

## Using Your System

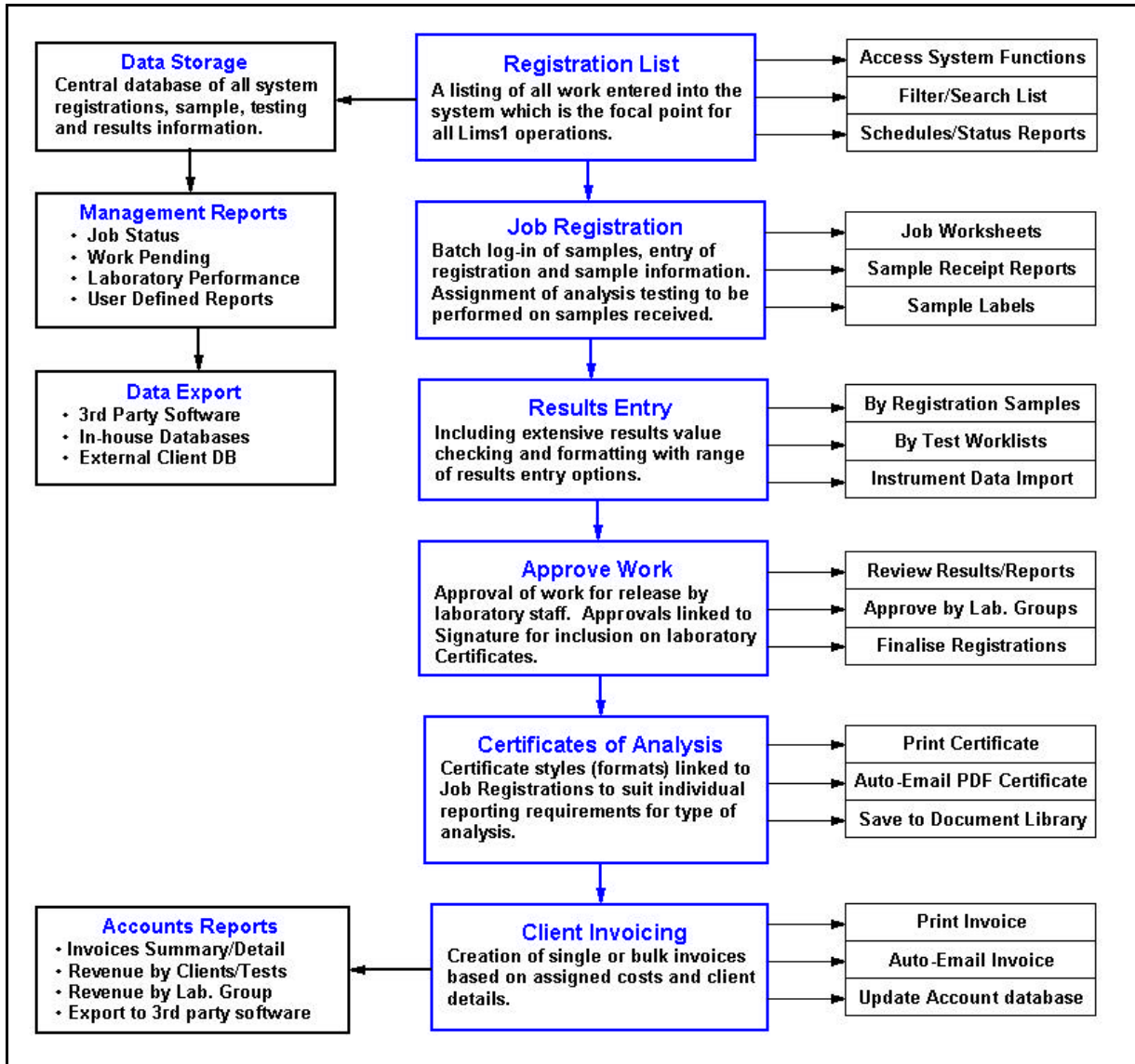
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## Overview

In this paper we review daily use of Lims1 in the laboratory including log-in of work, entry of results and creation of laboratory reports as well as other routine operations which are typically performed on a regular basis.

The diagram below shows key Lims1 processes for routine system operations with a range of data management and reporting functions. A important element of the system is that all of these processes are fully integrated into a single application which provides a **Total Management Platform** for all laboratory operations which is intuitive, easy to use and highly efficient.



