

GB – UNITED KINGDOM

NATIONAL INSTITUTE FOR BIOLOGICAL STANDARDS AND CONTROL (NIBSC)

UK Stem Cell Bank
Blanche Lane
South Mimms
Potters Bar
Herts. EN6 3QG

Telephone: +44 (0) 1701 641 000
Facsimile: +44 (0) 1701 641 050
E-mail: enquiries@nibsc.org
Internet: www.nibsc.org

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Animal cell lines, human cell lines and genetically modified cell lines that can be preserved without significant change to or loss of their properties from freezing and/or long-term storage.

Note that:

- No patent deposit should be sent to NIBSC without a Biohazard Risk Assessment having been first received and reviewed by NIBSC. For genetically modified cell lines this will include a formal review by the NIBSC Biological Safety Committee. Following a favourable review of the Risk Assessment the customer will be invited to ship the material for deposit. Risk Assessment forms can be accessed from the NIBSC website.
- Processing of material that requires handling at Containment Levels higher than Level 2 may require a longer period to completion depending on the availability of high containment facilities. The price charged for such high containment processing is necessarily higher to reflect the increased cost to NIBSC.
- NIBSC reserves the right to refuse to accept any material for deposit that, in its opinion, presents an unacceptable risk or is technically unsuitable to handle. NIBSC will only accept organisms that do not significantly change after long-term storage at the appropriate storage temperature.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Human Cell Cultures. Human material submitted to NIBSC for deposit must be in the form of cryopreserved cultures. NIBSC may refuse deposits which have not been packed in a manner capable of maintaining the material in its original cryopreserved state during transit. The minimum number of replicates that must be provided by the depositor for deposit is 12. Deposits of human cell lines cultured as monolayers or suspension cultures must contain at least 1×10^6 cells/ampoule (of viable cells as determined prior to cryopreservation). Deposits of human cell lines, if cultured as colonies from colony fragments, must contain at least 4 colony fragments per ampoule or straw. Where the cell line requires a feeder cell layer to support its growth in culture, a sample of this material must also be provided in a quantity sufficient to support the necessary testing. Any requests to deposit human embryonic stem cell lines will be subject to current UK regulations and guidelines. Any request to deposit human cell lines other than embryonic stem cell lines must conform to EU regulations and guidelines.

Animal Cell Cultures. Material of animal origin submitted to NIBSC for deposit must be in the form of cryopreserved cultures. Cells whose distribution is prohibited under the CITES convention will not be accepted by NIBSC. NIBSC may refuse deposits which have not been packed in sufficient dry ice to keep them frozen during transit. The minimum number of replicates that must be provided by the depositor for deposit is 12. Deposits of animal cell lines must contain at least 1×10^6 cells/ampoule (of viable cells as determined prior to cryopreservation).

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of the various kinds of microorganisms accepted by NIBSC is given below. Depositors should realize that viability testing may, under some circumstances, take significantly longer especially in the case of human embryonic stem cells. Depositors will be advised of this prior to the deposit being accepted.

Human embryonic stem cells	28 days
Human and animal cell cultures	14 days

(iii) Depositor Checks and Renewal of Stocks

NIBSC does not prepare its own batch of the deposited microorganisms. When the stock, originally provided by the depositor, has been depleted through furnishing samples, the depositor will be asked to provide a new deposit. In the case of human stem cell lines deposited in the UK Stem Cell Bank at NIBSC, it may be possible to transfer some of the stock held by the UKSCB to NIBSC patent deposit to provide a new stock of microorganisms. In this case, the depositor will be asked to check samples prepared by the UKSCB for authenticity.

(c) Technical Requirements and Procedures

(i) General

Language. The official language of NIBSC is English. Communications in any other language are not accepted.

Contract. The NIBSC deposit form, which the depositor is required to complete, binds the depositor to:

- provide all necessary information requested by NIBSC;
- provide a biohazard statement;
- provide material only in the form and quantity required by NIBSC;
- pay all necessary fees, including all charges for the transportation of deposits to NIBSC;
- observe the terms and conditions of the Budapest Treaty;
- accept the terms and conditions of deposit at NIBSC;
- indemnify NIBSC against any claim which may be brought against it as a consequence of the release of samples, unless such claims result from negligence on the part of NIBSC.

