Guiding principles for Establishment Licence Holders/Named Persons responsible for compliance, Named Training and Competency Officers, Named Information Officers and Home Office Liaison Contacts working under the Animals (Scientific Procedures) Act 1986

LASA/LAVA/IAT

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Glossary

ASC	Animals in Science Committee
A(SP)A	Animals (Scientific Procedures) Act 1986
ASPeL	Animals (Scientific Procedures) e-Licensing
ASRU	Animals in Science Regulation Unit
AWERB	Animal Welfare and Ethical Review Body
CoP	Code of Practice for the Housing and Care of Animals
CPD	Continuing Professional Development
DOPS	Direct Observation of Practical/Procedural Skills training and assessment sheets
ELH	Establishment Licence Holder
The Guidance	Home Office Guidance on the Operation of the Animals (Scientific Procedures) Act 1986
HOI	Home Office Inspector
HOLC	Home Office Liaison Contact
HOLTIF	Home Office Liaison, Training and Information Forum
IAT	Institute of Animal Technology
LASA	Laboratory Animal Science Association
LAVA	Laboratory Animals Veterinary Association
NACWO	Named Animal Care and Welfare Officer
NIO	Named Information Officer
NPRC	Named Person Responsible for Compliance
NTCO	Named Training and Competency Officer
NVS	Named Veterinary Surgeon
PEL	Procedural Establishment Licence
PELh	Procedural Establishment Licence Holder, also referred to as ELH (or Named Person Responsible for Compliance)
PILh	Procedural Personal Licence Holder
PPLh	Procedural Project Licence Holder
Three Rs/3Rs	Replacement, Refinement and Reduction

Introduction

The Animals (Scientific Procedures) Act 1986 (as amended in 2012 to take account of the requirements of European Directive 2010/63/EU) requires that the following persons are identified on the Establishment Licence:

(i) **Named Person Responsible for Compliance (NPRC):**
Ensures that the requirements of ASPA and the conditions of the establishment licence are complied with. Where the PELh is an individual, ASRU expect that the person named as the PELh will also be the NPRC. However where the Establishment Licence Holder is a corporate entity it is necessary to appoint an individual to serve as the Named Person Responsible for Compliance. In this situation, they should be of similar standing as expected for a PELh in terms of authority and seniority and undertake similar training.

(ii) **Named Veterinary Surgeon (NVS):**
A designated veterinarian with expertise in relevant experimental animal medicine, charged with advisory duties in relation to the wellbeing and treatment of the animals. Exceptionally, a suitably qualified expert may be appointed where more appropriate.

(iii) **Named Animal Care and Welfare Officer (NACWO):**
Responsible for overseeing the welfare and care of the animals in the establishment.

(iv) **Named Training and Competency Officer (NTCO):** responsible for ensuring that staff are adequately educated, competent and continuously trained and that they are supervised until they have demonstrated the requisite competency.

(v) **Named Information Officer (NIO):** to ensure that staff dealing with animals have access to information specific to the species housed in the establishment.

The **NPRC, NTCO** and **NIO** are roles that were introduced after the legislation was amended in 2013.

– Establishments may also have a **Home Office Liaison Contact (HOLC).** Though not legally required, this administrative management position can act as the central point of communication with the Home Office and facilitate the smooth running of the licensing system in an establishment.

The Establishment Licence Holder (or NPRC where the Establishment holds the licence) is responsible for the appointment and performance of Named Persons (Section 2C Establishment Licence condition (PEL) 15) and has a key role in supporting the Named Persons and HOLC and determining **how** these role requirements can be achieved efficiently and effectively.

Ultimately the PELh/NPRC must satisfy themselves that the local systems developed by the Named Persons and the AWERB meet the requirements under the Act and help to maintain a Culture of Care.

One of the key tasks of the AWERB is also to support Named Persons (and other staff dealing with animals) on Animal Welfare, ethical issues and the provision of appropriate training. A good level of communication and engagement with the AWERB will help the NTCO, NIO and HOLC to fulfil their roles.

This LASA/LAVA/IAT guidance document is intended to assist individuals with responsibilities under or related to ASPA – whether new to their role or already carrying out their roles. It will also assist others such as the Establishment Licence Holder/NPRC, AWERB members, Named Persons, managers, etc., to understand the role of the NPRC, NTCO, NIO and HOLC and therefore how they can assist the individuals performing these functions.

Many individuals and bodies, including the AWERB, will be involved in determining how the Named Person roles work within each establishment's infrastructure. It is useful to document formal discussion and activities around establishing and reviewing these processes.

Key points:

– **Each Named Person needs to know their role and be able to effectively communicate as necessary with other Named Persons and others in the animal research community within the Establishment.**

– **Roles should be properly resourced and supported by senior management and AWERB.**

– **Establishment Licence Holders/NPRC should define and agree a functional framework for their own establishment so that all individuals with responsibilities under ASPA are aware of the role and responsibilities of the Named Persons.**

The Home Office Guidance on the Operation of the Animals (Scientific Procedures) Act 1986 (March 2014) (referred to in this document as the Guidance) provides guidance on the administration and enforcement of ASPA. This includes information and advice about how the Named Persons are required to discharge their duties under ASPA (see Chapter 8) and highlights their importance within the establishment to assist the Establishment Licence Holder (PELh) in fulfilling their responsibilities. The Guidance also makes suggestions on training (see Chapter 9).

The Institute of Animal Technology (IAT) and the Royal College of Veterinary Surgeons (RCVS) also provide their own guidance for NACWOs and NVSs respectively (see references).

The purpose of this LASA/LAVA/IAT document is to provide additional practical advice on how the roles of the NPRC, NTCO and NIO, as well as that of HOLC, can be implemented.

This guidance has been written and structured with the expectation that some readers may not necessarily read the entire document but may refer to specific sections relevant to their role. It will be reviewed and updated as experience of these roles develops.

Establishment Licence Holder (PELh)/

Named Person Responsible for Compliance (NPRC)

What is the job? What are the responsibilities?

Interactions of the PELh/NPRC
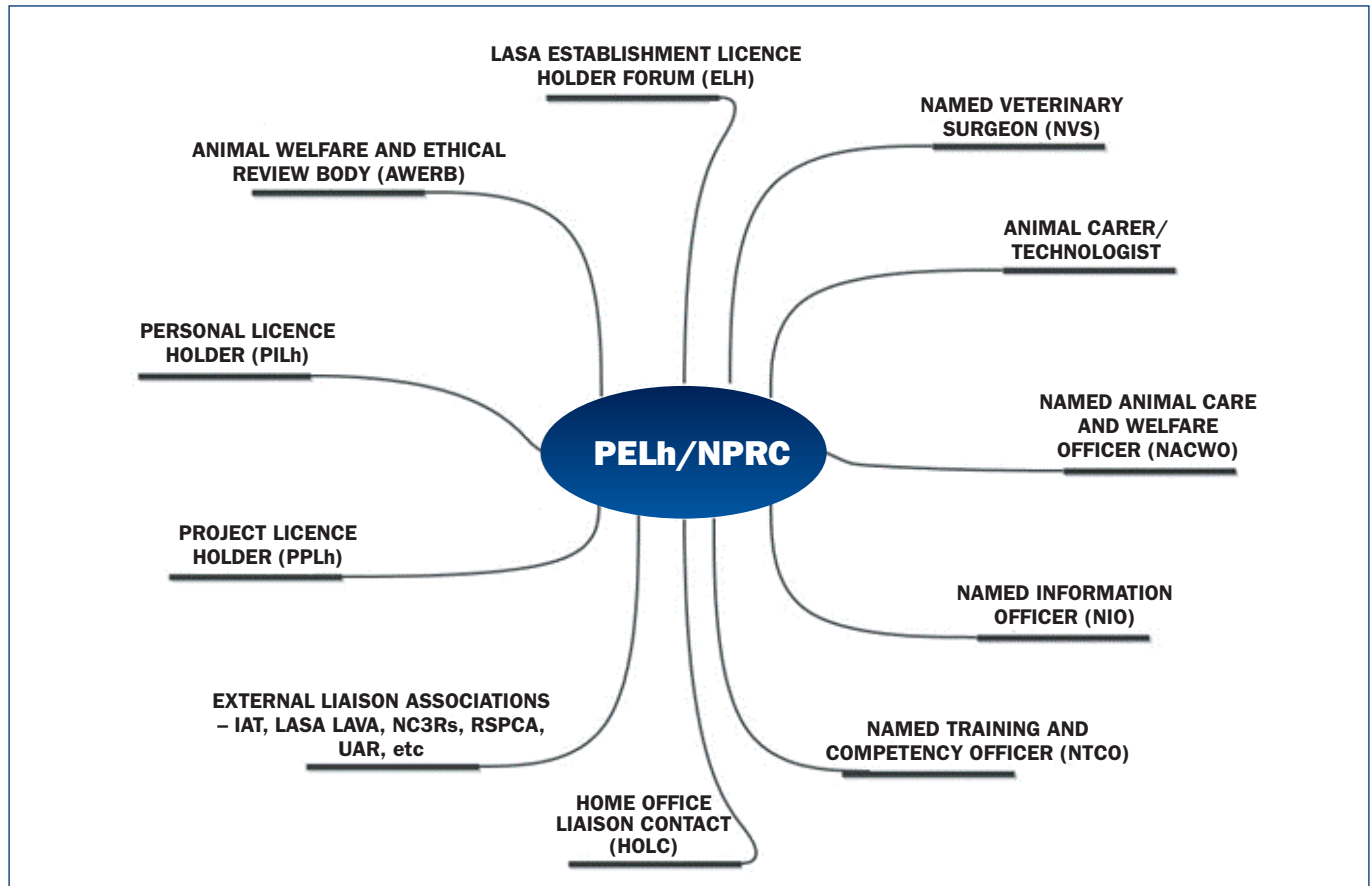
Where the PELh is an individual, ASRU expect that the person named as the PELh will also be the NPRC. However where the Establishment Licence Holder is a corporate entity it is necessary to appoint an individual to serve as the Named Person Responsible for Compliance. In this situation, they should be of similar standing as expected for a PELh in terms of authority and seniority and undertake similar training.

