2nd National MRS User Group

James Proctor

11th January 2018

AGENDA

Agenda

• 10.00	Arrival & Coffee	
• 10.15	Introductions & WJPS Update	J Proctor & WJPS
• 10.30	MRS 3 Overview	J Proctor
• 11.15	Coffee Break	
• 11:30	Moving Alert Limited	J Rhodes
• 12:00	MRS AF (New Features)	J Proctor
• 12:30	Lunch	

Agenda cont.

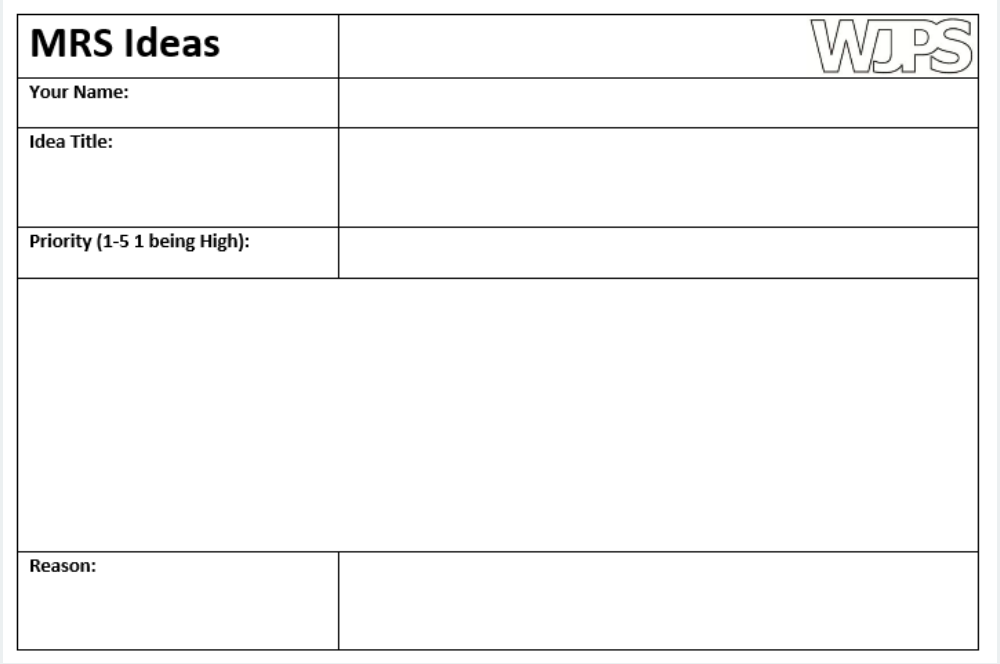
• 13:15	Implementation	QCNW
• 13:45	Your Ideas	All
• 14:30	Coffee Break	
• 13:45	Escrow Aggrements	J Proctor
• 14:15	Validation Updates	J Proctor
• 15:15	Q and A	All
• 15:45	Close	

Introductions

- Who are you?
- Where are you from?
- What WJPS systems do you already use?
- What do you hope to get out of the day?

Your ideas!

- All have a couple of Ideas slips.
- Throughout the day write down any ideas you would like to see.
- Discuss with your group the ideas later.
- Looking for small suggestions / improvements rather than whole new features.



MRS Ideas	
Your Name:	
Idea Title:	
Priority (1-5 1 being High):	
Reason:	

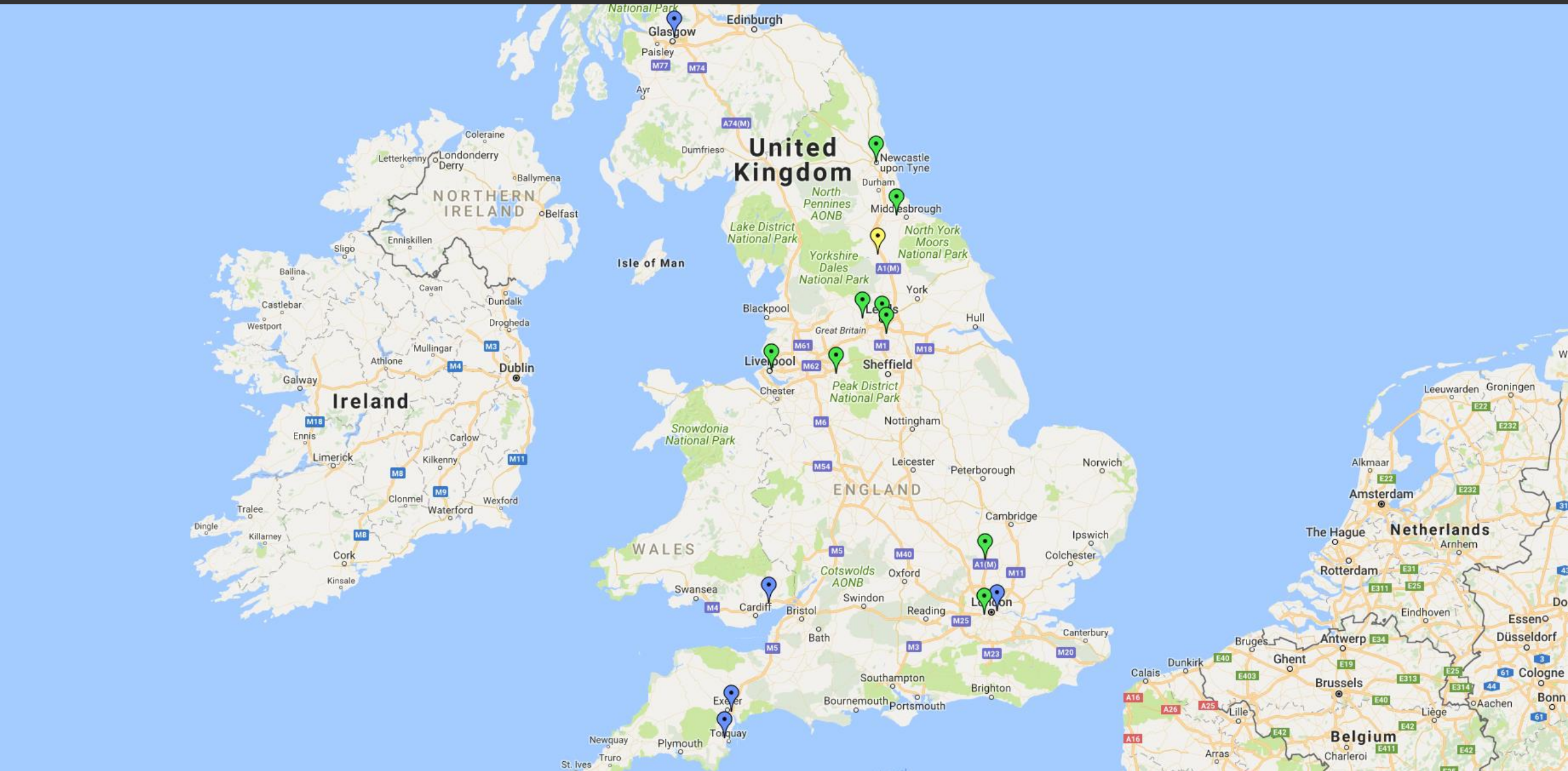
What have we been up to?

WJPS UPDATE

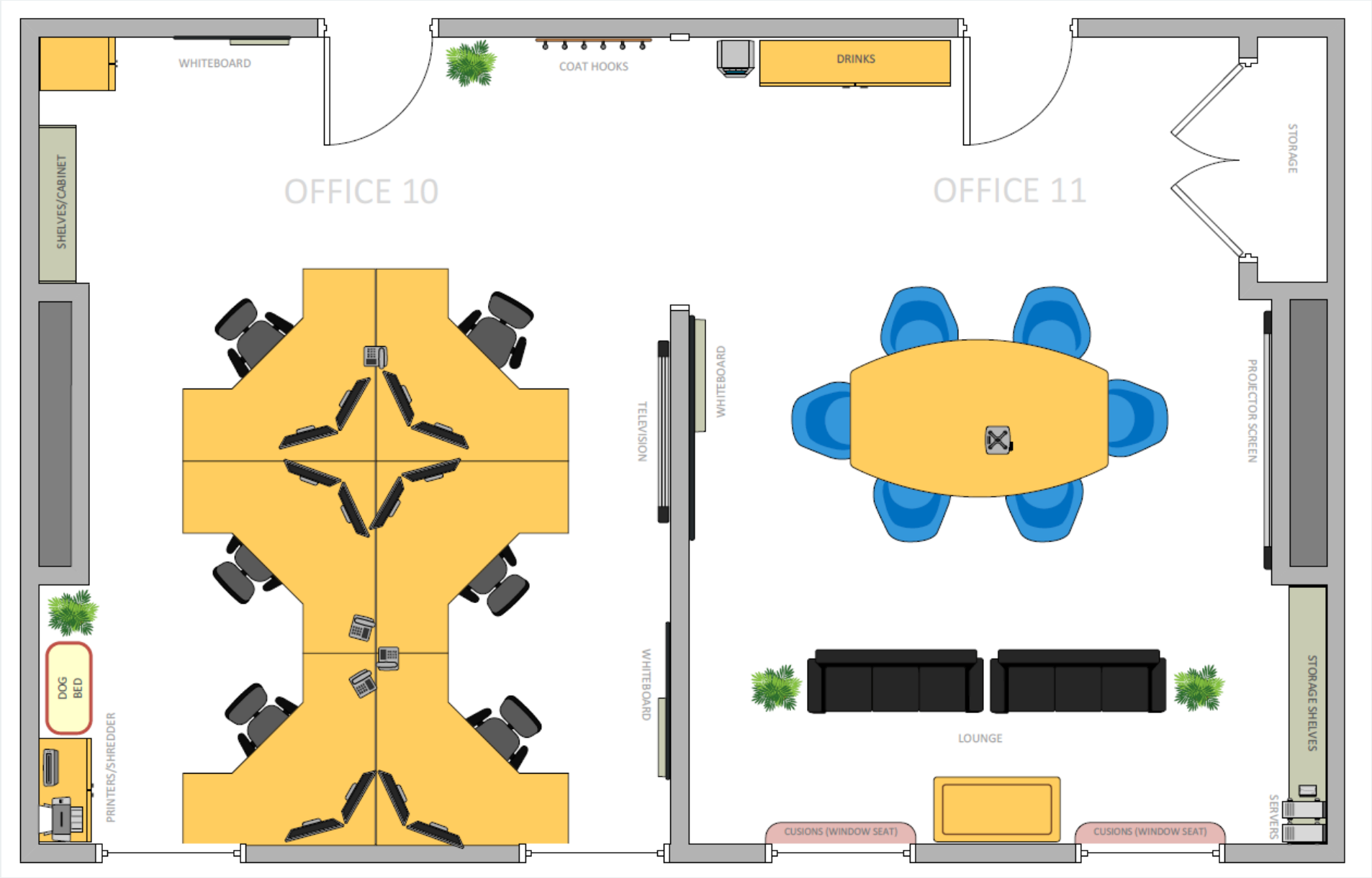
WJPS Update

- Team now 5 of us.
- ISO 9001 & 27001.
- Chartered IT Professional
- Customer expansion.
- Solution expansion.
- Team expansion.

