Wildlife DNA Forensics Course

Lecture A6

Laboratory Models and Quality Assurance

No: A6	Lecturer: R. Ogden	Date: 05/08/10

Introduction

One aim of the ASEAN WFN is to build capacity for wildlife forensics across the region, but this may not mean every country having its own lab. Here we discuss different laboratory models for performing wildlife forensics.

Quality Assurance (QA) is concerned with ensuring that management systems are in place to maximise the quality of the laboratory output. QA is particularly important in forensic analysis. This lecture will look at how quality is managed in laboratories and discuss quality management systems for use in wildlife forensics.

Lecture Aims

- **To demonstrate the difference between research and forensic laboratories**
- **To consider how different laboratory models suit your country's needs**
- **To explain how investigators can assess the forensic capacity of a laboratory**
- **To explain the need for quality assurance**
- **To introduce the key features of any QA system that you need to consider**
- **To discuss standardization and accreditation**

Lecture Summary

- **Forensic analysis must be carried out in a suitable laboratory environment**
- **Different models exist for establishing a lab, within and between countries**
- **Quality Assurance is about maintaining a system that generates quality results, fixes its own errors and continually improves**
- **Quality Assurance must be implemented in forensic analysis for results to be widely accepted; accreditation against a recognized standard is desirable**
- **Accreditation of your QMS against a recognized standard gives your work additional credibility and should improve quality**

Further Reading

Wildlife DNA Forensics Course

Ogden R (2010) Forensic science, genetics and wildlife biology: getting the right mix for a wildlife DNA forensics lab. Forensic Sci Med Pathol. DOI 10.1007/s12024-010-9178-5

DNA Advisory Board Quality Assurance Standards for Forensic DNA Testing Laboratories: http://www.cstl.nist.gov/div831/strbase/dabqas.htm#quality%20assurance%20standards

Laboratory models and Quality Assurance

ASEAN Wildlife Forensics Network

TRACE the wildlife forensics network

DARWIN INITIATIVE

TRAFFIC the wildlife trade monitoring network

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Introduction

ASEAN Wildlife Forensics Network aims:

"To provide the ability for ASEAN countries to undertake coordinated wildlife forensic analysis for CITES enforcement ..."

"Implementation of management systems and accredited protocols..."

- Development of laboratory capacity
- Understanding of Quality Assurance

Laboratory Models

Where should wildlife DNA forensic casework be performed?

1. Dedicated wildlife DNA forensics laboratory
2. Commercial DNA forensics laboratory
3. University forensics laboratory
4. University research laboratory

What is available?
What is acceptable?

Laboratory Models

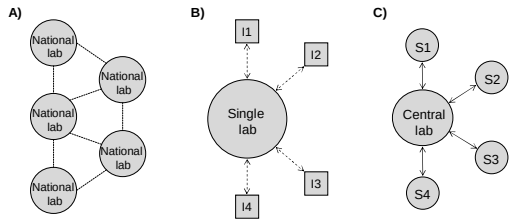
1. Dedicated Wildlife DNA Forensics Lab
2. Commercial DNA Forensics Lab
3. University Forensics Lab
4. University Research Lab

High cost → Low cost

Greatest QA potential → Least QA potential

- Easier to control quality of work
  Evidence likely to be accepted
- High overheads
  Requires subsidy of facility, or testing
- Reduced set-up and running costs
  More affordable service
- Security and QA harder to ensure
  More susceptable to legal challenge

International Models



International Models

A) Independent national laboratories	B) Single international laboratory	C) Central regional laboratory & national satellite labs
• High set-up & per sample costs	• Low set-up & per sample costs	• Medium set-up & per sample costs
• National independence	• International dependence	• International collaboration
• Maximum capacity building	• Minimal capacity building	• Targeted capacity building

Lab Model Summary

- Links with academia are important, but the forensic process can only be undertaken in a controlled environment.
- Different laboratory solutions will be appropriate in different regions.
- Explore if it is feasible to collaborate and coordinate resources from the local to the national to the international level.
- Ask for advice, learn from other people's mistakes.

Quality Assurance

Everybody's heard of it – but what does it mean?

