



Home Office

# **Animals in Science Regulation Unit Compliance Policy**

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## Glossary

3Rs	The principles of replacement, reduction and refinement
AI	Assigned inspector responsible for inspecting an establishment
ASPA	The Animals (Scientific Procedures) Act 1986
ASRU	The Animals in Science Regulation Unit, a part of the Home Office
AWERB	Animal Welfare and Ethical Review Body
CT	Compliance Team
NACWO <sup>1</sup>	Named Animal Care and Welfare Officer
NPRC <sup>2</sup>	Named Person Responsible for Compliance
NVS <sup>3</sup>	Named Veterinary Surgeon

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<sup>1</sup> Each establishment licensed under ASPA has one or more named animal technologists responsible for the care and welfare of animals bred and used there.

<sup>2</sup> Most establishment licences are held by individuals, 'Establishment Licence Holders', who also act as the NPRC. Some establishment licences are held by a corporate entity, in which case an individual is named as the NPRC.

<sup>3</sup> Each establishment licensed under ASPA has one or more NVS responsible for the health and welfare of animals bred and used there.

# 1 Introduction

The Animals in Science Regulation Unit (ASRU) is the unit within the Home Office that regulates the use of animals in experiments and testing under the [Animals \(Scientific Procedures\) Act 1986](#) (ASPA). As the regulator, ASRU seeks to set, uphold and advance standards of conduct and compliance at all establishments licensed under ASPA.

This document explains how ASRU identifies and investigates potential incidents of non-compliance and decides on appropriate and proportionate measures and sanctions aimed to minimise the risk of recurrence. This document is primarily aimed at those who work within the life science research community under ASPA, but will also be of interest to those wishing to know more about how ASRU regulates.

## 1.1 Who is responsible for ensuring compliance?

Every establishment licensed under ASPA has a Named Person Responsible for Compliance (NPRC). This individual is personally responsible for ensuring compliance with all the conditions placed on their establishment licence. Good compliance goes hand in hand with a good culture of care at an establishment, meeting both the letter and the spirit of the law. The NPRC must have in place robust systems and frameworks that support and encourage compliance. By so doing, they can ensure that all licensees (both personal and project licensees) comply with their licences when working at their establishment.

## 1.2 Better regulation and enforcement

In common with all UK regulators, ASRU operates under the Regulators' Code.<sup>4</sup> The Code's principles are that regulators should:

- carry out their activities in a way that supports those they regulate to comply and grow;
- provide simple and straightforward ways to engage with those they regulate and hear their views;
- base their regulatory activities on risk;
- share information about compliance and risk;
- ensure that clear information, guidance and advice is available to help those they regulate meet their responsibilities to comply; and
- ensure that their approach to their regulatory activities is transparent.

This policy document is issued to strengthen compliance with the Regulator's Code.

Compliance is facilitated by ASRU in a number of ways.

Guidance. The key resources are the *Guidance on the Operation of the Animals (Scientific Procedures) Act 1986*<sup>5</sup> and the *Code of Practice for the Housing and Care of Animals Bred, Supplied or Used for Scientific Purposes*<sup>6</sup>. All Home Office publications relating to the use of animals in research can be found at:

<https://www.gov.uk/guidance/research-and-testing-using-animals>.

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<sup>4</sup> See: <https://www.gov.uk/government/publications/regulators-code>

<sup>5</sup> Published in March 2014. See: <https://www.gov.uk/government/publications/operation-of-aspa>

<sup>6</sup> See: <https://www.gov.uk/government/publications/code-of-practice-for-the-housing-and-care-of-animals-bred-supplied-3or-used-for-scientific-purposes>

- Through a programme of risk-based inspection providing opportunities for inspectors to advise on addressing patterns of low-level concerns – see section 1.5.
- Through the application of remedies – see sections 5 and 6.

## 1.3 Openness and transparency

The public expects the highest attention to animal welfare and compliance in animal research. Nevertheless, ASRU recognises that, occasionally, mistakes happen. If mistakes are ignored or go unrecognised this can pose further risk to animal welfare and is also damaging to the culture of care. In this context a 'blame' culture is counterproductive. Fear of blame can adversely affect openness both within establishments and between establishments and ASRU. ASRU aims to foster a culture that encourages duty holders to learn from their own and each other's mistakes and to be open when things go wrong.

