



CPA ACCREDITATION



THE INSPECTION

Rebecca Walden, Microbiology Dept., Our Lady's
Hospital for Sick Children, Crumlin, Dublin 12
rebecca.walden@olhsc.ie

The Inspection

- n Day 1 - Documentation
- n Day 2 – Inspection of the laboratory



Documentation

- n List supplied by CPA before the inspection
- n Documentation required by the inspectors the day before the visit
- n Documentation required by the inspectors the day of the visit





Personnel

- § Hospital and Laboratory Management
- § Consultants
- § Chief Medical Scientist
- § Senior staff
- § Health and Safety Officer
- § Quality control/assurance officers
- § Quality manager
- § Training officer
- § Trainees
- § Lab aids/medical scientists

The Consultant

- n Management structures, difficulties, and issues with
- n Development plans
- n Hospital accreditation
- n Funding for courses/training
- n Specialist registrars, CME accreditation, CPD
- n Computer system
- n Job contracts



The Consultant (Cont'd)

- n Laboratory Handbook
- n Ward enquiry system
- n Clinical audit
- n Cover for absence
- n Reasons for CPA
- n The proportion of reports that get interpretative comments
- n Appraisal/Joint Annual Review
- n On-Call





Chief Medical Scientist

- n Relationship with consultant
- n Meeting attendance
- n Arrangements for time off and funding for MSc/courses
- n Relationship with Hospital Management
- n Service plan
- n Security
- n Monitoring staff absence

Chief Medical Scientist (Cont'd)

- n Hospital incident report forms
- n Back-up process for the laboratory system
- n On-call room
- n Medical Devices Agency/Irish Medicines Board
- n Function of the Academy
- n Checking of manually entered results



Chief Medical Scientist (Cont'd)

- n Hazard data/Risk Assessments
- n Reagent preparation manual
- n Establishing the accreditation status of laboratories to whom tests are referred to
- n Packaging of samples for disposal
- n Is the Chief involved in routine work?



Quality Manager/QA Officer

n Document Control System

- What does it do?
- How is it used?

n IQA and IQC

- What system is used?
- How are samples selected
- What are acceptable limits?
- Criteria for rejecting results
- QC plots



Health and Safety

- n Hospital Safety Committee
- n Hospital Safety Statement
- n Locked cabinet for dangerous chemicals
- n Hazard data
- n Risk assessments
- n Walk around
- n Decontamination of equipment
- n Spill kits



External Quality Assessment

- n NEQAS
- n Is the laboratory in all the schemes applicable to all tests
- n Treatment of EQA material received
- n Handling of reports received back
- n Meetings with other laboratories about Quality Control



Training

- n Speak specifically to trainees
- n How long training?
- n Training manual
- n Training on 'X' analyser



Equipment

- n Maintenance
- n Calibration-evidence of who/lot number
- n Quality control on instruments
 - How often?
 - 'Out of range' results
 - Sample results
- n Fridge/freezer/incubator temperature ranges



Waste Management

- n Segregation
- n Disposal
- n Treatment
- n Documentation regarding proper disposal of waste



Samples/Requests

- n Labelling/numbering
- n Audit trails of who numbers samples
- n Turnaround times
- n Referrals
- n Specimen retention
- n High risk
 - Are they treated differently
 - Disposal
- n Monitoring of certain requests/tests



Reagents

- n Reagent/product log
- n In-house reagents
- § How are they checked?
- § Criteria for accepting/rejecting batches
- n Storage
- n Disposal of used/expired reagents



Reporting

- n Telephoned reports
- § Record of details
- § Audit trail
- n Validation and authorisation of results



General Questions

- n On-Call
- § How often?
- § Breaks
- § Is it too busy?
- n CPD/CPEP
- n Joint Annual Review
- § Was it useful
- n Near Patient Testing



Inspection of the Laboratory-Tips

- n Don't use CPA inspection to 'get new facilities' or 'as a weapon against management'
- n Don't try to hide anything
- n Be honest
- n In bigger laboratories there will not be time to talk to everyone
- n Relax and enjoy the experience!

