Central Manchester University Hospitals NHS
NHS Foundation Trust

Directorate of Laboratory Medicine

Establishing Competency of Staff in Flow Cytometry

and achieve ISO standard 5.1.6.

Andrew Moran
Chief Biomedical Scientist
Dept of Immunology
Manchester Royal Infirmary

Immunology at MRI

CD4 counts
T, B, NK cell analysis
Leukaemia immunophenotyping
Stem cell counts
Neutrophil function
Immuno-haematology

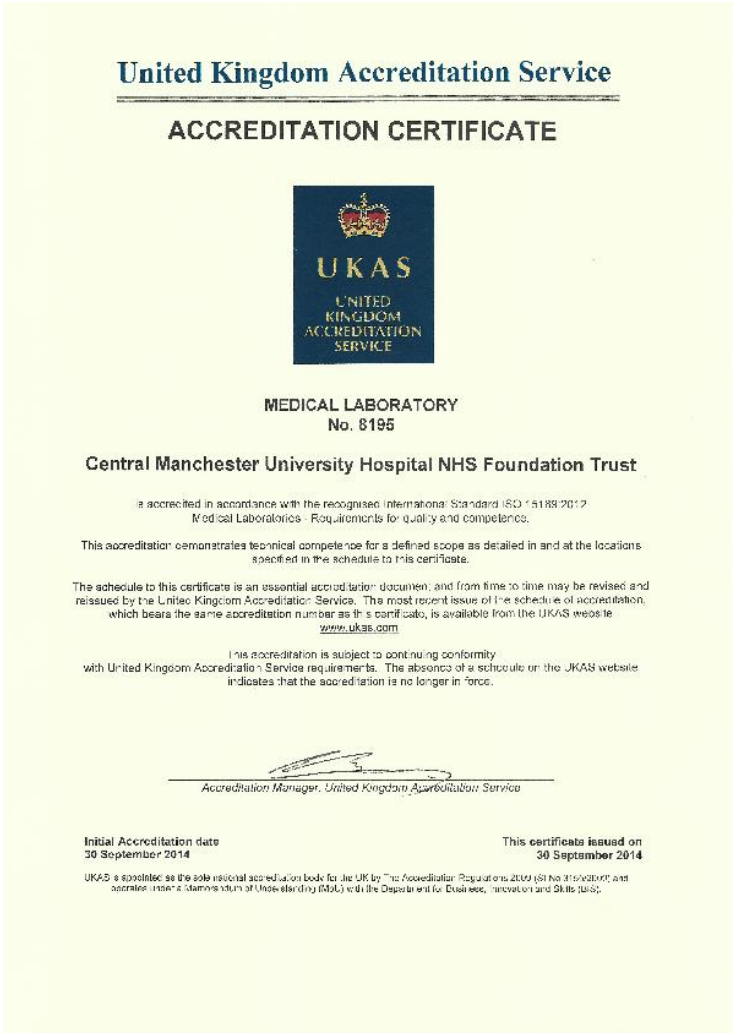
Directorate of Laboratory Medicine

Instrumentation

FP1000 Processor x 2

EPICS FC500 x 2
(5 colour, 1 laser)

ISO achieved 2014



United Kingdom Accreditation Service

ACCREDITATION CERTIFICATE

UKAS
UNITED KINGDOM ACCREDITATION SERVICE

MEDICAL LABORATORY
No. 8195

Central Manchester University Hospital NHS Foundation Trust

is accredited in accordance with the recognised International Standard ISO 15189:2012
Medical Laboratories - Requirements for quality and competence.

This accreditation demonstrates technical competence for a defined scope as detailed in and at the locations specified in the schedule to this certificate.

The schedule to this certificate is an essential accreditation document; and from time to time may be revised and reissued by the United Kingdom Accreditation Service. The most recent issue of the schedule of accreditation, which bears the same accreditation number as this certificate, is available from the UKAS website www.ukas.com

This accreditation is subject to continuing conformity with United Kingdom Accreditation Service requirements. The absence of a schedule on the UKAS website indicates that the accreditation is no longer in force.

Accreditation Manager, United Kingdom Accreditation Service

Initial Accreditation date
30 September 2014

This certificate issued on
30 September 2014

UKAS is appointed as the sole national accreditation body for the UK by The Accreditation Regulations 2009 (SI No 3155/2009) and operates under a Memorandum of Understanding (MoU) with the Department for Business, Innovation and Skills (BIS).

Directorate of Laboratory Medicine

Training

Prerequisite to competence assessment:

Institute of Biomedical Science Benchmark Policy on the Management of Laboratory Training.

