Home Office

Animals (Scientific Procedures) Inspectorate

Annual Report 2007

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Introduction

This is the fourth annual report of the Animals (Scientific Procedures) Inspectorate and covers the period January to December 2007. It includes sections on each aspect of the work of the Inspectorate during the year, and some chapters focussing on particular issues.

Background to the Inspectorate and the nature of its work was provided in the first report which can be found in full at http://scienceandresearch.homeoffice.gov.uk/animal-research/publications/publications/reports-and-reviews/annual-report. Some knowledge is presumed of the Animals (Scientific Procedures) Act 1986 (ASPA) under which Inspectors are appointed and operate. Any who may be unfamiliar with it will find the text of the Act and Guidance on its operation on the Home Office website (http://www.archive.official-documents.co.uk/document/hoc/321/321.htm).

Briefly, this Act regulates scientific work on "protected animals" (a wide range from fish to monkeys)[1] (which may cause pain, suffering, distress or lasting harm ("regulated procedures") by a mandatory licensing and monitoring arrangement. Licences are required for the programmes of work ("projects"), and the persons who do the work, and certificates are needed for the establishments ("designated establishments") where such work is carried out and where the common laboratory animals are bred or held for supply. Inspectors advise the Secretary of State on applications for these licences and certificates. They visit the places where the work is done, or animals bred or supplied, to check that the procedures undertaken and the local arrangements accord with what is authorised, and report when they do not[2].

As in previous reports, care has been taken to anonymise examples and preserve confidentiality, conscious that the 1986 Act prohibits the unauthorised disclosure of confidential material. It is also sadly necessary to safeguard places and personnel (including Inspectors) against the activities of animal rights extremists. For this reason no names, besides mention of the two Chief Inspectors, or location details are included in the report and confidential information or anything that might identify places or individuals has been omitted.

On 31 December 2007 there were 28 Inspectors, including some working part-time. As in 2006, Inspectorate strength during the year was, on average, 24.7 full-time equivalents. The Inspectorate remained stable during the year with the only change being the retirement of the Chief Inspector (CI), Dr Derek Fry, at the end of December and his replacement by Dr Judy MacArthur Clark. Reference to the CI in this report refers to Dr Fry.

Derek Fry joined the Inspectorate in 1990 and served in the Shrewsbury regional office for 8 years before his promotion to Superintending Inspector in 1998. He became Acting Chief Inspector in 2003 and assumed full responsibilities for that role in 2004. He qualified in medicine from Oxford and St Bartholomew's Hospital in 1969 and gained his D Phil from Oxford. His research interests were very diverse including ion transport and volume regulation, metabolism of xenobiotics, and the use of computers and interactive video in teaching anatomy. In addition to his duties as an inspector, he also taught in the Department of Anatomy and Physiology at Dundee University.

His personal contribution to the Inspectorate has been central to the success of ASPI over recent years. Under his leadership, the Inspectorate consistently produced advice of the highest quality on complex scientific and technical issues. That advice has made a significant contribution to important decisions and policies and has helped to enhance public understanding and debate around the use of animals in

1 Actually all living vertebrates except man and one invertebrate (Octopus vulgaris), including some immature forms.

2 The Act also provides for penalties if work is not authorised or conditions placed on licences or certificates are not met. Licences and certificates can be varied or revoked, and for serious offences fines or imprisonment are options.

science. Dr Fry's infectious enthusiasm for educating scientists, both young and old, in ways of improving their experimental design was widely recognised and undoubtedly resulted in reduction in numbers of animals used, improvement in quality of research data, and refinement in research protocols for the benefit of animal welfare.

Dr Fry left at the end of an extremely busy and productive year, during which his own expertise and knowledge of the legal and regulatory framework under which the Inspectorate has to work were fully tested. In addition his skill and technical expertise in experimental design and presentation were employed in a number of forums.

A Judicial Review (JR) and Freedom of Information (FOI) requests and appeals took up considerable time. Although the results of these appeals were not known until 2008, it is appropriate to record that in both case the courts found in favour of the Home Office (HO). Whilst it is both right and proper that the Act, and how it is administered, is challenged and tested by due process or through the Courts, the amount of time involved for the CI and other Inspectors should not be underestimated. The Inspectorate also contributed significant resources to the Better Regulation initiative during 2007. More information on all these is contained in the body of the report.

During 2007 the Inspectorate carried out 2,401 (mainly unannounced) visits to places where scientific work on animals was conducted, spending in total 6,749 hours on site, with a further 4,937 hours spent travelling. Inspectors provided advice on 632 project and 2,618 personal licence applications and on two applications for certificates to designate establishments for scientific work. Inspectors also advised on numerous amendments to granted licences and certificates.

Inspectors continued to put much effort into advising licensees and potential licensees on how to meet the provisions of the ASPA and keep to the conditions on licences. During 2007 they participated in further events designed to update and advise applicants on the information required for PPL applications. Both project licensees and certificate holders have indicated how valuable attendees had found these Inspector-led events.

Introducing the New Chief Inspector Judy MacArthur Clark

Dr Judy MacArthur Clark

In December 2007, following the retirement of the Chief Inspector Dr Derek Fry, Dr Judy MacArthur Clark was appointed as the Chief Inspector. The following brief interview was conducted by a member of the Annual Report Editorial Team to find out a bit more about the new Chief Inspector.

Ed: 'Welcome to ASPI. Can you tell us what initially attracted you to this post?'

JMC: The role of the Chief Inspector is a very challenging one demanding a balance of wisdom, sound judgment and leadership. Whilst I can't claim perfection in all these attributes, I do have an extensive background in biomedical research and animal welfare, professional and scientific politics, people management and strategic thinking, which I can bring to this role.

I was also much involved back in 1986 in the passage of the Animals (Scientific Procedures) Act and I have a detailed understanding of the legislation – although it is somewhat different to see it from the perspective of the regulator as opposed to the regulated! I am familiar with many individuals in the communities which work with the Act – both those performing the science and those caring for the animals – and I have always been very conscious of the professionalism and high regard with which Inspectors are viewed.

The opportunity to lead such a team of professionals is very attractive to me. I have always felt strongly that, appropriately implemented, the structure which the Act provides offers one of the best regulatory systems in the world in this complex area. For me, it's very exciting to have the opportunity to play a leading role in developing such a world-class regulatory system with a world-class team of colleagues.

Ed: 'What do you see as the biggest challenges in your new role and what do you consider to be the priorities?'

JMC: Our greatest challenge is to demonstrate how good this regulatory system really can be. To do this, we need to constantly revisit the balance between the public's concern to benefit from scientific advancements and their equal concern to have confidence that animals are not suffering unnecessarily. At present, an enormous amount of our resource goes into the assessment of licence applications and we need to look for ways of streamlining that approach without losing quality in our decision making. In addition, our stakeholders find preparing these applications very burdensome and we need to find ways of getting the necessary information from them more easily. I'm not aware of any other regulator in this field in the world who has cracked these problems – so the challenge for us is to do so.

A further big challenge is consistency in our decisions. All Inspectors are professionals in what they do and this is important because we are working in very complex fields. However, as professionals, we exercise our judgment in making our decisions. Ensuring consistency of decision making requires greater investment of resources on our part. We need to create small teams of Inspectors who can perform thematic reviews of specific areas of work, often in association with stakeholders, and ensure the decisions we have taken are consistent and the best. We need to focus particularly in areas of higher risk such as those involving

substantial severity or sensitive species. Also we need to do more joint visiting and perform more joint assessments to enable Inspectors to share best practices both with each other and with our stakeholders.

Of course, all this takes time and we need to carefully review Inspector work patterns to free up time wherever possible and divert that resource into these challenging areas. That in itself is a big challenge.

Ed: 'What special skills and experience do you feel you bring to ASPI?'

JMC: I have considerable experience in the field of bioscience, both as a scientist and as a veterinarian specialising in this field. I'm familiar, from first-hand, with the problems facing both industry and academia and, in addition to the UK, I have worked within a regulatory framework in both mainland Europe and North America. So I can view what ASPI is achieving now, and where we plan to be, from a very broad perspective.

I've also had a lot of experience in leadership and strategic planning and I appreciate the difficulties for people of coping with change and the importance of a sound strategic plan which has wide ownership within the organisation.

And I know many of the key players in our broad range of stakeholder communities, from animal welfare and protection through to industry, academia and funding bodies. I am interested in using all my skills and experience of networking and negotiating to find win-win solutions. Furthermore, my background on major government advisory committees and professional bodies has helped me understand the bureaucracy which we are dealing with. I am very tenacious and I don't give up!

Ed: 'What are you most looking forward to in the forthcoming year?'

JMC: By the end of 2008, my colleagues in ASPI will have come with me through significant challenges and change. I am looking forward to us emerging as a confident and stronger team. I believe we can channel the considerable energy and talents of the individuals within ASPI so that, working together, we can become much more influential than in the past. We need to make sure our voice is always heard, both internally within the Home Office and externally with our stakeholders. This involves us developing a culture which continues to build on our reputation for professionalism while focusing on behaviours which place transparency, trust and mutual support as priorities, and build sound partnerships with all our stakeholders. I am most looking forward to my colleagues telling me, at the end of the year, that they appreciate this fundamental change in how we work and which, together, we will have accomplished.

Events and Initiatives in 2007

Inspectors use their technical and professional skills, to act in a representational role, to take part in outreach and educational activities and to encourage good practice in science and animal welfare, in addition to their main statutory tasks of advice and inspection.

The Inspectorate made valuable contributions during the year to a significant number of events and initiatives, a selection of which is given below. The use of interactive voting software and equipment was introduced by the CI at the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs) meeting in March 2007. This innovation was subsequently copied by a number of Inspectors in a variety of forums to good effect. For the full range of participation by Inspectors in meetings and ongoing initiatives also see the representation and education sections.

Inspectors attending these types of meeting report back on points of interest to the rest of the Inspectorate and licensees, where appropriate, thus ensuring further dissemination of information.

National Initiatives

Better Regulation

During the year, continued efforts were made to stream-line assessment and administrative processes within ASPI in compliance with the commitment to Better Regulation. The Inspectorate contributed to numerous workshops and initiatives towards Better Regulation which have laid the foundations for changes that will take effect in future years. Whilst there is much enthusiasm within the Inspectorate to reduce bureaucracy, there are two important points to bear in mind about the Better Regulation programme. First, no action will be taken that might compromise animal welfare. Second, there is no intention to open primary legislation to amend ASPA.