The responsibilities of the NPRC are the same as those of an individual serving as Establishment Licence Holder:

- providing leadership

- ensuring compliance

- ensuring the 3Rs are applied as fully as possible

- promoting a Culture of Care

- ensuring the establishment has sufficient competent staff

- setting up and running an Animal Welfare and Ethical Review Body (AWERB)

- the performance and conduct of Named Persons

- avoidance of conflicts of interest

- ensuring animals have appropriate care and accommodation

- countersigning project licence applications

- record-keeping and ensuring appropriate identification of animals

- maintaining a register of those competent (initially under supervision) to kill protected animals

Refer to Chapter 3 of the Guidance

New Establishment Licence Holders/NPRC are expected to understand the relevant legal and ethical issues relating to the use of animals under the Act. They are expected to undertake accredited training in UK modules L (National Legislation) & E1 (Ethics, Animal Welfare and the 3Rs (level 1)) as a minimum to provide this understanding.

A course aimed at Establishment Licence Holders/ NPRC is held annually by LASA, generally in the autumn. This is a one-day training session that discusses current legal, ethical and management issues relating to the scientific use of animals.

ASRU provides operational and strategic updates via periodic electronic newsletters. It is also the responsibility of the PELh or NPRC to ensure that this information is circulated to the NIO and others within establishments as appropriate.

To ensure you receive the updates please register via this link. www.gov.uk/government/collections/animals-in-science-regulation-unit

Named Training and Competency Officer

What is the job? What are the responsibilities?

Interactions of the NTCO
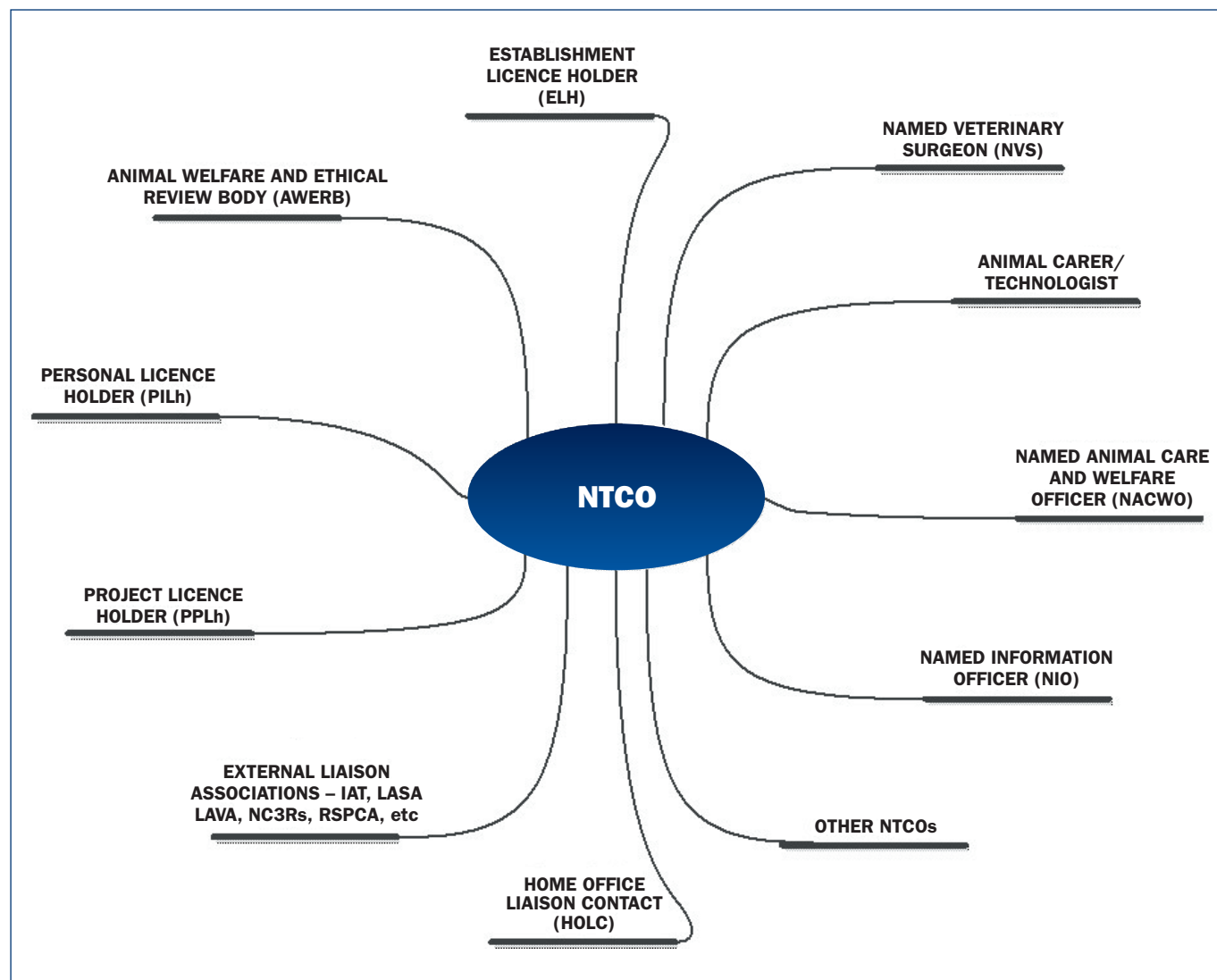
The Establishment Licence Holder/NPRC should support the NTCO in determining **how** the requirements set out by the Home Office (see the Guidance – Chapter 8.9) can be achieved efficiently and effectively. **The NTCO role needs to be properly resourced and supported by senior management to ensure that training requirements for all staff are met.**

> **The Named Training and Competency Officer (NTCO) is responsible for ensuring that all those dealing with animals are adequately educated, trained and supervised until they are competent and that they continue to undertake appropriate further training to maintain their expertise.**
>
> **Core Role:**
> - setting local standards
> - applying local standards
> - record systems
> - supervision and Competence Assessment
> - Continuing Professional Development (CPD)
> - ongoing review of local processes
> - communications

The role of NTCO may be a stand-alone defined position within an establishment. In some cases, it will be undertaken (where there are no conflicts of interest) in combination with other roles. In a large establishment, the role will often be undertaken by different persons at different sites or for different species. Where more than one person is tasked with this role it is important that they all work closely as a team, applying the same principles and standards, whilst ensuring that division of responsibility is clear. Oversight of these standards will be maintained, at establishment level, by the Establishment Licence Holder (PELh)/NPRC and/or the AWERB where appropriate.

