

Clinical Pathology Accreditation

Tips for laboratory preparation

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Clinical Biochemistry

OLHSC

Questions

- Go it alone or use outside help?
- How much funding is available ?
- Will locums be provided and/or can staff do overtime ?

How much is it going to cost ?

- Consultants
- Locums / Overtime
- Training for staff-Audit, Staff appraisals, word processing, Q-Pulse....
- ? Quality manager
- ? Printers, Computers, Q-Pulse,
- Stationary- paper, ink, ring-binders, laminating, label printer.
- Temperature monitoring system
- EQA schemes

Where to get help ?

- Communicate with other labs that have been through the process
- Log on to CPA website for guidelines on applying, preparation of documents, audits, information on inspection.

Where to start ?

- Obtain a copy of current CPA standards and perform a GAP analysis
- Get a copy of the Additional Guidelines for Inspectors (Discipline specific) refer to this throughout the preparation period
- Buy David Burnetts Book: *A Practical Guide to Accreditation in Laboratory Medicine* published by ACB Venture Publications

Accreditation Committee
Laboratory Management

Accreditation Co-ordinator

Quality Group
Representative from each department

Bio

Haem

Histo

Micro

Staff Training

- Basic computer skills and word processing
- Audit Training www.sqt.ie
- Staff Appraisal www.sqt.ie
- Q-Pulse www.gaelquality.co.uk

See www.cpa-uk.co.uk for
document templates and
guidelines on document
control

Documenataion

- Quality Policy
- Quality Manual
- Management SOP's
- Laboratory SOP's/Laboratory Instructions
- Health and Safety
- Forms

Documents available on CPA website

Word Docs: Quality Manual template

SOP template

Sample Audit Forms

Timetable for inspection

PDF: Quality Policy

CPA stds

Docs. Available on CPA website

PDF: Job description for Quality
Manager

An approach to Audit

An approach to Documentation

Conduct of CPA Medical

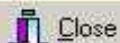
Laboratory Assessments

Document Control

- Decide on document control system
- Filenames: LP-BIO-Amylase
MP-GEN-BiolRisk
LF-GEN-BiolRisk
LI-BIO-AxSYM

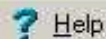
Tips for writing documents

- Get everyone to write up 1 SOP and then edit these
- Be flexible with SOP templates
- Keep them as brief as possible
- Refer to other documents



Close

Document Register



Help

Date : 10/10/2003

Total No. of Documents : 76

Number	Document Title	Rev. No.	Active Date	Note re: changes ▲
LP-BIO-170H PROG	Measurement of 17OH Progesterone	3	01/10/2003	
LP-BIO-ABL625	Blood Gas and pH measurement on the ABL625 blood gas	1	23/04/2003	
LP-BIO-ABL700	Blood Gas, Electrolyte and Metabolite Measurement on the	1	10/04/2003	
LP-BIO-AFP	Measurement of Plasma Alpha-fetoprotein (AFP)	3	26/08/2003	Dilutions
LP-BIO-ALBUMIN	Measurement of plasma or fluid Albumin	2	21/04/2003	
LP-BIO-ALP	Measurement of plasma Alkaline Phosphatase	1	20/08/2002	
LP-BIO-ALPHA1AT	Measurement of Serum Alpha 1 Antitrypsin	1	06/03/2003	
LP-BIO-ALT	Measurement of plasma ALT	2	21/04/2003	
LP-BIO-AMMONIA	Measurement of Ammonia in Plasma	2	24/04/2003	
LP-BIO-AMYLASE	Measurement of Amylase in Plasma and Urine	1	17/05/2002	
LP-BIO-AST	Measurement of plasma Aspartate Transaminase	2	21/04/2003	
LP-BIO-AVLOMNI9	Blood Gas and pH measurement on the AVL OMNI 9 blood	1	29/04/2003	
LP-BIO-BILI	Measurement of total and direct reacting Bilirubin	2	24/04/2003	
LP-BIO-C3C4	Measurement of Serum Complement (C3,C4)	1	10/03/2003	
LP-BIO-CALCIUM	Measurement of Calcium in Plasma and Urine	2	21/04/2003	
LP-BIO-CARB	Measurement of Plasma Carbamazepine	1	05/03/2003	
LP-BIO-CENTPOLICY	Centrifuge Policy	1	01/05/2003	

Document Type

DURES/2.2 LABORATORY PROCEDURE/2.2.1 BIO ▼

 Active
 Inactive
 Obsolete


View



Print

[Register](#)
[History](#)
[New / Edit](#)
[Distribution](#)
[Properties](#)
[Draft Register](#)
[Draft Details](#)


Browsing...