Openness and transparency is important for building trust and promoting accountability. Therefore, summaries of all cases of non-compliance dealt with by the Compliance Team are published on a yearly basis in the *ASRU Annual Report*. Since 2014 more detailed anonymised reports of substantial cases are also published on the ASRU website<sup>7</sup>. ASRU believes that these reports will help stakeholders to learn from the outcomes of investigations at the earliest opportunity; establishments can reflect on their own standards and identify areas of risk, thus creating a continuous cycle of improvement.

## 1.4 What is non-compliance?

Non-compliance with ASPA may be either a breach of the provisions of the Act itself, or a breach of the conditions applied to a licence. A set of standard conditions is applied to all establishment, project and personal licences. Some licences may have additional conditions applied, for example:

- reporting conditions;
- limiting conditions; or
- requirements to adhere to guidance on use of neuromuscular blocking agents.

All conditions must be complied with.

## 1.5 Risk-based inspection

ASRU takes a risk-based approach in determining the number of inspection visits each year<sup>8</sup>. All establishments are assessed in terms of whether they are low, medium or high risk. 'High risk' does not necessarily imply poor performance or a high likelihood of non-compliance; it may be associated with the use of sensitive species or severe procedures. In addition to the requirement for a risk-based approach, ASPA also requires that at least one-third of user establishments and all establishments keeping non-human primates are inspected every year. In practice ASRU aims to inspect all establishments at least once a year. The majority will be visited more frequently.

The frequency of inspection is determined by a number of factors including:

- the volume of work carried out at the establishment;
- the type and number of species used or kept; and

<sup>7</sup> See: <https://www.gov.uk/government/publications/compliance-investigations-by-the-animals-in-science-regulation-unit>

<sup>8</sup> See Chapter 11 of the Guidance above.

- the severity of the work.

The risk-based programme of inspections is carried out by a team of inspectors, each of whom is assigned a number of establishments for primary inspection duties. Inspections are undertaken, often without notice, to determine if licences are being complied with. Further, inspectors report to ASRU on compliance and, where potential non-compliance is noted, inspectors advise on the action to be taken (see Figure 1, section3).

The same inspectors evaluate project licence applications at their assigned establishments. This means that the assigned inspector has a good understanding of the scientific programmes of work being conducted including:

- the justification for using animals;
- the procedures involved; and
- the application of the principles of replacement, reduction and refinement (the 3Rs).

The inspector can build up a relationship of trust with the establishment, which helps to develop a collaborative approach to fostering improvements in animal care and practices. As well as reporting on the inspections to the Secretary of State, inspectors feed back their findings to key role holders at the establishment to encourage continuous improvement.

Through a structured and systematic programme of inspection ASRU can ensure that, over the course of a number of inspections, all the necessary elements at that establishment are checked. The outcomes of the inspection programme are:

- improved compliance with ASPA;
- increased attention to the 3Rs;
- dissemination of good practices and behaviours relating to the care and use of animals; and
- the encouragement of a culture of continuous improvement.

ASRU's programme of inspection is designed to provide public reassurance that scientific work using animals is being conducted in compliance with both the letter and the spirit of ASPA, resulting in high quality scientific outcomes with the minimum of animal suffering.

## 1.6 Policy review

During 2016 ASRU undertook a review of compliance operations and policy in order to:

- embed the principles of good regulation;
- continue to improve the efficiency and effectiveness of enforcement processes; and
- work with the research community to improve the openness and transparency of ASRU's operations and decision making.

There were three main strands to this review:

- an ongoing internal review of operations and sanctions;
- consideration of the lessons learned from some complex cases investigated during 2015; and
- outputs from establishment licence holder focus group conversations held in 2016.

This document is the result of that review.

## 2. Culture of care

A good culture of care is the starting point for a culture of compliance. The Animals in Science Regulation Unit (ASRU) expects every establishment that breeds or uses animals to have a culture that:

- expects caring and respectful attitudes and behaviour towards animals; and
- encourages acceptance of responsibility and accountability in all aspects of animal care and use.