The Davidson Review, which included consideration of the implementation of ASPA, recommended a headline 25% reduction in the administrative burden to licensees by 2010 and a number of interim targets. Substantial progress was made in 2007 towards achieving these goals, and licensees will have already begun to see changes in the way work is done.

Progress in 2007 included:

- The application form for a Certificate of Designation (PCD) was changed to reduce the number of amendments needed and simplify paperwork when the only amendments requested are changes to Named Persons.
- A standard list of wordings for techniques in section 15 of the personal licence was developed (it has subsequently been introduced to assist applicants): http://scienceandresearch.homeoffice.gov.uk/animal-research/publications-and-reference/publications/licences/personal-licences/Personal-Licenc-_S15-Tech-L1.pdf?view=Binary)
- A formalised system for fast-tracking certain types of personal licence applications was introduced.
- New procedures introduced in 2007 for reviewing personal licences should reduce the need to send in licences separately for review.
- Consultations were held with stakeholders on the format and content of the annual statistical report (note further progress in this area is dependent on the expected revision of EU Directive 86/609; see later in this report).
- Discussions were held with users to try to devise a more user-friendly version of the project licence application form that captures only the required information in a format that minimises the need for minor technical amendments.

ASPI and the Animals Scientific Procedures Division (ASPD) are working closely with stakeholders to ensure that any changes that are implemented actually tackle the problems they feel they are experiencing in practice. In August 2007 an e-mail consultation was started with a group of 40 practitioners on issues relating to personal and project licences, certificates of designation and the annual statistics. A practitioners' meeting was held in October where options for further development were considered. Further information can be found at:
http://scienceandresearch.homeoffice.gov.uk/animal-research/better-regulation/

Freedom of Information Requests and Appeal

ASPI was involved in advising on responses to several requests for information made under the Freedom of Information Act (2000) (FOIA).

These covered requests for information on alternative tests i.e. tests which do not use animals, information concerning alleged non-compliance with project licence authorities, information on the sourcing of wild caught primates and spending on animal research. Responses were provided where possible, but in some cases exemption under the FOI Act prevented information of a personal nature, information provided in confidence and already published information from being disclosed.

Home Office policy on the extent to which it is able to release information under FOIA has been tested. In January 2005 the British Union for the Abolition of Vivisection (BUAV) requested "the actual information contained in each of the following licences", and listed 5 licences for which abstracts had been published on the Home Office Website. Although some additional information was able to be provided, the actual content of the licences was for the most part considered to have been provided in confidence and therefore it was not possible to release this due to the constraints of both ASPA Section 24 and FOIA.

An appeal by the BUAV to the Information Commissioner was reported in June 2007 and found in favour of the Home Office, that the undisclosed information could not be released. A subsequent appeal to the Information Tribunal heard in December 2007 overturned the original decision and found in favour of the BUAV, requiring the Home Office to reconsider what information was provided in confidence and therefore needed to be considered exempt under both ASPA and FOIA Section 44.

That decision has since been set aside by the High Court in April 2008. The BUAV has subsequently been granted leave to appeal.

Home Office policy on the type of information that was provided in confidence and is contained within licences that can be released therefore remains unchanged.
For further information please follow the web link below:
http://scienceandresearch.homeoffice.gov.uk/animal-research/aboutus/ASPD_freedom_of_information/

Judicial Review

In December 2003 the BUAV initiated a Judicial Review (JR) about four aspects of the implementation of ASPA:

1. assessment of severity limits for protocols;
2. post-operative care;
3. death as an adverse effect;
4. status of the 'Home Office Guidance Note: Water and Food Restriction for Scientific Purposes'.

The JR was subject to a full hearing in the High Court in July 2007. The written judgement ruled against the HO on the first issue and against the BUAV on the other three, with leave to appeal granted to the HO and, subsequently, to the BUAV with respect to the second issue. Both appeals were heard in March 2008 and judgement issued in April 2008, with the Court of Appeal upholding the Secretary of State's appeal on the first issue. The Court of Appeal agreed that the severity limit is determined by the degree of suffering experienced by the animal prior to the point at which it is humanely killed. The BUAV's cross-appeal on issue 2 was dismissed by the Court of Appeal.

The preparation for and participation in this JR occupied much time for the CI and for other Inspectors in 2007. Scrutiny of file work, to ensure accurate and correct information was provided to ASPD, other officials, Legal Advisors Branch and Counsel, was an essential first step. This was followed by frequent discussions to explain the necessary technical background and give summary statements prior to, during and after the hearings.

Technical Input to the Animal Procedures Committee's (APC) Activities

The APC provides independent advice to ministers, but Inspectors attend its meetings and subcommittees to provide professional advice and expertise on technical and operational matters. Input on technical accuracy and operational feasibility is given, but particular care is taken not to affect the independence of the Committee's advice. As in all other previous years, this required a significant amount of Inspectorate time in 2007. Some subcommittees have been heavily reliant on Inspectors' professional and technical expertise. Examples of where Inspectors have contributed to the APC's considerations include:

- housing and husbandry;
- non-human primate use and care;
- the Ethical Review Process;
- care and use of fish;
- education and training of potential licensees;
- suffering and severity.

The supply of non-human primates from overseas breeders was considered by the APC during 2007. When considering the suitability of an overseas primate breeding centre, the APC Primate Subcommittee (APC PSC) reviews a comprehensive set of details provided by the centre. The subcommittee also has access to a technical commentary on the details prepared by ASPI and an Inspector who has visited the breeding centres normally attends the meeting to provide technical input. Details of four overseas breeding centres were reviewed by the APC PSC in 2007.

The CI and other Inspectors attended meetings of the Applications Subcommittee, which considers project licence application referrals, to provide technical guidance in these specialist areas.

Certificate Holders' Forum and Training Day

The CI provided the annual update on operational matters at this event including clarification of issues arising from the launch of the new PCD form, an update on the Better Regulation initiative and on relevant ASPA compliance issues. This event continues to provide an invaluable forum for certificate holders to meet and discuss current issues. A session during the meeting focussed on the development of new facilities 'Build and Commissioning Essentials', including a presentation by Inspectors on 'Achieving ASPA Compliance'. Information from this has been included later in this report in 'Focus on Facilities'.

The Training Day event, delivered by Inspectors, which had proved so successful in 2006, was repeated with particular emphasis on information for new certificate holders including workshops and presentations covering compliance issues, Ethical Review Process functions, lines of communication and support for licensees and named persons.

Preparation of the Annual Statistics

The collection, collation and reporting of the Statistics of Scientific Procedures on Living Animals is the responsibility of the Home Office's statisticians in the Science and Research Group, but Inspectors have, as usual, provided an important input into the interpretation of the results and analysis of trends for the 2006 statistics, which were published in July 2007.

Veterinary Medicines Directorate (VMD)

Inspectors have met with the VMD to discuss various issues related to the Veterinary Medicines Regulations 2007 (VMR). These were:

Changes in relation to ASPA

Recent changes to the VMR allow researchers themselves to legally acquire and use the medicines needed in the course of their research. This change has important 'knock on' consequences that Certificate holders, licensees and Named Veterinary Surgeons (NVS) should be aware of. Generally the final supply and direction for use of many drugs and prescription only medicines is restricted to veterinary surgeons. However, in 2006 these restrictions in the Veterinary Medicines Regulations (VMR) were removed in respect of medicines used in the course of a procedure licensed under ASPA. This exemption requires that the researchers assume responsibility for the acquisition, directions for use, storage and safe disposal of these medicines. Therefore, controls should be in place at designated establishments to ensure that medicines are used appropriately, and that there are adequate arrangements for handling, storage, disposal, stock control and auditing. The Home Office has assisted the Laboratory Animal Veterinary Association (LAVA) Council in drafting information to Certificate holders, licensees and Named Veterinary Surgeons.

Obtaining medicines from abroad

An exception to the disapplication of the VMR is the acquisition of medicines from abroad. In the past, researchers have experienced difficulty in obtaining medicines that are not available in the UK. The Home Office provided input into the development of Research Import Certificates by the VMD which are now in operation and provide a simple route to import a product or substance to be used in research.

Blood banks

The VMD authorises blood banks under the VMR. The premise of the current VMD licensing system is that the operation of a blood bank (which provides blood/ blood products for transfusion in veterinary clinical practice) is considered to be recognised veterinary practice, falling under the Royal College of Veterinary Surgeons (RCVS) Guidance on Blood Transfusions and, therefore, under the Veterinary Surgeons Act (VSA), not ASPA. Inspectors met with the VMD to consider issues relating to the authorisation of blood banks.

The VMR are now reviewed annually and thus it is intended that Inspectors will meet with the VMD at least once annually to discuss issues relating to the interface between the VMR and ASPA.

Liaison with the Department for Environment, Food and Rural Affairs (Defra)

Animal health matters are devolved areas of government and thus legislation can vary across the UK. ASPI has liaised with policy makers and scientific advisers from Defra, the Scottish Government, the Welsh Assembly Government and the Department of Agriculture and Rural Development in Northern Ireland. There were particular challenges in 2007 with the outbreaks of Foot and Mouth Disease, Avian Influenza and Bluetongue requiring discussions to facilitate the continuation of research work where this would not have a detrimental impact on UK animal health and welfare. The Inspectorate also participated in the Bovine TB Vaccine Steering Group, where Defra is the lead department, in formulating advice for establishments working with amphibians to minimise risks of spread of Chytridiomycosis and in the Government Veterinary Surgeons Steering Committee (see below).

Testing for Shellfish Toxins

Inspectors continue to participate in meetings with the Food Standards Agency (FSA), the Centre for Environment, Fisheries and Aquaculture Science (Cefas) and stakeholders from the shellfish industry with respect to testing for shellfish toxins using mouse bioassay. The initiative started in 2006 has continued, with reductions in mouse usage of between 80-90% from the period prior to the date when pre-screening was not utilised. Further reductions are envisaged in 2008 as fully quantitative in vitro tests are being used for some of the most commonly tested shellfish species. For more information on the monitoring programme see FSA Website http://www.food.gov.uk/foodindustry/farmingfood/shellfish/

The National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs)

The Inspectorate was represented at many of the varied NC3Rs events during the year and continued to contribute widely to NC3Rs activities during 2007. In February 2007 the NC3Rs hosted a poster event in Westminster to showcase the latest examples of 3Rs research for MPs, Peers and other stakeholders. Two posters were presented by Inspectors: 'How Animal Scientific Procedures Inspectors Encourage Application of the 3Rs' and 'Rules for Fish Tests: for the guidance of wise men?' Abstracts of the posters have been published either in the conference information pack or on line: http://www.nc3rs.org.uk/downloaddoc.asp?id=538

The CI gave a presentation on Experimental Design, incorporating interactive voting, which was especially well received, at the NC3Rs/Biosciences Federation – 'Science and the 3Rs' meeting in March. The CI and another Inspector were members of the NC3Rs Experimental Design Working Group.

