Global Provider
of Quality in Diagnostic
Medicine

POCT INR
Scheme Guide

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1. Scheme details

Frequency: Bimonthly
Number of samples: 1 vial per POCT site / operator
Volume: 0.5 ml volume supplied in sterile plastic dropper bottles.

Analyte	Range
International Normalised Ratio (INR)	2.0 – 8.0 Units

2. Material

The material is prepared from calf blood and supplied in a liquid stable ready state and is suitable for use on the Roche CoaguChek XS, XS Plus & XS Pro and the Siemens Xprecia Stride. No further treatment is necessary to activate the product.

Although every effort is made to ensure that the material is free from any known infectious agent, the samples should be handled as for clinical specimens. (e.g. gloves must be worn).

In the UK, samples are sent out by first class post. POCT co-ordinators / users are issued with a 6 monthly timetable of dispatch dates from Weqas.

If there is a delay in analysis please store at 4°C.

2.1 Instructions for use

Each POCT Co-ordinator/ PCT lead will receive multiple samples for each POCT site / operator. The sample must be analysed on the day receipt. If this is not possible, the sample may be kept in the refrigerator but MUST be analysed within 2 weeks. Sample handling should be as per patient samples. Full instructions are distributed to each user with every sample dispatch. Please see separate Intended Use document [**SI-QL2-INRIntUse**].

2.2 Participants' Distribution details and result forms

Example of Weqas Distribution Letter:

WEQAS POCT INR EQA SCHEME

POCT Team
St Elsewhere University Hospital
Cardiff
CF14 5WF
Tel no. 02920 748186
Fax No. 02920 748336

Distribution Code: **WEQAS 0209**

Send out Date: 16-02-2009

Return Date: 02-03-2009

WEQAS POCT INR EQA SCHEME

Dear Colleague,

Please analyse the INR sample enclosed as if it were a patient sample.

This procedure should not be carried out by the same operator on each Distribution.
Please ensure that if you have more than one operator, they should take turns to participate in the EQA programme.

Please photocopy this sheet, if you have more than one section.

Please return your results sheet by post or fax to the above address.

Lab No: IN1

Operator Name (PRINT): ________________________ Signed: ________________________________

Date sample analysed: ___________________

Section Name (POCT Site) : _____________________________

DISTRIBUTION	WEQAS 0613
STRIP LOT NUMBER	
METER TYPE	
METER SERIAL NUMBER	
INR RESULT	

3. Reports

The Point of care Co-ordinator or PCT lead is given a Group Administrator function and maintains the database for its own Trust. POCT Co-ordinators should refer to POCT web training guide for instructions on how to access the site, add new users to the database, enter results and print reports **[WI-QL2-INRGDP1 to 3].** Participants (both POCT co-ordinator and POCT user) are given unique username and passwords to enter data and retrieve reports on line.

The Target value default setting is the Median for the method. The performance criteria (limits of acceptable performance) are established by Weqas and fixed. These Limits can be displayed on the report as either a percentage or absolute deviation from the Target value. The default is relative deviation (%), however the POCT Co-ordinator can select their preferred display option on the report. The performance criteria are detailed in section 3.2. Results are compared with meters of similar type, (the method) across all organisations. Group Administrators can also run a Statistical report where results are confined to their own data subset. However, this should be used with caution for methods where the number of participants is low.

Group administrators can select from a range of overview reports - All results table / histogram or pie charts.
The POCT user can select from Standard report (individual histogram reports) for their monthly results or a cumulative Levey –Jennings report for an overview of long term performance.

3.1. Standard report (user) – page 6

The left hand graph (all results) illustrates the deviation from the target value (average) for all CoaguChek XS meter results as an example. The right hand graph illustrates the deviation from the target value for results received for an individual user (my result).

3.2 Interpretation and performance criteria

On the left hand graph, ALL RESULTS, 51 users returned results, giving a range of results from 3.6 (min) to 4.5 (max).
The average result was 4.0 Units and the median result was also 4.0 Units. Any difference in these values gives an indication to the degree of skewness.
Forty eight users produced excellent results (green bars), 3 produced acceptable results (yellow bars) and no unacceptable results were reported in this distribution (red bars).
The right hand graph, MY RESULT, (your individual site/ward), shows that this site had returned an INR result of 4.0 Units. This is 0% from the Median and is therefore denoted by a green bar.

