Our transition to ISO/IEC 17025:2017 at Fera Science Ltd.

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Original thinking... applied

EPPO Training Workshop
14/12/2020

Brian Carter

Bacteriology Team Manager

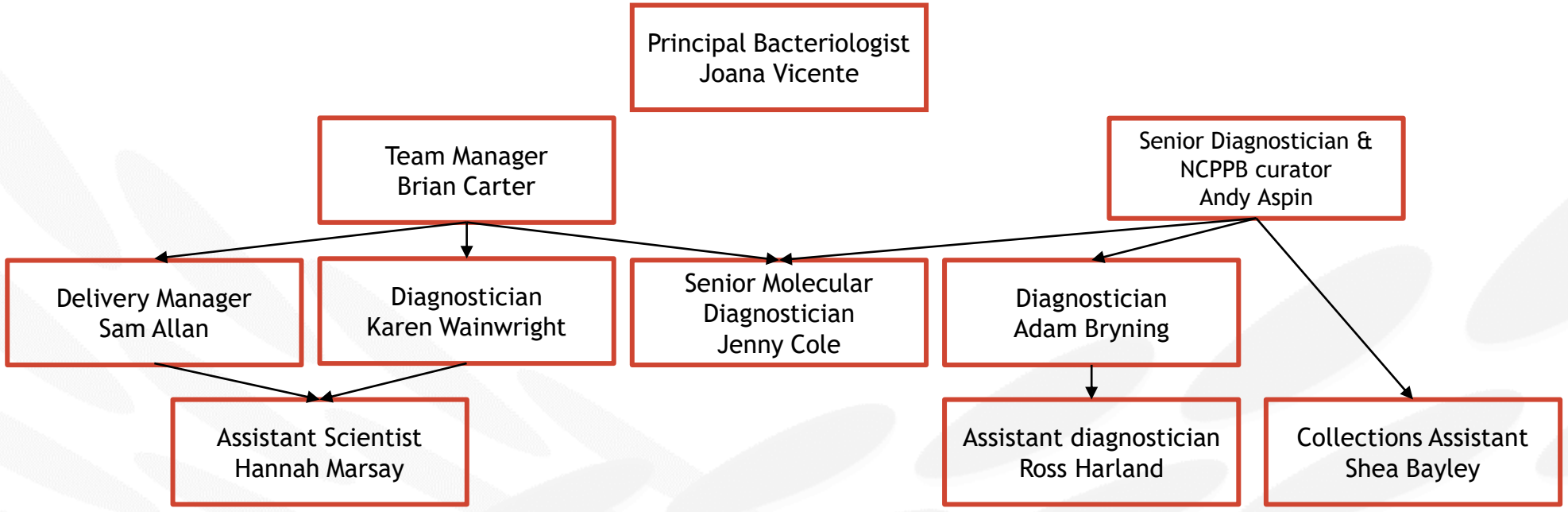
Team structure & Quality thread

Quality and Continuous Improvement Manager

Quality Team inc. GLP

Entomology | Virology | Bacteriology | Mycology | Nematology | Seeds

Molecular Technology Unit



Surveys | Projects | Diagnostics | Collections

Team structure & Quality thread

Key components

- Good lines of communication
- Co-ordination of overarching elements
- Joined up approach
- Efficiency
- Monthly meetings

ISO 17025:2017 transition process

Gap Analysis

- Review of new standard and training (November 2018)
- Identify changes required and impacts
- Completion of transition template (June 2019)

Audit

- UKAS visit (July 2019)
- Clearance of transition findings (October 2019)

Transition

- Following UKAS visit was audited against the new version of the standard. July 2020 – remote. November 2020 – on site.

Transition findings

- **8 findings –** requirements in the new standard can be addressed by clearance of the mandatory findings.
- **Impartiality** – although this is embedded when people start work in the organisation, we need to actively re-visit and confirm the impartiality responsibilities of staff.
- **Personnel** – documenting competence; although training records are in place we are not consistently documenting ongoing competence and the objective supporting evidence (except in the Plants Programme).
- **Equipment** – insufficient recording of software versions.
- **Reporting results** – need to ensure consistent implementation of the requirements of the new standard.
- **Complaints** – processes are in place but we need to include an independent review prior to the final customer response.