WJPS


Glasgow
Edinburgh
Paisley
Ayr
Dumfries
United Kingdom
Newcastle upon Tyne
Durham
Middlesbrough
North Pennines AONB
Lake District National Park
North York Moors National Park
Yorkshire Dales National Park
York
Hull
Blackpool
Great Britain
Liverpool
Sheffield
Peak District National Park
Chester
Isle of Man
Coleraine
Londonderry
Derry
Letterkenny
Ballymena
NORTHERN IRELAND
Belfast
Enniskillen
Sligo
Ballina
Cavan
Dundalk
Castlebar
Westport
Drogheda
Mullingar
Athlone
Dublin
Galway
Ireland
Ennis
Carlow
Limerick
Kilkenny
Clonmel
Waterford
Wexford
Tralee
Dingle
Killarney
Cork
Kinsale
Snowdonia National Park
Nottingham
Leicester
Peterborough
Norwich
ENGLAND
Cambridge
Ipswich
Colchester
WALES
Cotswolds AONB
Oxford
Swansea
Cardiff
Bristol
Swindon
Reading
Bath
Canterbury
Southampton
Brighton
Bournemouth
Portsmouth
Exeter
Torquay
Plymouth
Newquay
Truro
St. Ives
Leeuwarden
Groningen
Alkmaar
Amsterdam
The Hague
Netherlands
Arnhem
Rotterdam
Eindhoven
Essen
Düsseldorf
Bruges
Antwerp
Ghent
Dunkirk
Calais
Brussels
Cologne
Bonn
Aachen
Lille
Liège
Belgium
Arras
Charleroi

WJPS


WHITEBOARD
COAT HOOKS
DRINKS
STORAGE
SHELVES/CABINET
OFFICE 10
OFFICE 11
TELEVISION
WHITEBOARD
PROJECTOR SCREEN
DOG BED
PRINTERS/SHREDDER
WHITEBOARD
LOUNGE
STORAGE SHELVES
CUSIONS (WINDOW SEAT)
CUSIONS (WINDOW SEAT)
SERVERS

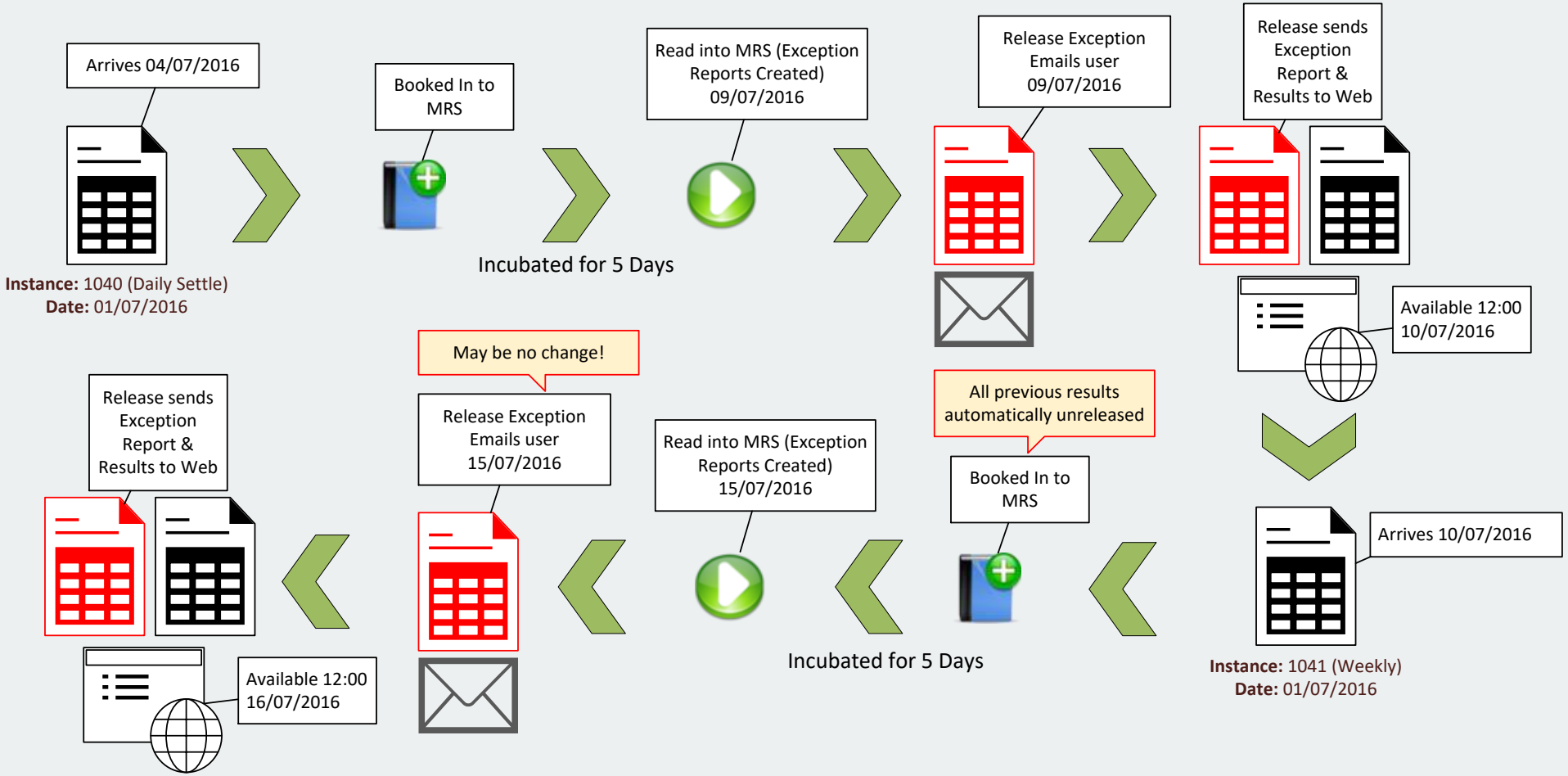
A new exciting product

MRS 3.0 OVERVIEW

Why Update

- MRS 2.5 is a very stable platform.
- However its 10 years old.
- Customers and the MHRA are wanting us to make the application even more advanced.
- There comes a point that adding on is harder than starting again.

Old Work Flows



Main Changes

- Grades on Plates
- Room versions + modifiable alert limits.
- GMP compliant request for analysis forms.
- Use of QRCodes
- No merged result sets
- New audit trail

- Streamlined reading of plates
- Single failure exception and alert reports.
- Streamlined release process (all in one).
- Integration with MRS AF.
- Single reporting tool.
- Improved web user management.

Data Migration

- The original system has been re-designed from scratch.
- The MHRA don't like data being manipulated and software making assumptions.
- Validating all your past data would be very difficult.

- All setups will migrate over (assumptions will be made but can be easily changes e.g. Grades)
- Trending will start again. However we will support both systems for a number of years so there is no worry about not being able to access data.

A new fresh look

MRS 3.0 IN LAB

Room Editor

- Customer B
- Stockton QC
  - Lab A
    - LFC Test
    - Manu Test
  - Lab B
  - Lab C
- Test Customer

LFC Test - V.5

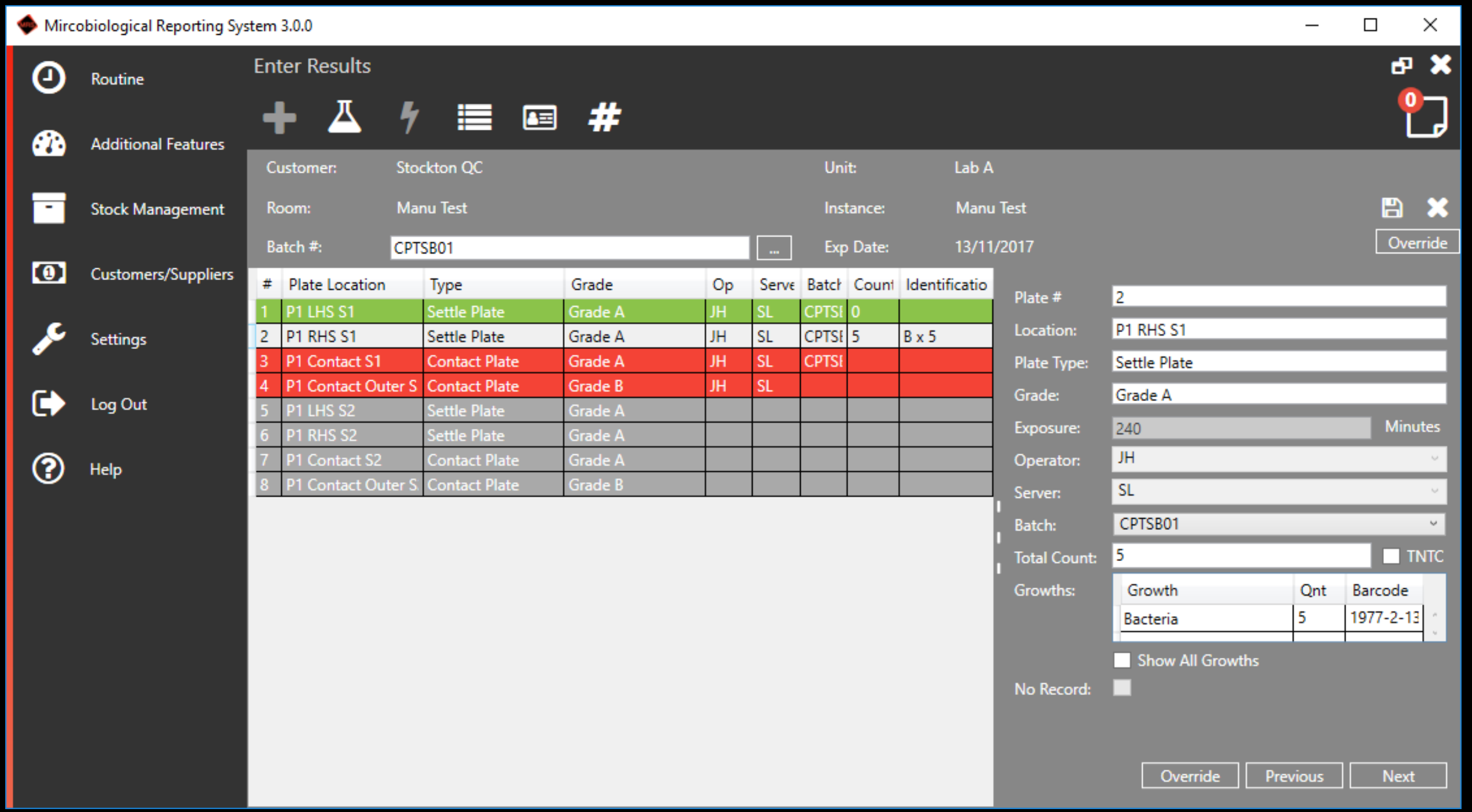
#	Location	Type	Grade	Alert	Action	Daily (1974)	Weekly (1973)
1	P1 LHS S1	Settle Plate	Grade A	5	1	☑	☐
2	P1 RHS S1	Settle Plate	Grade A	5	1	☑	☐
3	P1 Contact S1	Contact Plate	Grade A	5	1	☑	☐
4	P1 Contact Out	Contact Plate	Grade B	5	8	☑	☐
5	P1 LHS S2	Settle Plate	Grade A	5	1	☑	☐
6	P1 RHS S2	Settle Plate	Grade A	5	1	☑	☐
7	P1 Contact S2	Contact Plate	Grade A	5	1	☑	☐
8	P1 Contact Out	Contact Plate	Grade B	5	8	☑	☐
9	Pos Control	Positive Cont	Grade A	5	5	☐	☑
10	Neg Control	Negative Cor	Grade A	5	1	☐	☑
11	Swab S1	Swab	Grade A	5	1	☐	☑
12	Swab S2	Swab	Grade A	5	1	☐	☑

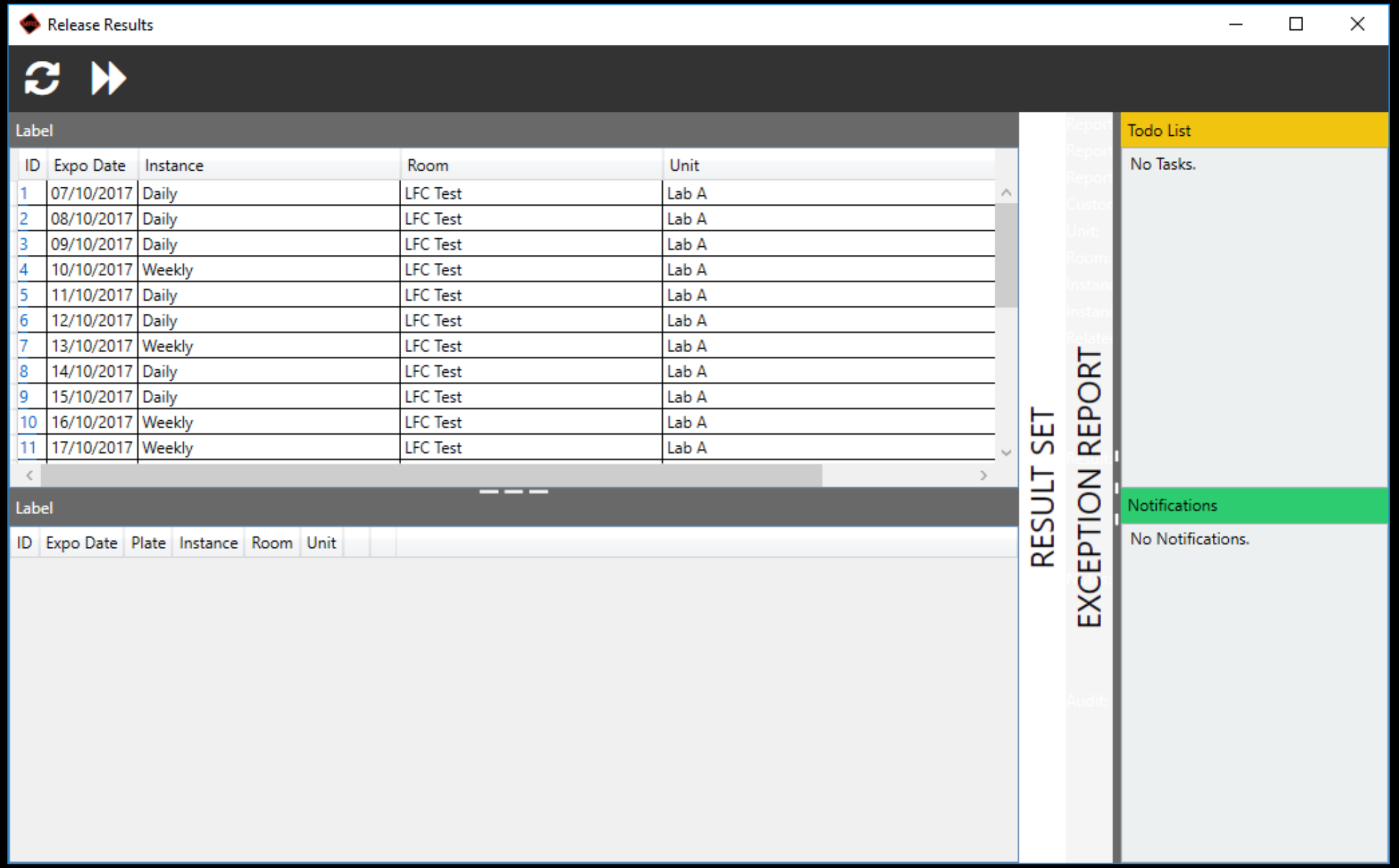
Book In

Customer: Stockton QC
Unit: Lab A
Room: LFC Test - Daily
Date: 04/01/2018 00:00:00