January 2014 (version 2)

Flow analysis - a special case

Errors in instrument operation, reporting and interpretation of results can have serious implications on the treatment and management of the patient.

What we want to avoid....

Quick Nurse, what does Google say...!

CPA

Standard B9.3

‘Competency to perform assigned tasks shall be assessed following training and periodically thereafter. Retraining and reassessment shall occur when necessary’.

‘Records of competency assessments shall be kept’.

ISO 15189

Standard 5.1.6 Competence Assessment

‘Following appropriate training, the laboratory shall assess the competence of each person to perform assigned managerial or technical tasks according to established criteria’.

‘Reassessment shall take place at regular intervals and retraining shall occur when necessary’.

ISO 15189 – Note 1

NOTE 1: Competence of laboratory staff can be assessed by using Any combination or all of the following approaches under the same conditions as the general work environment:

a) Direct observation of routine work processes and procedures, including all applicable safety practices.

b) Direct observation of equipment maintenance and function checks.

c) Monitoring the recording and reprinting of examination results.

d) Review of work records.

e) Assessment of problem solving skills

f) Examination of specially provided samples, such as previously examined samples, inter-laboratory comparison materials or split samples.

ISO 15189 – Note 2

NOTE 2: Competency assessment for professional judgement should be designed as specific and fit for purpose.

Standard 5.1.2 (personnel qualifications) :

“Professional judgements can be expressed as opinions, interpretations, predictions, simulations and models and values and should be in accordance with national, regional and local regulations and professional guidelines”

Putting a system in place....

Competence is ‘procedure’ based and assessed in two dimensions:

- Ability to practice
- Knowledge

Dependant on staff grade.

Competence levels

Four levels of competence:

- **1**. Limited or no experience.
- **2**. Some experience: requires assistance or supervision.
- **3**. Competent and can perform independently.
- **4**. Competent and can assess others.

Undertaking an assessment

Consider:

- Procedure/process.
- Staff grade
- Method(s) of assessment.

Individual must demonstrate:

- Knowledge – depth/breadth.
- Problem solving skills.
- Technical dexterity.
- Analytical skills.
- Interpretative skills.
- Safe practice.

Recording competence

Template documents for:

- Primary assessment (procedure or interpretation of results).
- Reassessment.
- Verifying assessor's competence.

Completed competencies are held within the department.

Primary assessment

Criteria - procedure:

Preparation of samples/worklists/reagents.

Carries out procedure according to SOP.

Equipment use and maintenance.

Health and safety.

Analysis of data.

Recording and reporting of results.

Review of IQC/EQA.

Problem solving skills.

Demonstrates an understanding of assay principles.

Demonstrates knowledge of disease associations.

Primary assessment

Criteria:	Assessment method:	Competency level and comments:	Assessor name and Date of assessment:
Preparation of samples/worklists/reagents	Observation	3 – Samples placed in correct order (checked) and prepared reagents correctly: lysing reagent, mcl ab cocktails.	A.S.Moran 10/03/15
Carries out procedure according to SOP	Observation (Examination audit)	3 - Observed carrying out several assays (see training records in portfolio). Each assay has been completed successfully in accordance with the SOP. Attention to mixing samples/Flowcount beads	A.S.Moran 10/03/15
Equipment use and maintenance	Observation/Q&A	3 – FC500 correct setup: checks & replenishment of sheath/clenz . Operation of FC500 as outlined in SOP. Able to gate/regate cell populations. Colour compensation carried out.	A.S.Moran 10/03/15
Health & Safety	Observation/Q&A	3 – Health & safety maintained in accordance with the SOP.	A.S.Moran 10/03/15
Analysis of raw data/unauthorised results	Observation/Review	3 – Interpret TetraCXP flow pages to derive results. T sum & lymphosum covered.	A.S.Moran 10/03/15
Recording and reporting of results	Observation/Review	3 – Results reported correctly and in accordance with the SOP.	A.S.Moran 10/03/15
Review and recording of Q.A	Q&A/Review	3 –IQC results correctly recorded in Unity QC management software package.	A.S.Moran 10/03/15

Assessing the assessors.....

The ability of an assessor to assess is verified every two years.

Must demonstrate kept up-to-date with new developments and maintained their knowledge base:

- Advance user training courses.
- Involvement in MDTs
- Staff presentations, CPD.
- Method verification & introduction.

Need to be imaginative and innovative!

Assessing the assessors.....