During 2007, members of this group conducted a detailed survey of experimental design and statistical analysis in published papers which used animals in UK or US publicly funded research establishments and which acknowledged support from any UK or US public funding body. The survey was conducted together with the NIH Office of Laboratory Animal Welfare , and the results are currently being collated. For further information see http://www.nc3rs.org.uk/page.asp?id=23

Further input from the Inspectorate was also provided to the group examining how to refine food and fluid control in macaque monkeys and to the Nausea and Emesis Workshop in July 2007. Inspectors attended the NC3Rs Primate meeting in November 2007.

Laboratory Animal Science Association (LASA) Activities

Several Inspectors are members of LASA. One Inspector liaises with the association and acts as observer on LASA Council. This Inspector also acts as observer on the LASA Education, Training and Ethics Section which is currently preparing two documents:

- 'Guiding Principles for Aseptic Technique' intended to help licensees and named persons with best current practice in the conduct of sterile experimental procedures
- 'Guiding Principles for Record Keeping for Personal Licensees'.

The same Section prepared 'Guiding Principles on the Supervision Requirements for Personal Licensees' in 2006 which was published in 2007.
http://www.lasa.co.uk/position_papers/publications.asp

Other Inspectors have provided technical input and contributed to discussions at the following LASA Working Groups and initiatives:

- LASA Retrospective Severity Working Party report and workshops;
- APC/LASA Suffering and Severity Working Group;
- LASA Project Licence Abstract Writing Day.

Feedback from LASA is that such input has been greatly appreciated.

Laboratory Animals Veterinary Association (LAVA)

Several Inspectors are members of LAVA and for 2007, as for a number of years, there has been an Inspector on LAVA Council. The LAVA Annual Named Veterinary Surgeons (NVS) Meeting 2007 was again attended by several Inspectors when they presented an update on Home Office issues, an interactive session on 'Standards for Sterile Experimental Procedures:– Common principles to help NVSs with

provision of advice on facility design and surgical techniques', and a workshop on 'Animal Models:- NVS Advice on Humane and Scientific Endpoints'. These were well received and have subsequently been published in Briefing (http://www.lava.uk.net/briefing.html), the official joint publication of LAVA and the European Society of Laboratory Animal Veterinarians (ESLAV).

Inspectors also provided technical input to other discussions that LAVA had during the year with the Veterinary Medicines Directorate (VMD) and the Royal College of Veterinary Surgeons (RCVS), and to LAVA's contribution to the British Veterinary Association's (BVA) review of their 'Policy on the Use of Animals in Research'.

Institute of Animal Technicians (IAT) Events

The 2007 IAT Congress was successfully held in Great Britain, the first time for several years, with the security arrangements providing a safe forum. As in previous years, an ASPI update on Home Office issues was provided as well as a presentation on European issues. Other Inspectors attended the whole event, contributing to the workshops and informal discussions. The Inspectorate also attended the IAT Autumn Symposium on the impact of Health and Safety legislation on animal facilities.

Government Veterinary Surgeons (GVS)

The Government Veterinary Surgeons is a network of government vets working across all government departments and agencies which employ veterinary surgeons in Britain. The principal purpose of GVS is to represent and promote the roles of vets in government. This is achieved via three work streams which encourage development of professional skills, facilitate communication (through the Government Veterinary Journal and the annual GVS conference) and establish links with the UK veterinary schools. The Inspectorate is represented on the GVS Steering Committee and the three working groups, and two Inspectors attended the annual GVS conference held in June 2007 in Glasgow. More information can be found at: http://www.defra.gov.uk/gvs/

Interdepartmental Group on Health Risks from Chemicals

The Home Office is represented by an Inspector on the Interdepartmental Group on the Health Risks from Chemicals (IGHRC). This group discusses a range of issues that may impinge on the safety of chemicals in man, animals and the environment, and is also actively involved in ensuring consistency of approach across regulatory authorities by holding conferences and training course for those involved in risk assessment. All of the reports and activities of the group can be viewed on the IGHRC website: http://www.silsoe.cranfield.ac.uk/ieh/ighrc/ighrc.html

OECD Test Guidelines Programme

Several of the health effects Test Guidelines (TG) of the Organisation for Economic Co-operation and Development (OECD) are under review and a number of new guidelines are also being drafted. All of these reviews have taken into account progress in the field of regulatory toxicology and, in addition, have considered ways of improving animal welfare in accordance with the 3Rs. The Home Office has commented on the review and drafting of these TGs.

Important proposals are a new TG for the detection of eye irritation using in vitro methods and also for an in vitro micronucleus assay. Once adopted, these TGs should lead to a reduction in the number of animals used. Two new draft proposals for less severe TGs for the determination of acute inhalation toxicity are also in an advanced state of drafting: these are TG433 and 436, the Fixed Concentration Procedure and the Acute Toxic Class Method respectively. These will compliment the welfare refinements already introduced for the determination of acute oral toxicity (TG420 and 423).

First International Forum towards Evidence Based Toxicology

An Inspector was a participant in this Forum arranged by the European Centre for the Validation of Alternative Methods. Following on from the success of evidence-based medical research, the use of evidence-based techniques in the field of regulatory toxicology could lead to a significant reduction in the number and types of toxicity tests conducted. It is hoped that a second meeting will be held this year to ensure that progress in this field is maintained.

RCVS/LAVA/HO Liaison Meeting

ASPI was represented at this annual meeting to discuss topics of mutual interest. The following topics were discussed:

- training for veterinary surgeons in laboratory animal medicine;
- continued discussions on delegation of minor procedures within laboratories e.g. blood sampling of rodents under the Veterinary Surgeons Act (VSA);
- discussions on the interface of VSA and ASPA;
- VMR and guidance for NVS (see above);
- Veterinary Certification for discharge of animals from the controls of ASPA;
- experimental therapies in clinical cases.

British Association of Veterinary Parasitology

An Inspector presented a paper 'Antiparasitic Drug Development – Ethical Consideration and Implementation of the 3Rs' at the Autumn Meeting of BAVP held in Edinburgh in September 2007. The paper stimulated discussion on experimental design and opportunities for refinement and reduction in this field. An abstract was published in the Newsletter of the Association in Jan 2008.

Industry Discussion Group

Inspectors met with pharmaceutical industry representatives to discuss the potential revisions in Codes of Practice as a consequence of changes to Appendix A of Council of Europe Convention ETS123 (see European Initiatives) and their implications for work in this field.

Nanotechnology Meetings (NIDG)

Following the 2004 report by the Royal Society into nanotechnology, ASPI participated in an inter-departmental working group steering the Government's response to the Royal Society's recommendations.

Contributions by the Inspectorate have ensured that no unnecessary animal based testing will be requested by bodies considering developments in nanosciences and that the 1986 Act will cover future developments in research which employs nanotechnologies.

A cross-departmental Ministerial statement confirming this position with respect to animal testing has been prepared (See: http://www.dius.gov.uk/policy/documents/statement-nanotechnologies.pdf)

Stem Cell Steering Committee

The Medical Research Council's Stem Cell Steering Committee (SCSC) was created, in part, to ensure that there is no regulatory impediment to the justifiable use of stem cells in experimental research and therapy in the UK, whilst recognising the sensitivities to this new technology, particularly in relation to the use of human embryonic stem cells. (For further information on the remit, aims, organisation and membership of the SCSC see: http://www.mrc.ac.uk/PolicyGuidance/EthicsAndGovernance/StemCells/SteeringCommittee/index.htm) The Inspectorate has been involved in discussions with the SCSC on the use of animal-human hybrids and chimeras in research and the regulation of stem cell use under ASPA involving the use of conventional animals in such areas as efficacy testing, regulatory toxicology and stem cell therapies.

European Initiatives

The regulation of the use of animals for experimental and other scientific purposes and the determination of minimum required standards of animal care and accommodation within Europe is generally informed by recommendations and conventions at the level of the Council of Europe (CoE) and by legislation within the European Union (EU). Each signatory party (CoE) and Member State (EU) is expected to use these "European" recommendations to inform standards in their own country. The United Kingdom has implemented these recommendations within the Animals (Scientific Procedures) Act and the related Codes of Practice for the Housing and Care of Animals Used in Scientific Procedures, and in Designated Breeding and Supplying Establishments.

EU Directive EC/86/609

The European Commission is presently undertaking a revision of EC/86/609. This has been ongoing for a number of years and a draft document is expected later in 2008. The main aims of the revision are to achieve a significant improvement in the welfare of animals undergoing scientific procedures and to promote a level playing field throughout Europe for those undertaking research on animals. The commission has sought advice from a number of experts and has undertaken a public consultation.

Among the main issues under consideration are:

- the scope of the Directive (for example should certain invertebrates or immature forms be afforded protection);
- the sourcing and justification for the use of non-human primates;
- a severity/benefit assessment of animal use;
- controls on re-use of animals, humane methods of killing and purpose-breeding for scientific use.

The nature and extent of the changes under consideration have led to concerns within industry and academia to such an extent that the Commission is now revising the draft. The Commission had originally intended a rapid revision process but it seems increasingly likely to be several years before a new Directive is agreed at which time there will probably need to be changes to UK legislation.

ASPD/ASPI leads an Inter-Departmental Group which co-ordinates UK lobbying on the revision of the Directive. This group also ensures that better regulation principles are given due consideration and is responsible for developing national strategy to support the 3Rs.

Council of Europe Convention ETS123

Following a lengthy technical review, the revised Council of Europe guidelines (Appendix A to Convention ETS 123), which provide guidance on accommodation and care practices for animals undergoing scientific procedures, were agreed by signatory parties, including the UK, in June 2006. In June 2007, the EU replaced the existing EC 86/609 Annex II guidance with new guidelines aligned to Appendix A.

Although the status of both Appendix A and revised Annex II is currently advisory, there is an expectation that member states will use these within local legislation. A previous Home Office Minister agreed that the UK Codes of Practice would be reviewed in the light of the changes to Annex II. This review was delayed in the expectation that the revised Directive would have been available in Autumn 2007. One potential element of the revision would change the status of Annex II from "guidance" to "minimum standards" and this would have many implications for any changes to the UK Codes of Practice.

