



Home Office

Full System Audit Process

**Animals in Science Regulation Unit
(ASRU)**

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Introduction

The purpose of this document is to outline the process to follow to conduct a full establishment systems audit.

The purpose of an establishment systems audit is to objectively measure the risk of non-compliance within that establishment in terms of assessing the robustness of its governance systems and making decisions about regulatory actions needing to be taken by ASRU required to change behaviour and reduce risk.

In this context establishing the `risk of non-compliance` within an establishment aggregates the risk from the governance systems of the establishment and those of project and individual licence holders. These three governance systems are so interlinked they cannot be separated. This assessment thus covers all ASPA-related activities occurring within the establishment.

A full systems audit represents the baseline assessment of compliance and will be supported by additional compliance assurance activities including partial systems audit to explore a particular area of concern, thematic audits, facility audits for changes to designated areas, investigations of potential non-compliance, review of reports submitted and information from other engagements with ASPA.

At this time the criteria for special measures are still being developed and any link between audit activities and special measures will be communicated in due course.

Culture and tone of audit activities

The purpose of audit is primarily supportive and aims to recognise areas where systems are strong to maintain compliance as well as identifying areas where improvements could be made. Although non-compliance may be detected during an audit it is not primarily an enforcement activity but a monitoring and educational activity.

This purpose must be clearly demonstrated by the tone of all ASRU documents and discussions occurring as part of a systems audit.

Frequency of full establishment systems audits

Each establishment will receive a full system audit at least every three years if it does not hold special species and at least every year if it holds special species.

The prioritisation of establishments selected for audits will be on the basis of their non-compliance history for the first cohort and based on overall risk assessment thereafter.

Determination of schedule for establishment systems audits

The Audit Lead within the Compliance Assurance Delivery Team is responsible for scheduling systems audits and assigning individuals to conduct audits in consultation with the Regulatory Delivery Transformation Lead allocated to the Compliance assurance Team and the Compliance assurance Delivery Team Lead.

A minimum of two individuals is required to conduct each systems audit.

Overall Process

1. Communication to Establishment

The establishment should receive formal written notification of the date for a systems audit to be conducted and a request for a ASRU inspection dossier and PPL spreadsheet to be returned within 14 days of the notification. The notification will include:

- The dates and times of the audit
- The ASRU staff who will be conducting the audit
- The purpose of the audit
- What will be required on site during the audit
- How and when feedback will be received after the audit

2. Documents to be requested from establishments and reviewed prior to on-site audit

- These documents will be reviewed prior to finalisation of the audit plan by the staff who will be conducting the audit.
- The purpose of reviewing these documents prior to the audit is to enable the staff conducting the audit to have best possible understanding of the establishment prior to the on-site visit thus ensuring the onsite time is spent on areas requiring highest focus.
- Review of these documents will identify areas of potential strength or weakness for which additional evidence will be obtained during the audit.

The main documents to be requested and the key review points are listed below:

Document(s)	Key review points
Organogram clearly showing all named persons and all animal unit staff	Planning of key interviews
Floor plan for all areas holding animals including Schedule 1 rooms	Planning of facility section of audit. Identifying areas which may be at higher risk of non-compliance
Job descriptions for named persons and role descriptor for AWERB Chair	Confirmation that all named persons have clear inclusion in their job descriptions their responsibilities under ASPA and have sufficient resources/authority to adequately conduct their responsibilities under ASPA.

Document(s)	Key review points
AWERB terms of reference/SOP	Confirmation that all required ASPA functions are included in the AWERB terms of reference
Minutes of last three AWERB meetings	Evidence that all required ASPA functions are adequately addressed in practice
Establishment policy on use of animals	Evidence of holistic policy for use of animals
List of animal facility SOPs	Evidence of completeness of PEL holder governance processes. May identify potential gaps which may need to be explored further during the audit.
Copy of SOP(s) on training and competency*	Detailed evidence of robustness of governance of training and competency
Copy of SOP on maintaining environmental conditions in animal facility and facility security*	Detailed evidence of robustness of governance of facility standards
Copy of SOP outlining process by which the establishment prevents the conduct of unauthorised procedures*	Detailed evidence of robustness of governance of regulated procedures
Copy of SOP for colony management*	Evidence that the management of breeding colonies is in line with the 3Rs.
Copy of SOP for environmental control*	Evidence that there are governance systems for environmental control
Copy of killing register	Evidence that a killing register system is maintained and kept up to date
Copy of extract of source, use and disposal records	Evidence that a system for ensuring tracking of source use and disposal of animals is in place and maintained
(If relevant) Copy of commissioning policy/SOP for any project licence where work is provided for the benefit of others	Evidence that establishment understands the scope of licences within the establishment and that adequate oversight is provided for `service` licences

