



**NORTH AMERICA
STANDARD OPERATING PROCEDURE**



Document No.: SOP QAS-113

Revision Level: 1

Issued Date: December 2017

Title: LIMS Overview

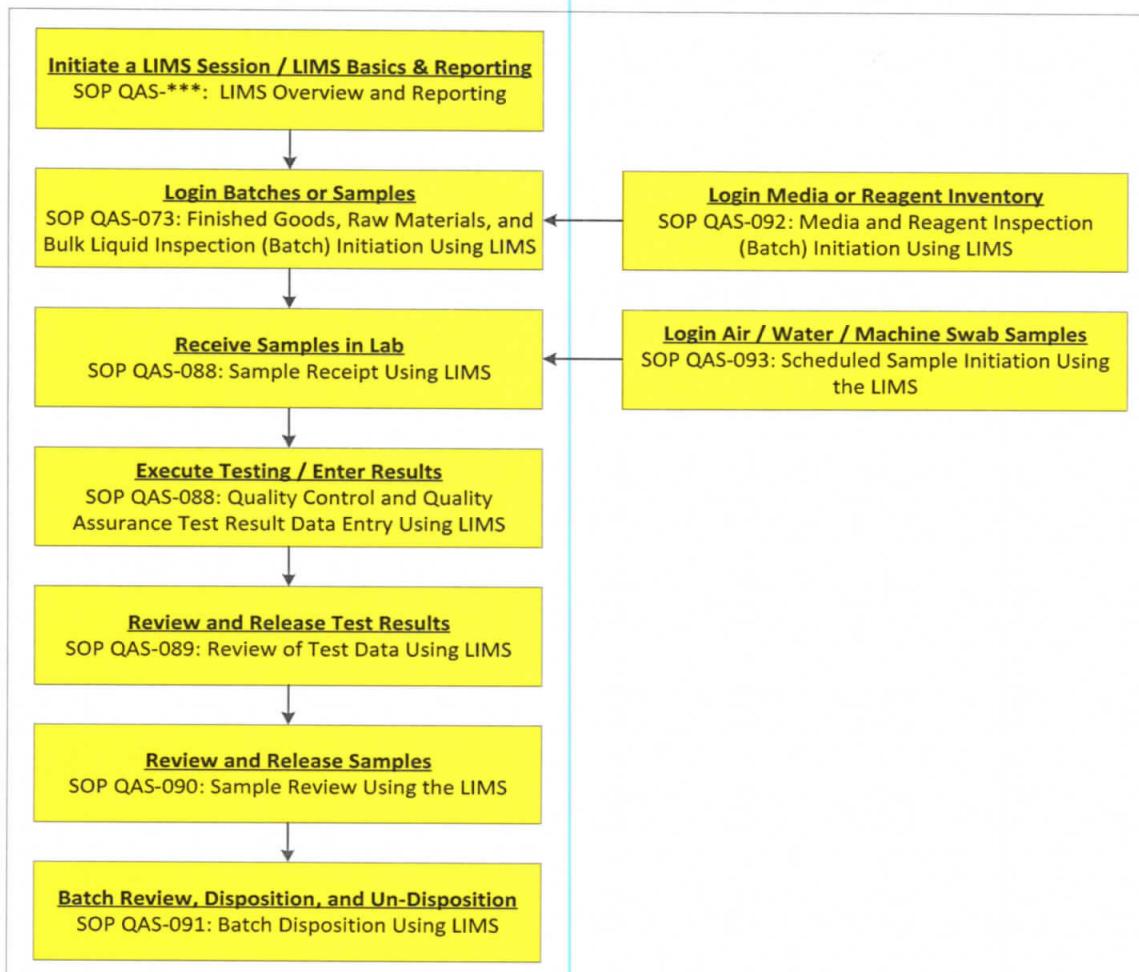
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1.0 Purpose

- 1.1 To provide an overview of the procedures, roles, and responsibilities for the Nice-Pak Products, Inc. (NP)/Professional Disposables International, Inc. (PDI) LIMS system.

