

The **ASC**

Animals in Science

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

The Animals in Science Committee (ASC) established a Working Group to draw up advice to the Minister following the allegations of non-compliance and other forms of bad practice at Imperial College London (ICL). This report, with its findings and recommendations, has been endorsed by the full ASC membership.

1. Findings from the two reports

The findings in this section are based on reading the independent report commissioned by the establishment and the Home Office Inspectorate (HOI) report. They are supported by an outline briefing that the Chair received from the Head of the Animals in Science Regulation Unit (ASRU) and the Compliance Notice¹ dated 4 December 2013.

a) The independent report

The independent report details a number of systemic failures at the establishment.

- i. The Animal Welfare and Ethical Review Body (AWERB)² – Failings in the structure and functioning of the AWERB rendered it “*not fit for purpose in terms of delivering improvements in the 3Rs [the replacement, refinement and reduction of animals in research]*”³. There was no effective forum for “*renewing approaches to animal experimentation, challenging existing approaches and delivering changes in the 3Rs*” (p. 8, para. 2.9). Retrospective reviews of project licence holders (PPLs) were not being undertaken and had not been “*for some time*”; nor were “*reviews undertaken of developments and outcomes of ongoing projects*” (p. 19, paras. 4.24–5).

These shortcomings constitute a failure to comply with the requirements specified in the Home Office’s 2000 *Guidance on the Operation of the Animals (Scientific Procedures) Act*, (Appendix J, p. 100, paras. 7.(1), (2) and (4).

- ii. Staffing – The provision of senior staff was inadequate, which resulted in an “*unsustainable*” burden of responsibility being placed on the Named Veterinary Surgeon (NVS) and contributed to failures of leadership in the AWERB process and the promotion of animal welfare more generally.

Overall staffing levels in Central Biomedical Services at ICL were judged to be just sufficient for “*basic husbandry and welfare duties*” under normal circumstances but were vulnerable to contingencies and appeared inadequate to guarantee “*sufficient attention ... to supervision and oversight of the animals undergoing procedures*” or post-operative care (pp. 23–4, paras. 5.18–9).

¹ Compliance notice: if a licence holder has breached a condition of their licence, or a provision of ASPA, the Secretary of State may require the licence holder to take action to prevent further non-compliance within a specified period, and issue a compliance notice. A notice will specify the licence condition(s) or ASPA provision(s) with which the licence holder has failed to comply.

² The role of an AWERB and statutory requirements are set out under 10 of the Animals (Scientific Procedures) Act 1986.

³ The first standard condition of the establishment licence requires that the holder must put in place measures to ensure that the regulated activities carried on at the establishment are carried out in a manner that is consistent with the principles of replacement, reduction and refinement.

In so far as these staffing issues represent failures to provide named persons with adequate resources they constitute a failure to comply with the responsibility of certificate holders as specified in the 2000 *Guidance* (p. 14, para. 4.51).

- iii. Culture and communication – The report draws attention to widespread failures of culture and communication at the establishment. In particular, an excessive reliance on e-mail resulted in insufficient face to face communication between biomedical staff and researchers, and very limited opportunities for discussion of issues relating to animal welfare and the 3Rs. AWERB minutes – where they existed – were not circulated among the research community in breach of the *Guidance*, which requires “*some formal outcome ... made as widely available as security and commercial/intellectual confidentiality allow*”. (Appendix J, p. 100, para. 8).
- iv. Named Animal Care and Welfare Officers (NACWOs) – The independent report questions whether NACWOs actively followed up animal welfare concerns “*to ensure that the matter was dealt with appropriately*”, and whether “*NACWOs’ decision making process was free from any additional pressures within the establishment*” (p. 25, para. 5.31). Failings in these respects may constitute failure to comply with the *Guidance’s* requirement that NACWOs ensure that the relevant standards of “*care, accommodation, husbandry and welfare ... are met*”. (p. 23, para. 4.51)

b) The Home Office Inspectorate report

The HOI investigated allegations of infringements stemming from an earlier, covert, third-party investigation and upheld a number of them. For the most part the latter reflected failures to notify the Home Office of end-point violations and involved PPL holders who – it appeared – were not properly aware of their responsibilities under the Act. The report concludes that a “*proportion of licensees were unfamiliar with and had poor working knowledge of the conditions attached to their licences*” (p. 20).

The HOI report refers to “*formal non-compliance cases, with few instances of animal suffering*” (p. 6, para. 2). In their view the identified infringements were not judged to involve unacceptable welfare costs to the animals. There was nonetheless a systematic pattern of infringements, of which the ASC notes that at least two involved tangible welfare costs, and there is no reason to believe that this was confined solely to the six-month period covered by the third-party investigation. The pattern itself reflects underlying failures in the mechanisms that should ensure appropriate levels of animal welfare, and the report could not be confident that the consequences were limited to technical infringements of the kind detected by the HOI investigation.

The report concludes that 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 the management structures*” (p. 6). It also concludes that there was “*a widespread poor culture of care*” (*ibid.*) and a “*poor uptake of refinements by researchers*” (p. 20). In the light of these conclusions it may reasonably be inferred that:

- i. infringements occurred on an unacceptable scale for an unknown, but extended, period; and

- ii. there was an unacceptable risk that some might involve appreciable welfare costs to the animals.

2. The role of the Home Office Inspectorate

Home Office inspectors visited the site 15 times in 2012. It was not clear from the HOI report whether the infringements that occurred were ones that the inspectors could reasonably have been expected to detect without the findings of the prior, third-party investigation. The underlying failings of leadership, management and culture noted above were, however, of a kind that should have been evident to visiting inspectors. The Working Group was therefore concerned that the latter did not appear to have been detected or, if they were detected, the inspectors did not feel that they either should or could take appropriate action.