*Some establishments do not allow the issuing of procedural documents electronically to outside agencies. If this is the case the establishment should provide the establishment policy which confirms this and these Standard Operating Procedures can be reviewed on site, However the audit agenda will need to accommodate additional time for this review.

3. Instructions to Establishments prior to audit

- Each establishment will be requested to provide two rooms for the use of the auditors during the audit if possible.
- In one room documents required must be available (this can be by electronic means where appropriate) and the other will be for the conduct of interviews.
- The room for interviews needs to be large enough to contain the individuals needed for the kick-off and close out meeting (8-10 individuals in most establishments)
- The establishment licence holder, named persons, biostatistician and the AWERB Chair need to be available for interviews as per issued agenda.
- In most cases the identification of personal and project licence holders selected for interview will be communicated ahead of the on-site visit.
- However, all animal unit technicians, personal and project licence holders need to be aware of the audit and advised that they may be selected on a random basis to attend an interview and if they are they need to bring with any copy of source documents related to their training and competency records which the establishment does not hold centrally.
- If any PPL holder holds a service licence (i.e. where work is performed to meet the needs / scientific objectives of other individuals regardless of whether this is performed for payment they should be advised that if called to interview they will be required to bring documentary evidence showing the process they use to commission work on this licence. These individuals will usually be notified early in the audit process to allow some planning.
- Establishments are requested to provide if possible, prior to the audit visit any regulated procedures which are scheduled to be conducted during the days of the audit especially those involving surgery. If this is not possible on the days of the audit a follow up visit as part of the same audit may be arranged.
- The inspectors will require one individual (usually the HOLC) to assist them when they are on site by bringing them documents or communicating requests

Documents to be available to inspectors at time of on-site audit

- Full list of animal facility SOPs and other SOPs / policies relevant to ASPA
- Two printed copies of the floor plans of all areas where animals are held
- Access to full establishment level training and competency records
- Killing register
- Source, use and disposal records
- Animal movement forms (or equivalent)
- Records demonstrating who has accessed areas holding animals

4. Details of the standard components of the on-site visit

The exact audit agenda will vary slightly depending on the purpose of the audit, the nature of the establishment and the outputs of the pre-audit document review. However, the following are likely to be the standard components.

a) Kick off meeting

Briefing meeting with PEL holder, AWERB Chair, Named Persons and Animal Facility Manager.

Where the establishment has a very large number of named persons Lead

Representatives of these named persons will attend these meeting and only a selection of individuals will be interviewed.

- Introduce ASRU staff conducting the audit
- Outline purpose and structure for audit

b) Document Review

Document	Review
Review of selected training and competency records	This will be those who will be interviewed, who may be interacted with on the facility assessment or under whose licence procedures may be observed. This assessment will provide evidence of the establishment oversight of training and competency is occurring in compliance with the stated governance processes. This will also provide evidence of governance systems used by PPL holders to manage their projects
Review of SOPS as required	To assess robustness of governance systems
Killing register	Cross checking of killing register against training and competence records for selected individuals to check completeness and accuracy
Source, use and disposal records and animal movement forms (if appropriate)	Assess robustness of systems to maintain oversight of animal movements