Other International Events and Initiatives

10th Federation of European Laboratory Animal Science Associations (FELASA) Symposium and the XIV International Council for Laboratory Animal Science (ICLAS) General Assembly & Conference, Italy

This meeting was attended by three Inspectors who participated in the main symposium and various satellite meetings and international working groups including the **Third Meeting of the ICLAS Working Party for Harmonization of Guidelines.** This meeting considered drafts of two harmonised guidance documents on Education and Training and Ethical Review. ASPI has provided input into both of these documents. Adoption is anticipated at the ICLAS meeting in the USA in 2008. The next guidance document to be prepared will cover care and use of genetically altered animals. An Inspector spoke on refinement and reduction in the production of genetically altered animals (see Focus on Genetically Altered Rodentss later) outlining the current position in the UK. Information from other countries was provided and a sub-group (including a UK Inspector) was established to draft harmonised guidelines for further consideration at the next meeting.

During the meeting the Scientists Center for Animal Welfare (SCAW) also sponsored a session on "International Perspectives of Research Animal Oversight". This allowed exchange of information and ideas about research animal welfare in respect to regulations and guidelines and the function of animal care and use committees or animal oversight committees in different countries. An Inspector gave a presentation on UK regulations and the role of the Ethical Review Process. Overviews of regulation in other countries were also provided. This proved an informative session for delegates from many countries.

The Institute for Laboratory Animal Research (ILAR) Focus Group Meeting on Adequate Veterinary Care. This meeting provided a forum to discuss guidelines on veterinary care of research animals from different countries throughout the world. The intention is to develop international guidelines for adequate veterinary care with the aim of improving care of research animals and training for veterinarians working in this field. The UK requirements for veterinary care for animals under ASPA were presented and Inspectors provided input into the discussions.

Sixth International Conference on Molluscan Shellfish Safety, New Zealand

An Inspector gave a paper titled 'The 3Rs Approach to Marine Biotoxin Testing in the UK'. The paper has been accepted for publication in the proceedings of the meeting. The Inspector was also an invited member of the discussion panel on shellfish toxins at this meeting. http://www.nzfsa.govt.nz/events/icmss07/

Sixth World Congress on Alternatives, Tokyo

The CI and another Inspector attended this conference, presenting a paper on UK and EU regulatory systems and controls within an international symposium on international regulatory systems. Two posters prepared by ASPI were also presented on 'The 3Rs Approach to Marine Biotoxin Testing in the UK' and 'Effect of policy decisions on experimental animal use in the UK' . http://altweb.jhsph.edu/wc6/ The conference provided an excellent opportunity to strengthen contacts with international regulators including those from Japan, Korea, China, USA, Canada and Australia.

American Association for Laboratory Animal Science National Meeting (AALAS), USA

Four members of the Inspectorate attended this annual meeting of AALAS and some of the satellite discussion groups. Inspectors provided input on laboratory animal issues and training opportunities in the UK at the ICLAS meeting. They participated in many debates providing useful insights on European and/or UK views. One Inspector also attended a two-day 'Primate Training and Enrichment workshop' at which the opportunities and practicalities of using food reward to train non-human primates to voluntarily participate in scientific and husbandry procedures were presented. As well as feedback to other Inspectors about this event, information has also been provided to licensees resulting in one licensee attending a follow-on practical course.

Providing Advice

On Licensing

Under Section 9 of the Animals (Scientific Procedures) Act 1986, before granting a licence or issuing a certificate the Secretary of State is required to consult an Inspector, and under Section 18 of the Act the Inspector should advise him or her on whether and under what terms the licence or certificate should be granted.

> "It shall be the duty of an inspector-
> to advise the Secretary of State on applications for personal and project licences, on requests for their variation or revocation and on their periodical review;
> to advise him on applications for certificates under this Act and on requests for their variation or revocation;"
> **Animals (Scientific Procedures) Act 1986 Section 18 (2) (a) & (b)**

It is estimated that some 40% of Inspectors' time is allocated to advice on licensing and prospective controls on work with animals, including formal assessment of fully signed applications, commenting on drafts, early discussions of programmes of work, training requirements and retrospective review of work with a view to replacement, reduction and refinement.

Assessments in 2007

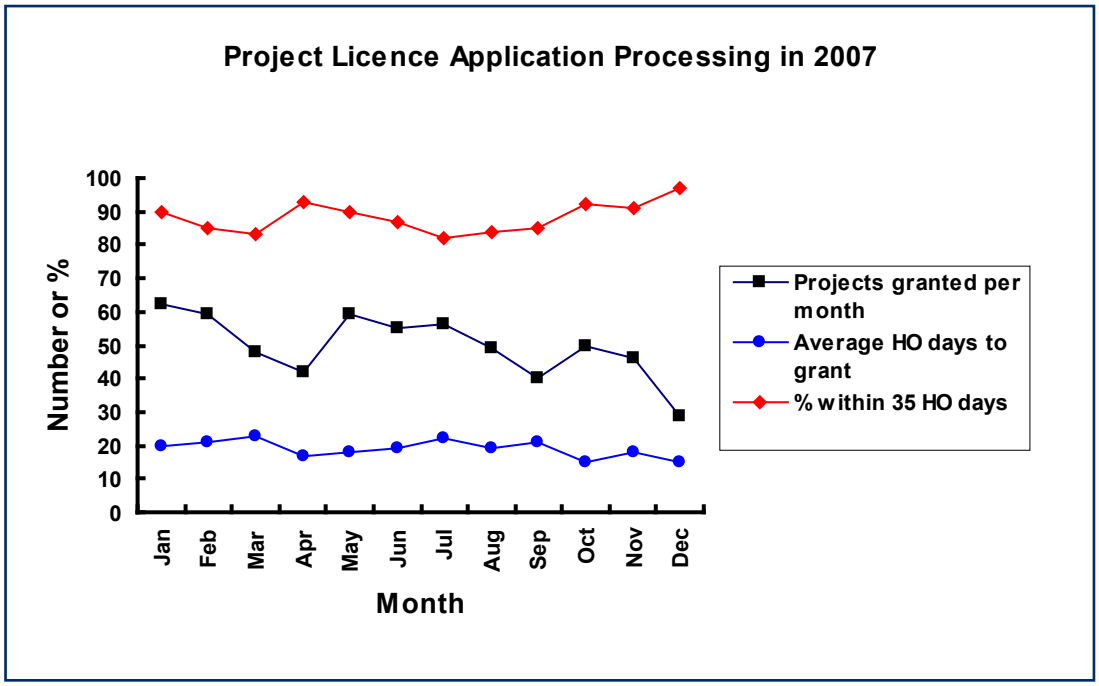
Personal licences and establishment certificates of designation
During 2007 Inspectors assessed 2594 personal licence applications (plus 24 not proceeded with) and 4310 amendment requests and reviews. They also recommended that certificates of designation be given to 2 new establishments, and evaluated 369 amendment requests to existing certificates.

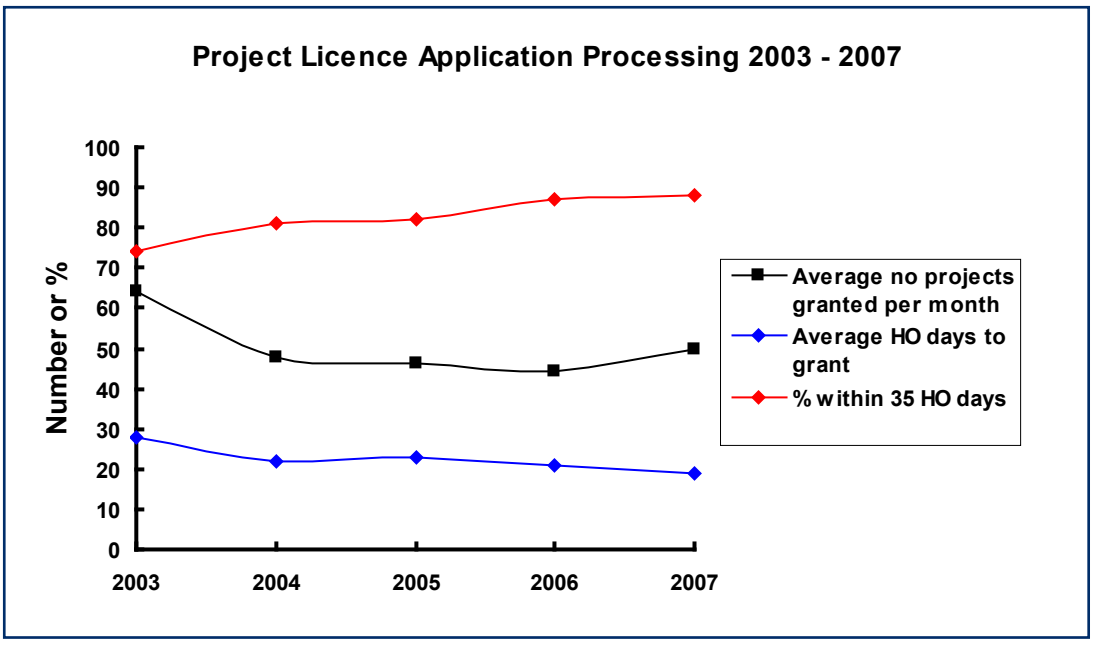
Project licences
In 2007 Inspectors evaluated and recommended for grant 595 project licence applications, and assessed 1872 amendment requests. In addition, 37 formal project licence proposals were not proceeded with.

These figures show increases in the number of licence assessments from 2006 of 19% and 10% for PIL applications and amendments respectively, and 15% and 19% for PPL applications and amendments respectively.

Targets for Assessment

The Inspectorate aims to assess proposals for new work so that those authorities that can be recommended are in place by the time the applicants need them. This is to avoid wastage of animals on continuing programmes of work, missing key dates for the progress of development of new medicines or delaying time-dependent funded programmes. Inspectors work with licensing staff to ensure that the target of 85% of new project licence applications are processed within 35 working days within the Home Office. As the following graphs show this was achieved for 2007 as a whole, with average processing time steadily decreasing over the last few years.