Import and/or Quarantine Regulations. Deposits must be covered by the appropriate regulatory documentation before being accepted. In the case of human embryonic stem cell lines this may include application to the UK Steering Committee for the UK Stem Cell Bank and the Use of Human Stem Cell Lines. The depositor will be advised to obtain the regulatory documentation once NIBSC has received a biohazard statement from the customer.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. As well as the NIBSC deposit form referred to in (i) above, the depositor must complete a NIBSC biohazard statement. In the case of human embryonic stem cell lines the depositor may also be required to complete the applicable form for the UK Steering Committee. The depositor should request information from NIBSC or the UK Stem Cell Bank concerning the appropriate forms.

At least 48 hours before the microorganism is dispatched the depositor must inform NIBSC of the number of ampoules being sent, the method of transportation and the estimated time of arrival. Dispatch must only be handled by couriers approved by NIBSC. If dispatch is by air, NIBSC must be told the flight number and destination, waybill number and handling agent for delivery together with their contact telephone number.

In the event of a later indication or amendment of the scientific description, and/or proposed taxonomic designation or other information supplied to NIBSC, the depositor must complete a revision form indicating the revised information.

Official Notifications to the Depositor. The receipt and viability statement are issued on mandatory "international forms" BP/4 and BP/9, respectively, but standard forms are not used for other official notifications.

Unofficial Notifications to the Depositor. NIBSC will notify the date of deposit and accession number after the microorganism has been received, but before the official receipt is issued. The result of the viability test will be communicated before the issue of a viability statement only where the viability of the deposit is unacceptably low.

Supply of Information to a Patent Agent. NIBSC does not routinely ask the depositor for the name and address of their patent agent. However, if requested, it will send copies of the receipt and viability statement to both the depositor and their patent agent for which a charge will be made.

(iii) Converting a Previous Deposit

Deposits made outside the provisions of the Budapest Treaty may be converted by the original depositor to Budapest Treaty deposits, whether or not they were originally deposited for patent purposes providing an accession number was supplied at the time the original deposit was made. However, any deposits previously made free of charge are subject, on conversion, to the storage fee normally levied for Budapest Treaty deposits. The administrative requirements for conversion are the same as those to be met in respect of an original deposit, except that requirements relating to shipping procedures do not apply.

(iv) Making a New Deposit

The depositor is required to complete the NIBSC deposit form and biohazard statement when making a new deposit, to send copies of the relevant documents and declaration (Rule 6.2) and to conform to the procedures mentioned previously in respect of shipping requirements. The receipt and viability statements for any new deposit will also be issued on the "international" forms BP/4 and BP/9, respectively.

2. Furnishing of Samples

(a) Requests for Samples

NIBSC does not advise requesting parties of the correct procedures to follow in order to make a valid request and does not supply copies of request forms in the case of requests requiring proof of entitlement. Such forms must be obtained from the relevant industrial property office.

Notwithstanding any entitlement of third parties to receive samples under patent regulations, NIBSC will withhold samples of potentially hazardous microorganisms until it has confirmed that the requesting party has the appropriate containment facilities to handle such organisms. When responding to requests from overseas, NIBSC assumes that the requesting party has met the import requirements of his own country, and the customer is responsible for provision of the relevant documentation to do so.

(b) Notification of the Depositor

Depositors are notified by letter when samples of their microorganism have been furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

NIBSC does not list Budapest Treaty deposits in its published catalogue.

3. Schedule of Fees

	<u>GBP</u>
Cell Lines	
(a) Deposits and storage including provision of certification and viability statements	1,000
(b) Issuance of a new (or updated) viability statement	100
(c) Furnishing of a sample (excluding carriage costs)	100
(d) Issuance of (new or updated) certification	50
(e) Administration fee for amendments	50

Fees plus VAT, where applicable are payable to NIBSC.

4. Guidance for Depositors

Guidance for depositors is provided on the NIBSC deposit form.