



# Maintaining a Quality Management System and Document Control – the Salisbury Experience

Tony Herbert

# WRGL 102 members of staff

Large Diagnostic Genetics laboratory with research staff and a National Genetics Reference Laboratory.

First accredited by CPA in 1994 and recently passed an inspection under new, more stringent regulations

CPA standards incorporate ISO 15189 (Medical laboratories 2007) but there are differences - Merger with UKAS, 10<sup>th</sup> April 2009, so will move to ISO 15189 in time.

Doesn't matter what the standards are – they have to be sensible & achievable

People are more likely to accept change if they are part of the process – so involve them.

# Benefits of accreditation

Verification by an independent body that the lab operates to acceptable standards

Maintenance of high standards

Regular review of performance

Co-ordinated approach to working practices.

Quality management team – 15 people

Team members – represent every section of the department

Team members are responsible for QM in their own section

Team meets every 6 weeks and carries out 2 audits  
between meetings – 16 scheduled audits/year

We discuss recent audits, NCN's, QIN's, problems, future audits

Display the results of audits and minutes of meetings to the  
Lab staff !!

Everybody contributes to quality, so involve everybody in  
the process

The QM system should benefit the service not impede it

System should be pragmatic, streamlined –  
essential paperwork only

Regular audits – it becomes a way of life

Regular surveillance, regular follow-up

Non-confrontational

It is the system that's being audited, not individuals

## Audits

Involve everybody at some stage but do not be disruptive

Lead auditor and an assistant – both conduct the audit and write the report ,QIN or NCN - also responsible for follow-up.

Lead auditor – member of QM team.

Assistant – another member of staff

Feed back to lab – invite staff member to next QM meeting

QM notice board – display minutes, EQA, surveys etc

No section ever audits its own section

There is an agenda item in every section meeting called 'Quality Management Matters'.

## **Managing the data – software (IPassport, Q-pulse)**

IPassportqms – [www.genialgenetics.com](http://www.genialgenetics.com)

Q-Pulse – [www.gaelquality.com](http://www.gaelquality.com)

We use iPassport – supplied by Genial Genetics Ltd

## **Benefits of QM software–**

Ease of re-call - good search facilities – links to other documents

Good Document control procedures

## **Problems -**

Can be too prescriptive – tail wags the dog!

## **Strategy –**

Avoid duplication of documents - always point to a source document if available – far easier to update

# Document Control

Knowledge that all staff are working to current procedures

Ability to know what version of which technique was in use at any particular time – litigation.

Important to destroy or be able to recall or mark any superseded documents - important to know where copies are and how many are in circulation.

Staff can print documents for their own use but these should be water-marked 'uncontrolled document' – by the system.

## Document control – CPA Standards 8.1 – 8.3

- documents are approved for use by authorised personnel prior to issue
- documents contain a title, unique identifier, a review date or date of issue or revision version, total number of pages and name of authoriser
- there is a readily accessible master list
- documents shall be legible, readily identifiable and retrievable
- documents shall be regularly reviewed and updated as required
- only current versions of documents shall be available at the appropriate locations.

# How documents are controlled in IPassport

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WRGL Safety Manual - DNA extraction from high risk samples - Version: 1.1.

Authorised on: 28-Apr-2008. Authorised by: Tracey Merrifield (Inactive). Sop Un

Author(s): Tony Herbe

- 4) A laboratory coat, plastic apron, disposable gloves must be worn during this procedure.
- 5) Open specimen bag in fume hood
- 6) Use the EZ1 extractor, extract sample separately and clean the piercing units after use. All waste products must be placed in a new CinBin and sealed and send for autoclaving.
- 7) Any blood spillages must be covered with Virkon powder. Leave for 10 minutes, then scrape the powder/spillage mixture into a CinBin and send for autoclaving.

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WRGL Safety Manual - DNA extraction from high risk samples - Version: 1.1. Index: WRGL SOP 0204. Printed: 28-Apr-2008 12:22PM  
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Author(s): Tony Herbert

## DNA EXTRACTION FROM HIGH RISK SAMPLES

High risk samples are those labelled with "Danger of Infection" stickers.

- 1) Inform the Scientist on the DNA extraction rota and await their advice.
- 2) Only skilled personnel should extract the DNA.
- 3) The samples should be handled separately from other specimens, during a quiet period.
- 4) A laboratory coat, plastic apron, disposable gloves must be worn during this procedure.
- 5) Open specimen bag in fume hood
- 6) Use the EZ1 extractor, extract sample separately and clean the piercing units after use. All waste products must be placed in a new CinBin and sealed and send for autoclaving.
- 7) Any blood spillages must be covered with Virkon powder. Leave for 10 minutes, then scrape the powder/spillage mixture into a CinBin and send for autoclaving.

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Full audit trail also recorded by the system

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salisbury.ipassportqms.com/desktop/overview/notices#

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# Inspections

Main CPA inspections are every 4 years

Advance notice is given – huge performance.

Staff tend to relax vigilance in between visits –  
difficult to motivate staff

The visit is not a true reflection of the QM system

In my opinion, Quality Management should be a way of life

These inspections should not be a big deal

A well organised lab should welcome spot inspections –

CAP (College of American Pathologists) – includes unannounced (spot) inspections within a 3 month window prior to a scheduled visit – or anytime following a complaint !

Good motivator !