Bacteriology audits

- September 2018 – External ISO/IEC 17025:2005 – Surveillance – Ring rot/Brown rot
- July 2019 – External ISO/IEC 17025:2005 to 2017 – Transition assessment – Ring rot/Brown rot
- August 2019 – Internal Vertical audit – Fatty Acid Profile analysis
- October 2019 – Internal Vertical audit – Ring rot/Brown rot

- ➢ Excellent opportunity to discuss both accreditation requirements and areas for improvement.
- ➢ Ensure to make the most of assessment meetings/discussions with assessors.

Staff Competency & Internal Proficiency

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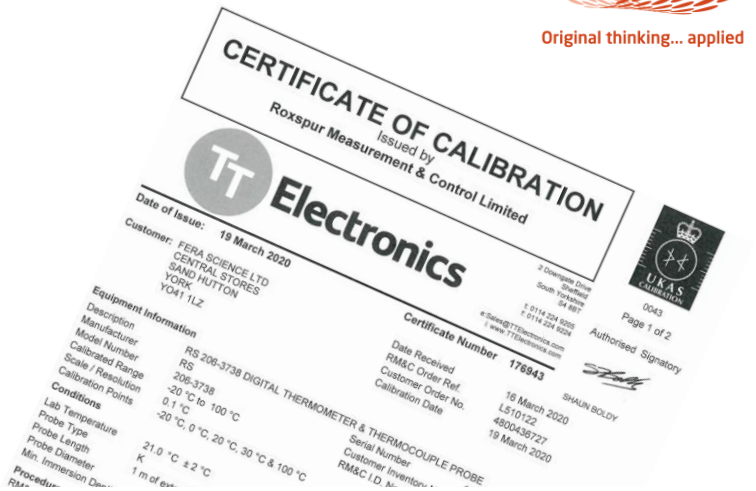
Internal Proficiency Test Programme (Demonstration of Ongoing Test Assurance) 2020

			Proposed Delivery Month(s)													
Documented procedure	**Discipline**	**Owner**	**J**	**F**	**M**	**A**	**M**	**J**	**J**	**A**	**S**	**O**	**N**	**D**	**Current status**	**Comments**
PLH/018, 019 & 020 - FAP analysis	Bacteriology	B. Carter													Completed	HM to sign off
PLH/164, 165 & 166 - Brown rot screen	Bacteriology	B. Carter													Pending	
PLH/164, 165 & 166 - Ring rot screen	Bacteriology	B. Carter													Pending	
PLH/102 - ID of Bemisia tabaci puparia	Entomology	M. Delaney													Completed	
PLH/155 - ID of Thrips palmi adults	Entomology	M. Delaney													Completed	
PLH/135 - Real-time PCR for qualitative diagnostics	Molecular	L. Laurenson													Pending	
PLH/899 - Screening for authorised GMO(s) using Real-time PCR	Molecular	L. Laurenson													Pending	
PLH/900 - Quantification of authorised GMO(s) using Real-time PCR	Molecular	L. Laurenson													Pending	
PLH/903 - Detection of H. fraxineus using LAMP	Molecular	L. Laurenson													Pending	
PLH/055 - Molecular diagnosis of P. ramorum & P. kernoviae	Molecular	L. Laurenson													Pending	
PLH/035 - Detection and ID of Colletotrichum acutatum	Mycology	A. Barnes													Pending	
PLH/056 - Detection and ID of P. ramorum & P. kernoviae (morphological)	Mycology	A. Barnes													Pending	
PLH/015 - Morphological ID of Potato cyst nematodes	Nematology	B. Lawson													Completed	
PLH/113 - Molecular ID of PCN using Real-time PCR	Molecular	L. Laurenson													Pending	
PLH/049 - Image analysis system for digital capture and measurement of nematodes	Nematology	B. Lawson													Completed	
PLH/104 - Morphological ID of D. dipsaci	Nematology	B. Lawson													Completed	
PLH/199 - The detection of CLVd by real-time PCR	Virology	A. Skelton													Completed	
PLH/809 - The detection of CSVd by real-time PCR	Virology	A. Skelton													Completed	
PLH/077 - The detection of PSTVd by real-time PCR	Virology	A. Skelton													Completed	
PLH/853 - Detection of virus by ELISA (TBRV)	Virology	A. Skelton													Completed	
PLH/901 - Detection of PepMV by ELISA	Virology	A. Skelton													Completed	

- Each accredited method within the plant protection program requires yearly internal proficiency checks to assess competency of newly trained staff and continued competence.
- Internal systems ensure that all staff members are checked, but do lack external input.
- External proficiency tests and ILC's are participated in where available.

