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Identification and management of patterns of low-level concerns at licensed establishments

Animals in Science Regulation Unit

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1. Aim and scope

All establishments that use animals in research, under the authority of licences granted under the terms of the Animals (Scientific Procedures) Act 1986, have a duty to be compliant with the requirements of the Act. Compliance is the responsibility of licensees and is monitored and assured by a proportionate regime of inspection from the Home Office.

In 2014 the Animals in Science Committee (ASC) published a report into *Lessons to be learnt, for duty holders and the regulator, from reviews and investigations into non-compliance*¹. The report demonstrated that achieving the requirement of compliance is not just about knowing what one has to comply with, but is determined by a more complex mix of culture, good governance and process. Furthermore, the ASC identified that recognition of early indicators of poor compliance (patterns of low level concerns) would support the Inspectorate and also establishments in monitoring compliance frameworks.

This document provides information on indicators of compliance for establishment licence holders to use as part of their assessment of the effectiveness of their governance systems. It gives examples of indicators of good practice as well as indicators of low-level concerns which can be used to gauge whether an establishment is at risk of non-compliance.

This document describes the approach that is taken when inspectors identify low-level concerns. Such concerns are not of themselves breaches of the Animals (Scientific Procedures) Act (ASPA) or licence conditions but, taken together, form a pattern which could indicate that a management and/or welfare regime may have weaknesses which could pose an increased risk of non-compliance or adverse animal welfare. The intended outcome of our actions is to help establishments reduce those risks. By discussing patterns of low-level concerns with the inspector, the key staff at an establishment can identify steps to strengthen their systems and processes as appropriate.

This document does not therefore deal with the action we take when non-compliance is identified or suspected, nor with isolated low-level concerns that are promptly remedied and do not form part of a pattern.

The document will be reviewed by December 2017.

2. Background

One of the statutory roles of an inspector is, at the direction of the Secretary of State, to report to the Secretary of State on licence authorities issued under the terms of ASPA and with the conditions attached thereto. One of the non-statutory roles of an inspector is to provide case-by-case advice to licensees on how non-compliance can be avoided and to promote a good culture of care at all establishments.

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https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/326003/ASClessonsToBeLearnt2Jul14.pdf

A good culture of care is an environment which is informed by societal expectations of respectful and humane attitudes towards animals used in research. Each establishment will have its own way of conveying its culture of care. However, all establishments are subject to similar governance and legal responsibilities under ASPA to deliver humane care.

The Inspectorate operates a risk-based approach to inspection, targeting additional resource where the risks are perceived to be high or increasing. In this context, 'risk' is considered to cover:

- the risk of unnecessarily poor animal welfare;
- the risk of non-compliance with licence authorities;
- the risk of inadequate consideration of the 3Rs (Replacement, Reduction and Refinement);
- the risk of a sub-optimal culture of care;

leading to:

- the risk of loss of public confidence in the regulatory system;
- the risk of poor quality science or failure to achieve the full benefits from the use of animals.

This document addresses recommendations made in the Animals in Science Committee (ASC) report published in July 2014 entitled, "Lessons to be learnt, for duty holders and the regulator, from reviews and investigations into non-compliance"². In their report, the ASC recognised the difficulties for the regulator in addressing a pattern of low-level concerns at licensed establishments.

Operational instructions for the Inspectorate are maintained as a living document and are subject to regular review. The operational instructions align with and complement the processes described in this document.

3. Ongoing monitoring

3.1 Pre-inspection review

When taking on responsibility for an establishment, inspectors review:

- previous visit reports for that establishment;
- notes prepared by the outgoing inspector and any other relevant documentation; and,
- any other relevant documents.

They also discuss the current and past risks of the establishment with the outgoing inspector. This process provides a fresh assessment of any patterns of low-level concerns that have been recorded.

Before undertaking an inspection visit, inspectors will review any concerns previously identified at recent inspections and determine the most appropriate inspection strategy to monitor progress with addressing the underlying issue.

² <https://www.gov.uk/government/publications/lessons-to-be-learnt>

Inspectors will regularly review patterns of low-level concerns for each establishment assigned to them, following up on how issues are being addressed at future visits and maintaining a dialogue with duty holders³ as necessary.

