



Home Office

Operational Newsletter

Animals in Science Regulation Unit (ASRU)

September 22, 2021

Table of Contents

1. Regulatory Delivery Update	3
2. Relationship Management Update	5
3. Full System Audits	6
4. Returns of Procedures Process	7
5. Reminder of Sessions on Project Licence Standard Condition 18	8

Regulatory Delivery Update

We have now completed and reviewed the second month of the new operating model.

We would like to continue to thank all of you for your commitment to and patience in making this new model a success.

In terms of delivery metrics these are still developing and should be in place for our first formal quarterly review in October 2021, but we can share the following information:

Regulatory Advice

Data	July 2021	August 2021
Number of queries	59	69
Median response time	2 days	1 day
Range of response times	1-10 days	1-8 days
Number (%) answered within same day	39 (66%)	59 (86%)
Number of establishments	38	45
Most frequent questioner	PPL holder	PPL Holder
Most frequent topic	PPL authorities	PPL authorities

Compliance Assurance

Data	July 2021	August 2021
PPL Standard Condition Reports processed	107	139
No of establishments submitting PPL SC 18 reports	35	38
No of PPL SC 18 reports referred for enforcement review	8	6
Median response time to PPL SC 18 reports(days)	2	1
Range of response times to PPL SC 18 reports (days)	1-8	1-8
New potential enforcement cases	TBC	23

Licensing

Tasks completed	Apr 21	May 21	June 21	July 21	Aug 21
PPL application reviews	34	39	61	58	61
PPL amendment review	104	93	109	78	162
PEL tasks	288	248	372	520	261
PIL applications	358	191	222	180	124
PIL amendments	65	50	61	48	58

- We continue to **manually triage amendments** within ASPeL to ensure they are processed more rapidly than new PPL applications and are working with the ASPeL development team to see if this process can occur electronically in future.
- We have agreed **typical timelines for licensing tasks** as shown below and will commence reporting on metrics against these timelines for licensed processed from Q4 2021 onwards. Please note these can vary based on the complexity of the task and overall workload. All days referenced are working days
 - Initial project application review requiring ASC referral: 55 days
 - Initial project application review: 40 days
 - Second/subsequent project application reviews: 20 days
 - Initial project amendment applications: 20 days
 - Second/subsequent project amendment applications: 14 days
 - Urgent project amendment applications: 10 days
- We continue to receive requests to expedite first review of applications which are submitted less than 3 months prior to their expiry date, and which require transfer of animals. A reminder that we will not be expediting any such requests unless there are exceptional circumstances and that it is the responsibility of PPL holders to ensure new licences are received in a timely manner and to have contingency plans for animals in these cases.

Relationship Management Update

We have commenced the quarterly meetings between HOLCs and our operational relationship management lead.

Nine meetings occurred in August and of the HOLCs interviewed four expressed that they were satisfied and five expressed that they were neither satisfied nor dissatisfied with ASRU delivery.

Most concerns related to not knowing where individual PPLs were in the taxi rank system. Our advice in this respect is that establishments should plan to receive feedback on applications in line with the typical timelines published.

We have undertaken the following activities in August:

- **Steering Team Meeting** on the 24th August which focused on leading regulatory practice related to audit and contributed to the development of our strategy for full systems audit.
- **Regulated Community Change Team Meeting** on 13th August where we received feedback on data and experience of the first month of the bridging ways of working.

The next PEL holder meeting is scheduled for October 18 from 12.00-13.30 with a follow up meeting to address questions and feedback on November 1 from 12-13.30.

The next stakeholder meeting is scheduled for October 19 from 12-13.30 with a follow up meeting to address questions and feedback on November 2 from 11.30-13.00.

Invites to these meetings have been issued -please contact Farai.Dangarembizi@homeoffice.gov.uk if you are a PEL holder or a member of our stakeholder communication group and have not yet received these invitation.

We will also be attending the **HOLTIF meeting on 22 October** to follow up with that network on messages communicated in the PEL and stakeholder meetings in October.

Full System Audits

Our compliance assurance system integrates evidence from a variety of sources in order to assess risk and compliance. These sources include but are not limited to:

- Review of reports submitted
- Audits
- Enforcement investigations
- Follow up from action plans
- License applications and regulatory advice requests

With regard to audits we conduct a variety of audits for different purposes:

1. **Full systems audit:** This is the baseline establishment audit which assesses (as far as possible) all important systems in place to ensure compliance with ASPA and standard conditions of all licences. These are conducted once every year for establishments holding special species and once every three years for other establishments. These audits will always be conducted on site.
2. **Partial systems audit:** These audits will focus on one or more systems and will be conducted whenever required based on evidence available. These may be conducted on site or via remote means. These may focus on establishment systems or on governance systems for one or more project licence.
3. **Facility audit:** This is an audit specifically focused only on the facility itself at an establishment. These will usually be conducted when changes are requested to the schedule of premises. These may be conducted on site or via remote means.
4. **Thematic audit:** This is an audit which is conducted on a focused topic across establishments or licences. These will usually be conducted quarterly and usually be conducted remotely.

We will be commencing our full system audit programme in October 2021. Between October and December 2021 we intend to conduct full system audits on 9 establishments.

These establishments have been selected to be in this first cohort based on their history of non-compliance in the year from June 2020 to June 2021. All these establishments will receive letters notifying them of the planned dates for these audits by the end of September 2021.

Processes for conducting these audits and the evidence which will be used to review compliance will be circulated with this newsletter and will be uploaded shortly to the website. We will be reviewing these processes and standards regularly and refining these based on feedback and experience.

Returns of Procedures Process

- A process has been established within ASPeL to facilitate the electronic submission of all Returns of Procedures through ASPeL.
- This process will go live on October 4, 2021 and from this date onwards returns of procedures can only be made through ASPeL.
- The ASPeL ROP form mirrors the Excel ROP form currently available on GOV.UK. The Excel version and guidance will be removed and no longer available to download after the 4th October 2021
- Instructions for how this can be done are present in ASPeL and supplementary information, including examples are attached as a separate document to this newsletter.
- Project licence holders will receive an automated email from ASPeL for expired or revoked licences requesting completion of the ROP form online. The deadline for these returns is 28 days following the expiry or revocation of the licence
- All active licences will require completion of the ROP form through ASPeL by January 31st, 2022.

Reminder of Sessions on Project Licence Standard Condition 18

- If your establishment has not yet assigned up to three individuals to attend the sessions in Project licence standard 18 please contact Farai.Dangarembizi@homeoffice.gov.uk as soon as possible.
- There are two sessions still to be conducted on:
 - Wednesday September 29: 12.00-15.30
 - Thursday October 14: 13.30-17.00
- After all sessions are complete updated regulatory guidance will be circulated and published on the ASRU website