Analyser SOP's / Instructions

- Do not reproduce the user manual
- Keep them brief
- Include any passwords
- Instructions on how to bypass warm-up period
- Schedule for maintenance

Health and Safety

- Safety Statement cross reference to other docs.
- Waste segregation and disposal
- Chemical stores
- Hazard labels on all containers
- Safety Audits
- Safety training-fire lectures, manual handling

Health and Safety

- Disinfection for benches, equipment
- Spill kits-chemical, biological
- COSHH not relevant in Ireland
SOP's do not have to be cross referenced, but should have at least a table at the front with hazard information

Health and Safety

- Risk Assessments-Chemical, biological, equipment, general
- MSDS info on all reagents
- Occupational health-vaccination records

Staff Training

- Staff Induction Programme
- Continuous Professional Education
- Conferences
- Journal Club
- Analyser Training courses
- Records for training for ALL staff

Consultants

- Records of meetings with other departments in the hospital
- CPE Records
- Records of teaching activities

Staff Appraisals/ Annual review

- **Everyone** must have one done before the inspection
- Inspectors checked the staff appraisal form but did not actually look at any individual's staff appraisal

Equipment

- Equipment inventory
- Electrical safety checks
- Service records-records of maintenance or repair carried out by lab. staff or engineers
- Equipment decontamination certs. for engineers

Temperature monitoring

Lennox Laboratory Supplies Ltd.

Ph: 4552201

www.lennoxlabs.com

REES Scientific, continuous temp.

monitoring supplied by accuscience

Near Patient Testing

- NPT Policy
- SOP's/Instructions
- Staff Training
- EQA
- Records of meetings with ward staff

Audit Trail

- Reagent records
- Calibration records
- Records of QC used in each batch
- Name of person numbering, data entry, performing assay, validating, authorising, phoning results

Miscellaneous

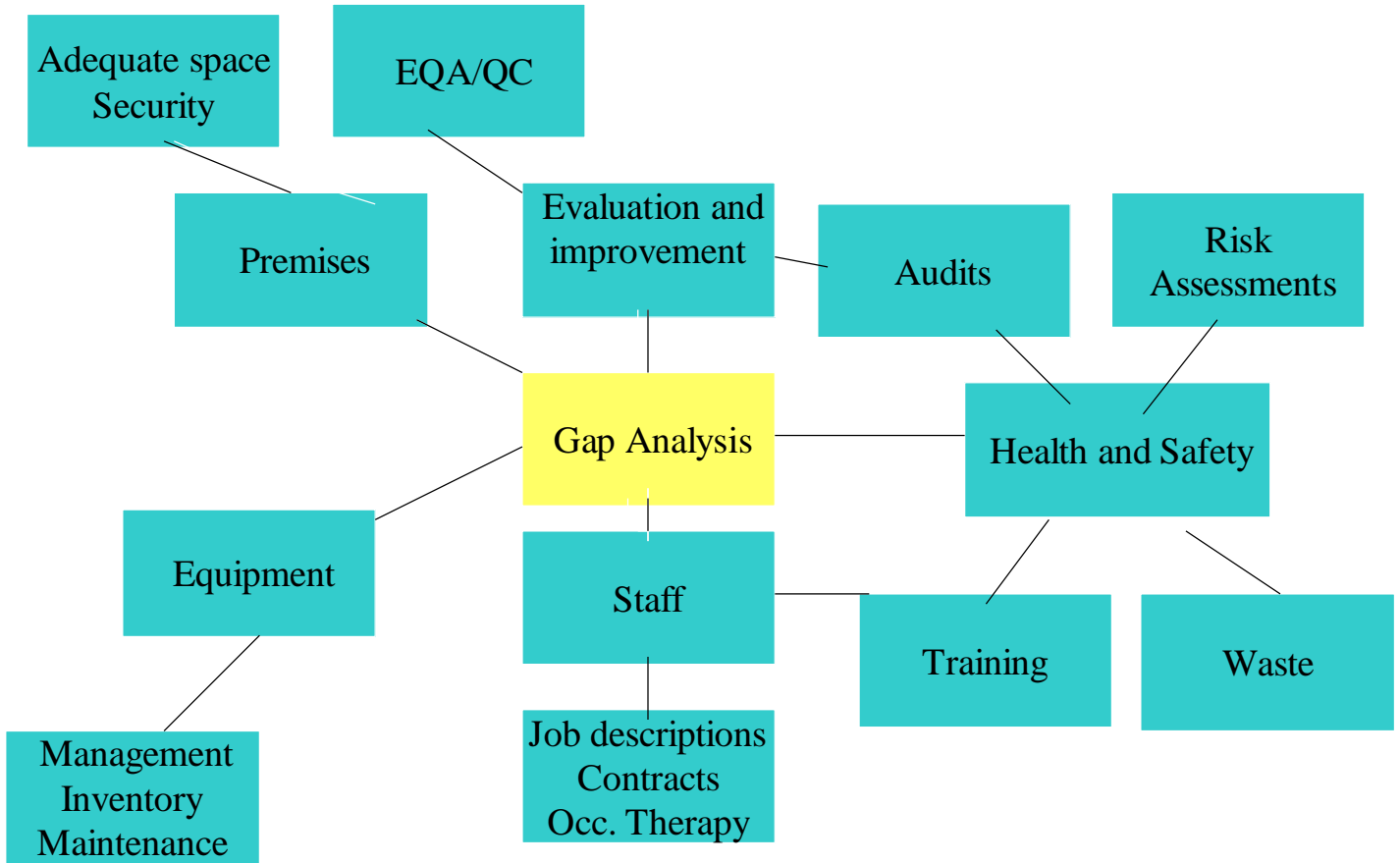
- Pipette calibrations
- Accreditation status of referral labs.
- User manual
- Audits
- Pre-service decontamination
- Getting used to batch logs

