

Evidence for assessment of compliance against ASPA and licence conditions

Animals in Science Regulation Unit (ASRU)

September 20, 2021

Assessment of Establishment Licence Holder Compliance

ASPA clause or licence condition	Summary of statutory requirements (full details contained in Guidance of the Operations of ASPA and on licences)	Examples of documentary evidence (these are examples only and are not intended to be comprehensive)	Examples of additional evidence
<p>PEL Standard Condition 1</p> <p>Compliance with 3Rs</p>	<p>The licence holder shall ensure that the regulated activities carried on at the establishment are carried on in a manner that is consistent with the principles of replacement, reduction, and refinement.</p>	<p>AWERB minutes demonstrating strategic, consistent, and holistic oversight of 3Rs</p> <p>AWERB minutes demonstrating processes for obtaining and sharing best practice on 3Rs with other establishments/AWERBs</p> <p>Documented job descriptions for named persons (especially NIO) specifying roles for 3Rs</p> <p>Documentary evidence of specific establishment initiatives aligned to the 3Rs</p> <p>Documentary evidence of new staff induction /training including specific information on how the 3Rs are ensured at the establishment</p> <p>If the establishment has a NC3Rs programme manager, documentary evidence of the role they play within the establishment governance systems</p> <p>Documentation of a 3Rs strategy and management of 3Rs challenges and initiatives</p>	<p>Interview with PEL holder confirming processes for ensuring compliance with the 3Rs including knowledge of current 3Rs challenges and /or initiative</p> <p>Interview with AWERB chair confirming AWERB strategy for promoting and ensuring compliance with 3Rs</p> <p>Interview with named persons confirming roles and responsibilities for 3Rs oversight and promotion of best practice</p> <p>Observation of animal care and/or regulated procedures conducted in compliance with 3rs</p>

ASPA clause or licence condition	Summary of statutory requirements (full details contained in Guidance of the Operations of ASPA and on licences)	Examples of documentary evidence (these are examples only and are not intended to be comprehensive)	Examples of additional evidence
<p>PEL Standard Condition 2</p> <p>Killing register and competence</p>	<p>The licence holder shall maintain a killing register which contains the names of those competent to kill protected animals together with the species and method for which they are competent to kill. All staff must be supervised until certified as competent to kill unsupervised. There must always be sufficient staff present to kill animals as needed.</p>	<p>Killing register containing all required fields including clear demonstration of those requiring supervision and those competent to kill unsupervised, including most recently trained individuals</p> <p>Standard Operating Procedures and/or Training Material related to training and competency to kill</p> <p>Process by which staff are allocated, particularly to weekend shifts, in such a way that all species of animals can be humanely killed if necessary</p>	<p>Observation of killing within unit and cross check of training and competency records and killing register for those performing killing</p> <p>Interview with PIL holder(s) confirming training and competency process for killing</p> <p>Interview(s) with animal care staff confirming training and competency process for killing</p>
<p>PEL Standard Condition 3</p> <p>Changes to establishment licence details</p>	<p>The licence holder shall update on their licence any named person, area within schedule of premises or animals kept.</p>	<p>Process to update establishment licence upon any changes occurring</p>	<p>Confirmation that all information on establishment licence is current and correct</p> <p>Interview with PEL holder, AWERB Chair and named persons to confirm processes for updating of establishment licence</p>
<p>PEL Standard Condition 4</p> <p>Suitable care, accommodation, and equipment</p>	<p>The licence holder shall ensure appropriate care, accommodation, food, and water for all animals. At least daily checks of equipment and animal health occurs.</p>	<p>Standard Operating Procedures for daily checks, equipment and accommodation checks, maintenance and repair and transportation of animals</p> <p>It is required such checks can assess the health of each individual animal unless they are too small to be visualised (e.g. zebrafish fry)</p>	<p>Interview of animal care staff with regard to training, competency performance and quality control/monitoring of daily checks</p> <p>Interview of PIL holders to determine their understanding and knowledge of the systems to ensure provision of food and water</p>

ASPA clause or licence condition	Summary of statutory requirements (full details contained in Guidance of the Operations of ASPA and on licences)	Examples of documentary evidence (these are examples only and are not intended to be comprehensive)	Examples of additional evidence
	<p>Processes are in place to address any deficits in equipment or animal health as soon as possible</p> <p>All care and accommodation is in line with Code of Practice.</p>	<p>Risk assessment and mitigation for completeness of daily checks especially at times of high risk, such as weekends or after PIL holders have moved animals</p> <p>Processes for resolving identifying health issues in animals, particularly at weekends or after standard hours</p> <p>Training and competency processes and records for performance of daily checks</p> <p>Records of performance of daily checks</p> <p>Mechanisms for assessing the effectiveness and completeness of daily checks</p> <p>Maintenance and repair backlog and time required to address maintenance and/or repair requests</p> <p>Processes followed when a new species is to be brought into the unit.</p>	<p>Interview of named persons to confirm processes used when new species are to be introduced to the unit</p> <p>Direct observation of daily checks</p> <p>Direct observation of maintenance and repair tasks outstanding</p>
<p>PEL Standard Condition 5</p>	<p>The licence holder must ensure suitable numbers of suitably trained and competent animal care staff are available.</p>	<p>Standard operating procedure or documented process for staffing the unit with specific reference to consideration for minimum staffing levels at weekends or outside regular working hours</p>	<p>Interviews with named persons and/or management staff to confirm staff allocation and training and competency process</p>