The NTCO should be sufficiently senior to influence others, make decisions, and lead on training issues within an establishment. They will ensure that training, supervision, competence assessment and Continuing Professional Development are undertaken and recorded.

In some establishments, the NTCO may not be directly involved themselves in the delivery or assessment of training or competency (in which case their role will be to ensure appropriate delivery of the requirements).

Practical responsibilities in these cases are delegated to experienced practitioners who are themselves competent to train (and/or assess) the necessary techniques.

Trainers/supervisors may be personal or project licence holders, members of the animal technical staff or a veterinarian. These people will make direct contributions to training/supervision/assessment of those involved in animal research.

Trainers/assessors/supervisors will be selected according to their expertise and competence in their day-to-day work as well as on their ability to teach the technique(s).

The project licence holder is responsible for ensuring an appropriate level of supervision is provided for all personal licensees carrying out procedures but the systems and record keeping for this should comply with the local establishment systems which have been set up by the NTCO. The AWERB should be aware of any standard procedures and practices for training within the establishment and there may be a role for the AWERB in the development, establishment and revision of these.

Setting local standards

The NTCO role holder should set local standards for training, supervision, competency and Continuing Professional Development which meet national expectations as outlined in the EU Education and Training Framework and adopted in the UK.

Identifying who needs training

Chapter 9 of the Guidance details the UK requirements for training. These should be understood in detail by the NTCO.

The initial training requirements vary for:
- Personal Licence Holders (PILh) – those carrying out procedures.
- Project Licence Holders (PPLh) – those responsible for designing projects and studies, who may or may not be personal licence holders.
- Those taking care of animals[*] (from a Trainee Animal Technician, through to Animal Technician and then to becoming a Registered Animal Technologist (RAnTech))
- People involved in the humane killing of animals.

[*] Not all technical staff will undergo Institute of Animal Technology (IAT) training but local training systems should be in place and properly documented so that it is clear they have been appropriately trained and assessed as competent in relevant practices <u>before</u> an animal carer is permitted to be responsible for animals.

Development and administration of such local training systems are the responsibility of the NTCO.

What standards should be met?

The standards for initial training of personal and project licence holders (when undertaken in the UK) are set by the Accrediting Bodies. At present these are the Scottish Accreditation Board, the Royal Society of Biology and the Universities Accreditation and Quality Audit Group. Accredited training for animal carers, including NACWOs can be accessed via the IAT. All these accredited courses will provide standard, specific and clear format certificates of successful completion of modules. The NTCO should be able to recognise training certificates from these accrediting bodies.

Identifying training needs

The NTCO will need to develop mechanisms to identify where there are new training needs, for example new procedures or species. The NTCO should also develop systems for routine re-assessment. In addition they should also identify triggers for re-training or re-assessment, such as poor surgical outcomes or where a technique is not used for a prolonged period. Approaches to training should be sufficiently flexible to accommodate differing individual skills and needs.

Flexible approaches to training/assessment of competence may be required. Full use should be made of local skills and knowledge, including involving others such as NACWOs, NVSs and the AWERB where appropriate. The AWERB has the task of establishing and reviewing management and operational processes for monitoring, reporting and follow-up in relation to the welfare of animals housed or used in the licensed establishment. Training and competence are essential to good welfare and therefore the AWERB is expected to have oversight/review the provision of training.

The NTCO is responsible for ensuring that mechanisms are in place to identify new learners. Good communication systems will need to be in place with NACWOs, Project Licence holders, etc., to ensure that new personnel are identified (preferably prior to their arrival) so that efficient and appropriately tailored systems can be put in place such that training requirements do not hold up their work unnecessarily.

A system should be in place to ensure that training, supervision and competence standards are met for animal technicians. Whilst some may go through formal IAT training, local training will also occur. Once trained and competent, Animal Technologists will be taking individual responsibilityfor the animals under their care and so the training must be formally recorded as evidence of the skills obtained. The NTCO will be responsible for ensuring that this process complies with local and ASPA Guidance requirements.

Killing of animals

All those who kill animals must have satisfactorily completed appropriate training, whether the killing method is one authorised within a project licence, under Schedule 1, or on the PEL.

Involvement of the NVS may be particularly helpful in considering killing methods. The Learning Outcomes described in EU Education and Training Framework – Module 6 must be achieved by the learners before undertaking killing unsupervised.

A personal licence is not required, if an individual is only killing animals by a Schedule 1 method but all individuals must be trained and competent.

A local module which complies with the requirements of Module 6.3 will need to be developed and in place and appropriate trainers and assessors identified. Personal training records of competence in each of the (species and stage dependent) Schedule 1 killing methods will need to be devised and kept. Those trained in Schedule 1 and other methods should be listed on the Schedule 1 register held within the establishment (Section 2C Establishment Licence (PEL) condition 2). Records should indicate the methods in which they have been trained and assessed as competent and for which species/stage of development. The format for these records and the system of completion and maintenance will need to be agreed internally and approved by the PELh/NPRC. These will often be maintained by the NTCO (or the HOLC) on behalf of the PELh/NPRC.

Exemptions

The NTCO may be asked about exemptions from training. They may use Home Office documents to understand what exemptions may be applied but other than for predefined described circumstances, they should consult with the ASRU Licensing team to obtain a final decision on the acceptability of the exemption request.

The NTCO and ASPeL

The NTCO has a role in the ASPeL process for approving personal licence applications. The NTCO is responsible for verifying and confirming that the applicant's training details are accurate and for signing off all PIL applications which are submitted in the system. The NTCO should declare:

– I have the authority of the establishment licence holder and they are aware that this establishment will have financial responsibility for this personal licence if granted.

In large institutions the NTCO is likely to rely on information from the PPL holder regarding things such

as the applicant's character and command of English for example and local systems may be put in place to confirm and record such details.

The NTCO should also make PIL applicants aware that the establishment can revoke their licence, on behalf of the PELh, if necessary.

Applying local standards

The key ongoing role for the NTCO is in ensuring compliance with the standards set by the institution for supervision, competence and CPD for each of the functions of Animal Technologists, personal licence holders, project licence holders and Named Persons as laid out in the EU Education and Training Framework and the ASPA guidance (2C.5).

How the system is delivered will depend on the nature of the NTCO's role within the establishment. If this role is solely a management/administrative role, then direct involvement in training/supervision/assessment will not occur. However regardless of whether they are directly involved in the provision of training, the NTCO will need to oversee the process of recording training, supervision, competence and CPD for all members of staff involved with ASPA within the establishment. This includes making sure that a consistent approach is being adopted and delivered by and for all staff.

Identifying appropriate training and trainers

A list of EU and UK associations and accrediting bodies providing information and guidance may be found at the end of this document.

The NTCO should be able to assist those learning to identify and attend appropriate training. For new learners, this will involve knowing which modules are required, where and when high quality species specific modules are available and how to book them. They may collect and collate feedback from previous attendees to select the best courses. It is important to use properly trained trainers who use modern practices with optimised Animal Welfare appropriate to the required science as a key outcome.

On completion, the NTCO will need to see and check evidence of training certificate(s)/DOPS to ensure successful completion of all required modules. Once the learner has obtained their personal licence, the NTCO will need to work with the project licence holder to identify which procedures/techniques the learner needs to become competent in. Either the NTCO themselves, or in communication with others such as NACWO and NVS, will then identify possible trainers and work with the learner to establish a suitable training schedule. NTCOs

are responsible for communicating requirements/expectations to trainers, supervisors and learners and for ensuring that staff are aware of their individual responsibilities within the local system which, for example, might include the use of DOPS sheets to record practical skills training.

LASA have a library of DOPS available from their web site to assist people developing training in procedural techniques.

The NTCO will need to make sure that new training needs are being identified as science develops, techniques become more refined, or as new species are brought into the establishment. Local mechanisms and procedures should be regularly reviewed to ensure that these are being identified. Issues arising where there is doubt or evidence of failure to maintain competence need to be dealt with promptly and in accordance with set local procedures.