Measurement Uncertainty & Error

- External calibration of digital thermometer to UKAS standard.
- Measured error and measurement uncertainty must be added to determine possible max. deviation from readout.
- All thermocouples must be checked against calibrated.
- Equipment utilised for temperature maintenance must have tolerance parameters set in consideration of potential uncertainty & error.
- Documentation of process within SOP prevents confusion, minimises risk and provides clear evidence of consideration at audit.


CERTIFICATE OF CALIBRATION
Issued by
Roxspur Measurement & Control Limited
TT Electronics
Date of Issue: 19 March 2020
Customer: FERA SCIENCE LTD
CENTRAL STORES
SAND HUTTON
YORK
YO41 1LZ
Certificate Number 176943
Page 1 of 2
Authorised Signatory
SHAUN BOLDY
Equipment Information
Description RS 206-3738 DIGITAL THERMOMETER & THERMOCOUPLE PROBE
Manufacturer RS
Model Number 206-3738
Calibrated Range -20 °C to 100 °C
Scale / Resolution 0.1 °C
Calibration Points -20 °C, 0 °C, 20 °C, 30 °C & 100 °C
Conditions
Lab Temperature 21.0 °C ± 2 °C
Probe Type K
Probe Length 1 m of ea
Probe Diameter
Min. Immersion Dep
Date Received 16 March 2020
RM&C Order Ref. L510722
Customer Order No. 4800436727
Calibration Date 19 March 2020
Serial Number
Customer Inventory
RM&C I.D. N

CERTIFICATE OF CALIBRATION
Issued by
Roxspur Measurement & Control Limited

Certificate Number
176943
Page 2 of 2

Calibration Results

Serial No: 13001539 & 13001539P in Ch T1

Reference Temperature °C	Thermometer Reading °C	Measured Error °C	Measurement Uncertainty ± °C
-20.05	-19.6	0.45	0.21
-0.01	0.9	0.91	0.21
20.04	20.3	0.26	0.21
30.04	30.1	0.06	0.21
100.03	101.0	0.97	0.21

Serial No: 13001539 & 13001539P in Ch T2

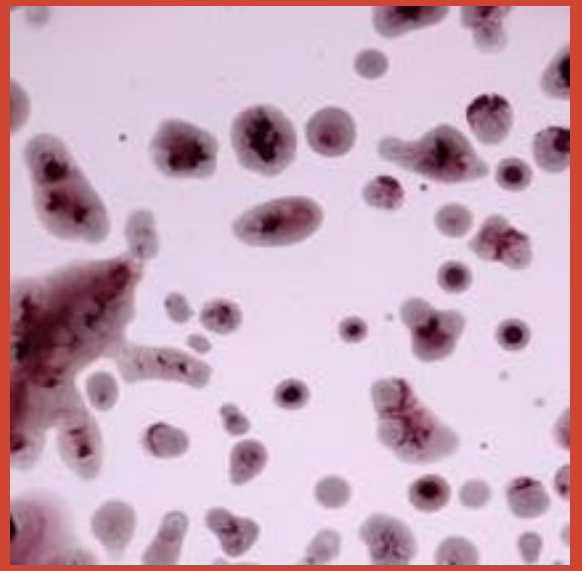
Reference Temperature °C	Thermometer Reading °C	Measured Error °C	Measurement Uncertainty ± °C
-20.05	-19.6	0.45	0.21
-0.01	0.9	0.91	0.21
20.04	20.3	0.26	0.21
30.05	30.1	0.05	0.21
100.04	100.8	0.76	0.21

- The certificate of calibration only applies to the instrument(s) listed on page one of the certificate -
- End of Certificate -

Media Productivity & Selectivity Challenge

- Semi-selective media productivity & selectivity should be determined for each media batch.
- Dilution plating of target organism suspension on semi-selective and non-selective media allows calculation of productivity ratio (P_R).
- Dilution plating of 'challenge' organism suspension on semi-selective and non-selective media allows calculation of selectivity factor (S_F).

