Advanced Therapy Treatment Centres

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Appendix A - Example Risk Assessment proforma for proposed activities involving;

Gene Therapy Medicinal Products (GTMPs) or Gene Therapy Investigational Medicinal Products (GTIMPs)

Creator: University Hospital of Wales & University Hospitals Bristol & Weston NHS Foundation Trust

Document version number: V1.1

Date written: November 2020

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Appendix A

Example Risk Assessment proforma for proposed activities involving;

Gene Therapy Medicinal Products (GTMPs) or Gene Therapy Investigational Medicinal Products (GTIMPs)

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Example Risk Assessment proforma for proposed activities involving GTMPs or GTIMPs

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Once complete please submit this form to Genetic Modification Safety Committee (GMSC).

If trial use complete section A1, if non-trial use complete section A2.

Section A1: Details of Proposed Research

(To be completed by Principal investigator)

Study reference number:	
Study full title:	
Planned start date:	
Planned end date:	
Location: Please state exact location (ie hospital site and ward/ clinical area)	
Status of regulatory submissions	
Gene Therapy Advisory Committee (GTAC)	
Health Research Authority (HRA)/ Research Ethics Committee	
Medicines & Healthcare Products Regulatory Authority (MHRA)	
Status of any notification to HSE if applicable - Class 2 and above(reference No.)	

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Example Risk Assessment proforma for proposed activities involving GTMPs or GTIMPs

Principal investigator:		Position:	
Directorate/ Division			
Full postal address:			
E-mail address:		Phone no.:	

Alternative contact person:		Position:	
Full postal address:			
E-mail address:		Phone no.:	

Please note other approvals may also be required prior to study commencement including (but not limited to):

- Gene Therapy Advisory Committee,
- Medicines and Healthcare products Regulatory Agency (MHRA)
- Research Ethics Committee
- Health Research Authority

Summary of the proposed research (include tasks/activities and frequency/duration):

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Section A2: Details of Licenced GTMP

Gene therapy medicinal product name (Generic, brand, form, strength, route)	
Approved by/reference no./date (e.g. NICE, TA101, 1 Oct 2019)	
Impact Assessment	☐ In process ☐ Submitted ☐ Approved pending GMSC approval ☐ Other.....
Implementation Lead (Clinician): Email Telephone no.	
Location of use (state hospital site and which ward/ clinical area)	
Directorate/Division	

Section B: Health & Safety

(To be completed by Principal investigator)

Consequence score (severity levels) and examples of descriptors					
	1	2	3	4	5
Domains	**Negligible**	**Minor**	**Moderate**	**Major**	**Catastrophic**
Impact on the safety of patients, staff or public (physical/ psychological harm)	Minimal injury requiring no/minimal intervention or treatment.	Minor injury or illness, requiring minor intervention	Moderate injury requiring professional intervention	Major injury leading to long-term incapacity/ disability	Incident leading to death
	No time off work	Requiring time off work for >3 days	Requiring time off work for 4-14 days	Requiring time off work for >14 days	Multiple permanent injuries or irreversible health effect
		Increase in length of hospital stay by 1-3 days	Increase in length of hospital stay by 4-15 days	Increase in length of hospital stay by >15 days	An event which impacts on a large number of patients
			RIDDOR/ agency reportable incident	Mismanage-ment of patient care with long-term effects	
			An event which impacts on a small number of patients		

Consequence score (severity levels) and examples of descriptors (continued)					
	1	2	3	4	5
Domains	**Negligible**	**Minor**	**Moderate**	**Major**	**Catastrophic**
Statutory duty/ inspections	No or minimal impact or breech of guidance/ statutory duty	Breech of statutory legislation	Single breech in statutory duty	Multiple breeches in statutory duty	Multiple breeches in statutory duty with high likelihood of enforcement action
			Challenging external recommend-ations	Critical report	Complete systems change required
			Improvement notice	Prohibition Notice	Severely critical report
					Prosecution
Environmental impact	Minimal or no impact on the environment	Minor impact on environment	Moderate impact on environment	Major impact on environment	Catastrophic impact on environment