#	Plate Location	Type	Grade	NR	Op	Server
1	P1 LHS S1	Settle Plate	Grade A	☐	JP	JH
2	P1 RHS S1	Settle Plate	Grade A	☐	JP	JH
3	P1 Contact S1	Contact Plate	Grade A	☐	JP	JH
4	P1 Contact Outer S1	Contact Plate	Grade B	☐		
5	P1 LHS S2	Settle Plate	Grade A	☐		
6	P1 RHS S2	Settle Plate	Grade A	☑		
7	P1 Contact S2	Contact Plate	Grade A	☑		
8	P1 Contact Outer S2	Contact Plate	Grade B	☑		

Batch Numbers: ABC123 ...
Incubation Date: 04/01/2018
Incubator: Incubator 1 ...


Mircobiological Reporting System 3.0.0
Routine
Additional Features
Stock Management
Customers/Suppliers
Settings
Log Out
Help
Enter Results
0
Customer: Stockton QC
Unit: Lab A
Room: Manu Test
Instance: Manu Test
Batch #: CPTSB01
Exp Date: 13/11/2017
Override
Plate Location Type Grade Op Serve Batch Count Identificatio
1 P1 LHS S1 Settle Plate Grade A JH SL CPTSI 0
2 P1 RHS S1 Settle Plate Grade A JH SL CPTSI 5 B x 5
3 P1 Contact S1 Contact Plate Grade A JH SL CPTSI
4 P1 Contact Outer S Contact Plate Grade B JH SL
5 P1 LHS S2 Settle Plate Grade A
6 P1 RHS S2 Settle Plate Grade A
7 P1 Contact S2 Contact Plate Grade A
8 P1 Contact Outer S Contact Plate Grade B
Plate # 2
Location: P1 RHS S1
Plate Type: Settle Plate
Grade: Grade A
Exposure: 240 Minutes
Operator: JH
Server: SL
Batch: CPTSB01
Total Count: 5
TNTC
Growths:
Growth Qnt Barcode
Bacteria 5 1977-2-13
Show All Growths
No Record:
Override
Previous
Next


Release Results
Label
ID
Expo Date
Instance
Room
Unit
1 07/10/2017 Daily LFC Test Lab A
2 08/10/2017 Daily LFC Test Lab A
3 09/10/2017 Daily LFC Test Lab A
4 10/10/2017 Weekly LFC Test Lab A
5 11/10/2017 Daily LFC Test Lab A
6 12/10/2017 Daily LFC Test Lab A
7 13/10/2017 Weekly LFC Test Lab A
8 14/10/2017 Daily LFC Test Lab A
9 15/10/2017 Daily LFC Test Lab A
10 16/10/2017 Weekly LFC Test Lab A
11 17/10/2017 Weekly LFC Test Lab A
Label
ID
Expo Date
Plate
Instance
Room
Unit
RESULT SET
EXCEPTION REPORT
Todo List
No Tasks.
Notifications
No Notifications.

Release Results

RELEASE

Date: 23/10/17
Status: Awaiting Exception Report Release
Customer: Stockton QC
Unit: Lab A
Room: LFC Test
Instance: Weekly
Mfg: Not associated with a batch manufacture.

Results:

#	Plate Location	Type	Grade	Op	Server	Batch	Count	Identifications	Excepti
9	Pos Control	Positive Control	Grade A	SL	JH		3	So x 3	
10	Neg Control	Negative Control	Grade A	JH	SL		18	S x 18	2017517
10	Neg Control	Negative Control	Grade A	JH	SL		18	S x 18	2017538
11	Swab S1	Swab	Grade A	JH	SL		0		
12	Swab S2	Swab	Grade A	SL	JH		90	M x 90	2017539

Notes:

Date & Time	Note Type	Note	User

Audit:

Audit	User	Type
Result Set Read	WJPS Admin	27/10/17 15:23:12
Exception Report Generated 2017538	WJPS Admin	27/10/17 15:23:12
Exception Report Generated 2017539	WJPS Admin	27/10/17 15:23:12

Edit

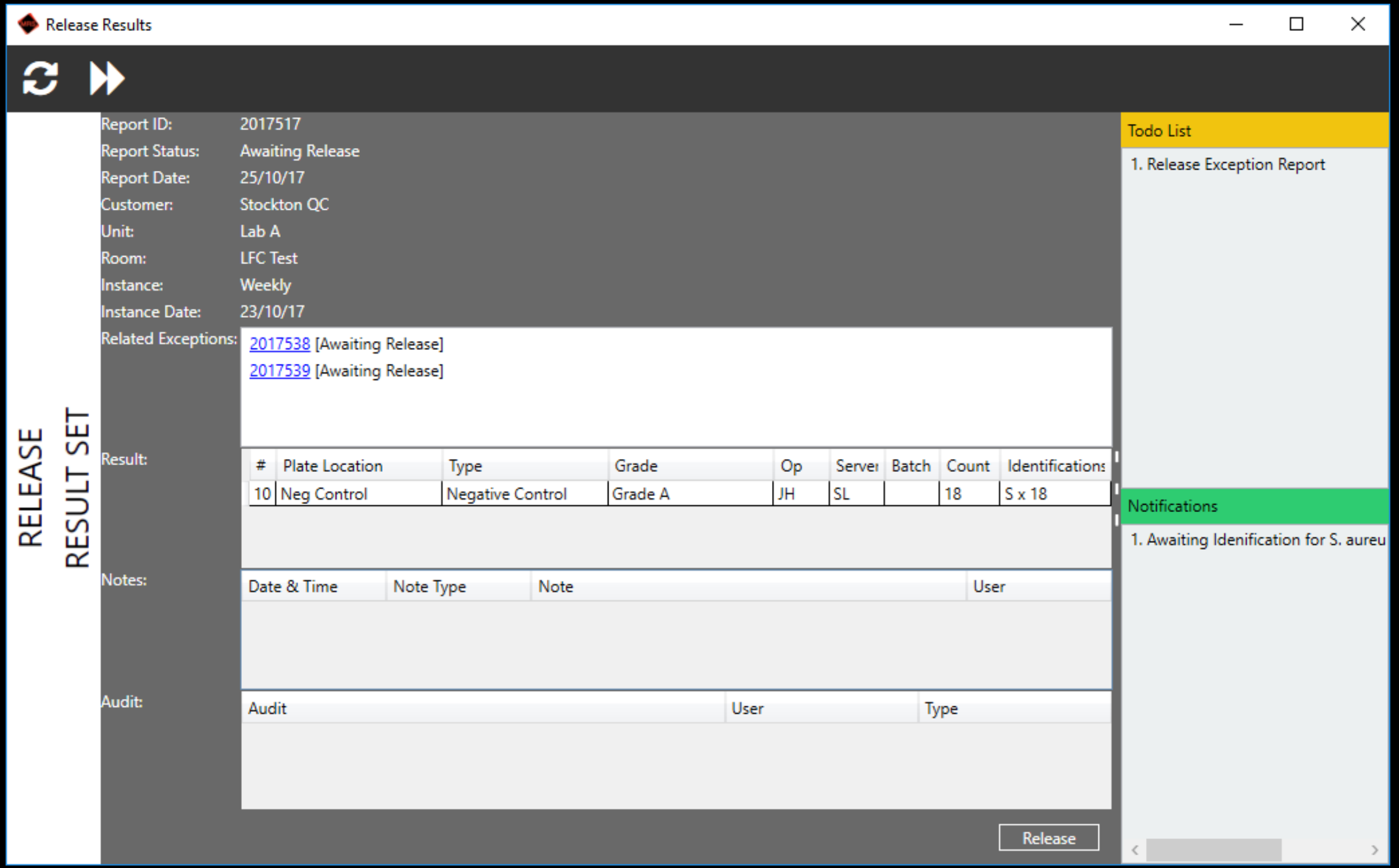
Unrelease Release

Todo List

1. Release Exception Report 2017517
2. Release Exception Report 2017538
3. Release Exception Report 2017539
4. Release Result Set

Notifications

1. Awaiting Identification for S. aureu
2. Awaiting Identification for S. aureu
3. Awaiting Identification for Mould [


Release Results
RELEASE
RESULT SET
Report ID: 2017517
Report Status: Awaiting Release
Report Date: 25/10/17
Customer: Stockton QC
Unit: Lab A
Room: LFC Test
Instance: Weekly
Instance Date: 23/10/17
Related Exceptions:
2017538 [Awaiting Release]
2017539 [Awaiting Release]
Result:
Plate Location Type Grade Op Server Batch Count Identifications
10 Neg Control Negative Control Grade A JH SL 18 S x 18
Notes:
Date & Time Note Type Note User
Audit:
Audit User Type
Release
Todo List
1. Release Exception Report
Notifications
1. Awaiting Idenification for S. aureu

View Results

Customer: Stockton QC | Unit: Lab A | Room: LFC Test | Search

Date Searc: Last Year | From: 08/01/2017 | To: 08/01/2018

Book In ID	Result Set ID	Instance	Exposure Date	Status
1	1	Daily	07/10/2017	Awaiting Release
2	2	Daily	08/10/2017	Awaiting Release
3	3	Daily	09/10/2017	Awaiting Release
4	4	Weekly	10/10/2017	Awaiting Release
5	5	Daily	11/10/2017	Awaiting Release
6	6	Daily	12/10/2017	Awaiting Release
7	7	Weekly	13/10/2017	Awaiting Release
8	8	Daily	14/10/2017	Awaiting Release
9	9	Daily	15/10/2017	Awaiting Release
10	10	Weekly	16/10/2017	Awaiting Release
11	11	Weekly	17/10/2017	Awaiting Release
12	12	Daily	18/10/2017	Awaiting Release
13	13	Weekly	19/10/2017	Awaiting Release
21		Daily	20/10/2017	Awaiting Read
14	14	Weekly	20/10/2017	Awaiting Release
15	15	Weekly	21/10/2017	Awaiting Release
16	16	Daily	22/10/2017	Awaiting Release
17	17	Weekly	23/10/2017	Awaiting Release
18	18	Daily	24/10/2017	Awaiting Release
23		Daily	24/10/2017	Awaiting Read
24		Daily	25/10/2017	Awaiting Read
19	19	Weekly	25/10/2017	Awaiting Release
20	20	Weekly	26/10/2017	Awaiting Release
22		Daily	30/10/2017	Awaiting Read
25		Daily	06/11/2017	Awaiting Read

