

**Animals (Scientific Procedures) Inspectorate**

**REVIEW OF  
THE 'ETHICAL REVIEW PROCESS'  
IN ESTABLISHMENTS DESIGNATED UNDER THE  
ANIMALS (SCIENTIFIC PROCEDURES) ACT 1986**

**November 2001**

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**The following documents, referenced in this report, are displayed at the Home Office web-site**

**[www.homeoffice.gov.uk/new\\_indexs/index\\_anima.htm](http://www.homeoffice.gov.uk/new_indexs/index_anima.htm)**

**Part A – Report on the response from designated establishments**

**Part B – Report of the response from interested organisations**

**Part C – Report on visits to selected designated establishments**

**Part D – Report on selected project licence applications and the ERP**

**Appendix 1 The process statement (reproduced from Appendix J to the Guidance on the Operation of the Animals (Scientific Procedures) Act 1986)**

**Appendix 2 Home Office ERP review consultation letter to certificate holders of 11 January 2001**

**Appendix 3 Home Office ERP review consultation letter to stakeholders and interest groups of 6 February 2001**

**Appendix 4 Home Office letter to establishments selected for site visits of 2 May 2001**

**Appendix 5 Letter to selected certificate holders requesting documentation associated with specific project licence applications considered by the ERP**

**Appendix 6    The local ethical review process: supplementary note by the  
Chief Inspector, December 2000**

# 1. Executive Summary

The Inspectorate review of Ethical Review Processes (ERP) has established that although local processes are still evolving, they are making a positive contribution to the welfare of animals bred, kept and used for experimental or other scientific purposes.

Although there are still some problems in practice, these seem to relate to the way individual ERPs have been designed and operated rather than to any flaw in the original concept or the Home Office Process Statement. Importantly, the review has identified examples of what has been termed ‘perceived best contemporary practice’ that may enable certificate holders to consider making changes to improve the efficiency and effectiveness of their current processes.

## **Recommendations**

As the result of the review the Inspectorate makes three recommendations

### **Inspectorate Recommendations**

- 1. Certificate holders should continue to establish and maintain local ethical review processes acceptable to the Secretary of State.**
- 2. The Process Statement as set out in Appendix J to the Home Office Guidance on the Operation of the Animals (Scientific Procedures) Act 1986 should remain unchanged.**
- 3. The Ethical Review Process should be seen as an evolving process, and the Secretary of State should draw the attention of those involved in ERPs to the insights into ‘best practice’ set out in this report.**

## **Problems in practice**

The review identified elements of some processes that might be improved:

- Not all processes have yet achieved a proper balance between the three key ERP functions derived from the original Home Office Process Statement.
- Some ERPs seem more focused on ‘process’ rather than ‘output’ and as a result some seem unnecessarily complex and bureaucratic.
- There is scope within some ERPs to reduce delays and improve efficiency and effectiveness by reviewing how straightforward requests are considered, and how members of the ERP communicate and interact.
- In some cases ERPs could be better resourced.

## **Perceived Best Contemporary Practice**

The review commends a number of examples of ‘good practice’ that under-pin effective and efficient ERPs and merit wider consideration.

Although it is hoped that these insights will be of use to certificate holders when reviewing their own ERPs, two notes of caution are required.

- First, the full meaning and significance of the insights offered can only be understood and appreciated when this report is read in its entirety.
- Second, not all of the best practice insights offered can or should be applied within all ERPs. The Home Office has always stressed that processes must be designed to suit local circumstances.

We would commend the following as examples of good practice that might be more widely applied:

- Actively seeking and considering changes improve to the effectiveness and efficiency of the ERP
- A focus on ‘outputs’ rather than ‘processes’
- An awareness amongst those caring for or using animals of how their local ERP operates and the benefits it brings
- Evaluating and publicising in-house the benefits achieved by the local process
- Ensuring effective communication between all parts of the ERP, and that the individual parts of the process are ‘joined-up’
- Adding value by providing support and advice on issues not otherwise provided for within other systems, rather than duplicating processes already better undertaken by others – including within other parts of the ERP
- Extending the scope of ERP to non-regulated animal use, and animal use commissioned by the establishment but performed elsewhere
- Members of the ERP having the opportunity to visit the animal facilities
- Fast-tracking requests and initiatives that will promote animal welfare and the 3Rs
- Involving high-quality, well-informed and enthusiastic lay people
- The use of informative lay summaries, structured templates and ‘case-tracking’ to record and measure the time taken, the value added and the resources consumed
- Activating ERPs at the project planning stage, supporting work in progress, and reviewing completed work
- Encouraging early contact with the Inspectorate for advice on the format and content of project licence applications and to identify possible contentious issues
- Early input from NVSs and NACWOs during the preparation of project licence applications
- Stream-lined processes for considering secondary availability

## 2. Introduction

### **Background**

1. On 6 Nov 1997 in response to the Labour Party pre-election pamphlet “New Life for Animals” Lord Williams of Mostyn, then Parliamentary Under-Secretary of State at the Home Office, announced –

#### **Welfare committees in designated establishments**

*“The Government will require all designated establishments to set up and maintain ethical review processes. These have sometimes been called “welfare committees”.*

*The exact nature of the processes used will depend on the particular establishment. An appropriate form of welfare committee will be mandatory: a standard condition of certificates will ensure that ethical review processes have been justified and demonstrated.*

*Their function will be to scrutinise the ethics of proposed work; to propose reductions in the numbers of animals used, refinements to the procedures to reduce any suffering, and replacement of animals wherever possible (the 3Rs); and to advise on the care and accommodation of laboratory animals.”*

2. On 23 Feb 1998 the Home Office wrote to certificate holders setting out provisional aims and objectives of the proposed ethical review process (ERP).

3. The Home Office letter invited comment on the proposals and indicated that formal guidance on the establishment of ethical review processes, taking account of comments received, would be issued by the Home Office on or around 1 April 1998.

4. On 1 April 1998 the Home Office wrote to all certificate holders formally setting out the requirement for each designated establishment to have an ethical review process, acceptable to the Home Office, in place by 1 April 1999.

5. An Annex to the letter set out the Home Office policy and defined the operational requirements for ERPs. The Annex was subsequently published as APPENDIX J in the Home Office Guidance on the Operation of the Animals (Scientific Procedures) Act 1986, and is referred to hereafter as the Home Office Process Statement. It is listed as Appendix 1 on the Contents page of this report.