When triggers, such as poor surgical outcomes or acute increases in unexpected adverse effects are identified, the NTCO should be involved in reviewing these, devising further training if required, and ensuring it is completed and recorded. Investigations and follow-up should largely be on a no-blame basis, as additional training and supervision will often resolve the issue.

Outcomes need to optimise Animal Welfare and reduce animal wastage and may be reported to the AWERB.

Record systems

Training records, for use throughout the establishment will need to be developed and agreed by all NTCOs when more than one person holds this post. A standard format will require approval by the PELh/NPRC and or AWERB, where appropriate, who retains overall responsibility for the performance of the NTCO(s).

Examples of training records that comply with the legislation can be found in the LASA Guiding Principles for Supervision and Assessment of Competence, along with examples of DOPS sheets but other compliance systems will also be acceptable, so long as it is clear what training has been undertaken, what further training/supervision is required and what techniques a person is competent to perform without supervision.

Records can be paper or electronic. If electronic, the system may be local bespoke or purchased from one of the systems commercially available. Training records should be readily available on request and accessible by all relevant staff, including the ASRU inspectors. Copies of training certificates should be retained within an individual's training records but may also be held by the establishment in a centralised electronic/paper filing system.

Whilst under ASPA the PILh must take responsibility for the maintenance of their own training, supervision, competence and CPD records, if the PILh is to move elsewhere (or work with secondary availability at another establishment) then the NTCOs of the two establishments will need to be in correspondence to confirm the accuracy of the PILh training records being transferred. However the Data Protection Act and establishment in-house policies may need to be considered and followed.

Keeping records up to date

Whilst each PILh is responsible for their own training record, the NTCO will be responsible for ensuring that the establishment is maintaining complete, accurate and up to date records of those working under the establishment licence. Individual records should be kept up to date by the learners themselves, in collaboration with their trainer and/or competence assessor and supervisor, as appropriate. The NTCO will need to review and check the records at a frequency which encourages learners and trained people to apply the local standards. With an effective recording system and staff engagement and support, an ASRU inspector should be unlikely to find out of date, inaccurate or incomplete records. The NTCO may keep the original records or may have ready access to them. They should always be available to the NTCO whether or not the individual to whom the record belongs is on site.

When individuals transfer from other establishments the NTCO will be responsible, in collaboration with the project licence holder, for checking and verifying training records and identifying any new training which might be required. Reassessment of competence of the procedures within the training record, when these are first performed after the person has started at the new establishment, is strongly recommended, to verify skills and identify if there are any differing approaches between establishments.

The NTCO is likely to be involved in maintaining an up to date list of those competent to kill by Schedule 1 methods on behalf of the PELh/NPRC as required by Section 2C Establishment Licence (PEL) condition 2. This will involve identifying new staff and ensuring they are trained and supervised and removing staff from the list who have left, or who, for whatever reason, are no longer competent.

Supervision and competence Assessment

Supervision of personal licensees remains the responsibility of the project licence holder (PPL condition 6). As well as ensuring consistent quality of training and assessment of competence, the NTCO has a role in ensuring supervision is adequate across the establishment. It is expected that the NTCO will work with project licence holders to ensure that all personal licence holders working unsupervised are competent and that their individual records detail this information.

Competence assessment should be objective, wherever possible using a different assessor to the trainer. For specialist techniques that are new to the establishment or where there are limited trainers available, consideration should be given to finding others outside the establishment who are already competent and able to provide support/advice. If this is not practicable, then someone with suitable skills and experience (for example the NVS) may invoke their acquired rights to act as a trainer/assessor, having had local discussions to define how competence will be judged.

The EU Education and Training Framework document (p13) provides helpful suggestions relating to supervision. The LASA Guiding Principles for Supervision and Assessment of Competence will also be of help.

Continuing Professional Development

The establishment should develop a Continuing Professional Development (CPD) strategy for all relevant staff.

The undertaking of relevant CPD helps to ensure that techniques remain current and that good practice is understood and followed as far as is practicable. CPD should cover 3Rs issues as well as Animal Welfare and science at an appropriate level. The NTCO should be appropriately networked (or ensure that the NIO is doing this on their behalf) to maintain an awareness of opportunities and activities for education, training and CPD relevant to ASPA work. They should be able to identify relevant personnel and disseminate information to them and encourage attendance. Where there are budgetary constraints or more potential attendees than places available, involvement of PELh/NPRC, other managers, other Named People and/or the AWERB may be helpful in decision making.

The NTCO will need to review records, perhaps in collaboration with supervisors/managers, to confirm that CPD (in science, Animal Welfare and 3Rs) is achieved and clearly recorded. Most people have an annual review of performance, which may be used as a trigger to review these records. Regular observation of procedures and review of training records can help identify good practice for dissemination and issues where further advice or assistance may improve outcomes.

Informal reviews and reporting by all staff with sight of procedures being performed and outcomes can assist the NTCO in achieving the desired goals. Other PILhs, NACWOs, animal care staff, PPLhs, and NVSs may also have a role in this. Good communications with these people should be maintained.

The NTCO should work with the AWERB to develop and monitor the annual CPD strategy/opportunities for staff. The AWERB can have a significant role in identifying issues requiring CPD, especially when it reviews unexpected adverse events.

Review

Regular review of the effectiveness of this role is critical to ensure that the function is being delivered effectively. As part of such a review it is essential for the PELh/NPRC to obtain feedback from all relevant staff. Those whose opinions should be sought, as they are expected to have regular interaction with the post holder, include PPLhs, PILhs, Animal Technologists, NACWO(s), NVS(s), PELh/NPRC and AWERB members.

Communications

Good internal communications are essential between the NTCO and all in the establishment.

Regular communication with the PELh/NPRC is important and required by Section 2C Establishment Licence (PEL) condition 21. There should be a two-way flow of information so that expectations are clear and that it is evident whether or not these expectations are being met.

External communication streams should be in place with training organisations, other licensed establishments, the Home Office and relevant external organisations such as the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs), Laboratory Animal Science Association (LASA), Institute of Animal Technology (IAT), Laboratory Animals Veterinary Association (LAVA), Royal Society for the Prevention of Cruelty to Animals (RSPCA) and Understanding Animal Research (UAR). Communication with external colleagues through Named Persons' Groups such as email discussion groups and/or attendance at meetings set up by the various organisations listed above is strongly recommended.

Training for a NTCO

What are the qualities of a good NTCO?

To be an effective NTCO you will need to be approachable with very good communication skills, good organisational skills (including data management), sound judgement, an ability to manage time and skilled in positively influencing people who may not be within your line management.

What does an NTCO need to know and understand?

– The ASPA legislation and relevant sections (in detail) of the Guidance, along with how the regulations are implemented in practice.
– Issues around the ethics of animal use in science.
– The Three Rs and how these can be fully implemented in your establishment.
– How the research processes and structures work in your establishment.
– Relevant institutional policies in detail.
– Principles of the local research programmes.
– The national training and supervision requirements.
– Where to access appropriate training in a timely manner for scientific and Animal Technologists.
– How to manage confidential data, including legal obligations.
– Good computer skills.
– In some circumstances it will be helpful to understand EU related requirements, e.g. for experienced scientists coming from abroad, and to keep abreast of training developments within the EU e.g. the Education and Training Platform for Laboratory Animal Science – www.etplas.eu

Initial training for NTCOs

Many new NTCOs will have already been involved with the ASPA system and will have completed formal training in their previous posts. Where a prospective post holder is already actively involved in the delivery of training, supervision or competence assessment, there may be no additional training needs.

For those involved in a more administrative role (e.g. the coordination, confirmation and recording of training), or for those without prior training experience, then some training will be necessary to properly perform the role. Such training is strongly recommended under Home Office requirements.

As a minimum, NTCOs should have undertaken:
– EU Education and Training Framework – Module **1**: Legislative framework.
– EU Education and Training Framework – Module **2**: Ethics, Animal Welfare and the three Rs (Level 1).
– EU Education and Training Framework – Module **50**: Introduction to the local environment (establishment).

They should also have good knowledge of:
– ASPA Guidance – with detailed understanding of Chapters 8, 9, 10.
– EU Education and Training Framework (in general).
– Local processes relating to the Home Office licensing process for licence applications, amendments, standard exemptions, etc.
– Knowledge of the species and procedures used within their establishment.