Under the Animals (Scientific Procedures) Act 1986 (ASPA), role holders have specific personal responsibilities. ASRU has expectations as to how Named Persons – the Named Person Responsible for Compliance (NPRC), the Named Veterinary Surgeon (NVS), Named Animal Care and Welfare Officer (NACWO), Named Training and Compliance Officer (NTCO) and Named Information Officer (NIO) – perform effectively. Their personal duties are laid out in the *Guidance on the Operation of the Animals (Scientific Procedures) Act 1986*, see in particular Chapter 8. An effective network to support a good culture of care, and therefore compliance, is developed by each of these role holders acting effectively in their individual roles and by communicating well with others both within and outside the establishment.

Key factors that represent an appropriate culture of care within an establishment include:

- appropriate and professional behaviour and approaches by all;
- a proactive, corporate commitment to high standards;
- shared responsibility, combined with individual responsibility, towards animal care, use and welfare;
- effective lines of communication at all levels both within the establishment and to the external community;
- good knowledge of individual roles and responsibilities;
- effective and well supported animal technologists and named persons;
- a 'no blame' culture, with effective channels for raising concerns, where people know that they will be supported both when raising concerns and acting upon them;
- high quality education and supervision;
- effective training, including competence assessments and benchmarking;
- efficient administrative practices;
- a culture of checking licence authorities before starting any new set of experiments; and
- sufficient time and resources allocated for daily, meaningful routine monitoring of all animals.

### 3. Investigation/process

Potential non-compliance may be discovered during the course of a visit to an establishment by the inspector or as a result of discussions about particular issues with licensees. However, incidents investigated are commonly those reported to the Animals in Science Regulation Unit (ASRU) by the licensee or others at the establishment.

Self-reporting indicates that an establishment is making efforts to ensure compliance. It demonstrates that role holders are aware of their responsibilities and are committed to building a good culture of care. ASRU expects self-reporting to be embedded within good governance frameworks and that employees are aware of the process for raising concerns within their establishment.

Details of the process for dealing with non-compliance can be found in Chapter 12 of the *Guidance on the Operation of the Animals (Scientific Procedures) Act 1986 (ASPA)*.

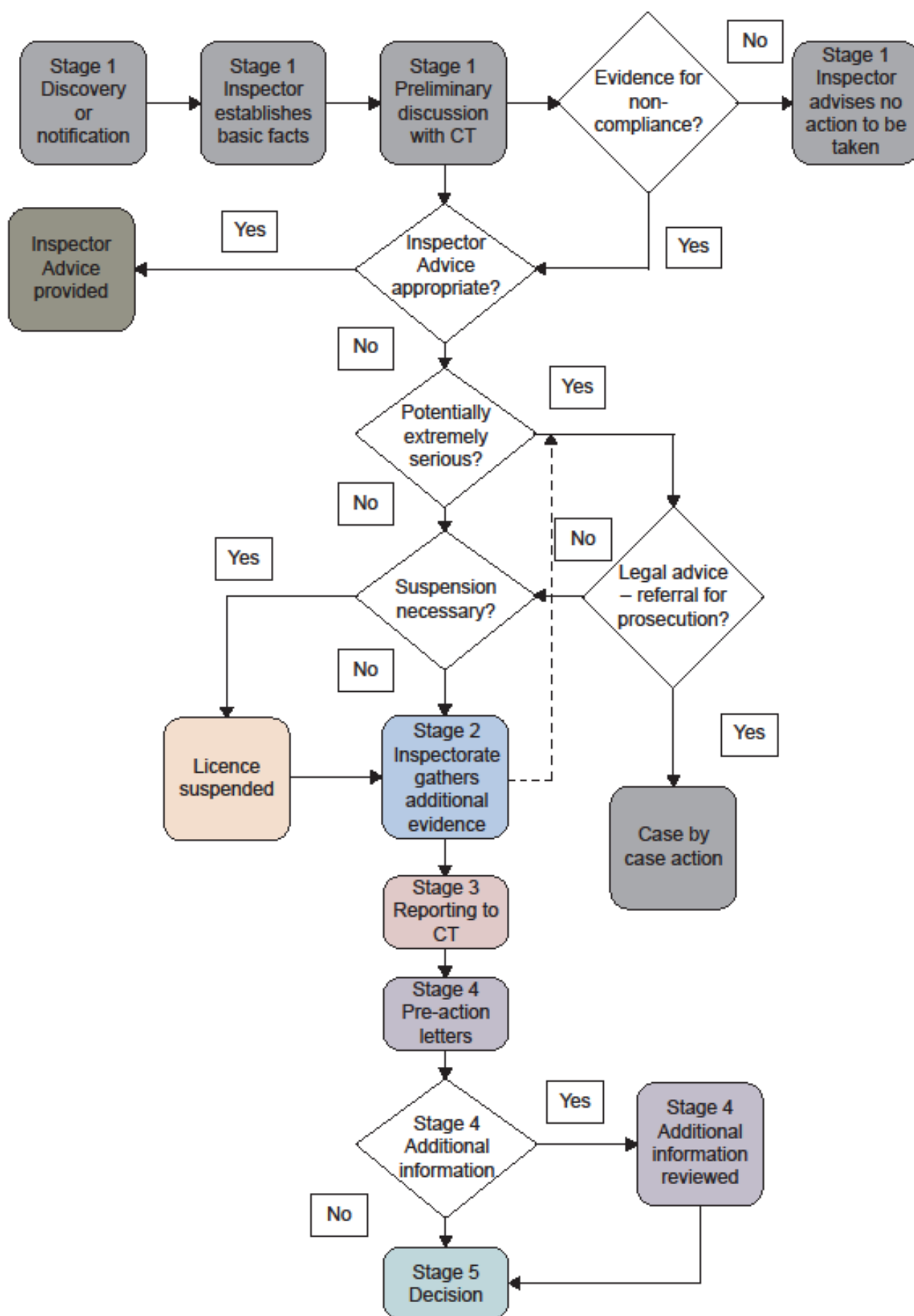
The ASRU Compliance Team (CT) is responsible for overseeing the conduct of an efficient and effective compliance process. This allows all cases to be considered fairly and consistently and provides reassurance that decision making is reviewed by people with particular expertise and oversight of all cases.