2.0 Scope

- 2.1 This procedure applies to all North America facilities of Nice-Pak Products, Inc. (NP)/Professional Disposables International, Inc. (PDI) facilities which utilize LIMS for the disposition of batches.
- 2.2 This procedure applies to the LIMS processes associated with the entirety of the LIMS batch, sample, test, and result workflow. See Exhibit A for a summary of the LIMS workflow, and the relevant SOPs.

Exhibit A: LIMS WORKFLOW



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3.0 External Standards / Reference Documents

- 3.1 SOP QAS-069, Quality Control and Quality Assurance Test Result Data Entry Using the LIMS
- 3.2 SOP QAS-073, Finished Goods, Raw Materials, and Bulk Liquid Inspection (Batch) Initiation Using LIMS
- 3.3 SOP QAS-088, Sample Receipt Using the LIMS
- 3.4 SOP QAS-089, Review of Test Data Using LIMS
- 3.5 SOP QAS-090, Sample Review Using the LIMS
- 3.6 SOP QAS-091, Batch Disposition in LIMS
- 3.7 SOP QAS-092, Media and Reagent Inspection (Batch) Initiation Using LIMS
- 3.8 SOP QAS-093, Scheduled Sample Initiation Using the LIMS
- 3.9 WI QAS-122, Adding Material Specifications to LIMS
- 3.10 Form SOP QAS-072-1, LIMS Access Authorization Form
- 3.11 Form SOP QAS-071-2, LIMS Electronic Signature Authorization Form
- 3.12 CFR 211 Part 11, Electronic Records: Electronic Signatures

4.0 Forms and Attachments

- 4.1 Exhibit A, LIMS Workflow
- 4.2 Exhibit B, LIMS Role – SOP Training Requirement Matrix
- 4.3 Exhibit C, LIMS Login Link
- 4.4 Exhibit D, LIMS User Login Tab
- 4.5 Exhibit E, LIMS Login Screen
- 4.6 Exhibit F, LIMS Dashboard
- 4.7 Exhibit G, Select “View Process Samples”
- 4.8 Exhibit H, Select Lot of Interest
- 4.9 Exhibit I, View Process Samples Screen with Lot Detail
- 4.10 Exhibit J, Opening the Sample History
- 4.11 Exhibit K, Report QBE Menu Option
- 4.12 Exhibit L, Report QBE Menu Option
- 4.13 Exhibit M, Setting Query Definition Parameters
- 4.14 Exhibit N, Setting Report Format and Running Report
- 4.15 Exhibit O, Report Viewer Window



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5.0 Definitions

- 5.1 **LIMS:** The StarLIMS Laboratory Information Management System deployed at the NP/PDII facilities.
- 5.2 **Dashboard:** The primary GUI (Graphical User Interface) to the LIMS.
- 5.3 **LIMS Login:** The process of establishing an electronic session with the LIMS system.
- 5.4 **LIMS Role:** A group of functional privileges defined in LIMS, roughly corresponding to a job-role.
- 5.5 **Username / Password:** The identifying credentials provided by an individual at the time of LIMS login. Additionally, these values are required by the LIMS system at various times when a GMP operation calls for electronic signature verification.
- 5.6 **Electronic Signature:** A prompt by the LIMS which requires the individual to enter their username and password in order to confirm identity for the audit history. Additionally, a comment may be required (depending upon the operation).
- 5.7 **Batch:** A collection of sample and test records in LIMS corresponding to an inspection. This term is used interchangeably with "Lot".
- 5.8 **Lot:** A collection of sample and test records in LIMS corresponding to an inspection. This term is used interchangeably with "Batch".
- 5.9 **Sample:** A collection of tests in LIMS corresponding to a single inspection-sample.
- 5.10 **Test:** A collection of analytes in LIMS.
- 5.11 **Analyte:** A property of a test in LIMS for which the entry or calculation of a result is required.
- 5.12 **Result:** An entered or calculated observation corresponding to an analyte.
- 5.13 **Replicate:** A number referring to the number of times that a result is entered into LIMS.
- 5.14 **Run:** A grouping of identical tests on separate samples in LIMS to be executed as a group.
- 5.15 **Batch Initiation:** The process of creating a new batch in LIMS, and logging-in the initial inspection samples.
- 5.16 **Sample Login:** The process of creating inspection samples in LIMS.
- 5.17 **Sample Receipt:** The process of acknowledging the receipt of samples into the testing laboratory, and that the samples are ready for testing.
- 5.18 **Run Creation:** Assigning a group of tests to a run, thus creating a unit of work and assigning it to an individual for execution.
- 5.19 **Result Entry:** Adding or calculating results in LIMS, generally corresponding to a run.
- 5.20 **Run Finishing:** The action taken by an individual entering results into a run whereby the results are committed to the LIMS.
- 5.21 **Test Release:** The process of reviewing another individual's test results at the test or