Continuing Professional Development (CPD) for NTCOs

– Remain up to date on developments in education and training on laboratory animal science and welfare.
– Follow the activities of the EU Education and Training Platform for Laboratory Animal Science.
– Maintain a basic understanding of teaching principles where training forms a part of the core role.

– Maintain awareness of new methodologies and/or people who can assist in the delivery of training.
– Attend events provided by accrediting bodies where relevant (e.g. the Train the Trainers day).
– Attend meetings of relevance provided by IAT, LASA, LAVA, NC3Rs, RSPCA, UFAW etc.
– Those NTCOs not already directly involved in training should visit the animal facilities.

Named Information Officer (NIO)

What is the job? What are the responsibilities?

Interactions of the NIO
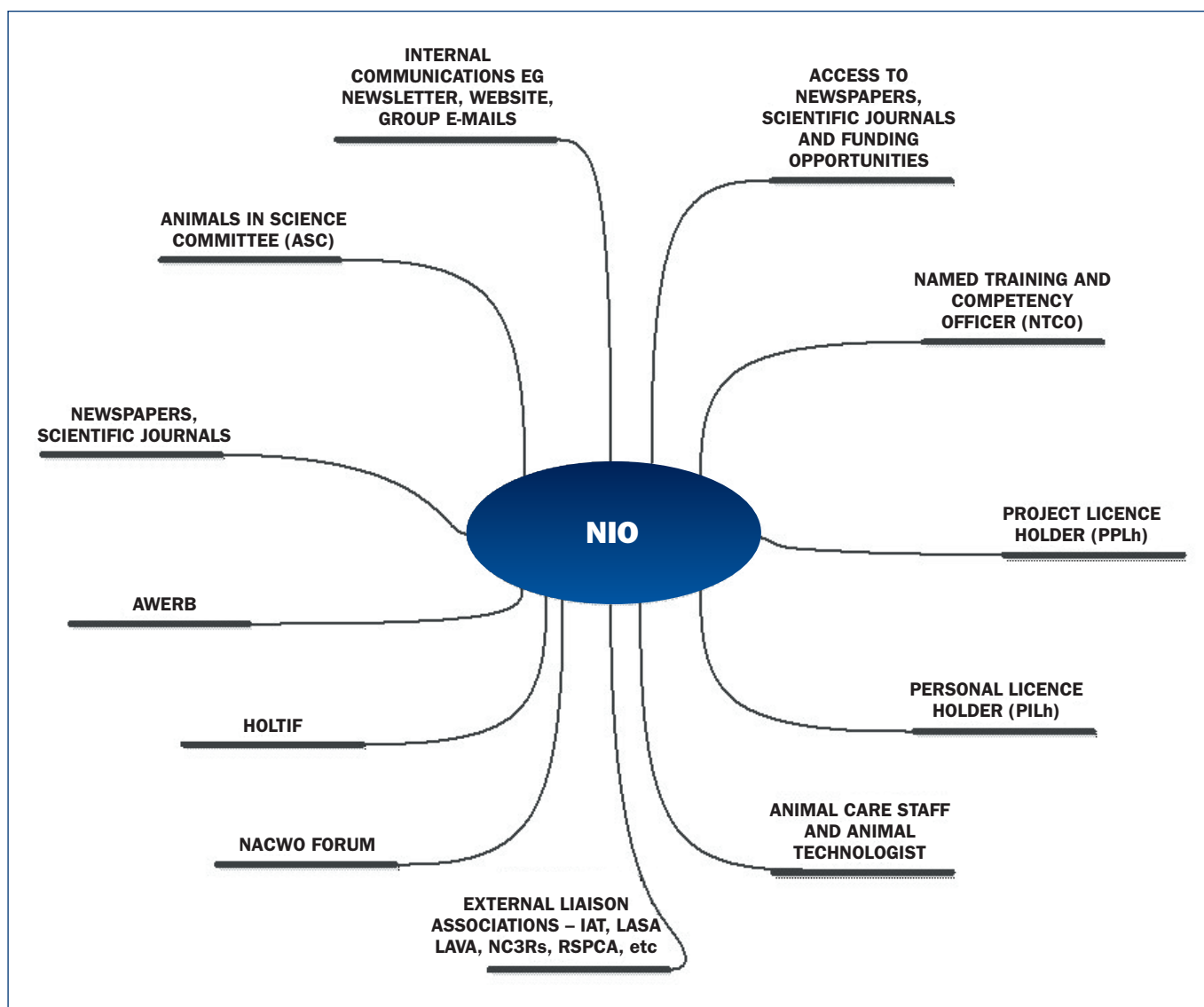
The Establishment Licence holder/NPRC should support the role of the Named Information Officer in determining **how** the requirements set out by the Home Office (see the Guidance – Chapter 8.10) can be achieved efficiently and effectively. **The role needs to be properly resourced and supported by senior management and AWERB where appropriate.**

> **The Named Information Officer (NIO) is responsible for ensuring that those dealing with animals in the establishment have access to information they need about the species held there and procedures being performed.**
>
> **Core Role:**
> - setting up information systems
> - applying the systems
> - ongoing review of local processess

The NIO will be involved in the coordination of access to information to those dealing with animals in the establishment, making sure information is disseminated regarding the species held, the procedures being performed and any other relevant information they may require.

Who is the NIO?

NIOs may be administrators or may come from a science or technical background. In some cases, the person will be familiar with some of the local activities but it is unlikely that any NIO will have a full understanding of all the activities undertaken for which they need to actively scope for information. However systems should be put in place to capture any new information being published and when presented with this, the NIO should be able to recognise where it may be relevant and to whom it should be disseminated.

The role may be combined with that of the Named Animal Care and Welfare Officer (NACWO), Home Office Liaison Contact (HOLC), Named Training and Competency Officer (NTCO) and/or Named Veterinary Surgeon (NVS). In some cases, the Establishment Licence Holder (PELh)/NPRC may choose to retain the role. The AWERB members may contribute significantly in assisting the NIO to meet the requirements of the role.

There will need to be active involvement with the AWERB, generally by being a full member, to ensure that there is adequate communication and support for the role.

Setting up information systems

The NIO role provides focussed dissemination of information. To do this the NIO needs to determine who needs the information and provide it efficiently, in a format which the person needing the information can

use (including the appropriate level for knowledge/skills), being aware that different groups may respond to different approaches and being able to adapt accordingly.

They will need to be able to provide guidance on where and how to search for information, or who to speak to, to enable such information to be accessed.

The NIO should be able to assist Project Licence applicants and/or personal licensees to find or search for information, or to be able to identify a specialist to assist – but they do not necessarily need to understand the key findings from such a search.

The PELh/NPRC needs to ensure adequate liaison between Named People (Section 2C Establishment Licence (PEL) condition 21)). The NIO will need to take an active part in this communication to ensure that their contribution is effective and is in line with what is required by the PELh/NPRC. Such liaison usually includes regular face to face communication at an agreed frequency depending on the size of establishment and local expectations/ requirements for the role. This will assist the NIO in identifying where information actively needs scoping but relies on them having access to good communication tools.

The NIO should be in position to disseminate key information to the right people in a timely manner; generally, this would be in an electronic format. A system of focussed communication will be required e.g. notification of new staff or personal licences to relevant people and after receipt of ASRU communications.

It is imperative that the NIO is on the ASRU email circulation list to receive their regular newsletters. To receive the relevant mailings NIOs should contact ASRU Operational Relationship Management (see ASRU contacts).

Applying the systems

What information to provide

Information may be provided in hard copy or electronic format and is likely to include:

- ASPA – legislation and Guidance on the Act.
- Local rules and information:
  - Handbooks and SOPs provided by the facility.
  - Local training module (EU Education and Training Framework document – Module 50).
- Information on the biology, behaviour and welfare needs of the species used at the establishment.
- Information on how to provide appropriate animal care and husbandry and promoting good Animal Welfare. Information should include minimum standards but recognises that these are minimum standards and therefore provide additional suggested good practice.

