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Home Office

Report of ASRU Investigation into compliance

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In the 2013 Animals in Science Regulation Unit Annual Report, ASRU set out details of plans to start publishing anonymised reports of substantial investigations upon their completion.

The publication of such investigations may be triggered by a number of factors including, but not limited to:

- an exposé making allegations in the public domain;
- a cluster of non-compliances or 'near misses' triaged by an inspector to ASRU management;
- a non-compliance apparently involving significant animal harm;
- a published paper that appears to describe unjustified pain, suffering or distress; and,
- concern raised by inspectors or others that a particular procedure may not optimally implement the 3Rs.

Such publication would be over and above the reporting of summary details of all cases of non-compliance in the ASRU Annual Report. This has routinely taken place for several years and will continue.

We believe such early publication of these investigations is in the interests of transparency and openness. We believe that this will also help ensure that all stakeholders can learn from the outcomes of these investigations as early as possible and enable them to address any potential weaknesses in their own management systems, creating a cycle of continuous improvement. These reports will also provide the public with an insight into this important aspect of ASRU's work.

ASRUI Report on ASPA Compliance

Purpose and scope of the report:

This report sets out for Ministers the investigations and evaluations made by the Animals in Science Regulation Unit (ASRU) Inspectorate in following up allegations made against it by an animal rights organisation.

The scope of this report is bounded by the legal framework for the protection of animals used in experimental or other scientific procedures, under the terms of the Animals (Scientific Procedures) Act 1986 (ASPA). The legislation requires inspectors to report on compliance with the provisions and conditions of licences issued under the legislation and to advise on the action to be taken by the Secretary of State in the case of non-compliance. This report sets out the sanctions which the Secretary of State has imposed upon individuals in response to recommendations from the Inspectorate.

The animal rights organisation also called for a separate independent investigation. A third party was engaged by the Establishment to investigate and assess the culture and approach to animal care and welfare. The remit of the two separate reports is largely complementary, although there are overlaps with regard to the general management and strategic work recommended to be taken forward by the Establishment.

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Glossary of abbreviations and terms used:

3Rs	Reduction, Replacement, Refinement
ASC	Animals in Science Committee
ASPA	The Animals (Scientific Procedures) Act 1986
ASRU	Animals in Science Regulation Unit
AWERB	Animal Welfare and Ethical Review Body
CPD	Continuing Professional Development
CT	ASRU Compliance Team
FELASA	European Federation of Laboratory Animal Science Associations
LASA	Laboratory Animal Science Association
NACWO	Named Animal Care and welfare Officer
NVS	Named Veterinary Surgeon
NTCO	Named Training and Competency Officer
The Act	The Animals (Scientific Procedures) Act 1986

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1 Executive Summary

An extensive and thorough evaluation by the ASRU Inspectorate has not substantiated the main claims of the allegations made by an animal rights organisation against the Establishment, that there was “appalling animal suffering on a very large scale, unlawful regulation by the Home Office, wholly inadequate care of animals by (Establishment) staff and inadequate enforcement by the inspectorate.”

2 Background

ASPA permits the application of procedures which may cause pain, suffering, distress or lasting harm to animals, within the context of the justification for likely valuable benefit to man, animals or the environment.

The Establishment is licensed under the terms of ASPA, rated in the high risk category by the Inspectorate and thereby subject to appropriate inspection and scrutiny. The animal rights organisation is committed to ending animal experiments

3 Allegations

It was alleged that animals were experiencing cruel treatment. The animal rights organisation’s report called on the Secretary of State to suspend project and personal licences at the Establishment and to instigate an independent enquiry.

4 Immediate actions

The publicly available video footage and the animal rights organisation’s 71 page report were promptly reviewed in detail. Nothing was identified to suggest that either referral for prosecution or immediate suspension of licences on welfare grounds were merited. A detailed inspection of the facility was undertaken to further evaluate the risk that any ongoing research might jeopardise animal welfare. This inspection did not reveal any indications for immediate suspension of licence authorities.

