



Department of  
**Health**

An Roinn Sláinte

Máinnystrie O Poustie

[www.health-ni.gov.uk](http://www.health-ni.gov.uk)

## **Advice Note**

# **Animals (Scientific Procedures) Act 1986**

## **Project Licence Standard Condition 18 notification**

April 2026

# Contents

Section	Page
Summary	2
1. Introduction 1.1 How will this Advice Note be reviewed and updated?	3
2. What is 'Standard Condition 18'? 2.1 Severity classifications and severity limits 2.2 Other controls	4–6
3. The purpose of Project Licence Standard Condition 18 notification 3.1 Unexpected or unforeseeable events 3.2 Events arising from failure to observe the project licence terms. 3.3 3Rs benefits of notification under Standard Condition 18	7–8
4. When are project licence Standard Condition 18 notifications necessary? 4.1 Are the adverse effects due to the regulated procedures? 4.2 Have the adverse effects exceeded the authorised limitations specified in the project licence? 4.3 Has there been a failure to observe the controls described in the project licence? 4.4 What if an actual breach of either a severity limit or the control was likely to occur, but was prevented? 4.5 Other reporting/notification	9–14
5. Notifying the Secretary of State 5.1 Notification process 5.2 Timeliness of notification	15–16
Glossary	17–18
Appendix 1 – Project Licence Standard Condition 18 Notification Form	19-21
Appendix 2 – Annotated Project Licence Standard Condition 18 Notification Form	22-25

# Summary

- The Department of Health (DoH) is the authority responsible for regulating the operation of the Animals (Scientific Procedures) Act 1986 (ASPA) in Northern Ireland.
- All project licences issued under ASPA by DoH contain 25 standard conditions, which set specific parameters for the package of work for any person working with animals under the terms of the licence.
- Project licence Standard Condition 18 (PPL SC18) requires project licence holders to notify the DoH if constraints on severity or observance of other controls described in the project licence have been or are likely to be breached.
- Breaches may have various causes; they might arise from human error, such as an unanticipated failure to observe the welfare controls specified in the project licence, or from unexpected or unforeseeable events.
- Notification of the DoH under PPL SC18 relates to breaches or likely breaches of either severity limits or any other controls set in the licence. Notification provides an important opportunity for the licence holder, the establishment and DoH to review whether any changes need to be made. Notification under PPL SC18 is not the same as reporting a non-compliance.
- Notification under PPL SC18 should be made without delay. The completed PPL SC18 Notification Form at **Appendix 1** should be emailed to the DoH [ASPA@health-ni.gov.uk](mailto:ASPA@health-ni.gov.uk) promptly within 72 hours of the events being identified.

# 1. Introduction

Project Licence Standard Condition 18 (PPL SC18) is one of 25 standard conditions applied to all project licences issued under the Animals (Scientific Procedures) Act 1986 (ASPAs).

This Advice Note explains both the purpose of PPL SC18 and how project licence holders can comply with the requirements of the condition, that is the circumstances under which they should notify DoH of a breach, or likely breach, of a constraint on the licence.

This Advice Note is aimed at those working under ASPA, to give them greater certainty about when to make a PPL SC18 notification, and when other methods of reporting should be considered instead.

It is aimed primarily at project licensees although it will be of interest to others with responsibilities under ASPA and those involved in training practitioners. This Advice Note will also inform non-practitioners wishing to know more about these issues.

This Advice Note does not provide specific advice on other types of reports or notifications that may be required or advisable.

Good communication is one of the indicators of a good culture of care and helps to build trust between those with responsibilities under ASPA and DoH.

## 1.1 How will the Advice Note be reviewed and updated?

The DoH intends to review the advice contained in this and other Advice Notes as required. The intention is that information in Advice Notes will eventually be incorporated into the *Guidance on the Operation of Animals (Scientific Procedures) Act 1986*.

Please submit any queries or comments on this Advice Note to: [ASPAs@health-ni.gov.uk](mailto:ASPAs@health-ni.gov.uk)

## 2. What is 'Standard Condition 18'?

The DoH grants project licences subject to 25 standard conditions. The wording of these conditions is fixed and does not vary between licences. Sometimes additional conditions may be set, but the 25 standard conditions are a consistent feature of all project licences. The wording of all the standard conditions can be found in the *Guidance on the Operation of Animals (Scientific Procedures) Act 1986 (ASPA)*, available at: [Animal scientific procedures | Department of Health \(health-ni.gov.uk\)](https://www.health-ni.gov.uk/animal-scientific-procedures)

(PPL SC18) is applied to all project licences, in order to ensure adherence to the specific severity limits (the scientific and humane endpoints that set limits on pain, suffering, distress or lasting harm) in each licence.

