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
Instrumentation

FP1000 Processor x 2

EPICS FC500 x 2
(5 colour, 1 laser)
ISO achieved 2014
Prerequisite to competence assessment:

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

January 2014 (version 2)
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...!
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’.
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’.
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.
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”
Competence is ‘procedure’ based and assessed in two dimensions:

- Ability to practice
- Knowledge

Dependant on staff grade.
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.
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.

Directorate of Laboratory Medicine
## Primary assessment

<table>
<thead>
<tr>
<th>Criteria:</th>
<th>Assessment method:</th>
<th>Competency level and comments:</th>
<th>Assessor name and Date of assessment:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preparation of samples/worklists/reagents</td>
<td>Observation</td>
<td>3 – Samples placed in correct order (checked) and prepared reagents correctly: lysing reagent, mcl ab cocktails.</td>
<td>A.S. Moran 10/03/15</td>
</tr>
<tr>
<td>Carries out procedure according to SOP</td>
<td>Observation (Examination audit)</td>
<td>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</td>
<td>A.S. Moran 10/03/15</td>
</tr>
<tr>
<td>Equipment use and maintenance</td>
<td>Observation/Q&amp;A</td>
<td>3 – FC500 correct setup: checks &amp; replenishment of sheath/clenz. Operation of FC500 as outlined in SOP. Able to gate/regate cell populations. Colour compensation carried out.</td>
<td>A.S. Moran 10/03/15</td>
</tr>
<tr>
<td>Health &amp; Safety</td>
<td>Observation/Q&amp;A</td>
<td>3 – Health &amp; safety maintained in accordance with the SOP.</td>
<td>A.S. Moran 10/03/15</td>
</tr>
<tr>
<td>Analysis of raw data/unauthorised results</td>
<td>Observation/Review</td>
<td>3 – Interpret TetraCXP flow pages to derive results. T sum &amp; lymphosum covered.</td>
<td>A.S. Moran 10/03/15</td>
</tr>
<tr>
<td>Recording and reporting of results</td>
<td>Observation/Review</td>
<td>3 – Results reported correctly and in accordance with the SOP.</td>
<td>A.S. Moran 10/03/15</td>
</tr>
<tr>
<td>Review and recording of Q.A</td>
<td>Q&amp;A/Review</td>
<td>3 – IQC results correctly recorded in Unity QC management software package.</td>
<td>A.S. Moran 10/03/15</td>
</tr>
</tbody>
</table>
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!*
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## Verification of Assessor Status

**Verifier’s Name:**
**Assessor’s Name:**
**Date:**

<table>
<thead>
<tr>
<th>Supporting Evidence</th>
<th>Requirement</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attendance of manufacturer’s training course/user group meeting</td>
<td>Mandatory</td>
<td>Attend and participate in adult morphology and paediatric MDTs held at CMFT. Contributes to the interpretation of flow results at the MDTs.</td>
</tr>
<tr>
<td>Preparation and acknowledgement of validation data, SOPs, risk assessments and COSHH</td>
<td>Mandatory</td>
<td>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 dp depletion flow analysis.</td>
</tr>
<tr>
<td>Mentoring and training of staff</td>
<td>Mandatory</td>
<td>Mentored staff members re immunophenotyping to enable them to complete their IBMS specialist portfolios and certificate of expert practice in flow cytometry.</td>
</tr>
<tr>
<td>Completion of competency assessment reports</td>
<td>Mandatory</td>
<td>Completed competency assessment of VE for reading and interpreting immunophenotyping.</td>
</tr>
<tr>
<td>Attendance of meetings or conferences</td>
<td>Optional</td>
<td>Attendance at UKNEQASLI participant’s meeting.</td>
</tr>
<tr>
<td>Presentations to staff</td>
<td>Optional</td>
<td>NA</td>
</tr>
<tr>
<td>Analysis of UK NEQAS data (including IEQA and interpretative schemes)</td>
<td>Optional</td>
<td>Review and reporting of NEQAS results for the immunophenotyping part 2 scheme.</td>
</tr>
</tbody>
</table>

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

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

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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).
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)
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).