The process is illustrated in Figure 1.

ASRU actions can be divided into a number of stages:

- Stage 1 – Notification
- Stage 2 – Evidence gathering
- Stage 3 – Reporting
- Stage 4 – Pre-action consideration
- Stage 5 – Decision
- Stage 6 – Monitoring

Figure 1: Flow chart of non-compliance process





## Stage 1 – Notification

This stage starts with the potential non-compliance coming to the assigned inspector's (AI's) attention, either directly from the establishment or through intelligence gathering during the course of an inspector's duties, published information or other sources. The AI will undertake preliminary discussions with key players at the establishment, review the information and discuss as necessary with the CT as soon as practicable, typically within five working days of discovery or notification.

- Where no potential breach is identified, the AI will monitor any concerns through the inspection process.
- If there is evidence for only minor breaches, the AI will provide 'Inspector Advice' (see section 5.1) and monitor the concern through the inspection process.
- In all other cases the AI will investigate further (Stage 2).
- In potentially serious cases the Chief Inspector will be informed.

### Suspension of a licence

ASRU may need to take immediate action to safeguard the welfare of animals pending the outcome of the investigation. Usually, appropriate action will be taken by the establishment. The Secretary of State will take action if there is an urgent welfare need to do so, including the suspension of a licence for up to three months at a time. If a licence is suspended, the Secretary of State has a duty to ensure that the welfare of animals is not adversely affected by the suspension.

## Stage 2 – Evidence gathering

The AI will carry out an investigation to gather evidence in a timely and proportionate manner. The purpose of the investigation is to establish and agree the facts of the case.

Where a case appears to be particularly complex or serious, or where there is conflicting or disputed evidence, the AI may be accompanied by another inspector to support the investigation and/or take notes, or by another member of ASRU to help with taking contemporaneous notes. The evidence gathered by the Inspectorate is reviewed with key people from the establishment either at the time of meetings or soon as practicable afterwards.

During the investigation process the AI will seek to identify any underlying cases for the non-compliance, such as weak governance systems, poor attitudes to the regulatory system, negligence, lack of knowledge by an individual or team or simple human error.

- Where no breach is identified, the AI will monitor any remaining concerns through the inspection process.
- If there is evidence for only minor breaches (see section 5.1), the AI will provide advice as above.
- In other cases the AI will complete a report to the Secretary of State (Stage 3).
- If the evidence suggests serious avoidable harm, a serious failure of governance or apparent wilful disregard for the provisions of ASPA then a prosecution referral is considered. In such cases legal advice will be taken.