## Routine Sample Processing

- Job Registration
- Results Entry
- Attachments
- Approval of Work
- Creating Certificates

### ***Job Registration (Samples Log-in)***

Your LIMS is configured to accept a full range of types of analysis performed by your laboratory. These configurations are established in the systems Setup Tables as **Sample Types**. As samples are received a new Job Registration is created. The first step in this process is to select a **Sample Type** which matches (or most closely matches) the type of analysis to be performed on the samples. When new Jobs are logged into the system a New Job Registration Reference is automatically incremented and assigned.

#### **Step 1: Select Sample Type**

***On selection the following information is established for the Job Registration...***

- The range of Registration Information Fields to be used in sample log-in.
- The range of individual Sample Information Fields to be used in sample log-in.
- All testing requirements for the samples with links to methods and sample preparation.
- Laboratory Groups responsible for the range of tests to be performed.
- A Login Date and Due Date (based on Sample Type turn-around time),
- The Report Format to be used for creating a Certificate of Analysis.
- Report Formats to be used for creating Job Worksheets and Sample Receipt Forms.

#### **Step 2: Enter Sample Information**

Lims1 is a sample batch orientated system. All samples received as a batch from clients are logged in as a single entity for processing and reporting.

- The number of samples received is entered.
- A Samples Information Form is used to enter details (eg. sample identifications) for the samples.
- The Client is selected (from the Setup Tables Library List) who provided the work.
- Information is entered related to the entire sample batch (Registration Fields).

***This completes the basic Job Registration process.***

#### **Step 3: Modifying Default Log-in Values and adding other Log-in details**

There are also a range of options for entry or modification of information related to the work including...

- Assign Test : Assigned default tests may be edited (tests or test groups added/removed).
- Tests to Samples : Sets of individual tests may be assigned to individual samples.
- Comments : Registration Comments may be added for laboratory use.
- Quality Control : QC samples may be assigned to the work.

#### **Step 4: Completing the Registration process**

A [Save] button is used to complete the Registration process and the follow final operations are carried out by the system...

- Sample Receipt Forms may be automatically emailed to the client.
- Sample Labels may be printed.
- A Worksheet may be produced based on the Job Registration for distribution to the laboratory.
- Laboratory staff are made aware of new work received for processing.
- The Registration List is updated with new Registration information.
- An audit trail is updated with the new Registration log-in.
- The Registration is made available for management Job Status Reports.

After completion of log-in, *Job Registrations may be edited at any time to reflect any changes related to the work.* This includes re-assignment of testing or sample conditions at any time prior to final approval of the Registration.

***The system has been designed to carry out these processes as quickly and efficiently as possible.***

## Results Entry

To meet individual laboratory and testing requirements Lims1 provides a range of options for entry of results of analysis including...

- By Job Registration : Results entered for all sample/tests against a given Job Registration.
- By Test Worklist : Results are entered for specific Tests over a range of Job Registrations.
- By Data Capture : Results are imported from laboratory instruments or external spreadsheets.

Sets of results may be entered by any combination of the above for given Job Registration.

### **What happens when Results are entered...**

- Job Registration, sample and results entry statuses are updated for each result.
- Numeric Result values may be checked against maximum/minimum entry limits.
- Results below minimum entry values are automatically assigned "<" [min. value] for reporting.
- Numeric Result values may be checked against pass/fail limits and assigned a status.
- Formula may be automatically applied to obtain calculated result values from entered results.
- Significant Figures are automatically assigned for reporting of Numeric Results.
- Text entry results may be selected from Pick Lists with Pass/Fail Values.
- The Job Registration is flagged if any 'Fail' status results are present.
- A Text Comment may be entered against any result value.
- Unlimited Text Comments may be entered for a given sample.
- Unlimited Text comments may be entered for a given Job Registration.
- An audit trail is maintained of all results entered and modified including staff who made entries.

As results are entered the Results Entry Status of Job Registrations is automatically updated. When all results have been entered the Status is set to Complete. A Registration Filter can be applied for Completed Results. These Registrations are now ready for final approval and release.

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## Approval of Work

Job Registrations with a Result Status of "Complete" are ready to be approved for release. When Registrations are approved for release the Status of the work is set to "Finalised" indicating the final approval. Staff passwords are used during this process to indicate who approved the work. Finalised Registrations are blocked from any further modifications unless an administration over-rides the status (an audit trail is maintained of these activities).