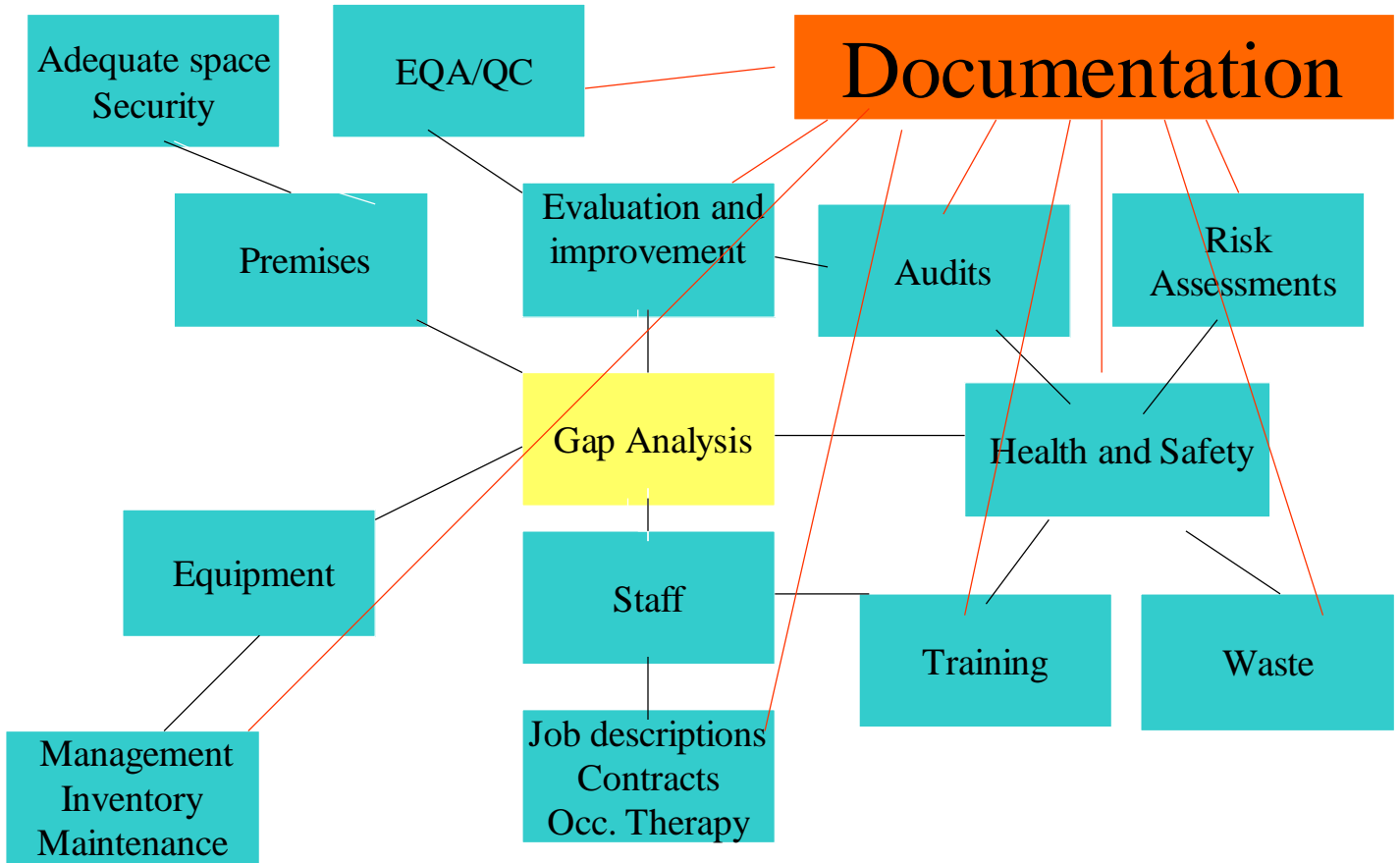
General Tips

- Must have leadership and enthusiasm from heads of departments
- Keep people informed of progress
- Educate staff on principles of doc. control, audits, standards, health and safety issues

General Tips

- Get people to work together in teams
eg risk assessments, audits
- Give everyone some area of responsibility
- Go over GAP analysis with all staff
- Accreditation noticeboard





MOTTO

**If it's not written down
It hasn't been done**