= A Management System – A Way Doing Things

Where QA appears:

- Standard Operating Procedures (SOPs)
- Project Management
- Feedback Systems

Aims

- To think about the need for quality assurance
- To describe the relevance of QA to our work
- To introduce the key features of any QA system that you need to consider
- To discuss standardization and accreditation
- To think about why QA is difficult to implement

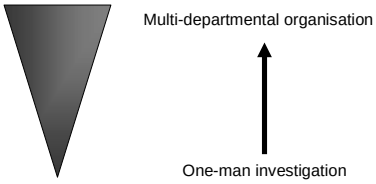
Why do we need QA?

Reasons for having QA systems:

- Repetition is difficult
- People change
- Techniques change
- Things go wrong
- To allow continual improvement

Why do we need QA?

Relevance of QA α Number of People in the System



Why do we need QA?

Relevance of QA to Wildlife Forensics:

- 'Quality' & 'Assurance' absolutely essential
- There are no 'one man investigations'
- External and internal protocols already exist
- QA used as a measure of forensic rigour

Quality Management Systems

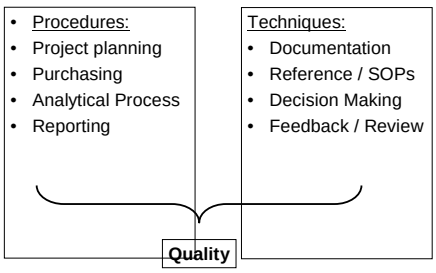
= How QA is normally applied to forensic analysis

Total system – Applies to everything that affects quality

Links together all processes within the laboratory

Joins the laboratory system to the outside world

Quality Management Systems



Quality Management Systems

Example: DNA species identification of meat

Producing a project plan:

Documentation – who, what, where, when, why, how

Reference / SOPs – need to devise method and instruct

Decision Making – logistics, timescales, consultation

Feedback / Review – need to cope with change

QMS Advantages

Benefits:

- Prevents things from going wrong!
- Makes processes more efficient
- Improves reproducibility
- Allows for changes in personnel, techniques
- Designed to continually improve your work
- Provides evidence of control

QMS concerns

Potential Problems:

- Needs to work for you, not against you
- Shouldn't produce too much bureaucracy
- Needs to be logical to all those involved
- Must meet external requirements
- Must be maintained

Accreditation

- Each QMS is specific to an organization
- Most QMS systems are designed to conform to a standard

- ISO 9001 = Quality Management System
- ISO 17025 = Quality Testing Service

Accreditation – How it works

- QMS developed and cross-referenced to generic international standard
- Both QMS and its implementation are audited externally
- Cost to setting up an accredited QMS
- Ongoing costs associated with audits

So What?

Excellent work can come from non-accredited labs

and

Terrible work can come from accredited labs

Accreditation in Forensics

- Accreditation now generally required in the UK
- International forensic committees recommend accreditation
- Courts are starting to look for accreditation

If you don't have accreditation, you may have to explain why not!

Accreditation in Forensics

What can I do if my institution is not accredited?

1. Implement QA in your own work
2. Devise a QMS controlling your forensic processes
3. Examine reasons why your institution is not accredited
4. Ensure that your QMS meets external standards
5. Explain the need for accreditation, justify funding!

…but in reality

The psychology of QA implementation

Do you honestly:
- *Always* where goggles & lab coat when you should?
- *Always* change pipette tips when you should?
- *Always* run +ve and –ve controls when you should?
- *Always* record your work immediately after you finish it?

Why not?!

QA Implementation

- ... because it's quicker
- …because it's obvious
- …because you know better
- …because you don't need to
- …because you're experienced
- …because you already know the answer
- …because you don't make simple mistakes

…because you're an arrogant scientist working subjectively

QA Implementation

- QA makes forensic analysis boring
- QA slows you down
- QA costs money

As research scientists undertaking forensic analysis, you have to have the right psychological approach.

Give yourselves time, leave your egos at the door

QA Summary

- Quality Assurance is about maintaining a system that generates quality results, fixes its own errors and continually improves
- Quality Assurance must be implemented in forensic analysis for results to be widely accepted.
- Quality Management Systems allow QA to be implemented
- Accreditation of your QMS against a recognized standard gives your work additional credibility and should improve it