ASPA clause or licence condition	Summary of statutory requirements (full details contained in Guidance of the Operations of ASPA and on licences)	Examples of documentary evidence (these are examples only and are not intended to be comprehensive)	Examples of additional evidence
Provision of sufficient suitably trained staff		<p>Animal care staffing strategy and recruitment plan</p> <p>Animal care training and competency process and records</p>	Direct observation of competency of animal care staff and cross check of their individual training and competency record
<p>PEL Standard Condition 6</p> <p>AWERB</p>	<p>The licence holder must ensure the existence of an effective AWERB constituted in line with statutory functions which performs all the functions required in law.</p> <p>All advice provided by the AWERB must be retained for 3 years.</p>	<p>AWERB Charter or Terms of reference are compliant with statutory requirements</p> <p>AWERB minutes demonstrate that the AWERB has conducted all the functions required by ASRU Guidance</p> <p>AWERB minutes or supporting documents clearly demonstrate the reviews and detailed advice given by the AWERB and demonstrate follow up of such advice.</p> <p>Metrics which demonstrate effectiveness and impact of AWERB activity</p>	<p>PEL holder and AWERB interviews confirms effective functioning of AWERB and processes by which their effectiveness and impact are assessed</p> <p>Named persons interview confirms effective functioning of AWERB and processes by which their effectiveness and impact are assessed</p> <p>PPL holder interview confirms effective functioning of AWERB and processes by which their effectiveness and impact are assessed</p> <p>Direct observation of changed processes or standards in operation resulting from AWERB recommendations</p>
<p>PEL Standard Condition 7</p> <p>Strategy to reduce number of wild caught non -human primates in breeding colony</p>	<p>The licence holder may not breed non-human primates from wild caught animals unless they have a strategy to reduce the use of animals bred from those captives born.</p>	<p>Written strategy to reduce use of wild caught non-human primates for breeding approved by ASRU (this may be contained within a breeding licence)</p> <p>Demonstration that any change in this strategy has been submitted to and approved by ASRU</p>	<p>Interviews with PEL holder, AWERB Chair, named persons and relevant PPL holder to confirm strategy for reduction in use of wild caught primates for breeding colonies</p>

ASPA clause or licence condition	Summary of statutory requirements (full details contained in Guidance of the Operations of ASPA and on licences)	Examples of documentary evidence (these are examples only and are not intended to be comprehensive)	Examples of additional evidence
		Breeding and colony records for non-human primates showing decreased reliance on wild caught non-human primates for breeding	
<p>PEL Standard Condition 8</p> <p>Keeping of source, use and disposal documents</p>	<p>The licence holder must maintain and keep for five years records which show details of source, use and disposal of all protected animals and summaries thereof.</p>	<p>Standard Operating Procedures for source, use and disposal documentation</p> <p>Source, use and disposal documentation which meets all statutory requirements</p>	<p>Interviews with PEL holder, AWERB Chair, Named Persons, PIL, PPL holders and animal care confirm processes for documentation of source, use and disposal for all animals.</p> <p>Direct observation of animals and/or procedures with cross checking of source, use and disposal records for those animals.</p>
<p>PEL Standard Condition 9</p> <p>Individual history file for cats, dogs, and non- human primates</p>	<p>The licence holder must ensure individual health records are kept for dogs, cats and non-human primates containing all required statutory information. This record must accompany the animal if transferred to another establishment or rehomed. These records must be kept for 3 years after the death, setting free or transfer of any animal (except to another licensed establishment).</p>	<p>Standard Operating Procedure for individual health records</p> <p>Individual health records which meet all statutory requirements including for those which have died or have been set free within the previous 3 years.</p>	<p>Interviews with PEL holder, AWERB Chair, Named Persons, PIL, PPL holders and animal care staff confirm processes for maintenance of individual history files</p> <p>Direct observation of cats, dogs and/or non-human primate and cross check with the relevant individual health care record</p>
<p>PEL Standard Condition 10</p>	<p>Dogs, cats, and non-human primates must be permanently marked in the most refined</p>	<p>Standard Operating Procedure for marking of dogs, cats, and non-human primates</p>	<p>Interviews with PEL holder, AWERB Chair, Named Persons, PIL, PPL holders and animal care staff confirm processes for marking of dogs, cats, and non-human primates</p>