### **PPL SC18 states:**

*"The licence holder shall ensure adherence to the severity limits as specified in the project licence and observance of any other controls described in the licence. If these constraints appear to have been, or are likely to be, breached, the holder shall ensure that the Department is notified as soon as possible."*

In order to understand whether a PPL SC18 breach has occurred, it is necessary to understand what is meant by the 'severity limits' and 'other controls' described in the licence.

### **2.1 Severity classifications and severity limits**

Each project licensed under ASPA will have a unique series of protocols. The protocols will describe a procedure or series of procedures carried out for a particular purpose within the authorised project.

Any persons working under ASPA must have a good clear understanding of the severity categories **and** the limits of the expected adverse effects set out in each protocol for any licence they work to.

#### **Severity classification**

Since ASPA was amended in 2013 project licence protocols have been categorised in accordance with Annex 8 of Directive 2010/63/EU: Severity Classification of Procedures.

The text of Annex 8 is reproduced in Appendix G of the [Guidance on the Operation of ASPA.pdf \(publishing.service.gov.uk\)](https://publishing.service.gov.uk/guidance/operational-guidance-on-the-operation-of-aspas)

The severity categories of project protocols are:

- non-recovery;
- mild;
- moderate; and
- severe.

The prospective severity category of a protocol is determined by the degree of pain, suffering, distress or lasting harm expected to be experienced by an individual animal during the course of its use in that protocol. The DoH's decision in assigning the category will be based on the most severe effects that the animal is likely to suffer after applying the relevant refinement techniques. More detail on the factors taken into account in assigning the severity category can be found in Appendix G of the operational guidance (*ibid.*).

### Severity limits

PPL SC18 requires the licence holder to adhere to the severity limits (and any other controls) specified in the licence.

The severity limits relate to the expected adverse effects and associated humane endpoints, which are usually specified in project licence protocols. Additional limitations are sometimes specified in the project plan of the licence schedule.

The term 'severity limit' should be thought of as a specific limit or limitation on suffering forming part of the controls of the project licence. The severity limits are the **scientific and humane endpoints** set out in the project licence. **Severity limits are not the same as the severity classification of a protocol.**

### Examples of severity limits:

Quantitative limits (engineering standards)	<p><i>“Tumours will be measured at appropriate intervals. If the product of maximum length and maximum breadth exceeds 1.44 cm<sup>2</sup> the animal will be killed.”</i></p> <p><i>“The percentage proportion of animals anticipated to experience [a particular adverse effect] is x %.”</i></p>
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Qualitative limits (performance standards)	<p><i>“Animals will be killed earlier if the tumour ulcerates or impedes any vital function (for example, locomotion, vision, mastication, excretion).”</i></p> <p><i>“If a large number of small tumours or cysts accumulate in an area that impedes vital function, the mice will be killed.”</i></p>
A humane endpoint applied to the protocol as a whole	<p><i>“Mice will be killed if they show signs of ill health, such as piloerection and hunched posture, inactivity or inappetence for a period of 48 hours. In addition, any animal that loses 20% of its body weight when compared to age-matched control or develops more serious clinical signs such as diarrhoea or dyspnoea will also be killed.”</i></p>
An endpoint defined for a particular adverse effect	<p><i>“If anaphylaxis occurs and animals are seen to do x, y and z, they will be humanely killed.”</i></p>

## 2.2 Other controls

PPL SC18 also requires the licence holder to ensure observance of *“any other controls described in the licence”*. Project licences may specify particular or unique controls, which are intended to provide additional safeguards to limit suffering, for example:

- monitoring regimes (without proper monitoring, breaches of severity limits and other controls may go undetected);
- use of score sheets; and
- supportive measures, such as defined housing conditions, provision of foodstuffs for convalescents, use of medicines or analgesics.

## 3. The purpose of Project licence

### Standard Condition 18 notification

Project licence Standard Condition 18 (PPL SC18) requires that ***“If these constraints appear to have been, or are likely to be, breached, the holder shall ensure that the Department is notified as soon as possible.”***

Notification under PPL SC18 is therefore how licence holders are expected to comply with the legal requirements.

**A person making a report under PPL SC18 is not reporting a non-compliance.** On further discussion with the relevant Inspector, a range of possible outcomes will follow notification. It might be that no action is required, or the project licence is amended, or a non-compliance is acknowledged. However, a failure to notify when there is a requirement to do so is a breach of SC18 and is likely to result in a non-compliance investigation.