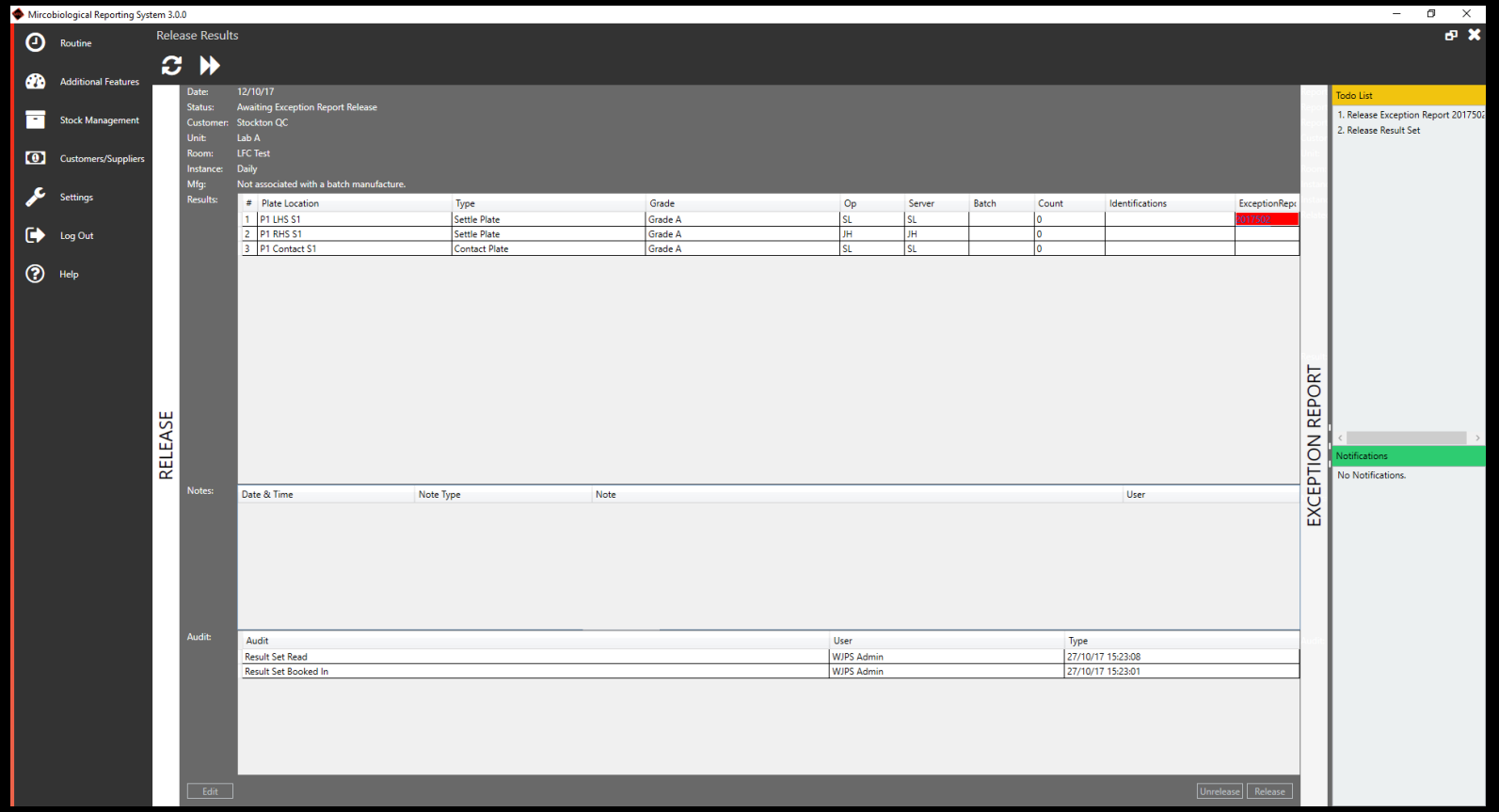
Hint

You can press ctrl + f to fill out all rows with the same values you have entered for row 1.

Add/Edit Grades

Grade	SP	FD	CP	AAS	Swab
Custom Grade	50	100	15	5	1
Grade A	1	1	1	1	1
Grade B	5	5	8	10	1
Grade C	50	25	25	100	1
Grade D	100	50	50	200	1

Save



A fresh start

MRS 3.0 WEB

Welcome to MRS 3 Web

Unit 1 - Customer 23

LFC Test

Manu Test

Test_Room

Test Room

Unit 2 - Customer 23

Unit 1 - Customer 1

Unit 2 - Customer 1

LFC TEST

DASHBOARD

Percentage Failure Rate

!

Days Since Last Failure

0

Open Exception Reports

0

Open Identifications

!

Last Result Date

0001-01-01T00:00:00

Room Status

OK

LFC TEST

RESULT SETS

Filter Result Sets

RESULTS DATE	INSTANCE	EXCEPTIONS
08/11/2017	Daily	-
10/11/2017	Daily	-
14/11/2017	Daily	⚠ 2

LFC TEST

ALERTS

Filter

REPORT ID	REPORT DATE	OUTSTANDING
AL201676	26/07/2016	No
AL201655	07/07/2016	Yes

LFC TEST

BOOKED IN PLATES

Filter Booked In Plates

PLATE NUMBER	EXPOSURE DATE	INSTANCE	PLATES	INCUBATION DATE	EXPECTED READ DATE
S21	20/10/2017	Daily	8	20/10/2017	25/10/2017
S23	24/10/2017	Daily	4	24/10/2017	29/10/2017
S24	25/10/2017	Daily	8	25/10/2017	30/10/2017
S22	30/10/2017	Daily	8	30/10/2017	04/11/2017
S25	06/11/2017	Daily	8	06/11/2017	11/11/2017

LFC TEST

REPORTS

Choose a month & year to view the monthly report.

KEY +

2017 | June

#	PLATE LOCATION	01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
1	LAF Cabinet (Left Side) session 1	0	0			0	0	0	0	0			0	0	0	0	0			0	0	0	0	0			0	0	0	0	0
2	LAF Cabinet (Right Side) session 1	0	0			0	0	0	0	0			0	0	0	0	0			0	0	0	0	0			0	0	1	0	0
3	LAF Cabinet (Left Side) session 2																					0	0	0							
4	LAF Cabinet (Right Side) session 2																					0	0	0							
5	LAF Cabinet (Left Side) session 3																							0							
6	LAF Cabinet (Right Side) session 3																							0							
7	Clean Room Floor	0	0			0	0	0	0	0			5	0	10	42	30			25	20	6	2	51			0	0	0	0	1
8	Clean Room Hatch	0	0			0	0	3	0	0			35	3	15	55	145			TN	34	16	12	4			0	0	0	0	1

LFC TEST

ROOM FORMS

Filter

INSTANCE NAME	INSTANCE STATUS
Default	Enabled
Session/Daily	Enabled
Weekly CP	Disabled
Weekly SP	Enabled

ALL EXCEPTION REPORTS

Filter Exception Reports

EXCEPTION ID	EXCEPTION INSTANCE	EXCEPTION REPORT DATE	ROOM
2017498	Daily	25/10/2017	LFC Test
2017520	Daily	27/10/2017	LFC Test
2017521	Daily	27/10/2017	LFC Test
2017525	Weekly	27/10/2017	LFC Test
2017527	Daily	27/10/2017	LFC Test
2017544	Daily	24/11/2017	LFC Test
2017545	Daily	24/11/2017	LFC Test

QR Codes

- QR Code is smaller (i.e. Smaller Labels)
- GS1 compliant
- QR Code can have a lot more data in it.
- More data allows us to validate the barcode.
- Its more than just a number typed in.
- QR Readers cost more (around £200)
- Label Printers capable of printing QR

Traditional Barcode

QR Code

Timescales

- Development on going but well on the way. Hope to have a good version by April 2018.
  - Customer, Suppliers and Identifications need integrating.
  - Recreate Web Reports.
- Roll out will be through Summer 2018. However this is no rush to upgrade.

Enjoy

COFFEE BREAK (15 MINUTES)

Approaches which could be adopted to

MOVING ALERT LIMITS

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Microbiological Result Trending in Aseptic Services

John Rhodes

Stockton QC Laboratory

Consultant

Stockton Quality Control Laboratory

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Session Aim

To gain an understanding of the reason for trending results as applied to aseptic services, how it can be applied to MRS results in practice and the consequences of not reviewing regularly any trends.

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Scope

- Session plates: finger dabs and critical area settle plates.
- Weekly plates: contact plates and room settle plates.
- Quarterly testing: air samples and swabs.

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Draft EU GMP Annex 1

Trend, trends or trending is mentioned 15 times.

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10.10 Environmental monitoring data generated in grade A and B areas should be reviewed as part of product batch release. A written plan should be available that describes the actions to be taken when data from environmental monitoring are found out of trend or out of specification.

9.17 The monitoring of grade C and D areas in operation should be performed in accordance with the principles of QRM to provide sufficient data to allow effective trend analysis.

9.10 If action limits are exceeded operating procedures should prescribe a root-cause investigation followed by corrective and preventive action.
If alert limits are exceeded, operating procedures should prescribe scrutiny and follow-up, which might include investigation and corrective action.

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WHAT IS TRENDING?

Oxford English Dictionary

Currently popular or widely discussed online, especially on social media websites

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A TREND

Oxford English Dictionary

A general direction in which something is developing or changing

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140 results for right hand finger dabs in a grade A environment

0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 1 0 0 0 0
0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
0 0 0 0 0 0 0 1 0 0 0 0 0 0 0 0 0 0 0 0
0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
0 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 1
0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 1 0 0 0 0
0 0 0 0 0 1 0 0 0 0 0 1 0 0 0 0 0 0 0 0

Failure occurred in the 4th, 10th, 17th, 20th, 24th, 26th, and 28th weeks

When would you conduct a root cause analysis and CAPAs?

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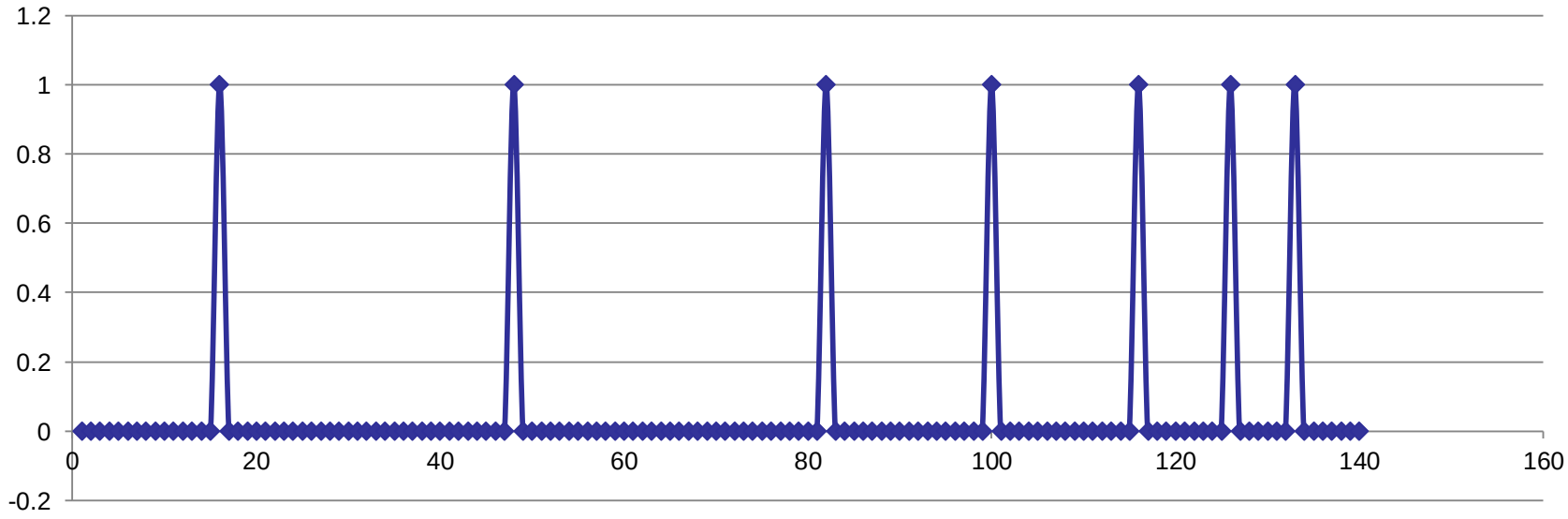

When would you conduct a root cause analysis and CAPAs?

