust data review procedures
- Clear chromatographic diagrams showing accurate Peak integration
- Processing Method templates to use with peak Retention Times populated

It is important to understand the impact to users when removing access to functionality. Removal of even one of the processing technical controls (Figures 7-9) changes how users must work in order to execute typical tasks. It is recommended to consult your local Waters Professional Services organization to understand the impact on your individual workflows, map your data flows, map your workflows, and assess the potential risks in your organization.

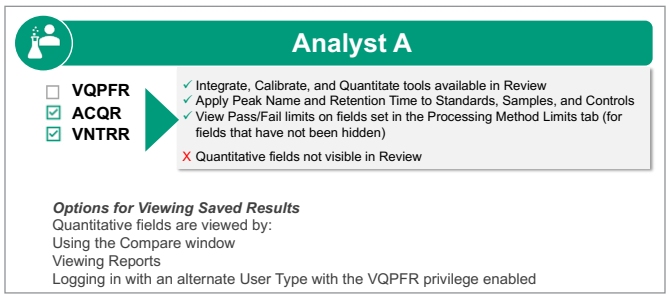


Figure 7. Capabilities in the Review window for an analyst with the View Quantitation and Peak Fields in Review privilege disabled.

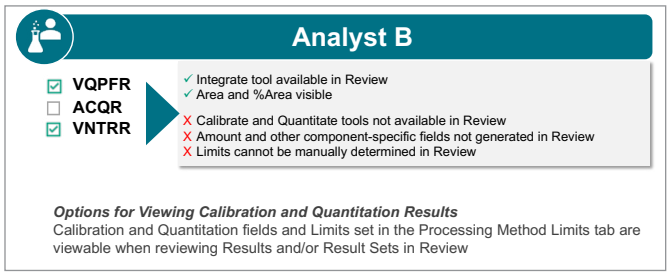


Figure 8. Capabilities in the Review window for an analyst with the Allow Calibration and Quantitation in Review privilege disabled.

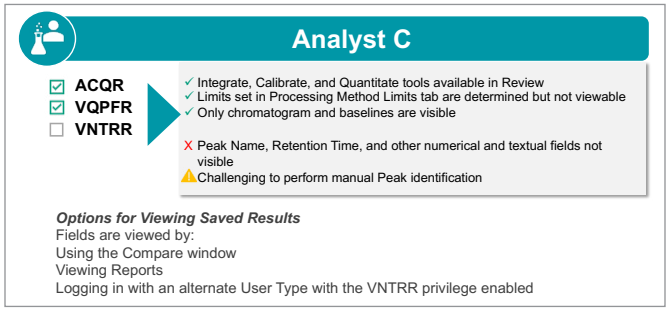


Figure 9. Capabilities in the Review window for an analyst with the View Numeric and Textual Results in Review privilege disabled.

For additional detailed information on these privileges, see Appendix A: Matrix of functionality with the View Quantitation Peak Fields in Review (VQPFR), Allow Calibration and Quantitation in Review A(CQR,) and View Numerical and Textual Results in Review (VNTRR) privileges.

SAVING RESULTS AND CALIBRATIONS PRIVILEGES

Typically, processing Sample Sets (or Result Sets) to create Result Sets is performed using batch processing. This approach ensures consistency, is more efficient than processing data in the Review window, and aids in data organization through the creation of Results Sets as opposed to individual Results. Batch processing is required to achieve more complex quantitation practices more easily such as:

- Standard bracketing
- Summary Custom Fields
- Using multiple Processing Methods for defined samples in the Sample Set
- Simplified 3D data processing

The privileges associated with saving Results govern a user's ability to batch process data and to process data within the Review window:

SAVE RESULTS PRIVILEGE

When enabled, this privilege allows the user to batch process data including saving the related calibration curves. Without this privilege, users cannot save Results via batch processing or in the Review window.

SAVE CALIBRATION CURVES PRIVILEGE AND SAVE RESULTS AND CALIBRATION IN REVIEW PRIVILEGE

These privileges are both required in order to save calibration curves in the Review window. When combined with the Save Results privilege, a user can also manually process and save Results in the Review window.

CALIBRATION CURVE PROTECTION USING THE SAVE CALIBRATION CURVES PRIVILEGE

Users given both the Save Results privilege and the Save Results and Calibration in Review privilege and not the Save Calibration Curves privilege can manually integrate and quantify unknown samples against the calibration curve associated with the processing method and save these Results. This user is unable however, to modify and save a calibration curve generated in the Review window. Disabling the Save Calibration Curves privilege can be used as an effective approach to prevent manual changes to a calibration curve.