6. For practical purposes, the Annex (sections 7.1 – 7.7) described three essential ERP functions:

**6.1 ERP Function 1 (Process Statement Annex 7.1 + 7.2)**

*To consider applications for project licences, amendments to existing project licences, and additional availabilities, with reference to the justification for the use of animals, and the balance between the likely welfare cost to the animals and the expected scientific benefit; and to promote the development and uptake of the 3Rs.*

**6.2 ERP Function 2 (Process Statement Annex 7.3 + 7.4 + 7.5 + 7.6 + 7.7)**

*To provide opportunities for discussion, and to provide a source of support, advice and awareness on these issues. This includes; ensuring that staff are kept up to date; best standards of care and accommodation are sought and implemented; managerial systems are appropriate; staff (including personal and project licence holders) are trained and competent; and general aspects of the 3Rs are considered with respect to all aspects of animal production, care and use.*

**6.3 ERP Function 3 (Process Statement Annex 7.1 + 7.4)**

*Retrospective review of ongoing projects in order to promote the development and uptake of the 3Rs.*

7. Certificate holders had until 1 April 1999 to establish ERPs acceptable to the Home Office. The Inspectorate advised the Secretary of State on the acceptability or otherwise of the proposed ERPs. No certificate of designation was revoked by the Home Office because of failure to comply with what was by then Standard Condition 23 for Scientific Procedure Establishments and Standard Condition 20 for Breeding and Supplying Establishments.

**Scientific Procedure Establishments: Standard Condition 23.**

*The certificate holder is required to have instituted, and to maintain, local ethical review processes acceptable to the Secretary of State. Details of the processes and records of the outputs from the processes shall, on request, be submitted to the Secretary of State or made available to an Inspector. Any substantial changes to the processes that are proposed must be submitted to the Secretary of State for approval.*

**Breeding and Supplying Establishments: Standard Condition 20.**

*The certificate holder is required to have instituted, and to maintain, local ethical review processes acceptable to the Secretary of State. Details of the processes and records of the outputs from the processes shall, on request, be submitted to the Secretary of State or made available to an Inspector. Any substantial changes to the processes must be submitted to the Secretary of State for approval.*

8. Paragraph 6.3 of the Home Office letter of 1 April 1998 stated:

***“We will institute a formal review of the ethical review process at some point after April 2000 when the procedures have been fully operating for at least a year.”***

### **The Review of Ethical Review Processes: Terms of Reference**

9. The Home Office review of ERP was launched, and its terms of reference established, in answer to a Parliamentary Question on 1 November 2000.

***“To review the efficiency and effectiveness of the operation of the Ethical Review Process, as set out in PCD Circular 3-4.98 issued on 1 April 1998, and in particular to consider:***

- (a) whether the aims of the process, as specified in paragraph 3 of the Annex to the Circular, have been achieved;***
- (b) what problems may have been encountered;***
- (c) what the resource implications have been;***

***and to recommend any changes in the arrangements and to identify best practice.”***

10. The Animals (Scientific Procedures) Inspectorate was asked to carry out the review.

11. The Inspectorate set out to -

- assess the effectiveness of the process in achieving the aims; and
- assess the efficiency and resource implications of the process.

By

- formal consultation with stakeholders, interest groups and professional organisations;
- obtaining robust, quantitative and qualitative information from detailed site visits to a selected, but representative, cross-section of establishments; and
- scrutiny of project licence applications processed after the introduction of the ERP to consider the impact of the ERP on project licence applications.



### **The Consultation Exercise**

12. The review started with a consultation exercise on the principles underpinning, and the operation of, ERPs. Consultation documents were sent to all designated establishments, selected other stakeholders and interested parties, and were displayed at the Home Office web-site. (See Appendices 2 and 3).

13. It was expected that views would differ between those who had a part in the process, those who had an interest but a limited involvement, those organisations that had provided lay representatives to ERPs, and funding bodies.

### **Site Visits**

14. The same member of the Inspectorate management team, referred to below as the Review Leader, led all site visits.

15. The Review Leader liaised with colleagues and others in selecting the places to be visited. The places selected represent a cross-section of categories and sizes of designated establishments.

16. During each site visit the following people were interviewed:

- the certificate holder;
- the NVS(s);
- the NACWO(s);
- a selection of project licence holders and personal licence holders (those playing a part in the process and those exposed to the process);
- lay persons involved with the process.

17. Structured interviews were held to gain insight into the practical operation of all parts of the processes and their contribution to the three key ERP functions set out above.

### **Project Licences post-ERP**

18. Certificate holders were requested to provide the documentation associated with the progress of selected project licence applications through the ERP. The Inspectorate selected the projects reviewed. This material was used to assess the impact of the ERP on project licence applications.

### **The Report**

19. This report considers whether the original Home Office Process Statement for ERPs requires to be revised, comments on some problems being encountered in practice, and sets out some examples of good practice that certificate holders might find of benefit in improving the efficiency or effectiveness of their ERPs.

### 3. Findings

20. This section summarises the Inspectorate's findings. More detailed information on the evidence collected and reviewed appears as Parts A-D on the Contents page of this report, and is available at the Home Office web-site.

21. The review findings are based upon the outcome of a formal consultation exercise with certificate holders (Part A) and other interested groups (Part B), the results of site visits (Part C), and an assessment of the documentation associated with a sample of projects considered by ERPs (Part D).

22. On the basis of these findings we offer the following general observations and conclusions with respect to the questions posed when the review was announced.