Performance criteria are based on data from biological variation and agrees with criteria used internationally for INR monitoring.

Analyte	Deviation	Interpretation	Colour
INR	<8% deviation	Excellent	Green
	8 – 16% deviation	Acceptable (fair)	Yellow
	> 16% deviation	Unacceptable – operator needs to evaluate technique/meter.	Red

The scores are colour coded for ease of identification.

Typical standard user report - Accident & Emergency Unit

report settings

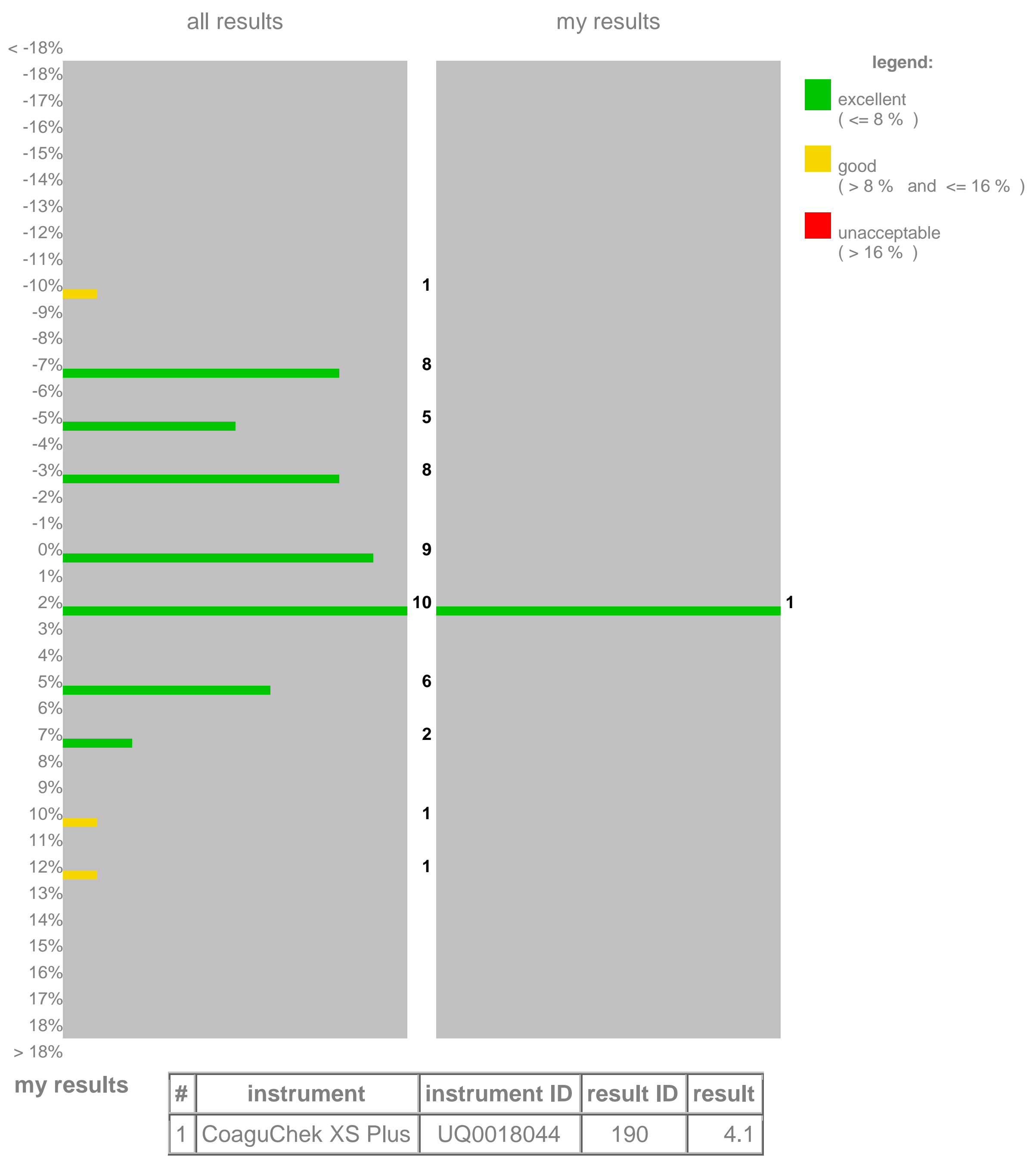
sample	DIST 0209
analyte	INR
reporting in	units
deviation	relative (resolution 1%)
reference method	median
reference value	4.0 units
comparison	all results and my results