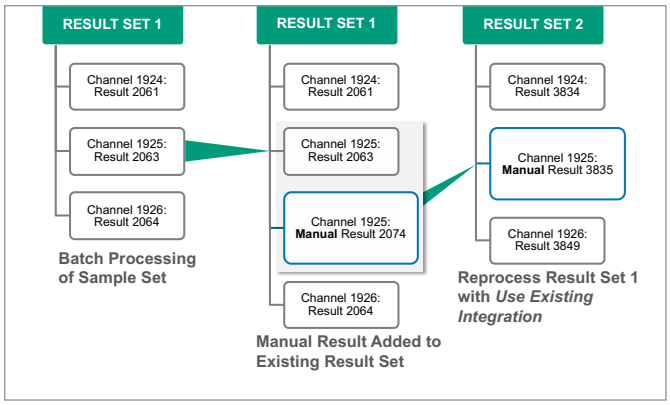
Knowing how these privileges impact processing of chromatographic data in the Review window allows regulated laboratories to have a more in-depth understanding of how data is generated, interpreted, and interacted with by their users during their workflow in Empower Software. With this knowledge, it is easier to identify potential risks related to this workflow and mitigate these potential risks accordingly.

SAVING MANUAL RESULTS IN RESULTS SETS

If your workflow allows it and data requires manual peak identification or manual integration, analysts will need to process and save Results in the Review window. A potential viable approach is to batch process initially, and then bring the Result Set into the Review window where the analyst applies appropriate allowable manual integration. Saving a manual Unknown Result adds it to the Result Set; the new Unknown Result supersedes the original result. To fully process the data while retaining the manual integration changes, the analyst then reprocesses this Result Set while specifying the Use Existing Integration functionality.

For more information on manually processing data, see Managing Manually Integrated Results in Result Sets and How to generate a Result Set when manually identifying components in Empower.

Figure 10. Saving a Manual Result into a Result Set and batch reprocessing



the Result Set with Use Existing Integration.

COMBINING PRIVILEGES TO MANAGE HOW USERS INTERACT WITH DATA IN REVIEW

Figure 11 provides an example of how privileges might be assigned to support a workflow within an organization. These examples are provided to illustrate the concept of least privileges and the ability to create roles optimized for each organization's workflow. These examples are not intended to define the appropriate configuration for any given organization or to imply that this configuration assures patient safety. Each organization needs to configure User Types for their own workflows and procedures based on needs commensurate with risk.

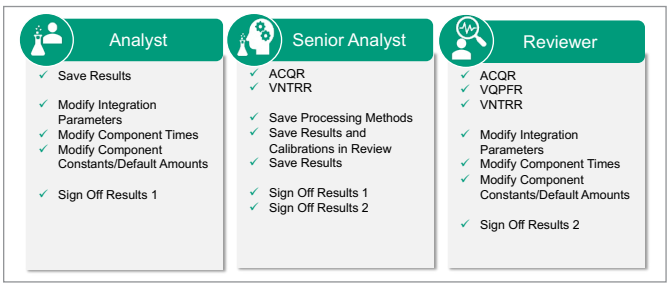


Figure 11. Examples of tailored Empower User Types.

Remember that a user who normally logs in as a Senior Analyst, may have the ability (via multiple User Types) to switch roles by logging out and logging in again with a Reviewer User Type role if they are responsible for both roles within a workflow.

ADDITIONAL CONSIDERATIONS FOR DATA INTEGRITY

LOCKING CHANNELS FROM FURTHER PROCESSING

There are two privileges associated with locking channels: Lock Channels and Unlock Channels.

Once Results are generated, the associated Channels can be locked so users cannot generate any further Results from the data Channels. In a Quality Control (QC) laboratory it is common for a Channel to be locked once the Result has been signed off. If a Result is deemed inaccurate the Channel can be unlocked for further processing by a user with the privilege to do so.

- A user can view information associated with a locked Channel.
- Allow Lock Channels after Sign Off 2 is a System Policy that, when enabled, allows a user to automatically lock the Channels after Sign Off 2. The parameter to do so is located in the Sign Off dialog box.

RECORDING THE REASON 'WHY?' FOR SAVING RESULTS

Empower software automatically records what actions are performed in the various Audit Trails. The user needs to document why the action was performed.

- Users should enter reasons why changes were made to Empower project objects such as methods, sample related data (via Alter Sample) and Results, as well as Empower system objects such as Chromatographic Systems, Users, and User Types.
- For example, when an analyst processes a Sample Set or re-processes a Result Set, the user enters the reason in the Comments fields of the Background Processing and Reporting dialog box (Figure 12).