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Likelihood Score (L)					
	1	**2**	**3**	**4**	**5**
Descriptor	**Rare**	**Unlikely**	**Possible**	**Likely**	**Almost Certain**
Frequency How often does it/ might it happen	This will probably never happen/ recur	Do not expect it to happen / recur but it is possible it may do so	Might happen or recur occasionally	Will probably happen/ recur but it is not a persisting issue	Will undoubtedly happen/ recur, possibly frequently
Probability Will it happen or not? % chance of not meeting objective	<0.1 per cent	0.1-1 per cent	1 -10 per cent	10-50 per cent	>50 per cent

Risk Scoring = Consequence x Likelihood (C x L)					
	Likelihood Score				
Consequence Score	**1 Rare**	**2 Unlikely**	**3 Possible**	**4 Likely**	**5 Almost Certain**
5 Catastrophic	5	10	15	20	25
4 Major	4	8	12	16	20
3 Moderate	3	6	9	12	15
2 Minor	2	4	6	8	10
1 Negligible	1	2	3	4	5

1-3 Low Risk **4-6 Moderate Risk** **8-12 High Risk** **15-25 Extreme Risk**

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Example Risk Assessment proforma for proposed activities involving GTMPs or GTIMPs

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Hazards identified	Consequence	Likelihood	Controls in place to mitigate risk	Risk assessment Severity X Likelihood	Further controls required
Micro-biological Hazard					
Mechanical including moving parts on equipment					
Environmental					

Emergency procedures:
Access restrictions/sineage:
Lone working:
Special training requirements:
Storage:
Waste disposal:

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Example Risk Assessment proforma for proposed activities involving GTMPs or GTIMPs

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Health & Safety section reviewed by: (Usually Biological Safety Officer) (include Name and job Title)	
Date:	
Health & Safety comments (including required actions to be taken prior to sign off):	
Date above actions completed (as applicable):	
Health & Safety authorisation for study: [Signature required Insert Full Name and Job Title underneath]	
Date:	

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Section C: Pharmacy

(to be completed by Principal Investigator and Clinical Trials Pharmacist or Consultant and Directorate/Divisional pharmacist)

1. Manufacture

Product, Manufacturer and License status	
Indication	
Presentation	
QP release by	
Is the GTMP/GTIMP linked to a specific patient? How is this achieved?	
Is there potential for >1 patient to be treated at the same time?	

2. Shipment

What container is used for shipment?	
What are the temperature requirements?	
Is liquid nitrogen used?	

3. Storage at Site

Specific storage requirements (e.g. temp, container)	
How long is storage allowed / required?	
Has a suitable location been identified?	

4. Preparation / Manipulation Required

What preparation / manipulation of the GTMP/ GTIMP is required?	
What are the handling requirements?	
Are suitably trained staff available?	
Have suitable facilities / location been identified? (provide specific location details)	
What is the shelf life following preparation / manipulation?	
What are the risks associated with spillage?	
How will the above identified risks be mitigated?	

5. Prescription

How will the GTMP/GTIMP be prescribed?	

6. Administration

How will the GTMP/GTIMP be administered?	
Staff training required for administration?	

7. Disposal

What are the arrangements for disposal?	
Staff training required?	

8. Other

Are there any other risk considerations to Staff and Public?	
How will the above identified risks be mitigated?	
What is the reporting process for an Adverse Drug Reaction?	
Logging Batch Number and patient details	
Patient information risk mitigation details (e.g. Alert Card/PIL)	

Example Risk Assessment proforma for proposed activities involving GTMPs or GTIMPs

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Pharmacy section reviewed by: (include Name and Job Title)	
Date:	
Pharmacy comments (including required actions to be taken prior to sign off):	
Date above actions completed (as applicable):	
Pharmacy authorisation for study: [Signature required Insert Full Name and Job Title underneath]	
Date:	