5 Investigations of potential non-compliance

Meanwhile, the Chief Inspector had instructed the ASRU Compliance Team (CT) to investigate the potential non-compliances and to deliver their findings to the Head of ASRU for preparation of a full investigation report. The Inspectorate conducted extensive and thorough investigations to evaluate whether there was any substance to the allegations.

The investigations included detailed interviews, inspections, meetings, examination of records, the review of inspection visit reports and the review of active project licence authorities. Reports of meetings and detailed compliance reports on the separate cases have been filed.

In addition a meeting was held with the investigator from the animal rights organisation and representatives to ensure that all key issues could be followed up.

It is notable that the investigator from the animal rights organisation, who was responsible for animal care and welfare whilst working at the Establishment, did not utilise readily accessible whistle blowing mechanisms provided by both their own employment agency and the Establishment to bring their concerns to the notice of relevant authorities during the time of their employment at the Establishment.

6 Outputs of investigations

Twenty-one potential cases of non-compliance were identified and 18 were formally investigated. Of these, all were found to be unsubstantiated apart from five formal non-compliance cases which have been completed – one category A and four Category B. Letters detailing the sanctions to be imposed by the Secretary of State have been sent to 8 individuals. The sanctions imposed on all individuals included:

- Letters of reprimand
- Requirements to complete further training

In addition, a Compliance Notice was issued to the PEL holder requiring changes in management structures, practices and training programmes to be reported to the Home Office by the end of February 2014, with plans for ongoing monitoring and a formal review of the resulting outcomes to be carried out and reported to the Home Office in a further 12 months' time.

7 Project licence authorities

When inspectors undertake the harm-benefit analysis of a project licence proposal the harms are considered to be the likely effects on the animals used in the light of the adverse effects expected and the proposed humane end points. The Chief Inspector has concluded that the harm-benefit analyses of the 19 projects identified in the animal rights organisation's report were appropriately carried out.

8 Inspectorate enforcement role

The inspector's role is to monitor compliance and report on cases of non-compliance. It is the responsibility of licensees to ensure compliance with the legislation.

Inspectors gather information from detailed inspections and interaction with all levels of personnel at an establishment. In addition, assessment of project licence applications provides valuable insights with regard to the applicant's scientific knowledge and standing, as well as their genuine commitment to application of the 3Rs and compliance with the legislation.

All of this information is integrated by the inspector to inform their professional opinion on the risks and realities of potential non-compliance, and how this might be prevented through advice to personnel at the establishment. This approach is a much more in depth evaluation of the actual use of the animals for scientific purposes, than can reasonably be achieved by an individual to whom only a part of this picture is visible such as a junior animal care assistant.

9 Conclusions

Overall, the animal rights organisation's allegations of cruelty at the Establishment have not been substantiated. There was no case for the immediate suspension of any licence authorities in order to safeguard animal welfare. The extensive investigations, interviews, inspection visits and meetings with staff during 2013 have confirmed the Inspectorate's view that this establishment is at high risk of non-compliance with the requirements of the legislation.

There were a total of five instances of non-compliance, with few instances of animal suffering. The non-compliances were of a persistent nature, including ongoing instances after April 2013 and all of these could broadly be traced back to failings in management structures. There was also evidence of failure to recognise the need to report potential severity breaches to the Home Office, lack of involvement of named persons and the AWERB in application of the 3Rs and poor records for training, supervision, and competence as well as the experimental records giving details of all animals on which procedures have been carried out.

In addition there were changes in key personnel in managerial roles at the Establishment including a newly nominated Establishment Licence holder in August 2012, which led to temporary animal facilities management structures for the particular campus, with staff moved to a more strategic role in the oversight of all of the Establishment's licensed sites.

It is concluded that there was a widespread poor culture of care. Accordingly, the Secretary of State has imposed sanctions on those few individuals identified as erring. Specifically the requirements are to review and revise the internal frameworks key to the support of diligent compliance which should lead to embedding an improved culture of care across the whole establishment. The Establishment must report instigation of revised processes by 28 February 2014 and follow this up with a further report by 28 February 2015, to review the changes put in place and their continued impact in fostering a good culture of care.

