QUALITY SYSTEM PROCEDURE   QMS/QSP/26/8

Title: <mark>Point of Care Testing</mark>   Effective date: 1 November 2017

Summary of Significant Changes at this Revision
Update at review: remove reference to CPA accreditation (section 10).

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1. Purpose

Point of Care Testing is not part of the scope of UKAS accreditation for Pathology and therefore is not included in the Pathology QMS, but described in its own Quality Manual against ISO 22870: 2006 (EN). The responsibility for the quality and safety of the results from POCT is shared between the users of the testing equipment and the RUH Medical Director Pathology provides support and has a monitoring role which has been given it by RUH Trust management.

2. Scope

The scope of this procedure is all the POCT testing equipment and disposable systems that are included in the POCT inventory that is maintained by Pathology. This equipment is in use by Wards in the RUH and Community Hospitals and in Primary Care.

3. Responsibilities

The RUH Medical Director has overall responsibility for POCT within the Trust.

There are two lead POCT Co-ordinators based in Pathology, one from within Haematology and one from within Biochemistry. These persons have responsibility for ensuring that SOPs & instructions are provided, that training is made available to users, ensuring that audits are conducted, that EQA is carried out and ensuring that failures and incidents are investigated and appropriate corrective actions are taken.

4. Definitions and Abbreviations

POCT = Point of Care Testing

POCT = the performance of analytical tests on patient specimens outside the laboratory by non-laboratory staff. The equipment used varies from simple dipstick tests to sophisticated analysers

QMS = Quality Management System

EQA = External Quality Assessment

SOP = Standard Operating Procedure

Procedure

1. RUH Trust Policies for POCT

1.1. POCT is managed in accordance with the RUH policies for Medical Equipment (713 / 2011) and for POCT (772 / 2013). The Medical Equipment policy covers a wide range of aspects and these are listed in Appendix 1 to this procedure. The POCT policy also covers a range of aspects of POCT equipment management and use. These are listed in Appendix 2. Both these policies are available to view on the Trust intranet

1.2. Other relevant policies are the Diagnostic and Screening Policy (7018 / 2013), Decontamination policy (618 / 2016), Information Governance (316 / 2014), Health & Safety (804 / 2013), Health Records Management (323 / 2015), Infection Control Precautions, Universal/Standard (622 / 2014) and the policy Incident Reporting and Management (213 / 2016). These are available on the Trust intranet.

2. Guidelines for POCT

2.1. There are a number of guidelines for POCT that staff need to be aware of when preparing SOPs and carrying out other activities relating to POCT. These are listed in Appendix 3 to this procedure and there are copies of or links to these from the POCT webpage.

3. New POCT Equipment

3.1. Once a decision has been made to purchase a new type of POCT equipment a master plan for validation must be prepared according to the Pathology Equipment Validation procedure. Where there are large numbers of items of equipment purchased, then one item should by fully validated and the others subject to appropriate checks before use.

3.2. Validation protocols and acceptance criteria need to take into account the operating environment, the manufacturer's specifications and the range of values for which the equipment is to be validated. Validation should be compared to existing equipment within the laboratory wherever possible and include calculation of uncertainty of measurement, and defining and recording metrological traceability and comparability.

3.3. Equipment users must be involved in the development of the Operational Qualification protocols to ensure that these cover all relevant aspects for near patient use.

3.4. SOP development and training of the initial group of equipment users should take place as part of the Operational Qualification part of validation.

4. POCT Premises

4.1. The locations and areas in which POCT is carried out must provide sufficient space and a suitable environment in which to operate the equipment in accordance with the manufacturer's recommendations and operating SOPs.

4.2. There must also be suitable storage facilities for consumables and reagents needed to operate the equipment, e.g. temperature controlled and in line with appropriate legislation and manufacturers instructions.

4.3. A checklist for premises and storage requirements must be produced during validation if necessary and be included in SOPs.

5. Health and Safety

5.1. As part of the validation, the hazards associated with the equipment, consumables and reagents must be determined and a risk assessment carried out. Control measures must be incorporated into SOPs and into training materials produced or used. Health and safety should be assessed as part of competency.