ASPA clause or licence condition	Summary of statutory requirements (full details contained in Guidance of the Operations of ASPA and on licences)	Examples of documentary evidence (these are examples only and are not intended to be comprehensive)	Examples of additional evidence
Marking for dogs, cats, and non-human primates	manner possible as soon as practically possible.	Documents confirming the marking of dogs, cats, and non-human primates	Direct observation of marking of cats, dogs and/or non-human primate and cross check with the relevant records
PEL Standard Conditions 11, 12, 13 not routinely assessed	Inspector access to all areas of establishment. Animals must only be kept in areas appropriately designated.	Animal records and cross checking against details of establishment licence	Direct observation of animals held in designated areas and cross checking against details of establishment licence
PEL Standard Condition 14 Health records	The licence holder will ensure health records are kept under the supervision of the NVS.	Standard Operating Procedure on maintenance of Health Records Review of health records	Interviews with PEL holder, AWERB Chair, NVS, NACWO, PIL holder and animal care staff confirming process for maintaining and accessing health records Direct observation of animals cross checked with accompanying health care records
PEL Standard Conditions 15 and 16 Performance of Named Persons	The licence holder is responsible for the performance of the named persons. There are adequate arrangements for cover when named persons are not available.	Organogram showing the named persons Job/Role descriptions for named persons which cover all responsibilities covered in the Guidance on the Operation of ASPA. Documented process/standards for appointment of named persons Documented evidence of engagement of named persons directly with PEL holder	Interviews with named persons to confirm their responsibilities, understanding of and conduct of their required responsibilities Interview with animal care staff, PIL and PPL holder(s) to confirm engagement with named persons and their effectiveness and performance

ASPA clause or licence condition	Summary of statutory requirements (full details contained in Guidance of the Operations of ASPA and on licences)	Examples of documentary evidence (these are examples only and are not intended to be comprehensive)	Examples of additional evidence
		<p>Documented evidence of NVS and NACWO engagement with contribution to AWERB processes</p> <p>Review of named persons training and competence records</p> <p>Process to be followed in case of absence of named person</p>	
<p>PEL Standard Condition 17</p> <p>Security and Prevention of Escape of animals</p>	<p>Licence holders must have systems to prevent access of unauthorised individuals to animal care areas.</p> <p>Licence holders must have processes to prevent escape of protected animals.</p>	<p>Standard Operating Procedures for access to animal areas including after standard working hours</p> <p>Records demonstrating individual access to animal areas</p> <p>Standard Operating Processes and Documented Strategy for preventing escape of protected animals</p> <p>Records of escapes of protected animals with associated preventive and corrective actions</p>	<p>Interviews with PEL holder, NACWO, animal care staff and PIL holder conform access arrangements and strategies to prevent animal escape</p> <p>Direct observation of mechanisms to prevent escape of animals</p> <p>Direct observation of access control to animal areas</p>
<p>PEL Standard Condition 18</p>	<p>Licence holders must ensure the provision and use of quarantine and acclimatisation facilities as needed.</p>	<p>Standard Operating Procedures for quarantine and acclimatisation</p>	<p>Interviews with PEL holder, NACWO, NVS, animal care staff, PIL and PPL holder to confirm process for quarantine and acclimatisation</p>

ASPA clause or licence condition	Summary of statutory requirements (full details contained in Guidance of the Operations of ASPA and on licences)	Examples of documentary evidence (these are examples only and are not intended to be comprehensive)	Examples of additional evidence
Quarantine and acclimatisation facilities		<p>Designated area on licence for quarantine and acclimatisation</p> <p>Records demonstrating use of quarantine and acclimatisation areas as needed</p>	Direct observation of quarantine and acclimatisation areas and cross check where possible with records
<p>PEL Standard Condition 19</p> <p>Precaution against fire</p>	The licence holder must maintain adequate precautions against fire.	<p>In-date risk assessment for fire</p> <p>Standard Operating Procedure for processes to be followed in case of fire</p> <p>Training records in actions to be taken in case of fire</p> <p>Records demonstrating last fire drill including recommendations and evidence that the recommendations have been followed</p>	Interviews with PEL holder, named persons, animal care staff, PIL and PPL holders to confirm processes to be followed in case of fire and training in prevention of and management of fire
<p>PEL Standard Condition 20</p> <p>Prevention of unauthorised procedures</p>	The licence holder must take adequate procedures to prevent unauthorised procedures.	<p>Standard Operating Procedure outlining processes used by establishment to prevent unauthorised procedures.</p> <p>Documentary records of the review processes which are part of the process to prevent unauthorised procedures</p>	Interviews with PEL holder, named persons, animal care staff, PIL and PPL holders to confirm establishment processes used to prevent unauthorised procedures
<p>PEL Standard Condition 21</p> <p>Effective communication</p>	The licence holder must ensure effective communication and liaison between animal care staff, named persons and licence holders.	<p>Standard Operating procedure or strategy for ensuring effective communication and liaison</p> <p>Metrics used to monitor the effectiveness of communication and liaison</p>	Interviews with PEL holder, named persons, animal care staff, PIL and PPL holders to confirm establishment processes used to ensure effective communication and their assessment of the effectiveness of such processes