The Working Group therefore conducted an examination of the HOI's inspection regime at ICL over the period in question based on a review of the relevant paperwork and interviews with the inspectors involved and the Chief Inspector. It found evidence that a pattern of concerns was identified by the HOI as early as 2012, and that a process was initiated which, on the basis of the information available at that time, was a reasonable response. The Working Group was advised that, at the end of 2012, the HOI was waiting for the new Establishment Licence (PEL) holder and ERP Chair to bed in. A meeting with the PEL holder, where the HOI's concerns would have been discussed and an action plan agreed and monitored, would have taken place, had it not been pre-empted by the publication of the third-party investigation. In light of this the Working Group has not found that there was any omission on the part of the HOI in dealing with the concerns identified at ICL.

3. Recommendations

a) The Home Office Inspectorate

The Working Group has found no evidence of omission on the part of the HOI in its oversight of ICL over the period in question. It does, however, recognise that there are difficulties for the regulator in addressing a pattern of low-level concerns, which may be individually insufficient to require action, but taken together are symptomatic of a management and welfare regime falling short of expected standards. The Working Group's examination has led it to conclude that some improvements to the HOI procedures would introduce greater rigour into their mechanisms for dealing with patterns of persistent low-level concerns, would reduce risk in this area and provide support to HOI staff and managers in ensuring a consistent and robust process.

The Working Group therefore *recommends* the following.

- 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.
- 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, as 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.

- 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.
- D. The HOI should review 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.

b) The certificate holder/establishment licence holder

The current guidance sets out more clearly than the 2000 version what is required of licence holders and establishments. This is to be welcomed, but if it is to have the desired effect it will be essential for the HOI to have a clear mandate in respect of an establishment's standard of provision, the structure and function of its AWERB and the overall institutional culture regarding animal welfare and the 3Rs, including the exercise of effective strategic leadership. It is particularly important that the responsibility of the establishment licence holders (ELHs) to promote a culture of care throughout their establishment is clearly understood and that the regulator ensures that this responsibility is properly discharged. Effective mechanisms must also be put in place to ensure that any deficiencies in these respects can be remedied as expeditiously as possible.

The Working Group therefore *recommends* the following.

- E. The HOI should ensure that the ELH's responsibility to promote a culture of care throughout their establishment is properly understood and discharged.

The Working Group notes that the current guidance, as well as being more specific in respect of the standards of provision required of establishments, also specifies that the ELH is 'accountable' to the Home Office for their fulfilment. This too is to be welcomed, but if it is to be effective, given the essential leadership role of the ELH, it will be necessary for appropriate sanctions to be available – and be seen to be available – where serious failures occur in this regard.

The Working Group therefore *recommends* the following.

- F. The accountability of ELHs to the Home Office is given concrete expression through the application of appropriate sanctions in case of serious failure to discharge their responsibilities.

c) The case of ICL

The regime at ICL clearly fell short of the standard required by the Animals (Scientific Procedures) Act 1986 (ASPA). The HOI investigation identified a pattern of infringements that reflected underlying systemic failings of the kind set out in the independent report. In particular, failings of culture and communications impeded the promotion of best practice and the 3Rs, whilst NACWOs and biomedical staff were insufficiently involved in procedures and post-procedure recovery. This was symptomatic of a deeper failure of leadership, giving rise to, and in turn compounded by, an inadequately-resourced Biomedical Services senior management team.

The 2000 *Guidance*, though less specific than the current version, is nonetheless unambiguous in setting out the ELH's responsibility to the Home Office for ensuring compliance with the terms and conditions of the certificate of designation. These include the provision of:

- i. sufficient staffing, education and training, to ensure animal welfare (Appendix B, paras. 4 and 19);
- ii. adequate resources to named persons (p. 23, para. 4.51); and
- iii. an ethical review process capable of, *inter alia*, "leading to the widest possible application of the 3Rs" (p. 18, para. 4.14).

Apart from the general failures of leadership identified by the independent report, the findings of both the independent report and the HOI report indicate that the CH/ELH failed in these specific responsibilities to the Home Office. The Compliance Notice lists three breaches of the certificate of designation and four of the establishment licence for which the CH/ELH is responsible. In view of this, and the considerations underlying recommendation E, the Working Group *recommends* the following.

G. The Minister should consider whether he can continue to have confidence in the current ELH at ICL retaining this role.

d) Employees with cause for concern

The reports are generally positive as regards the attitude, competence and commitment of the 'line' technical and animal care staff, but it appears that staff members with causes for concern in respect of animal welfare issues did not always feel able to raise these with their supervisors or the site management. This is a potentially serious shortcoming and the Working Group therefore *recommends* the following.

H. The HOI ensures that all those involved with work under ASPA have a readily accessible means of raising 'causes for concern' with the management of their establishment.

e) Full economic costing and animal research

Beyond the management and leadership failings identified in the reports there is a further issue concerning the funding of academic animal-based research that is subject to full economic costing (fEC). This generates powerful incentives to keep animal maintenance charges low, so as to attract grant funding, and thus to reduce the involvement of biomedical staff. In order to encourage the latter's wider involvement, as recommended by the independent report, consideration should be given to wider support, other than routine 'basic husbandry and welfare duties', from the institutions' central budget outside fEC.

The Working Group therefore *recommends*

- 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.

RECOMMENDATIONS

Recommendations to the Minister

- 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.
- 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.
- 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.
- 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.
- E. The HOI should ensure that the ELH's responsibility to promote a culture of care throughout their establishment is properly understood and discharged.
- 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.
- G. That the Minister should consider whether he can continue to have confidence in the current ELH at ICL retaining this role.

Recommendations to the institution

- 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.
- 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.

John Landers, Chair Animals in Science Committee

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