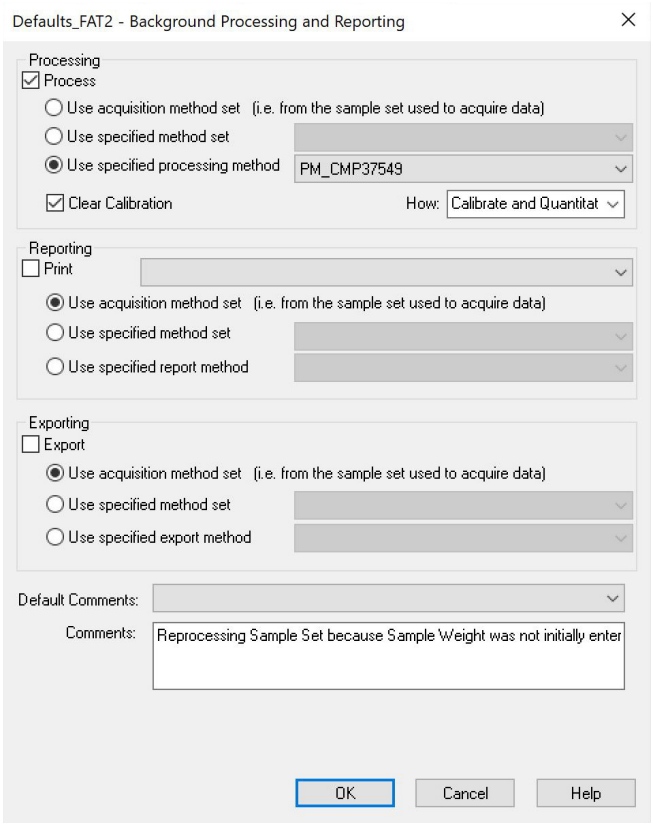


Figure 12. Background Processing and Reporting dialog box showing the reason 'why' in the Comments box.

The reason why a Sample Set was processed appears in the Project Audit Trail and the Result Audit Viewer (Figure 13).

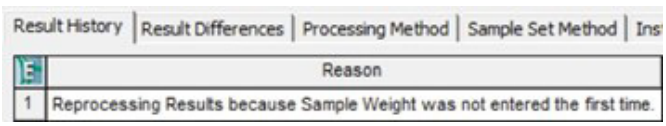


Figure 13. Reason why a Result was reprocessed in the Result Audit Viewer.

It is important that these reasons reflect why changes were made rather than what changes were made. In regulated laboratories this is a requirement. In non-regulated laboratories it is not a requirement; however, these reasons add value by giving extra details about activity in Empower Software and could be seen as good practice.

There are two approaches to entering these comments – in an unrestricted manner or a restricted manner:

- Unrestricted comments are the most flexible and allow the user to enter the comment (reason) as free text or by using a predefined reason from a drop-down menu.
- Restricted comments require the user to select only a predefined reason from the Default Strings list and do not allow for free text entry.

These predefined reasons in a drop-down menu are called Default Strings. It is important to make sure the Default Strings reflect the reason why an action was performed. Default Strings are created in Configuration Manager and can be created by any user with the privilege to do so. They are particularly useful for repetitive tasks which the analyst is carrying out in Empower Software. Predefined reasons are also useful when performing data analysis and trending since the Audit Trail comments can be discretely categorized and used for metrics.

See the New Project Policies section of the Empower Help topic *Setting Empower Software System Policies* for more information on the enforcement of Project Audit Trail comments.

MARKING AUDIT TRAILS AS VIEWED

The System Policy, Mark Audit Trail Records as Reviewed at Sign Off 2, is available with Empower 3.8.0 and newer versions. This System Policy enables the ability to attest Audit Trails as viewed when applying an electronic signature. At the time of a Level 2 Sign Off, a user can certify that they have reviewed the Audit Trails associated with the Result(s) they are signing. After sign off, the Audit Trail certification information is available in the Project window and on Empower reports in the following fields:

- The Results Audit Trails Reviewed field indicates whether the Audit Trails review was confirmed for a given Result.
- The Sign Off Audit Trails Reviewed field references the corresponding sign off action when the Audit Trail review was confirmed.

CONCLUSION

It is important for Regulators and Quality Units to understand how Empower Software System Policies and User Types control data processing, user actions, and user views in the Review window while also considering the impact to laboratory workflow, potential risk of data manipulation, and potential impact to patient safety. As you determine what is required for users to execute workflows based on your intended use of Empower Software, including your chromatographic methods and business processes, it is vital to perform continuous risk assessments and stay current with regulator expectations. Empower Software technical controls such as privileges and System Policies help to ensure adherence to your workflows.