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0 0 0 0 0 0 0 0 0 0 0 0 0 0 1 0 0 0 0
0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
0 0 0 0 0 0 1 0 0 0 0 0 0 0 0 0 0 0 0
0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
0 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 1
0 0 0 0 0 0 0 0 0 0 0 0 0 0 1 0 0 0 0
0 0 0 0 0 1 0 0 0 0 0 0 1 0 0 0 0 0 0

Average results over 140 results

% failure rate
Σ(results) / number of results x 100

0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 6.3 5.9 5.6 5.3 5.0
4.8 4.5 4.3 4.2 4.0 3.8 3.7 3.6 3.4 3.3 3.2 3.1 3.0 2.9 2.9 2.8 2.7 2.6 2.6 2.5
2.4 2.4 2.3 2.3 2.2 2.2 2.1 4.2 4.1 4.0 3.9 3.8 3.8 3.7 3.6 3.6 3.5 3.4 3.4 3.3
3.3 3.2 3.2 3.1 3.1 3.0 3.0 2.9 2.9 2.9 2.8 2.8 2.7 2.7 2.7 2.6 2.6 2.6 2.5 2.5
2.5 3.7 3.6 3.6 3.5 3.5 3.4 3.4 3.4 3.3 3.3 3.3 3.2 3.2 3.2 3.1 3.1 3.1 3.0 4.0
4.0 3.9 3.9 3.8 3.8 3.8 3.7 3.7 3.7 3.6 3.6 3.6 3.5 3.5 3.5 4.3 4.3 4.2 4.2 4.2
4.1 4.1 4.1 4.0 4.0 4.8 4.7 4.7 4.7 4.6 4.6 4.5 5.3 5.2 5.2 5.1 5.1 5.1 5.0 5.0

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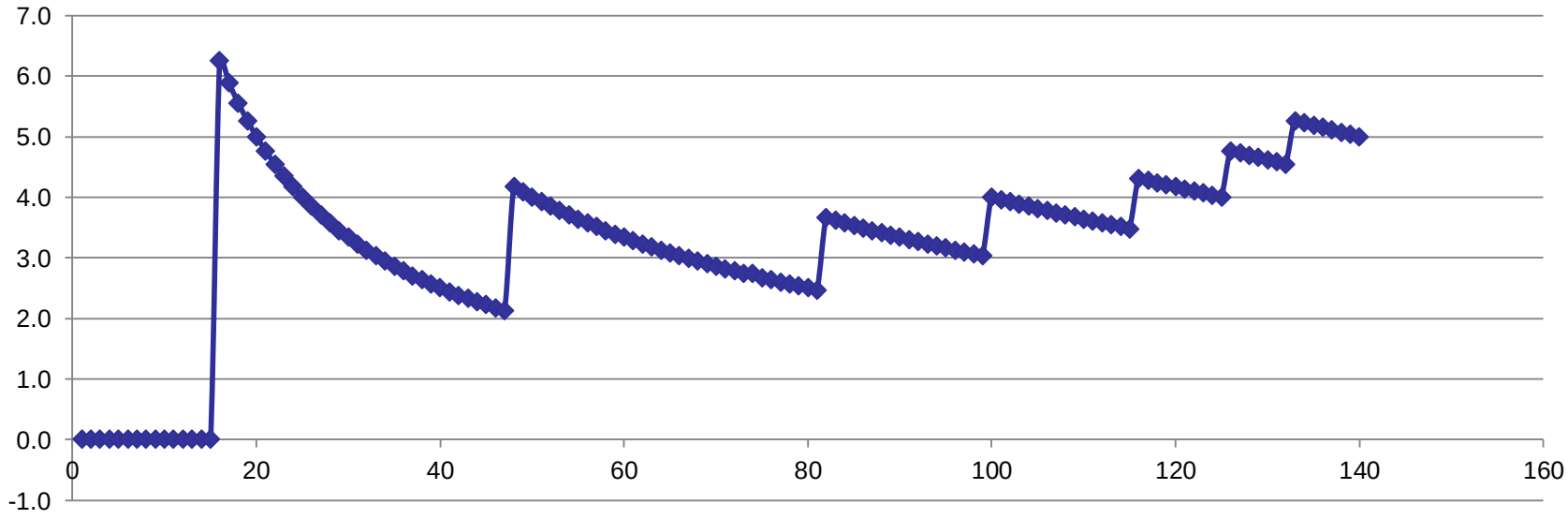

When would you conduct a root cause analysis and CAPAs?

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0 0 0 0 0 0 0 0 0 0 0 0 0 0 1 0 0 0 0 0 0 0 0
0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 1 0 0
0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
0 0 0 0 0 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 1
0 0 0 0 0 0 0 0 0 0 0 0 0 1 0 0 0 0 0 0 0 0 0
1 0 0 0 0 0 1 0 0 0 0 0 0

Moving Average Results (40)

% failure rate
Σ(40 results) / 40 x 100

- -
- - - - - - - - - - - - - - - - - - 2.5 2.5 2.5 2.5
2.5 2.5 2.5 5.0 5.0 5.0 5.0 5.0 5.0 5.0 5.0 5.0 2.5 2.5 2.5 2.5 2.5 2.5 2.5 2.5 2.5 2.5
2.5 2.5 2.5 2.5 2.5 2.5 2.5 2.5 2.5 2.5 2.5 2.5 2.5 2.5 2.5 5.0 5.0 5.0 5.0 5.0 5.0 5.0
2.5 2.5 2.5 2.5 2.5 2.5 2.5 2.5 2.5 2.5 2.5 5.0 5.0 5.0 5.0 5.0 5.0 5.0 5.0 5.0 5.0 5.0
5.0 5.0 5.0 5.0 5.0 7.5 7.5 7.5 7.5 7.5 7.5 7.5 5.0 5.0 5.0 7.5 7.5 7.5 7.5 7.5 7.5 7.5
10 10 10 10 10 10 10 10

0% = in control 2.5% = investigate all discrepancies or OOS 5% = warning investigate and corrective action 7.5% = action root cause and CAPA 10% = out of control (justify continuing or evoke contingency plan until unit requalified

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0 0 0 0 0 0 0 0 0 0 0 0 0 0 1 0 0 0 0
0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
0 0 0 0 0 0 1 0 0 0 0 0 0 0 0 0 0 0 0
0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
0 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 1
0 0 0 0 0 0 0 0 0 0 0 0 0 0 1 0 0 0 0
0 0 0 0 0 1 0 0 0 0 0 1 0 0 0 0 0 0 0

Moving Average Results (5)

% failure rate
Σ(5 results) / 5 x 100

- - - - - 0 0 0 0 0 0 0 0 0 0 20 20 20 20 20
0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
0 0 0 0 0 0 0 20 20 20 20 20 20 0 0 0 0 0 0 0
0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
0 20 20 20 20 20 0 0 0 0 0 0 0 0 0 0 0 0 20
20 20 20 20 0 0 0 0 0 0 0 0 0 0 0 20 20 20 20 20
0 0 0 0 0 20 20 20 20 20 0 0 20 20 20 20 20 0 0 0

0% = in control 20% = investigate all discrepancies or OOS 40% = warning investigate and corrective action 60% = action root cause and CAPA 80% = out of control (justify continuing or evoke contingency plan until unit requalified

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0 0 0 0 0 0 0 0 0 0 0 0 0 0 1 0 0 0 0
0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
0 0 0 0 0 0 0 1 0 0 0 0 0 0 0 0 0 0 0
0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
0 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 1
0 0 0 0 0 0 0 0 0 0 0 0 0 0 1 0 0 0 0
0 0 0 0 0 1 0 0 0 0 0 1 0 0 0 0 0 0 0

Moving Average Results (100)

% failure rate
Σ(100 results) / 100 x 100

-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
-	-	-	-	-	-	-	-	-	-	3	3	3	3	3	2	2	2	2	3
3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	4	4	4	4	4
4	4	4	4	4	5	5	5	5	5	5	5	6	6	6	6	6	6	5	5

0% = in control 1% = investigate and discrepancies or OOS 2% = warning investigate and corrective action 3% = action root cause and CAPA 4% = out of control (justify continuing or evoke contingency plan until unit requalified

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30 results for contact plates in a grade D environment

10 3 5 8 14 7 16 1 8 7 17 19 12 15 10 3
20 15 18 11 16 5 18 17 12 14 19 7 20 18

When would you conduct an investigation and take corrective action?

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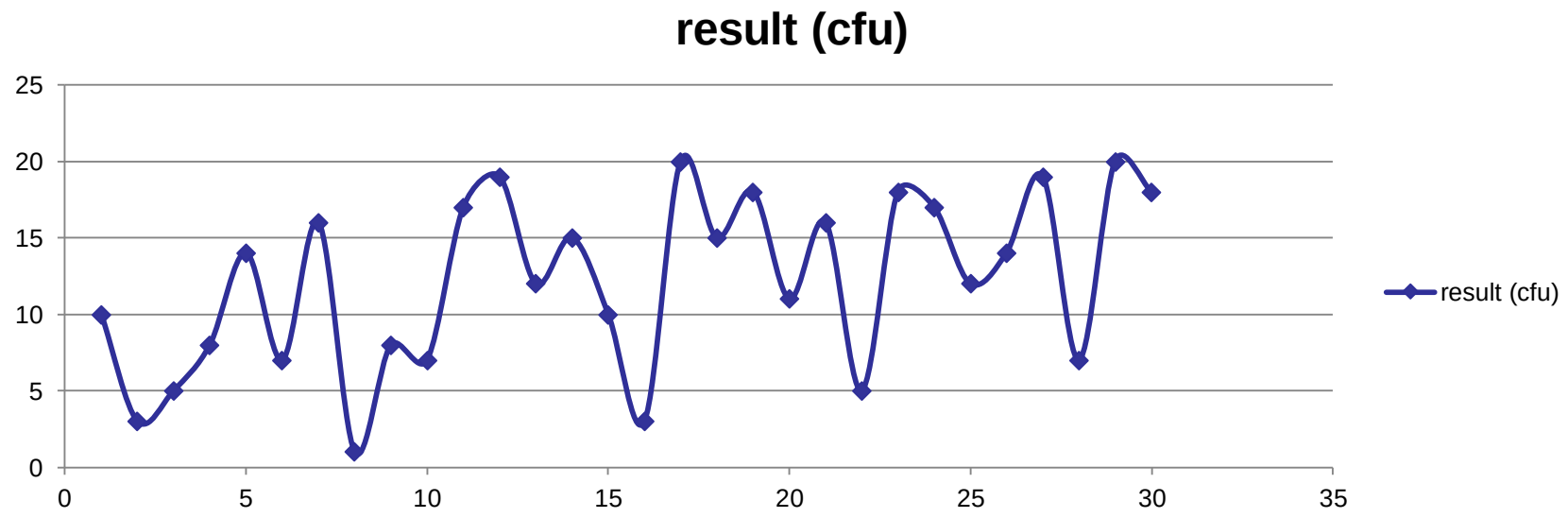
10 3 5 8 14 7 16 1 8 7 17 19 12 15 10 3
20 15 18 11 16 5 18 17 12 14 19 7 20 18



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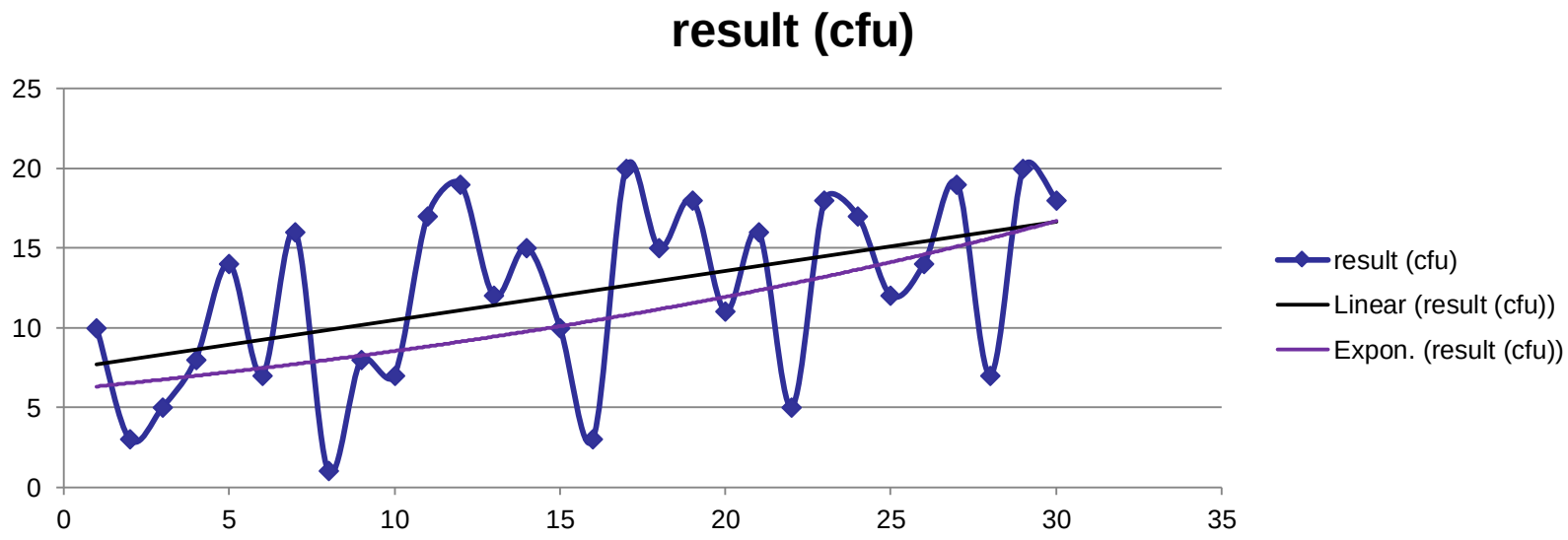
10 3 5 8 14 7 16 1 8 7 17 19 12 15 10 3
20 15 18 11 16 5 18 17 12 14 19 7 20 18