#### 3.1 Unexpected or unforeseeable events

DoH recognises that during the course of research unexpected adverse effects may occur. The PPL SC18 notification requirement provides a mechanism for compliance when the unexpected happens and animals may suffer more than is authorised.

Reviewing the cause of the unexpected adverse effects provides an opportunity for the project licence holder, the Animal Welfare and Ethical Review Body (AWERB) and others at the establishment to review study protocols, systems, processes and staff training to identify whether there are any changes that might prevent a recurrence of the problem. In some cases a procedure will simply not be repeated where either an alternative that is expected to be more refined can be found or where the harms now expected are greater than can be justified.

In some situations, the project licence holder will recognise that in order to continue with their research and achieve the satisfactory scientific results from that research, then these unforeseen or unexpected adverse effects are likely to reoccur. Often this will require an amendment to the project licence to specify:

- the now ‘likely adverse effects’;
- how they will be controlled and limited; and
- any relevant humane endpoints.

On submission to the DoH, the Inspector will carry out another harm benefit analysis to determine whether the revised programme of work should be authorised.

### 3.2 Events arising from failure to observe the project licence terms

Alternatively, a requirement to make a PPL SC18 notification might be generated by a personnel failure to observe the specified terms or control measures set out in the project licence. An example of this might be a failure to note that the onset of defined endpoints was happening faster than anticipated and had escaped detection despite normal monitoring. It could also happen as a result of an unanticipated independent factor, such as concurrent subclinical infection. Again, as long as the PPL SC18 notification is made, it may in due course be determined that there are alternative ways to resolve the matter, and it will not necessarily become a non-compliance matter.

### 3.3 3Rs benefits of notification under project licence Standard Condition 18

PPL SC18 notifications provide a key opportunity for the Inspectorate to work with licence holders to assess whether there is evidence that to comply with the principles of replacement, reduction and refinement (the 3Rs) an adjustment should be made to the project licence conditions or protocols. Adjustments are likely to be in relation to refinement or reduction, rather than replacement – but should be treated on a case by case basis, as illustrated by the following examples.

#### Refinement:

- by facilitating a review of the procedures to be undertaken and the likely adverse effects; and
- providing an opportunity for licensees, in conjunction with the Named Persons (the Named Animal Care and Welfare Officer, Named Information Officer [NIO] and the Named Veterinary Surgeon) to provide specific advice to minimise adverse effects in the future and to gather and disseminate 3Rs information.

#### Reduction:

- by ensuring that regulated procedures are not applied to animals that need to be humanely killed according to specified humane endpoints, which may need to be done before the desired data can be gathered; and
- by ensuring that unsuccessful approaches are not repeated.

PPL SC18 notifications may also alert licence holders to common themes of problems or emerging risks, and prompt them to address these issues with an establishment-wide approach. It might help to generate action to address reduction and refinement issues, for example, through discussion at the local AWERB or by improved information sharing by the NIO. Regular reviews of when and why PPL SC18 notifications are being made by an establishment should help to underpin the culture of care, improve 3Rs work and communication, and drive up collaborative working.

## 4. When are Project licence Standard Condition 18 notifications necessary?

A Project licence Standard Condition 18 (PPL SC18) notification needs to be made if the severity limits specified in the licence **or** any other control indicated in the licence has been, or is likely to be breached (the severity limit and the other controls may together be referred to as the 'limitations' specified in the licence). This can relate to any aspect of the project licence, and will depend on the information written into the licence. It should not be automatically considered as a notification of non-compliance.

### **What if there is breach or likely breach of a control, but the severity limit has not been exceeded?**

It is important to note that the wording of PPL SC18 requires notification where there has been a breach, or likely breach of a control even where a severity limit has not been exceeded.

### **What if an animal experienced an unexpected adverse effect?**

An unexpected adverse effect, by its very definition, is an unanticipated source of pain, suffering, distress or lasting harm. It has not formed any part of the consideration put into drawing up of the project licence. It has not been included in the harm benefit analysis that underpins the project licence and therefore has to be notified.

### **What if it was a simple personnel infringement, rather than a compliance failing?**

A PPL SC18 notification is not necessarily a report of a non-compliance. A personnel failure to observe the specified terms or control measures set out in the project licence is likely to require a PPL SC18 notification if a severity limit or any other control has either been breached, or is likely to be breached as a result.