- (a) **whether the *[three]* aims of the process, as specified in paragraph 3 of the Annex to the PCD Circular 3-4.98, have been achieved;**

#### ***3.1 To provide independent advice to the certificate holder, particularly with respect to project licence applications and standards of animal care and welfare.***

- The existence, support and advice of ERPs have provided reassurance to certificate holders in the discharge of their responsibilities.
- Many certificate holders now have a greater awareness of ethical, scientific and animal welfare issues, and of the work done in their establishments.
- ERP has provided the stimulus for people to come together at a local level to focus specifically on matters relating to compliance with both the letter and spirit of the legislation and on issues relating to animal welfare.
- ERP has raised the profile of ethics, animal welfare and the 3Rs, particularly with respect to local issues.
- The discipline of an ERP has made some project licence holders/applicants more critical of their research and more aware of its implications for animal welfare throughout the duration of the programme of work.
- The ERP has facilitated better communication between named persons (NVSs and NACWOs) and scientists, providing a better framework for the provision of expert advice to animal users, and a raised awareness of 'animal issues' within the establishment.
- Lay members of ERPs have asked questions from a different perspective. They have constructively challenged existing assumptions and practices, with the result that improvements have been made with respect to licence applications and animal care and use.
- ERPs have created a culture, or enhanced pre-existing cultures, in which continual, critical evaluation of costs and benefits, and implementation of best practice are 'second nature' to everyone involved in animal use.

### ***3.2 To provide support to named people and advice to licensees regarding animal welfare and ethical issues arising from their work.***

- ERP has been particularly successful in promoting the role of the NVS and NACWO, and ensuring their advice is sought and taken both in the preparation of project licence applications and whilst work is in progress.
- Involving licensees in the ERP has improved the communication, dialogue, co-operation and trust between management, licensees and named persons to the benefit of the animals produced, kept and used in designated establishments.
- Continuous review and periodic retrospective review of on-going work has facilitated consideration and application of strategies for replacement, reduction and refinement.
- Although significant additional demands have been made on named persons management support to deal with these additional expectations has not always been forthcoming (e.g. in the form of additional resources such as equipment and administrative support).

### ***3.3 To promote the use of ethical analysis to increase awareness of animal welfare issues and develop initiatives leading to the widest possible application of the 3Rs.***

- Bringing together named persons, licensees and lay people in an ERP has fostered and awareness of what others do in an establishment and the specialist skills and knowledge that they possess. The value of this educational and awareness raising role has been considerable.
- ERP has allowed wider, more thoughtful, considered and responsible discussion of ethical issues (in the widest sense) in relation to animal production, care and use for experimental or other scientific purposes than previously occurred.
- ERPs have actively raised awareness and prompted discussion of the production and use of animals by establishing IT intranets, holding seminars and other events, providing additional training, and the formation of task-oriented subgroups and working-parties.
- The remit of some ERPs also extends to animal use not requiring licences under the 1986 Act, and to studies commissioned by the establishment but conducted elsewhere in the UK or abroad.

<b>(b) what problems may have been encountered;</b>
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- It is acknowledged that ERP has only recently been introduced, is still being developed, and will require time to find optimal ways of working and to reap all of the benefits that such processes can bring.
- Flexibility to construct and operate the process that best meets the needs of a particular establishment is considered essential.

- The inherent flexibility in the Home Office Process Statement, coupled in some establishments with a focus on ‘process’ rather than ‘outputs’, has resulted in some processes that might be considered to be unnecessarily complex and bureaucratic.
- It is universally acknowledged that the ERP has caused an increase in bureaucracy, paperwork, administrative demands and professional time. This has not always been accompanied by the provision of the resources needed to meet these demands with, in some instances, consequential delays in ERPs considering requests for animal studies.
- Advantage has not always been taken of electronic methods of communication to minimise potential delays.
- The consideration of applications for, and amendments to, project licences has dominated the work of many ERPs, sometimes at the expense of the other mandatory ERP functions.
- There was a general perception that ERP caused unnecessary delays in obtaining the consents necessary to undertake animal studies. Stakeholders acknowledged that the frequency of meeting of key ERP committees often determines and dictates the rate of progress.
- Causes of unnecessary delays that seem to be within the control of scientists were also identified. It was acknowledged that some applicants engaged with the process too late in the planning cycle, were not familiar with the operation of their ERP, did not read the notes on the project licence application, and did not accept the advice of named persons. Some seemed reluctant to accept that the ERP would require a scientifically sound, clear and sustainable justification for the work they wished to undertake.
- Some establishments have been slow to recognise problems with the efficiency and effectiveness of their ERPs, and have difficulty seeing where improvements could be made within the flexibility allowed by the Home Office Process Statement.
- On the other hand other establishments have successfully integrated ERP almost seamlessly with pre-existing efficient and effective business processes.
- There was uncertainty within some ERPs about the extent to which the science should be challenged, especially if proposals had already been subjected to peer review and funding by a major grant awarding body.
- There was confusion in some quarters about the relationship between the work of the ERP and the role of the Inspectorate, and a poor appreciation of the advice and support available from the Inspectorate now that ERPs have been established.

<p><b>(c) what the resource implications have been</b></p>
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- The additional resources needed to service the ERP have been considerable.
- Some establishments have responded by providing additional hardware, recruiting administrative staff, and by increasing the number of veterinarians on staff and NACWO posts.

- Some establishments have appointed staff specifically to oversee and co-ordinate the ERP.
- Involvement in committee meetings (both in their organisation and conduct) as part of ERPs (and involvement in other parts of the process) has placed particularly heavy demands on the time of NVSs and NACWOs.
- NVSs, and to some extent NACWOs, commented that the additional ERP-related demands have removed them from more immediate contact with animals. However both groups acknowledged the benefit of being involved in the planning of studies at an early stage, and felt that in general the value of early interaction with applicants has more than outweighed this drawback.
- Some licensees observed that they had underestimated the time taken to consult with NVSs and NACWOs, to draft applications and to satisfying the ERP.
- In some establishments the costs of operating the ERP have included payment of the professional or lay people who participate.
- Where proper costings of the operation of ERPs are known, consideration has been given to 'cost recovery' by factoring indicative costings into grant applications.

## 4. Conclusions

23. There is no doubt that the ERP has made a positive contribution to the production, care and use of animals for experimental and other scientific purposes.

24. There are still opportunities to improve the efficiency and effectiveness of some ERPs. However, the main current shortcomings seem to relate more to how processes have been designed and implemented, rather than to any inherent or fundamental flaw in the concept of ERP as set out in the Home Office Process Statement.

25. It is hoped that the insights into perceived best contemporary practice offered in this review will be considered by certificate holders seeking to improve their ERPs.