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NHS Foundation Trust

Establish an Alert level based on mean + 2xSD

10 3 5 8 14 7 16 1 8 7 17 19 12 15 10 3
20 15 18 11 16 5 18 17 12 14 19 7 20 18

N	average	SD	mean + 2xSD
5	8	4.30	16.6

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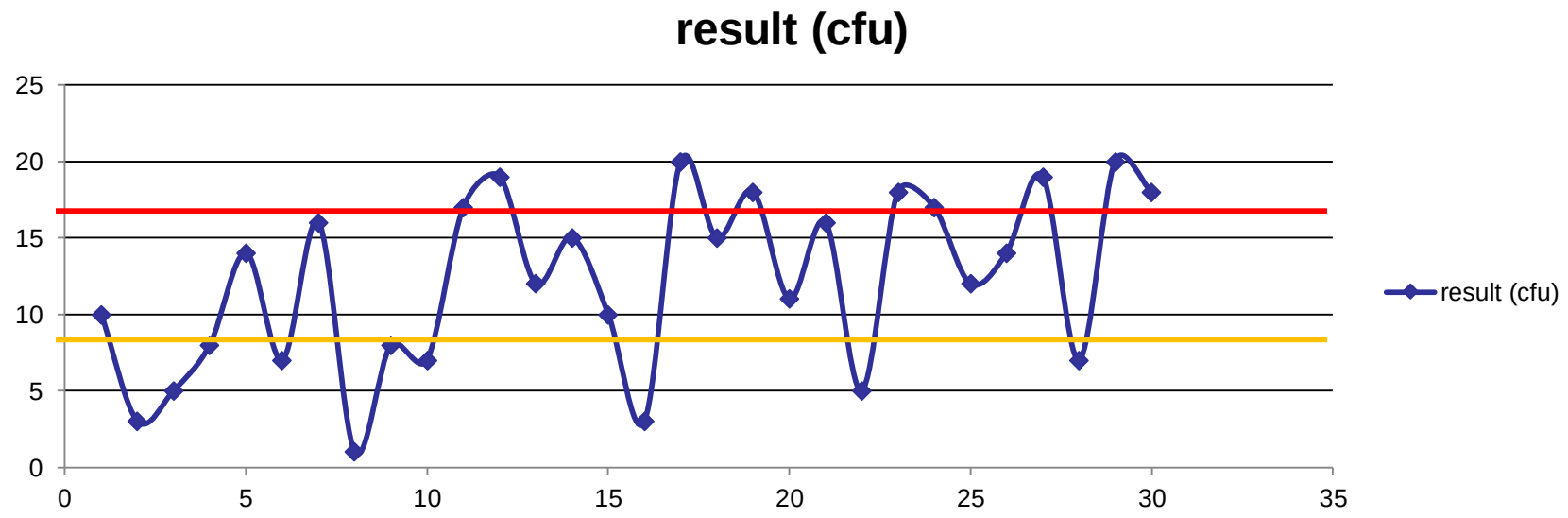
10 3 5 8 14 7 16 1 8 7 17 19 12 15 10 3
20 15 18 11 16 5 18 17 12 14 19 7 20 18



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Shewhart approach Average = 8, SD = 4.30 warning = 16.6

10 3 5 8 14 7 16 1 8 7 17 19 12 15 10 3
20 15 18 11 16 5 18 17 12 14 19 7 20 18

Test	Rule	Problem indicated
1	1 point is outside the control limits.	A large shift.
2	8/9 points on the same side of the center line.	A small sustained shift.
3	6 consecutive points are steadily increasing or decreasing.	A trend or drift up or down.
4	14 consecutive points are alternating up and down.	Non-random systematic variation.
5	2 out of 3 consecutive points are more than 2 sigmas from the center line in the same direction.	A medium shift.
6	4 out of 5 consecutive points are more than 1 sigma from the center line in the same direction.	A small shift.
7	5 consecutive points are within 1 sigma of the center line.	Stratification.
8	8 consecutive points on either side of the center line with none within 1 sigma.	A mixture pattern.

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EU GMP draft annex1 approach Average = 8, SD = 4.30

warning = 16.6

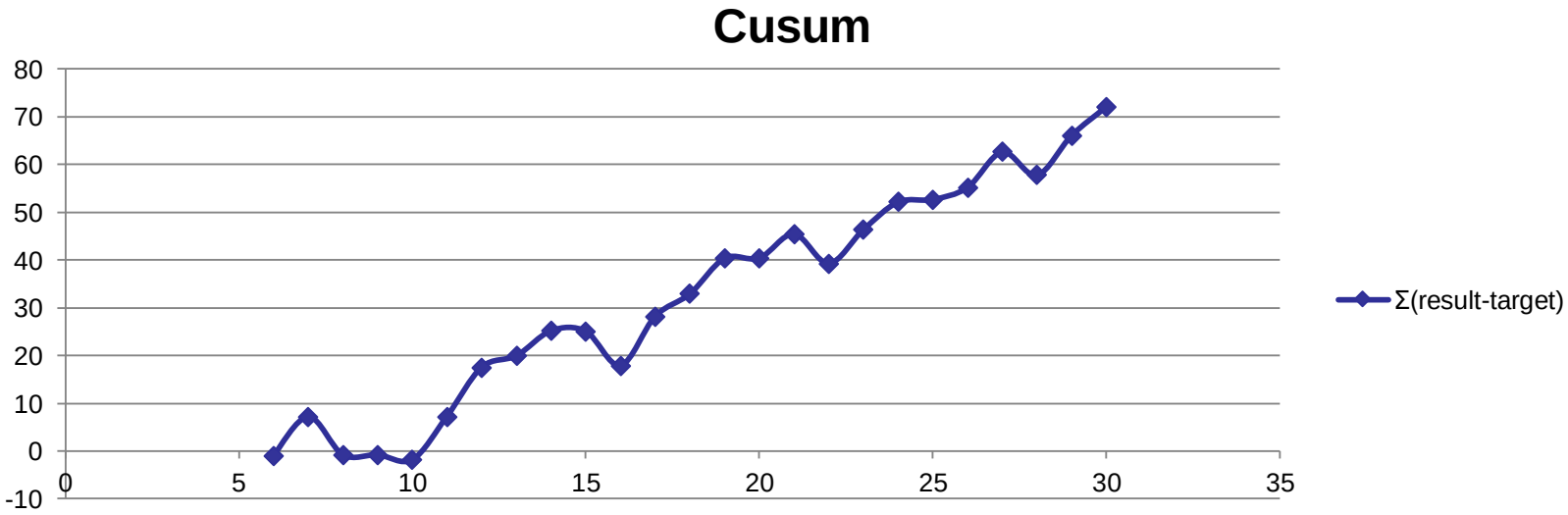
10 3 5 8 14 7 16 1 8 7 17 19 12 15 10 3
20 15 18 11 16 5 18 17 12 14 19 7 20 18

9.32 Trends can include but are not limited to:

a) Increasing numbers of action or alert limit breaches.
b) Consecutive breaches or alert limits.

CUSUM approach Average = 8 for n = 5

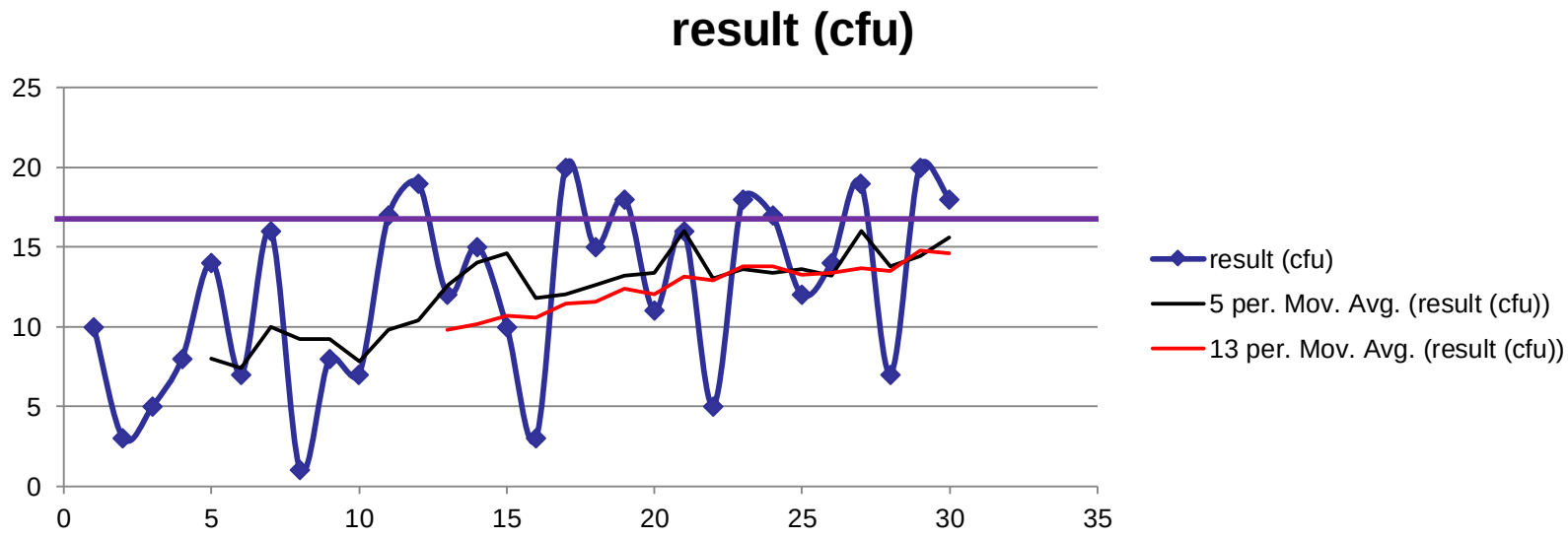
10 3 5 8 14 7 16 1 8 7 17 19 12 15 10 3
20 15 18 11 16 5 18 17 12 14 19 7 20 18



the purpose of a Shewhart control chart is primarily to keep the process in control and to see the impact of process improvement efforts. With a CUSUM control chart, you are trying to detect small shifts away from the process target.

10 3 5 8 14 7 16 1 8 7
17 19 12 15 10 3 20 15 18 11
16 5 18 17 12 14 19 7 20 18

Moving Average



10 3 5 8 14 7 16 1 8 7
17 19 12 15 10 3 20 15 18 11
16 5 18 17 12 14 19 7 20 18

Exponential Moving Average Results (5)

$= \text{result}_{n} * 0.333 + \text{result}_{n-1} * 0.667$

-	-	-	-	-	7.67	10.44	7.30	7.53	7.35
10.57	13.37	12.92	13.61	12.41	9.28	12.85	13.56	15.04	13.70
14.46	11.31	13.54	14.69	13.80	13.86	15.57	12.72	15.14	16.09

Warning is mean + 2xSD = 16.6

10 3 5 8 14 7 16 1 8 7
17 19 12 15 10 3 20 15 18 11
16 5 18 17 12 14 19 7 20 18

Exponential Moving Average Results (13)

$= \text{result}_{n} * 0.143 + \text{result}_{n-1} * 0.857$

-	-	-	-	-	-	-	-	-	-
-	-	-	10.32	10.62	10.43	10.77	11.17	11.72	12.01
12.36	12.21	12.40	12.73	12.88	13.02	13.39	13.29	13.55	13.92