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Section D: Genetically Modified Organisms

(to be completed by Principal Investigator or Consultant in consultation with sponsor or manufacturer)

SACGM guidance should be consulted for help and advice and where prompted:
http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/

Brief summary of the key features of this risk assessment

Parent vector details: Also specify ACDP hazard group	
Modified vector: List changes from parent and specify hazard group (take into account any SACGM guidance on reclassification)	
Description of modification. Include source of any inserted material and any control/maintenance sequences included	
Activity classification for a contained genetically modified microorganism (Class 1 – 4).	
If this considered deliberate release of a GMO and not contained use, provide consent to release authorisation.	
In vitro host cells used and inherent hazards	
Patients involved and route of delivery	

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Example Risk Assessment proforma for proposed activities involving GTMPs or GTIMPs

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Facilities in which the proposed activities involving the GMO would take place

Activity	Room No. and designation	Description of facilities/ACGM containment level

Detailed Characteristics of Each Component of the Genetic Modification Activity and its Intended Use

Full description of the "vector"
Full description of the "insert"; i.e. all additional nucleic acid sequences involved
In vitro recipients of the GMO (if relevant)
In vivo use of the GMO
Effects of the GMO

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Detailed Characteristics of Each Component of the Genetic Modification Activity and its Intended Use (continued)

Potential hazards of the GMO
Risks to human health
Human groups at increased risk from the GMO

Quantity of the GMO to be used

Activity and location	Volumes to be worked with	Concentrations of the GMO to be used

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Interim Assignment of Containment Conditions to Protect Human Health

Specify an interim assignment of containment requirements for the work, i.e. containment level that would be required for laboratory work, together with any additional special requirements for the protection of human health and safety (see current HSE/SACGM guidance particularly the sections on work in a clinical setting). Separate consideration should be given to each area or type of procedure in which the GMOs will be handled, including: preparation of the GMO for administration; administration to patients; subsequent care of the patient; and handling of any subsequent samples and waste derived from the patient.

Complete categorisation for each step of the process.

Identification of hazards associated with specific operations, and measures to control the resulting risks. Information in this document must be consistent, take into account the classification of the GMO and address the requirements of all applicable regulations.

HAZARD	COMMENT/ACTION (specify S.O.P if appropriate)
Specify arrangements for safe storage of the GMO.	
Specify arrangements for the safe preparation of the GMO for administration.	
Specify arrangements for the safe transport of the GMO to the site of administration.	
Are there any hazards associated with the accidental inoculation of a Health Care Worker with the GMO? Specify precautions to be followed.	

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HAZARD	COMMENT/ACTION (specify S.O.P if appropriate)
Are there any hazards to Health Care Workers associated with contact with the patients following administration of the GMO? Specify precautions.	
In addition to universal precautions are there any additional safety requirements for handling the patient's body fluids?	
In addition to standard hospital procedures are any additional safety arrangements required for the disposal of clinical waste from the patient's room?	
Will clinical samples (e.g. fluids, tissues) be collected from the patient for routine analysis by hospital laboratories? Specify arrangements for their safe handling.	
Specify clinical samples to be collected for specialised analysis by research laboratories. Specify arrangements for their safe handling.	
Identify any specific precautions or restrictions required for visitors to the patient.	
Other than standard arrangements, are any additional safety measures or procedures required for cleaning the patient's bed linen or laundry?	

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HAZARD	COMMENT/ACTION (specify S.O.P if appropriate)
Other than standard hospital cleaning procedures, specify any additional arrangements required when cleaning the patient's room during and at the end of the treatment period.	
Will the patient need to be transported within the hospital following administration of the GMO? Identify any specific safety procedures required for such transportation of the patient.	
Identify any specific safety arrangements required if it is necessary to evacuate the patient in the event of fire or other emergency.	
Identify any specific safety arrangements required in the event of death of the patient before the end of the treatment period.	
Identify any specific arrangements required in the event of the patient requiring resuscitation following a cardiac arrest or other accute medical emergency	
Specify any health surveillance requirements for staff involved in the work. Has a standard protocol been arranged with Occupational Health to this effect?	

