

St James's Hospital
Haematology Department

CPA Accreditation Experience:

IEQAS Meeting 16.10.03

Original CPA Standards:

These were grouped in six categories

- A. Organization and Administration.
- B. Staffing and Direction.
- C. Facilities and Equipment.
- D. Policies and Procedures.
- E. Staff Development and Education.
- F. Evaluation.

Overall Timescale:

1998: Concept introduced, discussed and early preparations started.

2001: Sufficient work completed to consider making application for inspection. Application made December, before deadline for applications under existing standards.

2003: CPA inspection, September.

Overall Timescale (neighbouring CMD department):

2001: New department occupied former coagulation laboratory space and started to recruit staff.
Joined Haematology and Blood Transfusion Accreditation working group later that year.

2003: CPA inspection, September.

Early preparations:

- Agreed on SOP format, drawing from available guidelines at time: NCCLS, AMLS, IBMS, BCSH.
- Beginnings of SOP writing, particularly “Policy” SOPs
- Formation of “Working Group”, to include at least one person from each laboratory section. (This group spanned the two disciplines of Haematology and Blood Transfusion and was later joined by Cancer Molecular Diagnostics in 2001).

Early preparations:

- Obtained sufficient noticeboards for display for EQAS performance, Health & Safety Information and staff training, short courses, meetings etc.
- Started to improve Health & Safety by carrying out audits, arranged short course by outside experts and purchased minor safety equipment.

“Policy” SOPs in Haematology:

AREA	TYPE	NO	TITLE
H	Policy	1.1	Protocol for writing Standard Operating Procedures
H	Policy	1.2	Department Organizational Structure, Scope and Strategy
H	Policy	1.3	Quality Assurance, Education and Training Policy
H	Policy	1.4	Sample Requirements and Reception
H	Policy	1.5	Out of Hours Service Definition
H	Policy	1.6	Overview of Computer System (Cross-refers to other SOPs)
H	Policy	1.7	Special Tests Out of Hours Service

“Policy” SOPs in Haematology:

AREA	TYPE	NO	TITLE
H	Policy	1.8	Department Major Accident Plan
H	Policy	1.9	Equipment Maintenance Policy
H	Policy	1.10	Result Reporting Policy
H	Policy	1.11	Procedure for Telephoning Results
H	Policy	1.12	New Staff Induction Policy & Procedure
H	Policy	1.13	Training Program for On-Call Staff
H	Policy	1.14	Student Training Program
H	Policy	1.15	Retention and Storage of Archive Data and Material

“Policy” SOPs in Haematology:

AREA	TYPE	NO	TITLE
H	Policy	1.16	Test Interview for On-Call Staff
H	Policy	1.17	Implementation of a new Laboratory Method
H	Policy	1.18	Sample Audit Trail and Turnaround Time Analysis
H	Policy	1.19	Policy for Staff Training and Confirmation of Competency
H	Policy	1.20	Training Records and Procedure in Stat Laboratory
H	Policy	1.21	Procedure for Receipt and Review of External Quality Assurance Scheme (EQAS) Performance
H	Policy	1.22	Policy and format of staff development plans in Haematology
H	Policy	1.23	Temperature Monitoring of Laboratory Equipment using Rees System

Extract From SOP H 1.12, New Staff Induction Policy & Procedure

RECORD OF COMPLETION OF INDUCTION OF NEW STAFF

Name and Starting Date:			
Induction Program Items Covered	Date Covered	Signature	Chief Technologist Signature
2.1 Tour of CPL and Haematology Department			
2.1.2 Safety points of immediate importance			
2.2 Other sites to be visited (Hospital site, canteen, TCD Medical Library)			
2.3 Documentation to be completed (Notification of appointment forms, Contract of employment, Application for staff ID badge, Submission of relevant documents including Bank Account Details and PRSI Number)			

