



Home Office

ASRU Bridging Ways of Working

Animals in Science Regulation Unit (ASRU)

June 2021

What is the Bridging Way of Working?

From July 5th, 2021 ASRU will be introducing a new operating model to deliver regulatory services.

From that date inspectors and executive officers will no longer be allocated to individual establishments.

Instead ASRU will provide regulatory delivery through three teams covering different areas:

Regulatory Advice Team

- This team will receive all requests and answers from the regulated community for advice related to the interpretation of ASPA and provide answers
- This team can be contacted at 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)
- This team can be contacted at 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

Regulatory Advice

When should I contact the Regulatory Advice Team?

Please contact the Regulatory Advice Team if you have any question related to the interpretation of ASPA, operational guidance relating to ASPA issued by ASRU or related to interpretation of your licence or you 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?
- Can I perform a particular procedure without anaesthesia?
- 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 document and emailing it to ASRURegulatoryAdvice@homeoffice.gov.uk

Please provide an indication of 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 you should refer to Named Persons 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 a member of the team will schedule a telephone call with you.

How quickly will I receive an answer?

The Regulatory Advice Team will respond to your questions as soon as possible. They will set and communicate Service Level Agreements for response times in due course. Our initial pilot indicates that response times will be the same or quicker than what you are used to.

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, requests to keep animals alive and Standard Condition 18 reports, should be conducted via the Compliance Assurance email address:

ASRUComplianceAssurance@homeoffice.gov.uk

How do I report a potential failure to comply with ASPA or 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

In the email subject heading, please clearly title with: **ENFORCEMENT_**
EstablishmentName_PPLnumber_PPLh surname_date. where PPL number is the number of your project licence and PPLh surname is the surname of the Project licence holder.

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

This form should be completed by the project licence holder within 72 hours of discovery of the incident.

In the email subject heading, please clearly title with: **SC18_ EstablishmentName_PPLnumber_PPLh surname_date**. where PPL number is the number of your project licence and PPLh surname is the surname of the Project licence holder.

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 requirement to submit Standard Condition 18 reports does not apply to these requests 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 immediately](mailto:ASRUComplianceAssurance@homeoffice.gov.uk)

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

In the email subject heading, please clearly title with: **REQUEST TO KEEP ANIMALS ALIVE SC18_ EstablishmentName_PPLnumber_PPLh surname_date**. where PPL number is the number of your project licence and PPLh surname is the surname of the Project licence holder.

How do I submit a completed Retrospective Assessment review?

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

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 and associated licence conditions, and to objectively measure the risk of non-compliance within the establishment by assessing the robustness of governance systems.

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 first 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 last 12 months (under ASPA Section 13 or as remedy to a non-compliance case).
- 2) Any establishment which has had any noncompliance 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 all inspectors 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.

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

- If you have an urgent application especially for an amendment and need to communicate this to ASRU please email ASRULicensing@homeoffice.gov.uk
- 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

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 the e-licensing system, please contact 020 7035 4469 or email 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 has been invited to three meetings with ASRU over the past three weeks to explain the overall strategic direction for ASRU and the reason for these changes.

Your establishment licence holder has 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 PEL holder or HOLC.

If you have further questions about our Change Programme overall or this new operating model and how it will work please contact ASRUChangeManagement@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

Will you review this way of working?

We will continuously review this way of working and value any feedback on this way of working at any time to ASRUChangeManagement@homeoffice.gov.uk