- Map your workflows and use critical thinking to identify and examine potential risks as well as to document your detailed analysis.
- Understand and leverage available technical controls as appropriate to assist your workflows based on your risk assessment of Empower System Policies and privileges in combination with a least privileges approach.
- Leverage procedural controls when needed based on your assessment and in the absence of technical controls that are fit for your purpose.
- Use vigilant monitoring, especially where procedural controls are employed.
- If you require assistance with determining what is best for your organization, it is recommended to consult your local Waters Professional Services organization to access Waters product experts.

References

1. ICHQ9 (R1) Quality Risk Management Guidance for Industry
2. U.S. Food & Drug Administration, Center for Drug Evaluation Research, Quality Management Maturity: Essential for Stable U.S. Supply Chains of Quality Pharmaceuticals
3. U.S Food & Drug Administration, Center for Drug Evaluation Research, CDER's Quality Management Maturity (QMM) Program: Practice Areas and Prototype Assessment Protocol Development

APPENDIX A: Matrix of functionality with the View Quantitation Peak Fields in Review (VQPFR), Allow Calibration and Quantitation in Review (ACQR) and View Numerical and Textual Results in Review (VNTRR) privileges

This matrix provides detail on what actions are allowed and what actions are not allowed with each of the VQPFR, ACQR, and VNTRR privileges disabled individually.

Action Available in Review	Disabled VQPFR Enabled ACQR and VNTRR	Disabled ACQR Enabled VQPFR and VNTRR	Disabled VNTRR Enabled VQPFR and ACQR
Use the Integrate tool	✓	✓	✓
Manually draw baselines	✓	✓	✓
Use the Calibrate and Quantitate tools *Component Names applied and Amount and other Component-specific fields are generated*	✓	×	✓ *Note: Quantitative fields are determined but are not viewable*
Use the Manually Identify Peaks tool *Use of this tool also performs Calibration and Quantitation*	✓ *Note: For workflows requiring manual Component identification in standards and/or Summary Custom Fields, click here.*	×	✓ *Note: Manually identifying peaks is challenging because the analyst cannot:* • *View Component Name and Retention Time in the Peaks table* • *Determine if Calibration and Quantitation has been successfully performed* *Note: Retention Time is available by hovering on the chromatogram*
View quantitative fields in Review *Fields controlled by VQPFR privilege*	×	✓	×
View numerical and textual fields in Review *Fields controlled by VNTRR privilege*	◎ *Note: Cannot view quantitative fields, a subset of the numerical and textual fields*	✓	×
View Component Name and Retention Time fields	✓	◎ *Note: Viewable for saved Results but cannot determine Component Name when processing in Review*	×
View System Suitability field values View field Pass/ Fail limits set in the Processing Method Limits tab for unhidden fields	✓ ✓	✓ ◎ *Note: Viewable for saved Results but cannot create values in Review*	× × *Note: Results are fully hidden*
Determine field Pass/Fail limits set in Processing Method Limits tab for unhidden fields	✓ *Note: Values and limits for both viewable fields and hidden quantitative fields are determined during processing in the Review window and then are stored when the Result is saved. Quantitative fields are not displayed in the Review window.* *Note: For hidden, quantitative fields the Component Name appears in bold red font (by default) to indicate that a fault has occurred although the faulted field and value is not displayed.*	× *Note: These values and limits cannot be created during processing in the Review window. For saved Results where this information is determined, it is viewable in the Review window.*	◎ *Note: All fields are hidden. Values and limits are determined during processing in the Review window and then are stored when the Result is saved; they are not displayed in the Review window.*
Process data without bias towards the quantitated Result	✓	◎ *Note: Viewable for saved Results but cannot create Component Name, Amount, or System Suitability Limits when processing in Review*	✓
View all fields in saved Results for Compare and on Reports	✓	✓	✓
Save Calibration Curve *User also needs: Save Calibration, Save Results and Calibrations in Review*	✓	×	✓
Add, delete, modify points on the Calibration Curve *User also needs: Save Calibration, Save Results and Calibrations in Review*	✓	×	✓
View Peak or Result Type Custom Fields	✓ Empower 3.7.0 and lower × Empower 3.8.1 and higher	◎ *Note: Custom Fields based on quantitative fields cannot be determined in Review*	×
View Spectrum Review and Mass Analysis window	✓	✓	×

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