2 Background

2.1 Evidence

On 15 April 2013, a 71 page document was delivered to the Home Office by an animal rights organisation providing material resulting from the placement of an investigator at the Establishment, between May and November 2012. The animal rights organisation's report alleged very large scale animal suffering, unlawful regulation by the Home Office, inadequate care of animals by staff at the Establishment and inadequate enforcement by the Inspectorate (*sic*). They also published a short video on YouTube purporting to be footage and audio material recorded during their investigation period.

Report

The animal rights organisation's written report and video (subsequently said by it to contain around 60 allegations of non-compliance) were reviewed by ASRU and the number of events which might have formed the basis for an allegation of non-compliance were counted and came to over 180. Some of these events turned out to be duplicates of, or related to the same individual event (for example in the written report and video) and a number of others could not subsequently be attributed to specific individuals or licence authorities. All allegations made by the animal rights organisation were considered, 21 potential cases of non-compliance were identified and ultimately 18 were formally investigated.

Video Material

The publically available YouTube clip of less than 10 minutes footage purporting to have been filmed at the Establishment was not submitted formally to the Home Office as evidence.

A video of approximately one hour duration covering most of the material in the YouTube video was given to the Home Office subsequent to a meeting with the investigator from an animal rights organisation and their representatives in July 2013.

Interview and additional information

At the meeting with the investigator from the animal rights organisation and their representatives on 2 July 2013, a number of points were raised for Home Office consideration and a short document detailing these was subsequently submitted by e-mail.

2.2 Requested outcomes

Through the animal rights organisation's report, the following was called for:

- An inquiry, wholly independent of the Home Office
- Suspension of relevant personal and project licences
- A review of the severity classification and the harm-benefit assessment of relevant projects
- A review of procedures and working practices of local Home Office inspectors

2.3 The Animals (Scientific Procedures) Act

The Animals (Scientific Procedures) Act 1986 provides a framework of a three tier licensing system for the protection of animals used in scientific procedures, which may cause pain, suffering, distress or lasting harm. This is permissive legislation allowing the conduct of procedures on animals, which might otherwise be deemed unnecessary suffering under other animal welfare legislation.

Licences impose responsibilities, among others, on the holders to ensure that the 3Rs, humane endpoints and avoidance of unnecessary suffering are applied throughout the term of the licences. The provision of a licence to an individual not only entrusts them to uphold their legal obligations but also to behave in ways which ensure the highest standards of animal care and welfare at all times.

Licences

Each establishment using animals in regulated procedures must have a licence to do so. The attached conditions clarify the responsibilities of the licence holder under ASPA, including an obligation to apply the principles of the 3Rs (replacement, reduction, refinement)

A project licence is required to specify a programme of work using protected animals. Such licences may only be granted if the 3Rs have been rigorously applied and a satisfactory harm-benefit analysis has been made, reflecting the scale and significance of the proposed harms and likely or potential benefits.

All individuals carrying out regulated procedures on animals must hold personal licenses providing specific authorisations.

Inspection

All establishments which carry out procedures on animals are subject to scrutiny by Home Office Inspectors, who play a key role in the implementation of ASPA. Inspectors follow a risk-based approach to inspection. This takes account of

objective criteria including the number and species of animals held, the number of regulated procedures undertaken, the prospective severity of those procedures and the compliance history of the particular establishment. In addition, subjective criteria are considered including: the effectiveness of the Establishment Licence Holder; the effectiveness of the local Ethical Review Process (AWERB, since 1 Jan 2013); the involvement and effective performance of Named Persons; training, supervision and competency checks and records; staffing levels; maintenance of facilities; and provision of environmental enrichment. Visits by inspectors to licensed establishments are an important aspect of determining compliance with ASPA: over 70% of visits to animal holding areas are unannounced. An additional key role of inspectors is to advise those working under ASPA on matters relating to compliance and encourage best practice with respect to the 3Rs. Inspectors have a right of entry to licensed establishments at all reasonable times and ready access to all records. By law, they are required to report on non-compliance and to provide advice on the action to be taken. It is, therefore, entirely appropriate that they should investigate allegations such as those made against the Establishment.

2.4 The Establishment

On its website, the Establishment says that it is highly ranked.

