



Establishment Licence Holder's Newsletter - February 2017

Dear Establishment Licence Holder (or delegate)

In this newsletter I am focusing on three current areas of our work:

1. Improving the licence application process
2. Improving the compliance process
3. Additional data returns for 2017

Improving the licence application processes

ASRU would like to collaborate with its stakeholders to develop more efficient and effective licensing processes. We are looking to reduce the regulatory burden placed on you while seeking opportunities to increase openness and transparency. We need to do this in a way that retains public confidence in the use of animals in science.

We have a specific opportunity this year to improve our processes because the ASPeL contract for e-Licensing expires in August 2017 and this provides the opportunity for us to re-examine the underlying processes and implement any recommendations for the new contract. We are committed to continue to provide an electronic licensing process.

However, the ASPeL contract cannot simply be renewed, due to public sector procurement rules, and the new contracted system must meet Government Digital Service standards. We need to identify all options for our post-August 2017 system, so we are undertaking a thorough review of all our processes for applying for licences, not just the technology used to do it.

For more than a year we have been engaging with stakeholders around the principles of our operations, including at the joint Royal Society of Biology (RSB)/Home Office meeting in December 2015 and at the PEL holders forum last March. More recently we held an exploratory meeting with 20 stakeholders across the spectrum of funders, licensees from all sectors and PEL holders. The meeting was a real success and brought out genuine new thinking on ways forward.

We are keen to broaden this engagement. However, we do need to ask for some patience and trust. With many thousands of licence holders (PEL, PPL and PIL) not to mention ASRU staff, legal advisers, welfare and protection stakeholder groups, we necessarily must begin with representative focus groups.

We intend to channel our engagement with our "user" stakeholders through our own stakeholder groups, the LASA PEL Holder's forum and the RSB. Very shortly we are

looking to bring together the ideas from last month's exploratory meeting and expose them to a wider audience and we will be continuing to consult with you throughout this process. Therefore it would be helpful if you could start considering the following:

- The best methods of ensuring that we effectively engage with all stakeholder groups, particularly all those who have an interest in improving the project licence process in your establishment; and
- Any ideas for improving the project licence application process

If you have any immediate thoughts on the above please send them to ASRUBusiness@homeoffice.gsi.gov.uk. However we will be following up these themes in more detail as we progress so you should have plenty of opportunities to contribute your ideas and feedback.

We are also sending out an Operational Newsletter that will ask for volunteers to help Home Office Digital with gathering feedback on ASPeL and to test ideas for improvement so that we can ensure the e-Licensing process reflects the general improvements we want to make.

Our aim is that together we improve licensing processes for the benefit of all stakeholders.

Improving the compliance process

In September and October last year two highly successful meetings were held between ASRU and a small group of PEL Holders that were largely focused on non-compliance matters. ASRU is now looking to repeat these types of meetings and engage further with this important group of stakeholders, building on relationships and broadening the range of subject matter for discussion. ASRU wishes these meetings to be very much focused on issues/concerns that you may have and wish to raise with senior ASRU staff.

In order to help facilitate a full and frank discussion of matters numbers will necessarily be kept relatively small and we are looking at how we can fairly invite a representative cross-section of PEL Holders to attend.

ASRU therefore invites expressions of interest from those Establishment Licence Holders who would wish to attend the next meeting, which will be held at the Home Office on either 18 May or 15 June 2017. When we have a list of those interested in attending, we will confirm the date which accommodates the majority, and we will also liaise with you in order to identify the agenda items that you wish to discuss with us. Up to ten places are available, though if demand exceeds the number of places available ASRU will repeat this meeting format and indeed, is hoping to make such meetings a permanent fixture in the ASRU calendar to be held two or three times each year.

If you wish to register your expression of interest in attending the next meeting would you please respond to ASRUBusiness@homeoffice.gsi.gov.uk by close on Friday 24 February, under the heading "Improving the compliance process" also indicating whether

you can attend on (a) 18 May, (b) 15 June, or (c) both dates.

Additional data returns for 2017

ASPA Section 21A(4) requires the Secretary of State to supply data to the European Commission as set out in Article 54 of Directive 2010/63/EU. Most of this data comes from establishments and the details of what the Commission requires the Home Office to collect from PEL Holders are set out in Annex I of Commission Implementing Decision of 14 November 2012. This can be found here:

http://ec.europa.eu/environment/chemicals/lab_animals/pdf/guidance/directive/en.pdf

Once every 5 years, and in accordance with PEL Standard Condition 8, PEL Holders are required to provide information relating to:

- i. The number of animals that were bred for scientific procedures and were killed during the target year but not used in procedures and not included in the annual Return of Procedures; and
- ii. Tissue sampling and its refinements for genotyping of animals.

Clarity on the detail of this data collection process was provided to us by the Commission towards the end of last year. We are now in a position to provide these explanatory notes to you to inform your data collection processes during 2017. The material for Table 1 should be readily accessible in your source, use and disposal records kept under the terms of Condition 8 of your licence. We recognise that collecting information for Tables 2 and 3 may require additional internal consultation, so we have negotiated with the Commission for that information to be collected only for the second half of 2017 (i.e. July to December).

We have attached the summary tables that each establishment will need to complete by 31st January 2018. Please note that there should be one return per establishment i.e. NOT one for each project. Although entirely separate, this information will be collected at the same time as the annual Return of Procedures for 2017 data. We will provide the guidance and the final version of the tables that should be used to return your data later in the year.

If you have any queries about this data collection please email ASRUBusiness@homeoffice.gsi.gov.uk

Best wishes

Dr Sue Houlton, BVSc, MA, DVR, DVC, MRCVS

Chief Inspector, Head of Unit, Animals in Science Regulation Unit