3.2 Inspection

Benchmarking for acceptable performance will follow requirements in the Guidance on the Operation of the Act⁴ and the requirements and advice provided in the Code of Practice for the Housing and Care of Animals Bred, Supplied or Used for Scientific Purposes⁵ and the controls within and standard conditions attached to licences issued under ASPA. Inspectors will also take account of current good practice in various aspects of ASPA-related business, including reference to guidance from other well-respected bodies, for example LASA, NC3Rs.

Inspectors consider many factors when assessing if there is an emerging trend or pattern of low-level concerns indicating an underlying, systemic problem. These include the factors described further in Appendix A which relate to:

- facilities and animal care;
- staffing, training and competence;
- conduct of regulated procedures;
- record keeping;
- effectiveness of the establishment's Animal Welfare and Ethical Review Body (AWERB); and,
- governance and communications.

Taken together, consideration of these factors will allow an assessment of the culture of care at an establishment. A pattern of low-level concerns suggesting a systemic weakness in one or more areas will be taken into account when assessing the risk of non-compliance at an establishment. This in turn informs the inspection resource assigned to that establishment.

3.3 Post-inspection review

Whenever possible, inspectors discuss low-level concerns identified during the inspection directly with the appropriate role holder(s). This might be one of the named persons or a licence holder, depending on the nature of the concerns. If this conversation cannot take place during the visit then the inspector will telephone the appropriate person as soon as practicable afterwards. The inspector will confirm to appropriate staff that their concerns must be addressed.

For minor or isolated issues, the inspector targets future inspection visits to confirm progress with remedy. Where a pattern of low-level concerns has previously been identified and discussed, the inspector will provide verbal feedback on progress towards remedying the issue to the appropriate role holder(s).

³ A duty holder is anyone with a responsibility under the Act (such as licence holders, animal care staff, named persons).

⁴ <https://www.gov.uk/government/publications/operation-of-aspa>

⁵ <https://www.gov.uk/government/publications/code-of-practice-for-the-housing-and-care-of-animals-bred-supplied-or-used-for-scientific-purposes>

4. Action to be taken

4.1 Identification of a pattern of low-level concerns

When a concern is identified, the inspector assigned to the establishment will assess if this represents an isolated failure to meet expected standards or, combined with previous concerns, indicates a systemic weakness. It is of particular importance to identify concerns about failings with respect to the establishment's standard of provision of care, the effectiveness of the AWERB and overall institutional culture regarding animal welfare and the 3Rs, including the exercise of effective strategic leadership.

The table at Appendix A will be used as a guide to relating issues identified to indicators of concerns. A 'pattern of low-level concerns' is typically the discovery of three separate issues of concern indicating a weakness in the same factor at either a single visit or in subsequent visits within the same year.

Notwithstanding this, should a single issue be identified that may be detrimental to animal welfare the inspector will act without delay.

Careful consideration is required to determine the scale of the pattern of low-level concerns to ensure proportionate and timely action and to decide:

- whom at the establishment to approach and how;
- how to monitor agreed actions;
- what level of action to take; and,
- if the underlying factor is being satisfactorily addressed at the establishment.

If a pattern of low-level concerns is identified, this will usually be discussed with one of the Principal Inspectors (PIs) or other colleagues as appropriate to confirm consistency of approach.

Inspectorate management practice is to hold a risk review meeting quarterly, allowing consideration of the risks posed by patterns of low-level concerns at individual establishments in the context of concerns at other establishments nationally. This ensures that the remedial actions proposed are reasonable and consistent with requirements and expectations elsewhere in the UK and that resource is focused where it is most needed.

The typical decision will be to require the establishment licence (PEL) holder to develop and implement an action plan to address the concerns.

4.2 Implementing an action plan

A typical action plan is:

- discussion with PEL holder to review findings and discuss areas where PEL holder⁶ action is required;
- post-meeting communication: written confirmation of the issues identified and any agreed actions by the PEL holder, and agreed timescales;
- follow-up inspections at the establishment;
- review of outcomes with local role holders; and,
- record outcomes.

