

Retrospective Assessment

Following the implementation of the Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012, the Department of Health is required to undertake the Retrospective Assessment (RA) of certain projects granted since 1st January 2013. Projects entailing the use of non-human primates, dogs, cats, equidae and endangered animals, procedures on any species that have been classified as severe, and projects for the purpose of education and training will be required to undergo RA. DoH has now formalised the process to achieve this.

In order that the RAs of licences are carried out in a consistent manner, and for everyone involved to have a shared understanding of the process, please find attached instructions for establishments which sets out a list of key points and frequently asked questions.

We trust this will be helpful but would welcome any feedback, including further questions or points for clarification. Please email these to Communicable Diseases Policy Branch (ASPA@health-ni.gov.uk) and write Retrospective Assessment in the subject line.

Instructions for establishments: Retrospective Assessment

Background

Retrospective Assessment (RA) is a legal requirement that needs to be undertaken on specific types of project licences that have been granted under the Animals (Scientific Procedures) Act (ASPA). This requirement is applied to certain project licences granted since 1 January 2013. The aim of the RA is to determine: whether the objectives have been achieved; the harms caused to animals; the number and species used; the severity of the procedures; and, whether lessons can be learnt to further the implementation of the 3Rs.

Project licences entailing the use of non-human primates, dogs, cats and equidae, the use of procedures classified as severe, endangered animals or for the purpose of education and training will have RAs applied to them.

The Home Office will publish the RA reports alongside the non-technical summary (NTS) that is already published.

This communication outlines the process and some key points to help establishments undertake their part in gathering the information required for the completion of the RA.

The Retrospective Assessment Process

The following process will be used for RAs:

1. When the licence is granted by the Department of Health, or following an amendment that requires a RA, a statement shall be applied to the project licence explaining that a RA is required.
2. The default position is for all RAs to be due at the expiry of the licence in question or upon completion of the project, whichever occurs first.
3. The project licence holder will be reminded 12 months prior to the expiry date of the Project of the need to undertake an RA.

4. The licence holder will need to gather the necessary information required for their local AWERB to undertake a review of the project paying particular attention to the progress made to meet the objectives of the project, the harms experienced by the animals and benefits accrued, and any 3Rs lessons learned.
5. The licence holder must then complete the template by summarising this information and submit the completed template to DoH.
6. The assigned inspector will assess the information submitted and complete their report on the RA. The report will confirm whether the information submitted is a reasonable reflection of the progress made in the project, determine whether the harms and benefits reasonably reflect those stated in the original application (including any unexpected harms or benefits) and highlight any 3Rs lessons learned during the project.
7. The inspector may need more information from the licence holder and will contact them directly if this is the case.
8. The Home Office will then publish the summary information in the completed template together with the report from the assigned inspector, alongside the original NTS to form the updated NTS. The RA will be published, normally within three months of the expiry of the project.
9. Confidential information, including personal information, commercial or intellectual property **must not** be included in the template since the RA will be published.

Points to note

- If a new project, or an existing project submitted for amendment, requires RA, the inspector will identify this during the assessment process. If an RA is required, the resulting licence will clearly indicate whether, and at what time, it is required to be carried out.
- DoH will set the date to undertake the RA at the expiry of the licence. This is so the majority of the work will have been undertaken by the time the RA takes place and a full picture of the objectives met and benefits accrued, together with any 3Rs advances made, can be obtained. In practice, the licence holder will gather the information required for consideration by the AWERB several months prior to the expiry of the licence in order that there will be sufficient time for the AWERB to conduct its review and for its summary to be submitted to DoH in good time for the report of the RA to be written and published.
- DoH will send a reminder letter to the licence holder 12 months before the RA is due to be undertaken.

- Your assigned inspector will consider the information you have submitted and in doing so confirm whether the information is a fair reflection of the programme of work undertaken under the authority of your project licence, comments on the actual harms and benefits accrued so far and any lessons learned regarding the 3Rs (3Rs opportunities identified and implemented). The RA will then be published alongside the licence's NTS, to form the updated NTS.
- DoH will additionally check the information you supply in a similar way to the NTS i.e. remove personal information that may identify the licence holder or the establishment.

Frequently Asked Questions

1. Q Is Retrospective Assessment the same as Retrospective or Interim Review?

A No. Retrospective or Interim review of project licences is a task undertaken by AWERBs on **all** projects being undertaken at the licensed establishment (see section 10.4(d) of the Guidance to the Act). Retrospective Assessments are undertaken by the Department of Health, with the assistance of the licence holder, the establishment's AWERB and the assigned inspector.

2. Q The severe protocol has not been used – do we still have to carry out a retrospective assessment?

A Yes. This is because the RA is carried out on the programme of work in its entirety not just the protocol with the severe severity category. It is possible that the licence holder has been able to complete the programme of work without the use of the severe protocol and this might represent a 3Rs advancement.

3. Q The information provided by the licence holder refers only to the severe protocol – is this acceptable?

A No. This is because the RA is on the entire programme of work and the severe severity protocol will be an integral part of that programme of work.

4. Q The licence holder has returned all the animals on the severe protocol as moderate – do they still have to provide the information for the RA?

A Yes. This is because experience and perhaps careful preparation, advice taken from named persons or use of an alternative method has resulted in a lower level of actual severity than the prospective severity. This may be an important 3Rs advancement that can be captured and disseminated.

5. Q I thought the NTS had to be updated to incorporate all the information to be supplied by me to complete the RA – is this right?

A No. The current version of the NTS should not be revised. The assigned inspector will create a report based on information requested. The information we require will be asked for in the form sent by the Licensing Team. It is this

information that will be reviewed by the AWERB and submitted to DoH for consideration by your assigned inspector. This DoH report will be published alongside the NTS. The RA report plus the NTS becomes the 'updated NTS'.

6. **Q** My project licence requires more than one RA at various times but the default position is for one RA at the expiry of the licence. What should I do?

A If more than **one** RA is required for your project you need only submit one RA at the expiry of your licence. If you have submitted information already, you may use this to help construct the RA at the end of the project.