Document	Review
Records demonstrating access to areas holding animals	Assess robustness of security systems and ability to limit access to animals to authorised individuals

c) Structured Interviews

Person / Group	Purpose of Interview
PEL holder	Assessing understand of ASPA and their responsibility. Answering specific questions about PEL governance systems in line with PEL Standard Conditions
AWERB Chair	Assessing understand of ASPA and their responsibility. Answering specific questions about AWERB performance.
AWERB lay member	Assessing understand of ASPA and their responsibility. Answering specific questions about AWERB performance.
Biostatistician	Assessing processes by which experimental design is optimised
NC3Rs programme manager (if appropriate)	Assessment of processes by which 3Rs are addressed at PPL and establishment level
NVS	Assessing understand of ASPA and their responsibility. Answering specific questions including systems for biosecurity, veterinary oversight, AWERB involvement
NACWO	Assessing understand of ASPA and their responsibility. Answering specific questions
NIO	Assessing understand of ASPA and their responsibility. Answering specific questions related to their area of responsibility
NTCO	Assessing understand of ASPA and their responsibility. Answering specific questions related to their area of responsibility
HOLC	Assessing how effectively their role operates within the governance systems of the establishment
Animal Facility Manager	Assessing how effectively their role operates within the governance systems of the establishment
Selection of PPL holders	Assessing understand of ASPA and their responsibility. This should include assessment of the systems in place for them to govern their project
Selection of PIL holders	Assessing understand of ASPA and their responsibility.
Selection of animal technicians	Assessing understand of ASPA and their responsibility.

d) Facility and animal welfare assessment

A walk through of all rooms on the Schedule of Premises including all rooms where Schedule 1 killing is performed. Is ideal where possible

If resource constraints are present which make this impossible a selection of rooms should be inspected on a risk-based basis.

Key purposes:

- Assess overall standards of care and accommodation for animals in alignment with Code of Practice
- Identify any welfare issues present
- Assess security, cleanliness, and environmental conditions in all rooms/facilities
- Assess compliance with systems for cage labelling

e) Inspection of conduct of regulated procedures (if possible)

If possible brief inspection of regulated procedures occurring in the establishment will be performed.

Key purposes:

- To assess conduct of procedure in line with licence authorities
- To assess documentation kept by personal licence holders related to conduct of regulated procedures
- Close out meeting

f) ASRU staff consolidation of evidence

The ASRU staff conducting the audit will take a period of time to consolidate the information they have reviewed and determine high level findings prior to the close out meeting.

g) Close out meeting

The inspectors will hold a close out meeting firstly with the PEL holder and then with the extended team who attended the kick- off meeting.

The key purposes are to:

- Thank all for the assistance in conducting the audit
- Share the draft high- level findings from the audit i.e. any critical or major findings making it clear these may change as the full report is drafted.
- Advise of any separate processes (such as enforcement investigations) which may occur as a result of audit findings without making any comment on specific breaches or potential remedies.
- Answer any questions
- Advise when the formal audit report will be issued and any other follow up processes.

A written record will be kept of the close out meeting including a record of all questions asked and answers provided

Audit review and report within ASRU

- The lead staff member for the audit will draft a report which will be reviewed by the Audit Lead to ensure consistency across audits.
- The report will be shared with the establishment and will include required actions.
- The establishment will have an opportunity to respond to the report and to update on any actions taken.
- Any identified potential non-compliance or assessment for evidence which will be used to assess inclusion in Special measures arising from the audit will be processed according to separate defined processes.
- The lead staff member for the audit will also identify lessons learnt from the audit for ASRU and draw up recommendations based on these.
- The audit findings and rating will be uploaded to the establishment folder and integrated into overall establishment profile so that they are visible to all within ASRU.

Classification of audit findings

Critical:

1. There is evidence to suggest system failure(s) have resulted in or have the potential to result in unnecessary suffering of protected animals, and/or
2. There is evidence of governance systems failure or absence of major governance systems and / or
3. There are a number of major non-compliances (defined below) across different areas, indicating a systematic quality assurance failure, and/or
4. Where inappropriate, insufficient or untimely corrective action has taken place regarding previously reported major non-compliances

Critical findings will always be reported to the enforcement team for further assessment

Major:

1. Where evidence exists that a departure from ASPA has occurred that may not have developed into an issue, but may have the potential to do so unless addressed, and/or
2. Where evidence exists that a number of risks exist within the governance of a single area.
3. Where inappropriate, insufficient or untimely corrective action has taken place regarding previously reported minor non-compliances

Major findings may be reported to the enforcement team for further assessment

Minor:

1. Where evidence exists that a single risk exists within the governance of a single area