6. Staff Training and Education

6.1. A training programme must be prepared for each new item of POCT equipment. This must cover these aspects below.

      6.1.1. Context and clinical utility of POCT
      6.1.2. Theory of the measuring system
      6.1.3. Sample handling and collection
      6.1.4. Reagent storage
      6.1.5. Quality control
      6.1.6. Infection control
      6.1.7. Limitations of measuring system
      6.1.8. Response to results outside a set range of values
      6.1.9. Recording and reporting results
      6.1.10. Health and safety

6.2. On completion of training all users of the equipment must undergo a competency assessment. Observed assessments are preferable, combined with a written element if necessary. Re-assessment of competency must be reviewed every 2 years or earlier if the task has changed significantly from its initial validation, there has been a long absence from work, e.g. maternity leave or there is a concern regarding current level of competency.

7. Specimen Collection

7.1. Where specimens have been collected and it is not possible to obtain a usable result a record of this failure must be kept in the Log Book and/or Datix with comment where possible on the reason for this event.

8. Results of Testing

8.1. Results must be interpreted according to the SOP and records of results must be made at the time and entered into the patient's medical record. They must state:

8.1.1. Result(s)
8.1.2. Date/Time
8.1.3. Device (incl. location and device unique identifier (where applicable)),
8.1.4. Test strip or cartridge lot no. (if testing equipment not connected, i.e. pregnancy test strips)
8.1.5. Operator identity (of both person performing and transcribing result (where applicable))

9. Quality Control Testing

9.1. Quality control of the equipment must be carried out according to the SOP. Failures to achieve results within the defined limits must be recorded in the Log Book (or equivalent) and investigated in conjunction with Pathology BMS staff if required.

9.2. Equipment must not be used until the results of the QC testing required by the SOP are satisfactory.

10. External Quality Assessment

10.1. All POCT equipment must operate with external quality assessment schemes where these exist. Schemes should be approved, e.g. accredited by UKAS to ISO/IEC 17043. Where there is no scheme, specimens and results must be shared with other Trusts on an informal basis.

10.2. Failure to return results for EQA will be reported by Pathology to the Ward or Unit Matron / Manager. Repeated failure to return results will be reported to the Chair of the Medical Equipment Committee at the time of occurrence and an Incident recorded on QPulse as a CAPA and/or on Datix.

10.3. Failure to achieve satisfactory EQA results will be investigated by Pathology and Ward or Unit staff. Repeated failure will be reported to the Chair of the Medical Equipment Committee with a request that the equipment be withdrawn. An Incident will be recorded on QPulse as a CAPA and/or on Datix.

