Guidance for licence holders on the containment and control of specified animal pathogens

This guidance is aimed at Specified Animal Pathogen Order (SAPO) licence holders, users and biosafety professionals, but managers and health and safety representatives may also find it useful. It describes the containment and control measures and related management arrangements which must be applied when working with specified animal pathogens.

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Foreword

The Specified Animal Pathogens Order 2008, The Specified Animal Pathogens (Wales) Order 2008 and The Specified Animal Pathogens (Scotland) Order 2009 (SAPO), are made under the Animal Health Act 1981[1]. The purpose of these Orders is to prevent the introduction and spread of specified animal pathogens into Great Britain which are not endemic and which, if introduced, would cause serious disease and economic loss to the livestock industry.

Those who wish to possess or work with a specified animal pathogen in England, Scotland or Wales require a licence to do so. *Guidance for licence holders on the containment and control of specified animal pathogens* explains the requirements of SAPO licences and how these requirements can be met.

This guidance is issued by the Health and Safety Executive. Following the guidance is not compulsory, unless specifically stated, and you are free to take other action. But if you do follow the guidance you will normally be doing enough to comply with the law. Health and safety inspectors seek to secure compliance with the law and may refer to this guidance.

The guidance has been developed in conjunction with the Department for the Environment, Food and Rural Affairs (Defra), Scottish Government and Welsh Government, who retain the policy lead for specified animal pathogens. HSE is the licensing authority and undertakes inspections, investigations and enforcement in relation to SAPO.

Introduction

1 HSE is responsible for regulation of specified animal pathogens' work activities through the administration, licensing, inspection and enforcement of the Specified Animal Pathogens Orders. These functions are carried out by HSE under Agency Agreements with the Department for the Environment Food and Rural Affairs (Defra) and the Devolved Governments of Scotland and Wales (DGs).

2 This publication gives guidance on complying with the requirements of licences issued under the Specified Animal Pathogens Orders 2008, 2009[2] (collectively known as 'SAPO') that apply in England, Wales and Scotland respectively. The guidance is aimed at licence holders, users and biosafety professionals, but managers and health and safety representatives may also find it useful. It describes the essential control measures and management arrangements which must be used when working with specified animal pathogens.

3 Specified animal pathogens are infectious agents, such as viruses, bacteria and parasites. The key purpose of the licence is to ensure that appropriate, proportionate and effective containment and control measures are applied, to prevent the release or escape of specified animal pathogens into the environment where they may cause serious animal disease. A specified animal pathogen can only be held or used by those who have a SAPO licence, which contains a set of conditions that must be met. Licence conditions are goal setting, so the guidance will help licence holders assess the extent of the arrangements required to comply with each licence condition. These should be proportionate to the level of hazard and complexity.

4 The guidance is organised so that each licence condition is supported by guidance explaining what the condition is intended to achieve and how the licence holder can comply with it effectively.

5 The guidance should be considered in the context of any policies, arrangements or procedures that already exist for other work related to biological agents carried out in an organisation (ie genetically modified microorganisms or human pathogens). The HSE website (www.hse.gov.uk/biosafety/index.htm) has additional guidance on these activities. Where these arrangements apply, they may be sufficient to meet the conditions set out in the SAPO licence with minor adjustments or additions, although the arrangements should always be checked to confirm this.

Specified animal pathogens

6 'Specified animal pathogen' means an animal pathogen listed in Schedule 1 of SAPO including:

(a) intact pathogens;

(b) pathogens which have been attenuated or genetically modified by any means; and

c) any nucleic acid derived from an animal pathogen listed in the Schedule which could produce that pathogen when introduced into a biological system in which the nucleic acid is capable of replicating.

7 'Carrier' means any living creature, except man, which may carry or transmit a specified animal pathogen or the tissue, cell culture, body fluid, excreta, carcase or part of a carcase of such creature by or by means of which a specified animal pathogen may be transmitted.

8 'Notifiable' diseases are animal diseases that must be reported to the Animal and Plant Health Agency (APHA). Notifiable diseases can be endemic, already present in the UK, or exotic and not normally present in the UK. Some endemic and exotic diseases are zoonotic which means they can spread between animals and humans. Further information on notifiable animal diseases is available at www.gov.uk/government/collections/notifiable-diseases-in-animals.

9 Defra has classified these pathogens into four groups, which helps to determine the most appropriate containment and control measures to be applied:

Group 1 – Disease-producing organisms which are enzootic (native in animals in this country) and do not produce notifiable disease.

Group 2 – Disease-producing organisms which are either exotic or produce notifiable disease, but have a low risk of spread from the laboratory.

Group 3 – Disease-producing organisms which are either exotic or produce notifiable disease and have a moderate risk of spread from the laboratory.

Group 4 – Disease-producing organisms which are either exotic or produce notifiable disease and have a high risk of spread from the laboratory.

10 Only Groups 2, 3 and 4 are specified animal pathogens and require a SAPO licence before they can be possessed or used. Group 4 includes foot and mouth disease virus (FMDV), to which additional and specific containment and control measures apply (ie 'Minimum Biorisk Management Standards (MBRMS) for laboratories working with foot-and-mouth disease virus' – 'the minimum standards').

11 A separate classification scheme for human pathogens for the purposes of protecting employees under the Control of Substances Hazardous to Health Regulations 2002[4] (COSHH) is given by the Advisory Committee on Dangerous Pathogens (ACDP) in the *Approved List of biological agents*.[5] The classification of a pathogen is not necessarily the same under the different regimes and where a specified animal pathogen falls under both regimes, licence holders must consult both classifications and apply the more stringent classification.

12 Where the work involves genetically modified derivatives of SAPO agents, both SAPO and the Genetically Modified Organisms (Contained Use) Regulations 2014[6] (GMO(CU)) will apply. The SAPO licence applies to both the wild-type pathogen and any genetically modified or attenuated derivatives and will not require amendment each time a new genetically modified or attenuated derivative is introduced. The notification requirements of GMO(CU) will still apply. For information on GMO(CU) notifications please see www.hse.gov.uk/biosafety/GMO/notifications/index.htm.

13 Work activities involving zoonotic specified animal pathogens are also covered by the Health and Safety at Work etc Act 1974[7] (the HSW Act) and relevant regulations made under the HSW Act. These include, where appropriate, the Management of Health and Safety at Work Regulations 1999,[8] COSHH and GMO(CU). Where the provisions of COSHH and GMO(CU) also apply (alongside SAPO), the risk assessment must consider all regulations when determining the most appropriate control measures for the work. In circumstances where the relative requirements differ, the more stringent control measure must be applied.

SAPO licences

14 The purpose of SAPO is to prevent the introduction and spread into Great Britain of specified animal pathogens which, if introduced, could cause serious disease and economic loss to the British livestock and poultry industries.

15 SAPO licences have goal-setting licence conditions, which when met achieve adequate containment (including transport, storage and disposal) of specified animal pathogens. Licences are usually valid for five years and inspections of SAPO-licensed premises may be carried out to assess compliance with licence conditions.

16 The SAPO licence requires that certain requirements are recorded either electronically or using paper documentation (eg a local code of practice, risk assessment, training records) and in a manner proportionate to the risks. For SAPO2 work these requirements could be captured in a single set of local rules or code of practice, while a greater level of detail will be required for SAPO3 and 4. Licence holders may find it convenient to combine these arrangements with those already existing for GMOs or human pathogens.

17 SAPO states that no person may have in their possession any specified animal pathogen listed in Part 1 of Schedule 1 of SAPO or any carrier in which they know such a pathogen is present except under the authority of a licence. It also states that no person may deliberately introduce into any animal any pathogen listed in Parts 1 and 2 of Schedule 1 of SAPO except under the authority of a licence. SAPO also requires any person who has in their possession anything in respect of which they have reasonable grounds for suspecting that a specified animal pathogen in Part 1 of Schedule 1 of SAPO is present, and who does not have a licence in respect of that pathogen, to immediately notify the Secretary of State via the licensing authority. SAPO has no application to any animal pathogen or carrier contained in veterinary or human medicines licensed for use in the UK by the Veterinary Medicines Directorate or the Medicines and Healthcare Products Regulatory Agency.

18 Any incident resulting from a breach of security, act of terrorism or deliberate vandalism involving specified animal pathogens is a matter for the police. Certain specified animal pathogens also fall under the Anti-Terrorism, Crime and Security Act 2001[9] (ATCSA) which is the responsibility of the Home Office. Where the use of

specified animal pathogens involves animals, additional animal welfare legislation (The Animal (Scientific Procedures) Act 1986)[10] will apply.

Applying for a licence under SAPO

19 Those who intend to possess or work with a specified animal pathogen or a carrier of a specified animal pathogen in England, Scotland or Wales must complete an application form for a licence under SAPO, which can be found on the HSE website. An electronically completed form may be submitted or a Microsoft Word version of the application form can be downloaded at https://www.hse.gov.uk/forms/sapo. As the licensing process can take up to three months to complete and may require a pre-licensing inspection, applicants should allow sufficient time before work with the specified animal pathogens is proposed to start.

20 The application form must be completed for any activities involving specified animal pathogens. For new or additional specified animal pathogens, and for the renewal of licences, the form should also be completed. The application must be accompanied by a risk assessment and include details of the management arrangements. Where appropriate, additional information or evidence to support the application should be provided. Where there is insufficient detail to make a full assessment, HSE will contact the applicant and request additional information.

21 Having considered all documentation, HSE will decide whether a pre-licensing inspection should be performed as part of the application process. This inspection will assess whether the risk assessment is sufficient, appropriate containment measures are in place, laboratories have the necessary trained staff, and there are appropriate operating procedures and facilities to ensure the safe containment, handling and disposal of the specified animal pathogens concerned. Pre-licensing inspection is unlikely to be required for SAPO2 licences but may be required for SAPO3 and 4.

Transferring specified animal pathogens

22 Licences issued under SAPO contain conditions intended to achieve the safe transfer of specified animal pathogens and/or carriers and their derivatives between licensed premises or holders (including movements to ports or airports) without the need for separate transfer licences. The licence condition requires the appropriate packaging, labelling and transport for the type of material and pathogen being transported. This also includes a requirement to check receipt of a consignment and notification to the licensing authority where the consignment does not arrive at its intended destination. Further information can be found in condition 7 on transport of specified animal pathogens.

23 For the domestic transfer to be licensed, both the sender and the receiver of the specified animal pathogen or carrier must hold a current SAPO licence for the specified animal pathogen(s) concerned. For international transfer, the sender is required to comply with international transport regulations and meet any additional regulatory requirements of the country to which the specified animal pathogen is being sent.

Importing specified animal pathogens

24 This guidance does not cover importation of specified animal pathogens or carriers from a country outside the EU. A separate licence under the Importation of Animal Pathogens Order 1980[11] (IAPO) will be required to authorise the importation.

These IAPO licences are issued by the Imports Team of APHA. An IAPO licence authorising the importation of a specified animal pathogen or carrier will only be issued if the applicant holds a SAPO licence to hold/work with the specified animal pathogen concerned. Further information and an application form can be obtained from APHA (Imports@AHPA.gsi.gov.uk).

25 The SAPO licence holder is required to make appropriate arrangements for the safe transport of the specified animal pathogen from the port of entry to the licence holder's laboratory. If a specified animal pathogen or carrier is being sourced from another EU Member State, the SAPO licence holder at the receiving laboratory must ensure that appropriate arrangements are in place for the movement of the specified animal pathogen from the port of entry in England, Scotland or Wales to the licensed laboratory. A separate IAPO licence will not be required for this procedure.

Section A: Front page of licence

General licence application and obligations

This licence is granted by the Health and Safety Executive of Redgrave Court, Merton Road, Bootle, L20 7HS ("the licensing authority") to [ADD NAME] of [ADD ADDRESS] ("the licence holder") under Article 4(1) of The Specified Animal Pathogens Order ("SAPO") and authorises the licence holder to have in their possession at [ADDRESS OF SITE] ("the licensed site") the specified animal pathogens listed in Schedule 1 to this licence and subject to the conditions at Conditions 1 to 11 of this licence document.

Section B contains certain defined terms used in the licence.

This licence expires on [ADD DATE], after which date it is no longer valid.

Failure to observe any condition in this licence without lawful authority or excuse is an offence under the Animal Health Act 1981.

26 The SAPO licence issued by HSE on behalf of the Secretary of State for Defra, the Scottish Ministers and the Welsh Ministers, provides the authority for the licence holder to undertake activities involving a specified animal pathogen, provided the licence holder complies with the conditions set out in the licence. The licence contains a number of goal-setting conditions intended to ensure the safe containment of the specified animal pathogen. The actual containment and control measures, extent of the arrangements and resources to ensure compliance with each licence condition will vary depending upon the SAPO classification of the specified animal pathogen, the findings of the risk assessment and the containment level which must be applied.

27 The licence holder will usually be the organisation or institute where the work with the specified animal pathogen will be carried out and only in rare circumstances will it be an individual. Consequently, the licence application form must be signed by someone empowered to act on behalf of the organisation. Similarly, the responsibility for ensuring that the licence conditions are complied with and that specified animal pathogens are adequately contained will rest with the organisation. Schedule 1 of the SAPO licence lists the specified animal pathogen(s) to which the licence applies and covers all forms of the specified animal pathogen (including genetically modified or attenuated versions) as defined in the Order. Schedule 1 also provides details of the containment levels required for their use and any derogations from this. For example:

Schedule 1: Licensed specified animal pathogens

Specified animal pathogen	Approved containment level	Approved derogation(s)
Trypanosoma brucei	SAPO containment level 2	Containment measure (7) of Table 1 relating to an autoclave being required in the building
Bacillus anthracis	SAPO containment level 3	
Bacillus anthracis Sterne strain	SAPO containment level 2	

28 The licence does not restrict the activities involving specified animal pathogens at the licensed address to a particular room or rooms, but the organisation must ensure that the rooms used for such activities meet the licence conditions. Work with a specified animal pathogen in a room which did not meet the containment requirements for that specified animal pathogen would be a failure to comply with the licence condition on the application of containment and control measures.

29 The licensing authority has the discretion to vary the duration of the licence. Licences are usually valid for five years. At the end of the licence period, the licence expires and the licence holder is therefore no longer authorised to possess or use the specified animal pathogen to which the licence applies. Before the expiry date, the licence holder must reapply for a licence if they intend to continue to possess or use specified animal pathogens. While HSE aims to send a letter reminding licence holders that their licences are due to expire, licence holders should not rely on this and it is their responsibility to ensure that they hold a valid licence for any activities with specified animal pathogens. When new licences are issued, the previous licence is revoked.

Section B: Glossary of defined terms

1. In this licence:

a) "**accident**" means an unplanned or uncontrolled event involving the escape of a specified animal pathogen from containment;

b) "**containment**" is a reference to the containment of a specified animal pathogen by means of physical, chemical or biological barriers, or any combination of such barriers, used to limit their contact with, and to provide a high level of protection for, animals;

c) "**dangerous occurrence**" means an unplanned or uncontrolled event involving a specified animal pathogen that has not resulted in its loss of containment, but which had the potential to do so;

d) "**inspector**" means a person appointed by the licensing authority under section 89 of the Animal Health Act 1981 for the purpose of enforcing SAPO;

e) "**specified animal pathogen**" has the meaning given in Article 3(1) of SAPO;

f) "**user of specified animal pathogens**" means any person whose actions may affect the containment of specified animal pathogens and includes any person who has in his or her possession specified animal pathogens or who works with or comes into contact with specified animal pathogens (as defined in Article 3(1) of SAPO; and "**use of specified animal pathogens**" should be construed accordingly;

g) a reference to "**waste**" includes waste in the form of solid, liquid, cultures, and contaminated materials; and

h) any reference to "**work**" involving specified animal pathogens is to be construed as relating also to the manipulation, storage, transport, waste and maintenance of specified animal pathogens.

2. In this licence a reference to the singular includes the plural and vice versa.

Section C: Licence conditions

Condition 1 Management arrangements

1(1) The licence holder must prepare and implement suitable and effective management and supervision arrangements for the prevention of loss of containment of specified animal pathogens, appropriate for the specified animal pathogens listed in schedule **1**.

1(2) In preparing and implementing the arrangements referred to in Condition 1(1) the licence holder must:
(a) prepare a suitable policy, which must include a plan of how that policy will be implemented, the performance benchmarks required to be achieved and the resources that are required to achieve those performance benchmarks;
(b) implement that policy, by identifying and assessing risk and control measures;
(c) measure and review performance through proactive monitoring, and investigation after accidents and dangerous occurrences;
(d) implement the findings from performance measurements and reviews undertaken in accordance with Condition 1(2)(c);
(e) consult, as appropriate, users of specified animal pathogens on the licensed site.

1(3) The licence holder must appoint one or more competent persons to assist in undertaking the measures required to comply with the requirements imposed under this licence, except where this would not be appropriate.

1(4) The licence holder must ensure that the:
(a) number of persons appointed under Condition 1(3);
(b) the time available for them to fulfil their functions; and
(c) the means at their disposal,
are adequate, having regard to the risk of loss of containment of specified animal pathogens, and the complexity of the licence holder's undertaking.

1(5) Where the licence holder uses or shares premises with other persons, the licence holder must prepare and implement suitable and effective arrangements for co-operation and co-ordination with those persons, as necessary, for the prevention of loss of containment of specified animal pathogens. Other persons includes other SAPO licence holders, persons who are not SAPO licence holders and persons who visit the premises on a temporary basis.

1(6) In preparing and implementing the arrangements referred to in Condition 1(5) each licence holder must:

(a) address, as appropriate, the matters at Conditions 1 to 11 of this licence; and
(b) ensure that suitable and adequate information is exchanged with other licence holder(s) and others, as appropriate.

1(7) The arrangements referred to in Conditions 1(1) and 1(5) must be recorded in writing.

30 The SAPO licence requires licence holders to implement appropriate arrangements for the effective management of activities with specified animal pathogens so that they are adequately contained. Most, if not all, licence holders will already have existing management arrangements for controlling health, safety and environmental risks from activities involving biological agents (eg GMOs or human pathogens). In most cases, these existing arrangements will be appropriate for activities involving specified animal pathogens. In practice, therefore, all that may be necessary to ensure compliance with this condition is to confirm that the existing arrangements are adequate to cover specified animal pathogens.

31 The complexity and hazards associated with the specified animal pathogen will also determine the extent of the management arrangements and the level of oversight required. For example, a single laboratory working with a single SAPO2 specified animal pathogen may include all the documentary requirements and management arrangements required by their licence in a single set of local rules for laboratory work. The management arrangements must cut across all activities involving specified animal pathogens and should be clear, practical and robust. To be effective, individuals at all levels of the management chain should understand, accept and commit to delivering these arrangements.

32 Other safety management systems apply the 'Plan, Do, Check, Act' cycle to implement their arrangements effectively. Although not a requirement, this approach is one way of implementing management arrangements for specified animal pathogens. The different steps in this process are explained for clarity, but in practice this may be condensed as appropriate to the activity being performed. This model emphasises the importance of not only devising and implementing appropriate containment management systems, but also their monitoring and appropriate adaptation to remain effective.

33 Underpinning each stage of the 'Plan, Do, Check, Act' model are core elements including leadership, management, competence, risk profiling, worker involvement and legal compliance. Additional information and detail on the Plan, Do, Check, Act model and its core elements are available from the HSE website.[12] A relevant example of its application to major hazard industries is available in the HID Regulatory Model.[13]

34 Devising and implementing an effective containment management system requires a sustained and systematic approach to reviewing performance against a plan, and subsequently modifying the plan to take account of new risks or new activities involving specified animal pathogens. This is an iterative cycle approach, where each full completion of the cycle will result in refinement and improvement to the arrangements.

35 Applying this approach is one way of complying with the SAPO management arrangement licence condition (summarised in Table 1).

Table 1 The actions involved in delivering effective arrangements

Plan, Do, Check, Act	Specified animal pathogens licence condition
Plan	Prepare a suitable policy to contain specified animal pathogens, which includes a plan of how this will be implemented (ie roles and responsibilities, scope of the activities encompassed); how the system will be monitored (ie the desired performance benchmarks) and the resources required to implement the plan and achieve those performance benchmarks.
Do	Implement that policy, by identifying and assessing risk and applying the containment and control measures.
Check	Measure and review performance, through proactive monitoring and investigation after accidents and dangerous occurrences.
Act	Implement the findings from the monitoring, investigations, performance measurements and reviews undertaken.

Preparation of suitable SAPO management arrangements

36 Setting out the arrangements is the first step in developing suitable and sufficient management and supervision arrangements. These arrangements should be appropriate to the nature and scale of the risk associated with the facility and activities with specified animal pathogens. They should be easy for all relevant people to read and understand. They may include the following:

(a) producing a plan and procedures to ensure sustained compliance with all licence conditions so that specified animal pathogens are suitably contained within the licensed facility;

(b) reducing the risk of a loss of containment of specified animal pathogens by appropriate hazard identification and conducting suitable and sufficient risk assessments, the output of which will be the implementation of the required control measures (including how these will be monitored, maintained, replaced and operated effectively);

(c) ensuring a high level of visibility from senior managers (leaders) and their support for specified animal pathogen containment;

(d) learning from accidents, dangerous occurrences, performance reviews and making any changes required for the continuous improvement of the containment management arrangements;

(e) providing clear roles and responsibilities and a suitable number of trained and competent people to ensure containment, particularly for those tasked with a biosafety role;

(f) arrangements for ensuring users of specified animal pathogens (or those involved in providing and maintaining control measures) are trained and competent;

(g) specifying performance benchmarks to be achieved and how performance against them will be monitored (by whom and at what frequency);

(h) arrangements for ensuring remedial work is carried out in an effective and timely manner, according to the importance to containment of specified animal pathogens; and

(i) providing adequate resources to achieve the policy's objective of preventing the loss of containment of specified animal pathogens.

37 As part of the management condition, senior managers must understand and fulfil their responsibilities to manage containment of specified animal pathogens.

38 In preparing the arrangements, individuals with first-hand knowledge of specified animal pathogens activities and experience of working in a containment laboratory should participate. This not only imparts a level of ownership, but also ensures that the arrangements are fit for purpose. Participation of others who may be affected by the management arrangements (eg maintenance staff, cleaners) should be considered and the extent of this will depend on the size and structure of the organisation. The key aims in consulting users are to ensure that all credible risks have been identified, appropriate containment and control measures are implemented, those assigned roles and responsibilities are competent to fulfil them and that the arrangements take account of the most relevant and up-to-date information.

Implementation of the SAPO management arrangements

39 The next step involves the implementation of the arrangements. To achieve this effectively, all risks arising from activities involving specified animal pathogens should be identified. While there is guidance on how to perform a risk assessment that complies with the requirements of the relevant licence condition (condition 3), the management arrangements should focus on the system for generating suitable and sufficient assessments, obtaining competent advice and obtaining an appropriate level of authorisation.

40 Having identified the risks, the key aspect of implementation is the application of the containment and control measures determined by the risk assessment. The effectiveness and importance of control measures must be considered when deciding on an appropriate level of supervision and management control. It should also extend to the level of training and competence of individuals in applying these containment and control measures, ensuring they are provided with the right tools and equipment to do the job, and are supervised appropriately to make sure that procedures are followed.

41 The extent of the arrangements must also include responding to circumstances where things do not go to plan. Procedures for dealing with unexpected events must be implemented to ensure that consequences arising from an accident or emergency are minimised. Those with allocated responsibilities must be competent to deal with such situations. The SAPO licence requires that specific emergency arrangements are put in place. The extent of these arrangements will be proportionate to the level of hazard (eg for SAPO2 and many SAPO3 activities, it is unlikely that emergency arrangements to deal with off-site issues will be required). Further information can be found in the guidance accompanying licence condition 8.

42 For critical control measures or procedures, the management arrangements should extend to ensuring that any changes to these measures or procedures are appropriately identified and that such changes are assessed. This will involve a change control mechanism, which must ensure that any changes to critical control measures or procedures do not increase the risks of a loss of containment of specified animal pathogens.

Measuring and reviewing performance

43 The performance measurement arrangements must be devised so they can determine if the management arrangements have been implemented successfully

and should provide an indication of the adequacy and ongoing effectiveness of the containment and control measures. Individuals tasked with undertaking performance measurement should be appropriately trained and competent to do this. The frequency of monitoring and review should be proportionate to the level of complexity and hazard (eg at SAPO4, these arrangements will be extensive, while at SAPO2, these may comprise an annual inspection supplemented by routine operator visual checks). Table 2 summarises key aspects of containment performance management.

44 Performance measurement requires time and planning to ensure the most informative and relevant measurements are used. The risk assessment will inform the range, type and number of control measures that require performance monitoring; sufficient resources (time, people and financial) should be allocated to ensure this is done effectively. For example, one method of measuring performance is through inspection. This can be used effectively to determine whether control measures are in place and if they are operating as intended, but is dependent on the inspections focusing on relevant and appropriate matters. An inspection proforma that specifies the areas to be assessed can facilitate an informative, consistent and effective monitoring regime. Inspections should not be limited to physical control measures (eg maintenance of microbiological safety cabinets (MSCs)), but extend to assessing procedural and administrative controls (eg risk assessments and training/competence records).

Table 2 Key actions in measuring performance effectively

Key actions in measuring performance effectively
Who will monitor what? You should involve different levels in the management chain. Whoever is involved requires the correct level of competence and training to enable them to fulfil their obligations. **Decide how often monitoring will take place** Be proportionate and take into consideration the risk profile of the activities undertaken. Focus should be on the key risks and the containment and control measures required to control those risks. This may require a more detailed inspection, possibly performed by individuals with specialist knowledge. The frequency of some monitoring or inspections is determined by law. Ensure that these are taken into account when determining your inspection programme. **Decide who the results of the monitoring will be reported to** The outcome of monitoring should be reported back to key individuals who have the responsibility and authority to initiate change in the containment and control measures employed.

45 There are two main types of performance measuring, categorised as either proactive or reactive. All licence holders must undertake routine proactive performance measurements, which focus on the status of the control measures at a specific point in time and are repeated at periodic intervals (eg laboratory inspections). This provides an indication of whether control measures are in place and effective. Arrangements of this nature should be performed frequently, with the periodicity, extent and complexity of the inspection being governed by the nature of the activities involving the specified animal pathogen.

46 Reactive monitoring involves investigation after adverse events have occurred (including dangerous occurrences and accidents). An effective investigation should have a methodical, structured approach to information gathering (evidence), collation and analysis, identifying the critical failures and the root cause of the event to determine the remedial action to take to prevent it from happening again.

47 Adverse event investigation arrangements should be devised, reviewed and then updated regularly to ensure they are relevant to the activities with specified animal pathogens and should include:

(a) definition of what constitutes an adverse event for the purposes of internal recording and reporting to management;

(b) means of reporting accidents/dangerous occurrences to the licensing authority;

(c) allocation of roles and responsibilities for undertaking investigations;

(d) analysis of investigation reports to determine any recurrent themes or common root causes;

(e) means of ensuring remedial action is completed (eg applied to risk assessments, procedures etc) so as to prevent a reoccurrence; and

(f) means of communicating key messages from the investigation to relevant individuals (eg other laboratory workers, line managers, safety officers and senior management).

48 Both proactive and reactive monitoring are important and will generate actions that should be implemented in a timely fashion to be effective and ensure that the containment and control measures continue to operate as intended. All remedial actions arising from performance measurement should be assigned to a person with a prioritised date for completion. Performance measurement data should be analysed and reviewed. This will indicate the overall adequacy of the management arrangements and the effectiveness of the containment and control measures. Ultimately, this will provide assurance to the licence holder that they are complying with the conditions of their licence. Licence holders are also able to revise performance benchmarks so they can improve performance and respond to other changes that may affect the activities with specified animal pathogens. Monitoring may also indicate potential efficiencies and lessons to be learned from the experience gathered.

Competent assistance/advice

49 When devising and implementing management arrangements, the licence holder must appoint one or more competent person(s) to help. Where, given the size and resources of the organisation, a relevant competent individual is not available, it is acceptable for an external person or consultant to provide this advice. It is important to note that the competent person(s) is providing advice on how to comply with the licence, however it is the responsibility of the licence holder (ie organisation) to ensure breaches of the licence do not occur.

50 The appointed person(s) should have sufficient relevant training, experience and knowledge of the risks associated with contained use of specified animal pathogens, and have the competence and authority to help the licence holder ensure compliance with the requirements of the SAPO licence. Depending on the nature of the work and the size and complexity of the organisation, it may be necessary to obtain advice from or appoint more than one person, each with expertise in a different area, to ensure that the risks are adequately assessed and the most appropriate containment and control measures are applied.

51 There is no requirement in the licence to form a safety committee. However, if a licence holder has access to a biological safety committee with the relevant expertise, it is acceptable to use this as a source of competent advice. Using a committee does not replace the requirement to appoint a competent person.

52 A biological safety committee can play a valuable role in the peer review of risk assessments, development of safety procedures (or local rules), assessment of accidents and dangerous occurrences and evaluation of wider information and literature on specified animal pathogens. This can only be achieved if the members of the committee have relevant expertise and knowledge in areas related to the containment of specified animal pathogens. Additionally, it is advisable that the committee contains a range of representatives from various technical disciplines with experience in relation to work with biological agents, including management, employees and biological safety advisers.

53 For example, it may be appropriate for a licence holder with one laboratory performing research with a SAPO2 specified animal pathogen to rely on the Principal Investigator for competent advice. In such circumstances, arrangements should be implemented to ensure a degree of independent peer review. For other licence holders that use a number of specified animal pathogens an individual, such as a biological safety advisor, may be appointed to provide competent advice or facilitate obtaining advice from a biological safety committee.

54 The person(s) appointed to provide competent help/advice must be provided with sufficient resource (time and financial) to enable them to discharge their duties in a timely and effective manner. If this role is in addition to their other duties, this should be factored into the amount of available time required to discharge their duties under SAPO.

55 The management arrangements must be recorded (either electronically or in hard copy), to ensure that they are effectively communicated to relevant people, they are understood and complied with, and to ensure that all parts of the system are adequately addressed, monitored and reviewed. This will also demonstrate how this licence condition has been met.

56 Table 3 provides an example of the application of management arrangements for inspection of a SAPO3 or 4 containment laboratory. For SAPO2, it is expected that the monitoring arrangements would be condensed and more proportionate to the level of hazard and complexity of the work.

Table 3 Example of the application of the plan, do, check, act model for implementing management arrangements to control the risks associated with SAPO3 and 4 specified animal pathogens.

Application of the plan, do, check, act model for performing an inspection (checking) of a SAPO containment level laboratory
Identify the most appropriate person to fulfil the task – this could be a person of a certain managerial level or specific named individual. The person tasked with this responsibility should have sufficient experience and knowledge of working with specified animal pathogens and be able to determine when the required standard is not being met.
Define the role – inspection of the containment laboratory to determine if control measures required by a risk assessment are in place and working effectively.
Define the level of competence required to fulfil the roles/responsibilities – individuals should have knowledge and understanding of how a containment laboratory operates and the correct functioning of control measures employed within the laboratory. This level of competence can be achieved using targeted and specific training or can be gained from working in such a laboratory.
Define the standard to be achieved – the inspection must be assessed against the control measures identified by the risk assessment, in addition to the legal requirement (SAPO licence condition) for that particular containment level. The inspection should be more than a tick-box exercise requiring the individual performing the inspection to be competent to identify and interrogate when things are not working as normal (effectively).
Define the frequency of the monitoring – ad hoc or determined by a program of inspections carried out against a pre-determined schedule.
Define what will happen to the results of the monitoring – the reports of the inspection, with non-compliances clearly labelled, should be reported to an individual (either a named individual or someone fulfilling a specific job role) within a time frame pre-determined by the plan. For example, by email to the laboratory manager within seven days of the inspection taking place. However, the individual tasked with performing the inspection must have sufficient competence to know when an identified non-compliance requires immediate remedial action to be implemented, escalating this information up the line management chain as appropriate.

Cooperation and coordination

57 There are circumstances where a premise is shared by multiple employers, such as university laboratories being shared by research council and university staff; centres consisting of a number of small start-up companies; or contractors undertaking maintenance or testing in SAPO-licensed laboratories.

58 Where this is the case, licence holders are required to make arrangements to ensure there is adequate cooperation and coordination to ensure that all parties operate in a manner that does not present a risk of a loss of containment of the specified animal pathogen. All parties should be sufficiently informed about all the risks that may be present, through an adequate exchange of information about the nature of the activities being performed. In certain circumstances, those sharing the premises should consider joint arrangements to meet the requirements of the licence (eg appointment of a health and safety coordinator). These arrangements must be documented and should be signed by all those concerned.

59 The extent of information that is exchanged between parties should be limited to that required to ensure the containment of animal pathogens. For example, there is no requirement to share information of a commercial or national security nature – the exchange should focus on aspects such as the main risks associated with the work, actions to be taken in the event of a loss of containment, and contact details for the individuals responsible for controlling the work. In its simplest form, this could result in the exchange of a pathogen-specific risk assessment.

60 Contractors or other individuals, who do not normally work with specified animal pathogens, may access facilities (such as laboratories) to undertake maintenance and/or repair of equipment, and carry out cleaning or perform other tests (both routine and non-routine). These individuals should be provided with information relevant to their activities to ensure that during their work they do not create a risk of a loss of containment of a specified animal pathogen. Information should be provided through a written permit-to-work system or similar documentation.

61 The information exchanged between parties must be periodically reviewed to ensure it remains up-to-date and accurately reflects the risks associated with the work being conducted. Additionally, changes in the management structure of an organisation are also likely to trigger a review and the revised position should be communicated accordingly to the other party. This ensures that in the event of a dangerous occurrence, an appropriate means of communication between parties can be established.

Condition 2 Training and competency

2(1) The licence holder must provide all users of specified animal pathogens with suitable and sufficient information, instruction and training for the prevention of the loss of containment of specified animal pathogens.

2(2) Without prejudice to the generality of Condition 2(1), the information, instruction and training provided under that paragraph must include:
- **(a) appropriate reference to the arrangements, referred to in Condition 1(1) and the significant findings of the risk assessment, referred to at Condition 3;**
- **(b) the appropriate precautions and actions to be taken by users of specified animal pathogens in order to prevent an accident or dangerous occurrence;**
- **(c) suitable reference to the emergency arrangements at Condition 8.**

2(3) The information, instruction and training required by Condition 2(1) must be:
- **(a) repeated where appropriate;**
- **(b) provided in a manner appropriate to the level of hazard and risk posed by activities undertaken with the specified animal pathogens;**
- **(c) adapted to take account of significant changes in the type and method of the use of specified animal pathogens.**

2(4) The licence holder must retain suitable and sufficient records of the information, instruction and training that has been provided.

2(5) The licence holder must ensure that so far as is reasonably practicable, every user acts appropriately and in accordance with any training they have received and instructions respecting appropriate behaviour, which have been provided by or on behalf of the licence holder.

2(6) The licence holder must ensure so far as is reasonably practicable, that all those persons who have received information, instruction and training (in accordance with this Condition) have understood that information, instruction and training and are sufficiently competent to act in accordance with that information, instruction and training.

62 The licence holder must ensure that all users of specified animal pathogens are provided with suitable and sufficient information, instruction and training and that having received this, the users are competent to use specified animal pathogens in a contained manner. The extent of the information, instruction and training will vary with the complexity of the hazards, risks, processes and controls associated with the activity. For example, given the greater hazards and procedures/practices, the training programme for SAPO4 should be more detailed and supported with appropriately detailed documentation. For SAPO2, the information, instruction and training, as well as records of this having been provided, may be appropriately captured in a single code of practice or local rules. The measures taken to demonstrate competence should be similarly proportionate to the level of hazard and complexity of the use.

Information, instruction and training

63 At the outset, the licence holder should aim to recruit internal and external individuals who are best suited for the role. Each role should have a set of core competencies assigned that details the required capabilities, knowledge and experience. This will enable selection of individuals who meet these criteria or have the qualities and potential to do so.

64 Information, instruction and training should be tailored to individuals to give them the skills to perform the job/task safely. In order to provide appropriate information, instruction and training, those requiring training should be identified in addition to the level of training that is required. To help with this, it should have a minimum set of job-specific competencies consisting of skills, knowledge and experience, that users should possess or attain for working at a specific containment level and for a specific job or role. This will also permit an assessment of the gap that should be bridged for new users, introduction of new techniques or refresher training for experienced individuals.

65 It is helpful to assign a level of competency to be attained for each task/activity. For example:

(a) **awareness** – has some knowledge, but not enough to act on;

(b) **basic** – has the minimum needed to work under direct supervision;

(c) **intermediate** – able to work unsupervised under routine, ‘normal’ conditions;

(d) **advanced** – able to work unsupervised under all conditions; or

(e) **expert** – able to develop and adapt working practices in response to events and unusual conditions.

66 Assigning competence levels ensures that the right people receive the appropriate level of training. For example, all users (including those not directly involved in handling) should have an ‘awareness’ of the risks associated with working with a specific animal pathogen, whereas those working in containment, directly handling the specified animal pathogen, should have an advanced or expert level of competency.

67 As the level of competency to be attained increases, the user should develop a wider appreciation of the properties of the pathogen and a better understanding of the measures required to undertake their work in a contained manner. This means that for someone aiming to become an ‘expert’ they should be fully aware of the biology of the specified animal pathogen and have a wider appreciation of the consequences of a loss of containment.

68 Before a user starts work their training requirements should be clearly identified – this is often referred to as a 'training needs analysis'. This analysis can take account of knowledge and experience from previous jobs/roles as well as considering the type of training and the best means of delivering it.

69 Training can be delivered in a variety of ways depending on the intended outcome and is influenced by a number of factors including the nature and complexity of the work. For low complexity, low-risk work (ie SAPO2) a multi-user classroom-based training program may be adequate and the most appropriate means of communicating key pieces of information. However, for SAPO3 and 4 work that involves specialised pieces of equipment or complex procedures, more detailed, user-specific training is required. Other forms of delivery can include e-learning courses, lectures, formal training courses (internal and external) and practical demonstrations. For SAPO3 and 4, a sensible and effective way of ensuring users develop the required skill set in a safe manner involves working at lower containment levels to gain experience of and become proficient in techniques and procedures using non- or less hazardous pathogens before starting work at SAPO3 and 4.

70 Information, instruction and training should focus on critical aspects to prevent a loss of containment. As a minimum, it should include:

(a) the significant findings of the risk assessment, including information on the inherent hazards of the specified animal pathogen and the consequences of a loss of containment;

(b) the selection of appropriate preventive and protective measures required to ensure containment, and how and when to correctly use these measures;

(c) the management arrangements implemented to ensure the risks associated with work with specified animal pathogens are being controlled;

(d) safe work practices, including use of equipment, handling, storage and disposal of material and waste contaminated with specified animal pathogens;

(e) correct use, including the dressing, removal and disposal of contaminated personal protective equipment (PPE), so as not to result in a loss of containment; and

(f) the procedures to be implemented following a loss of containment both within and outside the facility (emergency arrangements).

Competence

71 Completion of a training program does not automatically ensure that users are competent and able to do their job safely. To provide assurance that risks from work with specified animal pathogens are being adequately controlled, an assessment of the user's understanding of their information, instruction and training (ie competency) should be performed. The competency assessment measures a trained user against a set benchmark.

72 Competence can be assessed in different ways. It can involve simple written or verbal tests of knowledge; observing people using the skill that has been taught; collecting evidence of demonstrated skills for assessment; or setting up an assessment exercise to test how they act and respond to a situation (emergency scenario drills). The method used should be appropriate for the knowledge and skills, and the competency level for the task.

73 As with the training needs analysis, the competency assessment should be structured to identify if there are any gaps or weaknesses that should be complemented with further training. People acting as assessors should know what 'good performance' looks like and be competent to do the assessment.

74 For simple tasks, a peer assessment, carried out by someone competent in that task, is often enough to make an adequate assessment of performance. Whereas, at SAPO3 and 4, due to the increased complexity of the facility, coupled with the higher risks associated with a loss of containment, a dedicated trainer and assessor would be more appropriate to provide the assurance that users are both trained and competent. In either case, the individual who either trains and/or assesses users can be internal or external to the organisation, as appropriate to the task.

75 Training and competency is not a one-off exercise and unless it is periodically repeated there is a risk that the competency of the users will diminish over time. There is no defined period in which refresher training and assessment should be performed as it will be dependent on the complexity and risks associated with the work. However, for those working at SAPO4, there is an expectation that the stringency and frequency will be significantly higher compared with those working at SAPO2 and 3. As a minimum, refresher training should be provided for those involved with infrequent or rarely performed roles with a containment critical element.

Records of training and competence

76 The SAPO licence holder must keep a record of training to demonstrate that users have been provided with suitable and sufficient information, instruction and training. This should not be purely related to training, but also provide a record of a user's assessment of competency. An accurate and up-to-date record is an important part of being able to identify what competencies are in place and the actions being taken to address any gaps. The training record should have sufficient information to demonstrate the extent of the training provided (including knowledge, skills, procedures etc) and the competency level attained. The level of detail recorded in the training record should reflect the complexity and risks associated with tasks and activities performed with the specified animal pathogens. For SAPO2, this may be a single list of SAPO users cross-checked against the training provided and competency level demonstrated and may form part of the laboratory code of practice. For SAPO3 and 4, user-specific training records are likely to be more appropriate.

77 Training in the risks associated with specified animal pathogens should not only be limited to those users who will directly handle the pathogen, but should encompass others such as contractors and engineers. These individuals may or may not be employed by the licence holder and are usually used to carry out maintenance of equipment used in the containment facility. It is important these individuals receive the appropriate level of information, instruction and training, and that it is proportionate and appropriate, so they can perform their tasks without creating a risk of a loss of containment. At SAPO3 and 4, licence holders may find it beneficial to produce a training policy document that identifies all relevant individuals (including those not under the control of the licence holder) who should be trained and details of how the training will be managed, delivered and assessed. This should be monitored for their effectiveness so that changes can be implemented in a timely manner.

Condition 3 Risk assessment

3(1) A suitable and sufficient assessment of the risks from of loss of containment of specified animal pathogens ("risk assessment") must be carried out by the licence holder, which must include assessment of the risks arising from the work being undertaken involving specified animal pathogens.

3(2) The licence holder must review the risk assessment:
- **(a) before making any significant change to the conditions in which the specified animal pathogens in the licence holder's possession are kept;**
- **(b) before making any significant change to the work to which the risk assessment relates;**
- **(c) immediately if there is reason to suspect that the risk assessment is no longer valid;**
- **(d) immediately, following an accident or dangerous occurrence involving the specified animal pathogens to which the risk assessment relates; and**
- **(e) in any event periodically.**

3(3) The significant findings of the risk assessment or review must be recorded in writing.

78 A risk assessment for possession (including use) of specified animal pathogens is a condition of a SAPO licence. It is an important step in ensuring that the control measures applied to protect susceptible animal species are adequate and proportionate.

79 The risk assessment must take account of all risk paths leading to a loss of containment when using specified animal pathogens, including handling, storage, transport (between laboratories and off site), work area decontamination, inactivation, disposal and waste management. Additionally, the risk assessment should also take account of foreseeable misuse of the specified animal pathogen, including biosecurity risks.

80 Where existing risk assessments are in place in relation to genetically modified microorganisms or human pathogens, required by GMO(CU) and COSHH respectively, a similar approach can be applied to the risk assessment for specified animal pathogens. A single risk assessment can be completed to satisfy the requirements of the different legislative regimes, by considering as applicable the risk to human health, susceptible animals and the wider environment.

81 The process of risk assessment should be part of the management arrangements. The key requirement is to ensure that risk assessments are performed before work begins, are of a suitable and sufficient quality, are regularly reviewed and ensure access to adequate competent advice.

Categorisation of specified animal pathogens

82 Schedule 1 of SAPO contains a list of animal pathogens for which a licence is mandatory. This list is based on the intrinsic hazard posed by the animal pathogen to GB animal health but it does not separate the pathogens into groups based on different levels of hazard.

83 Categorisation of biological agents into one of four hazard groups has been the traditional method of separating out biological agents based on a range of

characteristics including: pathogenicity, mode of transmission, minimum infectious dose, host range, availability of preventive measures and effective prophylaxis or treatment.

84 The categorisation of animal pathogens is based on similar characteristics with the primary focus on the potential harm to susceptible animal species, the potential for the disease to spread from the laboratory and the subsequent economic impact (Table 4).

Table 4 Categorisation of animal pathogens

Information box: Categorisation of animal pathogens	
Group 1	Disease-producing organisms which are either enzootic (native in animals in this country) or do not produce notifiable disease.
Group 2	Disease-producing organisms which are either exotic or produce notifiable disease, but have a low risk of spread from the laboratory.
Group 3	Disease-producing organisms which are either exotic or produce notifiable disease and have a moderate risk of spread from the laboratory.
Group 4	Disease-producing organisms which are either exotic or produce notifiable disease and have a high risk of spread from the laboratory.

85 Applying the categorisation provided in Table 4 to the list of specified animal pathogens in Schedule 1 of SAPO allows the separation of each specified animal pathogen into one of three SAPO groups (SAPO2–4). Animal pathogens in Group 1 are not considered to be specified animal pathogens and do not require a SAPO licence. The SAPO hazard group determines the containment level at which the work must be performed. The range, type and number of control measures and the number of layers of protection increase in proportion to the increase in hazard group number, as does the stringency of the management arrangements implemented to ensure the controls are in place and working effectively.

Approach to risk assessment for use of specified animal pathogens

86 For basic and straightforward use of SAPO2 pathogens, it is appropriate for the risk assessment to be compressed into a simple application of the containment and control measures required at SAPO containment level 2. This would be suitable for small-scale laboratory work involving routine procedures.

87 For more complex activities and those involving SAPO3 and 4 pathogens, a full risk assessment is more appropriate. A risk assessment is intended to identify effective measures to control the risks from use or possession of specified animal pathogens.

88 The risk assessment should be performed and/or reviewed by an individual(s) who has experience in performing risk assessment, and knowledge and understanding of:

(a) the physical and biological properties of the animal pathogen (eg the infectious dose, routes of infection and susceptible species);

(b) the laboratory practices and procedures to be used;

(c) the laboratory facilities to be used, including existing biosafety and biosecurity requirements; and

(d) the animal facilities to be used, with specific containment requirements.

89 The categorisation of animal pathogens provides an initial assessment of the hazard of the specified animal pathogen and the consequences arising from a loss of containment. In certain circumstances, the assessment should identify who or what might be harmed, including susceptible animal populations, proximity of such animals and in certain cases extend to operators, the public, or the wider environment. This is relevant where there is a real possibility of specified animal pathogens being mechanically transferred by users who come in contact with susceptible animals outside the containment facility. A precaution that should be considered is a time-bound exclusion in which those working with certain animal pathogens are excluded from contact with susceptible animals for an appropriate length of time (quarantine period). This period should be based on a realistic consideration of the potential for inadvertent transfer of the pathogen via this route.

90 The quality of the completed risk assessment will be directly related to the level of understanding, knowledge and competence of the individual(s) performing this task and the quality of the advice provided. Advice on the risk assessment can be from either a person or committee with expertise in risk assessment relating to containment of biological agents, including specified animal pathogens. This will ensure that the assessment is of an appropriate standard.

Stage 1: Identify the hazards and the minimum set of containment and control measures

91 This approach to risk assessment takes account of the categorisation of the specified animal pathogen (and the associated different containment levels) and the relevant chapter of the World Organisation for Animal Health (OIE) manual for biosafety and biosecurity in veterinary microbiology laboratory and animal facilities.[14] The first stage in the process is to identify the SAPO group of the specified animal pathogen as listed in Appendix 1. The SAPO group determines the minimum set of containment and control measures that must be implemented.

92 The minimum containment and control measures required for the different containment levels (SAPO2–4) and for different types of containment facilities (ie laboratory containment, animal unit containment, arthropod unit containment and other containment facilities) are detailed in Appendix 2, Tables 1–4. For example for a SAPO2 animal pathogen being used in a laboratory, the containment and control measures in the containment level 2 column of Table 1 must be applied.

93 Where different specified animal pathogens are handled in the same facility, the risk assessment should consider the potential consequences arising from any cross-contamination and is likely to require the implementation of additional control measures including separation of work in time and/or space, and inactivation procedures that are effective for all pathogens handled in the facility. Consideration should also be given to the processes in which the specified animal pathogen will be used (eg scale, clinical sample, culture, tissue sample, waste material), as this will also inform which of the different containment tables is most appropriate.

Stage 2: Evaluate the risks and select control measures

94 The determination of the containment and control measures in Stage 1 is not based on risk or consideration of the work that is proposed with the specified animal pathogen. Stage 2 requires that these factors are taken into account to determine if the control measures identified in Stage 1 are adequate, as well as to determine if there are other measures beyond those listed in the containment tables that must be used to prevent a loss of containment.

95 To do this, the assessment should consider the nature of the work and it may be beneficial to link the assessment to a particular piece of research or procedure and/or break the assessment down into individual activities. There must be sufficient detail to identify situations that could foreseeably result in a loss of containment or exposure to susceptible animal species outside the containment facility. The assessment should include consideration of the following:

(a) where the work will be carried out, eg diagnostic facility or research facility;

(b) whether the facility will also be used by individuals not involved in using specified animal pathogens;

(c) whether temporal or physical separation should be applied in a facility where multiple specified animal pathogens or non-SAPO pathogens are used;

(d) the exact nature of the proposed use (eg *in vitro* or *in vivo*);

(e) the range of technical procedures (eg propagation and concentration, centrifugation and sonication) to be used and whether this involves high titres/ concentrations or large volumes and use of solid or liquid media;

(f) whether the procedures could create aerosols or splashes;

(g) arrangements to deal with contaminated waste material, including the decontamination of equipment and personal protective clothing;

(h) where and how specified animal pathogens will be stored and transported (within the same site and to external sites); and

(i) biosecurity arrangements to prevent the theft, loss or intentional misuse of the pathogen.

96 In considering the guidance in paragraph 94, the assessment should indicate the likelihood of harm arising and identify appropriate means of controlling these risks using appropriate containment and control measures. While the SAPO categorisation identifies a corresponding minimum level of containment (eg group 2 specified animal pathogens require measures from SAPO2 containment level) consideration of the nature of the work and credible release scenarios may identify additional containment or control measures, which must be implemented to provide adequate protection. Any containment and control measure implemented to control release of specified animal pathogens must be monitored to ensure it is effective and continues to be so over time. The assessment should also take account of failure mode scenarios of control measures, including emergency situations, and ensure that suitable arrangements are implemented to deal with these events.

97 Overall, the control of risk from work with specified animal pathogens should not rely on a single measure to afford protection to susceptible animal species. Risk management should be proportionate to the overall level of risk posed by the work and be multi-layered so that the failure of a single control measure does not result in a loss of containment or potential release from the laboratory. To achieve this goal, the layers of protection should address technical, managerial and procedural arrangements in addition to physical control measures.The HSE document Major Hazard Regulatory Model – Safety management in major hazard sectors provides further information, and is available at https://www.hse.gov.uk/regulating-major-hazards/assets/docs/major-hazards-regulatory-model.pdf

Stage 3: Record, implement and communicate the findings

98 Risk assessments must be written down or recorded appropriately. Such information as the hazardous properties of the specified animal pathogen (eg infectious dose, routes of transmission, disease etc), the type and nature of activities, details of the required containment and control measures and conclusions from the risk assessment process should be recorded. Administrative details should be recorded to enable sign off and review of the risk assessment (eg the author, approval/authorisation, the date of the assessment).

99 In addition to recording the outcome of the risk assessment, the key findings must be communicated, in an appropriate manner, to staff and other individuals who may be involved with their use. This ensures that these individuals are aware of the risks from the work, how these risks are to be adequately controlled, the importance of containment and control measures including how they are applied, their purpose and when their effectiveness is compromised.

Stage 4: Regularly review the assessment

100 Risk assessments must be periodically reviewed to ensure that they remain up-to-date, suitable and sufficient. While the overall aim of the work may stay the same, it is likely that over time, various aspects of the work may change (eg new agents, new equipment and alteration of procedures or changes in personnel). Such factors may have an impact on the biosafety of the work and therefore initiate a review of the risk assessment. Where there is reason to believe the assessment is no longer valid or any proposed changes may have significant consequences for the containment or control measures, work must stop and the assessment be reviewed before changes are made. Risk assessments must also be reviewed following any adverse event.

101 Inclusion of the risk assessment process as part of a management system will help in this process by providing a structured and coordinated framework for the review of the risk assessment and implementation of actions that may result. Any changes to the risk assessment should be undertaken with the benefit of advice from a competent person and be appropriately authorised.

Derogation from containment and control measures

102 It is possible that due to the nature of the proposed work and the intrinsic hazard of a specified animal pathogen, one or more of the containment measures from a particular containment level are not needed for adequate containment. Where this is the case, an applicant can apply for a derogation (as part of their licence application) from that specific containment measure(s), providing appropriate justification as to why the measure is not required or what alternative equally effective measures are proposed. If, in the opinion of the licensing authority, the justification is acceptable, the derogation from the containment measure(s) will be specifically listed in the SAPO licence.

103 If a derogation from a containment and control measure is required at a time other than during the licence application process, this would be considered to be a significant change to the licence conditions and an amendment must be submitted to the licensing authority for consideration. The case for this amendment must be supported by a suitable and sufficient risk assessment, and a justification of why the dispensation of the measure does not change the risk of a loss of containment.

104 It is important to note that the categorised list of specified animal pathogens contains both non-zoonotic and zoonotic pathogens. Zoonotic specified animal

pathogens are also capable of causing human disease and have been assigned an approved classification by ACDP. The containment and control measures required by the ACDP are not fully aligned with those for SAPO. When considering the derogation from a control measure(s), other relevant legislation, including but not limited to GMO(CU) and COSHH, must be considered. Where there is a conflict the higher standard must be applied.

Example 1: *Non-zoonotic specified animal pathogen.* If a SAPO3 pathogen is not infectious via the aerosol route, the risk assessment may indicate that an inward directional flow of air relative to the immediate surroundings or HEPA filtration of extracted air is not required. However, it would be appropriate to have other control measures from SAPO3 (eg a requirement for the facility to be separated from other areas in the same building).

Example 2: *Non-zoonotic specified animal pathogen.* A requirement for working with a SAPO3 pathogen at containment level 3 is to have an autoclave within the containment facility. In some instances, laboratories do not have access to an autoclave within the facility and rely on the transport of contaminated material to an autoclave that is beyond the containment boundary. A derogation from this measure could be justified based on the implementation of a means of transporting safely the contaminated material from the laboratory to the autoclave, so that it did not increase the risk of a loss of containment of the specified animal pathogen.

Example 3: *Zoonotic specified animal pathogen.* If a zoonotic SAPO3 pathogen is not infectious to animals via the aerosol route there may be a justified reason based on risk to animal health to dispense with the requirements to have and maintain an inward directional airflow relative to the immediate surroundings and the requirement for HEPA filtration of extracted air. However, as the risk of harm to human health still exists, consideration of how this might occur must be considered before dispensing with any containment measures. In such instances, where the containment requirements from COSHH are required to protect human health, they must be implemented.

Attenuated strains of specified animal pathogens

105 Certain strains of specified animal pathogens in the categorised list have a different degree of pathogenicity or virulence than expected and their pathogenic properties are significantly reduced. Attenuated strains may arise through genetic manipulation, exposure to certain chemicals or by natural reassortment. Where the mechanism of attenuation is robust, well defined and supported by evidence (eg from *in vitro* and *in vivo* testing), it may be appropriate to work at a lower level of containment than used for the non-attenuated strain. For example, whilst *Bacillus anthracis* is categorised as a SAPO3 pathogen, the Sterne strain of *B. anthracis* is sufficiently attenuated that it is routinely used in live vaccine development due to its ability to induce immunity but not result in disease. This level of attenuation allows this strain to be safely worked with at a lower containment level.

106 If using an attenuated specified animal pathogen, the licence application must include a full justification (including evidence of the mechanism of attenuation) of why the specified animal pathogen can be used at a lower containment level. Where this is accepted by HSE, this will be reflected in the licence detailing the specific containment level that must be implemented.

Emerging strains of specified animal pathogens

107 Exotic or non-endemic animal pathogens can emerge, which are not listed in Schedule 1 of SAPO but meet the criteria in Table 1 (which describes the different categories of specified animal pathogens) and pose a risk to susceptible animal species within the UK. Before these can be used, a suitable and sufficient risk assessment must be undertaken and the significant findings discussed with HSE. It may be that further advice on the most appropriate categorisation and containment measures should be sought from ACDP before determining whether a SAPO licence is required or finalising the most appropriate containment requirements for the work.

108 In this case, the starting point for performing a risk assessment is to determine a provisional categorisation of the pathogen by considering its intrinsic hazardous properties including pathogenicity, mode of transmission, minimum infectious dose, host range, availability of preventive measures and if a zoonotic pathogen, effective prophylaxis or treatment. Based on these properties, the pathogen can be categorised according to the criteria described in Table 4. Once an interim categorisation has been determined the risk assessment can then consider the nature of the activity in accordance with this guidance.

Condition 4 Application of containment and control measures

4(1) A licence holder who uses specified animal pathogens must apply the appropriate containment measures for the containment level specified in column 2 of schedule 1 (where the applicable containment measures for each containment level are set out in the relevant column of the applicable table at schedule 2) except that the licence holder need not apply a containment measure where:

- **(a) the risk assessment shows that the containment measure, otherwise required for the appropriate containment level, is not necessary or practicable in this instance for a specific activity;**
- **(b) the user has received the prior consent of the licensing authority that the containment measure need not be applied; and**
- **(c) the licensing authority's consent is recorded in column 3 of schedule 1.**

4(2) Without prejudice to Condition 4(1), the licence holder must also apply such additional measures appropriate to the activity, which have been identified by the risk assessment referred to in Condition 3(1) as being required for the prevention of the loss of containment of specified animal pathogens.

4(3) In addition to (and without prejudice to) the requirements in Condition 4(1), the licence holder must ensure that the General Principles of Good Microbiological Practice set out in schedule 3 are applied.

4(4) The licence holder must ensure that all plant and equipment used (including engineering controls and personal protective equipment), with the specified animal pathogens listed in schedule 1, are maintained in an efficient state, in efficient working order, and in good repair.

4(5) Where the licence holder intends to move plant, equipment and other materials contaminated with specified animal pathogens listed in schedule 1, out of containment the licence holder must prepare and implement suitable and sufficient arrangements to ensure that the plant, equipment and other materials are decontaminated by a validated means, before their removal from containment.

4(6) The arrangements referred to in Condition 4(5) must include:
(a) a decontamination management procedure; and
(b) a means of ensuring that all users of specified animal pathogens comply with the decontamination management procedure.

109 Licence holders must apply appropriate containment and control measures to ensure that activities involving specified animal pathogens will be adequately contained, thereby reducing or eliminating exposure of susceptible animals, laboratory workers, other people, and the outside environment to specified animal pathogens. The risk assessment for such activities will determine the appropriate combination of containment and control measures to achieve this purpose.

110 The containment and control measures required to prevent release of specified animal pathogens increase as the containment level increases. Similarly the level of assurance required to demonstrate that the containment and control measures are effective (and will operate as intended) will also increase as the containment level increases. At SAPO2, the extent of the maintenance and monitoring arrangements will be significantly less than at SAPO3, which in turn will be different from at SAPO4.

111 The various containment and control measures applied are a combination of design specification, physical integrity, chemical/biological controls, appropriate equipment, training, procedural and management arrangements. This is achieved by using a combination of primary (eg measures to protect or avoid contamination of the worker and immediate vicinity) and secondary (eg measures to protect susceptible animals, people and the environment outside the laboratory) containment measures and preventive or mitigation barriers.

112 Specified animal pathogens are categorised into SAPO groups 2, 3 or 4. The minimum containment measures required for each of these SAPO groups are set out in the containment tables in Appendix 2. This also defines a corresponding containment level to control the risk.

(a) **SAPO 2** categorisation requires **containment level 2**;

(b) **SAPO 3** categorisation requires **containment level 3**;

(c) **SAPO 4** categorisation requires **containment level 4**.

113 There are four containment tables which apply to different circumstances for use of specified animal pathogens:

(a) **Table 1** sets out measures for activities considered as ‘laboratory type’ in terms of scale and nature. Although not strictly defined, laboratory type contained use may typically involve use of Petri dishes, flasks and culture bottles and small bench-top chemostats and fermenters.

(b) **Table 2** contains additional measures and modifications to Table 1 with respect to activities in animal units or similar facilities. This would normally apply where animals are infected with, or exposed to, specified animal pathogens in an animal unit. The measures in Table 2 are applicable to both small and large animal containment with the exact nature of the measure applied being relevant to the size of the animal (eg the use of pens rather than cages for the containment of livestock). The measures in Table 1 must also be applied.

(c) **Table 3** contains additional measures and modifications to Table 1 (and where relevant Table 2) with respect to activities in units housing arthropods. This would normally apply where arthropods are infected with, or exposed to, specified animal pathogens in an insectory or experimentation unit. The measures in Table 3 are applicable to a range of arthropods with the exact nature of the measure applied being relevant to the size and type of the insect (eg the size of screen or mesh on cages). The measures in Table 1 must also be applied.

(d) **Table 4** sets out containment and control measures for activities carried out in 'other' premises. This table refers to premises that do not fall within the categories in Tables 1, 2 and 3. The types of premises that most commonly fall in this 'other' category are those where large-scale work is performed (eg industrial production, pilot plant facilities). There is no strict distinction between 'laboratory type' and 'large-scale' contained use, but the terminology used in Table 4 is more applicable to the latter.

114 For each of the containment and control measures listed in the containment tables, an indication is given as to whether the measure is '*required*' or '*not required*' for each of the containment levels. In some instances, the term '*required where and to extent the risk assessment shows it is required*' is used, which means the control measure must only be applied if the risk assessment indicates that the measure is required.

115 Users should not be constrained or confined to the containment tables but consider the measures identified by the risk assessment, in addition to those set out in the tables, that may be appropriate to the activity. For example, the use of sealed centrifuge rotor buckets might be required in certain circumstances to protect against the unintended release of aerosols containing specified animal pathogens. Alternatively, a time-bound exclusion in which those working with certain animal pathogens are excluded from contact with susceptible animals for an appropriate length of time (quarantine period) may be warranted. Where the risk assessment identifies such additional containment and control measures these must be implemented.

116 As described in the guidance for condition 3 on risk assessment, all containment or control measures required at an applicable containment level must be implemented unless there is an evidence-based justification that a containment or control measure shown in the tables is not required or practicable for the activity (either not appropriate or equally effective alternatives are available). Under these circumstances, it may be possible to obtain a derogation from the licensing authority (ie for the measure not to be applied).

117 COSHH also applies to zoonotic specified animal pathogens and the selection of containment and control measures to protect human health should be applied from the containment tables in Schedule 3 of COSHH. For example, while an open-fronted MSC may be appropriate for work with low pathogenicity avian influenza virus, a closed-fronted MSC would be required for a high pathogenicity avian influenza virus known to also be infective to humans. Consequently, while the containment tables have been aligned as far as possible, there are specific measures where the SAPO containment tables differ from those in COSHH and GMO(CU). Where this occurs, the more stringent requirement must be applied.

118 In addition to the containment and control measures set out in the containment tables, licence holders must also apply the *Principles of good microbiological practice* (Appendix 3). For each of the principles, the requirement is either mandatory or qualified to the extent to which it is appropriate.

119 The licence holder must ensure that the containment and control measures, equipment, components etc are appropriate for the work in terms of their specification, certification, verification and validation consistent with the intent and requirements of containing specified animal pathogens. In selecting particular control measures, the licence holder should consider:

(a) identifying equipment appropriate for the task and conditions of use (ie that is demonstrated as fit for purpose);

(b) controlling purchase/acquisition of equipment to ensure all risk assessments are completed, and safety critical equipment is included in a planned preventative maintenance regime and its use is authorised by a competent person; and

(c) controlling entry and exit of equipment to and from the containment facility, including decontamination requirements.

120 Licensed laboratories, animal facilities and the biosafety equipment they contain (eg MSCs, isolators, centrifuges with sealable buckets, process equipment, fermenters, isolators, individually ventilated cages, sealed biological waste containers) are key to effective containment of specified animal pathogens. Following installation and at appropriate intervals thereafter, relevant containment and control measures (including equipment) should be calibrated, tested and validated to demonstrate they achieve their intended containment function within specified safety parameters and achieve this in a reproducible and robust manner. Where external contractors are used to undertake these steps, the licence holder must take steps to assure themselves that the contractors are competent and have completed their tasks appropriately (ie all tests have been completed and any actions identified are addressed).

121 The containment and control measures must be maintained in an efficient state, in good repair and efficient working order. To ensure this is the case, the licence holder must implement a planned preventative maintenance programme that applies to all aspects of the physical structure and equipment and at a periodicity consistent with manufacturers' specifications and conditions of actual use. In planning and conducting maintenance activities the licence holder should consider:

(a) adequately maintaining the physical integrity of the facility and its fixtures and fittings;

(b) ensuring that maintenance activities are performed by competent individuals, and that risks associated with the work have been subjected to risk assessment;

(c) identifying and recording maintenance requirements for the facilities, or at the time of purchase/acquisition of equipment (eg maintenance register for equipment);

(d) identifying and conducting planned maintenance activities at an appropriate frequency;

(e) ensuring adequate provision for unplanned (breakdown) maintenance to ensure integrity of the facility is maintained at all times;

(f) determining and monitoring preventative maintenance requirements and associated indicators and alarms; and

(g) ensuring essential backup equipment to provide redundancy and/or spare parts are available in line with a frequency appropriate to the risk of failure and need for replacement.

Decontamination management procedure

122 A key purpose of decontamination is to ensure that it is safe to handle equipment, materials etc outside the containment laboratory such that it does not present a risk of release of a specified animal pathogen. To achieve this, licence holders must prepare and implement a decontamination management procedure that considers the full range of sources of contaminated materials, eg:

(a) personnel, including clothing and PPE;

(b) equipment (including glassware);

(c) cultures and associated contaminated materials (including spill clean-up materials and equipment);

(d) paper, plastic and waste;

(e) needles, syringes and sharps;

(f) waste water (eg from sinks and showers at SAPO4);

(g) filters and air handling systems;

(h) equipment to be removed from the facility;

(i) animal carcases and bedding; and

(j) facilities (ie surfaces in laboratory, air handling units and effluent treatment plant (ETP)).

123 The procedures should include the use of effective methods of decontamination appropriate for the material being decontaminated. The effectiveness of the method must be verified and the parameters of use validated. Following the initial validation, decontamination procedures should take account of the following:

(a) ensuring disinfectants contain sufficient active compound, are replenished regularly and are used in a consistent and prescribed manner appropriate to the conditions under which the disinfectant was validated;

(b) where circumstances change, the validation should be reviewed to determine if the process is appropriate for the activities (eg where waste material changes significantly);

(c) providing adequate facilities and procedures for the storage of waste (including short-term storage) to ensure containment;

(d) ensuring that methods are available for effective decontamination of mixed waste (eg infected animals that have received radioactive materials);

(e) ensuring that where appropriate, methods are available for decontamination of sensitive equipment that are not suitable for autoclaving (eg computers);

(f) where appropriate, implementing periodic monitoring measures to ensure the decontamination procedure is being implemented as intended (eg cycle recording in autoclaves);

(g) decontaminating protective clothing by appropriate means before leaving the facility; and

(h) ensuring adequate methods and resources are available to deal with routine work and any spillages or other incidents during handling and transport of materials inside and outside the facility.

124 The licence holder should ensure that the decontamination procedures are adhered to and recorded.

Condition 5 Operating procedures

5(1) The licence holder must prepare and implement written operating procedures, or their equivalent, for the safe handling of specified animal pathogens to prevent the loss of containment of specified animal pathogens and must ensure that all users of specified animal pathogens comply with these procedures.

5(2) The licence holder must review their operating procedures or their equivalent:
- **(a) before making any significant change to the conditions in which the specified animal pathogens in the licence holder's possession are kept;**
- **(b) before making any significant change to the work to which the risk assessment relates;**
- **(c) immediately if there is reason to suspect that the operating procedures or their equivalent are no longer valid;**
- **(d) immediately, following an accident or dangerous occurrence involving the specified animal pathogens to which the operating procedures or their equivalent relate; and**
- **(e) in any event periodically.**

125 This SAPO licence condition requires the preparation and implementation of written operating procedures for the safe handling of specified animal pathogens to prevent the loss of containment. Additionally, it requires that arrangements are devised and implemented to ensure users comply with these procedures.

126 At SAPO2, the level of hazard does not warrant separate operating procedures unless the risk assessment identifies containment critical processes that are complex or require detailed instruction to ensure containment or control measures are applied appropriately. In most cases, at SAPO2, the local rules or code of practice will be sufficient to set out the key containment-related procedures and information.

127 At SAPO3 and 4, operating procedures must be produced. Operating procedures are an important part of a containment management system and they must detail critical steps for adequate containment in a clear and consistent manner to provide the user with a level of information that enables them to perform a task or activity safely. Additionally, they provide a simple and robust way of minimising errors/failures and standardising working practice. They also provide a vital tool in ensuring that users are adequately trained and competent to perform their duties.

128 Operating procedures can range from detailed instructions, codes of practice, and step-by-step protocols, to short checklists. The format of the operating procedure and the level of detail contained should be determined by considering the risk associated with the activity. This should include the likelihood that containment will be lost, the complexity of the task, how often the task is performed, and the competence of the user. Above all the procedure provided should be verified as fit for purpose. Ultimately, the licence holder must devise and implement arrangements to ensure that operating procedures are adequate in content (eg are understandable and easy to follow), reflect the complexity and nature of the work, are periodically reviewed to verify their content and are kept up-to-date.

129 The safe handling of specified animal pathogens is a broad term and covers processes and procedures, but must include all activities critical to containment, arising from, or in connection with specified animal pathogens. This can include but is not limited to use (eg propagation, concentration, manipulation), receipt, storage, transport, waste, and use of plant and equipment.

130 The risk assessment will identify most steps that are critical to containment, from which a range of operating procedures can be developed. However, the following subject areas should be considered for documentation in written operating procedures:

(a) entry and exit from the containment laboratory/facility;

(b) receipt of and experimental procedures involving the handling of specified animal pathogens;

(c) storage of specified animal pathogens;

(d) inactivation, storage, collection and transport of waste containing specified animal pathogens;

(e) disinfection and decontamination, both routine and non-routine, following a loss of containment, if appropriate;

(f) emergency arrangements;

(g) operation and maintenance of equipment and infrastructure (buildings etc) critical for containment, and other equipment that may impinge on the functionality of this equipment; and

(h) inoculation, maintenance and disposal of deliberately infected animals/insects/invertebrates.

131 An operating procedure need not be a separate defined document and can contain other information that is not related to containment critical steps. This means that the production of a local code of practice that details a range of procedures and working practices within a containment facility may fulfil the requirements of this SAPO licence condition. However, it is imperative that if additional information is provided in an operating procedure or other document, that the information related to containment-critical steps is clearly identifiable.

132 A key part of implementing operating procedures is to ensure that users comply with them. The level of compliance can be maximised if the job or task to which the procedure relates is written so that performing the procedure in a different way is difficult. Furthermore, the procedure should be developed in

conjunction with users, so that it accurately reflects how the task is performed and arrangements are implemented to review and ensure that the procedure is kept up to date.

133 The operating procedures must be reviewed to ensure they remain fit for purpose. This should include a means of ensuring that any proposed changes are adequately risk assessed (eg change in process pipework or containment equipment). The triggers for review should be aligned to those for risk assessment due to the intimate link between the identification of containment critical stages in assessments and the implementation of procedures to ensure these stages are followed. The term 'periodically' indicates that the frequency of review should be proportionate to the level of risk associated with the specified animal pathogen (eg for SAPO3 and 4 the operating procedures will be reviewed more frequently compared with SAPO2).

134 A periodic review of operating procedures is important even if there are no apparent changes in the way the procedure is performed. A review of this nature will prevent creeping changes (or protocol drift) that often go undetected and can ultimately introduce new risks that have not been considered by the risk assessment and can potentially result in practices that increase the risk of a loss of containment.

135 Where written operating procedures are used, they should be subject to a change control system (eg documentation management system) where changes to operating procedures are scrutinised before being authorised and adopted as the current working version. This approach is particularly relevant where changes in one layer of protection have an impact on other containment layers.

136 Operating procedures must be reviewed following accidents or dangerous occurrences to identify if the adverse event was as a result of an inadequate procedure (eg users taking shortcuts because the operating procedure was not appropriate or changes in the procedures which have not been adequately assessed or planned).

Condition 6 Waste management

6(1) The licence holder must prepare and implement suitable and sufficient arrangements to ensure that all waste contaminated with specified animal pathogens listed in schedule 1, are inactivated by a validated means.

6(2) Where the licence holder intends to transport waste contaminated with specified animal pathogens listed in schedule 1, the licence holder must prepare and implement suitable and sufficient arrangements, as identified in the risk assessment, to ensure that the waste is inactivated by a validated means before its removal from containment.

6(3) The arrangements referred to in Condition 6(1) and 6(2) must include:
(a) a waste management procedure; and
(b) a means of ensuring that all users of specified animal pathogens comply with the waste management procedure.

137 Waste management is an integral part of effectively managing the risks associated with specified animal pathogens. Suitable procedures to deal with contaminated waste must be prepared, implemented and monitored. The arrangements should address all aspects of waste management including storage,

transport and inactivation as well as those required to deal with non-routine scenarios such as adverse events (eg an accident resulting in loss of containment) and failure of equipment used to inactivate waste. The complexity and stringency of the arrangements and inactivation methods will be proportionate to the level of risk posed by the specified animal pathogen. At SAPO2, the waste management arrangements can be incorporated into the local rules or code of practice.

138 In the context of this licence condition, the term 'waste' is used to cover all material that is, either potentially or known to be, contaminated with specified animal pathogens and that is intended for discard. On this basis, the type, amount and variety of waste material generated can be considerable. This is not limited to obvious materials such as consumables for routinely used equipment (eg pipette tips), but also items such as animal bedding, carcases, discarded materials and PPE. The decontamination of large pieces of equipment, (eg centrifuges, laboratory chairs) is covered in the guidance for the application of containment and control measures.

139 The waste management arrangements should be developed in consultation with users to ensure that all eventualities have been identified and that the final arrangement/procedure is appropriate to the activities being performed and is practical (ie it can be effectively implemented in the containment facility). The waste management arrangements should provide for a robust means to ensure that, regardless of the particular specified animal pathogen being used, the contaminated waste generated is safely handled, stored, transported and inactivated appropriately. As a minimum the arrangements must provide for the:

(a) identification of systems, including operating procedures and infrastructure to ensure the safe handling, transport and disposal of waste contaminated with specified animal pathogens;

(b) provision of suitable and sufficient training to ensure users who are tasked to handle waste are competent to do so;

(c) provision of suitable maintenance arrangements to ensure that equipment used to store, transport and inactivate waste is maintained and examined;

(d) means to verify that inactivation of waste is effective; and

(e) provision of a system to ensure that the above has been implemented and is effective.

140 The first step in preparing and implementing suitable and sufficient waste management arrangements is to identify all credible sources of contaminated or potentially contaminated waste. The determination of the form (liquid, solid, animal etc) and an estimate of the quantity of the specified animal pathogen (ie high, medium, low level) is an important next step as it will directly influence the arrangements for handling, storage, transportation and inactivation of the waste material. The risk assessment will help identify this information and should take into account the SAPO categorisation, the routes by which susceptible animals could be exposed, the volume and form of contaminated solid and liquid waste, whether effluent from showers/sinks should be inactivated and whether the waste has to be transported.

141 Handling of contaminated waste should only be performed by individuals who have been trained in the appropriate procedures. This applies to those directly involved in the work and who generate the waste, as well as others, who manage and/or maintain equipment used to inactivate contaminated waste and waste contractors. This ensures that all users are aware of and understand the risks

associated with a loss of containment from the inappropriate inactivation or mishandling of contaminated waste.

142 All waste from SAPO containment laboratories must be inactivated. At SAPO2 this means before leaving the building, and before leaving the containment/animal suite at SAPO3 and 4. Only under exceptional circumstances should non-inactivated contaminated waste be transported from the containment facility and only where this can be fully supported and justified by an up-to-date risk assessment and implementation of effective containment and control measures.

143 At SAPO2 and 3, where contaminated waste is to be transported (eg due to the location of equipment such as an autoclave or incinerator), pre-treatment with a suitable disinfectant will reduce the infectivity. The waste must be transported in suitable storage containers. As a minimum, when transporting waste, that is known to be or that could potentially be infectious, the containers must be robust, secure and leak-proof, and capable of ensuring a means of containment (eg double-contained) such that if there was an adverse event (eg being dropped) it would not result in the loss of containment. Procedures should be devised and implemented to deal with an adverse incident such as a spillage of material in a corridor.

144 Waste must be stored in containers that are appropriate for the nature and type of waste and which provide a suitable means of preventing the loss of containment. For liquid waste this could involve the use of plastic bottles or jars with screw-top lids, whereas for solid waste the use of autoclave bags may be sufficient. If there is a requirement to segregate waste then the containers should be clearly labelled. When waste is removed from the containment laboratory it should be done so in a manner that minimizes the physical handling to reduce the risk of an adverse event resulting in a loss of containment. This can be achieved by placing the waste inside a container that can be placed directly into an autoclave or incinerator without further movement between containers.

145 At SAPO4, and at SAPO3 where the risk assessment indicates, there is a requirement to inactivate effluent water from the decontamination shower, autoclave, sinks and drains. In such cases, the effluent should be collected into a contained drainage system and carried to an appropriate effluent treatment plant (ETP), where it can be inactivated by a validated means before being discharged into the environment. An ETP, or similar system, should also be used to deal with process effluent from large-scale manufacturing and may also be appropriate for inactivation of animal waste, some of which is not suitable for use in an autoclave.

146 The method used to inactivate specified animal pathogens and contaminated waste must be validated to demonstrate that it can achieve the appropriate parameters to inactivate the specified animal pathogens, taking account of the nature of the waste (ie form, amount, density). The common methods employed include steam sterilization and chemical disinfection. The method of validation will vary depending upon the method chosen to inactivate the waste. However, in general terms, the data generated from a validation experiment should indicate the degree of kill of the pathogen at the desired parameters and the factors that can negatively affect the procedure.

147 Once validated, the method of inactivation should be routinely monitored (eg via printouts) to ensure that the method is being applied as intended and is consistent with the conditions used for the validation. The validation should be repeated periodically where there are changes in the working practices or materials that could adversely affect the ability of the procedure to inactivate the pathogen in the waste material (eg the composition of the waste). Depending on the nature of the work it may be appropriate to use manufacturers' validation data assuming that

the conditions of use are comparable to those under which the manufacturer intends it to be used.

148 The key aspects of the validation process, such as concentration of disinfectant and contact time for kill, should be captured and recorded in operating procedures. The operating procedure should be used to train users tasked with the responsibility of handling waste to ensure they are competent to perform the task correctly and implement the waste treatment arrangements in a consistent manner. Additionally, it will inform users of the consequences arising from non-compliance with the procedure.

149 The maintenance requirements of equipment used to either store, transport or inactivate waste material are an integral part of waste management. Some pieces of equipment, such as an autoclave, ETP or incinerator will have a defined maintenance schedule, whereas others should be determined by the licence holder, defining what requires checking, at what frequency and how maintenance work is carried out. For example, containers such as metal bins with lockable lids used to transport waste to the autoclave deteriorate over time due to extended use and the effects of being exposed to high temperature and pressure.

150 Complex pieces of equipment, such as double-ended autoclaves, ETP and incinerators, should have extensive planned preventative maintenance. This may result in the equipment being out of service for undefined periods of time. The arrangements should consider the frequency of this maintenance and consider appropriate contingency arrangements (eg that waste generated during the down period is minimized; and that alternative autoclaves are available). Additionally, the arrangements should consider how to deal with emergency failure of equipment used to inactivate contaminated waste.

151 The waste management arrangements should be captured coherently in an operating procedure that details all the steps for the safe handling, storage, inactivation and disposal of contaminated waste. The level of detail should be proportionate to the risk of the work with the specified animal pathogen. The type of information that should be in the operating procedure is displayed in Table 5.

152 The waste management arrangements must be monitored to ensure that they are being complied with, are working effectively and achieving the desired outcome. This will involve a check or inspection of the suitability of the storage containers, the effectiveness of methods of inactivation of the waste (periodic comparison with validation data), the accuracy of the operating procedures, maintenance records and compliance of users to the waste management procedures. The individual tasked with determining if the arrangements are adequate must be appropriately trained and competent.

153 Where an external contractor is used in any part of the waste management procedure the suitability of their arrangements must be checked. SAPO licence holders are responsible for compliance with the licence conditions and so must ensure that the contractor is competent and that the process applied is appropriate for the effective inactivation/disposal of waste material. At SAPO3 and 4 this can be achieved by monitoring contractors and performing independent audits of their arrangements.

Table 5 Type of information contained in the operating procedure

Method of inactivation	Typical information contained in an operating procedure
Autoclaving	The type of waste and typical loads to be autoclaved (eg cultures and media, sharps, pipettes, other disposable and reusable articles, gloves and laboratory coats, paper towels and tissues) The containers that are to be used (eg for sharps) The sterilising cycle (eg temperature/time settings for each load) The loading and unloading procedure The checks to be made and recorded by users (eg cycle printouts, periodic use of chemical or biological indicators) The procedure in the event of a malfunction or failure; and planned preventative maintenance regime
Disinfection	The waste and contaminated articles that are to be disinfected (eg disposable or reusable articles that are heat sensitive, liquid waste and effluents other than cultures) The disinfectant that is to be used, its in-use dilution, the contact time to ensure inactivation; how often it must be changed and any safety considerations (eg manufacturer's safety information) The methods for validation of the disinfection process The safe disposal of used disinfectants Means for the safe removal and disposal of treated waste Fumigation procedure (eg decontamination of large pieces of equipment)
Incineration	Waste that is to be incinerated with or without prior treatment by autoclaving or disinfection Details of the containers that will be used (eg material of construction, robustness, size, sealability and labelling) The frequency and method of removal of containers from the containment facility to a place of secure storage The packaging and labelling requirements for transportation to the incinerator Keeping records of all waste transfers and disposals
ETP	The type of liquid effluent including content, volume, frequency to be inactivated Overflow control and capacity of storage tanks to deal with periods of heavy demand Validation of ETP – eg thermal mapping Various volume level alarms and interlocking of valves to prevent overflow Integrity of containment drains, pipework, manholes The sterilising cycle (eg temperature/time settings) The checks to be made and recorded by users (eg cycle printouts, periodic use of chemical or biological indicators) The procedure in the event of a malfunction or failure Planned preventative maintenance regime

Condition 7 Transport

7(1) The licence holder must prepare and implement suitable and sufficient arrangements to ensure that the transportation of specified animal pathogens listed in schedule 1, is carried out without creating a risk of loss of containment of those specified animal pathogens.

7(2) The arrangements referred to in Condition 7(1) must as a minimum include:
(a) a safe transportation procedure that implements steps to be taken, in transporting specified animal pathogens within the licensed site (on-site) and the transport of specified animal pathogens beyond the licensed site (off-site), for the prevention of the loss of containment of the specified animal pathogens listed in schedule 1;
(b) a means of ensuring that the relevant users of specified animal pathogens comply with the safe transportation procedure.

154 Licence holders must prepare and implement suitable and sufficient arrangements for the safe transport of specified animal pathogens (including materials containing specified animal pathogens or derivatives as specified in SAPO), encompassing both off-site and on-site transport. This should include arrangements for receipt of packages containing specified animal pathogens. The transport of specified animal pathogens is common to most routine laboratory-based activities in both research and diagnostic settings. The process, however, presents risk of exposure and infection in the event of incorrect packaging, misidentification, inappropriate access, spillage or other inadvertent release en route.

155 Where specified animal pathogens are transported beyond the facility boundary (eg between buildings or sites), there is potentially an increased risk of exposure of susceptible animals. Accordingly, in addition to the SAPO licence conditions, additional transport-related legislation applies such that, for the purposes of transport, specified animal pathogens are packaged, labelled and transported in a manner that minimises the risk of release during transit.

156 Previously, the SAPO licence conditions prohibited any transfer of specified animal pathogens and/or carriers and their derivatives to any other people or laboratories without the prior authority of the Secretary of State. This permission was given via a transfer licence. This is no longer required. Instead the responsibility is placed on the licence holder to ensure that when they are sending specified animal pathogens off-site, the material is packaged and transported in accordance with carriage of infectious substances legislation, that the material is only sent to premises that are licensed to hold such material and that assurance is provided that the specified animal pathogen has reached its intended destination. This assurance should involve a written confirmation (eg email) from the intended recipient that they hold an appropriate SAPO licence prior to the material being sent; and thereafter written confirmation (eg email) that the material has been received. Where the latter is not achieved or where it arrives in an ‘unfit’ condition, arrangements must include a means of notifying the licensing authority promptly.

157 When a specified animal pathogen or carrier is being obtained from a country outside the EU, a licence under IAPO will still be required to authorise the importation and can be obtained from the APHA Imports Team (imports@AHPA.gov.uk).

158 The licence holder’s arrangements for transport activities (either sending or receiving) involving specified animal pathogens, must include:

(a) identification of transport requirements and their implementation (including legal requirements under both national and international guidelines);

(b) provision of adequate packaging systems, materials, labels, PPE and documentation and their use as part of the transportation process;

(c) selection of a reliable transport contractor that is qualified to handle the package safely and securely;

(d) assurance of the status of the receiving laboratory (ie when consigning a specified animal pathogen, whether the receiving premise holds an appropriate SAPO licence and whether equivalent controls are applied);

(e) oversight by a responsible management representative to authorise movement of materials;

(f) arrangements for the traceability of material movements (ie ensure arrival at the intended destination);

(g) identification and implementation of adequate and proportionate emergency response and contingency plans associated with transportation, including adequate precautions for handling material inappropriately packaged, spillages and lost materials;

(h) a means of ensuring compliance with these transport arrangements.

159 The transport arrangements should be included as part of the information, instruction and training provided to users of specified animal pathogens. The arrangements (including user competence) should be routinely monitored to assess whether the arrangements are adequate, are being complied with, and steps to be taken to rectify any matters arising from the monitoring process are implemented.

Off-site transport

160 The Department for Transport (DfT) is responsible for legislation associated with the carriage of infectious substances (including animal pathogens) in the UK by all modes (road, rail, air and sea). DfT is supported by HSE and by the Civil Aviation Authority. HSE has primary responsibility for enforcement of The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009[15] (CDGR). These Regulations also allow suitably appointed police or Vehicle and Operator Services Agency officers to enforce the regulations applying to transport by road and rail.

161 The international regulations governing the transport of dangerous goods (including infectious substances) are based on United Nations (UN) Model Regulations produced by the UN Committee of Experts on the Transport of Dangerous Goods. These are reflected in law through more specific internationally agreed 'Model' regulations applying to transport by road, rail, air and sea; some of which are implemented in the UK through national legislation. Further guidance on international transport can be found in the World Health Organization publication entitled *Guidance on regulations for the Transport of Infectious Substances*.[16]

162 The principal UK-applicable law on the international and domestic transport of infectious substances by road, rail and air is as follows.

(a) **Road and rail:** CDGR applies to both international and domestic transport in the UK.

(b) **Air:** The International Civil Aviation Organisation Technical Instructions for the Safe Transport of Dangerous Goods by Air apply to air transport both in the UK and internationally.

163 Further guidance on UK-applicable law on transport of infectious substances (including specified animal pathogens), is produced by DfT and entitled *Transport of infectious substances UN2814, UN2900 and UN3373*.[17]

164 The UN Model Regulations divide dangerous goods into nine separate classes reflecting their hazardous properties. Infectious substances are allocated to UN Class 6.2. This class of dangerous goods includes pathogenic bacteria, viruses, parasites, fungi and any other biological agents that may cause disease in humans or animals, regardless of whether they are in native or genetically modified form. It also extends to biological waste and (with certain limited exceptions) clinical materials where viable pathogens are known (or reasonably expected) to be present.

165 Regardless of the mode of transport, the legislation requires that infectious substances are classified (Category A or B) and assigned a UN number (UN2814, UN2900, UN3373 or UN3291). This in turn determines the packaging instruction (PI620 or PI650), and marking and labelling requirements, including assignment of a 'Proper Shipping Name' and use of an appropriate hazard label collectively identifying the nature and hazard presented by the package contents.

166 Specimens and waste from animals known (or suspected) to be infected with a specified animal pathogen should be classified in the same way (ie specimens meeting the Category A criteria are classified as Category A). While not a legal requirement, the DfT guidance recommends, as a precautionary approach, that all human and animal specimens such as blood, tissue, excreta and secreta are classified as a minimum, Category B, unless the material has been treated to neutralise pathogens or verified as pathogen free. This includes specimens from apparently healthy animals.

167 Regardless of mode of transport, packaging for all infectious substances must consist of at least three layers:

(a) **Primary receptacle.** A watertight, leak-proof (or sift-proof for solids) receptacle containing the infectious substance.

(b) **Secondary packaging.** A durable, watertight, leak-proof (or sift-proof for solids) packaging to enclose and protect the primary receptacle(s) and containing sufficient absorbent material to absorb all fluid in case of breakage.

(c) **Outer packaging.** Outer packaging with suitable cushioning material. Outer packaging protects the contents from outside influences, such as physical damage, while in transit.

168 There are additional requirements, depending on whether refrigerants (eg ice, dry ice or liquid nitrogen) are used with the packages. Each completed package should be accompanied with appropriate documentation. An itemised list of contents should be enclosed between the secondary and outer packaging, along with the names and addresses of the consigner and the consignee.

On-site transport

169 The licence holder must ensure that the transport arrangements apply to the 'on-site' transfer between containment facilities (eg a different laboratory, a suite of laboratories, animal containment rooms or similar rooms), to ensure this is

undertaken safely. Transfer of a specified animal pathogen within a containment facility (eg from an MSC to an incubator or vice versa) must be undertaken in a way that minimises potential for drop, spillage, collision or similar events, and good laboratory practices should be implemented to prevent contamination and inadvertent spillage. The precautions implemented must reflect and be strengthened as the inherent hazard associated with the specified animal pathogen increases.

170 The transfer of infectious materials between containment areas within the same building (eg from one laboratory to another) must be planned, organised and carried out to minimise transit through communal areas and public thoroughfares. Unless otherwise justified by risk assessment, this must be undertaken in suitably robust, securely lidded, leak-proof containers to minimise the risk of spillage en route if the container is dropped. This includes for the transfer of infectious waste (eg where waste is transported from the containment laboratory to a remote autoclave located elsewhere within the building).

171 Transport containers must be suitably labelled to identify their contents, and surface-decontaminated before leaving the containment area. Large or unwieldy containers should be transported on a suitable trolley system and loaded in a way that prevents the trolley tipping or the containers falling en route. Trolleys with guard rails or raised sides are commercially available and widely employed for within-building transport purposes.

172 Where specified animal pathogens are transported between buildings located on the same site, steps must be taken to ensure that the transport is undertaken safely. Primary transport receptacles should not be transported directly by hand or in pockets, as this increases the risk of release if the container leaks, but should be enclosed in a secondary container. In some circumstances, the triple-component packaging system should be used to minimise the risk of loss of contents en route. Spill kits should be readily available for use if there is an adverse incident during transport, and appropriate personnel trained in their use. Before transfer, the recipient should be notified in advance of the risks associated with the material and confirmation should be provided that the receiving laboratory or containment facility is of the appropriate SAPO containment level with associated arrangements for the safe handling of the material.

Condition 8 Emergency arrangements

8(1) In order to prevent loss of containment of specified animal pathogens listed in schedule 1, the licence holder must ensure that suitable and sufficient procedures and systems have been prepared which can be put into effect in the event of an accident or dangerous occurrence or emergency related to the presence of specified animal pathogens.

8(2) The licence holder must ensure that information on the emergency procedures and systems is made available to the services who are liable to respond in order to enable those services to prepare their own response plans.

8(3) In addition to the requirements imposed by Conditions 8(1) and 8(2), in the event of an accident, dangerous occurrence or emergency related to the presence of a specified animal pathogen at the licenced site, the licence holder must ensure that immediate steps are taken to:
(a) mitigate the effects of the event;
(b) restore the situation to normal;

(c) identify the immediate and underlying cause(s) of the accident or dangerous occurrence; and
(d) record the measures taken or to be taken to rectify the situation.

173 Emergency procedures or systems must be prepared and recorded in the form of an emergency plan, and implemented if there is an accident, dangerous occurrence or medical emergency. The level of detail and extent of the emergency procedures and systems should be proportionate to the risks arising from the accident or emergency (ie these may be extensive for SAPO4, while minimal for SAPO2). The emergency procedures and systems should not only identify relevant and credible scenarios, but include measures to respond to them so as to limit the consequences that may arise. These should only relate to credible and foreseeable emergency scenarios that could result in the release of a specified animal pathogen. These emergency procedures and systems should also include contingency plans that would ensure continued operations in a safe and secure manner.

174 The initial step in developing appropriate emergency procedures and systems is to identify all foreseeable accidents and emergency scenarios. At SAPO2, it may be acceptable to conclude that there are no credible scenarios that require an emergency plan. This should be captured in the local rules or code of practice. At SAPO3 it is unlikely that all potential scenarios will be credible; however, all reasonable threats should be considered and recorded and, where appropriate, the rationale as to why non-credible scenarios were dismissed. At SAPO4, the number of credible scenarios will be the greatest, but similarly only those deemed credible should be addressed. Scenarios considered may include:

(a) major spillage/aerosol release;

(b) physical facility and equipment failure, including control system failure (eg ventilation system);

(c) escape of an animal deliberately infected with a specified animal pathogen;

(d) environmental release (eg effluent) from failure of decontamination, disinfection or sterilisation regime;

(e) accident or illness to worker and need for evacuation (eg medical condition, injury);

(f) infected/potentially infected or contaminated worker or other contact (eg family member, emergency responder or contractor);

(g) fire or explosion;

(h) utility failure including electricity, gas, steam and water supplies;

(i) potential loss of specified animal pathogen through theft or any other reason;

(j) breach of security, act of terrorism or deliberate vandalism;

(k) unexpected receipt of a specified animal pathogen without having the appropriate containment measures in place; and

(l) natural disaster (eg earthquake, flood, extreme weather conditions, disease pandemics etc).

175 When developing the emergency procedures and systems, laboratory and facility staff should be consulted to ensure that the final plan is comprehensive and integrated with facility-wide plans, where appropriate. This may include facilities management, scientists, principal investigators, laboratory personnel, Biological Safety Officers, and possibly those responsible for security. For some situations (eg medical emergency, fire), the licence holder should consult or coordinate with local first responders, including police, fire brigade and ambulance service, to establish their role in responding to a given situation and to establish the level of information they should be provided with upfront. They should also inform and educate parties on their role and any exposure risks they may face and ensure that their actions will not unnecessarily increase the risk associated with the emergency (eg uncontrolled use of water). Contact information should be documented, kept up to date and made available to personnel responsible for coordinating the emergency response activity.

176 The emergency arrangements or procedures may include, but are not limited to, the following:

(a) regular testing of alarms/indicators associated with equipment critical for the containment of specified animal pathogens;

(b) identification of personnel responsible for the development, implementation and testing of the emergency procedures and systems;

(c) coordination with local first responders;

(d) risk assessment tools allowing the identification of emergency scenarios and mitigation strategies;

(e) emergency exit/evacuation routes, avoiding evacuation of large numbers of people through higher containment areas;

(f) protocols for the safe removal, transport and treatment of contaminated personnel and/or objects;

(g) consideration of emergencies that may take place within and outside of regular working hours;

(h) emergency access procedures considering the override of existing access controls when appropriate;

(i) contingency plans to be implemented to ensure essential operations continue safely and securely;

(j) emergency training programs, including education on the safe and effective use of emergency equipment;

(k) emergency exercise plans, including type and frequency of exercises to be conducted, specific to the facility's risks;

(l) accident and emergency reporting and investigation procedures;

(m) description of the type of emergency equipment available in the containment area (eg first-aid kits, spill kits, eyewash and shower stations); and

(n) procedures for the notification of key people and the licensing authority.

177 The emergency procedures and systems (and associated measures and resources) should be reasonable and proportionate to the scale and nature of the accident or emergency. Once established, the emergency procedures and systems should be appropriately and effectively communicated to all relevant employees and others. Training must be provided for those with responsibility for implementing the emergency procedures and systems and the training should be tested to ensure those personnel demonstrate knowledge of their application and importance.

178 Structured and realistic exercises should be conducted to provide assurance of the effectiveness of the emergency procedures and systems and to identify any deficiencies or areas for improvement at regular intervals, based on risk. The emergency procedures and systems (eg development, implementation, training, exercises) must be recorded for training purposes and reviewed during an audit or inspection similar to other management arrangements.

179 The organisation should ensure that in an emergency, adequate contingency measures are in place to ensure the safety and security of continued operations (eg in an emergency or unforeseen event there may be disruption to normal operating conditions). This could range from safely shutting down work if there is a power failure, to obtaining alternative storage conditions if there is a breakdown. Such eventualities should be considered proactively and contingency plans set in place. Activities should address the need for adequate redundancy, replacement and other measures, which could involve the availability of alternative facilities or personnel, the introduction of backup systems (eg power supplies), alternative means of decontaminating materials if there is a failure of critical systems or equipment (eg effluent treatment tanks or autoclaves), or the complete safe shut-down of operations in extreme situations.

180 The emergency procedures and systems must be kept up to date and revised in response to any changes within the containment areas and/or the surrounding environment (eg the use of a new pathogen in the containment laboratories). It is the responsibility of the facility to determine how often the emergency arrangements and procedures should be reviewed, assessed and updated. Following an emergency in which the emergency procedures and systems were activated, those procedures and systems should be reviewed to identify any lessons that could be learned.

181 Following an accident, dangerous occurrence or emergency an investigation must be performed to identify the immediate and underlying cause(s). Findings from investigations can form the basis of action to prevent the accident, dangerous occurrence or emergency from happening again and to improve risk management generally. Further information on investigation can be found in the guidance accompanying condition 1 on management arrangements.

Condition 9 Notification requirements

9(1) The licence holder must notify the licensing authority immediately in the event of:

(a) an accident or dangerous occurrence involving any of the specified animal pathogens listed in schedule 1;

(b) the loss of a specified animal pathogen during its transportation.

9(2) The licence holder must notify the licensing authority as soon as it is reasonably practicable, in the event:

(a) of any significant change in the management arrangements referred to in Condition 1(1);

(b) of any significant change arising from the review of the risk assessment in accordance with the requirement at Condition 3(2);
(c) that the licence holder no longer needs this licence.

182 There are circumstances where licence holders must submit further information to the licensing authority. Guidance on when notification is required, the type of information and where the notification should be sent is provided below.

Accident/dangerous occurrence notification

183 Adverse events are situations where the activities deviate from the planned and expected course of events. This includes minor incidents, near misses but also more significant events such as accidents and dangerous occurrences. While licence holders should implement a management system to ensure all adverse events are reported within the organisation (and investigated accordingly), accidents and dangerous occurrences must also be reported to the licensing authority.

184 Licence holders must decide which adverse events constitute an accident or dangerous occurrence, based on an assessment of the circumstances surrounding the event weighed against the definition of an accident or dangerous occurrence. It is recognised that this assessment can be subjective, particularly where the adverse event has not resulted in an actual release of material.

Accidents
185 Accidents are defined in the SAPO licence (Section B: Glossary of defined terms). This is an adverse event that actually results in the release of a specified animal pathogen from containment. This may include a range of scenarios, such as:

(a) improperly treated waste sent to the sewer system;

(b) escape of an infected animal or insect;

(c) leakage of material from a consignment containing a specified animal pathogen during transit;

(d) physical transfer of a specified animal pathogen from containment via a contaminated person (eg on clothing or infection of that person); or

(e) unauthorised removal of specified animal pathogen from containment (eg theft or misuse).

186 Consideration of the risk to animal health from such examples is not part of the criteria that define an accident. However, such information should be submitted to the licensing authority. Accidents should be reported immediately to the licensing authority to ensure that steps can be taken to contain the potential spread of the specified animal pathogen.

187 Adverse events that are **unlikely** to be a reportable **accident** include events where:

(a) a preventative containment barrier is maintained or mitigation measures prevent the specified animal pathogen reaching the outside environment;

(b) a spillage within the confines of the laboratory, which is dealt with according to the pre-planned spillage procedure;

(c) a person is removed from the containment laboratory as part of a medical emergency and all procedures are followed effectively.

Dangerous occurrences

188 Dangerous occurrences are defined in the SAPO licence (Section B: Glossary of defined terms). This is an adverse event involving a SAPO3 or 4 pathogen, where the specified animal pathogen is not released from containment but where there was significant potential for this to happen.

189 When considering whether an adverse event has such potential, it is helpful to consider the layers of protection that have been breached. All facilities holding specified animal pathogens should have multiple layers of protection, including:

(a) preventive barriers that contribute to the containment of the specified animal pathogen; and

(b) mitigation measures that reduce the severity of a breach in a preventive barrier.

190 The layers of protection can be physical, procedural or managerial and all such layers should be considered when determining the extent or potential of the adverse event.

191 Any adverse event has potential to result in a release given appropriate circumstances. However, in practice, adverse events that involve a breach of multiple preventive barriers, meaning there is an over-reliance on mitigation measures or results in a loss of control, are considered to be dangerous occurrences. Examples of such dangerous occurrences include:

(a) a spillage in a laboratory where the pre-planned spillage procedure is not followed;

(b) failure of a valve joining process effluent pipework due to inspection arrangements not being followed or maintenance issues not being closed out;

(c) power outage leading to the loss of air handling systems where the backup power supply fails to activate within the pre-determined timescale.

192 Where the adverse event involves breach of a single layer of protection, the adverse event may still be considered to be a dangerous occurrence. This would be where the breach relates to a preventive barrier which is a critical containment measure or where a significant loss of control results. This is considered to be a significant step in the pathway to an escape from containment. Examples of such dangerous occurrences include:

(a) failure of a holding vessel resulting in large quantities of contaminated material flowing into a bunded area;

(b) positive pressurisation of a containment area housing animals infected with an airborne specified animal pathogen, meaning the integrity of the room/building is relied on to prevent a release;

(c) failure to follow showering and/or changing procedure before leaving the containment facility after working with an open source of specified animal pathogen (eg infected animals).

193 A significant number of adverse events involve a single layer of protection breaches that are minor incidents or near misses and are **unlikely** to be **dangerous occurrences**. This might include scenarios such as:

(a) leakage from a flask, where the flask is housed in a secondary container;

(b) spillage within the confines of a containment laboratory, which is dealt with in a controlled and pre-planned manner according to procedures;

(c) leakage from an autoclave while sterilising material that does not contain specified animal pathogens.

194 All adverse events (including accidents and dangerous occurrences) should be recorded and investigated internally. These may be indicative of failures in biosafety systems requiring corrective action, to prevent similar adverse events occurring. The extent and depth of the adverse event investigation will vary, depending on its severity. Reporting and investigation of adverse events should be part of the licence holder's management arrangements.

195 Accidents and dangerous occurrences must also be reported to the licensing authority. For accidents, this should be done immediately by telephone in the first instance, and a completed accident report form (available on the HSE website at https://www.hse.gov.uk/forms/sapo submitted within 24 hours of the matter being identified. For dangerous occurrences, this should be done within 24 hours of the matter being identified. Information to be provided to the licensing authority includes:

(a) the people involved in the accident or dangerous occurrence (eg laboratory personnel, engineers, bystanders);

(b) the specified animal pathogen involved in the accident or dangerous occurrence and an indication of the quantity of material involved;

(c) the date, time and location of the accident or dangerous occurrence;

(d) the circumstances or contributing factors that gave rise to the accident or dangerous occurrence and the measures being taken to eliminate any immediate hazard to animals outside the licensed premises.

196 Notification of an accident or dangerous occurrence under SAPO does not negate the requirement to report under other legislation (where applicable), which provides its own definitions of what constitutes an accident or dangerous occurrence. For example, an accident involving genetically modified highly pathogenic avian influenza virus that is transmissible to humans must be reported, not only as part of compliance with the SAPO licence condition, but also under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013[18] (RIDDOR) and GMO(CU).

Loss of a specified animal pathogen during transport

197 Where specified animal pathogens have been dispatched by the licence holder and fail to arrive at their destination within the pre-planned timescale and where there are not acceptable reasons for this delay, this must be reported to the licensing authority as a dangerous occurrence. Licence holders should have a mechanism within their management arrangements to confirm receipt of consigned specified animal pathogens.

Significant changes in the management arrangements associated with activities involving specified animal pathogens

198 The licence holder is responsible for implementing suitable and sufficient management and supervision arrangements. Consequently, provided this

requirement is being met, there are few circumstances where notification of changes in management arrangements is envisaged.

199 However, where the licence holder makes changes to key personnel, such as the person responsible for managing or supervising the activity, includes additional premises or changes the source of competent advice (eg competent persons), the licensing authority must be informed. Details must be provided of the person's suitability for the role they have been assigned or where there has been a change in the number of competent persons, how the capacity and capability has been assessed. Similarly there may be circumstances, where the nature of the activity changes requiring additional management controls (eg expansion in the scale of the work). See paragraphs 201–203 for more appropriate guidance on this.

200 When the licence holder must notify the licensing authority of any significant changes to the management arrangements, this must be done in writing (either by email or letter) and sent to the SAPO notification officer in HSE (bioagents@hse.gsi.gov.uk).

Significant changes to the risks associated with activities involving specified animal pathogens

201 The licence holder must notify the licensing authority of any significant changes affecting the risks associated with activities involving specified animal pathogens. In this context, 'significant' specifically refers to changes that increase or present different risks from the licensed activities. Risk means risk of loss of containment of the specified animal pathogen. 'Significant' change may relate to a proposed change to the ongoing work or where new information emerges that changes the rationale upon which the risk assessment is based. These changes are significant if they lead to the user having to change the way they work (eg containment or control measures) or if they present different or increased hazards/risks from the work (eg addition of a different specified animal pathogen). Many changes to ongoing SAPO licensed work will not meet these criteria, but will involve alterations having little or no effect on the hazards or risks associated with the work or the containment and control measures implemented to adequately control the loss of containment. In such circumstances, it is acceptable for these changes to be dealt with through the local risk assessment process, without further notification to the licensing authority.

202 The licence holder should use their judgement to decide if such changes are 'significant'. Where the type of changes to the ongoing licensed activity involve those listed in the following table, it is more likely that these changes will be deemed 'significant'.

Table 6 Examples of significant changes

Type of change	Example
Changes to containment and control measures	Risk-based requiring the implementation of additional controls (eg small- to large-scale culture volume, necessitating applying a different set of containment measures). Changes to procedures, such as different research procedures/techniques that increase the risks of release (eg type of filtration, centrifugation, use of sharps)
Use of different specified animal pathogens or strains of licensed pathogens with different inherent hazard characteristics	Relevant characteristics include route of transmission, pathogenicity, tropism, availability of treatment: this would include moving from attenuated to virulent strains or vice versa (eg replacement of vaccine strains, replication of incompetent strains, strains with a different host range)
Change in nature of the work	Moving from *in vitro* to *in vivo* work; changing the *in vivo* model (eg mice to birds) being studied
Changes counter to any licence conditions or Schedules	SAPO licences may have conditions attached to them (eg derogation of control measures, limits of the scope of the work)
New information emerges that changes the consequences of exposure	New information may be from scientific literature or preliminary research findings, which affects the rationale upon which the risk assessment for the work is based (eg research demonstrates more severe pathogenicity than envisaged at the outset)

203 When the licence holder must notify the licensing authority of any significant changes to the risks, this must be done in writing (either email or letter) sent to the notification officer in the Biological Agents Unit of HSE. It may be convenient to include a copy of the revised risk assessment with the appropriate sections highlighted. Agreement from the licensing authority must be granted before the change to the licensed activity can be implemented. In some circumstances this will involve amending the relevant section of the licence (eg addition of a different specified animal pathogen, derogation from applying specific containment measures).

Stopping licensed activities

204 Where the licence holder no longer intends to undertake activities involving specified animal pathogens and destroys all stocks or contaminated materials, so that the specified animal pathogen and related materials are no longer held at the licensed site, the licence holder must inform the licensing authority that a licence is no longer required. The licensing authority will then amend the existing licence to remove the specified animal pathogen, or where this relates to all specified animal pathogen activities at the site, the licensing authority will revoke the SAPO licence. Where the licence holder intends to store rather than use the specified animal pathogen, then notification to the licensing authority is not required and a licence will still be required.

205 When the licence holder must notify the licensing authority of a cessation of activities involving specified animal pathogens, this must be done in writing (either by email or letter) and sent to the SAPO notification officer in HSE (bioagents@hse.gsi.gov.uk).

Condition 10 Duties of co-operation with inspectors

10 The licence holder must:

(a) co-operate with an inspector and comply with any requirement imposed by the inspector;

(b) ensure that any employees, officers or agents at the licensed site co-operate with the inspector and comply with any requirement imposed by the inspector;

(c) permit and ensure that the licence holder's employees, officers or agents at the licensed site permit any inspector and any person an inspector considers necessary to accompany the inspector to inspect the licensed site and the conditions under which the specified animal pathogens are kept and used at the licensed site;

(d) permit and ensure that the licence holder's employees, officers or agents at the licensed site permit an inspector to take samples of the specified animal pathogen or carriers containing or believed to contain a specified animal pathogen;

(e) provide an inspector, and ensure that the licence holder's employees, officers or agents at the licensed site provide an inspector, when requested to do so, with any records or information (or photocopies of the documents containing the records or information) that is relevant to the licence and to the specified animal pathogen kept at the licensed site;

(f) comply, and ensure that the licence holder's employees, officers or agents comply, with any requirement imposed by an improvement notice served under article 7 or a prohibition notice served under article 8 of SAPO.

206 Most of the licence conditions relate to measures, procedures or systems that the licence holder must implement for the effective containment of the specified animal pathogen. Licence condition 10 is different, in that it relates to the interaction between HSE inspectors and the licence holder, their employees and relevant others (eg maintenance contractor(s)). SAPO is enforced by HSE inspectors who use enforcement powers (SAPO licence condition 10, SAPO Articles 6, 7 and 8, Schedule 2 and the Animal Health Act 1981) to ensure licence holders comply with their licence conditions.

207 Licence condition 10 requires that licence holders must ensure that all relevant people (including their employees and other individuals brought onto the licenced premises) cooperate with the inspector and comply with any requirement imposed by the inspector, where they are using their powers with respect to the containment of specified animal pathogens. HSE inspectors will use these powers and take appropriate action in accordance with the principles set out in HSE's *Enforcement Policy Statement*[19] and the application of HSE's *Enforcement Management Model*.[20] Inspectors may take enforcement action in several ways to deal with a breach of a licence condition, including but not limited to, prosecution and enforcement notices. Additionally, the licence can be revoked.

208 Licence holders must ensure that HSE inspectors can enter their licensed premises with or without giving prior notice. In most cases, licence holders will be notified of inspections and investigations. A routine inspection will look at compliance with licence conditions including application of containment and control measures and the implementation of relevant management arrangements. This will involve a mix of physical inspection, review of documentation, and interviews with relevant individuals. Where necessary, inspectors will take photographs and require copies of documents.

209 Licence sub-conditions 10(a)-(e) set out the range of requests that might be made by an inspector in relation to specified animal pathogens, where the licence holder must ensure that relevant people co-operate and comply. Additionally, licence sub-condition 10(f) requires that the licence holder or relevant people comply with any requirement of improvement or prohibition notices. As with other licence conditions, failure to comply with such requests from an inspector is considered a breach of SAPO and an offence by virtue of section 73 of the Animal Health Act 1981.

Condition 11 Containment of foot and mouth disease virus

11. The licence holder must ensure that when working with live foot and mouth disease virus (FMDV) the minimum standards specified in the international document *Minimum Biorisk Management Standards (MBRMS) for laboratories working with foot-and-mouth disease virus (*available at https://www.fao.org/3/cc8479en/cc8479en.pdf*)* are met. In the event of conflict between the terms of this licence and the requirements of the minimum standards, the higher standard applies. These minimum standards are updated periodically and licence holders should apply the standards specified in the most recent version of the document.

210 This licence condition is only applicable where FMDV is specifically listed inSchedule 1 of the SAPO licence. FMDV is a highly infectious SAPO4 pathogen. While all the licence conditions apply to the use of FMDV, this licence condition imposes the additional requirements set out in *Minimum Biorisk Management Standards (MBRMS) for laboratories working with foot-and-mouth disease virus* (available at https://www.fao.org/3/cc8479en/cc8479en.pdf). These standards are updated from time to time and Licence holders should refer to the most recently published revision of the minimum standards when applying for a licence.

211 The ‘minimum standards’ are a set of requirements to prevent loss of containment. Laboratories wishing to handle FMDV must apply the minimum standards as a requirement of this licence condition.

212 Where there is a difference in the requirements of the minimum standards and the requirements of any other licence condition, the licence holder must apply the more stringent requirement, to ensure prevention of loss of FMDV.

Appendix 1 The categorised list of specified animal pathogens

Amended from Schedule 1 of The Specified Animal Pathogens Order 2008, The Specified Animal Pathogens (Scotland) Order 2009, and The Specified Animal Pathogens (Wales) Order 2008.

Specified animal pathogen	Hazard group	Notes
African horse sickness virus	3	
African swine fever virus	4	
Aujesky's disease virus	2	
Avian influenza viruses	4	(a) uncharacterised; (b) Type A viruses which have an intravenous pathogenicity index in six-week-old chickens of greater than 1.2; or (c) Type A viruses H5 or H7 sub-type for which nucleotide sequencing has demonstrated multiple basic amino acids at the cleavage site of haemagglutinin.
Babesia bigemina	2	
Babesia bovis	2	
Babesia caballi	2	
Bacillus anthracis	3*	
Bluetongue virus	3	
Bovine leucosis virus	2	
Brucella abortus	3*	
Brucella melitensis	3*	
Brucella ovis	3	
Brucella suis	3*	
Burkholderia mallei (formerly Pseudomonas mallei)	3*	
Classical swine fever virus	3	
Cochliomya hominivorax	3	
Eastern and Western equine encephalomyelitis viruses	3*	
Echinococcus multilocularis	2*	
Echinococcus granulosus	2*	

Specified animal pathogen	Hazard group	Notes
Ehrlichia ruminantium	2	
Equine infectious anaemia virus	3	
Foot and mouth disease virus	4	
Hendra disease virus	4*	
Histoplasma farciminosum	3*	
Japanese encephalitis virus	3*	
Lumpy skin disease virus	3	
Mycoplasma agalactiae	2	
Mycoplasma capricolum sub-species capripneumoniae	2	
Mycoplasma mycoides var capri	2	
Mycoplasma mycoides sub-species mycoides SC and mycoides LC variants	2	
Newcastle disease (avian paramyxovirus type 1) viruses	4*	Including: (a) uncharacterised; or (b) have an intracerebral pathogenicity index in one-day-old chicks of 0.4 or more, when not less than 10 million 50% egg infections doses (EID50) are administered to each bird in the test.
Nipah disease virus	4*	
Porcine reproductive and respiratory syndrome (PRRS) virus genotype 2	3	
Peste des petits ruminants virus	4	
Rabies virus (including all viruses of the genus Lyssavirus)	4*	
Rift Valley fever virus	3*	
Rinderpest virus	4	
St Louis equine encephalomyelitis virus	3*	
Sheep and goat pox virus	3	
Swine vesicular disease virus	4	
Teschen disease virus	4	
Theileria annulata	2	
Theileria equi	2	
Theileria parva	2	
Trichinella spiralis	2*	
Trypanosoma brucei	2*	
Trypanosoma congolense	2	

Specified animal pathogen	Hazard group	Notes
Trypanosoma equiperdum	2	
Trypanosoma evansi	2	
Tryanosoma simiae	2	
Trypanosoma vivax	2	
Venezuelan equine encephalomyelitis virus	3*	
Vesicular stomatitis virus	3*	
West Nile virus	3*	
Live virus causing viral haemorrhagic disease of rabbits	2	This is only applicable if the virus is deliberately injected into rabbits.

Note (*) This specified animal pathogen also has an approved classification in the Approved List of biological agents as referred to in COSHH.

Appendix 2 Containment tables applicable to contained use of specified animal pathogens

1 The application of containment and control measures is required by licence condition 4, which includes measures set out in the following tables. There are four containment tables which apply to different circumstances for use of specified animal pathogens. The specific containment measures are listed in the 'containment measure column' and their application is indicated as required, not required or determined by the risk assessment according to the different containment levels. As well as the containment tables, guidance on each containment measure and its use is provided below.

2 The four tables in the licence schedule work in the following way. Table 1 sets out the containment measures applicable to the use of specified animal pathogens in laboratories. Tables 2 and 3 set out the containment measures applicable to the use of specified animal pathogens in animal units and arthropod facilities, respectively, and are in addition to those set out in Table 1. Where Tables 1 and 2 or 3 are not applicable, the containment measures set out in Table 4 apply.

Table 1 Containment measures applicable to contained use involving specified animal pathogens in laboratories

Containment measure		Containment level		
		2	3	4
1	The laboratory suite is to be separated from other areas in the same building or is in a separate building (**Note 1**)	Not required	Required	Required
2	Laboratory sealable to permit fumigation	Not required	Required	Required
3	Surfaces impervious to water, easy to clean and resistant to acids, alkalis, solvents, disinfectants and decontamination agents used for decontamination	Required for bench	Required for bench and floor	Required for bench, floor, walls and ceiling
4	Entry to laboratory via airlock	Not required	Required where and to extent the risk assessment shows it is required	Required
5	The laboratory to be maintained at an air pressure that is negative relative to the immediate surroundings	Not required	Required except for activities where transmission does not occur by the airborne route	Required

Containment measure		Containment level		
		2	3	4
6	Input and extract air from the laboratory to be filtered using HEPA or equivalent (**Note 2**)	Not required	Required on extract air except for activities where transmission does not occur by the airborne route	Required on input air, double on extract air
7	Infected material to be handled in a safety cabinet or isolator or other suitable physical containment	Required where and to extent the risk assessment shows it is required	Required	Required
8	Autoclave	Required in the building	Required in the laboratory suite	Double ended autoclave required in the laboratory suite
9	Access to be restricted to authorised persons only (**Note 3**)	Required	Required and via airlock where and to extent the risk assessment shows it is required	Required via airlock
10	Specific measures to control aerosol dissemination	Required so as to minimise	Required so as to prevent	Required so as to prevent
11	Shower before leaving the laboratory	Not required	Required where and to extent the risk assessment shows it is required	Required
12	Protective clothing to prevent the dissemination of specified animal pathogens	Suitable protective clothing	Suitable protective clothing required, footwear where and to extent the risk assessment shows it is required	Complete change of clothing and footwear required before entry and exit to the containment area
13	Gloves	Required where and to extent the risk assessment shows it is required	Required	Required
14	Efficient control of disease vectors which could disseminate animal pathogens	Required	Required	Required
15	Inactivation of specified animal pathogens in effluent from hand-washing sinks, showers and similar effluents	Not required	Required where and to extent the risk assessment shows it is required	Required
16	Inactivation of specified animal pathogens in contaminated material and waste	Required by a validated means	Required by a validated means with waste inactivated within laboratory suite	Required by a validated means with waste inactivated in the laboratory
17	A laboratory is to contain its own equipment	Not required	Required so far as is reasonably practicable	Required
18	An observation window or alternative is to be present so that occupants can be seen	Required where and to extent the risk assessment shows it is required	Required	Required
19	Safe storage of specified animal pathogens	Required	Required	Safe and secure storage required

Note 1 *Laboratory suite means one or more laboratories, together with the supporting infrastructure, equipment and services, including ancillary rooms such as airlocks, changing rooms, storage rooms and rooms for the inactivation or disposal of specified animal pathogens.*
Note 2 *Where viruses are not retained by HEPA filters, extra requirements should be used for extract air.*
Note 3 *Airlock – entry must be through an airlock which is a chamber isolated from the laboratory. The clean side of the airlock must be separated from the restricted side by changing or showering facilities and preferably by interlocking doors.*

Laboratory suite isolation (Table 1, measure 1)

3 For SAPO2, it is acceptable for the work to take place in a communal laboratory where other biological agents work is being performed. However, all users of the laboratory should be aware of the hazards within the laboratory and any safety-critical procedures that they may have to follow. At SAPO3 and 4, this reflects the intrinsically greater hazards and requirement for greater management oversight of the work. Separation of SAPO3 and 4 activities also ensures a means of ensuring access is restricted to only those with appropriate training and competence and reinforces the demarcation between the different working practices and management arrangements at SAPO3 and 4 compared with SAPO2.

Laboratory sealable to permit fumigation (Table 1, measure 2)

4 This measure is not required at SAPO2. At SAPO3 and 4 the laboratory must be sealable to permit fumigation. This reflects the greater hazards associated with SAPO3 and 4 specified animal pathogens and the consequences of release from containment. This measure provides an effective means of decontaminating the laboratory using a gaseous/vaporised disinfectant, which can effectively make contact with all exposed surfaces. The fumigation process must be validated to demonstrate its effectiveness for the size and shape of the laboratory. Whole room fumigation can be performed before maintenance shut-down, cessation of activities or following an accidental spillage within the facility.

5 The requirement for laboratory sealability is to ensure that the fumigant is retained within the laboratory at sufficient concentration for the required contact time to effectively decontaminate the surfaces. The sealed laboratory will also ensure that the gaseous fumigant, which may be harmful to humans, is not released in an uncontrolled manner. The integrity of the room should be part of the planned preventative maintenance programme and subject to routine visual inspections.

Laboratory surfaces (Table 1, measure 3)

6 Laboratories should be constructed of materials that are easy to clean and of such resilience to withstand a range of liquids used in the laboratory including chemicals and disinfectants. For SAPO2, this means that the benches used for activities involving specified animal pathogens should be of materials that are easy to clean (eg in event of spillage) and resistant to the range of chemicals used in the laboratory (eg disinfectants). Damage to surfaces (eg from use of acids, disinfectants etc) can result, in the event of a spillage, in liquid penetrating benches, making them difficult to decontaminate.

7 For SAPO3, this requirement is extended to the flooring as well as benches; while at SAPO4, there is an additional requirement relating to the walls and ceilings.

The extended requirements are particularly pertinent, where whole room decontamination is performed or where the room is used to house *in vivo* models, with associated waste streams.

Entry to laboratory via airlock (Table 1, measure 4)

8 This measure is not required at SAPO2. At SAPO3, the requirement for this measure is determined by the risk assessment and may indicate the use of an airlock or lobby (ie an entry chamber isolated from the laboratory). An airlock or lobby is a requirement at SAPO4, where the clean side of this airlock has to be separated from the restricted side by changing or showering facilities and preferably interlocking doors.

Laboratory maintained under negative pressure (Table 1, measure 5)

9 This containment measure ensures that there is a net inward airflow into a laboratory. In this way, it provides secondary containment to protect animals (and people) outside the laboratory and the environment if there were to be a breach of primary containment. This measure therefore should only be used when there is reason to be concerned about airborne transmission beyond the confines of the laboratory.

10 This measure is not required at SAPO2. At SAPO3 this measure is required where the specified animal pathogen could be transferred in a viable form via an airborne route. At SAPO4, the laboratory must be maintained at an air pressure negative to the immediate surroundings.

11 While the licence condition does not stipulate specific pressure differentials where this measure is required, typical values for SAPO3 should range between -30 to -50 Pa and for SAPO4 between -50 and -75 Pa. It is often the case, however, that the laboratory suite is designed with an air handling system that implements a sequence of pressure changes or cascade (eg approximately -30Pa between rooms) from the exterior of the suite to the containment laboratory. It may not always be possible to achieve this (eg in facilities with numerous rooms), and where this is not the case, the pressure differentials must be sufficient to maintain containment, specifically an inward movement of air into the containment area.

12 There are various means of achieving an inward airflow (eg through use of independent mechanical ventilation systems or MSCs). Depending on the size of the room, some facilities are able to generate sufficient inward airflow by means of an MSC ducting exhaust air to atmosphere using passive make-up air through vents in walls or doors. In other facilities, independent mechanical ventilation may be used to provide negative pressure, or there may be a combination of both. At SAPO4 independent mechanical ventilation must be used.

13 At both SAPO3 and 4, where independent mechanical ventilation provides the inward airflow, a mechanism must be implemented to prevent the room becoming positively pressurised in the event of an extract fan failure (eg interlocking supply and extract fans). Similarly, given the importance of the ventilation system, the system must have a sufficient level of redundancy and resilience to ensure that if there is an unplanned incident (eg power outage), the ventilation system continues to operate for long enough for the activity to be made safe.

HEPA filtration on a ventilation system (Table 1, measure 6)

14 This measure is not required at SAPO2. HEPA filters are required on the extract system at SAPO3, where there is a risk of transmission via an airborne route and at SAPO4, to ensure that any airborne specified animal pathogens are removed before the extracted air leaves the laboratory. For SAPO4 facilities, the extracted air should pass through two HEPA filters as a contingency to maintain containment if there is a failure in one of the filters and/or seals. For SAPO4 the supply air must also pass through a HEPA filter so that if the laboratory is becoming positively pressurised, the expelled air will return through a HEPA filter. These measures provide greater assurance that if there is a complete failure of the ventilation system, the likelihood of a release of contaminated air outside the laboratory is minimised. HEPA filters should be arranged in series and should be accessible for testing and changing without compromising the containment afforded.

MSC/enclosure (Table 1, measure 7)

15 At SAPO2, the requirement for this measure is determined by the risk assessment. For many SAPO2 specified animal pathogens, the risk assessment is unlikely to identify that the pathogen be handled in an MSC. However, where the specified animal pathogen can be disseminated by an airborne route or the activity involves procedures that are likely to generate aerosols (eg vigorous shaking, sonication), then an MSC or similar containment equipment will be required. Extract air from MSCs or equivalent must always be HEPA filtered.

16 At SAPO3 and 4 all activities involving specified animal pathogens should take place in an MSC or similar containment equipment. Where the specified animal pathogens are not capable of transmission via an airborne route, it is likely that the risk assessment would conclude that this specific measure is not required. At SAPO4, the risk assessment should also identify the most appropriate type of MSC depending on whether there are risks to the operator as well as animal health, and whether activities should be performed in a closed-fronted MSC.

Autoclave (Table 1, measure 8)

17 At SAPO2 an autoclave is required to be available in the same building as the laboratory. This requirement is intended to ensure that in the event contaminated waste requires inactivation, the means is available in the building to do this. However, the requirement is not intended to require that all waste at SAPO2 is inactivated by sterilisation. It is recognised that alternative means of inactivation may be appropriate (eg disinfection, offsite treatment) provided that the waste inactivation process has been validated and in the case of the use of waste contractors, that waste is stored, packaged, transported and inactivated in a safe manner.

18 At SAPO3 and 4 an autoclave is required to be available within the laboratory suite. Given the greater risk of spread from the laboratory, for SAPO3 and 4 pathogens, it is more appropriate for the waste to be inactivated within the containment facility. An appropriate procedure for the safe transfer of material into that autoclave from the laboratory should be devised and implemented.

19 At SAPO3 where the autoclave is located outside the laboratory suite, a derogation must be sought from the licensing authority. This must include details of the procedure to be implemented to ensure safe transport of the waste from the laboratory to the remotely located autoclave, sufficient to provide a level of protection equivalent to having an autoclave in the laboratory.

20 At SAPO4 an autoclave is required in the laboratory. The autoclave must be double-ended, with interlocking doors so that the doors on the clean and dirty sides cannot be opened simultaneously.

Restricted access (Table 1, measure 9)

21 Restriction of access to SAPO2, 3 and 4 laboratories is required to prevent inadvertent or deliberate access to the facility by people who are unaware of the risks posed in such facilities, or who have not received the appropriate level of training.

22 The means by which access is restricted will vary between containment level. At SAPO2, it would be acceptable to restrict access using management controls, ie monitoring who is entering the laboratory during periods when the doors are unlocked. At SAPO3 the management arrangement should be supplemented by installing a more secure measure (eg lock and key or swipe/proximity card system). Digital locks that operate by pressing a sequence of buttons on the lock may be acceptable, provided that the sequence code is restricted to authorised users and changed regularly (eg when staff members change). At SAPO4, at least two methods to restrict entry should be used simultaneously (eg proximity card and personal identification number).

23 Access may also be restricted for biosecurity purposes, covered by the separate security legislation ATCSA. It may be beneficial to contact your local counter-terrorism security advisor or national counter-terrorism security office when deciding on a system for restricted access at SAPO4.

Aerosol control measures (Table 1, measure 10)

24 This requirement is to minimise aerosol dissemination at SAPO2. Some work may be conducted on the open bench, but procedures that may result in aerosol production (eg shaking sonication or centrifugation), should be contained within suitable equipment (eg an MSC or sealed centrifuge buckets). At SAPO3 and 4, the requirement is to prevent aerosol dissemination.

Shower before exit from laboratory (Table 1, measure 11)

25 At SAPO2 there is no requirement for a showering facility to be present and workers are not required to shower when leaving the facility. At SAPO3, the requirement for showering before leaving the facility is determined by the risk assessment. At SAPO4, a complete change of clothing and showering is required before leaving the containment facility. Additional information for the user, (eg minimum time to spend in the shower), should be included in the local code of practice/operating procedures and training programme.

Protective clothing (Table 1, measure 12)

26 Suitable protective clothing must be worn at all SAPO levels. At SAPO2 this would normally comprise laboratory coats or gowns worn when in the laboratory and removed on exit. At SAPO3, suitable protective clothing normally comprises laboratory coats or gowns (side- or back-fastening) that are worn when in the laboratory and removed before hand washing on exit. Laboratory gowns should be changed regularly and immediately if they become contaminated. Gowns must be autoclaved before laundering. Where the risk assessment shows it is required,

protective footwear (eg disposable overshoes or dedicated footwear), must also be worn. At SAPO4 there must be a complete change of clothing and footwear. After work, clothing must be removed on the containment side of the airlock and placed in a container for autoclaving.

27 The specific requirements for protective clothing will vary according to the nature of the activities and whether the risk is only to susceptible animal species or whether there is an additional risk to people.

Gloves (Table 1, measure 13)

28 At SAPO2, the requirement for this measure is determined by the risk assessment. At SAPO3 and SAPO4 there is a requirement for disposable gloves to be worn for all working involving specified animal pathogens. This measure is in place to prevent their unintended spread beyond containment and in some instances to protect the operator.

29 If gloves are used, they must be removed and disposed of safely before leaving the containment area or handling items that may be touched by others who may not be wearing gloves (eg telephone handsets, door handles).

Control of disease vectors (Table 1, measure 14)

30 This measure is required at all containment levels, where there is a risk of disease vectors being able to disseminate the specified animal pathogen out of the laboratory. The precise control method will depend on the nature of the vector and the risk to susceptible animal species arising from a loss of containment. This measure is relevant when working with specified animal pathogens that can infect rodents or be transmitted by insects, or that can be mechanically transferred to susceptible species by vectors.

31 It is possible that for some specified animal pathogens, the disease vector will not be indigenous to the UK. Under these circumstances the risk of dissemination of the specified animal pathogen via such vectors is negligible. On this basis a derogation from this measure would be appropriate.

Inactivation of pathogens in effluent (Table 1, measure 15)

32 This measure is not required at SAPO2. At SAPO3, the requirement for this measure is determined by the risk assessment. Generally, where contamination of hands is minimised through the use of gloves, coupled with viable specified animal pathogens not being disposed of via the sink, the risk assessment will conclude that this measure is not required at SAPO3.

33 At SAPO4, this measure is required, to prevent any release of specified animal pathogens via this route. The method of inactivation of the effluent must be validated to demonstrate the effectiveness of the system. The most common method of inactivation of such effluent is through heat inactivation which is effective, reliable and reproducible and the performance can be easily monitored.

34 Where effluent is inactivated remotely, the suitability of the pipework used to transport the effluent must be assessed, particularly if and where the pipework leaves the containment envelope to ensure that the robustness of the containment is appropriate. The integrity of holding tanks should be periodically examined.

Inactivation of pathogens in waste (Table 1, measure 16)

35 At SAPO2, 3 and 4, waste material containing viable specified animal pathogens (eg spent culture fluid, animal carcases, contaminated disposables) must be inactivated by validated means before disposal. The choice of inactivation method will depend on the waste material (eg animal bedding/manure may require a different method of inactivation from laboratory consumables). Once the method has been validated, further validation is only required where the method changes so that there is reason to suspect that it is no longer effective (eg different type of waste; different type of disinfectant).

36 Inactivation methods should be monitored to ensure that they are working correctly and according to the set parameters (eg readouts from autoclave runs). Periodic testing should also be conducted to ensure inactivation equipment is appropriately calibrated (eg independent thermocouple testing for autoclaves). Contaminated material and waste should be stored in a safe manner before inactivation or in the case of equipment, disinfection. Where the contaminated material/waste is inactivated outside the laboratory, appropriate arrangements should be made for its safe transport (eg in leak-proof containers).

37 At SAPO3 and 4 all waste material containing viable specified animal pathogens must be inactivated within the laboratory suite before removal. Where the pathogen can survive in the environment, reliance on disinfection as a final method of inactivation is not appropriate. However, this may be an interim measure, to reduce the risks during transport, before a final inactivation method such as sterilization. At SAPO4, the autoclave must be double ended and maintain separation of clean and containment sides.

38 Where materials are removed from the laboratory, but are not suitable for autoclaving or the intention is not to inactivate the material, alternative methods of decontamination (eg for equipment) or surface disinfection must be used. This may involve the use of a double-ended dunk tank or fumigation chamber.

Laboratory to contain its own equipment (Table 1, measure 17)

39 At SAPO2 there is no requirement to have equipment solely dedicated for use in those laboratories. However, equipment must be cleaned and thoroughly decontaminated before removing from the laboratory for repair or servicing.

40 At SAPO3 there is a requirement for the laboratory to contain its own dedicated equipment, where this is reasonably practicable. However, there may be instances where specialised equipment is located outside the SAPO3 containment laboratory suite (eg ultracentrifuge, cell sorter, electron microscope) as it is not reasonably practicable (ie in terms of expense or usage) to have such equipment dedicated to SAPO3. In such circumstances, appropriate arrangements should be implemented to ensure there is no loss of containment.

41 At SAPO4, the equipment must be dedicated and only removed after appropriate decontamination. A doubled-ended fumigation chamber, or secondary ventilated airlock should be used to move equipment and material out of the laboratory.

Observation window (Table 1, measure 18)

42 At SAPO2 and 3, this requirement is determined by the risk assessment. Where the specified animal pathogen also presents a risk to human health, an observation window (or alternative) is required. The observation window facilitates rapid identification of problems that may have occurred within a laboratory (eg responding to a medical emergency or spillage). Being able to assess the situation before entering facilitates a more effective and safe response. The observation window also helps those wishing to enter the laboratory at the most appropriate time (eg when work is suspended).

43 At SAPO4, an observation window or alternative method is required. A glass panel in the laboratory door/wall is often sufficient, and where the view into a laboratory is restricted, it may be possible to solve the problem by installing a convex mirror in the laboratory. Alternatives are sometimes used, particularly at SAPO4 where laboratory suites are often stand-alone buildings where, for security reasons, there may not be windows or glass panels in doors. In such cases a closed circuit television system, or equivalent should be installed, in order to be able to observe occupants in the laboratory. At SAPO4, a buddy system is often operated, where there are always two competent people present in the laboratory suite when it is occupied.

Safe storage of pathogens (Table 1, measure 19)

44 A means of safe storage is required at all containment levels. Specified animal pathogens must be stored in appropriate containers, appropriately labelled and stored in a location appropriate to their categorisation (eg a SAPO3 pathogen stored at SAPO3 containment). However, it is recognised that for SAPO2 and 3, these pathogens may be stored in a communal storage facility, provided extra precautions are taken to ensure their safe storage. At SAPO4, specified animal pathogens must only be stored and handled within the containment level 4 suite.

45 At all containment levels fridges, freezers and storage containers should be kept locked when not in use. An increase in restricted access is apparent with increasing containment levels due to the increased consequences if unauthorised access was gained either accidentally or intentionally. There should be an inventory of the specified animal pathogens, including numbers of vials, location and reference number, to demonstrate the material is being stored safely.

46 For work with pathogens (and toxins) listed in Schedule 5, Part 7 of ATCSA, there may be additional requirements for safe storage.

Table 2 Containment measures applicable to contained use involving specified animal pathogens in animal units (to be read in conjunction with Table 1)

Containment measure		Containment level		
		2	3	4
1	Isolation of animal unit (**Note 1**)	Required	Required	Required
2	Animal facilities separated by lockable doors (**Note 2**)	Required	Required	Required
3	Animal facilities (cages, etc) designed to facilitate decontamination (waterproof and easily washable material)	Required where and to the extent the risk assessment shows it is required	Required	Required
4	Floors, walls and ceilings easily washable	Required for floor	Required for floor and walls	Required for floors, walls and ceiling
5	Appropriate filters on isolators or rooms (**Note 3**)	Required where and to extent the risk assessment shows it is required	Required	Required
6	Appropriate barriers at the room exit, and at drains or ventilation ducts	Required	Required	Required
7	Animals kept in appropriate containment facilities, such as cages, isolators, pens or tanks	Required where and to the extent the risk assessment shows it is required	Required where and to the extent the risk assessment shows it is required	Required where and to the extent the risk assessment shows it is required

Note 1 *An animal unit is a building or separate area within a building containing facilities and other areas such as changing rooms, showers, autoclaves and food storage areas.*
Note 2 *An animal facility is a facility normally used to house stock, breeding or experimental animals or which is used for the performance of minor surgical procedures.*
Note 3 *Isolators are transparent boxes where small animals are contained within or outside a cage; for large animals, isolated rooms may be more appropriate.*

47 For activities involving the use of specified animal pathogens for deliberate infection of animals, the containment requirements for the appropriate containment level in Table 1 must be supplemented with the additional measures required for the appropriate containment level in Table 2.

Animal unit isolation (Table 2, measure 1)

48 At SAPO2, 3 and 4 the animal unit must be isolated from areas used for other activities. This means separation of the animal unit from other areas in the same building (or situated in a separate building) and away from offices, communal areas and sections frequented by non-technical or non-authorised staff.

49 This requirement is the same as the laboratory containment measure for the workplace to be separated from other areas in the same building except that the requirement for separation is extended to SAPO2 for animal units. This does not mean that further separation is required within the animal unit at a particular containment level, provided there are appropriate precautions to prevent cross-contamination of animals.

Facilities separated by lockable doors (Table 2, measure 2)

50 At all SAPO containment levels this measure must be in place and is primarily aimed at security, ensuring that only authorised people are allowed access to the facility.

Decontamination of animal facilities (Table 2, measure 3)

51 At SAPO2, animal cages and other enclosure facilities must be designed to facilitate decontamination where the risk assessment shows this is required. At SAPO3 and 4 this measure must be used. Good hygiene should be maintained to minimise the potential for cross-contamination between cages. The use of waterproof and easily washable materials will help the effective decontamination of cages. The type of material used to construct cages should be compatible with the method of decontamination.

Animal facility surfaces (Table 2, measure 4)

52 At SAPO2, 3 and 4 the floors of animal containment facilities must be easily washable. At SAPO3 this also applies to the walls and at SAPO4 this requirement is extended to the ceiling as well as the floor and walls.

53 This requirement is in place to ensure that all surfaces that can potentially be contaminated are composed of material that will enable the facility to be cleaned effectively. This is particularly important in large animal containment facilities where contamination could be widely disseminated within the room.

Filters on isolators or rooms (Table 2, measure 5)

54 The need for appropriate filters on isolators and rooms is determined by the risk assessment at SAPO2 and is required for SAPO3 and 4.

55 Where an isolator (for small animals) or a room (for large animals) is used and is deemed required for the protection of those outside the isolator/room, it is likely that the risk assessment at SAPO2 will conclude that extracted air should be passed through a HEPA filter (similar to an MSC). Where this is not the purpose of the isolator/room then filtration is not required. At SAPO3 and 4 the isolator or room use is assumed to be a containment measure, so the air extracted must be HEPA filtered.

Appropriate barriers at entry/exit points (Table 2, measure 6)

56 This measure is required at all containment levels. The purpose of the measure is to prevent the entry or escape of animals which could act as vectors for specified animal pathogens. Appropriate barriers must be placed at the exits and major penetration points (ventilation ducts and drains) within the facility. The barriers should be appropriate for room and type of animal. Rodent barriers may be appropriate at the room entrance where small mammals are housed in traditional cages but may not be appropriate where the cages are in a secondary containment device (eg an isolator).

57 To contain larger animals a two-door entry system separated by a small chamber or change area should be used. Mesh barriers should be placed on ventilation ducts and floor drains and be sufficient to contain those species being handled within the facility. At SAPO4, any floor drains must be connected to a contained effluent treatment system (including pipework and plant) that is appropriate for the type of animal bedding/waste materials that may be deposited in the drains.

Animals kept in appropriate containment facilities (Table 2, measure 7)

58 This requirement is applicable to all containment levels, however it requires that the risk assessment should determine the most appropriate containment device or facility for the type of animal and the specified animal pathogen being used. A combination of measures (eg cages inside isolators) may be the most appropriate. The selection of the most appropriate containment will depend upon the size of the animal and be appropriate to prevent their escape.

Table 3 Containment measures applicable to contained use of arthropods infected with specified animal pathogens (to be read in conjunction with Table 1)

Containment measure		Containment level		
		2	3	4
1	Physical separation of arthropod rearing unit (**Note 1**)	Required where and to the extent the risk assessment shows it is required	Required to be separate from infected animals or infected arthropods	Required
2	Entry to the arthropod unit via an ante-room (**Note 2**)	Not required	Required where and to the extent the risk assessment shows it is required	Required
3	Floors, walls and ceilings easily washable	Required for floor	Required for floor and walls	Required for floors, walls and ceiling
4	Floors, walls and ceilings appropriate to facilitate recapture of escaped arthropods	Required where and to the extent the risk assessment shows it is required	Required	Required
5	Recapture devices installed	Not required	Required where and to the extent the risk assessment shows it is required	Required
6	Specific measures to prevent the release of arthropods via points of ingress and egress	Required where and to the extent the risk assessment shows it is required	Required	Required
7	Arthropods kept in appropriate containment devices, such as cages, boxes, tanks	Required	Required	Required with failsafe measures
8	Arthropod containment devices designed to facilitate decontamination (easily washable material)	Required where and to the extent the risk assessment shows it is required	Required	Required

Note 1 *A rearing unit is a room where uninfected arthropods are cultivated and stored.*
Note 2 *An ante-room is a room that provides separation between the arthropod unit and other areas. Entry through the ante-room must consist of two doors (solid or screened), which are organised so that the doors should not be opened simultaneously.*

59 The use of isolators is more likely where the specified animal pathogen presents a risk to the health of the operator as well as animals. Further guidance on the use, testing and maintenance of laboratory and animal isolators for the containment of biological agents is available from the HSE website.[21]

Physical separation of the arthropod rearing unit (Table 3, measure 1)

60 The arthropod rearing unit should be separated from non-contained areas used for other activities and away from offices, communal areas and sections frequented by non-technical or non-authorised staff. Access should be restricted to authorised users. At SAPO2, the level of separation from other activities with the specified animal pathogen should be determined by the risk assessment (eg where the risk of the arthropods escaping is nil or negligible, it may be appropriate to co-locate the rearing unit with other activities). At SAPO3, the rearing room must be separate from infected animals or other infected arthropods, but may be co-located within the same SAPO3 suite. At SAPO4, the rearing unit must be separate from any activities with SAPO4 specified animal pathogens.

61 All larvae should be reared in a manner which will prevent the escape of emerging adults. The culturing procedure should be carefully timed where possible, so that the expected emergence date of adults can be marked on cultures and appropriate measures taken to prevent their escape.

Entry via the ante-room (Table 3, measure 2)

62 This measure is not required at SAPO2, although other measures at the entrance of the unit to minimise the potential for escape should be considered. At SAPO3, the risk assessment will determine whether the measure is required, taking into consideration the nature of the pathogen and the risks posed by the release of an infected arthropod. At SAPO4 it is required.

63 An ante-room provides physical separation between the containment area housing infected arthropods and the clean side of the facility. Entry through an ante-room should be via two solid or screened doors, opening into the room and fitted with a self-closing mechanism. The ante-room must be large enough to allow one door to be closed before the other is opened. An additional mitigating control measure found in the anteroom can include capture devices applicable to the nature of the arthropod.

64 Where infected arthropods are housed in a dedicated room, an ante-room with interlocking doors is required at SAPO3 and 4.

Arthropod facilities designed to facilitate decontamination (Table 3, measure 3)

65 Arthropod facilities should be designed to facilitate adequate decontamination and depending on the containment level should be extended to the floors, walls and ceilings. Surfaces should be constructed of materials that are easy to clean and of such resilience to withstand a range of liquids used in the laboratory, including chemicals and disinfectants. The build-up of residues and other matter should be prevented to reduce the possibility that arthropods or pathogens may persist. Additionally, the surfaces should be designed so that cracks and crevices are avoided, as these provide hiding places for escaped arthropods.

Floors, walls and ceilings appropriate to facilitate recapture of escaped arthropods (Table 3, measure 4)

66 At SAPO2, the requirement for this measure is determined by the risk assessment. At SAPO3 and 4 the measure is required. Where required, the surfaces of rooms, including floors, walls and ceilings, should be designed so they are light coloured to facilitate detection and recapture of escaped arthropods. Additionally, crevices or cracks should be avoided, as these provide hiding places for escaped arthropods.

Recapture devices installed (Table 3, measure 5)

67 This measure is not required at SAPO2. At SAPO3, the requirement for this measure is determined by the risk assessment. At SAPO4, this measure is required. The type and number of recapture devices must be determined by the risk assessment taking into consideration the nature of the arthropod. Typical recapture devices include ultraviolet light electrocution traps, moats around cages for crawling insects or sticky traps for flying insects. Their use is intended to capture escaped arthropods and prevent their survival. These can also provide a monitoring function to provide assurance as to the effectiveness of the containment measures

Screening of ingress and egress points (Table 3, measure 6)

68 Specific measures to prevent the escape of infected arthropods through entry and exit points is required at SAPO2 where and to the extent the risk assessment determines. At SAPO3 and 4, this measure is required. Appropriate barriers should be implemented to ensure any escaped arthropod remains within the containment laboratory. The possible points of exit from the unit should be identified, including drains, ventilation ducts, and access points for electricity and other services. Where possible, the number of penetrations of the containment fabric should be limited. Air ducts, lights and plumbing fittings and any other openings into the room should be suitably screened or sealed.

69 The type of barrier used should be appropriate to the nature of the arthropod and can include mesh covers over ventilation ducts or filters in ventilation systems. Floor drains should be avoided. Sinks should be fitted with coverings over exit points and the use of appropriate chemical disinfectant in the sink traps should be considered.

70 Windows and other outlets of rooms leading off the arthropod unit should be screened against flying insects.

Arthropods kept in appropriate containment devices (Table 3, measure 7)

71 This measure is required at all SAPO containment levels with the added precaution that at SAPO4 the containment device must have a failsafe system to prevent the escape of infected arthropods. The containment device should be robust and screened with mesh of a size appropriate to prevent escape. The openings of the cages must be designed to minimise escape, when eg accessing the cage for feeding, removing arthropods, introducing arthropods. At SAPO4, the containment device must have a failsafe system which can include housing multiple containment devices, providing additional measures (eg the use of oil-filled traps or glycerine for crawling arthropods).

Arthropod containment devices designed to facilitate decontamination (Table 3, measure 8)

72 At SAPO2, the requirement for this measure is determined by the risk assessment. At SAPO3 and 4 it is required. Arthropod containment devices must be designed to facilitate adequate decontamination. The surfaces of the device should be constructed of materials that are easy to clean and of such resilience to withstand a range of liquids used in the laboratory, including detergents and disinfectants. At SAPO3 and 4, the containment device must be suitable to be decontaminated by the use of an autoclave or other appropriate sterilisation device. Where the use of an autoclave is not possible or practicable, the means of decontamination should be validated to confirm its effectiveness.

Table 4 Containment measures applicable to contained use of specified animal pathogens in premises other than those referred to in Tables 1, 2 and 3

Containment measure		Containment level		
		2	3	4
1	Viable microorganisms must be contained in a system which separates the process from the environment (closed system)	Required	Required	Required
2	Closed systems located within a controlled area	Required where and to the extent the risk assessment shows it is required	Required	Required
3	Control of exhaust gases from the closed system	Required so as to minimise release	Required so as to prevent release	Required so as to prevent release
4	Control of aerosols during sample collection, addition of material to a closed system or transfer of material to another closed system	Required so as to minimise release	Required so as to prevent release	Required so as to prevent release
5	Inactivation of bulk culture fluids before removal from the closed system	Required by validated means	Required by validated means	Required by validated means
6	Seals must be designed so as to minimise or prevent release	Required so as to minimise release	Required so as to prevent release	Required so as to prevent release
7	The controlled area designed to contain spillage of the entire contents of the closed system	Required where and to the extent the risk assessment shows it is required	Required	Required
8	The controlled area sealable to permit fumigation	Required where and to the extent the risk assessment shows it is required	Required where and to the extent the risk assessment shows it is required	Required
9	Entry via airlock	Not required	Required where and to the extent the risk assessment shows it is required	Required
10	Surfaces impervious to water, easy to clean and resistant to acids, alkalis, solvents, disinfectants and decontamination agents used for decontamination	Required for bench	Required for bench and floor	Required for bench, floor, walls and ceiling

Containment measure		Containment level		
		2	3	4
11	Specific measures to adequately ventilate the controlled areas to minimise air contamination	Required where and to the extent the risk assessment shows it is required	Required where and to the extent the risk assessment shows it is required	Required
12	The controlled area to be maintained at an air pressure that is negative relative to the immediate surroundings	Not required	Required where and to the extent the risk assessment shows it is required	Required
13	Input and extract air from the laboratory to be filtered using HEPA or equivalent	Not required	Required on extract air	Required on input air, double on extract air
14	Access restricted to authorised persons only	Required	Required	Required
15	Personnel must shower before leaving the controlled area	Not required	Required where and to the extent the risk assessment shows it is required	Required
16	Personnel must wear protective clothing	Work clothing required	Required	Complete change required before exit and entry
17	Inactivation of specified animal pathogens in effluent from hand-washing sinks, showers and similar effluents	Not required	Required where and to the extent the risk assessment shows it is required	Required
18	Inactivation of specified animal pathogens in contaminated material and waste, including those in process effluent before final discharge	Required by a validated means	Required by a validated means	Required by a validated means

73 Table 4 sets out the containment measures required at different containment levels for activities involving specified animal pathogens not applicable to Tables 1, 2 and 3. The type of activities applicable to Table 4 include large-scale propagation, such as vaccine manufacture that requires highly engineered, closed systems involving the use of seals, pipework, measures to control exhaust gases and *in situ* probes. The use of small bench-top chemostats and fermenters are likely to constitute laboratory-scale activities, whereas, pilot plant facilities may be more suited to large-scale control measures.

74 Many closed systems will be required to operate in accordance with good manufacturing practice (GMP). The requirements for GMP are to ensure the product quality, rather than containment of the specified animal pathogen. There may therefore be a degree of conflict between the measures designed to protect the product and contain the pathogen, which should be addressed at the design stage. Conversely some measures will serve both purposes effectively.

Utilisation of a closed system (Table 4, measure 1)

75 At all SAPO levels specified animal pathogens must be contained in a closed system and be physically separated from the workplace and the environment. The nature of the closed system will depend on the hazards and be determined by the risk assessment, but for most activities, a stainless steel fermenter with welded pipework will be suitable. Disposable single-use bioreactors or 'cellbags' are being increasingly used in the biopharmaceutical industry as closed systems. Their use in association with microorganisms should be carefully considered to ensure that they offer an equivalent level of containment as traditional systems.

Location of closed systems (Table 4, measure 2)

76 At SAPO2, where the risk assessment indicates, the activities must be performed within controlled areas, where access is restricted to trained and competent personnel. These areas should be separated from offices, laboratories and other facilities and be away from access routes. At SAPO3 and 4, the closed systems must be located within controlled areas.

Control of exhaust gases (Table 4, measure 3)

77 At SAPO2 exhaust gases must be treated to minimise dissemination of microorganisms. Exhaust gases can be controlled using a variety of methods, either individually or in combination. This includes filtration, impingement filtration, cyclone separation, spraying gases with hypochlorite in spray towers or off-gassing through chemical disinfectants. This list of examples is not exhaustive and other techniques may be used, provided they are sufficient to control the risks. It is important to keep filters dry to maintain their efficiency and they should be safely and easily removed for maintenance purposes.

78 At SAPO3 and 4, exhaust gases must be treated to prevent dissemination of microorganisms. Exhaust gases must be controlled using filtration through fit-for-purpose HEPA filters (preferably two filters in series). It is important to keep pre-filters and filters dry to maintain their efficiency and to prevent clogging and wetting. Filters must be sterilised before removal for maintenance or discard.

Control of aerosols (Table 4, measure 4)

79 At SAPO2, measures to minimise release of aerosols during addition of material to a closed system, transfer of material to another closed system or sample collection are required. Inoculation of seed vessels can be by direct injection using a sterile needle/septum technique or by using a transfer vessel that is part of the closed system. Where needles are used, procedures should be applied that minimise the likelihood of a needle-stick injury. All potentially contaminated liquids should be transferred in closed piping and all pipework and valves should be leak-tight. Samples should be taken using aseptic techniques into a vessel designed to minimise aerosol generation and release. Running a mid-stream sample directly to drain is not acceptable; all material collected must be inactivated and the sampling valve/connection sterilised.

80 At SAPO3 and 4, measures to **prevent** release of aerosols during addition of material to a closed system, transfer of material to another closed system or sample collection are required. Inoculation of seed vessels must be done using a transfer vessel that is part of the closed system although direct injection using a

sterile needle/septum technique may be adequate if well controlled for activities at SAPO3, but would not be acceptable at SAPO4. Again, where needles are used, procedures must be applied that minimise the likelihood of needle-stick injury. All potentially contaminated liquids must be transferred in closed piping which is leak tight. Sampling must take place using a closed aseptic technique. All material collected must be inactivated within the contained area and the sampling valve/ connection sterilised.

Inactivation of material in closed systems (Table 4, measure 5)

81 The purpose of this requirement is to avoid the release of bulk culture fluids to effluent before inactivation. If product needs removing from the closed system for further processing, eg for the production of live vaccines, it is likely that the product will have been purified from the remaining bulk culture which requires inactivation.

82 At all SAPO levels the requirements are that viable microorganisms in bulk culture fluids be inactivated using a known efficacious method before removal from the closed system. Chemical or physical methods are acceptable means of treatment before removal from the closed system, but must be appropriate to the organism and level of risk. In addition to this measure, all waste must be inactivated by validated means before final disposal. At SAPO3 and 4, it is likely that effluent that has been disinfected will require a final sterilisation step before disposal to drain.

Seals to minimise or prevent release (Table 4, measure 6)

83 At SAPO2 there is a requirement that all seals be designed to minimise release of microorganisms. This includes static seals on equipment. Examples of typical types of seals appropriate for most SAPO2 work include single 'O' ring seals, flat gaskets, sealed couplings, single or double-faced mechanical seals and sanitary couplings with gaskets. Seals can be enclosed in HEPA (or equivalent) filtered housings (these examples are not exhaustive and alternatives may be used provided they are appropriate to control the risks). Where the equipment is connected to utility services, backflow should be prevented using a pressure differential, steam locks or 'double block and bleed' systems (non-return valves may be unreliable from a microbiological point of view and their use should be considered very carefully). The operating pressure and the risk of the microorganisms being released through seal failure should be assessed. Pressure-relief systems may be used, but the design should be considered carefully to prevent microorganism release during venting. Fixed or retractable sensors can be used.

84 At SAPO3 and 4 there is a requirement that all seals are designed to prevent release of microorganisms. Pipework should be welded and mechanical seals be double faced with condensate fed to the interspaces (ideally with the condensate temperature being monitored and alarmed). Where possible, seals must be enclosed in HEPA (or equivalent) filtered housings. The equipment must not be connected to utility services and retractable sensors should not be used since duplicate sensors are safer for high-risk activities.

85 For further information on types of seals and valves used in closed systems, please refer to the ACDP publication *The large-scale contained use of biological agents*.[22]

Containment of spillage from closed systems (Table 4, measure 7)

86 At SAPO2, where the risk assessment indicates that the contents of the closed system require containing, some form of adequate bunding should be provided. Where the specified animal pathogen will survive in the environment then this measure will be required. At SAPO3 and 4, the controlled area must be designed to contain a spillage of the entire contents of the closed system. Possible approaches include bunding at the periphery, the use of enlarged drainage channels or a contained sump into which the effluent will collect. The containment method employed should allow for inactivation of the spillage and this could be achieved by direct drainage into an effluent tank or treatment *in situ* with an appropriate disinfectant.

87 The entire contents of a closed system could be extremely large if there are a number of vessels arranged in series. However, the risk assessment should indicate the approximate volume, which may be lost due to a foreseeable failure in a valve, seal etc. The findings from this should allow for a sensible approach to deciding exactly what volume of spillage the controlled area should be capable of containing and the volume of disinfectant required.

Controlled area sealable to permit fumigation (Table 4, measure 8)

88 As the activities involve closed systems, the requirement for the controlled area to be sealable to permit fumigation at SAPO2 and 3, is only required where the risk assessment shows that it is required. At SAPO4 the controlled areas must be sealable for the purposes of fumigation. Fumigation procedures must be validated to ensure their effectiveness if there is a major spillage. Air handling and externally ducted safety cabinets should be controllable from outside the laboratory so that fumigant can be vented safely without re-entering the room unless purging of the fumigant is achieved by another method.

Entry to controlled area via airlock (Table 4, measure 9)

89 There is no requirement for an airlock at SAPO2. At SAPO3, the requirement for this measure is determined by the risk assessment. Access to controlled areas operating at SAPO4 must be via an airlock or a separate chamber. The airlock forms part of the pressure cascade and must be maintained at a pressure negative to the corridor outside the containment laboratory, but will be positive with respect to the controlled area itself. The doors to either side of the air lock/lobby should be interlocked.

Controlled area surfaces (Table 4, measure 10)

90 The controlled area must be constructed of materials that are easy to clean and of such resilience that they can withstand a range of liquids used in the laboratory, including chemicals and disinfectants. For SAPO2, this means that the benches used for activities involving specified animal pathogens should be of materials that are easy to clean (eg if there is a spillage) and resistant to the range of chemicals used in the area (eg disinfectants). Damage to surfaces (eg from use of acids, disinfectants etc) can result, in the event of a spillage, in liquid penetrating the bench, making it difficult to decontaminate.

91 For SAPO3, this requirement is extended to the flooring as well as benches; while at SAPO4, there is an additional requirement related to the walls and ceilings. The extended requirements are particularly pertinent, where whole room decontamination is performed.

Ventilation to minimise air contamination (Table 4, measure 11)

92 At SAPO2 and SAPO3, the requirement for adequate ventilation of the controlled area to minimise air contamination is determined by the risk assessment. Adequate ventilation for the removal of heat from process operations and worker comfort should be considered as part of the risk assessment. Adequate ventilation of the controlled area to minimise air contamination is required at SAPO4.

Controlled area maintained under negative pressure (Table 4, measure 12)

93 There is no requirement to maintain negative air pressure to contain airborne specified animal pathogens at SAPO2. Where processes use positive air pressure to maintain product integrity, the design should include a means of ensuring that the pressure differential across the final containment envelope is not positive in the containment relative to the surroundings.

94 At SAPO3, controlled areas should be maintained at a negative pressure with respect to the immediate surroundings, despite the process being performed in a closed system, where the risk assessment identifies this measure. In terms of regulatory requirements 'immediate surroundings' can be interpreted as being outside the building or in adjacent parts of the building. Where this requirement is identified by the risk assessment the controlled area should typically be maintained in a range between -30 to -50 Pa and via a continuous inflow of air while work is in progress. If an airlock is used, this should be maintained at negative pressure, which should be an intermediate value, eg -15 to -25 Pa, to maintain the laboratory pressure differential with the surroundings.

95 Negative pressure is often achieved via the implementation of a controlled supply and extract of air by mechanical ventilation systems. The supply and extract airflow must be interlocked to prevent positive pressurisation of the room if the extract fan fails. Where processes use positive air pressure to maintain product integrity, the design should include a means of ensuring that the pressure differential across the final containment envelope is not positive in the containment area relative to the surroundings.

96 Typically, at SAPO4, the controlled area should be maintained at an air pressure between -50 and -75 Pa via a continuous inflow of and extraction of air while work is in progress. The airlock should also be at negative pressure at an intermediate value to maintain the laboratory pressure differential with the surroundings. The supply and extract airflow should be interlocked to prevent positive pressurisation of the room in the event of failure of the extract fan. The ventilation system should be alarmed, connected to an emergency uninterrupted power supply and incorporate a system to prevent reverse air flows.

HEPA filtration on ventilation system (Table 4, measure 13)

97 This is not a requirement at SAPO2. However, there may be other reasons why supply air should be HEPA filtered (eg for GMP purposes). At SAPO3, HEPA filters

are required on the extract system and only on the input air where the risk assessment indicates. The latter ensures that contaminated air cannot be inadvertently expelled through supply vents during a transient positive-pressurisation event. Easy and safe removal of HEPA filters should be possible for standard replacement and maintenance purposes.

98 At SAPO4 facilities, HEPA filters are required on input and extract systems. In addition, there is a requirement for double HEPA filtration on the extract system, which reflects the greater potential hazard associated with a release outside of the facility. Two HEPA filters are used, as a contingency in case one of the filters fails. HEPA filters should be arranged in series and be able to be accessed safely for testing and changing.

Restricted access (Table 4, measure 14)

99 Restriction of access to the controlled area is required at all containment levels, to prevent inadvertent or deliberate access to the facility by people who are unaware of the risks posed in such facilities, or who have not been appropriately trained.

100 The means by which access is restricted will vary between containment level. At SAPO2, it would be acceptable to restrict access using management controls, ie monitoring who is entering the controlled area during periods when the doors are unlocked. At SAPO3 the management arrangement should be supplemented by installing a more secure measure (eg lock and key or swipe/proximity card system). Digital locks that operate by pressing a sequence of buttons on the lock may be acceptable provided that the sequence code is restricted to authorised users and changed regularly (eg when staff members change). At SAPO4, at least two methods to restrict entry should be used simultaneously (eg a proximity card and personal identification number).

101 Access may also be restricted for biosecurity purposes, covered by the separate security legislation, ATCSA. It may be beneficial to contact your local counter-terrorism security advisor or national counter-terrorism security office when deciding on a system for restricted access at SAPO4.

Shower before exit from a controlled area (Table 4, measure 15)

102 At SAPO2 there is no requirement for a showering facility to be present and workers are not required to shower when leaving the facility. At SAPO3, the requirement for showering before leaving the facility is determined by the risk assessment. At SAPO4, a complete change of clothing and showering is required before leaving the containment facility. Additional information for the user, (eg the minimum time to spend in the shower), should be included in the local code of practice/operating procedures and training programme.

Protective clothing (Table 4, measure 16)

103 Suitable protective clothing must be worn at all SAPO levels. At SAPO2 this would normally be laboratory coats or gowns that are worn when in the laboratory and removed on exit. For production facilities, additional clothing may be required for GMP purposes (eg disposable suits). At SAPO3, suitable protective clothing normally comprises laboratory coats or gowns (side- or back-fastening) that are worn when in the controlled area and removed before hand washing on exit.

Laboratory gowns should be changed on a regular basis and immediately if they become contaminated. Gowns must be autoclaved before laundering. At SAPO4 there must be a complete change of clothing, which must be removed on the containment side of the airlock and placed in a container for autoclaving.

104 The specific requirements for protective clothing will vary according to the nature of the activities and whether the risk is only to susceptible animal species or whether there is an additional risk to people.

Inactivation of pathogens in effluent (Table 4, measure 17)

105 This measure is not required at SAPO2. At SAPO3, the requirement for this measure is determined by the risk assessment. Generally, where contamination of hands is minimised by using gloves coupled with non-inactivated specified animal pathogens not being disposed of via the sink, the risk assessment will conclude that this measure is not required at SAPO3.

106 At SAPO4, this measure is required, to prevent any release of specified animal pathogens via this route. The method of inactivation of the effluent must be validated to demonstrate the effectiveness of the system. The most common method of inactivation of effluent is through heat inactivation which is effective, reliable and reproducible and the performance can be easily monitored.

107 Where effluent is inactivated remotely, the suitability of the pipework used to transport the effluent should be assessed, particularly if and where the pipework leaves the containment envelope to ensure that this is not reliant on a single layer of containment. The integrity of holding tanks should be periodically examined.

Inactivation of pathogens in waste (Table 4, measure 18)

108 At SAPO2, 3 and 4 there is a regulatory requirement that contaminated material and waste (including process effluent, which has been treated before leaving the closed system) is inactivated by a validated means before final discharge or disposal.

109 At SAPO3 and 4, physical methods such as heat inactivation are most appropriate for large-scale discharge of waste. Once the method has been validated, further validation is only required where the method changes, so that there is reason to suspect it is no longer effective (eg different type of waste).

110 Inactivation methods should be monitored to ensure that they are working correctly and according to the set parameters (eg readouts). Periodic testing should also be conducted to ensure inactivation equipment is appropriately calibrated (eg temperature mapping of an effluent treatment tank).

Appendix 3 General principles of good microbiological practice

General principles of good microbiological practice

The general principles of good microbiological practice are as follows:

(a) keeping workplace and environmental exposure to specified animal pathogens to the lowest reasonably practicable level;
(b) exercising engineering control measures at source and supplementing these with appropriate personal protective clothing and equipment;
(c) testing adequately and maintaining control measures and equipment;
(d) testing, where applicable, for the presence of viable process organisms outside the primary physical containment;
(e) providing appropriate training of staff;
(f) establishing a biosafety committee, if required;
(g) formulating and implementing local codes of practice, as required;
(h) displaying biohazard signs where appropriate;
(i) providing washing and decontamination facilities for staff;
(j) keeping adequate records;
(k) in the work area, prohibiting eating, drinking, smoking, applying cosmetics or storing food for human consumption;
(l) prohibiting mouth pipetting;
(m) providing written standard operating procedures where appropriate to ensure containment;
(n) having effective disinfectants and specified disinfection procedures available in case of spillage of specified animal pathogens;
(o) providing safe storage for contaminated laboratory equipment and materials where appropriate.

1 The application of containment and control measures is required by licence condition 4, which includes the general principles of good microbiological practice.

2 Fundamentally, the purpose of the SAPO licence is to contain specified animal pathogens by applying barriers to limit their contact with susceptible animal species outside the containment facility. The nature and extent of these barriers should be consistent with the level of risk, so that a high level of assurance is provided. In addition to the containment tables, SAPO licence holders are required to apply the principles of good microbiological practice where relevant and appropriate to the type of activity being conducted.

3 Application of all these principles is a licence condition. However, several individual principles are qualified by reference to what is appropriate and in some instances may have been achieved through compliance with another licence condition (eg training requirements). For some specific measures, the degree to which they are applied is conditional and will vary depending on the containment level being used. In such circumstances, the application should be based on the outcome of the risk assessment for the contained use.

4 ***Keeping workplace and environmental exposure to any specified animal pathogen to the lowest reasonably practicable level.*** This sets out the overarching philosophy of the SAPO licence to contain animal pathogens. The concept of 'reasonable practicability' is based on risk, but also takes into account the cost (in terms of money, time or trouble) of controlling that risk. If the risk is significant, or uncertain, a precautionary approach should be taken, with containment benefits taking precedence over the cost of action. These measures can only be discounted if risks are negligible and the cost of control measures is grossly disproportionate to the containment benefit.

5 ***Exercising engineering control measures at source and supplementing these with appropriate personal protective clothing and equipment.*** This measure reinforces the containment and control licence condition. It sets out a philosophy of applying containment and control measures at source in a hierarchical manner, which resonates with the hierarchy of control measures set out in COSHH. It is recognised that for animal pathogens, the main purpose is to prevent exposure of susceptible animals rather than the user. Applying controls at source will provide an important layer of protection that reduces demand on secondary layers of protection.

6 For biological agents work, protective clothing (eg laboratory coats or overalls) is used on a precautionary basis at all containment levels, whereas at SAPO2 engineering controls may not be required.

7 ***Testing adequately and maintaining control measures and equipment.*** This principle applies to all SAPO containment levels. The licence condition related to application of containment and control measures also requires these measures to be used appropriately, tested to ensure they work as intended and maintained to ensure they continue to operate effectively. This also applies to any safety-related equipment. In most cases, complying with the requirements of this licence condition will meet the requirements of this principle.

8 ***Testing, where applicable, for the presence of viable process organisms outside the primary physical containment.*** This measure is only required in some exceptional cases, where the risk assessment shows that monitoring for specified animal pathogens outside the primary containment (eg culture vessel, safety cabinet, containment laboratory) is necessary to ensure the containment and control measures are effective. In such circumstances, monitoring could be done both within the workplace, in the surrounding environment or at the point of disposal. More commonly, proactive monitoring methods are preferable (eg monitoring performance of control measures), as they allow users to take action before a release can take place.

9 ***Providing appropriate training of personnel.*** At all SAPO containment levels, users must be given suitable and sufficient information, instruction and training. This is a separate licence condition, compliance with which should ensure that the requirements of this principle are met. Training should be appropriate to the level of risk and the complexity of the operations being performed. Trained individuals should be able to demonstrate competence, which should be subject to review and provision of refresher training or additional training where necessary.

10 ***Establishing a biosafety committee, if required.*** This principle is not an absolute requirement. The management arrangements may be such that alternative means of obtaining competent advice have been put in place, obviating the requirement for a biosafety committee. However, the biosafety committee may

already be in place for advising on risk assessments associated with human pathogens or genetically modified microorganisms, so may have pertinent expertise to perform a similar function for specified animal pathogens.

11 ***Formulating and implementing local codes of practice, as required.*** This principle is not an absolute requirement. The content and form of local codes of practice will depend on the level of risk and nature of the contained use. For SAPO2 laboratories, this may provide the means of capturing all the necessary documentation required by the SAPO licence (eg operating instructions for particular equipment, management arrangements, a list of authorised users, systems of work or maintenance regimes).Where local codes of practice are in place, users should be able to demonstrate their familiarisation and understanding of these documents.

12 ***Displaying biohazard signs.*** At SAPO2, 3 and 4, a biohazard sign must be clearly displayed at the entrance to the facility to inform people of the risks from specified animal pathogens and informing those who are authorised to enter.

13 ***Providing washing and decontamination facilities for personnel.*** This measure is required at all SAPO containment levels. What constitutes appropriate facilities will depend on the risk and nature of the work. Hand washbasins and a supply of antimicrobial soap should always be supplied. Showering facilities might also be needed if work is to take place at SAPO3 or 4.

14 ***Keeping adequate records.*** The SAPO licence requires a number of documents to be kept including the risk assessment, training records, management arrangements, operating procedures, decontamination/waste procedures, transport procedures and emergency arrangements. The extent and detail of these records will vary according to the scale and complexity of the licensed activities, but should be proportionate to the risk involved with the specified animal pathogen. At SAPO2, it is expected that most of this information would be consolidated in a single local rules document.

15 ***In the work area prohibiting eating, drinking, smoking, applying cosmetics or storing food for human consumption.*** This measure is required at all SAPO containment levels. Alternative areas should be provided for rest breaks, where food and drink can be consumed safely.

16 ***Prohibiting mouth pipetting.*** This measure is required at all SAPO containment levels. Appropriate mechanical devices must be provided to enable the safe pipetting of liquids.

17 ***Providing written operating procedures where appropriate to ensure safety.*** This is a separate licence condition, compliance with which should ensure that the requirements of this principle are met. The level of detail in operating procedures and the flexibility they allow in practice should be proportionate to the level of risk involved, taking into account the complexity of the equipment used and procedures being performed.

18 ***Having effective disinfectants and specified disinfection procedures available in case of spillage of specified animal pathogens.*** This measure is required at all SAPO containment levels. The disinfectants and procedures should include appropriate surface disinfectants and instructions for their effective use, as well as a procedure for effectively dealing with spillages. For all disinfectants used for these purposes, their effectiveness should be verified, where necessary by initial validation.

19 For SAPO2, it may be enough to use manufacturer's data provided that the manufacturer tests are representative of the conditions in which the disinfectant will be used. The type of disinfectant should be chosen carefully to ensure activity against the specified animal pathogen in use. The effectiveness of chemical disinfection is affected by many factors, including the presence of organic matter, contact time and concentration. At SAPO3 and 4, disinfectants may not be sufficient to ensure that all residual risk is removed and should be used in combination with physical methods or fumigation.

20 ***Providing safe storage for contaminated laboratory equipment and materials where appropriate.*** The containment and control licence condition states that safe storage of specified animal pathogens is required at all SAPO containment levels. At SAPO4, this storage should be secure. This principle extends the requirement to include contaminated equipment and materials, to ensure they do not present a risk of spread of specified animal pathogens, before the equipment or material is decontaminated and applies at all containment levels.

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