### **Use of Approval Signature Images**

Lims1 Certificates of Analysis are created as a pdf documents which may be automatically emailed and stored for future reference. To provide a complete Certificate Report ready for distribution, the Lims1 Report Format Generator will include corporate letter headers and other images (eg. NATA, ISO logos) as well as Signature Images and Title information based on staff who approved the work.

### **Methods of Approval**

There are two methods for final approval of work...

#### **1. Approval By Laboratory Groups**

Laboratory Tests are assigned to Laboratory Groups who are responsible for analysis. If the approval process requires individual approvals to meet regulatory requirements then Laboratory Groups approve the sets of results for which they are responsible. In these instances, Signature Images of all staff responsible for approving the work will be included on the Certificate of Analysis.

#### **2. Approval By Job Registration**

If only a single approver is required for the work then the a single Job approval step is undertaken and a single Signature Image appears on the report.

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## Attachments

Attachments are files related to the work which may be linked to a given Job Registrations for access directly from the Registration List. Examples of files which may be linked include images, MS-Word, MS-Excel and PDF files.

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## **Creating Certificates**

### **Lims1 Report Format Generator**

Lims1 has been developed to provide end users with a complete system which may be fully maintained by laboratory staff. One of the major challenges of this approach is providing a system which is capable of creating highly complex laboratory reports without recourse to 3<sup>rd</sup> party Report Generation products which require high level knowledge of database structures for report development {approach used by most LIMS vendors}.

The Lims1 **Report Format Generator** has been specifically developed for use with the system with report design undertaken using sets of Report Blocks for report headers, footers and data tables {*For further information see website topic: Lims1 – System Setup – Report Formats* }.

An unlimited number of Certificate Formats may be established in the Report Format Generator for use with Job Registrations (a Certificate Format is automatically assigned based on the selected **Sample Type** during the Registration process).

### **Creating Certificates of Analysis**

Certificates are created for a selected Job Registration by selecting a **Print** or **Email** option directly from the Job Registration List. Certificates are emailed as **pdf** documents. Certificates created as a pdf documents, can include corporate letter headers and other images as well as signature images and title information.

### **Emailing Certificates**

Selecting the Email option generates the pdf Document and automatically attaches it to a client email using email addresses assigned to the client in system Setup Tables. Default email message header and text can also be automatically assigned. An audit trail is maintained of email reports sent and the Certificates is saved in the Documentation Library.

### **Emailing MS-Excel Files**

In addition, the system can automatically create an MS-Excel spreadsheet of results to be emailed with the Certificate as an attachment.

### **Documentation Control**

Certificates which have been printed or Emailed are saved as **pdf** documents in the **PDF Documents Library** and may be retrieved for use at any time. If a revised Certificate is created the Documentation Library will include all revisions of the Certificate with Revision Numbers. The Documentation Library may be accessed directly from the main Lims1 Registration List for retrieval of documents for a given Job Registration or all Job Registrations.

### **Report Generation Options**

In cases where the default Report Format is not suitable for use or multiple styles of reports are required, a **new Report Format may be selected at any time** for creation of a Certificate. In addition the system provides an option to *Modify an Existing Format* specifically for a Job Registration without modifying the underlying Report Format.

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## The Registration List

• **Registration List Description** • **Filter/Search Operations** • **Registration Reports**

*The Job Registration List is the focal point for all Lims1 operations.* In addition to providing a detailed list table of all work logged into the system this screen *also provides access to all Lims1 core functions and operations* using a combination of access buttons and menus at the top of the list.

From the Job Registration List access is provided to Job Registration, Results Entry, Work Approval and Report Generation processes described in ***Routine Sample Processing*** as well as access to the following options and functions.

### ***Registration List Description***

The Registration list is sorted by Job Reference Numbers and includes a range detail on each Job Registration including a Job Description, Log-in Dates, Due Dates, Completion Dates, Job Priorities, Status, Sample Type assigned and Client References. The order of fields in the list may be set by the end user. Selecting (highlighting) a given Job Registration makes it active for a range of options related to the registration such as results entry, creating reports, approving work, etc.