ASPA clause or licence condition	Summary of statutory requirements (full details contained in Guidance of the Operations of ASPA and on licences)	Examples of documentary evidence (these are examples only and are not intended to be comprehensive)	Examples of additional evidence
		<p>Preventive and/or corrective actions taken when ineffective communication was observed</p> <p>Minutes of relevant meetings between groups</p>	<p>Direct observation of culture of communication and liaison</p>
<p>PEL Standard Condition 22</p> <p>Death (sudden departure) of a licence holder</p>	<p>The licence holder must notify ASRU within 7 days of becoming aware of the death (sudden departure) of a project licence holder and shall, unless otherwise directed take responsibility for compliance of the conditions of that project licence for 28 days.</p>	<p>Standard Operating procedure to be followed in circumstances of death/sudden absence of project licence holder</p> <p>Documented processes followed in cases where project licence holder died or suddenly departed</p>	<p>Interviews with PEL holder to confirm processes to be followed in circumstances of death/sudden departure of project licence holder including how the PEL holder would ensure compliance with the project licence conditions</p>
<p>PEL Standard Condition 23</p> <p>Keeping alive, rehoming, reuse and setting free</p>	<p>The licence holder must ensure that any animals kept alive at the end of regulated procedures are kept under the care of the NVS and all statutory steps taken and documented for reuse, rehoming or setting free.</p>	<p>Standard Operating Procedures for keeping animals alive after procedures, re-use, rehoming and setting free</p> <p>Records of veterinary assessments for keeping animals alive and as part of the process of reuse, rehoming and/or setting animals free</p>	<p>Interviews with PEL holder, NVS, animal care staff, NACWO, PIL and PPL holder with regard to processes for keeping animals alive and for re-use, rehoming and setting free.</p>
<p>PEL Standard Condition 24</p>	<p>The licence holder must ensure all named persons and licence holders have access to the establishment licence.</p>	<p>Documented mechanisms for accessing establishment licence</p>	<p>Interviews with PEL holder, named persons and PIL/PPL licence holders to confirm how they can access the establishment licence</p> <p>Direct observation mechanisms whereby the establishment licence can be accessed</p>

Assessment of Project Licence Holder Compliance

ASPA clause or licence condition	Summary of statutory requirements (full details contained in Guidance of the Operations of ASPA and on licences)	Examples of documentary evidence (these are examples only and are not intended to be comprehensive)	Examples of additional evidence
<p>PPL Standard Condition 1</p> <p>Compliance with licence conditions</p>	<p>The licence holder is responsible for the overall implementation of the programme of work specified in this licence and for ensuring that the programme of work is carried out in compliance with the conditions of the licence.</p>	<p>Documentary evidence of specific PPL training and updates.</p> <p>Documentary evidence of new staff induction / training including specific information on how compliance with PPL conditions are ensured</p> <p>Documentary evidence of how the work undertaken under this PPL is supervised by the PPLh</p>	<p>Interview with PPL holder confirming processes for ensuring compliance with licence conditions and oversight of the work undertaken under this PPL</p>
<p>PPL Standard Condition 2</p> <p>Non animal Alternatives</p>	<p>The licence holder shall ensure that the specified programme of work does not involve the application of any regulated procedure to which there is a scientifically satisfactory alternative method or testing</p>	<p>Documentary evidence of the search strategy used to identify non-animal alternatives</p>	<p>Interview with PPLh to discuss the strategy</p> <p>Interview with NIO to discuss the strategy</p>

ASPA clause or licence condition	Summary of statutory requirements (full details contained in Guidance of the Operations of ASPA and on licences)	Examples of documentary evidence (these are examples only and are not intended to be comprehensive)	Examples of additional evidence
	strategy not entailing the use of a protected animal.		
<p>PPL Standard Condition 3</p> <p>Duplication of work to meet regulatory requirements</p>	<p>The licence holder shall ensure that regulated procedures are not applied to an animal as part of the specified programme of work if the data to be obtained from the application of those procedures is already available in a member state and has been obtained there by procedures which satisfy any relevant regulatory requirements of the EU.</p>	<p>Process to ensure data is not already available.</p> <p>SOPs documenting the process</p>	<p>Interview with PPL holder, and any relevant administrators to ensure the process is being followed</p>
<p>PPL Standard Condition 4</p> <p>Experimental design</p>	<p>The licence holder shall ensure that the regulated procedures applied as part of the programme of work specified in this licence are those which to the greatest extent use the minimum number of animals, involve animals with</p>	<p>Establishment processes for ensuring experimental design, data collection and analysis is appropriate and likely to produce meaningful results</p> <p>Use of NC3R's EDA</p> <p>Review of publication history</p>	<p>Interview of PPLh and Establishment bio-statistician with regard to Experimental design data collection and analysis</p>

ASPA clause or licence condition	Summary of statutory requirements (full details contained in Guidance of the Operations of ASPA and on licences)	Examples of documentary evidence (these are examples only and are not intended to be comprehensive)	Examples of additional evidence
	the lowest capacity to experience pain, suffering, distress or lasting harm, cause the least pain, suffering, distress or lasting harm and are most likely to provide satisfactory results.		
PPL Standard Condition 5 Refinement of procedures	The licence holder shall ensure that the regulated procedures applied as part of the programme of work specified in this licence are designed so as to result in the death of as few protected animals as possible and to reduce to the minimum possible the duration and intensity of suffering caused to those animals that die and, as far as possible, ensure a painless death.	Establishment processes for ensuring experimental design, data collection and analysis is appropriate and likely to produce meaningful results Establishment processes for ensuring experiments are as refined as possible and for post experiment review to ensure any relevant lessons are learned before the next experiments are undertaken Animal care training and competency process and records	Interview of PPLh, NVS and NACWOs plus Establishment bio statistician with regard to Experimental design data collection and analysis Direct observation of competency of animal care staff and cross check of their individual training and competency record
PPL Standard Condition 6 Appropriate level of supervision	The licence holder shall ensure that the appropriate level of supervision is provided for all	Processes for ensuring experiments are adequately supervised Animal care training and competency process and records	Direct observation of competency of animal care staff and cross check of their individual training and competency record