Extract From SOP H 1.12, New Staff Induction Policy & Procedure

Name and Starting Date:			
Induction Program Items Covered	Date Covered	Signature	Chief Technologist Signature
2.4 Induction on Department Safety Procedures: Introduction to Safety Officer(s) Provision of White Coats and explanation of use of other safety equipment Provision of Department Local Safety Statement Fire alarm procedure explained and assembly point indicated			
2.5 Appointment arranged with Occupational Health Department (Vaccination and Mantoux testing if necessary)			
2.6 Other information to be provided and discussed: Departmental organisation structure Introduction of SOPs and clarification of particular points Confidentiality and professional ethics Staff training policy and opportunities			
2.7 Introduction to Computer System and provision of password			
2.8 Arrangement of attendance at Hospital Induction Day and training seminars			

Equipment Electrical Safety Check Logs:

INSTRUMENT	SUPPLIER	DATE CHECK PERFORMED	ELECTRICIAN SIGNATURE	RE-CHECK DATE
Beckman Centrifuge GS-15	Beckman			
Bio-Rad Variant HPLC	Fannin Healthcare			
Cytochemistry Fridge (Zanussi)	Bioscience Ltd			
Cytospin 3 Centrifuge	Fannin Healthcare			
Denley Refridgerated centrifuge.	Medical supply Co.			
FACScan	Becton Dickinson			
Freezer –20 C HA (powerpoint)	Bioscience Ltd			

Equipment Maintenance Log



HAEMATOLOGY DEPARTMENT

MAINTENANCE LOG FOR :

Manufacturer: _____ Model _____ :

Serial Number _____ : Year Commissioned (if Known): _____

SJH Maintenance & Service Policy: _____ By Order Number/ service contract _____

Maintenance & Service Provided By: _____

Company: _____

Address: _____

Telephone: _____

Service Contract Basis: _____

Expiry/Renewal Date _____ :

Number of routine annual visits _____ Due On: _____

Date	Description of Fault or reason for service callout (Include Routine Service)	Action Taken (In-house) or Summary of Engineer's action (Refer to engineer's maintenance report and file with this log)
------	---	---

Extract From Haematology Department Local Safety Statement

Statement of Department Safety Policy

It is department policy to ensure as far as possible the safety, health and welfare of all staff and visitors to the department. The means employed to achieve this objective are as follows:

To identify the hazards and associated risks to staff health, safety and welfare which arise from the work environment and activities carried out in the department

To define the necessary policies and procedures which are in place to eliminate or control these risks

To provide the information and training required for staff and visitors to the department to enable them to avoid or minimise risks to health and safety

To provide appropriate personal protective equipment as appropriate to the risks present

To monitor the working environment and to take measures to eliminate or minimise risks to health and safety arising from the working environment

To comply with all relevant Health and Safety legislation and guidelines

To define the responsibilities of the employer, Head of Department, Chief Medical Scientists, Safety Officers, employees, visitors and contractors

Extract From Haematology Department Local Safety Statement

SJH HAEMATOLOGY DEPARTMENT RISK ASSESSMENT FORM

Date Assessment Undertaken:

-
Name of assessors:

Signed:

Signed:

Date of signature:

-
Assessment Review Date:

1 LOCATION AND DESCRIPTION OF MAIN ACTIVITIES OR PROCESSES

2 DESCRIPTION OF MAIN HAZARDS PRESENT

3 DESCRIPTION OF HAZARD BEING ASSESSED, WITH ASSESSMENT OF SEVERITY (assess on a scale of 1-5, very low to very high)

6 PROBABILITY OF EXPOSURE TO THE HAZARD (LIKELIHOOD OF OCCURRENCE) (assess on a scale of 1-5, not likely to very likely)

7 RISK ASSESSMENT (with the current precautions, is the risk still unacceptable?)

8 ACTION REQUIRED

(consider the following in decreasing priority: eliminate, substitute, enclose, alter environment, guard, new procedure, better supervision, more training, warning signs and personal protective equipment)