This should be done in close collaboration with NACWOs and is likely to include:

- Code of Practice on the Housing and Care of Animals.
- Relevant DEFRA Codes.
- Specialist books on species held, particularly those relevant to scientific use of animals e.g. the Universities Federation for Animal Welfare (UFAW) 'Handbook on the care and management of laboratory animals', the IAT 'Manual of Animal Technology'.
    - Refereed journals that publish papers on animal behaviour, welfare and refinement, e.g. Laboratory Animals, Animal Technology and Welfare, Applied Animal Behaviour Science and Public Library of Science (PLoS).
    - Contacts at centres where behaviour and welfare research are conducted.
- Information on implementing the 3Rs including:
    - Relevant guiding principles for good practice (e.g. IAT, LASA, LAVA, NC3Rs (inc. the 'ARRIVE' guidelines), RSPCA).
    - Publications relating to new scientific initiatives, technical advances.
    - Links to websites/databases such as NC3Rs, Go3Rs, ECVAM, Pubmed, Altweb, NORINA, etc.
- Good practice relevant to types of work at the establishment e.g.:
    - Standard dosing/sampling websites.
    - Aseptic technique documents.
    - Assessing welfare/severity.
    - Outcomes of retrospective assessment, with lessons learnt, good and bad.
- Information on AWERB membership, functions and its outcomes.
- Home Office newsletters and other communications.
- Reports and other publications produced by the Animals in Science Committee (ASC).
- Details of meetings/conferences/events where such information may be exchanged and a list of staff within the establishment to whom they may be relevant.
- Reports from staff after attendance at meetings/conferences.

Who to provide information to?

To avoid information overload, information will need to be disseminated selectively and appropriately to:

- PPL holders.
- PIL holders.
- Specific research/interest groups (e.g. species, research field).
- Named People.
- Animal Technologists.
- Animal Welfare and Ethical Review Body members.

The NIO may also be a channel for communicating information to/from others including:

- External groups e.g. IAT/LASA/LAVA/NC3Rs/RSPCA/UFAW.
- Home Office (e.g. ASRU licensing team and inspectors).
- Animals in Science Committee (ASC) and AWERB Hub.

How to provide information

The methods used to disseminate information should facilitate access while reducing or avoiding information overload. They may include having a central repository for information that can be accessed by all concerned e.g. an intranet, SharePoint site or similar. The NIO will need to make sure that logical and intuitive subdivisions and 'filing' are used to make access easy and that version control management is used (e.g. using clearly dated documents/pdfs) and to purge/delete/archive out-of-date or superseded documents.

The use of emails can notify appropriate recipients of new relevant content. These should be brief and be directed only to relevant people. When sending papers or other information it may be helpful to summarise important points and use links to detail/documents/websites rather than duplicating other information.

Face-to-face meetings on specific issues with particular individuals or groups allow discussion as well as imparting of information. 3Rs focussed journal club meetings between scientific groups and meetings between scientists and Animal Technologists can facilitate information dissemination.

The NIO should report to the AWERB e.g. by formal report of relevant activities through a standing agenda item. The NIO is also likely to be involved in collating and disseminating relevant information from the meetings. This may involve reviewing AWERB and subgroup minutes to pick out individual packets of relevant information and then directing information out to relevant personnel.

NIOs can play a role in retrospective reviews by collating findings of interest to others and disseminating improved practices internally and externally.

Review

Regular review of the effectiveness of this role is critical to ensure that the function is being delivered as expected. As part of such a review it is essential for the PELh/NPRC to obtain feedback from all relevant staff. Those whose opinions should be sought, as they are expected to have regular interaction with the post holder include, PPLhs, PILhs, Animal Technologists, NACWOs, NVSs, PELh/NPRC and AWERB members.

What are the qualities of a good NIO?

The person responsible for dissemination of information should be someone who proactively seeks information from other people, collects and collates this information and then enables others to access it.

To be an effective NIO you will need to have good communication and networking skills and be a facilitator. You will need to be computer literate and well organised to ensure that the relevant information is available to those that need it when they need it.

You will need to know where to find current information on the 3Rs, including through networking or self-learning.

You will need to:

– Understand the main provisions of the ASPA legislation (including Guidance, Advice Notes and the Code of Practice on Housing and Care).

– Be familiar with the species used and the types of research performed in the establishment.

– Actively seek relevant information to disseminate, not just react to information requests.

– Proactively make and maintain external contacts for information sharing:

  – Home Office.

  – Specialist groups and bodies such as the ASC, IAT, LASA, LAVA, NC3Rs, UAR and Animal Welfare organisations.

  – Local contacts such as Named People and research interests of local groups.

Training for a NIO

Some NIOs will have already been involved in working under ASPA, either directly or alongside others and will already have completed formal training in their previous roles/posts, so additional training may not be needed. For those involved in the role without prior experience training is recommended, although not obligatory under Home Office requirements. It is recommended that at least the modular training in the legislation, ethics and 3Rs should be completed:

– EU Education and Training Framework – Module **1**: Legislative framework.

– EU Education and Training Framework – Module **2**: Ethics, Animal Welfare and the three Rs (Level 1); this will help to obtain an understanding of legal and ethical aspects of use of animals for scientific purposes and also covers the concepts and principles the 3Rs.

– EU Education and Training Framework – Module **50**: Introduction to the local environment (establishment)

which gives a good understanding of the local structure for management and responsibility relating to animal use at your establishment.

– EU Education and Training Framework also suggests that the NIO completes aspects of Module **51** – Information provision and retrieval. When such a module exists, if not completed before the post is taken up, then this will be valuable CPD within the first six months to a year depending on prior knowledge and skills, and extent of role and other local support.

Continuing Professional Development (CPD) for the NIO

A working knowledge of the contents of the following document from the European Commission will assist in the delivery of the outcomes required:
A working document on the availability of information on the Three Rs (2012).

You may wish to extend your skills by:

– Spending time reviewing the NC3Rs website and the links within it.

– Completing a suitable training module covering how to search, source, retrieve and store information, and methods of searching (e.g. see links to FRAME or SYRCLE in the References section).

– Receiving other training on information searching, storing and retrieval.

– Spending time in discussion with knowledge management experts (e.g. information technologists, librarians).

– Completing EU Education and Training Framework - Module 9: Ethics, Animal Welfare and the Three Rs (Level 2), a component of PPL training, which may be useful in extending the basic knowledge of ethics and legislation.

– Attending a specific NIO training course.

– Visiting animal facility/facilities.

– Attending topic specific IAT/LASA/LAVA/NC3Rs/RSPCA/UFAW meetings.

– Membership of HOLTIF and NIO discussion groups.

– Undertaking soft skills training:

  ● how to talk to people and influence them

  ● team-working

  ● diplomacy

Home Office Liaison Contact (HOLC)

What is the job? What are the responsibilities?