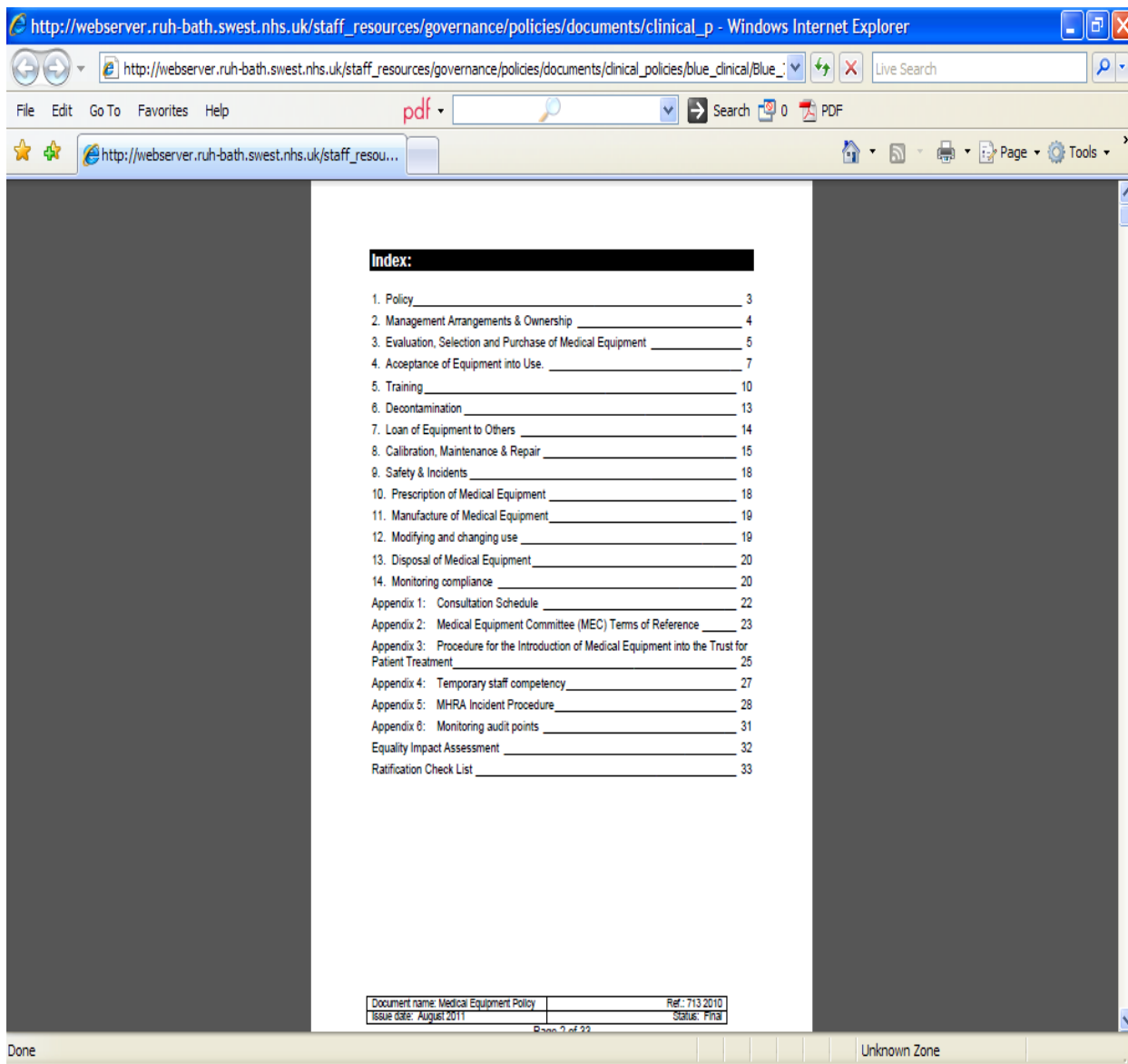10.4. A list of the EQA schemes participated in is given in Appendix 4.

11. Related Documents

11.1. There are a number of Pathology-wide procedures that relate to this procedure. They are shown in QPulse. Relevant aspects from these procedures are included in local SOPs.
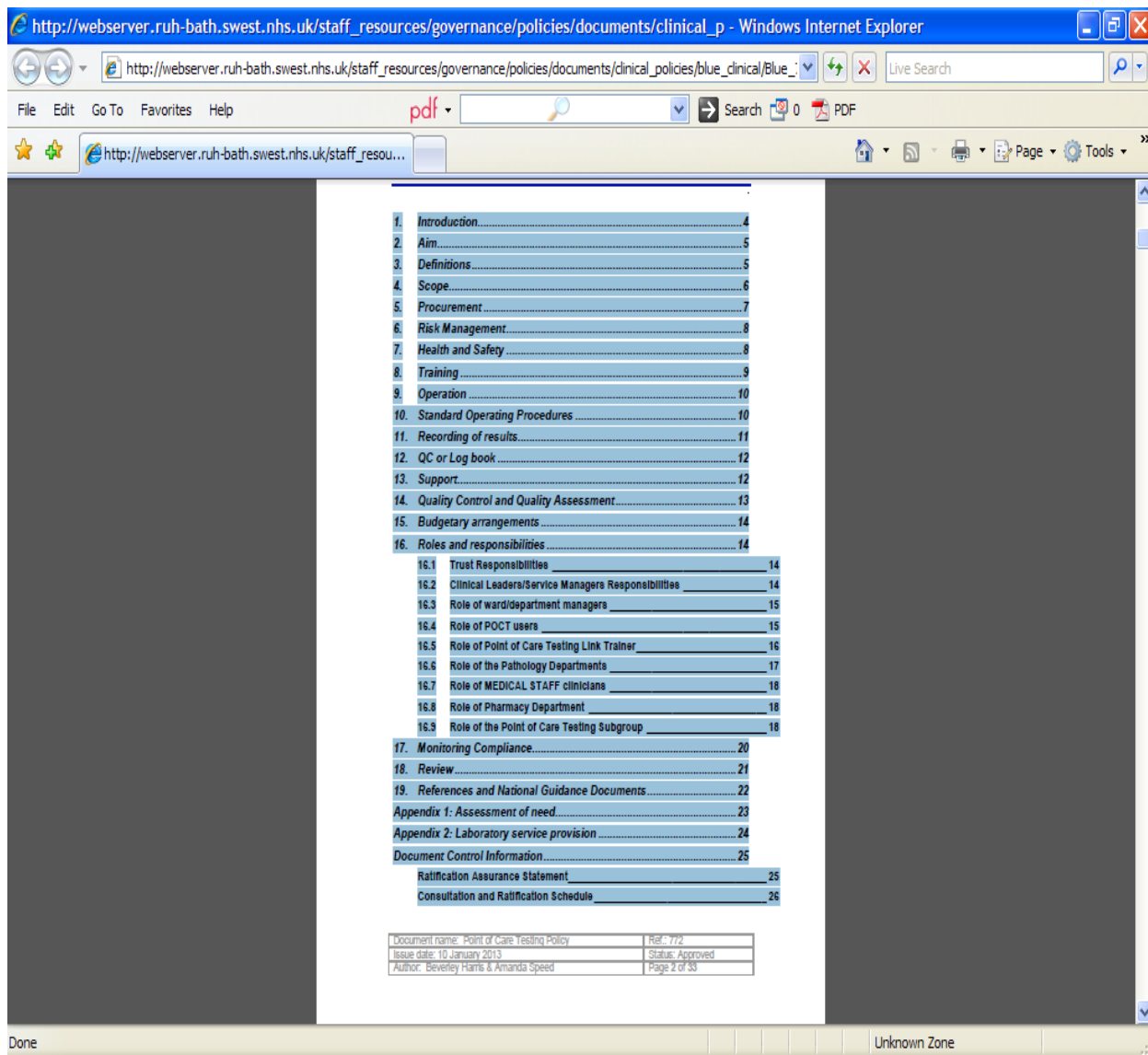
References