Project Licence Application Processing in 2007
Number or %
100
90
80
70
60
50
40
30
20
10
0
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec
Month
Projects granted per month
Average HO days to grant
% within 35 HO days


Project Licence Application Processing 2003 - 2007
Number or %
100
90
80
70
60
50
40
30
20
10
0
2003
2004
2005
2006
2007
Average no projects granted per month
Average HO days to grant
% within 35 HO days

On Animal Experimentation Issues

The Inspectorate provides professional advice and expertise to assist ministers and officials in the formulation of policy on the care and use of animals in laboratories and elsewhere. Inspectors also provide advice to officials and ministers on technical matters and licensing issues, and assist in drafting answers to parliamentary questions and public correspondence.

ASPI Contributions to Replies to Parliamentary Questions

During 2007, ASPI continued to provide advice in response to questions on animal research raised by Members of Parliament. Over 30 questions were asked of Ministers during the year, with the highest frequency being for information relating to non-human primate studies.

Progress with reduction in numbers/severity of tests ('3Rs'); aspects of European legislation; analysis of the annual Returns of Procedures; and Better Regulation also featured. Information on the work of the Inspectorate was provided in a written Ministerial Response during June 2007 along with guidance on the content and availability of the Annual Report of the Inspectorate. Further information can be found at: http://www.publications.parliament.uk/pa/cm200607/cmhansrd/cm070604/text/70604w0058.htm#07060529004952

ASPI Advice to Home Office Officials

During 2007 ASPI provided advice on topics such as on the use of animals for testing samples of shellfish for toxins and on the housing and conditions provided in overseas centres that breed non-human primates. Inspectors also communicate information gathered during visits to establishments, or provided by scientific contacts, such as the likely impact of scientific developments on animal welfare, the reaction of the scientific community to policies and practices, and the level and nature of animal rights extremist activity at establishments.

Inspection

Visiting

In accordance with statutory requirements, Inspectors aim to spend approximately 40% of their time on visiting functions, which includes preparation for visits, actual visiting, relevant travel and subsequent reporting. The majority of departmental inspections, especially to animal holding areas, are unannounced, in keeping with expectations of Ministers and the public.

> "It shall be the duty of an inspector-
> to visit places where regulated procedures are carried out for the purpose of determining whether those procedures are authorised by the requisite licences and whether the conditions of those licences are being complied with;
> to visit designated establishments for the purpose of determining whether the conditions of the certificates in respect of those establishments are being complied with;"
>
> **Animals (Scientific Procedures) Act 1986 Section 18 (2) (c) & (d)**

During 2007 ASPI inspected work under some 2,700 project licences carried out by around 14,500 personal licensees at the 200 designated establishments (actual figures in December were 2,716, 14,438 and 200 respectively). The establishments include breeding and supplying establishments, in some of which some scientific work is also carried out.

The variety of species inspected, with their widely differing housing, husbandry and handling needs, continues to be diverse – from fish, through amphibians, birds, small mammals, wild mammals, agricultural species to those species afforded special protection by the Act – dogs, cats, equidae and non-human primates. It is interesting to note that, at a time of increasing specialisation within the biomedical sciences, there is a need for Inspectors to maintain a broad knowledge basis which can only be achieved by continuous personal professional development and excellent communications between colleagues in ASPI. For example, two Inspectors attended a week long course on small animal veterinary medicine, and the use, care and husbandry of fish was a focus topic at one of the bi-annual Inspectors' Conferences during 2007.

During inspection visits, Inspectors continue to promulgate and encourage good practice such as providing suitable environmental enrichment and care arrangements and refinements to regulated procedures, including suggestions for the most suitable types of equipment and materials to use. Inspectors also facilitate communications between groups at different designated establishments using the same models or techniques, again to ensure that refinements are communicated around the UK and that licensees do not repeat model development or pilot studies unnecessarily. Consideration of the experimental design and group sizes for ongoing individual studies under general project licence authorities can also form part of routine inspections.

The distribution of establishments and of project and personal licences per establishment does not differ greatly from year to year, and the pattern can be seen in the figures provided in the 2004 annual report. Nearly a third of designated establishments have only one project licence holder and a few personal licensees; travel times to many of these are considerable, but all establishments carrying out regulated procedures in 2007 were visited. There were also visits to sites which were not designated, (PODEs - Places Other Than a Designated Establishment). These included visits to:

- a sheep farm for blood sampling and foot scoring for work on genotyping and susceptibility to foot rot;

- a wind tunnel on an aerodrome to inspect geese in flight;
- a farm to inspect ducks kept under altered environmental conditions;
- bat roosts to inspect biopsy sampling of wing membranes for studies on population dynamics and possible spread of rabies virus EBL-2;
- a commercial pig unit to inspect blood sampling for disease surveys and epidemiological studies;
- inspect fitting of radio transponders to badgers so that population movements could be surveyed;

Goose in wind tunnel

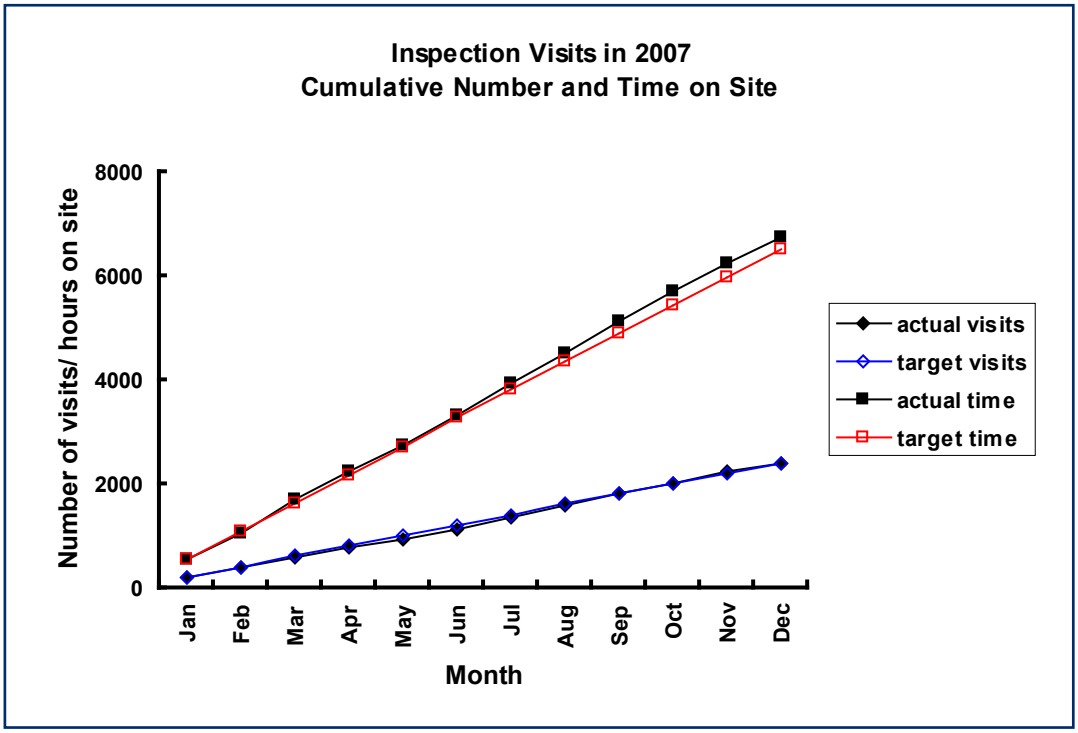
- livestock premises to observe the loading and departure for slaughter of horses;
- a riverbank to inspect the tagging and tracking of fish;
- a competition angling lake to inspect anaesthesia and passive induction transducer (PIT) tagging of rudd and perch.

Visits of Inspection in 2007

Targets for a full-time Inspector are about 100 visits of inspection per year and for the Inspectorate's total contact hours, i.e. time on site, to exceed 6,504 hours in the year.

This was achieved in 2007 with 2,401 visits to places and 6,749 contact hours. As the graph below shows, the numbers of visits and the time spent at establishments were above or on target throughout the year. As for 2006, the average visit time was 4.9 hours, with 2.1 hours of this spent travelling.

The majority of visits to establishments as a whole were unannounced and three quarters of the visits to animal houses were unannounced.



Reporting

A major purpose of inspection visits is to check that establishments and researchers comply with the provisions of the Act and the terms and conditions of licences and certificates.

> "It shall be the duty of an inspector-
> to report to the Secretary of State any case in which any provision of this Act or any condition of a licence or certificate under this Act has not been or is not being complied with and to advise him on the action to be taken in any such case."
> **Animals (Scientific Procedures) Act 1986 Section 18 (2)(e)**

Inspectors check compliance and investigate and report on non-compliance. Their report to the Secretary of State makes an appropriate and proportionate recommendation for the action required, which is generally aimed at the prevention of repetitive faults. They also advise licensees and others how to comply, and generally promote a culture of compliance.

In establishments with a good culture of compliance, it is often the licensees or the Certificate Holders who inform Inspectors of any apparent non-compliance. In 2007, fifteen of the thirty infringements which come within the scope of this report were self-reported.

Eighteen of the infringements involved minor non compliance issues, such as breaches of conditions, unauthorised procedures competently done or variations from authorities with little additional suffering. Eight of the infringements were self-reported and the rest were discovered by Inspectors. These included:

- inadvertently keeping animals in rooms that were not authorised for such use;
- failing to report unexpected effects of procedures on rodents. In all the cases the animals were appropriately cared for;
- failing to notify the HO that work was to be done at a place other than a designated establishment;
- use of significantly more animals on a new procedure than was authorised;
- regulated procedures done which were not authorised on the project licence;
- regulated procedures done which were not authorised on the personal licence;
- failure to keep appropriate records;
- re-use of animals without authority;
- minor regulated procedure done by a non-licensee;
- use of a species not authorised on the project licence.

The advice given to officials was that these cases merited a letter of admonition and no further action.

The other twelve infringements in the 2007 group, of which five were discovered by Inspectors and the rest reported by the persons involved or the establishment, were considered to be more serious, because additional action needed to be taken to avoid recurrence or because of welfare issues.

Some of these involved little or no avoidable suffering, but indicated defective controls or understanding for which remedial measures were considered necessary. For example:

- regulated procedures were performed on a number of animals either at a place not specified on the personal licence or without appropriate project licence or personal licence authority;
- a project licence holder failed to maintain adequate, contemporaneous records relating to regulated procedures performed on animals under the licence and exhibited a poor attitude towards the legislative provisions over some time.

For these, in addition to appropriate admonition, the project licensees were required to improve their management of the project or to complete further training.

