DEPARTMENT OF CLINICAL BIOCHEMISTRY

TRAINING MANUAL AND COMPETENCE MANUAL

TOXICOLOGY UNIT

NAME / GRADE:

TRAINING SUPERVISOR / GRADE:

Guidance on training

BMSs and Clinical Scientists must be trained by a Trainer who is HPC registered and are fully competent in the procedure(s) they are training.

Using the DEP column in this manual

The trainer should tick the DEP column when the item has been Demonstrated or Explained, or Practised by the staff member

Definition of competence

BMS/Clinical Scientists are competent when they have demonstrated that they can carry out each performance criterion associated with the performance objective (task) correctly and consistently on at least three occasions over different days at a speed which supports the turn-around times for work within the section.

Assessment of competence

Competence must be assessed by a HPC Registered staff who is competent in the task being assessed. The majority of competencies will be assessed by observation of the staff performing the task (defined in the manual as "Practical observation"). Oral assessment is necessary to check understanding where indicated (defined in the manual as "Oral")

Competence Levels:

LEVEL 1:

- BMS/Clinical scientist has read the appropriate Standard Operating Procedures (SOPs) applicable to the activity/task
- Understands relevant health and safety implications associated with the task
- Performs the practical procedures correctly and consistently (on at least 3 separate occasions) under **direct supervision**.

Level 2:

- Level 1 is attained
- Correctly performs the practical procedures and consistently (on at least 3 separate occasions) under **indirect supervision**
- Has a basic understanding of the operational principles of equipment used
- Understands basic theoretical concepts that underpin knowledge applicable to the activity / task

Level 3:

- Level 2 is attained
- Is proficient in the use of laboratory equipment and procedures, including routine maintenance and troubleshooting
- Maintains standards of laboratory quality control and quality assurance
- Be able to interpret results under supervision
- Takes an active role in teaching new members of staff

Signing off competence

HPC Registered staff who sign off competencies can be held responsible if an individual subsequently is found to be incompetent. It is therefore in the interests of the signer to be absolutely sure of the staff's competence before signing.

BMS/Clinical scientist should read the performance criteria carefully before co-signing the record. Signing the record indicates that they agree that they have been trained in each performance criterion that constitutes that objective (task) and that they have been given opportunities to practice the task before being assessed.

Maintenance of competence

The ability to perform a task competently may be compromised when the BMS/Clinical Scientist has not undertaken that task for some time.

The staff should be assessed **every two years** to ensure they have maintained their level of competence or progressed to a higher level. Staff returning to work after a period of 6 months or longer (eg maternity leave, sickness) should have their competency re-assessed upon returning to work.

All re-training and competence re-assessments are recorded at end of this manual.

TOXICOLOGY ASSAYS DOCUMENTS

Biomedical/clinical scientists must read, understand and follow the appropriate sections of the Standard Operating Procedures relevant to the work they undertake.

Senior biomedical/clinical scientists must assist the staff undergoing training to interpret the SOP and check understanding by asking appropriate questions.

Aim: To perform confirmation and classification of drug screen results

Performance Objectives	Performance Criteria	DEP	Assessment method(s)	Competence Attained			Level			Review	Review	Review
				Date	Trainer	Staff	1	2	3			
Understand the principles of Urine Drug Screening	• **Explain the need for classification and confirmation and the choice of methods**		Oral									
To understand all maintenance procedures	• **Demonstrate all the daily maintenance procedures** • **Demonstrate an understanding of how to ensure the ion transfer capillary is cleaned, and when cleaning is needed** • **Demonstrate how to perform the weekly maintenance procedures** • **Know how to vent the MS and remove the skimmer and tube lenses for cleaning**		Oral Practical observation									
Preparation of eluents and standard solutions	• **Be able to prepare the HPLC eluants needed** • **Be able to prepare the internal standard and cutoff calibrator**											
Understanding the principles of opiate chromatography	• **Demonstrate an understanding of the principles of solid phase extraction and reverse phase HPLC**		Oral Practical Observation									
Understanding the principles of ion trap mass spectrometry	• **Understand how full scan, MS2 and MS^n experiments are performed** • **Understand Data Dependent Scanning** • **Understand the principles of Electrospray Ionisation (ESI) and APCI**		Practical Observation									

Performance Objectives	Performance Criteria	DEP	Assessment method(s)	Competence Attained			Level			Review	Review	Review
				Date	Trainer	Staff	1	2	3			
To be able to interpret and edit the method file	• **Be able to adjust the retention time window for different parent masses** • **Understand the difference between segments and scan events** • **Be able to add new analytes to the method file** • **Know how to access alternative method files, and know when they may be used**											
To be able to run a sequence of samples	• **Be able to generate an outstanding work list from the Laboratory Computer System** • **Be able to import a worklist into the Xcalibur and Aria software** • **Be able to set a shutdown method, manually add samples and change the analytical method**											
To understand the use of quality control in the laboratory	• **Demonstrate the chromatography procedure, describing why the different non-patient samples are used**		Practical observation									
To be able to use the ToxID result program	• **Demonstrate how to use the ToxID software to analyse a single sample and change the config file** • **Understand the config file and what can be modified to select positive results**		Oral Practical Observation									
To be able to interpret ToxID result printouts	• **Explain what information the ToxID report gives** • **Explain how to determine if a drug**											

Performance Objectives	Performance Criteria	DEP	Assessment method(s)	Competence Attained			Level			Review	Review	Review
				Date	Trainer	Staff	1	2	3			
	test is positive • **Understand the use of multiple metabolites to confirm drug use** • **Understand the limitations of glucuronide-only results**											
To be able to use the Qual Browser	• **Demonstrate how to find and view sample data** • **Demonstrate how to produce an XIC and MS^2 TICs** • **Demonstrate how to perform a library search and understand the parameters (SI and RSI)**											
To know how to use the library browser	• **Demonstrate how to look up a spectrum in the library browser** • **Demonstrate how to change the libraries searched** • **Know how to add a library spectrum to the KCH libraries, including adding supplementary information**											
To be able to validate reagent and quality control materials before use	• **Demonstrate and describe the procedure for preparing and validating reagents. Include the procedures for recording usage and lot numbers**		Oral Practical Observation									
To be able to change gas cylinders safely	• **Describe the procedures for changing the helium gas cylinder and the safety precautions to be followed**		Oral Practical Observation									
To understand the quality control procedures present	• **Describe the quality control and quality assurance procedures in place within the laboratory, and the**		Oral									

Performance Objectives	Performance Criteria	DEP	Assessment method(s)	Competence Attained			Level			Review	Review	Review
				Date	Trainer	Staff	1	2	3			
within the laboratory	**actions to be followed in case of poor performance**											
Understand how EQA samples are processed in the laboratory, and how to interpret reports	• **Know which assays should be requested and why** • **Know how to fill in the EQA return** • **Be able to identify non-conforming results, and any actions to be taken** • **Know the value of the additional reports produced by NEQAS**											
To know and understand the hazards within the laboratory.	• **Spillage – Solvents, acids, bases, biohazard** • **COSHH – Assessments, Risks**		Oral									