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run level.

- 5.22 **Sample Disposition:** The process of reviewing all test results on a sample and determining whether the sample's results are to be released.
- 5.23 **Batch Disposition:** The process by which quality assurance, or their designee, make a final usage decision for a material in LIMS.
- 5.24 **Batch Un-Disposition:** The reversal of the disposition process, necessary when a disposition has been made prematurely, or the incorrect disposition decision has been applied.

6.0 Responsibilities

- 6.1 LIMS responsibilities correspond to an individual's roles within the Quality and Production environment.
- 6.2 An individual's privileges in LIMS are based upon the role that is specified during LIMS login.
- 6.3 LIMS roles are granted based upon an individual's job-roles, and must be approved by an individual's supervisor and the LIMS administrator through the execution of Form SOP QAS-072-1 (LIMS Access Authorization Form).
- 6.4 Each individual seeking access to LIMS must execute Form SOP QAS-071-2 (LIMS Electronic Signature Authorization Form).
 - 6.4.1 This form is a legally-binding document, which renders an individual's electronic signature legally-equivalent to their pen-and-ink signature.
 - 6.4.2 This form is essential to assure that each individual and the LIMS system as a whole is in legal compliance with 21 CFR Part 11, which defines the criteria under which electronic records and electronic signatures are considered to be trustworthy, reliable and equivalent to paper records.
 - 6.4.3 The sharing of an individual's LIMS login credentials may constitute a violation of 21 CFR Part 11, the agreement executed and witnessed in Form SOP QAS-071-2, and our corporate Password Policy. Therefore, the sharing of LIMS login credentials may subject an associate to disciplinary action, ranging from the loss of system access up to and including termination of employment.
- 6.5 Each individual is responsible for maintaining their training on the SOPs corresponding to their LIMS roles. Failure to do so will result in loss of system privileges.
- 6.6 See Exhibit B below for the SOPs corresponding to the LIMS user roles


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Exhibit B: LIMS Role – SOP Training Requirement Matrix

	LIMS Role						
	Viewer	LIMS_Admin	Mgr_Lab	Mgr_QA	QA_Release	USER_Lab	USER_QA
SOP QAS-113: LIMS Overview	X	X	X	X	X	X	X
SOP QAS-069: Quality Control and Quality Assurance Test Result Data Entry Using LIMS		X	X	X		X	
SOP QAS-071: Administration of the Laboratory Information System (LIMS)	X						
SOP QAS-072: Configuration and Change Control for the Laboratory Information System	X						
SOP QAS-073: Finished Goods, Raw Materials, and Bulk Liquid Inspection (Batch) Initiation Using LIMS	X	X	X			X	X
SOP QAS-088: Sample Receipt Using LIMS	X	X				X	
SOP QAS-089: Review of Test Data Using LIMS	X	X				X	
SOP QAS-090: Sample Review Using the LIMS	X	X				X	
SOP QAS-091: Batch Disposition Using LIMS	X	X		X	X		
SOP QAS-092: Media and Reagent Inspection (Batch) Initiation Using LIMS	X	X				X	



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7.0 Procedure

7.1 Logging into LIMS:

7.1.1 From the "Internet Explorer" window, select "LIMS" from the list. See Exhibit C below:

7.1.1.1 **Warning** – Do not use any other link to open LIMS (unless directed by IT), as it may point to an obsolete or incorrect location.

