

GB – UNITED KINGDOMNATIONAL INSTITUTE FOR BIOLOGICAL STANDARDS AND CONTROL (NIBSC)

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1. Existence of a practice regarding the handling of deposited microorganisms after the expiration of the period of storage prescribed in Rule 9.1 of the Regulations under the Budapest Treaty

The UKSCB has a disposal policy in place “Disposal of a Cell Bank” ID 1558 which details how to discard a non conforming cell bank. There is also “Disposal of Waste and Biological Materials from the UK Stem Cell Bank” ID 1572. Given that the UKSCB only accepts cells via WIPO which have been tested for sterility and mycoplasma, we would follow these SOP’s.

There are local Biological Waste Disposal guidelines, specific to the site on which the UKSCB is located

There is also an MHRA wide Waste Management Policy and Procedure. All staff are trained to this.

2. Description of the practice

Procedure:

(Redacted from the original ID1558 where appropriate)

1. Check that the cell line is authorised for disposal. Follow Disposal of Waste and Biological Materials from the UK Stem Cell Bank ID1572.
2. Use the LN2 inventory system to locate the vials for disposal.
3. Remove the cell bank vials from the LN2 refrigerator.
NB: The removal of vials from storage should be double witnessed by an additional trained member of staff.

4. Check that the labelling of the vials is correct for the cell bank.
5. Record the removal of vials.
6. Update the inventory for the LN2 refrigerator.
7. Cell bank vials contain DMSO and are therefore categorized as toxic waste and should be disposed of as per NIBSC protocol detailed in ID1572.

Redacted from the original ID 1572 where appropriate :

- Disposal of biological materials, including cell banks.
 - a. Cell cultures which fail to grow or do not recover from thawing are documented in the appropriate cell line production records and disposed of (as for biological material/laboratory waste) according to the local NIBSC procedures.
 - b. Once the appropriate permission for disposal of a cell bank has been received, the cell bank is disposed of (as for biological material/laboratory waste) according to the local NIBSC procedures. Details of the disposal are recorded in the Log of UKSCB Cell Banks for Disposal.

3. Documentation and links

Please see redacted information in section 2.