Loughborough University

| Health & Safety Unit Use Only | |
|---|---|
| Ref No: | |
| **Department Use Only** | |
| Ref No: | CBE/GMO/046 |

## RISK ASSESSMENT of WORK with

# GENETICALLY MODIFIED ORGANISMS

*The requirements of Genetically Modified Organisms (Contained Use) Regulations 2000 are reflected in the University Health and Safety Policy which requires that risk assessment of all work with Genetically Modified Organisms* ***must*** *be carried out in advance of work commencing and, in addition,* ***must be scrutinised and approved*** *by the University's relevant Safety personnel. The tables at the end of this document are drawn from the current legislation and the appropriate table* ***must*** *be completed as part of the assessment. Finally,* ***WORK MUST NOT BEGIN*** *until the proposal has been* ***approved*** *and clearance has been given via Health and Safety.*

| **Date submitted** | 21 May 2012 | **Date approved** | 07/06/12 |
|---|---|---|---|

**Please provide the following general information:**

| **School/Department** | Centre for Biological Engineering, Wolfson School of Mechanical and Manufacturing Engineering |
|---|---|

| **Principal investigator** | David Williams | **Position** | Professor of Heal4thcare Engineering |
|---|---|---|---|
| **E-mail address** | d.j.williams@lboro.ac.uk | **Phone no.** | 01509-22768 |

*Please give a brief and descriptive title for this risk assessment*

| **Title** | Studies Underpinning a Human Induced Pluripotent Stem Cell Bank - A short term pilot scale-up study to automate a manual iPSC culture process |
|---|---|

Please provide a brief description of the nature of the work, identifying any GMMs produced *(e.g. virus vector with insert)*, and their use to transform cells. Please identify the components of the project for which this risk assessment is carried out.

In collaboration with Cambridge University, this is a short-term translational pilot project to transfer a bench-scale manual cell culture expansion process for human induced pluripotent stem cells (iPSC) to an automated, scaled process using the CompacT SelecT system (TAP Biosystems) and to demonstrate feasibility of standardising a cell banking process . It is a key part of a wider ongoing project at Cambridge, aiming to establish the biological and technological basis for creation of a clinically-compatible bank of human induced pluripotent stem cells (iPSC) with homozygous HLA haplotypes,

Human induced pluripotent stem cell lines will be obtained from the Anne McLaren Laboratory at Cambridge University. The induced pluripotent stem cell lines ((BBHX8 and A1ATD) have been derived (at Cambridge) from human adult skin fibroblasts (obtained from skin biopsies after donor consent). IPSC were derived by transduction of a replication deficient retrovirus expressing OCT4, SOX2, KLF4 and C-MYC. The established iPS cell lines (in continuous culture; > 20 passages) and associated manual cell culture process will be transferred (maintained under the ownership of FS; Cambridge) to Loughborough for automated scale up activities using the CompacT SelecT (following SOP035).

**No Genetic Modification activities will take place in the CBE at Loughborough.** This GM Risk Assessment is therefore only applied to the handling the GM cell lines within the CBE Laboratory Unit. This risk assessment should be read in conjunction with the attached biological risk assessment (Ref: CBE/BRA/046) which describes the controls measures that will be implemented in more detail.

| **Donor** | Adult Human |
|---|---|

| | |
|---|---|
| **Name of gene/nucleic acid sequences** | OCT4, SOX2, KLF4 and C.MYC |
| **Vector** | Replication defective MuLV (Moloney Murine Leukemia Virus) derived Gamma-Retroviruses. |
| **Host** | Human adult skin fibroblasts from human skin biopsies |
| **ACDP category* of host** (where appropriate) | N/R |

*The ACDP categorisation of biological agents can be found in the *Approved List of Biological Agents* published by the Health and Safety Executive.