Warning is mean + 2xSD = 16.6

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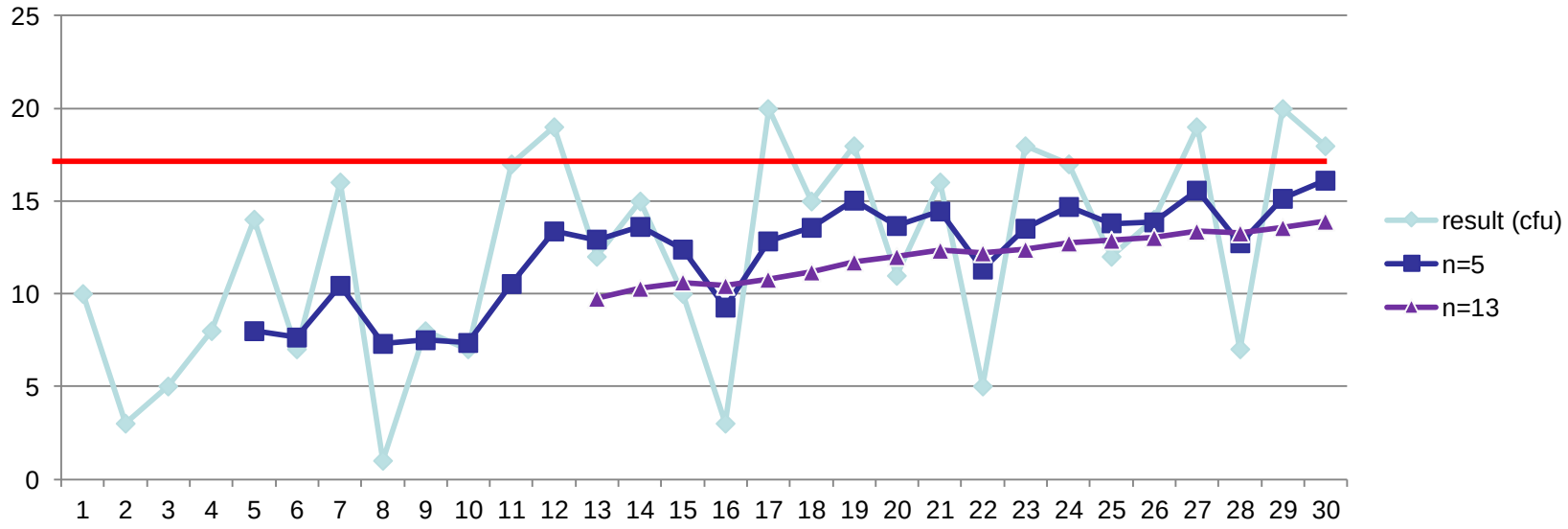
Exponential moving average chart



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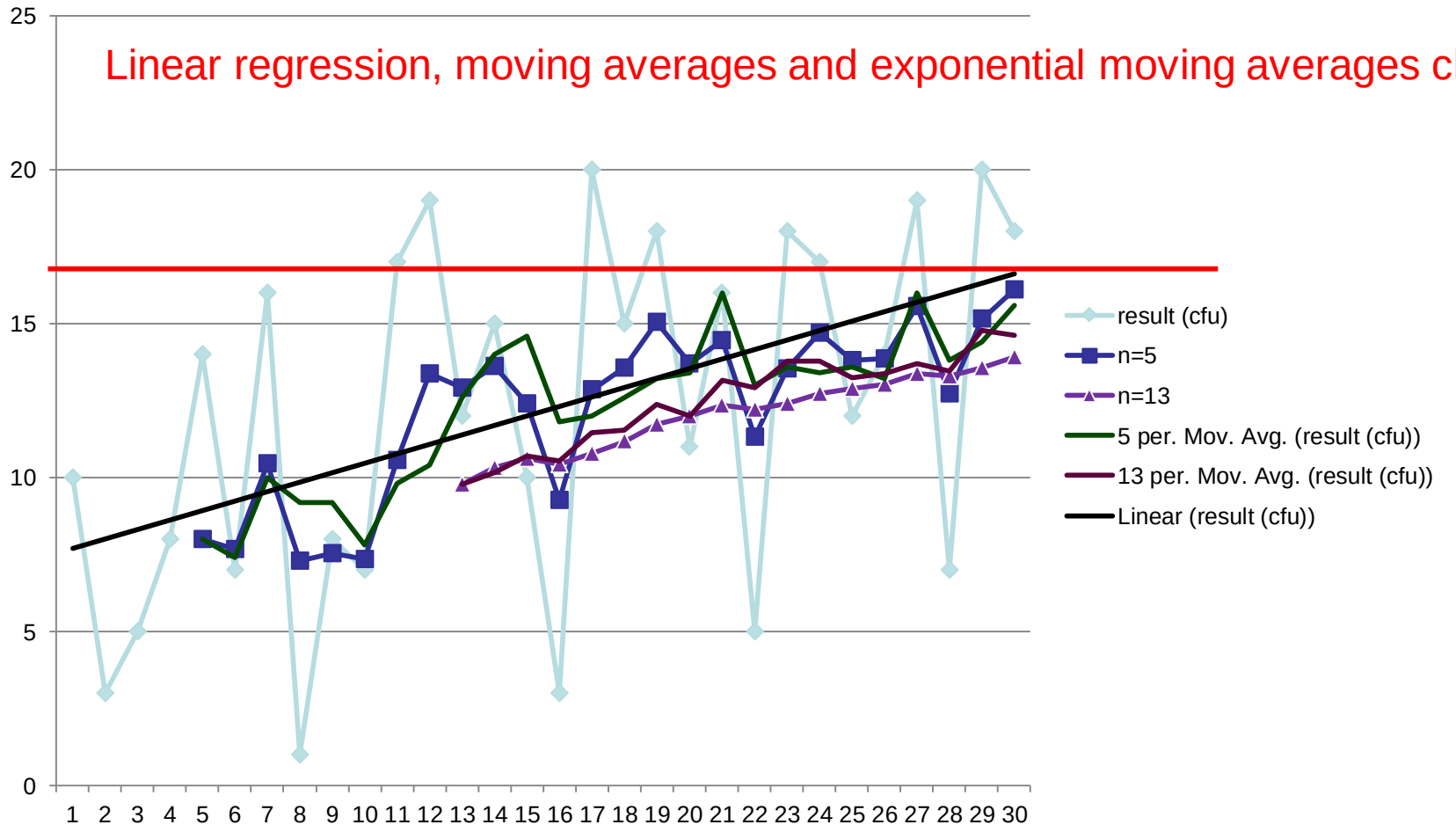
Linear regression, moving averages and exponential moving averages chart



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Review Alert level based on mean + 2xSD

10 3 5 8 14 7 16 1 8 7 17 19 12 15 10 3
20 15 18 11 16 5 18 17 12 14 19 7 20 18

N	average	SD	mean + 2xSD
5	8	4.30	16.6
10	7.9	4.58	17.1
15	10.1	5.29	20.7
30	12.2	5.77	23.8

How Trend analysis Helps

Reduces the workload: Unnecessary investigations are not carried out for occasional sessional plate failures or room results above alert levels but within action limits.

Reduces the need to carry out root cause analysis and CAPAs by taking corrective actions before action limits are exceeded.

How MRS can help

Provide moving average failure rate for session plates based on single plate results or multiple plate results. This allows trending for a single or multiple operator(s) or single or multiple server(s), based on a left hand, right hand or both hands. Results for a single or multiple workstatios based on a single or multiple operator(s)

Provide exponential moving averages for rooms based on single or multiple plate positions.

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Stockton Quality Control Laboratory

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Moving Averages (Developers Thoughts)

- We will be working with integer (round) numbers all the time. Only 5 points between 10 - 15
- How do we deal with plates not being read in the order they were exposed. (What plates do we use to calculate)
- Is this going to be very confusing to users?
- Would it be better as a 6 or 12 monthly review in the room editor.
- Shows a change has been considered.
- We can work with any calculation (should it be standardised by the Micro Working Group)

Product Tests, Instrument Registers, Lab Logs

MRS AF (NEW FEATURES)

What is AF

- MRS Additional Features are a collection of modules that help QA/QC Labs operate and store data in a managed application.
- It's a platform which modules can easily be added onto.
- Becoming a Laboratory Information Management System (LIMS) although more focused on Microbiology at the moment, we are moving into Chemistry more.

What is AF

- MRS Additional Features are a collection of modules that help QA/QC Labs operate and store data in a managed application.
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The two sides of AF

Media Management

- Supplier Management*
- Customer Management*
- Product Management
- Product Batch Management
- Standing Order Management
- Dispatch Management

* Early modules to be combined into MRS3.

Additional Results

- Product Tests - Tests (Legacy)
- Incubations
- Research
- Drug Contracts
- Kits
- External Services
- Identifications*
- Lab Logs
- Chemical Inventory
- Instrument Register
- Projects

MRS Additional Results - 1.7.1.0

Product Tests

New | Save | Delete | Print | Report | Product Manager

#	Custome	Product	Current Status	Test Result
PT136	Custo...	Morphi...	Waiting	Not_C...
PT135	Stockt...	Morphi...	Waiting	Not_C...
PT133	Stockt...	Morphi...	Appro...	FAILED
PT132	Stockt...	Morphi...	Appro...	PASS...
PT130	Stockt...	Morphi...	Appro...	FAILED
PT129	Stockt...	Morphi...	Appro...	Not_C...
PT127	Stockt...	Morphi...	Appro...	PASS...
PT124	Stockt...	Morphi...	Waiting	Not_C...
PT123	Stockt...	Morphi...	Waiting	Not_C...
PT122	Stockt...	Morphi...	Appro...	Not_C...
PT121	Stockt...	Morphi...	Appro...	Not_C...
PT120	Stockt...	Morphi...	Appro...	Not_C...
PT119	Stockt...	Morphi...	Appro...	Not_C...
PT118	Stockt...	Morphi...	Appro...	Not_C...
PT117	Stockt...	Morphi...	Appro...	Not_C...
PT116	Stockt...	Morphi...	Appro...	Not_C...
PT115	Stockt...	Morphi...	Waiting	Not_C...
PT101	Custo...	Morphi...	Appro...	FAILED
PT98	Stockt...	Morphi...	Appro...	FAILED
PT93	Stockt...	Morphi...	Reject...	Not_C...
PT92	Stockt...	Sodiu...	Waiting	Not_C...
PT90	Stockt...	Morphi...	Appro...	FAILED
PT89	Stockt...	Morphi...	Appro...	PASS...

Records : 26 of 26

QC Number: PT89 Date Recieved: 19/09/2017

Customer: Stockton QC

Product: Morphine Sulfate Injection (0.1%) [n/a] Manufacturer: Johnson & Johnson

Volume/Size: t12 Batch Number: 23 Expiry Date: 2017-09-19

Time Blocks: 4 Test Cost: £3.30

Booked In: 19/09/2017 WJPSAdmin Current Status: Approved 20/09/201 WJPSAdmir

Results: | Consumables: | Notes:

Test Name (Test Type):	Result Value:	Status:	Date:	User:	Pass or Fail:	Result Note:
Assay	100 mg	Completed	19/09/2017	lee.jones	PASS	
Description	Negative	Completed	19/09/2017	lee.jones	PASS	
ID (Chemistry)	Negative	Completed	19/09/2017	lee.jones	PASS	
Membrane Filtration (Sterilty)	Negative	Completed	19/09/2017	lee.jones	PASS	

Release: Released 19/09/2017 WJPSAdmin Final Result: PASSED

Invoiced: Yes 20/09/2017 WJPSAdmin

Test Retested (No:) T124

Notes:

Date Time	Note Type	Note	User
04/10/2017 14:39	Product Re-Tested	test	WJPS Admin

Status

Edit Product

Name: Morphine Sulfate Injection 2018

Work Sheet: n/a

Price Band: A ...

Category: Specials ...

Location: Test Room ...

Specification: test change

Strength: 0.1%

Material Cost (£): 10

Time Required: 2.2 Blocks of 15 minutes

Quarantine: ☐

Test Criteria: | Consumables: | Notes

Name:	Test Type:	Criteria Type:	Operator:	Accept Value:	Operator 2:	Accept Value 2:	Units:	Lab Log:
Assay	Chemistry	Range	>	95	<	105	mg	No Lab Log
Description	Chemistry	Positive/Negativ	=	Negative				No Lab Log
ID	Chemistry	Positive/Negativ	=	Negative				No Lab Log
Membrane Filtration	Sterility	Positive/Negativ	=	Negative				No Lab Log

Cancel Save

MRS Additional Results - 1.7.1.0

Instrument Register

New | Save | Delete | Report | Start Service

#	Name	Due Date	Days Until Calibration/S
IR48	Test Tube	09/01/20...	0
IR40	Telescope	10/01/20...	1
IR36	Bunsen B...	09/01/20...	0
IR31	Thermom...	N/A	N/A
IR29	Scales	03/01/20...	-6

Records : 5 of 5

ID: IR40

Name: Telescope

Description: Telescope description

Serial Number: T90340-56045

Category: Observation

Tested By: Stockton QC

Department: Biology

Instrument Type: Service

Archived:

Service Period: 85

Service Reminder: 23

Service Due Date: 10/01/2018

Date Of Service	Service By	Date Sent	Sent By	Date Returned	Receipted By	Certificate No
17/10/2017	Beta Software Li...	17/10/2017	james.proctor	17/10/2017	james.proctor	1234
25/09/2017	Beta Software Li...	25/09/2017	WJPSAdmin	25/09/2017	WJPSAdmin	abc

Date Time	Note Type	Note	User
09/01/2018 09:45	Instrument Override	Change of Department	WJPS Admin

Status

Enjoy

LUNCH (45 MINUTES)

A customers perspective of

IMPLEMENTATION

Quality Control North West

MRS

Phil Weir, Gillian Stokes, Ruth Barnes
Quality Control North West, Stockport.