all results

n	51
minimum	3.6
maximum	4.5
average	4.0
median	4.0
SD	0.2
CV	5.1 %

my results

n	1
minimum	4.1
maximum	4.1
average	4.1
median	4.1
SD	0.0
CV	0 %



my results

#	instrument	instrument ID	result ID	result
1	CoaguChek XS Plus	UQ0018044	190	4.1

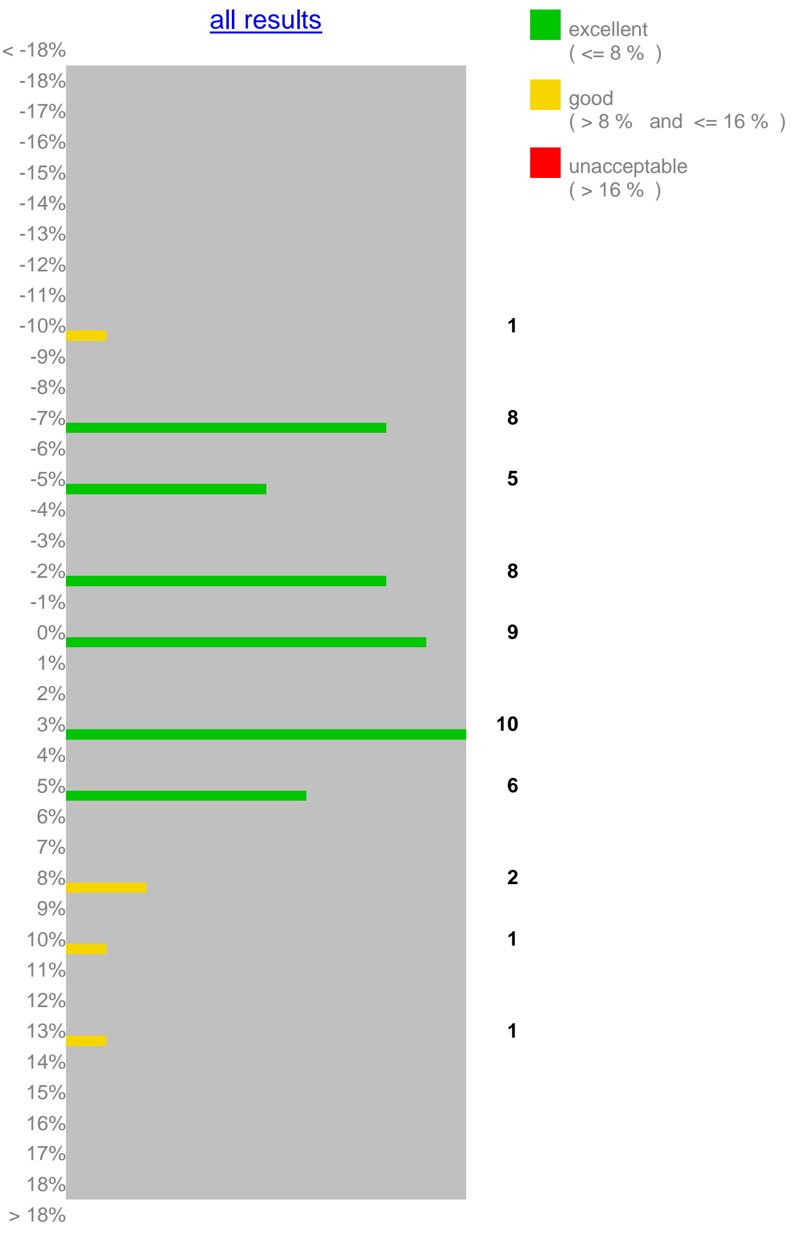
3.3 Group Administrator Report - All results – histogram.

