



Home Office

Norman Baker MP
Minister for Crime Prevention

2 Marsham Street,
London SW1P 4DF
www.homeoffice.gov.uk

Dr John Landers,
Chairman
Animals in Science Committee
c/o ASC Secretariat
2 Marsham Street
London
SW1P 4DF

10 July 2014

Dear Dr Landers

Lessons to be learnt, for duty holders and the regulator, from reviews and investigations into non-compliance

I would like to thank you and your Committee for the time you have spent on the Report on the lessons learned from reviews and investigations into non-compliance.

The Report provides nine recommendations: seven on the regulatory framework around the Animals (Scientific Procedures) Act 1986, and two for institutions. I have fully accepted the recommendations that relate to regulatory activities and will strongly encourage institutions to take up the intent of the other recommendations. The attached table shows how the Home Office intend to take forwards the recommendations that are for us.

Thank you again for looking into this important matter.

Yours sincerely

Norman Baker MP
Minister of State

ASC recommendation	Response and agreed action	Lead	Measures of success and key milestones	Timelines
<p>A. That the HOI is given a clear mandate to identify and remedy failings of the kind identified in the reports with respect to establishments' standard of provision, AWERB and overall institutional culture regarding animal welfare and the 3Rs, including the exercise of effective strategic leadership.</p>	<p>The changes to ASPA as a result of the transposition of EU Directive 2010/63 have strengthened the mandate of HO inspectors. These were enacted after the incidents of non-compliance referred to in the ASC report. Consequently, the ASC recommendation is now addressed within our new Guidance, providing a mandate for inspectors to monitor and report compliance.</p> <p>A project to review the Inspection process is in train which will consider current practices and make recommendations for reporting to ensure such information is also captured appropriately.</p>	<p>ASRU Inspect- orate</p>	<p>ASRU can demonstrate through information in inspection reports that these aspects have been inspected at establishments and appropriate remedies identified and, if necessary, remedial measures imposed.</p> <p>ASRU continue to report cases of Compliance Advice given, to licensees, to the Secretary of State.</p> <p>Annual meetings (as a minimum) with Establishment Licence Holders record identification and remedy of any failings</p> <p>Review of current inspection process and implementation of changes to current reporting systems to enable capture of this information.</p>	<p>On-going</p> <p>On-going</p> <p>Annual</p> <p>End 2014</p>

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<p>B. In order to ensure consistency of approach and appropriate standards in the HOI's response to patterns of low-level concerns in these areas, guidance should be produced for HOI staff on the process to be followed when dealing with them. This guidance would focus on HOI procedures rather than specific solutions to the concerns identified; these must be individually tailored to each facility and driven extensively by input from the facility itself. The guidance should promote transparency regarding the HOI's approach to these types of concerns.</p>	<p>Inspectors currently have an annual risk management meeting with all establishment licence holders. At this discussion, incidents of non-compliance and low-level concerns are reviewed and may lead to an agreed action plan where appropriate. Whilst there are processes for dealing with patterns of low-level compliance, these have not been explicitly codified.</p> <p>A project to review the inspection process and reporting is in train which will include improved mechanisms for recording low-level concerns at establishments so that patterns can be readily identified.</p> <p>Guidance for inspectors on reporting inspection outcomes is also being reviewed alongside this project and will include procedures for dealing with such concerns.</p>	<p>ASRU Inspect- orate</p>	<p>Clear guidance to inspectors on procedures for dealing with patterns of low-level concerns when these are identified.</p> <p>Improved reporting of the procedures that have been followed when such concerns are identified and outcomes achieved</p> <p>Improved mechanisms for identifying those establishments that have an emerging pattern of low-level concerns and taking proportionate action.</p>	<p>Sept 2014</p> <p>End 2014</p>

