



Establishment Licence Holder Newsletter – August 2018

Dear Establishment Licence Holder,

Workstreams in the Animals in Science Regulation Unit (ASRU) have been continuing over the past few months, to build on our further development of modern, consistent and responsive regulatory processes. This has included ongoing development of the new electronic licensing system, and publication of the [Standard Condition 18 Advice Note](#).

Annual Statistics of Scientific Procedures on Living Animals Great Britain 2017

The 2017 Annual Statistics were published on 19th July 2018 and can be found [here](#). In 2017, 3.79 million procedures were carried out in Great Britain involving living animals. This is a decrease of 4% compared to 2016.

Memorandum of Understanding between NC3Rs and ASRU

ASRU has recently agreed a Memorandum of Understanding (MoU) with the National Centre for the 3Rs (NC3Rs), which is attached to this Newsletter. The MoU represents an important milestone in the relationship between ASRU and the NC3Rs. High quality engagement between ASRU and the NC3Rs is vital to ensure information sharing and delivery of our mutual objectives to fully deliver the 3Rs.

Over the coming months, we will be developing strategies for us to work in more aligned ways together, to achieve our shared goals.

EU exit

A Statutory Instrument, which is a form of secondary legislation, is being prepared to amend the Animals (Scientific Procedures) Act (ASPA), to deliver EU exit. The only

changes that can be made to ASPA via the Withdrawal Bill are those that remove references directly tying us to the EU legislation. The Withdrawal Bill gives no powers to change the regulatory requirements for animals in science or the required high standards of animal welfare, so there is no change in regulatory requirements as a result of this new legislation.

If you have any concerns or questions about animals in science and EU exit, please email Kate.Chandler@homeoffice.gsi.gov.uk

Additional statistics

As you all know, in addition to the normal end of year Return of Procedures data collection, we collected additional data from each establishment for 2017, which was a requirement under Directive 2010/63/EU.

Three sets of information were completed for each return:

1. The number of animals bred for procedures, but not used.
2. Details of tissue sampling methods used for genotyping of genetically altered animals.
3. Information on efforts being made to refine tissue sampling techniques for genotyping at your establishment.

These statistics will be published on GOV.UK in Autumn 2018 and will provide further insight into the use of animals for scientific purposes.

Project licence applications and the AWERB's role

In June 2017, we circulated notes to establishments regarding the project licence application process, with a focus on submission of a high quality first draft. We have been asked to clarify the meaning of these notes, because the role of the AWERB in the project licence application was unclear in these notes.

The minimum and additional tasks of the AWERB are set out in our Guidance. There have

been no changes to these requirements. Section 10.5 states that:

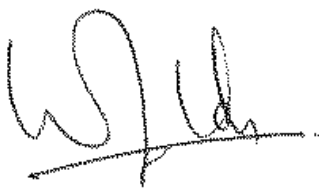
“AWERBs should also advise the establishment licence holder whether to support project proposals, primarily considering such proposals from a local perspective and bringing local knowledge and local expertise to bear”.

The AWERB is not responsible for the overall quality of the project licence application. This is the responsibility of the applicant, who may seek advice from AWERB members, named persons and other experts in their establishment during application preparation. The personnel involved and the mechanisms of achieving a high quality first draft will differ throughout establishments.

We still require that:

- All drafts uploaded into ASPEL are endorsed by the establishment via the AWERB in accordance with s10.5 of the Guidance
- The annotated project licence form [which can be found [here](#)] is used to prepare all draft applications to improve their quality

If you have any further questions regarding the project licence application process, please contact your assigned inspector.

A handwritten signature in black ink, appearing to read 'Will Reynolds', with a horizontal line drawn underneath the name.

Will Reynolds

Head of the Animals in Science Regulation Unit

Memorandum of understanding between the NC3Rs and ASRU

Introduction

1. This memorandum of understanding (MOU) sets out how the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs) and the Home Office's Animals in Science Regulation Unit (ASRU) will work together to advance the 3Rs (i.e. replacement, reduction and refinement of the use of animals for scientific purposes).
2. The NC3Rs mission is to support scientists, veterinarians, animal technicians and other stakeholders to advance and implement the 3Rs. This is achieved principally via the Centre's research funding and early career awards, innovation platform CRACK IT, data sharing working groups, peer review and advice service, regional staff, events, publications and online resources.
3. ASRU is the UK regulator for the use of animals in science. The Animals (Scientific Procedures) Act 1986 (ASPA) requires licence holders to follow the principles of the 3Rs. Establishment licences also place obligations on other Named¹ Persons to provide advice on the 3Rs. ASRU Inspectors assess and advise on the application of the 3Rs during licence assessment and inspection of regulated activities. ASRU staff, and those regulated under the Act, are key users of the various outputs from the NC3Rs.
4. This MOU will be reviewed annually by the NC3Rs and ASRU.

Intentions

5. The NC3Rs will:
 - a. Provide research funding, events, publications, online tools, expertise and other resources to enable those working under ASPA to implement the 3Rs.
 - b. Identify 3Rs advances, opportunities and priorities, and communicate these to ASRU.
 - c. Actively contribute its 3Rs expertise to ASRU conferences, working groups and consultations, where appropriate.
 - d. Provide 3Rs expertise to establishments and project licence applicants, via its Regional Programme Managers and staff membership of AWERBs.

¹ Other Named Persons include; Named Animal Care and Welfare Officer (NACWO), Named Compliance Officer (NCO), Named Information Officer (NIO), Named Training and Competence Officer (NTCO) and Named Veterinary Surgeon (NVS)

6. ASRU will:

- a. Actively disseminate 3Rs information and advice from the NC3Rs, for example by inclusion in communications, guidance notes, policy statements and at inspections where appropriate.
- b. Ensure the NC3Rs newsletter and other relevant communications are circulated to Inspectors and ASRU staff.
- c. Attend, and where appropriate contribute to, symposia and workshops organised by the NC3Rs to keep abreast of the latest 3Rs developments and opportunities, and demonstrate visible support for the NC3Rs mission and promote the 3Rs in general.
- d. Participate in NC3Rs working groups where specialist expertise on ASPA is required.

7. Senior staff from the NC3Rs and ASRU will meet at least quarterly to discuss current 3Rs priorities, activities and progress and monitor delivery of the intentions set out in this MOU.

Signed on behalf of the NC3Rs
Date 16 May 2018



Signed on behalf of ASRU
Date 21 May 2018

