



Home Office

# **Animals in Science Regulation Unit**

## **Bridging Ways of Working**

V2 updated 11 August 2021

## What are the Bridging Ways of Working?

From July 5<sup>th</sup>, 2021 ASRU now provides regulatory delivery through three teams covering different areas each of which has a dedicated inbox.

**Please note when submitting any email to any team inbox please ensure each email only covers one question/task/topic.**

**Please also submit all attachments in Microsoft Word format only as other formats require additional processing.**

### Regulatory Advice Team

- This team will answer requests from the regulated community for advice related to the interpretation of ASPA.
- This team can be contacted at [ASRURegulatoryAdvice@homeoffice.gov.uk](mailto:ASRURegulatoryAdvice@homeoffice.gov.uk)

### Compliance Assurance Team

- This team will deliver all activities which provide oversight and assurance to the public of licence holders compliance with ASPA and their licence conditions including:
  - Provision of facility, systems, and thematic audits
  - Monitoring of action plans for those establishments which are assessed as being of high risk of non-compliance (in special measures)
  - Enforcement activities through investigation and management of potential cases of non-compliance
  - Reviewing reports submitted which are part of compliance assurance (e.g. SC 18 reports, retrospective assessments, other reports required by a specific licence)
- This team can be contacted at [ASRUComplianceAssurance@homeoffice.gov.uk](mailto:ASRUComplianceAssurance@homeoffice.gov.uk)

### Licensing Team

- This team will deliver the processing of applications for licences and licence amendments
- These will continue to be managed through ASPeL.
- However should you need to contact this team you can do so at [ASRULicensing@homeoffice.gov.uk](mailto:ASRULicensing@homeoffice.gov.uk)

## Regulatory Advice

### When should I contact the Regulatory Advice Team?

Please contact the Regulatory Advice Team if you have any question relating to the interpretation of ASPA, operational guidance issued by ASRU, ASRU regulatory processes or about interpretation of your licence or licence conditions.

Examples of the types of questions you may ask the Regulatory Advice Team are:

- Do I need an ASPA licence to perform a specific task?
- Does my current licence authorise a particular experiment?
- How should I best structure my project licence application?

### How do I contact the Regulatory Advice Team?

Please contact the Regulatory Advice Team by completing the form attached to this newsletter and emailing it to [ASRURegulatoryAdvice@homeoffice.gov.uk](mailto:ASRURegulatoryAdvice@homeoffice.gov.uk).

Please indicate the type of advice requested in the subject heading of the email and mark as urgent if you need an answer within 24 hours or your question has an immediate impact on animal welfare

Please note that you should refer to your Named Welfare and Care Officer (NACWO) and/or Named Veterinary Surgeon (NVS) within your establishment in the first instance for any matter or question related to animal welfare.

### What if I need to speak to someone?

If you need to speak to someone please highlight this in your email and provide a contact name and number. A member of the team will then schedule a telephone call with you.

### How quickly will I receive an answer?

The Regulatory Advice Team will respond to urgent welfare related questions as a priority and to routine questions as soon as possible. They will set and communicate Service Level Agreements for response times in due course.

# Compliance Assurance

## Who are the Compliance Assurance Team and what roles will they fulfil?

The Compliance Assurance Team consists of a team of inspectors and enablement officers who perform the following functions via four delivery areas:

- Provision of facility, systems, and thematic audits
- Monitoring of action plans for those establishments which are assessed as being of high risk of non-compliance (in special measures)
- Enforcement activities through investigation and management of potential cases of non-compliance
- Reviewing reports submitted which are part of compliance assurance (e.g. SC 18 reports, retrospective assessments)

## How do I contact the Compliance Assurance Team?

All communications with the Compliance Assurance team (with the exception of completed retrospective assessments, which should be submitted via ASPeL), including reports of potential non-compliance, POLE Notifications, requests to keep animals alive Standard Condition 18 and other reports, should be conducted via the Compliance Assurance email address:

[ASRUComplianceAssurance@homeoffice.gov.uk](mailto:ASRUComplianceAssurance@homeoffice.gov.uk)

## How do I report a potential failure to comply with ASPA or licence conditions?

Where there is a need to notify ASRU of a potential non-compliance with ASPA, establishment licence standard conditions, project licence standard conditions, personal licence standard conditions or the Code of Practice, this should be reported via email to

[ASRUComplianceAssurance@homeoffice.gov.uk](mailto:ASRUComplianceAssurance@homeoffice.gov.uk)

In the email subject heading, please clearly title with: **ENFORCEMENT\_**  
**EstablishmentName\_ PPLh surname\_ PPLnumber\_ date** where PPLh surname is the surname of the Project licence holder and PPL number is the number of your project licence.

## How do I make a request to keep animals alive when the severity limits in a project licence and/or observance of any other controls appear to have been, or are likely to be, breached?

**These requests must always be marked as urgent and must be made immediately.**

Please note the 72 hour timeframe requirement within which to submit Standard Condition 18 report does not apply to these requests as **they must be immediate** as it is unlawful to

keep animals alive when severity limits in a project licence or any other controls have been breached and it is urgent to obtain authority to keep animals alive in these circumstances.