ASPA clause or licence condition	Summary of statutory requirements (full details contained in Guidance of the Operations of ASPA and on licences)	Examples of documentary evidence (these are examples only and are not intended to be comprehensive)	Examples of additional evidence
	personal licensees carrying out regulated procedures under the authority of this licence.		
PPL Standard Condition 7 Controls and limitations	The licence holder shall ensure that a regulated procedure is not applied to an animal as part of the programme of work specified in this licence if the procedure may cause the animal severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated.	Review of controls and limitations on the steps within the PPL	Interviews with PPLh, PILs NVS and NACWOs to discuss how these work in practice
PPL Standard Condition 8 Humane endpoints	The licence holder shall ensure that where a regulated procedure is being applied to an animal as part of the programme of work specified in this licence, any unnecessary pain, suffering, distress or lasting harm that is being caused to the animal shall be stopped.	Review of humane endpoints on the steps within the PPL	Interviews with PPLh, PILs NVS and NACWOs to discuss how these work in practice

ASPA clause or licence condition	Summary of statutory requirements (full details contained in Guidance of the Operations of ASPA and on licences)	Examples of documentary evidence (these are examples only and are not intended to be comprehensive)	Examples of additional evidence
<p>PPL Standard Condition 9</p> <p>Death as an endpoint</p>	<p>The licence holder shall ensure that where a regulated procedure is applied to an animal as part of the specified programme of work, death as the end point of the procedure is avoided as far as possible and is replaced by an early and humane end point; and as soon as the purpose of the procedure has been achieved, the procedure is stopped and appropriate action is taken to minimise the suffering of the animal.</p>	<p>Review of humane endpoints on the steps within the PPL</p>	<p>Interviews with PPLh, PILs NVS and NACWOs to discuss how these work in practice</p>
<p>PEL Standard Condition 10</p> <p>Actual severity classification</p>	<p>The licence holder shall ensure that where a regulated procedure has been applied to an animal as part of the programme of work specified in this licence, a suitably qualified person classifies the severity of the procedure as “non-recovery”, “mild”, “moderate” or “severe” using the criteria in Annex 8 of the Animals Directive. For the purposes of this</p>	<p>Standard Operating Procedure for severity classification and Return of procedures</p> <p>Experimental records</p> <p>Documents confirming the severity classification</p>	<p>Interviews with PPL holder PIL holders working on the PPL</p> <p>Cross checking with computer systems or other records which log severity for ROPs</p>

ASPA clause or licence condition	Summary of statutory requirements (full details contained in Guidance of the Operations of ASPA and on licences)	Examples of documentary evidence (these are examples only and are not intended to be comprehensive)	Examples of additional evidence
	condition, a series of regulated procedures applied to an animal for a particular purpose is to be treated as constituting a single regulated procedure.		
PPL Standard Condition 11 Keeping alive at the end of procedures	Where a series of regulated procedures are applied to an animal for a particular purpose the licence holder shall ensure that the animal is killed at the end of the series unless a veterinary surgeon or other competent person has determined that the animal is not suffering and is not likely to suffer adverse effects, as a result of the regulated procedures.	Review of end of procedures within the PPL Establishment SOP for keeping alive at the end of procedures	Interviews with PPLh, NVS and NACWOs to discuss how these work in practice
PPL Standard Condition 12 Stray animals	Regulated procedures shall not be carried out on any stray animal of a domestic species as part of the programme of work specified in this licence.	Process to prevent the use of stray animals	Interviews with PEL holder, NVS, NACWO, PPL holder and animal care staff confirming process

ASPA clause or licence condition	Summary of statutory requirements (full details contained in Guidance of the Operations of ASPA and on licences)	Examples of documentary evidence (these are examples only and are not intended to be comprehensive)	Examples of additional evidence
<p>PPL Standard Condition 13</p> <p>Special authorisation for animal use</p>	<p>Except with the authorisation of the Secretary of State, regulated procedures shall not be carried out as part of the programme of work specified in this licence on any of the following type of animal:</p> <p>a) any feral animal of a domestic species</p> <p>b) any animal taken from the wild</p> <p>c) a marmoset unless it is the offspring of marmosets bred in captivity or has been obtained from a self-sustaining colony of marmosets</p> <p>d) any animal of a description specified in Schedule 2 to the Act unless it has been bred for use in procedures.</p>	<p>Process to ensure correct authorisations are in place where necessary.</p> <p>Cross checked PPL authorities</p>	<p>Interviews with PEL holder, NVS, NACWO, PPL holder and animal care staff confirming process</p>

ASPA clause or licence condition	Summary of statutory requirements (full details contained in Guidance of the Operations of ASPA and on licences)	Examples of documentary evidence (these are examples only and are not intended to be comprehensive)	Examples of additional evidence
<p>PPL Standard Condition 14</p> <p>Work in the wild</p>	<p>If the application of regulated procedures to animals taken from the wild is authorised in this licence the holder shall ensure:</p> <p>a) that animals taken from the wild are captured by a competent person using a method which does not cause the animal avoidable pain, suffering, distress or lasting harm</p> <p>and</p> <p>b) that an animal taken from the wild which is found to be injured or in poor health is not subjected to a regulated procedure unless and until it has been examined by a veterinary surgeon or other competent person and, unless the Secretary of State has agreed otherwise, action has been taken to minimise the suffering of the animal.</p>	<p>Review of authorisations in PPL</p> <p>Standard Operating Procedures on work in wild</p> <p>Review of health records</p> <p>Review of capture methods</p> <p>Animal care training and competency process and records</p>	<p>Interviews with NVS, NACWO, PPL holder PIL holder and animal care staff confirming process for maintaining health records</p> <p>Direct observation of animals cross checked with accompanying health care records</p>