1.   ISO 22870: 2006. *"Point of care testing (POCT). Requirements for quality and competence."* 2nd edition.
2.   ISO 15189: 2012: *"Medical laboratories – requirements for quality and competence."* 3rd edition.

Appendix 1   Scope of Medical Equipment Policy

Appendix 2   Scope of POCT Policy

Browser window showing PDF table of contents:

Document name: Point of Care Testing Policy — Ref.: 772
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Author: Beverley Harris & Amanda Speed — Page 2 of 33

QUALITY SYSTEM PROCEDURE   QMS/QSP/26/8

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Appendix 3   POCT Guidance Documents

Joint Working Group on Quality Assurance: Near to Patient or Point of Care Testing Guidelines (1999)

The Royal College of Pathologists: Guidelines on point-of-care testing (2004)

Institute of Biomedical Scientists: Point of Care Testing; Guidance on the involvement of the clinical laboratory (2004)

ISO 22870: 2006: Point of Care testing (POCT) – Requirements for quality and competence (2006)

Clinical Pathology Accreditation (UK) Ltd: Standards for the medical laboratory (2010)

MHRA DB2010 (02): Management and use of in vitro diagnostic point of care test devices (2010)

Clinical Pathology Accreditation (UK) Ltd: Additional standards for point of care testing (POCT) facilities (2010)

BCSH: Guidelines for point-of-care testing: haematology (2008)

ISO 15189: 2012: Medical laboratories – requirements for quality and competence (2012)

Appendix 4   EQA Schemes

Test	Device	Scheme	EQA Frequency
Haemoglobin	Hemocue machines	NEQAS FBC scheme	Monthly
INR testing	Coagucheck devices	Coagucheck = XS users NEQAS scheme.	Quarterly
Blood gases and co-oximetry	Blood gas analysers and co-oximeters	WEQAS for blood gases	Monthly
Glucose testing	Optium Xceed and PXP hand held meters	WEQAS for glucose	Quarterly
Ketones	PXP hand held meters	WEQAS for ketones	Quarterly
HbA1c	DCA Vantage portable meter	NEQAS for HbA1c	Monthly
Pregnancy	One Step Pregnancy test – Urine Test Strip	WEQAS for urine pregnancy	Bi-monthly
Urinalysis	Uryxxon Relax Urinalysis meters	NEQAS for urine dipsticks	Monthly