report settings

sample	DIST 0209
analyte	INR
reporting in	units
deviation	relative (resolution 1%)
reference method	median
reference value	4.0 units

all results

n	51
minimum	3.6
maximum	4.5
average	4.0
median	4.0
SD	0.2
CV	5.1 %



My Trusts' results – St Elsewhere University Hospital

report settings

sample	DIST 0209
analyte	INR
reporting in	units
deviation	relative (resolution 1%)
reference method	median
reference value	4.0 units

all results

n	6
minimum	3.9
maximum	4.1
average	4.0
median	4.0
SD	0.1
CV	2.0 %

all results

back

#	instrument	instrument ID	result ID (strip lot no)	result	participant contact person	deviation from reference value	
							all
1	CoaguChek XS Plus	UQ0018045	183	3.9	Anticoagulation Clinic 2	-4 %	excellent
2	CoaguChek XS Plus	UQ0003280	190	4.0	Starlight	-1 %	excellent
3	CoaguChek XS Plus	UQ0018041	183	4.0	Anticoagulation Clinic 1	-1 %	excellent
4	CoaguChek XS Plus	UQ0017915	190	4.1	MDU	1 %	excellent
5	CoaguChek XS Plus	UQ0018044	190	4.1	Accident & Emergency Unit	1 %	excellent
6	CoaguChek XS Plus	UQ0018437	181	4.1	Pathology Department	1 %	excellent

3.4 Report Availability

Reports are available to print on line at close of business on the "return by" date. POCT Co-ordinators can either print the reports and distribute copies to their users or alternatively provide users with a username and password to download and print the reports themselves.

4. Performance Surveillance

The role of performance surveillance is retained with each individual POCT Co-ordinator. Non compliance and poor performance reports and letters are generated for each distribution. All group reports can be saved as an Excel file.

4.1 Non –Compliance summary report – *Typical Report for Trust 1*

	contact person	department	institute	late return
1	Nursing Staff	Surgery	Trust 1- Main Theatres Recovery	no
2	Nursing Staff	Surgery	Trust 1- Ambulatory Care Ward	No

4.2 Non-Compliance Letter - *Distribution 1*

POCT Team
St Elsewhere University Hospital
Cardiff
CF14 5WF

Main Theatres Recovery

Trust 1

Date: 9-03-2009

WEQAS POCT INR Scheme

Distribution: **Dist 1** Return date: **09-03-2009**

Meter ID ********** Meter Type **Xprecia Stride**

Dear Colleague,

No results were received for the above meter / location for the current distribution.
To comply with current guidelines, participants should please ensure that at least 75% of their EQA results are returned.

4.3 Poor performance Summary report-

A report detailing all sites with unacceptable results can be printed for the POCT co-ordinator.

instrument	Instrument ID	result ID	result	participant	deviation from reference value	
CoaguChek Xs	50601285	190	4.7	Theatre Sister	**17.5 %**	**unacceptable**

4.4 Poor performance Letter – *Distribution 1*

For ease of administration a letter can also be generated by the POCT co-ordinator for all sites with results outside the limits of acceptance (i.e. in the red box only.).

POCT Team
St Elsewhere University Hospital
Cardiff
CF14 5WF

Tel no.

Sister

Theatres

Date: 9-3-2009

WEQAS POCT INR Scheme

Distribution: INR **Sample 1**

Return date: 09/03/2009

Meter ID: 50601285
Meter Type: CoaguChek XS

Result: 4.7 Units
Deviation from reference value: +17.5 %

Dear Colleague,

Your results for the above Distribution are outside the limits of acceptable analytical performance.
Please contact me as soon as possible to discuss these results.

4.5 Referral to National Quality Assurance Advisory Panel.

When the individual / site performance is outside the performance criteria on 2 out of 3 consecutive occasions, the individual will be offered help by the WEQAS organisers. Failure to respond to this contact or to improve performance will lead to a further contact by the organisers. Persistent poor performance for that test will result in referral to the National Quality Assessment Advisory Panels.