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HAZARD	COMMENT/ACTION (specify S.O.P if appropriate)
Identify any work procedures likely to generate aerosols, and the control measures to be applied.	
Identify any procedures which will involve sharps, and specify arrangements for their safe use	
Specify the protective clothing and any other personal protective equipment to be used at each stage.	
Identify any stages involving transport of the GMO or GMO-contaminated materials within the healthboard, or between the healthboard and outside Institutions, and specify how this will be done safely.	
Specify the disinfectants to be used at each stage, and the concentrations at which they will be used.	
Specify the arrangements for safe disposal of contaminated materials appropriate for each stage of the work.	
Identify any stages of the work or manipulations of the GMO not already covered, which may pose increased risk, and the measures which will be applied to control those risks.	

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Emergency procedures

Environmental Considerations

Risk to animals, fish, plants etc.

Does the work involve a microorganism which is:	
an animal pathogen licensable under the Specified Animal Pathogens Order http://www.hse.gov.uk/biosafety/sapo.htm	☐ Yes ☐ No
a plant pathogen or pest controlled by the Animal and Plant Health Agency https://www.gov.uk/guidance/plant-health-controls	☐ Yes ☐ No
If you answered yes to any of the above, please provide details and status of any licence application or notification made and attach copies of any licences and approvals	

Example Risk Assessment proforma for proposed activities involving GTMPs or GTIMPs

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Specify any identifiable potential hazards to the environment, which might occur IF the genetically modified organism were to be unintentionally released, EITHER from the Healthboard premises OR following discharge of a treated patient. Classify the potential consequence as Catastrophic, Major, Moderate, Minor or Negligible.

	Likelihood Score				
Consequence Score	**1 Rare**	**2 Unlikely**	**3 Possible**	**4 Likely**	**5 Almost Certain**
5 Catastrophic	5	10	15	20	25
4 Major	4	8	12	16	20
3 Moderate	3	6	9	12	15
2 Minor	2	4	6	8	10
1 Negligible	1	2	3	4	5

In view of the characteristics of the GMO, consider the likelihood of accidental release from healthboard premises, and the occurrence of any above mentioned potential harmful effects, if the work were to be performed at the interim containment level specified above. Almost certain, likely, possible, unlikely or rare.

	Likelihood Score				
Consequence Score	**1 Rare**	**2 Unlikely**	**3 Possible**	**4 Likely**	**5 Almost Certain**
5 Catastrophic	5	10	15	20	25
4 Major	4	8	12	16	20
3 Moderate	3	6	9	12	15
2 Minor	2	4	6	8	10
1 Negligible	1	2	3	4	5

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In view of the characteristics of the GMO, consider the likelihood that the GMM will be released to the environment from a treated patient who has been discharged, and lead to the occurrence of any above mentioned potential harmful effects. Should this be considered as a deliberate release of the GMM to the environment?

Note: Deliberate release of GMOs to the environment will require consent from the Secretary of State for the Department of the Environment, Food and Rural Affairs (DEFRA). If consent has been obtained then this risk assessment must take into account any consent conditions. If consent has not been obtained then an application to DEFRA/Advisory Committee on Releases to the Environment (ACRE) will be required.

Grade the **Overall Risk** (= Potential consequence x Likelihood) to the environment as Extreme, High, Meoderate, or Low.(See HSE/ACGM Guidance Notes.)

1-3 Low Risk **4-6 Moderate Risk** **8-12 High Risk** **15-25 Extreme Risk**

Risk to animals, fish, plants etc.

If, in considering the potential for harm to the environment, you have concluded that the Risk to the environment is high or medium, then the containment conditions specified above are inadequate and must be modified to reduce the risk to an acceptably low level (Overall Risk 1-3).

Indicate below any additional containment facilities or provisions/procedures which will be used in order to meet this requirement (additional to those specified above for the protection of human health).

