This is an EXAMPLE Risk Assessment ONLY – Please amend so that it is an accurate, complete risk assessment of the GMO transportation being completed under your EPA licence. The EPA require this risk assessment to be provided to them in advance of these GMO materials being moved. Therefore please forward the completed risk assessment to the Safety Office as they are collating this response to the EPA.

Risk Assessment on Transportation of Genetically Modified Organisms from (Minus 80 Freezer, room 204, second floor, Biosafety Research Building A, to freezer number 4, room 119, first floor, Research Building B).

Genetically Modified Organism, (GMO) Register Number: G-123-01

Class of GM: Class 2 GMO

Licensee: Professor Aaron Aardvark, Tel: 091 49999, Email: Aaron.Aardvark@nuigalway.ie, tel : 086-8888999

Person co-ordinating the transport of these GMs is: Joe Bloggs, joe.bloggs@nuigalway, tel : 086-9998888

List of Genetically Modified Microorganisms to be moved are as follows:

1. Lentiviral vector (CLASS 2):
- encoding short hairpin RNA (shRNA) directed against human ATF6 mRNA, human PERK mRNA, rat XBP1 mRNA, human IRE1 mRNA, murine Noxa mRNA, murine ATG5 mRNA, human DR1 mRNA, human DR2 mRNA, human DcR1 cDNA, human DcR1 mRNA, human DcR2 mRNA;
- encoding Red Fluorescent Protein (RFP) from Discosoma, green fluorescent protein (GFP) from Aequoria victoria, murine PERK protein, murine PERK K618A protein, human Bcl-2, mStrawberry-Atg4BC74A fusion protein.

2. Retroviral vector (CLASS 2):
- encoding human PUMA DeltaABH3 mutant cDNA, human PUMA cDNA, human Bcl-2 cDNA, human BIM L150E mutant cDNA, human BIM and Bcl-2 cDNA, human RasV12 cDNA.

3. Adenoviral vector (CLASS 2):
- encoding human Bcl-XL cDNA, human Hsp27 cDNA, human dominant negative NIK cDNA, human dominant negative IKK cDNA, GFP gene, NF-kB reporter gene;
- directed against murine caspase-9 mRNA.

GMMs are currently contained in minus 80 freezer, room 204, second floor, Biosafety Research Building A, NUI Galway.

GMMs are to be transported to freezer number 4, room 119, on the first floor, Research Building B, NUI Galway.

Transit Containment Arrangements

The illustrations below are representative of the containment measures that should be used. For your risk assessment please show only the exact measures being adopted in this move.

Primary Containment: The GMM samples are contained in a clearly labelled watertight, leak proof tubes. The tubes are wrapped in Parafilm to prevent accidental opening. The tubes are then wrapped in enough absorbent material to absorb all fluid in case of breakage or leakage.


Secondary Containment: Tubes containing GMM material are then enclosed in a watertight, leak proof container. This container is appropriately labelled as to contents.

Tertiary Containment: The tertiary container will protect and enclose the secondary units. They are either polystyrene or Styrofoam containers and are:

(1) Rigid and damage free.
(2) Suitable to contain the primary and secondary contents during transit, handling and stacking.
(3) Appropriately labelled as to contents.
(4) Appropriately labelled with Class 2 containment
(5) Display the source and destination addresses on the box
(6) Display emergency contact details on the box.

An inventory form (Appendix 1) of dispatched and received GMM containers will be cross checked at dispatch and at destination locations. See Inventory Form at the end of this assessment. The forms will be maintained as a record by Aaron Aardvark or Joe Bloggs.

Transit Spill arrangements:

Lentiviral Vector constructs. These are classified as Class 2, GMM activities of low risk for which level 2 containment is appropriate to protect human health as well as the environment. The physical barriers described in this risk assessment are sufficient to limit contact with the general public and the environment. **Human Health Considerations.** Wild type HIV-1 on which most lentiviral vectors are based, is the believed causative agent of AIDS. In the lentiviral vector detailed here the genome has had the majority of the wild type HIV-1 genome removed. The lentiviral vector is pseudotyoed with a VSV-G envelope – i.e. it lacks the wild type HIV-1 envelope. The genes which are deemed necessary for vector production have been divided onto three separate plasmids, which are only expressed via transient transfection. In the produced vectors, no viral genes accompany the transgene and so the infection process limited to a single round. There the chance of recombination of the wild type virus is very unlikely and there is minimal risk to users.

Adenovirus. Human Adenovirus type 5 viral vectors are replication defective by virtue of the deletions in the E1 region. Adenovirus type 5 can cause mild upper respiratory tract infections in humans. These diseases are self-limited and do not require any specific treatment. There is no association with allergic or toxic effects. This class of adenovirus has never been associated with malignancy. The safety of adenovirus serotype 5 is attested to by the fact that they have been extensively used in vaccination in adults. Furthermore, most children exhibit immunological evidence of infection with type 5 adenovirus at a young age with no associated serious disease. Adenovirus type 5 has not been associated with disease in plants or animals and does not pose any environmental threat.