Central Manchester University Hospitals NHS
NHS Foundation Trust
Directorate of Laboratory Medicine

Verification of Assessor Status

Verifier's Name:

Assessor's Name:

Date:

Supporting Evidence	Requirement	Details
Attendance of manufacturer's training course/user group meeting	Mandatory	Attend and participate in adult morphology and paediatric MDTs held at CMFT. Contributes to the interpretation of flow results at the MDTs.
Preparation and acknowledgement of validation data, SOPs, risk assessments and COSHH	Mandatory	Reviewed and updated the SOP to fulfil requirements for UKAS ISO assessment, November 2013. Contributed to a further expansion of the SOP to cover samples such as CSF and TB-FNA/EBUS. Liaised with transplant lab to develop TCR αβ depletion flow analysis.
Mentoring and training of staff	Mandatory	Mentored staff members re immunophenotyping to enable them to complete their IBMS specialist portfolios and certificate of expert practice in flow cytometry.
Completion of competency assessment reports	Mandatory	Completed competency assessment of VE for reading and interpreting immunophenotyping
Attendance of meetings or conferences	Optional	Attendance at UKNEQASLI participant's meeting.
Presentations to staff	Optional	NA
Analysis of UK NEQAS data (including IEQA and interpretative schemes)	Optional	Review and reporting of NEQAS results for the immunophenotyping part 2 scheme

The production of the above evidence including ongoing practice and continual renewal of assessor skills contribute to the validation of the individual's ability to effectively assess competency for the following procedure(s):

Reading and interpretation of flow results

Verification of assessor status should be renewed again on the: ..... (*date)

Verifier's signature:

Assessor's signature:

(*An interval of no more than two years should elapse before re-verification)

Flow competency checklist

Processes/Staff Grade		MLA AP	BMS PTP	Senior BMS Chief BMS STP	Clinical Scientist STP-HSST FY2 ST3
Pre-Examination	Sample acceptance - type, age & storage	•	•	•	•
	Storage and handling of mcl abs	•	•	•	
	Replenishing sheath fluid and decontamination solutions.	•	•	•	
	Start up and shutdown routines	•	•	•	
	Analyser/processor maintenance	•	•	•	
	Analyser/processor troubleshooting (blockages - removal)	•	•	•	
Examination	Health & Safety - PPE, safety cabinet, disposal & decontamination	•	•	•	
	Processing sample - Automated approach	•	•	•	
	Processing sample - Manual approach (pipetting)	•	•	•	
	IQC - Instrument (detector performancce & linearity)		•	•	
	IQC - Procedure (whole blood)		•	•	
	Titration of mcl abs		•	•	
	Data management - housekeeping, storage & retrieval		•	•	
	Colour compensation		•	•	•
	ID of cells		•	•	•
	Gating strategies		•	•	•
	ID of positive/negative fractions - controls/analysis regions		•	•	•
	Devising and modifying protocols and panels		•	•	•
	Reanalysis of List mode data		•	•	•
	EQA - Processing, reporting & reviewing NEQAS samples,		•	•	•
	ISO - Verification, MoU, provenance of RRs and clinical decision values		•	•	•
Post-Examination	Reporting of results - technical validation		•	•	•
	Reporting of results - authorisation			•	•
	Clinical Interpretation of results			•	•
	Attendance and input to MDT meetings			•	•

ISO 15189 – Notes 1 & 2

Examples – pre examination:

Advice & information to users – panel selection, sample volume and type, transport, urgent/high risk samples (Q&A, phone log, report comments applied).

Booking in – data input (data entry to LIMS, horizontal audit).

Sample rejection criteria – correct application (error logs).

Maintenance – start up/shutdown procedures. Breakdowns, blockages and other faults (equipment logs, scenarios, manufacturer contact & service reports).

ISO 15189 – Notes 1 & 2

Examples – examination:

Skills test – experiment/protocol/panel design (review of data from subsequent analysis).

Direct observation – examination audit of procedure, prep & analysis of previously tested material (log - no of samples and sign off).

Data exercises - review of flow plots and trouble-shooting (correct ID of cells, gating, compensation, IQC, EQA, MoU).

Scenarios – what to do (breakdown, urgent request, follow up investigations, cytometer performance issues)

ISO 15189 – Notes 1 & 2

Examples – post examination:

Reporting of results – correct format, comments, accuracy of data (data entry to LIMS).

Library of results – clinical interpretation (log of cases with sign off).

MDT attendance – input, results presentation and discussion (MDT register, integrated report sign off).

Clinical/technical advice – telephone log, reflective diary (record of advice requested and given).