## 5. Recommendations

26. As a result of this review the Inspectorate makes the following recommendations:

### **Inspectorate Recommendations**

- 1. Certificate holders should continue to establish and maintain local ethical review processes acceptable to the Secretary of State.**
- 2. The Process Statement as set out in Appendix J to the Home Office Guidance on the Operation of the Animals (Scientific Procedures) Act 1986 should remain unchanged.**
- 3. The Ethical Review Process should be seen as an evolving process, and the Secretary of State should draw the attention of those involved in ERPs to the insights into ‘best practice’ set out in this report.**

## 6. Perceived best contemporary practice

27. An important objective of this review is to highlight practices that seem to facilitate the efficient and effective operation of ERPs.

28. Although the insights offered below are not appropriate in all contexts, they represent what we consider to be perceived best contemporary practice.

29. They are based on the comments received from certificate holders and interested parties, site visits to selected establishments, and the scrutiny of the documentation associated with the progress of a sample of project licence applications prepared following the implementation of ERP.

30. The observations below largely follow the order of the headings used in the original Home Office Process Statement.

31. “The local ethical review process: supplementary note by the Chief Inspector, December 2000” offers additional useful advice on the interpretation and implementation of the Process Statement. (see Appendix 6).

32. The Expert Group on Efficient Regulation (EGER) also published its report “The Regulation of the Use of Animals in Scientific Procedures” in October 2001. The EGER report also contains contemporary observations on the operation of ERPs that may contribute to their evolution.

### **Ethical Review**

33. The RSPCA has produced a useful and concise working-definition of ethics in relation to ERPs:

*“A local framework acting as an adjunct to the Home Office Inspectorate to ensure that all animal use in an establishment is carefully considered and justified, and that proper account is taken of all possibilities for reduction, refinement and replacement.”*

RSPCA, Progressing the Ethical Review Process, Oct 1997

34. A few scientists may have previously held a narrow view of ethics. Some may have considered that the only ethical issue was whether animals should be used for a particular purpose, not fully appreciating that the way animals are used is also an ethical issue. Some still seem to be unwilling to allow their science to be challenged within ERP, and are sometimes reluctant to offer a sustainable justification of proposed work.



35. Some project licence holders interviewed felt that the ERP had not resulted in significant animal welfare gains. They had perhaps failed to appreciate fully that as the direct result of advice and support provided by their in-house processes at the planning stage the resulting, better-prepared application had welfare gains built-in before animals were used.

36. ERP should be seen as a process with, potentially, beneficial outcomes throughout the course of an animal study. It is not, and should not be viewed as, a single event or committee only encountered before animal work can start. This is consistent with both the Chief Inspector's supplementary note on ERP, and the RSPCA concept of 'ethics' in relation to ERP.

37. The process should be activated when work is at the concept stage, it should inform the planning stages, continue once work is in progress, and reflect upon the lessons learned when work has been completed.

38. Some respondents complained that ERP was overly concerned with meetings, paper work and bureaucracy. In the course of this review it was established that this seems to be the case in some instances, with some ERPs being more 'process' than 'outcome' oriented.

39. We contend, however, that there is nothing in the Home Office Process Statement that requires that this be the case. It is for the certificate holder and others at the establishment to ensure that the local process is designed to meet the needs of their organisation, is focused on practical and beneficial outcomes, and operates efficiently and effectively.

### **Flexibility of the Policy**

40. In announcing the requirement to establish local ERPs on 6 Nov 1997 Lord Williams of Mostyn clearly stated that:

*"...the exact nature of the process used will depend on the particular establishment."*

41. That same principle of flexibility was developed in the Home Office commissioning letter of 1 April 1998:

*"It is critically important to devise a system appropriate to the individual establishment."*

42. The diversity of designated establishments makes it essential to retain flexibility in order to construct and operate the process best suited to the size and type of the establishment and the nature of the work it undertakes. All of the ERPs reviewed in detail during the preparation of this report were different but clearly recognisable as ERPs as envisioned by the Home Office Process Statement.

43. It is emphasised that designated establishments which discover in the light of experience that their ERP as originally agreed with the Home Office could be made more effective or efficient, or could otherwise be improved, are encouraged to devise and propose suitable amendments to the process. The revised proposals must, however, comply with the Process Statement and be agreed with the Home Office.

44. A number of establishments reported that they ‘...*had an animal care and use committee in place for years...*’ before the Home Office required a local ERP.

45. Some places with good pre-existing systems felt that they had seen very little gain for the additional inputs they had been required to provide. Undoubtedly some establishments had previously actively considered the ethical use of animals, but even in such places it was generally conceded that the breadth of the ERP now required, and the formality of the arrangements, improved the outcomes.

46. However, some establishments have not yet fully appreciated that advice and support in relation to animal facilities, environmental enrichment, management, staffing, training, competence etc are essential components of ERP (Function 2) with which their ERP must engage fully.

47. There is a need for all certificate holders to keep their processes under review, to ensure that individual parts of the process are ‘joined up’ where necessary, and to be prepared to identify and dispense with parts of the system that have become redundant.

### **Aims**

48. The terms of reference of the review of ERP question if the three declared aims of ERP have been achieved.

#### **ERP Aim 1**

*To provide independent ethical advice to the certificate holder, particularly with respect to project licence applications and standards of animal care and welfare.*

49. Without exception the certificate holders who took part in this review welcomed and valued the independent advice provided by the ERP with respect to project licence applications and amendments.

50. In some cases ERPs have yet to fully co-ordinate and integrate all of the activities that contribute to other aspects of animal care and welfare. This was on occasion most obvious in establishments that had an Animal Care and Use Committee in place prior to ERP, and where the pre-existing system has not been fully incorporated into the ERP.

51. On the other hand there is evidence that carefully considered advice from local ERPs has been instrumental in providing strong management support for the planning and funding of new and improved animal facilities, and better husbandry practices.

**ERP Aim 2**

*To provide support to named people and advice to licensees regarding animal welfare and ethical issues arising from their work.*

52. Almost without exception NVSs and NACWOs feel that ERP has provided them with additional, visible management support and has enhanced their status.

53. Advice regarding animal welfare and ethical issues arising from retrospective review of licensed work (Function 3) is still taking shape. However there is already evidence of on-going review resulting in additional refinement.

**ERP Aim 3**

*To promote the use of ethical analysis to increase awareness of animal welfare issues and develop initiatives leading to the widest possible application of the 3Rs.*

54. Delivery of this aim was the most difficult to evaluate.

55. One respondent observed –

*“We are not aware of any ERP that is actually using or promoting ethical analysis per se as part of their activities”.*

56. The respondent may in a sense be correct. However the essential objective is to encourage a positive attitude to new ways of promoting good science and good animal welfare.