Note: The questions in this proforma are designed to ensure that all the relevant issues have been addressed for the majority of Risk Assessments for work involving Genetic Modification at the University of Loughborough. However in the interests of streamlining the majority of applications, and because not all possible applications of genetic modification may have been anticipated, there may be instances in which answer of these questions alone may not be sufficient for a full risk assessment. The Genetic Modification Safety Committees reserve the right to request additional information. For a more complete description of the requirements of a Risk Assessment, refer to ACGM notes and newsletters, and the Guidelines to the 2000 Regulations. Less detail will be required for commonly used and familiar host/vector systems than for those less widely known or characterised. References may be helpful in some instances.

It may be appropriate to write the assessment to cover a range of closely related GMOs, e.g. a defined family of genes, a range of vectors with similar properties, complete and partial sequences, with and without expression; however the assessment and containment conditions proposed must reflect the greatest potential hazard of any of the range of GMMs covered by the assessment.

Do not feel constrained by the box sizes, in some cases considerably greater amounts of information may be required. The box sizes should expand to accommodate your text. To add further rows to a table, use tab key when cursor is in the last box.

Any potentially confidential information should be highlighted, e.g. by use of **red text**. This will include all personal information, and possibly e.g. commercially sensitive information, which the applicant wishes **NOT TO APPEAR ON THE PUBLIC REGISTER**. NB There are tight restrictions on what will be accepted as confidential. The remainder of the risk assessment must be understandable without the confidential information.

It may be possible for outside bodies to access information in this form under the Freedom of Information Act, unless it can be categorised as an exemption. Furthermore, work with organisms listed in Schedule 5 of the Anti-terrorism, Crime and Security Act 2001, or genetic material from those organisms, may be notifiable to the Home Office.

## Characteristics of the Donor, Insert, Vector and Host

**Name** (species/strain if appropriate) **and characteristics of the source of the nucleic acid sequences ("the donor)**

Human cDNA

Note: Species from which the nucleic acid sequences were obtained, whether a pest or pathogen, tissue (normal, tumour, healthy or diseased), health status of the donor, etc.

Name, description and function of the gene/nucleic acid sequences involved ("the insert")

Human cDNA: OCT4, SOX2, KLF4 and C-MYC are known to promote reprogramming of somatic cells into pluripotent cells.

Note: Biological function of the intact, natural gene; whether protein-coding sequence complete, partial, unknown, or known to be absent in construct; whether or not interrupted by introns etc; whether wild type or mutant; known, suspected or intended function of mutants; any other biological activities e.g. antisense, ribozyme, replication origin, mobilisation functions, etc. Genomic or cDNA library (consider the properties of the library as a whole; separate assessment is required for the specific clones you intend to isolate from the library).

**Name and characteristics of the "vector"**

Replication defective *MuLV* (Moloney Murine Leukemia Virus) derived Gamma-Retroviruses ie unable to multiply and propagate after initial cell transduction. Viral vector production encoding sequences for OCT4, SOX2, KLF4 and C-MYC (OSKM) was carried out by the company Vectalys.

Note: Name of parental plasmid, bacteriophage, etc; characteristics, i.e. mobilisable, mobilisation defective, non-mobilisable; host range; presence of drug resistance markers or other sequences of potential clinical or environmental significance. Whether constructs transferred into host cells e.g. as non-mobilisable DNA; presence of replication origins, conditional (e.g. SV40, EBV) or otherwise. Involvement of viral vectors (e.g. retrovirus, baculovirus); name, characteristics, whether replication defective and the basis of this (e.g. deletion); host range; pathogenicity; potential for complementation by products expressed in the host, or by superinfection, etc.

**Name and characteristics of the "host"**

Primary human adult fibroblasts from skin biopsy.

Note: Species/strain etc, whether disabled/ highly disabled; presence of other agents which may e.g. assist transmission; or affect pathogenicity; any history of safe use; whether an intact multicellular organism is produced at any stage (e.g. transgenic animals, plants); if host is (a) cell line(s) derived from multicellular organisms, the species, any potential for harm to humans or the environment; presence of other agents which are themselves transmissible or may assist the mobilisation of the transferred sequences e.g. as a result of recombination.