ASPA clause or licence condition	Summary of statutory requirements (full details contained in Guidance of the Operations of ASPA and on licences)	Examples of documentary evidence (these are examples only and are not intended to be comprehensive)	Examples of additional evidence
PPL Standard Condition 15 Participation in Inspections	The licence holder must give any necessary assistance to inspectors carrying out visits by virtue of section 18(2A)(b) and to experts of the European Commission carrying out duties under Article 35 of the Animals Directive.	Refusal to take part in an inspections visit is a breach of this condition. SOP for notification of breaches	Interviews with PELh to confirm this is recognised as a breach
PPL Standard Condition 16 Non-compliance	If the licence holder becomes aware of a failure to comply with any conditions of the licence the holder must take appropriate steps to rectify the failure (if it is capable of being rectified) and keep a record of the steps taken.	SOP for dealing with Non-compliance	Interviews with PPLh to confirm they understand what to do if a non-compliance occurs
PPL Standard Condition 17 Anaesthesia	All authorised procedures shall be carried out under general or local anaesthesia unless: a) anaesthesia would be more traumatic to the animal concerned than the procedures themselves	Standard Operating Procedures for General anaesthesia Authorities in PPL regarding no anaesthesia for regulated procedures Anaesthetic records	Interviews with PEL holder, PPL holder NVS, NACWO, animal care staff and PIL holders to confirm anaesthetic procedures are being followed Direct observation of anaesthesia

ASPA clause or licence condition	Summary of statutory requirements (full details contained in Guidance of the Operations of ASPA and on licences)	Examples of documentary evidence (these are examples only and are not intended to be comprehensive)	Examples of additional evidence
	<p>or</p> <p>b) anaesthesia would be incompatible with the purposes of the procedures.</p>		
<p>PPL Standard Condition 18</p> <p>Exceeding severity limits</p>	<p>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 Secretary of State is notified as soon as possible.</p>	<p>Standard Operating Procedures for SC18 reporting</p> <p>Review of SC18 reports</p>	<p>Interviews with PPL holder, to confirm process for SC 18 reporting and review</p>
<p>PPL Standard Condition 19</p> <p>Animal records</p>	<p>The licence holder shall maintain a contemporaneous record of all animals on which procedures have been carried out under the authority of the project licence. This record shall show the procedures used and the names of personal licensees who have carried out the procedures. The record shall, on request, be submitted to the Secretary of</p>	<p>Standard Operating Procedure for record keeping</p> <p>Review animal records</p>	<p>Interviews with PPL holder, animal care staff, PIL holders to confirm record keeping processes</p>

ASPA clause or licence condition	Summary of statutory requirements (full details contained in Guidance of the Operations of ASPA and on licences)	Examples of documentary evidence (these are examples only and are not intended to be comprehensive)	Examples of additional evidence
	State or made available to an Inspector.		
PPL Standard Condition 20 Return of procedures	The licence holder shall send to the Secretary of State, before 31 January each year (and within 28 days of the licence having expired or been revoked), a report in a form specified by the Secretary of State, giving details of the number of procedures and animals used, and the nature and purpose of the procedures performed under the authority of the project licence during the calendar year.	Standard Operating Procedure outlining processes used by establishment for return of procedures Documentary records of procedures, animals used, and the nature and purpose of the procedures	Interviews with PPLh holder, animal care staff, and PIL holders to confirm establishment processes for ROPs
PPL Standard Condition 21 Publications	The licence holder shall maintain a list of publications resulting from the licensed programme of work and a copy of any such publication shall be made available to the Secretary of State on request. The list shall, on request, be submitted to the Secretary of State or made available to an Inspector, and it shall be submitted to the Secretary of State when the	Review of PPLh publications	Interview with PPLh to discuss publications

ASPA clause or licence condition	Summary of statutory requirements (full details contained in Guidance of the Operations of ASPA and on licences)	Examples of documentary evidence (these are examples only and are not intended to be comprehensive)	Examples of additional evidence
	licence is returned to him on expiry or for revocation.		
PPL Standard Condition 22 Reports	The project licence holder shall submit such other reports as the Secretary of State may from time to time require.	Review of any reports requested by ASRU	Interview with PPLh to discuss reports
PPL Standard Condition 23 Management of regulated procedures	<p>The project licence holder shall ensure that details of the programme of work and regulated procedures specified in the licence, and any additional conditions imposed on those procedures, are known to:</p> <ul style="list-style-type: none"> a) all personal licensees performing those procedures b) the named person responsible for compliance c) the named animal care and welfare officers responsible for the day to day care of the animals d) the named veterinary surgeon, on request 	<p>Processes and procedures for informing PILs and named people of the work to be undertaken under the project licence.</p> <p>Review of documentation supporting these processes.</p>	Interviews with PEL holder, NVS, animal care staff, NACWO, PIL holder and NIO with regard to processes for informing them about the work to be undertaken