57. In that connection the enthusiasm for ERP encountered during all site visits is a sign of the success of ERPs to date, and augers well for the future.

**Personnel**

58. The review found that certificate holders had identified appropriate personnel to take part in their ERPs. Identifying the competencies required had formed part of discussions between establishments and the Inspectorate when draft ERP processes were considered prior to the 1 April 1999 implementation date.

59. The site visits conducted during this review provided an opportunity to assess the attitude of each stakeholder group. This is reported in greater detail in the Report of Site Visits (Part C).

#### **Named veterinary surgeon**

60. NVSs have found their profile raised, and their input more actively sought and more highly valued, with the introduction of ERP. In some cases NVSs had not previously been consulted routinely when project licence applications were drafted.

61. There is no doubt that this has increased the work of many NVSs. Some have complained that it has taken them away from more direct animal care duties.

62. We consider that involvement of NVSs in the construction of the project licence, and to the animal use protocols (Section 19b of the form of application) in particular, is an invaluable opportunity to ensure in advance of work commencing that animal welfare and wellbeing are properly considered and safeguarded.

63. Certificate holders should be aware that because of the key role played by the NVS in the process, it is necessary to have an NVS who is not only knowledgeable and competent, but who can also establish a rapport with both the animal care and scientific staff.

#### **Named Animal Care and Welfare Officer**

64. NACWOs have seen their status enhanced as the result of ERP.

65. They too complain about the time required to participate in ERP, but acknowledge that this cost is outweighed by the advantages of being involved early in the process and thus being better able to influence animal care and use.

66. Some establishments may only have one NACWO to contribute to the process. This may place a particularly heavy burden on one person. As a result in some places management changes have created additional NACWO posts.

#### **Project and Personal Licence Holders**

67. Most establishments have not sought separate representation from both groups. Rather they have involved project licence holders who are also personal licence holders.

68. The licensees who have been involved in operating their local ERPs are generally committed to the process provided they are not over-burdened by the administrative demands. ERPs should be organised in such a way as to keep these demands within reason.

69. It was also noted that project licence holders who were members of an ERP were generally more sympathetic to, and appreciative of, the value of ERP than those who had only been exposed to the process as applicants.

70. For these reasons there may be benefit in making provision for some 'turn-over' of the project and personal licence holders involved in the process.

### **Lay persons**

71. The Home Office Process Statement requires that, where possible, the views of lay persons in the establishment should be taken into account, and that the involvement of persons from outside the establishment should be considered.

72. An important and notable finding of this review is the universal enthusiasm for the process shown by lay participants.

73. Lay people particularly valued the opportunity to learn about animal work, to ask questions, and to be satisfied that animal welfare and 3R issues were being addressed.

74. The majority of establishments surveyed did not use external persons. The common solution was to involve lay people from other parts of the organisation.

75. Universities often involved people from their governing body, senate or council, and have found these to be good contributors. Some involved academic staff from non-biological subjects.

76. Research institutes, pharmaceutical companies and commercial organisations perhaps had greater difficulty finding appropriate lay people, possibly because such organisations do not embrace the same diversity of interests and disciplines. Nevertheless, the quality and commitment of those recruited was impressive.

77. To date responsible animal welfare organisations seem to have played only a limited role in providing external lay people for ERPs.

78. In keeping with the principle of flexibility, and mindful of continued concerns about security and commercial confidentiality, there is no proposal within this review to alter the terms of reference in relation to the participation of lay persons. That is a lay contribution should be incorporated from within the establishment when possible, and the involvement of people independent of the establishment should be considered.

### **Home Office Inspectorate**

79. The periodic attendance of the Inspectorate at ERP meetings as observers and, if required, to interpret Home Office policy and requirements was appreciated and should continue.

## **Operation of ERPs**

80. Although those who are involved with ERPs, and those who have been exposed to the process as project licence applicants and holders, were familiar with their local ERP, personal licence holders were often less familiar with the process and its aims.

81. There is still work to be done in bringing the work of the ERP to the attention of all appropriate employees within establishments. Those who work or care for animals should have access to an operating description of the process and be aware of the personnel involved.

82. In some establishments, not only those of large size, an individual has been identified or appointed whose major or sole function is to co-ordinate the ERP. This acknowledges the resource demands and addresses them by providing a source of sound advice and operational efficiency. The available evidence suggests that such an appointment avoids some of the delays experienced within other less well resourced and less well co-ordinated processes.

## **The three functions of ERP**

### **ERP Function 1 (Process Statement Annex 7.1 + 7.2)**

*Consider applications for project licences, amendments to existing project licences, and additional availabilities, with reference to the justification for the use of animals, and the balance between the likely cost to the animals and the expected benefit, promoting the development and uptake of the 3Rs.*

83. Consideration of ‘the justification for the use of animals, and the balance between likely costs to the animals and the expected benefit’ is a central component in ERP and must remain so.

84. There is a perception in some quarters that this is ‘doing the Home Office’s work’. Put in its most extreme form, we were told that ‘...*the scientists will attend to the science and the Home Office can attend to the ethics...*’.

85. That attitude is entirely at odds with the letter and spirit of the 1986 Act. It is, and has always been, the responsibility of an applicant to present the most humane science linked to the highest standards of animal care and accommodation, and to provide sufficient, balanced information for the Home Office cost/benefit assessment. ERP should be seen as a resource that assists the applicant to satisfy these requirements.

86. The 1986 Act requires that project licence applications, and amendment requests, are subjected to a cost/benefit assessment by the Home Office. The process by which this assessment is done is explained in detail elsewhere (“COST/BENEFIT ASSESSMENT, A Note by the Chief Inspector” published in the Report of the Animal Procedures Committee for 1997, pp50-59). The project licence application should be drafted to address the all of the relevant issues and to provide the information that the Inspectorate will require for the assessment to be undertaken.

87. A small number of establishments involved in the review maintained that the remit of their ERP is to look at the application ‘in the round’ and not to look in detail at the quality of the science and the cost/benefit analysis.