## Characteristics of the Genetically Modified (Micro)Organism

**Will there be expression of the protein (or other functional product) encoded by the insert, in the genetically modified organism?**

The viral vector is used to induce the autologous expression of the OSKM factors. The transgenes are silenced after transduction.

Note: Provide details, e.g. of the promoter, level of expression, secretion, presence of introns within the coding region which might preclude expression of a functional product in E. coli, or other specific hosts, etc.

**Specify any known or expected characteristics of the GMO which pose a risk to human health and safety and assess the severity and likelihood of such effects**

| **Effects on human health (include colonisation, infection, allergy, toxin-mediated disease)** |
|---|
| GM Cells: Insert expression, non-replicative vector, vector mobilization are very unlikely. GM cells may be transformed/oncogenic but are still relatively fastidious and would be incapable of colonising and causing disease. These cells could represent a genuine risk to corresponding donor but there will be no opportunity of donors to be so exposed.<br><br>Culture supernatants are virus free (gamma-RV) 24 hours after transduction. The established iPSC cell lines have subsequently been in continuous culture; > 20 passages<br><br>The cell lines are considered as especially disabled, non-pathogenic (for immuno-competent subjects) and unable to grow outside the laboratory environment. The human primary cells from which these lines were derived, although from screened donors, were largely uncharacterised and a risk that they may have contained unknown or untested adventitious agents cannot be excluded. Although the iPSC lines are considered lower risk, as a precaution they will be handled at Containment Level 2 (COSHH regulations) i.e. classified as Hazard Group 2. A biological risk assessment for these cells is attached to this risk assessment and should be referred to for further details of the controls measures that will be implemented. |
| **Humans at increased risk of the above effects (e.g. immunocompromised, pregnant or breastfeeding women)** |
| Immunocompromised workers exposed to pluripotent stem cells may be at an increased risk of developing teratoma. |

Note: Characteristics which might increase the pathogenicity of the GMO relative to the unmodified host, or decrease susceptibility to control measures, e.g. alteration in susceptibility to clinically relevant drugs or to immunological or other natural defences; any other potentially significant biological activities of encoded products, e.g. potential toxicity, allergenicity, growth promotion/inhibition, oncogenicity, other pharmacological activity, etc.

**Does this project involve work with animals? Provide details**

No

**Either use of transgenic animals or work with GMMs in animal models**

**Quantity of organisms to be used**

Cells will be grown in T175 flasks (maximum scale used). Cells grow in clumps and therefore are not counted. However from experience from other cell types that also grown in colonies but can be re-suspended in single cells we expect around $5x10^6$ cells per T175 flask. Each flask will contain a maximum of 50mL culture volume.

Per experiment:
Plan to split T175 flask in 5xT175 for 3 passages.

Specify volumes and concentrations/culture density

# Interim Assignment of Containment Conditions to Protect Human Health

Using the appropriate table(s) in Annex 1 of this form please select your control measures (you may place a **X** alongside each appropriate control measure to indicate that you have considered each one) and assign an interim level of containment for the work, i.e. ACGM containment level, (taking into account the hazard grouping of any biological agent). Please justify your decision to use this level of containment.
***NB*** CLASSIFICATION OF THE PROJECT IS DEPENDENT ON ONLY THOSE CONTROL MEASURES THAT ARE SHOWN BY THE RISK ASSESSMENT TO BE NECESSARY TO PROTECT HUMAN HEALTH OR THE ENVIRONMENT. MEASURES THAT RESULT FROM CONVENTION, CONVENIENCE OR ARE REQUIRED FOR PRODUCT PROTECTION ARE NOT RELEVANT TO THE CLASSIFICATION See ACGM Newsletter 27/ACGM Compendium of guidance for further information

**Interim containment level and corresponding Class (classes) of GMO(s) involved in the work (& explanation)**

Both cell lines were genetically modified at Cambridge University and cultured for 20+ passages. The viral vector integrates in the genome of the target cell, however it is replicative deficient and is silenced after transduction. Transduced cell culture supernatants were tested RCR *(retroviral particles competent for replication)* free, cell donor serology negative for known ACDP ≥ 2 agents and Mycoplasma free. The cell lines are considered especially disabled and unable to survive or propagate outside of laboratory culture

For classification purposes: Containment Level 1 is sufficient to control the risk associated with the GM cell lines, which is no more hazardous than the host cell. The cells are therefore given an interim classification of Class 1.