Extract From Haematology User Guide

Test Name	OCM Code	Specimen Type & Volume	Any Special Requirements or Comments	Units	Adult Reference Range (Male and Female > 18 yrs.)	Average Lab Turnaround Time OR Frequency of testing
+ESR	3333	1.4mL into DIESSE Vacutec ESR Tube		mm / hr	0-15 (Female) 0-10 (Male)	3 hours
Reticulocyte	3005	3 ml EDTA	Can be done on FBC tube	%	0.4-1.9	4 hours
+Malaria		3 ml EDTA	*N.B. Contact Haematology on 2990 prior to venepuncture. Information required: Clinical Symptoms, Travel history in past year, Any prophylaxis taken and what type, whether treatment commenced and what form. Sample required in lab within one hour of venepuncture.		Normally negative	4 hours

Reagent Log on Access Database

Immunophenotyping reagent log Back

Find	<input type="text"/>	In use 1	<input type="text" value="1"/>	Expiry	<input type="text" value="28/01/02"/>
Supplier	<input type="text" value="DAKO"/>	In stock 1	<input type="text" value="0"/>	Expiry	<input type="text"/>
Cat No	<input type="text" value="X0942"/>	In use 2	<input type="text" value="0"/>	Expiry	<input type="text"/>
		In stock 2	<input type="text" value="0"/>	Expiry	<input type="text"/>

Lot info

Lot No	Expiry	First specimen	Year1	Date(a)	Last Specimen	Year2	Date(b)
010(102)	01/01/02	228	2001	31/08/01			

Calibration Log Template



CALIBRATION LOG FOR.....INSTRUMENT

DATE OF CALIBRATION _____

REASON FOR CALIBRATION _____

AUTHORISED BY (*SENIOR TECHNICIAN*) _____

CALIBRATION MATERIAL USED _____

CALIBRATION MATERIAL LOT NO. _____ EXPIRY DATE _____

PRE-CALIBRATION PROCEDURES & TESTS (MUST BE WITHIN LIMITS):

E.g. Precision and Carryover tests. Purpose: to ensure instrument is operating correctly and no fault is (still) present.

CALIBRATION FACTOR RECORDS

Calibrator
Ref. Value _____

Mean Assay
Value (10 test) _____

Old Cal
Factor _____

New Cal
Factor _____

POST CALIBRATION CHECKS:

CONTROL VALUES WITHIN RANGE (*5 TESTS*) (Y/N) _____

CHECKED BY: _____


Title: Sudan black staining method.


2. Specimen Requirements

Unfixed films of well spread bone marrow are required.


A control peripheral blood film demonstrating neutrophilia is required.

3. Reagents


3.1 Formaldehyde 40%  DH 101133W. Stored in Flammable Chemical store.

3.2 Absolute Ethanol  Merck 100983. Stored in Flammable Chemical store.

3.3 $\text{Na}_2\text{HPO}_4 \cdot 12\text{H}_2\text{O}$. BDH 30156 5Y. Stored on chemicals shelf.

3.4 Phenol  BDH 29477. Stored on chemicals shelf.

3.5 Sudan Black (Gurr). BDH 34201 3F. Stored in press above staining machine.

3.6 Giemsa stain.  BDH 350144M. Stored in press above staining machine.

Title: Sudan black staining method.

12. COSHH Risk Assessment

12.1 Chemical Hazard

Formaldehyde 40% 2.5L

Formaldehyde is toxic by inhalation, in contact with skin and if swallowed. Causes burns. In case of contact with eyes, wash very well and seek medical attention.

Absolute Ethanol 2.5L

Flammable

Phenol 500g

Toxic in contact with skin and if swallowed. Causes burns.

Giemsa 500ml

Toxic by inhalation and if swallowed. Flammable.

In case of accident with any of the above wash affected area well with water.