88. Sometimes these ERPs concentrated on the protocols for animal use rather than the justification or rationale for the plan of work, or considered ethics only in terms of the acceptability of the type of work to the establishment. Such limited processes provide support with only a small subset of the issues considered when the Home Office cost/benefit assessment is performed. Consideration of ethical issues, including the validity of the science, is an indispensable component in the preparation of an application in which both the likely benefits and potential costs are displayed and evaluated.

89. ERPs might be able to take into account the prior peer review that is required to secure funding for animal use. The ERP might then focus on adding value in other ways rather than duplicating what might be better done by others involved in the review, funding, commissioning or oversight of animal use.

90. For example the issue of scientific validity should be well-addressed by major funding bodies. If proposed work has been peer reviewed and funded by a major, reputable grant awarding body then scientific validity should not be neglected by the ERP, but note taken of the fact that considerable expertise may already have been devoted to assessing the science. The ERP’s contribution in such cases might be better focused on ensuring that the 3Rs are fully implemented, that experimental protocols are properly constructed and that there is a coherent plan of work.

91. In other cases, however, applications will have been subjected to little or no previous independent scientific scrutiny. In this situation the ERP should give more consideration to scientific validity as part of its cost/benefit analysis.

92. It is important to appreciate the difference between what funding bodies require and what a project licence application requires. Applicants must also satisfy the Secretary of State that the animal welfare costs have been minimised – and ERP should play an active part in ensuring that this requirement is fully met.

93. It should also be noted that a project licence may describe work funded by several funding bodies or it may anticipate work for which funding has yet to be secured.

94. Good examples of ERP making positive contributions and adding value, by operating at levels not already the province of others rather than duplicating activities already undertaken by others, were encountered. For example, ERPs at some contract research organisations focusing and engaging with scientists on a ‘contract-by-contract’ basis, and some research institute ERPs undertaking effective ‘study-by-study’ scrutiny and support.

95. Some feel that an indirect measure of the success of this function of an ERP is that it should achieve a significant number of ‘Right First Time’ project licence applications, although in reality some opportunities for additional improvements are almost always likely to be identified when the Home Office scrutiny takes place. If an establishment has made a significant investment in ERP, and applicants are benefiting from the advice and support provided, then applications and amendments are likely to be more readily assessed by the Home Office.

96. Instead of perceiving the ERP as ‘doing the Home Office’s work’, it would be more correctly viewed as the ERP making the establishment’s resources and expertise available to the prospective project licence holder to produce requests for authorities that have been designed, refined and presented to the best of the establishment’s ability.

97. Variations in the way this part of the process was constructed and operated were seen between establishments, though all conformed to the Process Statement. These variations normally related to the size and type of establishment and were intended to address local needs.

98. A common element in all effective ERPs, and the factor believed to be essential to their successful operation, is that scientists should seek and obtain professional advice from the NVS and the NACWO early in the planning cycle – indeed, as soon as they have reason to believe that animal studies may be needed as part of their programme of work.

99. In some establishments an individual has been identified and trained to assist scientists prepare applications, and to facilitate interaction with the NVS and NACWO. At this preliminary stage there may or may not be contact with a statistician, an ‘information scientist’ (regarding alternatives) and the Inspectorate. Without exception the applicants interviewed in the course of this review testified to the value of this early consultation and the helpfulness, and value, of the advice given. They recognised and acknowledged that it is at this early stage that expert input can best be incorporated into plans for animal use.

100. This preliminary consultation is strongly endorsed, though it is clear that the NVS and NACWO must understand what the scientist is trying to achieve. To miss or be denied the opportunity to advise or to give poor advice, at this stage is to run a high risk of the resulting proposal being substandard and requiring subsequent refinement.



101. Within ERPs two main means of scrutinising proposals for animal use have developed. In both instances outputs tend to be advice to both applicants and certificate holders:

101.1 in some larger establishments small groups have been established to screen proposals for animal use and to deal with the more straightforward requests, passing the more significant or contentious items to a larger group for further consideration, and reporting all actions to the larger group;

101.2 in smaller establishments, this tiered approach may not be necessary and a single mechanism may suffice.

102. Applicants consistently applaud input from the NVS and NACWO but are sometimes critical of the contribution of others involved in the process.

103. There are always further changes that might be made to an application. However ERP committees considering requests almost ready for submission to the Home Office should recognise when a satisfactory application has been produced, and recognise and acknowledge the considerable work that is done earlier in the process as the proposal is developed and drafted.

104. Some ERPs do not involve the applicant in group/committee meetings and thus can lose time in waiting for supplementary information from applicants that cannot be considered until the next meeting.

105. Other processes have avoided or solved this problem by having the applicant in attendance to present the application to the meeting and to answer any questions that arise.

106. Some ERPs appoint a 'champion' to present the application to the meeting. Others systems use a champion skilled in extracting the salient points from the application, with the applicant present to correct any misrepresentation or to answer any questions that are raised. Most applicants interviewed would rather champion their own application as they know most about it, and if an application fails they cannot blame others for not making the best case.

107. A further element that has been found to be vitally important is the 'lay summary'. The current project licence application form asks for a summary at Section 17a, and the notes to applicants suggest that this may be used as a lay summary in the ERP. Some ERPs find that this is sufficient but many require a longer, more detailed lay summary to be provided.

108. Lay summaries have virtue in providing a précis of the work that can be understood by all of those involved in the process, and requiring that the applicant set out the rationale for the use of animals in non-scientific terms. The use of such material has also allowed establishments to build up a set of summaries that may be of value in preparing

an overview of animal use at the establishment. ERPs should reject lay summaries if they fail to provide the information required in language that all key participants can understand.

109. All ERPs should have a fast-track route for the consideration of amendments, particularly those that incorporate refinements to animal use or prevent animal wastage. ERPs should facilitate, not delay, requests that would further refine animal use.

110. Some establishments have developed criteria that determine whether or not an amendment should be fast-tracked. These criteria can be so strict that very little qualifies, and others seem to some to err on the permissive.

111. Fast-tracking processes typically involve consideration being given to suitable requests by the NVS, NACWO and others, with the decisions taken being recorded and reported centrally. The responsibility lies ultimately with the certificate holder to monitor the operation of this part of the ERP, and to provide feedback through the core committee to advise the named persons (and the others involved in the fast-track system) if inappropriate action is being taken.