The WEQAS Scheme organiser submits quarterly reports on participant numbers, new developments and overall Scheme performance including individual group performance to the Panel.

Referral criteria

When the performance of a site has not improved after two contacts by the organisers.

When the site has failed to submit a minimum of 75% of the distributions per annum.

Arrangements for any proposed changes in standards and notification of poor performers to the panel will be agreed with the WEQAS Steering Committee.

5 Communication and participant feedback

5.1 POCT Helpline

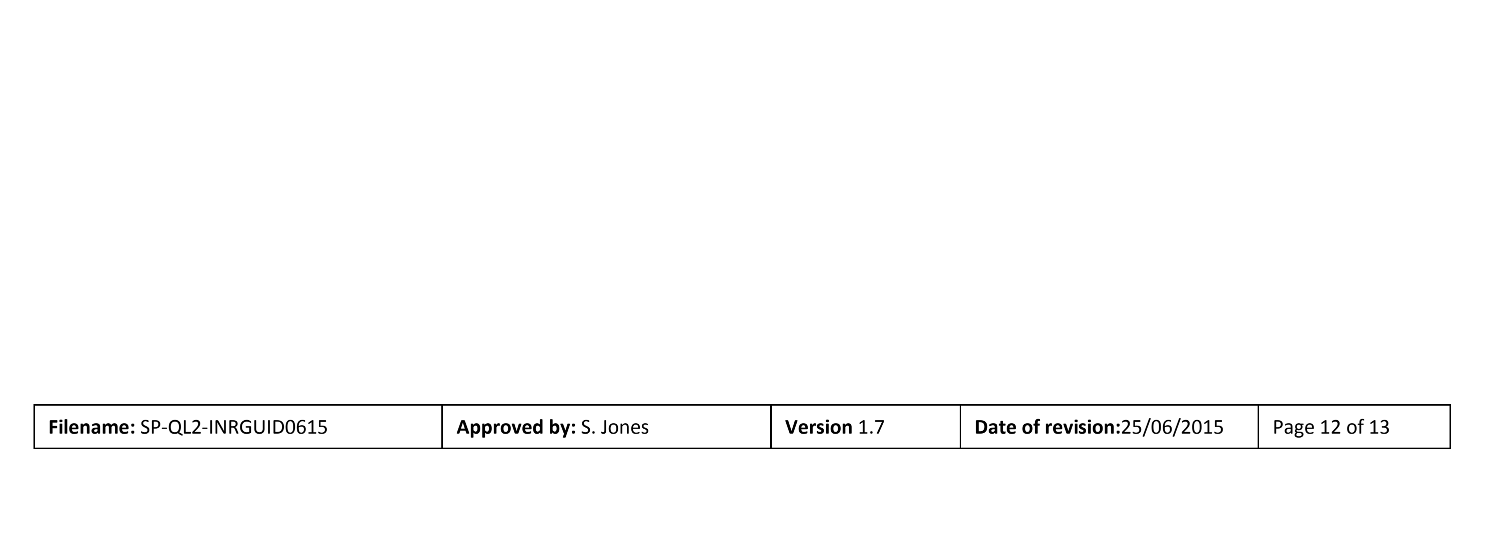
POCT enquiries: Telephone 02920 314755
e-mail: Weqas.poct@wales.nhs.uk