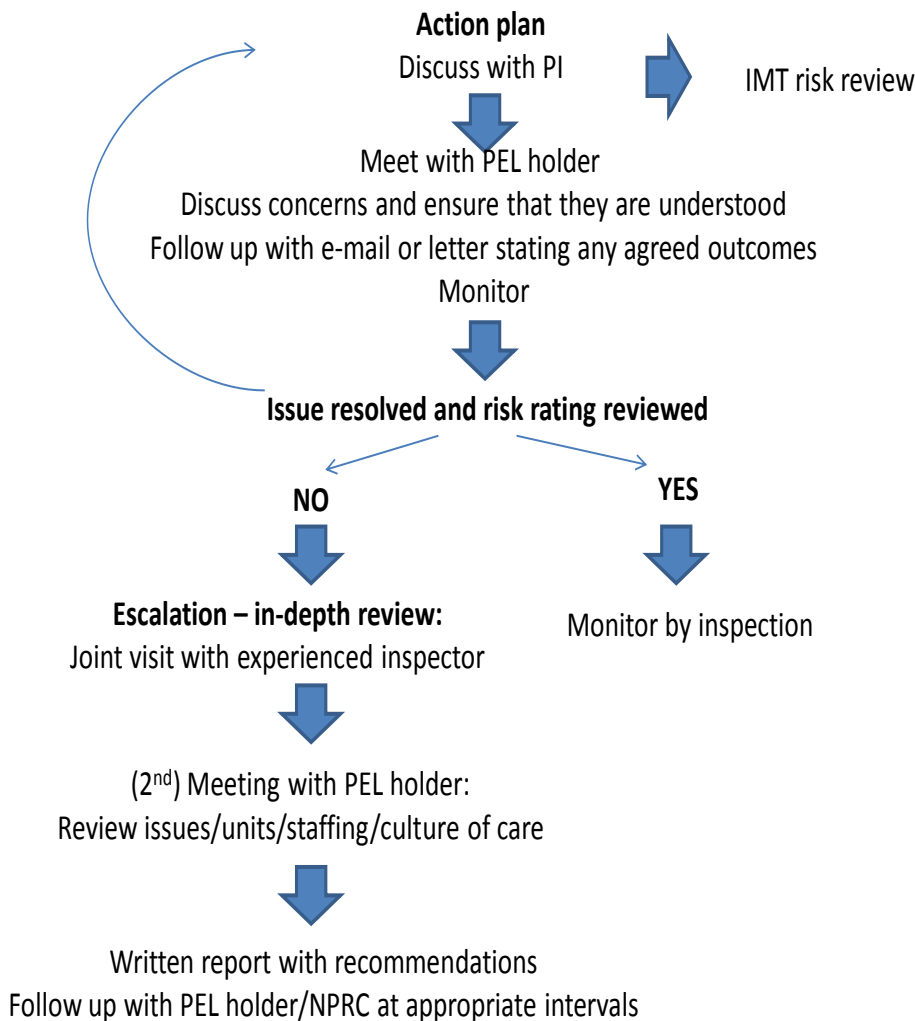
This process will usually result in the concerns being addressed, the underlying issues being remedied and a reduction in the establishment's risk of non-compliance or adverse animal welfare.

Rarely, if the establishment licence holder does not carry out appropriate remedial actions in the agreed, suitable timescale or the action fails to remedy the situation, then the assigned inspector will discuss with the Inspectorate management team (IMT) if the matter should be escalated further.

⁶ In all cases where the PEL holder is specified in this document this includes the named person responsible for compliance (NPRC) where the licence is held by a corporate entity.

4.3 Escalation plan

Figure 1: Summary of the escalation plan when a persisting pattern of low-level concerns is identified



An in-depth review is considered when there is a persisting or increasing pattern of low-level concerns at the establishment that has not been addressed satisfactorily by the establishment. This type of review will only be undertaken where the establishment does not deal with the Inspectorate's concerns in a timely manner and/or serious or multiple deficiencies in governance are identified.

If, as a result of the review, breaches of ASPA or licence conditions are clearly identified then a non-compliance investigation will be undertaken in consultation with the compliance team.

The in-depth review is led by a PI or other experienced inspector with knowledge of the establishment. The review process will formally identify any deficiencies in the establishment's governance and the desired outcomes.

There are several stages in this process:

- review and analysis of information about the establishment, including compliance history;
- discussion of findings with the Chief Inspector (CI);

- joint or independent visit to establishment, if necessary, to assess findings and to reinforce to duty holders the nature and significance of the concerns;
- discussion with PEL holder and invitation of potential remedies;
- review of findings with CI;
- post-visit communication with the PEL holder to discuss findings and invite a response;
- follow up on PEL holder actions by assigned inspector at appropriate intervals to assess progress against the expected timeline for improvements.