Risk assessment

The Inspectorate risk evaluation of the Establishment, against which the specific allegations were made, indicated a high level of risk of the likelihood and impact of non-compliance with ASPA. This evaluation took into account the number and species of animals used annually at the site, the compliance history, the number and severity banding of the project licences authorised at the site, and local management factors.

During the five years from 2007 – 2011 inclusive, formal action was taken by the Home Office on one case of non-compliance at the Establishment. Although none of the four special species have been used at this site, the number of regulated procedures conducted and the number of project licences authorised there places this establishment in the top quartile of licensed establishments in the UK. The evaluation of local management factors during 2011-12 indicated changes to key staff in managerial positions.

On this basis, the site was inspected 15 times during 2012. During that time compliance advice was provided on 5 occasions, including to a number of people who have featured in the allegations. Typically, compliance advice may be given verbally by an inspector upon discovery of a trivial breach of licence conditions. The outcome of compliance advice will be to note and record details of the advice in the visit

report, with no further action being necessary. No cases meriting formal infringement procedures were either discovered by the inspector or brought to their notice during 2012.

A number of incidents identified through inspection during 2012 suggested increasing risks at the site. In March 2012, a newly appointed veterinary surgeon was planning to take forward improvements in aseptic surgical techniques, but found some groups poorly receptive to training offers. In May 2012, the assigned local inspector advised, as compliance advice, refresher training for a personal licensee for blood collection in mice, as unnecessary post-procedure bleeding had been noted. Notably on 10th October 2012, an inspector reported an “unusually disappointing inspection” when compliance advice was given regarding several cases of poor cage labelling as well as an indication that one group had inadequate understanding of their licence authorities. In following these cases up, the inspector reported that the adverse effects in respect of one case were reported promptly and dealt with in a timely and appropriate manner. A decision was taken that these incidents were not sufficient of themselves to lead to an alteration of the risk rating, given the previous good level of compliance in the Unit. During November 2012 the inspector had separate discussions with licensees regarding the refinement options for work involving animals using a treadmill as well as refinement of anaesthetic technique for one research group.

The above factors suggested to inspectors that improvements to local culture and commitment to compliance with ASPA were merited. During late 2012 and early 2013 there were developments indicating that improvements should follow. In December 2012, two inspectors took part in a workshop instigated by the Named Veterinary Surgeon to foster consistency and refinement in procedures utilising cardiac disease models across the licensed facilities. Revision to the AWERB terms and conditions was submitted to the Home Office in February 2013, reviewed and considered to be satisfactory and acceptable.

3 The Allegations

The following list summarises the allegations made in the animal rights organisation's report dated 14 April 2013 submitted to the Home Office on 15 April 2013, as well as points identified in the YouTube and expanded video evidence provided subsequent to our meeting on 2 July 2013.

3.1 Main points

- “very large scale” “appalling animal suffering”
- unlawful regulation by the Home Office
- inadequate care of animals by establishment staff
- inadequate enforcement by the Inspectorate

3.2 Specific issues claimed by the animal rights organisation

The Establishment

- Failure to minimise suffering through effective responsibility being exercised by licensees with regard to care, application of humane endpoints and use of analgesia,
- Breaches of project licence severity limits
- Inadequate staff cover, especially out of routine working hours
- Improper administration of anaesthesia and analgesia
- Incompetence in carrying out procedures – e.g. gavage technique; ear notching
- Failure of effectiveness of Named Persons
- Inadequate or incompetent killing, including guillotine use
- Loud noise/music played in animal rooms
- Failure to promulgate the 3Rs
- Quality of science confounded by poor welfare

The Inspectorate:

- inadequacy of inspections and effective enforcement
- inappropriate severity assessment of licensed procedures - kidney transplants, thoracotomies, myocardial infarction models, gastric bypass surgery, dermatitis
- flawed harm-benefit assessments for project licences held at the Establishment - scientific justification critiqued for some for the research programmes – obesity; failure to promulgate the 3Rs
- Home Office was aware of some problems, particularly during the visit on 10 October 2012, but did not take appropriate action

Demanded of the Secretary of State

- Suspension of project and personal licences at the Establishment
- An inquiry, wholly independent of the Home Office
- The need for openness and greater transparency about animal research
- Public interest concerns if standards are lower than the Home Office publicly claims for animal research in the UK

4 Immediate actions

4.1 Inspectorate

The publically available video footage and the animal rights organisation's 71 page report were promptly reviewed in detail. Nothing was identified to suggest that either referral for prosecution or immediate suspension of licences on welfare grounds was merited. A detailed inspection of the Establishment on 19 April 2013 was undertaken to further evaluate the risk that any ongoing research might jeopardise animal welfare. This inspection did not reveal any indications for immediate suspension of licence authorities.