As long as the PPL SC18 notification is made, it may in due course be determined that some particular course of action is appropriate, rather than treating it as a non-compliance matter.

### **What if the breach has not actually happened, because the licensee realised and went back to following the protocol, should the licensee still report it?**

Yes. The licensee is asked to make a report where a breach has occurred or is likely to occur. Of course, it is helpful to have prevented a potential breach. However, it may be that others in the establishment need to be aware:

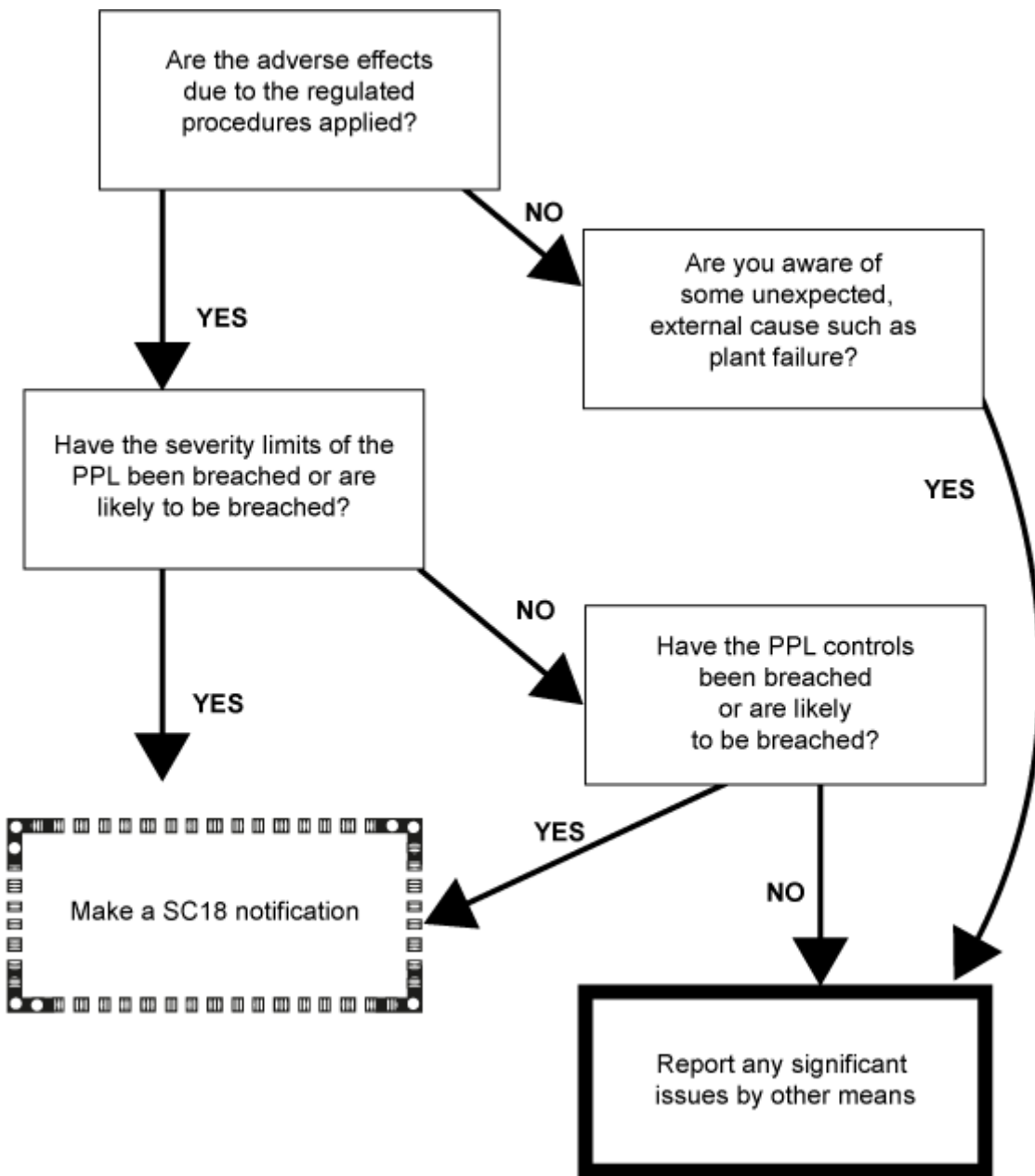
- of a change in practice; or
- that an amendment to the project licence is required to stop others from making the same mistake in the future.