## Stage 3 – Reporting

The investigating inspector will typically submit a report in a standard format to the CT within 30 working days of the discovery or notification of potential non-compliance. The report includes:

- details of the incident;
- the circumstances of the incident – what happened, where, when and who was involved;
- the evidence for the breach; and
- any areas of uncertainty or dispute.

The report will also note any aggravating or mitigating factors (see section 4.2) that should be considered and note actions already taken at the establishment to minimise suffering and/or to reduce the risk of a recurrence.

The AI will summarise their view of the provision(s) breached.

All reports are reviewed and summarised by a Lead Inspector in order to:

- provide a second opinion on the case; and thus
- ensure a consistency of approach to recommendations and remedies.

The Lead Inspector provides a provisional Inspectorate recommendation, including the reasoning for these recommendations.

The Senior Compliance Manager will review the report on behalf of the Secretary of State using the principles outlined in section 4. In cases of uncertainty or dispute, the case may be referred to the Chief Inspector or Head of ASRU, whose opinion will override that of all others.

Where the provisional remedies are agreed and Inspector Advice is not appropriate, the case will proceed to Stage 4.

## Stage 4 – Pre-action consideration

Typically within five working days of receiving a Stage 3 report, 'pre-action' letters will be sent to all those against whom provisional sanctions have been recommended. These letters include a summary of the reported facts and invite the recipient to clarify the facts and/or provide additional information. Typically these letters include any mitigating or aggravating factors that are being taken into consideration.

Response is invited within 28 calendar days. All responses received within 28 days will be reviewed and the final remedies determined.

## Stage 5 – Decision

The final decision as to sanctions or remedies is taken by the Senior Compliance Manager on behalf of the Secretary of State. This decision is based on recommendations from the Inspectorate, and takes account of all information supplied in the Inspectorate report or by other means. Particularly complex or serious cases will be discussed with legal advisors, as necessary, and the Chief Inspector and/or Head of ASRU will be kept informed as appropriate. In cases of particular concern, the Minister may be kept informed of progress.

The range of remedies and the rationale for their use is discussed further in section 5.

Where the proposed remedy is revocation or variation of a licence, for example to require a report or retraining, the CT must serve a notice on the holder of the licence in accordance with Section 12 of ASPA. This allows the licence holder 28 days to make representations about the sanctions to the Chief Inspector and/or Head of ASRU before they are applied.

## **Stage 6 – Monitoring**

In all cases, the AI will consider the underlying causes of non-compliance when planning future compliance inspections. See section 6 for desired outcomes.

## 4. Principles of decision making

In determining the remedies to be applied, deliberate non-compliances are viewed more seriously than those due to an error. Repeated failures are generally viewed more seriously than single incidents; and, significant avoidable animal suffering will increase the gravity of the case. Attempts to conceal the facts will be viewed most seriously. The Animals in Science Regulation Unit (ASRU) will also take a view as to whether or not the licensee is likely to behave appropriately in the future and what type of remedy is appropriate to drive this.

### 4.1 Individual approaches

Other regulators have devised and used a 'compliance and engagement spectrum' to describe different sectors of the regulated community<sup>9</sup>. These can be adapted and characterised for the animal research community as follows.

- **Champions** actively strive to create a good culture of care supported by strong systems of governance and succeed in doing so. They are highly effective licence holders.
- **Compliant** duty holders have a good level of knowledge and strive to comply. A failure to comply is often due to simple human error.
- **Confused** duty holders are careless or lacking in knowledge and are therefore at a higher risk of non-compliance. Non-compliance is not deliberate. It may be due to incorrect interpretation of licence authorities or weak leadership or communication.
- **Resistant or reckless** duty holders display a poor attitude to care for animals and for application of the principles of replacement, reduction and refinement (the 3Rs). ASRU would not wish people who persist in these attitudes to hold Animals (Scientific Procedures) Act 1986 (ASPA) licences.
- **Disengaged** individuals do not want to comply with the legal framework. This type of person would not be suitable to hold an ASPA licence.

Establishments themselves play a role in ensuring compliance by supporting the 'champions' and 'compliant duty holders', in guiding the 'confused duty holders' and educating the 'resistant'. ASRU expects establishments to take proactive action to manage the attitudes of any persons identified as 'resistant' or 'disengaged' and consider their suitability before agreeing that they can apply for a licence.