Classification and notification of the work if it involves a contained use (not deliberate release) activity under the GMO (Contained Use) Regulations 2014.

For a GM microorganism use the containment tables in Annex 1 to derive a class number. For other GMOs state whether the modified organism is more or less harmful to human health than the non-modified equivalent.

Activities with GM microorganisms that are Class 2 and above or those involving other GMOs that are more harmful to human health due to the modification will require notification to HSE. All deliberate release activities will instead require consent from the Secretary of State.

Will all the containment measures specified for this class of activity be applied? If not, justify any divergence (consent from HSE will be required for this.)

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Persons who may be affected by the work

Personnel involved in work: (List categories, e.g. Doctors, Nurses, Pharmacists, Laboratory Staff, Porters)	Specify any specific information or training to be provided for the listed categories of workers, over and above training and experience normal for such workers. Consider access restrictions and lone working.

Non-staff categories who may be affected	Information to be provided to this category

Section E: Human Tissue Act (HTA) Considerations

Does the starting material for the GTMP/GTIMP come from a patient or donor at the Trust?	☐ Yes ☐ No
If yes, have you consulted the Designated Individual (DI) to review whether the processes meet HTA requirements?	

Further information on the Human Tissue Act and the Human Tissue Authority can be found here: https://www.hta.gov.uk/

If you need assistance contact the DI relevant to this particular activity.

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Section F: Applicant Signatures

The Principal Investigator/Lead Consultant and Divisional Director must sign below to indicate their acceptance of the following statements.

Principal Investigator/Consultant:

For a GM microorganism use the containment tables in Annex 1 to derive a class number. For other GMOs state To the best of my knowledge and belief, the information provided in this risk assessment is accurate and complete. If the proposal is approved by the Genetic Modification Safety Committee (and by the HSE if required), I undertake to ensure that the containment measures specified in this risk assessment are appropriately applied in the conduct of the approved activities.

Principal Investigator			
Signature		Print name	
Date			

Divisional Director (or designee)

Subject to the approval of this risk assessment by the GMSC (and HSE if required), and approval from other relevant bodies if appropriate (e.g. the Gene Therapy Advisory Committee; Medicines and Healthcare Products Regulatory Agency; Research Ethics Committee, HRA), I agree to the conduct of the approved activities in accordance with the indicated containment provisions, within the Division for which I have responsibility.

Divisional Director (or designee)			
Signature		Print name	
Date		Division	

GMS committee

Outstanding issues following consideration at GMSC:

GMSC Chair or Deputy or Secretary			
Signature		Print name	
Date			

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Section G: Approval by the Genetic Modification Safety Committee

This risk assessment of proposed activities involving GTMP/GTIMPs has been considered by the GMSC, of which I am the authorised representative. The approval of HSE is either not required or has been obtained. Any modifications to the risk assessment required have been incorporated into this final version of the document. (To be signed by Chair, Deputy Chair or Secretary only)			
Review by GMSC		☐ Yes ☐ No	
Signature		Print name	
Date		Position	

Comments

Is HSE notification required?	
First Use Notification	☐ Yes ☐ No
Individual Activity Notification	☐ Yes ☐ No
If yes, date sent	
Date of approval	
HSE Reference number	

ANNEX 1

Tables of control measures and containment levels for 'contained' activities involving gm microorganisms

The basic principles of classification are that you:

1. Determine the containment and control measures required by the risk assessment to control the risk of the activity;
2. Where this corresponds to a single containment level this will read across directly to give you the activity class, i.e.level 1 = class 1, level 2 = class 2, etc;
3. Where the measures identified correspond to measures from two different levels of containment the class corresponds to the higher of the two levels.

Please consider the table overleaf, **Table 1a (Laboratory Activities) this is most appropriate to a clinical setting. Where your project involves the use of GMMs in plant growth facilities or animal facilities, you should refer to HSE for more information.**

Select your control measures. You should place an X in the appropriate box on each row to indicate whether that containment measure is required or not.