**The following questions may help the licence holder to decide whether or not to make a PPL SC18 notification.**

- Is an animal experiencing adverse effects due to the regulated procedures applied?
- If so, are the effects specified in the project licence or are they unexpected adverse effects?
- If an animal is experiencing adverse effects have they exceeded, or are they likely to exceed, the authorised severity limitations specified in the project licence?
- Is the licence holder aware of either a failure to observe a project licence control or that such a control is likely to be breached?
- Is the licence holder aware of some unexpected external cause not related to the regulated procedure, such as plant failure, leaking water supply, or incidental disease reports?

The decision tree at Figure 1 summarises these considerations.

Figure 1



#### 4.1 Are the adverse effects due to the regulated procedures?

Events that are unrelated to the regulated procedures should not be notified through PPL SC18. In some circumstances it may be necessary to consider whether any adverse effects that occurred, but not as a result of a regulated procedure, will affect the overall suffering of an animal such that a severity limit might be reached earlier than expected.

Examples of adverse effects not related to the regulated procedures are:

- adverse effects associated with plant failure;
- adverse effects associated with leaking water bottles;
- fight wounds in animals on study; and
- incidental disease/injury not related to the study.

In the event that animals undergoing procedures are found dead as a consequence of those procedures, and mortality at this rate is not an authorised adverse effect in the relevant protocol, this is an unexpected adverse effect. This should be reported to the relevant Inspector using the PPL SC18 notification process. In addition, in these circumstances licence holders should also review the guidance in *Advisory notes on recording and reporting the actual severity of regulated procedures* <https://www.health-ni.gov.uk/publications/aspa-actual-severity-reporting>

## 4.2 Have the adverse effects exceeded the authorised limitations specified in the project licence?

Where the adverse effects are due to the regulated procedures, the next stage is to consider whether the effects are unexpected, that is they were not specified in the protocol for the work or considered in the preparation of the project licence. Unexpected adverse effects should be the subject of a PPL SC18 notification.

Where the adverse effects are within the range of what was expected or specified in the terms of the project licence, the next stage is to consider whether they are within the authorised severity limits of the project licence. (See section 2.1 of this document for examples of how limits may be written in the project licence.)

Some examples of possible expected adverse effects that might need to be considered for PPL SC18 notification are:

- a humane endpoint is exceeded despite required monitoring or other measures;
- an unexpected harmful phenotype in a genetically altered animal being maintained on a 'mild' protocol causing pain, suffering or distress that is greater than mild and transient, for example, a genetically altered mouse exhibiting tremor that affects its ability to eat and drink; or
- adverse effects that are more severe or frequent than the descriptions on the project licence, for example, paralysis in all four limbs, when only partial paresis of one limb is authorised.

Note that there will be scenarios where the adverse effects noted are within the authorised limits, **and a PPL SC18 notification is not required**, as shown in the following examples.

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- The mortality rate is authorised by the project licence.
- The frequency and degree of adverse effects is authorised by the project licence;
- The rate of unusual events is authorised by the project licence and appropriate action has been taken to minimise suffering.
- Appropriate and timely action is taken when a humane endpoint is recognised. For example, the project licence specifies that animals will be killed if they lose more than a certain proportion of their original body weight. In the case where an animal is found to have lost slightly more weight but has been promptly and humanely killed, then the animal has reached its endpoint and the correct welfare intervention has been applied, in a timely fashion.

An informed decision needs to be taken by the project licence holder as to whether a notification is necessary. An 'informed decision' is a decision based on:

- knowledge of what an animal is known to have experienced, or is reasonably likely to have experienced, or is likely to be about to experience; and
- the actions taken by those responsible for the animal.

This requires a suitable level of competence in the person making that decision. If in any doubt, advice should be sought from named animal care staff and the Named Veterinary Surgeon. If there is uncertainty over other scenarios, advice can be taken from the assigned Inspector.

### **4.3 Has there been a failure to observe the controls described in the project licence?**

In some circumstances, a report may be required even where the severity limits have not been exceeded. Where there has been a failure to observe the project licence controls for whatever reason, PPL SC18 requires a notification to be made, including an explanation as to how or why the specified controls were not observed.

### **4.4. What if an actual breach of either the severity limit or the control was likely to occur, but was prevented?**

Under PPL SC18 a licence holder is required to make a report where a breach has occurred or is likely to occur. Of course it is helpful to prevent a potential breach. However, it may be that some permanent change needs to be made in order to prevent others making the same mistake. For example, a change in establishment operating practice, or an amendment to the project licence is required. By making a notification report, the licence holder can facilitate a conversation with colleagues and their Inspector about the right preventative actions.

