

POCT Training Requirements for ISO 22870

Meeting the Challenge

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What does the standard say?

- ❖ ISO15189/22870 Section 5.1 details the requirements for quality and competence particular to medical laboratories
- ❖ 5.1.1 --to implement and maintain the POCT quality management system and to continually improve its effectiveness and to ensure that all POCT personnel are trained to ensure satisfaction to all stakeholders
- ❖ 5.1.4-The Lab Director may appoint a suitable person with appropriate training and experience to manage training and competency.
- ❖ Training may be delegated
- ❖ Only trained personnel may use POCT devices
- ❖ Records of training must be available for inspection
- ❖ Retraining and CPD -- Sets out what should be covered

ISO 15189

While ISO15189 accreditation is deep-rooted in relation to centralised laboratory services, the application of this standard and ISO 22870 to the realm of POCT is less well established in both the UK and Ireland.

In St James Hospital We took a comprehensive approach a to training and competency to ensure accreditation of POCT services in a large Irish academic teaching hospital.

Biggest challenge -different skill sets, mindsets among the operators.

Not always encouraged from top down

St James Hospital



- ❖ St. James's Hospital, Dublin has a capacity of 1,020 beds and manage over 350,000 patients annually.
- ❖ POCT in the hospital includes 115 glucose meters (GM), 10 Blood Gas Analysers (BGA), 28 meters for urinalysis/HCG measurement, 22 Ketone meters (Ket), 4 Toxicology Meters (Tox), 2 Coag Meters (CM) and a DCA Vantage Analyser for HbA1C in its scope.
- ❖ There are over 3,000 POCT operators at present with most operators requiring training and access on at least three POCT devices .
- ❖ BGA, GM , CM and HCG testing were selected for inclusion in the scope in ISO15189 accreditation inspection by INAB in 2014 to 2017.

Management of Training

Supplier Training

- ❖ Training is provided by the supplier of each POCT device as part of the contract between the supplier and the hospital.
- ❖ It is important to have a good working relationship with the supplier to ensure training is managed as a partnership with the POCT team.
- ❖ The supplier training programme was edited to include the various aspects of training demanded by the POCT team.

Introduction to the Device

- ◆ Log on procedure
- ◆ Key components of the device
- ◆ Clinical relevance of the test, purpose of the examination,
- ◆ Principle of the test.

Pre Analytics

- ❖ Patient preparation, identification, contraindications
- ❖ Sample collection, preparation and identification
- ❖ How to use associated strips/cassettes
- ❖ Storage requirements of strip/cassettes
- ❖ Data entry
- ❖ Knowledge of potential sampling errors.

Analytics

- ❖ Ability to perform the test as per Standard Operating Procedure – this must be witnessed and documented
- ❖ Knowledge of any Calibration and Quality Control (QC) procedures
- ❖ Importance of traceability and accountability and associated audit trail

Post Analytics and Reporting

- ❖ Appropriate response to out of range results
- ❖ Significance of abnormal, unexpected and inconsistent results
- ❖ Correct recording of results(paper or electronic)
- ❖ Correct follow through to clinical team



- All
- Blood Gas
- Diabetes
- Uninanalysis

Recertify Operators - Blood Gas

Update operator recertification information. When multiple operators are selected, changes that you make to one record apply to all selected operators.

Filter Operators Clear Filters Records found: 1

Group: BioChemistry POCT Activity status: Active

Last name: Operator ID: 11606336

☐ Show only operators with expired certification

Operator	Operator ID	Active	Group	Email Address	Model Series	Recertify By	Trained	Trainer	Assessed	Assessor
Dempsey, Felicity	11606336	<input checked="" type="checkbox"/>	BioChemistry POCT	fdempsey@stjames.ie	RAPIDPoint 500	23/08/2019	23/08/2017	Carroll, Teresa	23/08/2017	Carroll, Teresa



Witnessed test

Help

Comments...

Select All

Clear All

History...

Advance by...

Apply

Undo

Cascade Training

- ❖ Training is also supplied on the wards by Cascade Trainers. Dedicated PC's provided.
- ❖ Any competent staff member can train as a trainer and we have obtained CPD points for this process as an incentive for staff members to undertake this position.
- ❖ Cascade trainers are regularly audited to assess their competency as trainers and to ensure that the quality of training is the same all over the hospital.
- ❖ Cascade trainers are supplied with a training pack which covers all the procedures listed previously. This pack is available on the hospital intranet

E-Learning

- ❖ E- learning modules are now an essential part of the training programme They are available from most suppliers as part of their contract.
- ❖ They usually consist of a video/still photos associated with a quiz at the end of the presentation .
- ❖ There will be a set no of mandatory questions and the trainee must achieve an agreed score to pass.
- ❖ The e- learning system is linked to the competency module remotely and updates the operators training certificate automatically for an agreed length of time
- ❖ All operators must complete the e-learning programme as well as training on the device itself