The remedies applied by ASRU aim to target the confused and resistant duty holders, with a sliding scale of remedies aimed to address the underlying issue requiring improvement. The intention is to apply the right remedy in the right situation, taking the licensee's attitude (which includes their efforts to comply) into account.

### 4.2 Aggravating and mitigating factors

When coming to a decision, ASRU takes into consideration aggravating and mitigating factors, for example:

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<sup>9</sup> See, for example: <https://www.sepa.org.uk/media/117142/better-environmental-regulation-consultation-document.pdf>  
<https://www.sepaview.com/2015/03/regulating-for-behaviour-change/>

- What was the degree of avoidable suffering? Four levels of avoidable harm are considered:
  - **no avoidable harm**;
  - **minor avoidable harm**;
  - **significant avoidable harm** (involving a major but brief, or a minor but prolonged departure from the animal's usual state of health or wellbeing); and
  - **serious avoidable harm** (involving a major and extended departure from the animal's usual state of health or wellbeing, or severe pain or severe distress).
- How many animals were affected?
- Was there negligence?
- Were procedures undertaken competently?
- Were the actions scientifically sound and could they potentially have been authorised under ASPA?
- Is there a history of good compliance or is this incident part of a pattern of persistent concerns?
- Was the case reported by the individual involved or by the establishment's governance systems?
- Have remedial actions been taken promptly?
- Have serious weaknesses in systems, processes or governance been identified?
- Was there a knowing disregard for the controls of ASPA?

All relevant factors will be considered, including what actions have immediately been taken by the establishment or individuals to minimise further avoidable suffering and reduce the risk of a similar breach in the future. ASRU will take a view as to whether the incident represents, for example:

- a simple human error with a low risk of repetition;
- a lack of knowledge or lack of competence with the risk of repetition;
- inadequate attention paid to animal care or the application of the 3Rs; or
- an intentional attempt to subvert the controls of ASPA.

## 5. Remedies

The Animals in Science Regulation Unit (ASRU) aims, by providing guidance and advice, to build capability within the biosciences community to comply with their legal responsibilities. Nevertheless, there are times when action is necessary. Remedies are designed to change behaviour to comply with regulatory requirements or educate regarding points of law, personal responsibilities or application of the principles of replacement, reduction and refinement (the 3Rs). Remedies are also selected to encourage the strengthening of governance, processes and systems where these are found to be weak. The remedies applied need to be adequate to maintain public confidence in the regulatory system.

There are a range of remedies available, including:

- inspector advice;
- letters recording the case;
- requirements for re-training; and
- variation, suspension or revocation of licences.

The most serious cases may be referred to the prosecuting authorities. This happens very rarely.

### 5.1 Inspector Advice

Where there is a minor breach the inspector will provide advice stating what provision was breached and what is expected in the future. A minor breach is one where:

- there are no or minor avoidable adverse animal welfare consequences;
- the facts are agreed;
- there was no intention to subvert the controls of ASPA; and
- the risk of a recurrence is judged to be low.

The aim is that the issue is resolved immediately or within a few days and that all at the establishment who need to know about the incident are kept informed, so that lessons can be learned. The advice may be provided orally to the relevant people and may be followed up in writing.

Minor isolated technical breaches may be appropriately dealt with in this way.

### 5.2 Compliance letters

Where Inspector Advice is not considered adequate most cases are dealt with by a letter from ASRU, with or without a variation of the relevant licence. Where a breach has been committed by a licensee, a letter of reprimand is sent. Where a non-licensee has contributed significantly to the breach, a letter of censure may be sent.

Letters note the breach(es) that have occurred and summarise the evidence for those breaches. The letter is a formal record of non-compliance that will be taken into account should there be a further breach within five years. All letters are copied to the Named Person Responsible for Compliance (NPRC) so that they can review local practices and processes.

A letter without variation of the licence is proportionate where there has been:

- no intent to subvert the controls of ASPA;
- no deliberate cruelty by omission or commission;
- the underlying cause of the breach has been remedied; and
- there is no indication that lack of knowledge or poor attitude contributed to the breach.

## 5.2.1 Variation of the licence

### 5.2.1.1 Requirement for retraining

Retraining, usually in accredited module training, is required where a duty holder has demonstrated that they do not have the expected level of knowledge. For example:

- retraining in module L where deficiencies in knowledge of the law are apparent;
- retraining in modules PILA where deficiencies in species-specific knowledge are apparent;
- retraining in PILB or PILC where anaesthesia or surgery have been inadequate;
- retraining in module PPL where deficiencies in the knowledge of the responsibilities of a project licence holder are apparent;
- retraining under supervision where deficiencies in technical competence are apparent.

