

Considerations for Maintaining a Validated State of Your Analyst® Software

INTRODUCTION

The purpose of this white paper is to describe the activities and systems that should be monitored or considered in order to preserve the validated status of Analyst® Software.

CONSIDERATIONS

Analyst Software Updates/Hotfixes

Once the system has been validated and put into production it is important to assess the impact on maintaining the validated state of installing updates to your Analyst Software. We recommend that you read the release notes that accompany each hotfix and determine if there are any updates that apply to your system.

If they do apply to your system, it is important to determine whether any of the updates have regulatory impact. If they do have regulatory impact, it is best to apply them. If they do not have regulatory impact, you will need to weigh the benefit of applying the updates in light of the time and effort that will be required for testing.

It is also worth noting that future hotfixes may require you to install prior hotfixes. It is especially important that updates to auditing and/or electronic signature functionality be applied since they have clear regulatory impact.

ANALYST SOFTWARE CONFIGURATION

Audit Map Configuration

When you make any changes to the Audit Map (either Instrument or Project), please ensure that the Audit Map version is incremented and that the newly created Audit Map is copied to all acquisition and processing workstations, if using Analyst Administrator Console (AAC). You will need to update the System Configuration Specification document by attaching the latest version of the Audit Map (in spreadsheet format) and, if necessary, incrementing the version of the System Configuration Specification in accordance with your document control Standard Operating Procedures (SOPs).

Configuration of Roles

If and when you make changes to Analyst Software roles – either by creating new roles, deleting roles, or updating existing roles by adding or removing functionality – you will need to update the System Configuration Specification by attaching the new version of the Roles and Functions document (print a report from Analyst Software or attach a spreadsheet). In general, we recommend that you not delete roles. It is better to keep the role as it is and not assign it to personnel. If you are not using AAC, please make sure that every acquisition and processing workstation is updated when changes are made to roles.

Changing Roles Assigned to Users and Adding and Deactivating Users

If you change the role(s) assigned to a person, add a user, or deactivate a user, you will need to update the System Configuration Specification document in accordance with your document control SOPs. Note that you should never delete a user from the system. We recommend that you keep the user in the system and not assign them any role. This also prevents duplicate usernames from being created in the system, which is very important once electronic signatures are used. Lastly, if you are not using AAC, you have to perform the action on every single acquisition and processing workstation.

WORKSTATION CONFIGURATION

Operating System Updates

Updates to the operating system should be applied in accordance with your IT SOPs. For regular critical updates issued by Microsoft, it is probably not necessary to run any tests.

For larger updates, such as Service Packs, we recommend that you initially update a single acquisition workstation, run a previously created batch, quantitate the results, and compare to previously acquired data.

When updates are made, it is a good practice for your IT staff to inform you of such updates and give you printed copies from asset management software regarding what updates were made. Such printed copies could be appended to the System Configuration Specification.

Hardware or Network Updates

If any changes are made to the hardware or the network configuration (domain changes, IP addresses), please update the System Configuration Specification by updating the System Details Spreadsheet.

File Server Configuration (if using network acquisition)

If any changes are made to the hardware or the network configuration, please update the System Configuration Specification.

CONCLUSION

The activities and considerations detailed here propose several ways in which you can maintain the validated status of your Analyst system. In addition to these activities, it may be necessary for you to follow SOPs specific to your environment. It is recommended that you consult with your IT and QA/Regulatory departments to find a comprehensive solution to help maintain the validated status of your computerized systems.

For more information on AB SCIEX Professional Services, contact your local AB SCIEX Sales representative or email:

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