112. The Home Office has always emphasised that ERP is a process and not an event, that should be implemented effectively and efficiently, and that appropriate use should be made of modern methods of communication. When e-mail is used by a group/committee, it is important that all the members of the group/committee are copied into all the exchanges. For each to respond in isolation, unaware of the advice and comment being offered by others, is counter-productive.

113. Despite a commitment to modern methods of communication, many ERPs report that members work together best when required to meet round a table, suitably briefed with the relevant papers in advance, preferably with the applicant in attendance, to discuss the application.

**ERP Function 2 (Process Statement Annex 7.3 + 7.4 + 7.5 + 7.6 + 7.7)**

*To provide an opportunity for discussion and a source of support, advice and awareness. This includes ensuring staff are kept up to date, best standards of care and accommodation are sought, managerial systems are appropriate, staff (including personal and project licence holders) are trained and competent, general aspects of the 3Rs are considered.*

114. The volume of, and the pressure to process, applications for and amendments to project licences has inevitably fostered the impression in some establishments that that is the most important task of the ERP. While this will remain a large proportion of the ERPs' work at many establishments, ERPs should not lose sight of Functions 2 and 3.

115. It was a common finding that establishments were attending to the items in Function 2, but through systems and structures other, and less conspicuous, than those dealing with proposals for animal use (see Part C, Report of Site Visits). Due to this separation of functions, the ERP was often not getting credit for the work done by less visible means on these more general issues.

116. It is not essential that ERPs deal with all three functions in single committees or processes, but certificate holders must ensure that all three functions are properly addressed and that there is adequate reporting and co-ordination of the outputs.

117. Where ERPs have realised that they have this more extensive remit imaginative and beneficial practical outputs have been delivered.

- ERP has been a powerful tool in helping to plan and find the large capital sums needed for new animal facilities.
- ERPs have played a part in encouraging clients to provide additional information on substances to be tested by some contract research organisations.
- ERPs have in some cases required that all potential project licence applicants, including those seeking to replace existing project licences, and all deputy project licence holders should undertake module 5 training.
- ERPs have set out the terms on which the establishment's employees shall work on animals when working in foreign locations or when doing collaborative work with other UK research groups.
- ERPs have drawn up guidance for non-licensed animal work.
- Some establishments have staged informative seminars and other awareness raising events for animal users on diverse subjects including the drafting of project licence applications.
- ERPs have co-ordinated applications for personal licences using a lexicon for techniques and have ensured appropriate supervision and training.
- Production schedules, both of conventional animals and genetically modified animals, are reviewed and optimised.
- The significance of transportation of animals (and embryos) to/from the establishment has been discussed in the context of the cost/benefit analysis.
- An interest has been taken in the standards and practices at the breeders and suppliers from which animals are purchased.

118. Lay members of the ERP who have visited animal facilities have been impressed by the standard of accommodation and care. They found such visits of great value in visualising how animals are used, the standards of care and accommodation provided, and in understanding the consequences of the regulated procedures performed. Consideration should be given to visits by those involved in ERPs to the establishment's animal facilities.

119. Some establishments are still very cautious about advertising the fact that they conduct experimental animal work. Nevertheless establishments should consider methods by which the work of ERPs might be more widely known and appreciated.

**ERP Function 3. (Process Statement Annex 7.1 + 7.4)**

*Retrospectively review ongoing projects, promoting the development and uptake of the 3Rs.*

120. In some establishments retrospective reviews (of completed work or of projects in progress) have only been introduced relatively recently. Some establishments have developed structured proforma to aid the project licence holder to assemble the information required for the ERP review.

121. Retrospective review seeks to look back on the animal welfare costs encountered and benefits realised. This permits assessment of the extent to which the original assumptions, including the severity limit of protocols, were correct when the request for authority was originally considered, and to consider if additional 3R strategies can be identified and incorporated. This information is of value to licensees and the ERP in planning future work and, as ERP records are available to the Inspectorate, it may also influence future Home Office assessments.

122. All project licensed work should be subject to periodic local review – that is, as a minimum, scrutiny by project licence holder, personal licensees, NVSs and NACWOs of the animal welfare problems and the outcomes of the procedures as they have been applied, with feedback to the full ERP.

123. The Home Office Process Statement gives ERPs flexibility in deciding when and how project licensed work should be reviewed. ERPs should not be committed to review all licensed work to the same schedule.

124. Some establishments have used the submission of a licence amendment as the trigger to carry out a review of a project. The benefits of such a routine have to be balanced against the irregularity (or in some cases the frequency and regularity) with which amendments may be required, and the additional administrative burden this imposes on the project licence holder and those involved in the ERP.

125. Provisional review dates might best be identified by the ERP when advising the certificate holder on the suitability of the application. The timing of the review should vary with the nature, novelty and severity of the procedures and the plan of work.

126. Certificate holders and ERPs might benefit from holding awareness-raising events or workshop to consider how retrospective reviews might best be performed within their establishments.

### **Additional availabilities**

127. Certificate holders sign a declaration at the end of each project licence application confirming that the application has been considered by the ERP. The Home Office cannot register an application unless this declaration has been completed.

128. When multiple licence availabilities are requested, a separate project licence application form Section 12 must be counter-signed by the certificate holder of each additional establishment at which availability is sought to confirm that it has been considered by the local ERP. The process of having to pass through more than one ERP in order to have additional availabilities approved is reported as one cause of extended delays in preparing applications for submission to the Home Office.

129. Certificate holders have, and must retain, the right to consider any use of protected animals at their establishment by those based at other establishments. Certificate holders have the right, if they so wish, to reject such proposals.

130. However, where the establishments involved have close ties it might be possible, and there are precedents, for the respective ERPs to agree 'mutual acceptance' of ERP recommendations. Alternatively, there might be an overlap in the personnel involved in the two ERPs, or two or more ERPs might consider the request simultaneously. Another option might be for the ERP at the availability to restrict itself to considering only the protocol(s) and the related justification(s) to be exercised at the relevant establishment.

131. The essential principles are that the respective ERPs may, subject to Home Office approval, agree arrangements to deal effectively and efficiently with requests for multiple availabilities; but each establishment must be allowed to act autonomously if it so wishes.