The Chief Inspector reviewed inspection reports for the relevant period – January 2012 through to March 2013. This demonstrated 18 visits, 76.5 contact hours; appropriate to the agreed high level of risk for the site. Whilst the reports identified some points, which were subsequently followed up (see Section 2.4 above), no specific issues requiring immediate follow up were identified.

4.2 The Establishment

The Establishment initially contacted the assigned inspector on 12 April 2013, prior to publication of the allegations. A telecom meeting was arranged between senior staff at the Establishment, the Head of ASRU, the Chief Inspector, the local inspector and the ASRU Compliance Team on 15 April.

The Establishment sent an internal e-mail message to all relevant staff on 13 April 2013 reminding them of their responsibilities under ASPA.

Individuals identified in the animal rights organisation's report were suspended by the Establishment from conducting live animal research until they had successfully completed local refresher training. This programme of refresher training was conducted over the next three months, initially targeted to those identifiable from the report but also then covering all licensees.

5 Investigations of potential non-compliance

5.1 ASRU Investigation Team

The Head of ASRU instructed the ASRU Compliance Team (CT) to investigate the potential non-compliances and to deliver their findings to the Chief Inspector for preparation of a full investigation report. The CT consists of a Principal Inspector, responsible for consistency of non-compliance investigation and advice from the Inspectorate and the Senior Compliance Manager, a senior member of the ASRU administrative team. The investigation would be taken forward together with the locally assigned inspector. There had been a change of the locally assigned inspector for the Establishment at the beginning of April 2013, when the previous inspector started a planned career break.

5.2 Review of inspection history

Inspection of the work from January 2012 through to April 2013 was reviewed in detail. Regular inspections were carried out at least once per month with an average duration of about 5 hours, in accordance with the risk profile of the site. In addition, procedures in progress were frequently witnessed and irregularities followed up.

The Establishment was inspected on a regular (approximately monthly) basis for the 15 months prior to the exposé, as befits its size and the number of licensees on site. The reports of these inspections included five where compliance advice was given, including to a number of people who have featured in the allegations, and who were subsequently investigated by the ASRU Team.

The risk assessment rating for the Establishment was reviewed during 2012. A new AWERB chairperson together with other changes signalled the potential for improvement in management practices and culture. There was no change in the risk assessment rating applied to the establishment throughout 2012.

5.3 Investigation Interviews

A meeting was held at the Establishment with Senior Establishment staff on 22 April. The Chief Inspector, the Principal Inspector from the CT and the locally assigned inspector represented the Home Office.

All relevant project and personal licence holders were identified from the animal rights organisation's evidence. A total of 18 cases of potential non-compliance, including 28 individual licence holders, were investigated. Meetings were arranged with all of these individuals as well as the Named Persons, other animal care staff and the Establishment Licence Holder amounting to some 23 specific meetings, as well as ongoing inspection, which all took place during April through to the end of July 2013.

Several references are made in the animal rights organisation's report to inadequate levels of staffing in the animal units. Appropriate investigations were made by the Compliance Team and the issue of unit staffing was discussed on 30 April 2013. The Compliance Team did not find evidence during their investigations to consider there to be a breach of licence conditions relating to the appropriate staffing of the units to ensure the well-being of protected animals. It was noted that there was a low staff turnover with a range of grades of animal care staff and a mix of agency and permanent staff employed.

5.4 Ongoing Inspections

A series of unannounced and announced inspections was instigated to gather further evidence as well as facilitate ongoing assessment of compliance to provide reassurance within the context of routine business. Good levels of commitment to responsibilities have been demonstrated by care staff.