## 4.5 Other reporting/notification

There may be other incidents, or significant events that do not require PPL SC18 reports but that Inspectors should be made aware of promptly. These include events where specially protected species or particularly unusual or unexpected scenarios are involved. Licence holders are encouraged to maintain good communication with their assigned Inspector emails.

**Note that a PPL SC18 notification is not for reporting an actual non-compliance with project licence authorities.** These should be notified to the DoH via email as soon as practicable so that the necessary enquiries can take place without delay. Examples of adverse effects that are potential non-compliance are:

- a failure to make the specified intervention in a timely fashion – for example, the adverse effects section of the project licence protocol states that animals will be killed if their tumours become ulcerated and such an animal is not killed in a timely fashion;
- continuing to breed genetically altered animals with an adverse phenotype not described in the project licence;
- failing to take all measures to minimise suffering – for example, failing to provide adequate analgesia to post-surgical animals; and
- a failure to monitor animals at a frequency specified in the project licence, resulting in avoidable harm.

## 5. Notifying the Department of Health

The project licence holder is legally responsible for notifying the DoH if constraints on severity or observance of other controls described in the project licence have been or are likely to be, breached. The project licence holder is responsible, amongst other things, for ensuring that:

- the degree and duration of adverse effects are minimised;
- the fewest animals die;
- long-lasting pain is ameliorated; and
- at the end of the procedures animals are killed promptly if they are suffering or likely to suffer due to the regulated procedures.

The project licence holder should therefore be aware of the adverse effects being suffered by animals being used under their project licences, and they should ensure that adequate monitoring regimes are in place.

Personal licensees have a responsibility under Personal licence Standard Condition 13 to *“notify the project licence holder as soon as possible when it appears either that the severity limit of any procedure listed in the project licence or the constraints upon adverse effects described in the project licence have been or are likely to be exceeded.”* Project licence holders need to ensure good systems of communication with personal licence holders working under their project licence.

### 5.1 Notification process

The project licence holder should notify the DoH Inspector assigned to the establishment. The report should be submitted using secure email to [ASPA@health-ni.gov.uk](mailto:ASPA@health-ni.gov.uk).

The PPL SC18 reporting template is at Appendix 1 and an annotated form with more information about the specific information needed at Appendix 2. The information provided should be clear and concise but sufficient to give the Inspector an understanding of what has happened and why, and what steps are being taken to prevent or minimise the likelihood of recurrence.

The Inspector will consider the contents of the notification and assess what action should be recommended to the DoH. This may be straightforward, for example, to note the details and agree that the appropriate remedial measures have been put in place so no further action is necessary. Sometimes further discussion is required with the project licence holder to seek information and reassurances regarding the conduct of future studies. It may be that an amendment to the project licence is required before the procedures giving rise to the unauthorised adverse effects may be repeated.

### **Repetition of 'unexpected' adverse effects**

Where an unexpected adverse effect is considered likely to arise again because it is now an expected adverse effect, an amendment to the project licence may be required to incorporate this adverse effect.

Typically the same unexpected adverse effects due to the same cause would become 'expected' after being observed twice or more in close succession.

The PPL SC18 notification may be the first step in recognising that a review of the circumstances by the Animal Welfare and Ethical Review Body, Named Persons and the assigned Inspector is required, and perhaps an application needs to be made to amend the project licence before the same type of study is undertaken again.

## **5.2 Timeliness of notification**

PPL SC18 requires notification 'as soon as possible'. DoH's expectation is that the Notification template at Appendix 1 should be emailed to DoH without delay. This email, should be received by the DoH within 72 hours of the events having occurred, or being identified as a potential risk.

Notification should not be delayed pending completion of internal investigations. In such instances a PPL SC18 notification should be made as soon as possible, and may contain text such as "results awaited" or similar. The project licence holder should then update the notification and submit it by email with the results of any internal investigation or test results when they are available. When the notification is updated / revised, the new version date should be added to the end of the filename.