For operational purposes: All procedures will be carried out under Containment level 2 (CL2) within the CL2 CBE Laboratory Unit i.e. under management standards imposed by a higher level of Containment according to CBE Policy and Code of Practice This is for reasons other than worker or environmental protection and includes the need to ensure research material protection (e.g. the use of a class II safety cabinet); to impose a quality assurance discipline and because other projects using HG1/HG2 BAs may be under way in the CBE Laboratory Unit simultaneously. This is reflected by the implementation of the control measures indicated in the attached Biological Risk Assessment (Ref: CBE/BRA/046) and which are briefly outlined below.

Note: You will need to consider the containment level necessary to control the risk of the host and then make a judgement as to whether the modification will result in a GMO more hazardous/less hazardous/about the same

## *Please provide the following information for the Committee:*

**Are any of the work procedures likely to generate aerosols? If so, is the work to be undertaken in a safety cabinet?**

Aerosols may be generated when pipetting or manipulating solutions. All such manipulations and vial openings will be conducted in a Biological Safety Cabinet as detailed in the attached Biological Risk Assessment.

**Identify any use of sharps in the work; justify their use and specify control measures**

No sharps are used as indicated in the attached Biological Risk Assessment.

**Protective equipment and clothing to be used**

Standard laboratory safety equipment will be used. Nitrile gloves and side fastening Howie type lab coats will be worn. Refer to section C1.2.10 Personal Protective Equipment (PPE) on Biological Risk Assessment (Ref: CBE/BRA/046).

**Transport and storage arrangements**

Refer to section C1.2.3, C1.2.4 and C1.2.5 on Biological Risk Assessment (Ref: CBE/BRA/046) for transport and safe storage procedures.

Specify arrangements for safe storage; whether, and if so how, materials are likely to be transported between buildings, on public roads, or posted)

**Disinfection**

Small spills on surfaces will be decontaminated immediately using 1% Virkon according to local procedures. Large accidental spills will be sprinkled with powdered Virkon before cleaning; according to local procedures. Bench and cabinet surfaces will be wiped with 1% Virkon following 70% IMS according to local procedures. NOTE: Virkon has a wide range of bactericidal, virucidal, fungicidal and sporocidal activities. Representative viruses from all the major virus families are inactivated by Virkon. Working solutions of 1% w/v have low toxicity and no irritancy.

Refer to section C1.2.9 Disinfection on Biological Risk Assessment (Ref: CBE/BRA/046).

Specify disinfectant(s) to be used, and their dilution. Have these been validated for use with the relevant organism?

**Inactivation of GMMs in waste, and subsequent disposal**

All disposable culture/lab ware from the CL2 CBE Laboratory Unit will be autoclaved (within the CBE Laboratory Unit) and properly labelled before leaving the building for incineration. All GM cultures (in flasks) will be or autoclaved before leaving containment. All aspirated media will be chemically destroyed (1% Virkon; 24hrs). All waste is inactivated by validated methods - refer to section C1.2.15 and C1.2.16 on Biological Risk Assessment (Ref: CBE/BRA/046) for inactivation and waste disposal procedures.

The Contained Use Regulations 2000 require that GMMs in contaminated material and waste are inactivated by validated means. You must specify the METHOD of inactivation of the GMMs, the expected DEGREE OF KILL of the GMM achieved by that method, and the VALIDATION of that method.

## Monitoring of Containment and Control Methods

**Monitoring of containment at point of use**

Not required as cells unable to survive or propagate outside of laboratory culture. Engineering controls (eg safety cabinet operation) in the CBE CL2 Laboratory Unit are monitored according to SOPs – refer to attached Biological Risk Assessment (Ref: CBE/BRA/046).

