



Perceptions of the ERP – summary of discussions at the 2007 RSPCA Lay Members Forum

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1. Introduction

This report presents a summary of the main points from discussion sessions at the 2007 Lay Members Forum. The discussions focussed on participants' perceptions of how local Ethical Review Processes (ERPs) fulfil the core functions defined by the Home Office (1998) (see Box 1).

During the Forum there were two activities:

- **a working group session** where participants discussed how their ERP dealt with each function, whether there were any difficulties, and the contribution lay member's felt they had been able to have;
- **a brief, informal survey** (the survey form is included as Appendix 1 to this document).

Box 1: The seven core functions of the ERP

The ERP should (where appropriate):

1. Promote the development and uptake of reduction, replacement and refinement alternatives in animal use, where they exist, and ensure the availability of relevant sources of information;
2. Examine proposed applications for new project licences and amendments to existing licences, with reference to the likely costs to the animals, the expected benefits of the work and how these considerations balance;
3. Provide a forum for discussion of issues relating to the use of animals and consider how staff can be kept up to date with relevant ethical advice, best practice, and relevant legislation;
4. Undertake retrospective project reviews and continue to apply the 3Rs to all projects, throughout their duration;
5. Consider the care and accommodation standards applied to all animals in the establishment, including breeding stock, and the humane killing of protected animals;
6. Regularly review the establishment's managerial systems, procedures and protocols where these bear on the proper use of animals;
7. Advise on how all staff involved with the animals can be appropriately trained and how competence can be ensured.



Function 2 was omitted from the working group session, since this issue had been discussed at previous Lay Members Forums and we felt it was more important to see how the other tasks were being dealt with. In the survey, participants were asked whether *they were aware* that their own ERP performed each of the 7 functions and whether they were satisfied with how each function was addressed. They were not asked *whether the function was performed* since it was taken as read that the Home Office guidelines would be followed. [Note that the survey represents a 'snapshot' of participants' impressions and is not intended as a comprehensive review of ERP functioning.]

Responses from both activities are collated and tabulated in Sections 2 and 3 below. The comments received will be fed into future discussions on the development of good practice guidelines. However, we are circulating the main points now, since lay and other ERP members may find them useful in initiating discussions on both the effectiveness of their own ERP and their individual role within the process.

2. Lay Member Forum participants and respondents to the survey

The Forum was attended by 69 participants who took part in the discussion session. Forty-three of these subsequently completed the survey form. All were associated with ERPs in some capacity. The majority comprised lay members, but other participants were Named Animal Care and Welfare Officers (NACWOs), Named Veterinary Surgeons (NVSs) and persons with administrative roles within their ERP.

Figure 1. Participant Affiliations

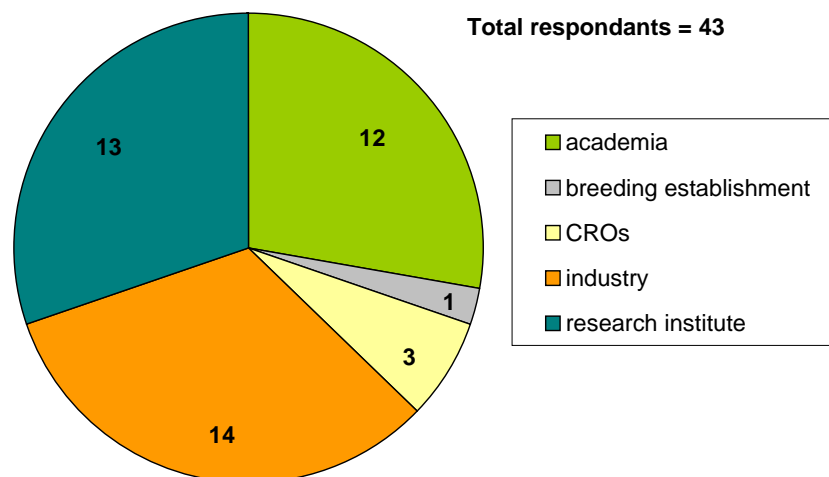


Figure 1 shows the types of establishments that the survey respondents were associated with. (This also reflects the participants in the meeting as a whole). All types of establishment were represented, with the largest numbers of participants associated with industry, academia and research institutes. Since there was only one breeding establishment represented, survey responses from this participant were combined with those from industry in the summarised survey results that follow.