Fourteen inspections of the Establishment have taken place between 15 April and 30 November 2013. Of these, 13 visits were unannounced. The facility has always been found to be in a clean and tidy state and the animal care staff knowledgeable and vigilant. There has been evidence of researchers making innovative refinements to procedures to reduce distress to the animals and of researchers being trained to use alternative surgical techniques to reduce pain and distress. In all cases where procedures have been applied to animals, these animals have been noted to be in satisfactory condition, with due regard to the observance of the restrictions within project licences and the application of humane endpoints. Where procedures have been observed, including those carried out by researchers singled out in the animal rights organisation's report, e.g. taking of blood samples or performance of surgical techniques, these have been carried out competently and with minimal suffering to the animals. Cases of sub-optimal compliance with aseptic surgical principles have been the subject of compliance advice, with resultant further improvements. In this time, communications between researchers and the Home Office appear to have improved. There have been cases where animal care staff, including the NACWOs, have been involved in the preparation and conduct of procedures. Evidence of improved communications has been noted e.g. posters on walls promoting aseptic technique; reminding licence holders and care staff of their responsibilities and

duties; the tissue exchange bulletin board and various other standard operating procedures. The involvement of the Establishment's named persons in 3Rs activity e.g. presenting at LASA and FELASA meetings, has been noted.

Since the delivery of a series of seminars by the locally assigned inspector to encourage more collaborative working and self reporting in accordance with project licence standard condition 18, there have been 5 self reported incidents of either not keeping within the controls of the licence or potentially breaching the severity limit. No further action has been taken for these since the problems identified have all been addressed locally with agreement of the assigned inspector. There has been one case of non-compliance (performance of non-schedule 1 killing without PEL or PPL authority) and this has been dealt with as a category A non-compliance and letter of reprimand sent.

It has, however, been disappointing to see evidence of intransigence by some researchers in the application of aseptic technique and this issue has progressed to the issue of compliance advice. There have been three cases of poor aseptic technique where compliance advice has been issued in August and October 2013. There is also ongoing evidence of inattention to the 3Rs e.g. the continued use of relatively heavy, metallic, identification tags in mouse ears.

5.5 Other Home Office meetings with the Establishment

Senior staff at the Establishment have met with the Head of ASRU together with the Chief Inspector on two occasions – 15 April 2013 by telecom and 4 June 2013 face to face at 2MS.

The Compliance Team have held two similar meetings on 22 April 2013 and 2 July 2013.

On 24 April 2013, the then Minister, Lord Taylor of Holbeach, called a meeting of senior establishment representatives at the Home Office which took place on 16 May 2013.

On all of these occasions discussions have indicated that the Establishment has a range of managerial systems in place through committee structures and training programmes, which are designed to support effective compliance with ASPA.

The Chief Inspector met with senior staff at the Establishment on 25 September 2013, to review the responsibilities in the light of the non-compliance findings up to that time. Specifically, their own non-compliance was discussed – standard

conditions 1, 5, 20 and 21 of the current Establishment Licence (i.e. under ASPA as amended from 1 January 2013). This meeting prompted further evidence to be provided before the Inspectorate gave their final recommendations to the Secretary of State regarding the specific non-compliance and the action to be taken.

Standard condition 1 states:

“The licence holder, who may be the establishment licence holder or the Named Person Responsible for Compliance, 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.”

Standard condition 5 states:

“The licence holder shall ensure that the establishment shall be appropriately staffed at all times to ensure the wellbeing of the protected animals. Staff shall be adequately educated and trained before they perform any function relating to the care of the protected animals and shall be supervised when performing any such function until they have demonstrated the requisite competence.”

Standard condition 20 states:

“If this licence authorises the applying of regulated procedures to protected animals, the holder shall take all reasonable steps to prevent the performance of unauthorised procedures in the establishment.”

Standard condition 21 states:

“The licence holder shall make adequate and effective provision for regular and effective liaison with and between those entrusted with responsibilities under the Act and with others who have responsibility for the welfare of the protected animals kept at the establishment.”