**Monitoring of waste inactivation methods**

Waste inactivation is monitored according to SOPs for Maintenance of autoclaves and Disposal of Biological Waste" - refer to attached Biological Risk Assessment (Ref: CBE/BRA/046).

**Emergency procedures - Is an emergency plan required? Provide details (or attach)**

An emergency plan is not required - small scale activities would not result in significant spills and consequent significant release of the Class 1 GMO. The risk of any low level release to health and safety and/or the environment is considered effectively zero. However, emergency response procedures for dealing with biological spills and reporting accidents/incidents are in place as part of the CBE CL2 Laboratory Unit operational Code of Practice – refer to Biological Risk Assessment (Ref: CBE/BRA/046).

Note: In the event of a reasonably foreseeable accident where the health and safety of people outside the premises is liable to be seriously affected or where there is a serious risk of damage to the environment then an emergency plan is required. This plan may need to be communicated to the emergency services and other relevant bodies. In most cases this will only be required for Class 3 and 4 projects (See ACGM Newsletter 27/Compendium of Guidance for further information). However, details of accident/spillage procedures should be provided for all projects.

**Occupational Health issues**

Health forms are submitted and monitored by the Occupational Health Office in the University as part of the authorisation process for entry into CBE CL2 Laboratory Unit.

Specify any requirements for immunisation, chemoprophylaxis or health monitoring, and any special requirements for record keeping

## Environmental Considerations

**ANSWERS MUST BE JUSTIFIED IN SOME DETAIL, i.e.- IT IS NOT ACCEPTABLE TO SIMPLY STATE THAT THERE IS NO RISK TO THE ENVIRONMENT.**

**Risk to animals, fish, plants etc**

| | |
|---|---|
| **If the recipient microorganism is controlled by DEFRA, do you have a DEFRA licence?** (delete as appropriate) | N/R |

Approval will not be granted until a copy of the DEFRA licence (if applicable) has been submitted to both the local GMSC and the Advisory Group for the Control of Biological Hazards

**Identify any identifiable potential hazards to the environment, which might occur if the genetically modified organism were to be accidentally released. Classify the potential hazard as Severe, Medium, Low or Negligible.**

Potential hazard classified as Negligible.

Cell lines are unable to survive or propagate outside of laboratory culture. Recombinant gamma-RV is replication defective and cannot produce progeny viruses able to spread to the wider human or other animal populations.

Note Potential hazards might be identified, and their severity assessed, dependent upon: the host species, the vector or the insert; or phenotypic changes caused by the genetic modification; the presence of host or susceptible species in the environment; the potential for survival, multiplication and dissemination in the environment; the stability of the GMO in the environment; the possibility of gene transfer to other species, etc. Refer to ACGM Compendium of guidance for further information

**In view of the characteristics of the GMO, specify the likelihood of accidental release and occurrence of the above mentioned potential harmful effects, if the work were to be performed at the interim containment level specified above. Classify this as High, Medium, Low or Negligible.**

| |
|---|
| Classified as Negligible, see above – consequence of the hazard is negligible and likelihood of release is low. |

Note: This includes the wider as well as the local environment in which the activity is to be carried out. Consideration should be given to any potential exposure of the environment to the GMMs and the magnitude and duration of such exposure. Refer to ACGM guidance for further information

**Grade the overall Risk to the environment (= Potential harm x Likelihood) as High, Medium, Low or Effectively Zero.**

| |
|---|
| Effectively zero, see above. |

## Additional Containment

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 previously specified may need to be modified to reduce the risk to an acceptably low level. Use these considerations to revise your provisional containment level so that all risks are controlled to low or effectively zero.

