

Appendix 11 Findings of the review meeting (raw data)

1 The time taken from submitting a written expression of interest in being audited to having the audit performed varied from 2-3 months. This time allowed the biobank to complete the self-assessment form and submit it, together with their quality manual (if any) to the audit coordinator. The audit coordinator sought volunteer auditors and agreed dates for the audit. Auditors and auditees all agreed that the time delay was appropriate; it was noted to be of value to audit the biobank “as is” rather than staff attempting to present a “polished” image of how the biobank is performing. Biobanks claiming to comply with the standard should do so at all times and not just at the time of the audit. There should not be a massive “flurry” of activity immediately prior to the audit, resulting in levels of quality going up, and back down once the audit is over. One auditee spent 2-3 days preparing documents for the auditors and felt this was excessive.

2 The procedure to request an audit was felt to be appropriate. Auditors felt that receiving a copy of the biobank’s quality manual and standard operating procedures in advance of the audit was helpful, allowing time to read and understand them.

3 The standard against which audits were performed was felt to be comprehensive and achievable. There was felt to be minimal overlap with other standards, such as Human Tissue Authority requirements, against which biobanks are already audited.

4 The self-assessment form is based on the sections of the standard, and asks the auditee to assess how well they meet the standard’s requirements. It was found to be useful by the auditors, however some auditees felt that it was overly long and repetitive, taking a long time to complete. It was felt to be helpful in presenting the standard in small sections, thus helping individuals to learn about and understand the requirements. The form asked the auditee to grade their compliance with the standard (1=non-compliant or not applicable, 2= some progress towards compliance, 3=compliant with regard to most important features, 4=fully compliant); this was felt to be subjective. The group was unable to identify areas of the self-assessment form that could be removed or shortened, however it may be that the standard on which it is based is itself repetitive and this should be reviewed next time the standard is reviewed.

5 The first pilot audit was completed in one day by three auditors. This was found, by both auditors and auditees, to give insufficient time to carry out a thorough assessment. Most other audits took place over two days, with the auditors meeting on the evening before the audit to assign areas to be covered and plan the audit. One auditee was surprised at the amount of her time required on the days of the audit and commented that this time commitment should be made clear to biobanks. Auditors reported that the two days of the audits were very labour intensive, but felt that two days is long enough.

6 The depth of the audits varied. At the first audit, too much detail was examined in the first part of the audit, meaning that other areas had to be skimmed. This was rectified at subsequent audits; auditors were reported as able to judge quickly when to drill down more deeply.

7 A lay person was asked to be part of the first audit team. This was a useful exercise since a lay perspective is different to that of biobank staff. There was a problem, however, in that the audit process is very technical and the experience brought by the lay person was relevant only to a small area of the audit. If lay people are to act as auditors in future there will need to be a detailed, tailored training programme covering the biobank standard and the principles of auditing. The

auditees felt that they needed to be audited by peers rather than lay people, and that it was unfair to put a lay person into that environment.

8 All auditors found it helpful to visit other biobanks and see how they work. Auditors and auditees reported that they found the opportunity to discuss their work with peers to be interesting and helpful and probably the most beneficial part of the audit.

9 The documents used to prepare for and record the audit were felt to be useful and necessary. One auditor tried to make direct electronic records but found this difficult and does not recommend it. Handwriting was sometimes unclear and difficult to read.

10 Auditors were chosen from volunteers; all had experience of internal auditing or of being audited. Training was minimal, consisting of being required to familiarise themselves with the requirements of the standard and read the auditing briefing note. Brief training was given the night before the audit. Auditors felt that training the night before the audit is too late if the auditor had not had previous training and experience of auditing. The training given did little to standardise the auditors' performance. Auditors recommended that more formal training should be given to auditors if the audit scheme continues.

11 The auditees felt that the auditors were the right people to carry out the audit, with appropriate experience, knowledge and understanding.

12 Some biobank staff were reported to be resistant to the audit process but this improved as the audit proceeded. Auditees reported that staff felt that their work was being challenged and became defensive, especially those staff who were new to being audited. It is important that auditors depersonalise the audit by paying attention to their style of questioning. Discussions between auditors and auditees, as a two-way process, were found to help.

13 The audit was used by auditees to improve their biobank. It highlighted areas of weakness, shared good practice and provided independent evidence that was used to highlight issues to biobank management. Auditees reported that being part of the audit taught them how to audit within their own biobank.

14 The number and severity of the non-compliances found varied. Auditees were not required to tell the auditors how they dealt with the non-compliances, although one auditee followed through with the audit coordinator, providing details of corrective actions. One auditee had ongoing dialogue with an auditor while addressing findings. Auditees all reported that they acted upon the non-compliances, most prioritising by importance and "quick wins". Some of the non-compliances were outside the control of the biobank staff and these have proved to be the most difficult to address.

15 The majority of the issues seen were around quality assurance and quality management, and often the biobank does not have a quality manager trained to deal with these areas. Document control and record keeping was another recurring theme. These are the normal areas that are picked up at all types of audits. There were, however, some serious findings relating to control of access to labs, temperature monitoring and control of sample storage, validation of equipment and procedures, consent, training and change control.

16 Auditors and auditees all felt that the pilot audit scheme was worthwhile and should continue to a wider scheme, involving formal auditor training and being available to all biobanks.

The audits were noted to have highlighted weaknesses, helped achieve improvements and given confidence to biobank staff – it was felt that biobanks had “something to show” for their efforts. The suggestion of “bronze, silver and gold” levels of compliance was mentioned; it was felt that this would allow biobanks to know how they compare to other biobanks and give an incentive for improvement.

17 The anticipated ISO biobanking standard was noted as a potential replacement for the CCB standard.

18 A clear preference for peer review was expressed by auditors and auditees. The pilot audit scheme was compared to a management audit, where the auditee spent a great deal of the audit time explaining to the auditor about biobanking, and an ISO 9001 audit where the auditor focused almost exclusively on the biobank’s equipment since that was his area of expertise. The importance of auditors having knowledge and experience of biobanking was noted, this allows the audit to be much more focussed. Peer review has the added benefit of allowing good practice to be shared.

19 Auditors and auditees were asked what would discourage their participation in an audit scheme. The cost of participation, in terms of finance, staff resource and time, balanced against the benefits to reputation and improvements in practices would be used to give an estimate of the value obtained. The benefits would need to outweigh the costs to encourage participation.

20 Auditors and auditees recommended that the standard be reviewed, especially in light of the proposed ISO biobanking standard. Once this has happened, the self-assessment form should be amended in line with any changes to the standard. In future, auditors should be trained formally and auditees should be required to submit details of corrective actions so that the audit can be closed by the audit coordinator.

21 Some of the biobanks audited did not have a formal quality manual. Auditees felt it would be useful to have access to a template quality manual to help them develop their own manuals.

22 Half of the biobanks had a named quality manager, the others did not.

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