5.6 Meeting

A meeting took place on 2 July between the investigator from the animal rights organisation and their senior representatives, and the ASRU investigation team, the Chief Inspector and a legal adviser for the Home Office.

Five cases where the current information did not provide sufficient detail for inspectors to follow up the allegations were discussed, and further evidence provided on 5 July 2013.

On 17 July, additional video footage was delivered to the Home Office.

5.7 Other considerations

The investigator from the animal rights organisation had been employed by the Establishment through an agency. The Chief Inspector met with the Managing Director of the agency on 5 July. This afforded the opportunity to confirm the identity of the investigator as the person they had employed and who had attended the meeting with the ASRU investigation team on 2 July 2013.

The agency operates a rigorous security clearance procedure which did not identify any triggers for consideration that the investigator from the animal rights organisation was unsuitable for the planned employment. In addition the training and management practices for the staff of the agency were reviewed and appeared thorough. The investigator was recruited at the lowest technical level for the basic husbandry of animals incorporating feeding, watering and cage cleaning.

Records identified regular contact between the agency and the investigator from the animal rights organisation, a system which is, in part, designed to facilitate any problems or concerns being promptly relayed to the agency. No concerns about animal welfare were recorded as raised by the investigator with the agency.

Similarly, the investigator from the animal rights organisation did not raise concerns through the recognised whistle blowing policy in place at the Establishment.

6 Outputs of investigations

6.1 Meetings and notes

A total of 23 meetings were held with licence holders and other key staff of the Establishment, with detailed records kept of these meetings.

6.2 Compliance reports

Five instances of non-compliance involving 8 individuals have been identified. These included cases of failure to keep adequate records, failure to adhere to humane endpoints, failure to monitor animals appropriately and failure to report to the Home Office when endpoints had been exceeded.

Five formal non-compliance cases have been completed– one category A and four Category B. Letters detailing the sanctions to be imposed by the Secretary of State have been sent to 8 individuals. The sanctions for all individuals included:

- Letters of reprimand
- Requirements to fulfil further accredited modular training

Twelve other detailed inspector reports confirm that there is no case to answer in relation to other allegations

6.3 Establishment Licence Holder requirements

It was concluded that the Establishment Licence Holder had breached standard conditions 1, 5, 20 and 21 of the current licence. The holder was required, by 28 February 2014, to:

1. Provide evidence of improving local training of all duty holders and licensees working under ASPA. This may be demonstrated through training, supervision and competence records;
2. Demonstrate how those involved in animal care, in particular the NVS and NACWO, are actively involved in experimental design and in the adoption of refined models and good practices;
3. Demonstrate Improvements in local systems of management to:
 - a. effect the reporting of likely or potential breaches of severity to the Home Office; and,
 - b. prevent the application of unauthorized procedures to regulated animals.
4. Explain improvements in record keeping. This should include:
 - Experimental records;

- Training, supervision of competence records; and
- Mechanisms for actual severity recording.

5. Demonstrate how the Animal Welfare and Ethical Review Body (AWERB) will be effective in promulgating the 3Rs; and

6. Demonstrate how communications between staff at the Establishment and the Home Office have been improved.

All the above points were to be reviewed to freshly demonstrate to the Home Office their continued impact after a further 12 months (28 February 2015).

7 Project Licence authorities

Nineteen project licences identified through the animal rights organisation's report have been reviewed with regard to their harm-benefit assessments. The protocols classified with either moderate or substantial (sic) limits were reviewed by one experienced inspector who had not been involved previously, either as an inspector for the Establishment or as a previous assessor for the relevant project licences. On the basis of their consideration, six project licences were further referred for a second, similarly independent, inspector opinion. There was agreement that some procedures may not have been classified of sufficiently high severity. Two of these project licences have since expired and any ongoing applications have been assessed in the light of contemporary knowledge. Three projects have one protocol each which are under review by the current assigned inspector to gain the benefit of local knowledge. It should be recognised that the knowledge of the local inspector with regard to the severity of procedures in the hands of the specific research groups may account for differences compared with the opinions of independent assessors.

When inspectors undertake the harm-benefit analysis of a project licence proposal the harms are considered to be the likely effects on the animals used in the light of the adverse effects expected and the proposed humane end points. It has been concluded that the harm-benefit analyses of the 19 projects were appropriately assessed.