A number of infringements resulted in significant avoidable suffering. In four cases holding and care arrangements were found to be at fault:

- five mice were inadvertently not provided with food for 4 days and were found dead;
- A number of Xenopus sp. died, or had to be killed, due to the effects of exposure to low temperatures when moved to temporary accommodation during a refurbishment programme;
- three rats inadvertently did not receive drinking water for about 48 hours;
- As a result of being inadvertently left in a transfer device, 2 mice were found dead due to lack of oxygen and a third mouse was humanely killed.

All four cases were mistakes and measures were promptly introduced by the designated establishments to prevent recurrence. These cases emphasise the need for robust and clear arrangements for the care of animals. Those involved were admonished and further inspected to ensure that the introduced measures were in place.

In two other instances licensees exceeded the project licence constraints or did not carry out procedures in the most refined way resulting in unnecessary animal suffering. These were:

- ten rats on a pilot study for a disease model exceeded the severity limit for the procedure and the project licence holder failed to notify the Secretary of State. There were significant welfare problems as three of the rats died and seven had to be killed due to the adverse clinical effects.
- A personal licence holder removed approximately 1cm from the end of the tail of a conscious mouse to obtain a blood sample without the use of local or general anaesthesia and without personal licence authority. This is not considered to be the most refined method of blood sampling.

In both cases licensees were unsure about their obligations under ASPA. They received letters of admonition and additional training was required.

No infringements this year required the revocation of licences and serious infringements continue to be infrequent. There was generally a high level of compliance with authorities and conditions and, as indicated above, where contraventions occurred unauthorised procedures were usually competently done and involved minimal severity. It is encouraging that remedial measures seem generally to be effective at preventing recurrence of non-compliance, and that many problems continue to be self-reported.

Non-Statutory Activities

Representation

Inspectors have represented the Inspectorate, and often the Home Office, at numerous meetings throughout the year. These included presentations or attendance at several meetings within the UK and abroad. A brief sketch of some of these events has been included in the Events and Initiatives section.

Attendance at meetings abroad

American Association for Laboratory Animal Science National Meeting
Federation of European Laboratory Animal Science Associations
44th Congress of the European Societies of Toxicology, Amsterdam, October 2007. (Proceedings published in Toxicology Letters (2007) Volume 172S)
First International Forum towards Evidence-Based Toxicology, Como, Italy October 2007. (Organised and sponsored by ECVAM)
International Conference on Molluscan Shellfish Safety, New Zealand, March 2007
Sixth World Congress on Alternatives, Tokyo, August 2007
Federation of European Companion Animal Veterinary Associations
European Society of Veterinary Dermatology

Attendance at UK meetings not covered in Events and Initiatives

Association for Veterinary Teaching and Research Work
Biosciences Federation
British Cattle Veterinary Association
British Small Animal Veterinary Association
British Society for Immunology
British Toxicology Society
British Veterinary Association
British Veterinary Association Animal Welfare Foundation
British Veterinary Dermatology Study Group
Clinical Governance in the Civil Service
Clinical Immunology and Allergy Section of the Royal Society of Medicine (Biologics in Medicine)
Easter Bush Research Consortium
European National Societies of Immunology (1st Joint Meeting)
European Xenopus Resource Centre Strategy Board
Institute of Biology – Accreditation Board
Laboratory Animal Breeders Association
National Extremism Tactical Coordination Unit – stakeholders' meeting
Research Defence Society
Royal Society for the Prevention of Cruelty to Animals/Universities Federation for Animal Welfare (RSPCA/UFAW) Rodent Welfare Group
Scottish Stem Cell Network
Sheep Veterinary Society
Shropshire Veterinary Association
Universities UK and Biosciences Federation Meeting
Veterinary Research Club

Education

Inspectors continued their involvement with the education and training of those involved in work regulated under the ASPA in 2007. This was not confined to passing on information and ideas about how reduction in severity, reduced numbers, and replacement by non-animal methods might be achieved, but also allowed Inspectors to encourage researchers and care staff to think of different ways of achieving results and about improvements in scientific practice for housing and care.

Inspectors educate in the talks they give and discussions they have in their statutory and representational roles, but they also contributed directly to specific educational events, for example the Institute of Animal Technology's and the ScotPIL Committee's training meetings, providing both technical input and assistance with material.

An Inspector continues to act as observer on the Boards of the Institute of Biology, Universities Training Group, and Scottish Accreditation Board, which are concerned with the accreditation of modular training that licence applicants have to undertake before a licence application will be considered.

In addition, an Inspector provides advice and support to the APC Education and Training subcommittee (APCET). Following the completion of the report in 2006 on training modules 1-4 (http://www.apc.gov.uk/reference/Personal%20Licensing%20paper.pdf), the APCET moved on to considering module 5 during 2007. As part of this process a workshop was held to develop ideas at which the Inspector was an active participant.

APCET has also been considering accreditation issues, following the foundation of the Scottish Accreditation Board. The three accreditation boards have begun working together to ensure there is consistency of standards, and the APCET subcommittee has been working on a guidance document for accreditation bodies and course providers, incorporating information from the FELASA guidelines on training to ensure a degree of harmonisation with Europe. The Inspector has provided technical advice, interpreted the syllabus for modular training and participated in drafting the reports.

During 2007 Inspectors have continued to run, in various parts of the country, refresher training courses and workshops on ASPA provisions relating to work under project licences and how to provide information on how such provisions would be met when applying for authorities under the Act. In addition Inspectors have organised or participated in a number of events on particular topics for licensees and care staff, including the legislation and ethics of the use of animals in experimentation, experimental strategy and design for project licence holders and issues around the humane killing of animals for tissue for scientific use. A number of these have been given as part of the formal course work for biosciences, medical or veterinary students, a testimony to the value placed on the presentational and professional skills of Inspectors. Feedback received following these training courses and workshops has been very positive with participants noting how interesting and valuable they have found them.

In 2007 the Scottish Metropolitan Division of the British Veterinary Association held a veterinary student meeting on "MRCVS - what next?", which addressed career possibilities following graduation. Three veterinary surgeons from each of the four categories, Industry and Commerce, Government, Research and Practice, gave a brief résumé as to why they had picked a particular area of expertise. An Inspector was one of the three Government representatives.

Focus on Refinement and Reduction in the Use of Genetically Altered Rodents

The Home Offices defines a genetically altered (GA) animal as an animal in which the heritable DNA has been intentionally altered, or which carries a genetic mutation recognised as harmful, or the progeny of such an animal.

This definition includes:

- animals produced by genetic modification (as defined in the Genetically Modified Organisms (Contained Use) Regulations 2000);
- animals produced by induced mutagenesis;
- animals created by nuclear transfer procedures;
- animals created by the use of certain selective breeding strategies;
- harmful mutant lines arising from spontaneous mutations.

It excludes animals with changes that are not heritable, such as gene therapy or DNA immunisations.

Use of GA Animals in the UK

The HO Statistics on the Use of Animals in Scientific Procedures provides separate figures for the use of normal animals and for those that have either genetic modifications or harmful mutations.

In the UK each GA animal generated or born is counted as 'a procedure' and consequently such animals need to be kept under the authority of a project licence. Many other countries in Europe only count the initial animals generated, subsequently animals of that strain or line are not counted. The eventual use of these animals is included in other figures.

The use of GA animals for scientific purposes has steadily increased from 1995, when they comprised 8% of the total procedures reported, to 45% in 2006. In 2006 60% of mice used in procedures were GA animals. After mice, the most common GA animals used are fish, then rats, amphibians, domestic fowl, rabbits and sheep. The majority, 90%, of all GA animals used are mice. However in 2004, mice represented 96% of such use. This change is a result of the increased use of GA fish, amphibians and domestic fowl.

It is worth noting that the Home Office publishes supplementary guidance to applicants for project licences: projects to generate and/or maintain genetically modified animals: http://scienceandresearch.homeoffice.gov.uk/animal-research/publications-and-reference/publications/code-of-practice/housing-of-animals-breeding/sub-transgenic?view=Binary

Opportunities for Refinement and Reduction

In 2003 the NC3Rs Mouse Welfare Assessment Working Group, comprising members from the scientific community and welfare groups, reported their recommendations for the care and welfare of GA mice (Laboratory Animal Vol 37 Suppl. 1, July 2003 and full report on the NC3Rs website: http://www.nc3rs.org.uk/page.asp?id=231). The report included advice on a number of different areas relating to the generation, maintenance and use of GA mice. Inspectors promulgate such good practice during discussions with licence applicants and during inspection visits.

Production Methods

Methods for minimising the numbers of animals used and ways of refining techniques for generating GA animals are encouraged. For example the use of conditional 'knock-outs' enables animals lacking the gene of interest to be created only when two GA animals are mated. This is achieved by generating two parent lines, one in which the gene of interest is still fully functional but 'flanked' by short stretches of specific sequences of DNA, and a second line in which a completely harmless 'deleter' protein is expressed. When the two lines are bred together the 'deleter' protein 'knocks out' the gene of interest by recognising the flanking DNA in the offspring produced. Experience shows that neither parent line suffers any adverse effects. However the offspring may suffer ill effects due to the lack of the gene but the number of these animals generated is limited to only those that are actually needed for the experiments.

An increasingly common way of reducing the time for which animals experience adverse effects as a result of having altered genes is through the use of inducible technologies. This means that in an individual animal the gene of interest can be 'switched on' or 'switched off' at times relevant to the experiment such that any effects of the gene are only experienced by the animal for the period of time the gene is switched on (or off) and not throughout their life. This is typically done by giving a drug in, say, drinking water or by injection which causes the gene of interest to be expressed or switched off. When the drug is removed the gene is no longer expressed/switched off.

Alternatively, by using tissue specific promoters, the deletion or switching on and off of genes of interest can be targeted only to the tissue of interest. This further minimises suffering in the offspring, particularly if the gene of interest has a global effect or multiple functions in different tissues or at different times in development.

Breeding and Maintenance

As well as managing and monitoring colonies to ensure minimum numbers of animals are produced and to reduce animal wastage, environmental conditions should be tailored to the needs of different strains of GA animals. For example some GA mice with hearing deficits can have problems caring for their pups. Many of these types of mice show whirling behaviour where they run round and round the cage which can disrupt the litter. To reduce the likelihood of this happening, 'C' shaped enclosures can be put in their cages around the litter to reduce the chance of pups becoming separated.

Enclosure used to protect litters from 'whirling' behaviour of adult mice. Photo: Courtesy of MRC Harwell

Another example is GA mice which have a curly or kinky tail. They may develop sores on their tails as a result of bedding sticking in the kinks. Consideration should be given to the use of a type of bedding that does not cause this problem.

