



Terms and Conditions of Deposit - Patent Deposits

1. Identity of Materials

To ensure that NCMA is aware of all characteristics that may impact regulatory compliance in handling, storage and distribution, the following information is required for each item deposited.

This information may be included on the Budapest Treaty patent deposit form or appended to the form as necessary:

Microorganisms: The complete scientific name including genus and species, and the source of the material. The source of the material includes both the source of isolation and the geographical location.

Viruses: The name of the virus and the source including geographic location.

Mixed cultures and consortia: Each component of the mixture must be identified.

2. Certificate of Deposit

A certificate of deposit is provided to the depositor immediately after the material is tested and found to be viable. A patent deposit number is assigned at this time. The deposit date is the date NCMA receives viable material.

Two copies of the certificate of deposit are provided to the depositor. If notarized certificate of deposit forms are required, then a fee of \$100 for two notarized copies will be charged. If non-notarized certificate of deposit forms are required, then a fee of \$75 for two non-notarized copies will be charged.

Please contact ncma@bigelow.org for your certificate of deposit requests.

If the material is found non-viable, then NCMA notifies the depositor and follows with a certificate of non-viability (Form BP/9). If the material is found non-viable, then there is no deposit. In this case, a deposit date is not issued and no patent deposit number is assigned.

3. Viability Testing

Deposit(s) may require approximately 3-4 weeks or longer for viability testing. Viruses can require as long as three (3) months (or longer in exceptional cases). High-risk materials can require as long as six (6) months or longer for viability to be determined.

NCMA strives to expedite processing of every deposit. NCMA will notify the depositor of the NCMA identification number immediately **after a deposit is found viable**.



4. Permit Requirements

Upon notification of your intention to deposit a culture with NCMA, the NCMA can assist you in obtaining the appropriate permits (if required). The permit application forms will be forwarded to you. The NCMA will apply for the permit and will advise the depositor when the permit is received.

Certain deposits received from outside the United States may require an import permit from the U.S. Department of Agriculture (USDA). A Public Health Service (PHS) permit, available from the Centers for Disease Control and Prevention (CDC), may be required for importation of agents that are potentially infectious to humans.

Approximately four (4) to six (6) weeks should be allowed to obtain permits. **Do not send the cultures until all pertinent permits are issued.**

5. Shipping Requirements

The depositor is ultimately responsible for the shipment of deposits to the NCMA and compliance with all applicable government regulations for the packaging and movement of the material. Delivery must be made directly to the NCMA. The NCMA will not retrieve shipments from airports.

To ensure your material arrives safely and is handled appropriately, the following guidelines should be followed: when packaging vials, put all similarly labeled vials together in the package. The material should be clearly labeled and identified. The designation on the vial labels should agree with the strain designation that you have listed on the deposit forms. When shipping frozen material, use enough dry ice in an insulated shipping container to ensure the material is adequately frozen upon arrival at the NCMA, taking into account any delays in transit.

6. Converting to Budapest Treaty

Only the original depositor of patent material may convert their deposit to meet the requirements of the Budapest Treaty. If viability of the deposit has been confirmed before the conversion, then another viability test is not required; *however*, a Budapest deposit form must be completed and the usual fee paid. The fee is the same as for new deposits, but if the fee for patent storage is already paid, then it is not charged again. Deposits under the Budapest Treaty also meet USPTO requirements.

7. Replacement Deposits

If a culture or other biological material should become non-viable or be destroyed during the effective term of the deposit, then it is the responsibility of the depositor to replace it. The Budapest Treaty permits replacement of a deposit that was originally found viable and later became non-viable as long as (i) the replacement is made within three (3)



months from the notification of non-viability and (ii) the replacement has the same characteristics as the original deposit. The deposit retains the same patent deposit number and deposit date.

However, the Budapest Treaty makes no provisions for replacements of material that was originally viable and later found to have different characteristics than those originally defined. In this case, a supplemental deposit may be made and a new deposit date and number will be assigned. All requesters of the original deposit may be notified of the supplemental deposit and given a choice as to which to purchase, as long as both deposits are freely available.

8. Interim Storage

Timely arrival of patent deposit material at the NCMA is critical to establishing the desired deposit date. Reliance on delivery services to transport the material to the NCMA on time and in a viable state is risky. Therefore, through our interim storage service, material intended for patent deposit can be placed into a safekeeping deposit at the NCMA until the intended date of patent deposit.

While in safekeeping the material will be handled under terms and conditions of propriety and confidentiality (see Safe Deposit below). When a patent deposit date is desired, the material in interim (Safe Deposit) storage can be converted to a patent deposit simply by notifying the NCMA. Viability testing of material received for interim (Safe Deposit) storage can be performed upon receipt and although retesting is necessary when converted to patent deposit, this can provide insurance that the earliest possible patent deposit date will be obtained. The interim (Safe Deposit) storage service provides a means of ensuring that the NCMA patent depository receives your material promptly and in viable condition.

The date of deposit for patent purposes will be the date of transfer from interim (Safe Deposit) storage, not the date it was received *for* interim (Safe Deposit) storage.

9. Safe Deposit

The NCMA also offers safe deposit services for those valuable biological materials for which patent protection has not yet been sought. Materials are stored in liquid nitrogen vapor in strict confidence and the depositor retains all proprietary rights. Multiple-year agreements are available, along with restricted distribution only after depositor approval. If patent protection is sought at a later date, then the biological material can be transferred to the Patent Depository by the original depositor.

10. Availability of Deposits

Requirements for availability of patent deposits are determined by the rules in the country in which the patent application is filed. Generally, the NCMA is required to make patent materials available *only after the issuance of a pertinent patent*. Prior to that time,



the deposit need only be made available to a requester if: (i) the Director of the USPTO (in accordance with 35 USC 122) issues a decision to release such deposit; (ii) the patent office of another country issues such a decision to release the deposit to a particular requester; or (iii) the original depositor requests in writing that the deposit be released to a particular requester.

Although in the United States availability of the deposited material is required only after the issuance of a patent, in Europe availability is made possible with European Patent Office (EPO) approval upon publication of the patent application. The requester must agree to use the biological material for experimental purposes only, and not to make the material available to a third party before the application is refused or withdrawn or the patent expires. There is also an option during the European patent filing process by which an inventor may choose, for a certain period of time, to have the biological material made available only through an expert.

It is the responsibility of the depositor to inform the NCMA of the issuance of pertinent patents.

The NCMA urges depositors to diligently inform the NCMA when the patent issues and which deposits to release.

11. Use of Patent Cultures

The deposit of a culture in the NCMA does not grant to the NCMA a license, either express or implied, to infringe the patent, and the NCMA's release of cultures to others does not grant them a license, either express or implied, to infringe the patent. Recipients of cultures from the NCMA are so informed using the following disclaimer: "This material is cited in a U.S. and/or other Patent and may not be used to infringe the patent claims."

The terms and conditions above are accepted as a condition of depositing the Materials with NCMA.

Signed: _____

Title and Organization: _____

Date: _____