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Reassessment occurs:

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

- Basic or full reassessment dependant on circumstance
Central Manchester University Hospitals 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 QA
- 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) ________________

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## Competence Records

<table>
<thead>
<tr>
<th>Staff Member</th>
<th>Grade</th>
<th>Competency</th>
<th>Date Achieved</th>
<th>Renewal Date</th>
<th>Level</th>
<th>Assessor</th>
<th>Lab Section</th>
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</thead>
<tbody>
<tr>
<td>PCO</td>
<td>BMS2</td>
<td>Image</td>
<td>01/09/2010</td>
<td>01/09/2012</td>
<td>3</td>
<td>GA</td>
<td>Immunology</td>
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<td>PCO</td>
<td>BMS2</td>
<td>EPI/FIX/BIP/Cryo</td>
<td>29/01/2011</td>
<td>26/01/2013</td>
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<td>BM</td>
<td>Immunology</td>
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<td>PCO</td>
<td>BMS2</td>
<td>C1Inhibitor Assays</td>
<td>06/05/2011</td>
<td>06/05/2013</td>
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<td>VM</td>
<td>Immunology</td>
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<td>PCO</td>
<td>BMS2</td>
<td>Haemolytic Complement Assays</td>
<td>06/05/2011</td>
<td>06/05/2013</td>
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<td>VM</td>
<td>Immunology</td>
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<td>PCO</td>
<td>BMS2</td>
<td>Autoimmunity/250</td>
<td>01/03/2012</td>
<td>01/03/2014</td>
<td>3</td>
<td>GA</td>
<td>Immunology</td>
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<td>PCO</td>
<td>BMS2</td>
<td>Allergy/1000</td>
<td>21/05/2012</td>
<td>21/05/2014</td>
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<td>JM</td>
<td>Automation</td>
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<td>PCO</td>
<td>BMS2</td>
<td>Immunodeficiency/TBNK analysis</td>
<td>18/05/2012</td>
<td>18/05/2014</td>
<td>3</td>
<td>RL</td>
<td>Cellular</td>
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<td>PCO</td>
<td>BMS2</td>
<td>Analysis &amp; Interpretation of flow results</td>
<td>08/01/2013</td>
<td>08/01/2015</td>
<td>3</td>
<td>AM</td>
<td>Cellular</td>
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<tr>
<td>PCO</td>
<td>BMS2</td>
<td>Sample Reception Duties</td>
<td>14/10/2013</td>
<td>14/10/2015</td>
<td>3</td>
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<td>Cellular</td>
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<tr>
<td>PCO</td>
<td>BMS2</td>
<td>Stem Cell Counts</td>
<td>31/10/2013</td>
<td>31/10/2015</td>
<td>3</td>
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<td>Cellular</td>
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<td>PCO</td>
<td>BMS2</td>
<td>DHR Assay</td>
<td>07/04/2016</td>
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<td>BMS2</td>
<td>Leukaemia Immunophenotyping</td>
<td>10/04/2014</td>
<td>10/04/2016</td>
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<td>Cellular</td>
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<td>PCO</td>
<td>BMS2</td>
<td>Giving Results Over the Phone</td>
<td>09/05/2014</td>
<td>09/05/2016</td>
<td>3</td>
<td>JH</td>
<td>Cellular</td>
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<td>PCO</td>
<td>BMS2</td>
<td>Unity Quality Control</td>
<td>17/07/2014</td>
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<td>4</td>
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<td>PCO</td>
<td>BMS2</td>
<td>Referred Tests</td>
<td>14/07/2014</td>
<td>14/07/2016</td>
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<td>VE</td>
<td>Cellular</td>
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<td>PCO</td>
<td>BMS2</td>
<td>Reporting &amp; Authorising Results</td>
<td>04/12/2014</td>
<td>04/12/2016</td>
<td>3</td>
<td>JH</td>
<td>Cellular</td>
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<tr>
<td>PCO</td>
<td>BMS2</td>
<td>Basic Lab Equipment</td>
<td>05/12/2014</td>
<td>05/12/2016</td>
<td>3</td>
<td>AM</td>
<td>Cellular</td>
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<td>PCO</td>
<td>BMS2</td>
<td>Immunodeficiency/TBNK analysis</td>
<td>22/03/2015</td>
<td>22/03/2017</td>
<td>3</td>
<td>RL</td>
<td>Cellular</td>
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<tr>
<td>PCO</td>
<td>BMS2</td>
<td>Analysis &amp; Interpretation of flow results</td>
<td>25/05/2015</td>
<td>25/05/2017</td>
<td>3</td>
<td>AM</td>
<td>Cellular</td>
</tr>
</tbody>
</table>

**COLOUR CODING**
- Red = Expired
- Grey = Renewal required
- Yellow = Recently added

**Directorate of Laboratory Medicine**
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.

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Other issues

- Break in service
- Locum/agency staff
- Out of hours working
- Persistent performance issues
- Moderation of assessors
- Updating questions
- Fitting it all in!
VERIQAS – ‘proof of principle’ for individuals (not just labs).


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).

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Publications:

A Practical Guide to ISO 15189 in Laboratory Medicine


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?