GA mouse with curly tail. Photo: Courtesy of MRC Harwell

If the presence of the gene of interest (or lack of the gene) does not cause significant clinical signs during a typical life span of a breeding animal then it is preferable to keep the strain as a homozygous breeding colony. This minimises the number of animals having to be produced and maintained. However, if the gene of interest (or

lack of the gene) causes significant clinical signs to homozygous animals (e.g. development of cancer at 10 weeks) then maintenance of a heterozygous colony should be considered (e.g. mating heterozygous to wild type for colony maintenance and mating heterozygous to heterozygous only when homozygous animals are needed). More animals need to be produced and maintained to keep the line going, but most of the animals will not suffer the effects of the altered gene.

Genotyping

Probably the most common regulated procedure performed on GA animals is the removal of a tissue sample to enable the genotype of a particular animal to be determined. Homozygous breeding colonies, once established, will not routinely need to be genotyped.

The tissue sample that has most commonly been used in the past for genotyping has been the end of the tail. There is an increasing body of literature indicating that sampling from this site can result in chronic pain to the animals. Laboratory tests have improved over time and smaller tissue amounts can often be used now. This means that for many genotyping studies the small sample of ear that is commonly removed to enable individual animals to be identified, can be used for genotyping. Removal of a small piece of ear does not appear to cause the problems that tail tipping can.

For some studies saliva or hair can be used and collection of these samples may not even constitute a regulated procedure. However there are still some circumstances when larger tissue samples may be needed. In these circumstances removal of the tip of the tail may still be the most refined way of obtaining the sample needed.

Some strains can be genotyped on their appearance alone. For example, animals carrying fluorescent genes can be identified by viewing them under ultraviolet light where they glow green.

The hairless extremities of this GA rat carrying the gene for the green fluorescent protein fluoresce under ultra violet light

The new-born GA mouse carrying the gene for green fluorescent protein can be easily distinguished under ultra violet light from its litter mate that does not carry the gene

Chimeric mouse carrying cell lines from both black and white mice alongside a non-chimeric white mouse

Other GA rodents may be identified by coat colour such as chimeras which are animals composed of cells originating from two sources. Such animals are produced during the production of GA animals using embryonic stem (ES) cell lines. If the two cell lines come from animals with different coat colours then the chimeric animal will usually display both coat colours. Consequently chimeras, which carry the gene of interest, can be identified by their appearance.

Animal Monitoring

There is increasing use of animal welfare recording sheets to monitor newly generated lines, crosses between different GA lines and in other instances where such assessments are needed. Various schemes have been published but it is advisable to tailor the scheme to the particular strain.

Further advice is available in the Report of the NC3Rs Mouse Welfare Assessment Working Group which is available on the NC3Rs website (see earlier link).

Health Status

The health status of GA rodents can have an impact on reduction and refinement in three main ways:

A) It is desirable for animals used in scientific experiments to be free of major pathogens as infection with these can cause clinical disease, pain and suffering and be a significant cause of variation between animals, particularly in immunological experiments.

B) GA animals are often a valuable resource to many scientific groups and are often transferred to different groups both in the United Kingdom and abroad. GA animals of a poor heath status may need to be rederived (this means using embryo transfer or hysterotomy and neonatal cross-fostering) to eliminate pathogens before the strain can be used by the receiving laboratory. This results in the generation of more GA animals and a delay before the 'cleaned-up' animals can be used.

C) Many genetic alterations can result in changes to the immune system and increase the risk of GA animals succumbing to infections by both pathogens and normally non-pathogenic organisms. Such immunocompromised animals need to be kept in special housing (barrier units, Individually Ventilated Cages or isolators) that reduces the risk of such infections.

For these reasons GA animals should be generated and kept, where possible, in facilities which take appropriate measures to keep the animals free of such pathogens.

Information Exchange

One of the best ways of minimising the effect of altered genes on an animal is to be knowledgeable about the effect of the gene before starting to keep the strain. This enables appropriate care and management schemes to be prepared before the animals arrive. Consequently it is recommended that each line is transferred with a passport detailing the clinical signs that might be expected and any advice on how to mitigate such signs (see link to NC3R's website above).

The sharing of such information is both valuable for refining the use of such animals and can also increase the benefit from their generation since it can allow scientists from unrelated areas of work to see whether or not GA animals could help advance progress in other scientific areas.

Researchers should check for the availability of lines/genotypes before creating their own. Online data bases are available to assist such a search. Further advice in this area will be available when the RSPCA Resource Sharing Working Group publishes a document on 'Sharing and Archiving of Genetically Altered Mice'. However there is still a need for locally maintained databases so that users in a particular establishment can use animals already on the premises rather than bringing in new animals.

Archiving of Lines

The use of a particular GA line can wax and wane dramatically depending on research needs. This can result in months or years when the line has to be bred and maintained to ensure its continuance even though it may not be used during this time. If possible, to reduce the number of animals that may experience clinical signs, consideration should be given to cryopreservation of the line as embryos, sperm, or ovarian or testicular tissue. These can then be used to regenerate the GA line should it be needed. A number of UK centres provide such services for mice.

Discharge of GA Rodents from the Protection of ASPA

At present all genetically modified animals used for scientific purposes are generated, bred and maintained under licence authority under ASPA. Animals carrying harmful mutations that either arose as a result of treatment with a mutagen (e.g. ENU) or during natural breeding also need licence authority if being kept for scientific purposes. Before such animals could be discharged from the protection of ASPA evidence would need to be submitted to the HO to show that the animals would not be likely to suffer if discharged. Practically, evidence of a lack of any harmful effect of the altered gene over the lifetime of animals carrying the gene would be needed, typically over two full generations, although further advice would need to be sought from the HO for any particular line.

As part of the Better Regulation initiative, intended to reduce unnecessary bureaucracy, the APC were asked to consider the criteria for the discharge of GA animals from ASPA controls. A number of options have been considered and a recommendation has been made, which the Minister has accepted, to investigate whether those GA animals which do not show adverse effects could be discharged. The first lines to be considered in this way will be 'reporter' lines, where harmless genes have been inserted to allow the labelling of cells and tissues, and some 'inducible' lines which need another 'trigger' factor before they can exert their effect. Discharge of these animals will be subject to the development of an agreed protocol to ensure there are no adverse consequences for their welfare.

Genetically modified animals are also covered by other legislation (Statutory Instrument 2002 No. 2443 Genetically Modified Organisms (Deliberate Release) Regulations 2002 http://www.opsi.gov.uk/si/si2002/20022443.htm) that would prevent their release except under very specific circumstances.

With respect to harmful mutations that have arisen as a result of natural breeding, such animals can be bred or maintained without licence authority under ASPA if their use is not scientific. In this way many 'fancy' strains of mice are bred by pet shops and enthusiasts, for the purpose of keeping them as pets or showing them in breed shows. However if they are kept for a scientific purpose and the nature of the mutation is such that it may cause pain, suffering, distress or lasting harm above the threshold defined in paragraph 2.16 of the Guidance on the Operation of ASPA 1986 (http://www.archive.official-documents.co.uk/document/hoc/321/321-02.htm#gen46) then licence authority under ASPA will be needed.

Further information can be found online by following the hypertext links in the text.

Focus on Facilities: Problems and Pitfalls When Building New Facilities or Renovating Existing Buildings

Introduction

Facilities for the housing and care of animals and conducting procedures under the Animals (Scientific Procedures) Act (ASPA) range from basic enclosures to very specialist laboratory animal holding units. Facilities should be tailored to the needs of different species used and research programmes. To ensure high quality science, animals should be healthy and well adapted to their housing conditions. Perturbations in their environment that could impact on the outcome of studies should be avoided.

Under ASPA the importance of maintaining animals in suitable facilities is recognised and implemented through the Certificate of Designation (PCD) and its conditions.

One of the duties of an Inspector is 'to visit designated establishments for the purpose of determining whether conditions of the certificates in respect of those establishments are being complied with'. Inspectors visit all types of facilities and are in the unique position of being able to compare standards. These visits enable Inspectors to gain a breadth of experience in design, function and suitability of various types of facilities. Where confidentiality issues permit, knowledge can be shared with other users to help inform improved housing practice. Inspectors are often asked to provide input early in the facility design process and they use their experience to help PCD holders and others to avoid particular pitfalls and situations that would render a facility unsuitable for designation.

Guidelines and Recommendations

The recommendations for housing and care facilities are included in various HO Codes of Practice (COP) issued under section 21 of ASPA :
http://scienceandresearch.homeoffice.gov.uk/animal-research/publications-and-reference/publications/code-of-practice/.
Inspectors and users utilise these to provide basic information on minimum standards.

The current UK COP provide fairly comprehensive guidance for rodents and a number of the other commonly used laboratory animal species such as dog and non-human primate. However, guidance for more unusual species such as wild mammals and birds is more generic. Guidance is produced by others such as;

- The Universities Federation for Animal Welfare (UFAW) (The UFAW Handbook on the Care and Management of Laboratory Animals);
- RSPCA (e.g. Guidance on the housing and care of the African clawed frog Xenopus laevis (2005) see http://www.rspca.org.uk)
- Defra (Codes of Recommendations for the Welfare of Livestock http://www.defra.gov.uk/corporate/publications/pubcat/anh.htm#c21)
- Publication in Laboratory Animals (e.g. Laboratory birds: refinements in husbandry and procedures Vol.35 suppl.1 2001)
- Canadian Council on Animal Care (CCAC) http://www.ccac.ca/en/CCAC_Programs/Guidelines_Policies/GDLINES/Fish/Fish_Guidelines_English.pdf

Inspectors can also provide advice based on their expertise gained from inspecting a wide range of sites and different species. In addition, changes to European legislation (see European Initiatives section) will provide guidance on a wider range of species.

Possible implications of changes to EU legislation

Current advice on new buildings or equipment purchase is still based on the UK Codes of Practice. However, as the new Annex II has been agreed within the EU, there will be consequential changes for the UK but these are unclear as yet. Those planning new buildings or equipment purchase may therefore wish to be mindful of the contents of the new Annex II.

Planning and Design

The planning and design stage is critical in the process of facility development. Inspectors can assist if involved at an early stage by identifying problems or omissions. Feedback from PCD holders suggests that this input can result in valuable savings in time and resources. However, advice from Inspectors at this early stage cannot guarantee that a recommendation to designate the facility will follow.

Refurbishment or new build?