Interactions of the HOLC
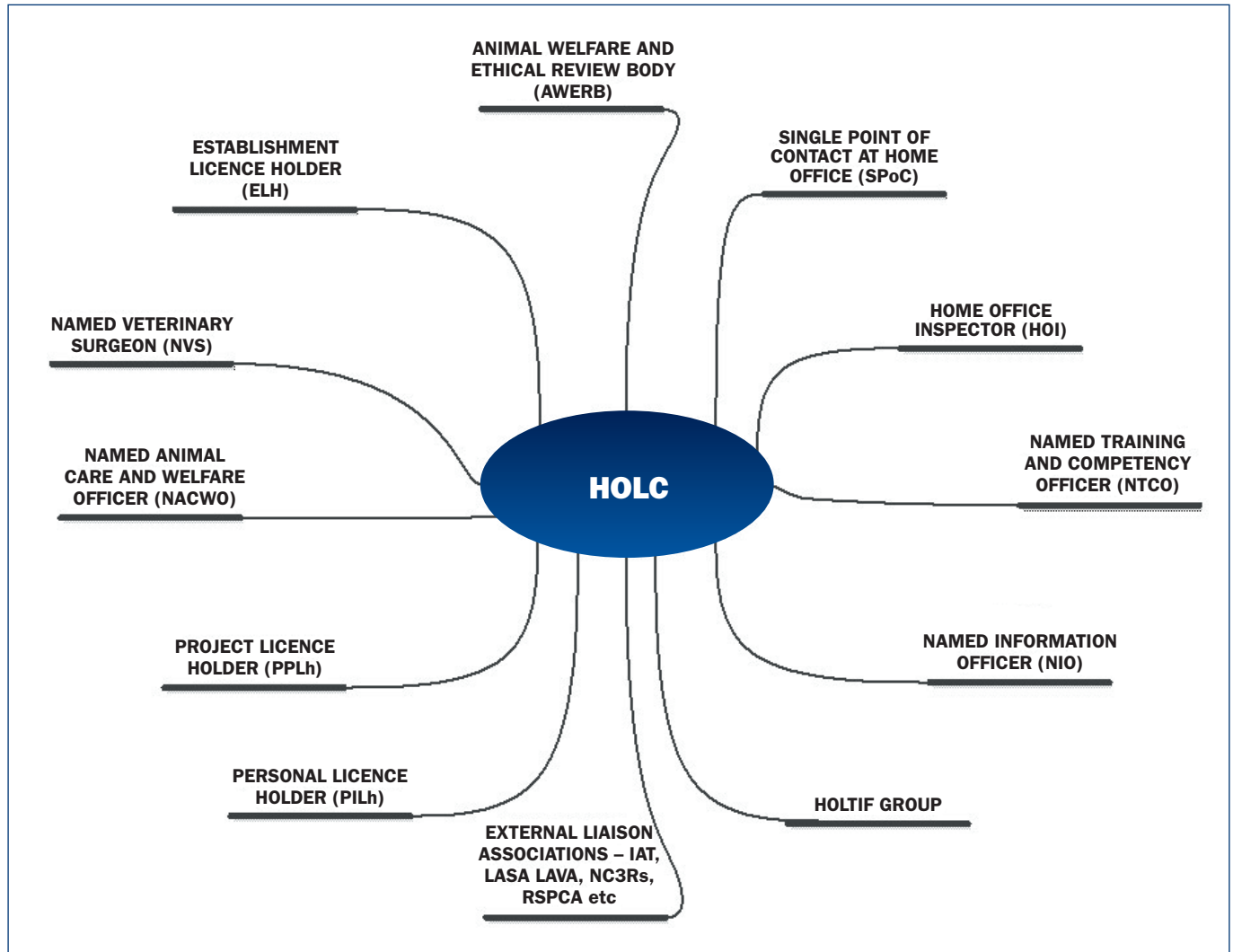
The Establishment Licence holder/NPRC should support the role of the HOLC in determining **how** their responsibilities can be achieved efficiently and effectively. **The role needs to be properly resourced and supported by senior management and AWERB where appropriate.**

The Home Office Liaison Contact (HOLC) is a non-statutory role that is not legally defined. It is a role strongly shaped by Home Office working practices and policies. The HOLC acts as a key contact with the Home Office, liaising over licence applications and other matters. The HOLC receives all Home Office communications on behalf of the establishment licence holder/NPRC and cascades those communications as appropriate to others in the establishment.

Core Role:

- communications
- setting up systems

- ASPeL (including interactions between HOLC and NTCO)
- applying the systems

Who is the HOLC?

The HOLC is the person within an establishment nominated to be the main liaison between the establishment and the Business Support and Licensing Team in the Home Office's Animals in Science Regulation Unit (ASRU). The HOLC may also be the first point of contact within an establishment for the ASRU Inspectors and ASRU Operational Relationship Management.

The HOLC has an important administrative role on ASPeL (Animals in Scientific Procedure e-Licensing) system (see below).

The role of HOLC may be combined with that of Named Information Officer (NIO), Named Animal Care and Welfare Officer (NACWO), Named Training and Competency Officer (NTCO), or Named Veterinary Surgeon (NVS).

The role requires that the HOLC liaise with, at a minimum, all licensed staff and prospective applicants in the establishment to:

Advise on licensing matters.

– Ensure a robust and efficient internal licensing application/amendment process.
– Set up ASPeL invitations and logins.
– Deliver/support processes to ensure all licensees have access to relevant licences.
– Monitor timely Returns of Procedures (ROPs) by all project licence holders.
– Liaise with licensees submitting ROPs to the Home Office and provide them with information and advice on completion as required.
– Pass Home Office communications to relevant person/ persons if they are the key contact for these – this would specifically include to the NIO where information is of relevance to them.
– Ensure that delivery of key messages from ASRU newsletters are disseminated to relevant staff at the establishment – this may be a function shared with/ devolved to the NIO.

Additional communication may be required with others, such as those on the Schedule 1 register, depending on the extent of the role given to the HOLC.

HOLCs may maintain and hold the following information on behalf of the PELh/NPRC:

– Schedule of Premises.
– Details of NACWOs and other Named People.
– Schedule 1 register.

In some cases, the HOLC may actively participate in the establishment's AWERB. They may be a full time member and may also fulfil the secretariat role.

Communications Internal

Good internal communications are essential. There should be a two-way flow of information between the HOLC and applicants/licensees.

The HOLC is likely to perform most effectively within an establishment if they develop and nurture an effective working relationship with the PELh/NPRC and the establishment's Named People. Regular communication by the HOLC with the PELh/NPRC will be of value, in particular when meetings of other Named People occur, to ensure the PELh/NPRC is kept informed.

The HOLC will work closely with the PELh/NPRC and may be the designated deputy to that person.

External

Contact between the HOLC and the ASRU Licensing Team at the Home Office should normally be through the ASRU Operational Relationship Management Lead, with whom the HOLC needs to develop and nurture an effective working relationship. Initially the ASRU Relationship Manager will contact the HOLC at a new establishment (by email or phone). HOLCs should participate in regular telephone calls from the ASRU Relationship Manager (known internally at ASRU as Field welfare calls) to build up a relationship with the HOLC – this relationship will minimise and prevent licensing issues.

For any major issues, problems, or complaints the ASRU Operational Relationship Management Lead should be contacted direct by email.

HOLCs are encouraged to develop relationships with other HOLCs to open a dialogue, share good practice and to identify procedures/processes that work well. Developing such relationships will also help to ensure smooth movement of PIL holders between establishments for example.

The LASA HOLTIF (Home Office Liaison, Training and Information Forum) can provide useful contacts and advice along with mutual support. Attendance at the annual LASA meeting or one of the regular HOLTIF meetings is encouraged and recommended. Virtual Teams meetings are held, generally four times a year, with attendance from ASRU. Separate member only virtual Teams meetings are also arranged as required. Presentations, minutes and action points from the meetings are circulated to the HOLTIF group, as appropriate.

Developing links and engaging with other establishments and organisations e.g. NC3Rs, IAT, LASA, LAVA, RSPCA, UFAW and UAR may also be beneficial but close communication with other Named People in the establishment is recommended to avoid overlap of efforts.

Setting up systems

It is likely that the HOLC will communicate regularly with ASRU on administrative issues relating to licences, and occasionally on other matters e.g. annual fees invoices.

It may be helpful for the HOLC to set up systems to track movements of PILhs wishing to work at a secondary location. This information should be shared with the NTCO and relevant PPLh at the establishment where work is to be carried out. This will allow the NTCO/PPLh for that establishment to check relevant licence authorities, ensure competency in the techniques to be carried out and provide training and supervision when necessary. HOLCs must ensure that shared information of a confidential nature is treated appropriately.

ASPeL (including interactions between HOLC and NTCO)

Three specific roles within an establishment must be registered within the ASPeL system for it to operate. These are the:

– Procedural Establishment Licence holder (PELh) (and where relevant also the NPRC).
– Named Training and Competency Officer/s (NTCO).
– Home Office Liaison Contact/s (HOLC/Admin).

The PELh or NPRC can authorise the HOLC or Admin person to endorse on their behalf in ASPeL. The way the establishment operates may vary but the roles within the ASPeL system are clear. The HOLC/Admin can undertake the following tasks on ASPeL:

– Invite new users (these may hold Named roles, require PILs or PPLs, or require access to PPLs as part of their work).
– Block applicants.
– Unblock applicants.
– Submit PIL licence revocations.
– Submit changes to approved areas.
– Liaise outside the ASPeL system with other HOLCs regarding transfer of licences and secondary availability.