5. Desired outcomes

The purpose of any action taken is to draw an establishment back from the brink of non-compliance, for the PEL holder to build competence at their establishment and to improve the resilience of their governance systems.

Outcomes from an action plan or in-depth review may include:

- the establishment achieves consistent good practice – building high-quality internal processes and using quality assurance systems to ensure effectiveness;
- duty holders engage externally to keep abreast of good practice;
- the PEL holder identifies where and how investment may be needed to achieve good standards of care and accommodation and actively seeks ways of achieving this;
- the PEL holder reviews the quality of governance structures and outcomes – sometimes with external input;
- effectiveness of named persons is improved;
- systems of communication improve – sound internal frameworks of communication are developed to minimise the risks of non-compliance and to promote high standards of animal welfare; more effective communication with the Regulator; with others;
- there is effective promulgation of the 3Rs, making good use of the Named Information Officer and the AWERB;
- there are clear training plans for all staff (including personal licencees and technical staff) and competence is regularly and effectively assessed;
- a good culture of care is evident to and embraced by all.

Glossary

3Rs	The Three 'Rs' – Replacement, Reduction, Refinement
ASPA/The Act	Animals (Scientific Procedures) Act 1986
ASRU	Animals in Science Regulation Unit
ASC	Animals in Science Committee
AWERB	Animal Welfare and Ethical Review Body
CI	Chief Inspector
Code of Practice	Code of Practice for the care and accommodation of animals issued under section 21 of ASPA
IMT	The Inspectorate Management Team, comprising the Chief Inspector, the Principal Inspectors and the Operations and Strategy Manager
LASA	The Laboratory Animal Science Association
NACWO	Named Animal Care and Welfare Officer
Named Persons	People with specific responsibilities at an establishment, including the NACWO and NVS
NIO	Named Information Officer
NPRC	Named Person Responsible for Compliance with the terms and conditions of an establishment licence
NTCO	Named Training and Competency Officer
NVS	Named Veterinary Surgeon
PEL	Establishment licensed under ASPA
PELh	Establishment licence holder (or NPRC where the establishment is held by a corporate entity)
PI	Principal Inspector; an experienced inspector with line management responsibilities
PIL	Personal licence
PPL	Project licence
RCVS	Royal College of Veterinary Surgeons
RSPCA	Royal Society for the Prevention of Cruelty to Animals

Appendix A

Examples of indicators of low-level concerns

Note: This is not an exhaustive list and other factors are also inspected and assessed. In particular, the effectiveness of named person performance is assessed being mindful of the following criteria:

- quality of relevant technical knowledge;
- engagement/accessibility to other duty holders;
- effectiveness of communication;
- commitment to continued professional development;
- quality of record keeping; and,
- approach to role and responsibilities.

Factor: Facilities and animal care	Indicators of good practice	Indicators of low-level concern
Is the establishment adequately resourced, including staffing?	<p>Good staff relationships with positive team-working by duty holders</p> <p>Staff numbers appropriate to the size of the establishment, type of work and type of animals</p> <p>Low turnover of staff and minimal need for agency staff to 'plug the gaps'</p> <p>Sufficient time and resource for daily, adequate routine monitoring</p>	<p>Care staff appear overburdened and/or unsupported by management</p> <p>Staffing levels seem low compared to units with a similar volume of work</p> <p>Key staff lack experience of the animals and work</p> <p>High staff turnover Disgruntled, demotivated, uninterested staff who indicate that they feel undervalued</p> <p>Frequent unexplained staff absences</p> <p>Unpopular management/ employment issues or other difficult staff relations</p> <p>Inadequate staffing cover at weekends. Higher animal mortalities at weekends</p> <p>Corners being cut to the potential detriment of animal welfare</p> <p>Lack of resilience to cope with natural fluctuations in staffing or unexpected equipment failure</p>
Are facilities appropriate for the type of animals held?	The holding rooms, procedure and service rooms are appropriately designed to enable care and tasks to be carried out in a hygienic and safe environment	<p>Poorly designed or makeshift accommodation</p> <p>Poorly controlled environmental parameters</p>