3. Survey results and discussion group feedback

Function 1: Promoting the development and uptake of reduction, replacement and refinement alternatives in animal use, where they exist, and ensuring the availability of relevant sources of information.

Survey question: Are you aware that your ERP performs Function 1?

Affiliation	Yes	No	Other Response	No Response
Academia	12	0	0	0
CRO	3	0	0	0
Industry	15	0	0	0
Research Institute	13	0	0	0
Total	43	0	0	0

Survey question: Are you satisfied with the way that your ERP performs Function 1?

Affiliation	Yes	No	Other Response	No Response
Academia	6	0	"Mostly" "Yes/No"	4
CRO	2	0	0	1
Industry	7	1	"partly" "50/50"	4
Research Institute	9	2	"mostly"	1
Total	24	3	6	10

Comments relating to how Function 1 is carried out

	Comments
ERP mechanisms	<p>Several mechanisms for dealing with the 3Rs within the ERP were described including:</p> <ul style="list-style-type: none"> • A dedicated subcommittee or group to address the 3Rs; • Input from the NACWO and NVS who report to the main ERP; • An <i>in vitro</i> specialist and/or a statistician on the main committee; • A standing 3Rs item on the agenda of every meeting. <p>Other useful activities:</p> <ul style="list-style-type: none"> • In-house seminars on issues such as experimental design run by the biological services department; • Group activity looking for opportunities for further application of the 3Rs when carrying out retrospective reviews; • Information provided through an intranet which links to various 3Rs resources; the NC3Rs newsletter was highlighted and information circulated re their 3Rs grants; • Scientists are encouraged to attend 3Rs conferences; • An in-house 3Rs prize is awarded annually; • Breeding wastage is reduced by better communication between groups and by following the LASA guidelines (LASA, 1998).



	Comments
Difficulties encountered	<p>There were more positive than negative comments on how this function is carried out, but some concerns noted were:</p> <ul style="list-style-type: none">• It is difficult to deal with this in large organisations in academia;• Best practice is discussed in meetings, but meetings are not very frequent;• The 3Rs need to have more focus/coverage generally;• It is difficult to make people read things; refinements are not published in journals that scientists read;• 3Rs activities are limited by time constraints;• Replacement is not discussed within the ERP.
Lay member input	<p>There were not many examples of lay member input other than:</p> <ul style="list-style-type: none">• Lay members want to make sure they understand the numbers of animals used in project applications and the justification for these, and ask questions accordingly;• Lay members also engage in debate on the species used;• The Lay Members Forum provides ideas and advice to input to the ERP, as does the RSPCA website.



Function 2: Examining proposed applications for new project licences and amendments to existing licences, with reference to the likely costs to the animals, the expected benefits of the work and how these considerations balance.

Question: Are you aware that your ERP performs Function 2?

Affiliation	Yes	No	Other Response	No Response
Academia	11	0	0	1
CRO	3	0	0	0
Industry	13	1	1	0
Research Institute	13	0	0	0
Total	40	1	1	1

Question: Are you satisfied with the way that your ERP performs Function 2?

Affiliation	Yes	No	Other Response	No Response
Academia	7	0	0	5
CRO	0	2	0	1
Industry	9	0	0	6
Research Institute	10	1	0	2
Total	26	3	0	14

Comments relating to how Function 2 is carried out

The meeting did not dedicate much time to this issue and it was purposely excluded from the working-group session. This was because it had been discussed in previous Lay Members Forums and so it was felt that it was more important to allow more for discussing the other functions. Therefore, just a few comments are recorded.

Many participants would like a clearer guide to:

- Defining the harms and benefits of a project as many lay members find the harm/benefit judgements difficult. This is a recurring theme at every Lay Members Forum we hold.
- How the judgement of the ERP related to that of the Home Office. It was stressed that the ERP should 'add value' in that it was making judgements in the context of the individual establishment and the nature of work that establishment could, and would be prepared to, do taking into account all the local issues. Setting objectives on what the ERP expected to achieve from the project review would be a helpful first step in resolving the confusion and preventing conflicts arising between the ERP and the Home Office requirements.

Some participants said it would be helpful to review the way that researchers present information to the ERP to ensure it is more 'user friendly'. Some were concerned that the project licence applicant did not attend the ERP meeting, that there was little active discussion, and that there was no real protocol for how people should put questions to the applicant or the ERP. Senior researchers in academia were identified as being most difficult to question because of the establishment hierarchy.