The HOLC submits requests for individual user accounts to be set up in the system, by logging onto ASPeL, selecting 'People', invite user and entering the new applicant's name and email address (this email address will be permanently associated with the user's account and can only be changed by contacting ASPeL support). After this the applicant will receive a one-time only link to enable them to finish setting up their account which has to be completed within 7 days or the invitation must be re-sent. Other actions are done in the same way by the HOLC selecting one of the options under Tasks. Responsibilities for different tasks in ASPeL will vary subject to the specific responsibilities and other roles the HOLC may hold within the establishment and hence in ASPeL (e.g. as NTCO).

Through ASPeL the HOLC will receive notification when a PIL has been granted, when action is required for a new PPL application, when an amendment to an existing PPL requires further action and when an application/amendment is approved.

The HOLC will also receive ASPeL notifications when amendments to the PEL are granted. Note, under ASPeL, PPL and PIL notifications will also go to the applicant/licensee concerned.

Local responsibilities relating both to applications in ASPeL (and Home Office licences more generally) are likely to include the HOLC maintaining any local records that are required and informing specific colleagues (e.g. the NTCO, NACWO, NVS and PPL holder) when a new licence has been granted or an existing licence amended. Again, this will vary subject to local arrangements.

The NTCO is responsible for verifying and confirming that the applicant's training details are accurate and for endorsing all PIL applications which are submitted in the system.

The PELh/NPRCs role in ASPeL is to sign off both applications and amendments to establishment and project licences after they have been considered and received approval from the local AWERB. The endorsement of these licenses can be delegated by the PELh/NPRC to the HOLC or another Named Person with administration rights in ASPeL.

Again, robust and structured local processes will be required to run, manage and record the AWERB's input and to check PPL applications prior to their final submission in ASPeL. The way that the HOLC coordinates these local processes (which have to be run outside the ASPeL system) will vary but it can be beneficial for the HOLC to maintain some oversight of tasks in ASPeL to be sure that these are picked up and actioned by the appropriate person/s.

Contact ASPeL Technical Enquiries for any questions regarding ASPeL functionality.

Applying the systems

Where urgent amendments to project licences are required contact ASRU Licensing directly, providing justification for the urgent need, whilst at the same time submitting the amendment in ASPeL in the normal way.

What are the qualities of a good HOLC?

To be an effective HOLC you will need to be organised so that licence application and amendment systems run efficiently and effectively. You will need to have good communication skills and ideally be a facilitator. You will need to be computer literate.

You will need to:
– Be familiar with the main provisions of ASPA legislation.
– Be aware where to find relevant information in sections of the Guidance.
– Have a detailed knowledge of ASPeL and the application and amendment processes.
– Make contacts internally:
  – PELh/NPRC
  – NVS
  – NTCO
  – NIO
  – NACWO
  – AWERB Members
– Make contacts externally:
  – ASRU Relationship Manager.
  – LASA HOLTIF – membership of LASA, although not a requirement of joining the HOLTIF, will also be extremely beneficial.

Training for a HOLC

Some HOLCs may already have knowledge of ASPA and will already have completed formal training in their previous roles/posts, so there may be no additional training needed. For those involved in the role without prior experience then training is recommended although not obligatory under Home Office requirements.

It is recommended that HOLCs complete at least the modular training in the legislation, ethics and 3Rs.

– EU Education and Training Framework – Module **1**: Legislative framework.
– EU Education and Training Framework – Module **2**: Ethics, Animal Welfare and the three Rs (Level 1); this will help to obtain an understanding of legal and ethical aspects of use of animals for scientific purposes and also covers the concepts and principles the 3Rs.
– EU Education and Training Framework – Module **50**: Introduction to the local environment (establishment), which gives a good understanding of the local structure for management and responsibility relating to animal use at your establishment.

The following will also be of benefit:
– Working knowledge of the ASPA Guidance.
– Awareness of other relevant documents and where to find them e.g. Code of Practice for the Housing and care of Animals Bred, Supplied or Used for Scientific Purposes; ASRU Advice Notes from the guidance for the regulated community pages.
– Collaboration with other HOLCs to develop an indepth working knowledge of ASPeL.
– There will be value in visiting the establishment facilities to develop knowledge and understanding of work conducted at the establishment.

Continuing Professional Development (CPD)

Involvement with staff on a day to day basis will allow you to develop and maintain effective working relationships with them and to extend your knowledge of local working groups that involve relevant personnel, e.g. AWERB and NACWO meetings.

Regular attendance at HOLTIF meetings and/or reading outputs from these will be of value.

Reviewing/reading all Home Office communications will be necessary.

Contacting ASRU

A number of ASRU dedicated mailboxes are available for:

– Licensing
– Enforcement
– Standard Condition 18
– Audit
– ASPeL technical queries
– Operational relationship management (for HOLTIF and complaints)
– POLE notification

References and further reading

Home Office:

Gov.uk – Animal Testing and research: guidance for the regulated community

Gov.uk – Animals in Science Regulation Unit for the general public

Animals (Scientific Procedures) Act 1986

Code of Practice for the Housing and Care of Animals Bred, Supplied or Used for Scientific Purposes

Guidance on the Operation of the (Scientific Procedures) Act 1986

European Commission:

Animals used for scientific purposes

Guidance documents

Including:
– A working document on the availability of information on the Three Rs (2012)
– A working document on the development of a common education and training framework (2014)
– Education and Training Platform for Laboratory Animal Science (EU E-learning modules)

Other:

ARRIVE Guidelines (Animal Research: Reporting of In Vivo Experiments).

FELASA FRAME

HOLTIF GROUP contact LASA Secretariat for further details.

IAT (including Guidance Notes on the Role of the Named Animal Care and Welfare Officer – NACWO).

LASA (publications including Guiding Principles for Supervision and Assessment of Competence as required under EU and UK Legislation).

LASA/RSPCA Guiding Principles on Good Practice for Animal Welfare and Ethical Review Bodies (2015 – 3rd Edition) NC3Rs.

Norecopa (3Rs and training resources) Prepare Guidelines.

RAT Research Animal Training – an interactive resource hub.

Royal College of Veterinary Surgeons – NVS roles, responsibilities and Code of Professional Conduct.

RSPCA Animals in Science.

SYRCLE network (Systematic Review Centre for Laboratory Animal Experimentation.

Training

Training courses are currently accredited by the following organisations:

Royal Society of Biology – Accreditation Board

IAT

FELASA

Scottish Accreditation Board

Universities Accreditation Group

ANNEXE 1 – Training for Other Named Persons

Figure 5: Training for other Named Persons		Function				
EU module	**New UK mobile**	**PEL holder/ NPRC**	**NVS**	**NACWO**	**NTCO**	**NIO**
1. National legislation	L	Recommended	Mandatory	Mandatory	Recommended	Mandatory
2. Ethics, Animal Welfare and the 3Rs (level 1)	E1	Recommended	Mandatory	Mandatory	Recommended	Recommended
3.1 Basic and Appropriate Biology – Species Specific (theory)	PILA (theory) (sp specific)		As appropriate	Mandatory		
4. Animal Care, Health and Management – Species Specific						
5. Recognition of Pain, Suffering and Distress – Species Specific						
7. Minimally Invasive Procedures Without Anaesthesia – Species Specific (theory)						
3.2 Basic and Appropriate Biology – Species Specific (practical)	PILA (skills) (sp specific)		As appropriate	Mandatory		
8. Minimally Invasive Procedures Without Anaesthesia – Species Specific (skills)						
20. Anaesthesia for Minor Procedures	PILB			As appropriate		
21. Anaesthesia, Advanced e.g. for Surgical Procedures	PILC			As appropriate		
22. Principles of Surgery						
6.1 Humane Methods of Killing (theory)	K (theory)		Mandatory	Mandatory		
6.2 Humane Methods of Killing (skills)	K (skills) (sp specific)			Recommended		
9. Ethics, Animal Welfare and the 3Rs (level 2)	E2		Mandatory	Mandatory		Recommended
10. Experimental Design	PPL		Recommended	Recommended		
11. Design and Management of Procedures and Projects						
23. Animal Husbandry, Care and Enrichment Practices	NACWO			Mandatory		
24. Designated veterinarian	NVS		Mandatory			
30. Introduction to the local environment	Local	Recommended	Recommended	Recommended	Recommended	Recommended