Charlotte Ollerenshaw-Ward
Aseptic Services Manager
Pennine Acute Trust

Introduction

- QCNW - laboratories in Stockport and Liverpool
- QCNW Stockport have taken the lead in introducing MRS
- QCNW Liverpool will follow
- QCNW provide a service to approx 38 units
- Approximately 20,000 plates are received each month

Current provision

- QSI LIMS
- 19 years old
- Designed for Chemistry C of A's
- Good reports but any further manipulation is by manual transfer to excel
- Large units – 0.6wte band 3

NHS
Quality Control North West

MRS Project Overview(1)

- Our Introductory meeting for MRS took place in November 2015- NWASG gave their indication that we should proceed.
- Initially we sketched out the “rooms” using data from our current LIMS system
- Then- QAAPS (5) was published so units took the opportunity to review and overhaul their monitoring locations – this took time! Required advice from RQA
- Excel spreadsheet of rooms and instances created as a working discussion document.

Research and Scientific Services | Good Practice | Medicines Management
ASSURING QUALITY CARE

MRS Project Overview (2)

- With JP's help we set up comms for respective IT departments.
- We created rooms on MRS using the revised locations provided by the units/RQA consultation.
- "Instances" and new monitoring maps were created from Excel template.
- Lots of back and forth fine tuning – finally ! target date set for change over.

Progress to date

- MRS was introduced for internal monitoring in the QCNW Micro Lab on the 1st June 2017.
  - September 2017 CMFT Pharmacy
  - Oldham & NMGH (Pennine Trust)
  - Salford NHS Trust

- We are currently working on introducing the following units:
  - Blackburn
  - CMFT Radio
  - Wythenshawe
  - Stockport Aseptics
  - Preston
  - Trafford

Operational hiccups along the way!

- GMP change control process
- Understanding how our current information translated into MRS
- How to input two different types of media
- Our laboratory staff identify all organisms to genius level which proved difficult
- IT issues due to firewalls
- Laboratory staff data imput issues.

Customer issues and benefits . . .

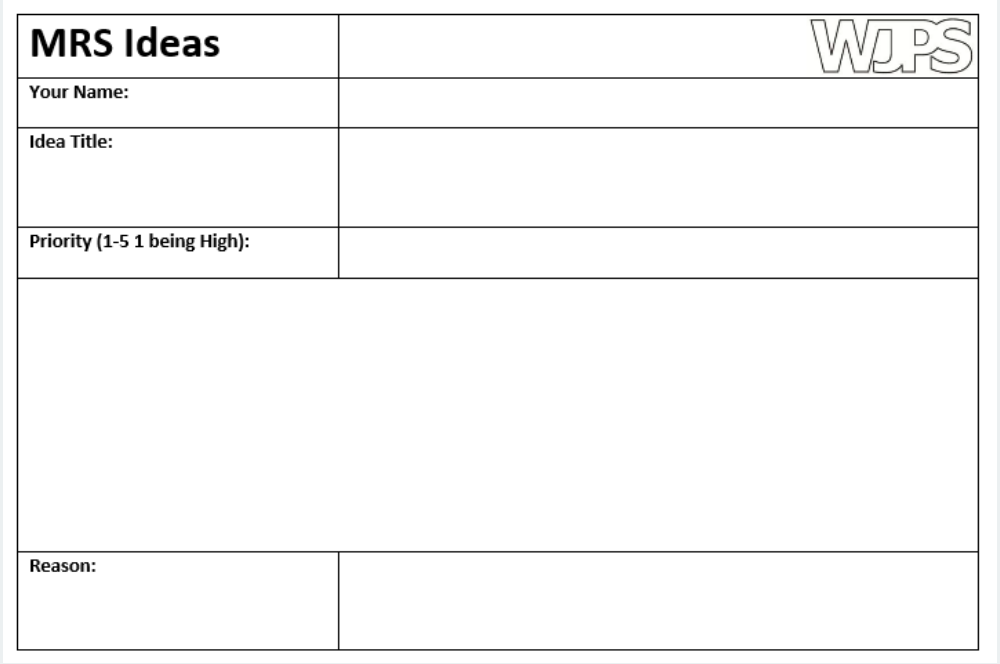
over to Charlotte

Over to you for

YOUR IDEAS

Your ideas!

- All have a couple of Ideas slips.
- Through the day write down any ideas you would like to see.
- Discuss with your group the ideas.
- Looking for small suggestions / improvements rather than whole new features.



MRS Ideas	
Your Name:	
Idea Title:	
Priority (1-5 1 being High):	
Reason:	

How this works

- You all have a letter on your badges which represent the groups you are in (2 groups in here, 2 outside)
- Discuss your ideas and solutions you may already have. This is an opportunity to learn from best practice as much as anything.
- Choose 2 best / most important ideas from each group and present back to everyone at the end.
- You have 30 minutes.

Enjoy

COFFEE BREAK (15 MINUTES)

Code Insurance

ESCROW AGREEMENTS

What is Escrow

- Most organisations are dependent on third part supplied software or applications to run day-to-day business processes. However, assuming at third parties will always be available to support and maintain business critical software brings about a high element of risk.

Escrow and Verifications

- Escrow and verifications services assure the long-term availability of business critical software and applications for end users and protect the IPR rights of software providers.
- Source code is held securely with both the end users and provider's agreement, ensuring that the material can be accessed and released should the need arise.

Who provides it

- WJPS have been in discussions with NCCGroup who are “The global experts in cyber security & risk mitigation.
- NCCGroup already works with many of the trusts we work with.
- NCCGroup are the third part who hold the code safely.

NCC Escrow

*Further levels of testing are available.

Key Features

- Minimise risk of using third part supplied business critical software
- Essential part of business continuity and disaster recovery
- Secure storage of code
- Provider protections during IT and software development.
- The main circumstance that this protects you against is, Voluntary bankruptcy, Involuntary bankruptcy, Breach of contact, Change of Ownership.
- Twice yearly update to NCC from WJPS.

Costs

- Per Trust costs:
  - Setup Fee (One off) £370 ex VAT
  - Annual Fee £760 ex VAT
  - Could be added to annual support.

- Provides piece of mind and another tick in the box for MHRA inspections.

Aligning validation to QAAPS 5

VALIDATION UPDATES

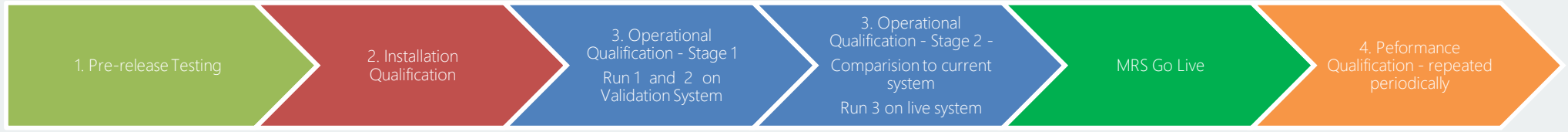
Validation Update

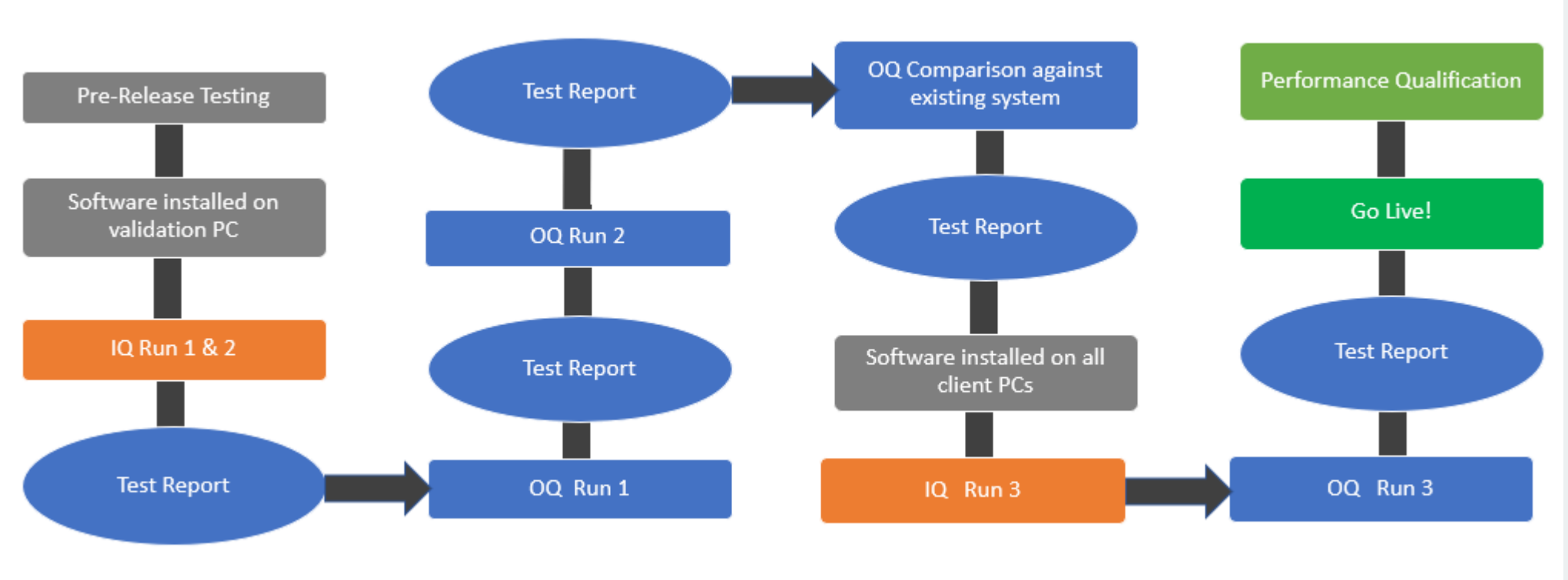
- MRS Validation was originally written with a very specific purpose and aimed at existing users.
- New users found the documents tricky to follow.
- Wanted to align to QAAPS 5.
- Brought in knowledge within the environment.

Validation Update

- Made the document easier to follow. Split data and instructions.
- Removed some repetition.
- Added more process, including Scopes.
- Clearly broke the document into IQ, OQ and PQ.
- Gave user profiles and explained the work flow more clearly.
- Improved the automated testing prior to release including providing certificates.
- Automated testing now continues on site.

Validation Update





Validation Update

Test Objective:	OQ Scenario test script 2 – Basic Workflow with Editing	**Test Type:**	Scenario
Intended Action:	This scenario checks that the basic workflow is functioning correctly. It includes single book in, multiple book in, entering read results, and release results and exception report work correctly. It also includes editing a result set. For further testing of the edit and delete function see OQ test script 4		
Pre-Requisites:	Pre-release and Installation Testing completed satisfactorily. OQ test script 1 – Pre-test reports completed		
Notes:			
Run 1 Performed By:		**Date Performed:**	
Run 2 Performed By:		**Date Performed:**	
Run 3 Performed By:		**Date Performed:**	

ID	Test Instructions – OQ Test script 2 Basic Workflow with editing	Expected Results	Actual Results			Result of Test Step (Pass / Fail)	Tester Initials/Date
			Run 1	Run 2	Run 3 - Live		
Booking In - single book in. This would be performed when plates were received in the lab.							
3.2.1	• Log in as an 'lab.user', password: lab123	The system should allow the user access to the system.					
3.2.2	• Ensure test reports completed prior to Run 1 (see OQ test script 1)	OQ test script 1 completed satisfactorily		Use reports generated after Run 1	Use reports generated after Run 2		

Validation Update

- Starting to revamp the MRS AF Validation to follow the MRS standard. This uses more of your data for validation.
- MRS 3 Validation will follow the similar standard.
- There will be a cost for our validation pack.
- Continual improvement

Quick overview of the Day

SUMMARY

Summary

- MRS 3 Development progressing well. Early versions available for demo April 2018.
- Moving averages needs a definite specification from the group / Micro Working Group.
- Continued improvements of MRS AF and more advanced testing functionality.
- WJPS continuing to expand both staff and customers.
- Escrow agreements could provided added protection and reduce risk.
- Validation evolving and continuing to improve.
- Implementation needs a project lead and move quickly.

National User Groups

- Try for bi-annual.
- Move around although Leeds seems a good location currently.
- Do we want to bring in more end users to the day?
- Any other suggestions for content?

Any questions from the day or as an MRS User

Q&A SESSION

Please complete and leave your feedback forms.

FEEDBACK

Have a safe journey back

THANK YOU