ASPA clause or licence condition	Summary of statutory requirements (full details contained in Guidance of the Operations of ASPA and on licences)	Examples of documentary evidence (these are examples only and are not intended to be comprehensive)	Examples of additional evidence
	<p>and</p> <p>e) the named information officer and named training and competency officer, on request.</p>		
<p>PPL Standard Condition 24</p> <p>Movement of animals</p>	<p>The licence holder must obtain the permission of the Secretary of State before:</p> <p>a) any animal undergoing regulated procedures is moved from a place specified in one section 2C licence to a place specified in another section 2C licence</p> <p>or</p> <p>b) any animal is released for slaughter, unless this is already explicitly authorised by the project licence.</p>	<p>Standard Operating Procedures for movement of animals</p> <p>Records of movement of animals</p>	<p>Interviews with PPL holder, NVS, animal care staff, NACWO, PIL holder with regard to processes for keeping animals alive and for reuse, rehoming and moving animals</p>
<p>PPL Standard Condition 25</p>	<p>The licence remains the property of the Secretary of State and shall</p>	<p>Not routinely inspected</p>	

ASPA clause or licence condition	Summary of statutory requirements (full details contained in Guidance of the Operations of ASPA and on licences)	Examples of documentary evidence (these are examples only and are not intended to be comprehensive)	Examples of additional evidence
Surrender of licence	be surrendered to them on request.		

Assessment of personal licence holder compliance

ASPA clause of licence condition	Summary of statutory requirements (full details contained in Guidance of the Operations of ASPA and on licences)	Examples of documentary evidence (these are examples only and are not intended to be comprehensive)	Examples of additional evidence
PIL Standard Condition 1 Compliance with 3Rs	In exercising his or her responsibilities, the licence holder shall act at all times in a manner that is consistent with the principles of replacement, reduction and refinement.	Documentary evidence of specific establishment initiatives aligned to the 3Rs Documentary evidence of new staff induction /training including specific information on how the 3Rs are ensured at the establishment	Interview with PIL holder confirming processes for ensuring compliance with the 3Rs including knowledge of current 3Rs challenges and /or initiative Observation of animal care and/or regulated procedures conducted in compliance with 3Rs
PIL Standard Condition 2 Welfare of experimental animals	The licence holder is entrusted with primary responsibility for the welfare of the animals on which he or she has performed regulated procedures - the licence holder must ensure that animals are properly monitored and cared for.	Standard Operating Procedures and/or Training Material related to training and competency to monitoring and care post procedures	Interview with NACWO, NVS and PIL holder(s) confirming training and competency process for monitoring and care post procedures
PIL Standard Condition 3,5,7&8 Humane endpoints	SC3	Evidence of training on humane end points on PPL protocols the PIL is working on	Interview with NACWO, NVS, PPL and PIL holder(s) confirming training and competency in understanding humane endpoints

	<p>The licence holder must not apply a regulated procedure to an animal if the procedure may cause the animal severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated.</p> <p>SC5</p> <p>Where the licence holder is applying a regulated procedure to an animal the holder must ensure that any unnecessary pain, suffering, distress or lasting harm that is being caused to the animal is stopped.</p> <p>SC7</p> <p>The licence holder shall ensure that where the holder applies a regulated procedure death as the end-point of the procedure is avoided as far as possible and is replaced by an early and humane endpoint.</p> <p>SC8</p> <p>In all circumstances where an animal which is being, or has</p>	<p>Evidence of discussions with PPLh re humane end points</p>	
--	---	---	--

	<p>been, subjected to a regulated procedure is in severe pain, suffering or distress which is likely to be long-lasting and cannot be ameliorated, the licence holder must ensure that the animal is immediately killed in accordance with section 15A.</p>		
<p>PIL Standard Condition 4 & 6</p> <p>Controls and limitations</p>	<p>SC4</p> <p>The licence holder must not apply a regulated procedure to an animal unless the holder has taken precautions to prevent or reduce to the minimum consistent with the purposes of the procedure any pain, suffering, distress or discomfort that may be caused to the animal.</p> <p>SC6</p> <p>Where the licence holder is applying or has applied a regulated procedure which is causing the animal severe pain, suffering or distress the holder</p>	<p>Evidence of training on controls and limitations on the steps in PPL protocols the PIL is working on</p> <p>Evidence of discussions with PPLh re controls and limitations</p>	<p>Interview with NACWO, NVS, PPL and PIL holder(s) confirming training and competency in understanding controls and limitations</p>

	must take steps to ameliorate that pain, suffering or distress.		
PIL Standard Condition 9,10,11&12 General anaesthesia and analgesia	<p>SC9</p> <p>The licence holder may apply a regulated procedure without the use of general or local anaesthesia only if the holder is satisfied that:</p> <p>a) the procedure will not inflict serious injuries capable of causing severe pain</p> <p>and</p> <p>b) the use of general or local anaesthesia would be more traumatic to the animal than the procedure itself or would frustrate the purposes of the procedure.</p> <p>SC10</p> <p>When anaesthesia (whether general or local) is used, it shall be of sufficient depth to prevent</p>	<p>Standard Operating Procedures plus Training Material related to training and competency for General anaesthesia</p> <p>Anaesthetic records</p>	<p>Interviews with PEL holder, PPL holder NVS, NACWO, animal care staff and PIL holders to confirm training and competency and anaesthetic procedures are being followed.</p> <p>Direct observation of anaesthesia</p>