Reassessment

Reassessment occurs:

- Every 2 years.
- Staff rotation.
- Break in service.
- Major change in procedure.
- Performance issues

-Basic or full reassessment dependant on circumstance

Reassessment

Central Manchester University Hospitals NHS
NHS Foundation Trust

Directorate of Laboratory Medicine

Competency Reassessment

Date:

Procedure:

Name: ..... Grade: ..... has been reassessed for the above procedure and the following components:

- Carries out procedure according to SOP
- Equipment use and maintenance
- Health & Safety
- Analysis of raw data/unauthorised results
- Recording and reporting of results
- Review and recording of Q.A
- Preparation of samples/worklists/reagents
- Demonstrates understanding of assay/ procedure
- Demonstrates knowledge of disease associations

	(tick)
Is competent to practice at level ..... for the period: ..... to	
Requires retraining as recommended below	

Notes:

Reassessment carried out by: ..... (date) .....

Competence Records

Staff Member	Grade	Competency	Date Achieved	Renewal Date	Level	Assessor	Lab Section	
PCO	BMS2	Immage	01/09/2010	01/09/2012	3	GO	Immunochemistry	
PCO	BMS2	EP/IFX/BJP/Cryo	26/01/2011	26/01/2013	3	BM	Immunochemistry	
PCO	BMS2	C1inhibitor Assays	06/05/2011	06/05/2013	3	VM	Immunochemistry	
PCO	BMS2	Haemolytic Complement Assays	06/05/2011	06/05/2013	3	VM	Immunochemistry	
PCO	BMS2	Autoimmunity/250	01/03/2012	01/03/2014	3	GA	Automation	
PCO	BMS2	Allergy/1000	21/05/2012	21/05/2014	4	JM	Automation	
PCO	BMS2	Immunodeficiency/TBNK analysis	18/06/2012	18/06/2014	3	RL	Cellular	Renewed on the 22/05/15
PCO	BMS2	Analysis & Interpretation of flow results	08/01/2013	08/01/2015	3	AM	Cellular	Renewed on the 25/05/15
PCO	BMS2	Sample Reception Duties	14/10/2013	14/10/2015	3	RL	Cellular	
PCO	BMS2	Stem Cell Counts	31/10/2013	31/10/2015	3	RL	Cellular	
PCO	BMS2	Pipette Maintenance	12/11/2013	12/11/2015	4	JG	Cellular	
PCO	BMS2	DHR Assay	07/04/2014	07/04/2016	3	AM	Cellular	
PCO	BMS2	Leukaemia Immunophenotyping	10/04/2014	10/04/2016	3	AM	Cellular	
PCO	BMS2	Giving Results Over the Phone	08/05/2014	08/05/2016	3	JH	Cellular	
PCO	BMS2	Unity Quality Control	17/07/2014	17/07/2016	4	VE	Cellular	
PCO	BMS2	Referred Tests	14/07/2014	14/07/2016	3	VE	Cellular	
PCO	BMS2	Reporting & Authorising Results	04/12/2014	04/12/2016	3	JH	Cellular	
PCO	BMS2	Basic Lab Equipment	05/12/2014	05/12/2016	3	AM	Cellular	
PCO	BMS2	Immunodeficiency/TBNK analysis	22/03/2015	22/03/2017	3	RL	Cellular	
PCO	BMS2	Analysis & Interpretation of flow results	25/05/2015	25/05/2017	3	AM	Cellular	

COLOUR CODING
Date in Red = Expired
Grey = Renewal required
Yellow = Recently added

Reviewing progress

Embed into the QMS:

- Records reviewed at the dept quality meeting – held every six weeks.
- Staff receive individual progress report. Informed of competencies that require completing/reassessing & assessor(s) who can facilitate.
- Appraisals/annual review – objective setting.

Responsibility of the individual to ensure they achieve competence and the assessment is undertaken.

Other issues

- Break in service
- Locum/agency staff
- Out of hours working
- Persistent performance issues
- Moderation of assessors
- Updating questions
- Fitting it all in!

Resources

VERIQAS – ‘proof of principle’ for individuals (not just labs).

UKNEQASLI: leukaemia diagnostic interpretation – part 2.

National Academy for Clinical Flow Cytometry.

Training courses (manufacturers, RMS).

IBMS certificate of expert practise in flow cytometry.

International Cytometry Certification Examination.

On line resources (Purdue, ISAC, ICCS, Salk, TSRI, RMS, etc).

Resources

Publications:

A Practical Guide to ISO 15189 in Laboratory Medicine David Burnett, 2013, ISBN 978-0-902429-49-9.

BCSH Guidelines on the use of multicolour flow cytometry in the diagnosis of haematological neoplasms. BJH 2014, 165, 455 – 488 (appendix II).

CLS entry level competencies in flow cytometry. Clin Lab Sci., 2011, 24 29-34

Summary

Process followed must be:

- Simple.
- Manageable.
- Realistic.
- Effective.

Thank you.

Any Questions?

andrew.moran@cmft.nhs.uk