Exhibit C: LIMS Login Link

The screenshot shows the NicePak/PDI Corporate Intranet homepage. On the left, there's a sidebar with links to various company applications and services. The main content area includes a banner for the '2016 Corporate Social Responsibility Report', news items about Grime Boss fishing wipes, and a product of the day for Sani-Wipe sanitizing wipes. A Facebook post from 'Grime Boss' is displayed on the right side of the page.



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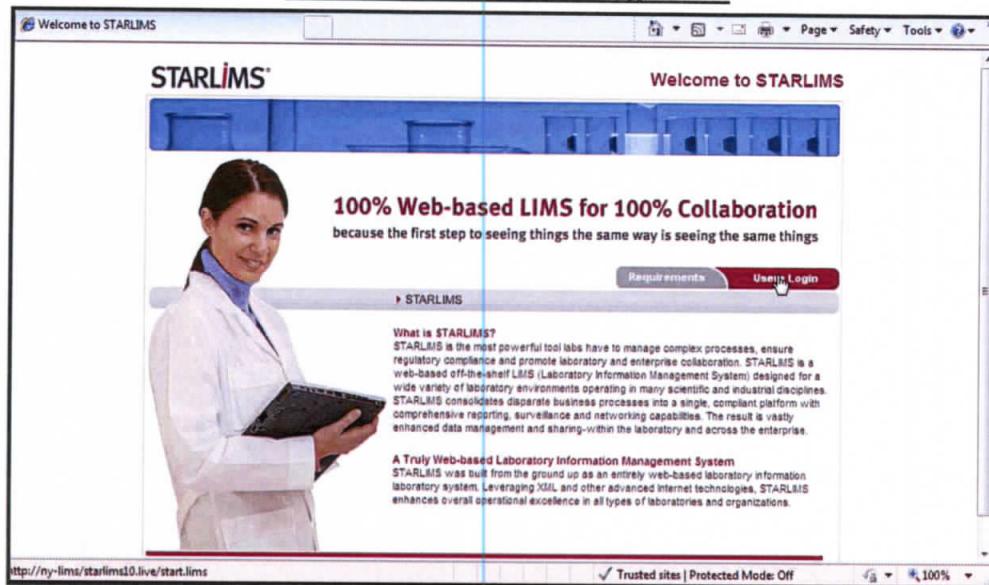
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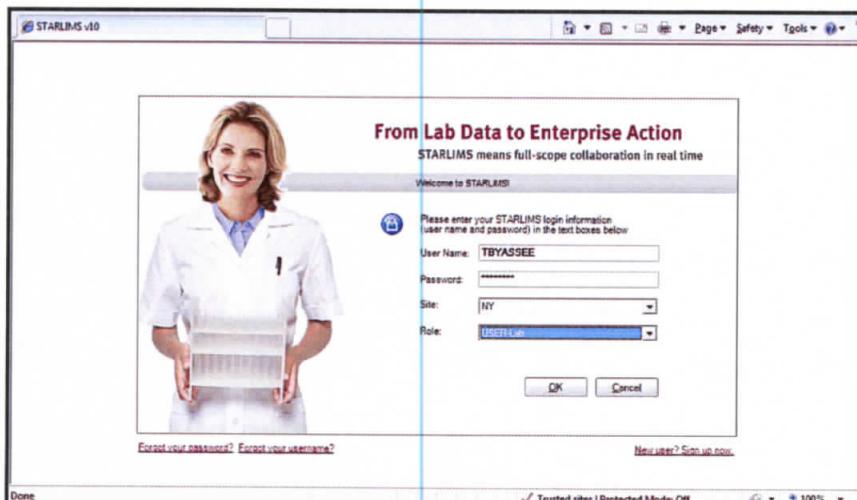
- 7.1.2 From the StarLIMS “welcome” screen, click on the “User Login” tab. See Exhibit D below.