Some members said that most of the questions and discussion occurred before an application came to the ERP either by email or within subcommittees or between individuals.

Some participants commented that it was important to have experts around the table and 'lots of lay members'.



Function 3: Providing a forum for discussion of issues relating to the use of animals and considering how staff can be kept up to date with relevant ethical advice, best practice, and relevant legislation.

Question: Are you aware that your ERP performs Function 3?

Affiliation	Yes	No	Other Response	No Response
Academia	10	1	0	1
CRO	3	0	0	0
Industry	14	0	"to a limited extent"	0
Research Institute	13	0	0	0
Total	40	1	1	1

Question: Are you satisfied with the way that your ERP performs Function 3?

Affiliation	Yes	No	Other Response	No Response
Academia	4	3	"partly"	4
CRO	2	0	0	1
Industry	9	2	0	4
Research Institute	9	3	0	1
Total	24	8	1	10

Comments relating to how Function 3 is carried out

	Comments
ERP mechanisms	<p>Industry was thought to be better at covering this activity than academia.</p> <p>The comments suggested that members interpreted this function as something that happened within the ERP itself, rather than as a discussion forum to which staff generally could contribute. In this context it was felt there was some overlap with Function 1 (promoting the 3Rs) and Function 7 (training). Bearing in mind this interpretation the ways this function is dealt with are:</p> <ul style="list-style-type: none"> • Discussion within the main committee often in the context of licence applications and, where they exist, through sub-committees for animal welfare, housing, 3Rs, and the project licence holders group. All of these may prompt general discussion. • Discussion within an intranet forum; • Through regular seminars or presentations on specific topics (e.g. CO² euthanasia, new procedures or protocols) for ERP members and/or the whole establishment. This could include both internal and external speakers.



	Comments
Difficulties encountered	<p>Most of the difficulties identified for this function relate to the problems of discussion within an ERP meeting, and in particular to discussion of a project licence application. Examples of this include:</p> <ul style="list-style-type: none"> • Discussion within the ERP is limited by time, frequency of meetings, the influence of the chair, and lack of encouragement for participants to engage; • Lay and other members may feel intimidated either within the committee (for example by senior professors) or within the management hierarchy, and are afraid of raising issues; • Lip service is paid to openness, but discussion is not really encouraged; it needs to be much more open; it needs to be better structured <p>Only one comment appeared to relate to the wider implementation of Function 3 and that was that general discussion of ethical issues is hard to deal with in a large establishment</p>
Ideas to improve the process	<ul style="list-style-type: none"> • Provide an 'ERP box' for staff to suggest topics for discussion by the ERP itself or for staff generally. • Ensure a good (interested and fair) ERP chair. • Write to the chair with issues of concern, or discussion topics. • Provide an in-house newsletter. • Invite different people to ERP meetings to advise/inform both them and the ERP. • Make sure discussion is openly encouraged. • Ensure there is more interaction with project licencees (at the application stage and more generally).
Role of lay member	<p>Lay members only commented on their input to the discussion of ethical issues that took place within their own ERP, rather than more widely within the establishment. Suggested input was:</p> <ul style="list-style-type: none"> • Ask questions and so make things more transparent; • Write to the chairman and ask for issues to be raised. • Contribute to the in-house newsletter.

Function 4: Undertaking retrospective project reviews and continuing to apply the 3Rs to all projects, throughout their duration.

Question: Are you aware that your ERP performs Function 4?

Affiliation	Yes	No	Other Response	No Response
Academia	8	3	"partly"	0
CRO	3	0	0	0
Industry	12	2	0	0
Research Institute	9	1	"in theory" "not yet"	1
Total	32	6	4	1

Question: Are you satisfied with the way that your ERP performs Function 4?