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<p>C. The HOI should review its process for recording the outcome of inspection visits to ensure that follow up of low-level concerns identified on inspection visits is clearly recorded to ensure that patterns of concerns are picked up appropriately and to improve transparency in relation to how these concerns are dealt with.</p>	<p>For immediate action: Current instructions to inspectors on reporting inspections are being revised to ensure information on low level concerns is captured and reported.</p> <p>Longer term: The project to review the process and reporting of inspection will incorporate changes to drive the process of following up low-level concerns and facilitate monitoring by management.</p>	<p>ASRU Inspectorate</p>	<p>Revised instructions to inspectors – see B. above</p> <p>Revised reporting system including necessary IT system upgrade</p>	<p>End 2014</p> <p>End 2015</p>
<p>D. That the HOI reviews its system of risk assessment so as to ensure that establishments where there may be an unacceptable risk of non-compliance and/or inadequate provision are rapidly identified.</p>	<p>The Inspectorate operates a detailed risk based approach to inspection, which has been published in ASRU Annual Reports.</p> <p>Short term action: The feasibility of revising the current report form to identify and collate reports of risks of non-compliance and or inadequate provision will be evaluated, such that this can be incorporated into the risk-based inspection approach.</p>	<p>ASRU Inspectorate</p>	<p>Evaluate feasibility of revising current report form to start capturing this information in an easily retrievable form.</p>	<p>On-going</p> <p>October 2014</p>

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D. Continued	<p>Longer term: The project to review the inspection process and reporting of inspection will incorporate changes to the reporting of inspection so that capture of this information in a manner that can easily be assimilated.</p>	ASRU Inspectorate	<p>Risk of non-compliance due to chronic low level concerns will be factored into the Inspectorate's risk-based approach to inspection.</p> <p>Capture of data including necessary IT system upgrade</p>	<p>October 2015</p> <p>End 2015</p>
E. The HOI should ensure that the ELH's responsibility to promote a culture of care throughout their establishment is properly understood and discharged.	<p>This is already explained in the published Guidance (2014).</p> <p>This aspect will be re-enforced in the updated Instructions to inspectors with specific reference to the regular (a minimum of annually) meetings with ELHs where risks and mitigation are discussed and relevant courses of action agreed.</p>	ASRU Inspectorate	Revised instructions to inspectors – see B above	<p>On-going</p> <p>Sept 2014</p>
F. The accountability of the ELH to the Home Office is given concrete expression through the application of appropriate sanctions in cases of serious failure to discharge their responsibilities.	<p>This is already explained in the published Guidance (2014).</p> <p>The suite of regulatory sanctions now available since the changes to ASPA in 2013 has been broadened to include Compliance Notices, which are a useful tool to promulgate changes at establishments, specifying the identified failures, the action to be taken and the timeframe for effective outcomes.</p>	ASRU	Now implemented	From 1 st January 2013

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<p>G. That the Minister should consider whether he can continue to have confidence in the current ELH at ICL retaining this role.</p>	<p>The Home Office was informed on 9 July that the current establishment licence holder had stepped down from holding that responsibility with immediate effect.</p>			
<p>H. Licence holders should ensure that all those involved with work under ASPA have a readily accessible means of raising 'causes for concern' with the management of their establishment, and the HOI's mandate should extend to monitoring these arrangements.</p>	<p>This recommendation is not directed to the Regulator (ASRU). ASRU will look to the ASC and other regulators to consider best practice in this area. Nevertheless, mechanisms for raising causes of concerns would be an integral component of a good culture of care and therefore now bought into the remit of the ASRU Inspectorate with the changes to ASPA. The ASRU Inspectorate have worked with the RSPCA and other stakeholders to develop guidance for stakeholders. Other stakeholders may develop and publish similar guidelines.</p>	<p>PEL Holders</p>	<p>PEL Holders will advise inspectors of the mechanisms they have put in place Include in review of inspection process/reporting</p>	<p>On-going End 2014</p>

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<p>I. In order to promote the wider involvement of biomedical staff in animal-based research, licence-holding academic institutions be encouraged to provide wider financial support to their biomedical services – beyond routine ‘basic husbandry and welfare duties’ – from their central budget outside the provisions of fEC.</p>	<p>This recommendation is not directed to the Regulator (ASRU).</p>	<p>PEL Holders</p>		