**Additional containment provisions for environmental protection**

| |
|---|
| None. |

**Assign your final containment level.**

| | |
|---|---|
| For the classification purposes – assigned Containment level 1. | |
| **Are all hazards now controlled by this proposed level of containment?** | Yes |

**Final classification of the activity, i.e.Class 1/2/3/4. Is the activity notifiable to HSE?**

| |
|---|
| Classification of activity assigned as Class 1. Does NOT represent first use of Class 1 material in CBE CL2 Laboratory Unit – no notification required. |

Where the containment and control measures fall between two levels, e.g. where level 1 is appropriate with some control measures from level 2, the classification for the activity is equivalent to the HIGHER containment level. All Class 2,3 and 4 projects are notifiable to the Health and Safety Executive through the Health and Safety Unit

**Do you intend to apply <u>all</u> control measures from your highest selected level of containment** (See Annex 1)**? If not, please justify the exclusion of any control measures not used.**

| |
|---|
| Yes |

Formal application to the Health and Safety Executive is required for derogation from the full containment level for all Class 2, 3 and 4 projects.

***EC Regulation requires notification of transboundary movements of Class 3 GMMs to the Biological Clearing House and European Commission *(transboundary movements are those entering or leaving the EC)*. If your work involves Class 3 GMMs please indicate below whether they will be subject to transboundary movements.**

| |
|---|
| N/R |

## Workers Involved in the Project and Facilities Used for the Work

| Please indicate the areas where work will be carried out (including Room No. and Designation): | |
|---|---|
| **Room No. and designation** | **ACGM Categorisation** |
| CBE Laboratory Unit H21 | 2 |
| CBE Laboratory Unit H22 | 2 |
| CBE Laboratory Unit H31 | 2 |
| | |

| **Workers initially involved in work:** | **Post/experience/training:** |
|---|---|
| F Soares | PhD Student/1 year experience in working in CL2 laboratory. Will complete local training programme to gain authorised entry into CBE CL2 Laboratory Unit before commencing work.<br><br>5 years CL1, 1 year CL2 working. 1 year experience working with iPSC/GM cells. Trained in Cambridge. |
| A Chandra | Research Associate and authorised user of CBE CL2 Laboratory Unit facilities, procedures and equipment<br><br>Has cultured GMO Cells previously in another project. |
| R Thomas | Senior Lecturer and authorised user of CBE CL2 Laboratory Unit facilities, procedures and equipment. Will be supervising the work and is not involved in the practical aspects of the work |
| | |
| | |

**Training and assessment of competence for existing and future personnel**
***Specify arrangements for provision for existing and future personnel***

AC and RT are fully trained in all required local procedures and equipment operation. FS will be trained in all required local procedures and equipment operation as a requirement for authorisation to commence work in the CBE CL2 Laboratory Unit. Formal records of training are kept for all workers authorised to work within the at Containment Level 2 (CL2) CBE Laboratory Unit.

## Authorisation and Notification

The work proposed should be discussed with the Departmental Biological Safety Officer.

**Signature of proposer** ..... **Date** 24 May 2012

**Please print name** F. Soares

**Other Signature (s) (if required – please state position)** ..... **Date** .....

Chris Hewitt
(Local Biological and GM Safety Advisor)

**Please print name** ..... 25/5/12

**Signature of Biological Safety Officer or authorised Deputy** ..... **Date** 7/6/12

**Please print name** C. M. Moore

NB The Approval of the University's relevant Safety Committee is required before work starts.

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## APPROVAL of the RELEVANT SAFETY COMMITTEE

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**On behalf of SC** ..... **Approval Date** 3/8/12

# ANNEX 1

# TABLES OF CONTROL MEASURES AND CONTAINMENT LEVELS

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.

Further information can be found in the guide to the Contained Use Regulations and in the ACGM Compendium of guidance

***

Please consider the table(s) overleaf. Select the appropriate table for the work you are involved in. In most cases this will be **Table 1A (Laboratory Activities). Where your project involves the use of GMMs in plant growth facilities or animal facilities, you should consider Table 1B or 1C in conjunction with table 1A.** (In the final column of Tables 1B and 1C "additional" specifies use of that control measure in addition to the measures in Table 1A, while "modification" specifies that this measure shall be substituted for the relevant measure in Table 1A).