Affiliation	Yes	No	Other Response	No Response
Academia	4	1	"could be improved" "not seen yet"	5
CRO	0	2	0	1
Industry	5	2	"partly" "no, except animals used"	6
Research Institute	4	5	0	4
Total	13	10	4	16

Comments relating to how Function 4 is carried out

	Comments
ERP mechanisms	<p>Few participants were clear what was expected from retrospective review, and almost none were aware of the LASA guidance on retrospective review (LASA, 2004) that has been circulated to certificate holders. As was discussed in the LASA guidance, different ERPs have developed different processes. Some examples follow.</p> <p><i>Timing:</i></p> <ul style="list-style-type: none"> • May be yearly, half way through a project, in the penultimate year, at the end of the project, or triggered by unexpected effects, or specific concerns such as humane endpoints. • Some participants felt retrospective review was the role of amendments and discussion of these. <p><i>The process may be carried out through:</i></p> <ul style="list-style-type: none"> • A retrospective review form • An annual report from project licensees • A termly report from department heads, and 'ongoing reports' of experiments • A full day of annual reviews of projects by the ERP • A personal and project licensee day <p><i>Points reviewed:</i></p> <ul style="list-style-type: none"> • Actual versus predicted harms (including severity) and benefits considered • Lessons learnt e.g. what went well/wrong with protocols and what could be learnt for the future • Opportunity for further application of each of the 3Rs and dissemination of best practice • Comments from the NACWO and NVS • Training and management issues



	Comments
Difficulties	<ul style="list-style-type: none"> • There are no clear guidelines (locally or nationally) • It is harder to manage and is less structured than review of the project licence application • It takes time and resources • It is not taken seriously (particularly by researchers in academia) because they see no value; it is just another form to fill in or process to go through <p>The problems identified mainly stem from the fact that the objectives and benefits are not clear – yet both welfare and science can benefit if the review is done well.</p>
Ideas to improve the process	<ul style="list-style-type: none"> • ERPs need to be very clear about the purpose and benefits of retrospective review, how it adds value to science and welfare, and about how it is to be done. The LASA report and poster on this subject provide useful guidance, including questions to discuss. We will not repeat the information in this document but refer the reader to the LASA references (LASA, 2004; Jennings <i>et al.</i>, 2007).
Lay member input	<p>Few lay members had carried out a retrospective review and this was reflected in the number of comments received about their role.</p> <ul style="list-style-type: none"> • Some felt it was difficult to come up with appropriate questions • Some welcomed an opportunity to see the project licence holder and for the licence holder to give a short summary and answer pre-set questions on animal numbers and alternatives. • Raising animal welfare issues when the researcher focussed solely on the scientific process was important – the ethical issues can get lost without this different perspective • Supporting the named persons and making sure their comments were taken notice of is also important. • The LMF was mentioned as a source of ideas for points to raise.

Function 5: Considering the care and accommodation standards applied to all animals in the establishment, including breeding stock, and the humane killing of protected animals.

Question: Are you aware that your ERP performs Function 5?

Affiliation	Yes	No	Other Response	No Response
Academia	10	1	0	1
CRO	3	0	0	0
Industry	14	0	"to some extent"	0
Research Institute	13	0	0	0
Total	40	1	1	1

Question: Are you satisfied with the way that your ERP performs Function 5?

Affiliation	Yes	No	Other Response	No Response
Academia	7	1	"yes for care, no for killing"	3
CRO	1	1	0	1
Industry	9	0	"partly"	5
Research Institute	11	0	0	2
Total	28	2	2	11

Comments relating to how Function 5 is carried out

	Comments
ERP mechanism	<p>This function seemed relatively straightforward to interpret and implement. It was dealt with by one or more of the following activities, with a number of participants stating that they felt the standard of attention was high:</p> <ul style="list-style-type: none"> • Within the whole ERP (sometimes occasionally, sometimes at every meeting as a standing item), • By an ERP subcommittee • By an animal welfare steering committee • Largely devolved to NACWOs • Ongoing within the animal unit with reports to the ERP • Through an 'animal welfare ombudsman' • Tours of facilities for ERP members
Difficulties	<ul style="list-style-type: none"> • Little discussion on humane methods of killing • Conflict perceived between best practice for welfare and the requirements of the science • Ensuring good communication between multi-sites and adoption of best standards throughout • Having enough resources and sufficient well trained staff • Time available for ERP members to visit the facilities • High security housing can limit visitor access, as do multi-site facilities
Improvements	<ul style="list-style-type: none"> • However housing, care and euthanasia are dealt with, there should be a standing item on the agenda of main ERP meetings to discuss this
Lay member input	<ul style="list-style-type: none"> • Raise issues such as CO² euthanasia, reporting back from the LMF • Ask to see the animal units and talk to animal care staff



Function 6: Regularly reviewing the establishment's managerial systems, procedures and protocols where these bear on the proper use of animals.

