

Appendix 5

Auditor briefing notes

Audit of a Biobank

Brief notes to help auditors.

The CCB's quality standard is designed to define the basic requirements for a biobank seeking accreditation. The standard has been set to cover all biobanking activities, from donor to researcher, and cover the management and governance of a biobank as well as its practical and technical operations.

The standard was devised by Working Groups whose members are active within biobanking and therefore have insight into the issues surrounding quality assurance in this field.

Our intention is to provide a systematic and independent examination to determine whether the auditee's activities and related results comply with the CCB's quality standard and their own planned arrangements, and whether these arrangements are implemented effectively and are suitable to achieve their objectives.

At present the audit process is under development.

Mock audit

We will carry out our mock audit against the requirements for biobanks described in the CCB's draft biobanking standard. The aim of the mock audit is to assess the audit system and to "sense test" the draft standard. The longer term intention is that the standard and audit system will be improved so as to enable them to be used to accredit biobanks within the UK.

The purpose of an audit is to collect objective evidence to permit an informed judgement about the status and effectiveness of the biobanks activities. It is a systematic investigation of the intent, implementation and effectiveness of selected parts of the biobanks activities. It is a formal process carried out against the biobank's policies, quality manual and procedures to independently examine objective evidence and verify compliance or otherwise with specified requirements.

Objective evidence is information which can be proved true based on facts obtained through observation, measurement, test or other means. It is uninfluenced by prejudice or bias. Evidence may be stated or (preferably) documented and must be verifiable.

Specified requirements include the requirements of contracts, company policy as described in manuals, procedures and work instructions, the CCB's standard, and relevant laws and regulations.

Intent is audited by comparing the biobank's quality manual and/or its policies against the CCB's standard.

Implementation is audited by looking for objective evidence of activities versus the quality manual, policies and procedures.

Effectiveness is audited by looking at internal reviews and audit reports, complaints, anomalies and other customer feedback.

The Auditor

Auditors must be knowledgeable, objective, polite, punctual, practical, principled, persevering, positive, communicative, prepared, unbiased and helpful.

The Auditor must:

- Take a positive approach
- Aim to help the auditee
- Not look for blame
- Help identification of solutions

Auditors must be flexible to:

- Changing situations
- Different management styles
- Different management/employee levels

Auditors must be competent in the reasoning of non-conformities and evaluating the effectiveness of corrective action.

How to audit

The audit team leader will assign areas to each of the auditors. Once you know which areas you will be looking at, use the documents supplied by the auditee to prepare for the audit. Checklists can be useful as an aide memoire and in keeping the audit on track. Checklists lose value if they are just a tick list or questionnaire. Remain open minded and do not stick to the checklist if the things you find need to be explored further. Decide to disregard them, make a note for later or follow them up straight away.

When preparing a checklist, consider what you are going to **look at** and what you are going to **look for**. For example:

Look at:	Look for:	Findings:
4. Environment	Cleanliness, tidiness, sufficient space? Facility temperature control – heat dissipation Humidity control – evidence of mould? Pest control	Environment was found to be clean and tidy with adequate space for current equipment and room for expansion. 28,000 sq.ft. facility at present, planning approval for 9,000 sq.ft. extension which is being actively pursued. Q Manager predicts that without the planned extension there is sufficient space for next two years if current increases in business are maintained. Displacement ventilation system. Computer controlled TREND IQ251 building management system. Air conditioning switches on automatically if outside temp. reaches 24°C or indoor temp. reaches 20°C. Repository felt cool, even in area with freezers. No evidence of mould. Good ventilation. Pest control company employed; use SOP: FC204 for cleaning and pest control. Records of last visit examined.

	Fire prevention	Laminated security glass and Class III fire doors seen. IR fire/heat/smoke detection in use. Area tidy; no paper/flammables around.
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Consider the major functions of the area you are auditing and make sure you do not spend too much time on minor activities.

It's good to find out what the auditee does when things go wrong.

The day of the audit

There are three parts to the audit, the opening meeting, the audit process (gathering information, validating the findings and evaluating their significance) and the closing meeting.

The **opening meeting** includes introductions, description of what will happen, allocation of guides, and logistics. Confidentiality is emphasised.

During the audit an auditor should remember:

- You are a guest – always introduce yourself
- Auditees will be nervous – make allowances
- Explain what you want to see
- Ask open questions (who, what, where, why, when, show me...) and listen to the auditee. Only ask closed questions to verify that you have understood.
- Investigate to the depth necessary and move on if no problems are found – don't keep auditing till you find something

Note taking may be viewed with suspicion by the auditee, however notes are a record of the audit, showing what was looked at, what was reported and what was observed. They form part of the audit record and may be referenced by subsequent auditors and so must be legible. When taking notes, record:

- The objective evidence
- Statements from persons with authority and responsibility
- Document identifiers and issue/version numbers
- Departments or units visited
- Titles of auditees, with names only where necessary
- Good findings as well as non-conformities

Non-conformity is the non-fulfilment of a requirement specified in:

- Conditions of a contract
- The CCB standard
- The biobank's quality manual, policies or procedures
- Legal or regulatory requirements

If you suspect a non-conformity:

- Discuss your concerns with the auditee
- Verify your findings
- Record all of the evidence
 - Exact observation

- What, where, who etc
- Use the auditee's terminology
- Make it helpful
- Make it concise but clearly identifiable
- Determine the seriousness of the finding
 - What could go wrong if it remains uncorrected?
 - What is the likelihood of it going wrong?
- Note that the auditee MUST be given the benefit of the doubt

The Auditee may react to the auditor by

- Seeking help
- Continual challenge
- Volunteering information
- Diversionary or time wasting tactics
- Blaming others – don't get involved
- Standing on their authority
- Antagonism

There should be no surprises for the auditee at the **closing meeting**. Keep the auditee informed of your concerns as you audit, but the confirmation of significant findings will be done at the closing meeting.

The closing meeting is preceded by an auditor team meeting which gives the auditors time to discuss the significance of their findings in private and reach agreement on how they will be presented. A summary report and non-conformity reports are prepared during this meeting.

The options for following up the audit are:

- No non-conformities found – audit is closed
- Minor non-conformities only – auditee to submit evidence in writing to be evaluated by the lead auditor. The audit may be closed at this point or further evidence requested.
- One major non-conformity - partial re-audit may be required to close the audit.
- Several major non-conformities – a full re-audit will be needed to close the audit.

Once the audit is closed, the auditee will receive formal notification of their accreditation status.

Auditor hospitality

The auditor must remain independent of the organisation being audited and so must not accept hospitality from that organisation. Provision of tea/coffee by the biobank is acceptable but auditors should provide their own lunch and any other refreshments they require. Reasonable auditor expenses will be reimbursed by NCRI – receipts will be required.