- Media batches must meet set parameters.
- Recording of results allows identification of failures and trends prior to use.



Handling of Control Cultures

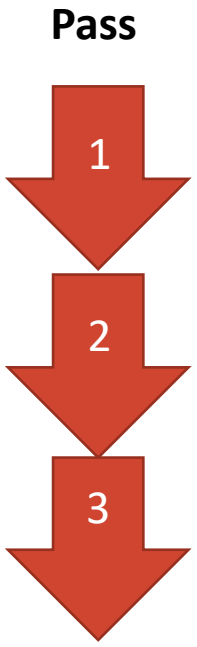
Reference strain – Obtained directly from a reference culture collection e.g. NCPPB.

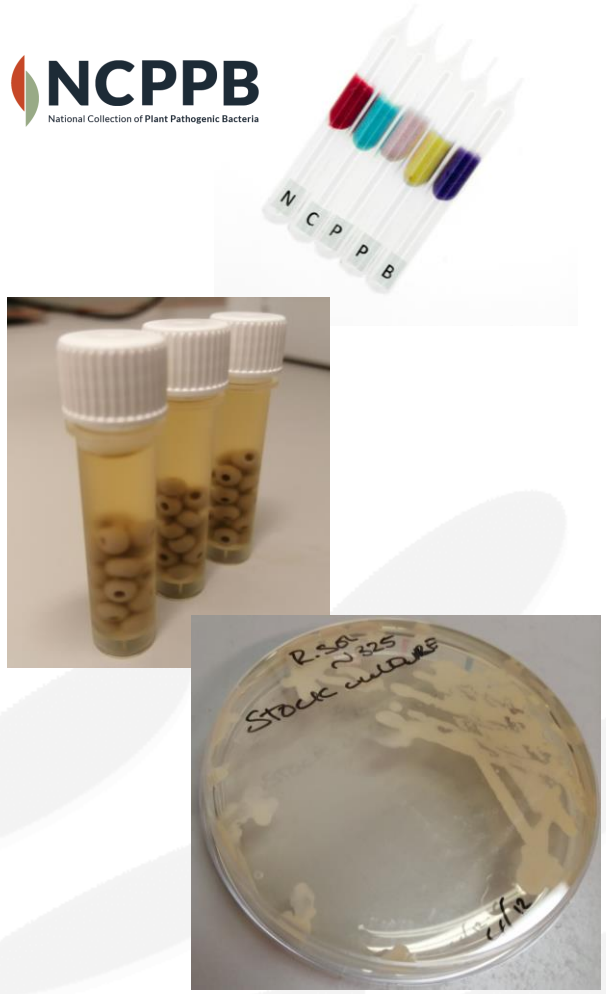
Reference stock – Prepared directly from a single sub-culture from the reference strain e.g. creation of multiple PROTECT vials.

Stock cultures – Prepared directly from the reference stock.