N.B. Discussions during the forum highlighted that few people understood the true nature of this function and therefore the survey results relating to this question should be interpreted cautiously.

Question: Are you aware that your ERP performs Function 6?

Affiliation	Yes	No	Other Response	No Response
Academia	4	4	"yes and no" "not sure" "partly"	1
CRO	1	2	0	0
Industry	10	3	"?" "once only"	0
Research Institute	6	4	"not in my experience" "not sure"	1
Total	21	13	7	2

Question: Are you satisfied with the way that your ERP performs Function 6?

Affiliation	Yes	No	Other Response	No Response
Academia	5	2	0	5
CRO	1	1	0	1
Industry	5	1	? "partly"	7
Research Institute	3	2	"mostly"	7
Total	14	6	3	20

Comments relating to how Function 6 is carried out

Most participants seemed unsure what this function was intended to cover and so were unsure whether it was addressed by their ERP. A number of participants questioned whether managerial systems within the establishment, as a whole, was really the ERP's remit.

The function does refer to "*managerial systems, procedures and protocols where these bear on the proper use of animals*". This could be interpreted, for example, as relating to building and management of animal facilities, whether the establishment has a Home Office Liaison Officer, how many veterinarians are employed, staff recruitment, allocation of resources or security issues. Such matters have a bearing on the work of the ERP and it might want to express a view on these, so there needs to be good lines of communication between an establishment's management and the ERP.

However, the main take home message from discussion of this function is that the meaning needs to be better defined.

Function 7: Advising on how all staff involved with the animals can be appropriately trained and how competence can be ensured.

Question: Are you aware that your ERP performs Function 7?

Affiliation	Yes	No	Other Response	No Response
Academia	3	4	"yes and no" "not sure" "kept informed"	2
CRO	1	2	0	0
Industry	9	6	0	0
Research Institute	9	3	"sometimes"	0
Total	22	15	4	2

Question: Are you satisfied with the way that your ERP performs Function 7?

Affiliation	Yes	No	Other Response	No Response
Academia	3	3	0	6
CRO	1	2	0	0
Industry	3	5	"partly"	6
Research Institute	5	3	"not always"	4
Total	12	13	2	16

Comments relating to how Function 7 is carried out

	Comments
ERP processes	<p>Participants generally agreed that training (including the Home Office modules and CPD) was important and could be a key welfare issue. However, few of them thought their ERPs dealt directly with this topic, believing that other departments or facilities covered it. Where training was an issue it was dealt with by one or more of the following:</p> <ul style="list-style-type: none"> • The animal unit manager, NACWO and/or in some cases the NVS deal with training issues and report to the ERP • A dedicated training group feeds into the ERP • Management/management committees inform the ERP on training issues. • The ERP considers the need for training, but does not specifically advise on how this is done • Training is dealt with when issues bring it to the attention of the ERP • ERP members merely want reassurance that staff are competent and appropriately trained – particularly in relation to new techniques. The ERP only asks/checks for competence and is not involved with training <i>per se</i>. Training and competence is dealt with through training records • Courses in good technique are advertised on the Intranet
Difficulties	<ul style="list-style-type: none"> • Lack of clarity within the ERP as to who/what process is responsible for training issues. • Inconsistency in training and feedback to the ERP where an establishment has a number of animal units. • The lay member has to rely on one or two people for information



	Comments
Improvements	<ul style="list-style-type: none"> • Oversight of training should not duplicate a management process or an 'audit', or generate unnecessary paperwork. • Somebody (the laymember?) on the ERP should make sure the question: "are people getting the training they want/need?" is asked. • Evidence of training records should be made available on request (particularly where new techniques are proposed) • ERP members should be made aware of issues such as staff turnover that may have a bearing on training and competence. • The ERP should receive updates with examples of the courses and conferences that staff attend in relation to type of work undertaken at establishment. • Training for ERP members (as happens within NHS ethics committees) could be useful.
Lay member input	<ul style="list-style-type: none"> • Lay members are not the best people to advise on training but may be well placed to ask relevant questions. • It is important for lay members to have a thorough induction - most establishments have no such system and suddenly a new person appears around the table.

Overall summary of survey results

The survey responses shown in the previous tables for each individual function are summarised below to enable easy comparisons between them.