Quality System Training

- ❖ In addition, SJH has developed a bespoke training model for all POCT operators which covers the various aspects of a quality POCT system
- ❖ Audits, Non Conformances and CA,PA
- ❖ This is a requirement of ISO15189 which ensures that all operators have an understanding not just of the devices but all aspects of a POCT Quality Management System.
- ❖ Underpinning all e-learning systems is a robust connectivity and data management system

Training Schedules

- ❖ The training schedule is set at the beginning of the year but is open to change depending on demand and workload in the relevant clinical areas.
- ❖ Retraining and reassessment occurs at appropriate intervals.
- ❖ Prospective trainees are contacted through email and the hospital intranet and may in some cases be alerted on the POCT device that training is due.

Documentation

- ❖ There is a requirement that all training must be documented.
- ❖ Training schedules Training registers,
- ❖ Competency documents.
- ❖ Competency must be assessed following training and periodically thereafter. All competency documents are designed to reflect the areas covered during training.
- ❖ All operators must also have read and understood the Standard Operating Procedure.
- ❖ The competency documents are scanned into a data management system by the POCT team and must be available for review during the accreditation inspection.

Required Reading			
SOP Number	Revision	Date	Signature
LP-POC-0018 RapidPoint 500	00		

Name: _____

Position: _____

Personnel Number: _____

email address _____

Email address is now required for notification of retraining and link to e learning module.If email is not supplied you will not receive automatic notice of your retraining date and you must be responsible for you own training schedule.

Performance Criteria

Able to Identify Key Components

Touch Screen

Printer

Replacable reagents

Bar Code Scanner

Ready Screen

Can recognize when analyser is ready to accept samples

Can recognise parameters that have failed calibration or failed QC

Pre Analytics

Can prepare sample correctly for analysis and has knowledge of potential errors due to incorrect mixing, incorrect labelling, transport delays.

Analysis - Patient Sampling

Can analyse a syringe/capillary sample

Has performed the test sample competently

Analysis - Data Entry

Can input password via touch screen/ scanner

Can input patient data via touch screen/scanner

Can recall results and obtain printout

Maintenance

Able to perform a calibration/QC

Can change cartridges/waste container

Can change a sample port

Can change paper roll.

Cleaning and decontamination procedures

Health and Safety

Understands the implications of password sharing

Understands the importance of Universal
Precautions

I have sufficient theoretical knowledge and practice to undertake this procedure/skill/role independently, and I acknowledge my responsibility to maintain my own competence in line with the Guidelines of Good Healthcare Practice.

Signature of Staff Member: _____

Date: _____

Signature

Trainer/Assessor: _____

Date: _____

Password Allocated: Yes ☐ No ☐

Introduction



Welcome to the Quality Requirements in Point of Care Testing course. This course is a mandatory requirement in compliance with ISO15189. This standard provides requirements for competence and quality that are particular to Medical Laboratories and Point of Care Testing (POCT). It ensures that the hospital provides a quality led system that meets the needs of all stakeholders and especially the patient.

A copy of the St. James's Hospital Point of Care Testing (POCT) policy is available to you in the *Resources* section above.

On completion of this course, you will understand:

- Why there is a Quality System in place for POCT
- The basic components of a Quality System
- The requirements of the ISO15189 standard
- The responsibility of each POCT user to adhere to the requirements of the POCT Quality System



This learning resource should take approximately 20 minutes to complete.

Quality and the ISO15189 Standard



The quality management system at St. James's Hospital is designed to proactively manage the safety, efficacy and efficiency of the POCT processes in use across the organisation.



Click each box to learn more.

ISO15189



Requirements

Quality System

Quality Management
System

- The ISO15189 standard is issued by the International Standards Organisation (ISO)
- The national inspection body is the Irish National Accreditation Board (INAB)
- Annual Inspections - deficiencies raised based on compliance with the standard where appropriate
- 3 Months to close out deficiencies
- Annual inspections thereafter with 1 month closeout times
- 5 Year cycle - Same team

Evaluation



ST. JAMES'S
HOSPITAL



Risk Management:

- Evaluation impact of processes & failures
- Risk can be identified by the POCT scientist or by users of the system and discussed with appropriate staff.
- Modifications required to reduce risk must be implemented.
- Risk assessments are carried out on Physical, Biological, Chemical hazards and sample processes by the POCT Scientist





Conclusion

- ❖ Quality Training and Competency systems in St James Hospital entailed the development of bespoke e-learning modules for POCT operators.
- ❖ A robust connectivity system was essential for providing an audit trail for competency and training with diverse POCT devices and operators who have a mixed skill set.
- ❖ A co-operative working relationship between all stake holders was essential and primarily facilitated by extensive and dedicated teamwork, IT support and well formulated training and competency systems

Thank You for Listening