	<p>the animal from being aware of pain arising during the procedure.</p> <p>SC11</p> <p>If the licence holder applies a regulated procedure to an animal with the use of general or local anaesthesia the holder must, unless it would frustrate the purpose of the procedure, use such analgesics or other pain-relieving methods as may be necessary to reduce any pain that the animal may experience once the anaesthesia wears off.</p> <p>SC12</p> <p>The licence holder must use analgesia or another appropriate method to ensure that the pain, suffering and distress caused by regulated procedures are kept to a minimum.</p>		
<p>PIL Standard Condition 13</p> <p>Severity limits</p>	<p>It is the responsibility of the personal licence holder to notify the project licence holder as soon as possible when it appears either</p>	<p>Standard Operating Procedure for PPLSC18 reporting. How does this SC dovetail with SC18 reporting?</p> <p>Review of SC18 reports</p>	<p>Interviews with PIL and PPL holder, to confirm process for PIL SC 13 and PPLSC18 reporting and review</p>

	that the severity limit of any procedure listed in the project licence or that the constraints upon adverse effects described in the project licence have been or are likely to be exceeded.		
PIL Standard Condition 14 Handover	The licence holder shall ensure that suitable arrangements exist for the care and welfare of animals during any period when the personal licence holder is not in attendance.	Standard Operating Procedure for handover	Interviews with, NACWOs, animal care staff and PIL holders to confirm handover procedure
PIL Standard Condition 15 Veterinary advice	The licence holder shall ensure that, whenever necessary, veterinary advice and treatment are obtained for the animals in his or her care.	Standard Operating Procedure or process for obtaining veterinary advice Individual animal health records	Interviews with, NVS, and PIL holders to confirm procedure for obtaining veterinary advice
PIL Standard Condition 16 Labelling	The licence holder shall ensure that all cages, pens or other enclosures are clearly labelled. The labelling must be such as to enable Inspectors, named veterinary surgeons and named	Standard Operating Procedures and/or Training Material related to training and competency for cage labelling	Interview with NACWO and PIL holder(s) confirming training and competency process for cage labelling Direct observation of cages

	<p>animal care and welfare officers to identify the number of the project licence authorising the procedures, the project licence protocol in which the animals are being used, the date the protocol was started, and the responsible personal licence holder.</p>		
<p>PIL Standard Condition17</p> <p>Competency in regulated procedures</p>	<p>In order to ensure that regulated procedures are performed competently, the licence holder shall not apply regulated procedures unless given the appropriate level of supervision by the project licence holder or an experienced personal licence holder deputed by him/her for such time as may be needed to achieve competence.</p>	<p>Standard Operating Procedures and/or Training Material related to training and competency for general and study specific procedures</p>	<p>Interview with NVS NACWO and PIL holder(s) confirming training and competency process for procedures</p> <p>Direct observation of procedures</p>
<p>PIL Standard Condition18</p> <p>Delegation</p>	<p>The licence holder is authorised to delegate to assistants, who do not themselves possess the requisite personal licence authority but are under his or her control, the delegable tasks which form an integral part of the regulated procedures the licence holder is authorised to perform</p>	<p>Standard Operating Procedures and/or Training Material related to training and competency for delegation and supervision of procedures</p>	<p>Interview with NVS NACWO and PIL holder(s) confirming training and competency process for delegation and supervision of procedures</p> <p>Direct observation of delegated procedures and supervision</p>

	by this licence. The tasks must not require technical knowledge or skill, and delegation shall be in accordance with any relevant guidance published by the Secretary of State under section 21.		
PIL Standard Condition 19 Prevention of unauthorised procedures	The licence holder must take all reasonable steps to ensure appropriate personal and project licence authorities exist before performing regulated procedures. The licence holder must be aware of the nature of the authorities given by this licence and the project licence, and of the conditions of issue attached to the licences.	Standard Operating Procedure outlining processes used by establishment to prevent unauthorised procedures Documentary records of the review processes which are part of the process to prevent unauthorised procedures	Interviews with PEL holder, named persons, animal care staff, PIL and PPL holders to confirm establishment processes used to prevent unauthorised procedures
PIL Standard Condition 20 Record keeping	The licence holder shall maintain a record of all animals on which procedures have been carried out, including details of supervision and declarations of competence by the project licence holder as appropriate. This record shall be retained for at least five years and shall, on request, be submitted to the	Standard Operating Procedures for recording procedures Records demonstrating recording of procedures	Interviews with PIL holder, to confirm records are being accurately kept

	Secretary of State or made available to an Inspector.		
PIL Standard Condition 21 Participation in Inspections	The licence holder must give any necessary assistance to inspectors carrying out visits by virtue of section 18(2A) (b) and to experts of the European Commission carrying out duties under Article 35 of the Animals Directive.	Refusal to take part in an inspections visit is a breach of this condition SOP for notification of breaches	Interviews with PELh to confirm this is recognised as a breach
PIL Standard Condition 22 Surrender of licence	The licence remains the property of the Secretary of State and shall be surrendered to them on request.	Not routinely inspected	