Exhibit D: LIMS User Login Tab



- 7.1.3 On the subsequent login-screen, enter your “User Name” and “Password”.
- 7.1.3.1 These correspond to your network login credentials.
 - 7.1.3.2 Passwords are case-sensitive.
- 7.1.4 If you have multiple LIMS-roles assigned, select the one whose privileges you wish to use for the current session.
- 7.1.5 If you have been granted access to multiple sites, select the one whose data you wish to affect in the current session.

Exhibit E: LIMS Login Screen





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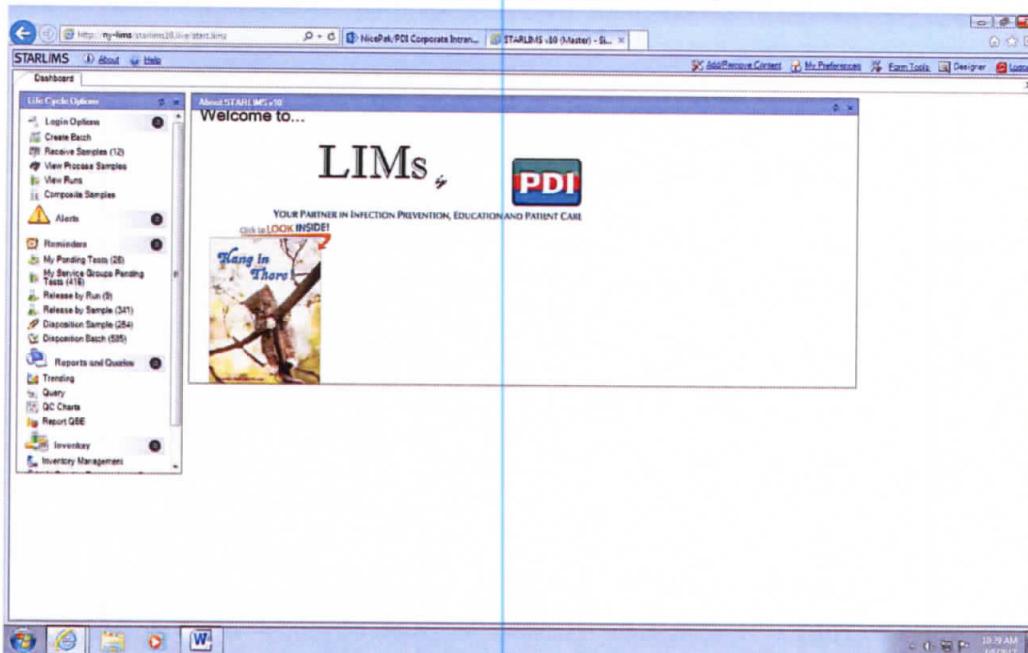
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- 7.1.6 The LIMS dashboard opens, and the functions corresponding to your role-privileges are displayed.

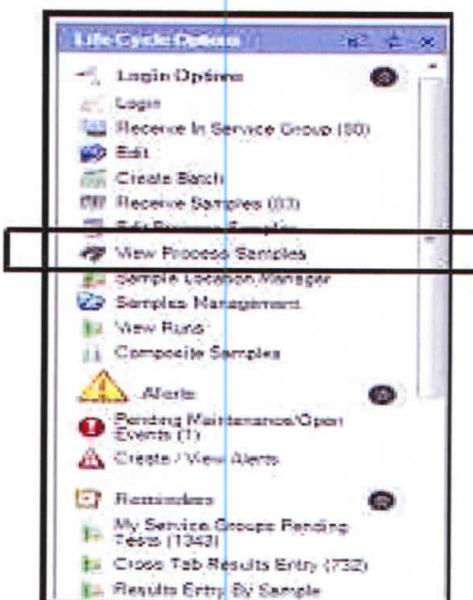
Exhibit F: LIMS Dashboard



- 7.2 Viewing Lot, Sample, and Test information:

- 7.2.1 Open the “View Process Samples” screen from the dashboard.