Refurbishment:

- flexibility is limited;
- current structures need to be maintained;
- can place constraints on layout within the given area;
- may not save on costs (some refurbishment projects prove to be more expensive than a new facility of the same proportions).

BUT there have been some very successful projects to modernise, convert and upgrade facilities within establishments in the UK.

At the planning and development stage, visits to other facilities can be useful to prevent the repetition of mistakes and Inspectors can facilitate this by arranging contact between designated establishments.

Flexible arrangement of feeding troughs in enclosure door allowing use by cattle, sheep, horse or pigs

Example

An innovative trough feeding system incorporated into the stable door, designed and used at one facility has been copied at several other new facilities. This door system allows flexibility in the different species that can be accommodated in the box, increases space, improves biocontainment and allows for safe handling of animals.

The Certificate Holder should ensure that the design team has the relevant experience and expertise to complete the project.

> Example
>
> A specialist facility for holding animals for infection studies was built by a team of people whose previous projects were car parks and commercial properties. The builders and engineers had no experience with the type of ventilation system required and air filters were placed inappropriately and not sealed. This ultimately led to a nine month delay in the project and increased costs as experts had to be recruited to correct the problems.

In the tendering process low-cost bids may reflect a lack of understanding of the type of facility required and lead to problems and delays, and hence greater costs, later in the project.

Flexibility in Design

Facilities should be planned and designed to be flexible enough to deal with different users and the continually evolving needs of science. Managers, users and animal care staff should be consulted to discuss requirements. Inspectors have seen areas that were designed very specifically to suit the needs of a particular user or group who then moved elsewhere leaving inflexible rooms unsuitable for other users.

The expected useful lifespan of a modern building is in excess of 25 years. It is very difficult to predict the changes that will occur in scientific approaches in the future so flexibility is essential. For example over the past few years, whilst there has been an increasing use of genetically altered mice in many disease models (see article in this report), many researchers are now exploring the potential for using fish as a possible alternative in some studies.

During the planning process the users and care staff will have an extensive 'wish list' and everyone will have expectations of the new facility. Decisions have to be made on the relative proportions of animal holding areas to other types of rooms, notably procedure areas, laboratory space, surgical facilities, storage areas, staff areas etc. The types of work being conducted at the site will affect the type and complexity of the facility and all special requirements should be identified at the design stage such as work with pathogenic organisms requiring containment facilities, or the requirement for specialist equipment e.g. MRI scanners.

Facilities are extremely costly to build and during the planning process priorities need to be set and cost savings made. Good communication during this process can avoid disappointments later on.

> Examples of compromises in design to save costs
>
> - Storage space is often the first area to be reduced when savings in costs are required. When the facility becomes operational there will be problems with finding space to store feed, bedding, and equipment to avoid clutter in the building, resulting in difficulties effectively managing the facility.
> - Scientists usually prefer specific, bespoke procedure areas within a facility but due to limitations on space and the high costs of these types of rooms only a limited number are typically included in the final building and users may need to share, timetabling their work accordingly.

When a specific design is available the individual needs of all those who will work in the building should be checked by tracking the flow of people (animal care staff and scientists), animals, cages, food, waste and bedding through the building, and identifying and rectifying problem areas at an early stage. There must be suitable access for deliveries to the unit.

Take home message

It is easier and cheaper to change things on paper than during or after building.
Ensure all changes are communicated to users to avoid disappointments later.

Specification and Standards

The initial consideration should be to meet the scientific and welfare needs. In the COP some standards are set. In general these are performance standards although for environmental controls, ranges and limits are set for some species.

The fabric of the building, both external and internal, should be suitable to stand up to the day to day requirements. This will depend on the type of facility, species to be housed, its location and use.

Example

- A polytunnel may be adequate to provide shelter and protection from the elements for cold water fish tanks for short periods but this type of building would be unacceptable for housing of dogs.
- A room which will floor house rabbits will require a more robust wall and floor finish than one holding rodent cages in racks.

Polytunnel providing protection from the elements for cold water fish tanks

There is sometimes a tendency to aim for a very high specification and although this can be advantageous, it is costly and may lead to compromises and cost savings in other areas. It is important to balance the needs against the costs in a realistic manner.

General advice

- Ensure that whatever is specified for the facility will be fit for purpose.
- Fixtures and fittings and finishes (the 3"F"s) in rooms should be of materials that will stand up to their proposed use e.g. in areas where cages are being washed the flooring material should be able to withstand water and chemicals and a high level of wear and tear.

Poor quality of the workmanship is one of the main problems during the building of new facilities; floor and wall finishes are a particular area of concern.

Examples

- Pressures to get the building completed quickly meant the final floor finish was laid before the concrete base had had sufficient time to dry out. This resulted in water getting trapped below the floor surface, pressure build up and separation of the floor surface from the base, seen as bubbling on the floor. The whole floor surface had to be removed and re-laid; this was very disruptive and costly in both time and money to rectify.
- Falls of floors to drains are challenging. In a surgery room the fall should have been to the central drain, but a low corner by the scrub sink meant water pooled here. That quarter of the epoxy resin floor had to be removed and re-laid.

The Challenge of Costs

In the development of new facilities there is always a concern over capital costs. Savings in initial building costs may lead to greater maintenance requirements and costs in the future in order to continue to meet the required standards. Certificate Holders need to balance these aspects.

Examples

- A wall coating with a lower specification may be cheaper, but requires more frequent replacement.
- Exposed ductwork or pipework may be less expensive than boxing in, but increases subsequent cleaning requirements.
- Reduction in the ventilation capacity in individual rooms to be fitted with individual ventilated caging systems (which meet the required environmental standards) costs less, but if user requirements change expensive upgrading of the ventilation system will be needed to provide adequate environmental conditions at the room level to allow holding of different species or in different housing systems.

The Building Stage

It is advisable for an appropriate user (often the Named Animal Care and Welfare Officer, or NACWO who will be responsible for the building when completed and designated) to be available to provide advice and inspect the unit as work progresses, working closely with the project and building managers. This helps to identify problems at an early stage and allows for quick resolution.

Example

During the building of a standard agricultural sheep shed the builders read the plan 'upside down' and started to place the drain pipes at the higher end of the building. Identification of the problem when only one pipe had been installed allowed for rapid resolution of the problem.

The preparation of a **'mock room'** can be very valuable early in the building phase i.e. an area utilising the proposed fabrics, finishes and fittings to allow these to be checked and any modifications suggested before replication throughout the building. In one such case a mock room in a new rodent holding facility allowed examination and discussion of the floor to wall junction. Major improvements in the design to support the coving and improve the seal were agreed and this change was then replicated when other rooms were prepared.

It is also useful to test innovative designs prior to installation. During the development of one large animal facility, different designs for the animal handling system and weighing equipment were tested in an existing facility to identify the most appropriate system for animals and staff.

Irrespective of whether a mock room is viewed early in the building phase, it is advisable for the Inspector to view the facility at least once before the building is completed and the main building contractors leave the site. Any problems identified can be notified to them and rectified.

Commissioning

This is important because it ensures that the building can perform to the stated specification and that those responsible for animal care can operate the facility to COP requirements. There have been a few disastrous failures with animal welfare consequences because the building had not been tested robustly prior to animals being housed. Once animals have been housed in the building it is very difficult to rectify major problems without causing disruption, welfare issues and possibly compromising health status.

It is essential during this phase for the animal care staff, particularly the NACWO, and maintenance staff to familiarise themselves with the building and its operation and capitalise on the expertise and training offered by the contractors, engineers and other experts before they leave the site. It is also the opportunity to investigate and, where possible, implement systems of operation prior to moving into the building.

Delays

Completion dates can slip by months and even years as a consequence of building and commissioning delays. Older facilities on site may need to remain open for longer than anticipated to allow animal studies to continue whilst awaiting completion of the new facility.

Good quality flooring material showing bubbles and wrinkles. Flooring problems are a common fault in new facilities

Common causes of delays

- Problems encountered during commissioning with ventilation, environmental control and balancing pressures across the building, due to faults in the system, inappropriate design, impact of other equipment in the building.
- Quality of finishes, in particular variability across the facility, can cause arguments as to whether they meet the specification and cause delay in the necessary remedial action being taken.
- Flooring disasters, although not common, are difficult and time consuming to fix.

Many delays are the result of poor workmanship or a lack of understanding of the types of materials and how they should be used, particularly their compatibility with other materials in the facility.

Other Legislation

In addition to ASPA the facilities and animals are subject to other UK legislative controls such as health and safety, environmental protection, and building regulations. Compliance with all relevant legislation can be particularly challenging due to differing requirements for human and animal welfare. For example, when scientists are planning work with dangerous pathogens, engineering solutions and systems of control need to be found that contain the hazard whilst ensuring that living conditions for the animals are suitable. There are some excellent examples in the UK where the collaboration of scientists and regulators, including ASPI Inspectors, during the planning stage has resulted in development of innovative, animal welfare friendly facilities for this type of work.

ASPI Annual Report 2007 Feedback

The ASPI Annual Report covers a range of subjects relating to the work of the Home Office Animals Scientific Procedures Inspectorate (ASPI). These include an overview of inspection patterns and assessment work, contributions to policy formulation and miscellaneous information about other activities undertaken by the Inspectorate during the year. In addition, the report contains more lengthy articles in which particular aspects of ASPI work are reviewed in detail.

The editorial board are keen to ensure that the ASPI Annual Report provides interesting, topical and relevant information about the work of the Inspectorate to the wider scientific community and the general public.

We would be grateful if you could take a few minutes to complete the feedback form **(see overleaf)** and return it to:

Post: Home Office, ASPI (Annual Report), 4st floor SW, Seacole Building, 2 Marsham St, London SW1P 4DF

Fax: 08703 369155

Email: aspa.london@homeoffice.gsi.gov.uk

ASPI Annual Report 2007 Feedback

Content:

1. How do you rate the content?

- ☐ 1 (poor)
- ☐ 2
- ☐ 3
- ☐ 4 (excellent)

Please indicate any other subjects you would like to see or continue to see in the ASPI Annual Report.

Do you have any comments or suggestions relating to content?

Design and layout

2. How do you rate the design?

- ☐ 1 (poor)
- ☐ 2
- ☐ 3
- ☐ 4 (excellent)

Can you suggest any improvements to layout and design?

Electronic vs. hardcopy

3. How would you like to receive the ASPI Annual Report? (tick all that apply)

- ☐ Hardcopy
- ☐ Email
- ☐ Website

Other information

4. Do you have any other comments about the ASPI annual report?