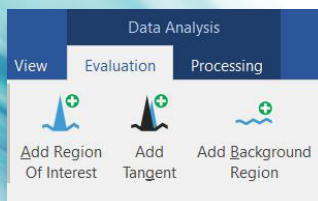
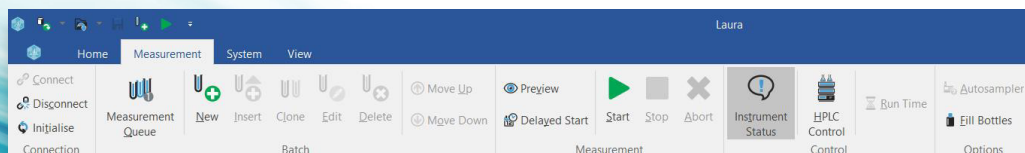
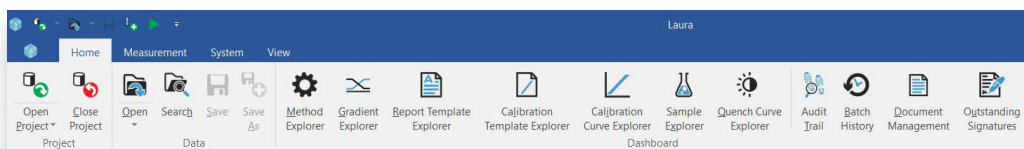




# Laura™

Radiochromatography Data  
Collection and Analysis Software



v6.0.4



EXPERIENCE & EXPERTISE

## Laura version 6.0.4 is now released!

The latest version of the industry standard radiochromatography software Laura has now been released. Here are some of the most significant enhancements in this new version.

### Added NEW Audit Review utility\*

One of the requirements from the regulators in terms of data integrity is that the audit trail should be routinely reviewed by a responsible individual and that review should be recorded.

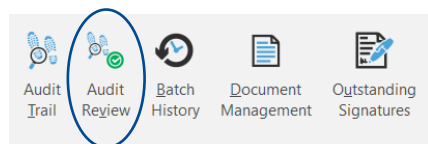
*"Audit trail review should be part of any routine data review process."*

*"There should be evidence available to confirm that review of the relevant audit trails have taken place at the time of study report finalisation."*

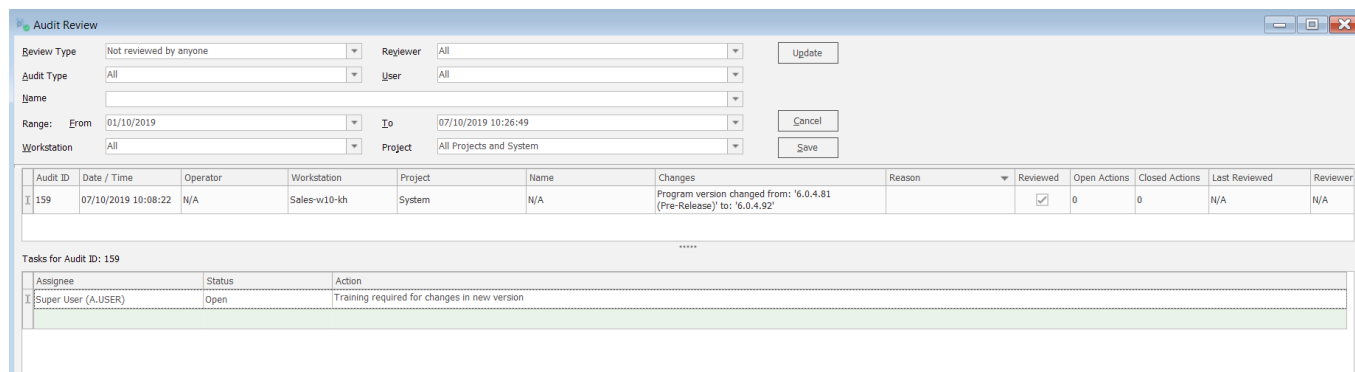
Currently that review process is recorded on paper which is not ideal when using computerised data systems.

Laura now features a utility to record and evidence that the audit trail was reviewed, by whom and when and also features the ability to record and track any queries and actions the reviewer has about an audit event.

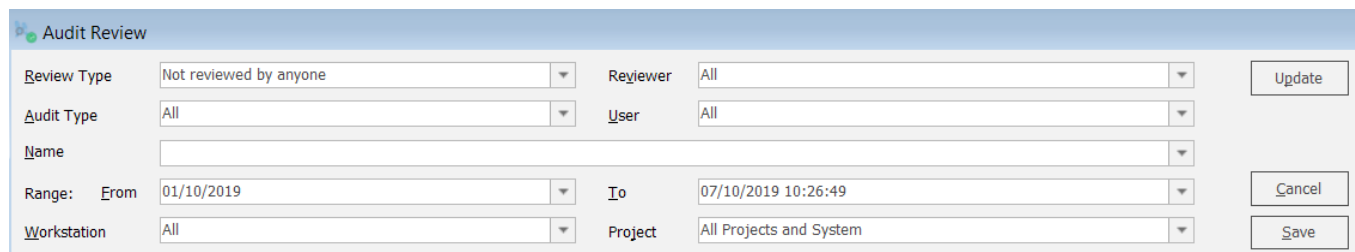
The tool is accessed via a new icon on the Home ribbon.