Exhibit G: Select “View Process Samples”



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7.2.2 Select the material lot of interest.

Exhibit H: Select Lot of Interest



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7.2.3 Click on “Ok” to display the selected lot’s details.

Exhibit I: View Process Samples Screen with Lot Detail

Lot Detail

The screenshot shows the STARLIMS software interface. At the top, there's a menu bar with 'STARLIMS', 'About', 'Help', 'My Preferences', 'FormTools', 'Designer', and 'Logout'. Below the menu is a toolbar with icons for 'Dashboard' and 'View Process Samples'. The main area is titled 'Lot Detail' and displays a table of process samples. The table columns include Type, Planned Start Date, Status, Batch#, Supplier Batch #, Sample Group, Sample Grp. Temp., Material Code, Batch Description, Current Mfg Step, Comment, Vessel, and Qty. A red box highlights the 'Sample Detail' tab at the bottom left, and a blue box highlights the 'Test Detail' tab at the bottom right. The 'Test Detail' tab is currently active, showing a table of test results for various media. The table columns are RT, All Rept, Analyte, Run#, Result, Status, Comments, and Limits. The results show growth or no growth for different media like Trypticase Soy Broth, Blood Agar, E.coli, DE Broth, and MacConkey Broth.

RT	All Rept	Analyte	Run#	Result	Status	Comments	Limits
1	Trypticase	52573	No Growth	Done	None	None Recoverable	None Recoverable
1	Bacteria	52545	0 cfu/g	Done	0 - 100		
1	Blood Agar	52670	No Growth	Done			
1	E.coli	52879	No Growth	Done			
1	DE Broth	52532	Not Turbid	Done			
1	MacConkey Broth	52675	Not Turbid	Done			

7.2.3.1 Changing the tab in the bottom-half of the screen changes the test detail “view”



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7.2.4 Viewing Audit History / Chain of Custody

7.2.4.1 Audit history is captured in LIMS as transactional metadata.

7.2.4.2 Right-click on the lot, sample, or test of interest and click on "View History".

Exhibit J: Opening the Sample History



Draw #	Event	Type	User	Date
N00022507001	Start Batch	Create	Isabel Muniz	3/16/2012 5:24:05 PM
N00022507001	Process Sample Receive In Lab	Edit	Maria Kris	3/19/2012 10:25:10 AM
N00022507001	N/A	Edit	Starlimsdb	3/20/2012 9:43:30 AM
N00022507001	Auto Status Update	Edit	Kristen Lotz	3/20/2012 9:43:31 AM
N00022507001	N/A	Edit	Starlimsdb	3/20/2012 9:43:50 AM
N00022507001	N/A	Edit	Starlimsdb	3/21/2012 4:03:11 PM
N00022507001	N/A	Edit	Starlimsdb	3/21/2012 4:03:35 PM
N00022507001	N/A	Edit	Starlimsdb	3/21/2012 7:51:00 AM
N00022507001	N/A	Edit	Starlimsdb	3/21/2012 7:51:21 AM
N00022507001	N/A	Edit	Starlimsdb	3/22/2012 3:48:32 PM
N00022507001	N/A	Edit	Starlimsdb	3/22/2012 5:00:24 PM
N00022507001	N/A	Edit	Starlimsdb	3/24/2012 11:50:44 AM
N00022507001	N/A	Edit	Starlimsdb	3/24/2012 11:50:44 AM
N00022507001	Auto Release	Edit	Kristi Emmert	3/24/2012 11:50:45 AM
N00022507001	Auto Status Update	Edit	Kristi Emmert	3/24/2012 11:50:45 AM
N00022507001	N/A	Edit	Starlimsdb	3/24/2012 11:50:53 AM
N00022507001	Disposition Sample	Edit	Ashley Clark	3/26/2012 10:39:52 AM