Retrovirus. The recombinant retroviral packaged particles are replication deficient and therefore can only replicate in HEK293 cells, which have been transfected with genes containing GAG, POL, REV, and ENV. The vector is not capable of replicating itself, *in vivo* or *in vitro*. Previous studies also indicated that the retroviral expression is silenced after the cell reprogramming. Furthermore since the modified virus is replication deficient it is less pathogenic than the wild type and there is minimal capacity for colonisation. If it is exposed to the environment it is unlikely to survive for extended

periods. The retroviral vector system used is based on the murine stem cell virus (MSCV), a retrovirus normally not infectious for humans. The gag, pol, and env genes have been removed, and the vector is pseudotyped with a VSV-G envelope, thus may infect human cells but is replication-deficient. The genes which are deemed necessary for vector production have been divided onto two separate plasmids, one expressing gag, pol, the other VSV-G envelope protein, which are only expressed via transient transfection during vector production. In the produced vectors, no viral genes accompany the transgene and so the infection process is limited to a single round. Therefore, the chance of recombination of the wild type virus is very unlikely and there is minimal risk to users. Modified retroviral vectors may mimic some of the characteristics of the wild-type or may pose a risk to immune-compromised individuals.

Environmental Considerations. There may be a possibility that the modified lentiviral vector may mimic some of the characteristic of the wild-type. However, recombinant lentiviral vector can only be produced in complementing cells such as HEK 293T that have been transfected with the three packaging plasmids. The vectors described here pose a low risk to animal/plant health and the environment.

Spill Procedure.

Refer to Standard Operating Procedure Unit XYZ 03-04-02 Spill Procedure: Treatment of GMO/GMM spillages of less than 100ml volume with disinfectants. Full SOP attached - please see brief description below.

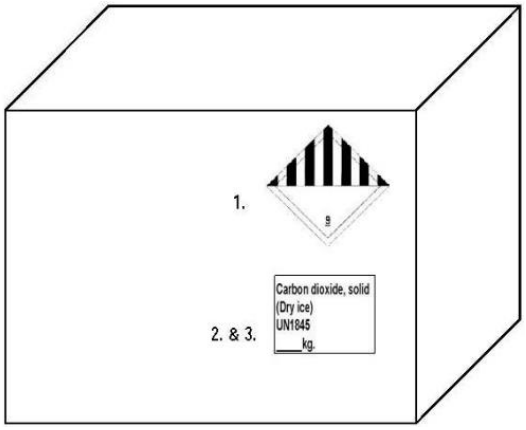
1. The area of the spill should be cordoned off to avoid spreading the spill.
2. Inform another member of staff of the spill and request assistance if necessary.
3. Wearing protective clothing, mop up the excess liquid with paper towels and place in autoclave bags.
4. Liberally pour 2% Virkon over the entire area of the spill and leave for 10 minutes before mopping up with paper towels. Wipe area with 70% Ethanol.
5. Wipe again with paper towels and allow the affected area to air dry.
6. Contents of autoclave bags are disposed of as described in SOP UNIT XYZ 11-16-01 (attached)
7. Where spills have occurred as the result of an accident, inform your supervisor immediately and enter details in the Incident Book.

Dry Ice Hazard.

The GMMs will be transported on dry ice. Dry ice is considered hazardous during transportation for the following reasons:

1. **Explosion hazard**: Dry ice releases a large volume of carbon dioxide gas as it sublimates. If packaged in a container that does not allow for release of the gas, it may explode, causing personal injury or property damage.
2. **Suffocation hazard**: A large volume of carbon dioxide gas emitted in a confined space may displace oxygen and create an oxygen deficient environment.
3. **Contact hazard**: Dry ice is a cryogenic material that causes severe frostbite upon contact with skin.

Labels and markings required for dry ice are to be added in addition to the other labels and markings detailed above. The risk to personnel trained to handle dry ice packages is low when correct PPE (lab coat, gloves, and goggles) are supplied and packages are assembled correctly.



Notify the EPA.
The EPA will be informed of the move. Details such as room numbers, floor numbers and building names need to be detailed by completing the **BRB EPA Move Notification** Table (Appendix 2).

Alternative Move option.

A spare minus 80 freezer is available on site.

Clearly labelled boxes containing GMMs may be placed in freezer unit.

Freezer unit may be loaded on to a truck with tail lift and transported to new location.

Boxes containing GMMs will be taken out of freezer and placed in new GMM freezer storage.

Correct PPE, lab coat, gloves, goggles should be worn and biological spill kit available during loading, transport and unloading of GMM materials.

Appendix 1

Inventory Form

Licence: G0999-01 Prof. Aaron Aardvark

Initial Location of GMs: Minus 80 Freezer Lab 204, Second Floor, Biosafety Research Building A.

	Contents Description	Number of Vials
Box 1		
Box 2		
Box 3		

(Continue table as appropriate)

Items Packed Correctly:

Name of person packing GMs (PLEASE PRINT)_____

Signature of person packing GMs: _____ Date: _____

Countersigned: _____ Date: _____

Final Location of GMs: Freezer number 4, Room119, first floor, Research Building B, NUI Galway.

	Contents Description	Number of Vials
Box 1		
Box 2		
Box 3		

Items unpacked and stored correctly:

Signature: _____ Date: _____

Signature: _____ Date: _____

Appendix 2

Name of PI (GM User)	EPA Licence #	GM Class (1 or 2)	Nature of GM', i.e. bacterium, virus, cell line, animal, plant	Current Room # (and building)	New Building Room #	New Building Floor Level	Move Date	Risk assessment completed? Y/N	Will residual GM material be left in current location? Y/N If YES, please confirm nature of material, room #s, person responsible for its safe use.