

ASRU Stakeholder Newsletter – 29 June 2021

Dear ASRU Stakeholder,

Re: Animals in Science Regulation Unit (ASRU) Change Programme

Please find within this newsletter operational information about the new bridging ways of working which will be operationalised within ASRU from July 5th.

Please also find attached a template form to be used for the submission of requests to the Regulatory Advice Delivery team.

Please continue to give us feedback as we embed and refine our new ways of working.

Kind regards

Will Reynolds

ASRU Head of Unit

What are the Bridging Ways of Working?

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

From that date inspectors and single points of contact (SPOCs) 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 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 and will consist of all inspectors within ASRU. 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 your 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 sent together with this document and emailing it to ASRURegulatoryAdvice@homeoffice.gov.uk.

This form is overleaf.

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 your Named Welfare and Care Officer (NAWCO) 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 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 urgent welfare related questions as a priority and routine questions as soon as possible. They will set and communicate Service Level Agreements for response times in due course.



Home Office

Regulatory Advice Enquiry Form

Please use this form to contact Animals in Science Regulation Unit (ASRU) if you require regulatory advice. Our aim is to respond to your request within 5 working days

Do **not use** this form to:

- Report a PPL Standard Condition 18
- Report a potential non-compliance

Please clearly title your document: '**ASRU_Establishment Name_Name_Date_**' and send to the Regulatory Advice Team with the subject heading 'Regulatory Advice Request Establishment [Number]'.

Establishment Licence Name and Number	
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In relation to your enquiry, which of the following best describes you?
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Choose an item.

PPLh/PILh Number if applicable:
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If selected Other above, please specify:

IS THERE AN <u>IMMEDIATE OR ONGOING</u> ANIMAL WELFARE CONCERN?
--

YES

NO

If answered YES above, please describe:
--

IS A RESPONSE REQUIRED URGENTLY?

YES

NO

If answered YES above, please provide a telephone number:

In relation to your enquiry, which of the following best describes the topic you are contacting us about today?

Choose an item.

Please provide details of your enquiry, providing PPL/Protocol number if applicable:

Print Name

Date

*******For official use*******

Regulatory Advice Given

Name

Date

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 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

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 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 \(publishing.service.gov.uk\)](#) and sent into ASRUComplianceAssurance@homeoffice.gov.uk immediately

Ensure that the 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 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 \(publishing.service.gov.uk\)](#) 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 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.

In the email subject heading, please clearly title with: **Notification_ EstablishmentName_PPLnumber_PPLh surname_date** or **Report_ 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

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 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 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.

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. If your application is required to be reviewed by the Animals in Science Committee the application should ideally be received no later than 6 months before it is 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.

How do I receive technical support for ASPeL?

For technical advice on the use of ASPeL, please email ASPELQueries@homeoffice.gov.uk.

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 six weeks 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).

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 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 ASRUChangeManagement@homeoffice.gov.uk