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- 7.2.4.3 The system captures all transactions whether they are performed by individuals, or are the result of the execution of system-level "rules" by the Starlimsdb user.
- 7.2.4.4 Sample custody is assigned based-upon the most-recent transactions affecting sample location. In the example above:
- 7.2.4.4.1 The sample was created by Isabel Muniz (Quality Assurance) on 3/16/2012 at 5:24:05 PM.
 - 7.2.4.4.2 The sample was received into the custody of the lab by Maryia Kris (Quality Control – Microbiological Testing Lab) on 3/19/2012 at 10:25:10 AM.
 - 7.2.4.4.3 Following testing, the sample was dispositioned by Ashley Clark (Quality Control – Microbiological Testing Lab) on 3/26/2012 at 10:39:52 AM.
- 7.2.4.5 Test-Level and Lot (Batch)-level audit trail information may be obtained in an analogous manner by right-clicking on the object of interest and clicking on "View History".

7.3 Running Reports:

- 7.3.1 From the LIMS dashboard, select "Report QBE" to open the "QBE (Query by Example)" screen. See Exhibit J.

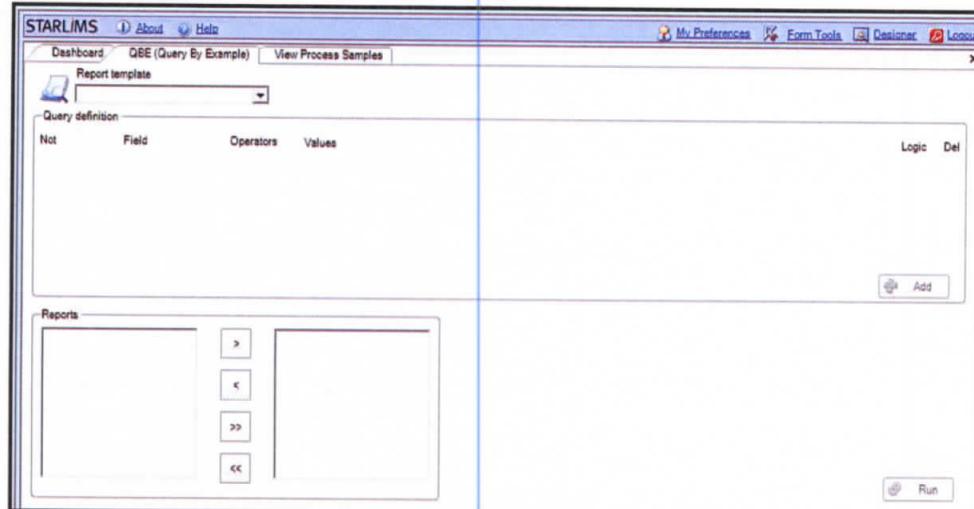
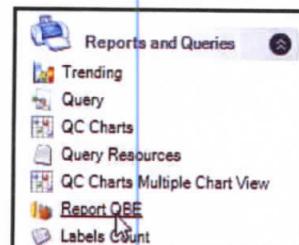
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16Exhibit K: Report QBE Menu Option

7.3.2 Select the desired "Report Template".

Exhibit L: Report QBE Menu Option



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The screenshot shows the STARLIMS software interface. In the top navigation bar, there are links for Dashboard, QBE (Query By Example), View Process Samples, My Preferences, Form Tools, Designer, and Logout. The main area is titled 'Report template' and shows a dropdown menu set to 'Nice-Pak/PDI Certificate of Analysis'. Below this, there is a 'Query definition' section with a table for defining search criteria. A red box highlights the first row of this table, which contains the field 'Batch #', the operator '=', and the value '11200686'. To the right of the table are buttons for 'Logic' and 'Del'. At the bottom of the interface, there is a 'Reports' section with a list of available reports, a 'Run' button, and navigation icons.

7.3.3 Set the “Query Definition” parameters.

Exhibit M: Setting Query Definition Parameters

This screenshot is similar to the one above, showing the STARLIMS software interface. The 'Report template' dropdown is still set to 'Nice-Pak/PDI Certificate of Analysis'. The 'Query definition' table is visible, but the red box highlighting it has been removed. Instead, a red box highlights the 'Reports' section, specifically the report 'Nice-Pak / PDI CofA'. Below this, the 'Run' button is highlighted with a red box. The rest of the interface, including the navigation bar and other sections, remains the same.