	Cages/tanks comply with Code of Practice and advisory standards	
Is there evidence of proactive and reactive maintenance of facilities and equipment?	A suitably planned maintenance, repair and replacement programme for infrastructure and equipment Effective emergency response systems	Deterioration in the fabric of the building, which might have detrimental effects on animals No planned maintenance programme/equipment not kept in good repair Emergency procedures fail when tested
Is environmental enrichment provided for all animals?	A sound environmental enrichment strategy is employed	Inconsistent use of environmental enrichment with no overall strategy of provision
Factor: Staffing, training & competency	Indicators of good practice	Indicators of low-level concern
Is the NVS visible, engaged and effective?	Specialist knowledge of the species and models used Regular visiting regime with sufficient availability for the provision of advice Regular reports, input into methods, timely advice on post-mortems of animals Proactively provides advice and training relating to aseptic surgery, anaesthesia and analgesia Clinical records meet RCVS standards and are easily accessible to animal technicians	Infrequent visits and contact with named persons. Anaesthetic/analgesic practices out of date Poor aseptic technique by personal licensees NVS does not routinely engage with scientists to promote refinements Does not challenge poor quality science, welfare or husbandry
Are NACWOs knowledgeable and effective and supported by the PELh?	NACWO appropriately supported and empowered by the PELh and senior management Well respected and a role model for junior technical staff Good attention to facility fabric and standards of hygiene and tidiness Regular liaison with PPL holders and personal licensees through meetings and with other named persons Awareness of the licensees	Dirty and/or cluttered corridor; inappropriate storage of materials in procedure and holding rooms and rooms not in use are often left dirty and/or untidy Overburdened by paperwork and rarely enters the animal unit/ insufficiently directly involved with animal care Poor knowledge of research going on in their unit, humane endpoints and their role in relation to the animal use

	<p>working in the unit and the type of work undertaken by them</p> <p>Expert in the husbandry and care of the species and types of animals they are responsible for</p> <p>Well organised</p>	Does not actively participate in the AWERB process
Is the NTCO active and effective?	<p>Understands their role and responsibilities</p> <p>Keeps up to date with developments in training and supervision</p> <p>Good system for managing contemporaneous training files</p> <p>Engages with other NTCOs and external networks</p>	<p>Little understanding of the role</p> <p>Lacks time to fulfil role effectively</p> <p>Training files are kept in an inconsistent format</p> <p>No system for regular review and reassessment of competence</p>
Is the NIO proactive and effective?	<p>Understands their role</p> <p>Enthusiastically and pro-actively gathers and disseminates relevant information</p> <p>Knows how to find appropriate sources of information</p> <p>Has adequate resource for the role</p>	<p>NIO has little guidance on and support for their role</p> <p>Duty holders not aware who the NIO is or what their function is</p> <p>Has little or no knowledge about the animal work at the establishment</p>
Factor: Governance & communications	Indicators of good practice	Indicators of low-level concern
Is the establishment licence holder visible, engaged and effective?	<p>PELh is knowledgeable about the Act, the 3Rs and issues at their establishment</p> <p>PELh is well respected by scientists and technical staff</p> <p>Regularly meets with named persons and AWERB</p> <p>Where another person acts for the PEL holder, regular meetings are held with the PEL holder</p> <p>Supports named persons</p> <p>Attends event for PELhs and keeps up to date with Home Office communications</p>	<p>PELh disinterested and relies on others for knowledge of the Act.</p> <p>Does not engage with the inspector</p> <p>PELh rarely visits facilities or meets with AWERB chair or named persons</p> <p>PELh lacks influence and/or respect</p>
Are there good working relationships between animal	Regular meetings to allow two-way communication	Animal technologists are disinterested in their work