**Large scale activities** should be classified using **Table 2.**

Select your control measures. You should place a **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 FURTHER INFORMATION PLEASE REFER TO ACGM NEWSLETTER 27 OR THE ACGM COMPENDIUM OF GUIDANCE**

**Please delete tables not relevant to your risk assessment. You may also delete this explanatory page from your final risk assessment**

**TABLES OF CONTAINMENT MEASURES**

**TABLE 1A: LABORATORY ACTIVITIES**

**TABLE 1B: PLANT GROWTH FACILITIES**

**TABLE 1C: ANIMAL FACILITIES**

**TABLE 2: OTHER ACTIVITIES (LARGE SCALE)**

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## TABLE 1A: LABORATORY ACTIVITIES

| Containment measures | Containment level 1 | | Containment level 2 | | Containment level 3 | |
|---|---|---|---|---|---|---|
| Laboratory suite - isolation | Not required | X | Not required | | Required | |
| Laboratory - sealable for fumigation | Not required | X | Not required | | Required | |
| | | | | | | |
| **Equipment** | | | | | | |
| Impervious/easy to clean surfaces | Required for bench | X | Required for bench | | Required for bench and floor | |
| Entry to lab via air lock | Not required | X | Not required | | Required where and to the extent the risk assessment shows it is required | |
| Negative pressure relative to the pressure of the immediate surroundings | Not required | X | Required where and to the extent the risk assessment shows it is required | | Required | |
| Extract and input air in laboratory should be HEPA filtered | Not required | X | Not required | | HEPA filters required for extract air | |
| Use of microbiological safety cabinet/enclosure | Not required | X | Required where and to the extent the risk assessment shows it is required | | Required and all procedures with infective materials required to be contained within cabinet/enclosure | |
| Autoclave | Required on site | X | Required in the building | | Required in the laboratory suite | |
| | | | | | | |
| **System of work** | | | | | | |
| Access restricted to authorised personnel only | Not required | X | Required | | Required | |
| Specific measures to control aerosol dissemination | Not required | X | Required so as to minimise | | Required so as to prevent | |
| Shower | Not required | X | Not required | | Required where and to the extent the risk assessment shows it is required | |
| Protective clothing | Suitable protective clothing required | X | Suitable protective clothing required | | Suitable protective clothing required; Footwear required where and to the extent the risk assessment shows it is required | |
| Gloves | Not required | X | Required where and to the extent the risk assessment shows it is required | | Required | |
| Efficient control of disease vectors (eg for rodents and insects) which could disseminate GMMs | Required where and to the extent the risk assessment shows it is required | X | Required | | Required | |
| Specified disinfection procedures in place | Required where and to the extent the risk assessment shows it is required | X | Required | | Required | |

| | Containment level 1 | | Containment level 2 | | Containment level 3 | |
|---|---|---|---|---|---|---|
| **Waste** | | | | | | |
| Inactivation of GMMs in effluent from handwash sinks and showers and similar effluents | Not required | X | Not required | | Required where and to the extent the risk assessment shows it is required | |
| Inactivation of GMMs in contaminated material and waste | Required by validated means | X | Required by validated means | | Required by validated means with waste inactivated in lab. suite | |
| | | | | | | |
| **Other measures** | | | | | | |
| Laboratory to contain own equipment | Not required | X | Not required | | Required, so far as is reasonably practicable | |
| An observation window or alternative to be present so that occupants of lab can be seen | Required where and to the extent the risk assessment shows it is required | X | Required where and to the extent the risk assessment shows it is required | | Required | |
| Safe storage/transport of GMMs | Required where and to the extent the risk assessment shows it is required | X | Required | | Required | |
| Written records of staff training | Not required | X | Required where and to the extent the risk assessment shows it is required | | Required | |

**HIGHEST LEVEL OF CONTAINMENT SELECTED ABOVE: Containment Level 1**

**CORRESPONDING CLASS OF GMM: Class 1**

amended 20.3.08