### ***Filter/Search Operations***

The Registration List may be **Filtered** for any of the above listed Registration Fields using the Filter Menu option. Any number of multiple filters may be applied.

Quick **Searches** are also provided to rapidly locate a specific Job Registration based the Registration Reference and other criteria.

### ***Registration Reports***

Provides either summary or detailed reports of listed Job Registrations, normally done after a Filter operation.

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## Management Reports

- **Work Status Reports**   • **Job Status Reports**
- **Laboratory Performance Reports**   • **dbQuery Management Reports**

### **Work Status Reports**

Provide summary information on work logged into the system.

Total Registrations:	53	
Finalised Registrations:	1	1.9%
Completed Registrations:	35	66.0%
Incomplete Registrations:	5	9.4%
Hold Registrations:	0	0.0%
Void Registrations:	0	0.0%
No Entry Registrations:	12	22.6%
Re-Enter Registrations:	0	0.0%
Clients:	14	
Samples:	222	
Sample Types:	30	

### **Job Status Reports**

Provides a listing of outstanding work Job Registrations by Due Dates with option to list results which have not been completed.

Due Date	Status	Job Reference	# Sm	Job Description	Sm #	Test
26/01/2004	Complete	EX0002	2	Lot 22 Trade Waste	11	BACLLUS
26/01/2004	Incomplete	EX0003	18	Micro Colony Count.	11	ROD
29/01/2004	Complete	EX0005	2	XRF Scan	11	ECOLI
30/01/2004	Complete	EX0006	1	Production QC w/Text pi	11	YEAST
30/01/2004	Complete	EX0007	1	Cement QC	11	MOULD
31/01/2004	Complete	EX0004	12	Water Analysis	11	TOTALCFU
01/02/2004	Complete	EX0008	1	Blood Screen Example.	12	BACLLUS

### **Laboratory Performance Reports**

The Laboratory Performance Option is available as a separate module and provides the laboratory with statistical analysis of work performed based on the actual time required to complete the work against standards established by the laboratory for completion of the work.

### **dbQuery Management Reports**

The primary purpose of the dbQuery system is to provide extensive access to all data entered into the system during routine operations including Registration, Sample and Results information.

A LIMS database is quite complex and will contain large numbers tables, records and field information. The traditional method of obtaining specific information from these databases is to write code or scripts using a Query Language to extract management information.

The dbQuery Module bypasses this requirement and allows the end user to create comprehensive Reports with rapid methods of establishing a range of 'Filters' to obtain specific information used in Management Reporting and Statistical Analysis through selection of field data to be filtered and assignment of filter values.

In addition to providing a range of standard Reports the dbQuery Module also offers **export capabilities for data**, which may then be imported into 3rd party software or corporate databases.

## **Lims1 in your Laboratory**

- Routine Sample Processing
- Improving Laboratory Efficiencies
- Improving Client Services

### ***Routine Sample Processing***

From arrival of samples into the laboratory to approval of work and issuing of Certificates Lims1 provides smooth, easy to use processes to perform these operations.

Typical steps performed for log-in and processing of a sample batch includes the following Lims1 processes..

1. Samples Registered by Log-in Staff.
2. Results Entered by laboratory Staff or by Instrument Data Import.
3. Results Reviewed/Approved.
4. Certificates Created – emailed or posted.

The Sample Batch is treated as a single Job Registration which can also include links to other documentation and processes related to the work. Individual samples are identified by Job Registration Numbers and Sample Number. Samples may be treated as individual entities for processing and entry of results.

As work progresses the main Lims1 Registration List is automatically updated to reflect the status of Job Registrations.

## Improving Laboratory Efficiencies

In considering implementation of a LIMS it is worth reviewing how much of your laboratory staff time is spending on various processes and how the LIMS might improve efficiencies.

The table below represents a range key areas where use of Lims1 can dramatically improve laboratory efficiencies, reduce sample turn-around times and laboratory cost overheads.