132. The Inspectorate is re-examining the Home Office practices in handling additional availabilities in order to ensure that the Home Office processes are efficient and effective.

### **Involvement of the Inspectorate with ERPs**

133. One of the 'frequently asked questions' encountered during the review was the role the Inspectorate plays in relation to the work of ERP.

134. The Home Office Process Statement signalled that the Inspectorate would abstain from detailed negotiations of technical authorities until applications had completed the ERP, in order to allow ERPs to become established and fulfil their role in supporting applicants to develop and refine proposals for animal use. There was concern in some quarters that comment from the Inspectorate on late-stage draft applications might be used by prospective project licence applicants to try to short-circuit or influence the view taken by their ERP.

135. Nevertheless the Inspectorate was still available to advise applicants at the earliest stages on the scope, structure and format of, and possible contentious issues relating to, potential applications. Inspectors were encouraged to attend ERP meetings periodically, primarily as observers and to provide advice on Home Office policy if required, but not to play any part in the decision making process.

136. We are satisfied that this policy assisted ERPs to become firmly established with a confidence and vigour that will not be easily displaced. Early consultation between applicants and the Inspectorate on the scope and format of applications is to be strongly encouraged. It might in some circumstances be appropriate for the inspector to be involved in the preliminary discussions between the applicant, the NVS and the NACWO.

137. This review has confirmed that early input from the Inspectorate is valued, and does not compromise the operation of ERPs: this practice should continue. It is also expected that Inspectors may, from time to time, continue to attend some formal meetings of ERPs and, if required, contribute technical advice.

138. Formal consideration and assessment of a project licence application by the Inspectorate will continue to begin only after the application has completed the ERP, is counter- signed to that effect by the certificate holder, and submitted to the Home Office.

139. The Inspectorate, certificate holders and ERPs need to consider how constructive feedback can best be given when, after applications have successfully completed the ERP, changes are required when they are assessed by the Inspectorate. It is important that appropriate and timely feedback is given, as the lessons learned may play an important role in ensuring the effectiveness and 'continuous improvement' of the ERP.

### **The paperwork and the paper-trail**

140. The preparation of a project licence application is a major undertaking. Much of the information required is supplied in the form of lengthy narratives. There is no intention or desire on the part of the Home Office to elicit more information than is required for the regulatory assessment. Professional judgement is required both on the part of applicants and the Inspectorate to ensure that relevant material is presented concisely, and that irrelevant information is not supplied. As judgement must be exercised on a case-by-case in determining what must appear on any application, we do not believe it is possible to be more prescriptive in the Notes to Applicants about the information that is required.

141. During the course of the review a list was made of the ten most common failings seen by the Inspectorate in current project licence applications (see Part D). They all relate to sections that require a narrative response on top of which professional judgement must be overlaid: and all cases the errors would not occur if proper use was made of the current Notes to Applicants. The available evidence suggests not that there is any significant deficiency in the Notes, rather it would seem that they are not being used as intended.

142. In order to help in the completion of the application, including those areas in which a narrative response is required, as much guidance as possible has been incorporated in the current project licence application form and Notes to Applicants. The Inspectorate is also available to give advice on a case-by-case basis.

143. One of the challenges in preparing a project licence application is to achieve an acceptable balance between detail and flexibility. Applicants are encouraged by the Home Office to construct 'low maintenance' project licences. However it must be clearly understood that 'low maintenance' applies mainly, if not entirely, to the protocols. 'Low maintenance' is not synonymous with a dearth of information, rather it relates to forms of words that allow a reasonable degree of technical flexibility within the severity limit of the protocol. The Inspectorate would support and encourage awareness raising activities in this area.

144. All designated establishments visited during the ERP review were able to provide documentation associated with the consideration of a sample of project licence applications. This documentation ranged from the copious and detailed, to brief and succinct notes of transactions. There was no obvious correlation between the bulk of the documentation and the demonstrable value added by the ERP.

145. A conspicuous feature of the documentation from some ERPs was the large amount of technical detail that was being supplied to, revisited and discussed at formal ERP meetings. Often these issues had previously been discussed and resolved in earlier discussions between the applicant, the NVS and/or the NACWO. It was difficult to see what value subsequent further deliberations within larger and less technically-expert groups contributed.

146. The full ERP should appreciate the value of the preliminary consultations between applicants and named persons, but must satisfy itself that there has been effective professional input at that early stage and that the advice offered has been taken. The full ERP consultation would then be bettered focused on the other ERP functions.

147. The use of structured templates may be useful in recording the input of the various ERP stakeholders, and the outputs of the process. Examples of templates were found that were informative, quickly completed, and recorded useful information. However, other templates were seen that required extensive narrative responses, reproducing material already contained in the draft project licence application. With the exception of the preparation of a lay summary, applicants should not be expected to restate on a proforma material that can be read on the form of application. Those involved in the ERP should become familiar with the structure and content of the project licence application.

148. Appendices and addenda are increasingly attached to project licence applications submitted to the Home Office. Some clearly assist the Home Office assessment of applications or help the project licence holder to manage the programme of work (e.g.

detailed list of humane endpoints linked to protocol severity limits, tables of limit volumes). Others seem primarily to facilitate completion of the ERP.

149. There is a need for some applicants to be better informed about the drafting of project licence applications. As previously stated, most common faults would be avoided if proper use was made of the project licence form Notes to Applicants. ERPs should ensure applicants become better informed. Prospective applicants should also be aware of the role the ERP can play in providing support and assistance.

150. We would welcome and support awareness-raising initiatives in this area, although at present few outside the Inspectorate have the knowledge and experience of project licence assessment to provide training or more advanced advice in this specialist field.

151. We consider it to be good practice for ERPs to maintain a ‘chronological index, or case-record, of the passage of project licence applications or amendments through the ERP. In this way it should be possible to track associated documents, to estimate the time and resources devoted to the different parts of the process, to determine the value added, and to consider if the processes can be further improved.

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**152. The insights to ‘perceived contemporary best practice’ offered above are made as a result of an extensive and comprehensive review of the ERP. They are intended to provide pointers to make the ERP more efficient and effective. Certificate Holders, and others involved with ERPs, are invited to give them serious consideration, and to adapt and adopt any practice(s) that they consider would enhance their ERP.**

**Quote from a site visit:**

***“The ERP has been too successful to be dismantled”***