Determine the corresponding level of containment and hence the class of GMO. Where controls are selected from more than one containment level the Class corresponds to the higher of the containment levels.

FOR ALL CONTAINMENT TABLES AND FURTHER INFORMATION PLEASE REFER TO THE GUIDANCE TO THE REGULATIONS (L29) OR THE SACGM COMPENDIUM OF GUIDANCE

http://www.hse.gov.uk/pubns/priced/l29.pdf

http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/

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Table 1A:

Containment measures applicable to contained use involving micro-organisms in laboratories

Containment measures		Containment Levels			
		1	2	3	4
Facilities					
1	Laboratory suite: isolation1	not required	not required	required	required
2	Laboratory: sealable for fumigation	not required	not required	required	required
Equipment					
3	Surfaces impervious to water, resistant to acids, alkalis, solvents, disinfectants and decontamination agents and easy to clean	required for any bench	required for any bench	required for any bench and floor	
4	Entry to laboratory via airlock2	not required	not required	required where and to extent the risk assessment shows it is required	required
5	Negative pressure relative to the pressure of the immediate surroundings	not required	not required	required except for activities where transmission does not occur by the airborne route	required

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Containment measures		Containment Levels			
		1	2	3	4
Equipment					
6	Extract and input air from the laboratory must be HEPA filtered	not required	not required	HEPA filters required for extract air except for activities where transmission does not occur by the airborne route	HEPA filters required for input and extract air3
7	Microbiological safety cabinet/ enclosure	not required	required where and to extent the risk assessment shows it is required	required, and all procedures with infective materials required to be contained within a cabinet/ enclosure	required, and all procedures with infective materials required to be contained within a cabinet/ enclosure
8	Autoclave	required on site	required in the building	required in the laboratory suite4	double ended autoclave required in laboratory
System of work					
9	Access restricted to authorised personnel only	not required	required	required	required (via airlock key procedure)
10	Biohazard sign on door	not required	required	required	required
11	Specific measures to control aerosol dissemination	not required	required so as to minimise	required so as to prevent	required so as to prevent

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Containment measures		Containment Levels			
		1	2	3	4
System of work					
12	Shower	not required	not required	required where and to extent the risk assessment shows it is required	required
13	Protective clothing	suitable protective clothing required	suitable protective clothing required	suitable protective clothing required; footwear required where and to extent the risk assessment shows it is required	complete change of clothing and footwear required before entry and exit
14	Gloves	not required	required where and to extent the risk assessment shows they are required	required	required
15	Efficient control of disease vectors (eg rodents and insects) which could disseminate GMMs	required where and to extent the risk assessment shows it is required	required	required	required

Containment measures		Containment Levels			
		1	2	3	4
Waste					
16	Inactivation of GMMs in effluent from hand-washing sinks and showers and similar effluents	not required	not required	required where and to extent the risk assessment shows it is required	required
17	Inactivation of GMMs in contaminated material and waste	required by validated means where and to extent the risk assessment shows it is required	required by validated means	required by validated means, with waste inactivated within the laboratory suite	required by validated means, with waste inactivated within the laboratory
Other measures					
18	Laboratory to contain its own equipment	not required	not required	required, so far as is reasonably practicable	required
19	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 where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	required
20	Safe storage of GMMs	required where and to extent the risk assessment shows it is required	required	required	secure storage required
21	Written records of staff training	not required	required where and to extent the risk assessment shows it is required	required	required

Notes

1. "isolation" means, in relation to a laboratory, separation of the laboratory from other areas in the same building, or being in a separate building.
2. 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.
3. Where viruses are not retained by the HEPA filters, extra requirements will be necessary for extract air.
4. Where the autoclave is outside the laboratory in which the contained use is being undertaken, but within the laboratory suite, there must be validated procedures for the safe transfer of material into that autoclave, which provide a level of protection equivalent to that which would be achieved by having an autoclave in that laboratory.