Operation	Lims1 Processes and Methods
<b>Sample Log-in</b>	<ul style="list-style-type: none"> <li>Predefined Setup Table templates to automatically establish all testing, information entry and reporting requirements for the samples.</li> <li>Modification of default testing assignments to suit varying requirements.</li> </ul> <p><b>Comments</b> Single point sample login with predefined selections for types of analysis is very rapid, intuitive and easy to use. All documentation and information related to the work is automatically established.</p>
<b>Work Scheduling</b>	<ul style="list-style-type: none"> <li>Worksheets, Worklists automatically updated for use in the laboratory.</li> <li>Automatic update of management work scheduling, due reports.</li> </ul> <p><b>Comments</b> All documentation and information related to the sample processing in the laboratory automatically established. Laboratory staff have ready access to schedules for work which is to be completed within a given time frame.</p>
<b>Entry of Results</b>	<ul style="list-style-type: none"> <li>Range of entry methods including import of results from laboratory instruments.</li> <li>Extensive system checking and status assignment as results are entered.</li> <li>Out of Limit Warnings.</li> <li>Formatting of results by Significant Figures.</li> </ul> <p><b>Comments</b> Entry of results is dependent on type of analysis being undertaken for a given batch of samples and a sample may undergo testing from a number of laboratory groups. In these instances a range of results entry processes can be employed. Import of results from laboratory instruments will also significantly improve laboratory efficiencies.</p>
<b>Work Review/Approval</b>	<ul style="list-style-type: none"> <li>Rapid access to result tables and pre-approved certificates for review.</li> <li>Passwords link work to approvers and includes Signature on reports.</li> </ul> <p><b>Comments</b> Laboratory staff create lists of work ready for approval and complete the approval process. Audit trails are maintained. Certificates can also be issued at this time.</p>
<b>Creation of Reports</b>	<ul style="list-style-type: none"> <li>Simple one step process for creating and emailing pdf Certificates to clients.</li> <li>Reports maintained in Documentation Library for rapid future access.</li> </ul> <p><b>Comments</b> A listing of work approved for released can be use to batch create Certificates. Creating and distribution of Certificates of Analysis becomes an easy task with significant improvements in laboratories efficiencies.</p>
<b>Accessing Information</b>	<ul style="list-style-type: none"> <li>All work and work details logged into the system may be accessed in seconds.</li> </ul> <p><b>Comments</b> All information related to work undertaken in the laboratory is contained in a single database which may be rapidly extracted to create reports on laboratory activities. Time required to locate this information manually is significantly reduced.</p>
<b>Laboratory Management</b>	<ul style="list-style-type: none"> <li>Extensive range of standard Management Reports.</li> <li>User established Management Report Query Templates and report styles.</li> <li>Export of data to 3<sup>rd</sup> party software or corporate databases.</li> </ul> <p><b>Comments</b> Management reports designed to provide information on current and historical laboratory activities with statistical analysis are provided and may be created in seconds.</p>
<b>Regulatory Requirements</b>	<ul style="list-style-type: none"> <li>System compliance with NATA, ISO standards.</li> <li>Provides a key element in demonstration of laboratory compliance conditions.</li> </ul> <p><b>Comments</b> Preparation time required for audits is reduced and a wide range of compliance issues may be addressed, demonstrated from within the Lims1 system.</p>

## ***Improving Client Services***

In the final analysis, it is your clients who drive your laboratory operations and good client services is the key element of these operations.

<b>Activity</b>	<b>Comment</b>
<b>Turnaround Times</b>	<ul style="list-style-type: none"><li>• Improvement in sample processing and reporting turn-around times for your clients.</li></ul>
<b>Reports</b>	<ul style="list-style-type: none"><li>• Create the type of reports your clients want using Lims1 Certificate Formats.</li><li>• Paperless reporting with automatic email of Certificates.</li><li>• Export of results and other data to clients via Excel or csv files by email.</li><li>• Automatic Email of Sample Receipt Reports.</li><li>• Automatic Email of Work Invoices.</li></ul>
<b>Queries</b>	<ul style="list-style-type: none"><li>• Client requests for information may be handled in seconds.</li><li>• Locate any item of work (Job Registrations) received into the laboratory.</li><li>• Advise client on when work is scheduled for completion.</li><li>• Provide preliminary information on results of analysis via email or telephone.</li><li>• Re-sent previous reports.</li></ul>
<b>Website Services</b>	<ul style="list-style-type: none"><li>• Clients log into Laboratory Website to obtain information on work underway.</li><li>• Listing of all current work being processed with status and due dates.</li><li>• Listing of preliminary results as available.</li><li>• Download of preliminary reports.</li><li>• Download of Final Certificates of Analysis.</li></ul>