Function	Participants aware that ERP performs function	Aware participants that were satisfied with how function performed
1. Promoting 3Rs, ensuring information available	43/43 (100%)	24/43 (56%)
2. Examining harm/benefit of new licences, amendments	40/43 (93%)	26/40 (65%)
3. Providing a forum for discussion	40/43 (93%)	24/40 (60%)
4. Undertaking retrospective project reviews	32/43 (74%)	13/32 (41%)
5. Considering care & accommodation, humane killing	40/43 (93%)	28/40 (70%)
6. Reviewing managerial systems	21/43 (49%)	12/21 (57%)
7. Advising on staff training	22/43 (51%)	9/22 (41%)



3. Concluding comments

Participants in the LMF were enthusiastic about the ERP although some lay (and other) members are dissatisfied with the way some functions are addressed. Some reasons for this were given within the working group discussions and these will be clear from the tables above. However, it would have been interesting to consider in more detail what participants at the LMF actually *expected* from their ERP. We hope to explore this question in the future.

Generally, survey participants were aware of their ERP's role with respect to promoting the 3Rs, examining new licences, consideration of animal care and accommodation, and providing a forum for discussion, and this was also reflected in the group work. However, provision of a forum for discussion seemed to be interpreted as being within the ERP rather than within the establishment as a whole.

Only three out of four survey participants were aware of their ERP performing retrospective review, and only about half of the participants were aware that their ERP advised on staff training. From the discussion session it was clear that there is still confusion about how retrospective review should be carried out and what it is intended to achieve, and that more clarity and guidance on what is required might be helpful. The LASA guidance on Retrospective Review (LASA, 2004) has since been emailed to all participants, but raising its profile within ERPs more generally could be beneficial.

Different ERPs approach the seven core functions in different ways and sometimes there is a lack of clarity about what the ERP should be trying to achieve in each case. Individual ERPs may not have defined their own objectives for each function, partly because they are uncertain of what the Home Office expects. This can lead to duplication of effort, for example between the ERP and the Home Office Inspectorate when reviewing project licences, or to the setting up of unnecessarily time consuming processes. This is an issue that has been raised in work on the Home Office Simplification Plan report (Home Office, 2006).

The generation and publication of simple best practice guidelines relating to each function, which clarify the Home Office requirements and help ERPs develop their own objectives would be very beneficial. The RSPCA will be considering how best to progress the issues raised during 2008 and hopes to develop further guidance in conjunction with the LASA Education, Training and Ethics Section. We will also be completely revising the Lay Members' Resource Book and looking to widen its audience.

4. References

Home Office (1998) The Ethical Review Process

<http://scienceandresearch.homeoffice.gov.uk/animal-research/publications-and-reference/publications/guidance/ethical-review-process/ethicalprocess.pdf?view=Binary>

Home Office (2006) Home Office Simplification Plan

www.homeoffice.gov.uk/documents/ho-simplification-plan/ho-simp-plan?view=Binary

Jennings, M.J., Howard, B. & Berdoy, M. (2007) The value of looking back: Improving science and welfare through retrospective review. *LASA Forum*, Autumn edition p8

Soon to be available at www.lasa.co.uk



LASA (1998) The production and disposition of laboratory rodents surplus to the requirements for scientific procedures. A report of a LASA task force meeting.

LASA (2004) Guidance notes on Retrospective Review: A discussion document prepared by the LASA Ethics and Training Group

Available at: www.lasa.co.uk/position_papers/publications.asp

6. Acknowledgements

We would like to thank all of the attendees of the 2007 RSPCA Lay Members Forum for their valuable input both to the meeting and this survey

APPENDIX 1

The Seven Functions of the ERP

Your help in generating meaningful output from this session is much appreciated.
Please help us by completing this questionnaire.

The type of establishment you are involved with
e.g. CRO, academia, industry, research institute

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The Seven Functions

**Are you aware of your
committee performing
this function?
(Yes / No)**

**If yes, do you feel
satisfied in how this
function is addressed?
(Yes/ No)**

Function 1. Promoting 3Rs,
ensuring information available

Additional Comments:

Function 2. Examining
harm/benefit of new licences,
amendments

Additional comments:

Function 3. Providing a forum for
discussion

Additional comments:

Function 4. Undertaking
retrospective project reviews

Additional comments:

Function 5. Considering care &
accommodation, humane killing
Additional comments:

Function 6. Reviewing managerial
systems

Additional comments:

Function 7. Advising on staff
training

Additional comments:
