Part 3

LABORATORY CONTAINMENT AND CONTROL MEASURES

Introduction

- 3.1 This section gives advice on safe working practices to help prevent the transmission of TSE agents during laboratory work with such agents or material that contains or may contain them. It covers:
 - all experimental work with preparations derived from body fluids, including work with abnormal purified prion proteins or tissues known or likely to contain either human or animal TSE agents;
 - all diagnostic laboratory work with preparations derived from body fluids or tissues known or likely to contain human or animal TSE agents – this includes work with animal tissues derived in the field for onward supply to laboratories for investigation where appropriate, for example, tissues derived for surveillance purposes; and
 - research work with infected animals.
- 3.2 Guidance on work with any hosts or vectors in which TSE agents have been cloned using genetic modification and where expression may be achieved is given in the Advisory Committee on Genetic Modification's Compendium of Guidance (www.hse.gov.uk/hthdir/noframes/acgmcomp/acgmcomp.htm).

Formal classification of TSE agents

- 3.3 The causative agents of the following diseases are all classified as Hazard Group (HG) 3 agents as listed in the Health and Safety Commission's Approved List of Biological Agents (http://www.hse.gov.uk/hthdir/noframes/agent1.pdf).
 - Creutzfeldt-Jakob disease (CJD) including variant CJD (vCJD);
 - Gerstmann-Sträussler-Scheinker Syndrome (GSS);
 - Kuru;
 - Fatal Familial Insomnia (FFI);
 - Bovine Spongiform Encephalopathy (BSE) and similar diseases, including feline spongiform encephalopathy (FSE), spongiform encephalopathy (SE) in captive exotic ungulates, transmissible mink encephalopathy (TME) and chronic wasting disease (CWD). BSE experimentally transmitted to other species is also included.
- 3.4 The appropriate containment level for an agent is derived from the hazard grouping of the agent. When working with an agent (e.g. propagation or concentration) in a particular hazard group, the Control of Substances Hazardous to Health (COSHH) Regulations 2002 require that the containment level selected must match the hazard group of the agent as a minimum. Although TSE agents are formally classified as HG3 (see paragraph 3.3), the containment measures required when working with them may not necessarily fully meet Containment Level 3 (CL3) because of the agent's unique features (paragraphs 3.6-3.10).

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The hazard group of the TSE agent forms the basis of a risk assessment to determine the appropriate containment and control measures.

3.5 Based on the current Hazard Grouping of TSE agents, the recommended overall Containment Levels are given in Table 3a below. Work is categorised according to the type of infectious agent and, for work with animals, the species being infected. Work with human TSE agents includes primary sources and any sub-passages of human derived agents in other species. Work with any animal TSE agent passaged in primates or in genetically modified mice with the human PrP gene should also be considered.

Infobox 1: Categorisation of work with scrapie

The causative agent of scrapie (and other TSE agents known not to be linked to BSE) is not listed in the Approved List of Biological Agents because there is no evidence of transmission of disease to humans to date. However, as a precaution, work with well characterised laboratory strains of scrapie should be carried out at CL2.

Recent concern about BSE transmission from sheep has led to a debate on whether all scrapie strains should be handled at CL3. As this debate is ongoing, a precautionary approach should be adopted where extra precautions, above those normally required at CL2, may be necessary for handling unidentified field isolates.

Table 3a						
Containment Levels recommended for work with TSE agents						
Laboratory work with:	Overall Laboratory Containment Level	Animal Containment Level				
Human TSE Agents	3	3 – small animals				
BSE and agents from animals with related TSE (FSE, SE in captive, wild bovines and felines) or any sub-passaged agents from these in any species TME and CWD		1* – large animals				
Scrapie agents	2	2 - small animals				
		1* - large animals				

^{*} ACL1 applies to housing of animals only, additional precautions will be required when working with such animals – see paragraphs 3.30 to 3.47

- 3.6 As well as the properties of the agent affecting the containment measures used, there may be other circumstances where consideration may be given to changing the containment measures to reflect the likely exposure of workers to TSE agents. InfoBox 2 gives one example of a situation (processing samples from a surveillance scheme) when this approach has been taken. However, any decision to change the containment conditions should only be taken after performing a local risk assessment (see COSHH ACoP and Guidance, in particular Schedule 3 and Appendix 2) that takes into account:
 - the nature of the work;
 - the quantity and type of material being handled; and
 - the procedures and equipment that will be used consider the potential for dispersal of the agent, for contamination of workers, equipment or surfaces at all stages of the activity including handling, processing and disposal, and for contamination during the setting up, servicing and maintenance of the equipment.
- 3.7 Having completed the risk assessment, local rules/standard operating procedures should then be prepared detailing safe working practices. Specific guidance on the situations where containment measures can be changed is given in the following sections.
- 3.8 Although in many respects the requirements of a CL3 laboratory are outwardly similar to CL2 laboratories, because of the more hazardous nature of the agents the standards that must be achieved are higher. The key differences between CL3 and CL2 laboratories relate to the way in which they are managed, the need for special training, and the degree of supervision, in addition to the physical requirements of the laboratory itself. In terms of work with TSE agents, managers should ensure that:
 - staff are competent and trained to carry out the work;
 - they have received suitable information, instruction and training about risks; and
 - there is appropriate supervision of the work in question.
- 3.9 Guidance on these aspects of laboratory management is given in the 'Management, design and operation of microbiological containment laboratories'.
- 3.10 It should be noted that changing some of the physical containment measures does not imply that the work can be carried out at CL2. But, subject to following the guidance set out in the subsequent sections, a CL2 laboratory may be appropriate for certain types of work (see paragraphs 3.27 and 3.28).

Infobox 2: Changing the containment level

In some circumstances the risk of a HG3 agent being present in a sample is extremely low.

For example, the appropriate containment measure for work with tissues derived for

surveillance purposes will depend on what is known about the incidence of infection in the population that is being studied, and as a result the risk assessment may show that Containment Level (CL) 2 is appropriate for work with the tissues.

For example, some of the Defra data from their current surveillance scheme indicate a low incidence of positives for BSE:

In 'high risk' cattle

	Fallen stock (OTM)	(OTM)	Casualties (OTM)	
	% A	ctual	%	Actual
2001	0.35 86/	24660	0.59	231/39487
2002	0.16 118	/73055	0.34	380/111633

Healthy cattle submitted to OTMS

2001	% 0.001	Actual 1/14320
2002	0.008	12/142887

Casualties on arrival at abattoir (2002)

Over 30 months old	% 0.12	Actual 3/2474
24-30 months old	0	0/961

(Matthews D, 2003, Pers. comm.)

Using these data the VLA risk assessment indicated that samples from these cattle could be worked at initially at CL2, due to the low risk of exposure.

GENERAL APPROACH TO SAFE WORKING PRACTICES APPLICABLE TO ALL LABORATORY WORK WITH TSE AGENTS

- 3.11 This general approach applies to all laboratory work whether human or animal diagnostics and to research work.
- 3.12 'The management, design and operation of microbiological containment laboratories' provides guidance on the management of biological agents including TSE agents, in the laboratory environment. The guidance sets out the standards for CL2 and CL3 microbiological laboratories, and it should be read in conjunction with this guidance

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which sets out the specific and/or additional requirements for work with TSE agents. The ACDP guidance 'Working safely with research animals: Management of infection risks' should also be read in conjunction with this guidance. The essential features of CL2 and CL3, as required by COSHH, are shown in Table 3b below.

Table 3b: Containment measures for CL2 and CL3 laboratories

0.41	Containment level		
Containment measure	2	3	
Air handling			
The work place is to be maintained at an air pressure negative to atmosphere	No	Yes	
Input and extract air to the workplace are to be filtered using high efficiency particulate absorption (HEPA) or equivalent	No	Yes, on extract air	
Security and access			
Access is to be restricted to authorised people only	Yes	Yes	
The workplace is to be separated from any other activities in the same building	No	Yes	
Efficient vector control, e.g. rodents and insects	Yes, for animal containment	Yes, for animal containment	
An observation window, or alternative, is to be present so that occupants can be seen	No	Yes	
Safe storage of biological agents	Yes	Yes	
A laboratory is to contain its own equipment	No	Yes, as far as is reasonably practicable	
Disinfection and disposal procedures			
The workplace is to be sealable to permit disinfection	No	Yes	
Specified disinfection procedures	Yes	Yes	
Surfaces impervious to water and easy to clean	Yes, for bench	Yes, for bench and floor (and for walls for animal containment)	
Surfaces resistant to acids, alkalis, solvents and disinfectants	Yes, for bench	Yes, for bench and floor (and for walls for animal containment)	
Incinerator for disposal of animal carcasses	Accessible	Accessible	
Protective equipment and procedures			
Infected material, including any animal, is to be handled in a safety cabinet, isolator or other suitable containment	Yes, where aerosol produced	Yes, where aerosol produced	

General protective measures

3.13 General, basic protective measures should be used wherever there is a risk of exposure to potentially infectious material, including TSE agents. These measures are summarised in Table 3c in the context of working with TSE agents.

Table 3c General protective measures

- apply general good hygiene measures such as not eating, drinking, smoking or taking medication in the laboratory
- protect skin wounds such as cuts, abrasions, eczematous lesions with water proof dressings
- wear the appropriate protective clothing routinely consider the use of disposable gowns and wear disposable gloves for all work with TSE material
- wear eye protection or full face visor to protect eyes and mucous membranes from splashes with potentially infected material
- minimise the use of sharps (needles, knives, scissors and laboratory glassware) wherever possible
- consider the use of suitable hand protection such as armoured glove(s) where the use of sharp instruments is essential (see Infobox 3) e.g. in post mortem examinations or the collection of human or animal brain/spinal cord
- remove protective clothing and wash hands before leaving the laboratory
- use closed systems such as sealed centrifuge buckets or where appropriate a Microbiological Safety Cabinet (MSC) to protect against splashing of material when mixing, centrifuging or homogenising samples
- use plastic single-use disposable items (containers, pipettes, inoculating loops and other such instruments); in the case of large items this could be interpreted as specified parts of the item e.g. dedicated ultracentrifuge rotors or electron microscope grids
- use recommended decontamination procedures see Annex C

Cleaning and decontamination

3.14 As many of the standard methods of decontamination cannot ensure complete inactivation of TSE agents, the emphasis must be on the removal of the agent by thorough cleaning, followed by an appropriate autoclaving or liquid chemical treatment. Annex C gives detailed guidance on cleaning, decontamination and waste disposal.

Handling emergencies

- 3.15 There should be plans in place in the laboratory to deal with accidents involving TSE agents, for example dealing with spillages or first aid arrangements for inoculation injuries. Employees must report immediately to their employer, or any of their employer's other employees with specific responsibility for health and safety, any accident or incident that results in the release of a TSE agent. The training of employees working with TSEs should prepare them for this responsibility. The training should include highlighting the readily foreseeable incidents that could occur and the procedures for dealing with accidents, incidents and emergencies, and the name of the person or people to whom accidents should be reported.
- 3.16 Spillages should be handled according to the guidance in Annex C. Any inoculation injury or contamination of broken skin with TSE agents (or material that contains the agents) should be gently encouraged to bleed, washed (not scrubbed) with warm soapy water and covered with a waterproof dressing. Disinfectants should not be put onto cuts or broken skin, as this could impair the body's localised defence reaction to the injury.
- 3.17 An official local record should be kept of any incident or occurrence that involves exposure to TSE agents. Certain incidents will need to be reported to HSE under RIDDOR (see Part 2, paragraph 2.25).

Transport of specimens

3.18 All TSE-infected specimens of human and animal origin are classed as infectious substances for the purposes of transport. Guidance on the transport of this material is given in Annex D.

EXPERIMENTAL WORK WITH TSE AGENTS

3.19 As previously outlined, it may not be necessary to use all of the measures normally required at CL3 but any decision to dispense with certain CL3 containment measures should only be made on the basis of a local risk assessment (as described in paragraph 3.6 above). The assessment must be specific to the laboratory and the work that is being carried out.

- 3.20 Following a risk assessment, which may indicate that other risks require the use of full CL3 (for example, if other HG3 biological agents are likely to be present see Table 3b), the main physical containment measures that might be dispensed with for experimental work are:
 - The need for the laboratory to be sealable to permit fumigation, as the TSE agents are not affected by normal fumigants. Therefore, another means of decontamination for TSE agents, in particular in the event of a major spillage, will need to be addressed in a local code of practice/Standard Operating Procedure.
 - It may not be necessary for the laboratory to be maintained at negative pressure. For example, if the work only involves the handling of small volumes of liquid, the work could be carried out within the confines of an appropriate microbiological safety cabinet all such devices will have HEPA filtered exhausts. If a cabinet is used, consideration will need to be given to the routine disinfection of surfaces and also the action to be taken when the cabinet requires servicing. If, however the work involves activities that can spread contaminated material around and outside the laboratory, for example, block cutting, local exhaust ventilation may be required to control the spread of contaminated material. In addition, maintaining an inward airflow may further help to control the spread of contaminated material outside of the confines of the laboratory.

3.21 There may be certain experimental situations where the amount of TSE agents present is likely to be significantly higher than levels normally encountered in naturally occurring disease, or else the risk of exposure is increased because of certain activities, for example when material containing TSE agents is disrupted or concentrated by homogenisation or centrifugation. If this is the case, such situations should be carefully assessed and it may be necessary to work at full CL3.

DIAGNOSTIC LABORATORIES

- 3.22 A range of laboratory tests may be required for the clinical management of patients with known or suspected CJD. Similarly, veterinary diagnostic tests will be needed in herds where BSE may be known or suspected. Diagnostic-type tests may also be carried out on human or animal tissues for surveillance purposes (see Infobox 2).
- 3.23 Again, assessment may indicate that not all the containment measures normally required by CL3 are necessary. As before, the main containment measures that might not be required are the need for a sealable laboratory and the requirement for an inward airflow. The assessment must be specific to the laboratory that is undertaking the work, as sample processing procedures and equipment are likely to differ between laboratories.
- 3.24 Brain and spinal cord samples present the greatest risk of exposure to the TSE agent as compared to other diagnostic specimens and although certain containment measures may be dispensed with (as in paragraph 3.20), additional protective measures will need to be taken as follows:
 - care should be taken to avoid accidental inoculation or injury, e.g. when preparing samples for microscopy or culture;
 - disposable equipment should be used wherever practicable, e.g. cell counting chambers etc;
 - any items contaminated by the specimens should be either destroyed by incineration, autoclaved or disinfected to the required standard (see Annex C for further details);
 - any residual contamination of automated equipment should be minimised;
 - any residual contamination of equipment should be dealt with before servicing;
 - delicate equipment such as microscopes should be cleaned and maintained regularly to avoid accumulation of potentially contaminated debris.

3.25 It may be appropriate for the diagnostic analysis of all brain and neural tissue preparations from known, suspected and at risk patients or animals to be handled in a specialist neuropathology laboratory or centre.

Neuropathology

3.26 In addition to ensuring appropriate containment measures are taken for this type of work (as set out in paragraphs 3.20 and 3.24), it should be remembered that, although standard formalin is used for optimal fixation of whole brain for general histopathology purposes, formalin-fixed TSE tissue retain infectivity for long periods and should always be handled with the same precautions as fresh material. Similarly, tissue for electron microscopy fixed in glutaraldehyde retains its infectivity. Formalin-fixed TSE tissue can be decontaminated with formic acid treatment (Taylor DM, Brown JM, Fernie K and McConnell I, 1997) – see Annex C for details. (Formic acid treatment has not been shown to be effective for non-formalin-fixed material.) Once tissue blocks are fixed and formic acid-treated, sections can be cut on a standard microtome (preferably using a disposable knife) and processed as usual. Debris (wax shavings) from section cutting should be contained (see paragraph 3.20) and disposed of by incineration. The handling of archive material stored in fixative blocks or as mounted slides should also be subject to the same precautions as for fresh material.

Low risk specimens

3.27 This section of the guidance considers work with 'low' risk specimens (see Annex A.1 for infectivity of human tissues and Annex A.2 for animal tissues) such as CSF, blood, urine and faeces destined for routine clinical analysis. **This advice should not be interpreted as a means of carrying out any other work with TSE agents, or any other HG3 agents, under such conditions.** In addition to dispensing with measures outlined in paragraph 3.20 other CL3 requirements (above those needed at CL2) may be adapted to enable work on such specimens to take place in a CL2 laboratory. When preparing a risk assessment for work with low risk specimens the following points could be considered.

- The need to separate the work from other activities does not necessarily mean having a separate laboratory, although this would be the preferred solution. Work could be carried out at the beginning or end of a work period.
- If an observation window, or alternative to allow occupants to be seen is not available, then there will need to be some means of checking on staff, for example using CCTV or regular phone calls/agreed check-ins. Such measures will ensure that adequate supervision is in place when individuals are working alone.

- In terms of equipment used for the handling of infectious material, this should be disposable as far as possible or else cleaned thoroughly before being autoclaved.
- The transport of infectious material also needs to be considered. Ideally it should be stored within the room where it is to be handled. If this is not the case, it should be transported in robust, properly labelled, secured containers that should only be opened within the confines of a microbiological safety cabinet.
- Low risk specimens should be autoclaved prior to disposal by incineration; further guidance on decontamination and disposal of waste is given in Annex C.
- If a cabinet is used at CL2 to handle material, it should be remembered that although this means that the laboratory is under negative pressure to some extent, given that there is likely to be increased traffic in and out of such a laboratory, this negative pressure will not be constant and so the work should remain within the confines of a cabinet (see also guidance in 3.28 for work with low risk samples in autoanalysers).

Automated analysis of human clinical specimens

- 3.28 'Low' risk samples can be analysed in a fully enclosed automated system at CL2 providing any manual processing such as decanting is carried out within a microbiological safety cabinet. The low risk of infectivity together with the use of a fully enclosed system is considered sufficient to reduce any risk of exposure to the laboratory worker to a very low level. The assessment of these types of procedures should take into account whether:
 - the system is fully enclosed and can contain spillage;
 - waste can be disposed of without risk; and
 - there are suitable maintenance and emergency procedures in place.
- 3.29 If the above cannot be ensured, then work should take place under the general conditions described in paragraph 3.27.

RESEARCH WORK WITH INFECTED ANIMALS

- 3.30 General guidance on laboratory work with infected animals is given in *Working safely with research animals: Management of infection risks*. In general, live animals infected with TSE agents do not pose a significant risk of exposure to TSE agents. However, the nature of experimental work with such animals means that there will be procedures/tasks that increase the risk of exposure. Work with specified risk material (SRM) or TSE agents in live animals may require a license (The TSE (England) Regulations 2002).
- 3.31 There are certain minimum containment requirements for work with animals experimentally infected with TSE agents, as shown in Table 3a. Small animal work

includes work with, for example poultry, rodents, rabbits, mink, cats and dogs. Large animal work includes work with, for example, domestic farm animals such as sheep and cattle.

- 3.32 Generally, the rationale for work with small animals requiring more stringent containment measures than large animals is because of the increased likelihood of biting and scratching when working with such animals. But, as with experimental laboratory work with TSE agents, a local assessment of work at Animal Containment Level 3 may indicate that not all the measures normally required are necessary to control exposure i.e. the room need not be sealable to permit fumigation. The risk of exposure when working with live large animals such as sheep and cattle is considered remote and Animal Containment Level 1 is appropriate. Where experimental sheep, goats and cattle are pregnant, guidance in paragraph 3.44 should be taken into account in planning for parturition or caesarean section.
- 3.33 Having identified the appropriate containment level for the work, the local risk assessment of the work must identify all potential exposure points to determine whether other additional precautions are required to control exposure, in particular for work with large animals. Additional precautions may also be required, for example, when concentrations of infectivity above those found naturally might be expected.
- 3.34 Potential points of exposure are illustrated in Figure 3.1, with further guidance given in paragraphs 3.36 to 3.47.
- 3.35 Having completed the risk assessment, local rules/standard operating procedures should then be prepared detailing safe working practices.

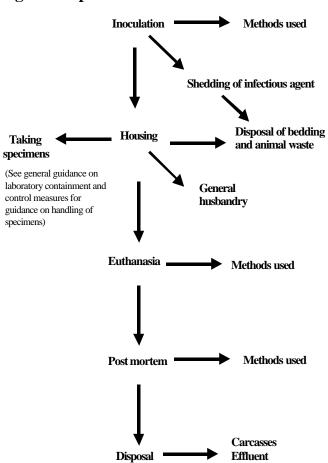


Figure 3.1: points to consider in assessment

Restraint

3.36 For procedures such as inoculation of infectious material and taking of blood, the need for sedation of the experimental animal should be considered to protect staff from injury. If the animal is not to be sedated, the animal should be appropriately restrained and procedures should not be carried out by lone workers. Adult cattle infected with TSE agents can be especially unpredictable and work should only be carried out by experienced staff.

Inoculation

- 3.37 The route of inoculation of infectious material should be assessed to determine whether this would allow leakage of this material post-inoculation and if this could contaminate bedding etc.
- 3.38 When infecting by injection, leakage from the injection site should be controlled and any leakage should be soaked up with absorbent material that should be treated as clinical waste. Sealants could also be applied to the wounds to control contamination of bedding etc.
- 3.39 Consideration should be given to whether inoculum remains exposed for any period of time, as may be the case when using feed as the source of infection.
- 3.40 As there is potential for excretion of infectious material post inoculation especially when infection is via the oral route (albeit for a limited period of time) (Dickinson AG and Taylor DM, 1978) then faecal waste and material contaminated by waste, e.g. bedding, should be collected and disposed of by incineration for at least 4 weeks post-inoculation.

Husbandry

3.41 Certain tasks with large animals such as foot trimming, ear tagging, and shearing of sheep may create a risk of exposure to blood and other body fluids. Given the potential for transmission of infection via blood (Hunter N *et al*, 2002), appropriate precautions should be taken to avoid exposure to blood and accidental puncture wounds. For example, wearing of appropriate personal protective equipment such as gloves which should be cut resistant (NB: cut resistant gloves do not offer protection from penetrating injuries – see Infobox 3), immediate disposal of needles when administering veterinary treatment and face protection if there is a possibility of exposure to blood under pressure coming into contact with mucous membranes such as the eyes.

3.42 The housing of small animals will need to balance the need for positive pressure, for example to maintain a germ-free environment or else protect immunosuppressed animals, against the need for inward flow of air at CL3. In such cases the use of simple engineering controls (e.g. flexible barriers) or respiratory protective equipment (RPE) may be necessary and should be addressed in the local risk assessment.

Infobox 3: Protective gloves

Gloves or other hand protection should be capable of giving protection from hazards, be comfortable and fit the wearer. The choice should be made on the basis of suitability for protection, compatibility with the work and the requirements of the user. The ability of the gloves to resist abrasion and other industrial wear and tear should be considered and the manufacturer's instructions and markings for appropriate use and level of protection should be followed. When selecting gloves for chemical protection, reference should be made to chemical permeation and resistance data provided by manufacturers.

Gloves made from chain-mail or leather and metal or plastic arm guards offer some protection against stabs and are used in those aspects of work where a knife is moved towards the user's hand and forearm. Gloves knitted from special man-made fibres such as Kevlar will provide protection against cuts and gloves manufactured from, e.g. Kevlar needlefelt, give good puncture resistance.

See also BS EN 374:1994 (Parts 1-3) Protective gloves against chemicals and microorganisms, BS EN 388:1994 Protective gloves against mechanical risks and BS EN 1082-1:1997 Protective clothing. Gloves and arm guards protecting against cuts and stabs by hand knives. Chain mail gloves and arm guards for further information.

Collection of specimens

3.43 The type of sample required will affect the control measures required. Taking of blood specimens should be carried out so as to avoid exposure to blood and accidental puncture wounds, e.g. wearing of appropriate personal protective equipment and immediate disposal of needles (needles should not be resheathed). Face protection may be necessary if there is a possibility of exposure to blood under pressure coming into contact with mucous membranes such as the eyes and the mouth.

Parturition

3.44 As there is the possibility of maternal transmission in sheep and a risk in cattle that cannot be discounted (Race, Jenny & Sutton, 1998; Onodera, Ikeda, Muramatsu & Shinagua, 1993; Pattison, Hoare, Jebbet & Watson, 1972) infected animals should give birth in a separate area and all non-viable products of parturition, e.g. placentae and any contaminated bedding etc disposed of via incineration. The area should be cleaned and disinfected after use with sodium hypochlorite (20,000 ppm available chlorine) for 1 hour. Staff attending large animals should wear appropriate protective clothing, i.e. parturition gown, gloves, face shield/mask. Where experimental animals are intended to be exposed to potential contaminating material at or around the time of birth, the above guidelines can be modified provided that a risk assessment is performed and appropriate measures are taken to control exposure.

Disposal of waste

3.45 Carcasses and other associated material, e.g. tissue samples, from all animals experimentally infected with a TSE agent should be disposed of by incineration. Bedding and faecal waste (following any initial shedding phase) can be disposed of in the normal way (e.g. by landfill burial, spreading on land or discharge to the sewer system) subject to the requirements of DEFRA, the Environment Agency [EA] and the Local Authority. (For further information see the duty of care under section 34 of the Environmental Protection Act 1990 on passing clinical waste to a registered carrier for disposal – note, the EA are still consulting on technical guidance to support this legislation.)

Post mortem examination

- 3.46 Before post mortem examinations are performed on animals naturally or experimentally infected with a TSE agent, an assessment should be made of the necessity for the procedure.
- 3.47 The control hierarchy set out in COSHH (see COSHH ACoP and Guidance) requires that exposure be prevented in the first instance. The following points should be addressed when drawing up local codes of practice.