This should be reported via the Standard Condition 18 reporting form at [Project Licence Standard Condition 18 notification \(publishing.service.gov.uk\)](https://publishing.service.gov.uk) and sent into [ASRUComplianceAssurance@homeoffice.gov.uk](mailto:ASRUComplianceAssurance@homeoffice.gov.uk) immediately

Ensure that the completed reporting form contains the request to keep animals alive and that clear scientific justification is provided for the request.

In the email subject heading, please clearly title with: **REQUEST TO KEEP ANIMALS ALIVE SC18\_ EstablishmentName\_ PPLh surname\_ PPLnumber\_ date** where PPLh surname is the surname of the Project licence holder and PPL number is the number of your project licence.

### How do I make a Project Licence Standard Condition 18 report?

Where there is a need to notify ASRU of procedural-related adverse effects that have exceeded or are likely to exceed the severity limitations or controls described in a project licence, this should be reported via the current Standard Condition 18 reporting form at [Project Licence Standard Condition 18 notification \(publishing.service.gov.uk\)](https://publishing.service.gov.uk) and sent into [ASRUComplianceAssurance@homeoffice.gov.uk](mailto:ASRUComplianceAssurance@homeoffice.gov.uk)

**All** information should be contained within the SC18 report form. Please avoid adding extra information onto the covering e mail.

This form should be completed by the project licence holder within 72 hours of discovery of the incident. Where possible and in line with establishment processes, SC18 report should be submitted via the HOLC or other nominated person at the establishment.

In the email subject heading, please clearly title with:

**SC18\_ EstablishmentName\_ PPLh surname\_ PPLnumber\_ date.**

where PPLh surname is the surname of the Project licence holder and PPL number is the number of your project licence

Please ensure that there is only **one** SC18 report attached per e mail to assist with onward processing.

### How do I submit a completed Retrospective Assessment review?

This should be done via ASPeL following the process specified there.

### How do I submit a specific notification, or a completed report required by an additional condition on my Project Licence or requested under PPL standard condition 22 for review?

This should be sent to the mailbox [ASRUComplianceAssurance@homeoffice.gov.uk](mailto:ASRUComplianceAssurance@homeoffice.gov.uk).

In the email subject heading, please clearly title with: **Notification\_ EstablishmentName\_ PPLh surname\_ PPLnumber\_ date** or **Report\_ EstablishmentName\_ PPLh surname\_ PPLnumber\_ date** where PPLh surname is the surname of the Project licence holder and PPL number is the number of your project licence.

### **What is the purpose of audits?**

An audit is a process which verifies conformance to standards through review of objective evidence. Therefore, in this context, the purpose of the audit process will be to assess compliance against the Animals (Scientific Procedures) Act 1986(ASPA) and associated licence conditions, and to objectively measure the risk of non-compliance within the establishment by assessing the robustness of governance systems.

### **How do I arrange for a new or refurbished facility to be assessed?**

Please submit a request to the Compliance Assurance inbox.

### **How will audits be conducted?**

Audits will be conducted primarily in three ways:

- Facility audit: based on the facility itself to ensure it meets code of practice and other standards.
- Systems audit: looking at governance systems within an establishment or a project to understand how robust they are at maintaining compliance.
- Thematic audit: looking at one particular area of compliance across the regulated community to assess the overall approach to maintaining compliance in this area.

### **What are the timelines for delivery of the new structured audit process?**

The Compliance Assurance Team will develop processes and standards for full audits of systems and facilities. During development, processes will be piloted and refined, and your establishment may, in the coming months, have a full or partial audit. If selected during the development and piloting phase, you will be notified in advance of our intention to audit your establishment. When the processes have been developed, piloted, and refined, an audit framework will be published including clear expectations and standards.

### **How will Establishments be assessed as requiring special measures?**

At the start of the bridging way of working, establishments that have a specific non-compliance history (see below) will undergo a systems audit. Based on the results from these audits, together with the establishment non-compliance history, an initial decision

will be made for the establishments to enter Special Measures no earlier than October 2021.

**What criteria will be used to identify establishments that will undergo the initial systems audits?**

- 1) Any establishment or any licensee within the establishment which has had a compliance notice, or any licence revoked/suspended in the last 12 months (under ASPA Section 13 or as remedy to a non-compliance case).
- 2) Any establishment which has had any non-compliance involving special species in the previous 12 months.

## Licensing

### How will the assessment of project and establishment applications /amendments be conducted, and licenses issued/amended?

- All project and establishment applications and requests for amendments will continue to be submitted through ASPeL.
- Project licences will be assessed by an inspector on a `taxi rank` basis. This means that as each inspector becomes available to perform review and assessment activities, they will be allocated the project licence which is next in the queue based on date of submission.
- The ASPeL system will be constantly monitored to ensure that the processing time for all applications is appropriate and in particular that amendments are processed in a timely way.