This opens the audit review tool.



Audit events to be reviewed can easily be filtered by any criteria relating to the data.



Specific audit events can be selected for review.

Audit ID	Date / Time	Operator	Workstation	Project	Name	Changes
159	07/10/2019 10:08:22	N/A	Sales-w10-kh	System	N/A	Program version changed from: '6.0.4.81 (Pre-Release)' to: '6.0.4.92'

Any queries or required actions to follow up review of that audit event can be recorded.

Tasks for Audit ID: 159			
Assignee	Status	Action	
Super User (A.USER)	Open	Training required for changes in new version	

Any audit events with outstanding action items from previous reviews will be highlighted in red.

Audit ID	Date / Time	Operator	Workstation	Project	Name	Changes	Reason	Reviewed	Open Actions	Closed Actions	Last Reviewed	Reviewer
159	07/10/2019 10:08:22	N/A	Sales-w10-kh	System	N/A	Program version changed from: '6.0.4.81 (Pre-Release)' to: '6.0.4.92'		<input checked="" type="checkbox"/>	1	0	07/10/2019 10:37:27	Super User (A.USER)

Once reviewed the reviewer can check the box to confirm the event(s) has been reviewed.

Reviewed

The reviewer is then required to enter their unique electronic signature to confirm the review.

**Sign Off - Audit Trail Review**

Electronic signatures are considered to be the legally binding equivalent to full handwritten signatures by the FDA according to 21 CFR Part 11.

Sign Off 1

Login ID:  Sign Off

Password:  Cancel

Meaning:

Reason:

Lock against modifications

A report of the review can also be printed by using the print active window tool.

- Logout  
Logout of the application
- Save To Method  
Save the evaluation back to the method file
- Save To Document Management  
Saves the report to the Document Management System
- Save To PDE  
Saves the report to a Portable Document File for data exchange
- Print  
Prints the report for the active window

<b>Audit ID:</b> 159	<b>Date/Time:</b> 07/10/2019 10:08:22
<b>Operator:</b> N/A	<b>Workstation:</b> Sales-w10-kh
<b>Project:</b> System	
<b>Name:</b> N/A	
<b>Changes:</b> Program version changed from: '6.0.4.81 (Pre-Release)' to: '6.0.4.92'	
<b>Open Actions:</b> 1	<b>Closed Actions:</b> 0
<b>Reviewer:</b> Super User (A.USER)	<b>Last Reviewed:</b> 07/10/2019 10:37:27

<b>Signature ID:</b> 3DA62576BCC0467D98254468BFFA1752-22
<b>Description:</b> Review Signature
<b>Name:</b> Super User (A.USER) on Sales-w10-kh
<b>Date/Time:</b> 07/10/2019 10:38:05 GMT Daylight Time
<b>Meaning:</b> Review
<b>Reason:</b> Routine review
<b>Status:</b> Unlocked

<b>Action 1:</b> Training required for changes in new version	<b>Status:</b> Open
<b>Assignee:</b> Super User (A.USER)	

\*Note: the audit review function is only available to Laura 6 in database mode.

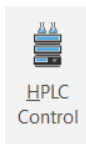
### Added audit detail

Functionality has been added to differentiate between 'measurement owner' and 'measurement completed' to show when a batch was created by one individual, but the measurement started by another, when workstations are shared resources for example.

**Audit ID:** 165  
**Operator:** Testing user (TESTER)  
**Project:** Sample Data  
**Name:** test #934\_audit Run 1 Test.Measurement  
**Changes:** Measurement Started: 07 October 2019 13:54:38  
 Measurement Owner: Super User (A.USER)

### Agilent electronic purge function

The control of the electronic purge on applicable Agilent systems has been enhanced so users can specify the purge time, flow rate and solvent composition independently using the HPLC control tool in Laura.



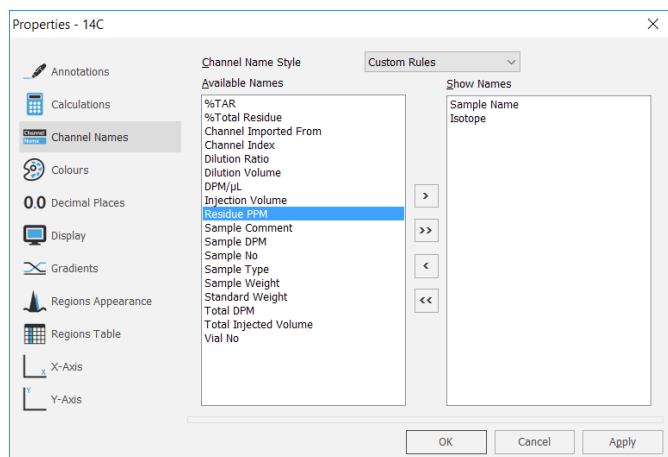
### Idle action definition

The 'idle action' control has been moved from the instrument SetUp tool into the Measurement queue window and the ability to specify an idle action from a specific project or method has been added. This is to place control of this function in a more suitable place and enable greater options for control of the idle action itself.

Idle Project	[Dropdown]
Idle Method	[Dropdown]
Idle Action	Standby (pump off, lamps and oven on)
Idle	

### Channel names

Greater flexibility has been added to the channel names function to allow even more sample fields to be used to define channel names. This now includes sample type for example.



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October 2019

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