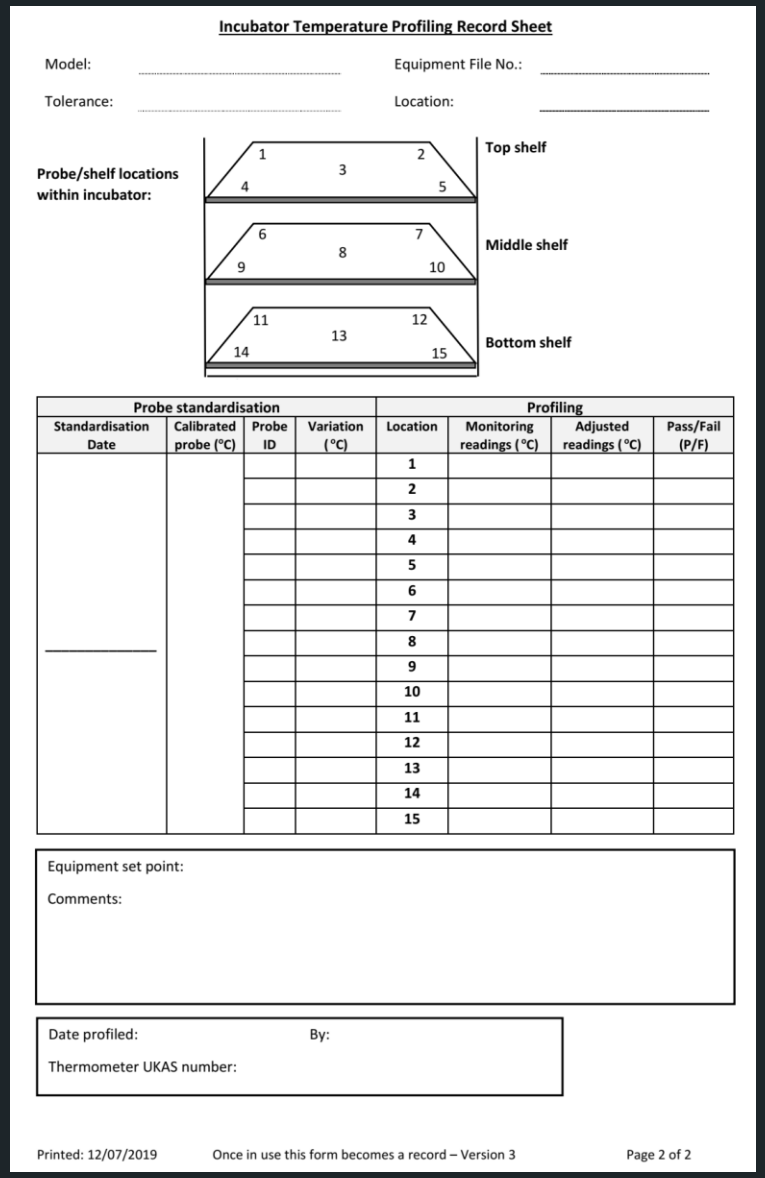
Working culture – Sub-cultured from the stock culture.

Formalised terminology and procedure protects against lab adaptation and aids user understanding, in turn minimising risk.





Temperature Profiling of Equipment



Incubator Temperature Profiling Record Sheet

Model: ..... Equipment File No.: .....

Tolerance: ..... Location: .....

Probe/shelf locations within incubator:

Probe standardisation				Profiling			
Standardisation Date	Calibrated probe (°C)	Probe ID	Variation (°C)	Location	Monitoring readings (°C)	Adjusted readings (°C)	Pass/Fail (P/F)
				1			
				2			
				3			
				4			
				5			
				6			
				7			
				8			
				9			
				10			
				11			
				12			
				13			
				14			
				15			

Equipment set point:

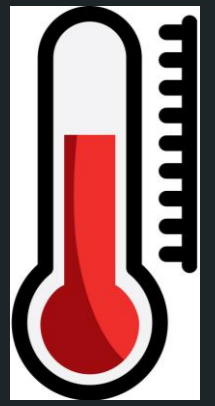
Comments:

Date profiled: By:

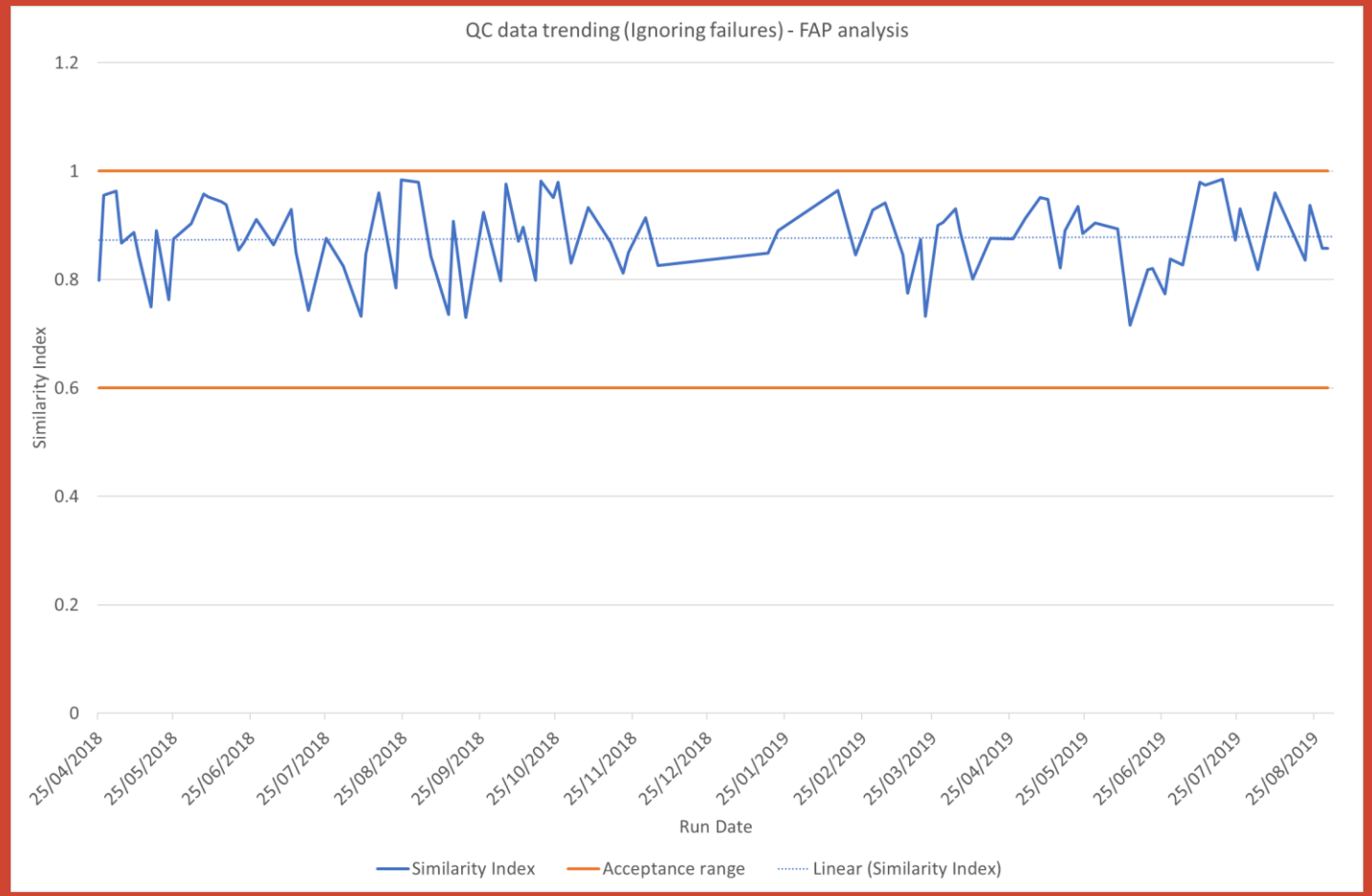
Thermometer UKAS number:

Printed: 12/07/2019 Once in use this form becomes a record – Version 3 Page 2 of 2

- Formalised procedure implemented via SOP, record sheets and training.
- Carried out to ensure whole equipment chamber meets set temperature tolerances.
- Number of required check points are determined by size and shelving.
- Checks are required:
  - On all new equipment
  - Yearly
  - After equipment moves
  - When set points are changes
  - After any remedial action



Trend Analysis



- Trend analysis identifies potential issues early.
- Allows remedial actions.
- Presentation of data in a meaningful manner.
- Assists in the monitoring of ongoing quality.

Impartiality

- Embedded when people start work in the organisation
- Part of Fera's commitment to quality is to ensure impartiality of lab activities and associated results
- A one page poster is available and circulated to all staff for acknowledgement yearly via QPulse.
- Impartiality is important in protecting objectivity
- Avoidance of conflicts of interest
- Ensure test results are correct and not intentionally or unintentionally influenced.
- Protect reputation alongside maintenance of accreditation.

Areas we are improving:

- **Internal proficiency tests** – we have implemented an annual programme of tests. A set of blind samples to test the diagnostician's ability to correctly perform a particular test. Evidence is recorded in training file and a process has been put in place to deal with failed tests. This process will be shared across the organisation.
- **Impartiality risks and conflicts of interest** – risk logs are being used to identify and analyse risks. High level and project management risk logs are in place to capture issues around impartiality and conflict of interest. We will be rolling out an annual reminder to all staff to review and declare any potential conflicts of interest.
- **Adoption of best practice across a large and diverse organisation** - some areas were already compliant with the new requirements, but implementation was not consistent across the whole organisation. More effective use of internal auditors to focus on particular areas and help implement best practice (e.g. reporting results and internal proficiency tests).

Original thinking... applied

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NCPPB

National Collection of Plant Pathogenic Bacteria

Original thinking... applied

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