### What timelines should I expect my application to be processed in?

The following are typical timelines for processing of applications. Please note these may vary based on individual applications and overall workload.

- Initial project application review requiring ASC referral: 55 working days
- Initial project application review: 40 working days
- Second/subsequent project application reviews: 20 working days
- Initial project amendment applications: 20 working days
- Second/subsequent project amendment applications: 14 working days
- Urgent project amendment applications: 10 working days

### If I have an urgent amendment how do I flag this to ASRU?

- There are two main reasons why an amendment may need to be expedited. These are as follows:
  - An amendment has been requested by the Compliance Assurance Team to enable animals to be kept alive which have experienced unauthorised adverse events
  - There is a commercial reason why an amendment is urgent
- In these cases please let the licensing team know by email at [ASRULicensing@homeoffice.gov.uk](mailto:ASRULicensing@homeoffice.gov.uk)



## What do I do if have an expiring licence and require authorisation to transfer animals to a new licence?

It is a project licence holder`s responsibility to ensure that they do not commence experiments in animals where they do not have authorisation to complete the planned work.

If authorisation is anticipated to be needed for the transfer of animals from an expiring licence to a new one it is the responsibility of the project licence holder to ensure review of the new licence is complete in sufficient time to facilitate this transfer.

It is the establishment licence holder`s responsibility to ensure they facilitate this timely submission of licence applications especially in ensuring planning for submission of applications is performed in line with planned AWERB meetings. It is also the establishment licence holder`s responsibility to ensure experiments are not planned for which there is not existing authorisation.

**Please remember that new applications should ideally be received by ASRU 6 months before they are required and no later than 3 months before they are required. If your application is required to be reviewed by the Animals in Science Committee (ASC) the application should ideally be received no later than 6 months before it is required.**

**If you submit a licence for which transfer of animals is requested less than 3 months(6 months for those requiring ASC review) prior to expiry date it is highly likely these will not be processed prior to the expiry of the existing licence. It is expected that you have made a contingency plan to manage any animals remaining on the licence at the time it expires.**

**Please note, unless in exceptional circumstances, we will not be expediting the processing of licences submitted in these circumstances and these will await processing in the taxi rank.**

## Can I submit an application for review prior to AWERB review?

No, any application received which has not undergone AWERRB review at each relevant establishment will be returned as incomplete and will not be processed.

It is a requirement under PEL standard condition 6 all amendments to licences must have been seen by the AWERB and their recommendation made to the Establishment Licence Holder to support a project proposal prior to its submission in ASPeL.

For urgent amendments the AWERB must have a process for achieving this timely review, ensuring the process is quorate and recording the advice provided. The process in which an establishment`s AWERB completes an urgent application review must be outlined in the AWERB Terms of Reference document and the minimum quorum must include a Named

Veterinary Surgeon (NVS), Named Animal Care & Welfare Officer (NACWO), a Scientific member (PELs that use animals on project licences only), one person who does not have responsibilities under ASPA, as well as one or more persons who are independent of the establishment

### **Will you be making any changes to ASPeL?**

We are reviewing ASPeL to prioritise improvements particularly those which aim to reduce the length and complexity of project licence applications. We will update you on these in due course.

### **How do I receive technical support for ASPeL?**

For technical advice on the use of ASPeL, please email [ASPELQueries@homeoffice.gov.uk](mailto:ASPELQueries@homeoffice.gov.uk).

The advice lines will be open from 9am to 5pm, Monday to Friday

### **Will you be issuing any guidance related to project licence applications?**

We will be issuing some guidance shortly to help you in completing your applications for project licences.

## **How do I get more information?**

Your Establishment Licence Holder was invited to three meetings with ASRU to explain the overall strategic direction for ASRU and the reason for these changes.

Your Establishment Licence Holder has been provided with a detailed Question and Answer document which provides more information on the reasons for these changes.

These documents should have been circulated throughout your establishment and if you want to see these and have not yet done so please contact your Establishment Licence Holder, Home Office Liaison Contact (HOLC) or Named Information Officer (NIO).

Please note these have not been updated since June 2021 and we currently do not envisage further updates until at least October 2021.

If you have further questions about our Change Programme overall or this new operating model and how it will work please contact [ASRUChangeProgramme@homeoffice.gov.uk](mailto:ASRUChangeProgramme@homeoffice.gov.uk).

The ASRU Programme Change Lead will answer these questions and will have a telephone call with you if needed to help clarify any questions you have.

## What do I do if I have a problem or complaint?

We have established a separate customer service business area which will focus on ensuring timeliness, completeness, and consistency of our engagement with you.

If you have concerns about the timeliness or completeness of response from any of our teams or any other concerns about any individual request or interaction please contact [ASRUOperationalRelationshipManagement@homeoffice.gov.uk](mailto:ASRUOperationalRelationshipManagement@homeoffice.gov.uk)

## Will you review these ways of working?

We will continuously review these ways of working and value any feedback on these ways of working at any time to [ASRUChangeProgramme@homeoffice.gov.uk](mailto:ASRUChangeProgramme@homeoffice.gov.uk)