- a) The Containment Level of the post mortem area must be appropriate for the agent involved. Where it is not possible to use a dedicated room, an area of the post mortem room should be set aside.
- b) The procedure should be planned so that all equipment required is readily to hand and work should be organised so that there are no interruptions (e.g. to answer the telephone); only essential persons should be present in the post mortem room when carrying out procedures with infected animals.
- c) At least 2 persons should be present; in addition a circulator should attend (remaining uncontaminated) acting as an observer and co-ordinator, for example taking care of record-keeping, and handing over sterile/clean instruments etc.
- d) Consideration should be given to the subsequent disinfection of working surfaces, for example, work with small animals may be conducted in a stainless steel or plastic tray (enamel trays are not recommended) which should be washed clean before being autoclaved¹ or disinfected with hypochlorite (20,000 ppm available chlorine) for 1 hour. Disposable coverings should protect other working surfaces.
- e) For large animal post mortems, consideration should be given to the means by which blood, body fluids and tissues that may be discarded during the post mortem examination will be collected and disposed of safely.
- f) Single-use disposable items should be used wherever practicable (alternatively a set(s) of dedicated instruments may be used) and appropriate protective clothing, including gloves, gowns, footwear, masks and visors or safety spectacles, should be worn. For large animal post mortems, heavy duty or waterproof clothing should be used. All items of reusable clothing should be rinsed clean in the post mortem suite before being autoclaved¹. For items that would not withstand repeated autoclaving such as rubberised boots, these should be washed clean then disinfected using hypochlorite (20,000 ppm available chlorine). All disposable clothing should be autoclaved before being disposed of by incineration.
- g) Carcases should be double bagged and placed in sealable bins prior to disposal by incineration. Small animal carcasses should be autoclaved prior to incineration.

(¹ although autoclaving will not completely remove the TSE agent it will reduce the level of infectivity and also eliminate any other infectious agents that may be present on contaminated surfaces or clothing.)

Use of specified risk material (SRM) in research

3.48 Those carrying out non-TSE research work should be aware certain animal tissues are designated SRM and subject to The TSE (England) Regulations 2002. If this is the case the material (e.g. bovine eyes from UK cattle over 6 months old) should not be

sourced from cattle slaughtered under the purchase scheme introduced under EC Regulation 716/96 or at the request of the Secretary of State to prevent BSE, to reduce the risk of exposure to TSE agents. If SRM is used for non-TSE research purposes it should not be allowed to come into contact with other non-SRM; particularly it must be kept in premises free from food, feedingstuffs, cosmetics, pharmaceuticals, medical products, their starting materials or intermediate products. A licence may be required from the Secretary of State to conduct research with SRM. COSHH requires a minimum of CL2 in laboratories that do not intentionally work with biological agents but handle materials in respect of which there exist uncertainties about the presence of Hazard Group 2, 3 or 4 biological agents. Even if there is a negligible risk from BSE in such material, it may contain other zoonotic agents, hence CL2 would be appropriate.

References for Part 3:

Legislation:

The Control of Substances Hazardous to Health Regulations 2002. SI 2002/2677. The Stationary Office. ISBN 0 11 042919 2.

The Reporting of Incidents, Diseases and Dangerous Occurrences Regulations 1995. SI 1995/3163. The Stationary Office. ISBN 01 1053 7523.

The TSE (England) Regulations 2002. SI 2002/843. The Stationery Office. ISBN 0 11 039914 5.

The Environmental Protection Act 1990. c. 43. The Stationery Office. ISBN 0 1054 4390 5

Commission Regulation No.716/96 of 19 April 1996 adopting exceptional support measures for the beef market in the United Kingdom.

Guidance:

Advisory Committee on Genetic Modification's Compendium of Guidance. Available at www.hse.gov.uk/hthdir/noframes/acgmcomp/acgmcomp.htm & HSE Books 2000 ISBN 07176 1763 7

HSC's Approved List of Biological Agents, also known as *Second supplement to* "*Categorisation of biological agents according to hazard and categories of containment*" (MISC 208) Available at www.hse.gov.uk/hthdir/noframes/agent1.pdf & HSE Book 2000. ISBN 0717620344

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Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection

BS EN 374:1994 Protective gloves against chemicals and micro-organisms.

BS EN 388:1994 Protective gloves against mechanical risks.

BS EN 1082-1:1997 Protective clothing. Gloves and arm guards protecting cuts and stabs by hand knives. Chain mail gloves and arm guards.

Information on Environmental Protection Act 1990 available at www.environment-agency.gov.uk/subjects/waste

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