<b>Glossary</b>	
<b>3Rs</b>	The three 'Rs' – replacement, reduction, refinement
<b>Actual severity</b>	The actual intensity of pain, suffering, distress or lasting harm experienced by an animal in a procedure or series of procedures. It should be the highest level experienced at any point during the course of the procedure and should take into account any cumulative effects
<b>ASPA/the Act</b>	Animals (Scientific Procedures) Act 1986
<b>AWERB</b>	Animal Welfare and Ethical Review Body
<b>DoH</b>	Department of Health
<b>Harm-benefit analysis</b>	An analysis in which the likely adverse effects in a procedure within a project are weighed against the potential benefits of the project for people, animals or the environment
<b>Humane endpoint</b>	Clear, predictable and irreversible criteria that allow the early termination of a procedure before an animal experiences harm that is not authorised or scientifically justified
<b>PPL</b>	Project licence
<b>PPL SC</b>	Project Licence Standard Condition. There are 25 standard conditions appended to every project licence issued under <b>ASPA</b>
<b>Project Licence</b>	A licence issued under <b>ASPA</b> authorising a scientific programme of work
<b>Protocol</b>	A procedure or series of procedures carried out for a particular purpose as part of an authorised project
<b>Regulated procedure</b>	Any procedure applied to a protected animal for a qualifying purpose, which may have the effect of causing the animal a level of pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle in accordance with good veterinary practice

<b>Reduction</b>	Methods that minimise the number of animals used for each experiment
<b>Refinement</b>	Methods that minimise suffering and improve animal welfare
<b>Severity classification</b>	The classification of severity as 'non-recovery', 'mild', 'moderate' or 'severe'
<b>Severity limit</b>	The limit of the severity authorised for that <b>protocol</b> in the <b>PPL</b> according to the <b>3Rs</b> measures written into the PPL and approved by the <b>harm–benefit analysis</b> . Note that the severity limit, unlike the <b>severity classification</b> will vary between every PPL.



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## Appendix 1

### PPL Standard Condition 18 Notification Form

Please use this form to notify the Department of Health (DoH) of procedural-related adverse effects that have exceeded or are likely to exceed the severity limitations or controls described in the project licence. DoH will use this information to determine whether any further action is required. **Read the accompanying Advice Note before completing this form.**

All Sc18 reports should be submitted within 72h of becoming aware of the incident. If full investigation cannot not be concluded within 72h, please report on the form what investigations are outstanding (where known) and that an update will be supplied once further information is available / internal investigations have been completed.

Do not use to report:

- adverse effects that are due to non-procedural issues;
- potential non-compliance (report by other means);
- issues without adverse welfare consequences.

If you are in doubt whether or not you need to fill in this form, please contact your assigned Inspector.

Please clearly title your document: **‘PPL [number] Standard Condition 18 Form – Severity Exceeded – [Date]’**. The date should be the date that the breach was identified. Send to DOH [e-mail] with the subject heading ‘PPL SC 18 Notification PPL [Number] Any updates should be identified with a version date added at the end. Urgent requests to keep animals alive should be sent by email marked “URGENT”.

<b>Establishment Licence name</b>	
<b>Establishment Licence number</b>	
<b>Name of PPL holder</b>	
<b>PPL number</b>	

<b>Protocol no</b>	
<b>Protocol title</b>	
<b>Severity classification</b>	
<b>1. Date of incident</b>	
<b>2. Species</b>	
<b>3. Brief details of study and how the limits or constraints have been breached</b>	
<b>4. Have you taken advice from the Named Animal Care and Welfare Officer/Named Veterinary Surgeon/others?</b>	
<b>5. Cause of Problem, if known</b>	
<b>6. Action that has been or will be taken</b> <i>(For example, formulation of drug changed, supportive treatment given, study design modified). If no action needed, indicate why (for example, none required as study has been terminated and will not be repeated)</i>	
<b>7. Reported by (name)</b>	
<b>8. Date</b>	

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

**Inspector's comments and recommendations:**

<b>Comments and recommendations</b>	
<b>Inspector name</b>	
<b>Date</b>	

# Appendix 2

## Annotated PPL Standard Condition 18 Notification Form

Please use this form to notify the Department of Health (DoH) of procedural-related adverse effects that have exceeded or are likely to exceed the severity limitations or controls described in the project licence. ASRU will use this information to determine whether any further action is required. **Read the accompanying Advice Note before completing this form.**

All Sc18 reports should be submitted within 72h of becoming aware of the incident. If full investigation cannot not be concluded within 72h, please report on the form what investigations are outstanding (where known) and that an update will be supplied once further information is available / internal investigations have been completed.

Do not use to report:

- adverse effects that are due to non-procedural issues;
- potential non-compliance (report by other means);
- issues without adverse welfare consequences.

If you are in doubt whether or not you need to fill in this form, please contact your assigned Inspector.

Please clearly title your document: **'PPL [number] Standard Condition 18 Form – Severity Exceeded – [Date]'**. The date should be the date that the breach was identified. Send to DOH [e-mail] with the subject heading 'PPL SC 18 Notification PPL [Number] Any updates should be identified with a version date added at the end. Urgent requests to keep animals alive should be sent by email marked "URGENT".