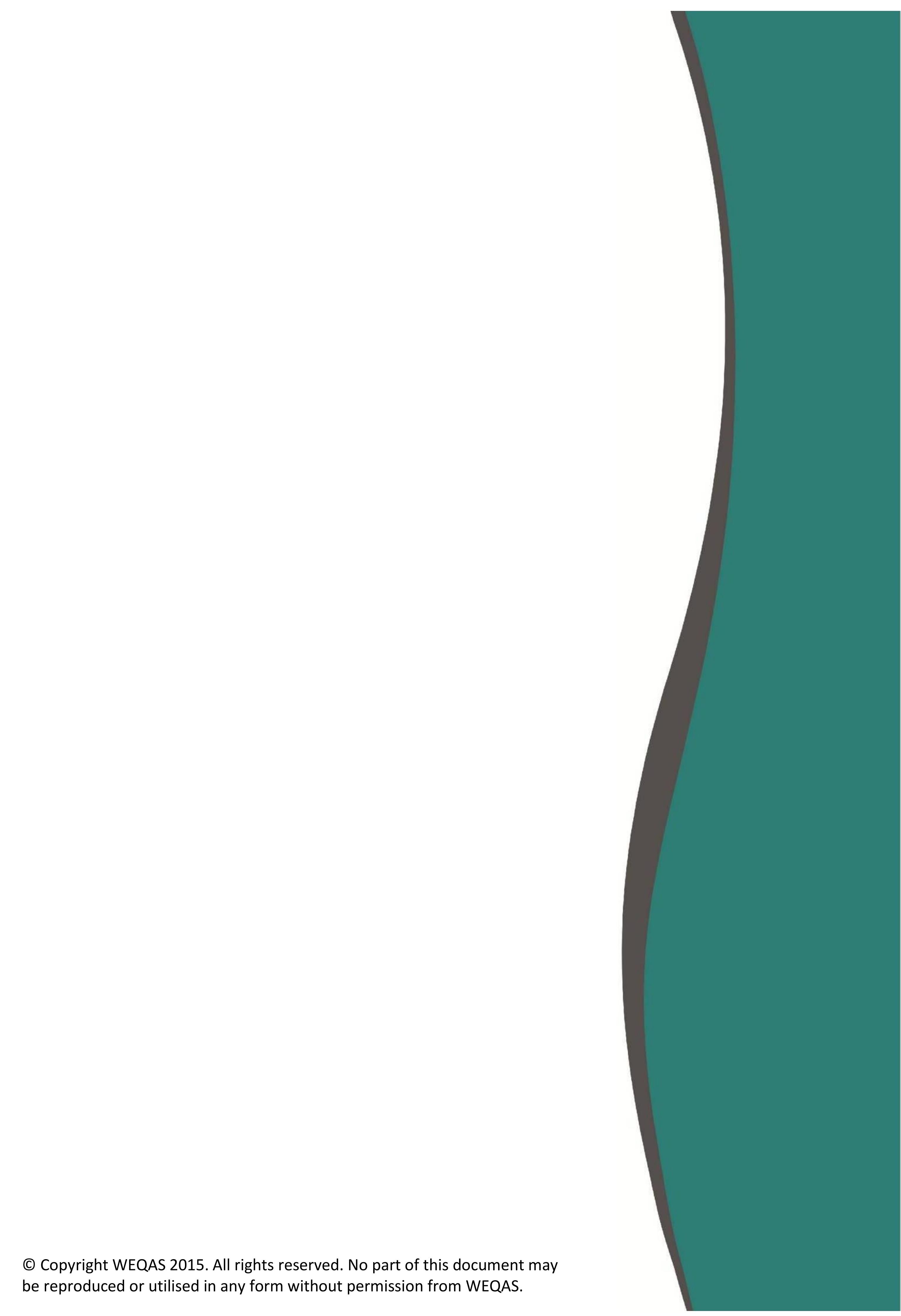
WEQAS Laboratory Manager: Samantha Jones.
WEQAS POCT Scheme Manager: Nicky Blount.

Participants can at any time during the working day (8.30 to 5.00 p.m. Mon to Fri) ring up for advice on their quality assessment. The POCT staff, which have experience in, and information relating to many different methods, are there to discuss problems and aid in the interpretation of QA data. This troubleshooting and educational activity is an important part of the Service. A telephone log is kept of each call and all calls are answered as soon as possible.

5.2 Complaints procedure

Participants can contact us through our website, fax, e-mail or by telephone. All complaints are logged and actioned within 24hrs. If a non compliance can not be rectified within this period the participant is informed. The Communication log / non-compliance reports are audited monthly. The results of these audits are documented and brought to the attention of the relevant section head. You can also contact Michele Thomas, our Quality Manager, directly on 02921 841289.





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