7.3.4 Set the “Report” format (there may be several to choose from), then click on “Run”.

Exhibit N: Setting Report Format and Running Report



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The screenshot shows the STARLIMS software interface. At the top, there are tabs for Dashboard, QBE (Query By Example), and View Process Samples. Below these are sections for Report template and Query definition. The Report template dropdown is set to 'Nice-Pak/PDI Certificate of Analysis'. The Query definition section contains a single condition: 'Batch #' equals '11200686'. In the center, there is a preview area for the report, which is currently empty. To the right of the preview area is a toolbar with various icons. A red box highlights the preview area, and a red arrow points from the bottom right towards the 'Print' button.

7.3.5 The report will open in a "PDF" window.

Exhibit O: Report Viewer Window

The screenshot shows an Adobe Acrobat viewer window displaying a PDF titled '14173ac3-23c0-4b3a-b643-b5fcf2427c8.pdf - Adobe Acrobat'. The PDF content includes the NICEPAK logo, the PDI logo, and a section titled 'Certificate of Analysis'. It states: 'This is to certify that the product listed below was manufactured according to cG.M.P. regulations and NICE-PAK/PDI specifications. The chemical and microbiological analysis performed has met the specified limits.' The product name is 'TARGET MAKEUP REMOVER 1000 CT BULK SHIPPER', MFG. SPEC # is 'H61780', DATE OF MANUFACTURE is '03/16/2012', LOT NUMBER is '11200686', and EXPIRATION DATE is '_____'. The analysis performed is 'Total Aerobic Microbial Count (TAMC)', Method is 'TM 602', Specification is '0≤ RESULT ≤100 cfu/g', and Results are '0 cfu/g'. The PDF also includes a 'Comments' sidebar on the left.



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7.4 Executing Queries:

- 7.4.1 Follow the instructions listed in WI QAS-122: AdHoc Querying of LIMS Results.

8.0 Records

Record and Description	Responsibility	Location	Retention Time
N/A	N/A	N/A	N/A

9.0 Revision History

Revision Level	Issued Date	Detailed Reason for Revision
0	January 2014	New Procedure (T. Byassee)
1	December 2017	Update to current SOP Template. Changed instructions in step 7.1.1 to reflect the current way of logging in to the system. Changed photo capture in Exhibit C to reflect where the new link for logging in to LIMS is located. Changed photo in exhibit F to a "user" screen capture instead of administrator capture as this is the screen that users actually see. (WPastor 7/6/17)

Signature Manifest**Document Number:** SOP QAS-113**Revision:** 1**Title:** North America: LIMS Overview

All dates and times are in Eastern Time.

SOP QAS-113 DZ**Approval**

Name/Signature	Title	Date	Meaning/Reason
Anu Joseph (ANU.JOSEPH)		05 Oct 2017, 03:18:06 PM	Approved
Wendi Ratajczak (WRATAJCZAK)		10 Oct 2017, 10:39:49 AM	Approved
William Pastor (WPASTOR)		10 Oct 2017, 01:34:46 PM	Approved
Ricky Lester (RICKY.LESTER)		11 Oct 2017, 04:14:49 PM	Approved
Kinnari Patel (KPATEL)		08 Nov 2017, 01:44:11 PM	Approved

Quality Approval

Name/Signature	Title	Date	Meaning/Reason
Jerry Shi (JSI)	Director, QA and Compliance	10 Nov 2017, 09:28:57 AM	Approved

DC Approval Set Dates

Name/Signature	Title	Date	Meaning/Reason
Dean Zollner (DEAN.ZOLLNER)	Documentation Specialist	14 Nov 2017, 03:54:59 PM	Approved

Quick Approval**Approve Now**

Name/Signature	Title	Date	Meaning/Reason
Dean Zollner (DEAN.ZOLLNER)	Documentation Specialist	07 Dec 2017, 09:22:46 AM	Approved