<b>Establishment Licence name</b>	
<b>Establishment Licence number</b>	
<b>Name of PPL holder</b>	
<b>PPL number</b>	
<b>Protocol no</b>	Note: Make sure this is the project protocol number and not any other document reference
<b>Protocol title</b>	

<b>Severity classification</b>	<p>Note: Include</p> <ul style="list-style-type: none"> <li>a) severity classification of the protocol in the granted licence and</li> <li>b) actual severity of the affected animals that are the subject of the report.</li> </ul> <p>e.g.</p> <ul style="list-style-type: none"> <li>a) <i>Protocol SW4</i>    <i>Moderate</i></li> <li>b) <i>Actual severity</i>    <i>Severe</i></li> </ul>
<b>1. Date of incident</b>	Date of discovery
<b>2. Species</b>	

**Brief details of study and how the limits or constraints have been breached**

Notes:

- a) A severity limit is an endpoint or limit specified in the licence. It is not the same as the severity classification on of the protocol.
- b) First, provide the number affected *e.g. 3 mice out of an experiment using 20 mice, in 4 groups.*
- c) Include numbers / type of experimental groups, and distribution of adverse effects across them, as it is important in considerations of likely cause.
- d) Include date of the start of experiment as well as the date of discovery. In the case of GA breeding, provide the age of the animal(s).
- e) Include time frames – *e.g. injection was on 15<sup>th</sup> March and animals were found dead 3 days later*
- f) Include the details of the personal licence holder responsible for the animal(s). If two or more personal licence holders are working on the same animal, it must be clear who is primarily responsible for the animal(s).
- g) If someone other than the personal licence holder was monitoring, explain why.
- h) If reporting unexpected adverse effects relating to the breeding of genetically altered mice or fish, please provide data about the incidence of such effects in the background strain if known.

*e.g. The experiment started (date). Following administration of 0.1ml of test substance (novel antimicrobial provided by the client) 10 days later by intra-peritoneal injection (step 3 of the protocol) the 3 mice were found dead by (person, role) at the last check of the day. Death is not specified as an expected adverse effect of this procedure. All the affected mice were from the same cage and had been part of one of the control groups. All mice in the study had been visually checked 30min and 2 hours after injection in accordance with the monitoring schedule specified in the protocol. One PiLh (Dr xyz) carried out all the injections. They had been trained and signed off as competent to do I/P injections approximately 2 years ago and have undertaken the technique several hundred times since then without incident.*

<p><b>4. Have you taken advice from the Named Animal Care and Welfare Officer/Named Veterinary Surgeon/others?</b></p>	<p>Note: The NACWO and/or NVS should normally be consulted  <i>e.g. The NACWO was contacted immediately and performed a PM on the three mice. There were no findings of note apart from slight inflammation around the entry point of the needle. Samples were taken for laboratory analysis. Photos have been sent to the NVS and a meeting arranged once the laboratory test results are available.</i></p>
<p><b>5. Cause of Problem, if known</b></p>	<p>Note: Update the report when the cause is determined.  <i>e.g., As yet unknown</i></p>
<p><b>6. Action that has been or will be taken</b>  <i>(For example, formulation of drug changed, supportive treatment given, study design modified). If no action needed, indicate why (for example, none required as study has been terminated and will not be repeated)</i></p>	<p>Note: If you wish to keep animals alive that have experienced or are experiencing unexpected adverse effects, you need to seek authority from the Department. You will need to provide scientific justification for continuing to use the animals and support from the NVS and NACWO.</p> <p><i>e.g. All remaining animals are currently behaving normally, and monitoring will be increased to at least twice a day until the end of the experiment. The study will not be repeated until the internal investigation has been completed.</i></p> <p><i>Samples from the test substance are being quality checked and the protocol and records relating to making up the test substance are being investigated.</i></p> <p><i>This report will be updated when internal investigations have been concluded.</i></p>
<p><b>7. Reported by (name)</b></p>	<p>Note: The project licence holder has a legal responsibility to submit PPL SC18 reports. It is acceptable for a senior personal licence holder to write and submit the report, but the project licence holder MUST be aware before the report is submitted, and will be assumed to have approved it, unless DoH is told to the contrary. The inspector will respond to the project licence holder, and may or may not include personal licence holders in the response.</p>
<p><b>8. Date</b></p>	<p>Note: Date report was written</p>