8 Inspectorate Enforcement Role

The animal rights organisation's report says that "*...inspections, however conscientious, could not detect some of the problems revealed by the (allegations).*"

Inspection is a process of information gathering, compliance assessment and relationship building, involving a number of elements including actual face to face inspection visits to animal units. The inspector's role is to gather intelligence about the likely compliance with the legislation at an establishment and to promulgate good practice on the 3Rs. To that end, inspectors develop effective, trust-based working relationships with key staff at establishments.

During evaluation of project licence applications and requests for amendments, inspectors interact with the applicants usually involving face to face meetings as well as telephone calls and exchange of correspondence. This affords the opportunity for the inspector to assess the quality of the individual both with regard to their scientific knowledge and standing, as well as genuine commitment to application of the 3Rs and compliance with the legislation.

This intelligence informs the conduct of subsequent inspection of the work in progress which can include direct observation of procedures, inspection of animals during the course of the procedures, discussions with licensees and care staff, and review of relevant records. Furthermore, additional information may be offered to the inspector by others holding technical, named or managerial positions at an establishment, as a result of the effective, trust-based relationships.

All of this information is integrated by the inspector to form their opinion on the risks of potential non-compliance, and how this might be prevented through advice to personnel at the establishment. This approach is a much more in depth evaluation of the actual use of the animals for scientific purposes than can reasonably be achieved by an individual to whom only a part of this picture is visible such as a junior animal care assistant.

The inspector's role is to monitor compliance and report on cases of non-compliance. It is the responsibility of licensees to ensure that they comply with the legislation. To that end they should utilise the frameworks provided by the legislation including the advice of their named persons (NVS, NACWO, NTCO) as well as the expertise of other staff in identifying whether humane end points have been reached during experiments and intervention is warranted.

The summary of the inspector's reports from 2012, noted above in the Background section, confirms that a number of actual incidents similar to those identified in the allegations, were indeed identified by the inspection process. The inspector was in a position to evaluate these occurrences in the light of their overall knowledge about the compliance attitude of the establishment. On that basis, it was determined that the risk profile of the Establishment was not raised in late 2012 given that work in progress was likely to improve the culture of care and reduce the risks of non-compliance e.g. newly appointed Establishment Licence holder; AWERB changes;

veterinary services work on training especially in relation to aseptic surgery and refinement of models such as the cardiac disease models.

In April 2013, the Chief Inspector required a temporary increase in inspection frequency for the period of the ASRU investigation, to be reviewed once the outcome of the investigation was known.

9 Conclusions

Overall it appears that there are a wide range of managerial tools in place at the Establishment, which should have the effect of supporting compliance with ASPA and encouraging a good culture of responsibility and care for the animals used in scientific procedures. Furthermore, there have been positive efforts by the Establishment at managerial and Named Person level to address a number of issues, both before and since the exposé.

However, evidence from the investigations shows that there is a significant level of technical non-compliance – 1 Category A and 4 Category B non-compliance cases. A proportion of licensees are unfamiliar with, and have poor working knowledge of, the conditions applied to their licences, in particular the need to comply with humane endpoints and reporting to the Home Office when these were exceeded.

There is a lack of effective involvement of the Named Persons and others responsible for animal care evidenced by poor uptake of refinements by researchers despite the knowledge and advice from others. Furthermore, there is ongoing evidence of the previous culture of unwillingness to adopt 3Rs via NACWO or HO advice.

Senior management appears somewhat remote from the persons actually conducting the studies on living animals. It is not common practice to actively involve the Named Persons – in particular the NVS and the NACWOs – when planning an experimental study

In essence, the Establishment provides a wide range of desirable inputs to the compliance process and in support of application of the 3Rs. However, the effects of these are not demonstrated in the outcomes of refined procedures and a commitment to a good culture of care evidenced by all staff at all levels.

Claims of having a culture of continuous improvement are not apparent as evidenced by continued out-dated practices and a general reluctance to seek advice from Home Office, Named Persons, or other sources - such a culture needs to be embedded in the day-to-day practices of the researchers.