External advice and training

- July 2002 – A CPA inspector and member of the board was invited to visit to carry out a “mock” inspection
- 2003 – A one-day training course on Staff Appraisal techniques for senior staff, plus brief overview for all staff

Staff Training Logs from Training SOPs

Training Log – Routine Haematology

Blue Sections indicate Saturday am and On-call requirements

Procedure	Trainee Signature	Trainer signature	Date of initial training	review frequency	Review Dates & trainer initials					
Laboratory Safety				1 year						
Specimen reception and PID				1 year						
ESR Analysis				1 year						
FBC Analysis – Part 1				1 year						
FBC Analysis – Part 2				1 year						
FBC Analysis – Part 3				1 year						
Reticulocyte Analysis				1 year						
Blood Film Preparation				1 year						
Phone Results				1 year						
Computer and Printers				1 year						
Malaria slide preparation and screening tests				1 year						
Parasite Microscopy				1 year						
Blood Film Screening				1 year						
Daily Start-up				1 year						
Miscellaneous Tests				1 year						

Sign-off at On-Call Training Interview

Candidate:		Date:	
Chief Medical Scientist:	Further training or experience required on:	Further study required on:	Understanding and Proficiency adequate in all areas (signature):
Haematology			
Coagulation			
3. Sign-off at completion of interview:			

Staff Development Plans

- STAFF MEMBER PREPARATION FORM (i)

General Information.

Position held: _____

Laboratory: _____

Department: _____

Date of meeting: _____

Facilitator: _____

SECTION 1: Performance in the review period

1.1 What were your objectives within your employment during the review period?

1.2 Have you achieved your objectives and what factors helped or hindered you in achieving these objectives?

1.3 Could you identify any areas where there is scope for improvement in your work, how could this improvement be achieved?

1.4 Could you identify any areas of your work or responsibility that have changed within the last year?

Improvements to facilities:

- A significant refurbishment was carried out to maximise use of existing space and also to modernise laboratories
- New safety equipment, including a plumbed eyewash station was installed
- A temperature-monitoring system was installed for fridges and freezers

Involvement of other staff / areas:

- Close liaison was maintained with Phlebotomy staff and guidance given on their documentation and training procedures
- “Common” MLA staff documentation and training was put in place
- All staff, e.g., Clerical staff were kept updated

Extract from staff seminar pre-inspection ("Questions you could be asked")

Possible Question	Where to find the Answer
Where does the department provide information about its services?	Department User Guide, available in paper form, on the Haematology G Drive and on the Hospital Intranet
What are the minimum requirements for Specimen identification? What do you do if a specimen fails to meet these requirements?	SOP H 1.4, Specimen Requirements and Reception
Where do you record details of the reagents you are using? OR where are the calibration records for this instrument?	Reagent logs; Calibration logs (where appropriate)

Extract from staff seminar pre-inspection ("Questions you could be asked")

Possible Question	Where to find the Answer
What would you do if the internal QC for this instrument / test failed?	Relevant Method SOP
How do you report abnormal results for this test / who do you report them to? What are the hazards associated with the reagent you are using?	Reporting Policy in Method SOP COSHH Information in Method SOP
What is the procedure for giving results over the telephone?	SOP H 1.11, Policy for Telephoning Results

Extract from staff seminar pre-inspection ("Questions you could be asked")

Possible Question	Where to find the Answer
Do you work out of hours as part of the On-Call service? What are the department policies on the service that is provided? How do you access Consultant advice out of hours if you need it?	SOP H 1.5, Out of Hours Service Definition Consultant On-Call Rota
Did you have a training program or undergo assessment before you started work on-call?	SOP H 1.13, Training Program for On-Call staff
What would you do if a sample leaked?	Safety Training, Safety Manual, Safe Work Practice Sheets. Be aware of location of spill kit and how to use it

Post-script:

- Inspection September 2003 – Passed “with no conditions!”
- CMD department also passed and await report
- Blood Transfusion still awaiting inspection team to be arranged – now going for inspection under new standards 2004

Members of the Accreditation Working Group

Mary Byrne Nora Kinsella Karen Young
Sheila Glynn Dave O'Brien Brian Kelleher
Nicola Gardiner Liz Doyle Jane Doyle
Anne-Marie McCann Brian Graham
Nicola Miller Mark Lawler