### 5.2.1.2 Requirement for reporting

Where action is required to improve weaknesses identified by the breach, including poor record keeping, a report would typically be required to monitor progress. Reports are also useful for formally monitoring improvements in scientific outcomes or the implementation of refinements.

### 5.2.1.3 Suspension

Where a breach has been identified, licences can be suspended as a sanction, where it is appropriate to do so. Animal welfare must be safeguarded in such circumstances. This is likely to be appropriate where a requirement for retraining has been identified and there are considered to be ongoing risks to animal welfare until retraining is completed.

## 5.3 Compliance Notice

Any licence holder (personal, project or establishment) can be issued with a Compliance Notice.

A Compliance Notice is issued where ASRU requires particular action to be taken to prevent further non-compliance. Such a Notice will specify:

- the licence condition(s) or ASPA provision(s) that have been breached;
- the action that must be taken to ensure that the failure does not continue or is not repeated; and
- any action that must be taken to eliminate or reduce any consequences of the breach.

The Compliance Notice will explain what will happen in the event of failure to comply. In this eventuality the licence holder may then be sanctioned with suspension, variation or revocation of their licence.

This type of remedy is particularly effective where weaknesses in governance have been identified, or where cultural change in attitudes towards welfare or compliance is needed. Such changes may reasonably take some time to remedy, for example:

- increases in staffing;
- refurbishment of facilities; or
- embedding an improved culture of care.

It provides a formal mechanism for assuring and monitoring improvements over time.

## **5.4 Revocation of a licence**

Revocation of any type of licence issued under ASPA is only used in the most serious cases. It is appropriate where a licensee has shown a disregard for the controls of the Act and has caused avoidable suffering. It may also be appropriate where significant avoidable suffering has been caused through negligence or ignorance or where the licensee otherwise appears to be unsuitable for the role. The Secretary of State has a duty to ensure that the welfare of animals is not adversely affected by the revocation of a licence.

## **5.5 Prosecution**

Only extremely serious cases would be referred to the prosecuting authorities to make a judgment as to whether it would be in the public interest to prosecute. Prosecution could lead to a fine or imprisonment.



## 6. Outcomes

In all cases the remedy applied aims to address the underlying cause. The Animals in Science Regulation Unit's (ASRU's) aim is to drive behaviour at both individual and establishment level towards the 'champion' attitude. The desired outcome is to build capability to:

- improve attention to compliance by individuals and the establishment as a whole;
- strengthen governance systems at establishment and scientific group level; and
- improve knowledge of the regulatory and licensing system.

The desired outcome is that licensees are ready, willing and able to be champions.

- Ready – understand what good compliance looks like.
- Willing – a positive attitude to compliance and application of the principles of replacement, reduction and refinement (the 3Rs), and understanding that compliance is the minimum expected for good practice.
- Able – are knowledgeable about roles and responsibilities.

By addressing patterns of low level concerns<sup>10</sup> as well as learning lessons from incidents of non-compliance, ASRU expects ongoing self-examination and self-improvement by all those with responsibilities under the Animals (Scientific Procedures) Act 1986 (ASPA).

The outcomes that remedies are intended to achieve include the following.

- 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 Named Person Responsible for Compliance (NPRC) identifies where and how investment may be needed to achieve good standards of care and accommodation, and actively seeks ways of achieving this.
- The NPRC reviews the quality of governance structures and outcomes – sometimes with external input.
- The NPRC ensures that the establishment is adequately staffed and that facilities and equipment are maintained to an acceptable standard.
- The establishment's Animal Welfare and Ethical Review Body (AWERB) functions effectively:
  - to fulfil all its tasks;
  - is well supported by the NPRC; and
  - is respected by all staff.
- The 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;
  - there is effective communication with the Regulator and 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 and records for all staff (including personal licensees and technical staff) and competence is regularly and effectively assessed.
- A good culture of care is evident to, and embraced by, all.

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<sup>10</sup> See document published October 2015:

[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/487787/Patterns\\_low-level\\_concerns.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/487787/Patterns_low-level_concerns.pdf)