<p>technologists and scientists?</p>	<p>Animal technologists and scientists working together to provide care of the animals</p> <p>Animal technologists are knowledgeable about the purpose of the work, likely adverse effects and the relevant humane endpoints</p> <p>Clear audit trails of communications between scientists and animal technologists</p>	<p>Scientists rarely discuss studies with animal care/technical staff</p> <p>PPL holder appears disengaged with animal work/project and personal licensees are “too busy” to check animals themselves and/or feel it is a burden for them to do so</p> <p>Animal technologists have poor knowledge of research going on in their unit and their role in relation to the animal use</p> <p>Poor understanding and delineation of roles and responsibilities by duty holders</p>
<p>Is there an effective system by which staff can raise their concerns?</p>	<p>A clear system is advertised whereby concerns can be raised, including anonymously</p> <p>It is made clear that anyone raising a concern will be properly supported by management</p>	<p>Disproportionate number of concerns being raised with the assigned inspector rather than using the establishment’s internal communication mechanisms</p> <p>No local mechanisms for staff to raise their concerns</p>
<p>Factor: Regulated procedures</p>	<p>Indicators of good practice</p>	<p>Indicators of low-level concern</p>
<p>Are personal licensees properly supervised, knowledgeable and their competency checked?</p>	<p>A planned training programme taking trainees from induction through to competency</p> <p>Well-maintained, contemporaneous training records</p> <p>A planned programme to review and reassess competency</p>	<p>Absence or difficulty in auditing training records</p> <p>Records are out of date and generally poor standard of record keeping</p> <p>Inadequate supervision evident on inspection or from the training records</p> <p>No evidence of how ongoing competence is assessed and recorded</p>
<p>Is the standard of asepsis during surgery acceptable?</p>	<p>NVS provides regular advice on aseptic technique and peri-surgical care</p> <p>The Guiding Principles for preparing and undertaking aseptic surgery published by LASA in 2012 are followed</p>	<p>NVS does not provide advice or advice is not taken</p> <p>Poor or variable standards of aseptic technique</p> <p>Poorly organised surgery/poor infrastructure to support the performance of aseptic surgery e.g. sterile kits, gloves</p> <p>Evidence of poor post-operative</p>

		outcomes and infections
Is analgesia used appropriately?	NVS advice on anaesthesia and analgesia readily accessible and always followed	Variable use of analgesia
Are licences readily available?	Project and personal licence details easily accessible to relevant staff	Licence authorities are not routinely checked before conducting procedures
Factor: AWERB	Indicators of good practice	Indicators of low-level concern
Is the Animal Welfare & Ethical Review Body (AWERB) active, engaged and effective?	<p>Regular meetings and feedback to PPL holders and the PEL holder</p> <p>Reasonable quality of PPL applications and amendments submitted to the Home Office</p> <p>All mandatory functions undertaken, not just consideration of PPL applications</p> <p>Members attend national meetings, such as the RSPCA Lay Members' Forum</p> <p>RSPCA/LASA Guiding Principles on Good Practice for AWERBs are followed</p>	<p>Fast-tracked PPLs with little scrutiny of the application</p> <p>Poor-quality or incomplete licensing paperwork regularly received by ASRU</p> <p>Infrequent and erratic AWERB meetings</p> <p>Poor engagement of committee members at AWERB meetings/ inadequate input from the NVS and NACWO</p> <p>AWERB discussions and outputs compromised by local management influences resulting in a reluctance for members to speak openly</p> <p>Poor discussion of 3Rs</p> <p>Poor consideration of animal housing, enrichment, welfare and operational processes to improve these</p> <p>Scientists do not respect AWERB outputs</p>
Factor: Records	Indicators of good practice	Indicators of low-level concern
<p>Is record keeping of an acceptable standard?</p> <ul style="list-style-type: none"> Do personal licensees and other role holders have clear training plans and records? Are establishment licence holder's records of acceptable content and quality? Are PPL and PIL records of acceptable content and quality? 	<p>Planned training programme for individuals across the establishment with planned review and reassessment</p> <p>Proactive NTCO</p> <p>All required records maintained contemporaneously and made available to all those who need to see them</p>	<p>Evidence of poor record keeping</p> <p>Incomplete or inadequate killing register</p>
Factor: Breeding &	Indicators of good practice	Indicators of low-level

maintenance		concern
<p>Is breeding carried out efficiently?</p>	<p>Clear management plans and control of surplus animals</p> <p>Consideration of options to minimise the breeding of surplus animals such as freezing down lines or importing lines that are rarely used</p> <p>Good planning and experimental design to minimise wastage/ good communications with users</p> <p>Active and informed colony management</p>	<p>Excess breeding animals and progeny awaiting genotyping</p> <p>High rates of culling of unused animals</p> <p>Poor colony key performance indicators</p>